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Original Article

Risk Assessment of Drug Management Process in Women Surgery Department of Qaem Educational Hospital (QEH) Using HFMEA Method (2013)

Reza Khani-Jazani[a], Yasamin Molavi-Taleghani[b], Hesam Seyedin[c], Ali Vafaee-Najar[d], Hossein Ebrahimipour[e*] and Arefeh Pourtaleb[b]

[a]Department of Ergonomics, Faculty of Health, Safety and Environment, Shahid Beheshti University of Medical Sciences, Tehran, Iran. [b]Student Research Committee, School of Health, Mashhad University of Medical Sciences, Mashhad, Iran. [c]Health Management and Economics Research Center, Iran University of Medical Sciences, Tehran, Iran. [d]Health Sciences Research Center, Department of Health and Management, School of Health, Mashhad University of Medical Sciences, Mashhad, Iran. [e]Research Center for Health Services Management, Institute for Future Studies in Health, Kerman University of Medical Sciences, Kerman, Iran.

Abstract

Evaluation and improvement of drug management process are essential for patient safety. The present study was performed whit the aim of assessing risk of drug management process in Women Surgery Department of QEH using HFMEA method in 2013. A mixed method was used to analyze failure modes and their effects with HFMEA. To classify failure modes; nursing errors in clinical management model, for classifying factors affecting error; approved model by the UK National Health System, and for determining solutions for improvement; Theory of Inventive Problem Solving, were used. 48 failure modes were identified for 14 sub-process of five steps drug management process. The frequency of failure modes were as follow :35.3% in supplying step, 20.75% in prescription step, 10.4% in preparing step, 22.9% in distribution step and 10.35% in follow up and monitoring step. Seventeen failure modes (35.14%) were considered as non-acceptable risk (hazard score≥ 8) and were transferred to decision tree. Among 51 Influencing factors, the most common reasons for error were related to environmental factors (21.5%), and the less common reasons for error were related to patient factors (4.3%). HFMEA is a useful tool to evaluating, prioritization and analyzing failure modes in drug management process. Revision drug management process based focus-PDCA, assessing adverse drug reactions (ADR), USE patient identification bracelet, holding periodical pharmaceutical conferences to improve personnel knowledge, patient contribution in drug therapy; are performance solutions which were placed in work order.

Keywords: Risk assessment; Medication therapy management; Healthcare failure mode; Effects analysis.

Introduction

Patient safety is one of the main components in quality of health care (1) and it is considered as the final goal of health care organization improvement programs (2). Medical errors are considered serious problems of health system and a threat to patient safety (3,4). Therefore; patient safety and its maintenance are essential

* Corresponding author:
E-mail: ebrahimipourh@mums.ac.ir

concerns in systems provide health care (5).

Surgical departments based on organizational, environmental and educational needs are one of the most high risk hospital wards (6). One of the most common clinical errors in them are drug errors, which based on patient safety audit commission, is the second common event in the world (7). Drug errors may occur in any steps of providing drug process and cause serious harms to hospitalized patients (1, 8).

The incidence of drug errors has been reported differently between 2-14% (7). USA Medical Organization Institute announced that every year 44000-98000 medical errors occur, which more than half of them – almost 7000 cases- are drug errors (9). In 2006 drug errors had cost 3.5 billion dollars for health system (10). Bates *et al*., reported the frequency of medication errors in 5.3% of the orders. (11). Furthermore drug errors caused 6.5% mortality in hospitalized patients and increased hospitalization length for two days (12), while at least 38000 adverse events related to drug errors are preventable (13).

Adopting comprehensive and systemic risk management methods has strategic role in decreasing failure modes in surgical departments and reducing drug errors (14-16). One of the most accredited programs for risk management and error prevention introduced by the U.S. department of veterans affairs national center for patient safety is failure mode and effect analysis (17). Health care failure mode and effect analysis is in fact a prospective and systemic approach for identifying failure modes and preventing them before their occurrence, which is specially designed for health care organizations (18, 19). This method is suitable for identifying and prioritizing risks to improve patient safety and reducing probable errors before their occurrence (18, 20).

Since evaluating and improving drug management process is considered essential in patient safety (21), and the incidence of drug errors is index of efficacy or quality in drug distribution system (9), with considering the fact that there is not any study about probable incidence and reasons for drug errors in women surgery department, therefore we conducted the present study with the aim of assessing risk of drug management process in women surgery department of educational-therapy center of Qaem Hospital with Failure Mode and Effect Analysis method for health care (HFMEA) during 2013.

