

Temperature and humidity conditions in the distribution and storage room for health products*

Condições de temperatura e umidade na sala de distribuição e armazenamento dos produtos para saúde

Mariana Brito de Souza Nunes¹ • Cintia Silva Fassarella² • Priscilla Alfradique de Souza³ • Ricardo de Oliveira Meneses⁴ • Maria Virginia Godoy da Silva⁵ • Aline Affonso Luna⁶

ABSTRACT

Objectives: To identify the environmental conditions of temperature and humidity in the area of storage and distribution of sterilized health products as a possible source of contamination of sterilized health products; and to analyze such environmental conditions as a possible source of contamination of health products sterilized in relation to national and international standards. **Method:** Retrospective documentary study, with quantitative approach, based on the analysis of the temperature and air humidity record form. The collected data were organized in spreadsheets, according to the two variables, summarized by means of the distribution of the raw data, the continuous variables were treated through quantitative descriptive analysis, with measures of central tendency and dispersion. **Results:** Although the references presented for the parameters of temperature and air humidity are widely recognized nationally and internationally, there is a fragility in the results that demonstrate the importance of air temperature and humidity control. **Conclusion:** it is necessary to develop researches that determine the relevance of scientific evidence of temperature and humidity control in the area of storage and distribution of sterilized health products.

Keywords: Sterilization center. Room temperature. Air humidity. Product storage. Patient safety.

RESUMO

Objetivos: identificar as condições ambientais, de temperatura e umidade, na área de armazenamento e distribuição de produtos para saúde esterilizados como possível fonte de contaminação dos produtos para saúde esterilizados; e, analisar tais condições ambientais como possível fonte de contaminação dos produtos para saúde esterilizados em relação aos padrões nacionais e internacionais. **Método:** Estudo retrospectivo documental, com abordagem quantitativa, realizado a partir de análise do formulário de registro da temperatura e de umidade do ar. Os dados coletados foram organizados em planilhas, de acordo com as duas variáveis, sumarizados por meio da distribuição dos dados brutos, as variáveis contínuas foram tratadas por meio da análise quantitativa descritiva, com medidas de tendência central e de dispersão. **Resultados:** apesar das referências apresentadas para o parâmetro de temperatura e de umidade do ar serem amplamente reconhecidas nacional e internacionalmente, encontra-se fragilidade nos resultados que demonstram a importância do controle de temperatura e de umidade do ar. **Conclusão:** mostra-se a necessidade de desenvolvimentos de pesquisas que determinem a relevância mediante evidências científicas do controle de temperatura e de umidade do ar na área de armazenamento e distribuição de produtos para saúde esterilizados.

Descritores: Centro de esterilização. Temperatura ambiente. Umidade do ar. Armazenamento de produtos. Segurança do paciente.

NOTA

¹Nurse. State University of Rio de Janeiro (UERJ). E-mail: marianabrito28@gmail.com

²Dr^a in Nursing at UERJ, Adjunct Professor at Grande Rio University and UERJ. E-mail: cintiafassarella@gmail.com

³Degree in Nursing from the University of Texas. Assistant Professor at UERJ. Email: prialfra@hotmail.com

⁴Master in Nursing from the Federal University of the State of Rio de Janeiro (UNIRIO). Assistant Professor of UERJ. E-mail: ricardomeneses@bol.com.br

⁵Dr^a in Nursing from the University of São Paulo (USP). Deputy Professor of UERJ. E-mail: godoydasilva@terra.com.br

⁶Dr^a in Nursing by UNIRIO. Assistant Professor at the University of Rio Grande and UERJ. Email: aline-luna@hotmail.com

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INTRODUCTION

The Material and Sterilization Center (CME) is the functional unit destined to the processing of health products (PPS) of health services, whose mission is to provide all healthcare and diagnostic services for processed health products, guaranteeing the quantity and the quality required for safe care. At the CME, the entire PPS is carried out from pre-cleaning, receiving, cleaning, drying, integrity and functional evaluation, preparation, disinfection or sterilization, storage until distribution to consumer units⁽¹⁻²⁾.

