The Utility of Failure Modes and Effects Analysis of Consultations in a Tertiary, Academic, Medical Center

Yaron Niv, MD, FACG, AGAF; David Itskoviz, MD; Michal Cohen, MD; Hagit Hendel, MSc; Yonit Bar-Giora, MSc; Evgeny Berkov, MD; Irit Weisbord, MSc; Yifat Leviron, BSc; Assaf Isasschar, MD; Arian Ganor, MSc

Background: Failure modes and effects analysis (FMEA) is a tool used to identify potential risks in health care processes. We used the FMEA tool for improving the process of consultation in an academic medical center. **Methods:** A team of 10 staff members—5 physicians, 2 quality experts, 2 organizational consultants, and 1 nurse—was established. The consultation process steps, from ordering to delivering, were computed. Failure modes were assessed for likelihood of occurrence, detection, and severity. A risk priority number (RPN) was calculated. An interventional plan was designed according to the highest RPNs. Thereafter, we compared the percentage of completed computer-based documented consultations before and after the intervention. **Results:** The team identified 3 main categories of failure modes that reached the highest RPNs: initiation of consultation by a junior staff physician without senior approval, failure to document the consultation in the computerized patient registry, and asking for consultation on the telephone. An interventional plan was designed, including meetings to update knowledge of the consultation request process, stressing the importance of approval by a senior physician, training sessions for closing requests in the patient file, and reporting of telephone requests. The number of electronically documented consultation results and recommendations significantly increased (75%) after intervention. **Conclusion:** FMEA is an important and efficient tool for improving the consultation process in an academic medical center.

Key words: consultation, FMEA, hospital medicine, quality assurance, risk management

The Institute of Medicine declared that "to err is human," and encouraged health institutes to search for potential harm in medical processes.[1] At that time medical errors were accountable for 44 000 to 98 000 deaths each year, and a total cost of $17 billion to $29 billion annually.[2–4] A higher estimation of 195 000 annual deaths (out of 37 million hospitalizations) due to medical errors was reported in 2002.[5] As most of the adverse events are the results of system and process failures, the new culture of the health organizations is to address the system errors rather than look for someone to blame.

Failure modes and effects analysis (FMEA) is a prospective risk assessment tool endorsed by patients' safety agencies to identify and prevent potential risks in health care processes.[6–13] A team of experts specifies the steps in the procedure, the failure modes (what could go wrong), the failure causes, and effects. For each failure, 3 scores are provided on a scale from 1 to 10: likelihood of occurrence, likelihood of detection, and severity. Subsequently, a risk priority number (RPN) is calculated by multiplying the 3 scores. The higher the RPN, the more attention will be given to design a more effective intervention plan for the specific potential failure.

Expert consultation is in the heart of the medical center daily performance and has a profound effect on patients care, treatment quality, and safety. In the era of modern medicine, with daily appearance of new drugs and procedures, expert consultation is a must for a proper case management.

In this study we examined the process of consultation, using the FMEA tool, for prevention of potential major errors. In addition, we demonstrate the feasibility and utility of applying FMEA for the implementation of a safe consultation process according to patients' needs.

METHODS

A team of 10 staff members—5 physicians, 2 quality experts, 2 organizational consultants, and 1 nurse—was established. The team participated in 9 separate FMEA sessions of 120 minutes each, over a period of 18 months. The consultation process was analyzed on a step-by step approach, from ordering the consultation to final documentation. Subsequently, all possible failure modes for each step in the consultation process were assessed for likelihood of occurrence (score of 1-10, from rare to very frequent), likelihood of detection (score of 1-10 from most likely to

Author Affiliation: *Rabin Medical Center, Tel Aviv University, Petah Tikva, Israel.*

Correspondence: *Yaron Niv, MD, FACG, AGAF, Rabin Medical Center, Beilinson Campus, Petah Tikva 49100, Israel (nivyaron80@gmail.com).*

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Table 1. Assessment of the Failure Modes for Each Step in the Consultation Process for Likelihood of Occurrence, Detection, and Severity[a]

