

## A STRUCTURED MEDICATION QUESTIONNAIRE TO EVALUATE THE CORRECTNESS OF THE MEDICATION ANAMNESIS

OCTAVIA SABIN<sup>1\*</sup>, AMALIA IOANA RADU<sup>2</sup>, ANCA DANIELA FARCAȘ<sup>3</sup>, ANCA DANA BUZOIANU<sup>4</sup>

<sup>1</sup>Department of Pharmacology, Toxicology and Clinical Pharmacology, Faculty of Medicine, "Iuliu Hațieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

<sup>2</sup>Faculty of Medicine, "Iuliu Hațieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

<sup>3</sup>Medical I Department of Internal Medicine, Faculty of Medicine, "Iuliu Hațieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

<sup>4</sup>Department of Pharmacology, Toxicology and Clinical Pharmacology, Faculty of Medicine, "Iuliu Hațieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

\*corresponding author: [octavia.sabin@umfcluj.ro](mailto:octavia.sabin@umfcluj.ro)

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### Abstract

This study evaluates the opportunity of using a Structured Medication Questionnaire (SMQ) for drug anamnesis to better identify current medication and to potentially reduce medication errors. The hypothesis is that using a SMQ the accuracy of medical anamnesis can be improved and the drug errors regarding the hospitalized patients can be reduced. The study was a pilot, interventional, pre-post, single-arm study design. The study enrolled all consecutive patients admitted to a cardiology ward in Cluj-Napoca, Romania, in 2 weeks-interval in February - March 2020. Fifty-six patients included in this study had a total of 429 drugs identified by SMQ compared to 338 drugs in the observation sheets (26.9% more drugs identified). Forty-three patients (76.78%) had at least one registration error in prescription drugs; if dietary supplements are added, forty-nine patients (87.5%) had at least one registration error. The classes of drugs where the most common errors were identified, were the non-steroidal anti-inflammatory drugs (ATC code M01A), the psycholeptics (ATC code N05) and the ophthalmic products, with 7 errors each (7.6% of the total errors by omission). A structured questionnaire implemented in the patient interview may improve the accuracy of the medication history and may reduce the frequency of omission errors.

### Rezumat

Acest studiu evaluează oportunitatea utilizării unui chestionar structurat standardizat (SMQ) pentru anamneza medicației, cu scopul identificării mai precise a medicamentelor actuale și pentru a reduce potențial erorile medicamentoase. Ipoteza este că, prin SMQ, acuratețea anamnezei medicale poate fi îmbunătățită și erorile medicamentoase privind pacienții internați pot fi reduce. Este un studiu pilot, intervențional, pre-post, cu un singur braț. Studiul a înrolat toți pacienții consecutiv internați într-o secție de cardiologie din Cluj-Napoca, România, într-un interval de 2 săptămâni, în perioada februarie - martie 2020. Cincizeci și șase de pacienți incluși în acest studiu au avut un total de 429 de medicamente identificate de SMQ comparativ cu 338 de medicamente notate în fișele lor de observație (cu 26,9% mai multe identificate). Patruzeci și trei pacienți (76,78%) au înregistrat cel puțin o eroare de medicație, înregistrată la medicamentele eliberate pe bază de prescripție medicală; dacă se adaugă suplimentele alimentare, 49 de pacienți (87,5%) au înregistrat cel puțin o eroare de înregistrare. Clasele de medicamente omise cel mai frecvent au fost medicamentele antiinflamatoare nesteroidiene (codul ATC M01A), psiholepticele (codul ATC N05) și produsele oftalmice cu câte 7 erori (7,6% din totalul erorilor prin omisiune). Un chestionar structurat standardizat, implementat în interviul pacientului, poate îmbunătăți acuratețea istoricului medicației și poate reduce frecvența erorilor de omisiune.

