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Sanitary inspections in endoscopy clinics in the state of Ceará

Inspeções sanitárias em clínicas de endoscopia no estado do Ceará

Inspecciones sanitarias en clínicas de endoscopia en el estado de Ceará

ABSTRACT

Introduction: Reusable endoscopes pose significant risks of microbial contamination, despite being widely used as diagnostic tools in medical practice. **Objective:** To describe the main nonconformities identified during sanitary inspections conducted in private endoscopy services. **Methods:** This is an experience report carried out in a municipality in the interior of the state of Ceará, Brazil, from 2023 to 2025. **Results:** The inspections revealed advances in structural and care-related aspects; however, they also identified relevant shortcomings related to endoscope reprocessing, the absence of formal records of cleaning and disinfection, deficiencies in staff training, and inadequacies in physical infrastructure. Biosafety conditions and waste management practices were also found to be inconsistent, requiring continuous improvement. **Conclusion:** It is concluded that inspection and technical monitoring are essential tools for ensuring the quality and safety of endoscopy services, contributing to the promotion of safer environments for both professionals and patients.

Keywords: *Endoscopy; Sanitary Surveillance; Patient Safety; Disinfection; Health Services.*

RESUMO

Introdução: Os endoscópios reutilizáveis apresentam riscos significativos de contaminação por microrganismos, apesar de serem amplamente utilizados como método diagnóstico na prática médica. **Objetivo:** Descrever as principais inconformidades observadas durante inspeções sanitárias realizadas em serviços privados de endoscopia. **Métodos:** Trata-se de um relato de experiência realizado em um município do interior do Ceará, no período de 2023 a 2025. **Resultados:** As inspeções evidenciaram avanços nos aspectos estruturais e assistenciais; entretanto, também revelaram fragilidades relevantes relacionadas ao reprocessamento de

endoscópios, à ausência de registros formais de limpeza e desinfecção, a falhas na capacitação das equipes e a inadequações na infraestrutura física. As condições de biossegurança e o manejo de resíduos mostraram-se igualmente inconsistentes, demandando melhorias contínuas. **Conclusão:** Conclui-se que a fiscalização e o acompanhamento técnico constituem instrumentos fundamentais para assegurar a qualidade e a segurança dos serviços de endoscopia, contribuindo para a promoção de ambientes mais seguros para profissionais e usuários.

Descritores: *Endoscopia; Vigilância Sanitária; Segurança do Paciente; Desinfecção; Serviços de Saúde.*

RESUMEN

Introducción: Los endoscopios reutilizables presentan riesgos significativos de contaminación por microorganismos, a pesar de ser ampliamente utilizados como métodos diagnósticos en la práctica médica. **Objetivo:** Describir las principales no conformidades observadas durante las inspecciones sanitarias realizadas en servicios privados de endoscopia. **Métodos:** Se trata de un relato de experiencia llevado a cabo en un municipio del interior del estado de Ceará, durante el período comprendido entre 2023 y 2025. **Resultados:** Las inspecciones evidenciaron avances en los aspectos estructurales y asistenciales; sin embargo, también revelaron fragilidades relevantes relacionadas con el reprocesamiento de los endoscopios, la ausencia de registros formales de limpieza y desinfección, deficiencias en la capacitación de los equipos y deficiencias en la infraestructura física. Las condiciones de bioseguridad y la gestión de residuos también se mostraron inconsistentes, lo que pone de manifiesto la necesidad de mejoras continuas. **Conclusión:** Se concluye que la fiscalización y el seguimiento técnico constituyen herramientas fundamentales para garantizar la calidad y la seguridad de los servicios de endoscopia, contribuyendo a la promoción de entornos más seguros para profesionales y usuarios.

Descriptores: *Endoscopia; Vigilancia Sanitaria; Seguridad del Paciente; Desinfección; Servicios de Salud.*

INTRODUCTION

Endoscopy is a procedure widely used in health services for the diagnosis and treatment of pathologies of the gastrointestinal and respiratory tract[1,2]. Reusable endoscopes present notable risks of contamination by microorganisms[2], with the most commonly found bacterial pathogens being *Klebsiella pneumoniae*, *Pantoea spp*., and *Staphylococcus aureus*[3], despite the adoption of strict cleaning and sterilization protocols. In this context of technological advancement, the use of endoscopic equipment has brought significant benefits, but it has also increased the risk of infection transmission, which is considered higher than that associated with any other health product[1].

