Continuing education as a Laboratory Management tool associated with Scientific Advice with a focus on quality and patient safety in the pre-analytical phase

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Abstract

The quality process is increasingly evident within health institutions, for standardization of processes, improvement in the profitability of protocols and patient safety. This work brings case reports in a medium-sized hospital in the northeast of São Paulo, Brazil and confronts the data with the literature on continuing education and the scientific advisory process by outsourced companies. It is possible to observe that, when closely monitored by the scientific advisory of the company Sarstedt do Brasil, good results were obtained in the pre-analytical phase, always relying on continuing education and the process of measuring factors through indicators, which is already indicated in literature. In short, the quality process is a long way and must be followed day after day while education is the only tool that can be used for this to happen and without a doubt, the help of a qualified scientific advisor assists this process.

Keywords: Laboratory**;** Laboratory Medicine; Education; Sarstedt; Scientific Advice.

1. Introduction

The provision of health services has as main objective to guarantee doctors and their patients a quality and safe care (Pedrosa & Cardoso, 2011; Saccucci et al., 2017). In these services, two basic components of quality are implicit, namely the operational, which corresponds to the process itself, and the perception, which is the way customers view the service offered (Plebani, 2009). These two components can be evaluated through quality indicators and recognition by obtaining certifications or accreditations, thus allowing internal comparisons or between companies that offer services with the same characteristics, facilitating decision-making by managers and professionals (Plebani, 2010).

The denomination of quality is something that is growing within the hospital area and mainly within clinical laboratories, which include the reception, screening, transport and carrying out laboratory tests (Plebani, 2017). An important factor to be evaluated and avoided is laboratory error, which is defined as a failure that occurred in any part of the cycle, whether in its request, interpretation and even by the professional's reaction to the reported result, or for any complication that generates an inappropriate result or misinterpretation of the test performed (Don-Wauchope & Kavsak, 2016).

The quest to reduce errors is continuous, which makes the Scientific Advisory a tool for improving the quality and safety of the entire laboratory process (Lee, 2019). In view of the processes presented, this work aims to highlight achievements made in a medium-sized hospital in the interior of São Paulo, in Brazil and to confront with a brief bibliographic review, highlighting some improvements and Scientific Advisory projects applied to the pre-analytical phase in order to demonstrate its applicability in the identification and reduction of errors, helping to expand the patient safety vision and impacting techniques both at the business and health level.

2. History of Brazil in its concern with laboratory quality

In Brazil, the concern with quality in the health area comes from the 1930s, with the creation of the Hospital Inquiry Form, by Odair Pedroso, in São Paulo, for the Hospital Assistance Commission of the Ministry of Health (MH) (Feldman et al., 2005). In this, the minimum standard of hospital organization included an organized clinical staff, administrative and nursing staff, radiological and physiotherapy services, clinical laboratory, morgue, pharmacy and auxiliary services (kitchen, laundry and disinfection) (Feldman et al., 2005; Plebani, 2010).

Laboratory medicine can be considered as a pioneer sector in the medical field to promote and introduce the concepts of quality. In the 1960s, Barnett and Tonks started studies on biological variability, which was improved by Harris and Fraser in the subsequent decades. In the 1990s there was a global consensus on the objectives of quality and its specifications in the clinical laboratory environment (Plebani, 2017). Thus, the concepts of Quality Control, Quality Assurance and Total Quality Management were defined (Lee, 2019).

In 1999 the National Accreditation Organization (ONA) was created, with the main objectives of heating up the implementation of a permanent process of improvement in health care, encouraging services to reach higher quality standards. In 2001/02, the National Health Surveillance Agency (ANVISA) officially recognized the Brazilian Accreditation System through Resolution No. 921/02 and signed an agreement with ONA for technical cooperation and training of personnel, which also counted on the participation of

several entities, such as the Brazilian Society of Clinical Pathology / Laboratory Medicine (SBPC/ML) (Feldman et al., 2005; Rafael & Aquino, 2019).

