EXPERIENCE REPORT
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Experience report on health regulatory actions in clinical laboratories in Palmas-TO

Relato de experiência sobre as ações de regulação sanitária nos laboratórios clínicos em Palmas-TO

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ABSTRACT

Introduction: The importance and necessity of sanitary surveillance in clinical laboratories and of mechanisms of quality control and promotion throughout the laboratory cycle are well known. **Objectives:** Due to the importance of clinical laboratories in Palmas, the Municipal Sanitary Surveillance created in 2010 a proposal to improve the regulatory activity in these establishments. **Method:** The work was developed in four stages in parallel to the Annual Sanitary Licensing. In 2010, the first phase was the re-registration of the establishments and the presentation of the technical dossier in these establishments. In 2011, this was complemented with the analysis, revision, correction and approval of legal and technical documents. In 2012, manuals, pest control plans, waste management, input control and the presence of internal and external quality control were reviewed, as well as the flow for notification of compulsory diseases already in place. In 2013, the presentation and implementation of quality management actions were required and in 2014 the monitoring of the application of these tools was intensified. **Results:** The results obtained were the acceptance of the regulatory processes, as well as the accomplishment of corrections and inclusion of norms and written procedures in the technical actions and management of the clinical analysis processes. It can be verified that by the requirement of training of technicians, already at the end of 2014, the culture of the training was observed and the need for improvements and corrections of the most probable points of sanitary and analytical problems was verified, mainly having the Sanitary Surveillance as support and partner. **Conclusions:** It is possible to conclude that the strategy used by the Sanitary Surveillance, associated to Sanitary Licensing and to actions of gradual improvements in search of better management of sanitary risks, culminated in a harmonious relation of advising, in which the action of sanitary surveillance required minimal restrictive measures and several actions of guiding and problem solving in partnership.

KEYWORDS: Clinical Laboratories; Sanitary Surveillance; Sanitary Risk

RESUMO

Introdução: São notórias a importância e a necessidade de garantias da normalidade sanitária nos estabelecimentos e de mecanismos de controle e promoção da qualidade em todo o ciclo laboratorial. **Objetivo:** Pela importância das análises clínicas em Palmas, a Vigilância Sanitária Municipal iniciou em 2010 uma proposta de aprimoramento da atividade regulatória nestes estabelecimentos. **Método:** O trabalho foi desenvolvido em quatro etapas em paralelo ao Licenciamento Sanitário Anual. Em 2010 foi realizada a primeira fase de recadastramento dos estabelecimentos e a apresentação do dossiê técnico existente nos estabelecimentos. Em 2011, ele se estendeu com a análise, revisão, correção e aprovação dos documentos legais e técnicos. Já em 2012 foram reavaliados os manuais, os planos de controle de pragas, de gerenciamento de resíduos, de controle dos insumos e da presença de controle da qualidade interno e externo além do fluxo para notificação de doenças compulsórias já em aplicação nos estabelecimento. Em 2013 foram

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exigidas a apresentação e a implementação das ações de gerenciamento da qualidade e, em 2014, intensificou-se o monitoramento da aplicação destas ferramentas. **Resultados:** Os resultados obtidos foram a aceitação dos processos regulatórios, bem como a realização de correções e a inclusão de normas e procedimentos escritos nas ações técnicas e de gerenciamento dos processos de análises clínicas. Pode-se constatar que, pela exigência da capacitação dos técnicos, já ao final de 2014, observava-se a cultura da capacitação e divulgação da necessidade de aprimoramentos e correções dos pontos de maior probabilidade de problemas sanitários e analíticos, e principalmente tendo a Vigilância Sanitária como um setor de apoio e parceria. **Conclusões:** Pode-se concluir com esse trabalho que a estratégia utilizada pela Vigilância Sanitária, associada em paralelo com o Licenciamento Sanitário, de ações de melhorias gradativas em busca de melhor gerenciamento dos riscos sanitários culminou em uma relação harmoniosa de assessoramento, na qual a atuação de controle e regulação sanitário necessitou de mínimas medidas impositivas e restritivas e várias ações de orientações e resolução de problemas em parceria.

PALAVRAS-CHAVE: Laboratórios Clínicos; Vigilância Sanitária; Risco Sanitário

INTRODUCTION

In the concept of sanitary surveillance, in relation to actions aimed at promoting health, we should observe the set of factors that directly or indirectly have the potential to inflict damage to health. Therefore, regulatory, inspection and monitoring processes, as well as health education, are important tools to address the existing health risks.

