1 **TITLE PAGE**
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3 **Title:**

4 Prevalence and predictors of inadequate Patient Medication Knowledge

5 **Author's names, addresses and affiliations:**
6
7   • Javier Romero-Sanchez
8   Community Pharmacist
9   B Pharm, M Pharm
10   Pharmaceutical Care Research Group
11   University of Granada
12   Facultad de Farmacia
13   Campus Universitario de Cartuja s/n
14   18071 Granada, Spain
15
16   • Victoria Garcia-Cardenas (Corresponding author)
17   Lecturer in Pharmacy Practice
18   PhD, B Pharm, M Pharm
19   Graduate School of Health
20   University of Technology Sydney
21   PO Box 123 Broadway
22   New South Wales 2007, Sydney, Australia
23   Email: Victoria.garciacardenas@uts.edu.au, Phone: +61295149297
24
25   • Raquel Abaurre
26   Community Pharmacist
27   B Pharm, M Pharm
28   Pharmaceutical Care Research Group
29   University of Granada
30   Facultad de Farmacia
31   Campus Universitario de Cartuja s/n
32   18071 Granada, Spain
33
34   • Fernando Martinez-Martinez
35   Head of the Pharmaceutical Care Research Group, University of Granada
36   Professor in Physical Chemistry
37   PhD, B Pharm, M Pharm
38   Pharmaceutical Care Research Group
39   University of Granada
40   Facultad de Farmacia
41   Campus Universitario de Cartuja s/n
42   18071 Granada, Spain
43
44   • Pilar Garcia-Delgado
45   Community Pharmacist
46   PhD, B Pharm, M Pharm
47   Pharmaceutical Care Research Group
48   University of Granada
49   Facultad de Farmacia
50   Campus Universitario de Cartuja s/n
51   18071 Granada, Spain

52

Running head:

54   Inadequate Patient Medication Knowledge

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ABSTRACT

Objectives: To assess medication knowledge in adult patients and to explore its determinants.

Method: Cross-sectional study. Medication knowledge was the primary outcome, and was assessed using a previously validated questionnaire. A multivariate logistic regression analysis was performed to explore the association between medication knowledge and the factors included in the model.

Results: 7,278 patients participated in the study. 71.9% (n=5,234) (95% CI: 70.9% - 73.0%) of the surveyed patients had an inadequate knowledge of the medication they were taking. The dimensions obtaining the highest level of knowledge were the "medication use process" and "therapeutic objective of medication". The items "frequency" (75.4%), "dosage" (74.5%) and "indication" (70.5%) had the highest percentage of knowledge. Conversely, "medication safety" represented the dimension with the lowest scores, ranging from 15.3% in the item "side effects" to 23% in the item "precautions and warnings". The Odds Ratio of having an inadequate medication knowledge increased for unskilled workers (OR: 1.33; 85%CI:1.00-1.78; p=0.050), caregivers (OR:1.46; 95%CI:1.18-1.81; p<0.001), patients using more than one medication (OR: 1.14; 95%CI: 1.00-1.31; p=0.050), and patients who didn't know the name of the medication they were taking (OR: 2.14, 95%CI: 1.71-2.68 p<0.001).

Conclusion: Nearly three quarters of the analysed patients had inadequate knowledge regarding the medicines they were taking. Unskilled workers and caregivers were at a higher risk of lacking of medication knowledge. Other factors that correlated with inadequate medication knowledge were the use of more than one drug and not knowing the name of the medication dispensed.

1. INTRODUCTION

Failures associated with pharmacotherapy have direct implications in terms of clinical, economic and humanistic outcomes. The prevalence of negative outcomes associated with the use of medicines is so high that it is considered to be a main public health problem [1-3]. In Spain, the prevalence of visiting emergency departments due to negative outcomes related to medicines is 35.7%, of which between 73% and 81% are considered to be preventable [4, 5].

