PROCESSING OF HEALTH PRODUCTS IN MATERIAL AND STERILIZATION CENTERS*

Processamento de produtos para saúde em centro de material e esterilização

Procesamiento de productos para salud en centro de material y esterilización

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ABSTRACT: Objective: To analyze the processing of health products in Material and Sterilization Centers (MSC) in Health Care Establishments of the city of Teresina – PI. **Method:** Transversal analytic observational study performed at three health care establishments through an interview with the professional in charge for the MSC and through direct observation *in loco* with a script. **Results:** Two of the health care establishments studied presented appropriate technical conditions and one presented partially appropriate techniques. The professionals in charge of the MSC related an insufficient staff for the work demand. **Conclusion:** It was observed, in one of the places studied, the noncompliance with the current legislation, which constitutes sanitary infraction and represents a risk to the safety of the process and the patient. Some structural and organizational adjustments are required. Also, human resources management is necessary.

Keywords: Sterilization. Nursing. Patient safety.

RESUMO: Objetivo: Analisar o processamento de produtos para saúde em Centro de Material e Esterilização (CME) de Estabelecimentos de Assistência à Saúde do município de Teresina (PI), Brasil. **Método:** Estudo observacional analítico de seguimento transversal realizado em três estabelecimentos de assistência à saúde, por meio de uma entrevista com o profissional responsável pelo CME e da observação direta *in loco,* a partir de um roteiro. **Resultados:** Dois dos locais pesquisados apresentaram condições técnicas adequadas e um apresentou condições técnicas parcialmente adequadas. Os profissionais responsáveis relatavam quadro de pessoal insuficiente para a necessidade de trabalho. **Conclusão:** Observou-se em um dos locais pesquisados o descumprimento das legislações vigentes, o que constitui infração sanitária e põe em risco a segurança do processo e do paciente, sendo necessárias adaptações estruturais e organizacionais. Além da necessidade de gerenciamento de recursos humanos.

Palavras-chave: Esterilização. Enfermagem. Segurança do paciente.

RESUMEN: Objetivo: Analizar el procesamiento de productos para salud en Centro de Material y Esterilización (CME) de Establecimientos de Asistencia de Salud en el municipio de Teresina-PI. **Método:** Estudio observacional analítico de seguimiento transversal realizado en tres establecimientos de asistencia de salud por medio de entrevista con el profesional responsable por el CME y observación directa in situ con un guión. **Resultados:** Dos de los locales analizados presentaron condiciones técnicas adecuadas y uno presentó condiciones técnicas parcialmente adecuadas. Los profesionales responsables relataban un cuadro de personal insuficiente a la necesidad. **Conclusión:** Se observó en uno de los locales analizados el incumplimiento de las legislaciones vigentes, lo que constituye infracción sanitaria y pone en riesgo la seguridad del proceso del paciente. Siendo necesarias adecuaciones estructurales y organizacionales. Además, la necesidad de gerenciamiento de recursos humanos.

Palabras clave: Esterilización. Enfermería. Seguridad del paciente.

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INTRODUCTION

The Material and Sterilization Center (MSC) is defined as a functional unit intended for processing health products[1]. Its mission is to supply the care and diagnostic services with processed materials, ensuring the quantity and quality needed for safe care[2].

The MSC is an important department that supports health institutions, associated to the quality of services provided[3]. With technological advancement and the development of surgical techniques, instruments have become more complex and sophisticated, resulting in the need for improvement in material processing techniques and personnel to the performance of these tasks[4].

Any failure during processing involves possible compromise to sterility, increasing risk of trans- or postoperative infection cases and in all non-surgical procedures, such as dressing[5].

Careful inspection of cleaning is one of the critical points so that a product can be reused, because waste can prevent the contact of the sterilizing agent, causing adverse immune effects in patients, such as Systemic Inflammatory Response Syndrome (SIRS) and eye Toxic Anterior Segment Syndrome (TASS), aside from contributing to accelerate damage to the instruments[2].

