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Evaluation of nonconformities related to sanitary regulations applied to clinical laboratories in public hospital in the city of Rio de Janeiro-RJ from November 2016 to November 2017

Avaliação de não conformidades às normas sanitárias aplicadas a laboratórios intra--hospitalares públicos de análises clínicas na cidade do Rio de Janeiro (RJ) no período de novembro de 2016 a novembro de 2017

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ABSTRACT

The study presents the main nonconformities related to the sanitary regulations found in clinical laboratory analysis (CLA) attached to a public hospital in the city of Rio de Janeiro (RJ) from November 2016 to November 2017. The evaluation of the nonconformities related to sanitary conditions is fundamental to ensure the goals in improving quality control, increasing the reliability of the results generated and reducing health risks. Through the evaluation of 20 federal and municipal public health laboratories, it was possible to analyze the main sanitary nonconformities in the different laboratories phases (pre-analytical, analytical and post-analytical), evaluating, through Fisher's exact test, the frequency and trend distribution of reported nonconformities. One hundred percent (100%) of the clinical analysis laboratories presented at least, one nonconformity. Among those with the highest frequencies of nonconformity related to sanitary conditions are those related to the lack of standard operating procedures (SOPs), presenting 45.5% in clinical analysis laboratories of federal hospitals and 66.7% in clinical analysis laboratories of municipal hospitals. Moreover flaws in the cleaning, disinfection and sterilization processes, in equipments and in the presence of the technical manager (TM) throughout the working hours. Sanitary surveillance actions seek to provide health services to the population that comply with established quality standards, even though the identification of nonconformities subsidizes the adoption of corrective actions by the health establishment.

Key words: clinical analysis laboratories; health surveillance; nonconformities.

INTRODUCTION

The 1988 Constitution guarantees to all sections of the population the right to health promotion, prevention and recovery care service[(1)]. The law no. 8,080, dated September 19, 1990, called the Organic Health Law, which creates the Unified Health System [Sistema Único de Saúde (SUS)], defines Sanitary Surveillance actions as a "set of actions to prevent, reduce and eliminate hazards and act on aid to the health concerns arising from the production and circulation of goods, the environment and the provision of services of health interest"[(2)]. In 1999, after the creation of the National Sanitary Surveillance Agency [Agência Nacional de Vigilância Sanitária (Anvisa)], the Sanitary Surveillance [Vigilância Sanitária (VISA)] actions were decentralized and became more autonomous. The law no. 9,782 intended to the Anvisa the responsibility of population health protection, through sanitary control[(3)]. The Anvisa's main attributions include the role of regulating, supervising and controlling all services that involve

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population health hazards, establishing regulations, proposing, monitoring, executing health policy guidelines and actions, and applying penalties to violators who not comply with sanitary legislation[4].

In the city of Rio de Janeiro, decree no. 33,360, dated January 17, 2011, introduces the organizational structure of the Municipal Office of Health and Civil Defense, defined as competences of the Secretariat of Sanitary Surveillance and Control of Zoonotic Diseases (SUBVISA) planning and coordination of the actions of the surveillance and sanitary inspection in the municipality[5]. In the year 2014, the resolution no. 1058 of the state of Rio de Janeiro transferred the delegation conditions of sanitary surveillance actions from the state government sphere to the municipal sphere[6]. In the year 2016, a resolution no. 1478 of the state government of Rio de Janeiro delegated to the municipal sanitary surveillance of the city the competence of the sanitary surveillance activities, sanitary control, concession, revalidation, cancellation of permit and sanitary inspection of laboratories of clinical analysis and pathological anatomy, collection points, pharmacies, radio diagnosis service and other health services included in the municipality of Rio de Janeiro[7].

In 2005, the board of Anvisa, considering the importance of the quality of diagnostic tests as health protection issue, established the Collegiate Board of Directors Resolution (RDC) no. 302/2005. This resolution provides technical regulation for the operation of clinical laboratories[8]. The RDC no. 302/2005 has as its scope to define general conditions, permit requirement and sanitary license of the clinical laboratories, as well as the presence of a legally qualified professional as technical manager (TM), enrolment of the establishment in the Brazilian National Registry of Health Facilities [Cadastro Nacional de Estabelecimentos de Saúde (CNES)], human resources, laboratory equipment and instruments, *in vitro* diagnostic products, biosafety, operational processes, records, control and quality assurance. The request for a sanitary license is the responsibility of the clinical laboratory, and inspection and sanitary concession issued by the VISA responsible[4].

The physical infrastructure of the clinical laboratories and collection points[8] must meet the requirements of the RDC no. 50/2002; Good Practices for operating health services[9], the RDC no. 63/2011; the external transport of biological samples[10], the RDC no. 20/2014; and the Good Practices for health-care waste Management[11] (BPGRSS), the RDC no. 222/2018.

