SEKOLAH TINGGI ILMU KESEHATAN TELOGOREJO

Science and Community Pharmacy Journal
Volume 2 *Issue* 2 *Year* 2023 *Pages* 112-123
E–ISSN 2830–6139| DOI:
12.23.23456/scienceandcommunitypharmacy.cj
Web https://ojs.stikestelogorejo.ac.id/

IMPLEMENTATION OF FMEA ON THE POTENTIAL OF MEDICATION ERROR IN PHARMACEUTICAL SERVICES IN BONANG II IN PRIMARY HEALTH CARE DEMAK REGENCY

Sri Suwarni[1)], Nur Haryanti[2)], Fransisca Gloria[3)]

1), 2) Sekolah Tinggi Ilmu Farmasi Nusaputera Semarang
3) Program Studi S-1 Farmasi STIKES Telogorejo Semarang

* Correspondence to: *warnisutanto@gmail.com*.

Abstract: Pharmaceutical service is one of the high risk areas in supporting the quality of health services, not least in the pharmacy service at Puskesmas. Failure Mode and Effect Analysis (FMEA) is one method that can be used to detect the existence of medication error, so it can be designed an action to minimize the risk of medication error in the pharmaceutical service. This research is a research action researched by applying FMEA method. This research was conducted in cross sectional, with prospective data taking on recipes in Pharmacy Room of Puskesmas Bonang II of Demak Regency in December 2017 and post implementation in February 2018. FMEA method in this research is expected to minimize the possibility of medication error in pharmacy service at Puskesmas Bonang II of Demak Regency. Through the FMEA method known RPN value before implementation for failure to read dosage dosage on an incomplete prescription is 420, the RPN value for failure to read the name of the drug on an unclear prescription is 486, in the failure mode fault filed the drug RPN value before implementation is 360. Measures implemented under the FMEA are the application of Standard Operating Procedure (SOP) prescribing, agreement on the use of abbreviations in recipes and the use of medicinal information systems of Puskesmas. The result of evaluation after FMEA implementation is reduced RPN value on failure to read dosage dose to 280, RPN value for failure to read drug name after implementation to 378, and failure mode error of taking drug name RPN value to 270.

Keywords: FMEA, Medication error, Pharmaceutical service.

INTRODUCTION

Pharmaceutical services at community health centers are an integral part of the implementation of health efforts, which play an important role in improving the quality of health services for the community (Kemenkes RI, 2016). Health services at community health centers, including pharmaceutical services, are an area that is at high risk of causing medication errors. Medication error is any avoidable event that can cause or result in inappropriate medication administration or endanger the patient while the medication is under the supervision of a health worker or patient (NCCMERP, 2016). Errors in administering medication were ranked first (24.8%) of the top 10 reported incidents. If we look further, in the process of drug use which includes prescribing, transcription, distribution and administration, dispensing is ranked first (Depkes RI, 2008).

One method that has been developed to identify, measure and prevent medication errors is Failure Modes and Effect Analysis (FMEA) (Supriyanti et al., 2011). FMEA / Failure Mode & Effect Analysis is a performance improvement method carried out proactively by identifying and preventing failures before they

occur with the aim of increasing the potential for patient safety (Kemenkes RI, 2015). The application of the FMEA method in identifying medication errors that occur in pharmaceutical services at the Bonang II Community Health Center, Demak Regency, is expected to be able to analyze risks and determine priority failure modes, so that it can identify the root causes of problems from these failure modes, and action factors can be taken to prevent and reduce their occurrence risk.

METHODS

This research was conducted at the Bonang II Community Health Center, Demak Regency using an action research approach. Where the elements are research elements, participation elements and action elements, as well as applying the FMEA method to detect medication errors that occur in pharmaceutical services. This stage begins with the diagnosing stage, continues with the planning action stage, then the taking action stage and ends with the evaluating stage. This research was conducted using a cross sectional method, with prospective data collection and a simple random sampling technique.

