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Assessment of the pre-analytical phase of a clinical analyses laboratory

Avaliação da fase pré-analítica de um laboratório de análises clínicas

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ABSTRACT

Introduction: The pre-analytical phase encompasses the procedures prior to the performance of the laboratory tests, which are the physician's requisition, patient and tests registration, collection and transport of samples. This phase involves different professionals and is responsible for the majority of the laboratory errors. **Objective:** To assess the pre-analytical phase of a public laboratory through quality indicators (QI). **Method:** Nonconformities (NC) in the physician's requisitions and in the patients and tests registrations were evaluated during the quality checking process. A questionnaire was applied to evaluate the service and the satisfaction of the laboratory's client. The QI were calculated considering the number of NC in the processes in relation to the total opportunities, compared with specifications described in the literature and evaluated by the Sigma metric. **Results:** The pre-analytical phase was evaluated by 34 QI. From these, 18 presented Sigma score lower than 3.0, six between 3.0 and 4.0, six above 4.0 and four presented Sigma score of 6.0. The completiton of requisitions presented worse performance than the process of tests registration. Regarding the three stages of the pre-analytical phase evaluated, the scheduling presented the worst performance, followed by the service at the reception and the sample collection. **Conclusion:** The evaluation of the QI allowed organizing the improvements that should be prioritized in the laboratory. The Sigma metric was useful for assessing the QIs considered important to the laboratory, for which there are no published specifications. The questionnaire for evaluating the laboratory's service and client's satisfaction was not a reliable tool for assessing the quality of the pre-analytical phase.

Key words: health management; quality management; public health laboratory services; laboratories; indicators; total quality.

INTRODUCTION

The process for carrying out the laboratory tests is classified into three stages, these are the phases pre-analytical, analytical and post-analytical phases[1]. The pre-analytical phase involves the procedures before the laboratory analysis, starting with the choice and requisition of the tests, going through the registration of clients and tests and the collection and transportation of samples. The sub-phases of the pre-analytical phase are performed by different health professionals, such as doctors, nurses and technicians[2].

The pre-analytical phase presents a high error rate, which are related to the complexity of the processes involved, to the limited automation and standardization of services and to the participation of several healthcare operators[3, 4]. Different studies indicate that 31.6%, 44% and 53% of errors related to laboratory tests occur in the pre-analytical phase; other authors found up to 75%[5]. In the pre-analytical phase, errors commonly occur in the test registration, client identification and preparation, sample collection, transport and storage[4, 6].

The awareness of the need to improve quality in the pre-analytical phase has drawn attention to the development of some aspects and technological initiatives, aiming at the greater standardization and quality of the operational procedures[7].

In the last decades, several evidences highlight the vulnerability of the pre-analytical phase and the recommendation of quality indicators (QI) to identify and reduce the risk of errors[8]. QI is a tool that allows the manager to quantify the quality of a selected aspect of the process by comparing it with a criterion. QI can be defined as an objective measure that can assess the different domains of health care, such as client safety, effectiveness, equity, client focus, punctuality, and efficiency[9].

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QI and performance criteria should be implemented in the clinical laboratory, but a small number of laboratories are measuring one or more QI from the pre-analytical phase. One of the bottlenecks in the implementation of QI is the lack of functionality in automated data collection in the laboratory information system, thus requiring manual data collection, which is time consuming and a waste of human resources[8].

Furthermore, there is little evidence of effective compliance with the current recommendations for requisition, assistance, registration and collection of biological samples. This fact led us to reflect on the need to focus the planning in the management of the quality of the pre-analytical phase, implanting and monitoring a QI in this stage. We believe that the evaluation of the pre-analytical phase performed by a QI can contribute to the analysis, control and improvement of the process, as well as to increase the degree of reliability of the results.

OBJECTIVE

To analyze the pre-analytical phase of a public clinical analysis laboratory using QI, quality specifications and Sigma metric.

METHOD

The study was conducted at the Division of Clinical Analysis of the HU/UFSC [Divisão de Análises Clínicas of the Hospital Universitário of the Universidade Federal de Santa Catarina (DACL/HU/UFSC)], which assists on average 170 outpatient clients per day, in addition to the hospitalized patients. The research was approved by the Research Ethics Committee of the UFSC (CAAE 59293516.0.0000.0121) and followed the recommendations of the Resolution no. 466/2012 of the National Health Council.

