

ORIGINAL ARTICLE

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KNOWLEDGE ASSESSMENT IN THE PROCESS OF MEDICATION USE BY OLDER PATIENTS ON CLINICAL ROUTINE: A PILOT STUDY

Short Title: Medication knowledge assessment on clinical routine

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Abstract

Rationale, aims, and objectives: The consumption of medicines has been increasing over the last decades. Lack of medication knowledge (MK) may affect the process of medication use and, consequently, may lead to negative health outcomes. This study aimed to carry out a pilot study using a new tool to assess medication knowledge in older patients in a daily clinical practice. **Methods:** An exploratory cross-sectional study was carried out, including older patients (≥ 65 years), taking two or more medicines, followed in a regional clinic. Data were collected during a structured interview which included an algorithm for the assessment of MK regarding the identification of the medicines and its use and storage conditions. Health literacy and treatment adherence were also assessed. **Results:** The study enrolled 49 patients, mainly between 65–75 years (n=33; 67.3%) and polymedicated (n=40; 81.6%), taking a mean of 6.9 ± 2.8 medicines per day. A lack of MK (score < 50%) was observed in 15 (30.6%) participant patients. “Drug strength” and “Storage conditions” were the items which presented lowest score. MK was positively correlated with higher scores for health literacy and treatment adherence. Younger patients (age < 65 years old) also had a higher MK score.

Conclusion: This study showed that the applied tool was able to evaluate the MK of the participants and identified specific gaps regarding MK within the process of medicines use. Further studies, with more participants will allow the confirmation of these findings and will stimulate the development of specific strategies to improve MK, thus contributing to better health outcomes.

Keywords: older patients, health literacy, patient medication knowledge, treatment adherence

1. Introduction

Aging and the global increase in life expectancy of populations lead to a greater number of health problems and, consequently, to a higher number of prescribed medicines, especially in the older population and in patients diagnosed with chronic diseases. This situation conduces to an increased risk of drug adverse events and potential drug-drug interactions (1–3).

Patients' medication knowledge (MK) may influence the process of how the medicines are taken, potentially leading to an incorrect use and lower effectiveness. Thus, MK may be a relevant factor to bear in mind when assessing the use of medicines by the patients, and their adherence to the prescribed therapy which, consequently, have a substantial impact on health outcomes (4).

According to Garcia-Delgado *et al.* (2009), the knowledge that a patient has about the medication can be defined as the amount of information that the patient acquires regarding that medication, which is needed to use medicines properly, including the proper process of use (regimen, dosage, duration of treatment and route of administration), the therapeutic objectives (indication and effectiveness), the security (adverse effects, precautions, contraindications, interactions) and the conservation (5).

Frequent changes in medication (prescriptions, doses, or new medicines) and the inability that patients may have to denote the medicines used may contribute to reduce MK (6–8).

Also, medicines which only recently became available in the market seem to lead to more knowledge gaps, as suggested by a medication review study in patients taking non-vitamin K antagonist oral anticoagulants (7). In addition, low MK has been correlated with non-adherence to the medication and the consequent risk of relapse, as reported in a prospective study held in patients diagnosed with inflammatory bowel disease (9). Also, for chronic diseases, a lack of MK has been identified as a factor contributing to a poor disease management (10).

It is not frequent to assess the MK during a patient care process nor during the evaluation of medication use. Despite MK is not a systematically assessed parameter in daily practice, some studies, which included this assessment, revealed a high prevalence of patients with low levels of MK (8,11–13). An increased rate of inadequate MK (72%) was identified in Spanish community pharmacies customers in a cross-sectional study. The lowest knowledge score was determined in the “medication safety” item (12.6% and 15.3%, for “contraindications” and “side effects”, respectively) (8).

There are a few tools available to assess patients' medication knowledge but the most used tools, which are structured interviews and specific questionnaires, are only available in English (12). However, studies that analyse their validity and reliability are still missing so that they can be used with confidence (6,13,15,16).

In 2009, Garcia-Delgado *et al.* proposed a questionnaire to assess patients' MK, which includes four dimensions (therapeutic goal, medicines use process, safety, and conservation). This tool is reported as reliable, presenting a Cronbach's alpha value of 0.68 (5,8). This questionnaire was applied in a group of patients followed in a Spanish community pharmacy, taking one or more medicines. Some predictive factors for low patient MK score were identified and included the use of several associated medicines, unqualified workers and caregivers, and the inability to identify the name of the medicines (8). This questionnaire was used as a starting point to produce a cultural adaptation to European Portuguese language designated as Patient Knowledge about their Medications, CPM-PT-PT. However, the authors mentioned that further studies are needed to demonstrate the equivalence of the psychometric properties (reliability and validity) of the Portuguese version, so it could be used in pharmaceutical care research projects in Portugal (17).

