

# CONFORMITY ASSESSMENT OF MEDICAL PRESCRIPTIONS AND DISPENSATION OF ANTIMICROBIALS

*Avaliação da conformidade de prescrições médicas e dispensação de antimicrobianos*

*Evaluación de la conformidad de prescripción médica y dispensación de antimicrobianos*

Original Article

## ABSTRACT

**Objective:** To evaluate the conformity of medical prescriptions and the dispensation of antimicrobials. **Methods:** Observational and descriptive study that analyzed the duplicates of all medical prescriptions of antimicrobials retained in a drugstore in São Luís-MA, from March to May 2012. A total of 563 prescriptions were evaluated according to the legislation guidelines: data readability; identification of issuer and patient; name; quantity; pharmaceutical form; dosage and posology; date of issue and dispensation; percentage of medications; average number of medicines per prescription and occurrence of drug interactions. **Results:** A total of 1192 medicines, including 631 (53.2%) antimicrobials were found. The prescriptions were classified as readable (n=526; 93.60%), partially readable (n=31; 51%) and completely unreadable (n=5; 0.89%); 1.78% (n=10) presented erasures; 15.45% (n=86) did not present date of issue; and 6.57% (n=36) were out of date. Four data of compulsory identification were missing in over 90% of the prescriptions assessed (issuer's address and phone number and patient's age and sex). The absence of two of the variables required in the dispensation of antimicrobials was observed in 100% of the prescriptions assessed (Medicine batch number and the pharmacist's signature). The most commonly prescribed antimicrobials were amoxicillin (n=220; 34.87%), metronidazole (n=136; 21.55%) and neomycin (n=81; 12.84%). Moderate (n=23; 4.08%) and minor (n=4; 0.72%) drug interactions were identified. **Conclusion:** The results of the present study demonstrate the non-compliance of both the medical prescriptions assessed and the dispensation process with the current legislation.

**Descriptors:** Drug Prescriptions; Anti-Infective Agents; Drug Legislation.

## RESUMO

**Objetivo:** Avaliar a conformidade das prescrições médicas e a dispensação de antimicrobianos. **Métodos:** Estudo observacional e descritivo, que analisou as segundas vias de todas as prescrições médicas de antimicrobianos retidas em uma farmácia em São Luís-MA, no período de março a maio de 2012. Avaliaram-se 563 prescrições, de acordo com a exigência da legislação: legibilidade dos dados; identificação do emitente e do paciente; nome, quantidade, forma farmacêutica, dosagem e posologia; data de emissão e dispensação; percentagem dos medicamentos; número médio de medicamentos por prescrição e presença de interações medicamentosas. **Resultados:** Encontrou-se prescrição de 1.192 medicamentos, sendo 631 (53,2%) antimicrobianos. Classificaram-se as prescrições como legíveis (n=526; 93,60%), parcialmente legíveis (n=31; 51%) e completamente ilegíveis (n=5; 0,89%); 1,78% (n=10) apresentaram rasuras; 15,45% (n=86) não possuíam data de emissão; e 6,57% (n=36) estavam vencidas. Quatro dados de presença obrigatória na prescrição médica estavam ausentes em mais de 90% das prescrições avaliadas (o endereço e o telefone do emitente e a idade e o sexo do paciente). A ausência de duas das variáveis cujo registro é obrigatório na dispensação de antimicrobianos foi observada em 100% das prescrições avaliadas (número do lote do medicamento dispensado e a rubrica do farmacêutico). Os antimicrobianos mais prescritos foram amoxicilina (n=220; 34,87%), metronidazol (n=136; 21,55%) e neomicina (n=81; 12,84%). Identificaram-se interações

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medicamentosas moderadas (n=23; 4,08%) e leves (n=4; 0,72%).

**Conclusão:** Os resultados do presente estudo demonstram a não conformidade tanto das prescrições médicas avaliadas como do processo de dispensação das prescrições em relação à legislação vigente.

