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Nonconformities in the pre-analytical phase identified in a public health laboratory

Não conformidades na fase pré-analítica identificadas em um laboratório de saúde pública

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ABSTRACT

Introduction: The nonconformities detected in the pre-analytical phase of laboratory tests sent to the Central Public Health Laboratories (Lacen) culminate in the loss of epidemiological data of great importance for public health and are detrimental to health surveillance. This study aimed to identify the most frequent pre-analytical nonconformities recorded by Lacen/PR and the major difficulties encountered by the primary and regional health units in the registration of exams in the Laboratory Environment Manager (GAL) system. **Results:** The analysis of data from the Paraná GAL system in 2017 identified 9,723 discards for disagreeing samples in a total of 132,567 tests performed in the same period. The most frequent nonconformities were: request canceled by the GAL management due to expiration of the screening period (28%), and sample unsuitable for the requested analysis (28%). **Discussion:** After identifying the vulnerabilities of this stage of the process, the greatest detected difficulty was requesting the correct test. **Conclusion:** Data indicate the need to strengthen training and improve the pre-analytical process in order to ensure patient safety and epidemiological data.

Key words: pre-analytical phase; public health; public health laboratory services; quality control.

RESUMO

Introdução: *As não conformidades detectadas na fase pré-analítica dos exames enviados aos laboratórios centrais (Lacen) do estado culminam em perda de dados epidemiológicos de grande importância para a saúde pública, além de prejudicar a vigilância em saúde.* ***Objetivos:*** *Este trabalho teve como objetivo identificar as não conformidades pré-analíticas mais frequentes registradas pelo Lacen/PR e as maiores dificuldades encontradas pelas unidades primárias e regionais de saúde no cadastro dos exames no sistema Gerenciador de Ambiente Laboratorial (GAL).* ***Resultados:*** *Do total de 132.567 exames realizados no ano de 2017, a análise dos dados do sistema GAL-Paraná identificou 9.723 descartes de amostras em desacordo. As não conformidades mais frequentes foram: requisição cancelada pela gerência do GAL devido à expiração do prazo de triagem (28%) e amostra imprópria para a análise solicitada (28%).* ***Discussão:*** *Ao identificar os pontos vulneráveis dessa etapa do processo, a maior dificuldade detectada foi solicitação do exame correto.* ***Conclusão:*** *Os dados indicam a necessidade de reforçar as capacitações e a melhoria do processo pré-analítico, a fim de garantir a segurança do paciente e dos dados epidemiológicos.*

Unitermos: *fase pré-analítica; saúde pública; laboratório regional de saúde; controle de qualidade.*

RESUMEN

Introducción: *Las no conformidades detectadas en la fase preanalítica de las pruebas enviadas a los laboratorios centrales (Lacen) del estado culminan en pérdida de datos epidemiológicos de gran importancia para la salud pública, además de perjudicar la vigilancia en salud.* ***Objetivos:*** *Este estudio intentó identificar las no conformidades preanalíticas más frecuentes registradas*

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por el Lacen/PR y las mayores dificultades encontradas por unidades primarias y regionales de salud en el registro de pruebas en el sistema administrador del ambiente de laboratorio (GAL). ***Resultados:*** *Del total de 132.765 pruebas realizadas en 2017, el análisis de datos del sistema GAL-Paraná identificó 9.723 descartes de muestras en desacuerdo. Las no conformidades más frecuentes fueron: solicitud rechazada por la gerencia de GAL pues la muestra está fuera de la fecha de caducidad (28%) y muestra inadecuada para el análisis solicitado (28%).* ***Discusión:*** *Al identificar los puntos débiles de esa etapa del proceso, la mayor dificultad detectada fue la solicitud de la prueba correcta.* ***Conclusión:*** *Los datos indican la necesidad de fortalecer las capacidades y la mejora del proceso preanalítico, para garantizar la seguridad del paciente y de los datos epidemiológicos.*

Palabras clave: *fase preanalítica; salud pública; servicios laboratoriales de salud pública; control de calidad.*

INTRODUCTION

Public health laboratories are those that do not operate for profit. The network of public laboratories in Brazil is divided into: collaborating center, national reference laboratories, regional reference laboratories, state reference laboratories, municipal reference laboratories, local laboratories and frontier laboratories[1].

