

Adverse events and incidents reported in a materials and sterilization center

Eventos adversos e incidentes notificados em um centro de materiais e esterilização

Eventos adversos e incidencias notificadas en un centro de materiales y esterilización

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ABSTRACT: Objective: To characterize the notifications of incidents and adverse events at the Material and Sterilization Center (MSC) of a teaching hospital. **Method:** Retrospective, documentary, descriptive, quantitative study in a class II MSC, in which the notifications contained in the database Quality Management and Patient Safety Management System between 2016 and 2020 were analyzed. As data collection strategy, a cause and effect diagram was used, and the descriptions of notifications were grouped according to the 6M diagram: method; material; man power; machine; measure; and mother nature. **Results:** Among the notifications made, the raw material and method variables were the ones that generated the most incidents throughout the period, representing 28.54 and 26.44%, respectively. In addition, the Surgical Center was the one that notified the most and was notified by the MSC. **Conclusion:** The incidents that most predominate in the MSC of the institution could be observed, and the material and method variables, with the surgical center, were the variables and sector that generated the most notifications in the research period.

Keywords: Notification. Nursing. Patient Safety. Sterilization

RESUMO: Objetivo: Caracterizar as notificações dos incidentes e eventos adversos do Centro de Material e Esterilização (CME) de um hospital de ensino. **Método:** Estudo retrospectivo, documental, descritivo e quantitativo em um CME classe II, em que foram analisadas as notificações contidas no banco de dados do Núcleo do Sistema de Gestão da Qualidade e Segurança do paciente, entre 2016 e 2020. Como técnica de análise dos dados coletados, utilizou-se o diagrama de causa e efeito, e a descrição das notificações foram agrupadas conforme o diagrama de 6M: método; material; mão de obra; máquina; medida; e meio ambiente. **Resultados:** Entre as notificações realizadas, as variáveis matéria-prima e método foram as que mais geraram incidentes durante todo o período, representando 28,54 e 26,44%, respectivamente. Além disso, o Centro Cirúrgico foi o que mais notificou e foi notificado pelo CME. **Conclusão:** Foi possível conhecer os incidentes que mais predominam no CME da instituição, e as variáveis materiais e método, com o centro cirúrgico, foram as variáveis e setor que mais geraram notificações no período pesquisado.

Palavras-chave: Notificação. Enfermagem. Segurança do Paciente. Esterilização.

RESUMEN: Objetivo: Caracterizar las notificaciones de incidentes y eventos adversos en el Centro de Material y Esterilización (CME) de un hospital escuela. **Método:** Estudio retrospectivo, documental, descriptivo y cuantitativo en un CME clase II, en el que se analizaron las notificaciones contenidas en la base de datos del Centro del Sistema de Gestión de Calidad y Seguridad del Paciente, entre los años 2016 y 2020. Como técnica de análisis de los datos recogidos, se utilizó el diagrama de causa y efecto, y la descripción de las notificaciones se agruparon según el diagrama 6M: método; material; mano de obra; máquina; medida y ambiente. **Resultados:** Dentro de las notificaciones realizadas, las variables materia prima y método fueron las que generaron más incidencias a lo largo del período, representando un 28,54 y un 26,44%, respectivamente. Además, el Centro Quirúrgico fue el que más notificó y fue notificado por el CME. **Conclusión:** Se pudo conocer las incidencias que más predominan en el CME del instuivo, y las variables material y método, junto con el centro quirúrgico, fueron las variables y sector que más notificaciones generaron, en el periodo de investigación.

Palabras clave: Notificación. Enfermería. Seguridad del Paciente. Esterilización.

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INTRODUCTION

The Material and Sterilization Center (MSC) is a service inside or outside the hospital institution, responsible for processing health products (HP), by chemical or physical methods. This service aims to promote contamination-free HP to be used in the most diverse hospital procedures¹.