**Descritores:** Prescrições de Medicamentos; Anti-Infeciosos; Legislação de Medicamentos.

## RESUMEN

**Objetivo:** Evaluar la conformidad de las prescripciones médicas y la dispensación de antimicrobianos. **Métodos:** Estudio observacional y descriptivo que analizó las segundas vías de todas las prescripciones médicas de antimicrobianos retenidas en una farmacia de São Luís-MA en el período entre marzo y mayo de 2012. Fueron evaluadas 563 prescripciones según la exigencia de la legislación: legibilidad de los datos; identificación del emisor y del paciente; nombre, cantidad, forma farmacéutica, dosificación y posología; fecha de emisión y dispensación; porcentaje de los medicamentos; número medio de medicamentos por prescripción y presencia de interacciones medicamentosas. **Resultados:** Fueron encontradas prescripciones de 1.192 medicamentos y de ellos 631 (53,2%) antimicrobianos. Se clasificaron las prescripciones como legibles (n=526; 93,60%), legibles en parte (n=31; 51%) y totalmente ilegibles (n=5; 0,89%); el 1,78% (n=10) presentaron tachones; el 15,45% (n=86) no tenían fecha de emisión y el 6,57% (n=36) estaban caducadas. Cuatro datos obligatorios en la prescripción médica estaban ausentes en más del 90% de las prescripciones evaluadas (la dirección y el número de teléfono Del emisor y la edad y el sexo del paciente). La ausencia de dos de las variables cuyo registro es obligatorio en la dispensación de antimicrobianos fue observada en el 100% de las prescripciones evaluadas (número del lote del medicamento dispensado y la rúbrica del farmacéutico). Los antimicrobianos más prescritos fueron la amoxicilina (n=220; 34,87%), el metronidazol (n=136; 21,55%) y la neomicina (n=81; 12,84%). Se identificaron interacciones medicamentosas moderadas (n=23; 4,08%) y leves (n=4; 0,72%). **Conclusión:** Los resultados del presente estudio demostraron la no conformidad de las prescripciones médicas evaluadas y del proceso de dispensación de las prescripciones respecto la legislación vigente.

**Descritores:** Prescripciones de Medicamentos; Antiinfecciosos; Legislação de Medicamentos

## INTRODUCTION

The fragmentation of the responsibility regarding the pharmacological treatment, especially because of the presence of multiple prescribers of medicines to a single patient, together with the large quantities of new medicines and the high rate of morbidity and mortality associated with medication, are largely responsible for problems related to medication use<sup>(1)</sup>.

The introduction of antimicrobials for medical treatment in the 1940's was a major breakthrough for public health<sup>(2,3)</sup> because generalized infections and diseases that killed millions of people in the past could then be cured<sup>(3)</sup>. However, health care professionals have not yet realized the big public health problem underneath the irrational use of antimicrobials. Considered a worldwide problem, its inappropriate and abusive use has been largely associated with the development of bacterial resistance, which, in turn, contributed to an increased time and cost of the treatment, and limited therapeutic options<sup>(4)</sup>.

Circa 30% of hospitalized patients use antibiotics, accounting for approximately 1/3 of hospital drug expenditures and 20-50% of hospital revenue<sup>(5)</sup>. The cost of bacterial resistance in the United States only is estimated to be 4-5 billion dollars annually<sup>(4)</sup>. In Brazil, the incidence of nosocomial infection in ICU ranges from 5% to 10%<sup>(5)</sup>.

Within hospitals, prescribers with less clinical experience might often decide to use broad-spectrum antimicrobials or combinations of narrow-spectrum antimicrobials for, among other reasons, feeling the pressure from high complexity acute cases<sup>(6)</sup>.

Considering the several strategies in the field of utilization and monitoring of medication use, studies assessing medical prescription stand out<sup>(7)</sup>. The prescription is a compromise between health structures and their users and a prescriber's instruction to the professional receiving it. Therefore, the information on it must be clear and adequate in order to avoid erroneous dispensations that can contribute to an inadequate use of medicines<sup>(8)</sup>.

In an attempt to act upon the aforementioned problems and contribute to the promotion of rational use of antimicrobials, the *Agência Nacional de Vigilância Sanitária – ANVISA* (Brazilian Health Surveillance Agency) published the resolution RDC No. 20, of May 05, 2011, which provides for the control of medicines containing substances classified as antimicrobials used under prescription, isolated or in association with other drugs<sup>(9)</sup>.

Within this context, this study aimed to assess the conformity of medical prescriptions and dispensation of antimicrobials.

