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ORIGINAL ARTICLE

SAFE ALTERNATIVES FOR TREATING HYPERTENSION AND DIABETES IN OLDER ADULTS OF THE FEDERAL DISTRICT – BRAZIL

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Highlights:
(1) The government of Federal District offers more safe alternatives compared to Farmácia Popular.
(2) Brazil's Popular Pharmacy Program Program does not offer a safe alternative of sulfonylurea for the older adults.
(3) It is essential to consider the adaptation of *Beers* Criteria at the national level, recognizing the distinct characteristics of the SUS.

ABSTRACT

Introduction: This study aims to present alternatives available in the Unified Health System for de-prescribing potentially inappropriate drugs (PIM) or potential drug interactions *(*PDI) in the treatment of hypertension or diabetes *mellitus* (DM) in the elderly in the Federal District. *Methods:* A cross-sectional study was carried out with an analysis of prescriptions to identify PIM and an analysis of clinical protocols and guidelines. The aim was to present alternatives from the list of standardized medicines of the Federal District Health Department and the Brazil's Popular Pharmacy Program. *Results:* The most frequent PIM was insulin (13.7%), followed by clonidine (1.6%) and glibenclamide (1.0%). The most frequent PDI was between angiotensin II receptor blockers, angiotensin-converting enzyme inhibitors or potassium-sparing diuretics (6.6%). *Discussion:* Antidiabetics with a lower risk of causing hypoglycemia, such as metformin and dapagliflozin, are available from the Federal District Health Department and the Brazil's Popular Pharmacy Program. Modified-release gliclazide is an alternative to sulfonylureas, with advantages in terms of efficacy in glycemic control, cardiovascular safety and low potential for triggering hypoglycemia; however, free access is restricted to the Federal District Health Department. The availability of thiazide diuretics, beta-blockers and calcium channel blockers in the SUS makes it possible to associate antihypertensives that act on the renin-angiotensin system more safely. *Conclusion:* The differences between the List of Medicines of the State of the Federal District and the Brazil's Popular Pharmacy Program showed that the Federal District Health Department offers more options for treating hypertension or DM, including safer alternatives for older adults and the possibility of more effective drug combinations.

Keywords: deprescriptions; potentially inappropriate medication list; hypertension; diabetes mellitus; aged; access to essential medicines and health technologies.

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INTRODUCTION

The high prevalence of chronic non-communicable conditions such as systemic arterial hypertension (SAH) and diabetes *mellitus* (DM) among older adults increases the demand for pharmacological treatment, which has led to an increase in both the number of drugs prescribed and the complexity of therapeutic regimens, especially when considering the coexistence of comorbidities. Additionally, the pharmacokinetic changes that are part of the aging process, which reduce the metabolism of drugs, while potentiating their effects, contribute significantly to the greater sensitivity of this age group to adverse events[1,2].

In this sense, *the American Geriatrics Society* (AGS) developed the *Beers Criteria* (*AGS Beers Criteria*®), which are a list of drugs and drug interactions that are potentially inappropriate for older individuals. These criteria are intended to advise healthcare professionals on with drugs or combinations that should be avoided in older people, in most cases or in specific situations, such as certain medical conditions. The *Beers* Criteria have gained significant importance among diverse group of professionals, including clinicians, educators, researchers, health service administrators and regulators[3].

The AGS classifies certain drugs as potentially inappropriate medicines (PIMs) for use in older adults when the risk of them causing adverse reactions exceeds the expected benefit for the person or when a safer, better tolerated or more effective alternative is available[3-5].

Therefore, a potential drug interaction (PDI) occurs when one drug modifies the intensity of the pharmacological effects of another, increasing or decreasing the expected result of pharmacotherapy. PDI is more frequent with polypharmacy[3,5,6]. The World Health Organization (WHO), defines polypharmacy or polymedication as the continuous and concomitant use of four or more drugs (with or without a prescription) by a patient[7].

It is imperative to establish effective therapeutic strategies aimed at intervening and optimizing the use of drugs, given the adverse reactions that can be triggered by the use of potentially inappropriate drugs or drug combinations. These practices should be applied consistently to older adults population in order to mitigate possible problems associated with the inappropriate use of drugs. Among the strategies adopted to promote rational use is drug deprescribing, a method that seeks to rationalize the therapeutic regimen by discontinuing potentially unnecessary or inappropriate drugs. In the context of polymedication, this procedure becomes fundamental for reducing risks and maximizing therapeutic results[8].

However, one of the main barriers to de-prescribing drugs or inappropriate combinations is the difficulty of discontinuing the use of essential drugs due to the health professional's lack of knowledge and skills in replacing them with a safer and more effective alternative drug[9], or even the availability of another safer alternative.