The centralized CME is the one that performs all the preparation and sterilization of the health products with exclusive physical area that houses the technical areas of the purge, preparation, sterilization, storage and distribution of sterile material. In this sense, the WEC work process is distributed among nursing workers in these different areas⁽³⁾.

The processing of materials and instruments in the hospital's CME should be carried out based on the knowledge and analysis of environmental risks, together with an adequate physical space, allowing the flow of health products and professionals safely⁽⁴⁾.

According to Collegial Board Resolution No. 15, of March 2012, the storage and distribution room for sterilized health products must be dimensioned according to the quantity of products and dimensions of the furniture used for storage, clean and dry place, protected from direct sunlight and subjected to minimal manipulation⁽⁵⁾.

The storage room must be centralized in an exclusive and restricted access area, and it can not occur in a circulation area, even temporarily; must have transport equipment with caster; stairs if necessary; and, wire baskets or baskets; the shelves should be made of non-porous material, resistant to wet cleaning and the use of sanitizing products. Being under the responsibility of the head of the CME to establish the rules for the control of the events that could compromise the integrity of the sealing of the packaging of the products for health⁽⁵⁾.

The shelf life of a sterile packaged health product depends on the quality of the packaging, the storage conditions, the conditions during transportation, the amount of handling and other events such as humidity and temperature that compromise the integrity of the package⁽⁶⁾.

The storage of the products for health is one of the critical points for the maintenance of the sterility, for this there are recommendations regarding the environmental conditions in the area of guard. Among them, the controls of the temperature (T°) and the relative humidity of the air (UR)⁽⁷⁾ are emphasized.

The packaging of sterilized health products should be stored in a dry, ventilated place protected from large

temperature variations, as well as dust and dirt from the environment. The premise is that loss of sterility is related to storage conditions, packaging quality, sealing and related events; researchers point out that failures in the T° and UR control process may imply a possible compromise in sterility, making it possible to increase the risk of infection related to health care (IRAS)⁽⁸⁻⁹⁾.

According to the table below, in the literature, several recommendations are made regarding the controls that must be done in the custody area of the sterilized material, both by associative entities and by independent, national and international authors; however, although SOBECC is the main Brazilian source for CME, its reference values for temperature and humidity control in the storage room for sterilized health products are of international origin, AORN. The questioning about these values in relation to the Brazilian reality, regarding the climate, seasons of the year, level of rainfall and humidity, and changes of climatic pattern among the Brazilian states.

In this sense, the object of study is directed to the environmental conditions, T° and UR, in the area of storage and distribution of health products. Thus, the attributions of the nurse responsible for the CME include contributing actions of programs to prevent and control adverse events in health services and coordinate activities related to the PPS; and a crucial way to collaborate on IRAS prevention is that health products are free from contamination until use. This only happens by subjecting them to adequate processing and validation^(1,5,10).

This study aims to promote discussion about the adequate storage of sterilized health products, highlighting the importance of CME as an essential sector for the prevention of IRAS, disseminating to the academic world the importance of papers whose subject deals with CME and PPS.

Considering the contextualization in question, this study is justified by the fact that the deficiency of the control of the standards, or the oscillations of the T° and UR do not follow the standards present a risk of causing/ causing the wetting of the packages and, consequently, favoring microbial growth; in addition, the need to redo the process increases costs^(2,11).

In view of the above, it is formulated as a research problem: Does T° and UR of the CME storage and distribution room of the institution in question conform to the standards recommended nationally and internationally?

The objective of this study is to identify the environmental conditions of T° and RH in the area of storage and distribution of sterilized health products as a possible source of contamination of sterilized health products; and to analyze such environmental conditions as a possi-

TABLE 1 – Comparison of the recommendations of temperature (T ° C) and relative humidity (UR%) at the storage site of materials sterilized by different authors. Rio de Janeiro, 2017.