**Keywords:** medication history, drug errors, medication questionnaire

### Introduction

Taking a complete and correct medical history or anamnesis is a crucial step in patient's assessment and an essential clinical skill. Medication or drug history is a key part of this anamnesis. In addition to information-gathering, performing the medical history is a way to begin a tight therapeutic doctor-patient relationship [1]. The medication history should include all current drugs taken by the patient, by prescription or over-the-counter medications (OTC), including

alternative or herbal therapies, and it should assess the patient's adherence to treatment as well as the side effects and allergies. This is the first step in preventing subsequent prescribing errors (such as omissions, duplications, or inappropriate dosing) and thus reducing the risks that patients may be exposed to. In addition to preventing such errors, a correct medication history can detect treatment-related pathologies such as side effects, drug interactions or inefficiency due to non-adherence or due to the prescription of inappropriate doses. Certain drugs may

also mask some clinical signs and may alter the results of laboratory tests so pharmacological effects, adverse or therapeutic, must always be on the physician's checklist as one of differential diagnoses [1]. However important is a correct drug history, errors in taking it occur commonly and several have a clinical significance. Numerous studies demonstrated that more than half of the patients had at least one error in the medication history, mostly by omission [2, 3] and up to one third of these errors may have moderate to severe potential to affect the patients [3]. A systematic analysis by Vincent C. Tam and colleagues showed that up to 41% of medical history errors were clinically important and 22% had the potential to harm the patients [17]. With such data cited from the existing literature on this subject, it can be stated that the problem of errors in medical history is a serious one and requires attention from health professionals.

In the most hospitals of Romania and other Eastern-European countries, the medication history is taken by the physician in charge or by interns, sometimes by nurses, in the form of a non-systematic interview consisting of open questions about current medication. The main information source is the discussion with the patient. Secondary sources may be used, such information from relatives, from the drugs brought to the hospital, from medical letters or other medical records. The data obtained are then entered in the hospital's general clinical observation sheet (COS), in a formal structure, in the Anamnesis section. No systematic medication reconciliation programs are developed so far in Romanian hospitals.

The aim of this exploratory study is to evaluate the opportunity of using a SMQ (Structured Medication Questionnaire) for drug history to better identify current medication and to potentially reduce the medication errors. The hypothesis is that through a Structured Medication Questionnaire the accuracy of medical history can be improved and the drug errors (especially those by omission) regarding the hospitalized patients can be reduced.

## Materials and Methods

### Patients

The study is a pilot, pre-post interventional, single-arm study design. The study enrolled all consecutive patients admitted to a cardiology ward in Cluj-Napoca, Romania, in a 2 weeks interval in February - March 2020. The exclusion criteria were altered mental status, the impossibility to speak, read or write in Romanian, severe visual impairments, refusal to communicate or to sign the informed consent. The study was approved by the hospital's ethics committee (no. 4307/2020) and all included patients signed an informed consent.

### Development of Structured Medication Questionnaire

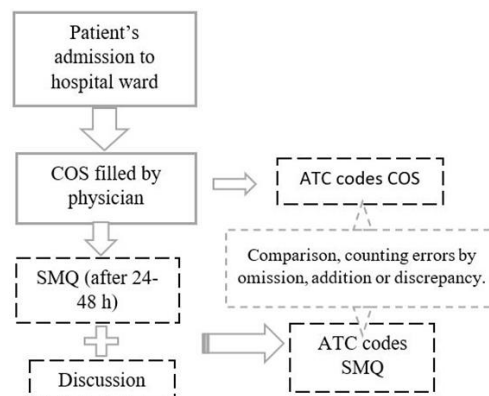
The SMQ was used as an additional intervention to usual care, to properly identify current medication.

The SMQ was developed in the Romanian language by the members of the research team and contained twenty rows specific to each organ or system, with explanatory text and an icon to facilitate the recalling of all drugs taken.

Specific questions were noted to assure that the patient did not forget to mention painkillers, sleeping pills, diabetes medication, hormonal therapy, herbal medicines, or other OTC drugs. At 24 - 48 hours after admission, patients received the SMQ. The SMQ was completed by the patients, together with a member of the research team (a medical student), who provided additional explanations to each patient and helped to complete the data, without knowing the content of the clinical observation sheet (COS). The average time spent with each patient to complete the questionnaire was approximately 20 minutes. Questionnaires were distributed and data were collected daily or every two days, between 4 and 8:30 p.m. In addition to completing the questionnaire, each patient gave their written consent by signing an informed consent and agreement on the processing and storage of personal data.

The medication lists provided by the patients in the SMQs were compared with the medication list at admission written by the treating physicians in the COSs. All medicines were registered by their Anatomic Therapeutic Chemical codes (ATC).

The complementary or herbal therapies were counted without classifying them (Figure 1).



**Figure 1.**

Steps in evaluating the medication in our study (COS – clinical observation sheet; SMQ – Structured Medication Questionnaire; ATC – anatomic, therapeutic and chemical drugs code; continuous line – standard care; dotted line – new intervention)

### Defining terms

We defined as error any omission or addition of a drug in the patient's COS compared to the SMQ. The term discrepancy was used to define any difference in dose, rhythm or route of administration found between the SMQ and COS.

