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Tools to organize the work process in patient safety

Ferramentas para a organização do processo de trabalho na segurança do paciente

Herramientas para organizar el proceso de trabajo en seguridad del paciente

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ABSTRACT

Objective: to discuss the use of Failure Mode and Effects Analysis tools and their application in health care. **Method:** this is a reflection article, aiming at presenting the proper application format for both tools, followed by their differences in execution in the work processes. **Results:** both models have the same purpose, being directed to the detection of failures even before their manifestation, directly assisting in the promotion of safety. The analysis of the error with the participation of the teams and the generation of failure rates has repercussions on the planning and implementation of practical actions aimed at patient safety. **Conclusion and implications for the practice:** although similar, there are distinctions regarding the prioritization of failures to list practical corrective actions, mainly in the calculation of the Risk Priority Index related to severity, probability of occurrence and failure detection. Both tools are shown to be important allies to health managers for the detection of serious failures that put care free from adverse events at risk.

Keywords: Patient Safety; Health Management; Process Assessment, Health Care; Healthcare Failure Mode and Effect Analysis; Quality of Health Care.

RESUMO

Objetivo: discutir acerca da utilização das ferramentas de Análise de Modo e Efeitos de Falha e sua aplicação na assistência à saúde. **Método:** trata-se de um artigo de reflexão visando à apresentação do formato próprio de aplicação de ambas as ferramentas seguida das suas diferenças de execução nos processos de trabalho. **Resultados:** ambos os modelos possuem a mesma finalidade, sendo direcionados para a detecção de falhas antes mesmo da sua manifestação, auxiliando diretamente na promoção da segurança. A análise do erro, com a participação das equipes e a geração de índices de falhas, repercute no planejamento e na implementação de ações práticas voltadas à segurança do paciente. **Conclusão e implicações para a prática:** embora semelhantes, existem, entre eles, distinções quanto à priorização das falhas para elencar ações práticas corretivas, principalmente no cálculo do Índice de Prioridade de Risco relacionado à gravidade, na probabilidade de ocorrência e na detecção das falhas. Ambas as ferramentas se mostram como importantes aliadas dos gestores de saúde para a detecção de falhas graves que colocam em risco a assistência livre de eventos adversos.

Palavras-chave: Segurança do paciente; Gestão em Saúde; Avaliação de Processos em Cuidados de Saúde; Análise do Modo e do Efeito de Falhas na Assistência à Saúde; Qualidade da Assistência à Saúde.

RESUMEN

Objetivo: discutir el uso de las herramientas de Análisis de Modos y Efectos de Falla y su aplicación en la atención médica. **Método:** este es un artículo de reflexión, con el objetivo de presentar el formato propio de aplicación adecuado para ambas herramientas, seguido de sus diferencias de ejecución en los procesos de trabajo. **Resultados:** ambos modelos tienen el mismo propósito, dirigidos a la detección de fallas incluso antes de su manifestación, ayudando directamente en la promoción de la seguridad. El análisis del error con la participación de los equipos y la generación de tasas de fracaso tiene repercusiones en la planificación e implementación de acciones prácticas dirigidas a la seguridad del paciente. **Conclusión e implicaciones para la práctica:** aunque son similares, existen distinciones con respecto a la priorización de fallas para enumerar acciones correctivas prácticas, principalmente en el cálculo del Índice de Prioridad de Riesgo relacionado con la gravedad, la probabilidad de ocurrencia y la detección de fallas. Se ha demostrado que ambas herramientas son aliadas importantes para los gerentes de salud para la detección de fallas graves que ponen en riesgo la atención libre de eventos adversos.

Palabras clave: Seguridad del Paciente; Gestión en Salud; Evaluación de Procesos, Atención de Salud; Análisis de Modo y Efecto de Fallas en la Atención de la Salud; Calidad de la Atención de Salud.

