

Effectiveness of Failure Modes Effect Analysis (FMEA) to Reduce Medical Error

*Putri Ingen Setiasih, **Purnawan Junadi

* Faculty of Public Health Universitas Indonesia

** Department Health Administration and Policy, Faculty of Public Health Universitas Indonesia

Email : putri.ingen@ui.ac.id

Abstract. One of the prevention efforts of medical errors that occur in health services is by identifying the potential failure of the service before the failure occurs. FMEA is one way to identify the risks of failure. Therefore, the authors wanted to find out whether FMEA was effective for reducing medical error based on previous studies. This article was a literature review using references in an online database such as EBSCOhost. The author found 280 articles while searching by using the keyword "FMEA". After filtered by publication period from 2012 to 2017, full text and language, finally got 7 articles. Finally, the author used the three most relevant literature. FMEA was proven to decrease the potential failure rate after follow-up to failure was done in service process, so medical error can be prevented. In the application of FMEA, bias can occur during the determination of potential failure and determination of scoring on RPN. Therefore, it is expected that the team involved in making FMEA experts in the process of service to be designed. FMEA could prevent medical errors by determining potential failures before failure occurs.

Keywords: FMEA, healthcare, medical error

Abstrak. Salah satu upaya pencegahan medical error yang terjadi di pelayanan kesehatan adalah dengan cara mengidentifikasi potensial kegagalan dari pelayanan sebelum kegagalan itu terjadi. FMEA adalah salah satu cara mengidentifikasi risiko-risiko kegagalan tersebut. Oleh karena itu, penulis ingin mencari tahu apakah FMEA efektif untuk mengurangi medical error berdasarkan penelitian sebelumnya. Artikel ini adalah tinjauan pustaka menggunakan referensi yang ada di online database seperti EBSCOhost. Penulis menemukan 280 artikel saat menelusuri dengan menggunakan kata kunci "FMEA". Setelah dibatasi rentang waktu publikasi dari tahun 2012 sampai dengan 2017, full text dan bahasa, akhirnya didapat 7 artikel. Akhirnya penulis menggunakan tiga literature yang paling relevan. FMEA terbukti menurunkan angka potensi kegagalan setelah tindak lanjut terhadap kegagalan dilakukan pada proses pelayanan sehingga medical error dapat dicegah. Pada penerapan FMEA, bisa terjadi bias saat penentuan potensial kegagalan dan penentuan scoring pada RPN. Oleh karena itu, diharapkan tim yang terlibat pada pembuatan FMEA ahli dalam proses pelayanan yang akan dirancang. FMEA dapat mencegah medical error dengan cara menentukan potensial kegagalan dan melakukan tindak lanjut terhadap potensial kegagalan sebelum kegagalan terjadi.

Kata kunci: FMEA, healthcare, medical error

INTRODUCTION

Background

Hospital is an organization with very high complexity, labor intensive, utilized modern technologies, and relatively regulated, and prone to error. Human error due to exhaustion and high working hours can lead to medical errors resulting in death, or patients coming home in worse condition.

In the early 1960s many studies had shown that patients were often harmed by medical treatments intended to help them. Medical error evidence has been established by the Institute of Medicine (IOM) in 1999. IOM estimated that medical errors caused between 44,000 and 98,000 deaths annually in the United States. Medical

error ranks eighth as the cause of death and kills more Americans than motor vehicle accidents, breast cancer, or AIDS. In addition to this tremendous human toll, medical errors also result in an annual cost of \$ 17 to \$ 29 billion in the United States. Further more, based on research results at John Hopkins University, medical error ranks third cause of death in the United States, as much as 250,000 cases per year 2013.

Since July 1, 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires every accredited hospital to conduct at least one proactive risk assessment action each year. Failure Modes and Effects Analysis (FMEA) is one of the tools recommended by JCAHO to be used. The FMEA process can eliminate potential medical errors or malpractices that can occur by preventing the occurrence of failure

effects. The benefits far outweigh the settlement after medical errors occur which cost a lot of money on litigation, compensation and other settlement fees.

In their book *The Basic of FMEA*, McDermott, Mikulak and Beauregard tell the story of the incredible success stories of automotive companies, airplanes and computer hardware. The success of FMEA leads participants to the International Workshop Agreement (IWA) on ISO 9001: 2000 in Health, to include FMEA as a useful tool in improving the quality of health care.

Objective

To conduct a narrative review on the implementation of FMEA as an effort to reduce the occurrence of medical errors in the process of health services and to elaborate its advantages and disadvantages.

METHOD

This research is conducted by exploring the literature (literature review) on the implementation of FMEA as one way to reduce the incidence of medical error in health services. This search was conducted from November - December 2017 using online journals available at the University of Indonesia library with lib-ui.ac.id link, using EBSCO host. The keywords used are "FMEA" and search by selecting "Medline with full text".

