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# Identification and assessment of common errors in the admission process of patients in Isfahan Fertility and Infertility Center based on "failure modes and effects analysis"

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# ABSTRACT

**Background:** Infertility and errors in the process of its treatment have a negative impact on infertile couples. The present study was aimed to identify and assess the common errors in the reception process by applying the approach of "failure modes and effects analysis" (FMEA).

**Materials and Methods:** In this descriptive cross-sectional study, the admission process of fertility and infertility center of Isfahan was selected for evaluation of its errors based on the team members' decision. At first, the admission process was charted through observations and interviewing employees, holding multiple panels, and using FMEA worksheet, which has been used in many researches all over the world and also in Iran. Its validity was evaluated through content and face validity, and its reliability was evaluated through reviewing and confirmation of the obtained information by the FMEA team, and eventually possible errors, causes, and three indicators of severity of effect, probability of occurrence, and probability of detection were determined and corrective actions were proposed. Data analysis was determined by the number of risk priority (RPN) which is calculated by multiplying the severity of effect, probability of occurrence, and probability of detection.

**Results:** Twenty-five errors with RPN  $\geq$  125 was detected through the admission process, in which six cases of error had high priority in terms of severity and occurrence probability and were identified as high-risk errors.

**Conclusions:** The team-oriented method of FMEA could be useful for assessment of errors and also to reduce the occurrence probability of errors.

Key words: Failure modes and effects analysis, infertility, Iran, quality, risk assessment

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# INTRODUCTION

ne of the goals of millennium development of the United Nations is public access to fertility health services until 2015.<sup>[1,2]</sup> One of the most important parts and components of fertility health is addressing infertility and its appropriate treatment.<sup>[3]</sup> Nowadays, the greatest health problem of developing countries is the high rate of infertility.<sup>[4]</sup> Therefore, it has been claimed a global health problem by the World Health Organization.<sup>[5]</sup> Although infertility is not a health-threatening problem, it could have

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serious effects on mental and social health. On the other hand, complications, medical errors, and adverse events, which are one of the greatest problems of health system and global concerns, would make this matter worse.<sup>[6]</sup> Studies that have evaluated the rate of medical errors have reported that the staff error was 42-53%.<sup>[7]</sup> It is unlikely to believe that in reproductive medicine, incidences and errors have a low prevalence in assisted reproductive methods. This would alert us to pay more attention to patient's security and detecting the errors in the process of health service provision. Also, paying attention to the quality of fertility and infertility services would decrease the rate of mortality among mothers. <sup>[8]</sup> For improving the quality, it is necessary to choose simple, standard, and dynamic scientific tools and methods.<sup>[9]</sup> One of the methods for improving and enhancing the quality is failure modes and effects analysis (FMEA) method.

FMEA is a systematic method based on team work that is used for detecting, evaluating, preventing, omitting, or controlling causes and effects of potential errors in a system before the final product or service would get to the costumer.<sup>[10]</sup> FMEA is an approach to prevent errors and improve processes to increase patient safety; through this method, errors would be reviewed systematically and by searching for methods to prevent their reoccurrence, errors and their consequences would be decreased.<sup>[11]</sup> Spat also believed that evaluation of human and process errors is necessary.<sup>[12]</sup> Results of a study showed that processes involved in infertility treatments are processes related to assisted reproductive treatments, as believed by Bennet et al. that it was necessary to evaluate the quality of services of these processes for the success of assisted reproductive treatments and increasing the chance of pregnancy.<sup>[13]</sup> Another study revealed that most of the errors occurred during hospitalization and they were due to the inability of reception staff in reading hospitalization orders.<sup>[14]</sup>

So, considering that FMEA has never been used as a method to improve the process of Iranian infertility centers, the researcher decided to use FMEA in order to evaluate and detect common errors in the reception of Isfahan Fertility and Infertility Center and to provide corrective measures for improving the quality of services.

# MATERIALS AND METHODS

The present study, which is a descriptive cross-sectional FMEA study, was conducted in 2014–2015 for 8 months in the Fertility and Infertility Center of Isfahan.

