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Research Article

**APPLYING THE ANALYSIS OF POTENTIAL FAILURE
MODES AND THEIR EFFECTS IN EVALUATING CLINICAL
RISKS IN OPERATING ROOMS**Sedighe Ghobadian^{1,2}, Mansour Zahiri^{3,4}, Amin Torabipour^{3,4}, Farzad Faraji-Khiavi^{3,4*}¹Student Research Committee, School of Health, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran²Applied research center of police Medicine. Department of Health, Rescue and treatment of police force. Tehran .Iran³Department of Health Services Administration, School of Health, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran⁴Social Determinants of Health Research Center, School of Health, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran**Abstract:**

Operating rooms are among the special hospital wards which constitute important stages in the treatment of patients with the use of special equipment and health standards. With the purpose of ensuring the safety of patients and the staff in the operating rooms and due to the necessity of clinical risk assessment, the current research focuses on the evaluation of clinical risks occurring in the operating rooms of an educational hospital. The current study is an applied research and the required data has been collected qualitatively through focus group discussions in Golestan hospital, Ahvaz, in 2015. The tools for data collection were the standard worksheet of potential failure modes. The priority matrix was used to analyze the potential failure modes and prioritize each failure mode. By performing needs assessment via Delphi method and reviewing the 50 processes in operating rooms, 10 processes were identified as being high-risk processes. After reviewing the processes in the focus group discussions, 121 potential failure modes were discovered out of which 7 potential failure modes were in the red zone after using the standard priority matrix and thus required immediate action. In order to improve the safety of patients during surgery, it is necessary to pay serious attention to the pre-operation procedures. In addition, by the use of team activities in the field of risk management, the safety culture can be institutionalized in special wards of hospitals.

Keywords: *Clinical risks, Operation rooms, potential failure modes analysis***Corresponding author:****Farzad Faraji-Khiavi,**

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INTRODUCTION:

Operating rooms are one of the most important parts of a hospital where the main treatment procedures take place for the patients. In addition, due to the complexity of the issues related to the patient as well as treatment protocols and high level of technology used in operating rooms, these sectors have been identified as one of the most complex work environments in health systems [1]. Although observation of safety related to the patient is essential in all sectors of a hospital, this is especially true for the operating rooms because of the complexity of the patient's condition and treatment process, the presence of special equipment, the lack of consciousness in patients, and the use of high-risk medications and combustible materials which can result in maximum failure and unpleasant events. In this regard, safety of the patient requires the managers and authorities in hospitals to pay serious attention to the area of clinical risk management [2]. Clinical risk management determines the path of a clinical program, and improves the quality and ensures the patient's safety in the healthcare service. It constitutes a great part of activities related to the safety of the patient despite the variations in the structures and the practiced processes in various treatment centers [3]. In the studies conducted on various treatment centers in Iran, risk management status has been evaluated as moderate and even as weak in some treatment centers [3-5]. Looking back at the history of medical errors, we find out that most of errors in the past were attributed to humans always blaming the doctors and medical staff for the errors. Today, however, most of the clinical errors are considered to be systematic errors [6, 7]. There are two approaches for the evaluation of the clinical errors: retrospective and prospective. Retrospective error analysis has been often used to identify the high-risk events and prevent their reoccurrence. These measures are presented in the form of root cause analysis (RCA). Another approach is the prospective method which proactively prevents the clinical errors and predict the occurrence of errors [8]. Failure modes and effects analysis (FMEA) is one of these methods and is nowadays a commonly-practiced method in healthcare risk management [6]. FMEA is a group process which is used to identify, prevent, eliminate or control the modes, causes and potential effects of errors in a service system [9]. This approach detects the errors through a preventive and systematic view and helps organizations to identify the potential problems and solve them before the problems affect the services and the customers in the system [10]. The systematic Prospective approach has taken the place of the traditional approach in which the wrongdoer Staff were rebuked. This

