

Free acquisition of psychotropic drugs by the Brazilian adult population and presence on the National List of Essential Medicines

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The aims of the present study were to estimate the free-of-charge acquisition of psychotropic drugs among Brazilian adults; analyze the distribution of psychotropics according to their presence on the *Relação Nacional de Medicamentos Essenciais* (RENAME [National List of Essential Medicines]) and acquisition according to the source of funding (free of charge or direct payment); and estimate the proportion of free-of-charge psychotropic drugs according to therapeutic class and presence on the RENAME. This study involved the analysis of data from the 2014 National Survey on the Accessibility, Use and Promotion of the Rational Use of Medicines considering psychotropic drugs used by the adult population (≥ 20 years; $n = 32,348$). The prevalence of the acquisition of free-of-charge psychotropic drugs was 53.3% and 64.6% of these drugs were on the RENAME. Among the psychotropic drugs acquired by direct payment, 70.8% were not on the national list. Regarding free-of-charge acquisition according to the therapeutic class and presence on the RENAME, differences were found for antidepressants, anxiolytics and antipsychotics ($p < 0.05$). In conclusion, the most used psychotropic medicines were listed in the RENAME, but free-of-charge acquisition was not provided for all of them.

Keywords: Access to Essential Medicines and Health Technologies. Essential Drugs. Drug Utilization. Psychotropic Drugs. Pharmacoepidemiology. Health Surveys.

INTRODUCTION

Although mental and behavioral disorders (MBDs) are responsible for more than one-third the total number of disabilities in the Americas according to the Pan American Health Organization, investments are far below what is needed to address the burden of these disorder in the public health realm (PAHO, 2018). The Global Burden of Disease study reports that, despite the low mortality rate, MBDs are the main cause of years lived with disability

(YLD) in Brazil, responsible for 24.9% of the total YLD for all causes and the third most common cause of the burden of disease in the country (disability adjusted life years), the most prevalent and incapacitating of which are depressive disorders and anxiety (Bonadiman *et al.*, 2017).

Access to medicines in Brazil is the duty of the State, incorporated in the principles and directives of the constitution as universal access, equity and comprehensive care, including pharmaceutical care (Brasil, 1990). Therefore, the establishment of a public policy addressing pharmaceutical care and incorporating actions that ensure access to medications is fundamental to the constitutional fulfillment of the right to health.

The *Relação Nacional de Medicamentos Essenciais* (RENAME [National List of Essential Medicines]) is the guiding instrument for orienting the offer, prescription

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and dispensing of medications at healthcare services to meet the priority needs of the Brazilian population and to make medications available to all segments of society (WHO, 2002). The RENAME is a technical-scientific instrument that adopts the criteria of scientific evidence proving efficacy, safety, therapeutic convenience, quality and favorable cost comparison (Wannmacher, 2006). In the field of mental health, psychotropic agents constitute an important resource used in the treatment of individuals in a state of suffering (Brasil, 2013a) and are available free of charge at the pharmacies of the public healthcare system in the basic and specialized components of pharmaceutical care (Brasil, 2013b).

In Brazil, the provision of psychotropics occurs through different arrangements: (1) free-of-charge provision at public pharmacies (Brasil, 2013b); (2) acquisition by full payment at private pharmacies; and (3) (until 2017) acquisition through co-payment in the network of the People's Pharmacy Program of Brazil (Silva, Caetano, 2015).

The aims of the present study were to estimate the distribution of sources of the acquisition (direct payment by the consumer or free access) of psychotropic drugs used by the adult population in Brazil and determine psychotropics according to therapeutic class obtained free of charge (through public financing, donation or other sources of free acquisition) and presence on the RENAME.

MATERIAL AND METHODS

A population-based cross-sectional study was conducted using records of psychotropic drugs used by the adult population (20 years or older; $n = 32,348$) from the *Pesquisa Nacional sobre Acesso, Utilização e Promoção do Uso Racional de Medicamentos* (PNAUM [National Survey on the Accessibility, Use and Promotion of the Rational Use of Medicines]) conducted between September 2013 and February 2014 (Mengue *et al.*, 2016).

The PNAUM sampling plan was complex and involved three-stage probabilistic sampling stratified by sex and age group. The data were collected using a structured questionnaire and face-to-face interviews with the population residing in urban areas with representation of

the five large geographic regions of the country. Details on the sampling and data collection procedures are described in the PNAUM methodological paper (Mengue *et al.*, 2016).