Experimental

Material and method

This research studied failure modes and effects based on HFMEA model with mix-method (qualitative action research- and quantitative -descriptive- cross sectional-). Study was performed during January to March 2013 on drug management process in woman surgery department of Qaem educational Hospital, Mashhad.

Qeam hospital as a general first degree hospital with 815 active beds, 18 departments, 7 emergencies, different clinics and Para-clinic services is one of the largest training-therapeutic centers in region and in country. Besides being a therapeutic center, this hospital is a medical training and research center which medical students are trained in that for specialty and subspecialty degrees.

This research used five steps of health care failure modes and effects analysis methodology which was presented by VA national center for Patients' Safety (17), however some modifications in performance were made duo to situation.

Step one: Define the HFMEA topic

Experts and specialists were interviewed and reported adverse events to clinical governance office in Qaem hospital were reviewed, and finally drug management process in woman surgery department was choose for analysis and was considered that it worth spending time and human resources.

Step two: Assembling the team

Ten persons were selected as the HFMEA team members including responsible person for risk management (team leader), one expert in health care management (consultant), supervisor, and department manager (assistant professor), resident, two nurses, secretary, technical head

Table 1. Hazard score and priority matrix.

Intervention level	Severity / Probability	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Critical	Frequent (4)	16	12	8	4
Programming	Occasional (3)	12	9	6	3
Programming	Uncommon (3)	8	6	4	2
Monitoring	Remote(1)	4	3	2	1

of pharmacy, and pharmacy manager(specialist team members).

Step three: Graphically describing the process

In this step drug management process were designed based on observation and personal interview. The validity of processes and sub-processes flow were assessed in a focus discussion group by team members and proper correction were made. The final process flow was designed by Visio.

Step four: Conducting hazard analysis which was done in 4 phases

First Phase

Determining the potential failure modes

In this phase failure modes for the sub-process of drug management process were identified based on triangle method (22) and were categorized based on levels of two following models: "Proposed model for reducing the patients' hospitalization duration"(23) and "Classifying nursing errors in clinical management (NECM)" model (24).

Second Phase: Determining the hazard score

The Hazard score was determined based on hazard scoring matrix (multiplying severity to probability of failure occurrence), and was registered in the HFMEA work sheets. The sum of failure mode severity scores according to team members' opinions and with considering weight for failure mode severity dimensions, and the sum of failure mode probability scores based on involved personnel opinion also with considering coefficient for each person, were calculated and documented in final worksheet. In this phase failure modes based on their scores in hazard scoring matrix were divided to four intervention levels;" emergency, urgent, programming and monitoring" (25) (Table 1).

Third Phase: designing decision making tree

The non-acceptable risks (risk score level more than 8) were transferred to decision tree. Decision for proceed or stopping each of failure modes were made based on three items; weakness points, Existing control and Detestability.

Forth Phase: in this phase factors that affect each of continues failure modes in decision tree were determined and were categorized based on approved model by the UK National Health System (26).

Fifth phase: Actions and Outcome Measures which were performed in two phases

Phase one, Description of Action: the suggested confronting strategies for each factor that affect failure mode were presented in accept, control or eliminate.

Second phase, Redesigning the process: action plan for improving each of failure modes were designed in team sessions with "Theory of inventive problem solving"(27), and its practicality was decided with considering organization resources.

The information for HFMEA worksheet items were collected through group discussion (five sessions, each two hours) and individual interview (six hours).

Results

For five steps of drug management process, 14 sub-processes and 48 failure modes were identified. Frequency percentage of each identified failure mode with regard to each step and in total, are presented in Table 2.

Table 2. Failure mode distribution in each sub-process phase in 4 priority matrix area and percentage of failure mode frequency to total process.

Process steps	Sub-process	Mode error	MAX RPN	MIN RPN	Emergency level (N)	Urgent level (N)	Programming level (N)	Monitoring level (N)	Mode error/step process(%)	Error mode/total process(%)
Supply of drugs by pharmacy Supplying)	Documenting drug shortage in HIS system by department	4	6	4	0	0	4	0	23.5	8.3
	Printing requested drug and sending it to pharmacy by department	2	6	4	0	0	2	0	11.7	4.1
	Drug preparation by pharmacy divided by departments	3	8	4	0	1	2	0	17.6	6.25
	Transferring requested drug by pharmacy	5	6	4	0	0	5	0	29.4	10.4
	Receiving requested drug by departments	3	6	4	0	0	3	0	17.6	6.25
Drug ordering & prescription	Drug administration by physician	5	9	6	0	1	1	0	50	10.4
	Reviewing and checking prescription by nursing staff	2	8	6	0	1	1	0	20	4.1
	Kardexing each patient prescription by nurse	3	6	6	0	0	3	0	30	6.25
Preparation	Drugs are placed in patients baskets based on drug card	5	12	6	2	2	1	0	100	10.4
Drug distribution & administering	Identifying patient by nurse	3	6	6	0	0	3	0	27.2	6.25
	The aim of prescribing drug and expected effects are described for patient by nurse	3	9	6	0	2	1	0	27.2	6.25
	Patient use drug under nurse surveillance	5	12	4	1	2	2	0	45.4	10.4
follow up & monitoring	Administrating drug by nurse is documented in nursing report	3	6	4	0	0	3	0	60	6.25
	Drug effects follow up and monitoring	2	8	8	0	2	0	0	40	4.1
	Total	48			3	14	31	0	100	100

