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The Role Of The Health Failure Mode And Effect Analysis (HFMEA) Method On The Quality Of Health Services In An Efforts To Improve Patient Safety

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ABSTRACT
safety is important because it is a system where hospitals make patient care safer. Patient safety is the foundation of good health care. Health workers' knowledge of patient safety includes proper patient identification, better communication, increased drug safety that needs to be considered, certainty of location, procedure, and proper operation for patients, reduction of infection risk, and risk of falls. But from a patient safety perspective, patient safety at various levels of health care is still poor worldwide and nationally. One of the most common adverse events in hospitals is patient falls. Worldwide, around 700,000 to 1 million patients fall in hospitals each year, causing around 250,000 injuries and up to 11,000 deaths. During hospitalization, around 2% of patients fall at least once. One of the international patient safety goals (IPSG) is to reduce the risk of patient falls. According to data from PERSI (Indonesian Hospital Association), the incidence of patient falls in Indonesia from January to September 2022 reached 14% of a total of 34 cases. This shows that the presentation of patient falls is included in the top 5 hospital medical incidents and is ranked second after medical errors. This shows a high rate of patient falls in Indonesia. The Hospital Patient Safety Committee (KKPRS) reported that the highest risk of patient falls in Indonesia occurred in the provinces of DKI Jakarta (37.9%), West Java (33.33%), Banten and Central Java (20%), Yogyakarta (13.8%), and East Java (3.33%). The purpose of this study was to determine the role of Health Failure Mode and Effect Analysis (HFMEA) on the quality of health services in an effort to improve patient safety, especially in hospitals

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INTRODUCTION

Patient safety is a system where hospitals make patient care safer (1). The issue of patient safety is currently a very important global issue and remains a challenge for development in primary care in many countries. Preventing injuries caused by errors due to carrying out an action or not taking the action that should be taken (2). The Health Failure Mode and Effect Analysis (HFMEA) method in hospitals functions to prevent errors or malpractice in the health service process and proactive risk assessment of the care process (3). According to the report

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of the Indonesian Ministry of Health, the incidence of patient safety incidents in 2018 in the number of IKP (Patient Safety Incident) reports was 1489 incidents, while in 2019 there was a very drastic increase with the number of incidents as many as 7465 cases (4). These incidents include KNC (Near Missing Incidents) of 38%, KTC (Non-Injury Incidents) of 31%, and KTD (Unwanted Incidents) of 31%.

Data obtained from one of the Hospitals that the reporting of Patient Safety Incidents (IKP) received in the 2019-2020 period reached up to 44 cases of incidents. Most KTD can be prevented, the success of prevention and the system approach lies in the system's ability to identify potential risks, recognize incidents as early as possible and establish a barrier mechanism, Health Failure Mode and Effect Analysis (HFMEA) a method for identifying high-risk processes, causes of errors and strategies to prevent these errors (5). HFMEA is one of the methods recommended by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to be used to identify high-risk processes that cause errors and ways to solve problems systematically (6). Factors causing potential risks are lack of nurse competence, absence of permanent operating doctors, lack of supervision, monitoring and evaluation, and many transitions that encourage neglect of communication procedures at each transition between sections or between shifts (7). Hospitals are health service institutions that play a role in improving health through quality services according to standards set by all health workers (8). Quality of service is a service provided by a profession in accordance with standards that are implemented comprehensively according to patient needs (9). Quality of service such as indicators of service results such as the incidence of phlebitis, the incidence of decubitus, the incidence of patient falls, the rate of medication errors , the level of patient satisfaction and the rate of blood drawing errors (10).