When the research was conducted for three months in 2022, medication error observations were carried out, the FMEA implementation process was carried out and then the evaluation stage. The samples in this study were prescriptions entered into the pharmacy room at the Bonang II Community Health Center in December 2020 and February 2021. The sample size was determined using the Slovin formula (Riduwan, 2005). So a sample of 324 prescription sheets was obtained.

The instrument used in this research was an observation sheet to determine medication errors in pharmaceutical services. Interview data form for problem identification. FMEA worksheet for determining RPN scoring. Data analysis was carried out descriptively in terms of the incidence of medication errors in incomplete prescription writing, unclear prescription writing and medication taking errors.

RESULT AND DISCUSSION

The research began by observing medication errors, namely by analyzing prescriptions received in December 2017 with a sample of 324 prescriptions, using an observation sheet. The recapitulation results from the observation sheet will be used as medication error data which will be used as the basis for action research using the Failure Modes and Effect Analysis (FMEA) method. The stages of the action research process using the FMEA method are:

1. Diagnosis stage

At this stage, identification and determination of service processes at high-risk community health centers are carried out through meetings at the community health center level. The results of the agreement show that pharmaceutical services are included in high-risk services, apart from laboratory services and general examination services. Pharmaceutical services themselves can be identified as high-risk services in each process.

This diagnostic stage is carried out to identify areas that have the greatest potential for failure in the pharmaceutical service process. At this stage, FMEA steps 1 to 5 are carried out, starting from selecting high risk factors and forming a team, compiling a service process flowchart, determining possible causes of failure, determining the possible severity and effect of failure by scoring (Risk Priority Number), and carrying out identification. problem with fishbone.

a. Determine high risk factors and form a team

The high risk factors in pharmaceutical services measured in this study are the prescribing phase, namely the completeness of the prescription, the transcribing phase, namely the ambiguity of the prescription, and the dispensing phase, namely errors in taking medication.

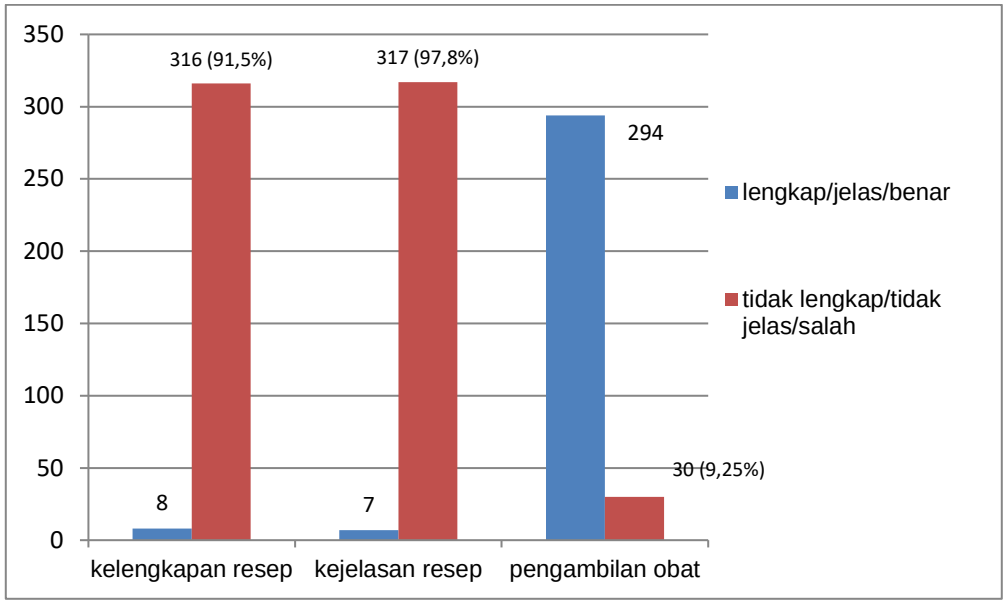

Figure 1. Distribution of Medication Errors in Pharmacy Services Before FMEA Implementation

From the picture above, it can be identified that there is a risk of medication error, namely in the prescribing phase (prescription completeness) there were 316 incomplete prescriptions (91.53%) out of a total sample of 324 prescriptions, in the transcribing phase (prescription clarity) there were 317 unclear prescriptions (97 .83%) from a total sample of 324 prescriptions and in the dispensing phase (errors in taking medication) there were 30 errors in taking medication (9.25%) from a total sample of 324 prescriptions. From the data above, each process can then be identified again to find out which areas have the most potential to fail.

