

ERGONOMIC EVALUATION OF WORK IN STERILIZATION MATERIAL AREAS IN A BASIC HEALTH UNIT

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ABSTRACT

The objective of this study was to develop an Ergonomic Work Analysis (EWA) in product sterilization area for health in a Basic Health Unit in western Santa Catarina, Brazil. The ergonomic approach followed four distinct stages characterized by demand analysis based on Collegiate Directory Resolution (CDR) 15 - National Health Surveillance Agency: analysis of tool construction of the minimum security of Material and Sterilization Center (MSC); tool construction for identification of compliance or not the tasks performed on MSC; instruments application; proposal formulation for adequacy of non-conformities found. The systematic showed possible situations to cause damage to health of workers and users of the health service involving: conformation of the physical structure and the organization of sterilization processes. Thus, the EWA, allowed greater interaction between teaching and service enabling point more accurately the risks in the workplace and formulate joint proposals for improving these conditions.

KEYWORDS: Occupational Health Nursing, health management, occupational health, sterilization, education, nursing.

1. INTRODUCTION

The health policy worker in Brazil has been drawing since the promulgation of Brazilian Constitution in 1988¹, and in 1990, the federal Health Law defines occupational health as "*a set of activities intended, [...] the promotion and protection health of workers [...]*"². However, only in 1998, via Administrative Rule 3120 approving the Normative Instruction of Health Surveillance Worker at Health System was published with the purpose of defining basic procedures for the development of their actions, in order to minimally equip the sectors responsible for supervision and protection of health, incorporating into their practices mechanisms of analysis and intervention in the processes and workplace³.

The Worker's Health Surveillance comprises many continuous and systematic action, over time, to detect, to know, research and analyze the determinants and conditioning of health problems related to the processes and work environments, in its technological aspects, social, organizational and epidemiological, in order to plan, implement and evaluate interventions on these aspects to eliminate them or control them.

The Decree 7602, November, 7, 2011, establishing the National Policy on Safety and Health at Work (NPSHW), which aims to promote health and improve the worker's quality of life and the prevention of accidents and damage to health coming, work-related or occurring in the course of its occupancy, through the elimination/ reduction of risks in the workplace⁴.

The actions in the context of NPSHW, should be developed following the guidelines of promoting implementation of systems and safety and health management programs in the workplace; restructuring of occupational health, training and safety at work and the encouragement of training and continuing education of workers; and, via promotion of integrated agenda of studies and research on health and safety at work.

In this context, many preventive actions in the workplace should be part of the set of company policies. Initially, the safety and health of workers are related to the development of industrial activities.

Whereas, the Basic Health Units make use of health products for the procedures performance which need to be processed in order to minimize the risk of contamination. In this way, CDR 15, March, 15, 2012, published by National Health Surveillance Agency, standardized the minimum elements to be considered for the sterilization process to occur in a secure mode, ensuring the quality of this process⁵.

The proposed adaptation of the physical structure and the current work process in the materials sterilization

area of dental-medical-hospital supplies in a Basic Health Unit was developed in partnership with the State University of Santa Catarina (UDESC), with the Municipality of Chapecó (Health Secretariat), Santa Catarina State, Brazil. The proposal aims at an ergonomic intervention where the researcher comes out of the analyst position to take a participatory approach, as an actor in the process of design of the work environment improvements.

Considering that the work (the activity) is the result of various activities and tasks performed by different workers, when the work is divided into parts, is possible to understand how does it works, to account for proposing changes allow (re)organize the work, optimizing human and financial resources.

The ergonomic intervention foresees the development of a few steps to the reorganization of work occur in order to involve the service and workers in planning these changes, by inspection of the viability (demand analysis) using: observation, primary diagnosis, depth analysis, the study of improvements proposition and validation of work reorganization proposal by the professionals.

The EWA is based on characterization, analysis and understanding of the work through confrontation of the prescribed work, i.e., the task to be performed and the actual work, i.e, the activity performed by the worker to achieve the task compliance. An example of the prescribed and actual activity occur in the sterilization process, and the rules about how to do the task, characterized as prescribed work, while the workers are performing this activity in its own way.

Due to the complexity and the cost associated with equipment and instruments involved in the sterilization process, is of great importance all health institutions use a theoretical framework to guide this process, investing in the training of professionals⁶.

