

BIOSECURITY IN CENTRAL STERILE SERVICES DEPARTMENT: THE DOUBTS OF PROFESSIONALS*

Biossegurança no Centro de Materiais e Esterilização: dúvidas dos profissionais
Bioseguridad en el Centro de Materiales y Esterilización: dudas de los profesionales

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ABSTRACT: Objective: This work aims at knowing the doubts health professionals may have about biosecurity in Central Sterile Services Department (CSSD), and reflect upon the answers. **Methods:** This is a qualitative, descriptive exploratory study. The research was about a well known Brazilian website, which offers a discussion list by e-mail. 2,260 messages were sent to this list in 2014. The sample was composed by 109 messages containing topics about biosecurity in CSSD; interpreted using the Bardin's Content Analysis. **Results:** Four theme categories emerged from the most frequent questions: chemical solutions, equipment and materials, Law, and process validation. Both in questions as in answers analyzed, there was a strong relation between the CSSD and Hospital Infection Control. **Conclusions:** Most professionals who referred questions were nurses. The most frequently asked questions on biosecurity related to the solutions used, equipment and materials. The answers were based on existing legislation and issued by professionals with experience. **Keywords:** Equipment safety. Nursing. Materials.

RESUMO: Objetivos: Conhecer as dúvidas dos profissionais da saúde sobre biossegurança no Centro de Materiais e Esterilização (CME) e refletir sobre as respostas emitidas. **Método:** Estudo exploratório descritivo qualitativo. O cenário da pesquisa foi um site nacional reconhecido que dispõe uma lista de discussão por e-mail. O *corpus* foram 2.260 mensagens enviadas à lista de discussão em 2014; a amostra foi composta por 109 mensagens com conteúdo relacionado à biossegurança no CME. Utilizou-se para interpretação dos dados a Análise de Conteúdo de Bardin. **Resultados:** Na análise emergiram quatro categorias temáticas das dúvidas mais frequentes denominadas: soluções; equipamentos e materiais; Legislação; e validação do processo. Evidenciou-se forte relação entre CME e Controle de Infecção Hospitalar (CIH), tanto nos questionamentos quanto nas respostas. **Conclusão:** A maioria dos profissionais que encaminharam dúvidas foram enfermeiros. As dúvidas mais frequentes sobre biossegurança relacionavam-se a soluções usadas, equipamentos e materiais. As respostas foram fundamentadas na legislação vigente e emitidas por profissionais com experiência. **Palavras-chave:** Segurança de equipamentos médicos. Enfermagem. Material.

RESUMEN: Objetivos: Conocer las dudas de profesionales de la salud sobre bioseguridad en el Centro de Materiales y Esterilización (CME) y reflexionar sobre las respuestas fornecidas. **Método:** Estudio exploratorio descriptivo cualitativo. El escenario de la investigación fue un sitio electrónico reconocido que dispone de una lista de discusión por correo electrónico. 2.260 mensajes fueron enviados a la lista de discusión en 2014; la muestra se compuso de 109 mensajes con contenido relacionado a la bioseguridad en el CME. El análisis de contenido de Bardin fue empleado para la interpretación de los datos. **Resultados:** Emergieron en el análisis cuatro categorías temáticas de las dudas más frecuentes, denominadas: soluciones; equipamientos y materiales; legislación y validación del proceso. Se evidenció una fuerte relación entre el CME y el Control de Infección Hospitalaria, en tanto en los cuestionamientos y en las respuestas. **Conclusión:** La mayoría de los profesionales que refirieron las preguntas eran enfermeros. Las preguntas más frecuentes sobre bioseguridad eran relacionadas a las soluciones utilizadas, a los equipos y los materiales. Las respuestas se basaron en la legislación vigente y fueron emitidas por profesionales peritos. **Palabras clave:** Seguridad de equipos. Enfermería. Material.

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INTRODUCTION

Biosecurity consists of a challenge for health professionals, especially in the practical field of a little known sector as the Central Sterile Services Department (CSSD). This support sector is of fundamental importance as it is responsible for the processing of health products (PHP), ensuring patient's safety and allowing the use of materials in appropriate conditions for preparation and sterilization¹.

