Proactive risk assessment of the laboratory management process in Ghaem Hospital, Mashhad (2013)

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ABSTRACT

Laboratory errors may occur in every stage of laboratory management process and lead to a considerable harm to inpatients. This study was aim to investigate the Proactive risk assessment of the laboratory management process in Ghaem Hospital, Mashhad (2013). This was a descriptive research that quantitatively and qualitatively analyzed some failure modes and effects. In order to classify the modes of failure and effective causes of them and also determining the improvement strategies, we have used "nursing error management association", "Eindhoven" and "theory of inventive problem solving" models respectively. In 5 steps of laboratory management process which is conducted on17 listed sub-processes, on average 59 error modes in each ward was identified. 18.7% of error modes were identified as high risk errors (hazard score ≥ 8). Most of error causes were related to human factors (42.7%).In addition, 31.6% of preventive measures were assigned in human resources management strategy group and 16.9% in team work group. The Healthcare Failure Mode and Effect Analysis method was very efficient in identifying failure modes, determining causes which impact each failure mode, and proposing improvement strategies for laboratory management processes of Ghaem Department.

Keywords: Risk assessment; Laboratory; Failure mode; Proactive

INTRODUCTION

Medical errors are considered as a serious problem in health system and a threat to patient's safety [1,2]. Laboratory errors were introduced as one of the most prevalent errors of healthcare system in medical council reports [3]. Performing laboratory test is a very complicated process [4]. According to laboratory management process, sample analysis process includes 3 main components: pre analysis, analysis and post analysis phases [5]. Laboratory errors may occur in every stage of laboratory management process and lead to a considerable harm to inpatients [6].

Results from a recent investigation indicates that while on average 46 to 68.2 percent of laboratory errors are related to the pre-analysis phase, 7 to 13 percent of them are related to analysis phase and18.5 to 47 percent are related to post analysis phase [7]. Results of a study showed that 95 % of the total 129 reported incidences of laboratory errors had led to harm to the patients [8]. According to estimations, almost one in 10 people who are admitted to hospital, experience an adverse event and about half of these events are preventable [9]. Adverse events have resulted in an extra expenditure of about 37 billion US dollars in America and one to two billion pounds in England [10].

Preventing treatment errors is one of the principles of quality in healthcare. During recent years many strategies have been used to reduce laboratory errors [6]. According to US accreditation commission for healthcare and national center for patient safety, Healthcare Failure Mode and Effect Analysis is one of the most reliable programs in risk management and preventing errors [11]. Healthcare Failure Mode

and Effect Analysis is a systematic and predictive strategy which is designed specifically for healthcare organizations to identify and prevent errors before they happen [12, 13]. This is a suitable method to identify and prioritize the risks in order to promote patient's safety and reduce potential errors in every system [12, 14]. Results indicate that during the past 60 years and after implementation of quality improvement programs, the rate of human errors in laboratory section has plummeted from16% to 0.04% [15]. Since the main concern of healthcare systems is preserving patients' safety [16] and clinical laboratory data are directly effective in medical diagnosis and treatment of patients and as a part of healthcare system are error-prone [6], this study is conducted in 2013 to assess the risk of laboratory management process in selected wards of Ghaem education and treatment center by HFMEA.

METHODS

This research studied failure modes and effects based on HFMEA model with mix-method(qualitative action research- and quantitative -descriptive- cross sectional-).. This study is conducted on laboratory management process in selected wards of Ghaem education and treatment center in Mashhad, from April to July 2013.

Ghaem as a general first grade hospital has 815 active beds, 18 wards and 7 emergency wards. It also has clinical and Para clinical services and is one of the largest education and treatment centers in the region and the country. This center is a medical education research unit and a training center for students in professional and super professional levels as well.

This research used five steps of health care failure modes and effects analysis methodology which was presented by VA national center for Patients' Safety (13), however some modifications in performance were made duo to situation.

Step1: Define the HFMEA topic

According to the opinion of 8 experts in Ghaem hospital and also adverse events which were reportedto clinical governance office in the center, the lab management process in 4 wards (ENT surgery, Emergency surgery, Pediatric emergency and Gynecology surgery) were chosen to be analyzed.