Given the inexistence of a range of tools properly certified to be applied to the Portuguese population directly in clinical practice, the aim of this study was to carry out a pilot study

employing a new tool to perform the assessment of older patients' medication knowledge in a daily clinical practice.

2. Material and Methods

Study Design

We conducted a descriptive, cross-sectional study, in an outpatient Diabetes Clinic in the municipality of Faro (Algarve, Portugal). This clinic is integrated in a regional association of patients with diabetes (in Portuguese, AEDMADA - Associação de Apoio ao Diabético do Algarve).

Patient selection

Patients were recruited for the study during their routine, previously scheduled, consultation with a physician. Prior to the consultation, following the usual procedure at the clinic, the date of the consultation was confirmed with each patient, by phone, and patients were specifically asked to bring with them all medicines and food supplements they were taking at date.

During the consultation, patients were invited to be a part of the study. Those who accepted filled and signed all necessary informed consent forms. Data collection took place at the end of the consultation and was registered anonymously. Patients with alterations in cognitive abilities that could hinder understanding the study aim were excluded.

Study recruitment was performed for three months (January – March 2018), using a convenience sample, according to patient acceptance.

Approval for this study was previously obtained from the clinic's administration board. This study only included patients with 65 or more years old.

Medication Knowledge Assessment

The assessment of patient medication knowledge (MK) was carried out through a structured interview using an algorithm, specifically developed for this purpose, which considers six different parameters: the name of the medicines, the strength of the drugs, the therapeutic indication, the timing of administration, dosing intervals and the storage conditions (Table 1). All six parameters were individually evaluated for each drug used by the patients.

Please insert Table 1 here

For each patient, the average percentage of the six parameters considered in the MK assessment was determined and then used to obtain the score for medication knowledge (SMK) according to the following formula:

$$SMK = \frac{\sum_{i=1}^6 MK_i}{\text{total number of medicines}} \times 100$$

The patient was considered as having "lack of medication knowledge" when the obtained score was less than 50%.

Furthermore, for each patient, data regarding sociodemographic characteristics, the clinical profile, and the number of physicians following patients at the moment of the interview were collected using an appropriate form created for this purpose. Health literacy was assessed throughout the Short Assessment of Health Literacy - Portuguese language: SAHL-PT (18), using a tool where patients were flagged as "low health literacy" when reached a score ≤ 14 (out of 18). WHO ATC index was used to perform medication classification (https://www.whocc.no/atc_ddd_index/). Treatment adherence was also assessed using the Haynes Sackett method (19). In this test, patients with scores between 80-100% were considered as "adherents to the therapeutic".

Statistical analysis

IBM-SPSS software, version 26.0 (SPSS Inc, Chicago, Illinois) and AMOS 24.0 (SPSS Inc, Chicago, Illinois) were used to analyse all the collected data. Quantitative variables are presented as minimum, maximum, mean, and standard deviation, and median. The qualitative data are described by counts (n) and the respective percentages (%). Adherence to normal distribution was assessed with Kolmogorov-Smirnov's test. Parametric (Student's-t test, Pearson correlation coefficient) or non-parametric (chi-square, Mann-Whitney's test, Spearman's correlation coefficient) procedures were used for analysing associations or group differences. Statistical significance for all procedures was considered when $p<0.05$.

Ethical consideration

Ethical approval of this study was obtained from the Cranfield University Research Ethics Committee (Reference: CURES/840/2016). All data was collected anonymously, without any identification of the participants.

3. Results

A sample of 49 patients was included in this study, of which 27 (55.1%) were males. The mean age of 73.22 ± 5.72 years old, with 16 (32.7%) over 75 years old. Patients were mainly retired (n=44; 89.8%), and only 4 (8.1%) was living alone. More than half of the sample (n=27; 55.1%) only concluded up to 6 years of schooling (Table 2).

Please insert Table 2 here

Patients were taking a mean of 6.9 ± 2.8 medicines and 7.7 ± 3.3 daily units per day, and a total of 346 medicines. Most of them were using 5 or more medicines per day (81.6%) which can be considered as polymedication (Table 2). Only 6 patients (12.2%) were using food supplements.

Medicines most frequently taken were those acting on alimentary tract and metabolism (group A), cardiovascular system (group C) and nervous system (group N) (Table 3).

