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Original Article

Health Care Failure Mode and Effect Analysis: A Useful Proactive Risk Analysis of Nutrition and Food Distribution in Mashhad Qaem Hospital's Women's Surgery Ward in 2013

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A B S T R A C T

Background and Objectives: Good medical nutrition therapy (MNT) is crucial to inpatients' health and treatment, and is part of routine hospital cares. Surgery ward is a highly danger-prone section in any hospital. The present study was conducted for a proactive risk analysis of nutrition and food distribution in Mashhad Qaem Hospital' Women's Surgery Ward in 2013 through health care failure mode and effect analysis (HFMEA).

Materials and Methods: A qualitative-quantitative research identified and analyzed the failure modes and effects through HFMEA. To rank error modes, we drew upon nursing errors in the clinical management model; to rank the effective causes of failure, we approved the model by the UK National Health System; and to rank the performance improvement approaches, we used the theory of inventive problem solving, TRIZ (theory of inventive problem solving).

Results: A total of 42 failure modes were identified for 15 sub-processes listed in 7 processes of nutrition and food distribution. In sum, 11.9% of the failures modes were classified as high risk (hazard scores >=8). Of 15 effective failure modes, the highest number of cause failure modes was associated with team factors, and the lowest number was associated with facilities.

Conclusions: Using proactive HFMEA is highly effective in detecting potential failures in medication, effective factors in failure modes, and performance improvement approaches in hospital food distribution. 'Monitoring proper patient-wards relationship,' 'committee establishment on diet, nutrition and medications,' 'performance assessment checklist making' and 'supervising by nutrition authority over food distribution in wards' were identified as effective performance approaches in the Women's Surgery Ward in Qaem Hospital.

Keywords: Risk analysis, Nutrition, Women's Surgery Ward

Introduction

Medical failure poses a real threat to both the health system and the patients' health. It is likely to happen in all diagnosis and treatment stages, which is often costly, and reduces the quality of life (QOL) of patients (1, 2). Good medical nutrition therapy (MNT) is crucial to inpatients' health and treatment, and is part of routine hospital cares (3). Many inpatients do not receive enough food when hospitalized; therefore, they may lack necessary proteins and energy, with consequent side-effects including weight loss, movement problems, elongated treatment period, and the risk of ulceration (4). The issue of food security and safety in health is quite different from food safety in the commercial environments; thus all high-risk foods should be eliminated from the hospitals' food preparation cycles (5).

Estimations have shown that one out of every 10 inpatients admitted to hospitals experiences bad events, and almost half of which can be prevented (6). Scotland Health Department has reported a high rate of growth in food waste in hospitals, soaring up from 8.9 % in 2008 to 10.7% in 2009 (7). Another study found that more than 40% of the inpatients admitted to the hospitals suffer from

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malnutrition, which becomes even more serious in 20-30 % of cases (8). Malnutrition in hospitalized patients is a critical issue, and has been associated with a significant increase in morbidity and mortality. Worldwide studies have indicated that 30% to 50% of hospitalized patients suffer from some degrees of malnutrition (9).

Quality improvement and inpatient safety provided an impetus to quality improvement programs in health care. In all of these improvement plans, failure prevention and risk management approaches were pivotal in establishment, implementation, and operation of the management systems in organizations (10). According to the US National Patient Safety and Accreditation Commission, health care failure mode and effect analysis (HFMEA) is a leading proactive risk management tool (12). HFMEA is, in fact, part of a proactive systematic approach to identify and prevent failures before they occur. It has been specifically designed for use in health and treatment organizations (13).

Surgery ward is a highly risk-prone hospital environment in terms of treatment, training, and technology requirements (14). About 234 million surgery operations are carried out in the world annually (15, 16). Surgical patients are often malnourished, which, in severe cases, is known to increase morbidity and mortality (16). Application of a systematic and comprehensive method in surgery wards will bring tangible results; however, even in the industrial nations, failure prevention is not properly addressed or carried out (17).

As surgery ward is very important in a hospital, since performance in this ward is highly effective in inpatients' evaluation of quality service and their satisfaction, and since proper food distribution and patients' nutrition are important in medication, patients' evaluation would be affected by the performance in the ward (18). Therefore, we conducted the present study with the aim of assessing the possible risks of nutrition and food distribution in Mashhad Qaem Hospital's Women's Surgery Ward in 2013 through HFMEA.

