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## RESEARCH ARTICLE

### STUDY ON DRUG USE BY THE ELDERLY IN A SPECIALIZED GERIATRICS OUTPATIENT SERVICE IN BRASÍLIA, BRAZIL

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#### ABSTRACT

**Background:** To evaluate the use of potentially inappropriate drugs and propose pharmacotherapeutic interventions for older adults cared for by a specialist service in Recanto das Emas, Federal District, Brazil. **Methods:** Analytical, cross-sectional research with a quantitative approach, conducted in the city of Recanto das Emas, Federal District, Brazil, with a sample of 191 older adults, of both sexes, during routine clinic visits in a specialized geriatric outpatient service. The variables analyzed were sex, age, educational level, origin, functional capacity, illnesses diagnosed and history of medications used. The data were investigated using bivariate analyses and multiple analysis through logistic regression. **Results:** A high prevalence of drugs used by the sample was observed ( $n=191$ , 1.111 medications, median of 06 drugs/patient). A total of 150 drugs (13.5%) was classified as potentially inappropriate according to the Beers criteria (2015), and 135 drugs (12.16%) were classified as potentially inappropriate according to the STOPP/START criteria (2014). According to the ATC/WHO classification (2017), a wide variety was presented in terms of both quantity and pharmacological classes. Orthostatic hypotension and hypoglycemia were the unwanted outcomes caused by the use of inappropriate drugs, confirmed in this study. **Conclusion:** Greater commitment is required from the multi-professional team to improve the prescribing of drugs for, and use of drugs by, the elderly.

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#### INTRODUCTION

The Brazilian population is passing through important epidemiological changes regarding aging. The reduced fertility rate and the increase in longevity are the main causes for the inversion in the age pyramid in Brazil (Chaimowicz, 1997). By 2050, 22.5% of the Brazilian population will be elderly, matching the current situation in countries such as Japan, Germany and Italy – moving from 15<sup>th</sup> to 9<sup>th</sup> position among the 23 nations analyzed (Brian et al., 2010). For the Federal District, Brazil, a population of approximately 3.3 million inhabitants is estimated, with a contingent of 10% of people aged over 65 years old (Ramos et al., 2016). The elderly are more affected by chronic-degenerative diseases and multi-co morbidities. They are also the heaviest users of the health system, because of which they are more exposed to the use of a variety of drugs, including many which are considered to be inappropriate for this age range (Ramos et al., 2016; Santos and Olm Cunha, 2017; Cruz et al., 2017). The number of drugs used correlates directly with possible unwanted outcomes. The concurrent use of two drugs involves a risk of adverse events of 13%. This increases progressively to 58% and 82%, respectively, with the use of seven or more drugs (Lemay et al., 2012).

The physiological process of aging involves a progressive reduction in the functional reserve of various organs and an increase in vulnerability. These can compromise pharmacokinetics and pharmacodynamics, compromising patient safety (Davies and O'Mahony, 2015). Factors which interfere in the aging process include homeostatic mechanisms, changes in receptors, changes in body composition, and hypoalbuminemia (Hämmerlein et al., 1998; Vrdoljak, 2015). In Table 1, the authors present recommendations for preventing adverse events involving drugs which are potentially inappropriate for the elderly, and the most common adverse events related to the use of these drugs – as well as suggestions for therapeutic alternatives. As a person ages, there is compromise of hepatic phase I and an increase in the concentration of certain drugs. As cytochrome P450 is involved in metabolizing various drugs, reduction in its activity impairs the metabolism process (Hämmerlein et al., 1998). The reduction in the rate of glomerular filtration and in renal plasma flow which takes place between the ages of 30 and 90 years old compromises the excretion of drugs, and the dosage of drugs must be adjusted to take renal function into account. Considering the loss of muscle mass found in the elderly, creatinine as the only parameter is not reliable, and it is

