Case Report
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The use of FMEA in process management within the sterilized material center (SMC)

Abstract

This is an experience report on the use of the Failure Mode Analysis Tool (FMEA) to identify the possible obstacles in the control and delivery of products by the Sterile Material Central of a private institution in Rio de Janeiro. Objectives: To present the experience of using the FMEA for the improvement of the production chain of sterile materials, to present the stages of implementation of the tool and to discuss the obtained results. It was concluded that it is possible to use the tool to control work processes, achieve better results with a view to patient safety, as well as stimulate financial control of the business unit within the hospital environment.

Keywords: risk management, FMEA, sterilization centre

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Introduction

The concern with quality in health care and the reduction of incidents with damage to patients, also known as Adverse Events, was first published after the release of the Institute of Medicine (IOM) report To Err is Human.[1] This report evidenced the impact on the health of patients and their families, caused by the incidence of adverse events, as well as the assessment of the financial loss caused by the increase in the length of stay in hospital and the expenses with associated legal issues.

In Brazil, the licensing of health establishments, the health inspection and the notifications of quality deviations have contributed significantly to the improvement of Patient Safety, mainly with the adhesion and the demand of health institutions for the external evaluation promoted by the Hospital Accreditation. The Accreditation is an external evaluation methodology that verifies the institutional resources: structure, processes and results and establishes levels of demand to guarantee the supply of Quality and Patient Safety certificates.

There are several process managements tools, initially created and used in industries, today adapted for use in hospitals, which aim to measure and control care processes with a view to safe care. In this sense, the use of the Failure Mode and Effects Analysis (FMEA) tool as an instrument to improve quality management in service provision has brought positive results in the process control of care products, whether direct or indirect to inpatients.

Thus, the present study brings the experience of the use of the FMEA tool in the improvement of the production chain of sterile materials by a Central of Sterile Material, in a private hospital in the city of Rio de Janeiro.

Objectives: To present the experience of using the FMEA for the improvement of the production chain of sterile materials, present the stages of implementation of the tool and discuss the results obtained.

The study is justified due to the scarcity of scientific production on the subject, evidenced through search in scientific databases. Virtual research was performed by searching studies in the Virtual Health Library (VHL) with the following descriptors: "Risk Management"; "FMEA"; "Sterilization Center"; using the Booleans "AND" and "OR". Two full-text studies were found, confirming the scarcity of practical publications that would contribute to the professionals and managers involved in this care process.

The work was carried out through joint collaboration between the nurse of the Patient Safety Center and the Surgical Center and Sterilized Material Center teams, with the support of the hospital's Medical Management. The work lasted 18 months, from the planning, monitoring of activities, use of the tool and spreadsheets, training of work teams, preparation and use of visual management panels and presentation of results. The improvement plan was also presented during the Joint Commission International (JCI) Recertification Visit in 2020, in the hospital unit studied.

Material and methods

This experience report was prepared by the leadership team, following the steps: survey of recurrent failures, root cause analysis and monitoring of each step of the process of preparation and sterilization of materials. Meetings were held with the work teams and notes were taken in a field diary of each stage, from the arrival of the material to be sterilized until the delivery to the destination sectors, analyzing failures, risks and creating Action Plans.

Subsequently, the FMEA was prepared, presented to the teams and then an ongoing education process was started within the working environment on the proposals made. Each work phase was monitored and measured. Subsequently, the results were presented to the hospital management for financial and strategic support.

Results

The CME is the sector, within a hospital, which has several activities, among them: cleaning, disinfecting and sterilizing materials, instruments or instruments used in health care. Until the 1950s, the CME was semi-centralized, that is, it belonged to the command of the Surgical Center, having low recognition and little control of the work flow.[2]

During my 22 years of experience as a nurse, I could observe that the CME nursing team was mostly composed of people away from their care activities due to various health problems, among them: musculoskeletal disorders, autoimmune diseases, chronic diseases and psychiatric diseases. With the improvement of techniques, processes and equipment, CME gained momentum and recognition. In 1991 the Brazilian Society of Surgical Center Nurses (SOBECC) was created, which within the context of CME, is responsible for proposing recommendations of good practices related to the areas of Surgical Center, Anesthesia Recovery (APR) and CME.[2]