AUTHOR/YEAR	T (°C)	UR (%)
SOBECC, 2008	25	30 – 60
SOBECC, 2013	-	-
APECIH/SP, 2010	12– 22	35- 70
Technical consultation 34, 2009	Máx. 24	40 – 60
AORN, 2008	24	≤ 70
AORN, 2017	-	-
Rose Seavey, 2008	20 - 23	30 – 60
AAMI, 2006	Máx. 24	30 - 60
AAMI, 2011	Máx. 24	20 - 60
AIA, 2006	-	Máx. 70
ASHE, 2008	22 - 26	Máx. 60

ble source of contamination of health products sterilized in relation to national and international standards.

METHOD

This is a retrospective documentary study, with a quantitative approach, based on the analysis of the T ° and UR registration form. The study was carried out in a CME of a university hospital in the city of Rio de Janeiro, belonging to the Sentinela network. It is characterized by a large hospital, has several specialties, without emergency and with outpatient clinics. It has 525 beds, more than 60 specialties and subspecialties, assistance functions, undergraduate and postgraduate teaching and research in the health area. Therefore, the CME is classified as class II, attending to the surgical center and other units of the hospital and performs the processing of non-critical, semicritical and complex critical non-complex health products that can be processed.

The research site was the storage and distribution room for sterile health products, where the acting professionals are the chief nurse of the CME, the nurse on call, resident nurses and the nursing technician scaled in this sector.

The documentary analysis was based on original CME documents in which the parameters of T ° (Celsius) and UR (%) were recorded twice a day by nursing technicians, nurses on duty or resident nurses, depending on the daily dynamics, once during the daytime service and another in the night service. The inclusion criteria were data recorded from January 2015 to December 2016, totaling 24 months. The exclusion criteria were the values before and after the time cut and those that were not registered by the professionals of the unit.

The data was composed by an instrument containing

information of date, shift of record and the values of the two variables (T ° and UR).

The collected data were organized in spreadsheets, according to the two variables of the study (T ° and UR), using Microsoft Excel® 2010 program and summarized through the distribution of the raw data. Subsequent to the organization of the data. Continuous variables were treated through descriptive quantitative analysis, with central tendency and dispersion measures. The reference values in the data analysis were from the Brazilian Association of Nurses of Surgical Center, Anesthetic Recovery and Central Material and Sterilization (SOBECC) (2008) and Association for Advancement of Medical Instrumentation (AAMI) (2011). The SOBECC reference values are 25°C for T ° and 30-60% for UR; and, the reference values for AAMI are max. from 24°C for T ° and 20-60% for UR⁽¹²⁻¹³⁾.

For the elaboration of the results, both daily diurnal (SD) and nocturnal (SN) records were used in each month of the data collection, to record each minimum, maximum, average and standard deviation; for making the tables, graphs and discussion of the results.

According to Resolution 466/12 of the National Health Council (CNS), the study was approved by the Research Ethics Committee (CEP) of the institution where the data collection was carried out, through the CAAE Report No. 62795516.5.0000.5259.

RESULTS

The data of the T ° and UR of the daytime service were presented monthly, as well as their respective averages, minimum and maximum values and standard deviation, Table I.

The dashes (-) indicated in the tables refer to the months that the original documents used in the collection of data were not found in the sector for the storage of these documents.

The data of the T° and UR of the night service were presented monthly, as well as their respective averages, minimum and maximum values and standard deviation, Table 2.

In Tables 1 and 2, in relation to UR, the standard deviation (SD) varies between 2-8 (σ), in relation to the T°, the DP varies between 1-2 (σ).

The data from Tables 1 and 2, based on the SD and SN for both T° and UR, show that the SN has the highest average temperature (28,70°C), and in the daytime service it has the highest temperature (35,00°C) during the months collected. It is evidenced that the night service has the lowest average temperature throughout the period of data collection. And, that the daytime service, the highest mean of UR, and in the daytime service presents the highest value of UR during the months collected. It is observed that the night service has the lowest T° average, and the night and day service, both have a lower UR value.