Literatures obtained were filtered based on the title and abstract that deemed relevant to the topic. Research / articles that were not relevant to the topic of research will not be used. Next, inclusion and exclusion criteria were used, to get research / articles that fit the topic for further narrative review. The inclusion criteria were studies published between 2012 to 2017, and used FMEA in hospital. Similar FMEA usage is excluded, to gain more variety. In addition researches written in other language than English were also excluded, merely due understanding limitation.

With the above scheme, 280 articles were obtained in EBSCO host in the University of Indonesia online library. Based on the inclusion and exclusion criteria, there were 60 full text and English articles left. Then by checking the title, I obtained 7 articles, and 3 articles were further used for narrative review.

RESULTS

The first article is *Preventing Blood Transfusion Failures: FMEA, an Effective Assessment Method*, written by Zhila Najafpour et al., Published in BMC Health Services Research (2017), Tehran. In this article FMEA was established in 2014, and corrective actions were implemented and evaluated after 6 months. FMEA was applied to the blood transfusion process for 16 sessions, each session length of 2 hours. The five steps

are: building context, selecting team members, process analysis, hazard analysis, and the development of risk reduction protocols for blood transfusion.

During the analysis, all the steps of blood transfusion were detected based on direct observation and the opinions of related experts. Potential failures and possible causes are identified in the blood transfusion process. A total of 31 failures were identified with a RPN score ranging from 2 to 100. S, O, and D for each risk were calculated. Four blood transfusion failures were identified with an RPN above 75, identified the cause and recommended appropriate risk reduction measures. The analysis showed that the risk of failure with the highest RPN was labeling of blood samples (RPN 100), blood transfusion or wrong blood component (RPN: 100), patient identification error (RPN: 80), and sampling (RPN: 75). The entire RPN ranges from a minimum of 5 to a maximum of 100. Based on a risk assessment, follow-up is determined to reduce risks in all four modes of failure. Expressed recommended risk reduction measures, as well as RPNs for failure modes applied before and after precautions. Then followed up with precautionary measures against those risks over a 6 month period, and evaluated. The results show the values of all PRNs on incorrect patient identification, false marks, blood transfusions or blood components and miss-sampling down to 25, 30, 30 and 20 respectively.

The strength of this research comes from the ability to improve blood transfusion processes. The strength of this study stems from the ability to improve on existing blood transfusion processes and the introduction of new procedures that significantly improve safety and reduce clinical risks in learning settings. The view of an expert team to discuss and analyze changes to existing transfusion practices is a key strength of the study. The lack of standardization of how failure modes should be prioritized can be regarded as a limitation. In the absence of alternative protocols, transfusion failures are assessed on the basis of the RPN value and resources, policies and plans in the hospital where the research was conducted.

The second article entitled *Clinical Risk Analysis with Failure Mode and Effect Analysis (FMEA) Model in a Dialysis Unit*, written by Giovanna Bonfant et al., Published in Journal of Nephrology (JNOnline), 2010, Italy. FMEA steps performed are (1) learning process: recorded phases and activities. (2) Hazard analysis: recorded activity-related failure events and their effects, control measures that determine the severity, incidence and detection scores for each failure mode and calculate the risk priority number (RPNs) by multiplying 3 scores. Total RPN is calculated by adding single failure mode RPN. (3) Planning: made priority matrix taking into account the three values, and analyzing the causes of failure, and making new control recommendations and actions. (4) Monitoring: after elimination or reduction of failure mode, compared to RPN generated with the previous one.

For the admissions process, the initial RPN was 32 and 40. After 2, 4 and 10 months, the authors repeated the audit after follow-up: the indicator decreased from baseline to 2.9%, 5.2% and 3.7% each sub-admission process (all $p < 0.001$). RPN decreases from 32 and 40 to 12 (O scores each from 4 to 3 and from 5 to 3, D scores both from 2 to 1).

Identification of clinical problems and laboratory tests or advice on prescription may be inadequate. The reason is that the monthly check scheduled medical checkups are not well organized and planned. Given 2 questionnaires about the modalities of nephrology visits to nurses ($n = 13$) and nephrologists ($n = 7$), and found evidence of the importance of nurses present during the visit, as well as finding planning and organizing inadequacies. Handling of nephrologic examination, medical organization and nursing reorganized. A nursing audit 2 months later showed an increase in satisfaction with planning visits from baseline 15.4% to 100% ($p < 0.001$), which was confirmed at 10 months. Satisfaction with interruptions during medical examination increased from 7.7% to 47.7% at 2 months ($p < 0.002$) and 80% at 10 months ($p < 0.001$). Overlapping activity is still a problem; Actually the changes applied do not increase enough satisfaction (from 7.7% to 53% at 10 months). This difficulty is not easily solved, as dialysis treatment is currently taking place during visits. Results from medical staff are similar, but small numbers of nephrologists do not allow statistical evaluation.