From the table above, it can be identified that there are failure factors (failure modes) that can cause medication errors in the pharmaceutical service process. At this stage an FMEA team is formed which will carry out observations and analysis in the next stages of FMEA.

b. Prepare a service process flowchart

The preparation of this flowchart is to provide an overview of the starting point to the end of the pharmaceutical service process, and can determine which processes are at risk of potential medication errors. Below is a flowchart of the pharmaceutical service process in the pharmacy room at the Bonang II Community Health Center, Demak Regency. Where the risky stages in the pharmaceutical service process are during the review of the prescription and during compounding.

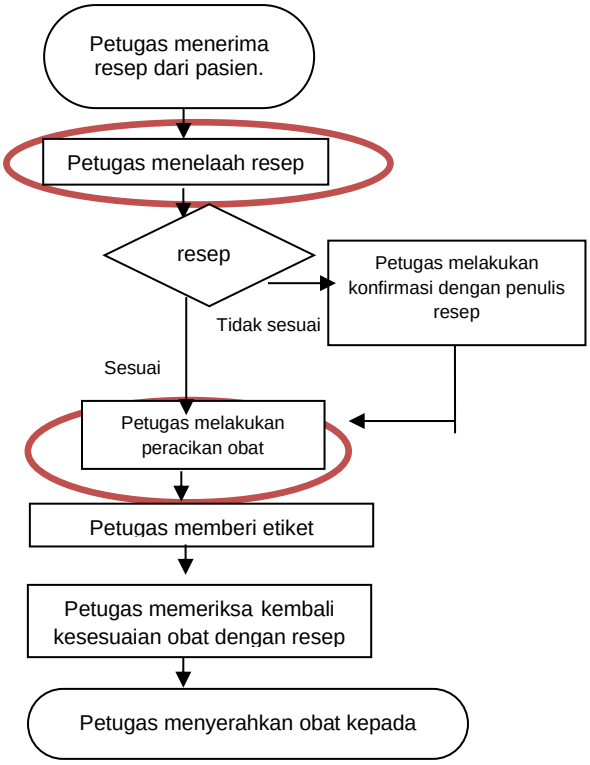

Figure 2. Flowchart of Pharmaceutical services at Bonang II Community Health Center

c. Determine the cause of failure

In this process, the cause of the failure, the consequences of the failure and a follow-up plan for the failure mode in the service flow are determined. This determination is made through brainstorming or brainstorming by the Puskesmas FMEA team. The FMEA team consists of the head of the quality team, the health center doctor who is the head of the UKP, the UKP secretary and members.

d. Determines the priority of the mode failure

Determination of mode failure priority is determined based on RPN (Risk Priority Number) scoring. The RPN value is obtained from multiplying the SEV*OCC*DET (severity, occurrence, detection) values. The purpose of calculating the RPN value is to determine the level of failure in pharmaceutical services so that improvements can be made to failures that are considered more priority. Determination of values for the level of severity (severity), frequency of occurrence (occurrence) and possibility of detection (detection) is determined by the FMEA analysis team.