While medicines are the most widely used technology to treat health problems, successful outcomes can only be achieved if they are used in an effective and safe manner. The World Health Organization concludes "No matter how effective and safe a product inherently is, it can only fulfill its function if it is properly used" [6]. Of all those involved in the medication use process, the patient is the one that plays a central role in the attainment of medicines effectiveness and safety, wether this is either actively through conduct or due to his particular characteristics. Patients lacking correct information regarding medication use can be at higher risk of inappropriate use and suffering negative outcomes related to medicines. In fact, a direct correlation between medication knowledge, health service utilization and patient's quality of life has been identified [7, 8]. It has also been documented that patients with low medication knowledge are two times more likely to not adhere to their prescribed medications [9, 10] with negative clinical implications. Therefore, in order to minimise the occurrence of negative outcomes related to medicines and improve clinical and humanistic outcomes, patients should be properly informed and educated about their treatment and the self-management of their health condition [11].

The concept "Patient Medication Knowledge" (PMK) is a term frequently used within healthcare professionals, but rarely defined in the literature [12, 13]. Likewise no standardised assessment tool to adequately assess medication knowledge exists for most countries. Nevertheless, there is some evidence on the prevalence of PMK with some studies suggesting room for improvement [10, 11, 14-16]. For example, the only two studies aiming at measuring PMK

111 using a previously validated tool stated that 82.46% of patients had insufficient knowledge

112 about the medications they were using [17, 18]. Similarly, although lack of PMK seems to be

113 common in different groups of population, only few studies have explored specific factors

114 associated with PMK. Health literacy, age, educational level or gender are some factors proven

115 to be associated with PMK [19]. Confirming and identifying further factors associated with PMK

116 would allow the development of more focused strategies targeted to specific population groups,

117 and consequently, a direct improvement in those outcomes associated with the use of

118 medications.

119 The objectives of the present study were to assess PMK in adult patients in Spain and to explore

120 the determinants of PMK.

121 **2. METHODS**

122 **2.1 Study design**

123 This cross-sectional study was conducted in community pharmacies located throughout the

124 Spanish territory in February 2013.

125 **2.2 Patients**

126 The study population consisted of patients attending the participant pharmacies to get one or

127 more medications dispensed (with or without prescription). Those patients having

128 communication difficulties, those who had already participated in the study and those who had

129 previously received some professional advice were excluded. Sample size was calculated to

130 detect a prevalence of 66% of patients with insufficient knowledge about their medications

131 (based on preliminary results obtained in the pilot study) with a maximum admissible error of $\pm$

132 4% at a 95% confidence level. Therefore a sample size of 8000 patients was required. A random

133 sample of 10 patients meeting the inclusion criteria was systematically selected in each

134 participant pharmacy.

2.3 Outcomes:

All pharmacists were trained on interview techniques and the use of the research tools before the beginning of the study. PMK was the primary outcome, and was assessed using a previously validated questionnaire [20]. When more than one drug was requested, one of them was randomly selected to measure PMK. The questionnaire consisted of 11 open questions that were asked by the pharmacist through a face-to-face interview. PMK was defined as the knowledge needed for appropriate use of the medication and was operationally defined and measured according to 4 dimensions: therapeutic objective of the medication (including its indication and effectiveness), medication use process (dose, frequency, administration form and duration of treatment), safety issues related to the use of the medication (adverse effects, precautions and warnings, contraindications and interactions) and storage of the medication [20]. Each question was assigned a score, ranging from -1 to 2 according to the degree of agreement between the patient's response and the Spanish medicines handbook (medication reference book designed by the General Council of Spanish Pharmacists)[21]. The scoring system is shown in table 1. Based on the scored questionnaires, overall PMK was calculated. Overall PMK was categorised according to the following cutoff points of the validated questionnaire [20]: no medication knowledge, insufficient medication knowledge, sufficient medication knowledge, and optimal medication knowledge. However, for statistical purposes Overall PMK was re-categorised into a dichotomous variable: inadequate medication knowledge (no medication knowledge and insufficient medication knowledge) and adequate medication knowledge (sufficient medication knowledge and optimal medication knowledge).

Insert table 1

2.4 Statistical analysis:

Statistical analyses were performed using SPSS for Windows 15.0 (SPSS Inc, Chicago, Illinois, USA). Quantitative variables were expressed as the mean SD and categorical variables were expressed as frequency and percentages. To assess the strength and direction of the correlation

161 between PMK and each independent variable, a bivariate analysis (Chi-Squared Test, Student's

162 t-test and ANOVA) was performed. The prevalence ratio was used as a measure of association.