The MSC is defined by the National Health Surveillance Agency (ANVISA) as a “functional unit destined to the processing of Health Products (HP) for health services”². The products processed at a MSC are very diverse. For this reason, cleaning, integrity, functionality, inspection and assembly loads for the sterilization of products require special care, to avoid possible consequences and jeopardizing the process¹.

The professional who works in this unit must have important characteristics/skills: responsibility, initiative, emotional balance, sense of teamwork, organizational capacity, ability to memorize specifications and standardizations, agility and manual dexterity, in addition to having knowledge, respecting the principles of aseptic techniques and, mandatorily, making use of personal protective equipment (PPE)¹.

Thus, working at the MSC requires adequate training to perform specialized techniques that minimize errors and failures, since the increased complexity of processed HP and the increasingly frequent use of implantable materials becomes a daily challenge in this environment¹.

Thus, it is extremely important to learn which are the main incidents involving the MSC and forwarded to the Patient Safety Center (PSC), as the notification and reporting of non-conformities become fundamental for knowing the cause(s), in order to implement interventions in an educational, preventive and non-punitive way³.

Notification is defined as a document that fulfills the task of informing someone about an important event or decision physically or digitally, which describes information related to nonconformities; the adverse event (AE) is the incident with damage, complication, medical error, with or without damage, which may be related to human, organizational or technical factors; technical complaint (TC) is the suspected alteration/irregularity of a product/company in technical or legal aspects, which may or may not cause harm to an individual's or a group's health³.

In Brazil, notifications of incidents and/or AE and TC have as fundamental objective the early detection of problems related to health care, triggering relevant measures so that the risk is interrupted or minimized³. They are an important

tool for risk management, and should be used both in health services and in management instances of the Unified Health System (SUS)³. It is essential that surveillance and monitoring of what is reported are carried out, as reported data can generate information that identifies patterns and trends in patient safety, prioritizing continuous learning and coping with identified problems and the adoption of managed measures, in order to prevent damage to patients from recurring, while improving the quality of care in these services⁴.

Thus, with the objective of getting to know the reality of the country and carrying out a situational diagnosis of incidents, the notifications and monitoring of incidents related to health care were regulated to be processed through the Information System for Health Surveillance (NOTIVISA), a computerized system developed by ANVISA to receive notifications of incidents, AE and TC related to the use of products and services under sanitary surveillance⁵.

In view of the above, it is noteworthy that failures are more present in health institutions and, in the context of the MSC, they can jeopardize patient safety and even of the safety of health professionals working in the sector.

OBJECTIVE

To draw the profile of notifications of incidents and adverse events in the MSC of a teaching hospital.

METHODS

This is a retrospective, documental, descriptive, quantitative study, developed in a class II MSC of a public teaching hospital in western Paraná, Brazil. Strategically attached to the Surgical Center (SC), the MSC is on 24 hours a day, seven days a week. The team is composed of a coordinating nurse, one nurse per work shift, nursing technicians and an administrative technician.

In the MSC of the present study, 700 health products are processed daily on average. The process begins with the arrival of dirty or expired materials from the inpatient and SC sectors. In the reception and cleaning area (dirty area), cleaning and disinfection begins, followed by drying in the clean area of the MSC. Then, there is the assembly of kits that each procedure requires and, subsequently, the sterilization. Cotton drapes or surgical grade paper are used for product packaging.

The sector has two thermal disinfectors and two ultrasonic washers that carry out high-level product cleaning and disinfection, and three autoclaves with saturated steam under pressure. Given the composition of some materials, they are sent to a third-party company that performs ethylene oxide (ETO) sterilization. All the processed materials are identified with date, expiry date, name of product and name of professional who packed it.

The sector has institutional protocols for processing HP, including cleaning, drying, evaluation of integrity and functionality, preparation, disinfection or sterilization, storage and distribution to consumer units.

