

(DIS)CONFORMITY OF THE WORKING PROCESS IN THE MATERIAL AND STERILIZATION CENTER

(Des)conformidade do processo de trabalho no centro de material e esterilização

(Des)conformidad del proceso de trabajo en el centro de material y esterilización

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ABSTRACT: Objectives: To evaluate the nursing work process in a Material and Sterilization Center (MSC) of a teaching hospital in Northeastern Brazil and to calculate the compliance rates of the work processes of hospital health products (HP) in the CME. **Method:** Observational study, with quantitative analyses. The target population consisted of nursing technicians and assistants, through systematic observation in the development of work processes. The sample resulted in 24 professionals, corresponding to 80% of the population. **Results:** Of the observed processes, the compliance rate was lower (29.17%) in sterilization and higher (56.94%) in the storage/distribution of the products. As for subprocesses, it was higher (90.28%) in sealing and lower (8.33%) in rinsing the HP. **Conclusion:** The average process compliance showed an index below the limit of 70%, compromising most of the nursing team's work process.

Keywords: Quality indicators, health care. Sterilization. Employee performance appraisal.

RESUMO: Objetivo: Avaliar o processo de trabalho de enfermagem em um Centro de Material e Esterilização (CME) de um hospital de ensino no Nordeste brasileiro e calcular os índices de conformidades dos processos de trabalho dos produtos para saúde (PPS) hospitalares no CME. **Método:** Estudo observacional, com análises quantitativas. A população-alvo constituiu-se de técnicos e auxiliares de enfermagem, por meio de observação sistemática no desenvolvimento dos processos de trabalho. A amostra resultou em 24 profissionais, correspondendo a 80% da população. **Resultados:** Dos processos observados, o índice de conformidade foi menor (29,17%) na esterilização e maior (56,94%) na guarda/distribuição dos produtos. Quanto aos subprocessos, foi maior (90,28%) na selagem e menor (8,33%) no enxágue dos PPS. **Conclusão:** A média de conformidade dos processos apresentou índice abaixo do limite de 70%, comprometendo a maioria do processo de trabalho da equipe de enfermagem.

Palavras-chave: Indicadores de qualidade em assistência à saúde. Esterilização. Avaliação de desempenho profissional.

RESUMEN: Objetivos: Evaluar el proceso de trabajo de enfermería en un Centro de Material y Esterilización (CME) de un hospital docente en el noreste de Brasil y calcular las tasas de cumplimiento de los procesos de trabajo de productos de salud (PS) en hospitales en CME. **Método:** Estudio observacional, con análisis cuantitativos. La población objetivo consistió en técnicos de enfermería y asistentes, a través de la observación sistemática en el desarrollo de procesos de trabajo. La muestra resultó en 24 profesionales, que corresponden al 80% de la población. **Resultados:** De los procesos observados, la tasa de cumplimiento fue menor (29.17%) en esterilización y mayor (56.94%) en el almacenamiento / distribución de productos. En cuanto a los subprocessos, fue mayor (90.28%) en sellado y menor (8.33%) en enjuague del PS. **Conclusión:** El cumplimiento promedio del proceso mostró un índice por debajo del límite del 70%, comprometiendo la mayor parte del proceso de trabajo del equipo de enfermería.

Palabras clave: Indicadores de calidad de la atención de salud. Esterilización. Evaluación del rendimiento de empleados.

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INTRODUCTION

Historically, the Material and Sterilization Center (MSC) was responsible only for the sterilization phase. From 1970, the MSC's spectrum of activity was broadened and, at the end of the 20th century, it started to perform all processes due to the requirement of a unique and appropriate physical structure, qualified human resources, and product complexity^{1,2}.

Thus, the functioning of the MSC became centralized, covering the services that need to process health products (HP)³, through good practices, preventing infections related to health care (IRHC), mainly to failures in any of the stages².