At the state sphere, there are laboratories that lend support to hospitals and outpatient clinics, and the Central Public Health Laboratory (Lacen)[2]. As a state reference, Lacen is responsible for the coordination of public and private laboratories that carry out tests of public health interest in their respective state[1]. Lacen, in Paraná, is linked to the State Department of Health, with activities of epidemiological, environmental and sanitary surveillance[3]. Its main goal is to provide data for public health surveillance practices; diagnosis is not its key objective, but diagnostic confirmation is a consequence of the rendered services[4]. Different from a routine clinical laboratory, Lacen units do not run tests to diagnose non-notifiable diseases[5].

The public health laboratory is also responsible for health surveillance, as it manages epidemiological data, uses specific methods, signals health emergencies and provides care with continuous education[1].

The work process of any clinical laboratory involves the whole path from medical order to report delivery. This sequence is divided into three phases: pre-analytical, analytical and post-analytical[6].

The pre-analytical phase precedes test performance itself; it encompasses physician request, patient preparation, specimen collection, storage, transportation, and handling before analysis. The analytical phase is that in which tests are conducted; it is monitored by strict programs of quality control. The last phase deals with processing results for transcription onto report forms and their delivery to patients and/or clinicians[7, 8].

In the latest 30 years, there was a considerable improvement in the analytical phase quality with laboratory automation, proficiency assays, internal quality control and constant training of clinical analysts. The pre-analytical phase, however, is still the main responsible for laboratory errors[6, 9]. For public health laboratories, whose bias is epidemiological surveillance, the key factor of pre-analytical phase is the opportune time for specimen collection[6].

The Lacen laboratories receive specimens from different parts of the state, as one of their responsibilities is to carry out more complex laboratory procedures for complementary diagnosis[4]. For this reason, ensuring quality of the pre-analytical phase of the received specimens is defying.

Pre-analytical errors or nonconformities culminate in loss of epidemiological data greatly important for public health, unnecessary expenses with storage, transportation and subsequent disposal of non-compliant unprocessed biological specimens, besides inconveniences and additional expenses with the active search of patients for recollection, where applicable.

High disposal rates of laboratory tests due to pre-analytical nonconformities justify the need to identify the vulnerable points of this process step. Therefore, the current study was aimed at listing the pre-analytical errors (nonconformities) more frequently identified by the Sample Management Sector (SGA) of Lacen/PR – Unit Guatupê and, based on them, suggest measures to eliminate or minimize such errors, as well as to point out the greatest difficulties encountered by the primary and regional health units (RS) during test registration in the Laboratory Environment Manager (GAL) computerized system.

METHODS

In order to reach the goals of this work, an analysis of data provided by GAL-Paraná was made in 2017. Nonconformities were

detected based on the instructions of *Manual de Coleta e Envio de Amostras Biológicas ao Lacen/PR* and the technical notes available at the website of Lacen/PR (http://www.lacen.saude.pr.gov.br/modules/conteudo/conteudo.php?conteudo=74;http://www.lacen.saude.pr.gov.br/modules/conteudo/conteudo.php?conteudo=56).

Data were evaluated by means of descriptive statistical analysis using the tools of Microsoft Excel® 2010.

Because this study used secondary data, with no involvement of human beings or laboratory results, it did not need evaluation by the Research Ethics Committee, according to a resolution by the National Health Council (CNS) no. 510, from April 7, 2016. This work was approved by the General Direction of Lacen/PR.

RESULTS

Non-compliance with a specific requirement for the processing of a sample is considered a nonconformity. In 2017, at GAL-Paraná, 132,567 tests and 9,723 disposals were reported of analysis directed specifically to Lacen/PR.