necessary to estimate renal function through formulas such as, for instance, Cockcroft Gault (Hämmerlein *et al.*, 1998; Vrdoljak, 2015). The prescribing of drugs for the elderly individual needs to be undertaken rigorously. The priority is to cause no harm to the patient, by avoiding inappropriate and unnecessary prescribing (Novaes, 2007). In the light of the difficulties faced in managing drugs, specialists have elaborated criteria for prescribing, with the aim of assisting the prescriber. The ones used most are the Beers criteria and the Screening Tool of Older Persons' Potentially Inappropriate Prescriptions (STOPP/START). Created by a panel of specialists supported by the American Geriatrics Society (AGS), the Beers criteria were published in 1991 in the USA. In 2011, the AGS took responsibility for updating the criteria, which was undertaken in 2012, and again in 2015. The current version – 2015 – brought new evidence, added new drugs to those already listed, and added two new components: drugs which require adjustment of dosage in accordance with renal function; and drug interactions and a list of strongly cholinergic drugs (Samuel, 2015). The STOPP/START criteria were originally proposed in Ireland in 2008, and a new version – Version 2 – was released in 2014. This updating was necessary due to the licensing of new drugs and the removal of certain criteria considered to be irrelevant. Specialists from various European countries participated in this version, which reflected the European context more broadly. Version 2 has 80 STOPP criteria – which encompass antiplatelet drugs, anticoagulants, anticholinergic drugs, and drugs which alter renal function – and 34 START criteria, which include drugs for the urogenital system, analgesics and vaccines (O'mahony *et al.*, 2015). In 2016, a document titled “The Brazilian Consensus on Drugs Potentially Inappropriate for the Elderly” was published. This was based on the 2012 Beers criteria and STOPP 2006 (Oliveira *et al.*, 2017). The present study aimed to assess the use of drugs considered to be potentially inappropriate according to the Beers Criteria (2012 and 2015) and the STOPP/START criteria (2016), and which affect the safety of the pharmacotherapy of older adults treated in a specialized geriatrics service in the city of Recanto das Emas, in the Federal District of Brazil.

## METHODS

The present study has a descriptive analytical character, is transversal, and has a quantitative approach. It is based on the analysis of the profile of the drugs prescribed in a public health service which specializes in geriatrics, in the city of Recanto das Emas, in the Federal District of Brazil. A total of 191 elderly individuals was assessed, and the basis for the calculation of sample proportions took into account that the sample population in question is finite with a qualitative characteristic. The total population of older adults in the city of Recanto das Emas is 6,377, a proportion of 9.18% of the total population, according to data from the Brazilian Institute of Geography and Statistics (IBGE). For the sample calculation, it was estimated that 15% of the elderly use inappropriate drugs, based on a study undertaken in Viçosa, Minas Gerais, Brazil, in 2013, and in Portugal in 2009, at the University of Coimbra.

The following criteria, therefore, were followed as a basis for the calculation:

$n$  = sample size;

$N$  = size of the universe (6,377);

$Z$  = is the deviation from the mean value used to achieve the desired level of confidence. In this case, we will use the level of confidence value 95%  $\rightarrow Z=1.96$ ;

$e$  = is the maximum margin of error which will be accepted (5%);

$p$  = is the proportion expected (15%);

The formula used will be:

$$n = \frac{N \cdot Z^2 \cdot p \cdot (1 - p)}{Z^2 \cdot p \cdot (1 - p) + e^2 \cdot (N - 1)}$$

Data collection took place in September 2016 – February 2017. It included all of the elderly people seen in the geriatric outpatient service in this period. All of the drugs in use at the time of the clinic visit were investigated. This included topical drugs, phytotherapeutic drugs and Brazilian herbal products – even though these are not covered by the Beers and STOPP/START criteria. The aim was to analyze at a later point their incidence and the importance of including these medications in future lists of inappropriate drugs. The following were considered for each drug: dose and medical indication (under prescription: yes or no, or self-medication). The drugs were classified by the ATC (Anatomical Therapeutic Chemical Code), 2017 and by RENAME (*Relação Nacional dos Medicamentos*), 2014 version, accessed on 07/26/17. A search was undertaken on the website of the Brazilian Health Surveillance Agency (ANVISA) and contact was made via email to obtain patient information leaflets and confirmation that the drugs were registered in the above-mentioned organ. Plant-based and phytotherapeutic drugs were classified as phytotherapeutic or herbal, as they were not found in the above-mentioned classifications and because at that time no ATC/WHO publication on herbal remedies was available (WHO, 2017).

