



Prescribing omissions and inclusion of new medications in the pharmacotherapy of older adults in primary care

Omissões de prescrição e inclusão de novos medicamentos na farmacoterapia de pacientes idosos na atenção primária à saúde

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ABSTRACT

The lack of use of a necessary medication involves considerable risks to the older person. Through the provision of comprehensive medication management (CMM) services, pharmacists may identify untreated health conditions that need pharmacological treatment. The purpose of this study is to describe potential prescribing omissions identified by pharmacists taking care of older adults in Brazilian primary care and whether they are included in the Screening Tool to Alert to Right Treatment (START). Data were collected directly from the records of 585 older adults followed up in CMM services in primary care in Minas Gerais, Brazil, from 2014-2017. Pharmacists identified the need to add at least one medication for 28.4 % of the older patients, totaling 233 drugs related to 31 different untreated health problems. One third (n=79) of the drugs suggested corresponded to some criterion proposed by START. These results emphasize the importance of holistic patient care in CMM services.

KEYWORDS: Aged. Primary Health Care. Drug Therapy. Pharmacists.

RESUMO

A falta de uso de um medicamento necessário envolve riscos consideráveis para o idoso. Por meio da prestação de serviços de gerenciamento da terapia medicamentosa (GTM), os farmacêuticos podem contribuir na identificação de condições de saúde não tratadas que precisam de tratamento farmacológico. O objetivo deste estudo é descrever potenciais omissões de prescrição identificadas por farmacêuticos que cuidam de idosos na atenção primária brasileira e se elas estão incluídas na ferramenta START -Screening Tool to Alert to Right Treatment. Os dados foram coletados dos prontuários de 585 idosos acompanhados em serviços de GTM na atenção básica em Minas Gerais, Brasil, de 2014 a 2017. Os farmacêuticos identificaram a necessidade de adicionar pelo menos um medicamento para 28,4% dos pacientes idosos, totalizando 233 medicamentos relacionados a 31 diferentes problemas de saúde não tratados. Um terço (n = 79) dos medicamentos sugeridos pelos farmacêuticos correspondeu a algum critério proposto pela ferramenta START. Estes resultados enfatizam a importância do atendimento holístico ao paciente nos servicos de GTM.

PALAVRAS-CHAVE: Idoso. Atenção Primária à Saúde. Tratamento Farmacológico. Farmacêuticos.

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INTRODUCTION

The Screening Tool to Alert to Right Treatment (START) proposes a set of criteria to identify potential prescribing omissions and the need to include drugs to benefit the health of the older person living in the community, which include those accompanied by primary care services¹. Studies show that the need to add a new medication to the pharmacotherapy is commonly identified, which may be related to an untreated health problem. The use of this tool helps to identify medications that would be useful for improving the health of older patients for certain indications. However, its use is still not as widespread and frequent as tools supporting the withdrawal of potentially inappropriate medications in geriatrics (such as Beers Criteria and STOPP - Screening Tool of Older Persons' Prescriptions), and the use of the START tool should be encouraged in the different settings of geriatric practices. In addition, studies on this issue are still scarce in the scientific literature in the field of geriatrics²⁻⁴.

As well as the use of unnecessary drugs, the lack of a necessary medication can bring considerable risks to the older person, and it is important to identify and solve this type of drug therapy problem (DTP)^{5,6}. A DTP can be defined as an unwanted event experienced by the patient which involves, or is suspected to involve, the pharmacotherapy and which interferes with the expected result of the treatment, requiring professional judgment in order to be resolved⁷.

In this sense, the pharmacist as part of the health care team plays an important role in the global assessment of the medications in use by the patient, through the provision of the comprehensive medication management (CMM) service. The CMM service, based on the theoretical and methodological framework of pharmaceutical care, is a patient-centered service that uses a structured and systematic clinical decision-making method, called pharmacotherapy workup, in order to ensure that the medications used by patients are the most indicated, effective, safe and convenient for their health conditions ⁵⁻⁷. In this way, through the provision of CMM services, pharmacists may help to identify untreated health conditions requiring drug therapy use.