In Brazil, the National Health Surveillance Agency (ANVISA) has established Good Operating Practices requirements for endoscopy services, ranging from the physical structure to the training of professionals and the adequate reprocessing of equipment, through Collegiate Board Resolution (RDC) Nº 06/2013[4]. Despite this, studies indicate that failures in these processes are still frequent, configuring an important challenge for patient safety, since they compromise the control of risks and the expansion of benefits[5].

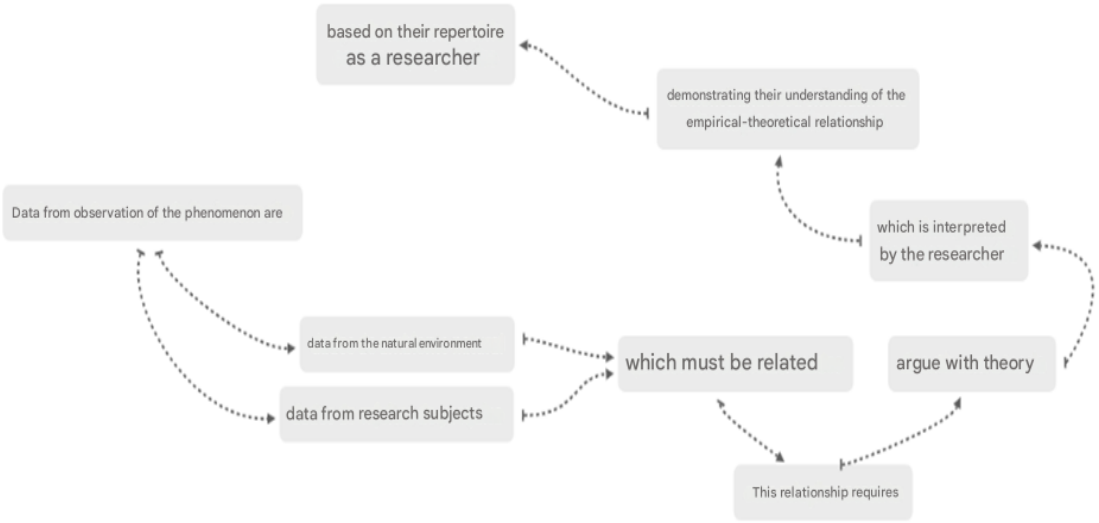
In this scenario, health surveillance plays a fundamental regulatory role, being responsible for supervising, guiding and promoting continuous improvements in health services, as well as acting in the granting of health licenses[6]. Adequate cleaning, disinfection, and storage of endoscopes are critical steps, the inefficiency of which can result in cross-contamination, adverse events, and additional risks to patients undergoing deep sedation during procedures[7]. Thus, it is essential to monitor and evaluate the units inspected by managers and health surveillance, in addition to the implementation of quality management systems in health services[8].

In view of the relevance of the topic to public health and the need to ensure safe practices in accordance with current legislation, it was justified to carry out health inspections in endoscopy services. Thus, the objective of this study was to report the main aspects observed during inspections carried out in endoscopy clinics in a municipality in the interior of Ceará.

METHODS

This study is a qualitative and descriptive experience report. The experience report is described by Antunes *et al.* as a phenomenon that can be observed in a systematized way that "in a flow that is interconnected with theoretical choices, data collection and analysis"[9]. They also state that the analysis process in this type of systematized research, shown in Diagram 1, is based on the arguments with epistemological guidelines described by Minayo for its internal validity[10].

Figure 1 – Analysis process in a systematized experience report research.



Source: Antunes et al. (2024).

According to Mussi, Flores and Almeida, this type of study enables "the critical presentation of scientific and/or professional practices and/or interventions"[11]. These authors recommend a roadmap for the construction of this type of study, which supported the organization of this work by listing the elements of each section of composition of this study. Emphasizing the importance of the Experience Report (ER), it appears in the opposite direction of positivist and generalizing empirical research, being reported by Daltro and Faria as an "important technology for the production of scientific knowledge", which emphasizes complexity and geography[12].