The identified nonconformities were classified under the 31 disposal options within the GAL system. **Table 1** highlights the frequency of reasons for disposal at GAL-Paraná – Lacen/PR in 2017.

Table 2 points out the most frequent nonconformity in a set of disposal of tests sent to Lacen/PR, considering each RS of the state of Paraná in 2017.

Figure 1 highlights the RS units of the state of Paraná and the distribution of occurrence of nonconformities for tests directed to the Epidemiology and Disease Control Laboratory Division (DVLCD) of Lacen/PR and the number of nonconformities in 2017.

Figure 2 reveals the health units (US) of the state of Paraná with most records of nonconformities for analyses referred to DVLCD of Lacen/PR in 2017.

DISCUSSION

In 2008, the Ministry of Health, by means of the General Coordination of Laboratories of Public Health and the Information Technology (IT) Department of the Unified Health System, created the GAL system, that has as the main objective to manage the activities developed by the state laboratory network of public health in the diagnosis of diseases of public health interest[10]. This is the system used by Lacen/PR.

The biological samples received at Lacen/PR arrive at DVLCD by SGA; from this initial screening, they are distributed to the sectors that conduct the required tests. At SGA, professionals evaluate if the registry was correctly entered and if the sample is adequate for analysis, according to orientations of *Manual de Coleta e Envio de Amostras Biológicas ao Lacen/PR* and the technical notes available at the website of Lacen/PR. After this

TABLE 1 – Frequency of nonconformities reported at GAL-Paraná, Lacen/PR, in 2017

Nonconformity	no. of records	Frequency (%)
Inadequate storage	181	2
Lipemic sample	2	0.02
Sample with illegible identification	0	0
Sample with inadequate identification	44	0.5
Contaminated sample	32	0.3
Sample disagreeing with request	33	0.3
Sample at inadequate temperature	35	0.4
Sample received after the collection period	271	3
Hemolyzed sample	77	0.8
Sample unsuitable for the requested analysis	2,694	28
Insufficient volume sample	1,370	14
Sample not corresponding to the indicated	76	0.8
Sample with no identification	16	0.2
Leaked sample	75	0.8
Absence of clinical epidemiological criteria for test conduction	660	7
Incorrect sample registry	358	4
Inadequate collection	36	0.4
Diagnosis made with another method/clinical specimen	290	3
Test previously carried out	172	2
Lack of kit	15	0.2
Patient identification different from sample and request	31	0.3
Technical incident	0	0
Method not used	36	0.4
Inadequate filling of request form/ epidemiological record	121	1.3
Container broken during transport	9	0.1
Container with no sample	17	0.2
Request canceled by GAL management due to expiration of the screening period	2,708	28
Illegible request	0	0
Improper request	7	0.1
Request received with no sample	357	4
Request with no identification of the responsible professional	0	0
Total	9,723	100

Source: Paraná State Department of Health (2017)[11].
GAL: Laboratory Environment Manager system.

TABLE 2 – Nonconformity of highest frequency for tests directed to Lacen/PR in each RS of the state of Paraná, in 2017

RS	Most frequent nonconformity	Percentage*
1st RS Paranaguá	Sample unsuitable for the requested analysis	43
2nd RS Metropolitana de Curitiba	Sample unsuitable for the requested analysis	24
3rd RS Ponta Grossa	Request canceled by GAL management due to expiration of the screening period	37
4th RS Irati	Lack of kit	43
5th RS Guarapuava	Sample unsuitable for the requested analysis	33
6th RS União da Vitória	Sample unsuitable for the requested analysis	27
7th RS Pato Branco	Sample unsuitable for the requested analysis	42
8th RS Francisco Beltrão	Sample unsuitable for the requested analysis	35
9th RS Foz do Iguaçu	Request canceled by GAL management due to expiration of the screening period	31
10th RS Cascavel	Sample unsuitable for the requested analysis	32
11th RS Campo Mourão	Request canceled by GAL management due to expiration of the screening period	23
12th RS Umuarama	Sample unsuitable for the requested analysis	44
13th RS Cianorte	Sample unsuitable for the requested analysis	26
14th RS Paranavaí	Sample unsuitable for the requested analysis	28
15th RS Maringá#	Sample unsuitable for the requested analysis	29
16th RS Apucarana	Request canceled by GAL management due to expiration of the screening period	38
17th RS Londrina	Request canceled by GAL management due to expiration of the screening period	32
18th RS Cornélio Procópio	Sample unsuitable for the requested analysis	22
19th RS Jacarezinho	Sample unsuitable for the requested analysis	29
20th RS Toledo	Insufficient volume sample	40
21st RS Telemaco Borba	Sample unsuitable for the requested analysis	28
22nd RS Ivaiporã	Sample unsuitable for the requested analysis	42