Study design

Two components are basic to the quality of service provided: the operational, which corresponds to the process, and the perception, which is the way clients perceive the service offered[10].

In this context, all DACL procedures are systematized and described in standard operating procedures. For the evaluation of the pre-analytical phase, the nonconformities in the processes of the stage were evaluated.

Briefly, nonconformity is the non-compliance with a requirement. A requirement refers to the need or expectation of what is stated, implicitly or explicitly. In other words, nonconformity is the occurrence of a non-standardized procedure[1].

The nonconformities in the requisitions and in the registration of the clients and the tests were evaluated during the quality checking process. The nonconformities in clients' assistance and satisfaction with the service provided in the pre-analytical phase were evaluated through a questionnaire (**Chart**).

Analysis of requisitions and registration of tests

The data collection to evaluate the process of registration of tests was carried out during three months in the stage of conference of the documents of outpatient clients, in the period of greater service flow: from 7:30 to 9:00. We considered nonconformities of the requisitions and the registration of the tests: registration of tests not required, exchange of registered tests, tests required and not registrated, incomplete name of the client, incorrect registration of the client, unreadable requisition, as well as abscence of clinical data, of specification of the material to be examined, the medical record number, date, stamp and/or signature of the ordering physician.

Analysis of assistance and clients' satisfaction

A questionnaire to assess the stages of clients'assistance and satisfaction with the service provided in the pre-analytical phase was developed by grouping the questions into three categories to analyze the assistance at the time of scheduling tests, at the reception service and during the collection of the biological material. In order to evaluate the service, 23 questions, used as indicators and evaluated by the Sigma metric, were related to the information provided to clients for the undergoing tests, regarding questions on medication use, information for accessing results, and during collection. Other seven questions were included to analyze clients' satisfaction during the pre-analytical stages, and three to assess waiting time and assistance.

QI analysis

Nonconformities were tabulated in the Microsoft Excel worksheet. Each type of nonconformity was considered a QI. QI were calculated considering the number of failures in the processes in relation to the total of opportunities and was expressed in percentage. For the QI assessment, the Sigma level was calculated considering the number of processes failures in a million opportunities, using the Six Sigma Calculator[11]. A Sigma lower than 3.0 was considered borderline unacceptable; between 3.0 and 4.0, acceptable; above 4.0, a good process performance, and Sigma 6.0, the desired goal[12, 13]. The QI evaluated were also compared with the quality specifications found in the literature.

CHART – Questionnaire to the evaluation of service and client satisfaction in the HU/UFSC clinical analysis laboratory

Date of filling out the questionnaire: / /

1. Please answer your degree of satisfaction regarding the following items related to the pre-analytical phase:

	Not satisfied	Neutral	Satisfied
Attendance during scheduling			
Password distribution system for sample collection at the HU laboratory			
Attendance upon arrival at the laboratory for collection			
Environment organization			
Time between reception service and collection			
Organization and cleaning of the collection box			
Phlebotomist attendance			

2. How long (approximately) took the service of each of the following steps:

	0-5 min	5-10 min	10-15 min	15-20 min	> 20 min
Time to reception service					
Attendance time at reception					
Time between reception service and sample collection					

3. Please answer yes or no to the following questions:

		Yes	No
In the scheduling	Were you instructed about showing photo identification on the day of collection?		
	Were you instructed about presenting the medical follow-up receipt?		
	Were you instructed about presenting the medical order on the day of collection also?		
	Were you questioned about medication use?		
	Were you instructed about the recommendations for undergoing the test?		
At the reception	Were all the waiting seats occupied?		
	Did the large number of people waiting at the reception displease you?		
	Were you instructed about the steps following the urine and blood collection service?		
	Were you informed about the use of the photo identification at the time of collection?		
	Were you questioned about medication use on the day of collection?		
	Were you well assisted?		
During collection	Were you called by the full name for the collection?		
	Were you called out loudly and clear for the collection?		
	Was more than one puncture performed to obtain the sample?		
	Do you have any doubts regarding the performance of any test?		
	Did you have the need for the phlebotomist to go to the front desk for correction or verification of any information?		
	Did you present malaise during collection?		
	Was the photo identification and receipt of collection returned to you?		
	Have you been advised by the phlebotomist to access your results online?		
	Were you instructed regarding the deadline for access to results?		
	Did you understand the Internet access to view and download the tests results?		
	Would you recommend the lab to someone?		
	Would you go back to the lab to undergo further tests?		

