

# Analysis of prescription and dispensation of psychotropic medications in two cities in the State of São Paulo, Brazil

## Análise da prescrição e dispensação de medicamentos psicotrópicos em dois municípios do Estado de São Paulo

Ana Regina Noto<sup>a,b</sup>, Elisaldo de A Carlini<sup>a,b</sup>, Patrícia C Mastroianni<sup>b</sup>, Vanete C Alves<sup>a,b</sup>, José Carlos F Galduróz<sup>a,b</sup>, Wagner Kuroiwa<sup>c</sup>, Jussara Csizmar<sup>c</sup>, Agrimeron Costa<sup>c</sup>, Mariluci de A Faria<sup>c</sup>, Sônia Regina Hidalgo<sup>c</sup>, Dirce de Assis\* and Solange Aparecida Nappo<sup>a,b</sup>

<sup>a</sup>Cebrid (Brazilian Information Center on Psychotropic Drugs). São Paulo, SP, Brazil. <sup>b</sup>Department of Psychobiology, Federal University of São Paulo, Paulista Medical School. São Paulo, SP, Brazil. <sup>c</sup>Sanitary Vigilance Agencies of the cities researched in the current study

**Abstract** **Objectives:** To investigate the prescription and dispensation of psychotropic medications through the analysis of the prescriptions/notices kept at various institutions in two cities in the state of São Paulo. **Methods:** The prescriptions kept at drugstores, magistral pharmacies, primary care settings and hospitals were collected and analyzed in collaboration with the Sanitary Vigilance agencies in the year of 1999. The information in the prescriptions/notices were typed and tabulated. **Results:** A total of 108,215 prescriptions were processed, being 76,954 for benzodiazepines, 26,930 for anorexigenic drugs, 3,540 for opiates and 788 for other drugs. The benzodiazepines most frequently prescribed were: diazepam (31,644), bromazepam (16,911) and clonazepam (7,929). Among the anorexigenic drugs, diethylpropion (14,800) and femproporex (10,942) were the most common. When compared to men, women were given more prescriptions, mainly for anorexigenic drugs: the ratio was 10:1 in the prescriptions for diethylpropion and femproporex. The few magistral pharmacies (n=6) handled even more prescriptions than did the drugstores (n=49). A number of errors and inconsistencies were detected in the prescriptions analyzed. **Conclusions:** The results confirm the occurrence of an irrational use of such medications and a series of inadequate practices related to their prescription in Brazil. Therefore, they point out to the need of a comprehensive review of the government's control system of these substances.

**Keywords** Psychotropic drugs. Legislation, drug. Prescriptions, drug. Anti-anxiety agents, benzodiazepine. Analgesics, opioid. Amphetamines. Drug and narcotic control. Health survey. Pharmacoepidemiology.

**Resumo** **Objetivos:** Analisar a prescrição e dispensação de medicamentos psicotrópicos por meio da análise das receitas/notificações retidas em diferentes estabelecimentos de dois municípios do estado de São Paulo. **Métodos:** Em parceria com as Vigilâncias Sanitárias dos municípios, foram coletadas e analisadas as prescrições retidas em drogarias, farmácias de manipulação, postos públicos e hospitais no ano de 1999. Os dados contidos nas receitas/notificações foram digitados e tabulados. **Resultados:** Foram processadas 108.215 prescrições, sendo 76.954 de benzodiazepínicos, 26.930 de anorexígenos, 3.540 de opiáceos e 788 de outros. Os benzodiazepínicos mais frequentes foram: diazepam (31.644), bromazepam (16.911) e clonazepam (7.929) e, entre os anorexígenos, dietilpropiona (14.800) e femproporex (10.942). As mulheres, em geral, receberam mais prescrições em comparação com os homens, especialmente para os anorexígenos, com uma relação dez vezes maior nas prescrições de dietilpropiona e femproporex. As poucas farmácias de manipulação (n=6) chegaram a movimentar mais prescrições do que as drogarias (n=49). Também foi detectada uma série de erros e incoerências nas prescrições analisadas. **Conclusões:** Os resultados confirmam a ocorrência de uso irracional e uma série de práticas inadequadas que envolvem a prescrição desses medicamentos no Brasil e, portanto, indicam a necessidade de uma ampla revisão no atual sistema de controle dessas substâncias no país.