The aim of this study was to present alternative drugs available in the Unified Health System (SUS) to replace the most frequent PIMs or PIMs used to manage hypertension or diabetes *mellitus* in prescriptions for older adults seen at a Basic Health Unit in the Federal District.

METHOD

The first stage was a cross-sectional, descriptive-exploratory study with a quantitative approach. This documentary analysis aimed to identify the most frequent medications and possible inappropriate interactions in the prescriptions of older adults being treated for hypertension or diabetes *mellitus*.

This study involved collecting and analysing prescriptions in Primary Health Care in the Southern Health Region of the Federal District Health Department. Specifically, it was conduced in a Basic Health Unit located in the administrative region of Santa Maria, Federal District. The Basic Health Unit in the study has 11 family health teams, six oral health teams, a laboratory test collection point, a pharmacy, medication, vaccines and dressing rooms. It also there is an X-ray room and a multiprofessional support team.

The drugs dispensed in the basic units follow the Federal District Health Department'guidelines and are included in the List of Medicines of the Federal District[10]. Considering the selected scenario, Ordinance No. 250, of December 17, 2014[11], establishes the technical and administrative guidelines for the prescription and supply of drugs and health products within the scope of primary care, under the jurisdiction of the Federal District Health Department. The dosage of the drugs is determined by the quantity supplied for a maximum of 30 days of treatment.

The medications available in Basic Health Unit pharmacies meet the main needs of Primary Health Care. However, any qualified health professional can prescribe medications and health products based on protocols approved by the Federal District Health Department or the Ministry of Health, as well as on resolutions from the respective professional councils. The prescription must comply with the technical-administrative and health standards to be filled by any Basic Health Unit in the Federal District. The supply of medications is not restrited based on the administrative region or address of the user's residence. The Basic Health Unit of reference, establishment or health unit responsible for issuing the prescription (public or private)[10,11] is also not a factor in these restrictions.

The prescriptions that were filled during the month of August 2022 were collected and analyzed because of the continuous use nature of drugs under analysis and monthly frequence of dispensing service carried out by the pharmacy. This strategy was implemented to avoid repeating prescriptions, given that patients are scheduled to return every month, and due to the constant flow of appointments at the pharmacy. It is important to note that there were no holidays or interruptions in the operation of the Basic Health Unit or the pharmacy.

The dispensing system SIS-Materiais (*Alphalink*®) filtered all the appointments made in August 2022 for people aged 65 or over on or before July 31, based on their date of birth, to to identify the prescriptions that would be analyzed in the study,

Next, an analysis was made of the medications or health products dispensed in each recorded visit. This made it possible to select prescriptions for people aged 65 or over from the second copies on file. Documents issued in both the public and private health systems in the Federal District within 365 days and containing at least one medication for continuous use in the treatment of SAH or DM were considered for inclusion in the study. In the research process excluded prescriptions containing only drugs related to other clinical conditions and prescriptions for drugs under special control.

Medication was dispensed according to the treatment protocols for diabetes *mellitus* or hypertension were documented, and these prescriptions were chosen for analysis.

The PIM and PDI adopted were those outlined by the *American Geriatrics Society* and indicated in the *Beers* Criteria, published in 2019. We evaluated the criteria for all antihypertensive and antidiabetic drugs, regardless of whether or not they were listed in the List of Medicines of the State of the Federal District or in the National List of Essential Medicines[12].

Regarding antihypertensive pharmacotherapy, all the drugs and combinations included in the Brazilian Guidelines for SAH[13] were taken into account. For antidiabetics, the Brazilian Diabetes Society[14] treatment regimen was considered, including all drugs in it.

In the second stage, we tried to identify alternative substitutions for the most frequently used drugs and identified inappropriate interactions. We based these findings on the List of Medicines of the State of the Federal District[10], which lists the essential drugs standardized by the Federal District Health Department, and the drugs made available by the complementary Brazil's Popular Pharmacy Program[15,16].

In this context, we analyzed the pharmacological treatment flowchart of the Clinical Protocol of Therapeutic Guidelines[17] for diabetes *mellitus,* currently approved by the Ministry of Health, and the current Protocol for the Management of Diabetes *Mellitus* at the Federal District Health Department[18]. Our goal was to identify which oral antidiabetics and insulins are indicated for pharmacological management.