The quality of the sterilization process depends on its monitoring, observation and record the performed activities ensure process efficiency, being able to evaluate all phases of sterilization in order to detect possible failures, where, and how, it will happens; the biological monitoring of the sterilization center should occur every week and require the use of a record book, in order to register the results.

Anticipate, recognize, evaluate and control the existing environmental risks in the workplace is essential and mandatory task for any company that admit workers as employees⁷. These measures must be taken in order to maintain the integrity of workers.

Several tools have been used for risk analysis according to the literature. However, considering the complexity of the workplace for the sterilization process, we opted for the development of "checklist" based on current legislation, which the study Burmann & Amaral

(2008)⁸, proved relevant for these workplaces with many specificities.

Thus, this study presents a system for risk analysis in sterilization room of health products in a Basic Health Unit in order to identify, evaluate and present possible improvement actions to, the risks are not eliminated, at least be reduced to minimum acceptable levels. Therefore, the aim of this study was to develop an Ergonomic Work Analysis (EWA) in the field of sterilization of medical devices in a Basic Health Unit in western Santa Catarina, Brazil, based on the CDR 15⁵.

2. MATERIAL AND MÉTHODS

To develop the EWA in the sterilization department for Basic Health Unit became the deepening of literature on the sterilization process to identify the minimum requirements to be met during this activity.

Our study was exploratory and descriptive, with a qualitative approach, resulting in a model for the analysis of working conditions in material and sterilization center in a Basic Health Unit. The methodological procedures are based on ergonomic approach to problem, consisting of observations and descriptive analyzes of situations observed together with professional that service. The main steps were followed:

1) Analysis of demand: were consulted the coordination of primary care, and the coordinator of the Health Unit under study, as well as workers involved in the sterilization process for identifying the real needs of the sterilization area of health products, based the CDR 15⁵;

2) Application of analysis tool to the minimum conditions of safety to MSC: we developed a checklist for evaluating of the workplace conditions and procedures involving the material sterilization area. The items on the checklist were based on the CRD 15⁵.

3) Construction tool for identification of compliance and noncompliance resulting from the tasks performed on MSC.

4) Proposal formulation for adequacy of non-conformities found.

* Demand Analysis

Whereas all work is related to an initial demand, this study was guided by research conducted in the Health Basic Unit in western Santa Catarina (Brazil) that link some weaknesses of the sterilization process, including the improper flow of materials in the sterilization areas, in disagreement with current legislation, as well as flaws in the labeling of products for the health, sterilization time, the records and the sterilization process validation tests performed.

However, it is possible that the managers of health services, which often hold political and/ or administrative positions, lack the technical knowledge to identify and intervene in dangerous situations.

Aiming the development of a work that accrues benefits to workers, the analyst must take into account the initial demand and make a local study of the processes and workers to identify possible needs for improvement. In this study, the demand analysis, were characterized by distinct stages:

- Local reconnaissance to identify the existence of problems and establish a hierarchy in need of solving these;
- Conversations with the professionals about the theme "sterilization" so they can help in understanding processes and elucidation of possible solutions;
- Data analysis to identify the situations that deserve more attention/ intervention to improve the health and safety of health workers and users.

*** Construction and application of the tool used to analyze the physical structure and the sterilization process developed by workers in the reprocessing of materials in Basic Health Unit**

a) Checklist development:

The development of this tool, nominated checklist should include all the provisions necessary for a company to identify possible flaws in the safety and health of location for further indication of what measures to control or eliminate the risks. It is emphasized that the tool should not be much extensive to not harm the peculiar agility of this type of evaluation.

Having the CDR 15⁵ and 50⁹, the recommendations of Brazilian Society of Surgical Center Nurses and Brazilian studies, one can make a checklist that contains the main legal provisions and necessary to maintain the safety and health of workers and users of health services.

The checklist has been structured to facilitate data collection, following a logical order, starting from the macro situation, considering environmental conditions and facilities, until you reach a micro analysis, where are observed individuals and the activities performed by them. This instrument was structured on the parameters: Description of the standard, identify whether the health service includes or not the norm, it is appropriate or not and observation reports, as example in Table 1.

Table 1. Checklist model developed for Ergonomic Work Analysis

CHECKLIST: MINIMUM SECURITY CONDITIONS					
SAFETY ITEM	EXIST		APPROPRIATE		OBSERVATIONS
	Yes	No	Yes	No	
STANDARD/RECOMMENDATION					

b) Checklist application

The application of the checklist was made from the workplace visit to be analyzed. Using the tool, the sterilization of materials area was analyzed and processes, observing all the items listed in the checklist. In case of disagreement, we recommend the use of images recording, since the picture can best illustrate the problem with

a view to solutions.

c) Improvement suggestions

The second part of the checklist is the completion of the action plan for correction of items completed as non-existent or inadequate in the first part of the checklist. In this step, we describe all items that need attention/ improvements according to the checklist.