In the hospital, the CSSD is considered a critical area for processing articles resulting from clinical and surgical interventions, presented, this way, risks to the professionals in this sector, making them more susceptible to occupational accidents².

Biosecurity may be focused toward two directions: both in relation to genetically modified organisms and their derivatives as for the activities inherent to biotechnology, social and occupational protection of the workers. This research focuses on the later, once that among their objectives is the preservation of health professionals, the community, the environment, and owing to the ethical and legal matters, once that negligence may become a threat³, resulting in lawsuits.

Regulatory Norm No. 32 (*Norma Regulamentadora nº 32 – NR-32*) is about safety and health in the work in health services, being considered a great advance for workers in this area, once they set guidelines for the implementation of measures for health protection and the security of the worker⁴. In order to implement NR-32 in the services, we need investments in physical, material, and personal resources, in addition to the training and motivation of employees and managers, creating new cultural and behavioral concepts^{4,5}.

In order to standardize all the work and to ensure the safety of the articles processed by the CSSD, the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária – Anvisa*) published, in 2012, the Resolution No. 15 (RCD-15), about the requirements of good practices for the PHP, being an important historical milestone for addressing, among other sections, human, safety, and health resources at work and the attributions of the responsible technician⁶. Although the RCD-15 does not specify the professional training of the responsible for this sector (it only mentions that they should have higher education), it is believed that the nurse is the most appropriate professional to hold this position, once their training gives them

technical and managerial skills to manage this sector, in addition to having a deep knowledge about the full treatment of the patient⁶. However, it is noticeable that nursing has been losing their interest in working in this area, making room for the work of other health or administrative professionals interested in this sector.

A work badly executed in the CSSD may result in risks for the health of both workers and patients, once that this sector is connected to all hospitals, providing articles for the provision of services, creating an interdependent relationship, in which the quality of the services performed is directly related to the quality and safety of the products processes in the CSSD⁷.

It is known that flaws in the CSSD may occur owing to the lack of updated professionals; lack of standardization of the actions; nonadherence to the use of Personal Protective Equipment (PPE); and execution of inappropriate techniques⁸.

The work in the CSSD may be compromised by various factors such as inappropriate infrastructure; dynamics in human relations; lack of professional qualification; pressure of the work; and the productivity demand⁹. Therefore, many factors may be related to accidents occurred in this sector such as work overload; wearisome working hours; physical weariness; night shifts; lack of attention; excess of confidence; lack of conditions; lack of technical capacity, etc. The highest risks of exposure of health professionals occur in unsatisfactory working places, disorganization of the services, deficiency of human and material resources, and inappropriate physical areas from the ergonomic point of view¹⁰.

In order to ensure the efficiency and safety of the working processes, it is necessary a constant update and the existence of a committed attitude of the professionals who perform their working activities⁹. The adoption of biosecurity measures is a priority for all sectors and health professionals exposed to occupational hazards, and education is essential; however, the biosafety themes and the CSSD are little discussed in the professional development process of nursing professionals¹.

During the undergraduate nursing course, it was learned the importance of biosecurity in order to ensure care safely, for both the patient and the professional, with the opportunity of learning the theory and having lived the practice in the CSSD. By knowing that many undergraduate nursing courses do not approach the theoretical and practical contents about

this area, there was then an interest in researching about the doubts of health professionals about biosecurity in the CSSD.

The restlessness and the search for knowledge led to the discovery of a nationally recognized website, which debates the doubts of health professionals on the subject. In this context, there came the interest in investigating the following problem of research: which are the most common doubts about biosecurity in the CSSD and how are they discussed and clarified in the website? In order to address the outlined problem, the objectives of this research are defined as getting to know the doubts of health professionals about biosecurity in the CSSD and reflecting on the answers given.

METHOD

It is a descriptive exploratory study with a qualitative approach.

In order to clarify the frequent doubts of health professionals, there is a national website about biological risks aiming at preventing occupational biological risks for their workers. Within this virtual environment, there is a space for discussion via e-mail. This website (<http://www.riscobiologico.org/>) has the objective of spreading information on occupational biohazard for health professionals by actions of education, research, surveillance, and exchange, disseminating updated information and helping in the technical aspects of matters related to the biohazard for health professionals.