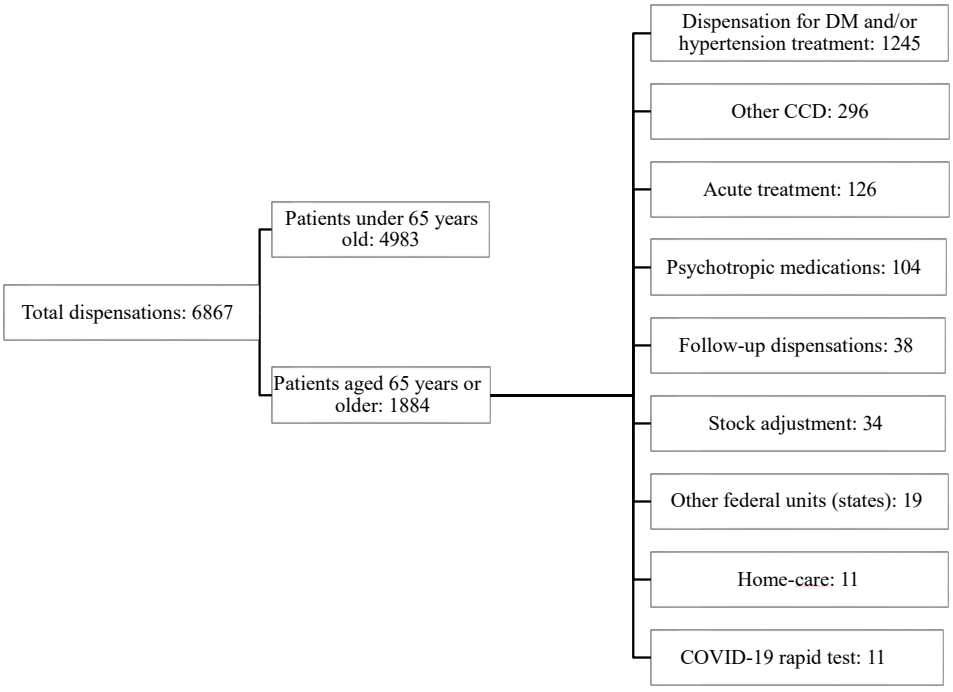
These is currently, there is no Clinical Protocol of Therapeutic Guidelines for the management of hypertension in the SUS. In view of this, we analyzed the treatment algorithm recommended in the Brazilian guidelines for arterial hypertension[13], the Ministry of Health's Care Line for Adults with Hypertension[19] and the current Federal District Health Department Protocol for the Management of Systemic Arterial Hypertension in Primary Health Care[20].

The guiding documents were then compared to the lists of medicines available from the Federal District Health Department and the Brazil's Popular Pharmacy Program. This was done to identify the options that can be accessed free of charge and that are safer for continuous use by older adults on the SUS.

The project was approved by the Research Ethics Committee under the certificate of submission for ethical appraisal 66652722.9.0000.5553. This study was conducted with strict confidentiality, safeguarding the privacy and security of user and prescriber data. We only collected technical information regarding the medications in the prescriptions. The study did not establish direct contact with users, so the free and informed consent form was waived.

RESULTS

During the month of August 2022, a total of 6,867 appointments were made, wich 1,884 (27.4%) of these appoitments designated for individuals aged 65 and over. Of these, 1,245 (N=6,867; 18.1%) involved medication for the management of diabetes or hypertension, representing 66.1% of prescriptions for older users (Figure 1). The prescriptions of these patients were selected for analysis.



Note: DM: diabetes mellitus; CCD: chronic non-communicable diseases.

Figure 1 – Number of visits for access the medication in August 2022, at the Basic Unit Health in Santa Maria, Federal District.

Source: Own authorship (2024).

After examining the 1,245 prescriptions selected, it was found that 301 of them (24.2%) included at least one PIM or PDI according to the *Beers* Criteria[3]. Of these, 232 (71.7%) prescriptions contained at least one PIM, 83 (27.6%) had some PDI and 14 (4.7%) contained both PIM and PDI. This accounts for 301 prescriptions (Table 1).

Table 1 – Frequency of inappropriate medications and potential drug interactions in prescriptions for the older adults, according to the *Beers* Criteria (Santa Maria, Federal District, 2022)

	N	% of total prescriptions with PIM or PDI (n=301)	% of total prescriptions (N=1245)
Presence of PIM or PDI in the prescription			
Yes	301	-	24,2
No	944	-	75,8
Frequency of prescriptions with PIM or PDI			
PIM Only	218	72,4	17,5
PDI Only	69	22,9	5,5
PIM + PDI	14	4,7	1,1

Note: PIM: potentially inappropriate drugs; PDI: potential drug interaction; N: total number of prescriptions analyzed in the study; n: total number of prescriptions with inappropriate drugs or drug interactions identified in the study.

Source: Own authorship (2024).

The analysis of the prescriptions containing PIM (n=232), revealed that insulin was the most prevalent PIM (Table 2), present in 73.3% of these prescriptions, which corresponds to 13.7% of the total prescriptions analyzed (N=1,245).

