

## COMPLIANCE AND NON-COMPLIANCE IN THE PREPARATION AND ADMINISTRATION OF ANTIBACTERIAL DRUGS\*

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**ABSTRACT:** The present study aimed to assess compliance and non-compliance in the preparation and administration of antibacterial drugs. Observational and cross-sectional study conducted from August to December 2014 in medical wards of a teaching hospital in Fortaleza-Ceará. The sample was composed by 265 doses of antibacterial drugs whose preparation and administration stages were observed during the three work shifts, with two checklists. Data were analyzed using descriptive statistics, and all ethical procedures were fulfilled. The most frequent non-compliance observed in both stages was compliance with the requirements of the several techniques performed by nursing professionals (semi-technique), 265 (100%). The hospital organization was associated with error in the choice of the (p=0.027), and the use of prescription and confirmation of patient's identity were not related to the errors (p=0.942). Thus, it is concluded that behavioral changes in the work process should be implemented to reduce non-compliance and, consequently, medication errors.

**DESCRIPTORS:** Antibiotics; Patient safety; Medication errors; Nursing; Nursing services.

### CONFORMIDADES E NÃO CONFORMIDADES NO PREPARO E ADMINISTRAÇÃO DE ANTIBACTERIANOS

**RESUMO:** Objetivou-se avaliar as conformidades e não conformidades no preparo e administração de antibacterianos. Estudo observacional e transversal, realizado de agosto a dezembro de 2014 em unidades de clínica médica de um hospital-escola em Fortaleza-Ceará. A amostra foi composta por 265 doses de antibacterianos, que tiveram suas etapas de preparo e administração observadas com dois checklist nos três turnos de trabalho. Os dados foram analisados por estatística descritiva e analítica, e todos os procedimentos éticos foram seguidos. Destaca-se que a não conformidade mais frequente em ambas as etapas foi o cumprimento dos preceitos da semiotécnica 265 (100%). A organização foi associada com o erro na escolha do medicamento (p=0,027), e o uso da prescrição e confirmação do nome do paciente não tiveram relação com os erros (p=0,942). Assim, conclui-se que modificações comportamentais no processo de trabalho precisam ser implementadas para reduzir as não conformidades e consequentemente os erros de medicação.

**DESCRIPTORIOS:** Antibióticos; Segurança do paciente; Erros de medicação; Enfermagem; Serviços de enfermagem.

### CUMPLIMIENTO Y INCUMPLIMIENTO EN EL PREPARO Y ADMINISTRACIÓN DE ANTIBACTERIANOS: IMPLICACIONES PARA LA SEGURIDAD DEL PACIENTE

**RESUMEN:** El presente estudio tuvo como objetivo evaluar el cumplimiento y el incumplimiento en la preparación y administración de fármacos antibacterianos. Estudio observacional y transversal realizado entre agosto y diciembre de 2014 en las alas médicas de un hospital universitario en Fortaleza-Ceará. La muestra fue compuesta por 265 dosis de fármacos antibacterianos cuya etapas del preparación y administración fueron observados durante los tres turnos de trabajo, con dos listas de comprobación. Los datos fueron analizados utilizando estadística descriptiva, y se cumplieron todos los procedimientos éticos. El incumplimiento más frecuentes observados en las dos etapas era el cumplimiento de los requisitos de las varias técnicas realizadas por los profesionales de enfermería (semiología), 265 (100%). La organización del hospital se asoció con error en la elección de la (p = 0,027), y el uso de la prescripción y de la confirmación de la identidad del paciente no estaban relacionados con los errores (p = 0,942). Por lo tanto, se concluye que los cambios de comportamiento en el proceso de trabajo se deben implementar para reducir el incumplimiento y, en consecuencia, los errores de medicación.

**DESCRIPTORIOS:** Antibióticos; Seguridad del paciente; Errores de medicación; Enfermería; Servicios de enfermería.

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## ● INTRODUCTION

Non-compliance with the preparation and administration of drugs is a public health issue due to its great frequency, particularly regarding antibacterial drugs. Inappropriate handling of these drugs generates additional costs to the health system as it is directly related to bacterial resistance. Thus, knowledge on the occurrence of compliance and noncompliance in the preparation and administration of antibacterial drugs is essential. The nursing staff is responsible for ensuring procedures of strict control in the administration of antibacterial drugs, also ensuring that these drugs are administered at the correct amounts, on the correct times, and at the appropriate time intervals to prevent the survival of resistant microorganisms due to inadequate plasma levels of antibacterial drugs. Hence this practice must be performed in a correct and safe manner to prevent and minimize errors.