Therefore, to evaluate the quality of the assistance provided at the MSC, there are structural indicators; material and human resources; organizational policy; process-activities that, when executed, transform inputs into results; and these results indicate a safe and satisfactory product⁴.

This research is justified due to the empirical finding of non-conformities in the processing of products³. Thus, it is intended to contribute to a situational diagnosis that will allow investments to ensure a more adequate and standardized assistance, aiming at excellence.

Therefore, the study's intention was to answer the question: what work processes, performed by nursing professionals in the MSC of a teaching hospital, have conformity indexes?

OBJECTIVES

- To analyze the work process of the nursing team at the MSC of a teaching hospital in Northeast Brazil.
- To calculate the compliance rates of the work processes of hospital HP in the MSC.

METHOD

This is an observational study, whose data were treated using quantitative methods. Its universe was a teaching hospital, located in the Brazilian Northeast, which provides hospital care of medium and high complexity to users of the Unified Health System (*Sistema Único de Saúde – SUS*), being a field for research and extension. The observation unit was a type II MSC³.

The target population consisted of 30 nursing technicians and assistants, from the three work shifts, through systematic

observation in the development of work processes. The sample, sorted by convenience, was composed of 80% of nursing professionals (24), ensuring the homogeneity of the facts.

Inclusion criteria were: being fully booked and present at the MSC on data collection days. Exclusion criteria were: absence due to vacation, leave, time off, and absences.

The data collection instrument was a checklist adapted from Graziano *et al.*⁵, after being authorized by these authors and based on the current national³ and international standards⁶⁻⁸. A pilot test was carried out which, after adjustments, consisted of 102 items corresponding to the cleaning, chemical disinfection, preparation, sterilization, storage/conditioning and distribution processes.

Each professional was observed only once in the full completion of each process.

Present and compliant processes (PC) were considered to be compliant and present non-compliant (PNC) and absent processes (AS) were not compliant. The data were analyzed using the Statistical Package for the Social Science (SPSS) ® 21.0.

For qualitative variables, in relation to the characterization of the sample, a descriptive analysis was carried out, obtaining frequencies and percentages. For quantitative variables, descriptive statistics were used, by calculating measures of central tendency (mean) and variability (standard deviation).

A significance level of 5% ($p \leq 0.05$) was used, along with the Student's *t* test, for paired comparisons with normal data, the ANOVA analysis of variance for data that follows the normal distribution, and the Tukey test for those who did not present normality. By calculating the Carter positivity index (CPI)⁹, the processes analyzed accordingly were classified as: CPI of 100% — desirable assistance; 90–99% — adequate; 80–89% — safe; 70–79% — borderline; and below 70% — poor. For this study, items with a CPI of 80% or greater for process safety were considered of quality.

The project was analyzed and approved by the Research Ethics Committee of the research institution (CAAE: 57210916.0.0000.5546) and is part of the Master's thesis in Nursing entitled *Evaluation of the work of the nursing team in a Material and Sterilization Center (Avaliação do trabalho da equipe de enfermagem em um Centro de Material e Esterilização)*.

RESULTS

Characterizing the sample, it was identified that of the 24 nursing professionals, 54.17% (13) were nursing technicians

and 45.83% (11) were assistants, of which 91.67% (22) were female, 33.33% (8) worked in the morning shift, 29.17% (7) in the afternoon, and 37.50% (9) on night shifts.

The age ranged between 26 and 54 years, with an average of 37.62 years. The mean working time was approximately three years in the hospital, one year in the sector under study, featuring professionals with a short time in the practice. As for the qualification in MSC, 54.17% (13) of the subjects did not have it and 45.83% (11) had improvement and participation in in-service education.

As for the professional category, there was a statistically significant relationship with the sterilization process; however, professional qualification and the compliance index did not show a statistically significant relationship. Nursing assistants had a higher average compliance rate than technicians.

The compliance rate of the processes observed in the MSC was low. The lowest rate was in sterilization and the highest in the storage/distribution of products (Table 1).