Studies show that the effectiveness of the CME becomes even more evident with the incorporation of technologies, from process control, test validation, sterilization quality control and instrument traceability, being allied to the work of searching for cases of infection carried out by the Hospital Infection Control Committee (CCIH), thus providing better control with a focus on infection prevention and the safety of the patient undergoing surgical and invasive procedures.[2]

In the hospital environment, the CME has the following responsibilities: reception, cleaning, preparation, disinfection, sterilization, distribution and control of supplies and instruments used in surgical procedures, invasive procedures performed in the assistance units, ventilatory materials and quality control and "life" time of these instruments. Its work dynamics is intense and, due to this demand, it was observed that in this environment, of many repetitive activities, of exposure to physical, chemical and biological agents, the distribution of personnel with previously described diseases is not recommended.

The compromise in the quality of what is provided by the CME contributes to the occurrence of adverse events, accidents with workers and increased costs for hospital operational management. Thus, monitoring the activities performed within the CME brings assistance, strategic and financial impacts, in addition to contributing to Patient Safety.

One of the premises of Patient Safety, i.e., the fundamental basis is the Safety Culture, which implies changing behaviors and implementation of Patient Safety Centers in care settings, according to Ordinance MS/DM No. 529/2013.[3]

However, for the implementation of Safety Centres in hospital institutions it is necessary to understand the context of Safety Culture through the following managerial characteristics:[4]

- All workers, including professionals involved in care and managers, take responsibility for their own safety and the safety of their colleagues, patients and families;
- Prioritising safety above financial and operational targets;
- Encouragement and reward for the identification, reporting and resolution of safety-related problems;
- Promotion of learning from the occurrence of incidents;
- Survey of resources, structure and accountability for effective maintenance of security.
- The recognition and notification of incidents is the primordial basis for the implementation of the Safety Culture in the organizations, with a view to structuring the Patient Safety Center.

The institution in question (study scenario), belongs to a private corporate network of hospital units, which has the Patient Safety Culture as a fundamental pillar of its structure and uses external evaluations and Quality Certification through national and international accrediting companies, to measure standards and processes that promote Patient Safety and incident prevention.

The unit internally uses tools to notify non-conformities and sentinel events, which can be described by any employee. These notifications are directed to the Quality sector and the Patient Safety Center, are stratified and reported to the notified sectors for the preparation of improvement plans. Managers are trained to use quality management tools to evaluate internal processes in order to reduce damages and notifications, improve the quality of the service provided, promote education from the error and control the Business Unit under their management.

There are methods and formulas that can be used by the manager to identify and control failures in the work process. The FMEA is a method that seeks to identify and eliminate known or potential failures in products and processes, in addition to proposing improvements for each step/activity developed.[5,6]

In this way, it was elaborated a project that had as main focus the improvement in the processes related to the Processing of Materials in Central of Material and Sterilization, considering the adequate monitoring of the processed materials, as well as the quality and durability of the instruments that are used in invasive and surgical procedures. The reason to perform this evaluation is due to: events notified by the surgical team, related to the wear of the material, processing methods inappropriate to the types of materials and lack of screening of implantables, measurement item in the JCI standards of Hospital Accreditation. Initially, a visit to the internal environment of the CME was performed for the adequate mapping of the sector's weaknesses, and were identified:

- Ninety-two broken video materials were found;
- A bottle with Cidex Opa was stored in the purge, being improperly handled by the team, reducing the useful life of the equipment and causing oxidation of the instruments;
- Out of use ultrasonic washer;
- Thermodisinfector with malfunctioning;
- There are no containers for the transportation of endoscopic materials;
- Chemical Disinfection room exhaust fan not working;
- Unmarked instruments, not allowing their traceability;
- Fan circuits without valves, not allowing their use in care areas;
- Failure to properly store bronchoscopes;
- Sterrad machines being used for inappropriate processing of instruments;
- There is no inventory of equipment and instruments in the sector;
- There is no traceability of the processing quality of the items.

From this mapping, the weak activities, the potential failure modes, the cause and the effect of the failure were identified, unfolding into the FMEA constituting this document.