The independent variables studied and dichotomized were: sex (male or female), age, educational level (illiterate, or expressed as years spent in education); whether the person was accompanied or not at the time of the clinic visit; self-reported previous diagnoses or previous diagnoses described in the electronic medical record; whether it was the first consultation with the geriatrician or not; and functionality (Lawton and Brody scale): dependent (9 points), semi dependent (10 to 18 points) and independent (19 to 27 points) (Pereira *et al.*, 2014). The information was received from the participants themselves or from their companions, if the participant was not capable of providing the information. In some cases, it was necessary to assess the medical records using the TRAK CARE system, available on the computer system of the Secretariat of State for Health (Federal District). Some patients returned later to provide information which had been left out on the first occasion. In this study, polypharmacy was considered to be the use of five or more medications (Mortazavi *et al.*, 2016). The Beers List, version 2015 (American Geriatrics Society), and the STOPP/START criteria, version 2, 2014 (Criteria for potentially inappropriate prescribing in older persons) were used to classify drugs as inappropriate. The data collected were analyzed using the SPSS software (Statistical Package for the Social Sciences), version 18.0. The results were expressed as mean  $\pm$  standard deviation for the quantitative variables, and as absolute and relative frequencies for the qualitative variables. The Shapiro-Wilk test was applied to ascertain the normality of the data for the quantitative variables (age, educational level and number of drugs). The Spearman correlation coefficient

was used to assess the correlation between these variables. The nonparametric Mann-Whitney test was applied when there were two groups, to analyze whether the number of drugs was different in one specific demographic group; where there were more than two groups, the Kruskal-Wallis test was used. For all the analyses, values of  $p \leq 0.05$  were considered significant. This study was conducted in accordance with National Health Council Resolution CNS/MS 466/12. The research project was approved by the Research Ethics Committee of the Foundation for Teaching and Research in Health (*Fundação de Ensino e Pesquisa da Saúde*) (FEPECS) /Secretariat of State for Health (SES) of the Federal District, under Opinion N. 1,717,152 and Certificate of Presentation for Ethical Consideration (CAAE) 57391016.0.0000.5553.

## RESULTS

Among the 191 older adults assessed, a wide variety in the number of drugs used was observed ( $n=1.111$ ), with a median of 06 (Table 2). A total of 150 (13.5%) were classified as potentially inappropriate according to the Beers criteria, and 135 (12.6%), according to the STOPP criteria. Among these older adults, 71.2% had already made at least one clinic visit to this geriatric service; a significant reduction was observed in the number of drugs used, at a level of 5% ( $p = 0.003$ ), in comparison with those making their first clinic visit. In this sample, the majority had a prescription (88.9%). Nevertheless, in every 10 drugs, one was used without prescription. Among the drugs for which there was no prescription, the most used were those for the respiratory system, in compound preparations against coughs and colds, according to the ATC (Anatomical Therapeutic Chemical Code) classification, 2017. The other drugs used for self-medication can be seen in figure 1. In total, 1,111 drugs were used. Of these, according to the RENAME classification, 44.7% were for the cardiovascular system, and 17.2% for the central nervous system. The percentages for the digestive (9.4%) and endocrine (8.1%) systems were also relevant. No significant correlation was observed in relation to educational level and age, or being alone or being accompanied during the clinic visit, according to the Spearman correlation. Female patients used more drugs than male patients. This difference was significant at the level of 5% ( $p$ -value = 0.014), as presented in the nonparametric Mann-Whitney test. Among the drugs used and considered inappropriate according to the Beers and STOPP criteria, omeprazole had the highest incidence, followed by clonazepam (Table 3). When the analysis covers not just one drug, but assesses a class of drugs, we observe that these values come to be more concerning. During the study, a classic case of episodes of hypoglycemia due to the use of glibenclamide was observed. This ceased after the drug was substituted with gliclazide. Complaints of dizziness, common among the elderly, were related in some cases to orthostatic hypotension – and in one specific case, were due to the use of methyl dopa. The suspension or substitution of this drug by an antihypertensive of another class corrected the problem. Drugs used topically were also assessed, such as ointments, dermatological creams and eyedrops. The study observed a frequency of use of 18 (1.8%). Of these, four (0.4%) reported only the use of an ointment and were unable to give the product's name. Moreover, 100% stated that they had no prescription. The most used was dexamethasone ointment (0.5%). All of the interviewees who used eyedrops did so with a medical prescription ( $n=12$ ), although approximately 40% were unable to provide the drug's name correctly (Figure 1).