HU/UFSC: Hospital Universitário/Universidade Federal de Santa Catarina.

RESULTS

A total of 375 requisitions, 375 tests registrations and 127 client satisfaction questionnaires responses were analyzed. The evaluation of the pre-analytical phase was performed by 34 QI, of which six from the requisition analysis, five from the tests registration and 23 from the client satisfaction questionnaire.

Analysis of requisitions

In 51% (193) from 375 requisitions analyzed 327 nonconformities were observed, that is, some requisitions had more than one nonconformity. From the 193 nonconformity requisitions, in 139 (72%) one nonconformity was found; in 33 (17%), two; in 16 (8%), three; and in five (3%), four.

The nonconformities in the tests requisitions were grouped into six different indicators and are presented in **Table 1** in absolute number, percentage, defects per million opportunities (DPMO) and corresponding Sigma level.

Nonconformities, such as abscence of clinical data, failure to complete the "material to be examined" field, abscence of date on requisition and abscence of medical records were the most prevalent (Table 1).

TABLE 1 – Nonconformities observed in the requisitions of tests

Nonconformities in requisitions	Number (%)	DPMO	Sigma
Absence of clinical data	98 (26.1)	261333	2.2
Failure to complete the "material to be examined" field	97 (25.8)	258667	2.2
Absence of date on requisition	64 (17.1)	170667	2.5
Absence of medical record number	51 (13.6)	136000	2.6
Unreadable requisition	13 (3.5)	34667	3.4
Absence of data regarding physician identification	4 (1.1)	10667	3.9
Total nonconformities	327	872000	0.4
Total requisitions with nonconformities	193 (51.5)	514667	1.5

DPMO: defects per million opportunities.

TABLE 2 – Nonconformities found in the registration of tests

Nonconformities in the tests registration	Number (%)	DPMO	Sigma
Tests not registered	28 (7.5)	74667	3.0
Incomplete patient's name	10 (2.7)	26667	3.5
Tests that were registered and were not included in the requisition	9 (2.4)	24000	3.5
Exchanging tests during registration	5 (1.3)	13333	3.8
Incorrect patient's name registration	2 (0.5)	5333	4.1
Total nonconformities	54 (14.4)	144000	2.6

DPMO: defects per million opportunities.

TABLE 3 – Level of laboratory clients' satisfaction regarding the different stages of the pre-analytical phase

Items evaluated	no. of not satisfied (%)	no. of neutral (%)	no. of satisfied (%)
Attendance during scheduling	2 (2)	2 (2)	86 (96)
Password distribution system for sample collection from the university hospital laboratory	7 (5)	13 (10)	107 (84)
Attendance upon arrival at the laboratory for collection	3 (2)	6 (5)	118 (93)
Environment organization	4 (3)	7 (6)	116 (92)
Time between reception and collection	5 (4)	15 (12)	107 (84)
Organization and cleaning in the collection box	1 (1)	1 (1)	125 (98)
Phlebotomist assistance	0 (0)	0 (0)	127 (100)

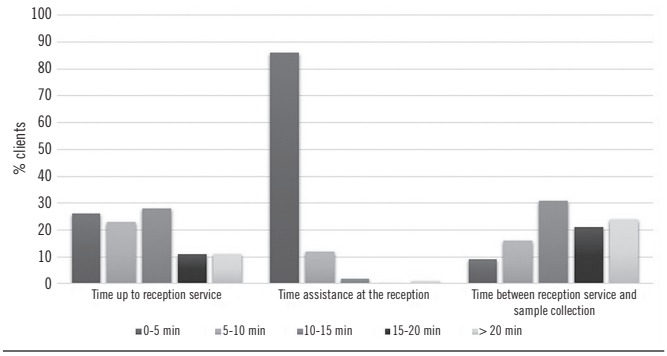

FIGURE – *Distribution of clients according to perceived service time*

Analysis of tests registration

From 375 registrations of requisitions analyzed, 54 (14.4%) presented nonconformities. Twenty-eight (7.5%) registrations with some tests not registered, nine (2.7%) with some tests registered that were not included in the requisition, and five (1.3%) with exchanged tests in the registered, were found. Regarding client identification data, two (0.5%) incorrect name registrations and 10 (2.7%) with incomplete name, were found (**Table 2**).

Analysis of client assistance and satisfaction

Clients were asked to respond to the questionnaire immediately after collecting the biological material. From 340 clients approached, 213 refused to respond it.