Figure 1 shows the T and UR distribution of daytime and night service in the CME health product storage and distribution room.

The small dispersion is shown in the values referring to the T of the SD and SN, indicating little variation between the means found of the T, where the lower limit is of 20,36°C and the upper limit is of 26,06°C for the SD; and, the lower limit is 20,90°C and the upper limit is 26,30°C for the SN. Regarding UR, compared to T, the dispersion interval between the means of UR is higher, since the lower limit is 48.60% and the upper limit is 66.20% for the SD; and the lower limit is 46.45% and the upper limit is 64.45% for the SN. That is, the dispersion of the T in SD is 5.70 ° C, and in the SN it is 5.40 ° C. And, the dispersion of RH in SD is 17.6%, and in SN it is 18.0%.

In the daytime service, in the year 2015, the months of November and December have averages of UR not recommended for both references. In relation to the maximum UR, the months of January, February, June, July, August, October, November and December do not have maximum UR recommended for both references. Regarding the minimum UR values, the month of August does not have an agreement with the international reference.

In the daytime service, in the year 2016, the months

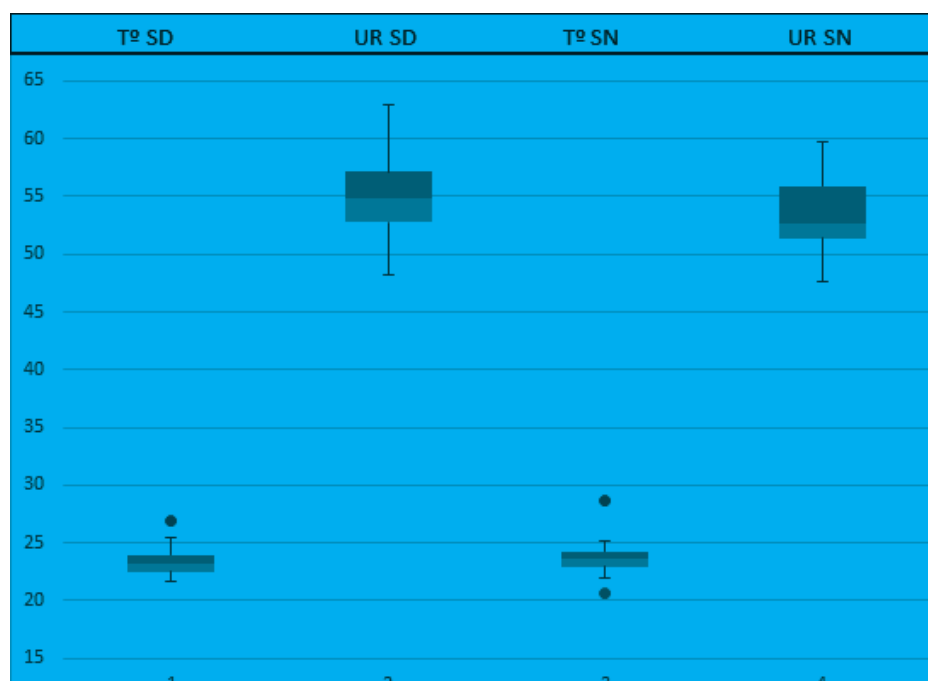
TABLE 1 – Temperature and humidity distribution of the distribution and storage room in the CME day service. Rio de Janeiro, 2017.

