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# Evaluation of pharmaceutical assistance in public primary care in Brasília, Brazil

# Avaliação da assistência farmacêutica na atenção primária no Distrito Federal

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## **Keywords**

Drug evaluation. Drugs, essential. Drug use habits. Prescriptions, drug. Primary health care. Drug utilization. Cross-sectional studies.

#### **Abstract**

## Objective

Pharmaceutical assistance is essential in health care and a right of citizens according to Brazilian law and drug policies. The study purpose was to evaluate aspects of pharmaceutical assistance in public primary health care.

#### Methods

A cross-sectional study using WHO drug indicators was carried out in Brasília in 2001. From a random sample of 15 out of 62 centers thirty exiting patients *per center* were interviewed.

#### Results

Only 18.7% of the patients fully understood the prescription, 56.3% could read it, 61.2% of the prescribed drugs were actually dispensed, and mean duration of pharmaceutical dispensing was 53.2 seconds. Each visit lasted on average 9.4 minutes. Of prescribed and non-dispensed drugs, 85.3% and 60.6% were on the local essential drug list (EDL) respectively. On average 83.2% of 40 essential drugs were in stock, and only two centers had a pharmacist in charge of the pharmacy. The mean number of drugs per prescription was 2.3, 85.3% of prescribed drugs were on the EDL, 73.2% were prescribed using the generic denomination, 26.4% included antibiotics and 7.5% were injectables. The most prescribed groups were: cardiovascular drugs (26.8%), anti-infective drugs (13.1%), analgesics (8.9%), anti-asthmatic drugs (5.8%), anti-diabetic drugs (5.3%), psychoactive drugs (3.7%), and combination drugs (2.7%).

#### Conclusions

Essential drugs were only moderately available almost 30 years after the first Brazilian EDL was formulated. While physician use of essential drugs and generic names was fairly high, efficiency was impaired by the poor quality of pharmaceutical care, resulting in very low patient understanding and insufficient guarantee of supply, particularly for chronic diseases.

## **Descritores**

Avaliação de medicamentos.

Medicamentos essenciais. Hábitos de consumo de medicamentos. Prescrição de medicamentos. Cuidados primários de saúde. Uso de medicamentos.

Estudos transversais.

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## Resumo

#### Objetivo

O acesso a medicamentos e seus serviços é indispensável às ações de saúde e um direito do cidadão segundo a política de medicamentos e a legislação brasileira. O objetivo do estudo foi avaliar aspectos da assistência farmacêutica na atenção primária, em centros de saúde.

This study is part of the Master's degree dissertation submitted to *Universidade de Brasilia* in 2002. Received on 24/10/2003. Reviewed on 1/6/2004. Approved on 23/9/2004.

#### Métodos

Estudo transversal utilizando indicadores da assistência farmacêutica propostos pela Organização Mundial de Saúde, em amostra aleatória de 15 centros de saúde dos 62 do Distrito Federal, em 2001. Em cada centro foram entrevistados 30 usuários.

#### Resultados

Apenas 18,7% dos pacientes compreendiam integralmente a prescrição, sendo que 56,3% conseguiam ler a receita. Foram efetivamente dispensados 61,2% dos medicamentos prescritos, o tempo médio de dispensação foi de 53,2 segundos e o de consulta 9,4 minutos. Dos medicamentos prescritos, 85,3% pertenciam à Relação de Medicamentos Essenciais, bem como 60,6% dos não atendidos. Da lista de 40 medicamentos-chave, 83,2% estavam disponíveis. Apenas duas unidades tinham farmacêutico responsável pela farmácia. O número médio de medicamentos por prescrição foi de 2,3. Foram prescritos pelo nome genérico 73,2% dos medicamentos onde 26,4% eram antibióticos e 7,5% injetáveis. Os grupos farmacológicos mais prescritos foram: cardiovasculares (26,8%), antimicrobianos (13,1%), analgésicos (8,9%), antiasmáticos (5,8%), antidiabéticos (5,3%), psicoativos (3,7%) e associações (2,7%).