From 127 clients who responded the questionnaire, only 85 (66.9% and Sigma 2.0) were instructed by the physician to schedule the tests in the laboratory; five (4%) came to the laboratory to be informed about the need for scheduling; 19 (15%) were scheduled through the Regulation Central State; and another 18 did not previously scheduled the tests. Therefore, 90 clients responded the first stage of the questionnaire. **Table 3** presents the general satisfaction of the clients regarding the laboratory pre-analytical phase.

The handling time up to client assistance at the reception desk, the time at the reception and the time between the reception service and sample collection in the laboratory, according to clients' perceptions, are shown in the **Figure**.

A **Table 4** represents the nonconformities during scheduling, during service at the reception and during the collection of sample, according to the clients' perception.

DISCUSSION

QIs can be evaluated in different ways, one of which is to compare the performance of the laboratory with target-performances, the quality specifications, which are obtained considering the state of the art of expected and/or observed outcomes. As well as being adopted for the evaluation of the analytical phase, the performance in view of quality specifications can be classified into three levels: optimal, desirable and minimum[14].

Another form of QI evaluation is using the Six Sigma metric, which has aroused great interest and importance in the healthcare area. The use of the Sigma metric allows estimating and monitoring efficiency variations associated with technical

TABLE 4 – Nonconformities found in the laboratory pre-analytical phase according to clients' perception

	Nonconformities	Number (%)	DPMO	Sigma
In the scheduling (n = 90)	Not instructed on presentation of photo document on the day of collection	19 (21.1)	211111	2.4
	Not instructed on presenting of medical return receipt	26 (28.8)	288889	2.1
	Not instructed on presenting the medical requisition also on the day of collection	20 (22.2)	222222	2.3
	Not questioned about medication use	62 (68.9)	688889	1.1
	Not instructed on recommendations related to the tests	13 (14.4)	144444	2.6
At the reception (n = 127)	All waiting seats were busy	4 (3.1)	31496	3.4
	The high number of people waiting at the reception was unpleasant	26 (20.4)	204724	2.4
	Not instructed on the steps following the assistance, for urine and blood collection	13 (10.2)	102362	2.8
	Not informed on using the photo document at the time of collection	17 (13.8)	133858	2.7
	Not questioned about medication use	115 (90.5)	905512	0.2
	Bad service at reception	0 (0)	0	6
During collection (n = 127)	Not named by full name for collection	1 (0.8)	7874	4
	Not named loudly and clear for collection	1 (0.8)	7874	4
	Carrying out more than one punch to obtain the sample	15 (11.8)	118110	2.7
	Were doubtful about any examination procedure	1 (0.8)	7874	4
	Need for the phlebotomist to go to the reception for correction or certification of some information	1 (0.8)	7874	4
	Presented malaise during collection	1 (0.8)	7874	4
	Non-return of the photo document and the receipt of collection	0 (0)	0	6
	Were not instructed by the phlebotomist to access the results online	46 (36.2)	362205	1.9
	Were not advised regarding the deadline for access to results	30 (23.6)	236220	2.3
	Did not understand the internet access to the results of tests	81 (63.8)	637795	1.2
	Would not recommend the lab to anyone	0 (0)	0	6
	Would not go back to the lab for further tests	0 (0)	0	6

DPMO: defects per million opportunities.

processes, as well as classifying and comparing different processes, procedures and equipment as regards their performance quality[15]. In Six Sigma terminology, the defects of a process are expressed in terms of DPMO and quantified in a "Sigma scale". The relationship between the Sigma value and the number of defects has a negative exponential correlation, so that each time a process improves a Sigma level, many failure opportunities have been eliminated. A process that is almost perfect is said to be operating at a Sigma level of 6.0 and will only have 3.4 DPMO, which equals an efficiency of 99.9997%[16, 17].

Analysis of requisitions

The Quality Management System (QMS) of a clinical laboratory should include measures aimed at the quality of the tests requisitions, so that they contain sufficient information to identify the client, the ordering physician, the sample or material to be collected and their respective analyzes. Such a guarantee is also necessary to promote patient safety[5, 18, 19].

The quality specifications proposed by Llopis (2011)[20] establish the Sigma level of 3.4 as acceptable for the total of nonconformities found in the requisitions. In our study, both the number of requisitions with nonconforming and the total number of nonconformities observed presented Sigma level below that proposed by Llopis (2011), which demonstrates a performance of filling out the requisitions process much lower than desirable. In this process, the relationship between the laboratory and the requesting client must be narrowed, aiming at clarifying the importance of correct completing of requisitions.

