

# Patient Safety Management Re-Design by Using Hospital Failure Mode Effect Analysis

(A Case Study of Assyifa Islamic Hospital Ward in Sukabumi)

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**Abstract**—The aim of this research is to analyse patient safety management with Hospital Failure Model Effect Analysis (HFMEA) in Assyifa Islamic Hospital ward. The method utilized in this research is a descriptive qualitative method. As much as 100 non-surgical inpatients units was taken as sample in this research. Meanwhile the sampling technique utilized in this research is an accidental sampling. The gathered data was further analysed by using HFMEA. Data collection techniques are observation and focus group discussion. The result of this research reveals that patient safety management in non-surgical ward is categorized as sufficient. Meanwhile HFMEA model application is still not referring to failure model analysis, hazard analysis, and effective control determination. This research concludes that it is necessary to improve HFMEA model application in Assyifa Islamic Hospital in Sukabumi City. The advantage of this research is that this research emphasis model HFMEA utilization, which is still rarely found in hospital management.

**Keywords:** *patient safety management, hospital failure mode and effect analysis, patient ward*

## I. INTRODUCTION

Patients' safety has become one of the most important global issues, due to the escalation of medical error claims from numerous patients. According to Indonesian Ministry of Health, hospital patients safety is a system, which is built by hospitals to create a safer medical attention for patients that includes risk assessment, risk identification and management, incident report and analysis, incident study and follow-up ability, and solution implementation to minimize risks and to prevent injuries caused by wrong practicing medical treatment or by neglecting the required medical treatment. Patients' safety culture is marked by the involvement of healthcare provider's perspective about patients' safety, loyalty, communication transparency, and trust [1].

Based on Indonesian Medical Law Number 1691/Menkes/Per/viii/2011 regarding hospital patients' safety, issued in August 8, 2011, the main goal of patients' safety in hospitals is to construct hospital culture of patients' safety, improve hospital accountability towards patients and society,

and minimize unexpected events. Patients' safety incidents are translated as every preventable event, whether incidental or intentional, which causes or create potential to injure the patients. These incidents are grouped into unexpected event, injuring events, non-injuring events, and potentially injuring events [2].

According to American Institute of Medicine (IOM), service quality is a challenge and also priority for healthcare managers to provide a safe, effective, punctual, just, and patients-prioritized service. Since IOM's report was issued, there are several initiative and global reformation produced to prevent patients' hazard, but unfortunately, the number of incidents that result injuries and deaths are still high [3].

Patients' safety incidents can be analysed by utilizing risk assessment. Indonesian Ministry of Health, states that risk assessment can be a useful mean to help organization measures risks caused by existing incidents. To analyse these risks, hospital can also utilize Failure Mode Effect Analysis (FMEA). FMEA itself is a group brainstorming tool and work improvement method to identify and prevent failure potential before it even happened [4].

FMEA is a time-consuming process and requires a multidisciplinary team which has good understanding of the process being analysed. FMEA only helps in identifying the possibilities of a process to fail, it does not eliminate them, additional efforts are required to develop action plans and implement them. Frank discussion and agreement among the team members is required not only for successfully conducting FMEA but also for implementing the corrective actions [5].

Failure modes and effects analysis (FMEA) is one of many techniques for risk assessment that has used in this study in order to identify, assessment and offering appropriate measures for control, decrease and eliminate probable hazards related to use, maintenance and repair ventilators in Al-Zahra Hospital of Isfahan [6]. Overall, 17 cases of the potential risk associated with ventilator in respiratory unit was detected that the highest risk priority number was related to the potential risk of failure to timely replace battery with a score of 225 and the lowest number by the score of 10 was related to the potential failure

modes of pulling the power cord from the machine. Since a large part of the cost of hospitals is spent on purchase and maintenance of medical equipment's, including equipment's such as ventilator, FMEA technique with its preventive approach can reduce these costs and assist hospitals in providing high quality services and achieving customer satisfaction [6].

