

Coverage by the public health services of medication and vaccines for the population with diabetes mellitus

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Abstract *This study analyzed the coverage by the public health service of expenses with medication and vaccines for the adult population of São Paulo with self-reported diabetes mellitus in 2003 and the implications for access to medicines and vaccination campaigns programs. Data were collected by the Multicenter Health Survey of São Paulo. The Unified Health System (SUS) was widely used by the population for vaccination against influenza and pneumonia and there was significant private sector participation for coverage of expenses with medication, with an estimated coverage of 38% by SUS. There were no significant differences in the prevalence of use of public services for vaccination among the categories of variables studied, suggesting a universal distribution of vaccination by the public health service. Unlike vaccinations, in 2003 the coverage of medication expenses by the public health service was recent in Brazil, which may explain the low level of coverage. An analysis of coverage of vaccination and medication expenses in diabetes mellitus population since 2003 may contribute to be the basis for policies to broaden access of the population to health services.*

Key words *Diabetes mellitus, Health service coverage, National medication policy, National policy of pharmaceutical assistance, Immunization programs*

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Introduction

Chronic, non-transmissible diseases are a public health priority in Brazil. Among such diseases, diabetes mellitus stands out as an important cause of morbidity and mortality in this country. Estimates indicate that by 2030, 366 million people will suffer from diabetes worldwide^{1,2}. In Brazil, there were 6 million diabetics in 2010; by 2030, the country should be among the world's top ten in the number of diabetic patients³. The prevalence of self-reported diabetes in Brazil is estimated to be 5.3%, and 6.2% in the city of São Paulo⁴.

This high prevalence of diabetes places a heavy disease prevention and control burden on the country's healthcare services. Using healthcare services can impact the health of diabetes patients, preventing the occurrence of the disease and its complications, and increasing survival among this population⁵. The healthcare service runs prevention programs and educates the population about the risks of diabetes and the importance of vaccines for their health of this population segment. It also provides medicines.

Vaccinations are an important element of healthcare services in Brazil, especially due to their superior performance in terms of cost-benefit, and the safety of the vaccines used⁶⁻⁸. Even people who have private healthcare plans routinely use the public service for vaccinations.

The National Immunization Program⁷, created in 1973, aims to control immunopreventable diseases such as influenza and pneumonia, both of which are associated with higher hospital morbidity and mortality among vulnerable populations, and are recommended for people with diabetes^{7,9}.

Influenza and pneumonia vaccinations for the population with diabetes mellitus form part of several interventions aimed at improving the quality of life of this population^{7,9}. Fostering better quality of life includes access to healthcare, which includes vaccines and medicines. An analysis of the supply of medicines to the population allows one to assess the healthcare provided, and provides subsidies to improve the health of the population¹⁰.

According to Oliveira et al¹¹, there has been an increase in the supply of medicines by the healthcare system since the unified health system (SUS) was created. The National Drug Policy (*Política Nacional de Medicamentos* - PNM) was created to promote the rational use and access to essential medicines, and was an important driver

of this increase^{11,12}. Among the PNM guidelines are decentralized management of Pharmaceutical Services and creation of the National List of Medicines (*Relação Nacional de Medicamentos-Rename*). The actual purchase of medicines is based on epidemiological criteria¹².

Korniz et al.¹³ refer to 'Rename' as the strategic and rationalizing tool of the Medicines Policy, as it provides a standard list of medicines, and can improve the quality of access to these drugs. Essential medicines for the control of diabetes covered by the public health services are those on the 'Rename' list. The National Medicines Policy led to changes in the organization of Pharmaceutical Services within SUS, the aim of which was to increase the coverage of free distribution of such medicines¹⁴.

In order to provide the medicines used to control diabetes mellitus and monitor information about the population with this disease, one must gather data about these patients. This data can be collected via health surveys, which provide information about the coverage of healthcare costs, and will enable an understanding of important aspects of the population's health. This in turn will provide the basis upon which policies may be deployed to ensure the population effectively has access to this service and the monitoring of these policies and¹⁵.

An analysis of the coverage of the population's spending on healthcare will help expand access to these services, which is related to its ability to respond to the population's demand for healthcare^{11,15}.

