

Analysis of access to hypertensive and diabetic drugs in the Family Health Strategy, State of Pernambuco, Brazil

Análise do acesso ao tratamento medicamentoso para hipertensão e diabetes na Estratégia de Saúde da Família no Estado de Pernambuco, Brasil

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ABSTRACT: *Objective:* To evaluate the access to drugs for hypertension and diabetes and the direct cost of buying them among users of the Family Health Strategy (FHS) in the state of Pernambuco, Brazil. *Methods:* Population-based, cross-sectional study of a systematic random sample of 785 patients with hypertension and 823 patients with diabetes mellitus who were registered in 208 randomly selected FHS teams in 35 municipalities of the state of Pernambuco. The selected municipalities were classified into three levels with probability proportional to municipality size (LS, large-sized; MS, medium-sized; SS, small-sized). To verify differences between the cities, we used the χ^2 test. *Results:* Pharmacological treatment was used by 91.2% patients with hypertension whereas 85.6% patients with diabetes mellitus used oral antidiabetic drugs (OADs), and 15.4% used insulin. The FHS team itself provided antihypertensive medications to 69.0% patients with hypertension, OADs to 75.0% patients with diabetes mellitus, and insulin treatment to 65.4%. The 36.9% patients with hypertension and 29.8% with diabetes mellitus that had to buy all or part of their medications reported median monthly cost of R\$ 18.30, R\$ 14.00, and R\$ 27.61 for antihypertensive drugs, OADs, and insulin, respectively. *Conclusion:* It is necessary to increase efforts to ensure access to these drugs in the primary health care network. *Keywords:* Unified Health System. Primary Health Care. Health Services Accessibility. Diabetes Mellitus. Hypertension. Drug Utilization.

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RESUMO: *Objetivo:* Avaliar o acesso a medicamentos para hipertensão e diabetes e o gasto direto relacionado à aquisição destes insumos entre os usuários da Estratégia Saúde da Família (ESF), no estado de Pernambuco. *Métodos:* Estudo transversal, de base populacional, numa amostra aleatória sistemática de 785 pacientes hipertensos e 823 diabéticos cadastrados em 208 equipes da ESF sorteadas em 35 municípios do estado de Pernambuco. Os municípios selecionados foram classificados em três estratos com probabilidade proporcional ao tamanho do município (GP: grande porte; MP: médio porte; PP: pequeno porte). A fim de verificar diferenças entre os municípios, foi utilizado o teste χ^2 . *Resultados:* Dos 785 hipertensos, 91,2% referiram o uso de anti-hipertensivos e dos 823 diabéticos, 85,6% utilizavam antidiabéticos orais (ADO), e 15,4%, insulina. Os anti-hipertensivos eram fornecidos pelas equipes da ESF para 69,0% dos hipertensos, os ADO, para 75,0% dos diabéticos, e a insulina e insumos, para 65,4%. Os hipertensos (36,9%) e os diabéticos (29,8%) que precisavam comprar os medicamentos referiram um gasto mediano mensal de R\$ 18,30, R\$ 14,00 e R\$ 27,61 para anti-hipertensivos, ADO e insulina, respectivamente. *Conclusão:* É necessário ampliar os esforços para assegurar o acesso aos medicamentos na rede de atenção primária de saúde.

Palavras-chave: Sistema Único de Saúde. Atenção Primária à Saúde. Acesso aos Serviços de Saúde. Diabetes Mellitus. Hipertensão. Uso de medicamentos.

INTRODUCTION

Important changes in the epidemiological profile occurred over the last century, culminating, in most countries, with the significant increase in life expectancy and the predominant occurrence of Chronic Noncommunicable Diseases (NCD)¹. Among them, the systemic arterial hypertension (SAH) and diabetes mellitus (DM) have affected a significant portion of the world population and are considered some of the main risk factors for diseases of the circulatory system, and the main cause of morbidity and mortality throughout Brazil²⁻⁴. In addition, the growth of NCDs and their disabilities due to an aging population generates demand for health services and represent relevant social and economic costs^{2,3}.