Health regulations should also be reimbursed for patients according to Ordinance n. 529, of April 1, 2013, which creates the National Patient Safety Program (PNSP)[1]. In this context, the regulation of laboratory activities, including the physical structure, the existence of records on the adequate education and training of technicians, the recording and evaluation of the controls adopted in the analytical processes, results and the quality management for sanitary compliance, as required by RDC n. 302, of October 13, 2005[2] of the Brazilian Sanitary Surveillance Agency (Anvisa), are considered important strategies for sanitary surveillance activities.

When considering the importance of the clinical analysis for the diagnostic decision and the therapeutic conducts, two things stand out: the importance of guaranteeing sanitary normality in the establishments and mechanisms of quality control and promotion throughout the laboratory cycle. In this respect, actions that produce and monitor quality control culminate in the construction of a vast organizational and technical setting that goes beyond the use of indicators and starts to actively involve all stakeholders[3].

In this sense, actions aimed at ensuring patient safety significantly improve the concept of quality management in procedures and techniques used within clinical laboratories. These actions should be included in the cycle of patient care, and this is a current challenge in health services. The main objective of the improvement in the analytical processes is also to increase the safety of the services provided to the patient. Therefore, it is not limited to isolated actions, it is rather a set of actions that complement each other[3].

In a scenario of adoption of new technologies and new procedures with different degrees of complexity, we must consider the importance of the processes that control the quality of the product/service provided by the clinical laboratory, as well as emphasize the recognition and construction of tools to prevent adverse events in healthcare services[4].

In this way, since the customer needs reliable results to ensure the fulfillment of this need, laboratories must have quality control procedures that are adjusted to the process to be controlled. It is up to the sanitary surveillance service to change strategies and adapt to new regulatory frameworks, considering cross-disciplinary knowledge and degrees of specialization beyond simple inspection, to contribute to the process of ensuring service reliability and patient safety[5].

We understand that the quality of the practices in sanitary surveillance should correspond to the adequate use of technical knowledge for the control of health risks[6]. In this sense, given the specificity of the pre-analytical, analytical and post-analytical phases and their importance in the clinical decision, laboratory analyses provide the opportunity to guide and lead these processes by disseminating the concept of sanitary risk and stimulating analysis, correction and monitoring as control and regulation strategies[7]. Furthermore, as a result of management with health quality and safety in work processes, together with the communication process, they can minimize the occurrence of analytical errors and facilitate the improvement of existing procedures involving the provision of services or new technologies, either alone or together, meeting the expectations of health actions in the context of sanitary risk management[8]. The sanitary field can also relate damage to the health and integrity of patients, including the possibility of illness and even death[9].

Because of their high degree of sophistication, clinical laboratories are a challenge for health regulation. This paper presents the work of the Sanitary Surveillance service in the city of Palmas, state of Tocantins, Brazil, which guided health licensing actions and new strategies beyond simple inspection. With that in mind, aspects that include the concepts of quality management, actions aimed at reducing sanitary problems, improvement in the processes of analysis and general measures of care and patient protection are important and need to be present in the approach to sanitary risks and patient safety[10].

The need for knowledge about the sanitary reality of the laboratories in the city of Palmas and about the degree of integration between the sanitary legislation for licensing and the existence of strategies to perform quality control and its full routine management resulted in a study proposing some changes in the reality found. Guidance and intervention actions were based on Anvisa's RDC n. 302/2005, which provides for Technical Regulation for the Functioning of Clinical Laboratories.

METHOD

The project was divided into four phases from the beginning of 2010 and encompassed some specific objectives mentioned below.

Phase 1: The process of sanitary regulation of clinical laboratory activity was initiated by updating the registration and active search of laboratory establishments and their existing collection points to determine their current quantity and location. We carried out an initial inspection in the laboratories and a sanitary notification was issued for requests for the annual sanitary license to be submitted to the sanitary surveillance body. At least the following documents had to be submitted: the company charter, the National Registry of Legal Entity (CNPJ), proof of ethical regularity, fees, Basic Architectonic Project approved by the Sanitary Surveillance project analysis sector, and a dossier with the existing technical documents and manuals. These activities were concluded at the end of 2010. The legal basis was Chapter 5.1/5.2 of RDC n. 302/2005, which provides for Technical Regulation for the Functioning of Clinical Laboratories.

Phase 2: After the evaluation and initial approval of the documents presented in phase 1, the second phase involved a new sanitary notification, with the request for submission for analysis of other documents generated by the establishment, in order to check the regularity of its activities in view of the common health legislation on healthcare facilities. The analysis of these documents generated a report that was used as the basic criterion for the issuance of the sanitary license for year 2011. The evaluation of these documents generated a notification to correct the errors found during the evaluation. The documents evaluated were the Basic Architectural Project based on RDC n. 50, of February 21, 2002[11], that provides for the Technical Regulation for planning, programming, elaboration and evaluation of physical projects of healthcare establishments, (GPM) Good Practices Manual, Waste Management Plan, maintaining the legal base in RDC n. 302/2005 and including RDC n. 306, of December 7, 2004[12], which deals with the Technical Regulation for the Management of Waste from Health Services.