Step 2: Assembling the team

In this process, 10 individuals participated from each ward including head of risk management(team leader), coordinator of healthcare management (consultant), head nurse, head of department(assistant professor), resident (medical assistant), two nurses, secretary and laboratory technical manager (laboratory supervisor) were participating as members of HFMEA experts team.

Step 3: Graphically Describing the Process

In this step, the primitive diagram of laboratory management process was drawn by observation method and interview with experts to make horizontal integration in selected wards. Then, 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 4: Conducting Hazard Analysis which was done in 4 phases:

Phase 1: Determining the potential failure modes

In this phase, by means of triangle method [17], modes of laboratory sub-process errors in each selected ward was identified and by "nursing errors in clinical management model (NECM)"was classified. Nursing errors relating to clinical management (NECM taxonomy) is a toolused to describe contributing factors and patient consequences. The main categories are: nursing care process, communication, administrative process and knowledge and skill [18].

Phase 2: 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" [19]. (Table 1)

Phase 3: Designing decision making tree

The non-acceptable risks (risk score level more than 8)of each selected ward were

transferred to decision tree. Decision for proceed or stopping each of failure modes was made based on three items; weakness points, Existing control and Detestability.

Phase 4: in this phase, through cause and effect analysis sessions, effective causes of every continuous error mode in the decision tree are identified and they are classified by means of Eindhoven model.Eindhoven Classification Model (ECM) is a tool used to analyze the root causes of a broad set of unintended events. This distinguishes five main categories and 20 subcategories. The main factor category is: technical, Organizational, Human, Patient-related factor, Unclassifiable. [20]

Step 5: Actions and Outcome Measures which were performed in two phases:

Phase 1: Description of Action:

In this phase the suggested confronting strategies for effective causes of every error mode was presented in the form of acceptance, control and elimination of errors.

Phase 2: Redesigning the process:

In team sessions and by means of "theory of inventive problem solving" method [21], improving strategies for each cause of error mode was presented and it was decided about feasibility of implementing every strategy according to organization resources.

It should be mentioned that after achieving consensus by interview and group discussion (seven sessions of 2 hours at the end of each step), all information of HFMEA worksheet items were put together. The whole spent time for individual interview in all stages of the research was 8 hours.

RESULTS

In 5 steps of laboratory management process in each selected ward, 17 sub-process and on average 59 error modes were identified. The proportion of detected error modes for each activity and in every step and the whole process, are shown in table 2. On average 35 (59.3%) error modes of the laboratory process in selected wards were related to pre-analysis errors, 15 (25.4%) of them were related to sample analysis and 9 (15.2%) of them were related to post- analysis errors.

According to "nursing errors in clinical management model", 63.3% of laboratory management process error modes were assigned in the category of care process (15.8% errors in clinical judgment,

40.2% in Clinical task execution and 7.3% in Continuity of care errors), 10.9% assigned in communication error category (9.7% error in written communication and 1.2% error in verbal communication), 15.8% assigned in administrative errors (0% error in fail to bed management, 15.8% error in supervision and planning) and 9.7% of errors assigned in knowledge and skill errors (8.5% lack of knowledge and 1.2% lack of skill). Overall 2 (3.5%) error modes in ENT surgery, 19 (31.6%) error modes in Gynecology surgery, 14

(23.7%) error modes in emergency surgery and 9 (15%) error modes in pediatric emergency wards were identified and transmitted to the decision tree as high risk and unacceptable errors in laboratory management process (risk score ≥ 8).

In addition in table 3, classification of causes of high risk and unacceptable errors (risk score ≥ 8) according to Eindhoven model and in table 4, classification of strategies and preventive measures for causes of high risk error modes in laboratory management process (risk score ≥ 8) are shown. In table 5, due to the great number of high risk error modes (risk score ≥ 8), only unacceptable high risk error modes (risk score ≥ 12) are presented in HFMEA worksheet.