Early diagnosis and prescription of drugs have contributed to prevent complications of these diseases. The Ministry of Health of Brazil, based on this evidence, has implemented policies addressing the NCDs. The first initiative, at the national level, was the launch of the Plan for the Reorganization of Care for Arterial Hypertension and Diabetes Mellitus⁵. Concomitant to this plan, the National Pharmaceutical Assistance Program for SAH and DM was established through Regulation/GM/MS no. 371 of March 4, 2002, to ensure the free supply of drugs. More recently, the ministry launched the Strategic Action Plan for tackling NCDs, aiming to prepare the country in the next ten years to refrain these illnesses. This plan incorporates several actions, among which is the expansion of the free distribution of drugs for hypertension and DM, both in public and in private health networks⁶.

The appropriate management of SAH and DM in all levels of care avoids sequelae and complications from the disease. Under the Unified Health System (SUS), regarding Primary Health Care (PHC), the Family Health Strategy (FHS) has played an important role in the care of patients with hypertension and DM, and is characterized as the environment chosen for the provision and monitoring of pharmacological treatment of these users³⁻¹⁰.

One of the quality and solvability indicators of the health system is the access to medicines, which enables to evaluate compliance with the prescribed treatment, in addition to promoting adherence to pharmacological treatment, especially in the lower income population⁹⁻¹². In Brazil, there are still few studies that evaluate access to drugs, as well as the expenses associated^{9,10,13}. Concerning these expenses, it is worth mentioning the study from Bersusa, which highlights the commitment of 70% of the minimum wage (MW) in the purchase of insulin, inputs for its application, and reagent strips for metabolic control⁹.

To contribute to the discussion of access to medicines in PHC, this study aimed to analyze the access to antihypertensive and antidiabetic drugs and to quantify the direct expenses to buy them by users that received treatment at Basic Health Units (BHU), linked to the FHS in the state of Pernambuco, Brazil.

METHODS

We conducted a cross-sectional quantitative study involving patients with hypertension (defined as having arterial hypertension, but no diagnosis of DM) and patients with DM type 2 (DM2), with or without a diagnosis of associated arterial hypertension. We used the SERVIDIAH study data (Health care services evaluation for diabetic and hypertensive patients under the Health Family Program)⁴. The sample of the SERVIDIAH study was designed to enable the representativeness of Pernambuco towns in terms of size (small-sized – SS: < 20 thousand inhabitants; medium-sized – MS: 20 thousand to 100 thousand inhabitants; and large-sized – LS: > 100 thousand inhabitants).

The selection process took place in three stages: at first, 3 LS municipalities were chosen (Recife, Caruaru, and Petrolina), using the criterion of representativeness, because they are largest cities of the three geographical regions of the state: Forest Zone, *Agreste*, and Hinterland; and by lot, 16 MS municipalities and 16 SS municipalities were chosen, within a sample scope of 84 MS municipalities and 89 SS municipalities in the state of Pernambuco. In the second stage, 12% of the FHS teams working in the selected municipalities were selected randomly, of a total of 1,774 teams working in the state of Pernambuco, in August 2008, according to the latest consolidated basis of the National Register of Health Facilities; 37 teams were selected in SS municipalities, 98 in MS municipalities, and 73 in LS municipalities. Finally, for each of the randomly selected teams, we carried out another systematic random drawing of patients with hypertension and DM (inclusion criteria: age greater than or equal to 20 years), from the manual registration of Community Health Agents. We tried to ensure a sample of approximately 300 patients with hypertension and 300 with DM in SS, MS, and

LS municipalities, a size calculated to show a 10% difference in the proportion of users with controlled pressure and/or glycemia, with an alpha error of 5% and statistical power of 80%. For this reason, the same proportion of patients with hypertension and DM was interviewed in each team, as follows: according to the population size 06, 03, and 04, respectively, with 785 patients with hypertension and 823 with DM of both genders. The majority (99% of patients with hypertension and 97.9% with DM) among those registered was found to be, in fact, accompanied by the FHS for care related to their condition.

The data were collected from November 2009 to December 2010, through a structured questionnaire by face-to-face interviews, conducted by a team composed of selected and previously trained field researchers. The participants were interviewed in their homes or in a room for the FHS team in the health unit. There was no replacement in case of no interview was performed, so the sample has no bias.