METHOD

The design of this research is a qualitative research where this research will discuss how the role of HFMEA on the quality of hospital services in an effort to improve patient safety. The research design used to explain, describe, depict existing phenomena and generate new ideas on a research subject to be studied. The population in this study involved professional staff at the PKU Muhammadiyah Kartasura Hospital consisting of medical personnel and non-medical personnel in providing care to patients. This research is adjusted to the criteria based on: 1. The highest patient safety risk in the work unit based on risk management in the unit. 2. The highest patient safety risk in the hospital based on risk management data in the hospital. The sample of this study was the hospital patient safety team. The research instrument used a special questionnaire to determine problem identification, Focus Group Discussion (FGD), and the sheets used were guided by HFMEA. This research procedure was carried out for 5-6 weeks starting with the following steps:

1. Defining HFMEA topics
2. Forming a multidisciplinary team
3. Describes the process flow
4. Making a hazard analysis

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RESULTS AND DISCUSSION

Respondent Characteristics

The respondents of this study consisted of 15 respondents who were employees of PKU Muhammadiyah Kartasura Hospital consisting of elements of the head of the installation, head of the inpatient room, head of the outpatient polyclinic room, head of the IGD room, head of the IBS room, head of the medical support room, medical committee, nursing committee, management or structural. The characteristics of the respondents were mostly women, namely 10 people (66%) and there were 5 people (36%) men, most respondents were in the age group between 35-55 years (73%), the majority of respondents' work period was more than 5 years, namely 90%, most respondents were Bachelor's graduates (S1) namely 10 people (73%), there were 3 people who were educated as Specialist Doctors (14.9%) and as many as 2 people (6.4%) who were educated as General Practitioners.

Conditions for implementing Patient Safety activities

Hospital services are comprehensive services, not only covering treatment activities, but also prevention efforts. Therefore, hospitals must be able to provide quality services according to standards. Patient safety is a major issue in the field of health services. Providing health services can pose risks to patients. For this reason, policy makers, health service providers and consumers place safety as the first priority of service. Patient safety is something that is much more important than just service efficiency.

Based on the research results, information was obtained that the conditions for implementing patient safety activities based on patient safety targets before the intervention at PKU Muhammadiyah Kartasura Hospital on target I, the accuracy of patient identification at PKU Muhammadiyah Kartasura Hospital in general was very good and increased after the intervention.

Meanwhile, in target II, information was obtained that the implementation of patient safety activities based on the target of increasing effective communication at PKU Muhammadiyah Kartasura Hospital was mostly very good. However, there were 27.7% of respondents who stated that it was very bad and 6.4% who stated that it was not good for patient safety activities based on the target of increasing effective communication at PKU Muhammadiyah Kartasura Hospital.

The standard is for hospitals to develop approaches to improve the effectiveness of communication between providers. Effective, timely, accurate, complete, clear and understood communication by patients will reduce errors and result in increased patient safety. In this case, the hospital must develop a policy that regulates communication between the order giver and the order recipient. In this case, it is important to note that the order given must be complete verbally and the order given by telephone or the test result must be written down in full by the order recipient. Complete verbal and telephone orders or test results must be read back in full by the order recipient. And no less important, there must be policies and procedures that guide the implementation of verification of the accuracy of oral or telephone communication consistently.

Patient safety activities based on target III obtained information that in general the implementation of patient safety activities based on the target of increasing the safety of

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high-alert drugs before the intervention at PKU Muhammadiyah Kartasura Hospital was very poor. This must receive attention from the management at PKU Muhammadiyah Kartasura Hospital considering that the standard that must be carried out by the hospital is to develop an approach to improve the safety of high-alert drugs . However, after the intervention, the conditions related to increasing the safety of high -alert drugs were declared very good.

Every activity in planning patient treatment must be oriented towards patient safety. High-alert medications are drugs that often cause serious errors (sentinel events), drugs that have a high risk of causing unwanted effects (adverse outcomes). Drugs that must be watched are drugs that look similar and sound similar (Drug Name Similar Appearance and Pronunciation (NORUM) or Look Alike Sound Alike (LASA)). Work units related to drug handling at PKU Muhammadiyah Kartasura Hospital must truly understand the safety of high-alert drugs .

The results of the study on standard IV, namely the implementation of patient safety activities based on target IV, namely the certainty of the right location, right procedure, right patient surgery, obtained information that the implementation of patient safety activities based on the certainty of the right location, right procedure, right patient surgery at PKU Muhammadiyah Kartasura Hospital was very good. However, there were 23.5% who stated that it was very bad and 29.4% who stated that it was not good. In principle, PKU Muhammadiyah Kartasura Hospital has developed an approach to ensure the right location, right procedure and right patient. In the implementation of surgical procedures, there has also been effective communication between members of the surgical team and involving patients in site marking . In addition, there is also a procedure for verifying the location of the operation.