FMEA studies how each activity involved in the work process or in the delivery of a product may fail, allowing the manager to calculate the estimated occurrence, the probability of the incident or failure happening and the organizational impact generated. The method has calculations that allow measuring which failure has the

greatest impact, whether strategic, financial or healthcare, in addition to proposing action and control plans to reduce the occurrence of failures.

Figure 1 refers to the characterization of each activity performed in the sector, the failure modes, their occurrence and impact. The activities that had scores above 100 received the red colour and were prioritized for the development of the improvement plan.

Function & Process Requirements	Potential Failure Mode	Potential Effect of Failure	Sever	Cause / Potential Mechanism of Failure	Ocorr	Current Controls of the Prevention Process	Current Controls of the Detection Process	Detec.	NPR
Entry of Materials via Warehouse or other units	material does not arrive in time for processing for processing	Lack of processed material for procedure, delay in the supply of suspended or rescheduled material/surgery	10	Routine non-compliance by warehouse and supplier of the	10	Incomplete	Notification	1	100
Conference of planned materials with the delivery man	material not conferred at the time of receipt	of incomplete material, incorrect processing, suspended surgery, need for loan application	10	Routine non-compliance of the CME team	10	There is no	Notification	2	200
Separation/Segregation for washing according to the standard of the instrumental	Do not perform separation and segregation for washing, do not wash the material	Poorly sanitized and/or unwashed material, surgical site infection	10	Routine non-compliance, team ignorance about processes	10	There is no	There is no	3	300
Washing of Materials: Implantable in Thermosinfectant and instruments in ultrasonic washer and manual washing	Do not wash the material/wash the material improperly	material, surgical site infection	10	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	There is no	3	180
to preparation and dryer environment according to the instrumental	Not performing proper routing of the instruments	material with incomplete assembly / with rechanged parts /trimestumpers/ not working correctly	10	Routine non-compliance, process failures, lack of training, reduced number of professionals	10	There is no	There is no	8	800
of materials for assembly of kits	Non-conference of materials received	Incomplete and/or defective material	7	Routine non-compliance, process failures, lack of training, reduced number of professionals	3	There is no	There is no	8	168
Assembly of boxes according to protocol	Non-conference of instruments in the assembly of boxes	Box missing instruments /incorrect labels/ Defective instruments.	7	Routine non-compliance, process failures, lack of training, reduced number of professionals	3	There is no	There is no	8	168
Packing of boxes and identification of the correct instruments	Unided, poorly packed box/Changed id	Boxes exchanged, Misprocessed boxes, incorrect identification, delay in surgeries	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	There is no	3	144
Sterilization (implantable- steam autoclave/ Nonsensitive materials - sterrad); Chemical disinfection of gynecological, endoscopic and uro materials (natural pathways)	Materials being processed in inappropriate equipment for their composition	Loss of material and/ or parts, material wear, increased cost in the sector, need for loan application in other units, need for new acquisitions	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	Current needs adequacy	Insufficient	9	432
New Material Conference + Surgical Map for assembly of the same	No conference, erroneously assembled surgical boxes	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	through notification or request of the team in the surgical act	8	384
and preparation for distribution for related areas or storage	absence of correct segregation, mixing between items, trays and boxes with missing or excess items, exchanged items	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	Current needs adequacy	Insufficient	5	240
Distribution in c.c/ ambulatory/ hemodynamics/ Consumer Units	delay in the delivery of instruments, delivery of compromised materials, lack of materials in satellite sectors	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	4	Current needs adequacy	Insufficient	6	192
Control of sterile materials in care units	sterile materials in the sector with expired sterilization shelf life	lack of supply of sterile materials in the sector, lack of control and replacement of materials with expired sterilization shelf life	5	with the audit routine in the care sectors	6	Ineficientes	Need adequacy	4	120
Preventive maintenance of existing equipment in the sector	equipment has unexpected defects or internal failures at the time of increased productivity in the industry	Delay in material processing, delay in distribution of materials, delay or cancellation of surgeries, need for sides in the processing mode of materials	9	Lack of evidence of preventive maintenance performed, failure in planning with Clinical Engineering	4	Inefficient	Need adequacy	3	108

Figure 1 FMEA of CME processes

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After raising the recommendations and working on the Action Plans, we followed for another 8 months the stages of completion of activities and checking what had been successfully completed. We present Figure 2 that illustrates this moment.