This research considered as a *corpus* all the e-mail messages sent for the discussion group of the website from January to December 2014, totaling 2,260 messages. The sample consists of 109 messages, which met the following inclusion criteria — having been sent to the discussion group in 2014 and presenting doubts regarding the CSSD in their contents.

For the collection of the data, the researcher initially performed the registration on the website in 2012, after learning about it through the indication of the advisor. In the same year, they made their registration in the list of discussion, in order to have access to it. All e-mails received were saved and stored in a file, beginning in January and ending in December 2014. The e-mails had the initial doubts and the answers discussed by the discussion group.

The researcher read the e-mails and, after identifying the theme about CSSD, saved the message in the file. Afterward, they created a flowchart in Excel® containing the quantitative

of the doubts, professions which submitted the doubts and answers presented.

There was conducted a Thematic Content Analysis of Bardin¹¹, according to the stages of:

1. preanalysis: organization of the material, brief reading of the e-mails, and identification of the repetitions and systematizations of the ideas for the analysis;
2. analytical description: categorization of the data by the thematic criteria, grouping the similar theme with the same meaning; and
3. inferential interpretation: data were interpreted through inferences, with the objective of making the results valid and significant.

The analysis was conducted through the full reading of all messages selected and grouped initially by the title of the forwarded message, reaching thus the total of 19, creating precategories related to the repetition of contents of the doubts. After performing again of the full content reading, the repeated registration units (RU) are highlighted, grouped according to the similarity of the doubts and answers, emerging the final categories and subcategories. In the sequence, the counting of the RU was performed, expressed in whole numbers, calculating the percentage.

In the analysis, the professionals who sent their doubts to the website were identified by the initials of their professions, followed by a number to differentiate the subjects. Adding numbers to the letters coded by profession was necessary owing to the quantitative of professionals of the same category. For the e-mails without professional identification, it was chosen to use the abbreviation NI (nonidentified). The research was submitted to the Research Ethics Committee of the University, being approved under endorsement number 93.4017. After approval, we contacted the technician responsible for the website, which authorized the research after receiving the project and approval.

RESULTS

The following professionals with college education were identified in the e-mails: 30 nurses (N), 5 doctors (D), 5 clinical engineers (CE), 5 pharmacists (P), 2 veterinarians (V), and 1 work safety engineer (WSE). Besides those, there were also

identified professionals of technical level: three work safety technicians (WST) and two hospital hygiene technicians (HHT). NI professionals totaled 19.

Chart 1 presents the four final categories, emerged subcategories, RU, and percentage of the main doubts sent for the list of discussion.

It was observed a strong existing relation between the CSSD and the Hospital Infection Control (HIC), both for the questions and the answers.

Solutions

Three subcategories emerged in this category: commercial names; concentrations, dilutions, and validity; and costs. In the subcategory “commercial names”, the professionals expressed

Chart 1. Categories, subcategories, and amount of registrations units, with corresponding percentages, resulting from the doubts of health professionals about the Central Sterile Services Department in the discussion website, from January to December 2014.

Categories	Subcategories	RU	%
Solutions	Comercial names	124	72.90
	Concentrations, dilutions, and validity	34	20.00
	Costs	12	7.05
	Total RU	170	100
Equipments and materials	Sterilization/disinfection methods	69	40.5
	Instruments	59	34.7
	Reprocessing	12	7.0
	Packaging	11	6.4
	Biofilm	10	5.8
	Maintenance (life, damage, preservation, conservation)	10	5.8
	Total RU	171	100
Legislation	Norms/Rulings	56	50.9
	Law/Legal	37	33.6
	Anvisa	17	15.5
	Total RU	110	100
Validation of the process	Time	39	54.9
	Tests	32	45.1
	Total RU	71	100

RU: registration units.

their doubts regarding which products are more appropriate to perform both high- and low-level chemical disinfection, of a variety of materials used in the hospital area, such as nebulizers, humidifiers, ambus, oxygen extenders, devices used for endoscopy, and surgical instruments, as expressed in the following:

I'd like to know what is being used for endoscope disinfection [referred to the commercial name of glutaraldehyde] or peracetic acid? (N11)

Does anyone have any information based on legislation about the high level disinfection of the peracetic acid in 10 minutes? Does anyone use or know the [...]? (N11)