The data considered in this study are available in the databank of medications referred for the treatment of chronic diseases and/or acute events (occurred in the 15 days prior to the interview) reported by interviewees ($n = 3,969$) with records of the use of psychotropic drugs. Information on the use of medicines was obtained by the following questions: “*Has any doctor ever told you that you have depression?*” (yes/no); “*Do you have a medical prescription for any medicine for depression?*” (yes/no); “*Are you taking any of these medicines?*” (yes/no); if affirmative: “*Which?*”. Considering these records and the variable of interest (free access to the set of psychotropic drugs used), independently of the reason for use, and the presence of these medications on the RENAME (at the time of the study), data on the acquisition of medicines were obtained using the following question: “*Was this medicine paid for?*” (yes/no/part of treatment paid/“I don’t know”/did not answer).

Psychotropics were classified into four therapeutic classes based on the definitions of the European Study of the Epidemiology of Mental Disorders (Alonso *et al.*, 2004): antidepressants (including tricyclics and last-generation antidepressants); anxiolytics (including benzodiazepine and non-benzodiazepines used as hypnotics, such as zolpidem, or for the treatment of anxiety, such as buspirone); antipsychotics (including atypical antipsychotics, such as clozapine, olanzapine, quetiapine and risperidone) and mood stabilizers (including lithium, carbamazepine, sodium valproate, gabapentin, topiramate and lamotrigine).

Percentages and 95% confidence intervals ($CI_{95\%}$) were estimated. Comparisons were performed using Pearson’s χ^2 (**Rao-Scott**) test, with a 5% significance level. All analyses took into account weights related to the complex sampling design of the study.

The frequency of the use of medicines referring to therapeutic classes of psychotropic drugs and the presence on the RENAME was described using the 8th edition of the list of medicines as reference, which was current at the time of data collection of the present study. All analyses were performed using the Stata 14.0 program. This study received

approval from the National Research Ethics Committee (certificate number: 398.131, September 16, 2013).

RESULTS

For the set of psychotropic drugs used by Brazilian adults, the prevalence of free-of-charge acquisition was 53.3% (CI_{95%}: 49.7 to 56.9). Among the psychotropics on the national list, most were acquired without payment by the user (64.6%; CI_{95%}: 60.9 to 68.1). Regarding those not on the RENAME, 70.8% (CI_{95%}: 66.2 to 74.9) were acquired through direct payment (Figure 1).

In the evaluation of psychotropics acquired by free access according to therapeutic class and presence on the RENAME (yes or no), differences were found for antidepressants (69.7% and 28.0%, respectively), anxiolytics (58.0% and 21.3%, respectively) and anti-psychotics (71.5% and 51.0%, respectively), with greater free-of-charge acquisition in the group of medications on the list ($p = 0.014$). Regarding mood stabilizers, the rates were 63.6% and 53.5% for medications on and not on the RENAME, with no statistically significant difference between the subgroups analyzed ($p > 0.05$) (Figure 2).