**Descritores** Psicotrópicos. Legislação de medicamentos. Prescrição de medicamentos. Agentes ansiolíticos benzodiazepínicos. Analgésicos opióides. Anfetaminas. Controle de medicamentos e entorpecentes. Levantamentos epidemiológicos. Farmacoepidemiologia.

\*Sanitary physician, specialized in Chemical Addiction

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## Introduction

According to the World Health Organization, 'although most of the industrialized countries control the selling and production of benzodiazepines, many developing countries do not have enough control over these drugs.'<sup>1</sup>

The WHO has plenty of reason, at least as concerns Brazil. In the past decade some papers pointed to a serious situation. For example, in Belo Horizonte the use of anti-anxiety/hypnotic agents by the elderly reached an astonishing figure of 95% of respondents;<sup>2</sup> in a small town with 10,000 inhabitants in the State of São Paulo, 50% of them would be taking benzodiazepines (according to the newspaper Folha de São Paulo 16/11/94). In the years 1988 and 1989 the Brazilian consumption of benzodiazepines was around 20 DDDs (Defined Daily Doses), similar to the daily consumption in the US.<sup>3</sup> In 1992, benzodiazepines were the main cause of poisoning in children aging up to 12 in São Paulo.<sup>4</sup>

The excessive and unadvised use of benzodiazepines is present in several other countries, such as Italy, Sweden, Belgium and Chile among others.<sup>5-8</sup>

Some studies have also suggested the irrational and widely spread use of amphetamine like stimulants as appetite reducers. The INCB (International Narcotics Control Board)<sup>9</sup> in its report of the year 1998, considers the use of anorexigenic drugs as one of the main concerns in South America, and Brazil, Argentina and Chile are the most affected countries. Accordingly, this international board recommends the adoption of legislative and administrative measures to face up the problem.<sup>9</sup> Brazilian studies have showed a yearly growth especially as receipts dispensed in Magistral Pharmacies.<sup>10</sup> A study in the cities of São Paulo and Recife showed also the carelessness with which physicians prescribe these anorexigenic agents associated to benzodiazepines.<sup>11,12</sup> A recent revision about the widely spread use of drugs such as amphetamines and its consequences shows how serious is this problem in Brazil.<sup>13</sup>

On the other hand, the exaggerated consumption is not the only noteworthy aspect; the WHO has indicated that the opiate analgesics are insufficiently prescribed, particularly in developing countries. In 1991 Latin America consumed 1% of the morphine world-widely used for therapeutic purposes.<sup>14</sup> The Brazilian consumption of opiates for analgesic purposes reached in 1990 and 1991 202.86 and 207.75 DDDs/million of inhabitants/day respectively. These figures mean that at least theoretically, only about 30,000 persons take 1 daily dose of an opiate; an insignificant number compared to Brazil's 1 million cancer cases.<sup>15</sup>

These data show that this issue deserves more attention and the first measure to be adopted in such cases is always to diagnose the situation. One classical example occurred in Malmo, Sweden, which had the highest rate of prescriptions of benzodiazepines and other hypnotic agents;<sup>6</sup> one study showed that a small percentage (2.4%) of physicians of private settings were responsible for a large percentage (24%) of all receipts. This finding allowed the adoption of corrective measures what led to a significant decrease in these receipts. We should mention

also that suicide attempts with these drugs (mainly barbiturates) have also decreased in Malmo.<sup>6</sup>

The prescription and selling of drugs based on narcotic or psychotropic substances in Brazil is regulated by the government regulation number 344/98,<sup>16</sup> which demands a Receipt Notice, a document that together with the receipt authorizes the dispensation. The notices are kept in the institutions for inspection and control and may be used as a valuable information source about the current practice of prescription/dispensation of psychoactive and psychotropic substances and medications.

## Objectives

In order to contribute to a better understanding of the Brazilian situation about the prescription and dispensation of narcotic and psychotropic medications, the current study aimed to analyze notices kept in drugstores, pharmacies, primary care settings, hospitals, among others, in two cities of the state of São Paulo in a year time (1999).

