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Repetition of biochemistry tests in a laboratory of public hospital in southwest of Bahia, Brazil, and associated cost

Repetição de exames de bioquímica no laboratório de um hospital público do sudoeste da Bahia, Brasil, e custo associado

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ABSTRACT

Introduction: Test repetitions are an age-old practice common to clinical laboratories used primarily for confirmation of results. However, knowing the history of patients, the repetitions become avoidable. They impair the time to release results, increase input consumption, and cost of services. **Objectives:** to evaluate the difference between the results of the laboratory tests repetitions and the expenditure generated by each additional test. **Materials and methods:** Data from repeated tests from September to November 2015 were used in the laboratory of a public hospital in the state of Bahia, Brazil. The classification of necessary or unnecessary repetition of these tests was performed according to international criteria, with subsequent cost estimation. **Results:** A total of 1,350 samples were analyzed, with a total of 1,429 repetitions; 1,162 (81.31%) were classified as unnecessary repetitions, generating an additional cost of R$ 1,198.00 to the service. The repetitions that made up the study generated a cost of R$ 1,488.61, the expense should be only R$ 290.61, an increase of 80.47%, an estimated annual impact of R$ 4,792.00. In addition to the impact on cost, the impact on turnaround time was evident, which consequently affects the speed in patient care. **Conclusion:** It was observed that most of the repetitions performed in the laboratory were classified as unnecessary when evaluated by the criteria used. These repetitions generated a potentially avoidable laboratory cost increase, negatively impacting the time to release the results.

Key words: medical laboratory science; public hospitals; cost control; hospital costs; laboratory tests.

INTRODUCTION

Laboratory medicine encompasses the selection, provision and interpretation of laboratory tests for diagnostic purposes[1]. Over the years, the methods of analysis have evolved. Currently, laboratories are in the age of total laboratory automation (TLA)[2], however, even though we are in that era, this total automation is restricted to the large centers, but technological development in clinical laboratories, generally, is notorious, and changes in the work process, which enables to perform multiple biochemical analysis[3] – besides favoring the repetition of any analysis, when necessary – as well as the development of computerized systems, facilitating service provision and allowing the use of mechanisms to reduce waste and increase efficiency[4] without losses in meeting the demands of health services.

A practice still very common in clinical laboratories is the repetition of exams in the same sample. In the laboratories' early days, this practice was appropriate because instrumentation was not so accurate compared to current instrumentation. Moreover, there was a routine of repeating tests if the results obtained were outside some set threshold value or other especially established rules[5, 6]. With current technological developments, accuracy in analysis has increased greatly, making today's equipment much more accurate than those of the last century[5]. Even so, repetition practice continues and, invariably, increases operating costs. Onyenekwu *et al*. (2014)[7] estimated an additional cost of 2.8%

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with duplicates of only four analytes, burdening services and sometimes causing a reduction in the offer of tests, especially in public services.

In the current scenario of more accurate instrumentation, many laboratories have rules for automatic repetitions in the same sample for certain situations: clinically significant result, critical alert value, test outside the linearity of the method or result that presents alterations beyond that established internally in a short period of time for a patient (delta-check)[8], among other parameters commonly defined by the team which do not always take into account technical and scientific parameters.

Following this scenario, the ideal is to define criteria for these replications, considering the analysis itself (with the aforementioned repetition criteria), in addition to patient's condition, so that the decision to repeat a certain exam will not be strictly dependent by the analyst reponsible for the biochemical analysis, since he/she usually does not know the clinical state of the patient, and does not participate in the care process.

In such context, unnecessary repetition of an examination can be avoided as long as the analyst considers the patient's medical history, procedures performed, water and nutritional replacements, medications used, among other parameters that may be used as a basis for understanding the tests results, therefore, knowing the patient is crucial in deciding whether or not to repeat a particular exam. Most of this information can be obtained at the hospital through the medical record, or by collecting information with the patient and the care team.

The repetition of exams without criteria, whether they are clinical or technical, can still hinder the turnaround time, which has several definitions, but in summary is the amount of time to release a test result. It is considered as one of the signs of good or bad quality of a laboratory of clinical analysis[9]. For the professionals in the hospital laboratories, a total attendance time (TAT) of up to 60 minutes is considered ideal[10]. Regarding a hospital, the ideal TAT is that the smallest as possible; however, with the need for repetitions, the increase in TAT is very likely and possibly may be harmful to the patient since the clinical managements are also based on the results of laboratory tests.

