FACTORS THAT INFLUENCE THE QUALITY OF THE STERILISATION PROCESS
FATORES QUE INFLUENCIAM A QUALIDADE DO PROCESSO DE ESTERILIZAÇÃO

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ABSTRACT
Objective: to identify how the processing of dental-medical-hospital materials in basic health units is carried out. Method: descriptive study, observational study, carried out in 25 basic health units (BHU) between August and September of 2011, through observation of sterilization processes, guided by a semi-structured script, after approval of the research project by the Committee on Research Ethics, conforming to concept No 120/2011. Results: the quality of the sterilization process is undermined by failures in the choice of enclosures for the types of sterilization practiced, by the absence of monitoring and records in different phases of this process. The physical, chemical and biological tests were not used concomitantly. Conclusion: security and validation of the sterilization process in BHU are compromised, requiring rapid intervention. Strategies such as the deployment of guidelines and continuing education can help in the suitability of the sterilization process. Descritores: Sterilization; Health Centers; Nursing.

RESUMO
Objetivo: identificar como tem se realizado o processamento de materiais odonto-médico-hospitalares em unidades básicas de saúde. Método: estudo descritivo, observacional, realizado em 25 unidades básicas de saúde entre agosto e setembro de 2011, por meio de observação dos processos de esterilização, orientadas por um roteiro semiestruturado, após aprovação do projeto de pesquisa pelo Comitê de Ética em Pesquisa, Parecer n° 120/2011. Resultados: a qualidade do processo de esterilização está prejudicada por falhas na escolha dos invólucros para os tipos de esterilização praticados, pela ausência de monitoramento e registros em diferentes fases deste processo. Os testes físicos, químicos e biológicos não têm sido utilizados concomitantemente. Conclusão: a segurança e validação do processo de esterilização nas UBS estão comprometidas, necessitando de rápida intervenção. Estratégias como a implantação de diretrizes e educação continuada podem auxiliar na adequação do processo de esterilização. Descritores: Esterilização; Centros de Saúde; Enfermagem.

RESUMEN
Objetivo: identificar cómo se desarrolló el procesamiento de materiales odonto-médico-hospitalarios en unidades básicas de salud. Método: estudio descriptivo, observacional, realizado en 25 unidades básicas de salud entre agosto y septiembre de 2011, por medio de observación de los procesos de esterilización, orientadas por un rutero semiestructurado, después aprobación del proyecto de pesquisa por el Comité de Ética en Pesquisa, Parecer n° 120/2011. Resultados: la calidad del proceso de esterilización está perjudicada por falhas en la escolta de los involucros para los tipos de esterilización practicados, por la ausencia de control y registros en diferentes fases de este proceso. Los testes físicos, químicos y biológicos no tienen sido utilizados concomitantemente. Conclusión: la seguridad y validación del proceso de esterilización en las UBS están comprometidas, necesitando de rápida intervención. Estrategias como la implantación de directrices y educación continuada pueden auxiliar en la adecuación del proceso de esterilización. Descritores: Esterilización; Centros de Salud; Enfermería.
INTRODUCTION

In the basic health network medical procedures, nursing and dentistry are performed that require materials free of pathogenic microorganisms, and the sterilization process guarantees security of the patient and the professionals who handle these instruments. The professional who works with the Center of Material and Sterilization (CME) must enjoy what he does and know how to perform the tasks. It is necessary that he attended at least the elementary school and has specific training in nursing.1,2

The effectiveness of the sterilization process may be affected by the method (type) of sterilization performed, structure of articles to be processed and equipment performance, among other things. In this sense, the cleaning, disinfection, sterilization, and the proper management of dental-medical-hospital materials are fundamental to the prevention of infection.2 Sterilization is the process of destruction of all forms of microbial life through the application of physical, chemical and physic-chemical agents.3,4 This indirect assistance given to the patient during the reprocessing of material deserves as much dedication as nursing regarding the assistance given directly to the patient.2

With the advances and investments in Primary Health Care (PHC) in Brazil there was an expansion of Basic Health Units (BHU), especially with the deployment of the Family Health Strategy (FHS). This modality of care has been responsible for inclusion in the system of high number of users and groups, as well as diversified health actions. In this context, it was necessary to improve the capacity of care and investment in infrastructure, equipment and materials in the BHU without prejudice to assistance and ensure the quality of the materials used in the various procedures performed in these services. Together with health teams in the BHU, an increase in dentistry teams occurred, which perform technical procedures using specific instruments that must pass through sterilization process daily.

Not all BHU were planned to ensure the quality of sterilization processes, especially associated with the hospital context. In this sense, studies on this topic emerge in this care scenario, among which questioning: how is the quality of the processes of sterilization of articles used in assisting users in basic health units?

OBJECTIVE

- Identify how the processing of materials dental-medical-hospital in basic health units is carried out.