Table 2 – Potentially inappropriate medications used by older adults, according to the *Beers* Criteria (Santa Maria, Federal District, 2022)

	N	% of total prescriptions containing PIM (n=232)	% of total prescriptions (N=1245)
Presence of PIM in the prescription			
Yes	232	-	18,6
No	1013	-	81,4
Distribution and frequency of PIM			
Hypoglycemic and antihyperglycemic agents			
Insulin	170	73,3	13,7
Long-acting sulphonylurea: Glibenclamide	12	5,2	1
Thiazolidinediones/Glitazones: Pioglitazone	4	1,7	0,3
Antihypertensives			
α2-adrenergic agonists: Clonidine	20	8,6	1,6
Non-dihydropyridine CCB: Verapamil	11	4,7	0,9
α2-adrenergic agonists: Methyldopa	8	3,4	0,6
Dihydropyridine CCBs: Nifedipine (immediate release)	6	2,6	0,5
α1 adrenergic antagonists: Doxazosin	6	2,6	0,5
Non-dihydropyridine BCC: Diltiazem	6	2,6	0,5

Note: PIM: potentially inappropriate drugs; PDI: potential drug interaction; CCB: calcium channel blockers; N: total number of prescriptions analyzed in the study; n: total number of prescriptions with potentially inappropriate drugs identified in the study.

Source: Own authorship (2024).

As for the prescriptions with PIMs (n=83), the interaction between angiotensin II receptor blockers (ARBs), angiotensin-converting enzyme inhibitors (ACEIs) or potassium-sparing diuretics (K^+) was the most common potential drug interaction, found in 92.5% of the prescriptions with PIMs, representing 6.6% of the total prescriptions analyzed (Table 3).

Table 3 – Potential drug interactions used by older adults, according to the *Beers* Criteria (Santa Maria, Federal District, 2022)

	N	% of total prescriptions with PDI (n=83)	% of total prescriptions (N=1245)
Presence of inappropriate interaction in the prescription			
Yes	83	-	6,7
No	1162	-	93,3
Distribution and frequency of PDI			
Antihypertensives			
ARB with K^+			
Losartan with Spironolactone	56	67,5	4,5
Association of Sacubitril and Valsartan with Spironolactone	7	8,4	0,6
Olmesartan with Spironolactone	2	2,4	0,2
Association of Sacubitril and Valsartan OR Losartan with Spironolactone*	1	1,2	0,1
Valsartan with Spironolactone	1	1,2	0,1
ACEI with K-sparing diuretic$^+$			
Enalapril with Spironolactone	12	14,5	1,0
ARB with ACEI			
Losartan with Enalapril	2	2,4	0,2
Losartan with Captopril	1	1,2	0,1
α1 adrenergic antagonists with loop diuretics			
Doxazosin with Furosemide	1	1,2	0,1

*prescription that indicated the possibility of using both associations;

Note: PDI: potential drug interaction; ACEI: angiotensin-converting enzyme inhibitors; ARB: angiotensin II receptor blockers; N: total number of prescriptions analyzed in the study; n: total number of prescriptions with potentially inappropriate drugs identified in the study.

Source: Own authorship (2024).

The Table 3 lists the options available in the the List of Medicines of the State of the Federal District and in the Brazil's Popular Pharmacy Program [15,16], for substitution in the event of non-prescription of the PIM or PDI identified in the prescriptions after analysis of the documents provided in the methods.

Table 3 – Options available in the SUS for de-prescribing medications and inappropriate interactions for older adults

Medication and inappropriate interactions	**Possible substitute or precaution for use if there is no substitute**		
	the List of Medicines of the State of the Federal District[10]	**Brazil's Popular Pharmacy Program[15,16]**	**Beware if kept**
Insulin	Insulin pen (*carpule*): ultrafast, regular, NPH, Determir and glargine; (dispensing according to protocol)	Insulin pen (*carpule*): regular and NPH	Avoid insulin therapy regimens using only rapid or ultrafast insulins, without the simultaneous use of intermediate or long-acting insulin. Carry out self-monitoring of glucose levels[3,5,17,20].
Long-acting sulphonylureas	Gliclazide MR 30 or 60 mg	There is no safer alternative available for the older adults	If possible, carry out self-monitoring of glucose levels[20].
Thiazolidinediones (Glitazones)	Metformin 850 mg (common); Gliclazide MR 30 or 60 mg; Dapaglifozin 10 mg; Insulin pen (carpule): ultra-fast, regular, NPH, determir and glargine (Dispensed according to protocol)	Metformin 500 mg (common and XR) or 850 mg (common); Dapaglifozin 10 mg; NPH and regular insulin in vial presentation	Use with caution in the older adults with asymptomatic HF, on insulin therapy, at risk of HF, osteoporosis, falls, fractures or macular edema. Contraindicated in cases of symptomatic HF. Thiazolidinediones are not incorporated into the SUS because they are not cost-effective compared to those available[5,14,17,20].
Dihydropyridine BCCs: Nifedipine (immediate release)	Hypertensive crisis: Captopril (25 mg); Anlodipine (5 mg or 10 mg) Hypertensive emergency (parenteral): Nitroglycerin, Metoprolol and Furosemide	Hypertensive crisis: Captopril (25 mg); Anlodipine (5 mg)	Increased risk of hypotension and myocardial ischemia. The existence of effective and better tolerated alternatives makes the use of this agent inadvisable[13].
Sympatholytics of central action (α2-adrenergic agonists)			They can cause bradycardia and orthostatic hypotension. Clonidine presents a risk of rebound effect with abrupt discontinuation[13]. Not recommended as first-line treatment for hypertension[21].

