COMPARATIVE PROFILE OF BIOCHEMICAL DOSAGE OF QUALITY CONTROL ACCORDING TO TARGET AVERAGE OF IT'S VALUES, STANDARDIZING THE ANALITYCAL PROCESSES

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ABSTRACT

Given the requirement of customers, over the years clinical laboratories began to develop a continuous improvement of processes, thus improving the quality of the product offered, or exams for their clients or patients. With the evolution in the clinical set up internal controls, which comes with its reference results provided by the manufacturer, to measure the reliability of the equipment daily. And the external control that comes without results, serving to compare with results from other laboratories. Through these concepts the study was conducted in a laboratory of outsourced clinical analysis of a public hospital in São Paulo, who spends every year by the audit that analyzes and evaluates the causes of deficiencies. The study used daily data controls in biochemical equipment routine Cobas c 311, within one month totaling 58 analytes. It was noted considerable heterogeneity in the values obtained, the vast majority of the results were outside the average, with both low values as above average, but the same were within the reference values, so were accepted in the routine laboratory. The solution to certain problems it is up to the challenge managers to broaden their knowledge, engage and trained team of employees, so the quality can be improved to reduce costs and increase laboratory productivity.

Keywords: Biocheimal profile, dosage and quality control

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INTRODUCTION

Since last century, it's noticed a significant evolution in the concept of quality in the presence of the client's demands. In consequence, the continued improvement of the processes became a goal and conduct of all institution or organization. In the clinical laboratories the improvement of the quality of the offered product(result of the exams) and its control were the natural consequences of this process[1]. In the three last decades the systematic of internal control in Brazil evolved mainly regarding the materials which transformed from pool of patient in only level to steady commercial controls and in different levels normal and pathologic.

The process of repeated analysis of a steady control was described by Shewhart in 1931 and introduced in the clinical area in 1950 by Levey and Jennings. Only in 1977[2] Westgard started to publish articles about methods of data analysis, in 1981 he launched the concept of Multiple Rules, sonly adopted as world's pattern[3].

Associated to the internal control we also have the external control or proficiency trial as a effective tool to determine the performance of the analytic phase of the laboratory ensuring reliability to its results, these are evaluation of results obtained by the laboratory in the analysis of unknown materials that simulate patients[4].

Though, for the improvements succeed it's indispensable the control of these processes, being able to identify possible mistakes that can occur or already occurred. Furthermore the laboratory ought to be ready to avoid or minimize the consequences and the recurrences of the failures, performing a process called quality guarantee[1].

Each process has two basic components of variation: the Imprecision and the Inaccuracy. To evaluate the occurrence of these variations, the technical processes are monitored by the internal and external control of quality, evaluating the imprecision and the inaccuracy, its evaluation is realized in a independent way[6]. The guarantee of quality besides evaluating the controls also evaluate and monitor a wider band of factors that affect the quality, as the sample collection and the reporting of results[5].

In a laboratory of clinical analysis the guarantee of quality is reached having total control over all stages of the process, including the pre-analytic, analytic and pos-analytic stage, on the other hand this management covers the actions applied to product, direct and control this quality, including the determination of a politic and objectives of quality, using indicators and goals.

METHOD

The study was done in a laboratory of clinical analysis outsourced of a public hospital, its content was obtained by researches in the database PubMed/MEDLINE, Academic Google,

Controllab and bibliographic available in library, using this search strategy: Quality control and Clinical biochemistry, Quality management, Audit in clinical laboratories. Articles that presented as priority the guarantee of quality of the analytical processes and yours possible variables were selected in the study.

RESULTS

For the present study, daily data of the biochemical controls on the routine equipment Cobas c 311 was utilized and they were processed between March and April 2013, totalizing 58 results of different analytes, being normal or pathologic. These data were inserted in the table 1 where it was established control limits defined as standard protocol internationally used, mean and standard deviation from the first 20 sampling data.

Average results of Normal and Pathological control within one month between March and April 2013