system codifies the patient's immune system according to the clinical standards and the identification of deviations from these standards. The system calculates quantitatively the severity of each failure by reviewing each element of the processes and identifying and analyzing the potential errors in each stage of the process and in the following, it will strengthen the capabilities of human resources to perform a safe process by providing appropriate solutions [11, 12]. In 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) declared the implementation of potential failure modes analysis in the high-risk sectors of hospital as necessary in all hospitals [13, 14]. In Iran, by conducting research in the field of failure modes analysis, the effectiveness of this approach has been observed in determining the high-risk modes and increasing the accuracy of the staff and their attention to the possible weaknesses and reduced failures [15-19]. Potential failure modes and effect analysis has been introduced as a successful approach to manage the risk. It can evaluate the complex clinical risks by spending a minimum effort and cost and lead to an improvement in the quality of healthcare [20]. Due to a dire need for a system of clinical risk assessment in various groups of service providers, a great economic burden, and the casualties resulting from hospital failures in healthcare systems [21], the employment of an effective method has been recommended to determine the risk-causing factors and controlling the failure modes in high-risk sectors of operating rooms [11]. Regarding the fact that the prospective approach to failures analysis has already been introduced as an effective method in reducing or eliminating the potential failure modes in various studies [14], this research was performed with the aim of assessing clinical risks in the operating room ward of Ahvaz Golestan hospital using potential failure modes and effects analysis (FMEA).

MATERIALS AND METHODS:

This research was an applied qualitative study which has been performed in the general operating room of Golestan educational hospital in Ahvaz. At first, the high-risk processes of the operating room were identified by the Delphi method. In the first stage of needs assessment, the data concerning the high-risk processes of the operating room were elicited from the operating room manager, the staff with 10 or more years of work experience, the OR safety coordinator, the education unit's reprehensive and the quality improving unit authority through written questions. A one-week period was offered to them to provide their opinions. After the prescribed period, the written responses were collected and they were set by a researcher in the form of a general list. The

mentioned list was given to the same people for re-approval to obtain their final opinion regarding the high-risk processes. At the end of the week, the written responses were collected and the final list was decided. In the next stage, the final list of high-risk processes was referred to the same individuals to be prioritized. The responses were then collected. Afterwards, the focus group discussion was selected by the researcher in an objective manner. Due to the specialized activities in the operating room, the criteria for the selection of people in the focus group discussion included the familiarity with the processes, the work experience, and more than five years of service experience. Accordingly, the hospital's matron, the operating room manager, the expert of safety coordinator, the clinical and educational supervisors and an experienced nurse in the operating room were selected as members in the group. Prior to beginning the study, a training session was held by the research team to train the members with the failure modes analysis technique, the principles of teamwork, and the method of brainstorming with the required coordination. Upon ensuring that the training was sufficient for the group members, the failure modes analysis was started by establishing the sessions of focus group discussions. Initially, the flow diagram of the selected processed was drawn through the opinions of process owners and the available documentations in the ward. The stages in the process under investigation were numbered sequentially and all the sub-processes related to the stages of the target process were considered in the process diagram. Then in each process stage, the group members listed the possible failure modes, the causes of this failure, the possible effects of the incidence of each failure mode and the current controls of each of them through brainstorming. In the next stage, a 1 to 5 standard scale was used to measure the indexes of effect magnitude, the probability of the failure occurrence, and the capability of failure detection. The scores

were then calculated according to the consensus views (Tables 1-3). The collected data were recorded in the worksheet of failure modes and their effects and, at the beginning of each session, they were examined by the focus group discussions. The obtained scores were inserted in the priority matrix which was utilized in previous studies (diagram 1)[10]. In this priority matrix, the severity of the error will be placed in the vertical axis and the sum of the probability of the error occurrence multiplied by the probability to detect the error will be placed in the horizontal axis. Accordingly, each failure mode will be placed in one of the color matrix boxes. The color green indicates low risk, the yellow indicates moderate risk and the need for managed corrective measures and the red indicates high risk requiring immediate corrective measures. By calculating the risk priority number, which is the product of three indexes of error magnitude, the probability of error occurrence, and the probability of error detection, the errors which have low severity and high probability of detection or occurrence are given similar scores as the errors with high severity and less probability of detection or occurrence. However, the separation of the error severity index prevents this defect by multiplying the probability of error occurrence and error detection in the mentioned priority matrix with an emphasis on the error severity index. The errors with high-risk priority and the need to take immediate measure were root analyzed using the fishbone diagram and, accordingly, the corrective measures were selected by the agreement attained through focus group discussions. The proposed corrective measures were evaluated based on the viewpoints of the hospital's chief executives and the head nurse of the ward for implementation. Among the measures, the executive corrections were prioritized and selected according to the environmental conditions and the hospital's resources.

