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Analysis of the frequency of biological sample recollections as quality indicators in a clinical laboratory of Distrito Federal, Brazil

Análise da frequência de recoletas de amostras biológicas como indicadores de qualidade em um laboratório de análises clínicas do Distrito Federal, Brasil

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ABSTRACT

Introduction: Clinical laboratory results influence more than 60% of medical decisions, impacting on disease prevention, diagnosis, and treatment. The use of quality indicators (QIs) is fundamental for quality assurance, once it allows monitoring the process and directs the taking of corrective actions. **Objective:** Classify the biological sample recollection requests for QIs identification in a clinical laboratory of Distrito Federal, Brazil. **Material and methods:** Data about the requests made in the biennium 2013-2014 were gathered and analyzed. **Results and discussion:** Among the 304,361 samples received, 1,914 (0.62%) had a request for recollection made in accordance with laboratory criteria. Most orders originated in the pre-analytical phase (57.7%). The most frequent reason for sample rejection was result confirmation (40.7%), followed by insufficient sample (21.9%), coagulated sample (18.1%) and hemolyzed sample (11, 9%). The hematology sector was responsible for most recollection requests (43.6%), followed by the biochemistry (29%) and the immunology (25.7%) ones. The laboratory emergency department accounted for only 0.1%. Orders were mostly placed by the outpatient clinic (40.7%), emergency (30.4%), and internal medicine (12.4%) departments. The percentage of orders is low, but does not exclude the need to reach lower rates. Underreporting was detected in the emergency sector, which indicates need for improvement in information registration. **Conclusion:** The numbers mentioned were selected as IQs for the pre-analytical phase, serving as guidelines for future actions taken by the team.

Key words: analytical quality control; quality improvement; quality management.

INTRODUCTION

The possibility of error occurrence exists in any area of service delivery. However, when it comes to the health sector, consequences can reach huge proportions. Incorrect laboratory results, for example, may cause harm to patients' health and generate additional costs to the institution. Identification of error sources is, therefore, necessary for the excellence of results and to ensure quality of the services rendered[1].

The tasks carried out at a clinical laboratory are included in a dynamic process that begins with specimen collection and progresses to reporting of test results. The total testing process (TTP) is divided into three phases: pre-analytical, analytical, and post-analytical[2]. Briefly, the pre-analytical phase begins outside the laboratory, with the physician selecting and ordering the test, and goes on to sample collection and preparation for analysis. The analytical phase comprises a set of operations used in the conduction of tests according to a certain method. The post-analytical phase encompasses the obtainment of valid test results and the report release, for interpretation by the clinician[3]. Important studies demonstrate that pre- and post-analytical phases are more prone to error than the analytical one. They conclude that TTP evaluation is the best form to reduce laboratory errors[4, 5].

The assessment of health services can be done by means of indicators, which are numerical measurements of qualitative or quantitative errors associated with an event, process or result in relation to its total number[6]. Classifying errors according to the frequency they occur is a valuable measure. It helps identify

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priorities for the taking of corrective and preventive actions, so ensuring quality improvement[7].

The clinical laboratory currently studied is a support unit of the university hospital providing care to the population of Distrito Federal (DF) by means of the Unified Health System (SUS). Depending on the type of test ordered, samples are analyzed in the sectors of biochemistry, emergency, immunology, hematology or hormones. Just the hospital's own demands are satisfied. The criteria for ordering sample recollection adopted by the laboratory were classified to identify the quality indicators (QIs) for the TTP.

OBJECTIVE

The objective of this study was to classify orders for blood specimen recollection in order to identify QIs for a clinical laboratory in DF.

MATERIAL AND METHODS

Data collection

For the conduction of this study, secondary data were retrieved from the laboratory databank on recollection orders made between January 2013 and December 2014. The number of analyzed samples was 304,361, and the data supplied as reports were transferred to a Microsoft Excel spreadsheet version 14.5.0.

The recollection order index was calculated for the biennium. We also investigated the distribution of these orders as to year, patients' gender (male/female), age group, hospital area from where the requests were placed, and the reasons for recollection. The age group was divided into population groups, according to a definition by the Ministry of Health[8]. For phase classification, reasons were divided based on TTP.

Data analysis

For frequency assessment, percentages were calculated. The variables with the highest frequencies were selected and investigated as to the distribution of reasons for recollection orders.