Analytes	Average	Unit	Resul	Standard Deviation
Magnesium(n)	1,77	Mg/dl	1,80	0,07
Magnesium(p)	3,47	Mg/dl	3,64	0,14
Sodium (n)	122	Mmol/l	122	4,0
Sodium (p)	152	Mmol/l	150	5,0
Phosphorus (n)	3,60	Mg/dl	3,80	0,18
Phosphorus (p)	5,95	Mg/dl	6,20	0,30
Protein (n)	6,37	G/dl	6,10	0,25
Protein (p)	4,45	G/dl	4,40	0,18
Uri prot (n)	18,1	Mg/dl	21	1,4
Uri prot (p)	133	Mg/dl	126	10,6
Triglycerides(n)	100	Mg/dl	99	5,0
Triglycerides(p)	212	Mg/dl	203	11,0
Uric acid (n)	5,16	Mg/dl	5,24	0,26
Uric acid (p)	9,79	Mg/dl	9,89	0,49
Urea (n)	39,6	Mg/dl	37	2,0
Urea (p)	138	Mg/dl	137	7,0
Glucose (n)	89,6	Mg/dl	86	4,5
Glucose (p)	222	Mg/dl	216	11,0
HDL (n)	44,5	Mg/dl	50	3,60
HDL (p)	29,7	Mg/dl	31	2,40
Potassium (n)	3,37	Mmol/l	3,31	0,10
Potassium (p)	6,23	Mmol/l	6,11	0,19
Lactate (n)	14,1	Mg/dl	14,5	0,80
Lactate (p)	26,4	Mg/dl	27,0	1,60
DHL (n)	161	U/l	159	10,0
DHL (p)	326	U/l	338	20,0
Cholesterol (n)	85,1	Mg/dl	85,1	4,30
Cholesterol (p)	183	Mg/dl	183	9,0
CPK (n)	166	U/l	166	10,0
CPK (p)	504	U/l	504	30,0
CKMB (n)	38,7	U/l	37	3,10
CKMB (p)	183	U/l	181	15
Cloro (n)	88,6	Mmol/l	87,9	2,7
Cloro (p)	126	Mmol/l	131,1	4,0
Creatinine (n)	1,13	Mg/dl	1,08	0,07
Creatinine (p)	3,89	Mg/dl	3,94	0,23
PCR (n)	10,9	Mg/l	10,0	0,7
PCR (p)	59,5	Mg/l	57,3	4,0
Dimer D (n)	770	Mg/ml	799	39
Dimer D (p)	3660	Mg/ml	3727	183
Gama gt (n)	47,1	U/l	46	2,8
Gama gt (p)	234	U/l	229	14,0
Albumin (n)	3,01	G/dl	3,01	0,29
Albumin (p)	4,89	G/dl	5,2	0,18
Alc phos (n)	75,6	U/l	75	4,50
Alc phos (p)	210	U/l	208	13,0
Tgp ALT (n)	52,8	U/l	53	3,20
Tgp ALT (p)	122	U/l	124	7,0
Amilase (n)	84,4	U/l	71	5,1
Amilase (p)	190	U/l	169	11,0
Tgo ASTL (n)	49,4	U/l	41	3,0
Tgo ASTL (p)	127	U/l	105	8,0
Bili direct (n)	0,83	Mg/dl	0,8	0,067
Bili direct (p)	2,58	Mg/dl	2,59	0,21
Bili total (n)	0,91	Mg/dl	0,96	0,055
Bili total (p)	4,18	Mg/dl	4,38	0,25
Calcium (n)	8,66	Mg/dl	8,7	0,35
Calcium (p)	13,1	Mg/dl	13,3	0,50

Average results of Normal and Pathological control within one month between March and April 2013

Analyzing the results its noticed that the following analytics present value according to the average: normal Sodium, normal and pathologic Cholesterol, normal and pathologic CPK and normal Albumin, this means that its controls were

prepared with the necessary concentration of attenuants.

On the other hand it was found analytics whose values of results were beyond the average: normal and pathological Magnesium, normal and pathological Phosphorus, normal Urinary Protein, normal and pathological normal and pathological Uric Acid, normal and pathological HDL, normal and pathological Lactate, pathological DHL, pathological Chloride , pathological Creatinine, normal and pathological Dimer, pathological Albumin, normal and pathological Tgp, pathological direct Bilirubin, normal and pathological total Bilirubin, normal and pathological Calcium, this means that its controls were improperly prepared with low attenuant making the control sample very concentrated.

Finally it was observed another group of controls: pathological Sodium, normal and pathological Proteins, pathological Urinary Protein, normal and pathological Triglycerides, normal and pathological Urea, normal and pathological Glucose, Potassium normal and pathological, normal DHL, normal and pathological CKMB, normal Chlorine, normal Creatinine, normal and pathological PCR, normal and pathological GammaGT, normal and pathological Alkaline Phosphatase, normal and pathological Amylase, Tgo normal and pathological, Bilirubin direct normal and pathological however they presented results below the average, this means that the controls were very diluted leaving the sample less concentrated.

Altogether, it's noticed a great heterogeneity in the values obtained, it was observed that the majority of the results were out of average with values above and below the average, but being inside the acceptability, in other words, between the reference intervals of the controls, because of that so were accepted in the laboratory routine.

According to Flauzino and Milani many factors can be the cause of these deficiencies of the majority quality controls, but there are tools which can be used by professionals who administer the clinical laboratories enabling the establishment of criteria of productivity and quality, and ways to reduce the cost/benefit ratios in the execution of tests[9].