This is a high complexity hospital, part of the West Macroregion, which is composed of five Health Regions (RS) of the State of Paraná, covering almost 2 million people. Currently, it has around 237 beds, 198 operational and 39 in intensive care, 100% of which are for patients in the Unified Health System (SUS). It covers several clinical and surgical specialties, including: craniomaxillofacial, oral and maxillofacial, head and neck, digestive, thoracic, vascular, general and specialized neurosurgery, orthopedics, maternal and child, among others⁶.

In 2015, the quality sector was implemented in the institution to develop the activities of the Patient Safety Center (PSC) and of the Quality Management System Center (QMC), along with the essential protocols required by ANVISA and the adverse event reporting form.

With instituted protocols, all notifications issued by the hospitalization or administrative sectors are forwarded to the QMC for evaluation and investigation, for later sending to the notified person; after return with justifications, it is destined to the notifier. With authorization by the QMC, which made available all the spreadsheets it feeds since its creation, the notifications issued by and sent to the CME were collected. Some notifications were excluded from the study for not complying with NOTIVISA requirements. These data were separated, grouped and entered into Microsoft Excel[®] version 10 spreadsheets for simple descriptive statistical analysis. In the spreadsheet, they were grouped respectively by year of incident, notified sector, notifying sector and reason for notification and variable related to the incident described by the notifier (Figure 1).

Then, according to the flowchart in Figure 1, the researchers grouped the data using the Ishikawa diagram, also known as cause-and-effect diagram, which is efficient for recording information that allows to identify possible

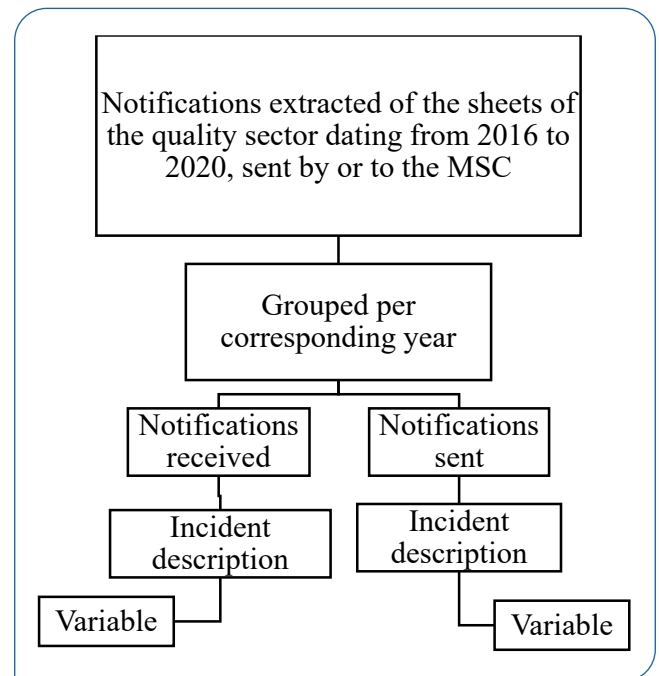


Figure 1. Flowchart of data collection

causes of a given problem or effect, as well as problem areas or processes in the organization⁷. In this tool, each spine of the fishbone points to a cause while the head refers to the problem the causes led to, and the diagram can be used in conjunction with other methods. In the industry, potential primary causes are known as manufacturing factors or 6M, however they can be adapted according to the needs of each institution⁸.

The effects were grouped into: method, or how the way of developing the work influences the problem; material, or how the quality and type of materials used influence the problem; man power, or how the people involved in the activity influence the problem; machine, or how the equipment used in the process influences the problem; measurement, or how the metrics used to measure the development of the activity influence the problem; and mother nature, or how the environment in which the activity is being developed influences the problem⁷.

This study is part of a larger research project that encompasses the Construction of Care and Management Indicators of the Nursing Service at Hospital Universitário do Oeste do Paraná (HUOP), approved by the Research Ethics Committee, as it involves human beings, in accordance with Opinion 3.323.244/2019 and Certificate of Presentation of Ethical Appreciation 58636916.5.0000.0107, in compliance with the guidelines of Resolution 466 of 2012⁹.