The goal of this study was to analyze the coverage of healthcare spending on medicines and vaccines among the adult population in the city of São Paulo reporting to suffer from diabetes mellitus in 2003, and discuss the current coverage offered by the healthcare services in terms of providing these inputs to this population.

Materials and methods

Data was collected using the city of São Paulo Multicenter Health Survey (ISA-Capital), a transversal study that collected data in population based household interviews conducted in the city of São Paulo in 2003. The objective of these interviews was to diagnose the morbidity to which this study refers in the population, the health and living conditions of this population, and the extent to which it uses healthcare services.

The ISA-Capital sample is representative of the non-institutionalized population residing within the urban perimeter of the city of São Paulo. The sample design was probabilistic, stratified and through conglomerates in two stages: census sectors (primary sampling unit) and households (2nd stage sampling unit). Census sectors were stratified by socioeconomic level, defined by the proportion of heads of household with different years of schooling. Heads of household with university degrees were considered at three levels: up to 5% (stratum 1), 5% to 25% (stratum 2) and 25% and more (stratum 3).

These weights were adjusted following stratification, according to the years of schooling of the head of household as follows: fewer than 3; 4 to 7; 8 to 11; and 12 or more years of schooling.

To ensure minimum sample size of the population sub-groups of interest to the study, eight study domains were defined, made up of the following groups: male and female under the age of 1, male and female aged 1 to 11, males aged 12 to 19, 20 to 59 and 60 and over, and females in the same age groups. 420 interviews were planned for each of these domains. In all, 3,357 interviews were conducted, of which 1,667 were with people aged 20 or over. Interviews were conducted by trained personnel who were supervised during the entire survey. Interviewees signed a Free and Informed Consent Form that explained the goals of the research and ensured that all data would be confidential and anonymous. For quality control purposes, about 10% of the completed survey questionnaires were checked in a second interview. A complete description of ISA-Capital 2003 methodology is available in the literature¹⁶.

This study analyzed men and women aged 20 or over who participated in the ISA-Capital survey and answered "yes" when asked if they had diabetes, or a total of 170 persons. Survey questions about vaccination using the public health system and coverage of the cost of medicines by the public health system were considered the dependent variables, and socio-demographic, living and health conditions were considered the independent variables.

The following socio-demographic, health and living conditions were analyzed: age, gender, race, marital status, years of schooling, paid work (two groups were created, one comprised of the economically active population (EAP), meaning people who are paid for work performed, and another for non-EAP individuals, meaning retirees, pensioners, homemakers, students

and others), *per capita* income and health self-assessment.

Estimates of the prevalence and prevalence ratios (PR) were calculated using the STATA survey module (Data Analysis and Statistical Software) version 10.0 and a Poisson regression analysis of vaccinations using the public health system and the independent variables. The same was done with coverage for spending on medicines. A multivariate Poisson regression analysis was performed, using 0.20 as the significance level for including the variable in the model.

The survey module enables incorporating the weights resulting from the complex nature of the sample: stratification, conglomerate drawing and weighting. Weights were introduced to offset the different selection probabilities applied to the study population, and to enable adjusting the sample to population distribution by years of schooling, age and gender, as described above.

The study project was approved by the Project Analysis Ethics Committee at the Hospital das Clínicas, University of São Paulo School of Medicine (CAPPesq).

Results

The prevalence of self-reported diabetes among the population was 5.0% (IC_{95%} 3.9 - 6.2). The prevalence of vaccinations among the interviewees was 46.8% (IC_{95%} 37.5 - 56.8) for the influenza vaccine and 17% (IC_{95%} 10.6 - 26.2) for the pneumonia vaccine. The public healthcare service was the most often used service for vaccinations: 74% of the interviewees who had been vaccinated against influenza and/or pneumonia used the public health system for this (n = 89) (Table 1). Of these, 3 were aged 20 to 59 and 105 were over the age of 60. The prevalence of using the public health system for vaccinations was estimated at 46% and 86% respectively. We found no statistically significant differences in the prevalence of using the public health system for vaccinations among the other categories of variable surveyed (gender, race, marital status, years of schooling, paid work, income and health self-assessment) (Table 1).