In this sense, the professionals working in the MSC should take active responsibility in the prevention and control of hospital infections, adopting measures to cause microbial death and ensure the safety of material processing[4,6].

Work on the MSC is full of difficulties associated with the work process itself, including the existence of occupational hazards, lack of human resources, lack of support due to the institutional demand, instability in the intersectoral communication and professionals acting without technical training for the job, reflecting directly on workers and on and the quality of the indirect assistance provided[4].

From these reflections, the following question arose: "How does the processing of products in the Material Sterilization Center (MSC) occur in Health Care Establishments (EAS) in the city of Teresina (PI)?".

OBJECTIVE

To analyze the processing activities of the Material Sterilization Center in Health Care Establishments in the city of Teresina (PI), Brazil.

METHODOLOGY

Transversal analytic observational study, carried out in three Health Care Establishments: a large hospital and education center, a large philanthropic hospital and a Health Unit of the city of Teresina (PI), in June 2014.

Data were obtained through interviews with the professionals in charge of the MSC and direct observation in loco with an observation script.

The observation instrument was elaborated with closed questions, based on the inspection checklist of the Brazilian Health Surveillance Agency (ANVISA)[7] for Material and Sterilization Centers, on the existing national legislation[1,8-10] and practices of the Association of Operating Room Nurses, Anesthetic Recovery and Material and Sterilization Center (SOBECC). It was based on three categories:

1. physical structure of the MSC;
2. product processing;
3. worker's health.

Each category was built with independent variables and the following scores: one (1) = adequate response; and zero (0) = inadequate response, totaling 96 points, allocated according to the categories described. After scoring each category, the percentage of responses were calculated.

The Establishments with a Class I MSC and the one with a Class II MSC received a score that was calculated, respectively, in the following formula: Final score = score obtained / maximum score (77) x 100, and final score = score obtained / maximum score (96) x 100. This difference occurred because some items of the instrument did not apply to both realities. They were classified into three levels: adequate (67 – 100%), partially adequate (66 – 34%) or inadequate (33 – 0%).

The inclusion criterion was fully operational MSCs with one professional in charge present during the direct observation; and the exclusion criteria was MSCs that did not meet these requirements.

The project was approved by the Ethics Committees of the Health Care Establishments (HCE) and the Research Ethics Committee (CEP) of Universidade Federal do Piauí, CAAE No. 30987614.7.0000.5214. All ethical guidelines of Resolution No. 466/2012 of the National Council on Health were met[11]. The participants also signed an Informed Consent.

RESULTS

The three health care establishments have their own Material and Sterilization Centers and performed the processing of products; one was a small MSC, classified as Class I (HCE 1); and two MSCs as Class II (HCE 2) and (3 HCE).

MCSs surveyed are coordinated by nurses. According to the profile, they are in the 25-35 years age group. In two HCEs, professionals had been working in the establishment for 1-3 years, and only one professional had been for more than three years. In the Class II MCSs, the professionals in charge were exclusive to the department, having been working there for 1-3 years. These units have 2 or more nurses.

Table 1 below shows that the three MSCs performed the cleanup, disinfection and sterilization activities on products in a centralized manner. They had all recommended areas for the activities performed. It was also noted that there were physical barrier between the areas considered contaminated and cleaned. All had containers for the disposal of perforating objects.

It is also noteworthy that HCE 1 did not have its own dryer with filtered hot air, medical air guns for drying products and magnifying lenses with at least 8x magnification, to visually assess the cleaning. In this MSC, the transportation of materials was not conducted with wheeled tables or trolleys, and distribution was not performed in closed containers.

The dimensions of workbenches in all MSCs were compatible with the activities to be performed. The workstations had ergonomic chairs or stools with adjustable height. The conditions of the floor, walls, ceiling and lighting were adequate. HCE 1 did not perform preventive maintenance of machines and had no system for keeping monitoring records for 5 years.