Year	Month	Temperature			Humidity		
		μ (σ)	Min.	Máx	μ (σ)	Min.	Máx
2015	jan	22,30 (± 2)	20,10	30,50	58,90 (± 4)	49,00	70,00
	feb	22,00 (± 1)	21,00	25,00	59,20 (± 2)	54,00	65,00
	mar	-	-	-	-	-	-
	apr	-	-	-	-	-	-
	may	21,70 (± 2)	19,00	29,00	56,20 (± 3)	49,00	60,00
	jun	22,30 (± 1)	20,20	24,70	56,90 (± 3)	51,00	67,00
	jul	22,70 (± 1)	19,00	24,20	57,30 (± 4)	50,00	69,00
	aug	23,30 (± 1)	21,08	26,40	55,80 (± 3)	67,00	67,00
	sep	-	-	-	-	-	-
	oct	23,10 (± 2)	20,80	27,80	58,70 (± 4)	46,00	65,00
	nov	23,10 (± 2)	20,00	26,90	65,40 (± 8)	56,00	82,00
	dec	23,90 (± 2)	20,60	27,00	60,10 (± 7)	50,00	77,00
2016	jan	23,30 (± 2)	20,30	26,10	62,80 (± 8)	52,00	76,00
	feb	22,50 (± 1)	20,70	28,00	-	-	-
	mar	25,10 (± 3)	22,10	35,00	60,20 (± 4)	52,00	68,00
	apr	25,50 (± 2)	20,20	28,00	53,00 (± 5)	45,00	61,00
	may	22,50 (± 1)	20,00	24,30	60,00 (± 6)	50,00	73,00
	jun	22,50 (± 2)	19,80	27,00	59,20 (± 5)	50,00	76,00
	jul	-	-	-	-	-	-
	aug	23,40 (± 1)	22,00	27,00	50,60 (± 3)	45,00	56,00
	sep	23,50 (± 1)	22,00	25,00	52,10 (± 4)	39,00	58,00
	oct	24,00 (± 2)	21,00	27,40	55,20 (± 3)	47,00	61,00
	nov	25,00 (± 2)	21,90	28,80	55,20 (± 8)	40,00	84,00
	dec	26,90 (± 2)	23,80	30,90	54,50 (± 8)	40,00	84,00

TABLE 2 – Temperature and humidity distribution of the distribution room and storage in the CME night service. Rio de Janeiro, 2017.

Year	Month	Temperature			Humidity		
		μ (σ)	Min.	Máx	μ (σ)	Min.	Máx
2015	jan	-	-	-	-	-	-
	feb	-	-	-	-	-	-
	mar	-	-	-	-	-	-
	apr	-	-	-	-	-	-
	may	20,60 (± 1)	18,00	22,50	56,60 (± 2)	52,00	60,00
	jun	23,30 (± 1)	20,00	25,90	53,20 (± 4)	45,00	64,00
	jul	23,30 (± 1)	20,40	25,20	53,70 (± 3)	45,00	60,00
	aug	22,80 (± 2)	21,00	26,00	54,20 (± 2)	52,00	60,00
	sep	-	-	-	-	-	-
	oct	23,10 (± 1)	22,00	25,80	56,10 (± 4)	52,00	64,00
	nov	23,00 (± 1)	20,00	25,00	60,30 (± 7)	52,00	82,00
	dec	24,90 (± 2)	21,00	28,70	61,00 (± 7)	51,00	70,00
2016	jan	24,20 (± 2)	20,00	27,00	61,60 (± 6)	54,00	75,00
	feb	22,00 (± 1)	19,00	24,00	-	-	-
	mar	24,10 (± 2)	22,00	26,00	55,00 (± 4)	42,00	60,00
	apr	24,60 (± 2)	21,50	28,00	51,70 (± 4)	43,00	56,00
	may	22,90 (± 1)	21,90	24,50	57,70 (± 7)	48,00	69,00
	jun	22,40 (± 1)	21,00	24,00	58,40 (± 6)	47,00	75,00
	jul	-	-	-	-	-	-
	aug	24,00 (± 1)	23,00	25,00	49,50 (± 3)	45,00	53,00
	sep	24,10 (± 1)	22,50	27,70	53,20 (± 6)	39,00	60,00
	oct	24,30 (± 2)	21,00	28,60	54,50 (± 4)	48,00	60,00
	nov	25,20 (± 1)	23,80	27,10	54,20 (± 3)	49,00	60,00
	dec	28,70 (± 1)	26,80	30,70	50,40 (± 4)	45,00	56,00

GRAPH 1 – Distribution of temperature and relative humidity in the storage and distribution room of the CME.



of March, April, and December do not have an average of T° suggested for both references. Regarding the values of maximum temperature, the months of January, February, March, April, June, August, October, November and December have temperatures above the recommended values for the national and international reference; already the month of May, has maximum temperature acceptable for national reference and not acceptable for international.

