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ORAL ANTIDIABETIC MEDICINES AND INSULINS IN THE LISTS OF ESSENTIAL MEDICINES OF BRAZILIAN CAPITALS AND THE FEDERAL DISTRICT

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Highlights: (1) There was diversity in the range of oral antidiabetic drugs and insulins; (2) Metformin was the most frequent oral antidiabetic medicine; (3) In four Brazilian capitals, no insulins were listed.

PRE-PROOF
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ORAL ANTIDIABETIC MEDICINES AND INSULINS IN THE LISTS OF ESSENTIAL MEDICINES OF BRAZILIAN CAPITALS AND THE FEDERAL DISTRICT

ABSTRACT

Access to medicines is essential for the treatment of diabetes. Essential medicines lists provide knowledge of the available options and offer opportunities for rational use from several perspectives. Thus, this article aims to analyze oral antidiabetic medicines and insulins in the essential medicines lists of Brazilian capitals and the Federal District. This descriptive study was conducted through the investigation of essential medicines lists in Brazilian capitals and the Federal District. Data were collected from September to November 2022. The comparison of lists considered the 2022 National List of Essential Medicines (RENAME) and the 2021 World Health Organization (WHO) model list of essential medicines. The frequency of oral antidiabetic medicines ranged from two in Curitiba to eight in Teresina. Regarding insulins, there were six in Belo Horizonte, while Boa Vista, Macapá, Fortaleza, and João Pessoa did not include them. Metformin was the most frequently used oral antidiabetic medicine, as were NPH and regular insulins. The average agreement of oral antidiabetic medicines and insulins with the RENAME was 97.7% and 75.5%, respectively. The average agreement of oral antidiabetic medicines was 47.1% and 72.5% for insulins with the WHO model list of essential medicines. We observe a diversity in the range of medicines available for diabetes. Lists of essential medicines are guiding instruments for pharmaceutical services, and the lack of a description of insulins proved to be a cause for concern.

Keywords: Diabetes Mellitus; Drugs, Essential; Access to Essential Medicines and Health Technologies; Hypoglycemic Agents; Insulin.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic non-communicable disease (NCD) of multifactorial etiology, consisting of a metabolic disorder in which the body does not produce insulin or is unable to adequately utilize its effects, resulting in persistent hyperglycemia.[1-2] It is currently considered one of the significant public health problems.[1-2]

Diabetes mellitus (DM) classification is based on its etiopathogenesis, which includes type 1 DM (DM1), type 2 DM (DM2), gestational diabetes mellitus (GDM), and other specific types of diabetes, with DM1 and DM2 being the most frequent. DM classification is

fundamental for determining management, since DM1 and DM2 are heterogeneous diseases in which clinical presentation and progression can vary considerably. It is known that, in these types of diabetes, genetic, environmental, and behavioral factors can interfere with the progressive loss of mass and/or function of pancreatic beta cells, resulting in hyperglycemia, leading to acute and chronic complications.[3]

Problems arising from DM result in higher rates of hospitalizations and use of health services.[4] Therefore, people with DM should be adequately monitored and followed up to prevent complications, and it is essential to provide access to health services and technologies to promote disease control.[5] Care management, focusing on Primary Health Care (PHC), seeks to streamline adherence to treatment and control or reduce complications.[6]

Self-care, prevention, health education, and assistance are recommended in the treatment of DM and can be divided into pharmacological treatment and non-pharmacological measures[3]. Pharmacological treatment provides improvement in quality of life, glycemic control, and reduction of complications. Non-pharmacological measures involve lifestyle changes and are effective in the overall control of the disease[5].

According to the Brazilian Diabetes Society (2023)[7], the list of medicines for the treatment of DM1 and DM2 is available in the Unified Health System (SUS) and was defined in Ordinance MS/GM N°2.583[8] of October 10, 2007, and under the terms of Federal Law N°11.347 of September 27, 2006[9]. This list is also updated periodically and found in the 2022 National List of Essential Medicines (RENAME). This list is a guiding instrument for Pharmaceutical Services (PS), which includes the range of medicines and supplies available for the treatment and control of the most prevalent diseases in the Brazilian population[10]. The RENAME is a document that supports the Municipal List of Essential Medicines (REMUME) or List of Essential Medicines (REME), as is the case in the Federal District (FD). Thus, these lists allow for the inclusion or exclusion of medicines per the local epidemiological profile[11].