Source: Paraná State Department of Health (2017)[11].

*RS: regional health unit; GAL: Laboratory Environment Manager system; *percentage of total nonconformities at the RS; #data from the Maringá Municipal Department of Health, because they are not provided at the 15th RS.*

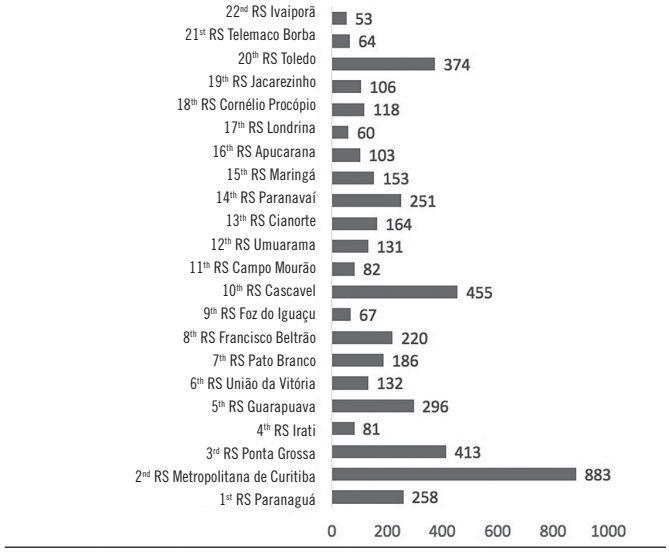

FIGURE 1 – *Distribution of nonconformities occurred in epidemiological tests directed to Lacen/PR by RS of the state of Paraná, in 2017*

Source: Paraná State Department of Health (2017)[11].

RS: regional health unit.

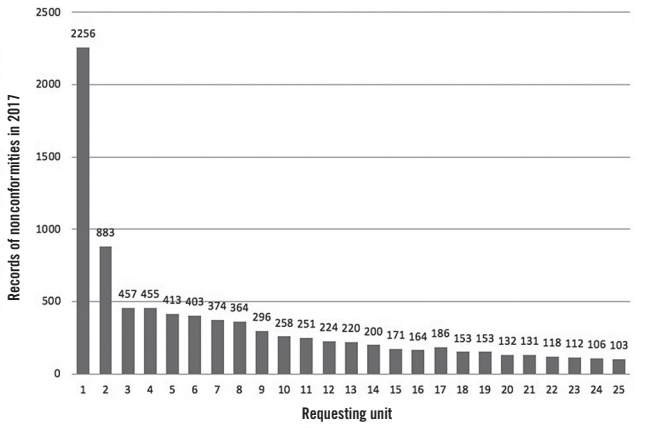

FIGURE 2 – *US with the largest number of nonconformities recorded in 2017. The graph displays the requesting units with absolute number of disposals greater than or equal to 100 records in 2017*

Source: Paraná State Department of Health (2017)[11].