METHOD

Descriptive and observational study, for which a semi-structured instrument from guidelines recommended by the Brazilian Society of Nurses in the Surgical Center (SOBECC) normative and National Health Surveillance Agency (ANVISA) in Brazil was used.

For selection of the research scenario the inclusion criteria were: all Basic Health Units in the municipality maintained with public resource, regardless of either or not having an area for sterilization of dental-medical-hospital materials, located in a municipality of reference in health of the state of Santa Catarina, totaling 25 Basic Health Units.

We used a semi-structured form about the sterilization process addressing the flow of articles, the types of casings and sterilization used, microbiological testing, and the form of registration and storage conditions of articles. The research participants were professionals responsible for a BHU, after clarification of the proposed study and signing of the consent form.

The data collection took place between August and September of 2011, in 25 Basic Health Units and has been carried out by researchers in the course of nursing of the University of the State of Santa Catarina/SC.

The project was submitted to the Committee on Research Ethics of the State University of Santa Catarina (CEP/UDESC), approved under concept no. 120/2011.

RESULTS AND DISCUSSION

We interviewed technicians responsible for the reprocessing of dental-medical-hospital, all of them being nurses. In addition, the study followed the professionals who actually perform the sterilization process, being nurses, technicians and nursing assistants, in 25 BHU (N= 25) in rural and urban areas. Each BHU offers dental service, where an Auxiliary Dental Consultant (ADC) is responsible for the reprocessing of dentistry material.

Within the framework of nursing professionals who performed the sterilization process, 28% (n= 7) are nursing technicians, 72% (n = 18) are nursing assistants and 4% of the material is reprocessed by a nurse.

The reprocessed material for daily use in the unit consists of surgical instruments,
Factors that influence the quality of the... gauze, compresses, spatulas, cotton fabric and intermediary of silicone for oxygen therapy. It was observed that all units reprocess surgical instruments, 8% (n= 2) compresses surgeries, 88% of them (n= 22) cotton fabric kits for bladder probing and 24% (n= 6) clean gauze while the other units receive sterile gauze with Ethylene Oxide, ready for consumption.

All surveyed units (N= 25) perform the reprocessing of dental-medical-hospital material in the BHU, i.e., receive the materials used, wash, inspect, perform the packaging, clean, store and distribute the materials to the sterile room and dressing procedures, doctors and dentists, among others.

As regards the methods of sterilization, the dry heat (oven) is used in 20% of BHU (n= 5), the damp heat under pressure (autoclave) in 36% (n= 9) and 44% of BHU (n= 11) using autoclave and oven for the reprocessing of material. However, some of the equipment used for sterilization under dry heat had spots of rust, two BHU had an autoclave, however, still not installed at the time of the study and at two BHU the autoclave was defective, awaiting maintenance.

Cleaning of sterilizing equipment (ovens and autoclaves) takes place on a weekly basis, before the completion of the microbiological test. The involucres most used are cotton fabric and graded surgical paper in 76% (n= 19) of the BHU, metal boxes in 68% (n= 17) and 48% (n= 12) use Kraft paper for the processing of the materials.

The periods of validity of articles reprocessed at basic health units range from 07 to 30 days. However, 44% of BHU do not have identification of validity of the sterilization process. None of the units investigated performed physical control and monitoring of sterilization cycle of articles.

44% of the BHU (n= 11) weekly test for the certification of the sterilization process using the biological Bacillus Stearothermophylus test. In 36% (n= 9) chemical tests are carried out with thermo sensitive tape in all cycles and biological tests are done weekly. Only the test chemical with thermo sensitive tape is performed in 12% (n= 3) of the units, and in 8% (n= 2) is not performed any type of test.

The results presented in Figure 1 show the control of sterilization process according to the existence or absence of sterilization records, the quantity of material reprocessed, realization and registration of microbiological testing, if BHU waits for the result of the microbiological test before releasing the material, if there is a specific location for the storage of processed material as well as the control of storage room temperature for dental-medical-hospital materials.

The microbiological test, considered as a quality control of sterilization, occurs in 80% (n= 20) of the BHU. However, 64% of the sample do not record the tests in a dedicated book. However, 36% of the sample that inform to keep a record in the unit, does not have a...
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log book for the control of sterilization. Only 16% of the units visited (n= 4), waited for the outcome of the tests with biological indicators before using reprocessed material. According to the responsible, the clinical laboratory (where the tests are forwarded to incubate) does not offer a report with the result of the performed biological test. Only when the result is outside the normal patterns the responsible of the BHU is contacted by telephone, on which occasion many times the material has already been released for use.

In 92% of the sample (n= 23) there is no specific location for the storage of sterile materials until the confirmation of microbiological testing. The sterilized articles are stored in the same environment in which they are used, even before the confirmation of the results of the microbiological testing. The control of ambient temperature is not carried out in any of the units.