The variables related to sociodemographic and economic characteristics, access to medicines, and the cost associated to the treatment were included. Access to drugs dispensed in the context of PHC prescribed in appointments in the public health system was evaluated through the initial questioning about the use of medicines to treat DM or SAH. In case of a positive answer, they were asked about the drugs, which can be classified in pharmacological classes using the National List of Essential Medicines – RENAME 2010¹⁴.

The participants were also asked about the provision of all these products and, in the event they did not have partial or total supply of the drugs by the BHU linked to the FHS, if they bought them and how much did they spend a month with that purchase. It is worth noting that, for those with DM using insulin, the same questions were asked in relation to inputs for the application.

In possession of the collected data, two digital data banks were constructed (one for patients with hypertension and one for those with DM) for storage and analysis of data using the statistical software Statistical Package for Social Sciences (SPSS), version 19. The quality control of data was electronic, through the variable distribution verifications. Initially, a descriptive analysis of the data was performed electronically to assess the sociodemographic and economic characteristics of users with hypertension and DM in the study. For this purpose, two-dimensional tables of frequency were prepared, and the continuous variables were reported by the mean (\pm standard deviation). In the data analysis, the variable that referred to the place of residence by population size (small, medium, and large) was considered to be independent. To verify differences between the municipalities, according to the variables that were studied, we used the χ^2 test (or Fisher's exact test when necessary).

Information on drugs in use and supply was obtained in percentage and compared to the recommended access parameters defined by the World Health Organization (WHO), which was as follows: very low access: < 50%; low-to-medium access: 50 – 80%; medium-to-high access: 81 – 95%; very high access: > 95%¹¹. To analyze the access, we took into account the total access, or supply of all antihypertensive drugs and OADs, when there was use of associated medications.

The expenses were analyzed using the information given about family income in MWs and the analysis of direct expenditure on drugs and inputs. In this case, the median was considered because of the not Gaussian distribution of the collected values. To compare the medians of spending, we used the nonparametric Kruskal-Wallis test.

Differences were considered statistically significant for p -values ≤ 0.05 .

The SERVIDIAH study was approved by the Research Ethics Committee of the Centro de Pesquisas Aggeu Magalhães – CEP/CPqAM (registration number 43/2008) and the National Research Ethics Commission (CONEP) because it is an international cooperation project. It was approved under the public notice 889/2008. All respondents were informed about the objectives and procedures of the study and signed a free consent form.

RESULTS

A total of 785 patients with hypertension and 823 with DM of both genders were interviewed in the 35 municipalities included in the SERVIDIAH study. The majority of the sample comprised women. The mean age was 60.5 ± 13.9 (hypertension) and 61.2 ± 13.0 (DM) years old. One-third of the participants were found to be illiterate and monthly family income was no more than 4 MWs (Table 1).

Of the participants with hypertension, 91.2% ($n = 716$) had continued use of one or more antihypertensive drugs. Of the respondents with DM, 85.4% ($n = 703$) had continued use of one or more oral antidiabetic drugs (OADs) or insulin. Those were the target of the following analyses. The response rate was 87.2% for SAH and 91.4% for DM. As shown in Table 2, the most commonly prescribed drug groups for antihypertensive patients were diuretics and inhibitors of angiotensin-converting enzyme (ACE) alone or associated with one or more drugs. The most frequent combination therapies were the following: diuretics and ACE inhibitors (36.7%); diuretics and β -blockers (16.2%); and β -blockers and ACE inhibitors (10.4%).

The most frequently prescribed OAD was sulfonylureas, followed by metformin. The use of metformin was more frequent the bigger the municipality was. Among patients with DM who used OADs, 63.8% ($n = 437$) only took that medicine and the others used two associated pharmacological groups. The proportion of users with associated drugs grew when the size of the municipality was bigger (Table 3). Among patients with DM who used insulin, 56.8% ($n = 71$) also used OADs. The most commonly identified associations were sulfonylureas with metformin and metformin with insulin.