## METHODS

This is a descriptive observational study that assessed all the duplicates of medical prescriptions of antimicrobials, used under prescription, isolated or in association with other drugs, retained in the basic drugstore of the Mix Health Care unit *Itaqui-Bacanga* in São Luís, MA, in the period from March 1 to May 30, 2012.

During this period, the basic drugstore of the Mix Health Care Unit *Itaqui-Bacanga* retained a total of 563 prescriptions containing at least one prescription-only antimicrobial.

The Mix Health Care Unit *Itaqui-Bacanga* is a basic health care unit that provides primary and integrated health care. The unit provides urgency and emergency services, a ward with 27 beds for hospitalization, laboratory, rooms for nebulization, observation and vaccination, dental office, physiotherapy room and basic drugstore, among other settings.

The same researcher assessed all the prescriptions, which were inked and stored in an appropriate place after the analysis in order to prevent duplicate analysis.

In order to assess the conformity of each medical prescription with the *ANVISA RDC* No. 20, of May 05, 2011<sup>(9)</sup>, the following variables were analyzed: data readability; identification of issuer and patient; name of the drug prescribed according to the *Denominação Comum Brasileira – DCB* (Common Brazilian Denomination)<sup>(10)</sup>; quantity; pharmaceutical form; dosage and posology; lack of other special control medications; adequate date of issue and dispensation within the time limit specified; percentage of prescribed medications on the *Relação Nacional de Medicamentos Essenciais – RENAME*<sup>(11)</sup> (Brazil's National List of Essential Medicines); average number of medicines per prescription and occurrence of drug interactions.

The occurrence of drug interactions in each prescription was assessed through a drug information database that is internationally recognized for being powered by four institutions providing medical information: Wolters Kluwer Health, American Society of Health-System Pharmacists, Cerner Multum and Thomson Reuters Micromedex. The aforementioned database classifies the interactions in “major”: high clinical significance (avoid combination because the risk outweighs the benefits); “moderate”: moderate clinical significance (avoid combination; use only in special cases); and “minor”: low clinical significance (establish measures to reduce the risk and/or monitor patient).

Data were analyzed using the software SPSS 19.0, which performed descriptive procedures, mean and percentage calculations.

The current study was approved by the Ethics Research Committee of the *Hospital Universitário da Universidade Federal do Maranhão – CEP/HUUFMA* (University Hospital of the Federal University of Maranhão) under Opinion No. 016/12.

## RESULTS

In all, 1192 medicines were found in the prescriptions analyzed, including 631 (53.2%) antimicrobials. Most (n=212; 37.65%) prescriptions contained two medicines, followed by three (n=176; 31.26%) and one medicine (n=140; 24.87%).

Analgesics, antipyretics and nonsteroidal anti-inflammatory drugs (NSAID's) (n=178; 14.93%), antihelmintics (n=48; 4.02%) and expectorant syrups (n=45; 3.77%) were the medicines that were most commonly prescribed as antimicrobials.

Considering the data readability, 527 (93.60%) prescriptions were classified as readable, followed by 31 (5.51%) partially readable and five (0.98%) totally unreadable.

Of all the prescriptions analyzed, 520 (92.37%) were provided in duplicate whereas it was not possible to identify whether there were duplicates of 43 (7.63%) of them because the originals were retained in the drugstore.

Moreover, several irregularities were found in the medical prescriptions assessed and are hereby presented in Table I.

Issuers could be identified in 549 (97.51%) prescriptions through their registration number in their corresponding regional councils. There were 509 (90.41%) doctors, 25 (4.44%) nurses, 15 (2.66%) dentist-surgeons whereas 14 (2.49%) prescriptions did not present the issuer identification. Of all the prescriptions assessed, 561 (99.65%) presented the signature; 538 (95.56%), the stamp; 29 (5.15%), the address; and four (0.71%), the issuer's phone number.

Table I - Irregularities identified in the prescriptions assessed. São Luís-MA, 2012.

Assessed Variable	n	%
Erasures	10	1.78
Retention of original prescription	41	7.28
Absent date of issue	87	15.45
Expired prescription	37	6.57
Absent prescriber's identification	14	2.49

Table II - Conformity of the variables related to the identification of the antimicrobial with the current legislation. São Luís-MA, 2012.