### Statistical analysis

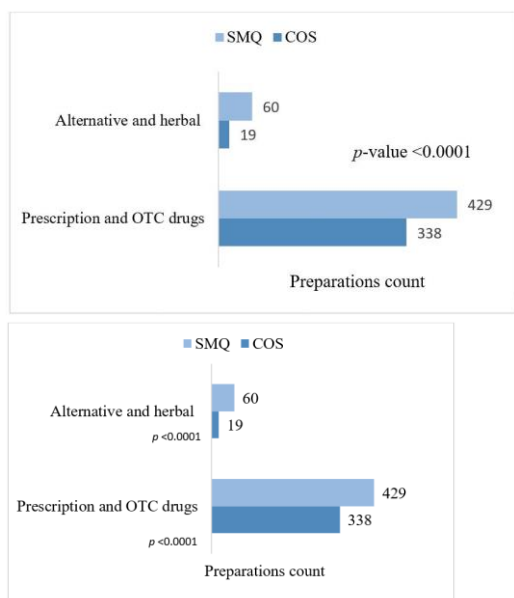
The following data were recorded: demographic variables, total drugs/patients by their ATC codes,

total errors/patient. The statistical analysis was carried out using the MedCalc Statistical Software version 19.4.1 (MedCalc Software bv, Ostend, Belgium, 2020). Quantitative variables were described using mean and standard deviation. Qualitative data were characterized by frequencies and percentages.

Between-group comparisons were performed using the Student T test for quantitative variables and Chi-square tests or Fisher's exact test, for qualitative variables. A p value < 0.05 was considered statistically significant.

**Results and Discussion**

Out of the 75 hospitalized adult patients, 56 patients were eligible for the study, 26 male patients (46.43%) and 30 females (53.57%), mean age 72.43 ± 10.61 years. A total of 429 drugs were identified in SMQs, compared to 338 drugs in the observation sheets, a difference of 91 prescriptions and OTC drugs (21% of total drugs identified). If alternative or herbal products were added to the count, SMQs found 60 preparations in 29 patients (51.78% of all patients), compared to 19 preparations in 12 patients noted in COS (21.42% of all patients), hence an additional 41 preparations. Significantly more alternative or herbal products were found with SMQ than drugs, compared with those find in COS (Chi-square, p < 0.0001) (Figure 2).



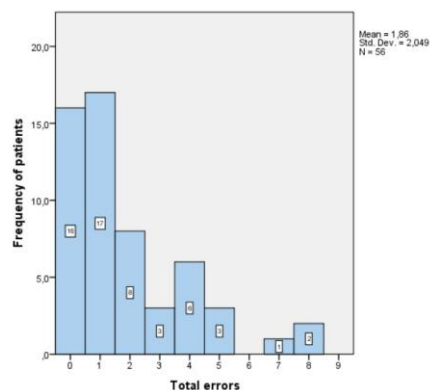
**Figure 2.**

Comparison between total prescription and OTC drugs or herbal and alternative preparations in Clinical Observation Sheet (COS) and respectively Structured Medication Questionnaire (SMQ) The differences are statistical significant (p < 0.0001 for both comparisons)

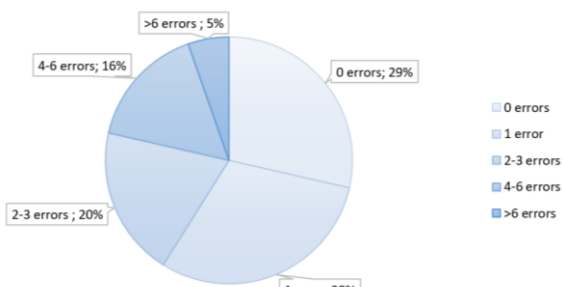
Considering the type of error, 92 errors were omissions, 15 addition errors and 19 discrepancies. Forty-tree of

the fifty-six patients (76.78%) had at least one type of error in the medical history with a mean of 1.86 errors/patient (standard deviation 2.05) (Figure 3). If we add to the count the alternative and herbals supplements, then forty-nine of the fifty-six patients (87.5%) had at least one error.