BCC Non-dihydropyridines **α1 adrenergic antagonists (alpha-blockers)** **Sympatholytics of central action (α2-adrenergic agonists)** **Associations between ARBs or ACE inhibitors or potassium-sparing diuretics** **Associations of α1 adrenergic antagonists with loop diuretics**	Thiazide diuretics or similar: Hydrochlorothiazide (25 mg); Indapamide (1.5 mg) ARB or ACEI: Losartan (50 mg); Enalapril (5 mg and 20 mg); Captopril (25 mg) BCC: Anlodipine (5 mg or 10 mg) Non-cardio-selective betablocker: Propanolol (40 mg) Cardioselective betablockers: Atenolol (50 mg and 10 mg); Metoprolol (25 mg or 50 mg); Carvedilol (3.125 mg, 6.25 mg and 12.5 mg) Direct vasodilators: Hydralazine (50mg)	Thiazide diuretics or similar: Hydrochlorothiazide (25 mg) ARB or ACEI: Losartan (50 mg); Enalapril (10 mg); Captopril (25 mg) BCC: Anlodipine (5 mg) Non-selective beta-blocker: Propanolol (40 mg) Cardioselective betablockers: Atenolol (25 mg); Metoprolol (25 mg)	The selection of combinations of antihypertensive drugs should follow the preferred scheme of drug combinations, taking into account the mechanisms of action and synergy. The combination of drugs should involve agents with different mechanisms of action in order to optimize the antihypertensive effect, acting synergistically on different pathophysiological pathways and inhibiting counter-regulatory mechanisms. The other classes of antihypertensive drugs (centrally acting drugs, aldosterone antagonists and direct vasodilators), as well as other invasive treatment modalities in the sympathetic system, should be seen as exceptional and non-routine options for the treatment of older adults[13].

Note: BBC: calcium channel blockers; ACEI: angiotensin-converting enzyme inhibitors; ARB: angiotensin II receptor blockers; XR: *eXtended release;* MR: *modified release;* HF: heart failure; IUD: diuretics; SUS: Unified Health System

Source: Own authorship (2024).

DISCUSSION

Other similar studies carried out in Primary Health Care in Rio de Janeiro[22], Minas Gerais[23], Porto Alegre[24] and Paraíba[25], identified the use of PIM in 35.4%, 32.9%, 55.1% and 44.8% of prescriptions, respectively. In these cases, the prevalence was higher than in this study. However, it is important to note that these studies analyzed a considerably small number of prescriptions and did not focus their analyses on specific clinical conditions.

Glibenclamide is highlighted as one of the most frequently prescribed PIMs in studies conducted in Rio de Janeiro[22], Porto Alegre[24] and Paraíba[25]. A study carried out with community-dwelling older adults in China[26], analyzing the prescriptions of 8,235 patients, revealed that the use of PIMs was present in 32.2% of the documents, with insulin being the second most frequent PIM, just behind estazolam (benzodiazepine). These results are consistent with those of the present study when evaluating hypoglycemic agents.

The Clinical Protocol of Therapeutic Guidelines for the treatment of DM, the Guidelines of the Brazilian Diabetes Society and the Federal District Health Department management protocol all recommend starting pharmacological management with metformin monotherapy. If the patient does not achieve the therapeutic goals, the use of other antidiabetics is indicated[14,17,18]. The main biomarker in the assessment of DM is glycated hemoglobin (HbA1c), with the aim of achieving values <7.5% in healthy older adults and <8.0% in compromised elderly individuals. In the case of the very compromised older adults, who have a terminal illness or severe functional or cognitive impairment, there is no established HbA1c target and the aforementioned guideline recommends avoiding symptoms of hypo- or hyperglycemia[14].

Compared to sulphonylureas, metformin, as the first choice of antidiabetic, shows beneficial effects on HbA1c, weight and cardiovascular mortality[20]. Metformin is contraindicated in patients with renal or hepatic insufficiency[17] and it should be noted that the Federal District Health Department protocol recommends that in cases of patients with impaired renal function, specifically with a glomerular filtration rate (GFR) < 30 mL/min/1.73m² or serum creatinine > 1.7mg/dL, the drug should be discontinued and replaced with NPH insulin (morning and evening)[18].