1: SMS of Curitiba; 2: 2nd RS Metropolitana de Curitiba; 3: SMS Foz do Iguaçu; 4: 10th RS Cascavel; 5: 3rd RS Ponta Grossa; 6: Hospital Infantil Pequeno Príncipe; 7: 20th RS Toledo; 8: SMS Londrina; 9: 5th RS Guarapuava; 10: 1st RS Paranaguá; 11: 14th RS Paranavaí; 12: Hospital de Clínicas; 13: 8th RS Francisco Beltrão; 14: Hospital Universitário Evangélico de Curitiba; 15: Hospital do Trabalhador; 16: 13th RS Cianorte; 17: 7th RS Pato Branco; 18 SMS Maringá; 19: 15th RS Maringá; 20: 6th RS União da Vitória; 21: 12th RS Umuarama; 22: 18th RS Cornélio Procópio; 23: LEPAC; 24: 19th RS Jacarezinho; 25: 16th RS Apucarana; US: health unit; SMS: Municipal Department of Health; RS: regional health unit; LEPAC: Laboratory of Teaching and Research in Clinical Analyses.

verification, the tests are approved and the sample is referred to the responsible sector, or the tests are disposed in the GAL system and the sample is kept in quarantine[12].

In cases in which the sample is adequate, but the test was incorrectly recorded by the health unit, SGA makes the necessary correction in the GAL registry not to lose the material. In cases of improper packaging of biological liquids difficult to obtain, such as the cerebrospinal fluid (CSF), the specimen is sent to the target department, and disposal is decided by the professionals responsible for analysis[13, 14]. Parameters such as patient identification, unnecessary additional tests or test repetition, centrifugation quality, degree of hemolysis and sample transportation can be classified into three levels: optimum, desirable, and minimum. Those parameters are called quality indicators, and monitor and improve quality for the pre-analytical phase. Non-compliance with a specific requirement is considered a nonconformity[9].

Frequency of nonconformities recorded at GAL-Paraná

In public health laboratories, as well as in any laboratory, test quality is essential, and the occurrence of sample disposal indicates there are flaws that impair the total quality of result. Specimens received by a public health laboratory are unrepeatable, and

many tests cannot be carried out later due to loss of data from that particular moment[13]. It is possible to verify that the number of disposals at Lacen/PR (9,723) is quite small if compared with the total number of performed tests (132,567). But for the public health network, sample rejection results in loss of epidemiological data about an opportune moment[15].

Among the 31 options of reasons for rejection in the GAL system, these stand out more frequently: requests cancelled by GAL administration due to expired screening period, sample unsuitable for analysis, and insufficient volume (Table 1). Samples rejected at the GAL system are quarantined and, after that period, are discarded in packages for group E wastes – sharps. Plates, tubes with bacterial means of transportation, vials containing feces or sputum are disposed of in the hospital waste after being sterilized in autoclaves[16].

The GAL system analysis of quality indicators allowed identification of the most common nonconformities in the pre-analytical phase of tests performed at Lacen/PR. Data point identification and collection errors, inadequate storage and processing of the specimen, and errors with the request form as the most frequent nonconformities in routine laboratories[15, 17]. Our results corroborate those data, despite being from public laboratory services with epidemiological characteristics.

The nonconformity "request cancelled by GAL management due to expiration of the screening period" occurs because of poor use of the GAL system. This system computerizes the public laboratory network and enables greater quality control of test results, providing data for epidemiological surveillances in the three spheres of the government[18]. However, many US use it just as a test scheduler.

GAL registration should be made after biological material collection; however, most users have registered tests before collection of biological material. As a result, several requests are in the system although the sample never gets to Lacen/PR. That happens because, in spite of having the collection scheduled, many patients do not show up on the scheduled date.

The second most used reason, "sample unsuitable for the requested analysis", presents two hypotheses: deficiencies of users to consult the *Manual de Coleta e Envio de Amostras Biológicas ao Lacen/PR*, the technical notes and all the pieces of information available at the institution website; and Lacen/PR technicians' failure to interpret the reasons.