RESULTS

The sample analyzed in this study was composed of 571 incidents reported between 2016 to 2020, related to non-compliance in the MSC.

Table 1 shows the distribution of notifications issued during the studied period according to the six dimensions of the cause-and-effect diagram tool, and Figure 2 is the fishbone chart with the variables and some grouped causes, composing the cause-and-effect diagram to support the discussion around the collected data.

Among the notifications issued, the variable “material” was the one that prevailed throughout the period, representing

28.54% of all notifications; in 2017 there were 51 notifications of this type.

Next, the method represented 26.44% of the total number of notifications, with emphasis on the year 2019, in which 47 of them were carried out, where a failure was found in the way of performing the work or a procedure, as well as lack of process validation.

Table 2 lists data from the sectors responsible for notifications throughout the study period, with emphasis on the SC, which in both situations (notified and notifying) had the highest number of notifications, since this is the unit that most uses the products processed by MSC.

In total, 402 notifications were issued and 169 were sent to the MSC, representing 51.0% of notifications received

Table 1. Total notifications dating from 2016–2020, according to the variables of the cause-and-effect diagram management tool, Hospital Universitário do Oeste do Paraná — Cascavel (PR)

Variables	Timeframe					FA (%)
	2016	2017	2018	2019	2020	
Material	24	51	45	40	03	163 (28.54)
Method	35	35	28	47	06	151 (26.44)
Man power	06	20	28	32	01	87 (15.23)
Machine	06	10	28	29	02	75 (13.13)
Measurement	23	11	28	10	03	75 (13.13)
Mother nature	07	0	07	05	01	20 (3.50)
Total	101	127	164	163	16	571 (100)

AF: absolute factor.

Source: Core of the Quality Management System of Hospital Universitário do Oeste do Paraná, 2021.