SBPC/ML had a fundamental role in the implementation of quality concepts and laboratory accreditation, since, in its founding in 1944, it already had in its statute as one of its objectives, the establishment of standards for carrying out the different laboratory exams (Rafael & Aquino, 2019; Vieira, 2004). During the 1970s, he proposed to review and adapt to the Brazilian reality the practices of the American College of Pathologists (CAP), through the Brazilian Journal of Clinical Pathology, published by SBPC / ML itself. In 1977, together with Control Lab, SBPC / ML launched the Medical Laboratory Excellence Program (PELM) and in 1998 created the Clinical Laboratory Accreditation Program (PALC), which was revised in 2004, 2007 and 2010 (Vieira, 2004). PALC opens a pathway for Brazilian laboratories to continuously improve quality, through audits carried out by peers, that is, by laboratories, providing opportunities for exchanging technical knowledge between auditors and auditees (Vieira, 2004, 2005).

3. Pre-analytical phase and its errors

The laboratory process is classically divided into three stages of execution: pre-analytical, analytical and post-analytical (Plebani, 2006). The pre-analytical phase corresponds from factors prior to the performance of tests (such as prescription, preparation and orientation of the patient, collection, identification, storage and transport of samples) until the moment of their analysis (Costa & Moreli, 2012).

According to Westgard and Darcy (Westgard & Darcy, 2004), the results of laboratory analyzes are responsible for 65% to 75% of the information relevant to medical decision. Thus, the search for improvements in this sector is of fundamental importance, requiring a thorough analysis of the different processes involved in carrying out the laboratory examination, including technical, organizational and administrative aspects, in addition to identifying deviations and proposing more assertive and efficient interventions (Souza et al., 2020).

Each laboratory step has sources of errors. However, the pre-analytical phase can include up to 70% of laboratory errors. Such misunderstandings can cause discomfort to patients, delay in therapeutic conduct and loss of credibility of the laboratory with the medical staff, in addition to reducing revenues and increasing costs. Due to its high percentage compared to the other two phases, a specific and differentiated view of quality management must be taken at this stage. However, the constant implementation of technologies and scientific advances, the realization and execution of action plans and measures of continuous improvement are modifying these frequencies. (Plebani, 2017; Plebani et al., 2011).

We can include among the errors that occurred in the pre-analytical phase, for example, the inadequate collection of samples, errors in the interpretation of the medical request or identification of the patient, loss of the medical request as well as tubes, sample taken from a member with an intravenous infusion route , empty tubes, no loading of the request in the system and sample without refrigeration (Carraro & Plebani, 2007), registration failures (Plebani, 2009), repetition of venous punctures (Kirchner et al., 2007), exam repetition rates (Plebani, 2010) and contamination rate of blood culture and urine culture (Kirchner et al., 2007).

Many of these errors are difficult to assess, control or improve, as they are mostly extrinsic to the laboratory

environment (Ak, 2004; Rafael & Aquino, 2019) and can be associated with professional turnover, negligence and even inefficient training (Lippi, 2009; Plebani & Lippi, 2009), mainly because it is a phase with low automation and, consequently, greater involvement of manual tasks. For these reasons, the laboratory's quality system requires discipline and organization at all stages of its processes.

4. Scientific Advisory actions applied to the pre-analytical phase

Technological evolution was one of the main levers that allowed the implementation of modern quality concepts in the clinical laboratory. However, the new practices resulted in an increase in the overall cost of the entire laboratory process, which was not always accompanied by an increase in remuneration for paying sources. On the contrary, clinical laboratories, particularly in Brazil, began to suffer strong pressure from the supplementary health service providers, in order to drastically reduce the costs for carrying out tests (Junior et al., 2019; Mosel & Gift, 1994; Westgard & Darcy, 2004). Data presented in table 1 demonstrate the effectiveness of the Scientific Advisory work with laboratories.

Tabela 1: Example of Scientific Advisory projects applied to the Pre-Analytical phase: with the methodology applied, as well as the results and impacts observed.