## DISCUSSION

The elderly are the proportion of the population that grows the most, leading to greater demands on the health services, and increasing use of drugs<sup>5</sup>. Studies conducted in Brazil show a high prevalence in the use of drugs by the elderly, varying from 83.5% to 99.7%<sup>4</sup>. In the present study, 95.8% of the older adults were using at least one drug, which is consistent with the findings of other Brazilian studies (Santos, 2017; Faustino *et al.*, 2013). The present study includes drugs considered inappropriate, regardless of the diagnosis. The prevalence of women found in this sample was also detected in other similar studies in Brazil (Santos, 2017; Cassoni *et al.*, 2014), and as a consequence, it is evidenced that women use more drugs than men. The literature describes various reasons explaining this greater prevalence among women, such as, for example, the process of feminization of aging and sociocultural aspects. Women make greater use of the health services and are more exposed to drugs (Santos, 2017; Faustino *et al.*, 2013). Among the inappropriate drugs, according to the Beers criteria and also to the STOPP criteria, omeprazole had the highest incidence, at 29.3% ( $n = 56$ ). The proton pump inhibitors are considered inappropriate when used for over 08 weeks. The prolonged use of this class of drugs can suppress gastric acid production by up to 95% and affect the digestion of proteins, the absorption of vitamin B-12 and of calcium, inhibit osteoclasts and increase the risk of bacterial growth (Cheung, 2010; Rodrigues, 2016; Vestergaard, 2006). The second group of most-used inappropriate drugs is made up of the benzodiazepines (11.9%), with clonazepam (9.9%) used most. This result is in accordance with studies undertaken in other regions of Brazil and abroad, which also found benzodiazepines to be the most prescribed and used drugs (Gonzalez Manso *et al.*, 2015; Tannenbaum *et al.*, 2017; Fochat *et al.*, 2012).

The reason for the inappropriacy of this class of drugs is the increase in the risk of sedation, cognitive compromise, delirium, and reduction in balance, with consequent risk of falls and fractures. The benzodiazepines cause dependence and many older adults who make chronic use of them refuse to stop – and may even deny the adverse reactions due to their fear of the drug ceasing to be prescribed for them (Oliveira *et al.*, 2017; Michael Soyka, 2017). The anti-inflammatories are mentioned as inappropriate under both the Beers and STOPP criteria; the most used in this sample was ibuprofen ( $n=17$  and frequency of use in the sample of 1.5%). However, on evaluating the class as a whole (considering the use of all of the anti-inflammatories, including those associated with muscle relaxants and other substances) we have  $n$  of 26, corresponding to 2.6% of the drugs used. The prevalence of use of potentially inappropriate drugs did not vary significantly between the criteria studied, at 13.5% for the Beers List, and 12.16% for STOPP. There are differences in the mentioning of some drugs from one or the other, which suggests that the use of these two lists in complementary fashion can lead to greater detection of the use of potentially inappropriate drugs among older adults in Brazil. The phytotherapeutic medications and home-made herbal remedies are considered by both users and prescribers to lack adverse effects – and end up not being routinely reported. However, the use of these medications is not completely innocuous, and there is a genuine risk of drug interactions – mainly for the elderly individual who routinely uses several drugs concurrently (Science *et al.*, 2006; Marlière *et al.*, 2008). Likewise, the use of topical medications is not

**Table 1. Drugs which should be avoided in older adults and therapeutic alternatives, adapted Compiled by the authors, 2017**