Table 2 presents the flow of continuous, unidirectional product processing in all MSCs surveyed. The products to be processed are received in the reception and cleanup area, cleaned, dried, checked and separated, sent to the preparation area, where they are inspected, packed and sent to sterilization, storage and distribution.

However, in HCE 1, workers in the dirty area transited to the clean area and vice versa. There was not a Standard Operating Procedure (SOP) for the processing steps either. All surveyed MSCs had appropriate devices for manual cleaning, during which the instruments are disassembled before cleaning and visual inspection during the drying stage. Only in HCE 2 the solution was not changed after every use.

The MSCs of HCE 2 and 3 performed chemical disinfection, which is made with a glutaraldehyde or peracetic acid

Table 1. Characterization of Materials and Sterilization Centers according to physical structure. Teresina, PI, 2014.

Items	HCE 1	HCE 2	HCE 3
Centralized department	Yes	Yes	Yes
Has all areas recommended by RDC nº 15	Yes	Yes	Yes
Has a recipient for the disposal of perforating materials	Yes	Yes	Yes
Has workbenches with dimensions that allow the conference of materials	Yes	Yes	Yes
Has cold and hot water taps	No	No	No
Has its own dryer with filtered hot air and compressed medical air guns	No	Yes	Yes
Has wheeled tables or trolleys for transportation	No	Yes	Yes
Has workstations with ergonomic chairs or stools	Yes	Yes	Yes
Has magnifying lenses with at minimum 8x magnification	No	Yes	Yes
Carries out preventive maintenance of machines	No	Yes	Yes
Has a system for keeping monitoring records for 5 years	No	Yes	Yes
The distribution of materials is carried out in closed containers	No	Yes	Yes
Clean environment, abrasion-resistant flooring, walls with waterproof coatings, roof in good condition and natural lighting	Yes	Yes	Yes

RDC: *Resolução de Diretoria Colegiada*; HCE: Health Care Establishments.

Table 2. Characterization of Materials and Sterilization Centers according to product processing. Teresina, PI, 2014.

Items	HCE 1	HCE 2	HCE 3
Continuous and unidirectional flow	Yes	Yes	Yes
Workers in the dirty area do transit in the clean clean and vice versa area without removal of PPE and adequate hand hygiene	No	Yes	Yes
There is a Standard Operation Procedure in place for processing stages	No	Yes	Yes
Has appropriate equipment for manual cleaning	Yes	Yes	Yes
Disassembles the instruments before cleaning	Yes	Yes	Yes
Changes the solution with every use	Yes	No	Yes
Conducts a visual assessment during cleaning	Yes	Yes	Yes
Uses a glutaraldehyde or peracetic acid solution in disinfection	-	Yes	Yes
Uses labels in the outer sealed package	No	Yes	Yes
The chamber in the equipment is filled up to 80% of maximum capacity	Yes	Yes	Yes
Uses packaging recommended by ANVISA	No	Yes	Yes
Conducts the Bowie-Dick test	No	Yes	Yes
Uses Class V or VI chemical indicator	No	No	Yes
The monitoring of the physical parameters is recorded in each sterilization cycle	No	Yes	Yes
Sterilization is daily monitored with a biological indicator in the loads	No	Yes	Yes
The sterilization process is documented and records are kept for a minimum of 5 years	No	Yes	Yes

PPE: personal protection equipment; HCE: Health Care Establishments.

solution. In these places, there is the complete immersion of the product in the solution, respecting the time recommended by the manufacturer. Professionals handle the disinfected materials with a clean technique and record the disinfection process in writing.

As also shown in Table 2, HCE 1 does not use packaging recommended by ANVISA or labels and in the outside of the sealed package. In all establishments surveyed, the critical heat-resistant materials are sterilized by saturated steam (autoclave) and the equipment's chamber is filled up to a maximum of 80% of the total capacity.

The HCE 1 does not use the Bowie-Dick test (Class II indicator) and does not perform monitoring with a biological indicator. Class V or VI chemical indicators are used for routine monitoring of the success of sterilization and release only in HCE 3.