163 A multivariate logistic regression analysis was performed to explore the association between

164 PMK and all the factors included in the model. PMK was introduced as dependent variable

165 (considering adequate PKM the reference category), and both those variables found to be

166 significant in the bivariate analysis (using the backward procedure, no significant variables at a

167 significance level of 0.05 were excluded), and those that were deemed necessary based on the

168 theoretical model were introduced as independent variables.

169 **2.5 Ethical approval**

170 Approval for the study was given by the Ethics and Research Committee of the Clinic Hospital

171 in Barcelona (Approval number: PFI-NUL-2012-01). A written information sheet was provided

172 and informed consent was obtained.

173 **3. RESULTS**

174 Overall, 800 community pharmacies from 49 Spanish provinces participated in the study. 8000

175 patients were selected, of which 9.03% were excluded, resulting in a response rate of 90.97%.

176 More than a half of the included patients were female (58.4%), with a mean age of 54 years

177 (SD: 17.2). Most of them were Spanish (95.3%), and non-workers (51.1%). 43.8% of them

178 expressed strong concern about their health problems. 88.9% of included patients acquired the

179 drug for their own use and 85.9% of them knew the name of the drug they were acquiring. Most

180 patients (87.9%) had used the drug before. In 90.7% of cases the drug was prescribed by a

181 physician (Table 2).

182 Insert Table 2

183 **3.1 Prevalence of PMK**

184 **3.1.1 Overall PMK**

185   71.9% (n=5,234) (95% CI: 70.9% - 73.0%) of the surveyed patients had an inadequate

186   knowledge of the medication they were taking; among them the 65.7% (n=4,782) had no

187   medication knowledge and the remaining 6.2% (n=452) presented insufficient medication

188   knowledge (Figure 1). Only 28% of the surveyed patients had an adequate knowledge of the

189   medication taken, with 14.0% (n=1026) presenting sufficient medication knowledge and 14.0%

190   (n=1018) optimal medication knowledge (Figure 1).

191   Insert Figure 1

192   **3.1.2 PMK by dimensions and items**

193   Those PMK dimensions obtaining the highest level of knowledge were the "medication use

194   process" and "therapeutic objective of medication". The items "frequency" (75.4%), "dosage"

195   (74.5%) and "indication" (70.5%) had the highest percentage of knowledge. Conversely,

196   "medication safety" represented the dimension with the lowest scores, ranging from 15.3% in

197   the item "side effects" to 23% in the item "precautions and warnings" (Table 3).

198   Insert table 3

199   **3.2 Factors associated with PMK**

200   **3.2.1 Bivariate analysis**

201   No statistically significant differences were observed between the prevalence of overall PMK

202   and gender (p=0.649), country of birth (p=0.805) and medication prescriber (p= 0.208).

203   Significant differences were observed for the variables age, level of education, professional

204   status, concern about health problems, knowledge of the medication name, number of

205   medications used, duration of medication use and medication user.

206   **3.2.2 Multivariate analysis**

207   After selecting the optimal model using the backward procedure, 7 factors clearly associated

208   with PMK were identified: educational level, professional status, medication user, concern

209   about health problem, number of medications used, duration of medication use and knowledge

210   of the medication name (Table 4). Based on this model, the Odds Ratio of having an inadequate

211   medication knowledge increased for unskilled workers (OR:1.33; 85%CI:0.99-1.78; p=0.050),

212   caregivers (OR:1.46; 95%CI:1.18-1.81; p<0.001), patients using more than one medication

213   (OR: 1.14; 95%CI: 1.00-1.31; p=0.050), and patients who didn't know the name of the

214   medication they were taking (OR: 2.14, 95%CI: 1.71-2.68 p<0.001). However higher levels of

215   education, being concerned about the health problem, and previous use of the medication were

216   found to be factors associated with adequate knowledge of the medication.

217   Insert table 4

218   **4. DISCUSSION**

219   The results from the present study show a lack of overall PMK among the Spanish population.

220   In fact, 72% of the analysed patients had inadequate knowledge of the medication they were

221   taking. The study expands upon previous work, analysing the factors associated with PMK.