In the first column of the action plan work sheet, repeated every non-conforming items displayed on the checklist. They will not be added items that were considered accordingly, i.e., those who met the minimum safety and health conditions in the work environment.

The second column of the work sheet entitled "HOW?" is filled with one or more suggestion corrective measure for the item; briefly, but allows for easy understanding by managers and workers. Whereas each item listed will have a person responsible for its implementation, the name responsible for improving or fitness must be completed in the third column, where it named "WHO?".

In the fourth column entitled "WHY?" the items of the standards are identified, which determine the need for resolution of non-compliance.

The last two columns identify the cost of the deployment of patches and the deadline for the elimination of non-compliance, respectively, as shown in Table 2.

Table 2. Structure of the Action Plan

ACTION PLAN: MINIMUM SECURITY CONDITIONS						
SAFETY ITEM	HOW?	WHO?	WHY?	HOW MUCH?	WHEN?	

Information relating to the technical area, columns entitled "HOW?" and "WHY?" were answered by the analyst who applied the checklist. Finished the development of the Action Plan was scheduled meeting with the coordination of primary care, Head of Unit and professional involved in the sterilization process to expose the points identified as not complying, doing a detailed explanation of each item for a full understanding of all gifts. Were listed priorities for the resolution of nonconformities considering the risks to health and safety of workers, demarcated by the workers through Likert scale of 1 to 10 points, in which 1-3 is low priority, 4-6, priority execution is average; Finally, from 7 to 10, high priority. This priority score was exhibit in column WHEN?

The completion of the "WHO?" and "HOW MUCH ?" columns are the responsibility of the managers involved in this process, and should be considered the priority provisions by the analyst.

3. RESULTS

Whereas the demand analysis is the first step towards the realization of the EWA, the researcher contacted with the Basic Care Coordination of the municipality, ex-

plained the proposal of EWA to be held in a Basic Health Unit, suggested by the municipality, which appointed two professionals involved in the reprocessing of materials to accompany the activities.

Secondly was held visit to the Basic Health Unit to present the proposal of EWA in the sterilization area to service professionals, recognition of the physical area and scheduled follow-up of professional activities in the sterilization department.

In the monitoring "*in loco*" of the sterilization process the experienced information was recorded on a "field diary". It was noticed that the Basic Health Unit does not have a central supply and central sterilization, as it performs the processing of health care products in a decentralized manner, by different professionals and several places of the Basic Health Unit.

Cleaning and preparation of products for the health happens in the rooms where they were used, such as dental office and procedure rooms. After, being wrapped and only sometimes identified, the materials are taken to another room, the autoclave's room, the place where it processes the sterilization of materials used by different customers, comprising this led by Dentistry assistant. The autoclave's room is the access for cleaning professionals to move to the area outside the Basic Health Unit. Therefore, after the sterilization, the materials are distributed and stored in the consumer units (medical and dental offices and rooms procedures); this flow is characterized as multidirectional.

During the monitoring period, it was not possible to see the realization of physical tests, chemical and biological concurrently for validation of the sterilization process, or the record thereof. All this information was guided by law arranged in the CDR 15⁵.

Based on the CDR 15⁵ it was possible to make a checklist to identify the existing conformities and non-conformities in the processing of health products. This checklist covers the following categories: definitions, organizational conditions of best practices for the processing of health products; responsibilities of directors, technical managers, nursing and other services; human resources; health and safety at work; assignments; equipment; infrastructure; reception available to health products; cleaning processes of health products; sterilization; monitoring the sterilization process; storage and transportation⁵.

The construction of the checklist and its application, enabled the group discussion about each item that the standard features, a situation that proved to be very positive and helped the reflection of professionals about the possible changes both physical structure, such as work process to ensure safety and health of workers and users of health service.

We developed a form for the submission of an action plan for adaptation of the items filled as non-existent or

inadequate in the first part of this evaluation instrument, which were described all the items you need in accordance with the rules of improvements.

Finally, it was organized a moment called "*moments of knowledge*": professionals reflected on the possibilities for improvements, ideas formulated and organized filling out this form, which was consolidated in the action plan and submitted to the Municipality Health Secretariat for consideration and implementation.