Regarding the doubts, a pharmacist answered:

The products follow legislation. In the referred case, for disinfectants, it's RDC 35 / 10, where it is specified the microbiological reports required for the registration, in which the maximum immersion time is the one of the microorganism which takes the longer to be eliminated. (P1)

In the subcategory “concentrations, dilutions, and validity”, the main doubt found was about the correct way to dilute several existing solutions, keeping the appropriate concentration in order to ensure the safe processes of cleaning, disinfection, and sterilization, without causing damages to users, according to the following RU:

What are currently the concentrations x need to rinse for the sodium hypochlorite of the masks used for nebulization/ambu [...]? (N14)

I've been reading about disinfection [referring to the hypochlorite] [...], but there are controversies regarding the dilution and concentration for such practice. I'd like to know what is recommended by Anvisa: 0.02%, 1%, 0.5%? (N26)

In response to the questionings about hypochlorite, a nurse answered:

Except for items used in case of active pulmonary tuberculosis, I recommend hypochlorite at 0.02%

for 30 minutes. The solution should be changed every day. (N27)

In the subcategory “costs”, some doubts regarding the most expensive solutions appeared; ways to reduce the cost of solution acquisition such as using solutions in a safe way without increasing the costs for the institutions owing to damage or misuse; and the correct way of storage.

I’m having difficulty in standardizing the purchase of hypochlorite in the stockroom [...], but the stockroom is complaining it’s expensive, to buy one with higher concentration and then dilute it, they suggested. (NI16)

The answers try to clarify and recommend, as follows:

[...] substitute it with 5% peracetic acid, the cost will be lower and the quality of disinfection better. (NI17)

And is this whole process cheaper than disposal? (CE5)

I recommend using peracetic acid. [...]. The solution may be used for many days, perfectly monitors, and, if the problem is the cost, you will be surprised. You have many options and prices in the market, powder, liquid, ready-to-use, concentrated, with or without corrosion inhibitors [...]. (CE2)

Moreover, in this subcategory, the best price for the acquisition of equipments is discussed, such as ultrasonic washing machines and more modern autoclaves, as alternatives to substitute the solutions as suggested.

Equipments and materials

In the category “equipments and materials”, six categories were suggested namely: sterilization/disinfection methods; instruments; reprocessing; packages; biofilm; and maintenance. About the sterilization/disinfection methods, the doubts were related to the methods used to carry out this process in which the solution is used and which choice is more effective, as in the excerpt:

What material do you use for disinfection of respiratory materials [...]? (N25)

Another nurse answered:

Except for the materials used in cases of active pulmonary tuberculosis, I recommend hypochlorite at 0.02% for 30 minutes. The solution must be changed every day. (N27)

There was a specific question about endoscope disinfection:

I’d like to know what is being used for endoscope disinfection [...]? (NI10)

Including also other doubts that showed up regarding this kind of equipment, followed by the following answer:

[...] we, controllers of hospital infection, recommend that the peracetic acid is used for endoscope disinfection, however, this product reduced the useful life of some devices, especially when not removed the film formed over its lenses which previously received the action of the glutaraldehyde. Currently, there is, in the market, a peracetic acid with more alkaline pH, which favors the conservation of the devices. As for the [...] [commercial name mentioned], it is also an excellent product which does not compromise the life of the device, though it has higher cost and needs to be inactivated for disposal. (NI8)

When discussing this topic, the professionals presented more than one way of disinfection/sterilization which may be used for the same material, depending on various factors for its choice such as the institution, the modernity of the equipments used in the CSSD, the indication of the manufacturer, and what is recommended by the HIC, as shown in the following excerpt:

Does anyone know with what product do I disinfect the esophageal thermometer [...]?

The answer was:

High level chemical disinfection, since the esophageal thermometer is sensitive to high

temperatures and wouldn't bear thermal disinfection. (P2)

In the subcategory "instruments," the doubts identified were regarding the marking of surgical instruments such as clamps, pneumatic drills, trays, clamps, and others, in addition to the possible biofilm appearance when using some kinds of materials in order to perform this marking, as in the excerpt:

[...] is there a legislation regarding the marking of surgical material? (N8)

The use of tapes to Mark the instruments is discussed, but once again there is the biofilm matter:

The steam really does not penetrate the layer of tape with adhesive and it stains the instrument and, with the adhesive's drying out, they certainly form a biofilm. There is nothing definitive about instrumental marking other than laser marking. (NI7)

In the subcategory "reprocessing", it is discussed the reprocessing of some materials, which should be single-use; however, for the most various reasons, sometimes they end up being reprocessed following a set of rules.