In the analysis of the requisitions, the abscence of clinical data, of filling out the "material to be examined" field, the date and the number of records represented QI of the process with performance far below the minimum desirable (Sigma 3.0). These results indicate that all of these stages present opportunities for improvement in the process of filling out the requisitions. On the other hand, according to the quality specifications proposed by Hawkins (2012)[21], the abscence of clinical data rate (in 26.1% of requisitions in our study) would be within the desirable range, which is 13% to 42%. The analysis of this quality indicator is important, since the conduct during the laboratorial analysis can be modified based on patient's clinical data. Therefore, the test requisition should contain all the data about the patient, including the hypothesis of diagnosis[22, 23]. In this regard, the patient's medical record number also enables the laboratory's access to the patient's clinical data. Furthermore, it helps during registration in the laboratory, for this reason the abscense of this data in the requisition is related to the effectiveness at the moment of registration, which can increase the probability of errors in the identification of the client, thus increasing the

workload[21] and decreasing patient safety[23]. The performance of 2.6 (13.6%) in the Sigma metric observed in relation to the abscence of medical records in the requisitions, is unacceptable (below 3.0). Unacceptable performance (Sigma 2.2) was also observed with the abscence of completion of the "material to be examined" field in the requisition. The material to be collected for analysis must also be specified in the requisitions[18], since the same test can be carried out on different sampling type.

The abscence of data regarding physician identification, observed in 1.1% of requisitions, is an indicator considered optimal according to the specifications proposed by Hawkins (2012)[21], which recommends less than 5%. Moreover, the Sigma level of 3.9 also represents that this process stage has an acceptable performance. The correct identification of the ordering physician in the test requisition allows the laboratory, as needed, their contact to obtain more information on the client and helps in the interpretation of the results[24].

According to Sciacovelli (2011)[24], the number (3.5%) of unreadable requisitions observed is considered unacceptable (> 0.30%). However, by evaluating the Sigma level (3.4), this indicator presents a level of performance within acceptable. Unreadable requisitions, in addition to generating a delay in assistance due to the difficulty of their interpretation, can lead to errors in the registration of the tests or of the client[19].

From the requisitions analyzed 64 (17.1%) were found with no date, representing Sigma level of 2.5, below the acceptable performance. The requisitions are valid for 30 to 90 days and, depending on the health plan, there may be a revocation of the test performed. Another fact to be considered is that the results may not reflect the signs and symptoms of the client if the tests are performed outside the period required by the physician[25].

For the nonconformities "abscence of completion of the material to be examined field", "abscence of date in requisition" and "abscence of number of medical records", no quality specifications were found described in the literature. In this context, the analysis of the indicators by the Sigma level is useful for the monitoring of the indicator over time.

Analysis of the registration of tests

The analysis of the registration of the tests was preformed immediately after the patient went through the reception of the laboratory and before the collection of the biological material.

We found 28 (7.5%) non-registered tests in a total of 375 requisitions. In the Sigma metric this nonconformity rate represents level 3.0, which is the lower limit of acceptability and, according to Plebani *et al.* (2015)[4], it is below the minimum performance that is 4.26. In the same regard, according to the quality specifications proposed by Hawkins (2012)[21], a rate higher than 0.5% of non-registered tests is considered unacceptable. The number of mistakenly registered tests that resulted in Sigma level of 3.8 (1.3%), according to the specifications proposed by the author, is considered unacceptable when greater than 0.30%. When one test is not performed, or is replaced by another, the abscence of information regarding missing results may lead to delays in diagnosis and in client treatment[24].

Likewise, the number of registered tests (2.4%) that were not included in the requisitions, is above the desirable performance proposed by Hawkins (2012)[21], which is less than 0.1%. The Sigma level of this indicator (3.5), although acceptable, is also below the minimum performance described by Plebani *et al.* (2015)[4]. The analysis of this QI was considered important, since it leads to the accomplishment of unduly tests, generating unnecessary costs to the laboratory.

The number of registrations incorrectly performed (0.5%, Sigma 4.1) and the registration of patient's incomplete name (2.7%, Sigma 3.5) is considered unacceptable by Hawkins (2012)[21], who proposes an index lower than 0.6% for errors related to patient identification and by Peblani *et al.* (2015)[4], which sets the minimum Sigma of 4.54. This type of error can result in serious consequences, such as the substitution of a client's analytical report for another, leading to errors in the diagnosis, prognosis, modification or discontinuation of the client's treatment, or even the course of a useless treatment can cause damage to him[20].