To our knowledge, there have been no studies that assessed the applicability of such a tool and the inclusion of drugs in the pharmacotherapy of older persons in the perspective of real-world CMM services. It is important to highlight that one of the key challenges for the global health community is implementing proven interventions in day-to-day practice⁸. Therefore, to contribute to overcome this gap, the aim of this study is to describe prescribing omissions identified by pharmacists taking care of older adults in Brazilian primary care, and whether they are included in the START tool.

METHODS

This is a descriptive study focused on the untreated health conditions identified and the medications suggested by pharmacists to be initiated by older persons followed up in CMM services in primary care in the state of Minas Gerais, Brazil. This study is based on secondary data from CMM services and was approved by the Ethics Committee of the Federal University of Minas Gerais – UFMG, report n.º 25780314.4.0000.0149, and secrecy of the identity of participants and confidentiality of the information were guaranteed. The study was exempt from the informed consent form.

The Patient Care Process

In the studied CMM services, the patient care process followed the Pharmacotherapy Workup method, proposed and refined by Cipolle, Strand and Morley^{6,7}. In the initial consultations, all medications used (prescribed or non-prescribed) are assessed in order to assure the best pharmacotherapy for each patient. This extensive assessment allows for the prevention, identification, and resolution of DTPs⁵⁻⁷.

DTPs are grouped into four categories: indication, effectiveness, safety, and adherence. Regarding the indication category, either the drug used is unnecessary (DTP 1) or the patient needs additional drug therapy (DTP 2). In the effectiveness category, after evaluating the therapeutic goals, it is established that either the drug product is not being effective (DTP 3) or the dosage is too low to be effective (DTP 4). According to the safety category, after evaluating the safety parameters for each medication, it is identified if the patient either has a problem involving an adverse drug reaction (DTP 5) or related to a high dose (DTP 6). The last category is associated with non-adherence (DTP 7)^{6,7}.

After the identification of the DTP, interventions are made directly with the patient or the prescriber for their prevention or resolution^{6,7}. This entire care process is properly documented in a standardized manner.

During the consultations, health issues and complaints presented by the patient are evaluated by the pharmacist in order to detect any untreated health condition that requires pharmacological treatment, which is the focus of this study. The decision for the drug to be suggested is based on national and international clinical guidelines, the clinical expertise, and the medication availability in the Brazilian public health system.

Setting

The CMM services were implemented in primary care in the cities of Belo Horizonte and Lagoa Santa, in the state of Minas Gerais, Brazil. The CMM service in Belo Horizonte was carried out from February 2015 to February 2017 by one pharmacist. In Lagoa Santa, consultations were carried out by five pharmacists, from July 2014 to November 2016. No particular inclusion criteria were adopted for the CMM services, and any primary care user could be followed-up by the pharmacists according to individual local demand.

Data Collection

The data were collected directly from the records of all the older patients (60 years or older) followed up in these CMM services. A total population of 585 older persons were included in the study, being 68 in Belo Horizonte and 517 in Lagoa Santa.

Patients for whom the pharmacist had detected at least one untreated health condition requiring the use of drug therapy were selected and the following sociodemographic data were collected: sex, age (years completed at the time of the first consultation); and clinical data: number of drugs used in the initial consultations (prescribed and non-prescribed), medication suggested by the pharmacist for inclusion in pharmacotherapy (active ingredient), and health problem associated with this medication. Additionally, it was identified whether the recommendation of inclusion of additional medication corresponded to any criteria proposed by the START tool.

The data were collected by three researchers with experience in CMM in a Microsoft Office Excel® program database, coordinated by a researcher who validated the data collected by double checking the sum of the variables with a fourth researcher with more than 10 years of experience in the CMM and database generation and analysis area.

Data Analysis

A descriptive data analysis was carried out, which consisted of determining the absolute and relative frequencies for categorical and average variables, and the minimum, maximum and standard deviation for quantitative variables. All statistical analyzes were performed using Stata® software, version 12.

