

SAFETY: PACKAGES, PACKING AND STORAGE PERIOD OF STERILIZED MATERIALS IN PRIMARY CARE

Graciela Machado de Araujo*

Nara Reisdorfer**

Luiz Anildo Anacleto da Silva***

Rafael Marcelo Soder****

Adriane Marines dos Santos*****

ABSTRACT

The basic health units have great demand for medical, nursing and dentistry procedures, on which the security of the assistance and the patient depends. The objective of this study was to understand how nurses, nursing technicians, assistants and dental office assistants proceed in managing packaging, guard and distribution of sterile materials in the health units of the primary care. This is a descriptive and exploratory research, with a qualitative approach. The participants of the research were nurses, nursing technicians and assistants of dental office operating in basic health units of three cities in the State of Rio Grande do Sul. The data were generated through semi-structured interviews between October and December 2015 and assessed through content analysis. One evidenced that the studied services lack structure, organization and process definition with regard to the packaging of critical objects. The conclusion is that the assistance to users with respect to procedures using sterile materials are exposed to risks, weakening the patient's safety, emphasizing the need for continuous training of professionals.

Keywords: Public health nursing. Patient safety. Sterilization.

INTRODUCTION

Concerning about patient safety has been one of the most debated topics in recent decades. Although health care is aimed at benefits, mistakes can occur in different forms, intensities and in the most diverse stages of care. The reduction of damages and risks involves the incorporation of good practices in health services, which favor the effectiveness of the care provided and its management in a safe way⁽¹⁾.

Despite the existence of many patient safety studies, the majority are concentrated in the hospital setting. Research on patient safety in Primary Health Care (PHC) are scarce, especially in developing countries, evidencing gaps in knowledge in this level of attention⁽²⁾.

Patient safety in PHC can be negatively influenced by problems such as limitation or shortage of human and material resources, work

overload and qualification deficit of professionals involved in the care process⁽³⁾. It should be noted that these failures are systemic, linked to processes, not often depending solely on professional action. One of the reflexes of patient safety failures in PHC is distancing the user from loss of credibility in the service. Therefore, there is an overload of hospital demands, making it difficult for the user to access, and contributing to adverse events (AD) in these institutions⁽⁴⁾.

The Brazilian Network of Nursing and Patient Safety (REBRANSP, Polo RS) proposes strategies regarding the prevention of infections in the surgical site, among them: defining basic elements of infrastructure, which must be constantly monitored and evaluated, personnel qualified for the function, water quality, light sources, supplementary oxygen networks, surgical equipment in use and in particular the availability of sterilized instruments⁽⁵⁾. These recommendations are relevant also to the extra-

*Academic Nursing. Universidade Federal de Santa Maria, Campus Palmeira das Missões. Palmeira das Missões (UFSM), RS, Brazil. E-mail: gra_m_a@hotmail.com

**Academic Nursing. Universidade Federal de Santa Maria, Campus Palmeira das Missões. Palmeira das Missões, RS, Brazil. E-mail: nara.reisdorfer@hotmail.com

***Nurse. Doctor of Nursing, Professor of Nursing Course. Universidade Federal de Santa Maria, Campus Palmeira das Missões. Palmeira das Missões, RS, Brazil. E-mail: luiz.anildo@yahoo.com.br

****Nurse. Doctor of Nursing, Professor of Nursing Course. Universidade Federal de Santa Maria, Campus Palmeira das Missões. Palmeira das Missões, RS, Brazil. E-mail: rafaelssoder@hotmail.com

*****Nurse. Specialist in Intensive Care. Nurse Assistant Hospital Regina, Novo Hamburgo, RS, Brazil. E-mail: adrianemarines82@gmail.com

hospital environment, as in the case of care provided in PHC units.

The unit sterilization process of PHC depends on several factors to make it occur in a convenient way. Favorable conditions for professionals, periodic training, supply of inputs such as packaging and solutions, and adequately organized structure, are some of these factors⁽⁶⁾.

The processing of materials follows the steps of cleaning, drying, choosing the appropriate packaging, disinfecting and / or sterilizing and storing. The nursing team and dental assistants are generally present at all stages of this process, from cleaning the material to its safekeeping, which must take place in a clean and dry place, protected from direct sunlight and subjected to minimal manipulation⁽⁷⁾.