Muzy et al. (2021)[6] highlighted that access to essential medicines is a primary factor in diabetes control and a citizen's right[6]. However, people living with diabetes face barriers to accessing healthcare, and there are gaps in the services of the healthcare network. For example, access to medicines is not universal, equitable, and effective, becoming a challenge in Public Health[12-13].

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According to Santos et al. (2018)[14], despite advances in diabetes policies and actions, it is still possible to observe that the SUS faces difficulties in meeting the specific needs of this group. Among the main strategies for improving DM therapy, it is necessary to improve existing public health policies or new protocols, besides continuously verifying the supply and access to essential medicines to meet the demands of the Brazilian population[5].

Currently, there is a clear need for improvements in care for people with diabetes through the implementation of new policies.[5] The Pan American Health Organization report elucidated the measures that health systems should adopt to improve care for people with diabetes, through access to medicines and other technologies, as well as early diagnosis, regular and continuous treatment, and the strengthening of surveillance and monitoring.[15]

Therefore, studies that can contribute to a broad discussion about pharmaceutical policies aimed at diabetes mellitus (DM) are necessary in order to achieve comprehensive care and implement effective actions for disease control in the country. In this sense, this article aims to analyze oral antidiabetic medicines (OAMs) and insulins in the essential medicines lists of Brazilian capitals and the FD.

METHODS

This descriptive study was conducted by retrieving lists of essential medicines from Brazilian capitals and the FD. Data were collected from September to November 2022. The lists were obtained from the official websites of the health secretariats. If they could not be located, the ombudsman's offices were contacted by email. If the unavailability persisted, communication was made through messaging applications to the Pharmaceutical Services program's municipal managers.

We entered the medicines into a specific database with double-checking, along with the following information: medicine, concentration, Brazilian capital, region, and year of publication of the REMUME or REME. In addition, we performed anatomical-therapeutic-chemical (ATC) classification.[16]

The medicines listed in the REMUME and REME were compared with those listed in the 2022 RENAME[10] and WHO 2021 Model List of Essential Medicines (LEM)2021[17]. The OAMs listed in the 2022 RENAME were glibenclamide 5 mg, gliclazide (30 mg, 60 mg, and

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80 mg), and metformin (500 mg and 850 mg), which were included in the essential component of pharmaceutical services (CBAF), and dapagliflozin 10 mg in the specialized component of pharmaceutical services (CEAF). The insulins listed were human NPH insulin 100 IU/mL and regular human insulin 100 IU/mL in the CBAF, as well as long-acting analog insulin 100 IU/mL and 300 IU/mL, and rapid-acting analog insulin 100 IU/mL, available in the CEAF.

The oral antidiabetic medicines (OAMs) listed in the 2021 List of Essential Medicines (LEM) were empagliflozin (5 mg and 10 mg) and therapeutic alternatives (canagliflozin and dapagliflozin), gliclazide (30 mg, 60 mg, and 80 mg), and therapeutic alternatives (sulfonylureas). The listed insulins were human NPH insulin 100 IU/mL and human regular insulin 100 IU/mL, long-acting insulin analog 100 IU/mL in 3 mL cartridges or pre-filled pens (degludec, detemir, and glargine).

The data were analyzed using R. Mean and standard deviation (SD) were calculated for quantitative variables, and percentages were calculated for qualitative variables. The lists obtained were publicly accessible and in the public domain, without data access restrictions for researchers and citizens in general. Also, they were not subject to limitations related to privacy, security, or access control. The public could freely use them, and submission to the Research Ethics Committee/National Research Ethics Commission was waived under the ethical considerations of Resolution N°510 of 2016.