## Methods

### Sample

We analyzed the notices of narcotic and psychotropic medications (Lists "A" and "B" of the government regulation 344/98),<sup>16</sup> kept in the year 1999, in drugstores, magistral pharmacies, primary care settings and public hospitals in two cities (450,000 inhabitants) in the state of São Paulo.\*

Although the government regulation 344/98<sup>16</sup> determined the notice as the standard, it contemplates some exceptions such as inpatients for which the prescription in non-controlled receipts is allowed. These receipts have also been analyzed in our study.

### Data collection

In order to enable the collection of prescriptions, it was necessary to collaborate with the local Sanitary Vigilance agencies and, therefore, the cities' authorities were responsible for the collection.

Although the government regulation 344/98<sup>16</sup> determined that these documents should be inspected some institutions initially resisted making them available. Due to the difficulties found the collecting process was divided into stages, starting with the public sources of dispensation (Primary Care Settings and Public Hospitals), followed by drugstores and thirdly by magistral pharmacies. The private hospitals were supposed to be the fourth and last stage which was not performed due to operational difficulties.

### Organization of the material

The material received was organized in the Cebrid by a staff responsible for verifying, quantifying, labeling and storing it. During this process we found difficulties, such as the number of documents (well above what was expected) the disorganization of the material (especially those originated from public sources) and the low quality of the professionals' handwriting.

\*We must highlight the fact that other cities were also invited to participate in the study, but only two of them were interested in. They belong to the Great São Paulo.

### Data processing and validation

The following fields were processed: general information (state, series and official number of the notice, city and issuing date of the notice); information about the issuing agency and the physician in charge (CGC – General Taxpayers’ Register – of the issuing agency, name of physician), CRM (Conselho Regional de Medicina – state council responsible for accrediting physicians and for the surveillance of medical practices) and medical specialization; patient’s information (name, address and gender); buyer’s information (name, ID number and address); information about the drug (name, concentration, quantity and presentation); supplier identification and dispensation date. Besides these fields, two others were added: the medical specialization (determined from a list of registered physicians in the CRM/São Paulo) and the patient’s gender (inferred from the patient’s name). For that purposes a program was developed in Delphi with a SQL Server 7.0 database.

In order to assure the quality of the processed data, the program blocked and/or highlighted the incoherent data entered.

Collaboration with the CRM enable us to create the field ‘medical specialization’, which although was not in the notice could be filled in after checking the CRM’s list of professionals.

## Results and Discussion

### The Sanitary Vigilance and the institutions

Table 1 presents the number of institutions (existent x surveyed) responsible for the dispensation of medications included in Lists ‘A’ and/or ‘B’ of the government regulation 344/98.<sup>16</sup> Almost all dispensation sources of the two cities were analyzed, except for two magistral pharmacies that refused to participate and the private hospitals.

This extensive participation was only possible after uncountable efforts performed by the local Sanitary Vigilance agency which, despite having the legal right to demand the presentation of prescriptions, chose to call for a voluntary participation. The lack human and financial resources in the Sanitary Vigilance agencies, besides some political disagreements, also represented hindrances for the collection the documents.

Although the government regulation 344/98<sup>16</sup> was elaborated aiming to control the dispensation of psychotropics, the operational difficulties found along the current study demonstrate the frailty of the public service to perform a true ‘surveillance’ regarding psychotropic medications.

### General aspects of notices and receipts

We analyzed 108,212 prescriptions, which, during the year 1999, had been kept in the cities’ public and private institutions (Table 1). Of these, 104,664 (96.7%) referred to drugs and substances included in List ‘B’ of the government regulation 344/98<sup>16</sup> and the remaining in List ‘A’ (3.3%).

Regarding the type of institutions 73.1% of the prescriptions analyzed had been dispensed through private sources. The number of documents dispensed in the only six magistral pharmacies was higher than in the 49 drugstores, demonstrating the significant participation of this type of institution in the dispensation of prescribed drugs. The greatest figure observed was in a magistral pharmacy that processed in 1999 19,792 notices (about 80 notices per working day).

List ‘B’ notices were dominant in pharmacies and drugstores, whereas all List ‘A’ medications were dispensed by hospitals, totaling 3,548 documents.