222   Our findings are in consonance with previous studies where a high prevalence of inadequate

223   PMK has already been identified in different groups of the population. Some authors have

224   estimated that the prevalence of inadequate PMK ranges between 42.5% and 57% [22-26]. A recent

225   study conducted in emergency department units concluded that 83% of patients had no

226   knowledge about the medications given on discharge [27]. In Spain, previous research has shown

227   similar results, with 66% (95% CI: 63.3%-68.7%) and 83% of patients lacking PMK [18,28]. Once

228   more, these rates are very similar to the ones found in a latter study undertaken in Portugal,

229   where the prevalence of inadequate PMK was found to be 82.5% (95% CI: 79.3% -85.3%)[17].

230   By observing the individual components of PMK assessed, our findings revealed that important

231   factors within the medication-use process, such as "duration of treatment" or "form of

232 administration", were only known by 58.9% and 58.1% of our population respectively. These

233 percentages are very similar to the ones previously reported in a study aiming at assessing PMK

234 in outpatients from a medicine clinic [29], suggesting there is a high percentage of patients who

235 lack the required information to ensure the proper use of their medication. There is evidence

236 that wrong administration leads to medication misuse and increases the risk of suffering from

237 negative outcomes related to medications. It is worth mentioning the negative implications this

238 has for different conditions such as COPD or asthma, in which improper use of medications has

239 been found to be associated with poor clinical outcomes and increased use of health care

240 resources [30-32]. Surprisingly, the dimensions "medication safety issues" and "storage of

241 medications" obtained the lowest scores, ranging from 12.6% in the item "contraindications" to

242 36.7% for the item "storage".

243 This fact highlights a big gap in the patient information process, causing potential negative

244 safety consequences. Health care implications of these findings include a need for implementing

245 effective and ongoing medication education strategies. Patients should be educated not only on

246 indications and doses (which are the elements of the medication use process best known), but

247 also on expected and possible adverse effects, interactions, and strategies to reduce potential

248 errors. Furthermore, a latter systematic review of systematic reviews, which aimed at

249 synthesising the evidence on the effects of interventions to influence medication use, found that

250 while some strategies (such as providing information or education as single interventions) may

251 be ineffective, complex interventions seem to be the most effective. Strategies that appeared to

252 improve medicines use included: medicines self-monitoring and self-management, simplified

253 dosing and direct involvement of pharmacists in medication management. Further interventions

254 including reminders, education combined with self management skills training, and counselling

255 or support; were promising but less consistent [33]. As evidenced, PMK is an important factor

256 determining patient´s adherence and is directly linked to health care resources use and quality of

257 life [34] [8]. Taking into account the global increase in the use of medicines, the need to design

258 improved medication education programs in order to contribute to the sustainability and
259 optimisation of the health care system is most relevant.

260 Our study results indicate that patients with no education, unskilled workers, or caregivers were
261 at a higher risk of inadequate PMK. A number of other studies have also identified associations
262 between some of these factors and a lack of PMK [10, 19, 35]. Although the mentioned socio
263 demographic characteristics are non-modifiable, and therefore cannot be altered or addressed
264 with feasible interventions, they may be used to identify patients with a lack of medication
265 knowledge. This would allow the provision of selective interventions in different settings,
266 targeted to specific groups of the population in order to improve PMK. The same rationale
267 could be applied to other factors found to be associated with inadequate PMK, such as patients
268 taking more than one medication, expressing low concern about their health care problem or
269 taking the medication for the first time. Physicians, pharmacists and nurses could use these
270 indicators as a tool for screening or detecting medication knowledge problems and address them
271 during their early interaction with the patient. It's worthwhile pointing out that although age has
272 been reported to be one of the most correlated factors associated with a lack of PMK in the
273 literature [7, 18, 36-38], no correlation was found in our analysis. While similar results were obtained
274 in our crude analysis, no association was identified in the multivariate model.

275 One of the strengths of this study is the use of a valid and reliable tool to measure PKM [20]. This
276 is an outcome that has been usually assessed with ad-hoc and non-validated tools, evaluating
277 individual epistemological components rather than PMK as a whole, therefore limiting the
278 validity of the results found. Additionally, the questionnaire used was designed to weight the
279 different indicators comprising PMK (*i.e.* The importance of not knowing the adverse effects of
280 the medication taken is not the same as not knowing how to administer the medication),
281 showing its effect on the final score obtained. Furthermore the high response rate and the large
282 sample of patients analysed and the sampling method used guarantees the representability of the
283 population attending community pharmacies in Spain. However some limitations must be
284 mentioned. Firstly only community pharmacy users were included in the study and therefore

285 extrapolation of our results to other settings may be limited. Secondly for those patients

286 requesting two or more medications, PMK was only assessed for one of the medications

287 requested. To minimise selection bias, the study medication was randomly selected.