RESULTS

We retrieved the Essential Medical Lists (REMUME) of the 26 Brazilian state capitals and the REMU of the FD. Twenty lists were obtained from the official websites of the health secretariats of Belo Horizonte, Boa Vista, Campo Grande, Cuiabá, FD, Florianópolis, Fortaleza, Goiânia, João Pessoa, Maceió, Manaus, Porto Alegre, Porto Velho, Rio Branco, Rio de Janeiro, Salvador, São Paulo, Teresina, and Vitória. The other seven lists were obtained through health ombudsperson offices or by contacting PS managers via messaging applications. For lists that included a publication date, variations were observed between 2013 and 2022.

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The OAM frequency ranged from two in Curitiba to eight in Teresina. Meanwhile, insulins were not listed in the Essential Medicines Lists (REMUME) of Boa Vista, Macapá, Fortaleza, and João Pessoa, and there were eight presentation forms in the Belo Horizonte list. Table 1 describes the frequencies by capital city and mean (SD) by Brazilian region.

Table 1. Frequency of oral antidiabetic medicine and insulin use in Brazilian capitals and the FD.

Region/Capital	Oral antidiabetic medicines (n)	Insulins (n)
South		
Curitiba	2	4[2,3]
Florianópolis	3	5[2,3]
Porto Alegre	3	4[2,3]
Mean (SD[1])	2.6 (0.5)	4.3 (0.5)
Southeast		
Belo Horizonte	4[4]	6[2,3]
Rio de Janeiro	4[4]	2
São Paulo	3[4]	4[2,3]
Vitória	4[4]	2
Mean (SD)	3.7 (0.4)	3.5 (1.6)
Midwest		
Brasília	4[5]	4
Campo Grande	4[4]	2
Cuiabá	2	2
Goiânia	3[4]	2
Mean (SD	3.2 (0.8)	2.5 (0.8)
North		
Belém	4[4]	2
Boa Vista	4[4]	0
Macapá	4[4]	0
Manaus	5[4,5]	2
Palmas	5[4,5]	4[2,3]
Porto Velho	4[4]	2
Rio Branco	4[4]	2
Mean (SD)	4.2 (0.4)	1.7 (1.2)
Northeast		
Aracaju	3	2

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Fortaleza	3	0
João Pessoa	5[6]	0
Maceió	5[4,5]	2
Natal	5[4,5]	2
Recife	3	4[2,3]
Salvador	3	2
São Luís	4[4]	2
Teresina	8[4,6,7]	2
Mean (SD)	4.3 (1.5)	1.7 (1.1)

1. Standard Deviation; 2. Human NPH insulin injectable suspension in a vial and pen; 3. Human regular insulin injectable solution in a vial and pen; 4. Metformin hydrochloride 500 mg and 850 mg; 5. Gliclazide 30 mg and 60 mg; 6. Gliclazide 30 mg and 80 mg; 7. Glimepiride 1 mg, 2 mg, and 4 mg.
Source: Prepared by the authors.

The Belo Horizonte, Curitiba, Florianópolis, Palmas, Porto Alegre, Recife, and São Paulo lists included human insulin 100 IU/mL and regular human insulin 100 IU/mL in pen form. Furthermore, Belo Horizonte included insulin aspart 100 IU/mL (pen) and insulin glargine 100 IU/mL (injectable solution). The FD list included insulin detemir 100 IU/mL and insulin glargine 100 IU/mL in injectable suspension form.

The capital city with the most OAMs was Teresina, namely, gliclazide (30 mg and 60 mg), glimepiride (1 mg, 2 mg, and 4 mg), and metformin (500 mg and 850 mg). Florianópolis, on the other hand, was the capital city with dapagliflozin 10 mg (tablet) and insulin glulisine 100 IU/mL (injectable solution).

Glibenclamide 5 mg was found in 23 capital cities and the FD, except for the capital cities of Florianópolis, São Paulo, and Goiânia. Gliclazide 30 mg was found in 16 capital cities and the FD, while gliclazide 60 mg was found in 13 capital cities and gliclazide 80 mg in 2 capital cities.