RESULTS

In the present study, patients had a mean age of 70.2 ± 7.8 years (minimum = 60; maximum = 98), with 25 % being 75 years old or more. Most of the older persons were female (n = 343; 58.63 %) and used five or more drugs in the first CMM consultation (75 %). An average of 3.4 ± 1.6 health problems (minimum = 0; maximum = 10) and 5.1 ± 2.7 drugs (minimum = 0; maximum = 18) used by the patient in the first consultation were identified.

Over the time of follow-up at the CMM service, pharmacists identified the need to add at least one medication for 28.4 % of the older patients, totaling 233 indications for adding medication. All health problems for which the need for medication to treat were identified, as well as the respective drugs suggested for inclusion, are listed in Table 1. A total of 31 different health problems were identified, the most frequent being dyslipidemia (n = 43), primary or secondary prevention of cardiovascular event (n = 37), and systemic arterial hypertension (n = 33).

A total of 233 drugs were suggested for inclusion in pharmacotherapy. The medications most frequently suggested for inclusion by the pharmacists were acetylsalicylic acid (n = 29; 12.45 %), simvastatin (n = 25; 10.73 %) and vitamin D (n = 11; 4.72 %). In 16.74 % (n = 39) of the cases, the pharmacists did not indicate a specific medication, they only identified the need for additional pharmacotherapy.

From the suggested drugs, 34.0 % (n = 79) corresponded to some criterion proposed by the START tool (Table 2). The most frequent criterion was the addition of medication for uncontrolled hypertension (n = 33) and the addition of vitamin D among older persons with osteopenia or a history of falls (n = 11).

Table 1 – Health problems identified that required pharmacological treatment and suggested drugs for inclusion

Health problem Mo	edication added	Absolute Frequency (n)	Relative Frequency %)
Cardiovascular system			
Hypertension	Amlodipine	9	3.86
	Atenolol	1	0.43
	Carvedilol	1	0.43
	Enalapril	2	0.86
	Spironolactone	1	0.43
	Furosemide	1	0.43
	Hydrochlorothiazide	6	2.57
	Losartan	8	3.43
	Not specified	4	1.72
Prevention of cardiovascular	Acetylsalicylic acid	29	12.45
event	Ciprofibrate	1	0.43
	Simvastatin	4	1.72
	Not specified	3	1.29
Cardiac insufficiency	Carvedilol	3	1.29
	Spironolactone	4	1.72
	Furosemide	1	0.43
Atrial fibrillation	Warfarin	1	0.43
Respiratory system			
Chronic Obstructive	Salbutamol	2	0.86
Pulmonary Disease (COPD)	Salmeterol + Budesonide	1	0.43
	Not specified	3	1.29
Sinusitis	Amoxicillin	1	0.43
Γuberculosis	Pyridoxine	1	0.43
	Salbutamol	1	0.43
Asthma	Not specified	1	0.43

(Continuation)

Health problem N	ledication added	Absolute Fre	quencyRelative Frequency (%)
Nervous system			
Depression	Fluoxetine	1	0.43
	Mirtazapine	1	0.43
Anxiety disorder	Fluoxetine	1	0.43
Migraine	Dipyrone	1	0.43
Dizziness	Cinnarizine	1	0.43
Fibromyalgia/ Neuropathic pa	in Amitriptyline	1	0.43
Smoking	Bupropion	3	1.29
	Not specified	4	1.72
Gastrointestinal System			
Constipation	Not specified	1	0.43
Gastritis	Clarithromycin	1	0.43
	Lansoprazole + clarithromycin + amoxicillir	1 1	0.43
	Not specified	1	0.43
Musculoskeletal system			
Osteoporosis	Alendronate	6	2.57
	Calcium carbonate	2	0.86
	Calcium Citrate	1	0.43
	Cholecalciferol	2	0.86
Tendinitis	Not specified	1	0.43
Osteoarthritis	Glucosamine	1	0.43
Gout or hyperuricemia	Allopurinol	7	3.0
	Not specified	2	0.86

(Continuation)