In regard to "Proposed model for reducing the patients' hospitalization duration", 35.4% of failure modes were in category of "failure or mistake to do something", 18.75% were "laps or slips to do something", 14.58% was "time errors" and 31.25% were because of "lack of doing something". Table 3 presented categorized failure modes for drug management process based on model presented by "Nursing Error Management Society".

Altogether; 17(13.4%) of failure modes were identified as high risk and unacceptable failures (score higher than 8) and were transferred to decision tree.

Fifty one effective factors were offered; 10.7% related to organization factors , 9.6% related to team factors, 4.3% were in regard to patient and companion, 13.9% was related to staff, 15.03% task factors, 21.5% working condition factors, 5.3% equipment, 9.6% communication and 9.6% were related to education and training factors.

Recommendation actions for influencing factors of each error mode were presented in the form of acceptance (11%), control (64%), and elimination (25%).

Table 4 shows HFMEA worksheet for high risk and unacceptable failure modes (score higher than 9).

Table 3. Classification of failure modes (n = 48) in drug management process based on NECM.

Process steps	care process errors				Communication errors	Administrative processes errors	Knowledge and skill errors	N
	Clinical judgment errors	Clinical task execution errors	Technology applied/ required errors	Continuity of care errors				
Supply of drugs by pharmacy)supplying	2	6	3	0	7	4	2	24
Drug ordering& prescription	1	5	0	4	4	0	1	15
preparation	1	2	0	1	0	1	1	6
Drug distribution & administering	4	4	0	4	4	2	0	18
follow up & monitoring	0	2	0	2	2	0	0	6
TOTAL	8	19	3	11	17	7	4	69

Finally, improvement strategies for each failure mode were presented through "theory of innovative problem solving" by reengineering of process, continues surveillance on drug presses, preparing practical guidelines, developing performance evaluation indexes and performing periodical assessment with feedback to personnel, reducing work load and providing human resources, in depth analysis of events and reporting their critical results, improving team communication, electronic prescription, change in replacing drug shortage with Combing card, re-training drug calculation, pharmacology book revision, revision of patient identification method , improving condition of drug store, performing periodical drug conferences, increasing personnel knowledge about drug and proper route of administration, using dosage charts, and preparing new forms with defined places for proper documentation.

Discussion

This study with using health care failure mode effect analysis model, prospectively analyzed probable failure modes in drug management process, identified effective factors and determined improvement guidelines.

HFMEA as a method for assessing risk prospectively, enable us to recognize failure modes before any catastrophic events occur (18). The number of drug errors in 2012 in training hospitals of Spine reduced from 79.9% to 28.5% after implanting HFMEA preventive program (28). since the first step in reducing health care errors, is to identify the failure modes, a comprehensive model must be used to categorize all failure modes, and help to identify and compare them (29,30). However regarding to wide domain of failure modes in health care system, most of studies evaluated part of failure modes and a comprehensive model for categorizing failure modes is not existed so far. Therefore we used Nursing Error Management model to group failure modes in drug management process.

In present study 59.4% of failure modes were in group of care process errors, 24.6% in communication errors group, 10.14% in Administrative processes errors group, and 5.79% in knowledge and skill errors group. Study that was performed by Nursing Error Management society reported the most common failure modes in descending order as follow: care process errors 66%, communication errors 22%, Administrative processes errors 6%, and Knowledge and skill errors 5%, which are similar to our results (24). However their study was performed retrospectively and their results are not quite comparable with the results of our prospective study.

Our results showed that 35.3% of failure modes were related to supplying step, 29.75% were in administration step, 10.4% were in preparing drug step, 22.9% relate to distribution and usage, and 10.35% were in follow up and surveillance step. These results are in consistence with the result of Lago *et al.* study which was conducted at the neonatal department in the university hospital in Padua (31).

Table 4. HFMEA drug management process decision tree (Hint) E: elimination; C: control; A: accept).