Methodology	Results and impacts
Monitoring blood collection and training employees when they start at the company, as well as recycling every three months.	Decrease in new venipuncture indicators and increase in continuing education indicators. Positive impact to the patient and financial to the laboratory.
Accompaniment of collection not only in the laboratory, but in the entire hospital network and collection points.	Multidisciplinary professionals with knowledge of material and technique used to perform the work. Decrease in indicators of new venous punctures due to newly hired employees. Greater patient safety and positive financial impact.
Training and validation of arterial collections by biomedical.	Decreased the waiting process for nurses to perform arterial collections by biomedicals, improving patient safety, especially COPD, who constantly collect blood gases. Decrease in complaints indicators for these reasons.
Performing venous blood gas collections with requests for multiple exams. Monitoring to identify changes in collections with and without tourniquet.	Validation of venous blood collections in blood gases for lactate dosage with and without the application of a tourniquet, decreasing expenses with material, repetition of exams and increasing the safety of the patient who only undergoes a single collection.
Monitoring of advisor in the sector of patient reception, conference of requested exams, choice of materials, volume of tubes, waiting time for clot retraction and centrifugation.	Camp of the pre-analytical phase, from the conference of request for reception, patient care, organization of material, location of venous access, order of tubes, as well as collection and homogenization. Decrease in indicators of registration errors, patient safety with reuse indicator and hemolysis index.
Monitoring the centrifugation and transport process from CACU's to CAPU	Validation of transport of biological material from CACU to CAPU as well as stability of transported material, directly impacting the process of hemolysis indicator and new venous collections for these reasons.
Validation of collections in tubes with smaller volumes to identify reproduction of results compared to tubes with standard volumes.	Validation of EDTA microtubes in volumes of 200µl and 600µl vs. 2.6mL and its impact on the diagnosis in terms of final volume, blood / anticoagulant ratio, release of reliable results and safety of the assisted patient.
Continuing Education to decrease hemolysis indicator results.	Training of 143 employees to reduce the rate of hemolysis due to collection error from 1.22% to 0.48%, with the help of managers and collaborators for better safety of the assisted patient.

Source: Author.

COPD - Chronic Obstructive Pulmonary Disease; CACU - Clinical analysis collection unit; CAPU - Clinical Analysis Processing Unit; EDTA-Ethylenediamine tetraacetic acid.

Tools can be used to assess, measure and correct non-conformities within the pre-analytical phase. The PDCA cycle (plan, do, check, act) (Fukui, 2012), consists of planning as the first stage, in which it is the moment to study the feasibility of a new project or process (Hanawa & Momo, 2019). The second stage, the execution, comprises the operationalization of the project, with the establishment of structures, responsibilities and communication channels. In the third stage, or verification, there is the checking and monitoring of the established process, where problems or non-conformities not foreseen in the planning phase can be identified. Finally, the fourth phase, or action, ends the cycle with corrective actions and critical analysis of the new project, to define its implementation or not in the organization (Demirel, 2019). Other methodologies similar to the PDCA used within the laboratory area are DMAIC and FMEA. In the first, the initials, in English, refer to definition, measurement, analysis, improvement and control, while FMEA means analysis of failure modes and their effects (Subriadi & Najwa, 2020). The Fish Skeleton, Fishbone Diagram, or Ishikawa Diagram, in honor of Professor Kaoru Ishikawa, who built the first cause and effect diagram to explain to some engineers in an industry how the various factors of a process were inter-related (Lira et al., 2017).

The Scientific Advisory actions are used to monitor laboratory tests, correlate results, methodological adaptations, systems implementation, technical and scientific updates, research and market evaluation with the purpose of reducing errors, improving the quality of the process and better commercial performance. Table 1 summarizes the methodologies used by different authors to assess the impact of improvements made and Scientific Advisory projects during the pre-analytical phase, focusing on the percentage or results found in each survey. (Junior et al., 2020; Song et al., 2015; Sunyog, 2004).

5. Final considerations

In view of the above, the phases within a clinical laboratory must be conducted in a serious manner, as even the smallest errors can have major implications, especially in the patient's health and in the costs themselves. For this, methodologies that focus on the assessment of risk factors, identification of sectors or activities with a high potential for errors, carrying out plans and implementing these plans, as well as continuous professional training must always be taken into consideration in clinical laboratories. The methodologies applied with the Scientific Advisory can assist a lot in the identification and resolution of problems, consequently making the client and health professionals have confidence in the results of the laboratories and the laboratories have a better profitability.