Regarding medicines to control diabetes, the main medicines mentioned by the study population were those on the 'Rename' list - insulin, metformin and glibenclamide. Regarding coverage for the cost of these medicines, 38.0% (IC_{95%} 31.9 - 44.5) reported they were covered by SUS.

Table 1. Prevalence of using the SUS for vaccination against the flu and/or pneumonia (USV) according to specific variables surveyed among vaccinated individuals reporting to have diabetes in the city of São Paulo, 2003.

Variables, categories and n*	Prevalence of USPV**	IC95%	PR	IC95% for PR	Value of p
Sex					0.976
Male (n=48)	75.1%	45.8 – 91.4	1		
Female (n=59)	74.6%	49.6 – 89.7	0.9	0.6 – 1.5	
Race/Ethnicity					0.894
Caucasian (n = 68)	75.4%	52.2 – 89.6	1		
Non Caucasian (n = 39)	73.6%	48.6 – 89.2	0.9	0.7 – 1.4	
Marital status***					0.316
With partner (n = 56)	69.1%	43.3 – 86.8	1		
No partner (n = 51)	82.5%	67.0 – 91.6	1.1	0.8 – 1.7	
Years of Schooling***					0.203
None or fewer than 3 years (n = 51)	89.3%	75.2 – 95.8	1		
4 to 7 (n = 40)	73.2%	42.9 – 90.8	0.8	0.6 – 1.2	
8 or more years (n = 15)	56.7%	20.1 – 87.2	0.6	0.3 – 1.3	
Paid work***					0.887
EAP (n = 22)	76.2%	50.7 – 90.8	1		
Not part of the EAP (n = 85)	74.4%	53.4 – 88.0	0.9	0.7 – 1.4	
Per capita income					0.171
≥ 1 mw (n = 42)	76.8%	52.7 – 90.7	1		
1-2 mw (n = 40)	88.8%	71.5 – 96.1	1.1	0.8 – 1.5	
≥ 2 mw (n = 25)	59.6%	26.4 – 85.8	0.7	0.4 – 1.4	
Health self-assessment***					0.594
Excellent, very good or good (n = 84)	76.3%	55.6 – 89.2	1		
Poor or very poor (n = 22)	69.1%	40.5 – 87.9	0.9	0.6 – 1.3	

* Number of interviewees who were vaccinated against the flu and/or pneumonia (n = 107). ** In all, 89 interviewees (74%) had been vaccinated against influenza and/or pneumonia using the public health system. *** Don't know/No answer responses excluded

The prevalence of public health system coverage for spending with medicines was 34.4% (n = 13) in the population aged 20 to 59, and 40.8% (n = 142) in the population aged 60 or over. Table 2 shows the prevalence of coverage for the cost of medicines by the public health system according to the variables of gender, race, marital status, years of schooling, paid work, *per capita* income and health self-assessment. Significant differences were found for the following variables: (Prevalence Ratio (PR) = 1.7 IC_{95%} 1.1-2.7), marital status (RP = 1.9 IC_{95%} 1.1-3.5), paid work (RP = 3 IC_{95%} 1.1-8.2 and health self-assessment (RP = 1.7 IC_{95%} 1.1-3.0).

A multivariate analysis using the variable SUS coverage of the cost of medicines as the outcome shows that coverage was 1.5 greater in the population claiming to have “poor or very poor” health (IC_{95%} 1.2-3.4) than it was in the population reporting “excellent, very good or

good health”, after adjusting the data for marital status, race, paid work, years of schooling and income *per capita*.

Discussion

This study presents a discussion of the coverage provided by the healthcare system for the cost of vaccinations and medicines for the population reporting to have diabetes mellitus, according to socio-demographic, living condition and health status characteristics. Although the data used comes from a health survey conducted the city of São Paulo in 2003, one can compare this to current data, thus contributing to discussions about expanding the population's access to vaccinations and especially to anti-diabetic medication. The 2003 ISA-Capital was an important milestone, given that it was a methodologically rigorous

Table 2. Prevalence of SUS coverage of spending with medicines according to the variables surveyed among individuals claiming to have diabetes in the city of São Paulo, 2003.