Of the 713 patients with hypertension experiencing drug treatment that reported on the supply of medicine, the prevalence of access to all drugs through BHUs linked to the FHS was 69.0%; this rate grew significantly with the municipality size ($p = 0.002$) (Table 4). For those who needed to buy one or more antihypertensive drugs in the private sector (36.9%), the median expenditure was R\$ 18.30 a month. For individuals with family income up to 1 MW, who needed to buy antihypertensive drugs, the median monthly spending was

Table 1. Sociodemographic and economic variables in individuals with hypertension and diabetes mellitus registered with the Family Health Strategy. Pernambuco, 2009 – 2010.

Variables	Individuals with hypertension		Individuals with diabetes mellitus	
	n	%	n	%
Age (mean)	60.6 ± 13.9		61.1 ± 13.2	
Gender				
Male	227	28.9	254	30.8
Female	558	71.1	569	69.2
Education in years of schooling				
Illiterate	294	37.4	312	38.0
Incomplete primary education	383	48.8	392	47.6
Complete primary education	54	6.9	55	6.6
Complete high school	49	6.3	48	5.8
University degree	5	0.6	16	2.0
Family income*				
Up to 1 MW	269	36.5	246	32.3
More than 1 MW and up to 4 MW	467	63.5	517	67.7
Occupation				
Works	157	20.0	133	15.9
Unemployed	39	5.0	32	3.9
Housewife/student	158	20.1	142	17.2
Retired/sickness assistance/pensioner/other	431	54.9	516	62.9
Total (n)	785		823	

MW: minimum wage; *Family income: equivalent to the average income of the interviewee's family at the time of the research.

R\$ 11.75, representing at least 2.5% of income, based on the MW of the time of the study. For individuals with family income above 1 MW and that resided in municipalities of LS and MS, the spending on antihypertensive drugs was significantly higher compared with the expenditure of residents of SS municipalities ($p = 0.033$); the median monthly spending (R\$ 17.18) represented between 0.8 and 2.5% of the monthly family income.

Of the 685 patients with DM who reported on the provision of OADs, 75.0% received them at BHUs linked to the FHS, with the same ascending relationship with the size of the municipalities ($p = 0.042$) (Table 5). A proportion of 29.8% patients with DM needed to buy OADs, with a median expenditure of R\$ 14.00 a month. Within the monthly family income

Table 2. Proportion of users, according to population size and the pharmacological class in use by patients with hypertension, registered with the Family Health Strategy, Pernambuco, 2009 – 2010.

Pharmacological class*	Large-sized		Medium-sized		Small-sized		Total		p-value
	n	%	n	n	n	%	n	%	
Antihypertensives	288	94.7	313	90.5	115	86.5	716	91.2	0.012
Diuretics	173	60.5	202	64.5	75	65.8	450	63.1	0.480
ACE inhibitor	167	58.4	177	56.5	65	56.5	409	57.3	0.125
β -Blockers	74	25.9	74	23.6	24	21.1	172	24.1	0.575
Direct vasodilators	43	15.0	31	9.9	10	8.8	84	11.8	0.087
Sympathetic inhibitors	9	3.1	21	6.7	5	4.4	35	4.9	0.125
Other antihypertensive	18	6.3	34	10.9	9	7.9	61	8.6	0.126
Monotherapy	127	44.4	129	41.3	50.0	43.9	306	43.0	
Association of a drug	126	44.1	144	46.2	56.0	49.1	326	45.8	
Association of two drugs	33	11.5	39	12.5	8.0	7.0	80	11.2	0.542
Total	288		313		114		713*		

*Three patients with hypertension were unable to inform the drug in use; ACE: angiotensin-converting enzyme.

levels, the expenses on oral antidiabetic medicine was not statistically different between the municipalities; based on the MW during the period of the study, these expenses accounted for up to 2.5% of income.

Also concerning the patients with DM, of the 121 patients with DM that mentioned supply of insulin, 64.5% received insulin and inputs at the BHUs linked to the FHS, with no difference regarding size of the municipality (Table 5). Those (22.3%) that needed to buy insulin and/or inputs reported a median monthly spending of R\$ 27.61, leading to a commitment of 5.4% of a MW of the period of the study.