In general, measured and optimal time of visit, reduced interference, nurses active participation and planning failure showed significant decreases, RPN values decreased from 27 to 6 (score O from 3 to 2 and score D from 2 to 1). The total RPN value decreased from 892 to 815 (8.6%) after the plan was implemented.

It was observed that FMEA's team selection, motivation and training were very important, because this analysis was subjective and depended on each member's ability and open-mindedness. The first implementation of FMEA actively involves all teams, and it takes some work, but it is fulfilled in a short time (6 months). The application of acquired knowledge for peritoneal dialysis and hemodialysis patient care was found to be faster and easier. In all the FMEA researchers did, the total reduction of RPN resulted in a substantial increase in service to the patients the researchers gave. FMEA will be combined with incident reporting and clinical audit at the Aosta Valley Health Care Organization, to verify its control measures and effectiveness.

The third article, *Validating FMEA Output Against Incident Learning Data: A Study in Stereotactic Body Radiation Therapy (SBRT)*, written by F. Yang et al., Was written at the American Association of Physicists in Medicine (2015).

This article describes the FMEA on the SBRT treatment planning process conducted by multidisciplinary groups including radiation oncologists, medical physicists, obstetricians, and IT technologists. Potential failure modes are identified through a systematic review of the process map. The failure mode is assessed for severity, occurrence, and detection ability on a scale of one to ten and calculates the risk priority number (RPN). The failure mode is then compared to the identified historical report relevant to the planning of the SBRT within an incident learning system (ILS) department that has been active for two and a half years. The differences between the anticipated FMEA failure modes and the existing incidents have been identified.

FMEA identifies 63 failure modes. 25% RPN value of the top failure mode ranged from 60 to 336. ILS identified 33 KNC incidents reported in relation to SBRT planning. Combining the two methods resulted in a total of 76 possible process failures, of which 13 (17%) were passed by FMEA while 43 (57%) were identified only with FMEA. When scored with RPN, 13 events passed by FMEA were below half of all failure modes and showed much lower severity than those identified by FMEA ($p = 0.02$).

FMEA has proven invaluable in identifying and treating risks in the process of radiation therapy. The FMEA-related validation of ILS in the SBRT treatment planning process indicates that FMEA fails to anticipate a large number of actual process errors (39%), although it is noted that this is low risk. Likewise, the large number of failure modes identified in FMEA were never observed in the two and a half years of active use of ILS. Integration of FMEA outputs with relevant retrospective event data taken from the ILS may be able to produce a more complete risk profile and reduce bias, from which risk management can gain more benefits.

DISCUSSION

Failure Mode and Effects Analysis (FMEA) is a method used to analyze failure and impact of systematic failure in order to improve the security and reliability of a system / process. FMEA is commonly used in military systems, industries such as aerospace, automotive, and health care systems. FMEA is a risk assessment tool initially used in military and new industries in 1990 used in health care. FMEA helps understand the effects of failure of a service process. The way in which a process can fail is called a failure mode. Each failure mode may have one or more failure effects. Each effect has its own risk and potential severity which, if not prevented, can lead to medical errors. The FMEA process is a method for identifying potential failures, the impact of such failures and the risk of a process that can occur. All are identified to eliminate or mitigate the effects of the failure. For example, it can be used to identify potential failures in new drug labeling systems. While analytical techniques using the newly retrospective Root Causes

Analysis (RCA) method can be used if a poor outcome has occurred with the drug labeling system.

From some of the literature that the author's narrative review, Zhila Najafpour, et al in Tehran, 2017, explains about how FMEA helps them reduce the potential risk of blood transfusion. The structured FMEA in this study was conducted in 2014, and remedial measures were implemented and evaluated after 6 months. During the analysis, all the steps of blood transfusion were detected based on direct observation and the opinions of related experts. In this study, FMEA score scores decreased from before and after follow-up intervention. But according to the researchers, for the application of FMEA requires the opinion of experts to assess the risks and follow-up to be done.

From another study, Giovanna Bonfant's 2010 study, in Italy, states that in all FMEA processes that researchers do, the total reduction of RPN results in a substantial increase in the Hemodialysis service process to patients. There was a decrease in the scoring of RPN numbers before and after the implementation of FMEA. In this study there is a researcher's suggestion that FMEA will be combined with incident reporting and medical audits at the Aosta Valley Health Care Organization, to verify the control measures and their effectiveness.