The AGS advises against the use of sulfonylureas as the first choice of antidiabetic unless there are no viable alternatives. If necessary, it is recommended to opt for short-acting sulphonylureas, such as glipizide, rather than long-acting ones, such as glibenclamide or gliclazide[5]. This recommendation is based on the higher risk of cardiovascular events, such as ischemic stroke, and hypoglycemia associated with sulfonylureas compared to other therapeutic options[3,5].

Although the *Beers* Criteria published in 2019 considered gliclazide to be a safer sulfonylurea option due to its lower risk of hypoglycemia[3]. However, the 2023 update now classifies all long-acting sulfonylureas as PIMs, including gliclazide on the list[5]. It is also important to note that gliclazide is not authorized by the *Food and Drug Administration* (FDA) and is therefore not marketed in the United States[27].

Although it is classified as an PIM in the United States, gliclazide is used in other countries and studies have concluded that the modified-release formulation, administered once a day, provides good efficacy in 24-hour glycemic control, comparable to most other hypoglycemic agents. Hypoglycemia and weight gain are less frequent than with other sulfonylureas. Similarly, cardiovascular events have a lower incidence with the use of gliclazide[28,29]. Therefore, in this study, it was presented as an option to the use of other sulfonylureas.

Although glipizide was presented as an option in the *Beers* Criteria, when compared to the other sulphonylureas it did not show any advantages in the studies carried out. With regard to the risk of hypoglycemia, it has similar results to other drugs in the class and with regard to cardiovascular safety and HbA1c reduction, it has shown inferior efficacy[27,29].

Glipizide is registered with the National Health Surveillance Agency (Anvisa) and is available for sale, but is not supplied by the SUS. The Maximum Government Sales Price (PMVG)[30], established by Anvisa, defines the maximum price applied to purchases of medicinal products by public administration entities. The PMVG list only includes the price of the reference drug for glipizide, Minidiab® (*Pfizer*), with a maximum price of R$1.04 per single 5 mg tablet, not including the Tax on the Circulation of Goods and Services (ICMS). Considering the WHO-defined daily dose (DDD) is 10 mg. The estimated monthly cost of treatment is R$62.40 per patient. In comparison, using the same parameters, the cheapest monthly treatment with gliclazide MR 60 mg would cost R$34.71.

Documents from the Ministry of Health and the Federal District Health Department indicate sulfonylureas as the second oral antidiabetic option for combination therapy and, in particular, the updated Clinical Protocol of Therapeutic Guideline, drawn up by the Ministry of Health, recommends preferably using gliclazide in older adults, in order to reduce the risk of hypoglycemia[17,18]. However, this recommendation is not included in the Federal District Health Department protocol.

The recent Federal District Health Department protocol, approved by the Undersecretariat for Comprehensive Health Care, does not address the risk and consequences of severe hypoglycemia in older adults related to the use of sulfonylureas, especially glibenclamide and insulins. The protocol's failure to consider the other particularities of pharmacological treatment for the management of diabetes *mellitus* in older adults, particularly PIMs. In this context, the current protocol fails to emphasize the importance of prescribing safe drugs for older adults in order to minimize risks and possible complications.

Despite its classification as an PIM, insulin is used in older adults due to the often absolute deficiency in its secretion[31]. The Clinical Protocol of Therapeutic Guidelines and the Federal District Health Department protocol indicate insulin therapy for people who are unable to reach the therapeutic HbA1c target with oral hypoglycemic agents[17,18]. In primary care in the Federal District[10] and in the Brazil's Popular Pharmacy Program[15], NPH and regular insulin are supplied in vials and pens. In specialized component pharmacies, ultra-fast-acting and long-acting insulin analogues (determir and glargine) are available in pens for application[10,14].

It is essential to emphasize the availability of insulin pens (*carpule*) in the SUS. These devices are purchased and distributed to the states by the Ministry of Health and are dispensed in public pharmacies[12]. Compared to the conventional use of vials and syringes, pens offer advantages in terms of precision, safety and ease of use, especially when administering higher doses. This option simplifies the insulin administration process, improving patients' quality of life and reducing complications associated with inadequate administration[32]. Thus, its use may be of greater benefit to older adults, the illiterate (illiterate and semi-literate), those with reduced visual acuity, and essential tremors[1].

The updates to the *Beers* Criteria and the American Diabetes Association's DM care guidelines recommend the use of Continuous Glucose Monitoring (CGM) devices or glucose sensors by older adults, especially those on insulin therapy or using sulfonylureas, in order to reduce the risk of hypoglycemia and glycemic variability, contributing to a reduction in HbA1c levels[20]. Federal District Health Department provides CGM devices exclusively for patients diagnosed with type 1 diabetes[33].