DISCUSSION

The results showed sociodemographic and economic aspects similar to those found in other studies involving patients with hypertension and/or DM assisted at BHUs in relation to the over-representation of the female gender, average age, monthly income, instruction level, and occupation^{9,10,13}. The prevalence of access to drugs in this study was 69% for patients with hypertension and 75% for those with DM. According to the parameters recommended by the WHO¹¹, this percentage is classified as low-to-medium access. We also found that, despite the fact that the prescription drugs were listed on RENAME and that their prescription was backed by the national and international protocols^{7,8,13-20}, there are

Table 3. Proportion of users, according to population size and the pharmacological class of drugs in use for patients with diabetes mellitus, registered with the Family Health Strategy, Pernambuco, 2009 – 2010.

Pharmacological class*	Large-sized		Medium-sized		Small-sized		Total		p-value
	n	%	n	%	n	%	n	%	
OADs	270	84.4	313	86.7	120	85.7	703	85.6	0.689
Sulfonylureas	182	71.4	234	74.8	89	74.2	505	73.4	0.649
Metformin	176	69.0	182	58.1	66	55.0	424	61.9	0.007
Another oral antidiabetic	5	2.0	2	0.6	1	0.8	8	1.2	0.334
Insulin	57	17.9	47	13.3	21	15.2	125	15.4	0.258
Monotherapy	147	57.9	206	66.2	84	70	437	63.8	0.036
Association of one drug	107	42.1	105	33.8	36	30	248	36.2	0.036
Association of insulin and an OAD	24	8.2	17	5.2	11	8.7	52	6.9	0.471
Association of insulin with two drugs	6	2.1	10	3.0	3	2.4	19	2.5	0.471
Total	255		313		120		688*		

*Fifteen patients with diabetes mellitus of large-sized municipalities were unable or unwilling to inform the drug in use. OADs: oral antidiabetics.

still patients with hypertension and DM assisted at BHUs that need to buy them, totally or partially. Finally, this study indicated possible differences in treatment regimens and access to medicines in favor of big cities.

It is worth noting that, because this is a cross-sectional study, without control of confusion factors, the results are purely descriptive and reflect only the period studied. Among other limitations of the study, we can highlight that, owing to the sociodemographic characteristics of the participants, especially the instruction level, in addition to the questionnaire being too long, there were unanswered aspects.

Discussing the issue of access, although classified by the WHO between low and medium, this result was higher than the National Household Sample Survey (PNAD), conducted in 2008 in Brazil by the Brazilian Institute of Geography and Statistics, which found a prevalence of 45.3% of access to drugs in the NHS in relation to prescription drugs¹⁶. It is worth noting that the PNAD considered several groups of drugs, unlike our study, focused on antihypertensive and antidiabetic drugs, which already have a better established pharmaceutical assistance policy^{5-8,16}.

Table 4. Analysis of access and median monthly direct expenditure for the acquisition of antihypertensive drugs, according to population size. Pernambuco, 2009 – 2010.

Characteristics of the use of the service	Large-sized		Medium-sized		Small-sized		Total		p-value
	n	%	n	%	n	%	n	%	
Pills provided by BHU*	217	76.1	203	65.7	69	60.0	489	69.0	0.002
Need to buy some of these pills**	90	31.8	124	40.1	47	41.2	261	36.9	0.070
Median expenditure (R\$)	17.50		19.40		12.65		18.30		0.274
Expenditure by income range									
Up to 1 MW	10.00		14.00		11.30		11.75		0.761
1 to 4 MW	20.00		20.00		11.50		17.18		0.033
Total	286		313		114		713		

*Five patients with hypertension did not report on the supply of medicines in use; **Seven patients with hypertension did not inform the need to buy them; BHU: Basic Health Unit.

This study found that 36.9% of patients with hypertension and 29.8% with DM seen in PHC need to buy the drugs, totally or partially. Paiva et al.²² found that 63.9% of users with DM and hypertension assisted by the FHS in a city of São Paulo had higher monthly expenditure on medications to control these diseases, a much bigger proportion than ours. However, the study was conducted in 2002, only two years after the implementation of the FHS in the city, and yet has identified improving access.