Materials and Methods

The present qualitative (case) – quantitative (descriptive-cross sectional) study analyzed the failure modes and effects through HFMEA, and examined the food distribution and nutrition processes in the Women's Surgery Ward of Mashhad Qaem Hospital during March 21 to late May 2013. Data gathering was done through focus groups, individual interviews, observation and brain storming. The reliability of the interviews was tested and confirmed by employing HFMEA (failure potential severity and probability), and data validity was controlled by the consensus of team members at the end of each phase.

This research used five steps of HFMEA methodology, which was presented by VA National Center for Patients' Safety (12); however, some modifications in performance were made due to situation.

First step: *High-risk process selection*

Experts and specialists were interviewed and the adverse events reported to the clinical governance office in Qaem Hospital were reviewed. Finally, nutrition and food distribution process in Woman's Surgery Department was chosen for analysis, and it was considered that it is worthy to spend time and allocate human resources.

Second step: *Assembling the team*

In this process, a multidisciplinary team of 10 people was established, which consisted of a risk manager (the team head), health and treatment services management expert (adviser), an specialist physician and his aid (a resident), a head nurse, two nurses, nutrition expert, hospital's kitchen head and his aid (specialist team members).

Third step: *Graphically describing the process*

In this step, the team first developed a flow diagram of the process by identifying the main processes and sub-processes. Then, in a discussion session, the team members corrected and verified the processes' and sub-processes' overall flow.

Fourth step: *Conducting hazard analysis*; this was done in 4 phases:

The first phase was to identify the potential failure modes. The failure modes in nutrition and food distribution sub-processes were identified through triangulation (one group discussion session, one session of reflection, and one session of document analysis) (19), which were ranked according to classifying the nursing errors in clinical management (NECM)" model. According to this model, failure modes fall in four major ranks (health care failure, communication failure, executive failure, and skills-related failure) (20).

The second phase dealt with scoring the failure modes. Scores of each failure mode were determined by the hazard scoring matrix (the product of severity and probability of a failure mode), and recorded in the HFMEA worksheet. Severity was rated as follows: *(catastrophic event—could cause death or injury), (major event—causes a high degree of customer dissatisfaction), (moderate event—can be overcome through modifications to the processes with minor performance loss), and (minor event—would be noticeable to the customer and would not affect the service delivery).* Also probability was rated as: *(frequent—may occur several times in one year), (occasional—may occur several times in one to two years), (uncommon—may occur once in two to five years), and (remote—may occur in five to 30 years)* (12). In this phase, the failure modes were divided into four intervention levels according to the scores given by the scoring matrix (*emergency 1; urgent 2; programming 3; and, monitoring 4*) (Table. 1) (21).

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Table 1. Failure mode and intervention scoring matrix

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

The third phase was to draw a decision tree. Routing high-priority failures (with the risk levels above 8) to decision tree and making decision to either to accept the failure mode or eliminate it were carried out according to three components (*weakness points, existing control and detestability*). In this phase, effective causes for any ongoing failure mode in the decision tree were identified through cause-and-effect analysis. Effective causes of all failure modes were identified and ranked according to the model approved by the UK National Health System (22).

In the **fifth step**, we identified failure control strategies. The recommended prevention strategies for effective cause of each failure mode were made as to eliminate, control or accept the failure mode causes. The next step was to redesign the processes. Improvement approaches for any failure mode were presented in a group discussion through inventive problem solving (TRIZ) (23), and the practicality of any approach was decided upon according to the organizational resources.

It is worth noting that all data related to the items in the HFMEA worksheet were collected through group discussion and interview (five two-hour sessions at the end of each step). A total of 7 hours were dedicated to individual interviews.

Results

For 15 sub-processes listed in the 7 steps of nutrition and food distribution, we identified 42 failure modes. 26.1 % of the failure modes related to diet services and nutrition treatment; 9.5 % to inpatient individual diet; 16.6 % to food request from the nutrition ward by the Surgery Ward; 11.9 % to food preparation in the hospital kitchen; 7.1 % to food distribution from the Kitchen to the Surgery Ward; 11.9 % to food delivery to the inpatients in the ward; and 16.6 % to food distribution to the inpatients (Table 2).