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INTRODUCTION

Healthcare organizations need to develop a safety culture so that their workforce and processes are focused on improving care.[1] The National Patient Safety Foundation (NPSF) highlights practices that improve patient safety by reducing the occurrence of preventable adverse events.[2,3] Thus, improving the safety culture is an essential component of preventing or reducing errors and generally improving the quality of health care.[4]

Patient safety is imperative and can have implications for each and every individual. From characteristics operationalized by the security management, all professionals must take responsibility for the damage-free care, encouraging the identification, notification and resolution of problems, culture that, from the occurrence of incidents, promotes organizational learning and provides resources, structure and accountability for its effective maintenance.[2,5] Based on the international goals of patient safety advocated by the Joint Commission International (JCI), health care institutions should seek strategies to work on their implementation and identify the occurrence of adverse events, as well as reduce or eliminate failures in care processes.[6-9]

The process of working in health is characterized by its complexity, and the essential activities of the nurse are of a caring, managerial, educational, research and participation character.[10] In the practice of Nursing, the professional is qualified to develop the Systematization of Nursing Care (SNC), which aims to improve the care provided to the patient.[11] Implemented by nurses, SNC provides safe and quality care, seeking an improvement in communication and bringing benefits to the patient and the health team.[11]

Some tools created and used in the industry, such as Failure Mode and Effects Analysis (FMEA), were directed to health in order to map, evaluate and propose the control of adverse events before they occur.[12] Healthcare Failure Mode and Effects Analysis (HFMEA) is also a systematic and proactive method for evaluating processes, identifying, in addition to failures, their impact on care, and can list priorities for an action plan. In this way, the reduction of errors can bring benefits of quality care with the least possible damage to the patient.[7,13,14]

There is evidence in the literature that exposes the applicability of the tools in daily health care.[15-18] Results are observed regarding the functionality of its use through the mapping of error-generating events, leading to the delimitation of strategies that avoid their manifestation.[15-18] In view of the need to apply methodologies for the analysis of the mode and effect of failures in health care, preventing errors and promoting safe and quality care, the importance of the knowledge of failure analysis models for their application by health professionals and managers as a health management strategy is highlighted. The purpose of this article is to discuss the use of Failure Mode and Effects Analysis tools and their application to health care.

METHOD

This is a reflection article that proposes a discussion about the evaluation of processes in health care with the application of the FMEA and HFMEA tools, aiming at patient safety, presenting both models as to their characteristics and differences of implementation.

RESULTS

Failure Mode and Effects Analysis

A FMEA is a tool that enables decision making to prevent the manifestation of avoidable errors and observed during the analysis of the steps of a work.[1] It is defined as a qualitative methodology that allows the analysis, in the workflow, of the flaws, their causes and effects, leading to the reflection of actions that allow the early correction of these errors.[19]

The FMEA is divided into seven stages: 1) selecting a work process to be evaluated; 2) recruiting a multidisciplinary team for the application; 3) establishing a workflow on the part of the team; 4) raising the inherent flaws in the processes, causes and effects; 5) for each failure, calculating the Risc Priority Number (RPN); 6) evaluating the flaws with higher RPN and defining the practical actions and 7) recalculating the RPN after the implementation of improvement actions.[20,21]

To select a work process, one must prioritize that which stands out for its greater observance of failures. The sub-processes should be evaluated in order to filter more precisely all the failures[20] after selecting a multidisciplinary team, knowledgeable of the process, to identify the causes that may lead to risk or damage, prioritizing corrective measures.[20,22,23]

The team should have a leader, who will present the tool and guide the other members, and an expert in the tool for clarifications.[16,20] Everyone will be able to change the steps of the work diagram as needed. Then, for each step of the process, the main failures must be listed and, for each one, their causes and effects identified. For each failure, a scale from zero to ten is used to check the severity value (S), the occurrence (O) and the probability of detection (D), multiplying the values to obtain the RPN: the higher the value assigned to the severity and occurrence, and the lower the probability of detection, the higher the RPN and the magnitude of the failure.[19]

According to the purpose and characteristic of the process, the reference values of the scale and their meanings may change, however, it is recommended to use the original scales.[24] The cut-off points for the RPN are determined by the members so that efforts are focused on the most important failures.[16] In the next step, the team should pay attention to the failure with greater RPN and, consequently, determine short-term corrective actions.[21] All steps of the FMEA should be documented, preferably by the leader, for the recording of all failures and processes highlighted.[20] The FMEA enables those responsible for corrective practices and their deadlines to be recorded.[21,25] It is recommended that, after incorporating the practices in the work process, the members

meet to recalculate the RPN and check whether the failure has been minimized or eliminated.[19]