This action plan only addressed the items that did not comply and was about the implementation of a centralized material and sterilization place containing reception area and purge, preparation and packaging, sterilization, storage and distribution of products and area records. Intend to deploy the MSC in restricted area, where there is less number of people circulating. Implementation of the record book of sterilization and labeling process, with complete data to enable the tracking of materials, standardization of surgical grade, paper wrappers prioritizing and Municipality Health Secretariat nonwoven. Review and implementation manual of technical standards, considering the in-service education for training of health professionals involved in the sterilization process.

The record book must include the faithful record of all sterilization steps, especially: date, equipment and sterilization batch of processed material number, physical, result of physical, chemical and biological tests, and recommended the filing of these records by at least five years.

With regard to human resources is suggested, which set internally professionals performing the sterilization process. Check annually if professionals are in active record in its class council, keeping own record. Check annually if professionals are in active record in its class council, keeping own record. Keep visible record in the Basic Health Unit/ MSC of the certificate of Technical Responsibility and check validity of the certification annually. Holding each year professional development and develop continuing education plan for employees.

Safety and health at work heading propose to resumption of guidance on the use of PPE (Personal Protective Equipment), and registry of PPE provided, and the orientation of its use. Supervise the use of PPE and keep record of adherence or not the employee, taking appropriate measures in case of non-compliance.

Due to absence of standardization that can guide workers about processing health products, we recommend the development of Technical Standards Manual Sterilization Process, which shall include the professional tasks and responsibilities of the MSC workers, to be used the training of new employees and for consultation during the activities in this unit. Among the tasks, there is the record of the products received in the MSC, sterilized and released to consumer units.

In line equipment is recommended: request report

about installing the equipment, the original parameters of manufacturing and current parameters for evidence of no change thereof; arrange the acquisition of reader biological indicator and sealing; develop annual scale calibration and provide the calibration by qualified service annually record keeping; organize the annual scheduled maintenance and record keeping; arrange the acquisition of biological indicator incubator.

The infrastructure item requires orientation of service professionals to perform technical barrier, physical barrier between soiled area and clean area, stand for materials conference, containers for waste disposal (cutting and perforating biological), equipment to transport the products, shelves or wired baskets and centralized, exclusive place for the storage of processed products.

With regard receipt of the products on the MSC, should be performed conference and registration of all incoming products. It is recommended to continuing education and standardizes the form of cleaning and rinsing of the products; provide quality examination of the water used in the processing of health materials annually and deploy biological control cleaning keeping track of the results; perform visual inspection after cleaning and prior to packaging. In case of soiling, restart the cleaning process. In the default presence in the product communicate the responsible technician to take action.

Acquire only wrappers settled by the National Health Surveillance Agency for use in sterilization. Acquire heat sealing and train professionals to use. Standardize labeling items: product name; batch and equipment; date of sterilization and date, name of person responsible for preparation, data that enable the tracking of product.

Sterilization heading collect the equipment called "Hothouses" the Basic Health Unit that are not used as method of sterilization. Make Bowie & Dick test on the first day of the cycle and maintain weekly in the minutes book; check the water potability as the autoclave manufacturer's recommendations annually and maintain records.

For the monitoring line of the sterilization process, it is recommended monitoring with chemical integrators (classes 5 or 6) once a month and record results in the record book; Monitoring of physical and chemical indicators to each sterilization cycle and in the record book; Monitoring with biological indicator at least once a week keeping track. Make reading the biological indicator and only release the load for use when the test is negative. In case of a positive test, seek review of the equipment and redo the sterilization process keeping in the record book. File a result of physical, chemical and biological tests for five years as stipulated in the current legislation.

Considering the storage, sterile products should remain *in situ* for this purpose until the time of dispensing for consumer units. Perform transport of health products

in a closed container and identified dirty material and another identified as sterilized material.

4. DISCUSSION

The literature^{6,10,11} signals the need to maintain a unidirectional flow of material. And yet, it is recommended that there is a barrier between the soiled area and clean area, and whenever possible other barrier between the area clean and sterile area¹¹.

The MSC is responsible for receiving unit, purging and cleaning, preparation, sterilization, storage and distribution of sterile or non-sterile materials, units of services providing care for the patient. This place facilitates the control and standardization of the nursing staff techniques regarding the preparation and cleaning, ensuring the quality of the material used¹².