This study was constructed from sanitary inspections (phenomenon) carried out for the renewal of sanitary permits in endoscopy services of private clinics, located in a municipality in the interior of Ceará (natural environment and subjects). The visits took place between July 2023 and July 2025 and were conducted by the municipal health surveillance team, more specifically by the technical team of the health service. The places visited were private clinics that offered endoscopy services, in line with the actions described in the municipal Annual Health Surveillance Plan (VISA).

The collection of information was carried out in two stages, starting with the documentary analysis of the pertinent legislation and, later, with on-site inspection, during which, whenever necessary, complementary documents were requested in accordance with the current legislation; in this phase, a standardized checklist was used by the municipal Health Surveillance, based on national, state and municipal standards and based on the Inspection Objective Script: Endoscopy of the National Health Surveillance Agency, in addition to informal conversations with professionals directly involved in the processes. As a technical-normative reference, Anvisa's Collegiate Board Resolution (RDC) No. 06, of March 1, 2013, was adopted, which provides for the requirements of good practices for endoscopy services, and the observations are systematized in a table

organized in the sections: Organizational Conditions, Human Resources, Attributions of the Technical Responsible, Physical Infrastructure and Material Resources, Processing of Equipment and Accessories, and Occupational Health and Safety. This made it possible to highlight the most recurrent non-conformities, especially related to reprocessing, disinfection, workflows, and compliance with regulatory standards.

As this is an experience report, there was no need to submit it to the Research Ethics Committee, since the study did not directly involve the participation of human beings, but rather the description of professional practices and experiences lived in the context of health inspections.

RESULTS

During the study period, seven private clinics that performed endoscopic procedures were inspected. During the visits, several non-conformities related to compliance with the sections established by Anvisa's RDC No. 06/2013 were observed. Chart 1 presents the main irregularities identified, with emphasis on those with the highest recurrence, as well as the corrective measures requested during the sanitary inspections.

Table 1 – Non-conformities identified and requests for correction during sanitary inspections in accordance with the sections of Chapter II - Good Operating Practices of RDC Anvisa No. 06/2013.

Section	Non-conformity identified	Correction request
I – Organizational Conditions	Lack of formal registration of cleaning and disinfection procedures.	Prepare and present updated SOP of rules and routines; Implement systematic recording of cleaning and reprocessing processes.
II – Human Resources	Teams without proof of up-to-date training in endoscope reprocessing and emergency care. When verbalized that there was training, there is an absence of formal records.	Conduct periodic training; Present certificates/documents proving the team's training.
III – Duties of the Technical Responsible	Presence of a designated technical responsible, but absence of a formally appointed substitute.	Present an official document that appoints the substitute technical responsible.
IV – Physical Infrastructure /Human Resources	Cleaning and disinfection areas without adequate physical barrier; Insufficient ventilation/exhaustion; Inadequate storage of equipment; Absence of some mandatory items, including defibrillator; Have medical compressed air, inert gas or filtered, dry and oil-free air.	Adapt physical structure according to RDC No. 6/2013; Provide adequate separation of clean and contaminated areas; correct ventilation and storage conditions; Immediately acquire the mandatory items.
V – Processing of equipment and	Standard Operating Procedure (SOP) without detailed information on all stages of the processing of equipment	Prepare and present updated SOP of procedure, reprocessing, standards and routines;

accessories	and accessories used in endoscopic procedures and the material used in this work process; Storage of inappropriate endocopies.	Correct storage of endoscopes and continuing education on the subject.
VI – Occupational Health and Safety	Absence of biosafety protocols; Lack of complete personal protective equipment (PPE) in some units; Segregation and improper disposal of sharps waste. Washing of linen carried out incorrectly.	Implement biosafety protocols; Ensure adequate supply and use of PPE; Regularize waste management and disposal according to current legislation; Regularize the washing of linen in accordance with the legislation.

Source: Prepared by the authors, based on the recommendations of good endoscopy practice in endoscopy, Anvisa RDC No. 06/2013 (2026).

Among the health services studied, the requests referred to the granting of sanitary permits, both for initial issuance and for renewal, and were not motivated by complaints or other factors. The inspections were carried out as a result of the expiration date of the permits, as provided for in the Annual Plan of the Municipal Health Surveillance.

With regard to the observations made during the sanitary inspections, the absence of records of processes, weaknesses in document management and training were identified, as well as inadequacies in the infrastructure and failures related to the biosafety of workers.