As inpatients are allowed to receive prescriptions in non-controlled receipts, all documents originated in hospitals (totaling 17,580 documents) were of this kind. Although this amendment in the Government Regulation minimizes bureaucratic procedures and consequently facilitates the use of psychotropics in hospital settings, on the other hand it may also provide loopholes to deviate drugs. In this sense, it is essential to analyze in detail the possible consequences of this common practice.

### Incoherent and wrong filling of notices

The low quality in the filling in of the notices was one the most striking results in the current study.

Besides the low quality in the handwriting, that in itself would deserve several considerations about how to fill in the documents, there were also lack of coherency and errors made both by physicians and institutions.

The most common errors were related to not filling in certain fields (“blank data”). Some documents even had only the patient’s name filled in (all other fields were empty, including those referred to the physician and prescribed drug).

The lack of information about the patient’s address was the most common error and this information was absent in 42.3% of the notices, followed by the dispensation date (24.5%), absence of state (13.1%, especially in pharmacies and drugstores) and the identification of the ‘buyer’ (7.1%, mainly in primary care settings).

**Table 1 - Number of institutions responsible for the dispensation and number of notices or receipts related to the medications and substances of Lists ‘A’ and ‘B’ of the Government Regulation 344/98. Data separately presented according to the nature of the dispensation source of the two cities.**

Sources	Existent	Number of institutions		Total number of analyzed documents	
		Analyzed		List A	List B
Private					
Magistral pharmacies	8		6	-	40,741
Drugstores*	49		49	-	38,372
Hospitals	6		0	-	-
Public					
Primary care settings	2		2	-	7,971
Hospitals (emergency care eetings)	2		2	781	9,969
Hospitals (hospitalization)	1		1	2,767	7,611
<b>Total</b>	<b>68</b>		<b>3,548</b>	<b>104,664</b>	

\*Drugstores that in the year 1999 were not contemplated did not dispensed drugs of Lists ‘A’ or ‘B’ of the Government Regulation 344/98.

Other blank fields in many documents, both in notices and non-controlled receipts, were the issuing date (9.7%) and the drug concentration (6.6%, especially in hospitals).

There were a small number of incoherencies of dates and, mainly in drugstores, erasures in the quantity (49 cases) and concentration (17 cases) of the dispensed drugs.

There were also cases of documents which had repeated official numbering, and even cases where the same official numbering was repeated in nine notices, what may suggest frauds.

**The study's impact in the rate of errors**

A noteworthy phenomenon was the impact of the current study in the rate of errors to fill in the documents. We may mention that the data collecting process started in the public institutions, more specifically in a mental health outpatient clinic of one of the cities. In the first months of the research we started preliminary analyses of the data, and several filling errors were observed in that institution. This result was informed to the professionals in charge of filling in the documents, and they voluntarily corrected the procedures. Thus, we verified a significant decrease in the filling errors. For instance, the rate of absence of information about supplier and dispensation date that reached 100% in the months of January and February, fell subsequently to only 4.6% (in March) and 5.2% (in April).

This phenomenon shows that the analysis of these documents represents in itself a preventive measure to improve the quality of handling them.

**Prescribed drugs**

Table 2 shows the number of analyzed documents, organized separately according to the medications substance class.

**List 'A' medications and substances**

List 'A' medications and substances were exclusively dispensed in hospitals and mostly to inpatients (77.8%). Among the substances contained in this List, the most frequent was meperidine (especially under the trade name of Dolantina™), totaling 2,038 documents. From the total of dispensed drugs in hospital settings, meperidine represented 46.6% of opiates used in inpatients and 96.6% of cases in Emergency Care settings. On the other hand, we observed only 3 documents which dispensed morphine (Dimorf™), all of them used in the Emergency

care setting and, therefore, none of them for inpatients. This information indicates the underprescription of this substance what, according to the scientific literature, apparently originates from a real 'opiophobia', i.e., a wrong medical approach based on excessive fears of prescribing morphine. Although psychotropic abuse is the most highlighted trend in the literature, the cases of underprescription are also severe, since they deprive patients from an adequate treatment.<sup>17</sup>

Regarding the profile of patients to whom List 'A' medications were dispensed, there was a distribution of about 1:1 between men and women (Figure).