The monitoring of the physical parameters is recorded in every sterilization cycle and the process is documented and filed for a minimum of five years in HCEs 2 and 3.

Table 3 shows that the professionals working in the department receive training in the three MSCs. The facilities provide PPE to employees; however, professionals in HCE 1 were not using them. MSCs have their own dressing room with toilets and showers for employees. HCE 1 does not have a room dedicated to the employee's rest period. In all MSCs, the professionals in charge reported insufficient staff for the workload.

According to the graph shown in Figure 1, in HCE 1, from a total of 77 observations, 43 (56%) were adequate. In HCEs 2 and 3, from a total of 96 observations, respectively, 82 (85%) and 90 (94%) were adequate.

In the study, the three institutions were classified based on the following score: inappropriate MSC = 0-33%; partially adequate MSC = 34-66%; and adequate MSC = 67-100%.

As revealed in Table 4, with a percentage of 56% of adequate observations, we can classify MSC in HCE 1 as partially adequate. With the percentage of 85 and 94% of

Table 3. Characterization of Materials and Sterilization Centers according to worker's health. Teresina, PI, 2014.

Items	HCE 1	HCE 2	HCE 3
There is training for professionals working in the MSC	Yes	Yes	Yes
The establishment provides PPE	Yes	Yes	Yes
Number of professionals is adequate to workload	No	No	No
Workers use the PPE	No	Yes	Yes
Has changing rooms with toilets and showers for employees	Yes	Yes	Yes
Has a room dedicated for the rest period	No	Yes	Yes
PPE available	Goggles, procedure gloves, long-barreled nitrile or butyl rubber gloves, mask and long-sleeve impermeable apron.	Goggles, procedure gloves, mask, long-sleeve impermeable apron and waterproof anti-slip footwear	Goggles, procedure gloves, long-barreled nitrile or butyl rubber gloves, mask, long-sleeve impermeable apron, waterproof anti-slip footwear and ear plugs.

MSC: Materials and Sterilization Centers; PPE: personal protection equipment; HCE: Health Care Establishments.

adequate observations, we can classify, respectively, MSCs in HCE 2 and 3 as adequate.

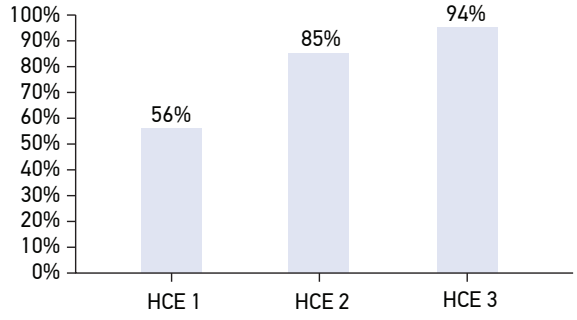
DISCUSSION

The professionals in charge of the MSCs studied were young nurses. The MSC must have a college-graduated professional in charge for the coordination of all activities related to the processing of products[1,2].

A study conducted in basic health units in the state of São Paulo found that the technical responsibility for the reprocessing of critical items in these places was legally assigned to the nurse. For the authors, this professional must possess basic knowledge for planning and evaluation of this process[12].

In the Class II MSC, the professional in charge should operate exclusively in this unit during their workday[1,2]. The exclusivity of the nurse in the department is supported by their knowledge on care actions and on their ability to see the needs of the work, giving them the fundamental characteristics to coordinate the MSC[13]. Thus, the surveyed units were adequate.

In physical structure category, the MSCs studied have all of the areas recommended, and the presence of a physical



HCE: Health Care Establishments.

Figure 1. Percentages of adequacy of Materials and Sterilization Centers of Health Care Establishments.

Table 4. Classification of Materials and Sterilization Centers of Health Care Establishments. Teresina, PI, 2014.