Hazard Analysis										Action and outcome measures
		Scoring			Decision tree analysis					
Failure mode	Potential causes	severity	occurrence	Hazard score	Weakness point	Existing control measures	Detestability	Proceed?	Action type	Actions or rationale for stopping
Failure in writing prescription on the order form(illegible handwriting; transcription error and oral prescription)		3	3	9		No	No	Yes		
	a-lack of familitarity with protocols	3	3	9		No	No	Yes	C	Revising and developing standard therapy protocols- providing feedback of catastrophic events to staff- developing educational protocol from guidelines
	b-lack of awarness regarding importance of subject	3	2	6		No	No	Yes	C	Developing clear policies and performance methods and regular review ,periodical and continuous training for staff who provide services, launching an electronic prescription system- encouraging rational drug administration, periodical physician evaluation and giving feedback-
Lack of writen notes and/or spoken information about prescription		3	3	9		No	No	Yes		
	a-Lack of familiraty with priscription principls	3	3	9		No	No	Yes	C	Teaching prescription standards especially to medical students, continuous medical education and physician retraining, drug prescription based on protocols, promoting electronic prescription, evaluating physician prescription and giving feedback regarding mistakes
	b-long working hours, tiredness, and crowdness	3	4	12		Yes		No	C	Planning and managing work actions during work shift, arranging proper work shifts and avoiding long work shift
	c- unfamility if new physisian	2	3	6		No	No	Yes	C	Rechecking orders by physician, increasing medical students knowledge about pharmacology
not determinaning dose and frequency of administration		3	3	9		No	No	Yes	C	
	a-lack of attention to patient clinical condition	4	2	8		No	No	Yes	C	Developing guidelines for physician function evaluation based on found errors, periodical evaluation of physicians and giving feedback, effective communication with patients
	b-lack of knowledge and skill in new physician	4	2	8		No	No	Yes	C	holding periodical pharmaceutical conferences, encouraging personnel for asking what they don't know, training programs for physician at beginning of work and periodical, using standard references and charts for drug dosage, providing appropriate pharmacy book in department
	c-lack of department guidline for priscription	3	4	12	No			No	C	developing guidelines based on volunteers reporting system and though journal clubs
not preparing drug for each patient individually		3	4	12		No	No	yes		
	a-high work load	2	4	8		No	No	yes	C	reducing work hours and load, establishing stress management program, adjusting work load with human resources, dividing work
	b- uncomplying with protocols	3	3	9		No	No	yes	E	training adjustment with providing finance, training practical recommendation , developing guidelines for evaluating staff function based on found deficiencies
	c- lack of knowledge regarding subject importance	4	2	8		Yes	No	No	C	deep analysis of catastrophic events and giving feedback to personnel, informing personnel about proper prescription guidelines, encouraging personnel to ask when they have doubt

Table 4. Continue.

Mistake in placing patient drug in right basket		3	3	9		No	No	Yes	
	a-incompliance with patient identification standards	4	2	8		Yes	No	No	C	revising policies of patient identification, identifying patient by two nurses, , identifying patient by two IDs, developing guideline for staff evaluation based on found deficiencies
	b-lack of proper attention	3	2	6		No	No	yes	C	improving drug storage condition, removing factors that confound and mislead staff attention , encouraging nurses for increasing their enthusiasm
	c- lack of sufiecient survillence by the matron	3	2	6		Yes	No	No	C	giving feedback of errors to staff, periodical evaluation and intervention
	d-lack of knowledge and skill	4	2	8		No	No	Yes	C	encouraging physician and personnel to ask when they have doubt, training nurses at beginning of the work and periodically
	e- great variety of drug in department	4	3	16		No	Yes	No	A	improving drug storage condition, notifying staff about new drugs, standardizing and managing equipment s and drug shelves
Lack of identifying or controling type of drug in syringe during infusion and before storing it in the refrigerator		3	4	12		No	No	yes	
	a- lack of awarness regarding importance of subject					No	No	yes	C	deep analysis of catastrophic events and giving feedback to personnel, informing personnel about proper prescription guidelines, encouraging personnel to ask when they have doubt
	b-high work load					No	No	yes	A	adjusting work load with human resources, establishing stress management program, dividing work reducing work hours and load
Failure to explain to patients how to monitor their drug's administration		3	3	9		No	No	yes	
	a-incompliance with protocol	3	3	9		No	No	yes	E	developing guidelines for evaluating staff function based on found deficiencies, training adjustment with providing finance, training practical recommendation ,
	b-unjustfication of nursing staff	3	3	9		No	Yes	No	C	Training practical recommendation with pamphlet, , training programs for physician at beginning of work and periodically
wrong dose, time or frequency of drug administeration		4	3	12		No	No	yes	
	a-lack of proper nursing staff compared with patients	3	4	12		No	Yes	No	C	adjusting work load with human resources, establishing stress management program, dividing work reducing work hours and load
	b- lack of proper team work	3	3	9		No	No	yes	E	promoting team work though performing training sessions, holding staff who provide care responsible and accountable through developing clear and documented responsibility charts, evaluating process , coordination of medical team
	c- lack of awarness regarding importance of subject	4	2	8		No	No	yes	C	deep analysis of catastrophic events and giving feedback to personnel, encouraging physician and personnel to ask when they have doubt, informing personnel about proper prescription guidelines,
	d- lack of survillance	3	2	6		Yes		No	E	Continues surveillance of shift matron on work cycle in department, giving feed back to staff regarding errors