Health problem	Medication added	Absolute Frequency (n)	Relative Frequency (%)
Blood System			
Hemorrhoid	Fluocortolone pivalate + lidocaine hydrochloride	1	0.43
Circulatory system			
Anemia	Erythropoietin	1	0.43
	Ferrocarbonyl	1	0.43
	Glycinate Fe+B12	1	0.43
	Ferrous sulphate	3	1.29
	Not specified	1	0.43
Immune system			
Rheumatoid arthritis	Not specified	1	0.43
Endocrine System			
Dyslipidemia	Atorvastatin	1	0.86
	Ciprofibrate	7	3.00
	Ezetimibe	1	0.43
	Fibrates	2	0.86
	Simvastatin	25	10.73
	Not specified	6	2.58
Diabetes Mellitus or	Glimepiride	1	0.43
pre-diabetes	NPH Insulin	1	0.43
	Metformin	9	3.86
	Not specified	1	0.43
Alimentary Tract and Met	abolism		
Vitamin supplementation	Vitamin B12	7	3.00
	Cholecalciferol	11	4.72
Vomiting or nausea	Metoclopramide	1	0.43

(Conclusion)

Health problem	Medication added	Absolute Frequency (n)	Relative Frequency (%)
Genitourinary System			
Benign prostatic hyperplasia	Doxazosin	1	0.43
	Not specified	1	0.43
	Amoxicillin + Clavulanate	2	0.86
Urinary tract infection	Cephalexin	1	0.43
	Ciprofloxacin	5	2.15
	Not specified	6	2.58
Chronic Kidney Disease	Losartan	1	0.43
	Not specified	2	0.86
Others			
Schistosomiasis	Praziquantel	1	0.43
Oxyuriasis	Not specified	1	0.43
TOTAL		233	100

Source: authors

Table 2 – Drugs suggested for inclusion in pharmacotherapy that corresponded to some criterion proposed by the START tool

START tool criterion	Absolute Frequency (n)	Relative Frequency (%)
Cardiovascular system		
Antiplatelet agents (aspirin, clopidogrel, prasugrel or ticagrelor) with documented history of coronary or cerebral or peripheral arterial disease	6	7.60
Antihypertensive, when systolic blood pressure is constantly >160 mmHg and/or diastolic blood pressure consistently >90 mmHg; if systolic pressure >140/90 mmHg or diastolic pressure >90 mmHg, if diabetic	33	41.78
Appropriate beta-blocker (bisoprolol, nebivolol, metoprolol or carvedilol) with stable systolic heart failure	3	3.79
Respiratory System		
Regular use of β2 agonist or antimuscarinic bronchodilator, for mild to moderate asthma or chronic obstructive pulmonary disease	3	3.79

(Conclusion)

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Absolute Frequency (n)	Relative Frequency (%)
2	2.54
6	7.60
5	6.33
11	13.92
7	8.86
3	3.79
79	100
	Frequency (n) 2 6 11 7

Source: authors

DISCUSSION

This article revealed a high number of patients with untreated health conditions and the need to add medication (233 drugs in total), corroborating national and international studies that point to the need for additional medication as the most frequently identified DTP in CMM services⁹⁻¹¹. In Brazil, a study carried out in a public specialty pharmacy showed that the most common DTPs were unnecessary medication (19.8 %) and the need for additional medication (19.5 %)¹⁰. Santos et al. (2019) and Neves et al. (2019) evaluated the clinical impact of the CMM services in the municipalities of Lagoa Santa and Belo Horizonte, respectively, and demonstrated that non-adherence (DTP 7) was more frequent, mainly due to lack of product in dispensing pharmacies, patient's forgetting to take the medicines and not understanding instructions. If this cause of DTP

was excluded from the analyses, the need for additional medication (DTP 2) would become the most prevalent in these scenarios^{12,13}.

Regarding the most frequent untreated health problems (dyslipidemia, prevention of cardiovascular event and systemic arterial hypertension), all were related to the cardiovascular system. It is known that cardiovascular diseases are the leading cause of global mortality in Brazil and worldwide, and non-treatment can result in strokes and sudden death¹⁴. However, when suggesting the inclusion of a medication, it is necessary to monitor these individuals due to the high risk of adverse effects, especially in older people. For example, the introduction of an antihypertensive drug can lead to orthostatic hypotension, syncope, and hydro-electrolyte disorders¹⁵. The evaluation of effectiveness and safety of drugs and the cardiovascular risk assessment should be constant, as well as of the definition of therapeutic goals according to the fragility profile of each patient.