Analysis of medication errors in the world revealed that these errors are common in Western Africa, occurring at a rate ranging from 9.4% to 80%<sup>(1)</sup>. Still in Africa, in adult and pediatric intensive care units, the prevalence rates of errors in the administration of medications were 51.8% and 90.8%, respectively<sup>(2)</sup>. In the United Kingdom, 26% of medication errors related to drug administration were potentially serious, with fatal events that resulted in aspiration pneumonia and intracerebral hemorrhage<sup>(3)</sup>.

In Brazil, a multicenter study on the subject conducted in five capitals showed that 39% of medication errors occur during drug prescription, 12% in the transcription process, 11% in the dispensing process and 38% during drug administration. The study also revealed that nurses and pharmacists intercepted 86% of medication errors related to prescription, transcription and dispensing, while only 2% of medication errors are intercepted by patients. Regarding the pharmacological class of medications most involved in errors, it concerns antimicrobials, ranging from 8.4% to 18.5%, and the most frequent errors concern the time of drug administration (87.7%) and dose (6.9%)<sup>(4)</sup>.

Medication errors related to drug administration have a significant impact on patients associated to morbidity, mortality, adverse event of drugs and longer hospital stay, and impose higher costs to the health systems<sup>(5)</sup>.

The main factors involved in medication errors include organizational aspects, such as interruptions, inappropriate storage, time taken in the preparation, illegible prescription, poor communication and failure to check the patient's name prior to drug administration<sup>(6-7)</sup>.

The relevance for research that related medication errors to organizational aspects of the work process is the justification for the present study, since it is necessary to understand the environment where these errors occur to attempt to prevent failures that compromise patient safety and medication effectiveness.

Therefore, the present study aims to assess compliance and non-compliance in the preparation and administration of antibacterial drugs.

## ● METHOD

Observational cross-sectional study conducted between the months of August and December 2014 in medical wards of a teaching hospital attached to the Network Sentinelae of Brazilian Health Surveillance Agency (ANVISA), located in Fortaleza-Ceará. The wards are divided into two nursing stations and are generally responsible for 114 beds in the following specialties: dermatology, cardiology, general internal medicine, endocrinology, gastroenterology, pulmonology, neurology, nephrology, hematology and rheumatology.

Data collection was made on the days and shifts randomly selected by the researchers to include the morning, afternoon and nightshifts. In order to determine the number of doses to be administered, or else, the sample, we asked the hospital pharmacy service to inform the number of doses of antibacterial drugs administered on each shift, which were dispensed to medical wards A and B within thirty days before the beginning of data collection. Only antibacterial drugs were included in the sample, due to the well-known close relationship between changes in environmental conditions and their chemical stability<sup>(8)</sup>.

Thus, the research sample was composed of 40% of the doses informed by the pharmacy service. Calculation of this sampling percentage was based on the average errors detected in the preparation and administration of antimicrobial drugs by another Brazilian study<sup>(9)</sup>.

In medical ward B, 157 observations were made: 67 in the morning, 30 in the afternoon and 60 at night. In medical ward A, 108 doses were observed: 44 in the morning, 22 in the afternoon and 42 in the night shift.

In order to achieve the proposed objective, observations began at the moment of preparation of the drug and ended when drug administration to the patient was finished. During the observation period, the observers used two check-list type tools, proposed by Cassiani<sup>(10)</sup>, containing the following variables: preparation (organization, interruptions, techniques, existence of protocols, drug labeling and use of prescription); and during administration (organization, interruptions, techniques, use of prescription, patient identification, control of the rate of infusion, management check and monitoring).

Compliance with activities or process consists in adherence to a given quality standard in order to ensure that a service is provided according to the recommendations<sup>(11)</sup>. In the present study, compliance was obtained when the process/situation observed entirely met the criteria of the data collection tool. Non-compliance was reported by the investigators when the referred criteria were not met.