Assessed Variable	Yes		No		Unreadable	
	n	(%)	n	(%)	n	(%)
DCB*	562	89.06	55	8.72	14	2.22
Concentration	221	35.02	396	62.76	14	2.22
Pharmaceutical form	284	45.01	337	54.41	10	1.58
Quantity	618	97.94	3	0.48	10	1.58
Posology	617	97.78	4	0.79	9	1.43
RENAME*	490	77.65	127	20.13	14	2.22

\*DCB: Denominação Comum Brasileira

\*RENAME: Relação Nacional de Medicamentos Essenciais

No controlled drugs were found in the prescriptions assessed; however, this identification could not be checked in five (0.89%) prescriptions due to data unreadability.

Table II presents the conformity of the variables related to the identification of medicines: name of the medicine or drug according to the DCB, concentration, pharmaceutical form, posology, quantity and percentage of antimicrobials prescribed that can be found in RENAME.

All the duplicates of prescriptions presented the dispensation date and quantity of the particular antimicrobial dispensed. However, none of the prescriptions presented the medication's batch number and the pharmacist's signature, variables compulsorily required in the prescriptions according to the RDC No. 20/11.

There were 16 different antimicrobials in the prescriptions assessed, of which 11 (68.75%) belonged to the list of antimicrobials registered in *ANVISA* according to the Resolution – RDC No. 20/2011 (Table III).

Other antimicrobials were identified: two (0.32%) ketoconazole, six (0.95%) fluconazole, three (0.47%) miconazole, 32 (5.08%) nystatin and 32 (5.08%) secnidazole.

The most frequent antimicrobials in the prescriptions were the amoxicillin (n=220; 34.87%), the metronidazole (n=136; 21.55%), the neomycin (n=81; 12.84%), the cephalexin (n=75; 11.88%) and the sulfamethoxazole/trimethoprim (n=71; 11.25%).

Table IV presents the detailed data on drug interactions observed in the assessed prescriptions.

Table III - Prescription antimicrobials dispensed in the *Unidade Mista Itaqui- Bacanga*. São Luís-MA, 2012.

Antimicrobial	n	Prescriptions	
		Frequency (%) among antimicrobials*	Frequency (%) among the total of prescribed medicines#
Amoxicillin	220	34.87	18.45
Metronidazole	136	21.55	11.41
Neomycin	81	12.84	6.79
Cephalexin	75	11.88	6.29
Sulfamethoxazole+Trimethoprim	71	11.25	5.96
Benzathine Benzylpenicillin	32	5.08	2.68
Azithromycin	7	1.10	0.59
Doxycycline	5	0.79	0.42
Ciprofloxacin	2	0.32	0.17
Ampicillin	1	0.16	0.08
Erythromycin	1	0.16	0.08

\*Of the total of antimicrobials (n=631)

#Of the total of prescribed medicines (n=1192)

Table IV - Frequency and classification of drug interactions observed in the prescriptions assessed. São Luís, MA, 2012.

Drug Interactions	Degree	n	%
Azithromycin+Amoxicillin	minor	1	0.18
Azithromycin +Benzylpenicillin	minor	1	0.18
Acetylsalicylic Acid+Spironolactone	minor	1	0.18
Acetylsalicylic Acid +Propranolol	minor	1	0.18
Acetylsalicylic Acid +Insulin	moderate	1	0.18
Losartan+Meloxicam	moderate	1	0.18
Mebendazole+Metronidazole	moderate	20	3.54
Propranolol+Hydrochlorothiazide	moderate	1	0.18

## DISCUSSION

The frequency of antimicrobials used under prescription identified in the medical prescriptions assessed (52.92%) in this study was higher than the frequency found in a study conducted in Bagé, RS (41.8%)<sup>(13)</sup>. This result may be associated with local epidemiological factors. According to the WHO, the acceptable average number of drugs per prescription is 2.6<sup>(14)</sup>. The average number of drugs per antimicrobial prescription in this study was 2.18. However, 31.26% of prescriptions included three drugs. Similar studies conducted in Brazil presented an average of 1.4-2.9<sup>(15-16)</sup>.