Altogether 11 QI of the requisitions and the registration of the tests were evaluated. All the indicators were evaluated by the Sigma metric. Among them, five indicators presented Sigma less than or equal to 3.0; five between 3.0 and 4.0; and only one showed Sigma above 4.0. Eight indicators were also evaluated by comparison with quality specifications. From these, six were out of the specification (unacceptable); one, within the desirable specifications; and only one, presented great performance. From the eight indicators that were evaluated by both methods, seven presented divergent results, of which six were considered acceptable by Sigma and unacceptable by the specifications; one indicator showed desirable performance under specifications and below the acceptable range for Sigma.

In this regard, there was a divergence between the quality specifications described in the literature, when comparing the goals of the Sigma metric and the percentage described by some authors. The Sigma metric proved to be a less demanding specification analysis parameter. Therefore, we understand that the cut-off point 3.0 of the Sigma metric should be used only for indicators with no specifications

of described quality. The literature describes that processes with performance below Sigma 3.0 are unaffordable and should be targets for performance improvements. Otherwise, they may compromise the company, both in terms of costs and client satisfaction[17, 26].

Analysis of service and clients' satisfaction

From the 127 clients who replied the questionnaire, only 90 (71%, Sigma 2.1) had previously scheduled the tests. Scheduling the tests is important because only then the instructions for sample collection are provided. However, among the clients that performed the scheduling, a high index of abscence of instructions for the collection was observed.

Shahangian and Snyder (2009)[9] state that lower satisfaction rates are related to poor communication. In our study, the failure of the physician/client/laboratory/physician communication, which resulted in 29% of the clients with no prior scheduling for the tests, may have directly reflected the dissatisfaction in the service, collection, time elapsed until collection and in the unpleasant feeling regarding the high number of clients at the reception.

The Clinical Laboratory Accreditation Program [Programa de Acreditação de Laboratórios Clínicos (PALC) 2013][15] standard describes that the laboratory and the collection stations must request the client a document that proves their identification to registration, and provide the client with clear instructions, written in accessible language, advising on preparation and collection of samples. For all these parameters, the laboratory performed below 3.0 in the Sigma metric, requiring significant improvements in this stage of service.

Regarding the service at the reception on the day of collection, 93% of clients are satisfied (Sigma 3.0). An outsourced company with great employee turnover carries out this service, which is one of the main factors that may have led to client dissatisfaction.

Clients do not have access to the area where the tests are performed, so the organization's perception of the pre-analytical phase can influence the reliability of the results. With this in mind, the satisfaction of 92% of the clients regarding the organization of the environment was considered appropriate.

Likewise, the satisfaction of the 127 (100%) interviewed with phlebotomist assistance was plausible. From 127, 11% reported that more than one punch was required to obtain the sample. This rate can be reduced with the continuous training of professionals and the use of devices to visualize the vessels[27]. Sample collection is one of the few areas in the laboratory that comes in personal contact with the client. Therefore, phlebotomy provides an important opportunity to measure the client's perception in relation to the laboratory[28]. Shahangian and Snyder (2009)[9] reported that 15% of outpatient clients are dissatisfied with phlebotomy. A survey conducted in the United Kingdom with 335 laboratories reported that only 27.6% of the laboratories performed client satisfaction surveys regarding phlebotomy[28].

The majority (90.5%) of the interviewed (Sigma 0.3) was not questioned on the use of medication on the day of collection. The laboratory performance in this indicator is very worrisome, considering that several drugs may interfere *in vivo* or *in vitro*, affecting the accuracy of laboratory tests results, and may reflect on client safety[26]. Information on the intake of therapeutic drugs between 1 and 72 hours prior to blood collection should be made available to the laboratory staff and physicians, since it should be considered during interpretation of the results and client monitoring. The laboratory staff can also assist physicians by adding technical notes in the reports to explain potential interference[2].