DISCUSSION

The experience showed that the service presented important advances in structural and care aspects, but still presented weaknesses that compromised patient safety and compliance with current legislation. Lima *et al*. emphasize that there is a partnership between the Health Surveillance and the Public Prosecutor's Office to reinforce compliance with sanitary requirements by health establishments[6].

Organizational Conditions

Initially, adequate basic structures were observed, such as the presence of trash cans in accordance with current legislation, washbasins equipped with liquid soap and paper towels for hand hygiene, in addition to the computerized record of medical records in all services. However, the absence of formal records of cleaning and disinfection procedures was found, which hinders traceability and compromises the safety of the processes. This gap can result in undetected failures during reprocessing, related to health care.

It was also observed the organization of the space, the availability of basic supplies, the presence of sinks with deep tubs and alcohol dispensers at strategic points, as well as essential equipment, such as autoclave and sealer, in full operation. These elements show an institutional effort to maintain adequate

conditions for the processing of materials and support for care. However, the absence of formal records of the cleaning and disinfection stages, as well as the lack of complete and standardized protocols, reveals a significant gap.

Biondi and Zocratto point out that the most frequent non-conformities are related to documentation, quality assurance and physical structure, with the most applied actions being guidance and notification. The authors also point out that renewals of sanitary permits occur more frequently in services monitored by sanitary surveillance[13].

Human Resources

In all the services inspected, the multiprofessional teams carried out the care routines; however, they did not present formal proof of training in endoscope reprocessing and emergency response. Although he was verbally informed that training had been carried out, there was no supporting documentation. This situation highlights the need for properly recorded periodic training, since the absence of records compromises the standardization of practices and exposes patients and workers to risks of iatrogenic events and failures in critical situations.

This finding dialogues with studies that highlight the role of periodic and documented training as an essential safety barrier, especially in critical areas, such as endoscope reprocessing. Without this systematization, the service becomes vulnerable to human error and variations in the execution of routines, which can increase the risk of contamination and the occurrence of adverse events[14, 15].

Duties of the Technical Responsible

The presence of a formally designated technical person was identified in all the clinics visited; However, there was no official indication of a replacement, which compromises the continuity of technical management and weakens the supervision of activities. The absence of a formal substitute can hinder decision-making in emergency situations, generate coordination failures, and imply issues of legal liability.

The commitment of the technical person in charge to the service was also highlighted, although there was no official provision for replacement in his absence. This reality is described in the World Health Organization (WHO) Patient Safety Manual as a risk of governance discontinuity, since, in the face of emergencies or inspections, the lack of formal leadership can compromise quick and assertive decision-making[16]. Cesar *et al.* emphasize the clarity of the requirements of the RDC and the need for educational actions by the public sector in health establishments, with a view to mitigating non-conformities, promoting good practices and patient safety[17].

Physical Infrastructure/Material Resources

The service's infrastructure had positive aspects, such as the organization of supplies, air-conditioned environments, and the availability of some life support equipment in rooms equipped with a microprocessed electronic scalpel, multiparameter monitor, oxygen cylinders, and properly registered endoscopes. However, in most units, there was no automated external defibrillator. It was also observed that there was a space reserved for post-anesthetic recovery, with adequate armchairs, as well as a purge area with the use of enzymatic detergent and a structured sterilization sector, with an autoclave, sealer and surgical grade paper, with indication of a physical barrier between clean and contaminated areas.

However, it was observed that some units had a clearly defined physical barrier between clean and contaminated areas, inadequate ventilation, and a lack of critical items, such as defibrillators and medical gas supplies at certain points. Inadequate storage of equipment, lack of mandatory items and absence of medical compressed air supply were also identified.

These non-conformities reflect systemic failures that weaken emergency preparedness and make it difficult to maintain safe flows of materials and people[18]. In addition, they compromise biosafety, favor cross-contamination, and put the lives of patients at risk in the face of possible cardiorespiratory complications.

In procedures that involve sedation and risk of serious events, the absence of available and ready-to-use equipment can have direct consequences on the patient's clinical evolution. It is noteworthy that, in one of the units visited, the drugs intended for cardiorespiratory recovery were out of date.

Equipment and accessories processing

The endoscopes were processed using enzymatic detergent, functional autoclave, and packages containing sterile instruments, demonstrating partial compliance with current standards. Another relevant step refers to the storage of endoscopes. Although, in most cases, this procedure was performed adequately, it was observed that some equipment was stored together with other materials, which favors contamination.