#### Conclusões

Após 30 anos da elaboração da primeira relação de medicamentos essenciais no Brasil, esses ainda estão apenas parcialmente disponíveis na rede pública, inclusive os destinados a doenças crônicas. Os prescritores utilizam a relação atualizada e nomes genéricos, mas a eficiência das ações de assistência farmacêutica está seriamente comprometida pelos baixos níveis de compreensão dos pacientes e pela dificuldade de acesso.

## INTRODUCTION

Brazil is a middle income country showing significant economic growth while it has one of the most markedly uneven income distributions in the world. This pattern of economic growth has led to grossly unequal access to medical and pharmaceutical care. A profound health reform, established by the 1988 review of the Brazilian Constitution, created a universal publicly-financed health system. One of its commitments was, in fact, the provision of pharmaceutical care to the population. Brazil has developed programs for the production and distribution of essential drugs since the early 1970s. Nevertheless, surveys have showed that most Brazilians acquire their drugs through private pharmacies, often at very high costs for their income, and proportionally higher for the poor. According to the national household survey on access to and utilization of health services family income is strongly correlated with access to health services, either public or private. Insufficient access to essential drugs due to inadequacies in acquisition and distribution and poor physician prescribing have been described as factors aggravating the unequal access to good quality pharmaceutical assistance.<sup>4,9</sup>

Pharmaceutical price regulation in the Brazilian market was greatly weakened during the 1990s, resulting in massive increases in drug prices, thus increasing the importance of public distribution to assure access to essential drugs.

Since the first international Essential Drug List (EDL) was published in 1977, the World Health Organization (WHO) has disseminated the concept of essential drugs as a fundamental steppingstone for improving access, equity, and quality in health care.<sup>11</sup> The WHO encourages countries to elaborate their own drug lists, adjusted to local needs. Brazil has its own essential drug list since 1974, and its Federal District, Brasília, recently updated its list in 2000.

The availability of essential drugs is considered an important indicator of the effectiveness and equity of health systems. WHO defines the rational use of drugs as demanding that "(...) the appropriate drug be prescribed, that it be available at the right time, at a price people can afford, that it be dispensed correctly, and that it be taken in the right dose at the right intervals and for the right length of time. The appropriate drug must be effective and of acceptable quality and safety".16

A number of organizations have worked with the WHO in the development of methods and indicators for evaluating essential drug programs at the primary care level. 10 Such methods have been applied in numerous countries in Africa, Latin America and Asia. In 1993, the WHO published *How to Investigate Drug* 

*Use in Health Facilities*, which delineated a small set of practical indicators. This manual describes in detail a set of reliable indicators to measure drug use. In fact, it defines 12 core indicators that measure key aspects of drug prescribing, patient care, availability of drugs and drug information at outpatient facilities. These highly standardized indicators do not require local adaptation.<sup>15</sup>

This study aimed at evaluating different aspects of the pharmaceutical assistance in public primary health care centers of a major urban region in Brazil using all 12 core drug indicators proposed by the WHO, as well as some new indicators.

#### **METHODS**

Amongst the various possibilities for evaluating pharmaceutical assistance, the method delineated in the manual *How to investigate drug use in Health Facilities*<sup>15</sup> was chosen as it analyses such aspects in primary services. Furthermore, this method has a solid validation, feasibility, and ability to capture relevant aspects of pharmaceutical assistance.

The study was carried out in the Federal District of Brazil, Brasília, an area of 5,782 km<sup>2</sup> and approximately two million inhabitants. A cross-sectional study was conducted aiming at describing selected aspects of the availability and use of essential drugs in the public primary care. Methods suggested by the WHO for rapid and simple analysis of drugs in primary care services were used in addition to few new indicators. A random sample of 15 out of a total of 62 (24%) public primary health care centers was selected and 30 exiting patients were interviewed at each center, based on 95% confidence interval and an error of  $\pm 4.6\%$ . These centers are part of the Sistema Único de Saúde - SUS (Brazilian Unified Heath System), whose legal duties include provision of medical and pharmaceutical care to the entire population.

Data was collected between July and September 2001. Consecutive patients leaving the pharmacy after the researcher's arrival were invited to participate up to a total of 30 subjects were obtained. Patients were included when they had been in a visit, received a prescription and were over 16 years of age. The University of Brasília and the Research Ethics Committee of the Federal District Department of Health approved the study and all patients signed an informed consent.