Types of drug	Which drugs?	Risks in prescribing?	Alternatives	What not to do
Anti-cholinergics	Amitriptyline Dexchlorpheniramine Promethazine Cyclobenzaprine Haloperidol Metoclopramide	Falls Cognitive compromise Delirium Dry mouth Intestinal constipation hypotension retention	Allergic reaction: second generation antihistamine (loratadine, desloratadine). Muscle pain: nonpharmacological alternatives: physiotherapy, relaxation, massage. Vomiting: Ondansetron or domperidone. Depression: citalopram, escitalopram, mirtazapine, escitalopram, sertraline.	Prolonged use of first generation antihistamines.
	Amitriptyline Imipramine Doxepin Fluoxetine* Paroxetine*	Cholinergic effects (dry mouth, intestinal constipation, orthostatic hypotension, sedation, cardiac arrhythmias, delirium, exacerbation of glaucoma, prostatic hypertrophy).	Nonpharmacological therapies ISRS (citalopram, escitalopram, sertraline) ISRSNa2 (mirtazapine) NB: Avoid doses of citalopram over 20mg	TCAs* for patients with dementia. TCAs for patients with cardiac conduction abnormalities. TCAs for patients with intestinal constipation. TCAs for patients with prostatism or history of urinary retention.
Anti-depressants		* hyponatremia, insomnia, mental confusion.		Selective serotonin reuptake inhibitors for patients with past history of clinically significant hyponatremia.
Antipsychotics	Typical (haloperidol) Atypical (quetiapine, risperidone)	sedation, risk of falls, increase in mortality	The atypicals must be preferred as their adverse effects are of lesser intensity	Antipsychotics in prolonged use in patients with parkinsonism. Antipsychotics in prolonged use as hypnotics.
				Anticholinergics for treating extra-pyramidal side effects of antipsychotics.
Digitalis drugs	Digoxin	Doses above 0.125mg must be avoided due to risk of renal toxicity	Tachycardia and atrial fibrillation indicate use of betablockers (metoprolol, carvedilol).	Digoxin > 0.125mg per day for patients with altered renal function.
Nonhormonal anti-inflammatory (NHA1)	Diclofenac Meloxicam Naproxen Ibuprofen Nimesulide Ketoprofen Others	These increase the risk of gastrointestinal bleeding, renal failure, congestive heart failure, SAH.	Nonpharmacological measures: physiotherapy, relaxation, massage. Dipyron Paracetamol NB: Should use be necessary (nonresponse to other measures) - use in association with gastric protection - does not eliminate the risk of gastrointestinal bleeding, but minimizes it. USE FOR SHORT PERIOD	Prescribe SAA for patients with past history of peptic ulcer disease and without concomitant use of proton pump inhibitors or H2 histamine receptor antagonist Proton pump inhibitors in full dose, for ulcer disease, for over eight weeks. Prescribe warfarine and NSAIDs used concomitantly.
	Laxatives	Senna Bisacodyl	Dysfunction of the colon Diarrhea; Fecal incontinence; Refractory constipation; Obstruction.	Fibre Hydration Osmotic laxative (Lactulose) NB: DO NOT USE MINERAL OIL - risk of aspiration (fat embolism), and interference in absorption of vitamins
Oral hypoglycemics	Chlorpropamide Glyburide	Chlorpropamide: has a prolonged half-life in older adults. Can cause prolonged hypoglycemia.	Gliclazide Metformin	Betablockers for patients with diabetes mellitus type 2 and frequent episodes of hypoglycemia (more than one a month).
Benzodiazepines	Diazepam Alprazolam Lorazepam Clonazepam Bromazepam	Delirium, falls, fractures, depression, dementia, paradoxical effect: (agitation, irritability, hallucinations), dependence.	Insomnia: sleep hygiene, antidepressants with sedative effect (mirtazapine, trazodone). Anxiety: citalopram, escitalopram Use in specific cases for short periods and give preference to those with shorter half lives (lorazepam)	Insist on the prolonged use of benzodiazepines with long half-life.
	Nonbenzodiazepine hypnotics	Zopiclone Zolpidem	Minimal improvement in sleep latency and duration.	Insomnia: sleep hygiene, antidepressants with sedative effect (mirtazapine, trazodone).
Diuretics	Furosemide Hydrochlorothiazide	Falls Orthostatic hypotension Urinary incontinence	Do not use as first choice for treating Systemic Arterial Hypertension - prescribe other class of antihypertensive	Thiazide diuretics for patients with history of gout. Loop diuretics for patients with intermittent edema in the ankle, with no other clinical signs of cardiac failure.

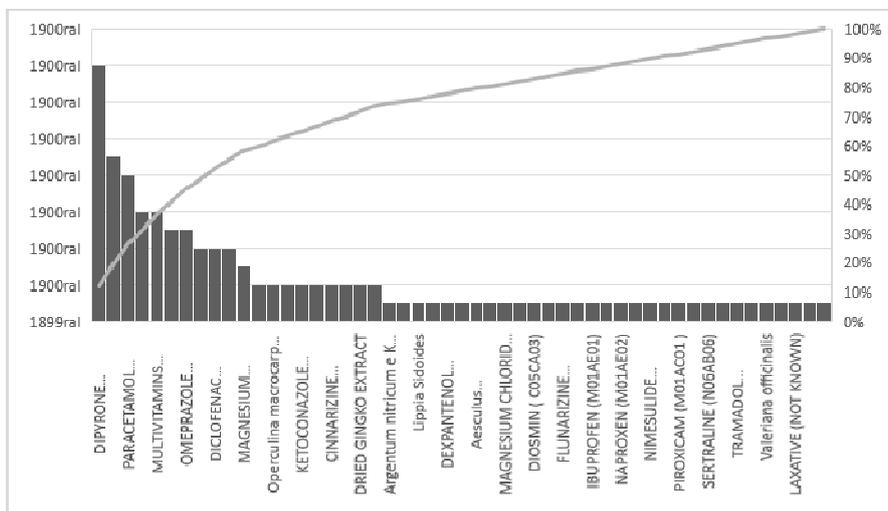
\* TCAs - tricyclic antidepressants

**Table 2. Proportional distribution of the older adults by sociodemographic characteristics and use of inappropriate drugs, in the city of Recanto das Emas. Brasília, 2017**