Classification	HCE 1	HCE 2	HCE 3
Adequate MSC	–	85%	94%
Partially adequate MSC	56%	–	–
Inadequate MSC	–	–	–

MSC: Materials and Sterilization Centers; HCE: Health Care Establishments.

barrier between the areas considered contaminated and clean was observed. These spaces are proposed with the objective of the organization and optimization of the work process, as well as environmental separation in order to reduce the risk of contamination[1,2].

In one of the establishments surveyed (HCE 1), the physical structure did not have the materials needed to carry out the processing, such as: its own dryer with filtered hot air, medical air guns for drying products and magnifying lenses. A Class I MSC must have medical compressed air, inert gas or filtered air, dry and free of oil, for drying the material, and the cleanliness of products should be assessed by visual inspection, with the help of magnifying lenses[1].

The dryers with filtered hot air and medical air guns ensure proper and complete drying of materials with minimal handling, and the magnifying lenses ensure greater accuracy in the visual assessment of cleaning[2].

The distribution of materials in one of the establishments (HCE 1) was not done in closed containers. The transportation of processed products should be done in closed containers, according to the Resolution of the Collegiate Board of Directors (RDC no. 15)[1].

These data show the absence of some physical conditions in HCE 1 for carrying out the basic activities. The physical structure of the MSC has significant importance in the control of hospital infections, since it can interfere with processing steps, and its microbiological barriers, if inadequate, can facilitate the transmission of microorganisms[14].

In the product processing category, the flow of materials is continuous and unidirectional in every MSC. However, in one case, workers transited between the dirty and the clean areas. The continuous unidirectional flow of material and personnel is needed in order to avoid cross-contamination of dirty materials with clean and sterilized materials, in order to ensure the rationalization of the work[2].

All MSCs surveyed had appropriate devices for manual cleaning, which occurs when instruments are disassembled before the cleaning and visual inspection during drying. One of the establishments did not change the solution after every use. The presence of suitable items and the implementation of best practices are indispensable in order to ensure safety and efficiency in processing and to prevent damage to the products[2].

Two establishments (HCE 2 and 3) perform chemical disinfection, which is made with a glutaraldehyde or peracetic acid solution. In these MSCs, the products are completely immersed in the solution, respecting the time recommended by the manufacturer. Professionals handle the disinfected materials with a clean technique and record the disinfection process in writing.

Germicides used for chemical disinfection must be approved and registered by ANVISA, such as glutaraldehyde and peracetic acid. The contact of the disinfectant solution with all surfaces of the product and the exposure time recommended by the manufacturer ensure process efficiency. The handling of products disinfected with a clean technique prevents recontamination of materials, and the record of disinfection allows monitoring and traceability[2]. The establishments were studied according to the recommendations, in order to ensure the safety of the procedure and the patient.

The processing of products, in one of the units surveyed, was held without labels on the outside of the sealed package, although identification is required on the packaging of the product undergoing sterilization by means of labels[1].

One of the establishments (HCE 1) did not use packaging recommended by ANVISA. The used containers should be regularized by ANVISA for specific use in sterilization. It is not allowed the use of kraft paper packaging, paper towels, manila, newsprint and aluminum blades[1].

The monitoring of sterilization with a Class II chemical indicator (Bowie-Dick), biological indicators and physical parameters was not performed. It is mandatory to carry out a test to evaluate the performance of the air removal system (Class II indicator) of the vacuum pump-assisted autoclave, in the first cycle of the day. The control with biological indicators must be done daily in a test pack, and with physical indicators, it should be recorded after each cycle[1].

In one of the establishments (HCE 1), the sterilization process was not recorded, the preventive maintenance of the machines was not performed and there was no Standard Operating Procedure (SOP) for the processing steps. MSCs must have a manual or automated information system to record the monitoring and control of the cleaning and disinfection or sterilization steps, as well as the maintenance and monitoring of equipment. Each step in the processing of medical materials must follow a SOP based on current scientific framework and appropriate standardization[1].

Two locations (HCEs 1 and 2) did not use class V or VI chemical indicators for control of the sterilization process. Monitoring should be done in each load in a test test pack with chemical integrators (V or VI classes)[1].