Function & Process Requirements	Potential Failure Mode	Potential Effect of Failure	Severi	Cause / Potential Mechanism of Failure	Occurr	Current Controls of the Prevention Process	Current Controls of the Detection Process	Detec.	NPR	Recommended Actions	Responsible and Term	Result of Actions Taken	Severi	Occurr	Detec.	NPR
Entry of Materials via Warehouse or other units	material does not arrive in time for processing for processing	Lack of processed material for procedure, delay in the supply of suspended or rescheduled material/surgery	10	Routine non-compliance by warehouse and supplier of the	10	Incomplete	Notification	1	100	Printed passage on duty structured according to surgical map and complications, Material receipt control book	nov/19	Made Book of control of receipt of materials, label with patient name, name of surgery and surgeon for subsequent verification with Surgical Map	3	3	2	18
Conference of planned materials with the delivery man	material not conferred at the time of receipt	of incomplete material, incorrect processing, suspended surgery, need for loan application	10	Routine non-compliance of the CME team	10	There is no	Notification	2	200	Team training, creation of the delivery flow and conference of materials.	nov/19	Materials are checked with delivery	3	3	2	18
Separation/Segregation for washing according to the standard of the instrumental	Do not perform separation and segregation for washing, do not wash the material	Poorly sanitized and/or unwashed material, surgical site infection	10	Routine non-compliance, team ignorance about processes	10	There is no	There is no	3	300	Team training	nov/19	Preparation of POP and training of teams	5	5	5	125
Washing of Materials: Implantable in Thermosinfectant and instruments in ultrasonic washer and manual washing	Do not wash the material/wash the material improperly	material, surgical site infection	10	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	There is no	3	180	Implementation of swab collection before and after cleaning of instruments by sampling per day. Endoscopes are total. Start on 09/10	nov/19	Acquisition of swabs for evaluation of pre- and post-wash instruments, institution of periodicity of internal cleaning of ultrasonic washers	3	9	1	27
to preparation and dryer environment according to the instrumental	Not performing proper routing of the instruments	material with incomplete assembly / with exchanged parts / rime stumpers/ not working correctly	10	Routine non-compliance, process failures, lack of training, reduced number of professionals	10	There is no	There is no	8	800	Team training	nov/19	Performed separation of environments and dryers according to the type and purpose of the instrumental, Training of the teams.	4	4	1	16
of materials for assembly of kits	Non-conference of materials received	Incomplete and/or defective material	7	Routine non-compliance, process failures, lack of training, reduced number of professionals	3	There is no	There is no	8	168	Load assembly training	nov/19	Training was carried out for the assembly of loads and proper control of autoclaves	5	2	1	10
Assembly of boxes according to protocol	Non-conference of instruments in the assembly of boxes	Box missing instruments/incorrect labels/ Defective instruments.	7	Routine non-compliance, process failures, lack of training, reduced number of professionals	3	There is no	There is no	8	168	Team training	fev/20	Acquisition of new instruments was performed to assemble the boxes according to instrumental requests in the surgical map	5	6	3	90
Packing of boxes and identification of the correct instruments	Unided, poorly packed box/Changed id	Boxes exchanged, Misprocessed boxes, incorrect identification, delay in surgeries	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	There is no	3	144	Training	fev/20	and proper identification are carried out	2	2	1	4
Sterilization (implantable - steam autoclave/ Nonsensitive materials - sterrad); Chemical disinfection of gynecological, endoscopic and uro materials (natural pathways)	Materials being processed in inappropriate equipment for their composition	Loss of material and/ or parts, material wear, increased cost in the sector, need for loan application in other units, need for new acquisitions	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	Current needs adequacy	Insufficient	9	432	Change in the protocol of sterilization and disinfection of the instruments correctly. Creation of protocol for materials submitted to chemical disinfection, endoscopic and Change in the protocol of sterilization and disinfection of the instruments correctly. Creation of protocol for materials submitted to chemical disinfection, endoscopic and emergency materials. Traceability Panel of endoscopic and	fev/20	Made new protocol of sterilization and disinfection of instruments, endoscopes and colonoscopes. Adequacy of the indication of chemical disinfection and contingency plan for situations of absence of Operation of Autoclaves. Training conducted	7	7	4	196
New Material Conference + Surgical Map for assembly of the same	No conference, erroneously assembled surgical boxes	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	There is no	through notification or request of the team in the surgical act	8	384	Creating the Material Conference Check list	fev/20	and routine checking of tables according to Surgical Map	6	5	2	60
and preparation for distribution for related areas or storage	absence of correct segregation, mixing between items, trays and boxes with missing or excess items, exchanged items	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	6	Current needs adequacy	Insufficient	5	240	Team training. Record of temperature and humidity control of the material storage room	fev/20	Standardized storage room temperature and humidity control check list, control of materials for distribution and training of teams	5	5	2	50
Distribution in c.c/ ambulatory/ hemodynamics/ Consumer Units	delay in the delivery of instruments, delivery of compromised materials, lack of materials in satellite sectors	delay in the procedure, risk of failures in the surgical process, suspension of the procedure, stress of the patient and surgeon	8	Routine non-compliance, process failures, lack of training, reduced number of professionals	4	Current needs adequacy	Insufficient	6	192	Creation of the Distribution Control Book.	fev/20	of the Distribution Control Book in the care units	5	5	5	125
Control of sterile materials in care units	sterile materials in the sector with expired sterilization shelf life	lack of supply of sterile materials in the sector, lack of control and replacement of materials with expired sterilization shelf life	5	with the audit routine in the care sectors	6	Ineficientes	Need adequacy	4	120	Adopt planning of regular visits to sectors to evaluate the shelf life of sterile materials	fev/20	audits by CME diarists (monthly)	9	5	1	45
Preventive maintenance of existing equipment in the sector	equipment has unexpected defects or internal failures at the time of increased productivity in the industry	Delay in material processing, delay in distribution of materials, delay or cancellation of surgeries, need for aides in the processing mode of materials	9	Lack of evidence of preventive maintenance performed, failure in planning with Clinical Engineering	4	Inefficient	Need adequacy	3	108	Contractualization with Clinical Engineering and Maintenance, have map with preventive maintenance plan available for consultations	fev/20	with Clinical Engineering, promoted internal training and greater control with the quality of maintenance and qualification of equipment within the sector	8	4	3	96