Variables, categories and n*	Prevalence of SUS coverage**	IC95%	PR	IC95% da RP	Value of p
Gender					0.308
Male (n = 67)	37.4%	20.5 – 58.0	1		
Female (n = 88)	38.4%	26.8 – 51.5	1.02	0.5 – 1.9	
Race/Ethnicity					0.026
Caucasian (n = 108)	31.1%	22.5 – 41.1	1		
Non Caucasian (n = 47)	52.0%	30.1 – 73.2	1.7	1.1 - 2.7	
Marital status**					0.047
With partner (n = 79)	27.4%	15.7 – 43.3	1		
No partner (n = 74)	51.9%	36.1 – 67.3	1.9	1.1 – 3.5	
Years of Schooling**					0.151
None or fewer than 3 years (n = 66)	52.5%	34.6 – 69.9	1		
4 to 7 (n = 57)	38.2%	23.8 – 55.1	0.7	0.4 – 1.3	
8 or more years (n = 29)	25.5%	10.5 – 49.9	0.5	0.2 – 1.2	
Paid work**					0.038
EAP (n = 35)	16.6%	5.8 – 39.3	1		
Not part of the EAP (n = 117)	49.1%	35.9 – 62.5	3	1.1 – 8.2	
Per capita income					0.372
≥ 1 mw (n = 65)	51.7%	33.7 – 69.3	1		
1-2 mw (n = 44)	35.1%	21.4 – 51.9	0.7	0.4 – 1.2	
≥ 2 mw (n = 46)	26.2%	5.1 – 46.0	0.5	0.2 – 1.5	
Health self-assessment**					0.043
Excellent, very good or good (n = 114)	31.3%	20.5 – 44.7	1		
Poor or very poor (n = 40)	55.1%	24.4 – 82.3	1.7	1.1 – 3.0	

* Number of interviewees using medicines in the three days prior to the interview (n = 155). ** The prevalence of SUS coverage for the cost of medicines was 38% (n = 68). *** Do not know/No answer responses excluded.

survey of a representative sample. It will be a very useful standard of comparison for future studies on this theme.

Diabetes mellitus was used as the example. This is a public health priority that requires continuous use of medicines and vaccines to promote the health of the affected population. The prevalence of self-reported diabetes in the city of São Paulo was estimated at 5.0%. Because this survey involved a self-reported morbidity, there may have been a selection bias in the sample of diabetics used, as anyone reporting to suffer from diabetes must have had access to the health system for a diagnosis. Thus, the population with diabetes that did not have access to the health service was not diagnosed. This under-estimates the prevalence of the disease, in particular among the segments more dependent on SUS services. This same bias could also lead to an overestimation of the use of SUS provided

medicines and vaccines, as the sample does not include a contingent of under-undiagnosed individuals.

The data for prevalence of diabetes in this study is similar to the data reported in the 2006 Vigitel study¹⁷, which estimated the prevalence of self-reported diabetes in the adult population in São Paulo to be 6.2%. The 2010 Vigitel¹⁸ study found a prevalence of 6.3% nation-wide.

The high prevalence of diabetes demonstrates the importance of promoting disease control and health among this population, which can be done via the healthcare services. One of the main reasons the population uses public health services is for vaccinations. Only 17.0% of those interviewed had been vaccinated against pneumonia, and 46.8% against influenza, despite the fact that the World Health Organization recommends vaccination and that vaccines are guaranteed as a SUS public health policy to

reduce the incidence of hospitalization among people with diabetes⁷.

Currently, the proportion of the vaccinations is higher: a household survey in Campinas (SP)¹⁹ found that 62.6% of the population had been vaccinated. Flu vaccine campaigns have intensified since 2009, when the Influenza A (H1N1) virus struck. Diabetic patients are a risk group and have been targeted in these campaigns.

Vaccinations are provided by both the public and private health systems. Among the group that received the influenza and pneumonia vaccines, 74.0% used the public health system. This is consistent with the study published by Silva *et al.*²⁰, which reported that the SUS was responsible for most of the vaccinations in all regions in Brazil. The majority of people continue to use the SUS for vaccinations¹⁹.