In another situation, it was found that an endoscope remained assembled, ready for care the next day. In addition, the Standard Operating Procedures had incomplete descriptions of the reprocessing steps, and the storage of the endoscopes did not fully comply with the normative recommendations. These failures can compromise the sterility of the instruments, facilitating the recontamination and transmission of microorganisms during the procedures.

In the processing of the materials, it was found that, although there were adequate inputs, such as enzymatic detergent, surgical-grade paper with an indicator, and properly sealed packages, the described protocol did not include

all the recommended steps, nor did it present objective validation criteria. Apparently simple details, such as the disassembly of valves, the use of appropriate brushes, the guarantee of the contact time of disinfectants, as well as correct drying and storage, are crucial for the prevention of outbreaks related to the use of endoscopes[19].

Hamdar *et al.* observed the heterogeneity of the reprocessing protocols used in endoscopy services, showing great variability among the practices adopted[2]. A fundamental point highlighted by the authors is traceability, which is necessary to ensure a safe outcome, allowing each step of the process to be proven and audited, ensuring consistency and reliability[2, 20].

Mendes and Arraes report that "low-risk establishments may be the ones that least comply with health standards and those that most endanger people's health" [21]. In turn, Boese *et al.* suggest the use of disposable endoscopes, which can reduce the risk of infections or cross-contamination, in addition to eliminating the need for sterilization, maintenance, and time-consuming and expensive repairs, and are, in some cases, cheaper than traditional endoscopes[22].

However, Eussen *et al.* advocate the use of reusable endoscopic instruments, emphasizing their environmental benefits, such as reducing pollution and damage to public health. The authors point out that there are still controversies regarding the costs related to the use of reusable and disposable endoscopes, in addition to highlighting the regulatory challenges and the need to adapt the standards for economic analysis and for the consideration of the environmental advantage associated with each type of endoscope by regulatory agencies[23].

Occupational Safety and Health

Regarding occupational safety, the use of Personal Protective Equipment was found in part of the services, as well as the presence of adequate containers for waste disposal in some sectors. However, the absence of biosafety protocols, the incomplete supply of PPE, failures in the segregation of sharps and inadequacies in the washing of linen were found. Such conditions increase the risk of work accidents, environmental contamination and exposure of the team to infectious agents.

It is important to highlight that the evidence identified in these units reflects the reality of the establishments located in the health region where the inspections were carried out. However, these findings cannot be generalized to other health facilities in the state or country, considering the particularities and specificities of each context.

The biosafety conditions of the workers also demanded attention. The availability and adequate use of personal protective equipment were inconsistent, the handling of sharps did not fully comply with current standards, and the processing of linen still had flaws. These findings are in line with the legislation, which provides guidance on worker protection and emphasizes its importance for

ensuring the quality of care, since unsafe environments for the team tend to reproduce vulnerabilities in patient care as well[24].

Investing in the occupational health of health service workers are strategies that allow for the development of safety, increased productivity, and prevention of diseases, and improving the image of institutions in the community[25].

FINAL CONSIDERATIONS

The experience showed that the service was in the process of advancing towards regulatory compliance, presenting positive points, but still requiring improvements related to the standardization of processes, systematic records and strengthening of governance. It was observed that patient safety depends on the implementation of structured, monitored and continuously reviewed processes, and not only on individual initiatives. The need to consolidate complete reprocessing protocols, documented training of teams, adequacy of physical barriers and preparation for emergency situations was highlighted, aligning care practice with normative guidelines and scientific evidence.

Among the limitations identified, weaknesses in the formalization of routines, in the systematization of records and in the consolidation of an organizational culture oriented towards safety were highlighted. The importance of deepening future investigations on the products used in reprocessing, the constituent material of endoscopes, risks associated with cleaning failures, biosafety aspects, use protocols, environmental impact and sustainability of services was also recognized, expanding the evidence base for the qualification of regulatory actions.

As contributions to the practice of health surveillance, the relevance of strengthening the dialogue between regulatory agencies and health services, the promotion of continuing education and the construction of clearer protocols applicable to the reality of the services were highlighted. It was evidenced that health care has an educational and transformative character, with the potential to qualify routines, prevent failures, promote concrete improvements, and consolidate a safety culture centered on the protection of patients and workers.

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