In order to obtain accurate data and prevent bias, the investigators were trained for 30 days by their leader. The concepts observed were standardized, based on the scientific literature, and the investigators were previously trained on the use of the data collection tools. Also, to avoid the Hawthorne effect, common in observational studies, the 20 observations conducted in August were not considered in the assessment.

The data obtained was grouped in the database using the Statistical Software for the Social Science (SPSS) 19.0 for statistical analysis and Kolmogorov-Smirnov and Mann-Whitney tests were conducted to determine the associations between the variables obtained and the medication errors.

The study was based on the error classification used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP)<sup>(12)</sup>, which characterizes medication errors according to their potential to cause patient harm in nine classes of errors according to their severity, occurrence or non-occurrence of damage, duration and extent of the damage and whether or not intervention was required. Category A (near miss) are circumstances or events that have the capacity to cause error; category B, an error occurred but the medication did not reach the patient; category C, an error occurred that reached the patient but caused no patient harm; category D, an error occurred that resulted in the need for increased patient monitoring but no patient harm. Categories E, F, G and H concern errors that cause patient harm and category I concerns errors that resulted in patient death. Whenever an error is identified, the involved worker was guided on the correct and safe way to administer the drug.

The project was submitted to the Research Ethics Committee of Universidade Federal do Ceará and approved under no 660.897. All ethical principles from national and international studies were observed.

## ● RESULTS

Considering the variables investigated in this study, it should be stressed that the most frequent non-compliance action during the steps of preparation and administration of antibacterial drugs concerned non-compliance with the requirements of nursing techniques: 265 occurrences, as shown in Table 1, which was manifested in the non-disinfection of drug vials, no use of sterilized gloves during the procedure, splashing of antibacterial drugs, syringe plunger contamination and preparation of the medication more than 30 minutes before its administration. These subitems were not quantified during data collection, because at that moment there was only concern with whether or not there has been wrong administration error.

Analysis of the variables of each stage showed higher frequency of non-compliance of drug labeling: 265 (100%) related to preparation and use of prescription to confirm patients' and medication data: 243

(91.7%) at the moment of administration of the antibacterial (Table 1). In contrast, during the preparation process, the highest level of compliance was found for the item related to the use of prescription to confirm patient's identity: 222 (83.8%) observations.

During medication administration, 147 (55.5%) compliance related to interruptions were observed. However, during medication preparation, 145 (54.7%) there was non-compliance related to the use of portable sound systems in the work environment, headphones connected with multimedia devices, and a larger number of professionals sharing the same physical space in the sector.

Non-conformities were most prevalent in the items related to the check of drug administration, monitoring and rate of infusion, with 172 (64.9%), 166 (62.7%) and 159 (60%) occurrences, respectively.

Regarding organization, inadequacy was observed in 187 (70.6%) and 138 (52.1%) doses during the steps of preparation and administration, respectively. These situations were most frequent in the morning period.

Still on the organization of the environment for medication preparation, nursing assistants and technicians were in average responsible for preparing the medication of 5-6 patients per period, and during their shifts, these workers placed the patients' prescriptions on a clipboard or separate sheet, and then sorted the medicines and attached a label to them, which included patient's bed number and medication administration time.

Assessment of workers' behaviors during the medication administration stage showed a prevalence of non-compliance regarding the behaviors during use of prescription, confirmation of patient's identity and monitoring. In ward B, the highest levels of non-compliance were observed for control of the rate of infusion and immediate check.

Also, association of organization in medication preparation and wrong choice of medication was observed at this stage. Fisher's test was conducted because chi-square test assumptions were not met. As shown in Table 2, the highest concentration of data is in the relationship between categories No-No when the two wards are added. A p-value = 0.027 was obtained with Fisher's exact test, indicating association between the two variables.

Table 1 - Compliance and non-compliance in the steps of preparation and administration of antibacterial drugs. Fortaleza, CE, Brazil, 2014

Characteristic	Compliance n (%)	Non-compliance n(%)	Total n (%)
Preparation			
Organization	78 (29.4)	187 (70.6)	265 (100)
Interruptions	120 (45.3)	145 (54.7)	265 (100)
Use of prescription	222 (83.8)	43 (16.2)	265 (100)
Nursing techniques	-	265 (100)	265 (100)
Correct labeling	-	265 (100)	265 (100)
Administration			
Organization	127 (47.9)	138 (52.1)	265 (100)
Interruptions	147 (55.5)	118 (45.5)	265 (100)
Use of prescription	22 (8.3)	243 (91.7)	265 (100)
Confirmation of patient's identity	55 (20.7)	210 (79.3)	265 (100)
Nursing techniques	-	265 (100)	265 (100)
Control of the rate of infusion	106 (40)	159 (60)	265 (100)
Check of the drug administered	93 (35.1)	172 (64.9)	265 (100)
Monitoring	99 (37.3)	166 (62.7)	265 (100)