Previous studies have demonstrated that sanitary nonconformities are observed during the laboratory professionals practice, as well as weaknesses of adherence and universal precautions of biosafety[12].

OBJECTIVES

To evaluate the nonconformities to the sanitary regulations referring to the public hospital laboratories of clinical analyzes in the city of Rio de Janeiro (RJ) from November 2016 to November 2017.

METHODOLOGY

Laboratories, both public and private, require accreditation and routine annual visits to release and monitor their activities. For this research, the reports of sanitary inspection of federal and municipal public hospital clinical laboratories analysis (CLA) were included. The period of the inspections took place between November 2016 and November 2017, in the city of Rio de Janeiro, covering 20 CLA. For CLA inspection, the municipal health inspectors used an inspection guideline developed based on the current resolutions of the Anvisa, the RDC, based on the guideline published by the Ordinance SES/CVS no. 743 de 2006.

Access to the data obtained was requested from the Scientific Committee of SUBVISA.

ANALYSIS

A database was developed to meet the objectives of this study that was fed by the information extracted from the health inspection reports of each of the 20 laboratories included in the study. The information extracted refers to the entry on the needs of structural and emergency adequacy of the CLA.

The database was developed in the Microsoft Excel 2010 software and is based on the CLA inspection guideline. The sanitary nonconformities were entered in the database as "no" and the conformities described "yes", based on the evaluation of each entry in the inspection guideline. A detailed analysis of the inspection reports of the 20 laboratories was carried out. The data were discussed and evaluated together with the sanitary inspector responsible for the service, in order to validate the adequacy, thus avoiding errors and/or deviations from the analysis performed in this study.

Regarding the statistical analysis, the data were submitted to extraction of the frequency of nonconformities reported in each entry. Thus, it was possible to analyze the nonconformities evidenced in the inspected CLA. The statistical evaluation

verified the percentage of nonconformity between the public spheres, federal and municipal. The Excel database was exported to the R Commander package of the statistical software, version 3.5.0, which generated the Conformity and Nonconformity frequencies of each entry analyzed. The "epiDisplay" package generated the double entry contingency tables with frequencies by category, separating into federal and municipal hospitals, as well as determining the exact Fisher's test value to verify the significance of the distribution between the groups (federal and municipal).

RESULTS AND DISCUSSION

General information

From the 20 laboratories inspected, as we can observe in **Figure**, 11 (55%) were from federal hospitals (FH) and nine (45%), from municipal hospitals (MH). One hundred percent of the inspected CLA raised a need to comply with the Anvisa sanitary regulations. The CLA analyzed need one or more adequacy, aiming to reduce the probability of health hazard to the worker and/or the low credibility in the results release.

According to the RDC 302/2005, all CLA must have a legally qualified professional as TM[8].

In the inspections carried out (**Table 1**), 27.3% of FH and 22.2% of MH did not present a certificate of technical responsibility or a document proving the registration of the TM in the professional council available in the workplace. It was verified that 9.1% of FH and 44.4% of MH did not have TM during the full operation hours.

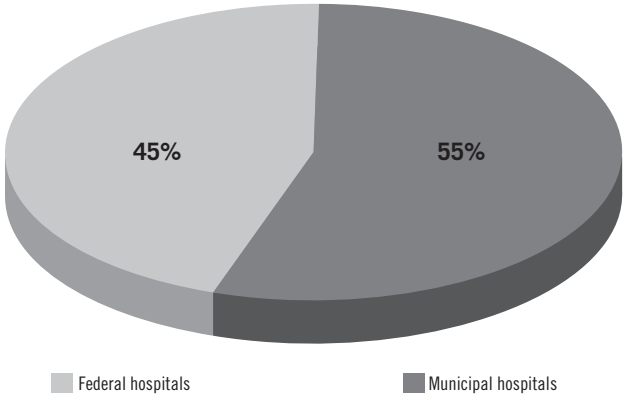

FIGURE – *CLA classification by the public sphere*

CLA: clinical laboratory analysis.

TABLE 1 – Number of certificates of technical responsibility and the presence of TM in municipal and federal CLA during CLA operating hours

	Federal	Municipal	Statistical test
Certificate in technical responsibility at the workplace	Yes 8 (72.7)	Yes 7 (77.8)	Fisher exact test (p-value = 1*)
	No 3 (27.3)	No 2 (22.2)	
Total	11 (100)	9 (100)	
TM presence during the operation hours	Yes 10 (90.9)	Yes 5 (55.6)	Fisher exact test (p-value = 0.127*)
	No 1 (9.1)	No 4 (44.4)	
Total	11 (100)	9 (100)	

*TM: technical manager; CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

Pre-analytical phase

The pre-analytical phase presents the highest frequency of errors, occupational hazard health to the health of professionals and high rate of human error[13]. As shown in **Table 2**, 36.4% of CLA from FH and 22.2% of CLA from MH inspected presented unsatisfactory hygienic conditions in the sample collection sector. It was observed that 36.4% of CLA from FH and 22.2% of CLA from MH inspected showed that the floor, wall or ceiling in the collection area were neither of waterproof material nor resistant to disinfection.