It is worth highlighting that there are some complicating factors detected by SGA, especially in what regards disposal of biological specimens that were not adequate to the desired assay. This means that the statistics of nonconformities may not reflect reality. To give an example, we use the case of a unit that sends CSF for cytomegalovirus serology. The specimen is adequate, but registry at GAL is wrong, as the used method for cytomegalovirus investigation in a CSF sample is real-time polymerase chain reaction (PCR), not serology. SGA rejects the incorrect registry at GAL, but not the specimen, just refers it for processing at the correct sector. Rejection, therefore, should have two reasons in the GAL system: "sample unsuitable for the requested analysis" and "incorrect registry of the specimen", but it does not happen.

Difficulties found by the US and RS of Paraná

The state network of laboratories of the state of Paraná is divided into 22 RS; there are laboratories that carry out tests and others that refer specific specimens to Lacen/PR[19]. By means of the report "Samples and Tests in Disagreement 2017", produced by GAL, it was possible to verify which pre-analytical error was more recurrent for each RS. The second, third and 10th RS stand out for having the largest numbers of discarded tests.

Some points must be considered to evaluate the difficulties found by each US and, consequently, the amount of nonconformities of each one. Thus, it is necessary to think that the percentage of disposals is influenced by the quantity of tests referred to Lacen/PR. When analyzing the US with the highest number of registries of nonconformities in 2017 (Figure 2), we notice that, despite the closeness with Lacen and because it is the capital of the state, with easier communication and trainings, Curitiba is the municipality of the second RS that has the largest number of nonconformities.

Most test orders from the Curitiba Municipal Department of Health (SMS) are aimed at investigating respiratory viruses and leptospirosis. The main nonconformity of this US is the incorrect registry of suspected leptospirosis cases. For such a scenario, there is an explanation: there are three researches at GAL involving leptospirosis (**Table 3**), what may cause confusion at registry time. Depending on the disease evolution, it is possible to run culture and analysis of the genetic material of the bacterium, or to investigate the produced immune response (antibodies). So that the test result is adequate, it is fundamental to ensure that collection, adequate method choice and registry are correctly performed.

Another important factor in this setting is the local epidemiological characteristic. There are differences among regional nonconformities, as some have prevalence of a certain disease in the locality. For example, there is the possibility of larger amounts of cases of suspected dengue fever according to the climate risk of the region. Consequently, a greater number of nonconformities can occur associated with this diagnosis confirmation in regions more affected by the disease[20].

TABLE 3 – Registry of the assay on leptospirosis

Assay	Method	Material	Collection period
Leptospirosis, culture	Culture	Whole blood (heparin)	Up to seven days after symptom onset
Leptospirosis, molecular biology	Real-time PCR	Whole blood (EDTA)	
Leptospirosis, IgM	Immunoenzymatic assay	Serum	At the first contact with patient

Source: Manual de Coleta e Envio de Amostras Biológicas ao Lacen/PR.

PCR: polymerase chain reaction; EDTA: ethylenediamine tetraacetic acid; IgM: immunoglobulin M.

Measures to avoid nonconformities

Lacen/PR offers in its website manuals and technical notes providing guidance on the correct form of shipping biological specimens to Lacen/PR. The *Manual de Coleta e Envio de Amostras Biológicas* is annually revised and describes all the steps for a correct registration in the GAL system, and shipping the adequate sample to the intended test.

It is possible that the complexity of the manual is an impacting factor in the occurrence of nonconformities. There is great difficulty to use the manual, and this may justify, for instance, the percentage of disposals due to specimen unsuitable for the requested analysis. An alternative for this problem would be the production of technical notes for sample shipping to the most frequent assays according to the characteristic of each RS.

Another reason to explain the number of disposals of tests/samples registered at GAL-Paraná in 2017 can be the fact that people engaged in the preparation and shipping of samples are, mostly, professionals with no technical knowledge about laboratory work, such as those of nursing or administration areas. Also, the difficulty in the training of several professionals involved in the pre-analytical phase (physicians, nurses, nursing technicians, administrative technicians, among others), either because of the different areas of formation, either because of the difficulty implementing a specific training program, contributes to the number of discards.