Source: Researcher data

Table 3 shows the relationship between use of prescription and confirmation of patient's identity in medication administration. A p-value of 0.942 was obtained, indicating that there was no association between these two variables. It should be stressed that the patients are identified only by bed number. Sometimes, the identification card stuck on the wall above the patient's bed also included patient's identity and date of admission. Thus, in Ward A only eight nursing workers used prescription and confirmed patient's identity. In Ward B, during the observations, 100% of the workers did not confirm patient's identity through prescription, and did not use it during drug administration. In general, all medication errors detected were of type B, i.e., an error occurred but the medication did not reach the patient.

Table 2 – Association between the variables organization and wrong choice of medication in the preparation of antibacterial drugs in Medical Wards A and B. Fortaleza, CE, Brazil, 2014

	Organization in (preparation)	Wrong drug choice (preparation)		Total	p-value*
		Yes	No		
MEDICAL WARD A	Yes	1	53	54	0.113
	No	6	48	54	
	Total	7	101	108	
MEDICAL WARD B	Yes	0	24	24	0.027
	No	22	111	133	
	Total	22	135	157	

Source: Researcher's data

\*Fisher's exact test

Table 3 – Association between used prescription and did not confirm patient's identity during medication administration in Ward A. Fortaleza, CE, Brazil, 2014

Used prescription (Administration)	Confirmed patient's identity (administration)		Total	p-value*
	Yes	No		
Yes	8	14	22	0.942
No	32	54	86	
Total	40	68	108	

Source: Researcher's data

\*Fisher's exact test

## ● DISCUSSION

In the present study, it was found that preparation and administration of antibacterial drugs was mostly performed by nursing technicians and assistants, which is consistent with the findings of another study conducted in Brazilian hospitals<sup>(13)</sup>.

The above finding was most frequent in the morning period, which can be explained by the higher circulation of health professionals in the sector and because most medication preparations and most adjustments in antibacterial doses by the medical team are performed in the morning in the referred wards. In up to 87% of the cases of medication errors, responsibility lies with human factors and organizational shortcomings<sup>(14)</sup>. The daily experience suggests that the excessive workload and the lack of experienced nurses, inadequate supervision and lack of feedback from nurses on the errors, as well as distractions, poor communication, haste and fatigue are factors that contribute to these errors.

Some conditions may have a negative effect on the work practice, generate distractions and the occurrence of lapses, especially the composition of the social and occupational profile of the workers

and environmental interferences such as overcrowded units and inadequate architectural dimensioning of spaces.

In this study, the most prevalent error concerned administration and was related to observation of the requirements of nursing techniques in 265 (100%) observations. This finding corroborates those obtained in a study conducted in two hospitals in Vietnam that observed 5,271 medication administrations. Wrong administration techniques were present in (23.5%) of the observations, followed by error in preparation techniques, omission, and incorrect medication dose (15.7%, 2.3% and 1.8%, respectively) <sup>(15)</sup>.

According to a review on intravenous medication errors <sup>(16)</sup>, wrong administration technique, wrong preparation technique, omission errors and dose errors were frequently observed.

Approximately half of the errors observed were wrong administration techniques and most concerned errors in the rate of infusion during IV bolus administration (faster than the recommended speed of 3 to 5 minutes).

Regarding behavioral variables, which are factors that generate interruptions in medication preparation, they were observed very frequently during the study: there were interruptions during the preparation of 145 doses and during the administration of 118 doses. Such interruptions were produced by different sources such as heavy traffic of people, side conversations, use of micro system stereos and headphones connected to smartphones. This scenario is not consistent with the recommendations, namely a reserved, quiet space, with restricted traffic, and without sources of interruption or distraction such as television and/or radio sets <sup>(17)</sup>.