Phase 3: As documentations were initially formalized, in 2012, the annual sanitary licensing was linked to the fulfillment of demands aimed at the improvement and construction of measures and actions for the implementation, adequacy, monitoring and evolution of strategies and tools used for quality control in pre-analytical, analytical and post-analytical steps. The GPM was reassessed with focus on updating techniques and procedures, applying and using routines, building ethical and accounting legalization of laboratories. We also requested the preparation and submission of an annual integrated pest control plan for evaluation and approval, as well as the registration of the technical staff and equipment in the establishment. The laboratories had to formalize the list of procedures performed and inform which were outsourced, in addition to compulsory registration with the Epidemiological Surveillance to meet the routine notification of compulsory diseases.

Phase 4: The last phase of the sanitary regulation process began when we notified the laboratories to provide sanitary licensing according to the criteria that we set forth in specific Technical Communication. It is important to note that due to the extension of the measures required for this phase, the requested organization has been extended until the 2014 annual sanitary licensing. Therefore, we requested the preparation of a dossier divided into chapters containing information and necessary proofs according to the following items:

Chapter 1: Introduction

- Proof of accounting adequacy.

Chapter 2: Ethical and technical proof

- List of the technical staff with the technical and ethical certificates of the team. There should be presented proof that all professionals mentioned in the technical staff list attended the annual training program of the team that was presented.

Chapter 3: Activities

- Presentation of the architectural project approval document;
- Declaration of the procedures performed, outsourced services with proof of relationship and accounting, ethical and sanitary legality of contractors;
- Statement of analysis and approval of GPM updates;
- Presentation of the Waste Management Plan (PGRSS) for the specific evaluation of the final destination of the waste with the implementation of a form for quantification and monitoring of waste generation.

Chapter 4: Quality Control

- The laboratories were asked to prove the application of the internal control previously proposed, with the registration and auditing and correction measures carried out in the previous year, as well as the proof of being performing external quality control in the laboratory;
- Presentation by means of individual equipment registration form, proposed by the Sanitary Surveillance, highlighting the field of registration of the maintenance and calibrations required in the manufacturer's manual and proposals in the previously presented GPM;

- Presentation of the control map of supplies for registration of the chemicals used in the establishment;
- Implementation of a form to present the routines of hygiene and conservation of the interior air conditioning system, using a specific form to evaluate the routines of hygiene per area of the laboratory;
- Presentation of the occupational health program for sanitary evaluation;
- Implementation of a quantification and monitoring form for notification of compulsory diseases.

In all phases, the documents were evaluated first and only after the conclusion of the assessment opinion were the establishments visited for sanitary inspection by the Sanitary Surveillance team.

RESULTS AND DISCUSSION

Clinical analysis activities in Palmas began along with the foundation of the city, which in 2016 was only 27 years old. During the whole period, the Sanitary Surveillance body issued the sanitary licenses to the activity according to the normality regarding the ethical and sanitary requirements. In this sense, the actions that occurred after the licensing with a view to the control of sanitary normality were motivated essentially by reports or complaints of the service users.

However, the evolution of laboratory activities, influenced by the population growth and also with the growing tendency of investments in customer service and satisfaction, as well as the increase in the offer of services to ensure commercial viability[13], led to the inclusion of new technologies in the sector. This increased the diagnostic capacity and also the complexity to achieve compliance with the sanitary regulation.

The proposal of Sanitary Licensing initiated in 2010 with notification to update registration with the sanitary surveillance agency resulted in an increase in the regulatory control of laboratory activity, as shown in Table 1, in which we can observe that there was a total of 62% of laboratories licensed in 2010 and 92% in 2014.

It so happened that, as the data were updated with the Sanitary Surveillance, we verified the need on the part of some establishments to adapt their company charters, CNPJ, Real Estate Registry, citing all the activities that they actually performed. They also needed to select the option of clinical laboratory according to the National Code of Economic Activities (CNAE)[14].

The initial phase of the licensing process was positive for the recognition of the presence of the activity in the municipal plan by the Sanitary Surveillance. Along the same lines, it is worth noting that, due to the ease of dialogue and collaboration of the sector in the resolution of bureaucratic conflicts, improvements were also seen in the relationship and harmonization of the vocabulary used between Sanitary Surveillance and regulated establishments.