Please insert Table 3 here

Low health literacy was flagged in 27 (55.1%) patients, with an average score of 13.3 ± 3.6 , and a prevalence of non-adherence to treatment in 9 patients (18.4%).

Regarding the use of medicines, 15 patients (30.6%) showed lack of medication knowledge (score <50%), but an average prevalence of $58.5\% \pm 15.2\%$ for correct information about the medicines currently used was determined.

Despite most patients (n=46; 94%) stated being able to read the packaging, the name of the medicine was only identified in less than half of the medicines used (n=21; 41.9%) (Table 4). For 279 (80.6%) of the medicines, patients were not able to indicate drug's strength and for 83 (24.0%) of the medicines, patients did not know their therapeutic indication or presented a wrong one. Problems related to the administration time were identified in 32 (9.2%) medicines, and in 25 (7.2%) of the analysed medicines difficulties related to the number of units were also pointed. Incorrect storage conditions were mentioned in relation to 207 (59.8%) of the medicines (Table 4).

Please insert Table 4 here

The “Administration Time” and “Number of Units” were the items with highest knowledge rate, followed by the item “Therapeutic Indication”. On the opposite, the items presenting the lowest knowledge rate were “Drug’s Strength” and “Storage Conditions” (Table 4).

Older patients, presenting fewer years of schooling, revealed significantly lower MK than younger patients ($p=0.049$) (Table 5). Patients with 12 years of schooling had significantly more MK than those with 4 years of schooling (72.5 ± 13.6 vs 55.4 ± 12.4 ; $p=0.036$).

No significant differences were observed for MK score in relation to the remain socio-demographic variables, number of medicines used per patient and patient’s medication adherence ($p>0.05$).

Polymedicated patients (taking 5 or more medicines) exhibited an increased score of MK (mean of 60.4 ± 14.7 vs 50.3 ± 15.0), although differences were statistically non-significant ($p>0.05$) in relation to patients taking less than 5 medicines.

An increased score for health literacy ($p<0.05$) and treatment adherence ($p>0.05$) was achieved for patients showing a higher MK (Table 5).

Please insert Table 5 here

A lower MK (score < 50%) was determined for the medicines belonging to C group (drugs acting in the cardiovascular system) and A group (drugs acting on alimentary tract and metabolism) compared to other therapeutic groups, but no significant differences were observed between all different groups ($p>0.05$).

In addition, patients being followed by 2 or more physicians presented a higher but not statistically significant ($p>0.05$) MK score.

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4. Discussion and Conclusion

4.1 Discussion

Some methodologies are emerging for the evaluation of medication knowledge, although each one includes different evaluation parameters making it difficult to compare the obtained results. By the time this study was carried out, for the Portuguese population, only one validated tool was available to assess MK. However, that tool only considers one drug per patient and the results of the psychometric tests were shown to be inadequate possibly due to the sample size (17).

Using the methodology presented in the current study, about a third of the patients enrolled ($n=15$; 30.6%) showed a lack of medication knowledge (MK) while another cross-sectional study which applied the questionnaire (PKM-PT-PT) and that was carried out in community pharmacies in the Lisbon Metropolitan area (Portugal) identified 65.9% of patients without appropriate MK. Although in the current study patients revealed a higher rate of MK, some items such as "therapeutic goal" (70.9%) and "process of use" (36.7%) were the items with higher score and results were similar in both studies. Likewise, the item with lowest rate was "Storage Conditions", which also had similar rates of knowledge in both studies. However, it should be noted that the patients' MK was assessed only for one of the medicines they were taking, (9) while in the present study, all medicines prescribed were considered for each patient and so the comparisons between the obtained results should be interpreted with caution.

The results obtained in the current study indicate a lower prevalence ($n=15$; 30.6%) of inappropriate MK compared to the score determined by Romero-Sánchez *et al.* (2016), in a study enrolling community pharmacy users, where an inadequate MK was determined in 71.9% of the patients, with 65.7% having no MK and 6.2% insufficient MK (8). The interpretation of these results needs to take in account that different tools were used to assess MK, using different weighting factors for the various parameters analysed, which may contribute to the different results reported.

One factor previously correlated with inappropriate MK is the lack of knowledge that patients revealed in relation to the name of the medicine they use (8), which was also verified in about 60% of the medicines used by the patients in the present study.

Although medicines included in group A and C are the most used by this group of patients, a particular lack of MK associated with these groups was observed, which is a surprising and worrying situation as we could expect that patients know more about the medicines they use regularly, highlighting the need of improving patients' knowledge.