Infection prevention and control is the biggest challenge in health care and the increasing cost of dealing with infections is a major concern for patients and health care providers. The results of the study based on target V obtained information that the implementation of patient safety activities based on the target of reducing the risk of infection related to health services at PKU Muhammadiyah Kartasura Hospital in general is very good. Activities that lead to reducing the risk of infection have been carried out by most work units at PKU Muhammadiyah Kartasura Hospital. One way to eliminate infection is by washing hands (hand hygiene). For this reason, the hospital has developed a generally accepted hand hygiene guideline procedure adopted from WHO.

The results of the study on the implementation of patient safety activities based on target VI obtained information that the implementation of patient safety activities based on the target of reducing the risk of patients falling at PKU Muhammadiyah Kartasura Hospital in general was very good. Although there were 19.1% of respondents who stated that it was very bad and 10.6% who stated that it was not good for patient safety activities based on the target of reducing the risk of patients falling at PKU Muhammadiyah Kartasura Hospital. The number of cases of falls is quite significant as a cause of injury for inpatients. For this reason, hospitals must evaluate the risk of patients falling and take action to reduce the risk of injury if they fall.

Therefore, if there is an incident of a patient falling, it can be used as a lesson. What the hospital must do is have a policy that directs the continuous reduction of the risk of patient

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injury due to falls in the hospital, then the hospital implements an initial assessment process for patients for the risk of falling and re- assesses the patient if there is an indication of a change in condition or treatment, and so on. In general, the results of the study on the implementation of patient safety activities based on patient safety targets at PKU Muhammadiyah Kartasura Hospital obtained information that most respondents stated that it was very good. However, there were 19.1% who stated that it was not good and 10.6% who stated that it was very bad regarding the implementation of patient safety activities based on patient safety targets at PKU Muhammadiyah Kartasura Hospital.

After intervention in the form of training and socialization on patient safety through the FMEA approach, information was obtained that the implementation of patient safety activities based on targets I to VI at PKU Muhammadiyah Kartasura Hospital was generally good. Although there were 2.1% of respondents who stated that it was not good. Based on this assessment, there was a significant increase. What needs attention is that current hospital services require quality improvement. The quality of service is an indicator of the performance of service services related to its ability to provide customer satisfaction. Quality in hospital services is useful for reducing defects or errors (Wijono, 1999). The quality of medical services is an inseparable part of patient safety. Mathematically, the quality of medical services is inversely proportional to the incidence of medical errors . Therefore, improving the quality of medical services will be able to reduce the incidence of medical errors in hospitals.

Formation of Patient Safety Team

The process of learning patient safety is not easy and simple, because it must start from the incident reporting process, followed by analysis of the report until the root of the problem is found and used as a basis for redesigning a system so that safer patient care is achieved in the hospital. From the process which is a cycle, it can be seen that the reporting system is the initial driver for the next process. The reporting system becomes the pulse or something very important from patient safety activities , so a valid and standard incident reporting system is needed so that it is easy to analyze as a basis for decision making. Therefore, it is necessary to form a patient safety team .

patient safety team was formed as an effort to learn and at the same time implement health services that focus on patient safety. The patient safety team consists of functional elements of PKU Muhammadiyah Kartasura Hospital, head of installation, head of room, head of outpatient polyclinic, and management (structural) at PKU Muhammadiyah Kartasura Hospital . The team that was formed participated in all patient safety training , plus 3 secretaries who had not participated in this patient safety training .

patient safety team of PKU Muhammadiyah Kartasura Hospital was formed to implement the patient safety program in the field by involving all sections and/or work units in the hospital, so that all parties are expected to know, understand and be able to practice the implementation of handling patient safety incidents using the FMEA method. As an initial stage, a work unit needs to be selected to implement the FMEA method. Based on the results of the agreement with KKPRS, the Inpatient Installation, Central Surgery plus Emergency and Outpatient were selected as pilot projects for the implementation of the FMEA method at PKU Muhammadiyah Kartasura Hospital. The basis for selecting the IGD and IRJA is because these

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work units are directly related to patients and the number of patients is quite large when compared to other work units. In addition, the IGD and IRJA are the front door of service for the entry of all patients in the hospital.