Complete clothing was considered as the use of individual clothing, cap, closed shoes, and disposable shoe cover. Analyzing this variable (Table 2), the highest mean of compliance was observed in cleaning (66.67%) and the lowest in preparation (46.87%). Among the elements of complete clothing, the use of closed shoes showed a lower rate of compliance, with incorrect use or non-use in cleaning equal to 58.33% (14), disinfection 70.83% (17), preparation 87.50% (21), sterilization and custody/distribution 83.33% (20). Private clothing showed compliance in 95.83% (23) of the cases, being considered adequate. The rest of the elements of the complete outfit were mostly PNC or AS. It was found that 62.50% (15) of the professionals wore adornments, such as long earrings and chains.

Regarding the use of personal protective equipment (PPE), the following were observed: gloves (long sleeve, procedure and thermal), goggles, simple mask, apron, waterproof cover,

Table 1. Mean rate of compliance and CPI of work processes in the MSC.

Sectors	Mean compliance	Standard deviation	CPI
Cleaning	41.38	05.80	Poor
Chemical disinfection	41.22	11.91	Poor
Preparation	50.77	04.14	Poor
Sterilization	29.17	05.84	Poor
Storage/Distribution	56.94	09.08	Poor

CPI: Carter positivity index; MSC: Material and Sterilization Center.

and ear protector. Higher conformity means were obtained in the storage/distribution of materials and in disinfection, 58.33 and 30.55% respectively, considered to be poor assistance.

It was found that the use of the simple mask was in compliance, although with lower rates in the preparation processes 54.17% (13). In the cleaning process, AS was present in 100% (24) of the observations, use of the long-sleeve glove, apron, waterproof cover, goggles in 75 (18), and 79.17% (19) in disinfection, all considered to be poor.

In preparation, it was proven that 75% (18) of the employees did not use procedure gloves when handling critically washed items. It should be noted that, in 100% (24) of the situations, there was no hand hygiene before and after the execution of the processes, showing poor assistance.

The mean compliance of processes, referred to in this study as subprocesses (Table 3), which obtained the highest conformities, were assembly (81.25%), sealing (90.28%), and separation (83.33%); on the other hand, the rinsing of semi-critical items showed less conformity (8.33%) in disinfection.

In Cleaning, it was found that the subprocess Reception of PNC HP was: conference of contaminated semi-critical materials 75% (18), critical 83.33% (20), and registration of material input control 95.83% (23).

In Pre-cleaning, PNC was 83.33% (20) in relation to the dilution of the enzymatic detergent; 45.43% (11) did not use graduated containers for dilution; 70.83% (17) did not wash the materials in running water; conversely, 66.67% (16) disassembled the articles before submersion in the detergent, characterizing poor assistance.

Table 2. Average rate of conformity and CPI in the use of complete clothing and PPE, according to the work processes at the MSC.

Conformity		Mean	Standard deviation	CPI
Cleaning	Clothing	66.67	24.08	Poor
	PPE	29.17	13.64	
Disinfection	Clothing	53.12	18.52	Poor
	PPE	30.55	09.41	
Preparation	Clothing	46.87	16.99	Poor
	PPE	14.58	31.20	
Sterilization	Clothing	48.96	20.16	Poor
	PPE	16.67	38.07	
Storage/distribution	Clothing	47.92	22.01	Poor
	PPE	58.33	31.85	

CPI: Carter positivity index; PPE: personal protective equipment; MSC: Material and Sterilization Center.

When Washing, PNC was evidenced, 91.67% (22) did not use the indicated sponge; 45.83% (11) did not rinse piece by piece; 75% (18) did not completely submerge critical and semi-critical articles in the enzymatic detergent; 70.83% (17) did not meet the recommended time; 62.50% (15) did not rub in the direction of the grooves, and 100% (24) of the items washed by hand were not brushed submerged in the enzymatic solution.