Table 1. RPN Values are Based on Priority Order for Incomplete Prescriptions

Tahapan proses	kegagalan	Jumlah kejadian	*SEV*	*OCC*	*DET*	RPN	*Priority*
Dosis sediaan	Kegagalan membaca dosis sediaan	316	7	10	6	420	1
Nomor antrian	Kegagalan membaca nomor antrian	96	7	9	6	378	2
Nama obat	Kegagalan membaca nama obat	10	9	7	6	378	3
Aturan pakai	Kegagalan membaca aturan pemakaian	11	8	7	6	336	4
Bentuk sediaan	Kegagalan membaca bentuk sediaan obat	312	5	10	6	300	5
Alamat pasien	Kegagalan membaca alamat pasien	9	7	7	6	294	6
Umur pasien	Kegagalan membaca umur pasien	3	7	7	6	294	7
Nama Pasien	Kegagalan membaca nama pasien	0	9	4	6	216	8
Jumlah obat	Kegagalan membaca jumlah sediaan yang diresepkan	74	5	7	6	210	9
Paraf	Tidak adanya paraf	217	3	10	6	180	10

Table 2. RPN Values are Based on Priority Order for Unclear Recipes

Tahapan proses	kegagalan	Jumlah kejadian	*SEV*	*OCC*	*DET*	RPN	*Priority*
Nama obat	Kegagalan membaca nama obat	245	9	9	6	486	1
Aturan pakai	Kegagalan membaca aturan pemakaian	257	8	9	6	432	2
Dosis sediaan	Kegagalan membaca dosis sediaan	313	7	10	6	420	3
Nomor antrian	Kegagalan membaca nomor antrian	113	7	9	6	378	4
Nama Pasien	Kegagalan membaca nama pasien	2	9	6	6	324	5
Bentuk sediaan	Kegagalan membaca bentuk sediaan obat	315	5	10	6	300	6
Alamat pasien	Kegagalan membaca alamat pasien	14	7	7	6	294	7
Umur pasien	Kegagalan membaca umur pasien	7	7	7	6	294	8
Jumlah obat	Kegagalan membaca jumlah sediaan	217	5	9	6	270	9
Paraf	Tidak adanya paraf	221	3	9	6	162	10

Table 3. The RPN Value is Based on The Priority Order of Medication Taking Errors

Tahapan proses	Kegagalan	Jumlah kejadian	*SEV*	*OCC*	*DET*	RPN	*Priority*
Nama obat	Kesalahan pengambilan nama obat	12	9	8	5	360	1
Bentuk sediaan obat	Kesalahan pengambilan bentuk sediaan obat	8	5	8	5	200	3
Dosis sediaan	Kesalahan pengambilan dosis sediaan obat	10	7	8	5	280	2
Jumlah obat	Kesalahan pengambilan jumlah obat	4	5	7	5	175	4

From the table above, it can be seen the priority order of failure as seen from the RPN value, namely:

1) Incomplete prescription: failure to read the dosage (RPN 420)
2) Unclear prescription: failure to read the name of the drug (RPN 486)
3) Errors in taking medication: errors in taking the name of the drug (RPN 360)

So the research will focus on the causes and consequences of the above failures and action will be taken to reduce the number of failures in the above processes.

In the process of determining the severity level and effect of failure on the patient, the result of the agreement made by the FMEA team was that failure to read the dosage on an incomplete prescription had an RPN of 420 with a severity value of 7, namely an error can cause mild to moderate injury, an occurrence value of 10, namely errors occur at least once a day or almost all the time, the detectable value is 6, namely there is no standard process for checking again. The RPN value for failure to read the name of a drug on an unclear prescription is 486 with a severity value of 9, namely an error can cause serious injury, an occurrence value of 9, there is no process for rechecking. The RPN value for an error in taking a drug name is 360, with a severity of 9 the error can cause serious/permanent injury, an occurrence value of 8 is likely to occur at least once a week, a detectable value of 5 (medium chance of being discovered) there is a re-checking process.

e. Identification of problems

Identification of this problem is the final step in the diagnostic process, namely by identifying the problem from failure at the highest RPN value using a fish bone diagram. The factors observed in this identification process are limited to aspects of officers (personal), methods, environment, facilities and infrastructure, and materials. This identification was carried out using an interview method with the officers concerned, namely prescription writers (doctors, dentists and nurses and midwives who are given authority from doctors to write prescriptions) and officers in the pharmacy room.