In this context, nursing performance, in addition to being based on institutional norms, should be based on scientific knowledge, workers' clinical experiences, the structural conditions of the service and knowledge of the legislation that regulates the practice of the profession⁽⁸⁾.

The study is justified in view of the fact that some infections linked to health care can be avoided through the correct sterilization, storage and handling of the instruments. Therefore, the objective of the study was to understand how nurses, technicians, nursing assistants and dental assistants proceed in the care of packaging and time of custody of critical articles in basic care aiming at patient safety. These stages of the process have been chosen in view of their importance, since they compromise the whole process in the event of a failure, although considered little complex.

METHODOLOGY

A study characterized as a descriptive and exploratory research, with qualitative approach⁽⁹⁾. It was carried out in the basic care units of three municipalities in the northwest region of the State of Rio Grande do Sul. The choice of municipalities is due to the fact that they have only small and medium-sized hospitals, with the primary health care network as a reference for various demands. Data collection took place from September to December 2014. The research subjects were

nurses, nursing technicians, nursing assistants and dental assistants working in primary health units. Among the inclusion criteria, the following units were considered: the nurse, technician or nursing auxiliary and dental assistant who had been working for at least one year in the primary health care network and who participated directly in some of the stages of sterilization and instruments' custody.

For the construction of this study, a semi-structured interview with open and closed questions was carried out, in the professional's workplace and individually. The questions were about the care taken by the professionals during the execution of the steps of the sterilization, with a view to patient safety. The interviews were recorded and performed in time agreed with the researched individual, and subsequently transcribed in full and submitted to content analysis⁽¹⁰⁾. In order to guarantee the privacy of the subjects, the participants were identified by codes: for the municipal secretaries surveyed, the letter 'S' followed by the numerical order of each secretary was used. For the subjects interviewed, the coding by functional category 'E' was used for nurses, 'TE' for nursing technicians, 'AE' for nursing assistants and 'ACD' to dental office assistant.

The secretariats in which the data were collected are located in cities with 34, 25 and 86 thousand inhabitants, respectively. The number one secretariat consists of seven teams of the Family Health Strategy (ESF) and one Basic Health Unit (UBS) (12 interviews), the number two secretariat consists of eight ESF teams and four UBS (15 interviews) and the number three secretariat counts with 12 ESF teams and 5 UBS (15 interviews). The sample consisted of 42 interviews, totaling 100% of the units that counted on professionals from the three areas (nurse, technician or nursing assistant and dental assistant).

The research project was submitted to and approved by the Research Ethics Committee of the Federal University of Santa Maria, according to the consolidated statement number 693,802.

RESULTS AND DISCUSSION

Of those interviewed, 14 were nurses, four were nursing auxiliaries, 10 were nursing

technicians, and 14 were dental assistants. The number of respondents was defined by the saturation of data in relation to the objective.

As far as this study is concerned, the focus is related to the discussions related to the risk management and patient safety related to the use of packages and the custody of critical articles in basic health units.

The analysis of speeches allowed the construction of three categories that will be presented below.

Casings used in the process of sterilization in health care units

The secretariats surveyed perform the processing in a decentralized way, that is, each unit processes its materials. Four forms of processing are used: disinfection by means of immersion in aldehydes and by means of alcoholic solutions, besides the sterilization in autoclaves and greenhouses, using different packages, or not making use of them.

In fact, there was a great variation between the types of enclosures used in each secretariat and even between units of the same secretariat. Seven different enclosures were cited by the professionals surveyed. Among the most used by the units, there are polypropylene blanket, surgical grade paper and crepe paper, as the following statements show:

These are polypropylene blanket and surgical grade paper (E1 S1).

We are using here the surgical degree (E3 S2).

We utilize the crepe paper (E1 S3).

Among the packages recommended by the National Agency for Sanitary Surveillance (ANVISA) for autoclaving critical articles, there are raw cotton fabric, surgical grade paper, crepe paper, metal boxes, nonwoven, 100% polypropylene. They must comply with a sequence in the execution of the folds in order to maintain asepsis in the work area and present identification in adhesive tape, including product name, lot number, date of sterilization, use deadline, sterilization method and the name of the person responsible for the preparation. It is also recommended that the sealing of envelope-type packages is made by a sealing term⁽⁷⁾.