In addition, 79.17% (19) of the washing of critical items was complemented with automated cleaning; 87.50% (21) opened the instruments, at the same time, reaching borderline and safe assistance, however 54.17% (13) performed the rinsing correctly. All critical and semi-critical items (100% / 24) were dried manually, appropriately and at a desirable rate; however, they were not dried immediately after washing.

The disinfected articles were the thermosensitive semi-critical ones, and safe compliance rates were verified in the

dilution of the disinfectant 83.33% (20), in the identification of the container regarding the expiration date of the 87.50% dilution (21). The PNC were 66.67% (16) not completely submersing the materials and 70.83% (17) the recommended time of submersion. In the sub-process Rinsing, there was PNC 83.33% (20) in duration and PC 100% (24) of the articles were adequately dried with air flow.

In the preparation of articles for sterilization, it was noted that PC was found to be 70.83% (17) observation of tears, holes, and darning in the tissues; 100% (24) placement of absorbents at the bottom of the case; 79.17% (19) packaging of surgical instruments in the boxes obeying 80% of their capacity; 83.33% (20) were arranged open; 95.83% (23) of the envelopes were tight; 100% (24) used an external indicator, and 75% (18) an internal one. PNC, 91.67% (22) did not inspect the instruments for functionality and 100% (24) did not verify cleaning with a magnifying glass, due to AS related to the latter.

In the Monitoring subprocess, the identification of the articles was 100% AS (24) regarding the registration of the number of the cargo or batch that would be sterilized. However, 95.83% (23) PC were the identification records of surgical boxes, 91.67% (22) the number of pieces, and 100% (24) the sterilization date and validity.

As for the Sealing subprocess, in a heat sealer, compliance was found in 100% (24) of the surgical grade packaging, in 95.83% (23) the temperature met the standards, and 75% (18) of them sealed the primary and secondary packaging based on the weight and nature of the material, showing adequate results.

In the Sterilization process, monitoring showed 100% (24) of compliance in the Bowie-Dick and biological tests, however the second is exclusive to the nurse, both its preparation and reading. 100% (24) of the actions referring to the registration of cargo entry control by autoclave were AS. Regarding the disposition of the articles in the autoclave, there was conformity in the positioning of the packages in 62.50% (15) of the actions, 79.17% (19) obeyed the gap between them and 95.83% (23) of the concave-convex items were arranged in an upright/ inclined position, resulting in poor, borderline, and adequate indices.

After sterilization, 75% (18) of the employees inspected the packages to check for the presence of moisture and cooling. It should be noted that the autoclave's internal camera did not use to be cleaned.

In the Storage/ Distribution process, the average non-conformity related to the Storage sub-process showed a high

Table 3. Mean compliance rates and CPI of the subprocesses performed at the MSC.

Subprocesses	Mean	Standard deviation	CPI
Cleaning			
Reception	15.28	29.97	Poor
Pre-cleaning	52.08	17.16	Poor
Washing	38.89	07.74	Poor
Drying	41.15	07.80	Poor
Disinfection			
Validation/Dilution	61.67	16.59	Poor
Immersion	31.25	43.77	Poor
Rinsing	08.33	19.03	Poor
Drying	66.67	00.00	Poor
Preparation			
Inspection/Functionality	20.83	15.18	Poor
Assembly	81.25	13.29	Safe
Monitoring	62.50	22.12	Poor
Sealing	90.28	15.48	Adequate
Sterilization			
Monitoring	17.71	11.61	Poor
Autoclave arrangement	59.72	27.76	Poor
Post-sterilization inspection	75.00	39.01	Borderline
Storage/ Distribution			
Storage	12.50	33.78	Poor
Sorting	83.33	28.23	Segura

CPI: Carter positivity index; MSC: Material and Sterilization Center.

percentage, since 87.50% (21) did not obey the sterilization chronological order. However, 95.83% (23) stored critical and semi-critical items in a clean, dry place, separating disinfected articles from sterilized ones and protected from the sun's rays, characterizing appropriate action.

