ORIGINAL ARTICLE

QUALITY EVALUATION OF A CENTRAL SUPPLY UNIT AT A UNIVERSITY HOSPITAL

AVALIAÇÃO DA QUALIDADE DE UMA CENTRAL DE MATERIAIS E ESTERILIZAÇÃO EM UM HOSPITAL ESCOLA PÚBLICA

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ABSTRACT

Objective: to evaluate the working process in a Central Supply Unit according to recommended practices from the Epidemiological Surveillance Center. Method: quantitative, descriptive and cohort study that evaluated 105 items by means of inspection, interviews and checking the unit records. Data collection was conducted from December 2009 to January 2010 and the results were analyzed in simple frequencies. The research project was approved under protocol No. 052/10 by the Research Ethics Committee of State University of Londrina (UEL). Due to the lack of reliable biological accident records this study opted for adding data from complement interviews with all CSU employees, a total of 20 professionals, including nurses, technicians, assistants and attendants. Results: the indicators divided into three groups: cleaning, preparation, packaging and sterilization, storage and distribution. Cleaning indicators achieved 32.4% non-compliance. Assembling and wrapping indicators achieved 26.9% and sterilization, storage and distribution indicators presented 26.2% non-compliance. Overall, 9.5% of the items were classified as not applicable to the CSU unit. Conclusion: according to the results, the evaluated Central Supply Unit needs improvement to meet higher quality standards.

Descriptors: central supply unit; quality indicators; nursing.

RESUMO

Objetivo: avaliar a estrutura, o processo e o resultado da Central de Material e Esterilização segundo as práticas preconizadas pelo Centro de Vigilância Epidemiológica. Método: estudo quantitativo, descritivo e transversal, que avaliou 105 itens por inspeção, entrevista e consulta aos registros da unidade de Central de um hospital de grande porte no Norte do Paraná-PR, Brasil. A coleta foi realizada nos meses de dezembro de 2009 e janeiro de 2010 e os resultados foram analisados por frequência simples. O projeto de pesquisa obteve parecer favorável do Comitê de Ética em Pesquisa da Universidade Estadual de Londrina com nº 052/10. Devido à inexistência de registros fidedignos de acidentes biológicos, optou-se pelo acréscimo de entrevistas para complementação dos dados, com todos os 20 funcionários da Central: enfermeiros, técnicos, auxiliares e atendentes de enfermagem. Resultados: os indicadores estudados foram divididos em três grupos: limpeza; preparo e acondicionamento e esterilização, guarda e distribuição. Para os indicadores de limpeza obteve-se 32,4% de não conformidade. Os indicadores de preparo e acondicionamento apresentaram 26,9% e os de esterilização, guarda e distribuição 26,2% de não conformidade. Ao todo 9,5% dos itens foram classificados como inaplicáveis para a realidade da CME estudada. Conclusão: de acordo com os resultados obtidos verificou-se que a Central estudada necessita de aprimoramentos para melhoria de seu serviço. Descritores: esterilização; indicadores de qualidade em assistência à saúde; enfermagem.

RESUMEN

Objetivo: evaluar el proceso de trabajo de una Central de Materiales de acuerdo con las prácticas recomendadas por el Centro de Vigilancia Epidemiológica. Método: estudio cuantitativo, descriptivo y transversal, que evaluó 105 artículos por inspección, entrevistas y verificación de los registros de la unidad. La recolección de datos se llevó a cabo entre diciembre de 2009 y enero de 2010 y los resultados fueron analizados por frecuencia simple. El proyecto de investigación fue aprobado el número 052/10 del Comité de Ética en Investigación de la Universidad Estadual de Londrina. Debido a la falta de registros fidedignos de accidentes biológicos, se optó por la adición de entrevistas para complementar los datos, con todos los 20 funcionarios de la Central: enfermeras, técnicos, auxiliares y atendentes de enfermería. Resultados: los indicadores se dividieron en tres grupos: limpieza, preparación, embalaje y esterilización, almacenamiento y distribución. Para los indicadores de limpieza obtuvo-se 32,4% de no conformidad. Los indicadores de preparación y embalaje obtuvieron 26,9% y los de esterilización, guardado y distribución 26,2% de no conformidad. En total, 9,5% de los artículos fueron clasificados como no aplicables para la realidad del CME estudiado. Conclusion: de acuerdo con los resultados obtenidos se verifica que la Central estudiada necesita de aprimoramientos para mejorar su servicio. Descritores: esterilización; indicadores de calidad en asistencia a la salud; enfermería.