The results of identification as a potential failure mode are failure to read the dosage on an incomplete prescription, failure to read the name of the drug on an unclear prescription and errors in taking the name of the drug. Each failure mode has effects that will certainly be detrimental to the patient, namely failure to cure the disease and errors in administering medication which can threaten patient safety. From the process of identifying the problem, each failure in this study was classified into a potential injury event (KPC) but not up to a sentinel event.

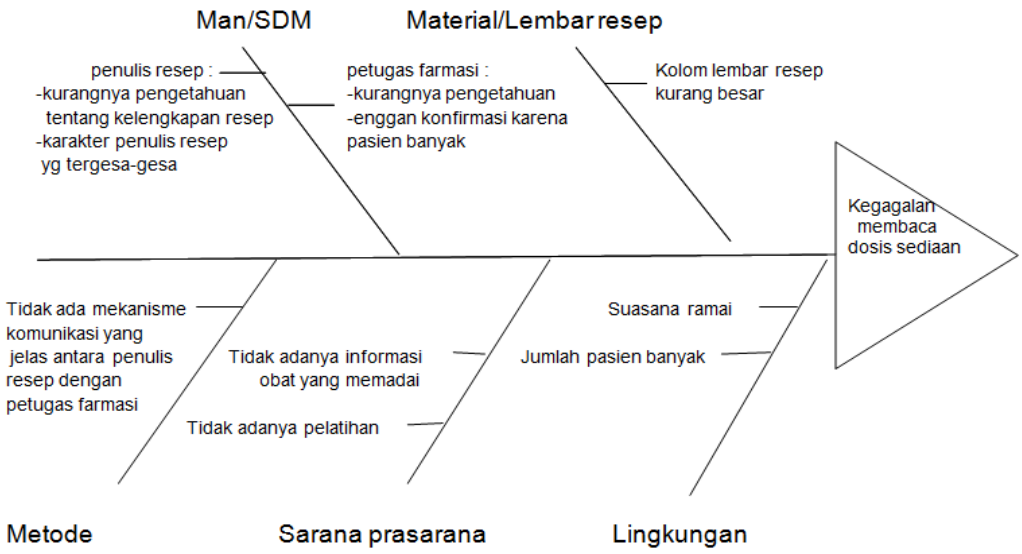

Figure 3. Fishbone Diagram for Failure to Read Dosage

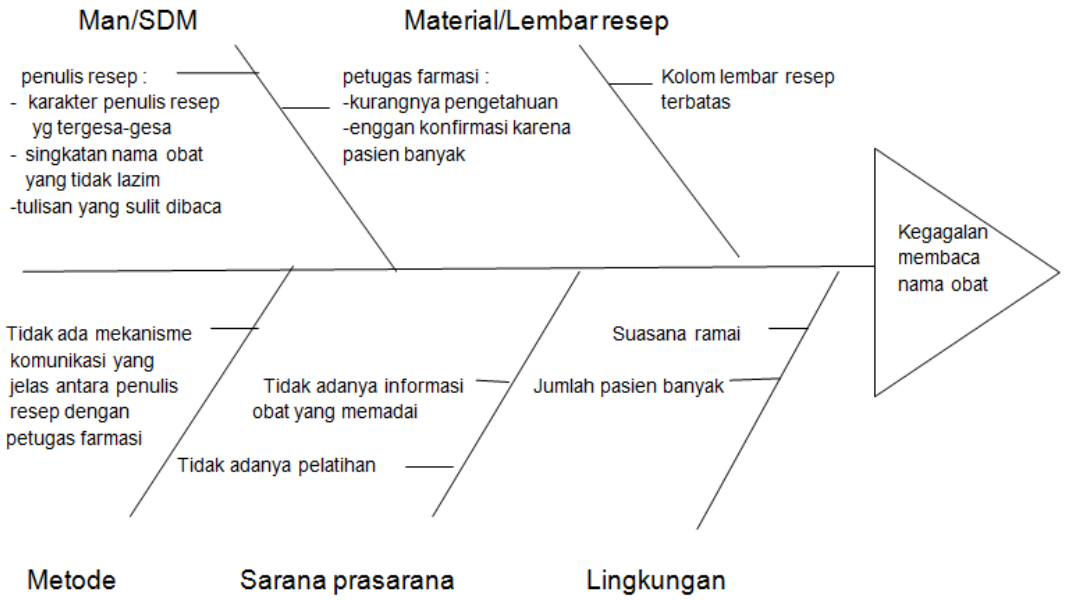

Figure 4. Fishbone Diagram for Failure to Read Drug Names

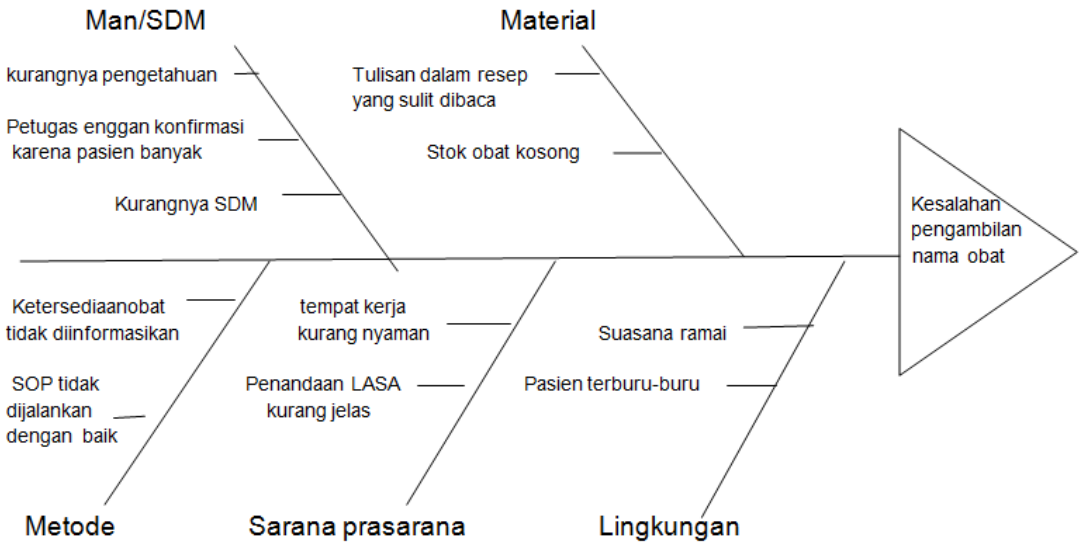

Figure 5. Fishbone Diagram for Drug Name Errors

2. Action planning stage

From identifying problems at the diagnosis stage, an appropriate action will be designed to reduce medication errors in the pharmaceutical service process. Efforts that are considered appropriate to reduce mode failures due to failure to read dosages are by establishing an SOP (Standard Operating Procedure) for writing prescriptions. The SOP for writing prescriptions contains the procedures or stages in writing a prescription, so it is hoped that the prescriber will write in a coherent manner the points that must be included in the prescription, including the dosage of the drug preparation.

Efforts made to reduce fashion errors in failure to read drug names are by making an agreement on the use of abbreviations in prescriptions. Because from the fishbone identification results, it was found that one of the causes of failure in reading drug names was the use of abbreviations for drug names that were unusual or not standardized. It is hoped that with this agreement on the use of abbreviated drug names, prescribers can comply and the writing of drug names will be clearer and easier to understand by staff in the pharmacy room.