Figure 2 Process FMEA after improvement implementation

Discussion

It was observed an intense restructuring of the service, acquisition of instruments and equipment, thus making the quality control process more dynamic, involving the internal teams of the sector, client teams, *stakeholders* and the patient. Improvement actions are highlighted:

- Acquisition of new instruments;
- Equipment repair and calibration;
- Adequate control of the water supply with Monthly Reports;
- Adequate control of the chemical disinfection room exhaust fan;
- Monitoring of the sector's production and the activities that increase consumption and cost through the creation of the CME Indicator Booklet;
- Increased participation of the teams in internal training sessions, including the proper use of equipment;
- Greater involvement of teams in the risk management process;
- Greater control of the loss of instruments, with description and analysis in the Indicators Notebook;
- Better control of the quality of instrument cleaning with the use of the indicators acquired.

Main challenges:

Despite the group's efforts to promote internal improvements in the flow and processing of sterile materials, some activities still need to be monitored and will be contemplated in the sector's prospective Improvement Plan:

- Training of teams regarding separation, segregation of materials for chemical and physical processing. We observed notifications related to failures in this item;
- Training the teams on the type of material and the type of processing as recommended by the manufacturer, to ensure better use and less chance of early wear;
- Acquisition of materials and supplies that have been lost through: wear and tear due to continuous use, breakage due to incorrect handling and processing.

Conclusion

We conclude that the FMEA is a useful method to be used in process management, product management and risk management, but the team that coordinates the business unit lacks capacity building and training on how to use it. FMEA does not end with the achievement of an improvement in the failure score, because improvement must be continuous. It is a starting point for new projects and new challenges to be launched, for this reason it is called "Improvement Cycle" and the team needs to understand that the process does not stop. It is important to search for new knowledge, training and learning exercises for everyone.

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Conflict of interest

The authors declared that there are no conflicts of interest.

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