Main Stage	Substage	Potential Failure	Frequency	Severity	Diagnosis ability	Risk Priority Number
1. Aim	1.1 Consultation/discussion	Consultation is not needed	3	2	2	12
		Wrong definition of consultation aim	2.5	2	3	15
	1.2 Belong to the consultant clinic	Mistake in the expert field	3	7	10	210
	1.3 Advancing place in the waiting line	Unjustified	3	1	1	3
	1.4 Sharing responsibility	Failure in expectation	6	2	1	12
2. Decision of consultation	2.1 While admitting the patient by a resident or an intern	No senior advice, failure of policy	6	5	2	60
	2.2 In doctors' round	According to the policy	5	1	1	5
	2.3 Due to event during hospitalization, with or without senior advise	No senior advice, failure of policy	6	5	2	60
	2.4 Another situation	No senior advice, failure of policy	4	7	8	224
	2.5 Update the patient about the consultation request	No senior advice, failure of policy	5	5	1	25
3. Urgency	3.1 Urgent	Failure in understanding the case	4	2	1	8
	3.2 Not urgent	Incorrect decision	2	8	8	128
		Incorrect presentation to the expert	3	2	5	30
4. Way of request	4.1 Paper form—secretary handling	Cannot be read	5	7	1	35
		Lack of information	8	8	3	192
		Wrong sticker (identification)	1	10	8	80
		Without the name and signature of the applying physician	4	5	1	20
		Secretary failure to deliver	2	10	2	40
		Request form stays in the department	2	10	2	40
		Request form lost	2	10	2	40
		No documentation of a lost form	2	10	10	200
	4.2 Computerized form—secretary handling	Report documented in a wrong patient file	3	10	4	120
		Lack of information	6	8	3	144
		Consultant is not available	1	10	5	50
	4.3 Computerized form for nonmedical consultation	Failure in sending/receiving	2	5	2	20
	4.4 Telephone call (secretary or physician)	The consultant forgot the request	4	4	7	280
		No documentation or follow-up	6	7	7	294
	4.5 Direct call	No forms	10	5	5	250
		No documentation	10	5	5	250
		No control	10	5	5	250
5. Transmission by the secretary or others	5.1 Fax—no receipt	Mistake in address	2	10	7	140
		Technical/digital failure	1	1	1	1
	5.2 Pneumatic transfer—no feedback	Mistaken address	2	10	7	140
		Technical/digital failure	1	1	1	1
	5.3 Hand delivery	Failure to arrive at the address	1	1	1	1
	5.4 E-mal/computerized delivery	The consultant cannot see the request (not received or read)	3	9	6	162
		Technical failure	1	3	1	3
	5.5 Telephone	Missed call	2	1	1	2
6. Consultation request reached its destiny and confirms	6.1 Request acceptance	The request did not reach the proper address	2	10	5	100
		Reached a wrong department	2	8	7	112
		No confirmation	2	8	6	112
	6.2 Confirmation	The request did not reach the proper address	2	2	2	8
		Reached a wrong department	2	8	8	128
		No confirmation	2	8	6	96

(*continues*)

Table 1. Assessment of the Failure Modes for Each Step in the Consultation Process for Likelihood of Occurrence, Detection, and Severity[a] (*Continued*)

