

NURSING DIAGNOSIS FOR MATERIAL AND STERILIZATION CENTER: CONCEPT ANALYSIS

DIAGNÓSTICO DE ENFERMAGEM PARA CENTRO DE MATERIAL E ESTERILIZAÇÃO: ANÁLISE DO CONCEITO

DIAGNÓSTICO DE ENFERMERÍA PARA EL CENTRO DE MATERIAL Y ESTERILIZACIÓN: ANÁLISIS DE CONCEPTO

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ABSTRACT

Objective: to validate the content of the diagnostic proposal "Risk for contamination of articles". **Method:** study of content validation by experts. Considering sampling error as 15%, 99% confidence level and 85% proportion of experts, it was determined sample of 38 experts. The binomial statistical test was applied for data analysis. **Results:** nine items of seventeen proposed were validated by experts, with overall scores above 0.80. Six items were validated as smaller, with overall score between 0.50 and 0.79. The items "Definition" (0.0066) and "Sterilization of implants in cycle for immediate use" (0.0396) were rated as inadequate by experts. **Conclusion:** the diagnostic purposal is appropriate, since the items have been validated. Two items were considered inadequate and should be reviewed prior to clinical validation. **Descriptors:** Perioperative Nursing; Material and Sterilization Center; Nursing Diagnosis; Validation Studies.

RESUMO

Objetivo: validar o conteúdo da proposta diagnóstica "Risco para contaminação de artigos". Método: estudo de validação de conteúdo por especialistas. Considerando-se 15% como erro amostral, nível de confiança de 99% e proporção de especialistas de 85%, determinou-se amostra de 38 peritos. Para análise dos dados, aplicou-se o teste estatístico binominal. Resultados: validaram-se pelos peritos, com escore geral acima de 0,80, nove itens dos dezessete propostos. Seis itens foram validados como menores, com escore geral entre 0,50 a 0,79. Os itens "Definição" (0,0066) e "Esterilização de implantes em ciclo para uso imediato" (0,0396) foram classificados inadequados pelos peritos. Conclusão: a proposta diagnóstica está adequada, uma vez que os itens foram validados. Dois itens foram considerados inadequados e devem ser revisados antes da validação clínica. Descritores: Enfermagem Perioperatória; Centro de Material e Esterilização; Diagnóstico de Enfermagem; Estudos de Validação.

RESUMEN

Objetivo: validar por expertos, el contenido de la propuesta "El riesgo de contaminación de los artículos" de diagnóstico a través del análisis por los expertos. Método: estudio de validación de contenido por los expertos. Teniendo en cuenta el error de muestreo de hasta 15%, el nivel de confianza del 99% y una proporción de los expertos de 85%, se determinó uma muestra de 38 expertos. Análisis de los datos aplicó la prueba estadística binomial. CAAE: 04960612.5.0000.5243. Resultados: validado por expertos, con las puntuaciones globales superiores a 0,80, nueve artículos de los diecisiete propuestas. Seis artículos fueron validados como más pequeño, con puntaje general entre 0,50 y 0,79.Los elementos de ajuste (0.0066) y 'Esterilización de los implantes en el ciclo para su uso inmediato' (0,0396) fueron calificados inadecuada por los expertos. Conclusión: se concluye que la propuesta de diagnóstico es apropiado, ya que los artículos fueron validados. Dos elementos fueron considerados insuficientes y deben ser revisadas antes de la validación clínica. Descriptores: Enfermería Perioperatoria; Material y Centro de Esterilización; Diagnóstico de Enfermería; Los Estudios de Validación.

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INTRODUCTION

In this study, we intend to develop the proposed nursing diagnosis "Risk for contamination of items". The professional practice as a nurse in a Material and Sterilization Center (MSC) of a public hospital in Rio de Janeiro emerged as a motivational factor for the development of this proposal, coupled with the need to identify the nurses' working phenomena in this sector.