However, it was also noticed that some units

use packages that are not recommended by ANVISA, claiming to be the ones the local Health Department makes available. This is evident in the following lines:

[...] What we have in the unit is the Kraft paper. We know is out of use but that's what we have for the moment. There is already a conversation, an initiative to replace it, but for now that's what we use. (E2 S2)

It is the Kraft paper. (TE2 S3)

Crepe paper. (TE5 S3)

A similar reality was observed in a study published in 2012, where 48% of the 25 basic units surveyed used kraft paper as the main casing⁽¹¹⁾. The packaging is necessary to protect the critical articles after their sterilization. By this fact, the use of suitable envelopes allows the conservation of the materials.

Therefore, it is important to emphasize the importance of health units to comply with the recommendations of the regulatory body regarding the types of enclosures that can be used, based on the assumption that it has carried out studies and tests that prove which products allow and maintain the sterilization of the materials and instrumentation, thus ensuring patient safety.

The management of safe attention to users, with risk modeling, is one of the essential functions in nursing practice. The contextual safety of patients is linked to the establishment of structures, processes and working methods according to what has been recommended, whose main objectives are to coordinate actions to minimize risks of damages to health care. The availability of safe medical and dental products is one of the infection control strategies in health procedures⁽¹²⁾.

Although the justification given by the professionals for the lack of adequate enclosures in the units points to the Health Department, it is emphasized that the management of material resources is among the duties of the professional nurse, being him/her responsible for requesting the necessary inputs to ensure the quality of the assistance provided. If this professional does not have his / her request answered, in the capacity of technical responsible for the unit, he/she can refuse it and guide the team, so that they do not perform procedures that require materials

sterilized by the risk of possible aggravations.

Understanding the factors that put patient safety at risk is the first step in developing strategies and tools for improving the quality of care. It establishes a system of monitoring and risk management, directing resources and efforts proactively to prevention⁽¹³⁾.

Another common practice in the Secretariat is the dispensing of materials for home use, packed in brown paper, even if it is not indicated. This practice happens because of the units' material saving, evidenced in the following speeches.

[...] we involve in the brown paper for patients to take it home, even because the patient will take it home [...] it will contaminate the material itself, so for saving the material we use here, patients who take home the material carry it wrapped in brown paper (TE1 S1).

[...] for patients who make dressing at home, the gauzes are dispensed, and brown paper is used (TE4 S1).

The safety of the patient is linked to a number of factors, with emphasis in this study on the type of packaging used in the sterilization of critical articles. Therefore, any article to be sterilized must be packed in carefully selected packaging, for the safety of the process and the patient. Considering that this type of material is stored in the unit until dispensing, often in an inadequate place, that is, they are exposed to risk of contamination. It should be emphasized that the performance of home procedures does not exclude the correct use of materials / instrumental, since the non-use of a standard procedure, regardless of location, can compromise user safety.

The conditions of storage and handling of this material at home are unknown, doubting the treatment of the patient, which can negatively interfere in their recovery time. Respondents' answers allow us to understand that, in many situations, users of services are exposed to risks and, consequently, to the weakening of security.

Place of custody of materials and instruments after sterilization

In this category, it was possible to identify the locations used by the services to store the materials after sterilization. We can say that there is uniqueness among the three secretariats studied.

In the cabinet (TE4 S1).

We are looking to store sterile material in glass cabinets [...] (E1 S2).

We have a cabinet (TE2 S3).

The temperature and relative humidity of the air at the storage site of sterilized materials should also be considered for determining the expiration date of the products. The storage location must be clean, dry and ventilated, protected from direct sunlight and subjected to minimal manipulation⁽⁷⁾. The management of risks and safety of users is a priority, as more and more procedures are done using sterilized materials in basic care services.

Although professionals use cabinets to store materials, they do not report knowledge about issues such as the need for exclusivity of the place of custody and the interferences that the material suffers from such factors as temperature and relative humidity.

[...] the dressing material is in the dressing room, inside a tray [...] (E4 S2).

We come here in the sterilization room, in that part that is the place that we consider sterilized. There is a drawer where we place the gauze packets and in the ambulatory there is a closet that is specific for that (TE1 S1).