The readability of the prescription influences the communication and can interrupt or hinder the patient's care process<sup>(17)</sup>. The lack of readability has been responsible for reports of severe health problems in addition to being considered unethical by the Art. 11 of the Medical Code of Ethics<sup>(18)</sup>. Failures in reading and the misunderstanding of written information can contribute to medication errors. Therefore, this information should be provided in order to facilitate the adequate dispensation and the understanding of the prescribed treatment<sup>(17)</sup>. Thus, despite the apparent low frequency of unreadable prescriptions (0.89%) and erasures (1.78%) in this study, they are still relevant due to the fact that, according to the *RDC* No. 20/11, the prescriptions can only be dispensed by the pharmacist if they are readable and have no erasures<sup>(9)</sup>. Results even more worrying were found in another study<sup>(17)</sup>, which presented an unreadability rate of 53.3% in 167 prescriptions assessed. In this current study, 1.24% of the prescriptions were typed and were fully and precisely understood, reflecting the easy comprehension and contributing to the reduction of errors in prescription, dispensation and understanding of the proposed treatment.

According to the guidelines of the *RDC* No. 20/11, the prescription of antimicrobials of use under prescription should present the date of issue since it expires within 10 days. Additionally, during the dispensation the duplicate

should be retained and the original returned to the patient<sup>(9)</sup>. This current study observed that some prescriptions were dispensed although they were expired. By evaluating the date of the prescription in relation to problems related to the pharmacotherapy it is possible to identify problems regarding the need for medicines, taking into account the indication, patient's characteristics and the situations of reutilization of the same prescription<sup>(19)</sup>.

According to the *RDC* No. 20/11, the concentration, pharmaceutical form, posology and quantity are data that must be compulsorily informed in the prescription of antimicrobial drugs<sup>(9)</sup>. The concentration and pharmaceutical form were present only in 35.02% and 45.01% of the assessed prescriptions, respectively. Another study<sup>(13)</sup> presented a similar result regarding the concentration (38.5%) and a higher percentage regarding the pharmaceutical form (15.96%). Researchers<sup>(20-21)</sup> have also reported a high frequency of omission of such information. The lack of such information requires more time and effort from the pharmacist in order ensure the dispensation of the right medicine and the user's comprehension of the proposed treatment.

Of all the antimicrobials prescribed in this study, only 77.65% were in the RENAME. The prescription of medicines present in the RENAME is of great importance to the patient since the essential medicines constitute one of the main steps for an effective drug policy and are chosen in order to meet the health needs of the population<sup>(11)</sup>. Additionally, these medicines are provided free of charge to the population in the drugstores of *SUS* (The Brazilian National Health System), contributing to an increased adherent to the treatment.

According to the *RDC* No. 20/11, the full name, age and sex of the patient are compulsory data and should be in the prescription<sup>(9)</sup>. However, only the name was present in most of the prescriptions assessed (99.11%) in this current research, a result that is similar to that found in a previous study<sup>(22)</sup>,

which was 98.8%. The absent age was verified in 90.57% of the prescriptions whereas sex was missing in 99.64%. Such results demonstrate the prescriber's misunderstanding and/or non-compliance with the information required in the prescription of antimicrobials, hindering the identification of the patient and the dispensation process.

During the dispensation of antimicrobials, the duplicate of the prescription should be retained, and the original returned to the patient. At the time of the dispensation, the pharmacist must register the date of issue, the quantity, the medication's batch and sign on the back of the duplicate, testifying the service<sup>(9)</sup>. The batch of the dispensed medication and pharmacist's signature were missing in 100% of the prescriptions assessed in this investigation.

The high frequency of amoxicillin in the prescription has also been evidenced by other researchers<sup>(23)</sup> and it is expected to happen due to the fact that it is a broad-spectrum antimicrobial with low toxicity, constituting a first-choice treatment for several infectious problems and providing the prescriber with a greater confidence<sup>(24)</sup>. The metronidazole was the second most frequent antimicrobial in the prescriptions. The high frequency in the prescription of metronidazole may be associated with the high rate of women and children attending the *UBS* (Basic Health Care Unit) where this study took place. This medicine is widely used in the treatment of amebiasis, giardiasis and trichomoniasis. The neomycin (12.84%) was prescribed in a number of prescriptions that is higher than that of another study<sup>(23)</sup>, which verified a frequency of 5% in the prescriptions. The prescription of neomycin in this study may be associated with its use in bandages.