In daily practice, there is the challenge of preparing nursing professionals to work in the MSC. Many of them did not choose to work in that sector, there is no previous training for the development of activities, and the routine is passed from one professional to another without scientific basis. However, with the publication of the Collegiate Board Resolution (RDC) No. 15 of National Health Surveillance Agency (ANVISA) in 2012, a new paradigm on the importance of MSC in processing health products was consolidated.¹

In the professional staff of the MSC, which is made up of nurses and nursing technicians/assistants, the presence of nurses is required during the period of operation of the sector, and they are responsible for the direct supervision of activities in the sector.^{1,2}

The decision-making related to coordination activities, staff administration and technical and administrative activities stands out, being restricted to the visibility of indirect care promotion activities as the control and validation of the sterilization process.³⁻⁴

The nursing process provides guidance on clinical judgment and the decision making is constituted of the following steps: research or data collection, nursing diagnosis, planning, implementation of nursing interventions and evaluation of results.⁵

Of the five steps that comprise the nursing process, the diagnosis should be the second and it provides to nurses the necessary support for decision-making, choice and targeting of interventions to achieve results. 5-6

The choice of interventions requires a clinical reasoning, and this occurs daily in nursing work process in the MSC, but empirically, without determination of the phases of the nursing process and without documentation with standardized language.

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The formulation of a diagnosis targeted at MSC would provide to the nurse a line of clinical reasoning for planning, coordination, implementation, monitoring and evaluation of the steps related to the processing of materials, which consist in the reception, cleaning, drying, evaluating of integrity and functionality, preparation of materials, disinfection or sterilization, storage and distribution of these materials to the units for patient care.²

Whereas the work on MSC would be directly linked to the prevention infections related to health care and that the failure in prevention generates sanitary violations, the relevance of this study is justified in order to systematize the indirect patient care and nursing care with the environment. So, authors sought to consider the actions taken in MSC as caretakers, systematizing them by validating a nursing diagnosis, recognizing the direct relation to infection control through the care for the environment and indirectly with patient.

Since the days of Florence Nightingale, nurses claim the individual as the basis of nursing care, which is corroborated by several theories. But Florence herself showed us that the environment also has its importance in patient care. ⁷ Thus, it is necessary to think in environmental care, in indirect care, as one of the ways of care in nursing. Therefore, it is suggested a diagnosis focused on the environment and in indirect care, taking as a basis these interventions and nursing outcomes.

The preparation of a specific nursing diagnosis for the labor phenomenon, performance and professional practice of nurses in the MSC is important to contribute to the visibility of systematization of nursing care provided by these professionals, who in turn, may provide to the patients of the health facility an indirect quality care, since the presence of nursing diagnosis requires a nursing intervention and vice versa.

This study aims to contribute to the application of the nursing process in the practical scenario, offering theoretical and methodological tools for health promotion and early environmental diagnosis based on scientific evidence. Also, it provides resources and encourages research to assist in the implementation of Systematization of Nursing Care and of the nursing process, which is linked this dissertation.

It is proposed to formulate the nursing diagnosis "Risk for contamination of items" as emerging from the need to validate and document the activities developed by the MSC nurse. Authors opted for the development of a risk diagnosis, since the goal of a MSC is to provide material in safe conditions of use in direct care.

The contamination of these products favors the increased susceptibility to infections, which makes the work of the staff of this sector a factor of great importance for the prevention of infections related to health care.⁸⁻⁹

The objective of this study was to validate the content of the diagnostic proposal "Risk for contamination of items".

METHOD

This article was prepared from the data of the dissertation << Risk for contamination of items: a proposal for nursing diagnosis >> submitted to the Professional Masters in Nursing Care of the Nursing School Aurora de Afonso Costa, Fluminense Federal University (UFF-EEAAC / RJ), in December 2013.

Authors opted for the concept analysis, since it is considered essential for nursing, as it contributes to the development of a

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standardized language that describes its practice. 10

The sample consisted of 38 nurses, considering an acceptable sampling error of 15%, confidence level of 99% and 85% proportion of experts for diagnostic validation.¹¹

It was used a formula to define the estimate of sample size and the expected proportion of experts where:

- Z1- α /2: refers to the confidence level used (1.96);
- P: is the expected proportion of experts indicating the suitability of each item (85%);
- e: is the acceptable proportion difference in relation to what is expected (15%).

The calculation was made as follows: $n=1.96^2*0.85*0.15/0.15^2=38$ experts. ¹¹

Seeking to meet the predetermined criteria, the sample consisted of nurses who met the expert definition adapted from Fehring model, ¹² as described in Figure 1.