Table 1. Hazard score and priority matrix

	Intervention level
	emergency =level1
	urgent=level2
	Programming =level3
	Monitoring=level4

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

Table 2. Distribution of error modes according to matrix of intervention levels and proportion of error modes for every step to all error modes of laboratory management process

	stage	Process steps	No. of sub-process	Proportion of error modes of each step to all of errors in that ward %	Proportion of error modes of each step to all errors of the process %	Maximum error score	Minimum error score	emergency levels(N)	critical levels(N)	Programming levels(N)	Monitoring levels(N)
ENT surgery	Pre-analysis	Test request	6	17 (30.3%)	7.2%	6	1	0	0	6	11
		Sampling & sending	4	15 (26.7%)	6.3%	6	2	0	0	3	12
	analysis	analysis	4	15 (26.7%)	6.3%	6	4	0	0	13	2
	Post analysis	Result issuance	1	4 (7.1%)	5.9%	9	6	0	2	2	0
		Report to physician	2	5 (8.9%)	2.1%	6	2	0	0	2	3
surgery	Pre-analysis	Test request	6	19 (31.6%)	8.08%	12	2	1	3	13	2
		Sampling & sending	4	17 (28.3%)	7.2%	9	4	0	8	9	0
	analysis	analysis	4	17 (25%)	6.3%	12	6	1	1	13	0
	Post analysis	Result issuance	1	4 (6.6%)	1.7%	12	9	2	2	0	0
		Report to physician	2	5 (8.3%)	2.1%	9	6	0	1	4	0
Pediatric emergency	Pre-analysis	Test request	6	19 (31.6%)	8.08%	9	2	0	3	14	2
		Sampling & sending	4	17 (28.3%)	7.2%	9	3	0	1	15	1
	analysis	analysis	4	15 (25%)	6.3%	9	6	0	2	13	0
	Post analysis	Result issuance	1	4 (6.6%)	1.7%	9	6	0	3	1	0
		Report to physician	2	5 (8.3%)	2.1%	6	4	0	0	5	0
Emergency surgery	Pre-analysis	Test request	6	19 (32.2%)	8.08%	9	3	0	4	14	1
		Sampling & sending	4	16 (27.1%)	6.8%	9	4	0	3	13	0
	analysis	analysis	4	15 (25.4%)	6.3%	9	6	0	3	12	0
	Post analysis	Result issuance	1	4 (6.7%)	1.7%	9	6	0	3	1	0
		Report to physician	2	5 (8.4%)	2.1%	9	6	0	1	4	0

Note: This table describes the numbers concerning sub-process and failure modes identified for the 5 phases of the laboratory management process in selected wards .Also, the MAX and MIN hazard score were calculated for each phase.

Table 3. Classification of causes of high risk error modes according to Eindhoven model

error cause \ ward		ENT surgery	Gynecology surgery	Emergency surgery	Pediatric emergency	Total
technical	External	0	0	0	0	0
	Design	0	0	0	0	0
	Structure	1	3	2	2	8
	Material	1	8	3	3	15
organizational	External	1	2	6	5	14
	Transfer of knowledge	0	1	2	1	4
	Protocols	1	2	1	0	4
	Priorities management	0	3	1	1	5
	culture	2	6	3	2	13
2Human factors	External	1	1	6	5	13
	Knowledge based	0	1	3	1	5
	Competence	0	2	1	0	3
	Cooperation	0	0	3	3	6
	Evaluation	0	2	0	0	2
	Action	0	2	1	1	4
	Monitoring	1	7	4	3	15
	Slips	0	1	3	1	5
	falling	0	0	0	0	0
Other factors	Related to patients	0	3	0	0	3
	Unclassified factors	1	1	1	1	4
Total		9	46	40	29	124

Table 4. Classification of strategies and preventive measures for causes of high risk error modes (risk score ≥ 8)

strategy classification \ ward	Emergency surgery	Pediatric emergency	Gynecology surgery	ENT surgery	Total
Human resources management	44	32	51	11	138
Installation of electronic prescribing system	1	1	0	0	2
Making people accountable to patient's safety	7	5	15	2	29
Medical equipment management and process standardization	8	6	9	4	27
Improvement of patient identification process	6	6	8	0	20
Making clear and transparent policies and procedures	9	2	9	5	25
Making sure about availability of suitable technology for quality improvement	3	8	4	0	15
Continuous training and briefing care providers at the beginning of employment	16	0	13	2	31
Participating patients in treatment process	1	12	8	1	22
Implementing and monitoring suitable changes in clinical processes based on analysis of reliable data	13	2	12	0	27
Promotion of communication amongst treatment team members	2	22	1	1	26
Team work	22	22	28	2	74
Total	132	118	158	28	436