RESULTS

In the period between January 2013 and December 2014, 304,361 specimens were registered in the sectors of biochemistry, emergency, immunology, hematology, and hormones. Among them, 1,914 had a recollection order based on a criterion employed by the laboratory, representing an index of 0.62% for the studied period.

The distribution of recollection orders according to the considered variables can be seen in **Table 1**.

TABLE 1 – Distribution of recollection orders according to the considered variables

		n	%
Year	2013	1,104	57.7
	2014	810	42.3
Reason	**Pre-analytical phase**		
	Clotted sample	346	18.1
	Sample collected in inadequate tube	15	0.8
	Contaminated sample	7	0.4
	Hemolized sample	228	11.9
	Insufficient sample	420	21.9
	Sample not found	86	4.5
	Registry error	2	0.1
	Analytical phase		
	Lack of reagent	110	5.7
	Post-analytical phase		
	Result confirmation	700	36.6
Sex	Female	1,066	55.7
	Male	848	44.3
Age group	Child	336	17.6
	Teenager	99	5.2
	Adult	984	51.4
	Elderly	495	25.9
Laboratory sector	Biochemistry	556	29
	Emergency	2	0.1
	Hematology	835	43.6
	Hormones	29	1.5
	Immunology	492	25.7
Origin of request	Outpatient department	779	40.7
	Nursery	9	0.5
	Bronchoscopy	1	0.1
	Pediatric surgery	4	0.2
	Surgery department	33	1.7
	Internal medicine	238	12.4
	Adult ER	49	2.6
	Pediatric ER	19	1
	Dermatology	1	0.1
	Emergency department	581	30.4
	Hemodialysis	24	1.3
	Maternity ward	20	1
	Labor medicine	5	0.3
	Outpatient pediatric clinic	73	3.8
	Pediatric clinic	49	2.6
	Chemotherapy	1	0.1
	Transplantation	21	1.1
	Neonatal ICU	7	0.4

ER: emergency room; ICU: intensive care unit.

Recollection orders decreased in 2014. The pre-analytical step represented most of the orders. The main reasons for recollection were result confirmation, insufficient sample, coagulated sample, and hemolyzed sample.

Regarding gender, orders are equally distributed between both sexes. Observing the distribution between age groups, most orders were placed for adults, elderly people and children.

Concerning the laboratory sector and the origin of the request, most request frequencies are distributed among the sectors of hematology, biochemistry, and immunology, coming from the outpatient clinic, emergency, and internal medicine departments.

The most frequent variables previously cited were investigated as to the reasons for the recollection order. According to sex, the most common reason was result confirmation (39% for women, 34% for men), followed by insufficient sample (20.3% for women, 23.9% for men), and clotted sample (17.5% for women, 18.7% for men). The other six reasons amount to less than 20% for both sexes (**Table 2**).

According to age group, the main reason for recollection in children was insufficient sample (40.77%). Result confirmation represented the highest percentage of reasons for adults (46.84%) and the elderly (31.31%).

The main reasons for recollection ordered by the hematology sector was clotted sample (39.8%), and insufficient sample (3%); for biochemistry, hemolyzed sample (33.9%), insufficient sample (18.5%), and lack of reagent (11.1%); for immunology, result confirmation (90%).

Samples from the outpatient department had as the main reason result confirmation (53%). For the other departments, such as emergency, insufficient sample represented 31.3% of reasons; and clotted sample, 27.3%. In internal medicine, the reason result confirmation had a 41% index, and insufficient sample, a 25.2%.

DISCUSSION

The rate of repeat collections is very close to that of other studies reporting 0.54% and 0.57%[9, 10]. They are considered low when compared with the 2.7% of a recent study, in which 55.8% of rejections were caused by sample clotting[11]. There are no acceptability limits described in the literature[6], but, in the current study, the decreased number of recollection orders in 2014, when compared to 2013, may be explained by the use of automated equipment (BC-ROBO-888 Techno Medica®), which was installed in the laboratory in 2014. This instrument performs specimen labeling in the blood collection room and reinforces data observed during the automated pre-analytical processes using barcodes, what drastically reduces errors associated with this phase[12].