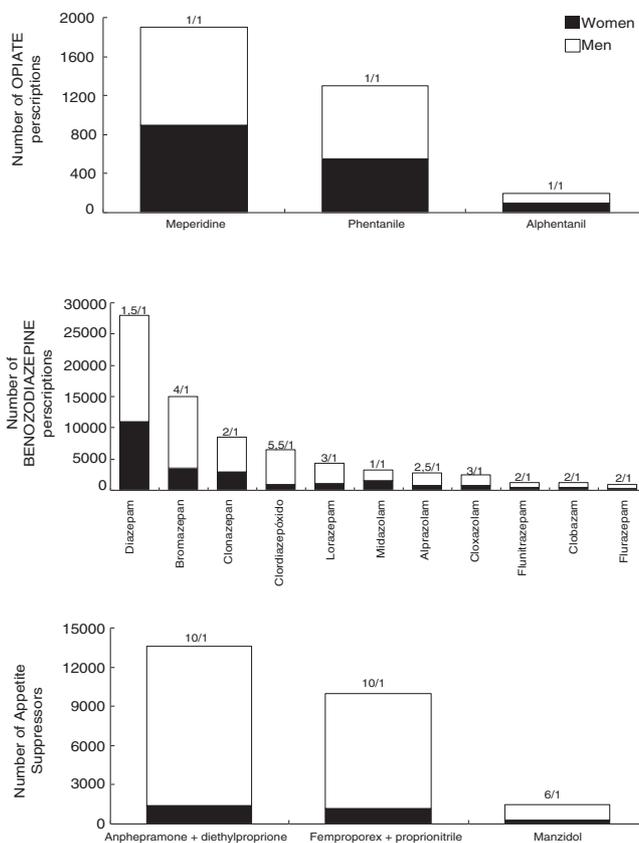


Figure 1 – Most frequently prescribed/dispensed psychotropics in the two analyzed cities. Data separately presented according to the lists of the Government Regulation 344/98 and according to the gender of patients who received the prescription. Amounts are expressed in number of prescriptions.

Table 2 - Number of prescriptions of each therapeutic class of medications and substances of lists 'A' and 'B' of the Government Regulation 344/98. Data displayed according to the nature of the dispensation source of the two cities.

Therapeutic class	Private		Institutions			Total
	Magistral pharmacies	Drugstores	Primary care settings	Public Emergency care settings	Hospitals Hospitalization	
Benzodiazepines	15,159	36,389	7,944	9,968	7,494	76,954
Non barbiturate hypnotic*	0	375	0	0	0	375
Barbiturate hypnotic	0	0	0	0	111	111
Antiparkinsonian	0	145	0	0	0	145
Anorexigenic	25,489	1,438	0	1	2	26,930
Opiates and opioid	0	0	0	781	2,759	3,540
Illegible	92	20	27	0	2	144
Blank	1	5	0	0	10	16
<b>Total</b>	<b>40,741</b>	<b>38,372</b>	<b>7,971</b>	<b>10,750</b>	<b>10,378</b>	<b>108,215</b>

\*zolpidem and zopiclone.

### List 'B' medications and substances

Benzodiazepines were preponderantly dispensed in all sources analyzed, except in magistral pharmacies (Table 2). Diazepam was the most frequent one, reaching almost 100% in public primary care settings and hospitals. However, we must stress the fact that the available medications in public institutions were those included in a list standardized by the government what reduces the possibility of other options.

On the other hand, when we analyzed the profile of drugstores and magistral pharmacies we could verify a quite different picture, with a much more diversified range of benzodiazepines. Bromazepam (especially Lexotan™) followed by clonazepam (Rivotril™), lorazepam (especially Lorax™), alprazolam (Frontal™), cloxazolam were predominant in drugstores, among others. However, in magistral pharmacies, besides diazepam, the preparations with other benzodiazepines were also frequent, especially bromazepam and chlordiazepoxide.