Regarding the impact of these expenses on the users' income, our study only allowed an evaluation by income, in the manner that the variable was collected, in other words, monthly family income up to 1 MW, or between 1 and 4 MWs. Given this caveat, the costs seem relatively modest in relation to income, probably below 10%, even for patients with DM treated with insulin. It is much less than what was observed in the study by Lima et al.²³, who have estimated that the Brazilian elderly, retirees, and pensioners, spend up to 51% of the MW with medications. The authors also showed that the oral hypoglycemic and antihypertensive drugs are among the 10 therapeutic groups of largest individual expenditure. However, the study was conducted in 2003 on a sample selected without reference to the type of health services used. The situation may have improved since that time, with the more widespread implementation of the FHS and the public policies promoting access to essential medicines. Furthermore, a comparative analysis of the Household Budget Surveys and the PNAD on the expenditure and consumption of Brazilian families shows that expenses on medicines in low-income families represent approximately 4 to 6% of monthly family income²⁴, that is, a result that confirms our estimate.

Table 5. Analysis of access and median monthly direct expenditure for the acquisition of antidiabetic drugs, according to population size. Pernambuco, 2009 – 2010.

Characteristics of the use of the service	Large-sized		Medium-sized		Small-sized		Total		p-value
	n	%	n	%	n	%	n	%	
OAD provided by BHU*	208	79.1	229	74.6	77	67.0	514	75.0	0.042
Need to buy some of these OAD**	64	24.2	104	33.7	37	32.2	205	29.8	0.038
Median expenditure on the OAD (R\$)	15.55		12.45		13.70		14.00		0.463
OAD expenditure by income range (R\$)									
Up to 1 MW	10.00		12.94		11.43		11.45		0.497
1 to 4 MW	20.00		13.50		14.00		15.83		0.238
Total	270		313		120		703		
Insulin and input for application provided by the BHU***	40	71.4	25	56.8	13	61,9	78	64.5	0.306
Need to buy insulin or input for application ***	11	19.6	10	22.2	6	30.0	27	22.3	0.634
Median of the expenditure on insulin (R\$)***	17.5		33.33		38.23		27.61		0.355
Total	57		47		21		125		

*Eighteen patients with diabetes mellitus did not report on the supply of oral antidiabetic in use; **Fourteen of these did not report on the need to buy them; ***Four using insulin not informed about the supply and the need to buy insulin and inputs; OAD: oral antidiabetic; MW: minimum wage; BHU: Basic Health Unit.

Some findings of this study point to possible inequalities of pharmacological access or management between municipalities, according to the size. In terms of supply of pills by BHU for both hypertension and DM, the rate was found to grow according to the size of the municipality and the proportion of patients with DM who had to buy their tablets was found to be lower in big cities. This indicates perhaps that small municipalities can face more problems in organizing the appropriate response to the health conditions of its population. Moreover, with regard to pharmacological management, this study showed that the proportion of patients with hypertension using antihypertensive drugs grew with the size of the municipality. For patients with DM, there was greater use of metformin, in addition to a larger number of antidiabetic drug associations, in big cities, which is more in line with national and international

recommendations^{8,20,21}. This suggests a better dissemination of information for better management of pharmacological treatment in big municipalities.

CONCLUSION

Boing et al.¹⁶ highlighted the important progresses made with the National Drug Policy and the National Policy of Pharmaceutical Assistance, which established definitions and guidelines to ensure access to medicines. It should also be noted the importance of targeted policies to people with NCDs, including hypertension and DM. However, the findings of this study point to some shortcomings concerning the access and pharmacotherapy for hypertension and DM. We found an average to low access, and the need for some users to buy the drugs. Moreover, the results lead to a reflection about the possibilities and difficulties arising from decentralization for small municipalities, considering that, although the decentralization avoids large displacements of the population, it also generates difficulties of knowledge organization and update of health professionals.

On the basis of these findings, the study indicates the need to strengthen strategies to promote access to medicines in municipalities in the state of Pernambuco.

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