The classes of drugs with the most common errors were anti-inflammatory and non-steroidal anti-rheumatic drugs (ATC code M01A), psycholeptics (ATC code N05) and ophthalmic products with 7 errors each (7.6% of total errors by omission), followed by antacids, antiulcer agents (ATC code A02), antiplatelet agents (ATC code B01AC), topical preparations for muscle injuries and pain (ATC code M02) and the category "other" in which a potassium mineral supplement (ATC code A12BA30) was most often found, with 6 errors by omission for each one (respectively 6.52% of the total errors by omission).



**Frequency of patients with medication anamnesis errors**



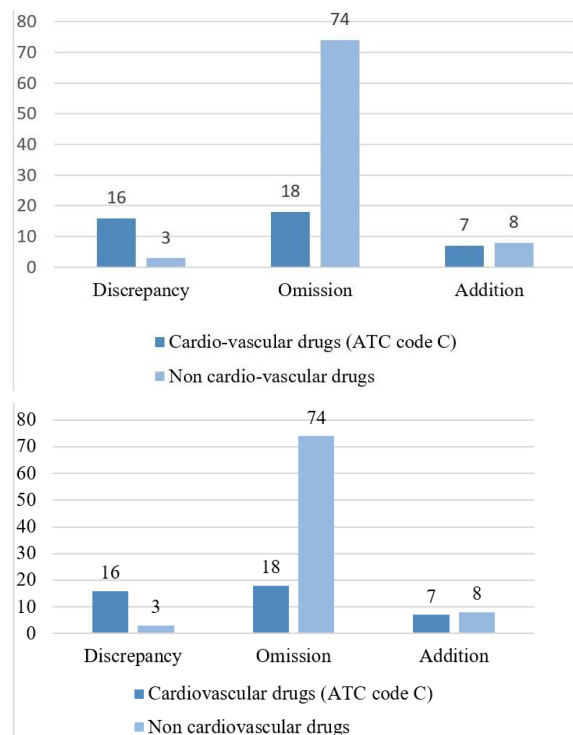
**Figure 3.**

Error count for medication anamnesis (prescription drugs and over-the-counter drugs) and patients' frequency with different errors

Omissions were more common (Chi-square p < 0.001) for non-cardiovascular drugs, with a total of 74 omissions out of 106 drugs compared to 18 omissions for 157 cardiovascular drugs (Figure 4).

We studied the correlations between gender or age and errors in the medical history. The student T test for comparison of means showed that there is no significant association (p = 0.125) between the average number of drugs on COS in women (mean 5.43 ± 2.648) and men (mean 6.73 ± 3.573). In the same way, it showed

that there is no significant association ( $p = 0.951$ ) between the average number of drugs in the SMQ in women (mean  $7.60 \pm 7.60$ ) and men (mean  $7.54 \pm 3.860$ ). No association between gender and total drug errors ( $p = 0.053$ ) or total herbal products errors ( $p = 0.454$ ).



**Figure 4.**

Type of medication errors for cardiovascular and non-cardiovascular drugs

Regarding age, there is no statistically significant correlation between patients' age and the number of drugs in COS ( $p = 0.397$ ) or SMQ ( $p = 0.341$ ) or between the number of errors and number of drugs. There was no statistically significant correlation between the number of errors and the age of the patients ( $p = 0.8$ ).

The medical and financial implications that derive from the consequences of drug errors of clinical importance have led to the study of the phenomenon and the development of new methods of improvement in international health systems [5-7]. Multiple methods of improving the medical history were studied and, in some countries, even implemented. Drug reconciliation has proven to be the best method of improvement [5, 7-11]. Involving clinically trained pharmacists and delegating responsibility for obtaining the best possible medical history appears to be an effective solution [6]. Cornish *et al.* also studied the financial implications of such a decision and it proved to be beneficial in terms of cost-benefit [6].

The implementation of electronic systems for recording, prescribing and monitoring medication can also play

a beneficial role in reducing the risk of errors in the medical history [1, 12, 13], but they are still dependent on how correctly and completely the interview with patient was. Medication errors can be reduced by electronic systems, but they can also facilitate the occurrence of new errors [1] and do not remove the need for medical staff trained in the field. Another way to improve is to educate all health professionals about the importance of a proper medical history. It is an effective solution in the absence of the possibility of implementing pharmacists-led drug reconciliation. Although some preliminary studies that evaluate a systematic interdisciplinary team approach to increase the appropriates of medication for hospitalized patients exists [14], no clinical pharmacist/pharmacologist-led hospital-based medication review programs are available in Romania.