The results show non-compliance with legal requirements. The sterilization practice within pre-established criteria, based on official investigations and standards, is essential to ensure that procedures involving critical items are not responsible for the transmission of infections[12]. Failures in control may reflect on the quality of customer service, since they constitute a risk factor for transmission of infections[6].

In all HCEs, the absence of cold and hot water taps was observed. These items are recommended in order to avoid adverse events to the patient and damage to the processed products and equipment[2].

From these results, we can see the disparity of realities in different aspects (municipal hospital, state hospital and philanthropic hospital). Due to the complexity of the procedures performed in large hospitals, they are equipped with an adequate MSC and complex physical and operational structure. But the small hospital, for performing less complex procedures, has neglected its MSC, endangering the security of the processing activities and of the patient.

A study conducted in hospitals of Salvador, which aimed to analyze the technical conditions for the reprocessing of medical products, found structural and procedural inadequacies in the MSCs studied. According to these authors, the results are reflexes of managerial and organizational difficulties of the MSC, the result of lack of investment and limited supply of material resources[15].

On the workers' health category, the establishments surveyed offer training to the professionals working in the department. These should be given specific and periodic training according to RDC No. 15[1].

In the MSCs surveyed, the professionals in charge reported insufficient staff for the workload. This finding is consistent with findings in the literature. Despite the vital role that MSCs plays in the quality of care, it is noted that that this sector has an insufficient number of employees, or a lack of proper employee qualification for the development of activities[16].

A study conducted in a MSC of a public hospital in Goiania (GO) analyzed the forced that drive and restrain work in that department and found that the deficit of human and material resources restrict the work process, pointing to a need to find solutions that can count on the support from managers and the institution[17].

The nurse responsible for the MSC needs to establish strategies to cope with the shortage of human resources[4]. In this sense, activities to be developed should be managed, foreseeing and organizing priorities without jeopardizing the safety and quality of processing[12].

All establishments surveyed provided PPE to employees. However, in HCE 1, the professionals did not use such equipment. A study conducted in a hospital in Rio Grande do Sul with nursing assistants and technicians who work in a Materials and Sterilization Center, noted that most reported use of PPE, which reinforces the importance that the worker attributes to the use of this equipment for the prevention of occupational accidents[14].

Another study conducted in primary care units in the State of São Paulo with professionals working in the MSC found that these workers do not make proper use of PPE[12]. It is worth noting that these equipment, when used, are extremely important for worker protection, but it is considered that, for adherence to its use, companies need to test them with workers and hear their suggestions and criticisms[18].

Two of the HCEs showed adequate technical conditions and presented good scores in all three categories. In these places, we found adequate physical structures and organizational conditions for the activities developed by the MCS, showing interest and investment in this department, in addition to compliance with current legislation. One of the establishments had partially adequate technical conditions and showed some level of non-compliance in all categories, requiring structural and organizational adjustments in the establishment surveyed.

Work in a MSC requires risk planning and management, and this is only possible with adequate physical and operational structure and committed professionals[15].

CONCLUSION

This study allowed us to analyze the product processing activities in Material and Sterilization Centers in Health Care Establishments, as this department plays an important role in the prevention of nosocomial infection and in the quality of care delivered to the customer.

Of the establishments surveyed, two had adequate technical conditions and one had partially adequate technical conditions, demonstrating the disparity of interest and investment from managers in the different realities. It was observed that, in one of the establishments, there was non-compliance with the existing laws, such as RDC No. 15/2012, which constitutes a health violation and endangers the safety of processing and

the patient, requiring structural and organizational adjustments in the surveyed site.

In the MSCs surveyed, professionals in charge reported insufficient staff for the workload, pointing to the indispensability of human resource management with the support of managers and institution. It was also noted that one of the places that workers that did not use PPE. These equipments are of fundamental importance for the protection and safety of the worker.

To ensure the quality and safety of the processing, adequate physical structure, organizational conditions and human resources are essential.

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