In the daytime service, in the year 2016, the months of January and March, the mean of UR is not recommended for both references. Regarding the maximum UR values, the months of January, March, April, May, June, October, November, and December do not have values suggested for both reference organizations.

In the night service, in the year 2015, in relation to the average temperature, the month of December, the reference value is acceptable for national reference and not acceptable for international reference. In relation to the maximum temperature values, all the registered months are not acceptable values for both references, except the month of May, where the maximum temperature is acceptable for both references.

In the night service, in the year 2016, the months of January, April, September and October, the average temperature is acceptable for SOBECC and not acceptable to AAMI; since the months of November and December do not have an average temperature acceptable for both references. In relation to the maximum temperature values, the months of January, March, April, September, October, November and December are not acceptable values for both national and international reference; already the months of May and August, have maximum temperature acceptable for SOBECC and not acceptable for AAMI. Regarding the minimum temperature values, monthly values were registered in the reference standards, except for the month of December, where values are not acceptable for both.

In the night service, in the year 2015, the months of November and December, the average of UR is not recommended for the references. Regarding the maximum UR values, the months June, October, November and December do not have values recommended for both national and international reference.

In the night service, in the year of 2016, all the registered months have the average of UR according to the reference values, except the month of January of 2016, that has average of UR not acceptable for both. Regarding the maximum RU values, the months January, May and June do not have acceptable values for SOBECC and AAMI.

DISCUSSION

In analysis of each relative temperature and humidity of the air, they are inversely proportional, since, the smaller the T° the greater the UR, and the larger the

T° the lower the UR. For example, the highest temperature (28.7°C) found was in December 2016, hence the second lowest relative humidity in December 2016 of 50.4%; and, in January 2016, the highest UR of 62.80% was found, but not the highest T° of the data.

In the daytime service, in the year 2015, each month had an average of T° according to the values recommended by SOBECC and AAMI. Specifically, in relation to the values of maximum T° , the months of February, June and July, have T° recommended for SOBECC (2008) and not recommended for AAMI (2011). In relation to the minimum temperature values, all the months that have been recorded have values recommended for both reference organizations.

There are several factors related to the event that contribute to the contamination of a product, including the biological load (ie the amount of contamination in the environment), air movement, traffic, location, humidity, insects, worms, floods and storage, as well as the temperature and properties of the wrapping material¹⁴. There is data that supports the practice of stacking related to the event. Thus, DRC 50 regulates the requirement for air conditioning and not direct sunlight into the storage room and distribution of sterilized materials and clothing¹⁵.

Falhas na limpeza, desinfecção e esterilização de produtos para saúde podem resultar em custo significativo institucional, morbidade e mortalidade do paciente¹⁶.

When considering the complexity of the CME mission, the work processes at that location can not be considered simple, repetitive and of less importance within the institution. Today, CME practices are based on scientific evidence that points to serious consequences for patient care when recommendations are not followed, such as belittling material processing steps, thinking that one process can replace another, and that flaws can be compensated. In this way, it is considered essential to monitor each phase of health product processing as well as the description of all standard operating procedures¹⁷.

The abrupt variation of UR and T° ranges reflects the conservation of the packages, which can become very dry or even wet, interfering with the resistance of these casings to remain inviolable. The shelf life of a packaged sterile item depends on the quality of the packaging, the storage conditions, the conditions during transportation, the amount of handling and other events (humidity) that compromise the integrity of the packaging. If event related storage of sterile items is used, then packaged sterile items can be used indefinitely unless packaging is compromised. It is necessary to make sure that the sterile storage area is a well ventilated area that provides protection against dust, humidity, insects and extreme temperature and humidity, and it is the responsibility of each institution to evaluate this physical area to determine the expiration date of the sterilized health products stored there¹⁴.