I have a doubt about the reprocessing of a material. (N28)

If the manufacturer says the product is for single use, it mustn't be reprocessed. (N29)

In the subcategory "packages", the doubts focused on which kind of material is safer to pack boxes and other surgical instruments which will go through the sterilization process or which is the best kind of packaging for items that will just go through the sterilization process. The doubts were associated to which kind of packaging is more adequate for each material, considering the costs of each ones, associated to the safety of the process at matter and the rules involved in these processes.

I'm beginning the activities in a surgical Center and in there they use crepe paper packaging of

surgical boxes. I'd like to know if there is any rule prohibiting the use of this material [...]. (N1)

There are still no rules prohibiting this kind of sterile barrier system, but the paper should present appropriate technical specification and being registered in Anvisa. (N1)

In the subcategory named "maintenance", there are questions about the useful life of the equipment/ material; damages; preservation and conservation; solutions used to clean, disinfect, and sterilize; and substitution of some products for another, keeping conservation and prolonging the life of the equipments ensuring safety for those who will use those products.

[...] all the laparoscopy instruments should be sterilized, but here in my institution not all video surgery materials may be autoclaved. How is it done in the other hospitals? (N11)

This question was not answered since the answers discuss the change of methods of disinfections and sterilization and the change of more modern equipment (thermoresistant).

[...] the change of the disinfection method from glutaraldehyde to peracetic acid may damage the equipments [...] High risk of losing the equipments. (D2)

Legislation

In this category, there are three subcategories namely: "Norms/ Rulings"; "Law/ Legal"; and "Anvisa". In the subcategory "Norms/ Rulings," the professionals expressed their doubts in relation to which norm or ruling should they base on to make the decision regarding the product to be used or how to use it and, at the same time, there were doubts about the legal aspects and the laws which regulate the use of products, packaging, substances, and equipments, making these subcategories appear in several moments.

Does anyone have any information based on the legislation about high level disinfection of peracetic acid? (N11)

The current legislation for the registration of the High Level Disinfectant (Peracetic) is the RDC 33/2010. (CE4)

In the subcategory “Anvisa,” the main doubts were focused on the reprocessing of materials and about which materials are present in the list of the ones that shall not be reprocessed.

I had this doubt, but with help I was able to solve it. Because it needs to be verified how the manufacturer registered the product in Anvisa, the product I use by [...] is registered as for single use, therefore the cannulas of Guedel are not reusable. (N23)

Validation of the process

In the category “validation of the process”, there were two subcategories: “time” and “tests”.

The subcategory “time” is related to the doubts of the professionals regarding the time a product should remain immersed so that the cleaning or disinfection occurs in an efficient and safe way.

[...] high level disinfection of the peracetic acid in 10 minutes? (N11)

According to the methodology of the INCQS used for the trial of microbactericidal efficiency the time of contact is of at least 30 minutes. (P1)

In the subcategory “tests”, the main doubts were in relation to the tests which should be carried out in order to validate the burdens of sterilization in the autoclaves, what amount of those should be used in each burden, and which is the best location with the objective of ensuring a safe sterilization process.

[...] Four ampoules or it can be used just one inside the autoclave and another as control? (N20)

What is biological indicator?” (CE1) The answer: “The RDC 15, March 15th 2014, of Anvisa, is very good, it explains about the tests you should use and the frequency. (N21)

DISCUSSION

In the category named “solutions,” many doubts referred to the commercial names of such solutions used in all the stages of the process of material preparation (cleaning, disinfection, or sterilization). The professionals wanted to know which was the most efficient, safest, and lowest in cost solution to be used in the institution.

A study¹² points out the difficulty found by the professionals in choosing the enzyme solutions for the cleaning of materials owing to the diversity of the brands in the market lately, each one with their own characteristics. It is noteworthy that most professionals demonstrated knowing which solutions are most commonly used for the cleaning, disinfection, or sterilization; however, for 20% (RU=34), the doubts were about which kind of solution and what concentration of it should be used for each kind of specific material.