Definition of expert	Score	Adapted definition of expert	Score
Master in Nursing	4.0	Master in Nursing	4.0
Master's degree in nursing with a dissertation with relevant content to the diagnosis of interest	1.0	Master's degree in nursing with a dissertation related to MSC, Hospital Infection Control Service (HICS) and / or nursing diagnosis	1.0
Research publication on the given diagnosis or relevant content	2.0	Publication of research on diagnosis, MSC, Control Center (CC) and / or HICS	2.0
Article published on diagnosis in reference journal	2.0	Article published on diagnosis, MSC, CC and / or HICS	2.0
Doctoral dissertation on the diagnosis	2.0	PhD in Nursing	2.0
Current clinical practice for at least one year in an area relevant for the diagnosis of interest	1.0	Clinical practice for at least one year in MSC, CC, HICS or teaching	1.0
Certification of clinical practice in relevant area for the diagnosis of interest	2.0	Specialization in CC, MSC and RPA or Certification of expert by SOBECC	2.0

Figure 1. Expert definition adapted from Fehring model. Niterói /RJ, 2013.

The adaptation of evaluation of experts was due to the need to specify certain criteria, so that it allows the inclusion in the sample of a larger number of experts with knowledge on the proposed subject. Studies show that clinical experience and theoretical knowledge are extremely relevant. So, authors tried to choose nurse

experts in clinical practice and nurse experts in nursing diagnosis. 11

Each specific criterion has an associated score, so that the nurse who reached a minimum score of five points was selected as an expert.

The purpose was the assessment and evaluation of the nursing diagnosis by

specialists or experts, based on an instrument built according to the structure of the NANDA-I, consisting of the operational definition of each risk factor.

A total of 352 nurses were approached, 52 through e-mail and 300 through personal contact with the expert. The expert who did not express their willingness to participate in the survey by answering the e-mail had this positioning understood as a rejection of the invitation.

The data collection instrument, of questionnaire type, was divided into two parts:

1st - Characterization of the expert - identification data (name, age, workplace) and study areas (area of expertise, time of experience, academic degrees, work with nursing diagnosis, identification of the nursing diagnosis in practice).

2nd - Validation instrument - at this time, the expert should evaluate according to a Likert scale: 1 - Nothing; 2- A little; 3-Somehow; 4- Very much; 5 - Excellent.

The values would be used to assess the following criteria: adequacy, relevance, clarity, precision and objectivity.

The experts were asked about the suggestions of items other than those listed in the instrument or identified when filling out thereof, and that should be added in the blank spaces designed for this purpose. Each risk factor contained the operational definition, the proposed intervention and the expected results.

After the instrument was filled, the data were stored in a spreadsheet generated by Microsoft Office Excel (2010). The quantitative analysis of the relevance of diagnosis and its adequacy of definition of their respective titles was conducted, applying descriptive statistics (frequency distribution).

In conducting the analysis of data on the degree to which each defining characteristic may be indicative of a diagnosis, the Likert scale was codified in a dichotomized way, where the items marked as 1, 2 or 3 were considered inadequate and items marked as 4 or 5, adequate.¹¹

Authors calculated the number of experts who consider the clinical indicator as adequate, applying the statistical binomial test. ¹¹

The application of the test aimed to verify the proportion of experts who

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classified the defining characteristics as adequate, answering the following question: what is the probability of the proportion of experts who classified the defining feature as adequate be greater than or equal to 85%?

Where:

n= number of experts (38);

x= number of experts who classified the indicator as adequate;

p= proportion considered adequate to validate the indicator (0.85).

For this, it was considered the two statistical hypotheses:

 H_0 : the proportion of experts who classified the indicator as adequate is not equal (or greater than) 85%.

 H_1 : the proportion of experts who classified the indicator as adequate is equal to 85%.

The rejection of the null hypothesis occurred only when the descriptive test level (p) showed up lower than the significance level (0.05). This reasoning was applied for each component of the nursing diagnosis that has been validated. ¹¹

This research was developed after approval by the Ethics Research Committee of the University Hospital Antonio Pedro, under Certificate of Presentation for Ethical Consideration number: 04960612.5.0000.5243.