Table 1: Ratings regarding severity magnitudes of errors(S)

score	Error type	
5	Death or losing the function of a main bodily function	Extremely high severity
4	The Chronic loss of a bodily function	High severity
3	Temporary injury which requires longer convalesce in hospital or requires greater health intervention	Moderate severity
2	Temporary injury requiring treatment and health intervention	Low severity
1	No damage suffered by patient. The patient only needs to be supervised.	Extremely low severity

Table 2: Ratings regarding probability of error occurrence(O)

Score	Probability of error occurrence	
5	An error which occurs once out of every 20 times	Extremely high
4	A repetitive error – An error which occurs once out of every 100 time	High
3	An error which occurs every once in a while– An error which occurs once out of every 200 times	Moderate
2	An error which has a relatively low occurrence -- An error which occurs once out of every 1000 times	Low
1	The Error is very rare– An error which occurs once out of every 1000 times	Extremely low

Table 3: Ratings regarding the probability to detect an error(D)

score	Probability to detect an error	
5	the error might not be discovered until the patient is released from the hospital and its discovery requires lab experiments and other procedures irrelevant to the treatment– An error which occurs zero out of every 10 times	Extremely low
4	The error or cause of the error might be discovered due to the diligence of the downstream treatment staff and mitigated – An error which occurs two times out of every 10 times	Low
3	The error or cause of error can be identified through the diligence of the direct care giver– An error which occurs five times out of every 10 times	Moderate
2	The error or cause of error is identified through the diligence of the direct care giver based on existing protocols – An error which occurs seven times out of every 10 times	High
1	The Error or cause of error is prevented through a written and imposed protocol– An error which occurs nine times out of every 10 times	Extremely high

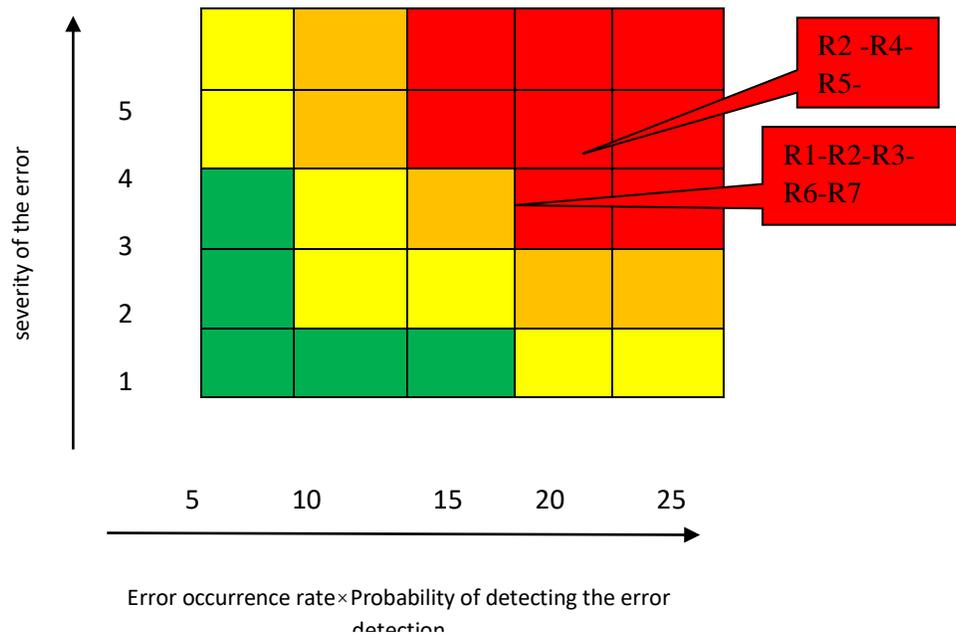


Diagram 1: Unacceptable failure modes in Golestan hospital according to the priority matrix

R1- Simultaneous Delivery of several patients in the process of patient admission in the operating room. **R2-** Wearing the wrong bracelet in the process of patient admission in the operating room. **R3-** Lack of proper communication with the patient in the process of patient admission in the operating room. **R4-** Failure to mark the surgical site in the process of admitting the patient to the operating room ward. **R5-** failure to match the patient file with the patient's bracelet / and the statements by the anesthesia technician in the process of patient identification. **R6-** Lack of Check the patient's general condition and performance of the mechanical connections in the process of continuity of care in changing work shift. **R7-** lack of accountability of the ward or accountability of an irresponsible person in the process of discharging the patient from recovery.