The reception area and purge is characterized as an area for reception, conference, cleaning and separation of contaminated materials from consumer units¹³. It is one of the most contaminated workplace in the MSC, the diversity of materials soiled with secretions¹⁴.

The materials staging area includes the reception activities of material from a purge; drying the material; visual inspection of the articles; verification of integrity, operation manual lubrication thereof; separation and replacement of non-conforming items for evaluation and conduct; spare and replacement of parts required; assembly, packaging and labeling of packages¹⁵. The packages already closed must be identified during the preparation of the package containing the worker's name, the type of article and the processing date¹⁶.

The sterilization area of materials intended for sterilization of materials after preparation¹⁷⁻¹⁸. This area must have biological indicators of incubators and system for custody of the records of the sterilization process monitoring should be performed daily with chemical and physical indicators, following routine defined by the MSC¹⁷.

The area of storage and distribution aims to centralize all processed and sterilized articles to their subsequent distribution to the consumer units should be a restricted area access and exclusive use¹⁴.

Sterilized products should be stored in clean, dry area under protection from direct sunlight and subject to minimal manipulation. One should be careful not to allow, at the time of distribution, the crossing of sterile items with non-sterile items¹⁷.

For nurses who work in the MSC, unit management is its main activity involves the planning issues, development of administrative and operational instruments, with the supervision and decision making, essential elements for quality of care¹⁸.

According to the 421 Resolution of Federal Nursing Council, of February 15, 2012, is among the nursing assignments participate in the development of Standard

Operating Procedure (SOP) for the processing steps of health products, available to employees for consultation, should also participate in the monitoring and control of cleaning and disinfection or sterilization steps. It is MSC nurse's responsibility to propose and use quality control indicators processing health products, monitor and document the qualification of technical visits and the operation of the MSC equipment performance, or processing company health products¹⁹.

Should ensure the use of PPE, according to the MSC workplace, develop terms of reference, or submit the technical report on the acquisition of health products, equipment and supplies to be used, and update continuously on technological innovations related to the processing of health products⁹.

Nurses are responsible within the MSC coordination of work processes and the tasks of passing records of the period. In addition, nurses are responsible to the guiding questions about the routine work in the MSC, supervising the activities in each area²⁰, preparation of daily scale work, development and programming skills and training, further of the participation of purchases of materials and supplies for the unit, assessment and forecasting of the stock of materials consumed²¹.

The nursing technician assignments are related to receive the material from other industries, check, wash, dry and pack these instruments, identifying correctly²². Furthermore, it is for that professional conduct records, prepare loads for sterilization, sterilize materials and store them appropriately. Make incubation and reading of indicators, the removal of materials with the term of the losers sterilization and the completion of the Bowie-Dick test, daily²².

As regards the envelopes, studies indicate that should allow the entry and exit of air and sterilizing agent and prevents the entry of microorganisms and should be regulated by the National Health Surveillance Agency, for specific use in sterilization^{5,14,23}.

About the recommended tests, for validation of the sterilization process are chemical and biological, testing and maintenance of equipment and records the sterilization process (physical indicator). The chemical tests indicate whether there was a potential failure in the sterilization process by means of changing its color²⁴. The biological tests consider all sterilization parameters, are used and monitors critical parameters, such as temperature, pressure and time exposure, improving the safety of the materials²⁴.

In the records must contain the name of the material, sterilization type, batch and validity of the product and responsible for packaging material. Each sterilization cycle must be conducted registration with the lot, its contents, the sterilization time and the temperature reached by the equipment. Must be registered the name of the operator, the results of biological and chemical

tests, and any complications that happened during the sterilization process²⁵.

Workers of materials sterilization area are exposed to risks, including, can highlight the risks related to the handling of chemicals, work with biological agents, fire, explosion and electric shock. The complexity of this workplace involves products and techniques constantly changing making it necessary to adapt to the EWA legislation and above all, to make the workplace healthier and organization of work.

5. CONCLUSION

There has been a concern of regulators in health and other institutions the minimum safety conditions both for professionals and for the population served by primary care services with regard to the sterilization process.

Considering the importance of the one-way flow of materials, standardization of forms of cleaning and packaging, sterilization type, process validation testing and adequate recording, this Ergonomic Work Analysis for technical standard deployment will provide the basis for new employees training, assisting primary health care services to standardize said process minimizing public costs wrapped in reprocessing dental, medical and hospital supplies, ensuring better health quality users of the Unified Health System and security workers.

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