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7. References

Ak, S. (2004). The laboratory is a key partner in assuring patient safety. *Clinics in Laboratory Medicine*, *24*(4), 1023–1035. https://doi.org/10.1016/j.cll.2004.05.017

Carraro, P., & Plebani, M. (2007). Errors in a stat laboratory: Types and frequencies 10 years later. *Clinical Chemistry*, *53*(7), 1338–1342. https://doi.org/10.1373/clinchem.2007.088344

Costa, V. G. da, & Moreli, M. L. (2012). Principais parâmetros biológicos avaliados em erros na fase pré-analítica de laboratórios clínicos: Revisão sistemática. *Jornal Brasileiro de Patologia e Medicina Laboratorial*, *48*(3), 163–168. https://doi.org/10.1590/S1676-24442012000300003

Demirel, A. (2019). Improvement of hand hygiene compliance in a private hospital using the Plan-Do-Check-Act (PDCA) method. *Pakistan Journal of Medical Sciences*, *35*(3), 721–725. https://doi.org/10.12669/pjms.35.3.6

Don-Wauchope, A. C., & Kavsak, P. A. (2016). Error detection in routine clinical chemistry laboratory test results. *Clinical Biochemistry*, *49*(3), 199–200. https://doi.org/10.1016/j.clinbiochem.2016.01.013

Feldman, L. B., Gatto, M. A. F., & Cunha, I. C. K. O. (2005). História da evolução da qualidade hospitalar: Dos padrões a acreditação. *Acta Paulista de Enfermagem*, *18*(2), 213–219. https://doi.org/10.1590/S0103-21002005000200015

Fukui, T. (2012). [Patient safety and quality of medical care. Editorial: From evidence-based medicine to PDCA cycle]. *Nihon Naika Gakkai Zasshi. The Journal of the Japanese Society of Internal Medicine*, *101*(12), 3365–3367. https://doi.org/10.2169/naika.101.3365

Hanawa, T., & Momo, K. (2019). [PDCA Cycle for the Development of Clinical Formulation Thinking in Actual Example]. *Yakugaku Zasshi: Journal of the Pharmaceutical Society of Japan*, *139*(10), 1267–1268. https://doi.org/10.1248/yakushi.19-00121-F

Junior, S. de A., Cardoso-Brito, V., Moreira, M. E. S., Melo, M. R. S. de, Andrade, G., & Bulgo, D. C. (2020). Biosafety evaluation and characterization of occupational risks in a ready care unit paulista, Brazil. *Research, Society and Development*, *9*(2), 74922028. https://doi.org/10.33448/rsd-v9i2.2028

Junior, S. de A., Silva, F. C. da, Moreira, N. I. T., Bulgo, D. C., Oliveira, L. N., Rodrigues, A. A., Silva, G. H. V., Gonçalves, C. R., Souza, B. C. de, Pereira, L. A., Melo, M. R. S. de, Nakamura, F. de C., & Andrade, G. (2019). Bases pedagógicas em curso profissionalizante de Farmácia e Laboratório Clínico como apoio na construção profissional do indivíduo. *Revista Eletrônica Acervo Saúde*, *25*, e649–e649. https://doi.org/10.25248/reas.e649.2019

Kirchner, M. J. A., Funes, V. A., Adzet, C. B., Clar, M. V. D., Escuer, M. I., Girona, J. M., Barellas, R. M. P., Alsina, C. P., Aguilá, C. R., Isern, G. T., & Navarro, C. V. (2007). Quality indicators and specifications for key processes in clinical laboratories: A preliminary experience. *Clinical Chemistry and Laboratory Medicine*, *45*(5), 672–677. https://doi.org/10.1515/CCLM.2007.122

Lee, N. Y. (2019). Types and Frequencies of Pre-Analytical Errors in the Clinical Laboratory at the University Hospital of Korea. *Clinical Laboratory*, *65*(9). https://doi.org/10.7754/Clin.Lab.2019.190512

Lippi, G. (2009). Governance of preanalytical variability: Travelling the right path to the bright side of the moon? *Clinica Chimica Acta; International Journal of Clinical Chemistry*, *404*(1), 32–36. https://doi.org/10.1016/j.cca.2009.03.026

Lira, L. H., Hirai, F. E., Oliveira, M., Portellinha, W., & Nakano, E. M. (2017). Use of the Ishikawa diagram in a case-control analysis to assess the causes of a diffuse lamellar keratitis outbreak. *Arquivos Brasileiros De Oftalmologia*, *80*(5), 281–284. https://doi.org/10.5935/0004-2749.20170069

Mosel, D., & Gift, B. (1994). Collaborative benchmarking in health care. *The Joint Commission Journal on Quality Improvement*, *20*(5), 239–249. https://doi.org/10.1016/s1070-3241(16)30068-2