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INTRODUCTION

The logistics that involves the provision of dental-medical-hospital material in relation to the quality and quantity has a direct impact on care provided in a health institution. The Central Supply Unit (CSU) as a centering and strategic cell in the forecasting and delivery process of dental-medical-hospital material and is faced with concepts of efficiency, effectiveness, provision, and nosocomial infection for the quality assurance, required.

Although the CSU is considered a production unit, it is not currently consistent with the concepts of logistics, effectiveness and efficiency used by production engineering. Within the industrial unit concept, the CSU also faces decisions involving production, investment in technology, creation of measures to improve the performance of their activities, innovation and knowledge.1

Added to that there are issues to be incorporated into this work process as new technologies, surgical techniques and norms that add greater responsibility to the process and unit manager. Given this scenario it increases the need for quality to guarantee a legal support. In addition to these factors, it is essential that the CSU manager includes issues, inherent in the work process of this unit as physical, chemical, mechanical, physiological and psychological occupational responsibilities and the continuing need for instruction and training that greatly impact the workers’ health in the CSU.2

The result quality of the actions developed in the CSU is related to their work process from the combination between physical structure, material and human resources involved in the tasks they performed.

There is a pressing need to optimize processes and increase productivity that result in patient care improvement and reduce costs with material processing.3 The continuous search for quality of service is to ensure the satisfaction of customers serviced being the, Inpatient Units, Operating Room, Intensive Care Unit and others of equal importance, supplied by the work done in the CSU.4

This quality can be measured by indicators, defined as measures adopted to evaluate the performance and in this context, essential managerial instruments.5

In health, the quality evaluation was initiated by the American College of Surgeons by establishing the Hospital Standardization Program which was characterized as a set of standards to ensure the quality of care delivered to patients.6 The quality must permeate all activities of the units in a health institution, however it is essential in a sterile materials producing unit.7

In order to develop parameters for the foundation of hospital practices, the State Department of Health of Sao Paulo through the Center for Epidemiological Surveillance (CES), developed the Manual for Quality Assessment Practices for Hospital Infection Control organizing indicators for quality assessment of health institutions.

The Manual for assessing the quality of Hospital Infection Control practices includes all items that, when according to the normalized standardization, shows the degree of compliance in relation to the expected quality.8

According to the need for improving the assistance provided in hospital units, excelling through excellence, this research aims to evaluate the structure, process and outcome of Sterilized Material Center using quality indicators according to the practices recommended in the Manual for Quality Assessment Practices for Hospital Infection Control of CES/SP.

METHOD

Quantitative, descriptive cross-sectional study, developed in the CES unit in a large hospital in Northern Paraná.

Data collection was performed with the use of a spreadsheet for data relating to the Processing Dental-Medical-Hospital Items Manual of Quality Assessment Practices for Hospital Infection Control, developed by the Ministry of Health Department, Division of Hospital Infection Surveillance Center published in 2006. With 105 assessment items, this covers inspection procedures, interview and consulting the records of the service unit under study, including the cleaning, preparation, packaging, sterilization, storage and distribution in this unit. The items were evaluated with this manual follow the triad proposal by Donabedian9 - structure, process and outcome.

The collection was carried out, between December 2009 and January 2010 after approval by the researchers of the institution and protocol No. 052/10 by the Londrina State University Ethics Committee in Research.

Researchers observed the daily activities in the different work shifts according to the
request of the corresponding items from worksheet used and performed the registration on the instrument proposed by the manual.

The data on the structural aspects, in-service education and maintenance were collected by means of a documentary records search in the unit. Due to the lack of reliable biological accident records, additional interviews with all employees of the CSU a total of 20 professionals, including nurses, technicians and nursing assistants were chosen to complement the data. A semi-structured instrument developed by the researchers was used, and the interviews we conducted after signing of the Free and Informed Consent.