The repetitions of duplicate, triplicate exams, and so on, do not only promote an increase in TAT, the additional analysis consume reagents and analyst time, which consequently increases the cost with laboratory tests[11], regardless of whether the service is public or private. It is also worth noting that it can generate an underestimation of the actual consumption of tests by the laboratory, since many computerized systems only provide the number of tests already reported by the person in charge for the analysis, not informing the number of additional analysis, that is, the control of consumption will most likely be inaccurate. Thus, using the number of tests performed as a basis for the acquisition of tests, there will be an underestimation of the actual expenditure with inputs, which may affect scarce resources.

Considering what was addressed and taking into account the rationalization of the use of resources and the best service with most appropriate TAT for patient care, the present study aimed to evaluate the difference between the results of laboratory tests and the expenditure generated for each additional test.

MATERIALS AND METHODS

The present study presents a cross-sectional design in which the results of repeated biochemical tests were collected from September to November 2015 in the laboratory of a general hospital in the southwest of Bahia, a reference hospital for urgency and trauma, with a level of attention of medium and high complexity (polytrauma, surgeries, coronary artery disease, among others)[12]. This hospital unit has two adult intensive care units (ICUs), one pediatric, one neonatal, one unit for critical patients, surgical center, pediatric wards, medical clinic and surgical clinic, as well as urgency and emergency care; it is provided with a medium-sized laboratory.

The laboratory assists an average of 83 patients/day and, in the period selected for the study 36,608 tests were registered in the report management system – Complab®, for the biochemistry, hematology, immunology, parasitology and urinalysis sectors. For this work, the biochemistry repetitions were selected, since it is a sector where most repetitions occur. At the time of the study, the biochemical sector had two Miura® equipment (ISE S.r.l®) with capacity to perform up to 500 tests/hour, with selective ion module integrated to the equipment. It is operated by a biochemical pharmacist in all processes, from the validation (internal control and calibrations), through the execution and release of the reports of the exams.

The tests chosen to constitute the sample plan were: uric acid, albumin, amylase, aspartate aminotransferase, aspartate alanine transferase, direct bilirubin, total bilirubin, calcium, creatine kinase MB fraction, total creatine kinase, chloride, creatinine, alkaline phosphatase, phosphate, glucose, lactate, lactate dehydrogenase, magnesium, potassium, C-reactive protein (CRP), total protein, sodium, urea and γ-glutamyl transferase.

Total cholesterol and its fractions, besides iron, were not selected because they had low volume of tests performed.

All the results of repeated exams were included in the same sample, regardless of the repetition criterion adopted. The criteria used for exclusion were: 1) analysis in which there was uncertainty regarding the fact that the duplicate actually was from the same sample (e.g., re-collections); and 2) analysis with dilution factor different from the first one adopted.

The data were collected through search from Miura® software (ISE S.r.l®), selecting only the exams with registered repetitions. The data obtained were allocated in spreadsheets in Microsoft Excel Professional Plus 2016®. The variation between the test result and the repetition was established through the following categories of analysis: mean, standard deviation, coefficient of variation, absolute difference in module between the highest and the lowest repetition value and percentage change between the first result and the repetitions.

The results of the replicates were classified as acceptable or not, using the criteria of the table of the College of American Pathologists/Clinical Laboratory Improvement Amendments (CAP/CLIA) allowable errors and, for the missing cases, we selected the criteria of other institutions using the allowable errors [2014 update of the Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) table of Desirable Quality Specifications based on Biological Variation (BV), The Royal College of Pathologists of Australasia and the Australasian Clinical Biochemist association Quality Assurance Program (RCPA), Wisconsin State Laboratory of Hygiene (WSLH), American Association of Bioanalysts (AAB)][13]; for CRP, the validity of the result was determined considering a coefficient of variation of 10% (**Table 1**).

The classification was performed by two evaluators (biochemical pharmacists), first by one; and then, the second would check the validity of the classification. The data allocated in the spreadsheets in Microsoft Excel Professional Plus 2016® was divided by analytes and each criterion revised separately.