Demographic characteristics	n	%
Sex		
Male	55	29
Female	136	71
Age (years)*	79 (61-103)	
Educational level (anos)*	0 (0-11)	
Dependence		
Dependent	49	26
Semidependent	20	11
Independent	118	63
Companion		
No	67	35
Yes	124	65
Clinic visit		
First	55	29
Second	136	71
Number of drugs*	6 (0-15)	

\* Data expressed as median (minimum – maximum)

Drug	Frequency	%	Incidence
Omeprazole	56	37.6%	29.3%
Clonazepan	19	12.8%	9.9%
Ibuprofen	17	11.4%	8.9%
Cyclobenzaprine	6	4.0%	3.1%
Methyl dopa	6	4.0%	3.1%
Cinnarizine	4	2.7%	2.1%
Amitriptyline	3	2.0%	1.6%
Flunarizine	3	2.0%	1.6%
Nortriptyline	3	2.0%	1.6%
Mineral oil	3	2.0%	1.6%
Pantoprazole	3	2.0%	1.6%
Zolpidem	3	2.0%	1.6%
Metoclopramide Chloride + dimethicone + Pepesin	3	2.0%	1.6%
Diazepan	2	1.3%	1.0%
Diclofenac	2	1.3%	1.0%
Fluoxetine	2	1.3%	1.0%
Promethazine	2	1.3%	1.0%
Caffeine/Carisoprodol/Diclofenac/Paracetamol	2	1.3%	1.0%
Haloperidol	1	0.7%	0.5%
Anti-inflammatories	1	0.7%	0.5%
Alprazolam	1	0.7%	0.5%
Clozazolam	1	0.7%	0.5%
Gibenclamide	1	0.7%	0.5%
Bromazepam	1	0.7%	0.5%
Meloxicam	1	0.7%	0.5%
Naproxen	1	0.7%	0.5%
Nimesulide	1	0.7%	0.5%
Piroxican	1	0.7%	0.5%
<b>TOTAL</b>	<b>149</b>	<b>100.0%</b>	<b>-</b>



**Figure 1. Relationship between the frequency of drugs used through self-medication and their frequency of use in older adults, Brasília, 2017**

risk-free. Eyedrops with strong corticosteroids in the formula, used for prolonged periods, are related to cataract and glaucoma. Corticosteroid creams and ointments, depending on duration of use, extent of the skin to which they are applied and the strength of the corticosteroid can – although this is rare – cause suppression of the hypothalamic-pituitary-adrenaline axis (Daniel, 2015; Böckle *et al.*, 2014). It is concluded that the use of inappropriate drugs, polypharmacy and self-medication continue to have a high prevalence among the elderly and that it is necessary to implement measures providing guidance to prescribers and the population regarding the risks posed by the inappropriate use of drugs. The use of lists and of prescribing criteria helps to reduce inappropriate prescribing. Nevertheless, a gap was observed in the lists used, as there was no reference to topical or phytotherapeutic drugs. There is, therefore, a space for further studies, with the aim of assessing whether these should be included in the lists of inappropriate drugs for the elderly.

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**Conflict of interest:** the authors declare there to be no conflicts of interest.

#### Authors' contributions

Flavia L.P.G. Tuyama has full access to all of the study's data and takes responsibility for the integrity of the data and the accuracy of the analysis of the data. She was responsible for data collection, study design, statistical analyses, data interpretation, elaboration of the manuscript, the final approval of the data for publication, and submission of the manuscript.

Carmelia M. S. Reis: study design, concept, data interpretation, elaboration of the manuscript, submission of the manuscript, and final approval of the data for publication.

Maria R. C. G. Novaes: study design, concept, data interpretation, analysis and interpretation of the data, elaboration and final revision of the article, and approval of the manuscript for publication of the data.

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