The medications most frequently suggested for inclusion by the pharmacists were also primarily related to the cardiovascular system. It is important to highlight the introduction of aspirin, which in most cases when suggested (n = 15; 51.72 %), was recommended for primary cardiovascular prophylaxis (results not shown). A study conducted in the United States and Australia with 19,114 patients demonstrated that the use of aspirin in older persons, with no history of previous cardiovascular events, did not prolong survival for a period of 5 years, but led to a higher rate of bleeding¹⁶. It should be noted, however, that at the time of this study (July 2014 to February 2017), such knowledge was not consolidated, which may justify the suggested inclusion of aspirin for primary cardiovascular prophylaxis of older patients. Conversely, the use in secondary prevention for reducing rates of acute myocardial infarction and ischemic stroke is proven and, in this context the benefits seem to offset the risks of bleeding^{16,17}.

Simvastatin was also included for cardiovascular prophylaxis and treatment of dyslipidemia, and no patient had diagnosed coronary arterial or cerebrovascular disease (results not reported). It is important to note that statin selection is not only according to the patient's lipid profile but calculating cardiovascular risk¹⁸. A study carried out in the United States demonstrated that the rates of use of high-intensity statins were low in patients with coronary arterial disease, which is different from what is recommended by the dyslipidemia guidelines¹⁹. It is important to point out that the CMM services included in this study were inserted into the Brazilian public health system. Therefore, the suggestion to include a particular statin took into account, in addition to clinical protocols, patients' free access to the medication.

The use of statin in primary and secondary prevention reduces morbimortality mainly in individuals up to 75 years, and it is still controversial to use it in patients older than 75 years or frail²⁰, which requires professional critical sense and broad assessment to indicate statins. Therefore, it is important that pharmacists, patients, and prescribers work together as a team and

that professionals are constantly updated in the guidelines, ensuring improvements in health care for the older person.

Despite the identification of untreated health conditions requiring medication, in a considerable proportion of cases (16.73 %) pharmacists did not suggest a specific drug to be included. This can be justified by the fact that the CMM services in the referred scenarios were new and the professionals were still in the process of learning the practice. Thus, these factors may also have influenced the documentation, which improves over time and experience⁵. It is important to point out that the chances of interventions being accepted increase when there is a professional shift towards a patient centered-care, taking co-responsibility for the patient's pharmacotherapy suggesting exactly the medication, the dosage, and the reason why the pharmacist believes it is more indicated, effective, safe and convenient for each specific patient²¹.

Regarding the suggested medications included in the START tool, the main ones were related to the cardiovascular and musculoskeletal system. Similar data were found in other studies in which the main potential prescribing omissions were antihypertensive therapy, calcium and vitamin D^{22,23}. However, only one third of the suggested drugs fit any criteria proposed by the START tool, demonstrating that being limited to a single tool, disregarding a broad and holistic patient assessment, can limit clinical results. At the same time it is reinforced that START is an interesting and easy to consult tool, and should be available and taken into consideration by the professional who provides CMM.

The present study has some limitations, such as the short time of experience of the pharmacists responsible for CMM consultations regarding clinical care for the older people, which may have underestimated the identification of untreated health problems. In addition, the descriptive aspect of the present study is limited to the frequency of identified omissions, without specifying their acceptability or associated outcomes, which is suggested to be considered in future studies that aim to explore more broadly the clinical aspects relevant to the identification of omissions.

However, studies involving the START tool are still scarce in Brazil^{26,27} and, to our knowledge, this is the first article to assess the applicability of such tool and the inclusion of drugs in the pharmacotherapy of older persons in the perspective of real-world CMM services. The use of this tool has the potential to improve geriatric clinical outcomes and its adoption should be encouraged not only for pharmacists but also for other healthcare professionals.

CONCLUSION

The number of untreated health conditions requiring additional medication identified by the pharmacists stresses the importance of holistic patient care and the role of this professional as

an integral part of the healthcare team. The identification of potential prescribing omissions may be supported, but are not limited to the use of tools such as START.

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