The steps of the study were based on eight determined steps of FMEA methodology<sup>[15]</sup>:

A. Selecting the reception processes and establishing a team

At first, an error-evaluating team including the researcher, two supervisors of the infertility center, one obstetrician, center's manager, receptionist, and a few experts like advising professors, quality management consultant, and experts on FMEA was established. During all the steps of FMEA, FMEA worksheet, specialized panels, brainstorming, and observation for gathering information were used. During a 2-h session, necessary training about FMEA and its eight steps were provided in the presence of guiding professors and consultant for the authorities and beneficiaries of this study. Then, the reception errors were evaluated through FMEA method.

- B. Drawing the flowchart of reception processes At this stage, the researcher accurately observed the reception process of Isfahan Fertility and Infertility Center and talked to and consulted the staff and authorities of each ward, and then drew the flowchart of reception process of the center during 2014–2015. The determined reception process was drawn by the researcher as a flow diagram using VISIO software (electronic development company walnut shahmirzad). Then the primary version was sent to the team members and was evaluated, modified, and finally approved during a session with them.
- C. Categorizing potential modes

At this stage, first activities related to the desired process, through team members' opinion, were recorded in the final FMEA worksheet. Then, by participation of team members in a joint panel, possible errors were listed consensually through multiple panels and separately for each part of the process.

- D. Determining the possible causes of errors Using fishbone diagram, underlying causes of reception process were gathered through nine brainstorming panels with the team members and recorded in the "causes" column of the final worksheet for each error.
- E. Determining the potential effect of each error At this stage, direct and immediate effect of each failure mode or consequences of each error were determined by the evaluation team through specialized panels and were recorded at the "effects" column of the final worksheet.
- F. Prioritizing failure modes

At this stage, each determined failure mode was prioritized based on its risk priority number (RPN), which was the result of multiplication of severity of error's effect (S), possibility of error's occurrence (O), and detectability of error (D). These indicators were scored from 1 to 10. For severity of error's effect, a score of 1 indicated nonserious effect of the error or its insignificance and a score of 10 indicated life-threatening risks and death. For possibility of error's occurrence, a score of 1 indicated unlikeliness of error's occurrence and a score of 10 indicated 100% possibility of error's occurrence. For

error's detectability, smaller scores meant that the error was detectable before reaching the patient and bigger scores<sup>[10]</sup> meant that the error could probably only be detected through patients' and beneficiaries' complaints. Eventually, the obtained scores were reviewed at the end of each panel and their accuracy was approved by the team members. The range of RPN was set from 1 to 1000, and considering the 1–10 scoring scale of the three indicators, errors with RPN  $\geq$  125 were considered high-risk, high-priority, and unacceptable errors. Also, considering the importance of patient's safety, corrective measures were provided by the team members for high-risk and high-probability errors, regardless of their RPN

G. Providing corrective suggestions for potential risk modes to reduce or omit errors

At this stage, the team members suggested corrective measures for failure modes with RPN of more than 125.

Data were analyzed using descriptive analysis.

## **Ethical considerations**

After obtaining permission from the ethics committee of Isfahan University of Medical Sciences and taking informed consent from the authorities and personnel who participated in the sessions of the center. During this study, the process of reception was considered a risky process.

# RESULTS

Overall, based on the reception process flowchart, 44 potential failure modes were determined and after calculating their RPN, based on the scores of severity of effect, probability of occurrence, and detectability, 25 errors of reception process that had an RPN  $\geq$  125 and six failure modes that were highly significant based on their high severity and occurrence possibility, regardless of their RPN, were determined as prioritized and high-risk errors. Prioritized errors along with their three indicators of severity of effect, probability of occurrence, and detectability are shown in Table 1.