Glimepiride (1 mg and 4 mg) was listed in Teresina, and glimepiride 2 mg was listed in Boa Vista and Teresina, although this medicine was not listed in the 2021 LEM and the 2022 RENAME. Metformin 500 mg was listed in 18 capital cities, while metformin 850 mg was listed in 25 capital cities and the FD, but not found in Fortaleza, where the list included metformin 500 mg. The lists for Florianópolis, Belo Horizonte, and the FD included both

rapid-acting and long-acting analog insulins. Table 2 compares OAMs and insulins in the essential medicines lists by region with the 2021 LEM and the 2022 RENAME.

Table 2. Frequency of agreement between OAMs and insulins in the essential medicines lists with the 2021 LEM and 2022 RENAME, by Brazilian region.

Região	**OAMs**		**Insulins**	
	2021 LEM[1] (%)	**2022 RENAME[2] (%)**	**2021 LEM (%)**	**2022 RENAME (%)**
South	37.5	100.0	30.7	38.5
Southeast	53.3	100.0	64.2	71.4
Midwest	46.1	100.0	100.0	100.0
North	50.0	96.1	80.0	80.0
Northeast	48.7	92.3	87.5	87.5
Mean (SD)	**47.1 (5.9)**	**97.7 (3.4)**	**72.5 (26.7)**	**75.5 (23.2)**

1. List of Essential Medicines; 2. National List of Essential Medicines.
Source: Prepared by the authors.

The agreement between the OAMs and insulins listed in the REMUME and the 2021 LME and the 2022 RENAME varied between regions. Notably, the pen pharmaceutical form was not specified in the 2022 RENAME.

DISCUSSION

This study highlighted the range of OAMs and insulins in the (REMUME) of Brazilian capitals and the FD. A variety of OAMs was observed, especially in the Northeast, and insulins in the South, when compared to the 2022 RENAME, mainly due to the pharmaceutical presentation form.

First-line pharmacological management of type 2 diabetes mellitus (DM2) is generally done with metformin, given its efficacy and safety, reduced chance of hypoglycemia, reduced cardiovascular risk, possibility of weight reduction, improved lipid profile, and low cost.[19] This medicine belongs to the biguanide class, which aims to decrease glucose production by the liver, resulting in a drop in blood glucose, without directly stimulating pancreatic beta cells and, consequently, preventing the release of more insulin.[18] In this study, we observed that metformin was identified in all lists, even if in different concentrations.

Glibenclamide and gliclazide belong to the sulfonylurea class and act directly on pancreatic beta cells, boosting insulin release, reducing plasma glucose, increasing calcium influx, and consequently insulin release.[18] These two medicines are indicated as second-line

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treatment for type 2 diabetes, usually associated with other OAMs, especially metformin, if the glycemic target is not achieved.[18] These medicines are indicated due to their low cost, few microvascular complications, and the possibility of significantly reducing glycated hemoglobin[18]. However, sulfonylureas are associated with an increased risk of hypoglycemia. Therefore, it is important to emphasize the need for guidance to healthcare teams in capital cities that provide these medicines, since they are inappropriate for use in specific groups such as older adults[19].

Regarding the treatment of type 1 diabetes, insulin replacement is the basis for glycemic control from diagnosis onwards, to prevent metabolic decompensation and diabetic ketoacidosis; strategies that mimic the physiological secretion of insulin should preferably be chosen.[20] Insulin replacement for people with type 1 diabetes (T1D) is based on 50% of secretion as a basal component throughout the day, and the other part as a postprandial component.[20] Thus, human NPH insulin 100 IU/mL, human regular insulin 100 IU/mL, rapid-acting insulin analogs, and long-acting insulin analogs constitute the treatment line for T1D.

This study identified that there was no description of any insulin in the REMUMEs (Municipal List of Essential Medicines) in four Brazilian capitals. Notably, for insulins dispensed within the PHC, the Ministry of Health is responsible for the financing, acquisition, and distribution of human NPH 100 IU/mL insulin and human regular 100 IU/mL insulin to state and FD pharmaceutical supply warehouses or centers. Subsequently, the state health secretariats distribute the insulin to the municipalities.[7] Therefore, these medicines should be listed in the REMUMEs given the centralized acquisition and distribution format, and because insulins ensure the lives of people with diabetes.