The analysis of data generated by observation, interview and data collection documentary was performed by means of descriptive statistics, with use of simple frequency as recommended by the manual for

the indicator preparation. Each indicator was composed by: title; description; scientific reasoning and or legal; type of evaluation; numerator and denominator; sample for calculation of the indicator; information sources; evaluation criteria and assessment spreadsheet, according to the instructions from the instrument, using sampling and parameters recommended by it. The answers to open questions from the interview were also tabulated by the frequency of occurrence.

RESULTS AND DISCUSSION

The indicators were divided into three groups: indicators for cleaning, preparation and packaging, sterilization, storage and distribution. Figure 1 portrays the indicators by their degree of distribution and compliance, not compliance and does not apply.

![Figure 1. Indicators of cleaning, preparation and packaging and sterilization, storage and distribution and the degree of compliance in a CSU, Londrina - PR, 2009/2010.](image)

**Cleanliness Indicators**

For the cleanliness indicators, 37 items were checked with an ideal value of 100% compliance, being divided between the indicator for the assessment of technical-operational resources, process evaluation, and the cleanliness conditions. Of these, 2 (5.4%) were classified as not applicable. These indicators referred to the sector’s ventilation and the footage for day hospital.

**Compliance**

There were 23 items (62.2%) in compliance, divided into several steps. Regarding the sector’s structure the following were compliant: lighting and finish, materials to provide effective cleaning such as: benches, sinks, taps, air and water guns, jets, brushes of various diameters and soft bristle, air-
conditioned environment, piece by piece drying for manual washing process and without abrasive material usage.

In relation to the receipt of materials the articles were not grossly soiled or immersed in solution; soiled articles were not previously submerged in disinfectant chemical solutions and were disassembled by means of an existing service protocol.

The correct use of the material resources was also identified in the following situations: the nurse participates in the decision to purchase products supplies used in the purging; routines and rules are present in the cleaning sector, easy access and revised at least annually. Enzymatic detergents and other resources to aid in cleaning for hospital usage and published in the official bulletin are available, and its solution - dilution and change - are in accordance with the factory specifications.

Items processed in automatic washers are loaded in racks and in appropriate quantities, with the instruments removed; arranged opened, with the lighter over the heavier and items with complex conformations and cannulated are replaced by ultrasonic cleaning and/or manual with appropriate utensils (brushes for cannulated materials of different sizes, cotton swabs, water and air guns).

All these precautions are necessary, because the effective step of cleaning the dental-medical-hospital items is what will guarantee the effectiveness of any sterilization method, knowing that the bio-burden, microbial load in the dental-medical-hospital instruments, varies according to their location of use.

After cleaning, the washed materials are dried using an air flow heat source, and clean fabric absorbent that does not leave residual particles. It is argued that adverse effects can be caused by fabric fibers that are entangled in the instruments during the drying process.

Regarding health of the CSU worker there is availability of the employee records with some employees do not use safety glasses, even being available for use and receiving specific training, being in disagreement with the Regulatory Standard (RS) No. 32. The nursing workers experience negative feelings regarding the use of PPEs as suffocation, inconvenience, discomfort and heat, which causes them to resist the use of these tools for their own protection.

In the sector there is no preventive maintenance which allows for the anticipation of problems and failures in the equipment used; this is very common in public health services, where there is only curative maintenance, in which the repairs and reforms occur when the equipment is already broken. Maintenance must focus on quality management and productivity generating reliability and cost reduction.

In the assessment of the indicators it was found that the sector does not verification use tests for cleanliness, the checklist and performed visually by the employee with the use of a magnifying glass. Currently, studies show that only a visual inspection is not enough, for residue detection, especially in cannulated materials and complex conformities. For this reason the public consultation 34 of 2009, proposes that regular tests for the cleaning quality evaluation are used, to detect the presence of protein residues, tests for the proper functioning of ultrasonic washing thermal sterilizers, among others.

In the CSU evaluated there is an annual continuing education program, performed by
the nurses responsible for the unit; however there are no records of them. This subject has been the subject of many discussions regarding the role of the nurse having no visible activities, among other factors, the absence of records. The planning and implementation of project records can also be used for legal proof of their intellectual and managerial production.

Another point to consider is the difficulty in co-participation from the Commission of Hospital Infection Control (CHIC) in these trainings. This partnership is highly desirable for the planning and development of actions that effectively collaborate with infection control.