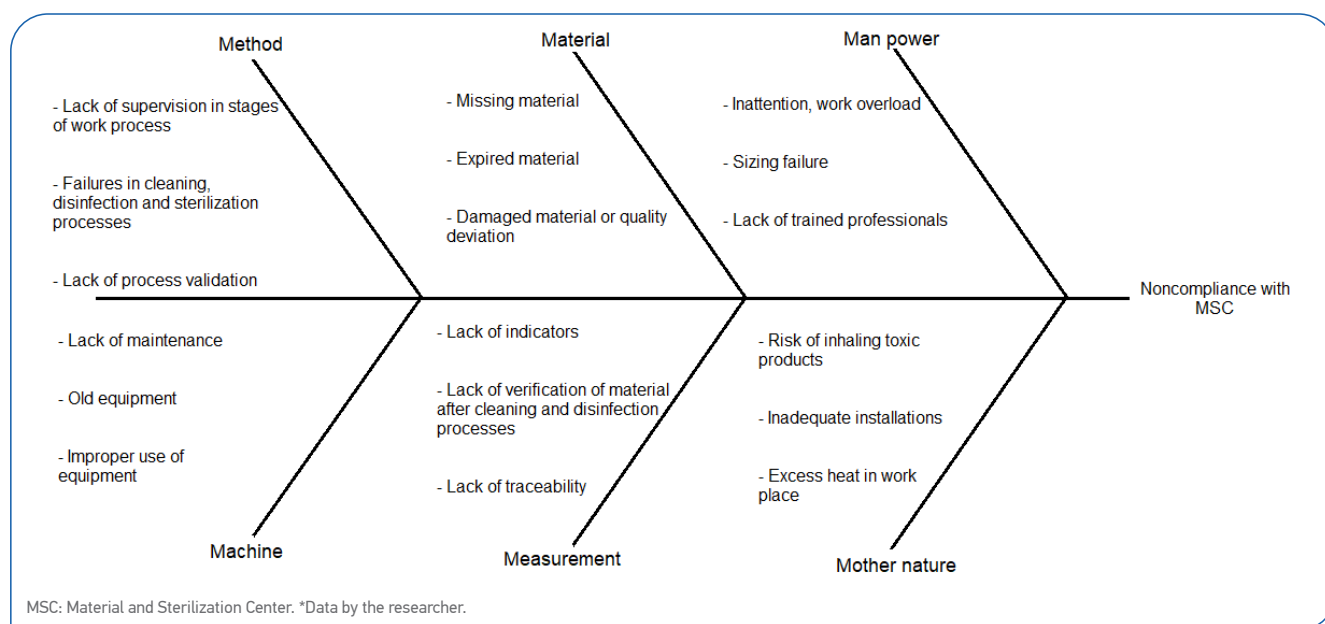


Figure 2. Fishbone diagram with variables and causes grouped to compose the cause-and-effect diagram.

Table 2. Distribution of notifications sent by and to the MSC, from 2016 to 2020, according to notifying sectors, Hospital Universitário do Oeste do Paraná — Cascavel (PR).

Variables	Notifications received (%)*	Notifications sent (%)*
Surgery Center	87 (51.0)	120 (30.0)
Obstetric center	22 (13.0)	25 (6.0)
Wards	18 (11.0)	66 (17.0)
Laundry	01 (1.0)	42 (10.0)
Technical surveillance	00 (0.0)	44 (11.0)
Intensive care unit	26 (15.0)	16 (4.0)
Others	15 (9.0)	89 (22.0)
Total	169 (100)	402 (100)

* Data by the researcher.

Source: Core of the Quality Management System of Hospital Universitário do Oeste do Paraná, 2021.

and 30.0% issued by the department. The wards and intensive care unit (ICU) correspond to 17.0 and 11.0% of notifications, respectively.

DISCUSSION

The number of reported incidents increased over the years until 2019, with a significant decline in 2020. This decrease coincided with the beginning of the COVID-19 pandemic in the country and, therefore, many institutions concentrated their efforts on the care for patients infected with the virus, and some protocols and issues related to patient safety were in the background. However, it is known that notification is a fundamental source of information for risk monitoring and management of adverse events occurring in health services, as well as prioritizing investigations of these events¹⁰.

The variable “material” represented the type of material used in the work, which could be the cause of the problem and/or that generated an occurrence or an EA. The notifications observed in this variable were lack of materials, their expiry date, their damage and their quality deviation. Notoriously, some public hospitals suffer from inventory control problems, including lack of adequate structural resources for storage and, mainly, disarticulation between supply sectors¹¹.

Faced with possible damages that HP may cause to users, it was necessary to monitor their production and use to learn their characteristics and plan preventive actions to reduce risks. In this context, as an integral part of health control strategies, technical surveillance has been structured and

improved as a subsystem capable of timely detecting AE, inefficiency and product quality deviations aiming to generate corrective measures, provide feedback to health surveillance institutions and subsidize scientific knowledge about the design, production and use of products³.

The variable “method” represented 26.44% of the total notifications issued. Considered a vital unit of a hospital, the MSC performs complex tasks of cleaning, disinfection, sterilization and distribution of HP to the care units, prioritizing the quality of each processing stage, with the aim of reducing unwanted events, with monitoring, supervision and validation of the primary cleaning steps by promoting the effectiveness of subsequent processes, such as disinfection and/or sterilization¹².

Man power represented 15.23% of notifications. The MSC has some specificities, such as the organization of work processes in smaller areas, great complexity of tasks, absence of patient and lack of professional recognition¹³. The work at the MSC is often associated with difficulties that are directly reflected on the workers and on the quality of the indirect assistance provided when not overcome. It is noteworthy that the MSC of the institution under study has a structure at odds with its size, which created new services, increasing demand, but maintained its structure. This generated discomfort for the team, which works in inadequate conditions, which causes inattention and work overload.