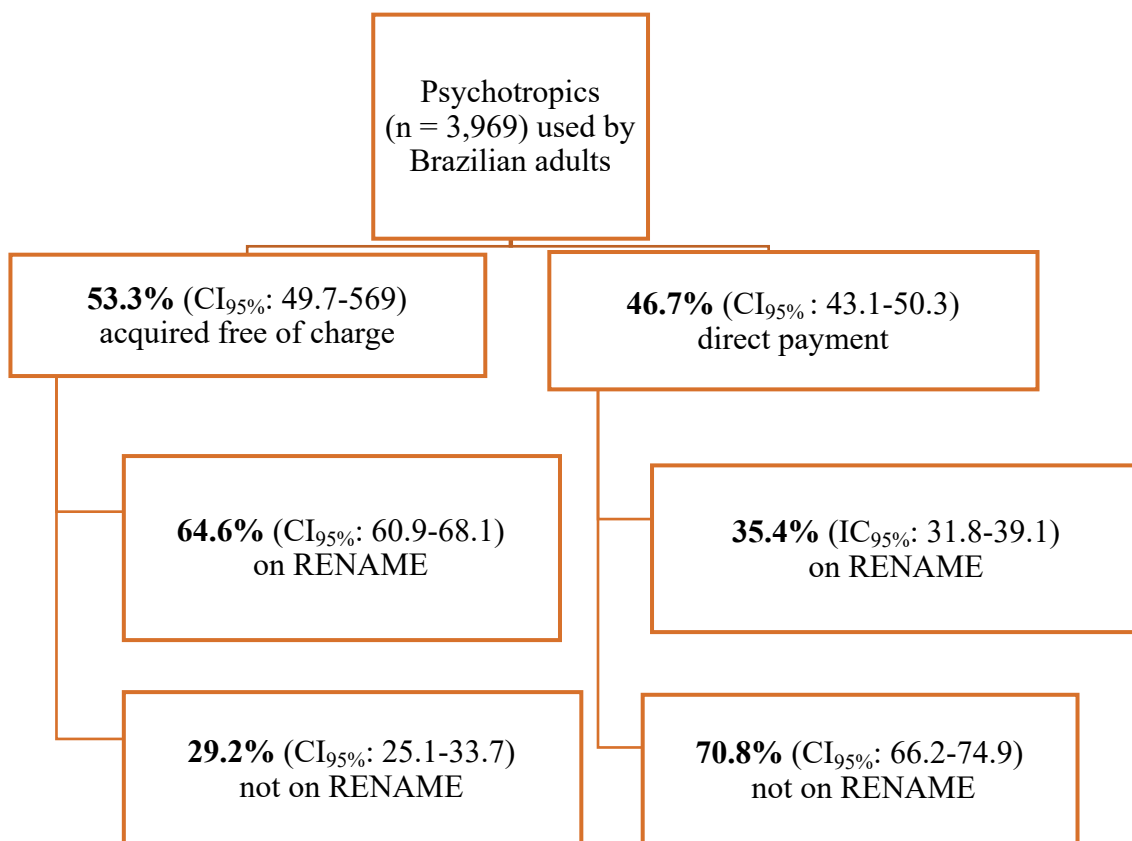


FIGURE 1 - Distribution of psychotropic drugs used by adult population in Brazil according to source of funding (direct payment or not) and presence on RENAME. National Survey on Accessibility, Use and Promotion of Rational Use of Medicines, Brazil, 2014.

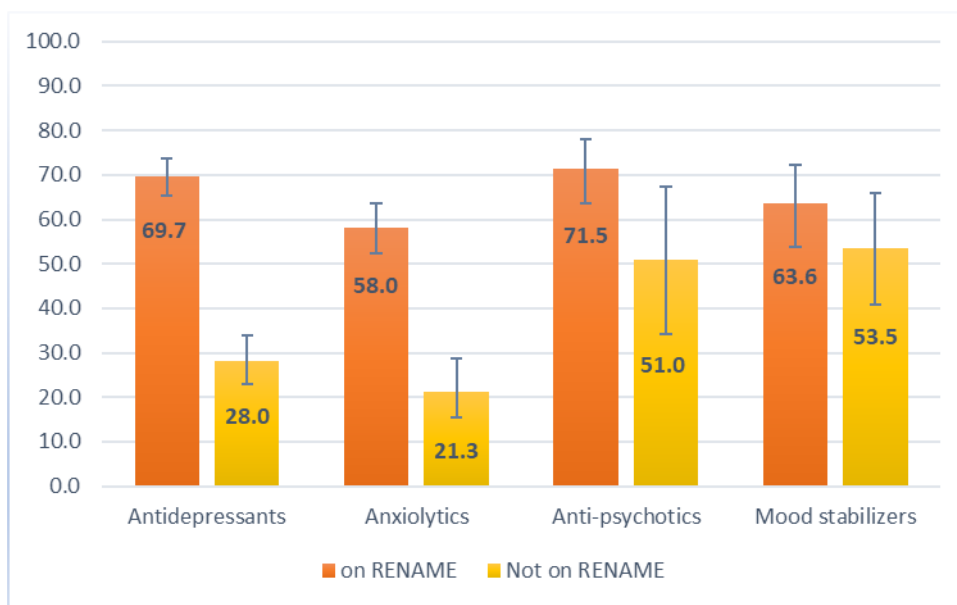


FIGURE 2 - Acquisition of psychotropics free of charge (no payment) according to therapeutic class and presence on RENAME. National Survey on Accessibility, Use and Promotion of Rational Use of Medicines, Brazil, 2014.

DISCUSSION

Among the Brazilian adults who took psychotropic drugs, most drugs were acquired free of charge, especially antipsychotics. The majority of medicines obtained without payment were provided by pharmacies of the public healthcare system. The present evaluation included medications prescribed through the Brazilian public health care system and those prescribed through the Supplementary Health System.