There are studies that validate the potential risks found in stereotactic body radiation therapy (SBRT) service processes and compare with incident learning system (ILS). The study was conducted at the American Association of Physicists in Medicine in 2015. In this study FMEA successfully identified 63 failure modes. 25% RPN value of the top failure mode ranged from 60 to 336. ILS identified 33 KNC incidents reported in relation to SBRT planning. Combining the two methods resulted in a total of 76 possible process failures, of which 13 (17%) were passed by FMEA while 43 (57%) were identified only with FMEA. When scoring with RPN, 13 events passed by FMEA are below half of all failure modes and show much lower severity than those identified by FMEA. The FMEA-related validation of ILS in the SBRT treatment planning process indicates that FMEA fails to anticipate a large number of actual process errors (39%), although it is noted that this is low risk. Likewise, the large number of failure modes identified in FMEA were never observed in the two and a half years of active use of ILS. According to the researchers, the integration of FMEA outputs with relevant retrospective event data taken from the ILS may be able to produce a more complete risk profile.

By preventing the occurrence of failure identified from the FMEA process, it can be said that the result of the failure of the medical error, can be prevented. By applying FMEA in a service process, and scoring to determine the effects of the biggest failures, policy makers can determine the priorities of potential failures that are found. Of course, every policy maker has diverse

views and reasons that are tailored to the current hospital conditions.

Although the use of FMEA is exhausting and time-consuming, this technique is very useful for designing health care processes and improving patient safety, thereby increasing the vigilance of leaders and hospital owners. Involving many teams in the making, can create a sense of involvement of all elements in the hospital. So that the patient's safety culture can be created. However, FMEA techniques still cause bias. It could be considered one person, a high potential risk, but according to other people's assumptions including low-risk potential. Potential failure according to each person can be different. Important during the creation of FMEA, the team focused on efficiency, healthy environment, patient focus and focus staff.

CONCLUSION

Based on literature search conducted by the author, it can be collected that FMEA is proven to decrease the number of potential failure before failure occurs after, so that medical error can be prevented. In the application of FMEA, bias can occur during the determination of potential failure and determination of scoring on the RPN, therefore, it is expected that the team involved in making FMEA experts in the process of service to be designed. Some studies also suggest that in order to verify the effectiveness of FMEA, it is important to compare the potential failure of FMEA with other risk management tools, such as incident reporting reports and medical audits.

REFERENCES

- Bonfant, G., Belfanti, P., Paternoster, G., Gabrielli, D., Gaiter, A.M., Manes, M., Molino, A., Pellu, V., Ponzetti, C., Farina, M. & Nebiolo, P.E. 2010, "Clinical risk analysis with failure mode and effect analysis (FMEA) model in a dialysis unit", *Journal of nephrology*, vol. 23, no. 1, pp. 111-118.
- Fibuch, Eugene, MD, CPE, F.A.C.P.E., F.A.B.Q.A.U.R.P. & Ahmed, Arif, BDS, PhD., M.S.P.H. 2014, "The Role of Failure Mode and Effects Analysis in Health Care", *Physician Executive*, vol. 40, no. 4, pp. 28-32.
- Growing Concerns About Medical Errors. Agency of Healthcare Research and Quality. [https://archive.ahrq.gov/quic/report/mederr4.htm] accessed on 28 October 2017.
- Marx, D.A. & Slonim, A.D. 2003, "Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modeling in health care", *Quality & Safety in Health Care*, vol. 12.
- McCains, Vannesa. 2016. Johns Hopkins study suggests medical errors are third-leading cause of death in U.S. Johns Hopkins University.
- Najafpour, Z., Hasoumi, M., Behzadi, F., Mohamadi, E., Jafary, M. & Saeedi, M. 2017, "Preventing blood transfusion failures: FMEA, an effective assessment method", *BMC Health Services Research*, vol. 17.
- Reiley, T.T. 2002, "FMEA in preventing medical accidents", *Quality Congress. ASQ's ... Annual Quality Congress Proceedings*, pp. 657-664.

-
- Reiling, J.G., Knutzen, B.L. & Stoecklein, M. 2003, "FMEA -the cure for medical errors", *Quality Progress*, vol. 36, no. 8, pp. 67.
- Shebl, N.A., Franklin, B.D. & Barber, N. 2012, "Failure mode and effects analysis outputs: are they valid?", *BMC Health Services Research*, vol. 12, pp. 150.
- Yang, F., Cao, N., Young, L., Howard, J., Logan, W., Arbuckle, T., Sponseller, P., Korssjoen, T., Meyer, J. & Ford, E. 2015, "Validating FMEA output against incident learning data: A study in stereotactic body radiation therapy", *Medical physics*, vol. 42, no. 6, pp. 2777-2785.
- Zheng, Y., Johnson, R. & Larson, G. 2016, "Minimizing treatment planning errors in proton therapy using failure mode and effects analysis", *Medical physics*, vol. 43, no. 6, pp. 2904-2910.