The lack of rapid-acting and long-acting analog insulins in most of the analyzed lists is justified because, in the RENAME, this list falls under the scope of the Specialized Pharmaceutical Services Component (CEAF). Dispensing is guided by clinical protocols and therapeutic guidelines for people with type 1 diabetes mellitus (DM1), in which Ordinance N°10 of February 21, 2017, approved the incorporation of rapid-acting analog insulin for the treatment of DM1, as well as long-acting analog insulin, which was incorporated through Ordinance N°19 of March 27, 2019.[21-22]

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However, some Brazilian capitals, like the FD, through their own funding, make such medicines available for clinical situations of type 2 diabetes mellitus (DM2), following pre-defined criteria for prescription and dispensing. The DF's REME selects a group of medicines already established by the RENAME and adds specific medicines in a complementary way, fulfilling the attribution given to the DF to select the most appropriate medicines to meet the local demand of the population.[23]

In 2020, the Ministry of Health approved, through Ordinance N°16 of April 29, the incorporation of dapagliflozin for the treatment of diabetes in the CEAF. Dispensing should occur to people with type 2 diabetes, aged 65 years or older, and with established cardiovascular disease who have not achieved glycemic control with other OAMs. In 2022, the medicine committee of the National Commission for the Incorporation of Technologies (CONITEC) in the SUS approved treatment with dapagliflozin for patients with type 2 diabetes mellitus (DM2) at high risk of developing cardiovascular disease or with established cardiovascular disease and aged between 40 and 64 years. In the same year, the dispensing of dapagliflozin was approved for patients over 18 with any etiology of chronic kidney disease (CKD) within the SUS[7,25].

Dapagliflozin acts as a selective inhibitor of the sodium-glucose cotransporter and causes a decrease in glucose levels. It is considered a therapeutic possibility for the treatment and control of DM2[7]. Also, studies have shown positive effects related to the kidney and heart systems[7]. In this study, we observed that dapagliflozin was listed only in the Florianópolis list. The hypothesis is that this REMUME includes medicines from the CBAF, a strategic PS and CEAF component, whereas this may not have occurred in other lists, which prioritized medicines from the CBAF.

The proper treatment and control of diabetes primarily includes pharmacological measures combined with non-pharmacological measures, which involve lifestyle changes such as healthy eating and regular physical exercise, as well as diabetes education.[1,2] Therapeutic goals aim at glycemic control to prevent complications arising from the disease; therefore, educational actions, access, and adherence to medicines are important points for the proper control of DM.[26] However, adherence to medicine treatment for DM is a troubling

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public health problem in Brazil and deserves continuous interventions, especially in PHC services.[27]

Access to medicines is fundamental to achieving adherence to treatment. Therefore, the lack of OAMs and insulins in the investigated lists may compromise adherence to diabetes pharmacotherapy and lead to disease loss. Thus, pharmacy and therapeutics committees (PTCs) should carefully analyze the list of medicines for diabetes mellitus (DM). The selection of essential medicines is based on criteria of efficacy, safety, quality, and cost-effectiveness, as well as the epidemiological situation and local health needs, to promote the safe and rational use of medicines.[3,11]

One relevant limitation of this study is the lack of updated lists in agreement with the 2022 RENAME and the 2021 (LEM). Furthermore, specific protocols for diabetes treatment and state medicine lists, which generally include the CEAF list, were not analyzed. However, this study highlights aspects that need improving within pharmaceutical services. The lists of capital cities are known to influence those of other municipalities. Therefore, we underscore the need for constant updating, qualified technical staff in the PTCs, and an analysis of the comprehensive care for people with diabetes, focusing on pharmacotherapy.

CONCLUSION

The study points to a diversity in the list of OAMs and insulins included in the essential medicines lists of Brazilian capitals and the FD. We stress that these lists are guiding instruments for pharmaceutical services. Thus, the lack of insulin listed in the capitals of the North and Northeast is a matter of concern, given that this medicine is essential for the treatment of diabetes mellitus (DM), and these therapeutic options are indispensable to the lives of people with type 1 diabetes. Therefore, we suggest that public health policies be improved to guarantee access to medicines for diabetes control.

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