The indicator for the clean conditions, recorded by the visual inspection of 326 items, zero being the optimal value, showed a value of 1.8% of non-compliance. Despite not being a very high value, this shows that there are flaws in the work process and that these items have gone through the cleaning process and remained soiled, and may not be an effective sterilization process if not detected, making them unsafe.22

Another indicator assesses the number of occupational accidents with cleaning items. In the sector there is an absence of these records, only being able to access this information through data provided by occupational medicine. Through the interviews it was discovered that an employee had an occupational accident with biological material, with a spatter of blood in their eye when performing the drying with compressed air in a material with lumen, indicating lack of PPE use, following the hospital protocol for attending biological material accidents. This type of accident is totally avoidable, because the use of protective eye wear is mandatory when this type of work is performed, particularly when the use of compressed air.12 Even this study by detecting that only one worker suffered this type of accident, one must reflect that the index is too high the risks they entail.

∗ Indicators for preparation and packaging

The indicators for preparation and packaging of materials were divided into technical-operational resource indicators, for the process and outcome, on the sealing of packages. Presenting 3 (11.5%) of the items as inapplicable, these were related to the use of dry heat or sterilization of oils not performed in the unit.

• Compliance

Among the 16 (61.5 %) indicators related to the preparation area that were in compliance for proper lighting, presence of image intensifier lenses and air guns, stricter inspections for cleaning and materials conservation by employees who use a cap, as recommended by the manual.

The semi-critical thermal sterilized material is completely dried before being placed in a clean package.

The CSU nurse participates in partnership with the CHIC of acquisitions of the packaging, sealing machine, chemical and biological tests and other supplies for the preparation area. The packages are appropriated for the type of sterilization process and they possess a Ministry of Health registration. There is rational use of chemical integrators or emulators (5th or 6th generation), and the use of the indicator strip process (class I) in the whole item to be autoclaved. The materials are identified by a tag containing a bar code, lot number, sterilization method, expiration date and name of the employee responsible for the packaging.

The rational use of chemical and biological tests for sterilization recommended by the manual can have several interpretations. There is no consensus among the professional associations and official recommendations on the need and frequency of chemical and biological testing use. It is argued that at a time of reflection on the rational use of resources, one could use the 5 and 6 class integrators to replace the much higher cost biological control. 12

• Non-compliance

Once again physical structure incompatibility problems appear that requires 0.25 m²/space- totaling a minimum of 79.25m² - and found it was a preparation and packing area of 51.09 m² and the lack of preventive equipment maintenance.

AA very important indicator for non-compliance with the instrument is related to the cotton fields in packaging materials used for steam sterilization, which do not have a control on the number of reuses. That leads to questions as to the effectiveness of this as a microbial barrier, since the literature which provides its maximum utilization should be 65-70 times.21

The purchase of this fabric is not performed by the CSU, nor does it count on this unit’s nurse participation. In the
descriptive purchase there is no specification of fabric, 100% cotton with standard denim 2/1, weight and not even a number of the required threads, as recommended in Brazilian Standards of Technical Regulations (NBR) 14027/2007 for standard one and NBR14028/2007 for the double one. 

Non-compliance is the size of packages to be autoclaved which exceed 25x25x40cm or 5 Kg, hindering its entrance into the sterilizing agent. 

Regarding the package sealing thickness studied 136 (100%) were non-compliant items having a seal from 10 to 12 mm. According to the instrument used, the optimal thickness for sealing is 20 mm. 

Despite this incompatibility regarding the sealing, one should take into consideration that both equipment for sealing as the packages purchased have registrations with the Ministry of Health - National Health Surveillance Agency (Anvisa). NBR14990-1 to 11/2005 indicates a minimum sealing width of 6mm, as for both the packaging and the CSU sealing equipment studied are in line with Brazilian standardization.

The sealing distance from the edge presented in 126 (92.6 %) sample items used, sealing lower or equal to 3 cm from the edge, also not in accordance with the manual and in non-compliance in the packaging with the Anvisa certifications.

♦ Sterilization Indicators, storing and distribution

Indicators related to sterilization, storage and distribution were divided into technical and operational, process and evaluation of conservation packages. As inapplicable items 5 (11.9 %) were classified, referring to the ventilation, presence of gases and gaseous equipment qualification.