Concerning the distribution of recollection orders according to the TTP phase, the result of this study reflects the reality of clinical laboratories, regardless of its peculiarities. A recent literature review demonstrated that the pre-analytical phase is the main error source, and may be responsible for values between 53% and 75% of the total documented errors. When assessing the financial

TABLE 2 – Distribution of reasons for repeat collections regarding sex, age group, laboratory sector, and origin of request that showed the highest frequency rates

		Pre-analytical												Analytical		Post-analytical			
		Clotted sample		Contaminated sample		Hemolyzed sample		Insufficient sample		Sample not found		Collection in an inadequate tube		Registry error		Lack of reagent		Result confirmation		Total	
		n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Sex	Female	187	17.5	4	0.3	123	11.5	217	20.3	44	4.1	9	0.8	2	0.1	65	6	415	39	1,066	100
	Male	159	18.7	3	0.3	105	12.3	203	23.9	42	4.9	6	0.7	0	0	45	5.3	285	34	848	100
Age group	Children	84	25	1	0.29	41	12.2	137	40.77	2	0.59	2	0.59	0	0	21	6.25	48	14.28	336	100
	Adult	133	13.51	6	0.6	96	9.75	156	15.85	63	6.4	8	0.81	1	0.1	60	6.09	461	46.84	984	100
	Elderly	119	24.04	0	0	80	16.16	98	19.79	16	3.23	3	0.6	1	0.2	23	4.64	155	31.31	495	100
Laboratory sector	Hematology	333	39.8	3	0.3	34	4	276	33	43	5.1	5	0.5	0	0	38	4.5	103	12	835	100
	Biochemistry	11	1.9	3	0.5	189	33.9	103	18.5	33	5.9	7	1.2	1	0.1	62	11.1	147	26	556	100
	Immunology	2	0.4	1	0.2	3	0.6	31	6.38	3	0.6	0	0	1	0.2	8	1.6	443	90	492	100
Origin of request	Outpatient department	109	13.9	2	0.2	63	8	102	13	55	7	9	1.1	1	0.1	22	2.8	416	53	779	100
	Emergency department	159	27.3	4	0.6	102	17.5	182	31.3	10	1.7	1	0.1	0	0	56	9.6	67	12	581	100
	Internal medicine	25	10.5	1	0.4	32	13.4	60	25.2	9	3.7	1	0.4	0	0	13	5.4	97	41	238	100

impact, the study revealed that errors in the pre-analytical phase may produce up to 1.2% of the total costs of a hospital[13].

The most frequent causes of pre-analytical errors described in the literature are incorrect identification of the patient (49.3%), hemolyzed sample (19.5%), clotted sample (14.2%), and insufficient volume (13.7%)[14]. Except for the first cause, not analyzed in this study because it is not listed in inclusion criteria, all the others reflected what happened in the DF laboratory. This allows concluding that regardless of the differences between laboratories, the main reported problems are similar.

Each of these three variables has great potential to negatively influence the quality of laboratory results. Hemolyzed samples may be consequence of shaking the tubes during transport, storage at incorrect temperatures or for long periods, or even by the use of narrow bore needles[15]. Improper mixing of tubes may result in sample clotting; besides, clots may clog equipment and analysis instruments[16]. Collection of an inadequate volume may also cause blood clotting. For the anticoagulant to perform the expected action, it is necessary that the proportion of blood/anticoagulant is according to the tube manufacturers' recommendations. Moreover, insufficient sample volumes may preclude the conduction of all the ordered tests[13].

As could be observed, the criteria adopted by the laboratory do not consider the steps of selection, exam order and patient preparation. For some authors, these steps are not part of a pre-analytical phase, but of a "pre-pre-analytical" one[17]. A study carried out in the USA investigated the reasons for sample rejection in steps prior to collection. Based on a questionnaire answered by patients, the main reasons were observed to be inadequate fasting (32.2%), and test order missing information (22.5%). Specimens difficult to draw, patients leaving collection area before collection, and other reasons represent the remaining 45.3%[18]. It was possible to note that the reasons do not comprise all the steps of the pre-analytical phase. Specimens were not reported as to barcodes (absent or illegible), adequacy of the collection tube, time between collection and analysis, preservation and transport conditions. A detailed control of the sample pathway, including the involved variables, will provide precise failure detection[2, 11].

Two steps of the post-analytical phase were not considered: result interpretation and appropriate action. Such steps are sometimes classified as parts of the "post-post-analytical" phase[19]. The non-adoption of these steps in the rejection criteria of the studied laboratory (reasons for recollection) is understood by the fact they are not part of routine of laboratory professionals, but of other hospital professionals, such as doctors and nurses.