Chemical disinfection should be the last option for the processing of thermosensitive materials owing to the complexity of the process, and the risks offered to workers who handle the product and for the environment, when discarded in inappropriate locations¹³. The germicides used for high-level disinfection are the aldehydes (glutaraldehyde, ortoformaldehyde, formaldehyde), the peracetic acid, the hydrogen peroxide, and the electrolyzed water; for the disinfection of the intermediate and low levels, the chlorinated solutions, alcohol, quaternary ammonia, phenols, and iodophors are used¹³.

The concentration of the solutions remains the same recommended by the manufacturer for the immersion of the material, what varies is the time of exposure to it in order to occur disinfection of high, medium, and low levels. The RDC 8¹⁴ forbids the sterilization of health products considered critical. The Anvisa reinforced this measure with the publication of RDC 33¹⁵, in 2010, prohibiting the registration of new sanitizing agents in the category of “sterilizing” as a liquid, establishing a deadline for the adequacy of the sterilizing products and hospital disinfections for semicritical articles.

In the category “equipment and materials”, there were doubts about methods of sterilization/disinfection directly related to the first category, in which the professionals asked for the most recommended disinfectant solutions and how to use them for the disinfection of the materials. In this category, the subcategory “instruments” was the second more

recommended one, with doubts in relations to all the stages in the process of preparations of the material (cleaning, packaging, and sterilization) of specific instruments such as endoscopy equipment, surgical instruments, nebulizers, ambus, etc.

According to the NR 15⁶, all health products subject to processing must go through cleaning by mechanical actions (manual or automated), acting on internal (lumen) and external surfaces, in a way they make the product safe for handling and prepared for disinfections or sterilization. After cleaning, the materials must go through the processes according to their classification such as critical, semicritical, or noncritical products. Some should receive a simple disinfection, others, a high level disinfection or proceed to sterilization depending on the kind of material they are made of⁶.

Some professionals reported their doubts in relation to the reprocessing of single use materials. A study¹⁶ approached the classification of the health products as single-use or reusables. The first should be used one single time, however, the reuse of these materials has become a reality, involving a series of issues — technical, economic, environmental, ethical, and legal ones, once they may result in risk to the health of users of these products. The reusable products are considered durable goods and require, for reprocessing, an evaluation of performance, cleaning, disinfection or sterilization, and quality control in all the stages in order to ensure their reuse.

In 2006, Anvisa published the Resolution No. 2.605 with a list of hospital products prohibited to be reused¹⁷. In case there are any doubts, one should contact the committee of reprocessing of products of the institutions, but if this committee is not implemented, who will decide is the technical responsible for the CSSD, who should evaluate the conditions of the product, the costs for its reprocessing and, if after reprocessing, there will be no risk for users⁶.

Another doubt still in relation to the category “equipments and materials” was about the safer kind of packaging to ensure the sterility of the material for longer. The main functions of the package should allow sterilization of the material, keeping their sterility up to the moment of use, and the aseptic removal of the packaging material, protecting them from possible adverse events¹³. The variety of products used to pack the materials to be sterilized is large; therefore, in order to choose which will be the most appropriate casing, it is necessary to take into account a series

of factors such as money, financial condition of the institution, waste production, training of the team of employees of the CSSD, etc.¹³. Thus, the packaging gives the material the protection necessary for the maintenance of the sterilization, being directly connected to the conditions of handling, transportation, and storage; thus, the material should be stored in a dry, ventilated place, protected from dirt and large temperature variations — these conditions should always be monitored and events which may put at risk the sterilization of the material¹⁸.

The least expressive doubt was in relation to the formation of biofilm, when for some reason the cleaning of the equipment is not enough or when the solutions used are not according to the dilution. A study on the removal of biofilm, in devices used for endoscopy, pointed out a high risk of developing the biofilm in this kind of equipment, considering they are complex, cannot be disassembled, and are not transparent, which difficulties the internal visualization and may compromise the cleaning process¹⁹; therefore, if the cleaning is not enough, the process of disinfection and/or sterilization will be all compromised.