No significant differences were found in the use of public services for vaccination among the categories of variables surveyed. This suggests that vaccinations are universally distributed through the public healthcare system. The Brazilian immunization program (PNI) has been embedded in the system for a very long time⁷, which could explain the universal distribution of vaccines. Unlike vaccination, coverage for medicines is rather recent, and has only existed since the National Medicines Policy¹² was created, and the SUS started to intensify its inclusion of programs and policies to cover medicines.

Of the medicines provided to the population by the healthcare system, the main antidiabetic products used by the study population (insulin, metformin and glibenclamide) are on the 'Rename' list, which is consistent with the literature^{21,22}.

The prevalence of SUS coverage for the cost of essential medicines among the population claiming to be "white" was 1.7 times the coverage among the population claiming to be "nonwhite". Schnittker *et al.*²³ report on the inequity of health services in the United Kingdom and United States when it comes to ethnic background. According to the authors, this inequity in the healthcare service reflects the ethnic inequity that prevails in these countries, with significant differences in the access to the health services by the population of African descent, which could be the case in this particular study population.

SUS coverage of medicines among the population reporting to have "no partner" was 1.9 times larger than for the population reporting to "have a partner". SUS coverage for individuals reporting no paid work when the data was collected was 3.0 times as large as the medicines

coverage for those reporting paid work. This can be explained by the fact that the categories "with no partner" and not economically active includes the elderly, who use more medicines, thus SUS coverage tends to be larger.

Coverage among the population claiming to have "poor or very poor" health was 1.5 times the coverage in the population reporting "excellent, very good or good health", after adjusting the data for marital status, race, paid work, years of schooling and income *per capita*. The population with a negative health analysis tends to seek out the public health services more²⁴, and thus they receive more SUS coverage for the medicines they use.

Although the SUS covers the cost of essential medicines, only 38.0% of the population with self-reported diabetes reported that their spending with these medicines was covered by the public health system. This suggests a gap in the SUS system, and the need to expand access to medicines among diabetes mellitus patients. The literature reports a difficulty in ensuring access to medicines in the day-to-day operations of the public health system²⁵, which is underlined by this study.

In 2003, when the data was collected, the Medicines Policy was part of the emerging National Medicines Policy that was being created at that time, along with procedures to effectively implement generic medicines so as to expand access to medicines in this country. The federal, state and municipal governments have all managed to expand access. In the intervening 11 years, two federal programs have considerably increased access to medicines for diabetes. These are the "Low Cost Pharmacy Program in Brazil" and the "Health is Priceless Program".

The "Low Cost Pharmacy Program" is subsidized by the Federal Government and enables the purchase of specific diabetes medicines. It is available in all states, with 14,005 affiliated pharmacies and drugstores that, as of December 2010, had sold R\$ 245.191,00 in medicines under this program²⁶. The "Health is Priceless" program distributes anti-diabetics on the 'Rename' free of charge. Since the program was created in 2011, it has benefited 19 million people suffering from diabetes and hypertension²⁷. All of the policies and programs have contributed to changing the situation found in 2003.

There has been an increase in the access to healthcare, and expanded coverage of basic care coverage through the Family Health Strategy. Meanwhile, the country has also reduced the

levels of extreme poverty, although significant challenges remain. Of the nation's 190 million inhabitants, 145 million depend on SUS for their healthcare, posing a major challenge²⁸. The challenge for healthcare professionals and researchers is how to formulate public policies to provide universal access to healthcare, including, among other measures, vaccination and access to medicines.

Research into the coverage of the spending on vaccines, medicines and associated factors, which

is the case of this study, enables the analysis of healthcare coverage and access since 2003, and can be used to show the trend in public health coverage for vaccines and medicines, which will contribute to the discussion of spending on healthcare inputs by the population with diabetes mellitus. The results presented herein demonstrate the challenges and priorities of the public healthcare services to reach universal coverage.

Collaborations

CN Monteiro, RJ Gianini, M Goldbaum, CLG Cesar and MBA Barros participated equally in all stages of preparation of the article.

Acknowledgement

São Paulo Research Foundation-Fapesp.

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Article submitted 20/03/2014

Approved 28/07/2014

Final version submitted 30/07/2014