Regarding the patients' gender (Figure), we observed a clear-cut predominance of females for almost all benzodiazepines. The female/male ratio was near 2/1 in one of the cities and 3/1 in the other. This ratio was even more disproportionate for bromazepam (4/1) and chlordiazepoxide (5/1), as both are frequent in magistral pharmacies, usually associated to appetite suppressants which are consumed mostly by females.

For List B2 of medications (appetite suppressants), 95.0% of the documents were processed by magistral pharmacies, showing that this is the major dispensation source of these substances. The most frequent psychotropics of this class were: anphepramone (or diethylpropione), fenproporex (or propionitrile) and, much less, mazindol.

Patients to whom were prescribed appetite suppressants were mostly females, in a male/female ratio of 1/10 for amphepramone, 1/10 for fenproporex and 1/6 for mazindol.

### Physicians in charge of the prescriptions

Most professionals (81.5%) issued less than 10 documents during all the year, many of them only 1 document. On the other hand, we observed that 13 professionals issued more than 1,000 documents/year.

Among the cases in which we detected overstatements, we may mention a physician who issued 7,678 documents in 1999 (about 30-documents/working day), with almost all of them (99%) being dispensed by the same magistral pharmacy. The following physician with the greatest number of documents issued 3,633 (about 14 receipts/working day) followed by another with 2,075 (about 8/working day).

Most prescriptions were issued by general practitioners. For the remaining, the most frequent specialty was psychiatry, followed by labor medicine. However, for the latter we may say that most of these prescriptions were issued by the same "labor physician" (the same previously mentioned, with 7,678), but who probably was prescribing to reduce the appetite (considering the great number of prescriptions of appetite suppressants). Other medical specialties were also frequent, such as endocrinology, gynecology, cardiology and neurology.

We observed 321 documents issued by physicians that were not included in the CRM-SP list. These cases were checked with this institution and notified to the Sanitary Vigilance agencies. Among these, there were several physicians originated from other states, some foreigners that had not a license to practice the profession in the country, cases of physicians that had been previously forbidden to work by the CRM and even cases of physicians who had died several years before.

### Patients

Despite the different possibilities of abbreviated writing of the same name, we observed 225 patients' names that were repeated in more than twelve documents each, that is, a number equivalent to more than one monthly notice. We must emphasize that this figure does not include hospitalized patients, to whom there would be a plausible reason for a greater number of documents.

Considering that notices can refer at most to medications for a 60-day treatment and that generally that was the quantity observed in most of the analyzed documents (excluding hospital settings), we might expect that a single patient would receive up to 6 notices per year, or up to 12, considering a monthly frequency or treatment using two psychotropics.

Several countries recommend that the treatment with appetite suppressants must not overpass 3 months and, regarding benzodiazepines, the WHO suggests that it must not overpass 4 weeks. Thus, the cases of patients with excessive prescriptions must be assessed in detail in a second phase of the current study, as many of them do not seem compatible with the therapeutic purpose.

### Buyers

The process to analyze buyers was simpler, as for the 78,468 documents that had their buyer field filled in, 68,834 (87.7%) had the corresponding ID number. In that way, the information could be analyzed not by its name but rather by its ID number.

We observed one case of 326 notices with the same ID card number. However, when we analyzed the documents more in detail we observed that, as a matter of fact, buyers' (and patients') names were different but all of them were dispensed in the same drugstore.

Except for the mentioned case, the greatest number of prescriptions under the same ID card number was 41, followed by two cases with 40 and one with 36. As a whole, 18 buyers' ID card numbers had more than 24 documents each (equivalent to more than 2 documents per month).

### Conclusions

The results confirm the Brazilian trend to an irrational use of narcotic and psychotropic medications. They also reveal several inappropriate practices which involve the prescription and dispensation of these drugs.

Consequently, the results suggest the need to reassess the policies adopted to date regarding these substances in our country, but also indicate that it might be possible to change this reality adopting relatively simple inspecting measures.

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## Correspondence

Ana Regina Noto

Cebrid (Centro Brasileiro de Informações sobre Drogas Psicotrópicas), Departamento de Psicobiologia da Universidade Federal de São Paulo

Rua Botucatu, 862, 1º andar

04023-062 São Paulo, SP, Brazil

E-mail:ananoto@psicobio.epm.br

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