TITLE PAGE

Title:

Prevalence and predictors of inadequate Patient Medication Knowledge

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Running head:

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 ±
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

between PMK and each independent variable, a bivariate analysis (Chi-Squared Test, Student's t-test and ANOVA) was performed. The prevalence ratio was used as a measure of association. A multivariate logistic regression analysis was performed to explore the association between PMK and all the factors included in the model. PMK was introduced as dependent variable (considering adequate PKM the reference category), and both those variables found to be significant in the bivariate analysis (using the backward procedure, no significant variables at a significance level of 0.05 were excluded), and those that were deemed necessary based on the theoretical model were introduced as independent variables.

2.5 Ethical approval

Approval for the study was given by the Ethics and Research Committee of the Clinic Hospital in Barcelona (Approval number: PFI-NUL-2012-01). A written information sheet was provided and informed consent was obtained.

3. RESULTS

Overall, 800 community pharmacies from 49 Spanish provinces participated in the study. 8000 patients were selected, of which 9.03% were excluded, resulting in a response rate of 90.97%. More than a half of the included patients were female (58.4%), with a mean age of 54 years (SD: 17.2). Most of them were Spanish (95.3%), and non-workers (51.1%). 43.8% of them expressed strong concern about their health problems. 88.9% of included patients acquired the drug for their own use and 85.9% of them knew the name of the drug they were acquiring. Most patients (87.9%) had used the drug before. In 90.7% of cases the drug was prescribed by a physician (Table 2).

Insert Table 2

3.1 Prevalence of PMK

3.1.1 Overall PMK

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; among them the 65.7% (n=4,782) had no medication knowledge and the remaining 6.2% (n=452) presented insufficient medication knowledge (Figure 1). Only 28% of the surveyed patients had an adequate knowledge of the medication taken, with 14.0% (n=1026) presenting sufficient medication knowledge and 14.0% (n=1018) optimal medication knowledge (Figure 1).

Insert Figure 1

3.1.2 PMK by dimensions and items

Those PMK 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” (Table 3).

Insert table 3

3.2 Factors associated with PMK

3.2.1 Bivariate analysis

No statistically significant differences were observed between the prevalence of overall PMK and gender (p=0.649), country of birth (p=0.805) and medication prescriber (p= 0.208). Significant differences were observed for the variables age, level of education, professional status, concern about health problems, knowledge of the medication name, number of medications used, duration of medication use and medication user.

3.2.2 Multivariate analysis

After selecting the optimal model using the backward procedure, 7 factors clearly associated with PMK were identified: educational level, professional status, medication user, concern about health problem, number of medications used, duration of medication use and knowledge of the medication name (Table 4). Based on this model, the Odds Ratio of having an inadequate medication knowledge increased for unskilled workers (OR:1.33; 85%CI:0.99-1.78; 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). However higher levels of education, being concerned about the health problem, and previous use of the medication were found to be factors associated with adequate knowledge of the medication.

Insert table 4

4. DISCUSSION

The results from the present study show a lack of overall PMK among the Spanish population. In fact, 72% of the analysed patients had inadequate knowledge of the medication they were taking. The study expands upon previous work, analysing the factors associated with PMK.

Our findings are in consonance with previous studies where a high prevalence of inadequate PMK has already been identified in different groups of the population. Some authors have estimated that the prevalence of inadequate PMK ranges between 42.5% and 57% [22-26]. A recent study conducted in emergency department units concluded that 83% of patients had no knowledge about the medications given on discharge [27]. In Spain, previous research has shown similar results, with 66% (95% CI: 63.3%-68.7%) and 83% of patients lacking PMK [18 28]. Once more, these rates are very similar to the ones found in a latter study undertaken in Portugal, where the prevalence of inadequate PMK was found to be 82.5% (95% CI: 79.3% -85.3%)[17].

By observing the individual components of PMK assessed, our findings revealed that important factors within the medication-use process, such as "duration of treatment" or "form of

administration", were only known by 58.9% and 58.1% of our population respectively. These percentages are very similar to the ones previously reported in a study aiming at assessing PMK in outpatients from a medicine clinic [29], suggesting there is a high percentage of patients who lack the required information to ensure the proper use of their medication. There is evidence that wrong administration leads to medication misuse and increases the risk of suffering from negative outcomes related to medications. It is worth mentioning the negative implications this has for different conditions such as COPD or asthma, in which improper use of medications has been found to be associated with poor clinical outcomes and increased use of health care resources [30-32]. Surprisingly, the dimensions "medication safety issues" and "storage of medications" obtained the lowest scores, ranging from 12.6% in the item "contraindications" to 36.7% for the item "storage".

This fact highlights a big gap in the patient information process, causing potential negative safety consequences. Health care implications of these findings include a need for implementing effective and ongoing medication education strategies. Patients should be educated not only on indications and doses (which are the elements of the medication use process best known), but also on expected and possible adverse effects, interactions, and strategies to reduce potential errors. Furthermore, a latter systematic review of systematic reviews, which aimed at synthesising the evidence on the effects of interventions to influence medication use, found that while some strategies (such as providing information or education as single interventions) may be ineffective, complex interventions seem to be the most effective. Strategies that appeared to improve medicines use included: medicines self-monitoring and self-management, simplified dosing and direct involvement of pharmacists in medication management. Further interventions including reminders, education combined with self management skills training, and counselling or support; were promising but less consistent [33]. As evidenced, PMK is an important factor determining patient´s adherence and is directly linked to health care resources use and quality of life [34] [8]. Taking into account the global increase in the use of medicines, the need to design

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

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

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

extrapolation of our results to other settings may be limited. Secondly for those patients requesting two or more medications, PMK was only assessed for one of the medications requested. To minimise selection bias, the study medication was randomly selected.

In conclusion, a high prevalence of inadequate patient medication knowledge among the Spanish population has been identified. Nearly three quarters of the analysed patients had no knowledge or insufficient knowledge regarding the medicines they were taking. Patients with no education, unskilled workers, and caregivers were at a higher risk of lacking of PMK. Other factors that correlated with inadequate PMK were a lack of concern about the health problem, the use of more than one drug, being a first time user of and not knowing the name of the medication. Future research should address the development and implementation of effective educational strategies in primary health care settings.

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441 **7. TABLES:**

442 ## Tables

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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)

Table 3. Classification of patients' responses by items and dimenssions of the questionnaire					
Dimensions	**Items**	**Incorrect answer**	**'Don't know' answer**	**Incomplete answer**	**Correct answer**
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%)

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

8. FIGURES

Figure 1. Prevalence of overall Patient Medication Knowledge (N= 7,278)