From the 23 QI obtained through the responses of the clients to the questionnaire, 13 presented a Sigma performance below 3.0; one, between 3.0 and 4.0; and five, above 4.0. On the other hand, four indicators presented Sigma 6.0. When nonconformities or doubts about laboratory compliance arise regarding their own procedures, the laboratory should be proactive in identifying, documenting and eliminating the main cause(s)[1]. The evaluation of the processes in the clinical laboratory, based on the use of the Sigma scale associated to a methodology of continuous improvement of these processes, allows the laboratory to decrease the indexes of nonconformities[15].

In relation to the three stages of the pre-analytical phase evaluated by the questionnaire, the one that presented the worst overall performance was scheduling, with an average Sigma of 2.1, followed by the reception service (Sigma 2.9) and collection (Sigma 3.8), which presented satisfactory performance. The client satisfaction rate and the Sigma level found were conflicting, showing that the questionnaire may not be the best option for the evaluation of these indicators. Furthermore, it requires a lot of time for collection and analysis, since the results are subjective and more susceptible to bias.

One of the conduct to be adopted to achieve better laboratory performance is to advise physicians on the importance of filling out a requisition with all client information, as well as clearly and legibly[18]. Another way is the investment and training to improve the operational processes as good practices in the pre-analytical phase. Because there is no physical means to measure and control the action of pre-analytical effects, as occurs in the analytical phase, the control of this stage is based on training of personnel, standardization of procedures and documenting the activities[29]. On the other hand, a study observed small improvements in blood collection practices after an important educational intervention[27].

In this regard, several other management tools can be used to identify causes and/or solutions for nonconformities (e.g., the Ishikawa Diagram), brainstorming and mapping of improvement activities (5W2H: What, When, Who, Where, Why, How and How Much). Or, multiple Plan, Do, Check, Act (PDCA) cycles can be rotated until each indicator reaches a satisfactory Sigma level[30].

CONCLUSION

We quantified the pre-analytical nonconformities, which are daily obstacles in our laboratory. Some of these can lead to misleading results and, consequently, to late and/or wrong medical decisions, potentially harming the client. Each laboratory develops their own methods of dealing with nonconformities, and at various occasions we are led to produce results from an inadequate pre-analytical stage, as there are no protocols on how to deal with requisitions failures, for example.

The evaluation of the pre-analytical phase allows inferring that the process of filling out the requisitions presents worse performance than the registration of the tests. However, both processes need improvement as they compromise the identification and, consequently, patient safety. The Sigma metric was useful for evaluating the pre-analytical phase through QI, considered important for the laboratory, for which there are no published specifications. The evaluation of the indicators allowed classifying the improvements that should be prioritized in the laboratory. The questionnaire evaluating service and client satisfaction was not a reliable tool to evaluate the quality of the pre-analytical phase.

RESUMO

Introdução: *A fase pré-analítica abrange os procedimentos antes da execução dos testes laboratoriais, sendo eles a requisição, o cadastro de clientes e exames, a coleta e o transporte de amostras. Essa fase envolve diferentes profissionais e é responsável pela maioria dos erros de laboratório.* ***Objetivo:*** *Analisar a fase pré-analítica de um laboratório público por meio de indicadores da qualidade (IQ).* ***Método:*** *As não conformidades (NC) nas requisições e no cadastro dos clientes e dos exames foram avaliadas durante o processo de checagem. Foi aplicado um questionário para avaliar o atendimento e a satisfação dos clientes do laboratório. Os IQ foram calculados considerando o número de NC nos processos em relação ao total de oportunidades, comparando-os com as especificações encontradas na literatura e avaliando-os pela métrica Sigma.* ***Resultados:*** *A fase pré-analítica foi avaliada por 34 IQ. Desses, 18 apresentaram Sigma menor que 3,0; seis, entre 3,0 e 4,0; seis, acima de 4,0; e quatro, Sigma 6,0. O preenchimento das requisições apresentou pior desempenho do que o processo de cadastro dos exames. Em relação às três etapas da fase pré-analítica avaliadas, a que apresentou pior desempenho foi o agendamento, seguido do atendimento na recepção e da coleta.* ***Conclusão:*** *A avaliação dos IQ permitiu ordenar as melhorias que devem ser priorizadas no laboratório. A métrica Sigma foi útil para avaliar IQ, considerados importantes para o laboratório, para os quais não há especificações publicadas. O questionário de avaliação do atendimento e da satisfação do cliente não se mostrou uma ferramenta confiável para avaliar a qualidade da fase pré-analítica.*

Unitermos: *gestão em saúde; gestão de qualidade; serviços laboratoriais de saúde pública; laboratórios; indicadores; qualidade total.*

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