DISCUSSION

The processes developed at the MSC are complex, thus highlighting the relevance of their validation, as it prevents contamination, controls quality and avoids IRHC. Thus, nursing professionals must adopt national/international regulations and receive periodic training².

The profile observed consisted, in its majority, of young women, with little time in the MSC and without specific professional qualification. This result was close to the profile of the study carried out by COFEN¹⁰ in a teaching hospital in the state of Rio de Janeiro¹¹. As for age, this similarity may have occurred due to the fact that the institution under investigation held a public tender shortly before the survey.

Most of the observed work processes showed compliance rates below the borderline for desirable assistance, considering the CPI similar to that of surveys carried out in São Paulo¹², Bahia¹³, and Piauí¹⁴. This result may be a reflection of the population being mostly newly hired, without experience in this unit and without participation in a continuing education program. Therefore, permanent education practices overcome difficulties, can standardize and reduce failures, and encourage a culture of safety¹⁵.

It was found that nursing assistants had a higher rate of compliance in processing than nursing technicians. This finding can be justified by the assistants having more time in the institution and being more experienced.

Correlating the rate of compliance of processes with professional qualification, it was found that there was no statistically positive relationship. Whether or not qualification, in this sample, did not interfere with compliance rates. However, this finding does not diminish the importance attributed to training, proven by scientific studies that recommended periodic training to MSC professionals³. This result can be justified due to the sample's being small.

Complete clothing is indispensable for everyone who works at the MSC, to promote safety for professionals, their families, and patients⁶; however, it was observed to be in disagreement, mainly due to the inappropriate use of closed shoes, disposable shoe cover, and adornments. In relation to the

use of disposable shoe covers, probably due to there being strong divergences in the specific scientific literature regarding their effectiveness, one can induce isolated non-use conducts.

Although the use and disposal of PPE are essential for the safety of the professional¹⁶, it was observed that they were not compliant, mainly in cleaning and preparation, similarly to the result obtained in a survey conducted in the states of Bahia¹³ and Minas Gerais¹⁷, but unlike the observations found in Rio Grande do Sul¹⁸, where there was a culture of safety among professionals. This divergent finding may be justified by the fact that Rio Grande do Sul invests more in Permanent Health Education Programs and update courses for its employees¹⁹.

The sectors in the CME require the full use of PPE: elbow-length impermeable, thermal⁷ and procedure gloves, waterproof apron with long sleeves, face mask or goggles, ear protector, and simple masks^{3,15,20}, mainly in purge⁶, however, their complete use showed non-conformity due to the lack of some PPE.

In the Preparation area, the average compliance was lower in the use of full clothing and PPE, especially gloves for the preparation of surgical boxes, which may expose professionals to occupational diseases. A French study carried out in a teaching hospital on the use of gloves found that trained professionals complied more than untrained ones²¹. This result is in line with that found in the present study, referring to the professional qualification that presented low rates, which may have corroborated to the non-compliance in the use of PPE in this environment.

Another unfavorable result was the non-hygiene of the hands by the professionals, violating the recommendation of the indispensability of this action, before starting the work, when completing it, during breaks, after removing the gloves and always when the hands are contaminated⁷.

PPS have become increasingly complex, which requires automated cleaning, abundant rinsing, and drying²². The cleaning process observed, in its majority, showed non-conformity regarding the use of inputs and performance, contrary to normalization³ and allowing the formation of biofilm, which interferes with the action of the sterilizer and increases occupational risks².

A study on prion contamination after cleaning and sterilization found that decontamination occurred after the complete processing cycle, that is, achieving safe results depends on the process, inputs, temperature, and time in physical and physical-chemical sterilization²³. Thus, automated cleaning was performed and the handling of the washing machine

obeyed the recommendations, contrary to what was found in the research carried out in public health establishments in Santa Catarina²⁴.

Regarding HP Rinsing, it should be carried out in abundant running water, without leaving a trace of the sanitizing agent. Contrary to the specific literature^{2,20}, there was a failure in this process, resulting in a break in the effectiveness that interferes with product safety.