Based on the stages of FMEA after determining RPN, errors were extracted and the most common causes of reception process errors that were expressed at specialized panels included: Lack of appropriate recording system, lack of appropriate notification at midwifery ward, and also lack of informative brochures for patients, insufficient space, not having a written form of processes for each ward and not putting it in sight for patients, inappropriate accommodations, not holding educational sessions for patients at the time of their admission to the center, lack of focus in reception staff, unnecessary referrals to the reception, wrong arrangement of the ultrasound room, mistakes in writing the prescription by the physician, crowding of patients in the room, transition of wrong information to the midwife by the physician, patients' lack of information about referring to the reception after transferal ultrasound, mistakes in recording the information in the system by the reception staff, reception staff's multitasking, midwives writing some physicians' prescriptions, and also patients providing some wrong information. The most common causes of prioritized errors were mistakes in writing the prescription by the physician, patients crowding in the room, and transition of wrong information to the midwife by the physician, and the least common ones were patients crowding in physician's room, midwives writing some physicians' prescriptions, and also patients providing wrong information.

The final stage of FMEA is providing corrective measures, and here, these corrective suggestions were provided due to their causes: Preparing and showing educational videos after patients' admission for increasing their knowledge, making them sensible toward treatment process and controlling the consequences of treatments, providing appropriate and categorized educational CDs and brochures and making them available to patients, providing more space at an appropriate place for midwifery consultations, using separating partitions for increasing the focus on the patient and maintaining their privacy, a midwife accompanying the patient from their admission through treatment process, establishing interactive voice response (IVR) section and creating an active website for patients, preparing a form of all the processes of the center and installing it at patients' waiting rooms, registering and making appointments through internet and telephone (IVR) and giving defined medical codes to patients so that they would refer at the defined time which would reduce the tiredness of patients who come a long way to the center, holding an educational session for patients at the time of their admission, installing appropriate sound systems at information waiting room, establishing the midwifery consultation room at an appropriate and private place next to physician's room, informing and educating patients about the importance of on-time referral for injecting ovulation stimulant drugs and perform serial ultrasound at the designated time of the mensrural cycle to see mature folicle, recording the necessary drugs by the physician after performing ultrasound and reviewing them, determining the accurate job description of each reception personnel, and providing medical guidelines of center's patients to the midwife assisting the physician.

# DISCUSSION

In the present study, the highest number of prioritized and significant errors during the reception process belonged to

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Row	Error priority	Severity	Occurrence	Detectability	Number of risk priority
1	Wrong explanation to patients about correct drug consumption		6	9	378
2	Dropping the treatment, lack of control over postoperative complications		4	8	288
3	Patient's inappropriate condition when referring for performing tests (fasting)	8	4	9	288
4	Environmental noises and incorrect transmission of information to the patient	6	7	6	252
5	Personnel's exhaustion and inadequate transfer of information to the patient and also patient's mental confusion	6	7	6	252
6	Confusion, waste of time, increased stress and anxiety of clients	3	9	9	243
7	Patients' exhaustion and nervousness	3	9	9	243
8	Lack of proper timing between patient arrival and their visit by the physicians	6	8	5	240
9	Lack of awareness about the effects of drugs (particularly drugs that stimulate ovulation), medical costs, the process of diagnosis, and treatment of infertility	5	5	9	225
10	Physical side effects, waste of time, and giving up the treatment	5	5	9	225
11	Failure to properly follow the treatment process	8	4	7	224
12	Patients' lack of information and awareness	4	6	9	216
13	Multitasking of reception personnel and confusing the patients	6	6	6	216
14	Inappropriate drug consumption (especially the drugs that stimulate ovulation)	9	3	7	189
15	Patients' wrong perception of the treatment process	6	6	5	180
16	Delay in diagnosis and treatment, especially in injecting drugs and performing ultrasound	7	5	5	175
17	Patients' stress during ultrasound	7	4	6	168
18	Incorrect timing for patient's referral by the injection manager using their ultrasound report	9	2	9	162
19	Patient's inappropriate referral for drug injection at the wrong time (including ovulation induction drugs)	8	3	6	144
20	Physician's error in writing orders for ovulation induction drugs during ultrasound	6	4	6	144
21	Mistakes in preparing the drug's dose for injection	8	3	6	144
22	Disruption in the provision of reception (step-by-step process service)	5	9	3	135
23	Delay in sending patient's report from the laboratory to the ultrasound section	9	3	5	135
24	Physician's mistake in writing the correct prescription (type or dose) in patient's health insurance notebook or records	7	3	6	126
25	Errors in recording the correct type of operation and operation code	7	3	6	126