Main Stage	Substage	Potential Failure	Frequency	Severity	Diagnosis ability	Risk Priority Number
	6.3 Delivery of the request to the proper consultant	Secretary mistake	3	7	7	147
		Regular round that cancelled	2	7	1	14
		Regular days for consultation—cancelled without notice	2	7	1	14
		Grand round cancelled	2	5	1	10
		No regular process of confirmation	2	5	1	10
7. Updating the request status	7.1 Consultant identity	The secretary does not know	10	2	1	20
		Switched positions without notice	2	7	1	14
		The consultant is missing with no replacement	2	7	1	14
	7.2 Time to performance	No definition	10	110	1	100
		No policy	10	2	1	20
	7.2.1 No definition of urgency or estimation of waiting time	No definition of urgency	3	10	2	60
	7.3 Urgency definition—medical, administrative, family stress	No characteristics	10	6	2	120
	7.4 Quality of the consultation request	Missing important data	8	8	1	64
		Low quality of the consultation service	8	8	1	64
8. Consultation given according to the request	8.1 Bedside consultation including physical examination	The patient was out of the department	4	7	1	28
		Mistake in identification	3	10	7	210
		The staff is not aware of the consultant arrival	5	7	1	35
		Failure in communication—the physician could not meet the consultant	6	7	1	42
		Incomplete consultation (missing data, physician or patient not present)	6	5	1	30
		Patient died or released without notice	5	6	1	30
	8.2 Consultation according to file data	Written but not delivered to the ward; incomplete report; done without the patient presence	5	4	2	40
	8.3 Telephonic consultation	Physician speaks with the consultant, no documentation, incomplete or missed information	8	3	1	24
9. Proper documentation	9.1 Full documentation in the patient file	None	3	3	1	9
		Partial	4	2	1	8
		Mistake in identification	2	10	2	40
		Handwriting cannot be read	2	4	1	8
	9.2 Date, hour, signature	No date	2	4	1	8
		No hour	2	4	1	8
		No signature and stamp	2	4	1	8
10. Summary and closure of the consultation	10.1 Notice about performance and closure	No closure	10	8	3	240
		No report on performance	8	2	1	16
		The physician is not informed	8	2	1	16
	10.2 Validation of consultation understanding and acceptance	The recommendation is not understood	3	3	1	9
		No direct answer	3	3	1	9
		Failure in fulfilling the recommendation	3	7	1	21
11. Continuity of care and responsibility of the consultant	11.1 Coordination of continuity of care with the consultant	No appointment for the consultant clinic	4	3	1	12
		No letter of recommendation	2	7	1	14

[a]Frequency = 1 to 10 (1 low, 10 high); severity = 1 to 10 (1 low, 10 high); and diagnosis ability = 1 to 10 (1 high, 10 low).

Table 2. Failures With the Highest Risk Priority Number

Failure Mode	Failure Cause	Likelihood of Occurrence	Likelihood of Severity	Likelihood of Detection	Risk Priority Number
Decision to order consultation	Consultation requested by a junior physician	4	7	8	224
Way of ordering	Telephone call	6	7	7	294
Closing consultation	Failure to document the consultation result	10	8	3	240

very unlikely), and severity of the failure (score of 1-10 from very mild to very severe). An RPN was calculated by multiplying the 3 scores. Steps of consultation processes, such as order, assign, complete, and close, were thoroughly computed in a flowchart (Table 1).

Among the raised and discussed possible failure modes for each step in the referral process, those that reached the highest RPN were selected for intervention and follow-up (Table 2). The team identified 3 main categories of failure modes that reached the highest RPNs: asking consultation by a junior staff physician without senior approval (n = 224), asking consultation on the telephone (n = 294), and failure to document the consultation in the electronic patient file (n = 240). Taking into consideration the highest RPNs for potential adverse events, an intervention plan was designed (Table 2).

A structured inspection process of monitoring, reporting, and recording failures in consultation request was established. We demanded that all consultation requests by junior physicians were approved by a senior physician. Consultation requests using telephone calls were forbidden without proper documentation. Implementation of training and lesson learning sessions for closing consultation requests in the patient electronic file was performed. Meetings to update knowledge of the process of consultation request and to stress the importance of approval by a senior physician were done.

Thereafter, we compared the percentage of completed computer-based documented consultations before and after the intervention performed by the gastroenterology service between June 1, 2015, and May 31, 2016. We stratified patients undergoing consultations into 2 groups: group I comprised patients who had a consultation before the FMEA process, and group II comprised patients who underwent consultations following the FMEA process and intervention.

Statistical analysis

Data analysis was performed with the SPSS version 20 (Chicago, Illinois). The χ^2 test was used to compare differences between the groups. The χ^2 and t tests for independent samples were used to compare demographic characteristics between the 2 groups.