Medication adherence has been considered as one of the factors which may limit the improvement of chronic diseases (e. g. diabetes, hypertension) control. Participants in the current study presented a 18.4% prevalence for medication non-adherence, adding to the observed lack of MK will contribute to aggravate health outcomes, with negative impacts in disease control (21–23).

Education level has been considered as a relevant factor to achieve positive health results, given its ability to influence treatment adherence and patients' self-care (19,24). In a study carried out in Portugal with university students, the level of MK identified was low for self-medication (25). The results obtained in this study have shown that patients with lower schooling levels tend to present low MK scores as described in the previous section, which reinforces the need to pay additional attention to those patients to help them achieving the desired positive outcomes with the prescribed medication.

In this study, a failure in the identification of drugs (name and drug strength) was clearly observed which may represent a risk in case they need to give information about the medication they are taking (for example, to other physicians or in any health service).

Therefore, it could be useful, in the future, to draw up the list of medicines, or to develop

appropriate tools (IT tools or others) for each patient, considering information from different sources (e.g., hospital, community pharmacies) so they can carry it with them whenever they access health services or whenever they need to identify their medicines (26,27).

The signalling of patients with low MK score may allow the identification of patients who could benefit from participating in therapeutic education programs. An improvement in MK was achieved for patients under polymedication, through the provision of a counselling session after being referred by physicians to a medication review service, provided by pharmacists, due to signalling problems with therapeutic adherence or knowledge (23). Farsaei *et al.* (2011) have shown that progresses could be achieved in disease management, including a significant metabolic improvement, through the implementation of an educational program (interventional approach, conducted by pharmacists) which addressed several topics, such as medicines, therapeutic adherence, daily self-care records and pill box usage (24).

A more recent systematic review and meta-analysis which evaluated patient-centred outcomes reported in studies searching for interventions to increase treatment adherence has shown that medication knowledge assessment may be an important tool to be used in clinical services such as medication review (23).

Also, in the management of chronic diseases, such as Parkinson Disease, the MK can have a relevant influence on physical and social performance, impacting on the health-related quality of life (30).

The current study has some strengths and limitations. The main strength is that the assessment of MK was applied to all medicines used by patients. Although this methodology may be time-consuming and exhaustive, it allows to specifically identify the items in which the patients have more difficulties regarding their MK.

The obtained results show that for each patient, the knowledge varies with the medicines they are taking, which may compromise their full benefits.

One limitation of the MK assessment carried out in this study is that the questionnaire did not include questions related to drug safety (side effects, interactions, and contraindications). In the future, this MK tool should include questions related with this item, using a perceptible format that allows to assess patients' knowledge about the safety of the medication.

Our sample size was low, as we were unable to recruit additional patients, and the methodology we used to assess MK was not previously validated. In addition, the descriptive nature of this work does not allow us to establish causation but, despite these limitations and shortcomings, the use of a novel tool in a population that is scarcely studied in regard to the subject of this paper leads us to assert that the data we gathered was an important starting point, which will soon lead us to carry out further research in this matter.

4.2 Conclusions

The results obtained in the current study gave us access to detailed information about the MK of each medicine used by the enrolled patients which seems to be useful in the future for scheduling pharmaceutical interventions and customizing the needs for each patient according to inappropriate points in the use of each medicine.

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TABLES

Table 1: Parameters for the assessment of patients' medication knowledge and the respective possible results and indicators

Parameters	Results	Indicators
Medicine's Name* <i>What is your medicine name?</i>	<input checked="" type="checkbox"/> knows medicine's name. <input checked="" type="checkbox"/> Patient does not know medicine's name.	Rate (%) of medicines whose name was correctly identified
Drug's strength* <i>What is your medicine strength?</i>	<input checked="" type="checkbox"/> Knows drug's strength <input checked="" type="checkbox"/> Does not know drug's strength	Rate (%) of medicines whose drug's strength was correctly identified
Therapeutic Indication* <i>For what purpose do you take this medicine?</i>	<input checked="" type="checkbox"/> Knows the correct therapeutic indication <input checked="" type="checkbox"/> The information on the therapeutic indication is not complete <input checked="" type="checkbox"/> Does not know the correct therapeutic indication <input checked="" type="checkbox"/> Does not know the therapeutic indication	Rate (%) of medicines whose therapeutic indication was correctly identified (answer 1 or 4)
Timing of administration* <i>At what time of the day do you take your medicine?</i>	<input checked="" type="checkbox"/> Knows the correct time for the administration of the medicine <input checked="" type="checkbox"/> Does not know the correct time for the administration of the medicine	Rate (%) of medicines whose administration time was correctly identified
Dosage Intervals* <i>How often do you take your medicine?</i>	<input checked="" type="checkbox"/> Knows the correct time for dosage intervals <input checked="" type="checkbox"/> Does not know the correct time for dosage intervals	Rate (%) of medicines whose dosage intervals were correctly identified
Storage Conditions* <i>Where do you keep your medicines at home?</i>	<input checked="" type="checkbox"/> Knows the correct storage conditions <input checked="" type="checkbox"/> Lack of information on medication storage <input checked="" type="checkbox"/> Does not know the correct storage conditions	Rate (%) of medicines whose storage conditions were correctly identified