In the category “legislation”, most doubts were in relation to the “Norms/Rulings” and about the laws. Regarding this category, it may be mentioned the RDC 15⁶, an essential document for those who work in the CSSD, provides for good practice requirements for the PHP and offers other measures aimed at the safety of the patient and the professionals involved⁶. In addition to those, there are other Resolutions, New Techniques, and Rulings, published by Anvisa, which complement the recommendations for good practices in the CSSD addressing the aspects not discussed by the RDC 15.

In the category “validation of the process”, most doubts were focused on the time in which the materials should be exposed in each stage of cleaning, disinfection or sterilization, and what tests should be carried out in order to ensure an effective sterilization at the end of the process. It is known that health users are exposed to risks inherent to an inappropriate processing; when the time is inappropriate, the potential of microorganisms transmission is kept, and the toxicity caused by residues of the solutions used may reach the patient¹⁹.

According to the recommendation from RDC 15⁶, each and every burden of sterilized products should be followed by a monitoring with challenge test packaging

with chemical integrators class 5 or 6. As for the monitoring with physical tests, there is a need of registration for each sterilization cycle⁶. The monitoring with a biological indicator should be carried out daily, placing the challenge packaging at the point with the greater difficulty to perform the sterilization of the internal chamber of the autoclave⁶. The results of these tests should be stored in the unit and be available for consultation when requested⁶.

Observing the doubts sent to the list of discussion and evaluating the answers issued, it was concluded that most of them were correct — those which were inappropriately answered would be immediately presented the correct solution by another professional. The answers would always be fundamented in existing legal references, with the indications of chapter of norms and legislations available mainly in the websites of the Ministry of Health, Anvisa, and in the website itself.

Although different professional categories have manifested their doubts, it was observed that they were similar and directed in order to ensure the biosecurity of the health products. The existing doubts, if not solved, would represent a risk for the quality of the PHP and consequently health assistance.

FINAL CONSIDERATIONS

This research allowed knowing the doubts about biosecurity related to the CSSD presented by health professionals and their answers, consistent with the existing national reality. It was observed that the most frequent doubts were related to the solutions, equipments, and materials; to the legislation; and to the validation of the process.

It was evidenced that the group of discussions of the website researched is an important tool available to help health professionals to solve their doubts, contributing for a quality health assistance. The doubts were, mostly, solved based on the existing norms and laws that guide the work in the CSSD.

About the solutions, the main difficulties pointed out by the patients were in relation to commercial names, the dilution concentrations, and its validity in order to perform the processing of materials in the CSSD. Regarding equipments and materials, the doubts were about the method of sterilization/disinfection and the concern with marking surgical instruments safely, ensuring the life of the material without affecting the sterilization process. As for the legislation, the main doubts of the professionals are related to which Norms/Rulings or Laws are indicated for the activities developed in the CSSD, in order to ensure the quality of the assistance. In the validation of the process, the professionals expressed their doubts regarding time and which materials should remain in each stage of the processing, in order to ensure an effective cleaning, a safe disinfection, and a fail-safe sterilization process. Besides that, there was also a concern as for the tests carried out in order to ensure that the processes would be fail-safe ensuring user's safety.

Many professions connected to the health area expressed their doubts and answers to the questionings related to the CSSD, although the number of professionals involved in the discussion was of nurses. There were concerned professionals about providing quality assistance, trying to solve their doubts based always on some legal information. It is considered that the website researched offered a sort of opportunities so that the professionals of health areas/managers use it as a source of consultation, working both for the continued education of the specific of the CSSD and in any area related to biosecurity in health services nationwide. The social contribution of this research is inferred, serving to spread the existence of a space where professionals may search for support to their doubts, always with legal support.

As limitations of this study, it may be mentioned the scarce national publications in the nursing area focusing on biosecurity in the CSSD within the last eight years, most publications being previously related, although the legislations have changed especially within the last four years.