Moderate and minor drug interactions were observed in the prescriptions assessed in this research. Among the moderate interactions related to antimicrobials, 20 prescriptions (3.54%) were identified containing metronidazole and mebendazole. According to the literature, this combination must be avoided because it may be associated with the Stevens-Johnson Syndrome/toxic epidermal necrolysis, though clinical data are limited<sup>(12-25)</sup>.

Additionally, moderate interactions were identified between acetylsalicylic acid and insulin (0.18%), losartan and meloxicam (0.18%) and propranolol and hydrochlorothiazide (0.18%). The salicylates can increase insulin secretion maximizing its hypoglycemic effect<sup>(12-25)</sup>. Thus, it is recommended the careful monitoring for the development of hypoglycemia when salicylates are combined with insulin, especially in elderly patients and/or with renal failure<sup>(12-25)</sup>. Patients should also be monitored for loss of glycemic control when salicylates are removed<sup>(12-25)</sup>. The use of losartan in association with meloxicam can attenuate the anti-hypertensive effects of losartan (Angiotensin II receptor antagonist) due to the induced inhibition of renal

prostaglandin synthesis, which results in an activity without pressure opposition, causing hypertension. The NSAID's can cause fluid retention, which also alters blood pressure and can cause deterioration of renal function, especially in elderly patients or with extracellular volume depletion (including those undergoing treatment with diuretics)<sup>(12-25)</sup>. Acute kidney failure may occur; however, the effects are often reversible. Thus, patients who need prolonged treatment should have blood pressure monitored after starting, interrupting or changing the dosage of NSAID. Kidney function should also be assessed periodically during prolonged concomitant administration<sup>(12-25)</sup>. Although the combined use of propranolol and hydrochlorothiazide is very common in clinical practice, it can increase the risk of hyperglycemia and hypertriglyceridemia in certain patients, especially diabetic ones. Non-potassium sparing diuretics can increase the risk of prolongation of the QT interval and arrhythmia. Thus, the monitoring of serum levels of potassium, blood pressure and glycemia is recommended during the co-administration<sup>(12-25)</sup>.

In addition to the interactions between antimicrobials, minor interactions between other types of medications were also found. The combined use of acetylsalicylic acid and spironolactone represents an interaction in which salicylates can hinder the secretion of canrenone (the principal active metabolite of spironolactone), inhibiting its natriuretic properties. If diuresis is inadequate, the doctor should consider the interruption of salicylate or increase the dosage of spironolactone monitoring patient's potassium levels<sup>(12-25)</sup>.

A limitation of this current study was the fact that it did not cover fundamental aspects in the selection of antimicrobials, such as the indication of these drugs based on diagnosis, which could complement the approach of formal aspects of prescription and dispensation of antimicrobials.

The quality of the prescription of antimicrobials has an important role in the promotion of the rational use of medicines and the consequent decrease in the development of resistant strains. The omission or unreadability of any information that should be compulsorily written in the medical prescription can hinder since the dispensation until the use of the medication by the patient, contributing to the forgery of medical prescriptions, the inappropriate use of antimicrobials and an increased chance of developing microbial resistance. The results of this current study can contribute to the development and diffusion of actions aimed at collective health, the rational use of medicines and the reduction of bacterial resistance by raising prescriber's awareness of the importance of a quality prescription. It also raises pharmacists and managers' awareness of the importance of providing patients with a proper dispensation and orientation for the correct use of medicines.

## CONCLUSION

The absence of at least four data that should be compulsorily written in the medical prescription of antimicrobials was verified in more than 90% of the prescriptions assessed. Considering the prescription data, issuer's address and phone number, as well as patient's age and sex were absent. In addition, the absence of two variables that should be compulsorily registered in the dispensation of antimicrobials was observed in all the prescriptions assessed: the medication's batch number and the pharmacist's signature testifying the service.

The results of this current study show that the medical prescriptions and the process of dispensation of prescriptions are not in accordance with the RDC No. 20/11, the current legislation that provides for the control of medications containing substances classified as antimicrobials used under prescription, isolated or in association with other drugs.

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