An important thing that needs to be considered by both the patient safety team and all officers at PKU Muhammadiyah Kartasura Hospital is to report when a patient safety incident occurs. As an effort to meet the demands of the community for quality services and attention to patient safety , as well as in order to provide effective, safe and friendly health services in accordance with the quality policy that has been initiated by PKU Muhammadiyah Kartasura Hospital, patient safety training activities are carried out using the FMEA approach to patient safety targets for the entire patient safety team and heads of work units at PKU Muhammadiyah Kartasura Hospital. The aim is to conduct patient safety training in the hospital to implement the FMEA method to patient safety targets.

Various preparations have been made by the training committee formed specifically for the implementation of patient safety training and FMEA socialization. The preparations include preparation of the place, decoration, supporting equipment, seminar kits, backdrops for training purposes. Participants in this patient safety training are the patient safety team that has been formed and the head of the work unit consisting of the head of the field, head of the section, head of the installation, and head of the room, specialist doctors, general practitioners, nurses and non-medical personnel. The number of training participants is 55 people.

To see the success of the training process or to see the effectiveness of training participants in understanding patient safety training, a pre-test and post-test were conducted . Based on the results of the pre-test and post-test, information was obtained that the average value for the pre-test and post-test increased by 26.21%. The minimum value which was previously 50 became 130. Likewise, the maximum value increased by 70 (the previous value was 70 then during the post-test the maximum value became 140). This shows that the patient safety training was successfully understood by the participants.

Implementation of FMEA Implementation

In health services, there is often a sense of dissatisfaction or loss experienced by patients due to medical actions. Errors can be accepted as accidents, namely an unplanned, unexpected and unwanted event with the emergence of a negative result. A negative result after an error must be considered an accident. Because no one will plan an error , no one wants an error to occur , no one expects an error . One effort to minimize the occurrence of incidents due to medical errors is to implement a patient safety culture and apply various methods that in principle prevent patient safety incidents and make patient care safer.

Currently, most errors in processes or systems that result in adverse events are handled privately by health workers. Many health care systems are not designed to prevent errors . Careful, in-depth and timely analysis of a medical error is an essential element of any patient safety plan, regardless of whether the actual activity has caused harm to the patient. One method for finding solutions to problems related to patient safety is FMEA.

In evaluating system planning from a reliability perspective , Failure Mode and Effect Analysis , hereinafter referred to as FMEA, is a vital method. FMEA is one of the tools of Six

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Sigma to identify the source or cause of a quality problem. The initial goal of FMEA is to prevent accidents that can endanger people's lives. This goal is still valid today, only the target of FMEA use is now very broad. But the point is to prevent failure and its impact before it occurs.

Stamatis (2013) in his book Failure Mode and Effect Analysis: FMEA from Theory to Execution states that in general there are four types of FMEA, namely System FMEA, Design FMEA, Process FMEA, and Machinery FMEA. In this study using the process type . Process FMEA is used to analyze the production or service process. In addition, it is also to ensure that potential failure modes , causes and effects have been considered in relation to the characteristics of the process. Process . This FMEA focuses on failure modes caused by process or service deficiencies.

In an effort to implement the patient safety program as a new procedure, a trial was conducted on the Inpatient Installation, Central Surgery, Emergency and Outpatient work units, namely by conducting an assessment based on the stages in FMEA so that recommendations for the implementation of FMEA were obtained. There are ten steps in implementing FMEA. The following is a discussion of four work units in implementing FMEA.

In the first step, namely reviewing the patient safety target process from 4 (four) teams (IRNA, IBS, IGD, IRJA) that implemented FMEA. From the results of the implementation, information was obtained that all teams had reviewed the patient safety target process well. Reviewing the patient safety target process needs to be done to get a common understanding of the process. Ideally, the team uses a map or flowchart, all team members must conduct a field review (process walk-through) to improve understanding of the process being analyzed. If the process map or flowchart does not exist, the team must compile the process map or flowchart before starting the FMEA process itself. All four teams have used flowcharts and conducted field reviews of the processes to be analyzed. After conducting the process review, the second step is continued, namely brainstorming .