A total of 5 (11.9 %) as high-risk and thus unacceptable failure modes (with risks higher than or equal to 8) were identified in nutrition and food distribution and transferred to the decision tree. Among the 15 effective causes detected in the high-risk failure modes of the decision tree, 26.6 % related to team factors; 20 % to organizational factors; 20 % to communication factors; 13.3 % to duties; 6.6 % to staff; 6.6 % to environment; and 6.6 % to facilities and technologies. Table 3 gives the HFMEA worksheet for high-risk and unacceptable errors (with risk values higher than 8 points).

Table 2. Frequency distribution of failure modes in processes, sub-processes, and high-risk failure modes in each zone of hazard scoring matrix for food distribution and nutrition in Women's Surgery Ward

Steps	Sub-process frequency	Failure mode frequency	Maximum hazard score	Minimum hazard score	Intervention level frequency				Failure mode frequency based on nursing errors management association model			
					Emergency	Urgency	Programming	Monitoring	Care failure	Communication failure	Administrative failure	Skill and knowledge failures
Demand for diet therapy and advising	3	11	9	2	0	1	8	2	11	6	1	0
Patients' diet specification	2	4	6	4	0	0	4	0	7	0	0	0
Demand for food from nutrition section	2	7	6	4	0	0	7	0	6	2	2	1
Food preparation	3	5	9	4	0	2	3	0	4	0	3	1
Patients' food transfer	1	3	8	3	0	1	1	1	3	0	1	0
Food delivery	2	5	8	2	0	1	2	2	4	1	2	1
Food distribution among patients	2	7	6	3	0	0	6	1	4	3	2	0
Total	15	42	9	2	0	5	31	6	39	12	11	3

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Table 3. HFMEA worksheet for high-risk failure modes (>=8)

Hazard analysis										Actions and outcome measures
		Scoring			Decision tree analysis					
Failure mode	Potential causes	Severity	Probability	Hazard score	Weakness points	Existing control	Detestability	Continuing the analysis	Action type	Recommended actions or reasons for stopping the analysis
Failure to bring the case to the dietition and self-sufficiency	→	3	3	9	↳	No	No	Yes		
	1)Lack of responsibility and care over patient	3	2	6	→	No	No	Yes	Controlled	1) Examine the qualifications of official(s) for diet; 2) supervision by higher authorities over the clinical services; 3) regular evaluation of the dietitian's performance; 4) preparation of a duties' worksheet and taking responsibility over the duties
	2) Lack of enough awarness of the issue	3	2	6	→	No	No	Yes	Controlled	1) A general review of and standardization of policies; 2) requiring the nursing staff to be responsible about the patients' safety; 3) higher management's commitment to promote the culture of patient safety
Inconsistency in the		3	3	9	→	No	No	Yes		
number of demanded food with the ward's patient number	1) Carelessness in registering statistics by the ward secretary	3	2	6	→	No	No	Yes	Eliminated	1) The head nurse controls consciousness of the service providers;2) reduced workload and preventing the subsequent shift work for the nurses through shift change; 3) providing a safe and standard workplace; 4) supervision over the processes by the ward director
	2) Patient reception at the final hours of shift work	3	2	6	→	No	No	Yes	Controlled	1) Coordination among the treatment team members; 2) sharing and reporting patient reception; 3) food preparation in additional amounts for emergency circumstances
	3) Poor supervision over the processes in the ward	3	2	6	→	No	No	Yes	Controlled	1) Regular supervision by the shift official over the ward activities; 2) providing feedback to the staff in case of pitfalls; 3) surveillance over the processes
Lack of conrol over the food received by the patients	→	3	3	9	→	No	No	Yes		
	1) Kitchen official and dieteition do not sufficiently supervise over food distribution	2	2	4	→	No	No	Yes	Controlled	1) Regular supervision by dietician over the patients' diet and over the distributed food; 2) feedback to the staff about pitfalls; 3) surveillance of the processes; 4) coordination and sharing of information between the ward and kitchen