From the identification of problems that occurred in errors in taking drug names using fishbone, it was found that one of the causes was the repetition of writing empty stock of drugs on prescriptions, so that the pharmacy staff replaced drugs that had already been confirmed by the prescriber previously. So efforts were taken to create a community health center drug information system that would be communicated to prescribers. This puskesmas drug information system will be updated every month or every time there is a shortage of drugs and new drugs are added.

3. Taking action stage

This stage is the implementation stage of the design that was designed at the planning action stage. The trial of the Standard Operating Procedure (SOP) for prescription writing began with socialization of the SOP for prescription writing to all UKP (Individual Health Effort) members, including doctors, dentists, nurses, midwives, pharmaceutical technical personnel and other health personnel in clinical services. Efforts made to reduce fashion errors in failure to read drug names are by agreeing on the use of abbreviations in

prescriptions. The results of this agreement were discussed at the UKP meeting and the results of this agreement were in the form of a list of the use of abbreviated drug names in writing prescriptions. The health center's drug information system was created by the drug manager which contains empty drug stock, a list of new drugs, and drug stock with expiry date. This Puskesmas drug information system is provided to the general examination service room, dental and oral health room, maternal health and family planning room, child health room.

4. Evaluation stage

At this evaluation stage, the level of success of the new design that has been implemented is observed. Evaluation was carried out by observing the incoming prescriptions, a sample of 324 prescription sheets was taken. This observation process is the same as the observations made during medication error observations at the start of the study. The recapitulation results from the observation sheet will be used as a basis for determining the severity value, frequency of occurrence and possibility of detection, so that the RPN (Risk Priority Number) value can be calculated after implementation. The RPN value after this implementation will be compared to the previous RPN value.

At this evaluation stage, the distribution of medication errors after implementation that occurred in each research variable can be seen again and can be compared with the distribution of medication errors before FMEA implementation. Distribution of medication errors in incomplete prescriptions before FMEA implementation was 316 (97.53%) and after implementation 207 (63.88%). In the distribution of medication errors in unclear prescriptions before implementation, there were 317 incidents (97.83%) to 231 (71.29%). For the distribution of medication errors, errors in taking medication before implementation were 30 incidents (9.25%) after implementation to 8 (2.46%).

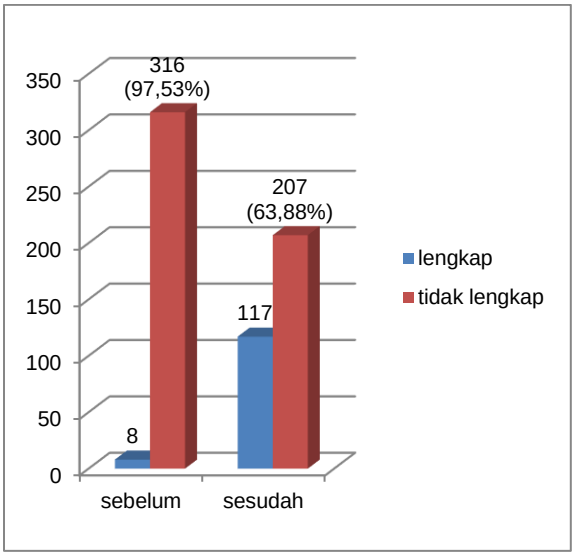

Figure 6. Distribution of Medication Errors in Incomplete Prescriptions Before and After FMEA Implementation

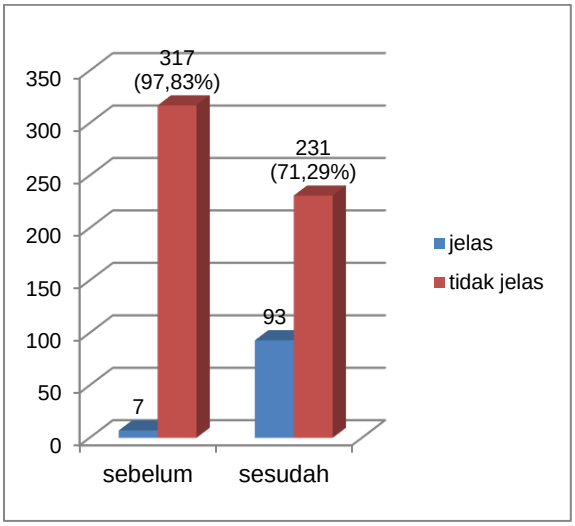

Figure 7. Distribution of Medication Errors in Unclear Prescriptions Before and After FMEA Implementation