Our hypothesis was that a simple, cheap, structured medicine questionnaire used in the interview with the patient can improve the medical history and thus can reduce medication errors (especially those by omission) when patients are hospitalized. The objective of the study was to evaluate the value of such intervention by comparing the information noted by the medical staff in the general clinical observation sheets (COS) with the information obtained using a SMQ.

Our study indicates that the medical history obtained in the hospital by the classical method is often incomplete, since 21% of prescription or over-the-counter drugs in patients' treatment plans had not been noted in the COS. According to the results, 76.78% of the patients included in this study had at least one error, regardless of its type (omission, addition, or dosage error). Also, these values are comparable to those of other studies that obtained percentages of between 50% and 83% [7, 10, 15, 16] of patients affected by at least one error. However, the differences between the methods used in the studies and the different definitions regarding errors makes it difficult to compare the results. We also observed that for the patients with multiple medication, the standard space of COS is insufficient for a proper recording.

Most errors in our study belonged to the group of omissions, like other studies [5-8, 10, 16, 17]. The classes of drugs, where the most common omissions were found, were the anti-inflammatory and the non-steroidal anti-rheumatic drugs (NSAIDs), psycholeptics and ophthalmic products. The fact that NSAIDs were more frequently omitted may be a matter of concern, as the patients included in the study were predominantly elderly and frequently affected by musculoskeletal pathologies causing pain (hip and knees osteoarthritis, chronic back pain). These patients are more likely to request or to have an anti-inflammatory and analgesic prescribed during hospitalization, and physicians need to be sure that they do not provide patients with higher or even toxic doses by combining them with preparations that their patients already use. The use

of NSAIDs is also correlated with an increased prevalence of gastroduodenal ulcer or upper gastrointestinal bleeding. Studies such as that of Lau *et al.* have observed that NSAIDs are among the classes most affected by errors [15]. We assumed that psycholeptics have been omitted mainly because patients are reluctant to specify their use for fear of stigmatization; in the absence of targeted questions on this topic, most prefer not to mention the fact that they have been prescribed or that they have sought the help of a psychiatrist. Regarding the ophthalmic drugs, their omission is mainly caused by the little attention given to them during usual care. The fact that they are most often formulated in the form of drops makes the patient perceive them as less important drugs for the systemic treatments even if they address serious pathologies such as glaucoma or have severe adverse reactions or interactions. This may be overturned by using SMQ that includes questions about medicines for each organ or system, including the sense organs, to avoid such omissions. The study by Nilsson *et al.* revealed the same problem about ophthalmic preparations [10]. Given the specifics of Cardiology department where we conducted the study, we assumed that doctors give more importance to these drugs during the interview to the detriment of drugs in other classes. Yet, errors were present, mostly omissions in antihypertensives, peripheral vasodilators, and dyslipidaemia medication, but there were significantly less errors that for non-cardiovascular drugs. In the study of Giannini *et al.*, conducted in a department of internal medicine in Switzerland, the drugs most affected by errors were those in the cardiovascular system, followed by those for the nervous system and gastrointestinal tract [5]. However, cardiologists and pulmonologists appear to obtain the most detailed medical history [18]. Variations related to local conditions, internal protocols are imminent, so more comparative studies are needed, to highlight which interventions such as medical education, SMQ, medicine reconciliation, or pharmacist-led specialized teams we may be used to reduce medical errors.

For alternative and herbal supplements, we have confirmed an observation found in other studies [19, 20], that medical staff are documenting incompletely the use of these preparations, despite the clinical importance they may have, and we demonstrated that a SMQ can improve drug history. Of the 29 patients (respectively 52% of the total) who used such supplements, only 12 patients had information noted on COS, representing a percentage of 21% and even those 12 patients did not have complete information about the preparations they used. Although we expected to have more errors in older people, that was not confirmed.

#### *Limitations of the study*

The study was limited on a single Cardiology department, from a single hospital and with a relatively small number of participants. This fact does not allow

us to generalize the results for other wards, but it may point out that errors in medical history are a real and a common fact that deserve to be studied in other wards or hospitals. Also, we did not study the clinical significance of the errors discovered.

#### **Conclusions**

We conclude that errors in patients' medical history are common and can be a problem, which should be a wake-up call for improving this important process in the patient's subsequent medical care. Our results suggest that a structured questionnaire implemented in the patient interview may improve the accuracy of the medication history and may reduce the frequency of omission errors.

#### **Conflict of interest**

The authors declare no conflict of interest.

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