288 In conclusion, a high prevalence of inadequate patient medication knowledge among the

289 Spanish population has been identified. Nearly three quarters of the analysed patients had no

290 knowledge or insufficient knowledge regarding the medicines they were taking. Patients with

291 no education, unskilled workers, and caregivers were at a higher risk of lacking of PMK. Other

292 factors that correlated with inadequate PMK were a lack of concern about the health problem,

293 the use of more than one drug, being a first time user of and not knowing the name of the

294 medication. Future research should address the development and implementation of effective

295 educational strategies in primary health care settings.

296 **5. ACKNOWLEDGMENTS**

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441 **7. TABLES:**

442 **Tables**

443

Table 1. Scoring system for the Patient Medication Knowledge Questionnaire		
Classification	**Score**	**Explanation**
Incorrect answer	-1	The information provided by the patient does not match with the medication reference book.
'Don't know' answer	0	The patient declares through verbal or non-verbal communication that he/she doesn't know the answer for the question asked.
Incomplete answer	1	The patient's response is incomplete and does not ensure the correct and safe use of the medication in relation to the question asked.
Correct answer	2	The information provided by the patient matches with the medication reference book.

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Table 2. Sociodemographic characteristics of study patients (n=7,278)	
Variable	
Gender (Female); n(%)	4,153 (58.4)
Age (Years); mean (SD)	54 (17.2)
Professional status	
Non-workers; n(%)	3,654 (51.1)
Unskilled worker with no qualifications; n(%)	467 (6.5)
Skilled labourer with qualifications; n(%)	682 (9.5)
Administrative workers; n(%)	1,246 (17.4)
University qualified; n(%)	785 (11)
Managers and business persons; n(%)	318 (4.4)
Country of birth	
Spain; n(%)	6,877 (95.3)
European country other than Spain; n(%)	119 (1.6)
European country not a member of the EU; n(%)	45 (0.6)
North American country; n(%)	34 (0.5)
Central or South American country; n(%)	74 (1.0)
Other; n(%)	67 (0.9)
Level of education	
No education; n(%)	1,035 (14.3)
Primary ; n(%)	2,266 (31.3)
Secondary/Vocational education; n(%)	2,128 (29.4)
University ; n(%)	1,816 (25.1)
Concern about the health problem	
Low; n(%)	1,386 (19.1)
Fair; n(%)	2,366 (32.6)
High; n(%)	3,512 (48.3)
Aquisition of medicine for own use; n(%)	6,368 (88.9)
Use of more than one medication; n(%)	4,576 (62.9)
Knows the name of the medication; n(%)	6,250 (85.9)
First time user	877 (12.1)
Source of medication recommendation	
Prescribed by a physician; n(%)	6,600 (90.7)
Recommended by a pharmacist; n(%)	428 (5.9)
Self medication; n(%)	221 (3.0)

Dimensions	Items	Incorrect answer	'Don't know' answer	Incomplete answer	Correct answer
Table 3. Classification of patients' responses by items and dimenssions of the questionnaire					
Therapeutic objective of medication	**Indication**	168 (2.3%)	293 (4.0%)	1685 (23.2%)	5132 (70.5%)
	Effectiveness	312 (4.3%)	1430 (19.6%)	2317 (31.8%)	3219 (44.2%)
Medication use process	**Dosage**	211 (2.9%)	423 (5.8%)	1221 (16.8%)	5423 (74.5%)
	Frequency	162 (2.2%)	395 (5.4%)	1230 (16.9%)	5491 (75.4%)
	Duration of treatment	250 (3.4%)	1143 (15.7%)	1597 (21.9%)	4288 (58.9%)
	Form of administration	308 (4.2%)	659 (9.1%)	2085 (28.6%)	4226 (58.1%)
Medication safety issues	**Precautions and warnings**	1163 (16.0%)	2703 (37.1%)	1736 (23.9%)	1676 (23.0%)
	Side Effects	1065 (14.6%)	3385 (46.5%)	1718 (23.6%)	1110 (15.3%)
	Contraindication	991 (13.6%)	4211 (57.9%)	1158 (15.9%)	918 (12.6%)
	Interaction	837 (11.5%)	3344 (45.9%)	1657 (22.8%)	1440 (19.8%)
Storage of medication	**Storage**	707 (9.7%)	1426 (19.6%)	2472 (34.0%)	2673 (36.7%)