The Drying subprocess, relevant for sterilization/disinfection, prevents bacterial growth and prevents disinfectants from inactivity due to hyperdilution, and must be dried in hot air or by hand with a clean towel that does not release particles⁷. However, it was found that the washed material was left on the bench to dry in room air and placed for disinfection before drying, which could cause loss of sanitizing effectiveness².

Regarding non-compliance with the identification of the packages related to the number of the autoclave, batch or load and identification of the assembler, it goes against international standards⁶, resulting in the difficulty or impossibility of tracking the articles^{3,8}. Thus, in addition to the indispensability of the information, the record must be legible, with non-toxic ink and that does not smudge. However, for tissue fields, identification on adhesive tape is permitted in the absence of self-adhesive labels⁶, as found in this and in other hospital units in Rio Grande do Sul²⁵. This routine differs from research in a teaching hospital in São Paulo, as the identification was made by a traceability label²⁶.

The inspection of the fields followed what is recommended by the rules^{3,6}, contributing to patient safety. The opposite situation was found in public establishments in the city of Goiânia, state of Goiás¹.

To guarantee the surgical sterile barrier, especially when preparing perforating, heavy or large-sized items, they must present double sealed packages^{1,2,6}. Such determinations showed conformity, once that the assembly of HP was standardized and followed the recommendations^{2,6}. Most of the HP were organized in the autoclave accordingly, as was the case in Goiânia, with the largest packages being arranged at the bottom of the chamber and the smallest ones at the top²⁷.

A study on sterilization control carried out in Tabriz, Iran, for a period of 14 years, found that there was a significant result regarding the use of chemical indicators²⁸. Likewise, it was observed that chemical integrators were used and placed in surgical boxes, in the fields that cover the patient, in packages for invasive procedures.

It was found that the sterilization control of the autoclaves was performed daily, although the validation practiced

was only chemical and biological, without verification of the physical parameters, due to the absence of printed tape and records. Such occurrence demonstrates insufficient financial investment in the health sector and the need for management control. The opposite situation was found in 60% of public institutions in the city of Goiânia²⁷.

In addition, there was no routine for disinfecting autoclaves and surfaces, a worrying result, as this increases the risk of cross and occupational infections, contrary to the recommendation that all surfaces and equipment should be disinfected²⁹.

The products, when carried to the Storage/Distribution sector, must be inspected for humidity, completeness, color change of the external indicator, and arrangement in the cabinets/shelves in chronological order of sterilization². These items were observed accordingly, except in relation to the chronological order of sterilization, a data similar to the study carried out in Goiânia, where a health establishment carried out the process in a properly manner²⁷. This non-compliance can be a contributing factor to the increase in health care costs.

Monitoring the processing of articles in the MSC is complex and requires specific attention from cleaning to distribution, so institutions must plan work according to quality and patient safety paradigms.

Summarily, it is the nurse's role not only to have technical-scientific knowledge about the functioning of the MSC, but mainly to coordinate, guide, supervise, stimulate, and support the technical-scientific improvement of nursing professionals, fulfilling their functions ethically and in observance of the guiding principles of the profession.

As a limitation of this study, there is a little comparative discussion between Brazilian states and other countries due to the scarcity of articles with an international approach on this topic.

CONCLUSION

The calculations of the conformity indexes of the work processes of hospital HP in the MSC allowed to conclude that the mean of compliance presented indifferent indexes of classification by the CPI. However, these processes were compromised by the deficiency in the physical structure, absence of periodic training, and supervision of nurses.

The general analysis of the nursing team's work process in a MSC of a teaching hospital in Northeast Brazil adds conformities and non-conformities similar to the studies

carried out in other Brazilian regions, in non-compliance with current national and international standards, mainly in public services and in investment in health care and, in particular, MSC.

The results obtained reflect the need for greater investment in the physical structure, inputs, policies and practices of continuing education, in order to abolish flaws in the processes necessary for safe care for patients.

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