Failure modes and effects analysis (FMEA) is a preventive method to improve and increase system safety. Using this technique, four selected process errors were identified, evaluated, prioritized and analysed, in medical records section in Qadir hospital in Shiraz [7]. Using FEMA methodology, they found that 41 failure modes in 4 selected processes. Totally, 13 failure modes with risk priority number  $\geq 100$  were identified as "non-acceptable risk" and their root causes were classified according to Eindhoven Classification model. By emphasizing on preventive approach and team work, FMEA technique can enhance staff precision and attract their attention to their possible professional weaknesses in recording medical errors and prevent their failure [6]. There are two types of FMEAs: process FMEAs and design FMEAs. Process FMEAs assume the product works perfectly and assess potential process failures and their effects. Conversely, design FMEAs assume the process works perfectly and assess the product and its potential failures and effects [7].

Numerous countries in the world regularly report numbers of safety incidents in hospital every year. National Patient Safety Agency reports that in between January and December 2016, patients' safety incident in England alone is as much as 1,879,822 incidents. Based on KKPRS's report in first three months of 2011, there are 457 patients' safety incidents reported in Indonesia [8]. Based on reports presented in National Patients' Safety Incident Map congress in 2007, medication error is the number one recorded mistake (24.8%) among 10 highest patients' safety incidents, which includes 46.7% almost injuring events that is significantly higher than unexpected events with only 46.2% [8].

These data shows that patients' safety incident in Indonesia is significantly high. Based on the latest data, in between 2006 and 2011, HPSC reports that there are 877 patients' safety incidents event happened in Indonesia. These incidents are respectively found in Jakarta (37/9%), Central Java (15.9%), Yogyakarta (13.8%), East Java (11.7%), South Sumatera (6.9%), West Java (2.8%), Bali (1.4%), Aceh (10.7%), and South Sulawesi (0.7%). These reports have driven world health system to shift healthcare paradigm towards patients' safety. This movement have also played a significant role to change Indonesian healthcare service, which is shown by the formation of Hospital Patients' Safety Committee (HPSC) in 2004.

Hospitals need to improve their quality of services to create people's trust. One way to do that, is to apply patients' safety program, which is initiated by World Health Organization (WHO) in 2004. In Indonesia, Hospital Patients' Safety Movement was initiated by Indonesian Ministry of Health in August 21, 2005. Every hospital is obligated to form hospital patients' safety team. Assyifa Islamic Hospital in Sukabumi City in West Java Province, is one of those hospitals that have formed hospital patients' safety team. Furthermore, Assyifa

Islamic Hospital have already formed Patients' Safety and Quality Improvement Committee (PSQIC) in 2015, which is responsible to initiates various programs and activities to ensure the hospitals' patients' safety.

Despite the improvement, apparently patients' safety incidents are still occurred in Assyifa Islamic Hospital. Based on Patients' Safety and Quality Improvement Committee (PSQIC) data, since the committee is formed until November 2017, there are 11 cases reported, and 65% of them are medication error. These incidents are further grouped into unexpected event (57%), non-injuring events (14%), and nearly injuring events (29%), which 60% of them happened in wards. Based on the description above, a research on Patients' Safety Management Re-Design by using Hospital Failure Mode Effect (HFMEA) Analysis in Assyifa Islamic Hospital is vital.

The contribution of this research at the hospital is to reduce and eliminate the patient safety incidence after an analysis using HFMEA by means of the process of monitoring and evaluation also needs to increase management awareness about the importance of the follow-up efforts of the HFMEA results because HFMEA can be called as a preliminary tool so that potential injury events do not occur. This research wants to explore by Knowing the big picture of the management of patient safety in Assyifa Islamic Hospital in Sukabumi and Knowing the big picture of the Hospital Failure mode effect analysis in Assyifa Islamic Hospital

## II. RESEARCH METHOD

This research was conducted by using a qualitative method. This research begins on February 2019, meanwhile sampling was occurred in March 2019. Assyifa Islamic Hospital's Inpatient Unit was taken as the place of research. The populations of this research, which also acts as samples, are 100 inpatients of Assyifa Islamic Hospital. Sample selection criteria is divided into inclusion and exclusion criteria. Sampling technique in this research is using accidental sampling. In this research, the data required was collected by doing interview, observation, documental research, and focus group discussion. Data collected was further analysed by using Failure Mode and Effect Analysis (FMEA) method, by taking the following steps, which is formed by Joint Commission Resource;

- Determining high risk process and creating team.
- Arranging process diagram.
- Applying Brainstorming potential failures modes and identifying the results.
- Creating failure mode priority by viewing priority determination steps based on Risk Priority Number (RPN).
- Identifying the root of failure mode's problem.
- Re-designing the process.
- Analysing and testing new process.
- Implementing and monitoring the re-designed process.