After sorting the repetition between acceptable or not, the cost estimate of the reagents for dosages was calculated. With the test values of each analyte from the bidding used to acquire the reagents of the biochemistry, obtained through the Hospital's Permanent Bidding Commission [Comissão Permanente de Licitações (COPEL)], values in Brazilian Real were multiplied by test by the repetitions considered unnecessary (acceptable tests), considering the criteria indicated.

TABLE 1 – Criteria used to validate repetitions

Test	Acceptable error	Criterion
Uric acid	± 17%	CLIA
ALT	± 20%	CLIA
Albumin	± 10%	CLIA
Amylase	± 30%	CLIA
AST	± 20%	CLIA
Direct bilirubin	0.4 mg/dl or ± 20% (the highest)	CAP
Total bilirubin	0.4 mg/dl or ± 20% (the highest)	CLIA
Calcium	± 1.0 mg/dl	CLIA
Chloride	± 5%	CLIA
CK-MB	6 U/l or 15%	RCPA***
CK-Total	± 30%	CLIA
Creatinine	± 0.3 mg/dl or ± 15% (the highest)	CLIA
Alkaline phosphatase	± 30%	CLIA
Phosphate	0.4 mg/dl or 15%	AAB
Glucose	± 6 mg/dl or ± 10%	CLIA
Lactate	0.2 mmol/l or 2 SD**	WLSH
LDH	± 30%	CLIA
Magnesium	± 25%	CLIA
Potassium	0.5 mmol/l	CLIA
CRP	CV 10%	Criterion adopted*
Total Protein	± 10%	CLIA
Sodium	± 4 mmol/l	CLIA
Urea	± 2 mg/l or ± 9% (the highest)	CLIA
γ-glutamyl transferase	22%	BV

: Established in light of the fact that the limit provided by BV is 56.6%, it tolerates large differences; **: SD were not used because this was a retrospective study, it would not be possible to analyze their value for the controls of such analytes at the time of the study; *: CLIA criteria can not be used since the control standard deviations at the time of the study were not available.*

ALT: alanine aminotransferase; AST: aspartate aminotransferase; CK-MB: creatine kinase fraction MB; SD: standard deviation; LDH: lactate dehydrogenase; CRP: C-reactive protein; CLIA: Clinical Laboratory Improvement Amendments; CAP: College of American Pathologists; RCPA: The Royal College of Pathologists of Australasia and the Australasian Clinical Biochemist Association Quality Assurance Program; AAB: American Association of Bioanalysts; SEQC: 2014 update of the Spanish Society of Clinical Chemistry and Molecular Pathology; BV: biological variation; WSLH: Wisconsin State Laboratory of Hygiene.

The study was approved by the Research Ethics Committee of the Multidisciplinary Institute of Health of the Universidade Federal da Bahia (UFBA) under the process number 54407316.0.0000.5556.

RESULTS

The study is composed of 1,350 samples, of which 1,429 repetitions were recorded, as shown in **Table 2**. After analysis of the data, it was found that from the 1,429 repetitions performed, 1,162 (81.31%) were classified as unnecessary, following the CAP/CLIA criteria or the AAB, BV, RCPA, WLSH criteria (Table 1).

TABLE 2 – Tests and repetitions selected from September to November 2015

Laboratory test	Total tests	Samples	Repetitions	Unnecessary repetitions (%)
Uric acid	140	7	7	7 (100)
ALT	1401	50	39	39 (78)
Albumin	107	23	23	23 (100)
Amylase	361	11	9	9 (81.81)
AST	1413	57	53	53 (92.98)
Direct bilirubin	557	8	8	8 (100)
Total bilirubin	557	9	9	9 (100)
Calcium	2574	52	34	34 (65.38)
CK-MB	82	4	4	4 (100)
CK-total*	617	13	9	9 (69.23)
Chloride	636	29	24	24 (82.75)
Creatinine	4508	199	175	175 (87.94)
Alkaline phosphatase	384	6	4	4 (66.67)
Phosphate	291	13	7	7 (53.85)
Glucose	1298	91	77	77 (84.61)
Lactate	666	29	20	20 (68.97)
LDH*	189	5	3	3 (60)
Magnesium	2450	40	30	30 (75)
Potassium	4152	266	235	235 (88.35)
CRP	3538	155	130	130 (83.87)
Total Protein	338	20	17	17 (85)
Sodium	4063	129	76	76 (58.91)
Urea*	4755	203	161	161 (79.31)
γ-glutamyl transferase	506	10	8	8 (80)