 Table 1: Error priority along with severity, occurrence, detectability

wrong explanation to the patient about right consumption of their drugs with a score of 378 and the lowest number belonged to mistakes of the physician in writing the prescription (drug type or dose) and mistakes in correctly recording the type and code of the action with a score of 126. Their consequences might be financial damage and dissatisfaction for the patient and errors could be detected by the patients or their families before discharge and during the final stages of overall treatment processes. Abbasi *et al.* in their study on evaluating the causes and effective factors in medical malpractice have reported the

incidence of communicational errors as 24% and clinical and prescription errors as 8%, and have recommended the physicians to spend more time with their patients and write their prescriptions in a better handwriting.<sup>[16]</sup> Also, Burroughs *et al.*, in their study that was aimed to evaluate medical errors in emergency wards, mentioned that the incidence of physician's errors was 16%, medication errors was 12%, and nursing errors was 10%.<sup>[17]</sup> Results of these studies could not be compared to each other due to the differences in their research environment, but many studies have mentioned that communicational errors and lack of

professional knowledge have severe effects on patients and would lead to repetition of errors. Also, the study of Walsh et al., which was aimed to evaluate medication errors at home among children with cancer, reported that the highest prevalence of medication errors belonged to drug consumption that was caused due to miscommunication between parents and physicians.<sup>[18]</sup> Results of a study by Hosseinzadeh et al. on the causes of medication errors and effective factors in staff's reporting revealed that the most important cause of medication errors was exhaustion and heavy load of work. Their results showed that illegibility of medication orders, physicians' poor handwriting, limited and small environmental conditions, exhaustion, and personnel's insufficient pharmaceutical information result in occurrence of medication errors.<sup>[19]</sup> Therefore, considering the importance of extracted errors in the Fertility and Infertility Center, managers of infertility centers should pay attention to therapeutic and effective processes to reduce these types of errors by observing the operation of fertility and infertility center personnel, increasing personnel's professional knowledge and skills by holding educational sessions for them, observing personnel's communication with patients, observing medication consultations, and establishing a specific spacious place for drug consultation after physician's prescription.

Another measure is establishing a system for reporting an error wherein each personnel, without any fear or concern, would report the medication error that occurred. One of the benefits of applying this method is maintaining and improving patients' safety, which is the essential component in reducing the possibility of error occurrence and its severity. Furthermore, establishing an IVR system in case of emergency medication consultation is necessary; and it has also been mentioned in the study of Khamse *et al.*,<sup>[20]</sup> which is in line with the present study.

On the other hand, 42 potential errors determined during the reception process and defining 25 prioritized errors indicates useful application of FMEA method from primary evaluation and detection of underlying causes for minimizing the probability of error occurrence to providing corrective measures at a sensitive center like the fertility and infertility center. However, the effectiveness part of FMEA method for corrective measures has not been determined in the present study, which necessitates more studies and researches in this regard. Moreover, team-oriented nature of this method could create an interaction between staff that leads to a safe context for reducing or eliminating the risks of errors for infertile couples. So, considering that FMEA method has successfully determined the potential errors of reception process in one fertility and infertility center and also has defined the causes of unacceptable errors and provided corrective measures, it is recommended that to achieve desirable quality in services, required interventions should be conducted following the corrective measures mentioned in this study in order to modify the processes and decrease or omit prioritized errors.

One limitation of this study was the insufficient amount of time for the researchers to apply corrective measures and evaluate their results in reducing errors.

## CONCLUSION

Results of this study led to definition of 44 potential errors in the reception process and 25 prioritized errors with RPN  $\geq$  125. The highest number of prioritized and significant error belonged to wrong explanation to the patient about drug consumption and the lowest number belonged to making mistakes in writing the prescription by the physician. This study showed that team-oriented method of FMEA could be useful in evaluation of errors for reducing the possibility of their occurrence.

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#### **Conflicts of interest**

There are no conflicts of interest.

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