### III. RESEARCH FRAMEWORK

There are 6 main goal of patients' safety according to Law of Indonesian Ministry of Health Number 1691, year 2011; effective communication improvement; medicine safety improvement; location accuracy certainty; procedure and patient in operation; infection risk minimalization; and minimizing risk of falling patients. These components are further analysed by using FMEA. The conceptual frame in this research are input, process, and output. The input of this research is Assyifa Islamic Hospital Inpatient Unit, the process focuses on patient's identification accuracy, and output will be Assyifa Islamic Hospital Patients' Safety Incidents.

### IV. PATIENT SAFETY MANAGEMENT RE-DESIGN BY USING HOSPITAL FAILURE MODE EFFECT ANALYSIS (HFMEA)

Based on preliminary study conducted in March 2019 by interviewing 20 Sukabumi City Assyifa Islamic Hospital's ward, patients' safety goal No 1 is the identification conducted by the nurses. 80% of the patients aware of the function of their medical wristband, and 70% of these patients say that the nurses usually check their wristband before giving medical attention, it's mean 30% nurses often neglect patients' identification process.

This finding shows that patients' identification procedure in Assyifa Islamic Hospital is well-run and well-socialized, even though it is not yet entirely applied. Patients' safety management in Assyifa Islamic Hospital is already conducted but the application is not yet optimum, especially in sectors relating with regulation making, which require quite some time to realize and applicable as a guideline for hospital service unit applied.

Hospital Failure Mode Effect Analysis in Assyifa Islamic Hospital is already conducted, but still require improvement due to the existence of patients' safety incidents. FMEA analysis can act as a tool to detect potential problems, and identify causes of incidents to prevent possibilities that similar incidents could still occur in the future.

FMEA is a team-based, systematic and proactive approach for identifying the ways that a process or design can fail, why it might fail, and how it can be made safer. The purpose of performing an FMEA for JCAHO was to identify where and when possible, system failures could occur and to prevent those problems before they happen. If a particular failure could not be prevented, then the goal would be to prevent the issue from affecting health care organizations in the accreditation process [9].

The FMEA process was extremely useful for understanding and analysing the complex process of screening high-risk admissions for multidrug-resistant pathogens at a university-affiliated medical centre. The FMEA used to identify potential failures in the process of admission screening of high-risk patients thus delaying early identification and timely isolation of patients colonized or infected with MRSA. The process facilitated communication among the various departments that resulted in the identification of creative and sustainable solutions [10].

As mentioned in Law Number 44, year 2009, hospitals are obligated to provide safe, quality, non-discriminating, and effective services that emphasizes patients' interests according to hospital standard service. It shows that safety issues practice is still not optimally conducted. Because of that, this condition has become one of many contributing factors that would create hospital patients' safety incidents in Assyifa Islamic Hospital ward. This factor can be utilized by the management of the hospital as a reason to conduct re-design on patients' safety assessment goals, so that the hospital can provide an optimum and safer services towards the patients.

### V. CONCLUSION

Based Patients' safety management in Assyifa Islamic Hospital is not yet optimally applied, because a number of nurses (30%) often neglect patients' identification process.

Hospital Failure Mode Effect Analysis in Assyifa Islamic Hospital is already conducted, but still require improvement due to the existence of patients' safety incidents. FMEA analysis can act as a tool to detect potential problems, and identify causes of incidents to prevent possibilities that similar incidents could still occur in the future.

Patients' safety management re-design utilizing FMEA in Assyifa Islamic Hospital is already conducted but the application is not yet optimum, especially in sectors relating with regulation making, which require quite some time to realize and applicable as a guideline for hospital service units applied.

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