The analysis of the other variables in relation to their recollection reasons allowed observing that distribution between sexes was homogeneous, and supposing that the high frequency of insufficient samples in children may be related to difficult drawing and/or low cooperation of pediatric patients.

Concerning sectors, hematology and biochemistry have, in the studied laboratory, the highest load of tests to be analyzed. This could be a hypothesis to explain the high frequency of recollection orders. Nevertheless, when analyzing the distribution of orders according to reasons, one notices that in the hematology sector the most common cause was clotted sample, and in the biochemistry, hemolized sample; both reasons are part of the pre-analytical phase, common to both sectors. These notified errors may be avoided by corrective actions in the phase before analysis, that is, at the phlebotomy moment.

The immunology sector, on the other hand, has as its main reason the result confirmation, which is part of the post-analytical phase. This can be explained by the requirements of a Ministry of Health directive regarding the procedures for detection of anti-human immunodeficiency virus (HIV) antibodies in subjects aged over 2 years. According to the flow chart of the directive annex II, up to four samples may be collected so that the report can be released[20].

The low frequency of recollection orders in the emergency sector of the laboratory deserves special attention. Given the routine speed and the adversities that interfere with sample collection of patients from this sector, underreporting of recollection orders is believed to have occurred. A study investigating just the indices of sample rejection from the emergency sector pointed to an index of recollection order of 3.19%, and hemolysis of 65.39% as main reason[21]. The only two reports observed in the emergency sector of the DF laboratory had as the main reason "insufficient sample".

Unlike what was observed in the DF laboratory, in a study carried out in India, the outpatient department had the lowest percentage of errors in relation to other sectors of the hospital. It is relevant to observe that such a study took into consideration just the pre-analytical phase. When considering just this phase, the laboratory of the current study also presented low error rates, and this may be the result of the automated collection of outpatient specimens[22].

CONCLUSION

The recent costs in health services, along with the necessity of ensuring citizens' constitutional rights, are a challenge

for managers. In the case of clinical analysis, the use of QIs is fundamental. They are a managerial tool whose aim is the continuous improvement of all the analyzed steps. Those pointed out in this study will be able to help the laboratory staff in corrective measures, monitoring and improvement of the process. Even so, there is no quality improvement without cooperation from the staff, especially in the steps of the pre-analytical phase, which involve a great number of professionals. Promoting change demands effort and motivation from the involved ones.

RESUMO

Introdução: *Os resultados dos testes laboratoriais influenciam mais de 60% das decisões médicas, impactando na prevenção, no diagnóstico e no tratamento de doenças. O uso de indicadores de qualidade (IQs) é fundamental para a garantia da qualidade, pois permite monitoramento do processo e direciona a implementação de ações corretivas.* ***Objetivo:*** *Classificar pedidos de recoleta de amostras biológicas para identificação de IQs em um laboratório de análises clínicas do Distrito Federal.* ***Material e métodos:*** *Foram coletados e analisados dados acerca de pedidos de recoleta feitos no biênio 2013-2014.* ***Resultados e discussão:*** *Das 304.361 amostras registradas, 1.914 (0,62%) tiveram solicitação de recoleta de acordo com os critérios do laboratório. A maioria dos pedidos teve origem na fase pré-analítica (57,7%). O motivo de rejeição mais frequente foi confirmação de resultado (40,7%), seguido por amostra insuficiente (21,9%), amostra coagulada (18,1%) e amostra hemolisada (11,9%). O setor de hematologia foi o responsável pelo maior número de pedidos de recoletas (43,6%), seguido pelo de bioquímica (29%) e o de imunologia (25,7%). O setor de emergência do laboratório representou apenas 0,1%. Quanto à procedência, a maioria das recoletas foi solicitada pelo ambulatório (40,7%), pelo pronto-socorro (30,4%) e pela clínica médica (12,4%). A porcentagem de pedidos de recoleta é baixa, porém não exclui a necessidade de busca por menores índices. Sugere-se que tenha ocorrido subnotificação no setor de emergência do laboratório, o que aponta necessidade de melhoria no registro de informações.* ***Conclusão:*** *Os números destacados foram selecionados como IQs para a fase pré-analítica, servindo como norteadores para as futuras ações corretivas efetuadas pela equipe.*

Unitermos: *controle analítico de qualidade; melhoria de qualidade; gestão de qualidade.*

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