**: Numerous repetitions excluded from the study because they had different dilution factors between analyzes.*
ALT: alanine aminotransferase; AST: aspartate aminotransferase; CK-MB: creatine kinase MB fraction; LDH: lactate dehydrogenase; CRP: C-reactive protein.

TABLE 3 – Cost-of-service based on reagent prices with epetitions performed from September to November 2015

Laboratory test	Repetitions	Unnecessary repetitions	Cost with repetitions*	Avoidable cost*
Uric acid	7	7	R$ 5.53	R$ 5.53
ALT	50	39	R$ 39.50	R$ 30.81
Albumin	23	23	R$ 15.87	R$ 15.87
Amylase	11	9	R$ 8.10	R$ 6.63
AST	57	53	R$ 39.33	R$ 36.57
Direct bilirubin	8	8	R$ 6.56	R$ 6.56
Total bilirubin	9	9	R$ 7.38	R$ 7.38
Calcium	52	34	R$ 42.64	R$ 27.88
CK-MB	4	4	R$ 4.36	R$ 4.36
CK-total	13	9	R$ 18.07	R$ 12.51
Chloride	29	24	R$ 34.80	R$ 28.80
Creatinine	199	175	R$ 35.82	R$ 31.50
Alkaline phosphatase	6	4	R$ 4.74	R$ 3.16
Phosphate	13	7	R$ 8.58	R$ 4.62
Glucose	91	77	R$ 45.50	R$ 38.50
Lactate	29	20	R$ 49.30	R$ 34.00
LDH	5	3	R$ 3.85	R$ 2.31
Magnesium	40	30	R$ 56.80	R$ 42.60
Potassium	266	235	R$ 319.20	R$ 282.00
CRP	155	130	R$ 401.45	R$ 336.70
Total Protein	20	17	R$ 10.00	R$ 8.50
Sodium	129	76	R$ 154.80	R$ 91.20
Urea	203	161	R$ 164.43	R$ 130.41
γ-glutamil transferase	10	8	R$ 12.00	R$ 9.60
		Total	R$ 1,488.61	R$ 1,198.00

**: Based on the values applied to the bidding in force in 2015.*
ALT: alanine aminotransferase; AST: aspartate aminotransferase; CK-MB: creatine kinase MB fraction; LDH: lactate dehydrogenase; CRP: C-reactive protein.

We highlight the following analytes that had more than 80% of the repetitions considered unnecessary: uric acid – seven unnecessary repetitions (100%); albumin – 23 (100%); amylase – nine (81.81%); aspartate aminotransferase – 53 (92.98%); direct bilirubin – eight (100%); total bilirubin – nine (100%); creatine kinase MB fraction – four (100%); chloride – 24 (82.75%); creatinine – 175 (87.93%); glucose – 77 (84.61%); potassium – 235 (88.34%); CRP – 130 (83.87%); total protein – 17 (85%); γ-glutamyl transferase – eight (80%). Table 2 shows all the tests and repetitions.

It was verified a total cost of R$ 1,488.61 for the repetitions in the study period. From this amount, R$ 1,198.00 was considered avoidable because it represents repetitions considered unnecessary. Thus, only R$ 290.61 of expenses were justified. It is emphasized that this is a cut-off of only one sector and many repetitions could not be evaluated. The reagent and avoidable costs of each evaluated analyte are listed in **Table 3**.

DISCUSSION

The repetition of exams, especially those with critical results, has been discussed by some authors from different countries[5,6,11,14]. In these studies, there is agreement that the repetition of exams does not increase the accuracy of the results and only tends to add cost to the service.

Based on this assumption, however, without limiting to critical values, the present study analyzed the variations between tests and their repetitions. The service operates on duty regime, with an analyst responsible for the biochemical analysis every day of the week (biochemical pharmacist), there is no determination or criteria to repeat an exam, and therefore, each pharmacist on duty defines how to conduct the sector.