The management and the adequate conditions in the collection environment are fundamental for the reduction of accidents and the quality of life of the professionals who work in this area; training and awareness of the biological risks that they face should be continuously over time[14].

TABLE 2 – Satisfactory sanitation conditions, floor, wall and ceiling in waterproof material resistant to disinfection in samples collection area from municipal and federal public hospital CLA

	Federal	Municipal	Statistical test
Satisfactory sanitation conditions	Yes 7 (63.6)	Yes 7 (77.8)	Fisher exact test (p-value = 0.642*)
	No 4 (36.4)	No 2 (22.2)	
Total	11 (100)	9 (100)	
Floor, wall and ceiling in waterproof material resistant to disinfection	Yes 7 (63.6)	Yes 7 (77.8)	Fisher exact test (p-value = 0.642*)
	No 4 (36.4)	No 2 (22.2)	
Total	11 (100)	9 (100)	

*CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

External transport of samples

Regarding the external transport of patient samples, hospitals that received sample from external collection points (perform collection of material outside the hospital environment) were observed. The external transport of biological samples must comply with the adequacies[11] of the RDC 22/2014. As shown in **Table 3**, 63.6% of CLA from FH and 33.3% of CLA from MH do not have external collection points and do not carry external transport of samples, so these were grouped into the Does Not Apply category (NA); 36.4% of CLA from FH and 33.3% of CLA from MH carry out external transport of samples improperly, requiring adequacies in the shipping box and monitoring of the exit temperature from the collection points and arrival at the central laboratory. From the federal hospitals receiving samples by external transportation, all of them (four) require to follow adjustments; in the municipal hospitals, half (three) of those who receive samples by external transportation need adequacies, which is a nonconformity found with high frequency.

TABLE 3 – Number of federal and municipal CLA that have adequate shipping boxes

	Federal	Municipal	Statistical test
Boxes for transporting samples from the collection points to the CLA is adequate	Yes 0 (0)	Yes 3 (33.3)	Fisher exact test (p-value = 0.112*)
	Does not apply 7 (63.6)	Does not apply 3 (33.3)	
	No 4 (36.4)	No 3 (33.3)	
Total	11 (100)	9 (100)	

*CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

Analytical phase

The analytical phase refers to the accomplishment of the laboratory analyzes, and there must be a strict control so that the results generated can be precise and accurate[15].

As shown in **Table 4**, 45.5% of CLA from FH and 44.4% of CLA from MH inspected showed no monitoring and recording of the room temperature in the technical area. The accurate temperature and good condition status of the structure of health facilities are required as basic principles for proper functioning[10]. From the CLA inspected, 45.5% (FH) and 44.4% (MH), presented cleaning and disinfection of environments, workbenches and inadequate materials at the time of inspection, representing almost half of the CLA inspected from both spheres. It is important to remember that the contaminated environment and unsatisfactory cleaning and disinfection methods favor the occurrence of health care-associated infections (HCAI) and the spread of microorganisms of epidemiological relevance, which are frequently found on health care service surfaces and environments[16].

Table 5 reports that 36.4% of FH and 55.6% of MH presented inadequacies regarding operation, preventive and corrective maintenance and cleaning of equipment in the inspected CLA. The reported frequency represents more than a half (five) of the municipal hospital CLA. It was also reported that 54.5% of CLA from FH and 44.4% of CLA from MH inspected presented nonconformities in the monitoring and recording the refrigerators temperature. The state of good repair, temperature recording and monitoring of the refrigerator are criteria of quality control in the storage of samples[8] and must be followed according to the RDC 302/2005.

Regarding SOP, according to **Table 6**, we observe that 45.5% of CLA from FH and 66.7% of CLA from MH inspected presented absent SPO at the workplace, meaning more than a half (six) of CLA inspected from municipal hospitals and nearly a half (five) of CLA inspected from FH.