Its effectiveness has been criticized for having low precision.[26] However, it is widely used in many settings, especially in health, being recognized as a method to improve quality, even in potentially erroneous situations.[26,27]

Healthcare Failure Mode and Effects Analysis

The HFMEA was developed as an adaptation of the FMEA, aiming the analysis of the critical points of health services.[24] HFMEA also promotes corrective actions before the adverse event occurs, being a hybrid prospective analysis model, because in addition to identifying the proactive risk, it also performs a root cause analysis. Its application focuses on five steps: 1) defining the scope and the process to be analyzed; 2) organizing and gathering a multidisciplinary team; 3) describing the process steps in a diagram; 4) determining the Hazard Score Matrix for each failure mode and 5) elaborating the practical actions.[23,28]

The participants, knowledgeable of the process under analysis, should enter into consensus on the activity listed for the evaluation, in addition to including the participation of an HFMEA expert. Sub-processes may be assigned according to the pre-determined workflow.[23] Likewise, for each failure mode, the team observes the inherent causes in the flow processes: for a single failure, there may be several causes.[23,28] Then, the severity and frequency of failure modes are determined and the Hazard Score is checked.[14] The Hazard Score severity rating and its values include "catastrophic" (4), "critical" (3), "moderate" (2) and "negligible" (1).[14,23] The probability categories include "frequent" (often in one year), "occasional" (often in two years), "rare" (sometimes between two and five years), and "remote" (five to 30 years), also adopting values of four to one, respectively.[14,23] Severity and probability values should be multiplied and the Hazard Sore Matrix score category observed.[14,23,28]

The Decision Tree is the one in which, among the failure modes raised, those with greater criticality, low control effectiveness and little detection are verified, that is, scores equal to or greater than eight.[14,23] As a criticality, we understand the impact of failure at a certain point in the process, checking whether it is a point of weakness that, when occurring in isolation, generates the error and destabilizes the workflow.[14,23]

It is a model of screening where all failures should pass, focusing the team's attention on the most serious, determining actions in the short term. The following questions are asked: "is the risk intolerable? Is it a weak point? Are there control procedures inserted in the process? Is the failure easily detected to the point of not needing to be controlled?".[23,28] If the failure is not considered a critical weak point in the process or, if considered, there are already control actions inserted or, if it can be easily detected, it is oriented to interrupt the analysis of the Decision Tree.[14,23] However, noting that there is a critical point, we proceed to the next step.[14,28] Thus, practical corrective actions should be designated and those responsible for implementing them.[14,28]

DISCUSSION

FMEA and HFMEA have the common purpose of preventing failures through detection. In both, the flow is almost equal in relation to the structure and conduct of failure mode analysis. In both, it is oriented both the establishment of how the functionality of the work environment occurs and the construction of a flow/diagram that determines the subsequent steps.[20] Likewise, a multidisciplinary team should be formed and the inherent causes should be established individually by failure mode.[14,20,21] Although the process is the same, the numerical categories used differ.[24]

In the FMEA, after surveying the causes, the effects of the failure on the work processes are verified and then the RPN is calculated, multiplying the values of severity, occurrence and probability of detection of each failure determined by scale from zero to ten. Afterwards, the designation of the actions to correct or avoid the manifestation of the failure mode is made.[16] For HFMEA, after establishing the causes, for each failure mode, the severity and occurrence are categorized into a score of one to four, multiplying the values to subsequently apply the Hazard Score Matrix.[14,23,28] Only failures with a value equal to or greater than eight are classified as "intolerable" and will be submitted to screening in the Decision Tree: only when representing a critical point will they pass to the next step, from orientation to corrective action.[23] Instead, through the FMEA, all failure modes are evaluated and given practical action, listing priorities.

This feature can be a limit point of the FMEA: if the team is not well oriented to the correct use and end of the tool, it can focus on several failure modes, allowing the deviation of attention from the less worrying failures. On the other hand, failures classified as low or non-priority may generate interventions and improvements, even if small, that can be implemented later.