All interviews were performed by the same researcher, and other data collected were by especially trained pharmacy students. The Essential Drug List of the Federal District Department of Health was used and a subset of 40 drugs considered most important for primary care was selected by researchers after consultation with local experts and the local Essential Drug List (Annex).

In addition to the indicators suggested by the WHO, data concerning demographics of the sampled population, presence of a pharmacist, pharmacological groups and most prescribed drugs, identification of non-dispensed drugs and prescribed drugs that are not in the local Essential Drug List were also collected. The classification of pharmacological groups followed that of the National Essential Drug List.

Prescriptions were considered legible through a generous estimate if the patient was able to read the name and dosage of at least one of the drugs. Overall knowledge was considered positive if a patient knew the drug name, dose and duration of treatment.<sup>10,15</sup> The unit of analysis was the health center.

Instruments were developed and applied after pretesting. Statistical analysis was carried out to compare knowledge of the prescribed drug between different educational levels using the chi-square ( $\chi^2$ ) test and p<0.05 was considered statistically significant.

# **RESULTS**

# **Characteristics of Health Centers**

The health care centers have relatively similar physical and human resource infrastructures. All but one of the centers studied had small scale pharmacies with limited space for storage and dispensing. The drugs were stored on metal or wood shelves. Pharmacies were generally easily accessible to the population and patients were served at a small stand often with a glass window. Stocks were replenished monthly after presenting maps and standardized requests following a schedule with the option of making additional requests. Most drugs were dispensed without the secondary packages or package inserts. In all visited units, drugs for special programs, such as Hansen's disease, tuberculosis, sexually transmitted diseases or Aids, were stored separately outside the pharmacy. Local regulation also limited dispensation to a 30-day supply. In all but two centers, drugs were dispensed by one pharmacy attendant and lines were frequent.

## Characteristics of the patients

A total of 450 patients were interviewed, of which

Table 1 - Indicators of patient care in health centers of Brasília, Brazil, 2001.

| Health center   | Drug dispensed<br>(%) | Visit time<br>(minutes) | Dispensing time (seconds) | Prescription legibility (%) | Patient knowledge (%) |
|-----------------|-----------------------|-------------------------|---------------------------|-----------------------------|-----------------------|
| Mean<br>Maximum | 61.2<br>73.0          | 9.4<br>12.6             | 53.9<br>96                | 56.2<br>70.0                | 18.7<br>30.0          |
| Minimum         | 39.4                  | 6.4                     | 40                        | 40.0                        | 6.7                   |

Table 2 - Education and prescription knowledge, public health centers of Brasília, Brazil, 2001.

| Educational level  | n                            | Prescription knowledge<br>N (%)                          |
|--|------------------------------|--|
| No formal education/ illiterate 1-4 years of schooling 5-8 years of schooling Incomplete/complete high school Incomplete/complete university | 42<br>168<br>130<br>97<br>13 | 0 (0)<br>30 (17.8)<br>27 (20.8)<br>22 (22.7)<br>5 (38.5) |
| Total  | 450                          | 84 (100.0)   |

72.7% were female. A higher rate of refusal to participate was seen among males but it was not quantified. Patients were 38% between 16 and 30 years of age, 28.9% between 31 and 45, 18.9% between 46 and 60 and 14.4% older than 61 years. Of them, 42 (9.3%) were illiterate, 168 (37.3%) had 1-4 years of schooling, 130 (28.9%) had 5-8 years, 97 (21.5%) had initiated or completed high school, and 13 (2.9%) had some higher education.

## **Indicators of patient care**

Of all groups of indicators, those related to information and patient care had the poorest results (Table 1). Only 61.2% of prescribed drugs were actually dispensed in the pharmacy. This indicator ranged from a low 39% in one health center to a maximum of 73%. Visit times were also short, 9.42 minutes for medical care and 53.9 seconds for drug dispensing. Patient's prescription knowledge was extremely low. Only 18.7% of all patients fully understood the prescription (Table 2), and even among those at university level, knowledge was quite low (38.5%). A high proportion of prescriptions were illegible; i.e., only 56.2% of patients were able to read them.