The regulation of factors, such as temperature and relative humidity, is hampered by the fact that the storage rooms are often contiguous to the sterilization area, where the autoclaves are found, which, at the end of the process, eliminate steam, constantly increasing both the humidity and the ambient temperature⁽¹⁴⁾.

Despite the importance of controlling air temperature and humidity, a review of the literature evidences the existence of divergences, which requires standardization by the health services. The parameters range from 18° to 25°C for temperature and 30% to 70% for relative humidity⁽¹⁴⁾.

Critical item custody time

In this category, we sought to understand the temporal delimitations regarding the materials and instrumental custody adopted in each municipal secretariat. It was noted that there is disagreement as to the time the materials remain stored, both between secretariats and between

the units of the same secretariat.

After sterilization, if the material is not used, it is re-sterilized seven days later. (E1 S1).

The material packed in cotton fabric remains so for seven days. And this surgical grade paper has a longer time when well sealed. We use 6 months as standard in the unit. (E2 S2).

A maximum of 15 days [...] (E4 S3).

Here it gives a maximum of 14 days, because the rotation of dressings and the removal of stitches are longer, speculums too. So it is no more than 14 days (TE2 S2).

International recommendations associate sterilization expiration dates with events related to damaged packaging, folding type, external moisture, material damaged by elastic or surface friction. This is because these events make the integrity of the packages questionable and, consequently, the preservation of the sterility of the material⁽¹⁴⁾.

The units surveyed rely on small amounts of materials and great demand of procedures. As a result, the material is not stored for long periods, not exceeding the shelf life or suffering damage to its packaging.

In addition to these events, sealing may also be cited as a determinant factor of the validity of sterilized instruments. RDC 15/2012 states that the sealing of "envelope-type" packaging must be done by heat sealer or as directed by the manufacturer⁽⁷⁾.

The identification label of the processed products shall remain legible and affixed to the packages during sterilization, transportation, storage and distribution until the moment of use. Another aspect refers to the lack of availability of structure and basic materials, which are cost drivers, since the treatment of infections is costly to users and the municipality, imposing risks to the users' integrity. Likewise, failure to observe the steps of the process of sterilization, storage and distribution of critical articles compromises the safety of these procedures.

Related to the fact, it can be observed in the following statements that some difficulties were found for the correct execution of the sterilization process:

[...] We do not have a sealer for each ambulatory (ACD4 S3).

We do not have a sealing machine. We end up doing it with the autoclave tape. It is not the correct method, because some of them have already opened, so I have to sterilize everything again, even if it has not been used, because as they are stored, they open, so I think this method is not the correct one. We are waiting for the sealing machine (TE2 S2).

In addition to the lack of sealing machine in the whole secretariat, and in one unit and another, it is evident that the lack of equipment, instruments and basic materials in general, is common in the secretariats of health of the three municipalities. This fact culminates with the lack of strict observance of the safety norms in the process of sterilization and custody of critical articles in the secretaries studied.

The insertion of safety precepts in education implies rethinking the educational approach in training, adding its inherent aspects of risk management and safe care. Research is an important strategy for the development and improvement of safe care.

FINAL CONSIDERATIONS

User safety is linked to several factors: structuring, organization and processes. With reference to the study, it is understood that the services researched lack adequate structure, which includes the deficiency of equipment (autoclaves) for the correct sterilization of the critical articles, sealers and, mainly, the non-existence and correct use of the packages, suitable sites for the conservation of these articles in some of the services studied.

Another fact to be highlighted refers to the organization. The analysis of the interviews reveals weaknesses in the organization of services, especially regarding the decentralization of sterilization, that is, each unit is responsible for the processing of its critical articles. Decentralization makes it difficult to control and standardize all phases of the sterilization process, generates higher costs and can compromise safety and make it difficult to establish an appropriate standard for such procedures. There is no evidence in the study of the existence of a room (or cabinets) suitable for storing critical articles. Basic equipment, such as the sealers, are indispensable to the safety of the

entire process. The lack or use of inadequate packages compromises the safety of patient care.

Another factor that may interfere with patient safety concerns processes, that is, who prepares, sterilizes, stores and distributes these articles. The control of sterilized materials should include: date of sterilization, date of expiration, batch number, product name, sterilization method and identification of the person in charge of the preparation. Although it is a common practice in material centers, and to establish period of validity for instruments, it was not observed that this practice is adopted in the services surveyed.