RESULTS

In a comprehensive analysis of the instrument, the Validation Index of Items for the Diagnosis (IVID, in Portuguese) was calculated as the average of all items evaluated by the expert. ¹¹

It was observed that the items evaluated with weight equal to or greater than 0.80 were validated by the experts, accounting for risk factors of greatest relevance. The items weighing from 0.50 to 0.79 were classified as risk factors with a lower relevance in the view of experts. Risk factors with lower average than or equal to 0.50 were classified as irrelevant and were discarded. 11-2

Figure 2 shows an overview of the IVID of the items analyzed by the experts. With regard to the overall score, the experts validated the following items:

Overall score above 0.80:

Domain;

- Risk factor 1 Failure in the vacuum pump;
- Risk factor 6 Use of autoclaves without microbiological control;
- Risk factor 7 Sterilization of loads without the use of challenge testing packet (CTP);
- Risk factor 8 Manual cleaning of instruments with lumen;
- Risk factor 10 Use of autoclaves without the periodic conduction of preventive and / or corrective maintenance;
- Risk factor 11 Packages not identified correctly;
- Risk factor 12 Storage of sterile packages in non-restricted area;
- Risk factor 13 Transport of sterile packages in open trolley.

Overall score between 0.50 and 0.79:

- Class;
- Diagnostic statement;
- Definition;

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- Risk factor 2 Presence of impurities in the product after cleaning;
- Risk factor 3 Inadequate physical parameters at the end of cycle;
- Risk factor 4 Failure in the chemical indicator after sterilization;
- Risk factor 5 Use of implantable material before the result of the biological indicator;
- Risk factor 9 Cycle implants sterilization for immediate use.

No feature was considered irrelevant by the experts, i.e., overall score below 0.50.

Regarding the score obtained by the items Definition (p-value 0.0066) and Risk factor 9- Cycle implants sterilization for immediate use (p-value 0.0396), the results lead us to reject H_0 : the proportion of experts who classified as the indicator as adequate is not equal to (or greater than) 85%.

HO: the proportion						-	than) 85%
H1: the proportion of experts who classified the indicator as adequate is equal to 85%							
	Adequacy	Relevance	Clarity	Precision	Objetivity	Overall	Binomial test
Domain	0.8421	0.8421	0.7368	0.8092	0.8289	0.8118	0.5128
Class	0.8289	0.8026	0.7763	0.7763	0.7829	0.7934	0.3476
Diagnostic statement	0.7632	0.7763	0.7566	0.7368	0.7632	0.7592	0.1864
Definition	0.6974	0.7303	0.7039	0.6974	0.7368	0.7132	0.0066
Risk factor 1- Failure in the vacuum pump	0.8618	0.8355	0.8487	0.8158	0.8487	0.8421	0.7206
Risk factor 2 - Presence of impurities in the product after cleaning	0.8026	0.8224	0.7829	0.7632	0.8092	0.7961	0.3988
Risk factor 3- Inadequate physical parameters at the end of cycle	0.7829	0.8158	0.7105	0.7566	0.7763	0.7684	0.1686
Risk factor 4 - Failure in the chemical indicator after sterilization	0.8158	0.8092	0.7434	0.7829	0.7829	0.7868	0.1546
Risk factor 5- Use of implantable material before the result of the biological indicator	0.7763	0.7895	0.7763	0.7763	0.8092	0.7855	0.1930
Risk factor 6- Use of autoclaves without microbiological	0.8618	0.8816	0.8882	0.8684	0.8618	0.8724	0.6810

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control							
Risk factor 7- Sterilization of loads without the use of challenge testing packet (CTP)	0.8684	0.8618	0.8684	0.8421	0.875	0.8632	0.6524
Risk factor 8- Manual cleaning of instruments with lumen	0.8421	0.8487	0.8421	0.8421	0.8618	0.8474	0.3476
Risk factor 9- Cycle implants sterilization for immediate use	0.7763	0.7632	0.7434	0.7303	0.7829	0.7592	0.0396
Risk factor 10- Use of autoclaves without the periodic conduction of preventive and / or corrective maintenance	0.8816	0.8882	0.8684	0.8684	0.8947	0.8803	0.8982
Risk factor 11- Packages not identified correctly	0.8684	0.875	0.8026	0.8487	0.8618	0.8513	0.6166
Risk factor of 12- Storage of sterile packages in non-restricted area	0.8816	0.8816	0.8882	0.875	0.8947	0.8842	0.8982
Risk factor 13- Transport of sterile packages in open trolley	0.8553	0.8487	0.8816	0.875	0.8816	0.8684	0.7452

Figure 2. Validation index of the items for diagnosis. Niterói / RJ. 2013.