When viewed sequentially, patients obtained only 61% of their prescribed drugs in the public pharmacy, and only 18% on average understood their use. Such findings suggest that a mere 11% of drugs prescribed through health care centers were both received and had their proper use understood by the patient.

## Indicators of the health services

The essential drug list was available in 60% of the centers, but even when available it was not often distributed to prescribers. Of the 40 key drugs studied (Annex), an average of 83.2% was in stock, but interruptions in the supply of widely used drugs

such as hypertensive, diabetes mental illness or asthma drugs were common. Stocks ranged from 67.5% to 90%. Only two out of 15 pharmacies had a on-site pharmacist though this is legally required.

# **Prescribing indicators**

For 450 patients interviewed, a total of 1,024 drugs were prescribed with a mean of 2.3 drugs per patient. About one in four prescriptions (26.4%) included an antibiotic and 7.5% an injectable drug, most consisting of insulin or penicillin. Antibiotics most prescribed were amoxicillin and sulfamethoxazole-trimethoprim. Prescribers seemed to have reasonably complied with the essential drug list: 85.3% drugs prescribed were from the list. Prescribing by generic name is mandatory in the Brazilian public health service and compliance to this recommendation was also fairly high, 73.2%, or full compliance.

The study evaluated data not included in the WHO drug indicator proposal, such as highly prescribed drugs, drugs on the essential drug list which were not dispensed, drugs frequently prescribed but were not included in the essential drug list, and availability of pharmacist. The most highly prescribed pharmacological group was cardiovascular drugs (26.8%). The ACE inhibitors (captopril and enalapril) were the most prescribed antihypertensive treatments, 25.9% of all cardiovascular prescriptions, followed by hydrochlorothiazide and propranolol, 19.7% and 5.1% respectively. There were also 28 prescriptions for a variety of irrational combination drugs, representing 2.7% of drugs prescribed.

The second additional aim was to identify drugs on the essential drug list which were not dispensed to identify priorities for supply management. The leading non-dispensed drugs were paracetamol (42 prescriptions), followed by captopril (36), phenoterol drops (11), cephalexin (eight), diclofenac (eight), and metformin (seven). Another aim was to identify the most prescribed drugs which were not included on the essential drug list. The most prescribed drugs in this category were metamizole (19 prescriptions), indapamide (nine) and nystatin vaginal ointment (seven).

## DISCUSSION

The study shows both progress and serious deficiencies in assuring access to essential drugs in this major urban center. Significant progress has clearly been achieved in assuring a fair drug stock for most primary care centers, physician's compliance with the Essential Drug List, and use of the generic denomination while prescribing. However, there is still much to be improved. Yet Brasília seems to be ahead of other countries experiences. 36,11 In these researchers' experience, when doctors can rely on having essential drugs in stock in their centers, most willingly prescribe these drugs and use generic names in order to facilitate patient drug access. 11

Nevertheless, this study found that 38.8% prescriptions, of which 60.6% were essential drugs, were still not filled. Such finding illustrates the need for improving both financing and managing of the public essential drug supply system. The Brazilian unified health system basic principles of universal access, equity and integral care are clearly not yet fulfilled in this area. Other studies carried out in Brazil have similarly identified only a partial ability to dispense prescribed drugs.<sup>2,12,13,\*</sup> It suggests serious problems in planning and logistics for drug procurement and distribution. These lead to interruptions in supply, losses, and high expenditures for low-priority medicines. No pharmacy was found to record the unmet needs of patients. Implementing a simple system to record these needs could clearly help to better supply management.

Hypertension, diabetes, and asthma, major causes of morbidity and hospitalization, showed an important therapeutic drug gap. While the essential drug list includes asthma inhalers and prednisolone oral solution, these were not available in all centers. Although captopril, phenoterol, and metformin are essential drug treatments for hypertension, asthma, and diabetes – three of the most common chronic diseases – lack of treatment continuity almost certainly generates significant suffering and costs to the health care system, usually in the form of preventable morbidity and hospitalization. Similar

results were seen in different regions of Brazil and other developing countries. 1-3,12,13

In the most highly prescribed pharmacological group of cardiovascular drugs, a deviation from prescribing recommendations was observed. Although diuretics and beta-blockers are recommended as first choice treatment for hypertension, ACE inhibitors were the most prescribed antihypertensive treatment.