Pre-analytical errors cause a negative financial impact due to test repetition, loss of diagnostic usefulness of the test, and loss of epidemiological data. Actions to improve this scenario would be training programs, prioritizing areas where the incidence of errors is higher[21].

The nonconformities occurring in the pre-analytical phase of laboratory tests represent round 60% of all laboratory errors[15, 17]. Although laboratories create strategies of quality control to reduce these nonconformities, the problem remains, as also highlighted in this work. There are no national data published on the frequency of rejection/disposal of samples in the GAL system. However, it is known that some nonconformities found in this study are frequent also in similar studies that have evaluated the processes of routine laboratories[22]. Failures may happen in sample identification, selection of biological sample to be collected for a certain assay, volume of sample collected in tubes, correct storage of the sample, occurrence of hemolysis and lack of information about the patient, with incomplete request forms or forms filled incorrectly[23].

Information management systems such as GAL allow identification of quality indicators that are fundamental tools to indicate the most frequent errors and nonconformities, and, based on them, implement corrective and educational necessary measures, as well as improve quality of the rendered service[24].

In order to periodically enhance the pre-analytical phase, Lacen/PR carries out training in the 399 municipalities of the state. The most relevant points covered in those trainings are: 1. main problems found in the filling of the GAL system; 2. training for the correct filling of test request; 3. correct sample storage and shipping.

Encouraging participation in those training programs by all the involved professionals and disseminating information to work places by means of multiplying agents are important challenges to take on.

FINAL CONSIDERATIONS

In 2017, a total of 9,723 disposals were recorded at Lacen/PR due to nonconformities; the most frequent reasons were: request cancelled by the GAL administration due to expired screening period (28%) and sample unsuitable for the requested analysis (28%). The most common difficulties found by US and RS were associated with the correct exam request. The second, third and 10th regionals were those presenting the greatest number of nonconformities.

For a public health laboratory, the sample is unique and, despite the whole technology employed in the analytical phase, the phase that precedes it is essential to ensure quality of results and epidemiological information. Quality indicators in that phase are an important tool for process improvement. The results found in this study indicate the necessity to reinforce measures to improve the pre-analytical process, in order to ensure safety of patients and epidemiological data.

REFERENCES

1. Brasil. Ministério da Saúde. Fundação Nacional de Saúde. Vigilância epidemiológica. Reestruturação do sistema nacional de laboratórios de saúde pública. Brasília, DF: Ministério da Saúde; 2001.

2. Brasil. Ministério da Saúde. Sistema Nacional de Laboratórios de Saúde Pública (SISLAB). Brasília, DF; 2018 a.

3. Paraná. Secretaria do Estado da Saúde. Laboratório Central do Estado do Paraná. Institucional; 2018.

4. Brasil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Portaria nº 33 de 22 de junho de 2017. Define o processo para habilitação dos laboratórios de referência nacional e regional, no âmbito da rede nacional de laboratórios de saúde pública. Brasília: Ministério da Saúde; 2017.

5. Brasil. Ministério da Saúde. Portaria nº 2.031, de 23 de setembro de 2004. Dispõe sobre a organização do Sistema Nacional de Laboratórios de Saúde Pública. Brasília: Ministério da Saúde; 2004.

6. Costa VG, Moreli ML. Principais parâmetros biológicos avaliados em erros na fase pré-analítica de laboratórios clínicos: revisão sistemática. J Bras Patol Med Lab. 2012; 8(3): 163-8.

7. Lima-Oliveira G, Volanski W, Lippi G, Picheth G, Guidi GC. Pre-analytical phase management: a review of the procedures from patient preparation to laboratory analysis. Scand J Clin Lab Invest. 2017; 77(3): 153-63.

8. Vieira KF, Shitara ES, Mendes ME, Sumita MN. A utilidade dos indicadores de qualidade no gerenciamento de laboratórios clínicos. J Bras Patol Med Lab. 2011; 47(3): 201-10.