The majority of samples and/or repetitions excluded were due to the need for automatic dilutions performed by the equipment, dilutions required when a particular test exceeds the linearity of

the reaction due to the high concentration of the analyte[15]. The other exclusions occurred when there were differences of more than two hours between the first analysis and the repetition, or a sample re-registration, so that it would be impossible to define whether a new sample had been requested.

To determine the validity of the 1,429 repetitions, the criteria already mentioned were used. The CRP was the only exam in which it was decided to use the coefficient of variation of 10% as the limit to decide whether the sample would be acceptable or not. This choice was due to the fact that the value adopted as a limit for BV was 56.6%, a limit very permissive to differences in analysis.

After repetitions analysis, 1,162 of them, corresponding 81.31%, were considered unnecessary. The results of these repetitions, when analyzed in the light of the results of the first analysis, did not violate the established criteria: AAB, BV, CAP, CLIA, RCPA[13] and CRP: coefficient of variation (CV) of 10%.

Although 81.31% of repetitions, it is still below that found by similar studies[5, 6, 11, 14]. Chima *et al*. (2009)[5] found 97.6% of the repeated results that agreed with the initial values. Deetz *et al*. (2012)[6] did an analysis with 25,553 repetitions, only 668 were in disagreement with the CAP/CLIA criteria (2.61%), thus 97.39% of unnecessary repetitions. Motie *et al*. (2015)[14] found 98.02% of unnecessary repetitions. Toll *et al*. (2011)[11] reported that between 0% and 2.2% of the analysis were outside the established limits, therefore approximately 97.8% of the repetitions were unnecessary, in agreement with the findings of the other studies.

The use of the other sectors of laboratory analysis besides biochemistry, may justify the difference between the results of the present study in the light of the studies mentioned above. Studies have included hematology and coagulation, which use samples with anticoagulants[5, 11, 14]. In these cases, the tests have less aggregate error in the analysis and their repetitions are usually unnecessary. There are samples that do not require the separation of serum (reducing the chance of repeating analysis due to the presence of fibrin), and they also are analysis that require less pipetting by the equipment, less chance of contamination of reagents, inadequate functioning of the mechanical arms, probes and lamps[16].

For the electrolytes, it was observed that from the 89 repetitions considered necessary (chloride: five, potassium: 31, sodium: 53), the Ion-Selective Electrode module, which is integrated to the equipment in use in the period, presented many module error flags, besides being something common in the daily routine of the laboratory in study, mainly due to the constant blockages with fibrin, which could have directly impacted in the high number of repetitions invalid for these exams.

Although the number of repetitions found in the present study is lower than expected according to other authors[5, 6, 11, 14], most of the repetitions would be avoidable. The selected repetitions led to an increase in cost of service in the amount of R$ 1,488.61 in the three-month period. Considering that 81.31% are unnecessary, there is an avoidable expense of R$ 1,198.00, a small amount at first sight considering three months in the laboratory, but it is important to note that since it is a public laboratory, it is not uncommon that there will be a shortage of tests at some times of the year, especially during the transitions of the tendering contracts, which directly impacts the care of patients in the hospital, so any extra consumption of reagents should be well evaluated. Extrapolating the estimated cost for the three months of the study, in 12 months the estimated cost would be approximately R$ 4,792.00, a sufficient amount for the acquisition of 26,622 creatinine tests.

If the additional cost were considered only for repetitions with dilution [excluded from analysis by the large analytical difference, due to deviations from Beer's law[15]]: the creatine kinase was repeated 153 times in the period, 140 (91.50%) were performed with dilutions, an extra cost of R$ 194.60; the lactate dehydrogenase was repeated 75 times, 70 (92.10%) with dilutions, extra cost of R$ 53.90; the urea was repeated 374 times, 171 (45.72%) with dilutions, extra cost of R$ 138.51. The values of these repetitions were not considered for the study, but there is still an additional cost involved in such repetitions, so it is important to take some measures to mitigate these costs: 1) establishment of pre-dilutions prior to automatic analysis for such analytes; or 2) observation of previous results of hospitalized patients. Such measures could avoid an extra consumption of reagents and a reduction of R$ 387.01 in laboratory costs.