The observed proportion of antibiotics (26.4%) and injectable drugs (7.5%) prescribed may be considered acceptable according to WHO recommendations (20-30% and less than 10%, respectively). 9.15 Moreover, most antibiotics and injectable drugs prescribed were recommended for primary care treatment.

Only three centers studied distributed drugs acting on the central nervous system. This represents a significant access barrier to patients with mental illness, including epilepsy and Parkinson's disease. Also, it was found that only seven of the 62 health centers stocked these products. Patients with common conditions such as schizophrenia, Parkinson's disease, depression, and epilepsy are often required to travel far to obtain their medicines.

Drugs for specific vertical programs such as tuberculosis and Hansen's disease, as well as for contraception programs, were regularly supplied to the centers but they were only available outside the pharmacies. Local regulation also limits dispensation to a 30-day supply creating a care barrier for patients with chronic diseases. This is significantly aggravated due to the frequent lack of essential drugs.

The most dramatic problems identified were related to the extremely poor level of patient knowledge and understanding. Less than one in five patients understood what drug they were to take and how to take it. Similar results were found in other Brazilian cities such as Campo Grande, Salvador, Ribeirão Preto, and Fortaleza.<sup>2,12,13,\*</sup> This low level of information can have serious consequences regarding the effectiveness and efficiency of the investment in essential drugs. Silva et al<sup>14</sup> reported that, after outpatient visits in Rio Grande do Sul, only 34% had good knowledge regarding the drugs obtained.14 According to Fletcher, the term compliance refers to the degree in which patients follow the prescribed medical advice. Although initial analysis indicates that noncompliance to prescribed actions might suggest negligence or unwillingness to submit to medical advice, in fact many factors may contribute to that such as inadequate knowledge or prescription understanding.<sup>5</sup> That, in turn, may be related to factors

such as short visit and dispensing times, no pharmaceutical care practices in place, no pharmacy-generated labelling at the time of prescription, high frequency of illegible prescriptions, illiteracy, poorly trained workers performing the task of drug dispensing and low population schooling. In this study, knowledge was not significant correlated with the level of education. Although the former was also not significantly correlated to other factors, this likelihood can not be excluded and should be analysed as a whole. Visit times were short, 9.42 minutes for medical care and 53.9 seconds for drug dispensing, both well below the ideal.

Pharmacies' physical infrastructure was also found to be not conducive to activities of patient orientation and human resources. Drug dispensing was performed on average at the very high rate of 53.2 seconds. In a similar study in Ethiopia, dispensing times were found to be at 1.9 minutes ( $\pm 0.6$ ), having a positive effect on patient satisfaction and knowledge of drug usage.<sup>3</sup>

High proportion of illegible prescriptions is another problem. Only 56.2% of the patients were able to read the prescription, which is the main or only source of drug usage information in Brazil. Most products were dispensed without secondary packaging, product inserts, or any pharmacy-generated labels. In Brazil, conversion of the physician's prescription into any kind of patient label is not customary in public or private pharmacies. Pharmacy labelling of dispensed drugs with legible and easily understood identification and use instructions, accompanied by verbal explanation, may potentially be an important and low cost intervention for improving rational drug use in the short- and medium-term.<sup>11</sup>

An additional factor which may create difficulties is that while physician prescriptions usually included generic names, products were often labelled with brand names. This might change from month to month, increasing error risks.

The WHO drug indicators were useful for capturing important aspects of pharmaceutical care. <sup>16</sup> These methods can identify the level of supply but do not provide by themselves the causes of inadequate supply. The reasons of inadequate supply are important and need to be identified and corrected in order to improve access. Evaluating prescribed drugs with unmet demand and those not listed on the Essential Drug List, were considered useful for evaluating insufficient supply. The prescription of drugs outside the list can reflect either poor prescribing habits, lack of physician compliance or a poorly formulated list

and this analysis helps to identify which is the case. Other studies in Brazil have found prescribing predominantly from the EDL, such as in Campo Grande (92.7%), Salvador (67.6%), Ribeirão Preto (80.0%) and Fortaleza (70.2%).<sup>2,12-14</sup>