REFERENCES

1. Cararro TE, Gelbcke FL, Sebold LF, Kempfer SS, Zapelini MC, Waterkemper R. A biossegurança e segurança do paciente na visão de acadêmicos de enfermagem. *Rev Gaúcha Enferm.* 2012;33(3):14-9.
2. Bartolomei SRT, Lacerda RA. Trabalho do enfermeiro no Centro de Material e seu lugar no processo de cuidar pela enfermagem. *Rev Esc Enferm USP.* 2006;40(3):412-7.
3. Pereira MEC, Jurberg C, Soeiro MNC, Borba CM. A estruturação do Programa de Capacitação Profissional de Biossegurança no contexto do Projeto de Modernização da Gestão Científica do Instituto Oswaldo Cruz. *Saúde Soc.* 2010;19(2):440-8.
4. Ministério do Trabalho e Emprego (BR). Norma Regulamentadora nº 32. Portaria nº 485, de 11 de novembro de 2005. Estabelece as diretrizes básicas para a implementação de medidas de proteção à segurança e à saúde dos trabalhadores dos serviços de saúde, bem como daqueles que exercem atividades de promoção e assistência à saúde em geral. Brasília, DF: MTE; 2005.
5. Santos MR, Ribeiro RP, Martins MB, Nascimento LA, Martins JT, Broff MCC. Avaliação da implantação da Norma Regulamentadora 32 em um Hospital universitário. *Cogitare Enferm.* 2012 Jul-Set;17(3):524-30.
6. Agência Nacional de Vigilância Sanitária. Resolução nº 15, de 15 de março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. Brasília, DF: Anvisa; 2012.
7. Silva AC, Aguiar BGC. O enfermeiro na Central de Material e Esterilização: uma visão das unidades consumidoras. *Rev Enferm UERJ.* 2008 Jul-Set;16(3):377-81.
8. Brand CI, Fontana RT. Biossegurança na perspectiva da equipe de enfermagem de Unidades de Tratamento Intensivo. *Rev Bras Enferm.* 2014;67(1):78-84.
9. Martins VMF, Munari DB, Tipple AFV, Bezerra ALQ, Leite JL, Ribeiro LCM. Forças impulsoras e restritivas para trabalho em equipe em um Centro de Material e Esterilização de hospital escola. *Rev Esc Enferm USP.* 2011 Out;45(5):1179-86.
10. Gallas SR, Fontana RT. Biossegurança e a enfermagem nos cuidados clínicos: contribuições para a saúde do trabalhador. *Rev Bras Enferm.* 2010 Out;63(5):786-92.
11. Bardin L. Análise de conteúdo. São Paulo: Edições 70; 2011.
12. Schmidt DRC, Yonekura ONEKURA CSI, Gil RF. Instrumento para avaliação de detergentes enzimáticos. *Rev Esc Enferm USP.* 2008;42(2):282-9.
13. Graziano KU, Silva A, Psaltikidis EM. Enfermagem em centro de material e esterilização. Barueri: Manole; 2011. 417p.
14. Agência Nacional de Vigilância Sanitária. Resolução RCD 8, de 27 de fevereiro de 2009. Dispõe sobre as medidas para redução da ocorrência de infecções por Micobactérias de Crescimento Rápido em serviços de saúde. Brasília, DF: Anvisa; 2009.
15. Agência Nacional de Vigilância Sanitária. Resolução RCD nº 33, de 16 de agosto de 2010. Dispõe sobre a proibição de registro de novos produtos saneantes na categoria esterilizante para aplicação sob a forma de imersão, adequação dos produtos esterilizantes e desinfetantes hospitalares para artigos semicríticos já registrados na Anvisa e dá outras providências. Brasília, DF: Anvisa; 2010.
16. Costa EAM, Costa EA. Risco e segurança sanitária: análise do reprocessamento de produtos médicos em hospitais de Salvador, BA. *Rev Saúde Pública.* 2012;46(5):800-7.
17. Zilberstein B, Silva RCR, Valim SG, Yukui KTH, Valentim R. Reprocessamento de pinças de alta resolução para corte e coagulação. *ABCD, Arq Bras Cir Dig.* 2013;26(3):230-3.
18. Carvalho R. Enfermagem em centro de material, biossegurança e bioética. Barueri: Manole; 2015. 380p. (Manuais de especialização, 11).
19. Balsamo AC, Graziano KU, Schneider RP, Antunes Júnior M, Lacerda RA. Remoção de biofilme em canais de endoscópios: avaliação de métodos de desinfecção atualmente utilizados. *Rev Esc Enferm USP.* 2012;46(n. esp):91-8.