Patients with diabetes on insulin therapy should know that they can obtain glucometers to self-monitor their capillary blood glucose. These devices and reagent strips are supplied by the pharmacy at the patient's primary care unit. However, older adults who only use oral antidiabetics do not, in principle, have the right to free access to glucose self-monitoring devices or other supplies for monitoring[33].

Before insulin therapy, the Clinical Protocol of Therapeutic Guidelines and the Federal District Health Department protocol indicate sodium-glucose cotransporter-2 (iSGLT2) inhibitors as the third antidiabetic drug for combination therapy. These drugs are recommended in order to intensify

treatment in people with diabetes over the age of 40 and with established cardiovascular disease (CVD) or; men ≥ 55 years or women ≥ 60 years at high risk of developing CVD, defined as at least one of the following cardiovascular risk factors: hypertension, dyslipidemia or smoking[17].

Dapaglifozin is the representative present in the the List of Medicines of the State of the Federal District, and is dispensed in specialized component pharmacies for patients who meet certain requirements, such as age over 40, established CVD and GFR > 25 mL/min/1.73m^2. Another access option is the Brazil's Popular Pharmacy Program, because since June 2023, dapaglifozin has been available in the program through the co-payment system and in the case of beneficiaries of the Bolsa Família program, the drug is provided free of charge[15,16].

However, it is important to note that the version published in 2023 of the *Beers* Criteria includes dapaglifozin as a drug to be used with caution in older adults, due to the increased risk of urogenital infections, especially in women during the first month of treatment, and an increased risk of euglycemic diabetic ketoacidosis[3,5].

As for the potential interactions established in the *Beers* Criteria, studies carried out in hospitals in Sergipe[34] and the Federal District[35], identified the presence of PIMs related to the management of SAH in 9.80% and 5.88% of prescriptions, respectively. These identified interactions are between drugs that act on the renin-angiotensin system or with potassium-sparing diuretics. No additional studies were identified that specifically investigated or identified the presence of the drug interactions established in the *Beers* Criteria for the management of SAH. The other studies found analyzed the presence of the other interactions established in this document, mainly between drugs that act on the Central Nervous System, which are associated with the risk of falls.

According to the Brazilian Hypertension Guideline and the Ministry of Health's Line of Care, pharmacological treatment can be started with monotherapy or a combination of drugs, depending on the stage of hypertension and cardiovascular risk[13,19]. The algorithm of the Brazilian guideline recommends starting treatment with monotherapy or a combination of drugs at low doses and, when necessary, making incremental adjustments to therapy, respecting a minimum interval of two weeks[13]. The current Federal District Health Department protocol adopts the same algorithm for pharmacological treatment of SAH management[20].

The main classes of antihypertensive drugs recommended for use in monotherapy or association are: diuretics (IUDs), calcium channel blockers (CCBs), angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs) and beta-blockers (BBs)[13].

The Brazilian guidelines for hypertension indicate that diuretics are the drugs of first choice, taking into account tolerability and cost-effectiveness, and specifically recommend the use of thiazides or similar to start monotherapy in the older adults. The use of loop diuretics should be reserved for clinical conditions with sodium and water retention, such as renal failure and situations of edema (HF, nephritic syndrome)[13].

Spironolactone is classified as a drug to be used with caution and is listed under PDI. Its presence in the *Beers* Criteria is justified by the risk of hyperkalemia, since the drug reduces potassium excretion and the association with drugs that act on the renin-angiotensin system, such as ACEIs or ARBs, and aggravate this hydroelectrolytic disorder. As such, the *American Geriatrics Society* recommends that this diuretic be used with caution in the older adults, recommending avoiding its use or adjusting the dose in patients with a creatinine clearance of less than 30 mL/min[3,5]. Hyperkalemia is correlated with high rates of morbidity and mortality, as well as an increase in the use of health resources and associated costs, especially among older people[36].

Although the use of CCBs in monotherapy or in combination is provided for in the guideline and in the SAH line of care, the *Beers* Criteria contraindicate the use of non-dihydropyridine blockers

such as verapamil and diltiazem in older adults due to their potential to promote fluid retention and aggravate heart failure[3,5]. Together, they belong to class IV of antiarrhythmics, and can delay atrioventricular conduction and reduce heart rate[13,36].

If the patient is unable to achieve the therapeutic goal of blood pressure control, established on the basis of the presence or absence of CVD and other comorbidities or risk factors for development, the SAH clinical guideline recommends a combination of drugs, which should be done with an ACEI or ARB, combined with a thiazide or similar diuretic, CCB or beta-blockers. The Ministry of Health's Line of Care suggests the same combination scheme[19].

With regard to the use of spironolactone as a fourth antihypertensive agent, it is important to note that there are alternative therapeutic options that offer greater safety with regard to the risk of hyperkalemia. BBs, both non-selective and cardioselective, can be considered viable choices for combination therapy[3,5,10].