Brainstorming is an activity to explore various forms of possible errors or process failures. The activities carried out by four teams during the implementation of the 2nd step of FMEA obtained information that the entire team had brainstormed various forms of possible errors or process failures. This brainstorming process can take place more than once to obtain a comprehensive list of all possible errors that can occur. The results of this brainstorming are then grouped into several causes of errors. The process chosen by team I (Inpatient Installation) is drug management at IRNA. Team II (Central Surgical Installation) chooses services for surgical patients at IBS. Team III (Emergency Installation) chooses patient services in the ER. Team IV (Outpatient Installation) chooses new general patient services at IRJA. The entire team identifies up to the sub-process of the selected activity.

After brainstorming , the next step is to compile the impact (potential impact of failure) of each error. In this 3rd step for each error, the impact that occurs can be only one, but it may also be more than one. If more than one then all must be displayed. This process must be carried out carefully and thoroughly, because what is missed from this process will not get attention to be handled. This step also determines the potential cause of failure of each error or failure found.

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The results of the study on the activities carried out by four teams during the implementation of the 3rd FMEA step, namely making a list of the impacts of each error, obtained information that all teams had made a list of the impacts of each error. All teams had made a list of the impacts of the failure mode on the selected process or subprocess. The results of the compilation of potential failure impacts from each failure mode from the stages of the activity process selected by the entire Team. The results of the failure mode are used as a basis for steps 4 to 7, namely assessing the level of impact (severity) of the error, assessing the level of possibility of occurrence (occurrence) of the error, assessing the level of possibility of detection (detection) of each error or its impact and calculating with the Risk Priority Number (RPN).

The principle in assessing the level of impact is the estimation of the magnitude of the negative impact caused if an error occurs. If it has ever happened, the assessment will be easier, but if it has never happened, the assessment is based on estimates. Likewise with assessing the level of possibility of occurrence of errors. While the total RPN value is calculated for each error that may occur. If the process consists of a certain group, the total number of RPNs in the group can indicate how serious the process group is if an error occurs.

The results of the study in step 4 assess the level of impact (severity) of the error, step 5 assesses the level of possibility of occurrence (occurrence) of the error, step 6 assesses the level of possibility of detection (detection) of each error or its impact and step 7 calculates the Risk Priority Number (RPN) of each error and its impact, information is obtained that the entire team has carried out the activity. This is a continuation of the steps before determining the recommendations given to the problems faced.

At the end of step 7, each team determines the priority of the RPN value that has been calculated from the highest to the lowest value. Several causes of the same failure even though with different RPN values by researchers are grouped into one because they produce the same recommendations. Activities carried out during the implementation of step 8 FMEA are developing an action plan for patient safety targets, researchers integrate the results of the RPN calculations of all teams based on the RPN priorities of each team. The priority chosen is the RPN value in the first to fifth order. While the order of more than five is ignored. The priority based on the RPN value determines the recommendations given to be followed up on the cause of failure from each error or failure found.

CONCLUSION

Based on the research results, it can be concluded that (1) the condition of the implementation of patient safety activities based on patient safety targets at PKU Muhammadiyah Kartasura Hospital is good. However, there are still some that are not good, especially in the target of increasing effective communication, the target of increasing drug safety that needs to be watched out for (high-alert) and the target of ensuring the right location, right procedure, right patient surgery, (2) the process of intervention activities through the FMEA approach begins with the formation of a patient safety team. Then, patient safety training activities are carried out using the FMEA approach to patient safety targets for the entire patient safety team and the head of the PKU Muhammadiyah Kartasura Hospital work unit. Based on the

average pre-test and post-test value indicators , there is an increase in value so that the training is successful, (3) The results of the intervention through the FMEA approach to patient safety targets at PKU Muhammadiyah Kartasura Hospital were carried out in four installations, namely the Inpatient Installation, Central Surgery, Emergency and Outpatient. The four installations have implemented the FMEA method by applying steps 1 to 4. However, the four work unit teams have not carried out Step 5. Because this step takes a long time

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