Helen Faye *et al.* in their study with using HFMEA model in drug management process found 54 failure modes in 7 steps of drug management, which 4 of them were introduced as high risk. Their results are not similar to our results which could be related to differences in culture and medical department.

In that study interventional levels of emergency, Urgent, programming, and monitoring for each failure mode, was predicted based on failure mode level. The advantage of this method is that considering lack of human resources, the correcting actions are performed on failure modes based on their interventional levels (25). Lage *et al.* also stated that determining intervention level is important in complex processes (31).

In Bonfant *et al.* study (25) 93 failure modes was diagnosed in dialysis center which 0% were in emergency intervention zone, 9.6% were in programming zone, 37.8% in programming zone, and 51.6% were in monitoring zone. These results are alike our results, in present study the frequency of failure modes in intervention zones in ascending order were programming, immediate and emergency.

In HFMEA studies appropriate to evaluated process, the score of unacceptable risks are different. In present study the failure modes with hazard score ≥ 8 were considered as unacceptable risks, and were chosen for finding their root causes. The used score for unacceptable risks in this study was in agreement with most of other studies that used HFMEA (32, 33).

Seventeen failure modes with unacceptable risks were determined in this study; most of failure modes (8 cases) were in group of not doing an action, which team members for most cases stated that environmental factors (including high load of work and crowded ward) and responsibility factors (including lack of definite protocol and method) as the main reasons for failure modes. Yamazaki and Seki in their study found a significant relation between long working hours, high load of work, low job experience and drug errors (34). Furthermore in Kositchaiwat study the most essential reason for drug error in outpatients was related to environmental factors with 24% frequency which is also similar to our results (35). On the contrary Pham *et al.* in their cross sectional study on the total drug errors, reported the most important reasons as follow: incompliance with protocols (17%), insufficient communication (11%), lack of team work (7.5%), emergency condition (4.1%), and sufficient increase in work load (3.4%) (36).

Present study results showed that most of failure modes are critical and without appropriate control system, therefore paying attention to them is important. In this regard some of suggested solutions based on theory of innovative problem solving are including auditing and reengineering drug management process, revision and updating the correct method of drug administration, evaluating adverse drug reactions (ADR), patient identification bracelet, holding periodical drug conference to increase personnel knowledge, patient contribution in treatment process, increasing surveillance and control systems, and improving the condition of drug store, were accepted as performing solutions in Qaem hospital. Implementing suggested strategies and actions is highly depend on team works and financial and performance supports by organization leaders as Duwe *et al.* showed in his study that successful implementation of prospective FMEA require strong, effective leadership and a sustained commitment of leaders (37).

Limitation

The real failure modes in HFMEA studies is not measurable and defined scores are based on people mind therefore a specific failure modes may receive different scores from different team members. To prevent bias caused by group effects in team sessions, individual interviews were performed with each of team members.

Furthermore determining high risk failure modes in each organization depend on organization and environmental condition. The results of HFMEA in one institute cannot be compared with other institutes because the frequency of failure modes and their severity is different even among different department of hospitals. Finally in HFMEA studies, it is hard to show that adverse events decrease after

implementing interventions like other qualitative approaches. In addition we cannot confirm improving patient safety and cost benefit with HFMEA programs (38).

Conclusion

Finding 48 possible failure modes, identifying 17 failure modes with unacceptable risk, finding their reasons and suggesting solutions are all pointing high capability of HFMEA in identifying, evaluating, prioritization and analyzing failure modes. Therefore considering the importance of identifying types of failure modes in health care system for implementing risk management, and because of lack of proper categorization of failure modes due to their variety, using HFMEA for other medical process is recommended. Finally the effectiveness of this method in implementing corrective actions was not confirmed by this study and requires further studies.

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