Pedrosa, P. B. S., & Cardoso, T. A. O. (2011). Viral infections in workers in hospital and research laboratory settings: A comparative review of infection modes and respective biosafety aspects. *International Journal of Infectious Diseases: IJID: Official Publication of the International Society for Infectious Diseases*, *15*(6), e366-376. https://doi.org/10.1016/j.ijid.2011.03.005

Plebani, M. (2006). Errors in clinical laboratories or errors in laboratory medicine? *Clinical Chemistry and Laboratory Medicine*, *44*(6), 750–759. https://doi.org/10.1515/CCLM.2006.123

Plebani, M. (2009). Exploring the iceberg of errors in laboratory medicine. *Clinica Chimica Acta; International Journal of Clinical Chemistry*, *404*(1), 16–23. https://doi.org/10.1016/j.cca.2009.03.022

Plebani, M. (2010). The detection and prevention of errors in laboratory medicine. *Annals of Clinical Biochemistry*, *47*(Pt 2), 101–110. https://doi.org/10.1258/acb.2009.009222

Plebani, M. (2017). Quality in laboratory medicine: 50years on. *Clinical Biochemistry*, *50*(3), 101–104. https://doi.org/10.1016/j.clinbiochem.2016.10.007

Plebani, M., Laposata, M., & Lundberg, G. D. (2011). The brain-to-brain loop concept for laboratory testing 40 years after its introduction. *American Journal of Clinical Pathology*, *136*(6), 829–833. https://doi.org/10.1309/AJCPR28HWHSSDNON

Plebani, M., & Lippi, G. (2009). Hemolysis index: Quality indicator or criterion for sample rejection? *Clinical Chemistry and Laboratory Medicine*, *47*(8), 899–902. https://doi.org/10.1515/CCLM.2009.229

Rafael, D. N., & Aquino, S. (2019). PERCEPÇÃO DE GESTORES SOBRE A AUDITORIA ONA EM UM COMPOUNDING CENTER EM PROCESSO DE ACREDITAÇÃO. *Gestão & Planejamento - G&P*, *20*(0). https://revistas.unifacs.br/index.php/rgb/article/view/4293

Saccucci, M., Ierardo, G., Protano, C., Vitali, M., & Polimeni, A. (2017). How to manage the biological risk in a dental clinic: Current and future perspectives. *Minerva Stomatologica*, *66*(5), 232–239. https://doi.org/10.23736/S0026-4970.17.04087-0

Song, W., Shen, Y., Peng, X., Tian, J., Wang, H., Xu, L., Nie, X., & Ni, X. (2015). [Study of continuous quality improvement for clinical laboratory processes via the platform of Hospital Group]. *Zhonghua Yi Xue Za Zhi*, *95*(20), 1595–1598.

Souza, R. K. L., Coan, E. W., Anghebem, M. I., Souza, R. K. L., Coan, E. W., & Anghebem, M. I. (2020). Nonconformities in the pre-analytical phase identified in a public health laboratory. *Jornal Brasileiro de Patologia e Medicina Laboratorial*, *56*. https://doi.org/10.5935/1676-2444.20200027

Subriadi, A. P., & Najwa, N. F. (2020). The consistency analysis of failure mode and effect analysis (FMEA) in information technology risk assessment. *Heliyon*, *6*(1), e03161. https://doi.org/10.1016/j.heliyon.2020.e03161

Sunyog, M. (2004). Lean Management and Six-Sigma yield big gains in hospital's immediate response laboratory. Quality improvement techniques save more than $400,000. *Clinical Leadership & Management Review: The Journal of CLMA*, *18*(5), 255–258.

Vieira, L. M. F. (2004). SBPC/ML: 60 anos. *Jornal Brasileiro de Patologia e Medicina Laboratorial*, *40*(3), 0–0. https://doi.org/10.1590/S1676-24442004000300002

Vieira, L. M. F. (2005). Nova era para a acreditação de laboratórios. *Jornal Brasileiro de Patologia e Medicina Laboratorial*, *41*(4), 0–0. https://doi.org/10.1590/S1676-24442005000400001

Westgard, J. O., & Darcy, T. (2004). The truth about quality: Medical usefulness and analytical reliability of laboratory tests. *Clinica Chimica Acta; International Journal of Clinical Chemistry*, *346*(1), 3–11. https://doi.org/10.1016/j.cccn.2003.12.034