FINDING:

From the entire range of the performed needs assessments, nine processes were identified as high-risk processes in the operating room. In 12 sessions, the identified high-risk processes were drawn by the focus group discussions and were analyzed through evaluating the failure modes and causes, the effect and failure severity indexes, the failure occurrence rate, and the probability of error detection. In 51 available stages of the 10 identified high-risk processes in Golestan hospital, 123 failure modes were detected. By positioning the failure modes in the priority matrix, 7 failure modes could be identified in the red zone, thus requiring immediate measures (Table 4). The unacceptable failure modes and their need for immediate measures included the simultaneous delivery of several patients, wrong bracelets, failure to communicate effectively with the patient, the failure to mark the surgical site in the

process of patient admission, failure to match the patient file with the statements and the patient's bracelet by the anesthesia technician in the process of patient identification, failure to check the general condition and connections of the patient in the process of continuity of care during the shift changing time and the lack of accountability of a sector or the accountability of an irresponsible person in the patient's discharge process from the recovery. The reasons for each unacceptable failure mode were analyzed using the fishbone diagram and the corrective measures were determined through brainstorming in focus group discussions (diagram 2). A list of corrective measures was set and given to the hospital's matron, the head of the unit of quality improvement, the authority in charge of the operating room and the technical assistant of the hospital to determine the executable cases and prioritize their implementation.

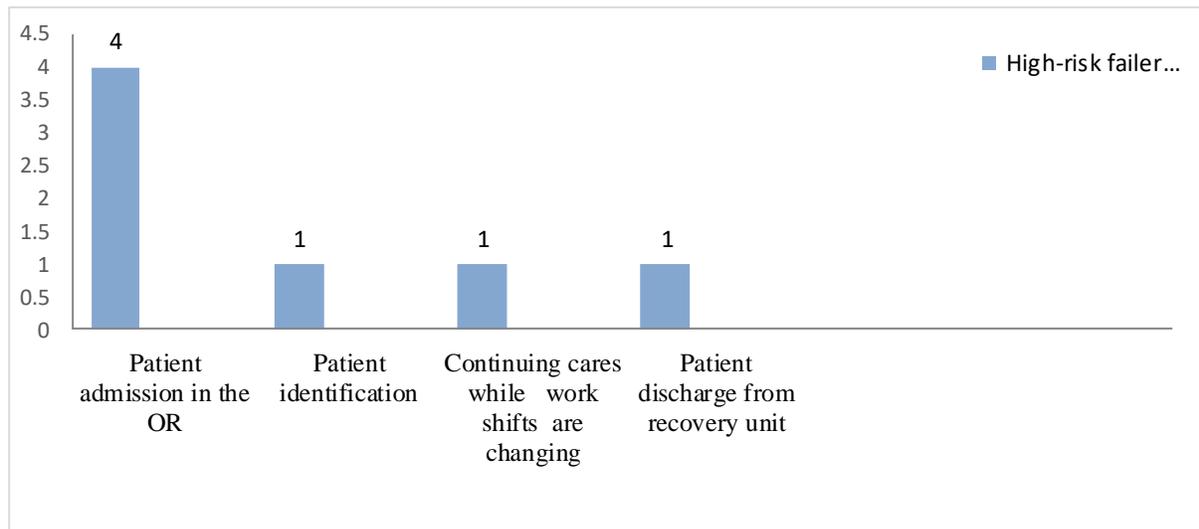


Diagram 2: Frequency of unacceptable failure modes in high-risk processes

Table 4: High risk failure modes and their reform efforts

Process name	Error mode	D	O	S	Corrective measures based on priority
Receiving the patient in the operating room	the delivery of several patients simultaneously	3	5	3	1. prioritizing the surgery list from pre-surgery day by surgical assistants 2.Coordination of surgical assistants with the charge of operating room to deliver the patient from the ward 3. coordination of surgery section with the operating room to send the patient to the operating room
Reception and triage of the patient in the operating room	Wrong bracelet	4	5	3	1.Considering several stumbling block for checking patient file (the head of the sector, the first person- the nurse of the sector, the second person-paramedic, the third person) 2.Determining the policies in surgical wards for patients who are hospitalized for more than a day and they bracelet is corrupted or missing
Reception and triage of the patient in the operating room	failure to communicate effectively with the patient	5	3	3	1. Learning to communicate effectively with patients in hospital periodical trainings and in-sector conferences 2. Employing people with high ability to communicate with patients
Reception and triage of the patient in the operating room	and failure to mark of the surgical site	4	5	4	1.Determining appropriate of this policy action in cooperation with the operating room, surgical wards and improvement quality unit 2. Giving information to the wards and surgical assistants of each group 3. Giving information of unexecuted cases through the sheets of failure records
Patient identification	failure to match the patient file with the statements and the patient's bracelet by the anesthesia technician	4	5	4	1.Accuracy in filling the safety surgery checklist by anesthesia technicians 2. Recording each patient's identification in the available panel in each operating room
Continuity of cares in changing the	failure to check the general condition and connections of the patient	3	4	3	1. Correction of the time for the movement of hospital bus services in line with the correct timing, delivery of the patients to the nurses of the next shift 2. Training for the SBAR technique
Patient discharge from recovery	and lack of accountability of a sector or accountability of an irresponsible person	5	3	3	Providing staff to convey patients to the operating rooms in all days in order to transfer the patients to the surgical wards in time and paying attention to paraclinical measures needed by the patients after surgery