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Table 4. Multivariate analysis to assess factors associated with lack of PMK			
Variable	**Adjusted OR**	**IC 95%**	**p**
Level of education			
No education	1	-	-
Primary	0.58	(0.47-0.73)	<0.001
Secondary/Vocational education	0.55	(0.43-0.70)	<0.001
University	0.52	(0.40-0.69)	<0.001
Professional status			
Non-workers	1	-	-
Unskilled worker with no qualifications	1.33	(0.99-1.78)	0.050
Skilled labourer with qualifications	0.83	(0.67-1.03)	0.091
Administrative workers	0.80	(0.66-0.97)	0.020
University qualified	0.73	(0.56-0.94)	0.014
Managers and business persons	0.74	(0.54-1.01)	0.050
Person acquiring the medication			
Own user	1	-	-
Caregiver	1.46	(1.18-1.81)	0.001
Concern about the health problem			
Low	1	-	-
Fair	0.91	(0.76-1.08)	0.282
High	0.80	(0.67-0.94)	0.009
Number of medications used			
One medication	1	-	-
More than one medication	1.14	(1.00-1.31)	0.050
Duration of medication use			
First time user	1	-	-
Not a first time user	0.74	(0.61-0.91)	0.004
Knowledge of the medication name			
Yes	1	-	-
No	2.14	(1.71-2.68)	<0.001

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452 **8. FIGURES**
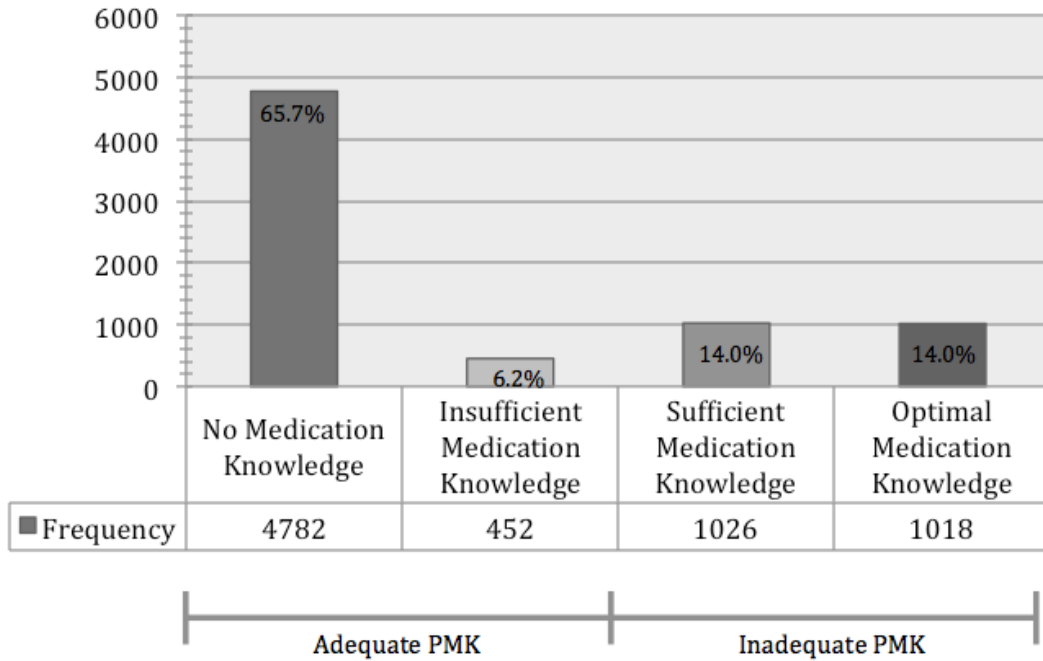453
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455 **Figure 1. Prevalence of overall Patient Medication Knowledge (N= 7,278)**
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	No Medication Knowledge	Insufficient Medication Knowledge	Sufficient Medication Knowledge	Optimal Medication Knowledge
■ Frequency	4782	452	1026	1018

Adequate PMK   Inadequate PMK

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