9. Plebani M, Sciacovelli L, Aita A, Pelloso M, Chiozza ML. Performance criteria and quality indicators for the pre-analytical phase. Clin Chem Lab Med. 2015; e.53-6.

10. Jesus R, Guimarães RP, Bergamo R, Santos LCF, Matta ASD, Paula Jr FJ. Sistema gerenciador de ambiente laboratorial: relato de experiência de uma ferramenta transformadora para a gestão laboratorial e vigilância em saúde. Epidemiol Serv Saude. 2013; 22(3): 525-9.

11. Paraná. Secretaria do Estado da Saúde. Laboratório Central do Estado. Gerenciador de ambiente laboratorial. Amostras e exames em desacordo de 01/01/2017 a 31/12/2017. São José dos Pinhais; 2018.

12. Paraná. Secretaria do Estado da Saúde. Laboratório Central do Estado do Paraná. Sistema de gestão da qualidade e biossegurança. Recebimento de amostras biológicas. Procedimento Operacional Padrão nº 1.3.70.002; 2011.

13. Coan EW. Implantação de programa de gestão da fase pré-analítica no Lacen/PR – Unidade Guatupê. São José dos Pinhais: Escola de Saúde Pública do Paraná. Secretaria do Estado de Saúde; 2017.

14. Paraná. Secretaria do Estado de Saúde. Laboratório Central do Estado – Unidade Guatupê. Manual de coleta e envio de amostras biológicas ao Lacen/PR; 2017.

15. Morita MLM, Baldin R, Farias N. Avaliação da qualidade da informação nas requisições e condições das amostras biológicas nos laboratórios de saúde pública Lapa e Ipiranga do município de São Paulo. Bepa. 2010; 79: 12-22.

16. Paraná. Secretaria do Estado de Saúde. Laboratório Central do Estado do Paraná. Sistema de gestão da qualidade e biossegurança. Tratamento de não conformidades na recepção de amostras. Procedimento Operacional Padrão nº 1.3.70.003; 2011.

17. Plebani M, Sciacovelli L, Aita A, Padoan A, Chiozza ML. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Chim Acta. 2014; 15: 432-44.

18. Paula Jr FJ, Matta ASD, Jesus R, Guimarães RP, Souza LRO, Brant JL. Sistema gerenciador de ambiente laboratorial – GAL: avaliação de uma ferramenta para vigilância sentinela de síndrome gripal, Brasil, 2011-2012. Epidemiol Serv Saude. 2017; 26(2): 339-48.

19. Paraná. Secretaria do Estado da Saúde. Resolução SESA nº 0610/2010. Dispõe sobre a organização do Sistema Estadual de Laboratórios de Saúde Pública do Estado do Paraná – SESLAB/PR, inserido no contexto do Sistema Nacional de Laboratórios de Saúde Pública – SISLAB. 2010.

20. Paraná. Secretaria do Estado da Saúde. Superintendência de Vigilância em Saúde. Centro de informações e respostas estratégicas de vigilância em saúde – CIEVS. Informe epidemiológico CIEVS – Paraná/ Semana Epidemiológica 51 e 52/2017 (17/12/2017 a 30/12/2017). 2017.

21. Campana GA, Oplustll CP, Faro LB. Tendências em medicina laboratorial. J Bras Patol Med Lab. 2011; 47(4): 399-408.

22. Tapper MA, Pethick JC, Dilworth LL, McGrowder DA. Pre-analytical errors ate the chemical pathology laboratory of a teaching hospital. J Clin Diagn Res. 2017; 11(8): BC16-8.

23. Sciacovelli L, Lippi G, Sumarac Z, et al. Quality Indicators in Laboratory Medicine: the status of progress of IFCC Working Group "Laboratory Errors and Patient Safety" project. Clin Chem Lab Med. 2017; 55(3): 348-57.

24. Noble MA, Resrelli V, Taylor A, Cochrane D. Laboratory error reporting rates can change significantly with year-over-year examination. Diagnosis (Berl). 2018; 5(1): 15-9.

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