The registration adequacy with monitoring and verification of the information provided influenced the general profile of the authorizations for operation and the amount of the fees charged. It sometimes resulted in the permanence of the only activity set forth in the National Classification of Economic Activities, subclass n. 86.402/02 (Clinical Laboratories). It is important to note that the accumulation of commercial activities was not forbidden, however, it was required that all the health control requirements for the operation were met, always guaranteeing that there were no damages to the laboratory routines nor to the patients.

In Table 2 we can see that, when starting the Sanitary Licensing process, we had to emphasize the fulfillment of the documentary requirements, whose main objective was to guarantee the minimum legality for the operation and to serve as proof of quality control and tools for management and reduction of sanitary risks. Based on the results presented in

Table 1. Comparison of the ratio of existing and licensed laboratories in 2010 and 2014, in Palmas, TO, Brazil.

Items evaluated	Year 2010	Year 2014
	n (%)	n (%)
Laboratories registered at the sanitary surveillance body	18 (100%)	25 (100%)
Sanitary license issued at the end of 2009	11 (62%)	23 (92%)

Source: Registration of processes of the Municipal Sanitary Surveillance of Palmas.

Table 2. Situation of clinical laboratories regarding the existence of documents in 2010 and 2014, in Palmas, TO, Brazil.

Documents	Situation in 2010	Situation in 2014
Establishments registered at the sanitary surveillance body	18 (100%)	25 (100%)
Sanitary permit issued by the sanitary surveillance body	11 (62%)	23 (92%)
Basic Architectural Project approved by the sanitary surveillance body	2 (5%)	24 (95%)
Updated Real Estate Registry	15 (84%)	25 (100%)
External Quality Control (EQC)	No record	25 (100%)
Internal Quality Control (IQC)	6 (31%)	25 (100%)
Published good practices manual	8 (45%)	25 (100%)
Health Waste Management Plan (PGRSS)	9 (50%)	25 (100%)
Formalization of relationship with support laboratory	None	25 (100%)
Records of the technical staff	10 (55%)	25 (100%)
Equipment control	Not available	25 (100%)
Calendar of internal and external training	None	25 (100%)
Integrated Annual Pest Control Plan	None	25 (100%)
Publication of sanitation practices by sector	None	25 (100%)
Record of notification of compulsory diseases	None	25 (100%)

Source: Registration of processes of the Municipal Sanitary Surveillance of Palmas.

Table 2, we can verify that, in 2010, in the 18 registered laboratories, there was no record in the establishment of external quality control and there were no agreements or proof for the evaluation of the support laboratories. It was a common practice for professionals to be present without proper staffing records. Confirming the need to make changes to the health situation found in 2010, 55% of the laboratories were then carrying out activities without records or operational protocols, regardless of the importance of the GPM and of procedure records. The same was also verified with the negligence in the internal quality control as set forth by the legislation (RDC n. 302/05 of Anvisa). The procedures regarding the treatment and disposal of products were in a similar condition, and there was no waste management program known and evaluated by the Sanitary Surveillance in none of these establishments. Another important piece of information is that there was no registration in the sanitary surveillance body (unregistered) of the external quality control tests being performed by the laboratories.

Awareness and adoption of criteria for evaluation of sanitary normality, quality and biosafety contribute to the evaluation of the risks involved in the activity performed. Therefore, the absence of controls and records in the processes or information generated presupposes that, in order to obtain sanitary licensing, they should be better managed and proven. There are no recorded reports, nor complaints of laboratory errors or deviations of analytical quality, nor even epidemiological indicators related to laboratory activity reported or related in this period to collaborate with the subject.

The registration of establishments and the monitoring of health interest criteria after the end of the licensing process, together with the verification of the measures adopted with the implementation of tools and operational practices aimed at raising quality assurance at all stages (pre-analytical, analytical and post-analytical), have produced important changes in the perspective of the operation of these establishments.

The evolution in the improvement of the information provided together with the accomplishment of structural adaptations, investment in the technical conducts guided by published operational procedures, required commitment and reorganization of the technical staff, in addition to strategies of care and other conducts.

In the same sense, we perceived greater understanding of the need to recognize and manage critical points in analytical control, as well as the need to make investments in team training. There have been advances that deserve to be highlighted, like the expansion of measures and actions to control analytical quality, since the laboratories began to seek and adopt new internal measures to control, evaluate and record the results in the performance of analytical routines. This was combined with the policy of control and monitoring of normality in the operation of equipment and inputs, directly enhancing the reliability of the results.