It was found that only 8% of BHU (n= 2) use a location for storing the reprocessed material, the other store the materials in various, decentralized locals. The BHU store sterilized material in drawers 84% (n= 21), cabinets 80% (n= 20), shelves 12% (n= 3), and 64% (n= 16), however, sometimes the boxes are metal or cardboard or plastic. One unit uses a closed plastic container for the storage of material.

The control of the flow of people in areas intended for the storage of reprocessed material is deficient in all followed units. The BHU perform invasive procedures that involve the use of material classified as critical and it is recommended to follow the standards recommended by the National Agency of Sanitary Vigilance with regard to sterilization process. 3

This study identifies the implementation of microbiological tests and the recording of the sterilization process in basic health units, which revealed that all BHU sterilize dental-medical-hospital material. The work of those responsible for reprocessing of critical articles covers much more than receiving, cleaning, wrapping, sterilize, store, distribute articles and handling equipment to complex technology. It requires in-service education for process monitoring, acquisition and testing of products and materials, involving the interfaces with other services. 3

It stands out that the articles are reprocessed by mid-level professionals, as has been demonstrated by other studies. Study shows the predominance of nursing assistants in activities in centers of material and sterilization. The vocational training is important, but by itself is not sufficient to ensure that the operator performs the reprocessing with the technical-scientific background necessary for the maintenance of quality, being required continuing education of professionals. 6

The types of reprocessed material must be consistent with the method chosen, ensuring greater effectiveness of process. 2,3,4 The sterilization methods used in most of the surveyed units were dry heat (oven) and damp heat under pressure (autoclave). The recommendation is however, to use the oven only for sterilization of oils and powders. 7 The use of dry heat is a still widely used sterilization method. Although, a study on the effectiveness of the oven of Pasteur, describes that in almost half of the dental offices the results of microbiological test in ovens was not effective as sterilizing equipment. 8

When obeyed the parameters indicated by the manufacturer, the process of sterilization by dry heat becomes effective, but it is not automatic, a time that depends on the variable human that performs cycles. Requiring thus, in addition to the vocational qualification, conscience and ethical commitment in their practice, essential conditions for the safety of users. 1 However, the methods of sterilization and the means of control will be effective only if the products are scrupulously clean and dry. 7

This study showed that the involucres used in BHU, are unsuitable for the sterilization method chosen, in addition, when used graded surgical paper, after sterilization, this failed sealing the involucres in various surveyed units.

The disposable packaging for sterilization should allow adequate penetration and steam output, acting in conservation equipment. 2,10 Enclosures are required for protection of critical material after sterilization. They also must meet the specifications of the equipment to ensure that the material has been sterilized with security, as to the permeability for penetration and elimination of the sterilizing agent. 2,10,11

The selection of involucres should be compatible with the method of sterilization and sterility assurance of the product. 2,10 Wrappers should operate as microbiological barrier, be flexible, nontoxic, allow cold sealing and allow the sterilizing agent in contact with the product. The wrapper must be suitable for the method of sterilization, allow for the removal of air, have low memory and a good cost/benefit ratio. 10
A specialized professional, suitable for the activity, shall perform the preventive maintenance of the equipment. Concurrent cleaning of the internal chamber of sterilizing equipment, oven and autoclave, should be performed on a daily basis with a product for the removal of oxidation. Which differs from the results found once again that the BHU do not perform preventive maintenance and daily cleaning with antioxidant products. Preventive maintenance should occur at least monthly.

Noteworthy is the fact that there is no uniformity as to the period of validity of sterilized material, varying from 07 to 30 days from one unit to another. Some reprocessed packages had no date of sterilization of the material, nor the validity of sterilization, contrasting the literature that emphasizes that all packaging should contain date of sterilization and the validity of the product.

Authors argue that the period of validity should be defined in each location where sterilization is performed and, according to the method of sterilization, the type of articles, the characteristics of the packaging, the method of sealing of packages, the number and condition of handling of packets before the use and storage conditions. The stock should be reviewed weekly, leaving the articles that have the due date in front of recently processed articles, to promote their advanced use.

The discussion as to the period of validity of the sterilization of articles links to the quality of used packaging, storage conditions and minimum handling. The closing of the casings must remain hermetically sealed. Control of the efficacy of sterilization should include physical, chemical and biological monitors together. Diverging from the findings in this study, which identifies that 8% of BHU do not test to control the efficacy of sterilization, 12% perform chemical tests, 36% perform chemical tests and biological and 44% perform only the biological test.

The absence of control of physical indicators was reported in another study also signalling absence of temperature monitoring of ovens by thermometer accessory and time/temperature relations not recognized for sterilization cycles. The sterilization cycles should be accompanied with mechanical/physical, chemical and biological monitors, and preventive maintenance of the equipment shall be performed whenever necessary and as standards of the institution.