Table 5. Healthcare failure mode and effect analysis worksheet for laboratory management process in selected wards

Risk analysis									**Identification of actions and indices**	
Error modes	Probable causes	scoring			Analysis of decision tree			Analysis continuance	Type of action	Suggested strategies or reasons of cessation
		severity	occurrence	hazard score	Weakness point	Existing control measures	Detect ability			
Repetitive requests of physician from patent for laboratory tests	→	3	4	12	➡	No	No	Yes		
	1)Lack of supervision on medical residents' work	3	3	9	➡	No	Yes	No	eliminate	1)periodic monitoring & evaluation of residents 2)investigating competence of team leader and responsible persons 3)coordination between treatment team & residents 4) holding initial and periodic tests of competence & improvement for care providers
	2)lack of awareness of results of previous tests	3	3	9	➡	No	No	Yes	eliminate	1)clear signing and sealing by reports registrar 2)review of policies and procedures in hospitals 3)providing supportive infrastructures 4)monitoring the process procedure 5)information sharing amongst treatment team
	3)mismatching of test results with patient's clinical situation (rechecking the test results)	3	4	12	➡	No	No	Yes	control	1)monitoring clinical plans 2)regular calibration of medical equipment 3)identification of care providers' weaknesses and planning corrective interventions to resolve identified failures
Delay in initiation of testing the samples in laboratory	→	3	4	12	➡	No	No	Yes		

	1)crowded laboratory	3	4	12	➡	No	Yes	No	acceptance	1)reducing the workload and creating shift table and preventing successive shifts 2)providing extra work force 3)fitting the workload with number of human forces 4)coordinating the treatment team and establishing stress management
	2)lack of awareness of importance of the issue	3	3	9	➡	No	No	Yes	control	1)holding briefing sessions at the beginning 2)appoint a leader or head for the team 3)sharing the information with treatment team
	3)lack of supervision of technical manager on procedures	3	3	9	➡	No	No	Yes	control	1)periodic monitoring and evaluation of laboratory ward 2)checking the competence of team leader or the responsible person 3)monitoring temporal sequence of process
Delay in or failure to register the test results	→	4	2	8	➡	No	No	Yes		
	1)test characteristic (culturing positive samples)	3	4	12	➡	No	Yes	No	acceptance	1)providing a protocol about time scales for fungal and bacterial tests and offering that towards 2)sending emergency samples to laboratories out of hospital
	2)fail to analyze the sample due to sample problems	3	3	9	➡	No	Yes	No	control	1)promotion of personnel awareness of correct method of sampling 2)notifying the true way of sampling by technical manager
	3)high workload	3	4	12	➡	No	No	Yes	control	1)reducing the workload & creating shift tables & preventing successive shifts 2)providing extra work force 3)fitting the workload with number of human forces 4)coordinating the treatment team & establishing stress management
3)Mistake in registration of test results by laboratory	→	3	3	9	➡	No	No	Yes		

	1)high workload & employees' fatigue	3	4	12	➡	No	No	Yes	control	1)planning and managing actions during a work shift 2)division of labor 3)creating the shift tables & preventing long shifts
	2)lack of enough experience	3	2	6	➡	No	No	Yes	control	1)investigating & controlling activity & checking the final test results by technical manager 2)policy making for introducing new personnel with standards of the ward

DISCUSSION

In this study, by using a preventive method of "healthcare failure mode and effect analysis" we have worked on identification of probable errors and effective causes of every error mode and determining the improving strategies of laboratory management process in selected wards. On average, 35 (59.3%) of laboratory process error modes in selected wards were related to pre-analysis errors, 15 (25.4%) were related to sample analysis errors and 9 (15.2%) of them were related to post analysis errors. This result is consistent with Dunn and Moga study results. In a study Dunn and Moga performed the root analysis of laboratory errors from 2000 to 2008 and found out that from 253 reported catastrophic events, 150 (59%) were related to pre-analysis errors, 68 (27%) were related to sample analysis errors and 35 (14%) of them were related to post analysis errors [22]. The Results of Hammering's[7] study, in which he has done a literature review on laboratory errors, is consistent with results of the present study too. Since the first step in reducing healthcare errors is identification of them, a comprehensive model should be created to classify various error modes and facilitate cause identification and comparison of error modes [23,24].