The evolution in the perspective of health care in laboratories is also shown in Table 3, since the documentary requirements, together with the process of advising the construction, approval and application of these procedures, improved the commitment of graduates and technicians in the establishment. By the end of 2014, it was possible to observe the concern to maintain the routines in compliance with the portfolio of technical manuals and standards that regulate the existing procedures. The behavioral change of those involved in the laboratory activity with proactive attitudes is confirmed by the increase in time and in the number of training opportunities offered in the calendars of refresher courses, revision of practices, production of scientific events of improvement and education.

Promoting actions aimed at increasing quality assurance controls and assisting in the promotion of the accuracy and reliability of laboratory results involves several activities that complement each other. Combined actions in the control of routines, whether in the preparation stages of the laboratory to receive and manipulate the samples, or in the analytical and post-analytical phase, occupational health and customer satisfaction, are fundamental because, in addition to complying with legislation, they enhances ethical and technical commitment to minimizing the occurrence of errors.

We can see that the sanitary surveillance strategy to monitor actions in Table 2, such as the hygiene of environments in defined criteria, the cleaning of air circulation and internal refrigeration equipment, together with the monitoring of the control of the urban vectors, produces positive results and steers actions toward concrete attitudes that complement the immediate results in containing the hazards and the possibilities of generating damages by the sanitary risks involved.

Restructuring existing operational procedures, reviewing routines and adjusting internal responsibilities demonstrate that improvements are feasible and do not compromise the viability of the activity. The development of monitoring actions on internal quality control and verification of external quality control in laboratories may have been the best sanitary measure to improve the quality control in these establishments. If we observe the quantitative increase in these processes from 2010 to 2014, we can conclude that there were laboratories performing clinical analyses with few controls and little verification of normality and accuracy of the results produced.

Table 3. Percentage of growth of the actions to increase the quality of the clinical laboratories, in Palmas, TO, Brazil.

Training title	% execution in 2010	% execution in 2014
Good practices manual	45%	100%
Cleaning and care routines	None	100%
Biosafety standards	11%	100%
Biosafety standards for sample transport	None	98%

Source: Sanitary processes carried out by the Municipal Sanitary Surveillance of Palmas.

Table 2 shows the growth of the Internal Quality Control (IQC) and the External Quality Control (EQC), showing the establishments that currently perform the routine analytical check with the external laboratories, thus reducing the possibility that inadequate routines remain in execution.

After the process of regularization of the sanitary requirements and observing that the laboratory results can be useful and support the process of registration, mapping and epidemiological investigation, the sanitary surveillance body determined, by means of notification with immediate fulfillment, the provision of book opening for registration and proof of submission of compulsory notifications of diseases and injuries according to ordinance n. 104/GM of January 25, 2011[15].

Following the notification flow of compulsory diseases, the need for the verification of training regarding the flow to be observed between the establishment and the responsible sector in the Directorate of Health Surveillance allowed the epidemiology sector to establish a channel of importance in the actions that relate the laboratory activity to the process of epidemiological investigation and feeding of information systems and municipal health indicators.

CONCLUSIONS

The initiative to license the clinical laboratories under the responsibility of the municipal sanitary regulation of Palmas, combined with measures to recognize the sanitary conditions in which each one was and to initiate a gradual process of improvements in their quality, taking into account the financial and technical conditions as well as the ability to afford and produce the necessary changes, is one of the strategies that Sanitary Surveillance can use instead of the traditional mode of operation, using prior document analysis and on-site inspection. The monitoring of the actions of the clinical analysis laboratories should not have the intention to punish or question the routines, but rather to establish partnerships, encouraging the laboratories to associate and facilitate the dissemination of knowledge and solutions to common problems.

In parallel to these actions, the sanitary surveillance service sought to always position itself as a support sector, to assist and collaborate, monitoring the results and orienting the activities with a view to reducing the sanitary risks, ensuring that sanitary legislation was enforced as the activities were performed as expected.

We can conclude that Sanitary Surveillance can act in several ways to guarantee the objectives of preventing and reducing direct and indirect damage to the health of the population. The requirement of the Annual Sanitary License that guarantees the normality of the activity and that associates goals in stages is a strategy to be considered.

With proper follow-up and guidance for document and structural adjustments, record-keeping and improvements in the publication and application of procedures, as well as promotion and participation in the training processes of technicians and involved in the pre-analytical, analytical and post-analytical steps, enabled the laboratories to establish new paradigms of action in Palmas. This study in partnership with the Sanitary Surveillance resulted in a deeper understanding of sanitary regulatory functions and demonstrated that the interactions between the regulated and regulatory sectors can occur in a harmonious and collaborative way in practice.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.