Considered are mechanical time indicators (clock and timer), temperature (thermometers), pressure gauges, vacuum meters and operated manually or computerized issued by the machine itself. Being evaluated are the performance of the equipment by means of observation and record the parameters of pressure and temperature presented during the sterilization process.

The biological testing should be, at a minimum, weekly, despite recommendations for daily operations, always in the first load of the day and at the end of all maintenance performed, be they preventative or corrective. The tests should be carried out in the first cycle of the week and recorded on the connector or control book for results.

The BHU do not have record of sterilizations performed and the amount of material for sterilization. 20% do not achieve biological tests and 64% does not keep record of the tests for the control of sterilizations performed. However, recommendations are for the records of sterilization to contain the results of biological, chemical and physical indicator parameters, in addition to the testing of Bowie & Dick for the equipment with the vacuum pump in the first cycle of the day; the number of the batch or form adopted to identify each cycle; name of the operator responsible; and the complications during the cycle, if any, making it possible to track these articles.

All steps of the process of sterilization of materials must be documented. If the reprocessing is performed under adverse conditions, this entails risk to users and health professionals, compromising the quality and safety of the process and the assistance provided by this health establishment.

The quality control of sterilization is a continuous process. It is recommended that the validation of the sterilization process by any method is carried out at all stages of this process. In this context, it is important that the professional involved with the supervision of the sterilization process is in constant improvement and attentive to the technological changes of the health sector, in the field of validation of sterilization. Health Managers and other members of the health team also need to be aware of that are attentive and highlighting the sterilization processes of materials used in health services.

In this study, it was observed that the BHU do not have exclusive areas for the storage of materials, which should be closed, with entry for renewal of air, strict control of ambient temperature, maintaining the temperature between 18 to 22 °C and relative humidity.
between 30 and 60 %, to maintain the quality of the products. 3,4,10

The sterilized material is stored in a separate clean area, free of dust, in cabinets for easy viewing for control of lots, with temperature and humidity control for thermal hygrometer and sealed windows. 7 Being forbidden saving the materials close to the sinks, water or drain tubes. 3 However, the storage can be in closed or open shelves, provided that there is a flow control of staff, cleanliness and ventilation, in addition to the adequate space. 10 Yet, it was evidenced in the reviewed places that the movement of people on site for the storage of items is not restricted to professionals reprocessing material, which compromises the security of the sterilization process. When there is a specific place for the custody of the material in the institutions, the same should be the shortest possible time in sectors, because these places do not have ideal conditions for storage. The conditions of storage and transportation must be controlled and documented. 3,10,12

There are some precautions to be taken in the distribution and storage of dental-medical-hospital material, among them, the storage of packages with protection against contamination, damage, loss, compression and moisture; observe the validity period of the manufacturer determines the type enclosure used; record of distribution of sterile products, enabling the tracking of article for the control of validity. 10 In this sense, the development of continuing education directed to teams is recommended. 15 Technical improvement should be seen as a measure essential to align the specific knowledge of the members of the nursing team, along with the advances in the area, as a way to ensure the quality of the articles made available and the consequent security of its users and professionals.

CONCLUSION

This study showed that the dry heat and moist heat under pressure are the methods of sterilization practiced. However, the involucres are inadequate for the type of sterilization. There is weakness of the periods of validity of reprocessed material. The physical, chemical and biological tests are not performed concurrently and two BHU do not test for certification of the sterilization process. It should be emphasized that no researched unit records daily sterilizations performed and neither has specific location for the storage and distribution of sterile items.

The physical structure of the BHU surveyed does not have a barrier between the soiled area and clean area, the choice of the casings is unfit for the type of sterilization practiced, the tests for validation and security of the sterilization process is not carried out in all the units and, when performed are not recorded, which makes it impossible to control and ensure the effectiveness of the sterilization process.

Some of the equipment for the sterilization process (ovens and autoclaves) show signs of wear such as rust and burning of materials, it is essential to the evaluation of the available equipment, as well as the preventive maintenance of autoclaves and ovens.

As a result of flaws in the various phases of the sterilization process, it is necessary to guide the professionals involved in the enclosures indicated for each type of sterilization, the physical, chemical and biological testing in all units surveyed, and standardization of methods of sterilization from the articles to be reprocessed. It reinforces the importance of monitoring of the entire sterilization process keeping a faithful record of steps, including the release of the results of validation tests for later release of material to use.

It is believed that continuing education can be an alternative for professional improvement of the sterilization process, involving the nursing and dentistry professionals that is, those who are currently performing the sterilization processes in the majority of the BHU. Also, it is important to sensitize managers and professionals about the magnitude of the problems encountered in order to take measures aimed at problem solving and safety of procedures performed at these locations, as well as assume legal responsibility towards the community that assists.

REFERENCES


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