Data from the National Survey on the Accessibility, Use and Promotion of the Rational Use of Medicines conducted at pharmaceutical services in primary care of the public healthcare system revealed that 55.2% of all medicines prescribed were on the RENAME (Lima *et al.*, 2017). Particularly regarding the use of psychotropics, a study conducted in the city of Porto Alegre with all patients at primary care units found that 75.1% were on the RENAME (Rocha, Werlang, 2013). The World Health Organization (WHO) considers the ideal situation to be 100% of medications prescribed to be on a list of essential medicines (WHO, 2002; Kaddar, Velasquez, 1998). No previous population-based studies were found in the literature on the use of psychotropics according to their presence on a national list of essential medicines.

Although the adoption of Lists of Essential Medicines is a measure that promotes the expansion of access of the population to safe, efficacious and cost-effective medications for the treatment of the most prevalent illnesses, contrarily to what the WHO recommends, RENAME is not a list of the mandatory offer of medicines. Since 2012, with changes resulting from Law Lei 12.401/2011 (Brasil, 2011a) and Decree 7508/2011 (Brasil, 2011b), RENAME became a list that compiles and orients the funding of medicines in the pharmaceutical care sector of the Brazilian public healthcare system (Bermudez *et al.*, 2018). Thus, the Brazilian national list of medicines is an instrument to guide what can be funded with resources from the financing components of pharmaceutical care, which administrators use as a model to prepare the list of fundable medicines. Moreover, due to political-administrative autonomy, states and municipalities can define the inclusion of medicines on their state and municipal lists, funding them with their own resources (Vieira, 2010). This may partially explain the percentage of free-of-charge psychotropics with public funding not on the RENAME as well as the direct payment on the part of consumers of medicines on the national list.

Another factor that may, to some extent, explain the free-of-charge access to medicines not on the RENAME through public funding is the phenomenon of judicialization, which had been an important alternative route to ensure provision or expand access to medicines in the public healthcare system (Pepe *et al.*, 2010). Different pressures from users of the system or representative patient organizations, prescribers and, especially, the pharmaceutical industry establish forces that place tension on the provision of medicines not on the RENAME by the public healthcare system. A survey conducted by the Health Ministry identified that the demand in approximately 60% of judicial processes is for treatments not incorporated in the public healthcare system, although most could be performed with medicines provided by the public system (Soares, Depra, 2012).

The influence of new drugs recently released on the market and presented as a therapeutic innovation is the result of high investments in marketing by the pharmaceutical industry targeting prescribers and all of society. However, “new medications” are most often products with the molecular structure of an existing therapeutic group and with a similar pharmacological mechanism of action, known as “me too drugs” (Cañas, 2008), and there is an increasing demand for the incorporation of these medicines in the public healthcare system. A study that evaluated the selection of psychotropic drugs on lists of medicines in Brazilian cities identified a large portion of psychotropics not on the RENAME, especially antidepressants and anxiolytics, which were incorporated to municipal lists and were “me too” drugs of other medicines on the standard list of Brazilian medicines (Fulone *et al.*, 2016). This suggests that a large proportion of antidepressants and anxiolytics not on the RENAME and obtained free of charge in the present study, especially those provided at pharmacies of the public healthcare system, occurred in a similar way as that found in the study cited.

MBDs are among the chronic diseases that most cause disabilities and the discontinuous use of treatment or non-acquisition due to difficulties affording the cost of psychotropic drugs can lead to a greater temporary or permanent disability and negative impacts on the family (Razzouk, 2013). Thus, the control of MBDs and

associated risk factors depends on a set of health actions that include timely care and the adequate provision of medications, fundamentally through the offer of publicly funded psychotropics. However, a recent study found that the prevalence of complete access to all psychotropics prescribed and acquired through the Brazilian public healthcare system was only 23.0% (Rodrigues *et al.*, 2019).

Although the presence of psychotropics on the RENAME is unsatisfactory considering the standard defined by the WHO, the most widely used drugs were on the national list. However, free-of-charge acquisition was not provided for all medications used. Knowledge on the psychotropic drugs used by the adult population in Brazil can contribute to the organization and planning of interventions in the Psychosocial Care Network as well as the planning and management of pharmaceutical policies in the public healthcare system, especially actions related to broadening access, including a revision of the lists of essential medicines.

This study has limitations that should be considered, such as the impossibility of acquiring the totality of information on the presentations of the medicines used during the home interviews, which precluded the analysis of products by concentration and pharmaceutical form. Other limitations are those inherent to the conduction of population-based surveys and the PNAUM described by Mengue *et al.* (2016).

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