DISCUSSION

It was obtained agreement between the proposed and the validated by experts in the items: Domain. Failure in the vacuum of pump; Use autoclaves without microbiological control; Sterilization of loads without the use of challenge testing packet (CTP Manual cleaning of instruments; Use of autoclaves without the periodic conduction of preventive and / or corrective maintenance; **Packets** not identified correctly; Storage of sterile packages in non-restricted area; and Transport of sterile packages in open trolley.

It is known that patient safety is a fundamental guideline to assist and influence of the quality of care. ¹³⁻⁴ Thus, this is one of the reasons why the provision of the nursing diagnosis in the Domain 11 of the NANDA-I, Safety and Protection, was relevant in the evaluation by the experts.

The presence and early detection of failures in the machinery also showed relevant both in literature and in the evaluation of experts, denominated in the diagnostic construct as "failure in the vacuum pump", "Use of autoclaves without

microbiological control", "Sterilization of loads without using a challenge testing package (CTP)" and "Use of autoclaves without the periodic conduction and preventive or corrective maintenance", as it is inconceivable for the safety of care the use of defective equipment and / or without proper periodic maintenance. Besides that, using tests for the detection of possible failures in the equipment is of utmost importance. 1,3,9,15-9

In the literature, it was found differences as to the items that deserve to be listed in the adequate identification of the package^{1,17-8}, but the factor "Packages not identified correctly" was validated by experts as relevant.

Experts agreed that special attention should be given to the items "Storage of sterile packages in non-restricted area" and "Transportation of sterile packages in open trolley", and both were validated. Although the literature is not so specific as to transportation of sterile articles, the experts highlighted the prevention of events that would lead to loss of sterility and consequent destruction of packages. 1,20

Among the events that can impair the sterility of a package, there are the disruption or loss of integrity of a package for multiple handlings, the penetration of moisture and exposure to contaminants and stored under controlled environmental conditions. 15,18-21 However, the items Class; Diagnostic statement; Definition; Presence of impurities in the product after cleaning; Inadequate physical parameters at the end of the cycle; Failure in the chemical indicator after sterilization; implantable material before the result of the biological indicator; and Cycle implants sterilization for immediate use classified as minors (those with a general

The Definition had the lowest score of the smaller features, perhaps because its description contained two confounders terms, namely: re-contaminated and material. This was also supported by experts' speeches:

score between 0.71 and 0.79).

- Expert 08- "In assessing the risk factors, I realized that they are not only about recontamination, but also related to lack of cleanliness, disinfection and / or effective sterilization. So, I suggest reviewing the definition".
- Expert 33- "I believe that the wording of the definition was somewhat confusing and little relevant the name of the proposed diagnosis is "Risk for contamination of items and materials" and the definition brings the sense of "re-contamination", which are different things Reading the related factors, the researchers argue that contamination can occur due to failure in the cleaning or sterilization process, and this must be considered in determining the diagnosis. I suggest the following definition: Risk of the item not being cleaned, disinfected or sterilized by human or mechanical failures in the processes of preparation and risk of the already clean, disinfected or sterilized item being intentionally or accidentally contaminated".

The use of diagnosis was directly related to patient care and the proposal of a nursing diagnosis for the care of the environment seems to sound strange at first. However, even though it was classified as minor feature, it has achieved an expressive score by the experts.

Regarding the class "Protection against infection to pathogens", literature shows that improperly sterilized or contaminated

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instruments used in a surgical procedure may result in serious consequences.²⁰ Perhaps the inadequacy of the term "protection", instead of "contamination", proposed by experts, has earned its borderline rating, with 0.79 score.

The completion of the steps of the sterilization process within the standards of good practices is a key factor to ensure that procedures involving the use of critical item are not responsible for the transmission of infections. 15,18-21

It is observed that, despite the literature pointing cleaning as an essential factor, the assessment of experts did not classify it in this way:

- Expert 20- "The presence of impurities should be detected or not by what is visible to the eye, devices such as magnifying glass and specific sensors (for proteins. e.g.)".
- Expert 26- "One can use specific test for cleaning, besides the observation with intensifying lenses to better assess the result of cleaning".
- Expert 34- "Intervention: Adding the use of artifacts in cleaning, products mentioned in the cleaning, as well as equipment, for example, ultrasonic washer. Result: I suggest including cleaning monitoring tests".