It was also estimated the extra cost related to the analyst's workforce. Considering a salary of R$ 994.07 (base salary) + R$ 2,232.33 (bonus) for 30 hours/week, then an additional hour of work would mean an additional cost of R$ 26.88, if we consider only one hour more per day; in one month would be R$ 806.40 additional pay. It should be noted that this estimation was not part of the present study. Other unmeasured costs, such as wear of equipment and equipment out of use for repair, can generate even greater impacts if there is a delay in patient care.

Another, no less important, impact generated by the repetition of tests is the increase in TAT[9], this study was not able to measure the impact on the time of release of the results due to non-computerization of the hospital, with no possibility to calculate the time between the examinations request until the arrival of this order to the laboratory, sample collection, analysis and release of results. However, it was possible to

observe that in some cases there was a difference of up to 4 hours between the first examination and the last examination. And, considering the precarious computerization, in which there is still a need to deliver the printed report to the open units, the results would only be delivered after the release of all the exams by the analysts. This fact has a greater impact on the TAT of the laboratory under study, negatively impacting patient care, especially because it is a reference hospital for urgency and trauma, however, the study did not intend to evaluate clinical impacts, since the purpose was to evaluate direct costs and within the laboratory environment.

Analyzing the limitations of the present study, such as retrospective data collection, analysis of the biochemical sector only and exclusion of a reasonable number of repetitions, it was still possible to notice results in the same direction of other studies of the same kind[5, 6, 11, 14], demonstrating that the routine of exams repetition was potentially avoidable. Chima *et al*. (2009)[5] point out that the control and quality assurance and good functions of the equipment make the repetitions of the tests become unnecessary. Good quality management is recommended, with internal and external controls, establishment of standards of conduct and implementation of standard operating procedure (SOP)[17], improvement of traceability of samples, constant maintenance of equipment, assuring that the results of tests are reliable, contributing for better performance of clinical conducts, resource savings and most appropriate runtime for the hospital reality.

CONCLUSION

In the evaluated period, it was observed that most of the repetitions performed in the laboratory under study were classified as unnecessary, when evaluated by the criteria used. These repetitions generated to the service a potentially avoidable increase in laboratory cost, besides other costs not evaluated in this study, negatively impacting the time to release the results

RESUMO

Introdução: *A repetição de exames é uma prática antiga comum aos laboratórios clínicos, usada basicamente para confirmação de resultados. No entanto, ao conhecer a história dos pacientes, as repetições tornam-se evitáveis. Elas prejudicam o tempo de liberação de resultados, aumentam consumo de insumos e geram custo aos serviços.* ***Objetivos:*** *Avaliar a diferença entre os resultados das repetições de exames laboratoriais e o dispêndio gerado por cada teste adicional.* ***Materiais e métodos:*** *Foram utilizados dados de exames repetidos de setembro a novembro de 2015 no laboratório de um hospital público do estado da Bahia, Brasil. Procedeu-se a classificação de repetição necessária ou desnecessária desses exames seguindo critérios internacionais, com posterior estimativa de custo.* ***Resultados:*** *Um total de 1.350 amostras foram analisadas, com 1.429 repetições ao todo; 1.162 (81,31%) foram classificadas como repetições desnecessárias, gerando um custo adicional ao serviço no valor de R$ 1.198,00. As repetições que compuseram o estudo geraram um custo de R$ 1.488,61, o gasto deveria ser de apenas R$ 290,61, ou seja, um acréscimo de 80,47%, um impacto anual estimado em R$ 4.792,00. Além do impacto no custo, ficou evidente o impacto no tempo de resposta, o que consequentemente afeta a celeridade na assistência aos pacientes.* ***Conclusão:*** *Observou-se que a maioria das repetições realizadas no laboratório foi classificada como desnecessária quando avaliada pelos critérios utilizados. Essas repetições geraram ao serviço um acréscimo de custo laboratorial potencialmente evitável, impactando negativamente no tempo para liberação dos resultados.*

Unitermos: *ciência de laboratório médico; hospitais públicos; controle de custos; custos hospitalares; testes laboratoriais.*

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