The guideline for the management of hypertension recommends the use of a fifth antihypertensive drug, BB, α2-adrenergic agonists, alpha-blockers or vasodilators[13]. In contrast, the Ministry of Health's Line of Care recommends the use of BB as the fifth antihypertensive agent and, if necessary, the sequential addition of centrally acting sympatholytics or direct vasodilators[19].

The Federal District Health Department protocol warns against the use of BBs in patients over 65, as they are at greater risk of developing bradycardia. In addition, abrupt discontinuation of these drugs is related to the risk of tachycardia, hypertension and/or ischemia, so the document suggests that they should be withdrawn gradually[20]. It is important to note that this protocol does not specifically address the particularities of the pharmacological treatment of hypertension in older adults, superficially mentioning the increased risk of drug interactions in this population due to polymedication. Like the DM management protocol[18], this protocol also fails to consider the other particularities of pharmacological treatment in the older adults, with regard to PIMs and PIMs. In this scenario, the current protocol does not adequately highlight the importance of prescribing safe medication for older adults, with the aim of reducing risks and avoiding complications[20].

Despite the suggestion to use sympatholytics, the latest publications of the *Beers* Criteria discourage this practice due to the considerable risk of adverse effects on the central nervous system, as well as the tendency to cause bradycardia and orthostatic hypotension. It is important to note that the use of α2-adrenergic agonists as the first choice of antihypertensive agent or their use on a continuous basis is also contraindicated, which is why they are considered PIMs[3,5]. Although the SAH Care Line presents clonidine as an option for hypertensive crisis, there are other safer options available[10,15,19].

As for alpha-blockers such as doxazosin, it is important to note that they are considered PIMs due to their high risk of orthostatic hypotension. In addition, there is a potential interaction between these drugs and loop diuretics such as furosemide, associated with an increased risk of urinary incontinence in elderly women[3,5].

The presence of multimorbidities in older adults and the consequent polypharmacy makes the process of analyzing the safety and effectiveness of prescribed pharmacotherapy more complex. Furthermore, the *Beers* Criteria are not the only validated clinical criteria for analyzing inappropriate medication in older adults. Another validated tool is the *Screening Tool to Alert doctors to Right Treatment* (START) and *Screening Tool of Older Person's Prescriptions* (STOPP) criteria, which allow the identification of other inappropriate drugs and combinations and, in a complementary way, make it possible to identify drugs omitted from prescriptions, which are considered potentially beneficial for older people[37].

It is therefore necessary to carry out further studies in Primary Health Care, using the *Beers* Criteria and START/STOPP together, especially prospectively, in order to assess the results related to reducing adverse events and improving the effectiveness of pharmacotherapy. This comprehensive approach would allow for a more complete and accurate analysis of therapeutic regimens in older adults, with a view to optimizing patient care and safety. In conjunction, additional studies need to be carried out to assess the presence of PIMs or PIMs used in the treatment of DM or SAH, in order to compare and discuss the results obtained.

As described in the methods, the prescriptions were collected and analyzed based on the *Beers* Criteria published in 2019. However, the update of these criteria was published in May 2023. As a result, the drugs included in this update were not taken into account when analyzing the prescriptions, which limited the results of this study. In addition, it is worth mentioning that no medical records or other documents were analyzed, which restricted the inclusion of PIM or PDI correlated to biochemical parameters. Another limitation of this study is the generalization of the results, based on data collection in only one Basic Health Unit in the Federal District.

CONCLUSION

The differences identified between the List of Medicines of the State of the Federal District and Brazil's Popular Pharmacy Program drug lists revealed that the Federal District Health Department offers a wider range of options compared to the Brazil's Popular Pharmacy Program for the management of SAH and DM, especially in terms of the availability of safer alternatives for older adults and the possibility of making more effective drug combinations.

This context has highlighted the importance of prescribers being properly updated on the list of standardized drugs, as well as on current protocols and guidelines. Continuing education and constant updating of health professionals in Brazil play a fundamental role in adapting prescription safety and quality analysis tools, such as the *Beers* Criteria, to national particularities, ensuring access to medications that are both effective and safe for older people.

Therefore, the importance of analyzing the updates to the *Beers* Criteria becomes clear, highlighting the need to evaluate drug options when drawing up clinical protocols and other guidance documents for prescribing professionals, as well as the therapeutic plan. It is essential to consider that these criteria were developed based on the North American reality, which requires careful adaptation to the Brazilian context. It is therefore clear that health professionals in Brazil must assess the safety of medication provided by the SUS for older adults, thus guaranteeing access to treatments that are both effective and safe and ensuring comprehensive therapeutic and pharmaceutical care.

It is essential to move forward with the national adaptation of the availability of safe medicines for older adults. Given the uniqueness of the health system, the availability of medicines, and the specific characteristics of the country's elderly population, an adapted approach is necessary to apply these criteria more effectively.

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