In the research and construction of the text, a series of limitations was found, with emphasis on the lack of studies in this area, since research and publications focus almost exclusively on the care of critical articles in the hospital

environment. Although the research has limitations, it is possible to identify that, in the study scenario, there is a need to invest in the structuring, organization and, in particular, to review the processes, which must be reconfigured from the security precepts.

Establishing and strictly observing safety standards means restructuring, reorganizing and introducing new processes, ensuring that professionals work more effectively and more efficiently, and service users receive more qualified assistance. Standardization of services is indispensable in managing risk and assuring service. The population of people served by these services is significant, so it is urgent to establish a risk and safety management committee, as a preponderant factor for the recovery and maintenance of users' health.

SEGURANÇA DO PACIENTE: EMBALAGENS, ACONDICIONAMENTO E TEMPO DE GUARDA DE MATERIAIS ESTERILIZADOS NA ATENÇÃO BÁSICA

RESUMO

As unidades básicas de saúde possuem grande demanda de procedimentos médicos, de enfermagem e odontológicos, dos quais dependem a segurança da assistência e do paciente. O objetivo deste estudo foi compreender como enfermeiros, técnicos, auxiliares em enfermagem e auxiliares de consultório dentário procedem no cuidado com embalagens, acondicionamento e tempo de guarda de materiais esterilizados nas unidades de saúde da atenção básica. Trata-se de uma pesquisa de caráter descritivo e exploratório, com abordagem qualitativa. Os participantes da pesquisa foram enfermeiros, técnicos de enfermagem e auxiliares de consultório dentário, atuantes em unidades básicas de saúde de três cidades do interior do Estado do Rio Grande do Sul. Os dados foram produzidos por meio de entrevistas semiestruturadas realizadas nos meses de outubro e dezembro de 2015 e submetidos a análise de conteúdo. Evidenciou-se que os serviços estudados carecem de estruturação, organização e definição de processos no que tange o tipo de embalagem e o acondicionamento de artigos críticos. Conclui-se que a assistência aos usuários, no que se refere a procedimentos que utilizam materiais esterilizados, está exposta a riscos, fragilizando a segurança do paciente, evidenciando a necessidade de capacitação contínua dos profissionais.

Palavras-chave: Enfermagem em saúde pública. Segurança do Paciente. Esterilização.

SEGURIDAD DEL PACIENTE: ENVASES, ACONDICIONAMIENTO Y TIEMPO DE GUARDA DE MATERIALES

RESUMEN

Las unidades básicas de salud poseen gran demanda de procedimientos médicos, de enfermería y odontológicos, de los cuales depende la seguridad de la atención y del paciente. El objetivo de este estudio fue comprender cómo enfermeros, técnicos, auxiliares en enfermería y auxiliares de consultorio dentario proceden en el cuidado con envases, acondicionamiento y tiempo de guarda de materiales esterilizados en las unidades de salud de la atención básica. Se trata de una investigación de carácter descriptivo y exploratorio, con abordaje cualitativo. Los participantes de la investigación fueron enfermeros, técnicos de enfermería y auxiliares de consultorio dentario, actuantes en unidades básicas de salud de tres ciudades del interior del Estado de Rio Grande do Sul-Brasil. Los datos fueron producidos por medio de entrevistas semiestruturadas realizadas en los meses de octubre y diciembre de 2015 y sometidos al análisis de contenido. Se evidenció que los servicios estudiados carecen de estructuración, organización y definición de procesos con relación al tipo de envase y el acondicionamiento de artículos críticos. Se concluye que la atención a los usuarios, en lo que se refiere a procedimientos que utilizan materiales esterilizados, está expuesta a riesgos, fragilizando la seguridad del paciente, evidenciando la necesidad de capacitación continua de los profesionales.

Palabras clave: Enfermería en salud pública. Seguridad del Paciente. Esterilización.

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Corresponding author: Graciela Machado de Araujo. Rua João José da Silva Martins, 51, Bairro Vila Velha, Palmeira das Missões, RS. CEP: 98300-000. E-mail: gra_m_a@hotmail.com

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