These difficulties may be associated with the work process itself, involved in the following situations: existence of risks (physical, chemical and biological); fragility in nursing human resources scale; lack of support, considering the institution's demand; poor communication between sectors; professionals acting without technical capacity to perform the

function; and overwhelmed professionals working on tasks that are incompatible with their abilities¹⁴.

The variables machine and measure generated few notifications. The variable machine represents the use of old equipment, lack of maintenance and also its inappropriate use, which reflects the Brazilian situation of many public health institutions lacking resources and investments¹⁵. The variable measurement shows the importance of surveillance in work processes and reprocesses. In addition, it constitutes an instrument of strength to change internal processes, generating continuous improvements in the development of work¹⁶.

The traceability system helps in surveillance, identifying the history of HP processes, adding quality and standardization and enabling a more assertive management, but many institutions do not have this system due to the high investment cost¹⁷.

“Mother nature” was the variable that least generated notifications. Occupational hazards are a set of causes that have the ability to cause consequences and impacts on the health of professionals who provide indirect patient care. Professionals are exposed to biological, physical, chemical, ergonomic and psychological risks on a daily basis. In this context, the importance of self-care mechanisms is evident through preventive behavior in the use of HP, in order to avoid infectious diseases and occupational injuries to which nursing professionals may be susceptible in the work environment and during their activities¹⁸.

In the cause-and-effect diagram, the nonconformities in the MSC were grouped. “Method” generated notifications related to lack of supervision and validation in stages of the process. The variable material generated nonconformities often due to lack of quality, as well as quality validity and deviation. In terms of man power, sizing, work backlog and lack of trained professionals were the factors that most generated notifications. As for machine, lack of maintenance, old equipment and inappropriate use were events related to notification. The variable measurement was notified as a result of lack of indicators, traceability and verification at the end of processes. And, finally, mother nature originated some notifications due to infrastructure and some occupational hazards.

The notifications issued by the MSC to the SC are related to incorrect disposal of sharps, which in some cases end up returning to the sector, with the risk of causing an accident with biological material, damage or loss of surgical instruments, generating expenses with their replacement. The notifications sent to the MSC by the SC stemmed from lack

of indicators in sterilized kits that prove sterilization and the presence of dirt in the materials after disinfection and sterilization. Distraction and interruption in the development of work may have contributed to reported failures, events that are present in the daily life of a SC and MSC, as they interfere with routine and are related to multiple factors¹⁹.

As for the limitations of this study, underreporting stands out, as a result of lack of information and commitment, as professionals often do not fill in the notification. In addition, there were few published articles related to the subject, and it is suggested that research be expanded to provide improvement and functionality in processes, creating strategies and contributing to the reduction and prevention of incidents in the MSC.

CONCLUSION

The MSC is of fundamental importance in the prevention and control of healthcare-associated infections (HAIs). Therefore, for all stages of the work to be carried out efficiently and safely, one must know the incidents that mostly occur in this service, as they indirectly influence the quality of care provided to the patient.

Based on the results of this study, we learned the incidents that most predominate in the institution’s MSC and, even with the decrease in notifications in 2020, the 6M diagram showed that the materials and methods generated the most notifications in the period. Furthermore, as this is a sector that directly supplies material to the SC, the materials and methods sector was the one that most notified and was notified by the MSC.

This study contributes to the production of knowledge regarding the topic addressed, as notifications, in addition to being an easy-to-fill instrument, have a low cost and are an effective indicator of AE and useful for the quality management in the hospital environment.

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None.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

CRML: Project Management, Investigation, Writing – original draft, Writing – review and editing, Software. KAM: Data

curation. DCIA: Formal analysis. DL: Resources, Validation. MMPL: Visualization. NST: Conceptualization, Methodology, Writing – original draft, Supervision.

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