Availability of a pharmacist is not necessarily linked to patient outcomes but was a useful indicator given law requirements in Brazil. Furthermore, drugs acting on the central nervous system, however necessary, are often not dispensed when there is no pharmacist available. When available, their role was limited to supply management and law controls, especially on controlled substances, with a small participation in promoting rational drug use or direct patient care. This also needs to be considered as has been recommended by many for addressing the role of pharmacists.<sup>17</sup>

This is a service-based method, which does not take into account population access through private health services, or even public secondary or tertiary care facilities. The study conclusions are, therefore, limited to access to essential drugs via the public primary care system.

In summary, the study suggests that while an improved drug supply is critically needed, major progress in the quality of pharmaceutical assistance can also be achieved by relatively low cost through investments in improving information to patients and more rational use.8 Improvement of physical infrastructures, providing better communication between the dispenser and patients having difficulties or proper stocking, and personnel education in rational drug use are also key steps for improving pharmaceutical service. Inadequate functioning of the essential drug system forces patients to resort to the private drug market using their personal finances to cover far higher cost, or to remain untreated. The consequences for health and government health spending on preventable illnesses are unknown. However, the reliable distribution of AIDS treatment drugs through the public system in Brazil has lead to excellent results, significantly reducing AIDSrelated hospitalizations, incidence of opportunistic infections, and mortality.

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## ANNEX

## **Key drugs studied**

# **Key Drugs**

- 1. Acetyl salicylic acid, 100 mg tab.
- 2. Acetyl salicylic acid, 500 mg tab.
- 3. Aminophylline, 100 mg tab.
- 4. Amoxicillin, 500 mg cap.
- 5. Amoxicillin powder for suspension, 250 mg/ 5 ml oral bottle
- 6. Benzathine benzylpenicillin powder for suspension, 1,200,000 IU bottle/amp. inj.
- 7. Procaine benzylpenicillin + Potassium benzylpenicillin suspension for suspension, 300,000 + 100,000 IU bottle/amp. inj.
- 8. Captopril, 12.5 mg tab.
- 9. Captopril, 50 mg tab.
- 10. Cimetidine, 200 mg tab.
- 11. Dexamethasone cream, 0.1% tube
- 12. Dexclorpheniramine, 2 mg tab.
- 13. Digoxin, 0.25 mg tab.
- 14. Erythromycin oral suspension, 125 mg/ 5 ml
- 15. Erythromycin, 500 mg tab./cap.
- 16. Glibenclamide, 5 mg tab.
- 17. Gliclazide, 80 mg tab.
- 18. Hydrochlorothiazide, 50 mg tab.
- 19. Aluminum hydroxide, 300 mg tabs or suspension 35.6 mg + 37 mg/ml
- 20. Hyoscine, 10 mg tab.
- 21. NPH insulin, 100 IU/ml bottle/amp.
- 22. Regular human insulin, 100 IU/ml bottle/amp.
- 23. Levonorgestrel + ethynilestradiol 0.03 mg + 0.15 mg tab.
- 24. Mebendazole, 100 mg tab.
- 25. Mebendazole, 100 mg/ 5 ml suspension bottle
- 26. Metformin, 500 mg or 850 mg tab.
- 27. Methyldopa, 500 mg tab.
- 28. Metoclopramide, 10 mg tab.
- 29. Metronidazole, 250 mg tab.
- 30. Metronidazole, 200 mg/ 5 ml oral suspension bottle
- 31. Paracetamol, 750 mg tab.
- 32. Paracetamol, 100 mg/ml drops
- 33. Propranolol, 40 mg tab.
- 34. Oral rehydration solution powder for oral solution 1L bag
- 35. Salbutamol, 2 mg tab.
- 36. Salbutamol, 2 mg/ 5 ml syrup bottle
- 37. Sulfamethoxazole + trimethoprim 400 mg + 80 mg tab.
- 38. Sulfamethoxazole + trimethoprim 200 mg + 40 mg/ 5 ml oral suspension bottle
- 39. Ferrous sulfate, 40 mg tab.
- 40. Ferrous sulfate, 25 mg/ml oral solution drops.