RESULTS

In total, 1769 consultations performed in between June 1, 2015, and May 31, 2016, by the gastroenterology consultants were included in this project: 885 consultations before the FMEA process (group I) and 884 consultations after the process ended (group II). Patient characteristics were similar between the groups and are presented in Table 3. The number of consultations that were documented in the electronic patient files was significantly higher in the second group (Figure). There was an increase of 75% consultations between June 1, 2015, and May 31, 2016.

The other 2 failures found with a high RPN: asking consultation by a junior staff physician without senior approval, and asking consultation on the telephone without documentation, was also corrected. In the second period every consultation request was assigned by a senior physician, and every consultation request by telephone was documented.

DISCUSSION

Theoretically, complication rates of procedures and treatments would have been much higher in patients who had not undergone a proper consultation prior to

Table 3. Patient Characteristics

Patient and Consultation Characteristics	Group 1 (July to December 2015)	Group 2 (January to June 2016)	*P* Value
Consultations, n	884	885	NS
Male gender, %	49.8	53.0	NS
Age, mean (SD), y	64.3 (14.1)	64.9 (11.5)	NS
Admission ward, %			
Internal medicine	68	70	NS
Surgery	23	22	NS
Other	9	8	NS

Abbreviations: NS, nonsignificant; SD, standard deviation.

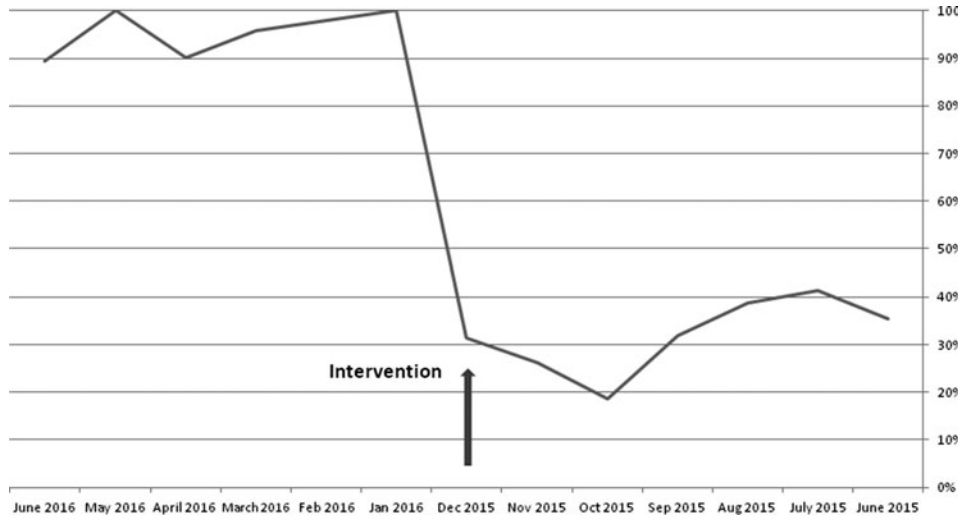

Figure. Percentage of electronically documented consultations before and following intervention.

a specific treatment or a procedure. Assurance of a correct indication, exclusion of contraindications, and providing proper instructions for effective diagnostic procedure, management and treatment, are always endorsed by properly performed expert consultation.[14–18] For this reason we used the FMEA tool analysis to intervene to reduce potential harm due to an inadequate patient management.

In this study we found that the overall complete consultation process was higher after the intervention following the FMEA process. By conducting a process of FMEA, we identified a risk profile for the expert consultation practice in our medical center. Analysis of our FMEA results served for the implementation of a novel approach for consultation request, focused on the quality of patient management and safety. After an intensive study, we found 3 main potential failures in the consultation request process, with the higher RPN: asking consultation by a junior staff physician without senior approval, asking consultation on the telephone, and failure to document the consultation in the electronic patient file. Thus, we intervened in these 3 particular issues and achieved impressive results.

We found this initiative useful, as it enables us to perform more proper procedures and giving better treatment, thus reducing the local costs and wasted time for both patients and medical services, making consultation more achievable and relevant.

As a result, we believe that in the near future this process may have a direct impact on reducing adverse events, increasing well-being, and even survival of our patients.

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