TABLE 4 – Monitoring and recording room temperature, satisfactory cleaning and disinfection of environments, workbenches and materials in municipal and federal public hospital CLA

	Federal	Municipal	Statistical test
Monitoring and recording room temperature	Yes 6 (54.5)	Yes 5 (55.6)	Fisher exact test (p-value = 1*)
	No 5 (45.5)	No 4 (44.4)	
Total	11 (100)	9 (100)	
Satisfactory cleaning and disinfection of environments, workbenches and materials	Yes 6 (54.5)	Yes 5 (55.6)	Fisher exact test (p-value = 1*)
	No 2 (45.2)	No 4 (44.4)	
Total	11 (100)	9 (100)	

*CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

TABLE 5 – Operation, preventive and corrective maintenance, cleaning of equipment, refrigerators temperature monitoring and recording in municipal and federal public hospital CLA

	Federal	Municipal	Statistical test
Operation, preventive and corrective maintenance and cleaning of equipment	Yes 7 (63.6)	Yes 4 (44.4)	Fisher exact test (p-value = 0.653*)
	No 4 (45.5)	No 5 (55.6)	
Total	11 (100)	9 (100)	
Monitoring and recording refrigerators temperature	Yes 5 (45.5)	Yes 5 (55.6)	Fisher exact test (p-value = 1*)
	No 6 (54.5)	No 4 (44.4)	
Total	11 (100)	9 (100)	

*CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

TABLE 6 – SPO availability at the workplace in municipal and federal public hospital CLA

	Federal	Municipal	Statistical test
SPO Available at workplace	Yes 6 (54.5.8)	Yes 3 (33.3)	Fisher exact test (p-value = 0.336*)
	No 5 (45.5)	No 6 (66.7)	
Total	11 (100)	9 (100)	

*SPO: standard operating procedures; CLA: clinical laboratory analysis; *non-significant* p-*value found; does not show a trend between federal and municipal hospitals in the nonconformities found.*

All activities of the clinical laboratory should be documented through SPO, approved and be available in the technical area for consultation and support by the team[15].

Post-analytical phase

The post-analytical processes refer to the procedures after performing the laboratory analyzes and cover the calculations and the consistency in the release of the results for interpretation[15]; they begin in the laboratory area and encompass all the actions of validation and release of the final report. Its final phase ends when the physician receives the report, followed by the interpretation and clinical choice in relation to the result recorded in the report[17].

In the FH inspected, less than 10% of nonconformity was reported in the manual or electronic signature of the TM in the report; all other evaluated entries presented nonconformities at this stage. In MH, nonconformities were reported in the registration system, in the storage of the raw records of the exams, in the SPO manual for the laboratory computer system, in the registry number generated by the laboratory, in the manual or electronic signature, and name and no. of registration in the TM Regional Council in the report. All entries presented less than 12% of nonconformity.

CONCLUSION

The presence of nonconformities in the laboratories inspected demonstrates the need for corrective measures by health institutions, as well as the importance of the educational role developed by VISA. In relation to the public spheres (municipal and federal), nonconformities were reported to occur with no significant statistical difference between these groups, demonstrating that the verification of nonconformities is not directly related to public management. However, the lack of statistical significance is due to the small sample size obtained in this study, and new studies in other municipalities are important for the reproducibility of these findings.

The CLA are a safety environment that need to ensure the reliability of the results generated. When we found at least some sanitary nonconformity in 100% of the CLA inspected in the city of Rio de Janeiro we observed the severity of the current scenario in the public and hospital area. The high frequencies presented demonstrate the need for monitoring and improvement of these services provided to the population of Rio de Janeiro, showing a high possibility of risk in the results generated by these CLA, which can generate health hazard to the population and compromise the effectiveness of diagnosis and treatment for patients attending in these establishments.

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RESUMO

Este estudo apresenta as principais não conformidades às normas sanitárias encontradas em laboratórios de análises clínicas (LAC) intra-hospitalares públicos localizados no município do Rio de Janeiro (RJ) no período de novembro de 2016 a novembro de 2017. A avaliação de não conformidades sanitárias é fundamental para garantir metas na melhoria do controle da qualidade, aumento da confiabilidade dos resultados gerados e diminuição de riscos em saúde. Por meio da avaliação de 20 laboratórios públicos, federais e municipais, foi possível analisar as principais não conformidades sanitárias nas diferentes fases laboratoriais (pré-analítica, analítica e pós-analítica), avaliando a frequência e a tendência da distribuição através do teste exato de Fisher. Os resultados evidenciaram que 100% dos LAC analisados apresentaram ao menos uma não conformidade; entre aquelas com maiores frequências de não conformidades sanitárias estão as relacionadas com inexistência de procedimentos operacionais padrão (POPs), apresentando 45,5% em LAC de hospitais federais e 66,7% em LAC de hospitais municipais, além de falhas nos

processos de limpeza, desinfecção e esterilização, nos equipamentos e na presença do responsável técnico (TM) durante todo o horário de trabalho. As ações de fiscalização sanitária buscam a prestação de serviços em saúde à população que esteja de acordo com padrões de qualidade estabelecidos, ainda que a identificação de não conformidades subsidie a adoção de ações corretivas pelo estabelecimento de saúde.

Unitermos: *laboratórios de análises clínicas; vigilância sanitária; não conformidade.*

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