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	2) Insufficient raw material	3	3	9	→	No	Yes	No	Eliminated	1) Allocation of more resources to the hospital kitchen; 2) polling the patients and staff on the kitchen disorders, and preparing necessary interventions based on the results of polling; 3) introducing changes into the work agreements
	3) The dietitian does not lend importance to food quality	3	2	6	→	No	No	Yes	Controlled	1) Examine the qualifications of the official for diet; 2) supervision by higher authorities over the clinical services; 3) regular evaluation of the dietitian's performance; 4) preparation of a duties' worksheet and taking responsibility over the duties
Poor qualiy and quantity in food distribution	→	2	4	8	→	No	No	Yes		
according to the ward statistics	1) Thee staff distribute food carellessly	3	2	6	→	No	No	Yes	Controlled	1) The head nurse controls consciousness of the service providers; 2) reduced workload and preventing subsequent shift work for the nurses through shift change; 3) providing a safe and standard workplace; 4) supervision over the processes by the ward director; 5) patient identification process while the food is distributed.
	2) The ward secretary does not record the number of patients acurately	3	3	9	→	No	No	Yes	Eliminated	1) The head nurse controls consciousness of the service providers;2) reduced workload and preventing subsequent shift work for the nurses through shift change; 3) providing a safe and standard workplace; 4) supervision over the processes by the ward director
	3) The kitchen official and dieteition do not sufficiently supervise over food distribution	3	2	6	→	No	No	Yes	Controlled	1)Regular supervision by the dietician over the patients' diet and over the distributed food; 2) feedback to the staff about pitfalls; 3) surveillance of the processes; 4) coordination and sharing of information between the ward and kitchen
	4) Lack of coordination between kitchen official and dietitian	3	2	6	→	No	No	Yes	Controlled	1)Evaluation of qualifications of the team leader; 2) clear and well-written duties' worksheet, which is signed by the individual members.
The distributed food lacks sufficient quality and quantity based on the patients' diet	→	2	4	8	→	No	No	Yes		
	1) Agreement conditions in purchase of food ingredients	3	4	۱۲	→	No	No	Yes	Accepted	1) Allocation of more resources to the hospital kitchen; 2) polling the patients and staff on the kitchen disorders and preparing necessary interventions based on the results of polling; 3) supervision over the kitchen processes
	2) The kitchen does not know about the patients' diet	3	2	6	→	No	No	Yes	Controlled	1) Sharing the patients' diet information with the kitchen; 2) coordination between the dietician and the kitchen supervisor; 3) electronically recording the diets; 4) coordination among the treatment team members
	3) The dietitian does not supervise sufficiently over distributed food	3	2	6	→	No	No	Yes	Controlled	1) Regular supervision by the dietician over the patients' diet and over the distributed food; 2) feedback to the staff about pitfalls; 3) surveillance of the processes

Finally, 'effective supervision over the ward nurses and inpatient communication,' 'preparation of a training pamphlet and holding a session on food services to brief the inpatients,' 'purchase of protective lattice' 'purchase of packages facilitating food serving,' 'establishment of a committee for nutrition, diet, and medication quality', 'continued training sessions for the kitchen staff to improve their knowledge of the job', 'preparing checklists to evaluate kitchen performance', 'supervision by the nutrition authority on food distribution to the wards' and 'HACCP system implementation in Qaem Hospital's Nutrition Section' were recommended as improvement strategies for food request, distribution, and advising processes in the Women's Surgery Ward.

Discussion

The present study was conducted for a proactive risk analysis of nutrition and food distribution in Mashhad Qaem Hospital's Women's Surgery Ward in 2013 through HFMEA technique. Since, the first step in reducing errors in any health sector is to identify failures, a comprehensive model to rank failure modes is all but necessary so that failure modes could be compared and error causes detection could be facilitated (24).

In present study, 60% of the failure modes were in the group of care process errors, 18.4% in the communication errors' group, 16.9% in the administrative processes errors' group, and 4.6% in the knowledge and skill errors' group. The study conducted by the Nursing Error Management Society reported the most common failure modes in descending order as: care process errors 66%, communication errors 22%, administrative processes errors 6%, and knowledge and skill errors 5%, which are similar to our results (20). However, their study was performed retrospectively and thus the results are not quite comparable with those of our prospective study.