The experts judged essential the presence of monitoring tests associated with the use of image intensifiers lenses in order to validate this item.

The "Presence of impurities in the item after cleaning" means a prominent circumstance when processing items, since the cleanliness is a prerequisite for disinfection and sterilization. The cleaning should start as soon as possible, preferably immediately after completion of the surgical procedure and can be carried out manually or by an automated method. 15.18-21

Failure to follow the recommended procedures for cleaning and disinfection is one of the main reasons for the spread of infection, as cleaning by itself reduces the microbial load. 3,18-21

Two other items of special attention to MSC and that have not been validated in a significant way by the experts were "Inadequate physical parameters at the end of cycle" and "Failure in chemical indicator after sterilization," but these obtained marginal values of 0.76 and 0.78, respectively.

Physical indicators include graphs and parameters of time, temperature and pressure, whereas chemical indicators are process monitoring devices that are used to check whether the items have been exposed to one or more critical parameters required for sterilization. A visual change, usually a color change, indicates a defined level of exposure based on the classification of the chemical indicator used.^{3,18-21}

That way, these two factors indicate that parameters of the sterilization process were not achieved, setting procedural error and equipment malfunction.^{3,18-21}

The "Use of implantable material before the result of the biological indicator" and the "Cycle implants sterilization for immediate use" are other risk factors that have been validated in the literature. According to the opinions of experts, these factors were classified as minor features.

The cycle sterilization for immediate use is designed when an instrument on which the progress of the surgery depends is accidentally or unpredictably contaminated, so it can be processed as quickly as possible, respecting the processing steps.^{1,3,18-21}

The processing of an implantable material through the MSC is a sensitive issue because after sterilization, it is recommended that the implant is placed in quarantine until knowing the result of the biological indicator. 1,3,18-21

The cycle sterilization for immediate use is not recommended for implantable devices, once the implants are foreign bodies, thus increasing the risk of surgical site infections. 1.3.18-21

The only two items rejected according to the binomial test were Definition (0.0066) and Cycle implant sterilization for immediate use (0.0396). As stated earlier, it is suggested an adjustment to the Definition terms. As for the inadequacy of the factor Cycle implant sterilization for immediate use, its indication is still controversial and because of this, its restriction may be appropriate.

It is noteworthy that some infections related to health care are preventable through the adoption of well-known effective measures that can interfere with a microorganism transmission chain. Among these measures, it can be mentioned the processing of items. ¹⁴

The control of infections related to health care is intrinsic to the care process.¹⁴

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The work of MSC nurse facing unusually for the bureaucratic activities, without proper emphasis on the nursing process and the systematization of care and supported by a theory constitute an obstacle to the development of science in nursing.

CONCLUSION

The provision of the diagnosis "Risk for contamination of items" within the NANDA-I classification is adequate, since the experts validated the proposed items. No feature was considered irrelevant by the experts. And only two items were considered inadequate according to the binomial test, which should be reviewed prior to submission and clinical validation.

There is the need of adjustments proposed by the experts themselves, besides the applicability in clinical practice of the MSC nurse with clinical validation purposes, thus representing a limitation of the study.

The main relevance of this study is the importance of defining a nursing diagnosis and identifying its risk factors for indirect care in MSC, thus featuring the work of nurses in this unit.

As risk factors for the nursing diagnosis "Risk for contamination of items", it was identified: failure in the vacuum pump; presence of impurities in the product after cleaning; inadequate physical parameters at the end of the cycle; failure in the chemical indicator after sterilization; implantable material before the result of the biological indicator; use of autoclaves without microbiological control; sterilization of loads without the use of challenge testing packet (CTP);manual cleaning instruments with lumen; cycle sterilization for immediate use in implants; use of autoclaves without the periodic conduction preventive and / or corrective maintenance; packages not properly identified; storage of sterile packages in non-restricted area and transport of sterile packages in open trolley.

It is expected that this study contributes to the improvement of indirect care in MSC and that, with the development thereof, in the Systematization of Nursing Care. However, it is necessary to build a look at the indirect nursing care, paying attention to its importance in favor of direct care.

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