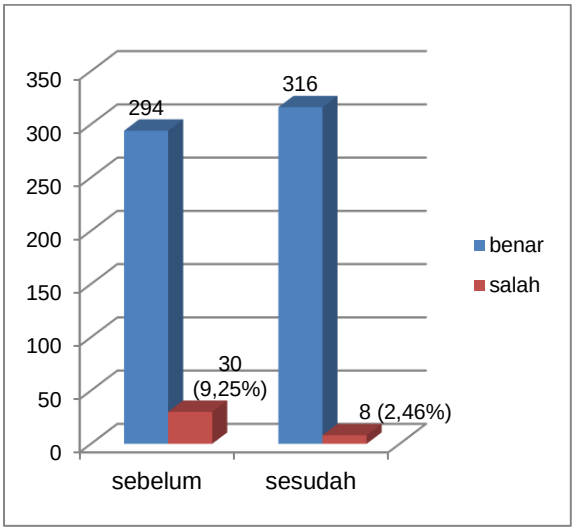

Figure 8. Distribution of Medication Errors in Medication Taking Errors

From the results of the comparison of RPN values before and after FMEA implementation, it was found that the RPN value for the failure mode failure to read the dosage of the preparation before implementation was 420, after the implementation of the SOP for writing prescriptions the RPN value became 280. The RPN value for failure to read the name of the drug before implementation was 486, after Implementation was carried out in the form of an agreement on the use of abbreviated drug names, the RPN value became 378. In the error mode failure for taking drug names, the RPN value before implementation was 360, and after using the community health center drug information system, the RPN value became 270.

Table 4. Comparison of RPN values before and after FMEA implementation

Tahapan proses	Kegagalan *(failur mode)*	Sebelum implementasi				Sesudah implementasi			
		Sev	*occ*	*det*	RPN	*sev*	*occ*	*det*	RPN
Kelengkapan resep	Kegagalan membaca dosis sediaan	7	10	6	420	7	8	5	280
Ketidak jelasan resep	Kegagalan membaca nama obat	9	9	6	486	9	7	6	378
Kesalahan pengambilan obat	Kesalahan pengambilan nama obat	9	8	5	360	9	6	5	270

The decrease in the RPN value was due to a decrease in the frequency (occurence) of each mode failure, which was identified from the recipe, namely after the new design implementation process, so that the FMEA analysis team agreed to reduce the occurrence value. Meanwhile, for the severity value, the team agreed not to change, this is because if a mode failure occurs, the impact on the patient will remain the same. This is in line with research conducted by Supriyanti et al (2011) which states that the severity value cannot decrease because the intervention is the service system, if an error occurs it will still have the same fatal effect on the patient. The detectable value for failure to read dosages for incomplete prescriptions decreased because the team assessed that the SOP for writing prescriptions included a step to ensure the completeness of the prescription, so that the new design implemented was considered to influence the possibility of detecting mode failures.

CONCLUSION

The incidence of medication errors in pharmaceutical services at the Bonang II Community Health Center before and after the implementation of FMEA is shown by the RPN value for the failure mode failure to read the dosage before implementation was 420, after implementing the SOP for writing prescriptions the RPN value became 280. The RPN value for failure to read the name of the drug before implementation it was 486, after implementation of the agreement on drug name abbreviations the RPN value became 378. In the error mode failure for taking drug names the RPN value before implementation was 360, and after implementation using the public health center drug information system the RPN value became 270.

AUTHOR CONTRIBUTION

Nusaputera College of Pharmacy and Bonang II Community Health Center, Demak Regency

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