DISCUSSION:

In the present study, from among the seven identified unacceptable failure modes, five modes were in the pre-surgery stages and among the high-risk modes of pre-surgery, 4 cases were in the process of patient admission in the operating room. Thus, among the processes of the operating room in the studied hospital, patient admission was known as a process which has the highest probability rate for the occurrence of high-risk failures. Patient admission is one of the most important pre-surgery processes and has a great effect on other operating room processes. Four unacceptable and high-risk failure modes were observed in this process, justifying the need for implementing the corrective measures. Marjamma et al [22], emphasized the accuracy in the process of patient admission and the correction of high-risk areas related to this process. The high-risk failure modes of the patient admission process were placed in the categories of human and procedural causes with the root analysis of unacceptable modes by the fishbone diagram. Regarding the role of staff in the implementation of patient admission process in the

operating room, continuous and periodical training of the staff, employment of skilled staff highly capable of communicating with the patients and improving the high-risk points were considered as corrective measures [23]. The process of identifying the patient in the operating room is one the main processes in the operating room ward whose accurate implementation can result in the right surgery for the right person and in the right area [24]. Any defect in this process will have irreparable damages for the patient as well as many legal consequences for the surgical team [25]. This process has been placed in the stage of pre-surgery measures and is closely connected to the process of patient admission in the operating room. Also, to correct the implementation of this process, various stages must be identified: the patient, the type of surgery, and the surgical site. Lack of accuracy in each stage can lead to a disturbance in the process of identifying the patient [26]. By analyzing the failure modes in the patient identification process in the operating room, a high-risk failure mode was detected which was placed in the category of human and procedural doing the root analysis by the

fishbone diagram. Moreover, the accurate completion of the checklist of safety surgery by the anesthesia nurses and recording each patient's identification in the available panel in each operating room were considered as corrective measures. From the viewpoint of Marjaama [22], offering periodical trainings can be recommended for the surgical and anesthetic staff due to the role of the staff in the implementation of patient identification process. One of the working principles in all health centers is the continuity of patient care throughout the treatment and hospitalization [27]. Van walraven et al [28], declared in their study that the optimal continuity of care is effective in improvement and satisfaction of the patients. In this regard, Kabanov et al, have recommended that nurses pay serious attention to the optimal cares needed by the patients during the shift changing time [23]. In reviewing the continuity process of optimal patients' cares covering the in- and post-surgery, an unacceptable failure was detected which was placed in the categories of structural and process problems using the root analysis by the fishbone diagram. In this regard, there were some suggestions including correcting hospital bus services move for best timing (considering of delivering recovery patients to the nurses of the next shift), the shift authorities supervising and finally training new techniques and methods such as SBAR, which is a simple and standard technique and a mental model for effective communication between nurses in the delivery of the patient. This can strengthen the team work and the safety of the patient [26]. Using this technique is has also been recommended in other studies and has been considered as corrective measure [30]. Mason et al, have recommended using the complete and organized clinical guidelines in the patient's discharge from recovery [29]. This failure mode was placed in the categories of structural, human and procedural with the root analysis by the fishbone diagram. Thus, using clinical guidelines such as Aldrete's criterion [31], which is used in discharging the patients from discovery, for discharging patients from recovery and providing special patient transporting staff in the operating rooms for everyday in order to transfer the patients to the surgical sectors in time, and paying attention to para-clinical procedures needed by the patients after the surgery were all considered as executable corrective measures.

CONCLUSION:

In order to improve the safety of patients during the surgery, we need to pay serious attention to the processes before starting the surgery. Also, using team work in the field of risk management can help establish the safety culture in special wards of a hospital.

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