♦ Compliance

Presented line 26 (61.9 %) items. Sterilization, storage and distribution of articles in the CSU has adequate physical infrastructure, as well as equipment, supplies and actions to ensure this process and occupational health against chemical and physical risks. The nurse participates in the decision to purchase the equipment and supplies used in the sterilization and storage sector. Equipment is only used with registration from the Ministry of Health awarded by Anvisa.

There is no accumulation of coarse dust, garbage, and the presence of rodents or insects in the area assessed.

The architecture of the storage room is prepared in a way to limit traffic, facilitate item identification and promote cleaning. On site there are no sources of water, open windows, exposed pipes and drains are siphoned and sealed and cleaning is performed daily.

The sterilization area is located between the preparation area and the storage and distribution; it is equipped with pulsating vacuum steam autoclaves. The Bowie & Dick test is performed before the first cycle of the day. The minimum parameters for the sterilization of packaging materials for pulsating vacuum autoclaves is 134 degrees Celsius for 4 minutes at a minimum or other validated parameters adopted by the institution. The records for temperature parameters, pressure and time of all cycles of autoclaves are micro-processed and stored for five years.

There is preventive maintenance planning documented on equipment used for sterilization, being the clinical engineering sector responsible for its implementation. The autoclaves are the only hospital equipment that has this type of preventive service, being that the other only is dressings.

The items to be sterilized are not stacked, but arranged in a vertical position, with clearance (25 to 50 mm) between the packages. The items conformation concave-convex in the baskets are arranged in vertical or inclined and items such as jars, buckets and bottles are arranged upside down. The larger packages occupy the lower position. The packages come out of the autoclave dry.

The sterilization control of the autoclaves is carried out by biological indicator at a minimum weekly or daily frequency. The control of autoclave sterilization is performed by a biological indicator after corrective maintenance and whenever the implant material and / or prosthesis, the result is expected to be released. The results of biological indicators are recorded and archived for five years.

The area employees for sterilization, storage and distribution of critical articles use caps. The employee responsible for the sectors of sterilization and storage of sterilized equipment did not perform actions which contaminate the hands and touch the upper airway during the observed period.

In the storage of materials, the packages are stored in chronological order based on production. The materials to be distributed are inspected for integrity and their indicators

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revealed.

Standards and routines of the sterilization and storage sector are easy to access and reviewed at least annually.

- Non-compliance

The greatest problems were related to the storage of the material that has a physical structure with an improper size.\textsuperscript{14} In addition, the shelves are made of wood and the temperature is not within the parameters required which is 18 to 22 degrees Celsius.\textsuperscript{24}

In relation to sterilization, there is a lack of medical reports proving the effectiveness of the water treatment for autoclaves and their thermal qualification.

There are no records of a recall routine or recollection of the materials in the event of problems with the parameters of the effectiveness of sterilization.

There is a continuing education program with a member from CHIC, problems appearing such as the transfer of materials still warm to the storage area and the lack of hand washing for the completion of the unloading of the autoclave contents, which could compromise the sterilization process.\textsuperscript{24}

The indicators used for sterilization, 201 packages were inspected for evaluation of their conservation, value with zero being their ideal value. This indicator has obtained 29 (14.43 \%) items in incompatibility. This relates to the packaging with holes or very wrinkled because of the intensity of handling, preventing its use by failing to ensure the sterility of its content. This problem is related to, reduced storage space with surgical boxes stacked packages, surgical grade materials stacked in small compartments, causing such problems to appear.

Validity of sterilization-related events is an approach that considers and values the integrity of the packaging, among other items, to ensure their safe use.\textsuperscript{12} It is not the case of the CSU, it still has assessed fixed validity periods and not examining the integrity of their packaging.

**CONCLUSION**

According to the results it appears that the CSU studied needs more improvements to obtain a service of excellence, since the general index according to the instrument was 65 (61.9\%) for the items, and 100\% is needed for ideal compliance.

It is known that many of these items are not governed by the nurse. Case Studies such as this must be done to support the search for improvements of these units, higher professional training, safe work environment, safety and quality service, and give visibility and voice to the CSU manager on the institution’s master plan for the demand for improvements.

When assessment methods are used to search for quality of services provided, methodologies and tools from different sources may be used. There are several national and international organizations focused on this service, which can be used to support change processes and quality programs. Thus, the successive level resources no longer have to support an empirical connotation solicitation with change generation proof and increase in the quality of service.

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