In a study conducted in two hospitals in Australia, the increased number of interruptions was associated to increase in error rates <sup>(18)</sup>. Some factors that cause distractions during the work tasks of nursing professionals include lack of formal planning of nursing care, mobile telephone or hospital telephone ringing, overlapping of different tasks, non-standard changes in medical prescriptions and interruptions caused by other professionals <sup>(19)</sup>.

Some strategies have been adopted to reduce potential interruptions during the preparation and administration of drugs such as vests with bright colors and catchphrases like "do not disturb" worn by the professionals responsible for this function. However, despite the significant decrease in the number of medication errors related to interruptions obtained with the use of these strategies, they caused a negative impact on patients who believed the messages were targeted to them <sup>(20)</sup>.

Regarding organization, one study <sup>(21)</sup> explains that the physical structure of several environments of the hospital should be focused on meeting three requirements: functional, technical and psychosocial. Thus, in the context of functionality, a properly arranged work environment certainly facilitates the execution of work processes, speeds up the work pace and contributes to the delivery of safer care.

The ergonomic factors of the medication preparation room in a teaching hospital in Florianópolis <sup>(22)</sup> were similar to those described in this study, such as drawers without dividers, limited space available for medication preparation, visual and noise pollution and heavy traffic of workers in the room where medication prescription is performed.

Based on an integrative literature review of 25 international publications <sup>(23)</sup>, it was concluded that proper organization of the health care environment is a key factor for the prevention of any adverse events related to prescription of health care and most studies reviewed stressed that the multitude of tasks performed in these environments make it impossible to ensure a well-structured medication preparation and administration system.

One study corroborates that the methods used in medication preparation are defective in most medication systems, and in their attempt to deal with these issues, many hospitals face such as lack or inadequate use of materials, furniture arrangement not functional (small benches, drawers without identification labels) and a multitude of tasks performed in the environment <sup>(24)</sup>.

Another important aspect concerns checking patient's identity, which comprises one of the nine certainties related to limitation of errors during medication administration. The general justification for omission during the step of patient's identification provided by the nursing staff is the long stay of

patients that leads to a sort of bond between the team and the patient, which makes such identification unnecessary. This is strongly associated to the way in which the nursing staff conducts the work process: although there was no error, the system was defective. In this regard, the performance of the staff was also inadequate, since no significant alterations were detected in the process of administration of antibacterial drugs in the units, demonstrating that most errors are systemic, and may be the associated to non-compliance in the work process of the health facility.

According to recommendations of the Ministry of Health <sup>(17)</sup>, confirmation of patient's identity must be performed by two patient identifiers: patient's name in the medical record and patient's date of birth or medical record number. Patient identification must precede the delivery of any type of care, including medication administration. The habit of not checking patient's identity because of their long hospital stay observed in this study should be eliminated for the sake of safe care. The closer relationship established between health workers and long-stay patients explains this habit. Patient identification using the patient's bed number is still a common form of communication between health teams.

However, the risk of medication error or adverse event is proportional to the length of hospital stay, i.e. the longer a patient stays in the hospital, the greater the chances of occurrence of these events. This probability is even higher for antibiotics <sup>(25-26)</sup>.

This check is particularly important in the case of antibacterial drugs, since the indication of the drug is based on clinical and laboratory criteria of the antibiotic resistance profile and sensitivity of bacterial strains, and if the antibiotic is administered to the wrong patient, antimicrobial resistance may occur, which will culminate in the worsening of the individual's clinical status, including septicemia.

## ● CONCLUSION

The study indicates that work routine and organizational factors contribute to medication administration errors. Thus, in this study medication errors in administration, during the steps of preparation and administration of the drugs were of category B, without patient harm. At least one medication error was found in all the observations made. Noncompliance with the execution of several techniques performed by nursing professionals (semitechnique) was the most prevalent error, followed by incorrect labeling.

Organizational factors such as cleaning, spatial arrangement to optimize space, reduction of personnel in the room, reduction of visual and auditory pollution, error reporting systems and routine checks might contribute to reduce the occurrence of medication errors.

Therefore, further studies in other medical centers are needed for comparison of the results and to establish strategies to ensure patient safety, and evaluate their effectiveness in reducing the problem.

One limitation of this study concerns the physical structure of the hospital, which favors the occurrence of errors in medication preparation, because the area is affected by many environmental variables that generate discomfort to nursing professionals, in addition to being a place where several activities are performed.

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