Legend: *All parameters described in the current table were also analysed for food supplements, whenever applicable.

Table 2: Sociodemographic characterization of the patients enrolled in the study.

	N (%)
Gender	
Female	22 (44.9)
Male	27 (55.1)
Age (mean age, minimum, maximum)	
Mean age	73.22 ± 5.72
Minimum	66
Maximum	88
Marital Status	
Married / Committed	38 (77.6)
Widower	6 (12.2)
Divorced	5 (10.2)
Living With	
Alone and autonomous	3 (6.1)
Alone with support	1 (2.0)
Other family members	45 (91.8)
Schooling	
Can read or write without formal education	1 (2.0)
Cannot read or write	2 (4.1)
4 years	22 (44.9)
6 years	2 (4.1)
9 years	11 (22.4)
Professional / Technological course	
12 years	3 (6.1)
Higher Education	3 (6.1)
Use of medicines	
[< 2 medicines]	0 (0.0)
[2 – 4 medicines]	9 (18.4)
≥ 5 medicines	40 (81.6)
Use of food supplements (mean age, minimum, maximum)	
Number of patients	6 (12.2)
Mean	0.12 ± 0.3
Maximum	0
Minimum	1

Professional Situation	
Retired	44 (89.8)
Employed	1 (2.0)
Retired with activity	3 (6.1)
Without professional activity	1 (2.0)

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Table 3: Medicines Anatomical Therapeutic Chemical (ATC) classification (level 1) consumed by the participants in the study.

ATC Classification (level 1)	Nr (%)
A - Alimentary tract and metabolism	114 (32.9)
B - Blood and blood forming organs	22 (6.4)
C - Cardiovascular system	135 (39.0)
G - Genito urinary system and sex hormones	11 (3.2)
H - Systemic hormonal preparations, excl. sex hormones and insulins	5 (1.4)
J - Antiinfectives for systemic use	2 (0.6)
M - Musculo-skeletal system	12 (3.5)
N - Nervous system	33 (9.5)
R - Respiratory system	6 (1.7)
S - Sensory organs	1 (0.3)
Total	346 (100)

Legend: Nr – number of medicines per ATC classification.

Table 4: Characterization of patients' medication knowledge.

1	N (%)
Name	
✓ Knows the name of the medicine	145 (41.9)
✓ Does not know the name of the medicine	201 (58.1)
Drug's strength	
✓ Knows the drug's strength	67 (19.4)
✓ Does not know the drug's strength	279 (80.6)
Therapeutic Indication	
✓ Knows the correct therapeutic indication	220 (63.6)
✓ Does not know the correct therapeutic indication	16 (4.6)
✓ Does not know the therapeutic indication	67 (19.4)
✓ The information on the therapeutic indication is not complete	43 (12.4)
Administration time	
✓ Knows the correct administration time	314 (90.8)
✓ Indicates an incorrect administration time	32 (9.2)
Units Number	
✓ Indicates the correct number of units per day	321 (92.8)
✓ Indicates an incorrect number of units per day	25 (7.2)
Storage Conditions	
✓ Indicates the correct storage conditions	112 (32.4)
✓ Indicates incorrect storage conditions	207 (59.8)
✓ Lack of information on medication storage	27 (7.8)

Table 5: Patients' health literacy, treatment adherence and medication knowledge scores.

	Health Literacy		Treatment Adherence (%)		Age (years)	
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median
Lack of MK	11.0±4.1	10	87.8±13.6	88.9	74.7±4.9	73
Appropriate MK	14.3±2.9	15	90.9±15.9	99.2	72.6±6.0	71
p value	0.006		0.160		0.049	

Legend: MK: Medication Knowledge; SD – Standard deviation.

Statistical significance was considered when $p<0.0505$ (Mann-Whitney test).