The HFMEA, on the contrary, due to the differentiated screening structure, at all times, leads the team to direct the efforts to the most serious failure mode in order to then rethink the practices in order to prevent the occurrence of the adverse event. Still on the calculation of the RPN in the FMEA, mistakes can occur due to the inversely proportional meaning of the classification categories for the probability of detection and occurrence; different scores can originate the same RPN with the risk of not expressing the magnitude of the failure.[19,22] In this way, one of the members should be familiar with the tool of choice in order to lead the others to the correct use and clarification.[20,25]

More recent studies have demonstrated the effectiveness of the tools to evaluate work processes and raise the errors that can directly harm patient safety.[16-18] There is also evidence of the use of the FMEA in the Surgical Center (SC) through the verification of critical points of the Nursing care possible error generators.[17,18] In SC, failure modes with high risk indexes were verified in the scheduling stages of surgeries, distribution of drugs by the satellite pharmacy, preparation of materials at the Center for Materials and Sterilization (CMS) and care activities in SC.[18] After the application of the corrective actions, it was evidenced the fall in the recalculation of the Risk index for the four stages.[18]

Another international study applied HFMEA to assess quality in blood transfusion processes in a pediatric emergency.[28] A total of 77 failure modes were identified, 13 of which were identified as unacceptable risk (Hazard Score higher than eight). For each failure mode, corrective actions are suggested, such as training with the teams on the blood transfusion procedure, alerts for the correct identification of patients and monthly audits for the re-evaluation of the processes.[28] In both tools, there is the possibility to evaluate the results and observe their influence on health work. The HFMEA and FMEA instruments demand time and full commitment from the team.[16] Thus, all participants must understand the importance of analyzing each stage and be committed to the success of the applicability of these instruments.[16,24]

Through application between teams, each member analyzes and observes the failure modes that put the care activity at risk. Thus, its methodology enables collective reflection on the effectiveness of care in relation to patient safety and the suggestion of corrective actions by members.[15] The collective construction inserts the professionals as direct agents of changes in the work environment, enabling the construction of a culture of safety.

CONCLUSIONS AND IMPLICATIONS FOR PRACTICE

It was possible to present the FMEA and HFMEA tools as to their use in health processes for application in practice, because they are methods that help, in the area of health, the correction of failures before they occur and can promote safe care and a proactive assessment of risks related to care.

Despite the common purpose, there are differences in the monitoring of use and it is up to the teams to determine which models to apply according to the characteristics and demands of the work process to be analyzed. Among them, there are distinctions regarding the prioritization of failures to list practical corrective actions, mainly in the calculation of the Risk Priority Index related to gravity and the probability of occurrence and detection of failures. To do so, services must take ownership of the methods of application of both tools and participants need to have knowledge about health processes to ensure effectiveness and achievement of objectives.

Health care institutions have been more intensely concerned in recent years with the organization of failure-free care. To this end, applying tools that evaluate the work processes, in order to achieve safe care, should become a practice in the institutions, set up by managers and nurses, allowing the improvement of the work processes. When thinking about patient safety in the health area, the FMEA and the HFMEA point out, in the system, errors or the potential occurrence of failures, which may manifest themselves in serious adverse events to the patient. In this way, they prove to be important allies for health services, allowing the reflection and practice of risk management and the elimination of adverse events responsible for reducing the safe care to the patient.

Proactively, besides delimiting the failures, they enable the teams to rethink the processes as well as the new prevention practices and whether they are being effective or not. Through the prevention of adverse events, it is possible to avoid the increase in hospital costs and the risks for health professionals.

Therefore, the implications of this study for the practice of Nursing are destined to the application of these tools in the analysis of the work processes, in the care and research scope, as well as considering the nurse with educative role in front of the health team, promoting the identification of failures, proposing actions of improvements related to the patient's safety and approaching the practice of the theory in the search of the quality and safety in care.

It is identified, as limitations of the study, that there is still little research that applies these tools in health institutions. It is understood that future studies are needed to address this issue, since they are models of failure analysis with potential size to prevent and correct serious events present in health care.

AUTHOR'S CONTRIBUTIONS

Conception of the reflection design. Marielli Trevisan Jost. Aline Branco. Bárbara Rodrigues Araujo. Karin Viegas. Rita Catalina Aquino Caregnato.

Survey of the theoretical framework for the conduction of reflection. Marielli Trevisan Jost. Aline Branco. Bárbara Rodrigues Araujo. Karin Viegas. Rita Catalina Aquino Caregnato.

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