In the present study, according to classification of nursing error management model, on average 63.3% of laboratory management error modes in selected wards were classified as care process errors, 10.9% as communication errors, 15.8% as administrative errors and 9.7% were classified as knowledge and skill errors. In a study conducted by "nursing errors in clinical management model", most of the errors were classified care process errors (66%), communication (22%), administrative (6%) and knowledge (5%) categories [19]. Since the study conducted by nursing error management association is retrospective and in our research we have prospectively identified and classified laboratory management errors, it is not possible to compare results with each other.

In this study, the frequency percentage of error causes, according to Eindhoven model, showed that 50.7% of error causes are in the group of latent errors and subgroups of technical factors (18.5%) and organizational factors (32.2%) and 48.3% of error causes are in the group of obvious errors and subgroups of human factors (42.7%) and the other causes (5.6%).

Smith's study in surgery ward showed that according to Eindhoven model, 72.3% of error causes are related to human factors, 16.1 % are related to organizational factors and 5.7% are related to technical factors [25]. In affirmation of this subject, results of Snijders et al.'s study in NICU ward indicated that according to Eindhoven model, 64% of error causes are related to human factors, 9% to technical factors, 22% to organizational factors and 3% are related to patient factors [21]. From this aspect that human factors are causes of most of incidences, results of the present study is consistent with Snijders et al.'s study.

In this study, most of the preventive measures of laboratory management process in selected wardsare assigned in human resources management strategy (31.6%) and team work (11.9%) groups.

Human resources management strategies are basic approaches that help organizations to shapeindividual's skills, attitudes and behaviors so that they can reach optimum performance to achieveorganizational goal [26, 27]. By means of this strategy, senior managers of health sector can identifyand develop approaches related to manpower [28]. In addition, team work strategy is an approach topromote association and communication between health sector personnel

who work independently to improve care providing to patients [29]. Shostek and his colleagues and US accreditation commission for healthcare and also national centerfor patient safety believe that achieving patient safety depends on team work [30, 31]. In Wong,Beglaryan[28]and Nasiripour [32] opinion, utilization of human resources management strategy is the most important approach to improve patient safety and reduce clinical errors . Finally it should be mentioned that implementing strategies and suggested measures, are highly dependent on team work and administrative and financial support from organization leaders. Duwe et al.'s study showed that successful performance of prospective risk assessment programs are related to effective and strong leadership and continuous commitment of the manager [33]. From suggested strategies, "theory of inventive problem solving", "root analysis of events and reporting critical results", "continuous supervision and procedure control", "improvement of team communication", "creating equipment maintenance checklist and equipment management", "matching workload with staff", "process simplification and elimination of unnecessary steps", "fundamental upgrade of software to register physician's test order", " determining the critical scales for tests" and "introducing a reference laboratory to randomly do some of the important tests in duel form (by hospital laboratory and the reference laboratory)" as strategies of improvement in process of performing, sending and result follow up in all selected wards will place on the agenda. HFMEA will lead to allocation of resources to problematic parts of the process [34]. But determination of high risk errors of every organization is based on its environmental and organizational atmosphere. Since frequency of errors and their severity even in the similar units of various hospitals is not the same, we cannot compare the results with other institutions. Like other qualitative approaches, in HFMEA studies, it is hard to show the reduction of adverse events after intervention. Therefore we cannot prove the promotion of patient safety and analyze the cost effect by HFMEA [35].

CONCLUSION

Identification of 235 potential error modes and 44 high risk and unacceptable error modes from identified errors, performing cause detection by means of Eindhoven method and offering corrective measures, indicates that HFMEA has a high capacity in detection, assessment, prioritization and analysis of laboratory management risks in selected wards.
Considering the necessity of healthcare error detection for establishing risk management and also failure in classification of errors in preventive method due to diversity of errors, it is suggested to use HFMEA method in other treatment processes too. Ultimately, efficacy of the mentioned method in the level of performing corrective measures is not examined in this study and some more investigations are needed to be done on it.

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