We highlight a study in Brazil in which the researchers proved that the RU and the temperatures tested in a sterile storage environment do not influence the sterility of the sterile PPS stored there for a challenging period. Thus, it is questioned: What is the real influence of these two variables in the maintenance of the sterility of the articles? It is known or was evidenced, or researchers, consultants determined, with reference to the quality of the ideal conditions of the storage place, the balance between temperature and RH is aimed at preserving the packaging, avoiding its rupture and conservation, and not properly the contamination of articles⁽⁷⁾.

The RDC in force does not have information regarding the control of T and UR in the storage and distribution room, nor in possible reference values; only in the Public Consultation of this DRC, it was discussed on this subject and reference values. Bringing with it, more questioning as to the Brazilian references such control⁽¹⁾.

The AORN manual (2017) points out that guidelines that ambient temperature, humidity and ventilation should be controlled according to local, state, and federal policies and regulations. In addition, it contains reference values only from AAMI and the American Society for Healthcare Engineering (ASHE) 18. Thus, it is questioned that the main guidelines on CME worldwide do not stipulate their reference standards for T and UR control of the storage and distribution room for sterilized health products.

The current national source⁽²⁾ emphasizes that it is the health services that must determine the best methods so that the sterilized materials are not subject to events related to their storage. Thus, it is worth highlighting the particularity of each health service; and of this institution in question, understanding its physical and architectural structure as a possible factor so that the T and UR of the sector in question are not in agreement with the main references analyzed. Since the storage and distribution room is near the sterilization room, in which the autoclaves work most of the time, often causing the internal temperature of this site of the CME to be greater than the temperature of the external medium, directly influencing the T° and UR of the storage and distribution room; and in relation to the effectiveness of the refrigeration system of this storage location.

Knowing what the CME is, its mission, particularities and dynamics, as well as each step of the sterile health care product processing, means the importance of the storage and distribution room as one of the processing steps; and its environmental and physical particularities for the safety of this process, thus, performing patient safety in direct care and an active sector in the prevention and control of infection⁽⁸⁾.

The loss of sterility of a packed item is related to the event in question and not to shelf life, emphasizing

the great importance of the individual structure of each CME⁽¹⁸⁾.

The importance of the professional practice of the CME nurse is understood by the fact that he is a professional with scientific knowledge to understand each step of the sterilization process as a possible source of contamination and possible adverse event in the patient. Therefore, it is understood the importance of elaborating the development of well-designed research by these professionals to understand and determine the importance of T° and UR control in the environment where the sterilized materials are stored.

CONCLUSION

This study complied with its proposed objectives, analyzing the environmental conditions, T ° and UR, in the area of storage and distribution of sterilized health products; in which the results found, for the most part, are outside the standards recommended by the organs (SOBECC and AORN), both national and international; and, in some cases, T° and UR, are inversely proportional.

Although the references presented for the parameter of T° and UR are widely recognized nationally and internationally, there is a fragility in the results that demonstrate the importance of T° and UR control.

As a result of this fragility, it is necessary to develop researches that determine the relevance of the T and UR control in the area of storage and distribution of sterilized health products through scientific evidence. Mainly associated with other aspects such as infrastructure of this place, mandatory aspects such as not entering sunlight, restricted area to large circulation of people, adequate shelves and spaced from the ground and walls, transportation equipment; and, the positive pressure, since the route of contamination of the CME is mainly by contact.

Understanding, therefore, the importance of professional practice to evaluate each stage of the work process in the processing of health products; since the inspection of the storage location, inspection of the packaging, registration of T and UR, are part of the process; thus, I understand it as a crucial part for the maintenance of sterility, until the effective use of the product for sterile health.

LIMITATIONS OF THE STUDY

The study presented limitations on data collection, in relation to the documentary search for the state of custody of the documents evaluated; the lack of full registration of all annotations; and, the financial crisis by which the hospital of this research passes, limiting the number of members of the nursing team.

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