Approach of performance audit

The approach proposed by Gilbert (1978)[7] differs from traditional performance evaluation systems in five basic aspects:

• Systematizes the periodic collect of the impact of intervention, allowing reapply and improve the process and indicate solutions[8]

• Collects and analyzes only the behaviors linked to reactions expected and that cause deficiency in performance, rationalizing the work of the analyst[7]

• Identifies the differences in performance, analyzing and resolving the causes of deficiencies, which allows the development of human and organizational potentials[8]

The audit approach of the performance analyzes and evaluates by identifying the causes of disabilities and determines what to improve, intervenes on the causes of disabilities and systematically evaluates interventions therefore assist company managers to make decisions on the measures to be adopted, prioritizing more effective measures and cost/benefit, allowing improvement of performance[9].

According to Lundberg interpretation and appropriate action must be taken before actually completing the cycle of laboratory tests[10].

According Goldschmit and Lent estimate that up to 75% of errors produce results still included in the reference intervals[11].

However it is possible to maintain a quality system working fine without targeting only the marketing that is done once the company gets the seal which in turn is a proof of the quality system correctly implemented, showing to the society that the company was approved by the external auditors. To keep this system it is needed to do the daily monitoring, with the right and trained people to monitor processes such as: instruments, reagents, equipment, if there is no control it will occur variability in laboratory measurements[12].

The skills displayed by the executor necessary to the realization of the tasks can be acquired by training of employees, however due to its high cost, it is necessary to plan it based on the expected realizations and limit it to a practical program of instructions, thus it will be able to prepare people to perform specific patterns of work[13].

This approach consider people very similar in their behavioral repertoires, but very different in what they perform: a hunter can perform almost the same behavior from the other and not hit the target. Only after knowing if he missed is when it should be investigated what went wrong, because it would not be correct to analyze the existence of a different behavior if it did not affect the result [14].

In the health sector the management for quality has high relevance, because the credibility crisis in the area, due to the great decay of hospitals facing a irregular policy[15].

The guarantee of quality in general, not only regarding to controls, can be achieved by standardizing each of the activities involved, from the care of the patient until the release of the report.

CONCLUSION

The initial focus of the results obtained thus enables the selection of observable behaviors directly linked to achievements, thus the quest for standardization of quality indicators is not always an easy task when it involves various clinical laboratories, each with distinct characteristics, but looking for exchange experiences with other laboratories. It is up to the managers the challenge to broaden their knowledge, engage and train a team of collaborators, aiming to spread the

concepts and the importance of the indicators in the management of processes. With improved quality, waste can be avoided by reducing the costs and increasing the productivity, thus there will be significant improvement in competitiveness in the market.

REFERENCES

1-CHAVES,C.V, Revista Brasileira de Patologia. Medlab. Volume 46 n 5 Outubro 2010.
2-SOUZA, M.O, Padronização em Bioquímica clínica. Faculdade de farmácia de UFMG, 1998.
3-WESTGARD, J.O, Points of care in using statistics in metho comparison studies. Clin. 44: 2240-2235, 1998.
4-CONTROLLAB, (www.controllab.com.br).
5-ETRIDGE, B.H, REYNOLDS, A.P, livro: Técnicas Básicas de laboratório clínico 5º edição pg 90-92, 2011.
6-WESTGARD, J.O, Basic qc practices 2º edição, Westigard Quality corporation, 2002.
7- GILBERT, T.F. Human competence: engineering worthy performance, new York mcgraw-hill, 1978.
8-SCHULTZ, I.M. et al. Preanalytic erros tracking in a laboratory medicine department. Results of 1 year. Experience. Clin chem, v 52, n 7, pg 1442-1440, 2006.
9-FLAUZINO, D.P, MELANI, L. Revista de administração São Paulo , v 35, n 3 pg 81-90 julho/setembro de 2000.
10-LUNDBERG, G.D. The need for na outcomes research agenda for clinical laboratory testing, 280: 565-560, 1998.
11-GOLDSCHMIDT, H.N.J, LENT, R.W. Gross errors and work flow analysis in the clinical laboratory 3 : 131-40, 1995.
12-LARSSON, A, PALMER, M, HULTEM, G, TRYDING, N. Large differences in laboratory utilization between hospitals in Sweden. Clin chen lab Med 38: 383-380, 2000
13-KHOURY, M, BURNETT, L, MACKAY, M.A. Error rate in Australian chemical pathology laboratories pg: 128-120, 1996.
14-MOTTA, U.M, CORRÊA, J.A, MOTTA, L.R.Gestão da qualidade no laboratório clínico 2º edição, editora médica Musau, Porto Alegre, 2001.
15-PLEBANI, M. et al . Laboratory net work of excellence: enhancing patient safety and servisse effectiveness clin. Chen lab Med v 44, n 2 pg 70-60, 2006.
16-CORNETTA, V.K, FELICE, S.A. Desenvolvimento da qualidade. Garantia da eficiência nos serviços de saúde. 15: 58-60, 1994.