In the present study, we predicted the interventional level of emergency, urgent, program and monitoring according to the error scores. Lago et al. (25) found that predicting the intervention levels in complex processes is effective.

The failure mode frequency in the intervention levels was in program, monitoring and urgent, respectively. Bonfant et al. (21) found that of the total of 93 errors in Dialysis Ward, 9.6 % fell into urgent; 38.7 % into program; and 51.6 % into monitoring level; this finding is consistent with our findings here.

Failure modes with error scores higher than or equal to 8 were selected as unacceptable risks to identify effective causes, which are consistent with the scores of unacceptable risk reported in Tilburg et al. (26) through employing the HFMEA technique.

We also found that 11.9% of the errors detected required corrective measures, and addressing such errors was highly important.

One of the advantages of the use of HFMEA is to prioritize the effective causes of each failure mode (27). The present study revealed the most causes of error for team factors (26.6 %), communication factors (20 %), and organizational factors (20 %). Given the nature of the process, high number of admissions to Women's Surgery Ward, and limitations on communication between the Emergency Ward and the Kitchen, it is highly likely to find process failures in the communication and team factors.

In line with documentation for the impact of team factors in Women's Surgery Ward, Gilchrist and Franklin (28) suggested that 123 (57 %) of potential high-risk failure modes detected through HFMEA have roots in poor team cooperation and poor supervision over the process.

Working with HFMEA, Cilchrist et al. (29) mentioned that lack of information and communication were serious threats in an operation room, which provided evidence to highlight the role of organizational and communication factors. Bonfant et al. (21) drew upon Failure Mode Effect Analysis (FMEA) to detect the major cause of error in Dialysis Ward as being organizational issues, which is consistent with our findings in this study. Given the restrictions on resources at the disposal of any health organization, and since major high-risk errors are rooted in team and communication factors, 'effective supervision over the ward nurses and inpatient communication,' 'preparation of a training pamphlet and holding a session on food services to brief the inpatients,' 'purchase of protective lattice,' 'purchase of packages facilitating food serving,' 'establishment of a committee for nutrition, diet, and medication quality,' 'continued training sessions for the kitchen staff to improve their knowledge of the job,' 'preparing checklists to evaluate the kitchen performance,' 'supervision by the nutrition authority on food distribution to wards,' and 'HACCP system implementation in Qaem Hospital's Nutrition Section' are recommended as improvement strategies for food request, distribution, and advising processes in this hospital's Women's Surgery Ward.

It is to be noted that successful implementation of the recommended strategies is closely linked to individual participation as well as the financial and executive support by the organization leadership. Latino (30) found that even if an organization runs a proactive risk analysis for a high-risk process annually according to the validation standards, and if the organizational leadership does not support long-term safety improvement strategies, the results of the proactive risk analysis will be short-lived. Duwe et al. (31) indicated that successful running of

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proactive risk analysis is associated with strong, effective and committed leadership of the organizational head.

A possible weakness and limitation of any HFMEA study is that it is difficult to reduce the number of adverse events after introducing interventions like that in any other qualitative approach, and to the same level, it is difficult to improve inpatient safety and perform an opportunity-cost analysis through HFMEA technique (32).

Detection of high-risk errors in any entity is carried out according to the organizational milieu, and the results would be incomparable to those reported in other wards of the hospital as failure severity and probability are different even in similar wards of a hospital.

Conclusions

Detection of 42 potential failure modes and 5 modes with unacceptable risk, seeking the causes, and introducing corrective measures in the food distribution and advising process revealed the HFMEA technique's higher capabilities in identification, evaluation, prioritization, and error analysis. Combination of 'voting according to ranking,' 'error ranking according to the Nursing Error Management Association model', and 'ranking of high-risk failure causes using Eindhoven method' rules out some of the limitations of HFMEA such as timing and the strong correlation between the results and the individuals' participation in team activity, and subsequently, improves the performance of the method.

To summarize, FMEA is currently in its childhood in Iran; therefore, it is recommended to implement proactive risk analysis regularly in different parts of the health sector to foster an error preventive reaction as organizational culture.

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