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Original investigation

Implementation of a Risk Management Model to Identify and Prevent Preanalytical Errors in Medical Laboratories

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ABSTRACT

Objective: The aim of the study is to apply a risk management model for the examination and prevention of errors occurring in the pre-analytical laboratory phase.

Method: The data used in this study were obtained from the Error Reporting Sheet of Dokuz Eylul University Hospital Central Laboratory for 2013–2015. The Failure Mode and Effects Analysis (FMEA) method was used in the study. The pre-analytical laboratory process was defined and FMEA team was formed. By determining the potential effects of failure modes detected in the pre-analytical process, the severity, probability and detectability of them were calculated and potential causes were identified. An action plan was prepared to eliminate or reduce the high-risk failure modes.

Results: In the pre-analytical laboratory phase, processes are defined as test request, sampling, identification, barcoding and transfer. The errors that occurred in the pre-analytical phase were classified under 9 types of errors. The highest number of errors was observed in the patient identification process and the number and the ratio of total errors in 2013 are 71 (29.58%), in 2014 it is 81 (29.89%) and in 2015 it is 102 (53.97%). It was observed that the failure mode with the highest risk priority number value with 576 points in the pre-analytical phase occurred in the identification process.

Conclusion: With the FMEA procedure that can be included in the laboratory's quality system, it is expected to minimize the possibility of errors in the pre-analytical phase and improve the quality of laboratory tests.

Keywords: Medical laboratory, pre-analytical phase, risk management, failure mode and effects analysis.

INTRODUCTION

In order to effectively plan, execute, monitor, record and report laboratory services, which support the majority of medical diagnoses and play a critical role in health care, all health care providers must serve in accordance with national and international criteria (1). It is important to establish a good laboratory management system, to adopt the basic policies and values of this system and to determine responsibilities for all services to provide a safe laboratory service (2).

Quality control, quality management and accreditation in medical laboratories make contribution to standardization of laboratory services, reduction of laboratory errors, improvement of service quality and patient safety (1). Although the accreditation criteria for laboratory services vary according to different institutions, the main purpose is to provide the best service to the patient and ensure the protection of personnel health (3). Many potential failure modes can occur in medical laboratories that cause unexpected conditions in all test processes. It is necessary to plan and implement specific control procedures for each possible type of error at each phase where errors can occur (4).

Laboratory errors can occur at any stage of the laboratory process. When errors are classified, pre-analytical errors are clotted, hemolyzed or insufficiently taken sample, incorrect identification or barcode, using the wrong sample material, and improper storage conditions. Analytical errors are defined as incorrect calibration and malfunction of the devices and post-analytical errors are divided into sending laboratory results to the wrong physician, long-term procedures and incorrect results (1).

The "To Err is Human" report published by the "Institute of Medicine (IOM)" in 1999 states that every year, 44.000 of 98.000 deaths in the USA are due to medical errors (5). According to the report, the ratio of medical laboratory errors varies between 0.05 and 0.61% in all medical errors. In addition, 50.0% of medical

laboratory errors are caused by inappropriate test selection and 32.0% are due to misinterpretation of laboratory results. Delays in obtaining the diagnostic result of the tests also have a large proportion of medical errors. The rate of errors occurring in the pre-analytical phase is 32.0–75.0%, and the rate of errors occurring in the analytical phase is 13.0–32.0% (6).

Proactive methods are required in order to analyze, evaluate and manage the risks involved in potential errors in laboratory processes. With application of risk management in medical laboratory processes, potential failure modes can be defined and these risk related failure modes can be classified. In addition, a systematic approach can be applied in order to develop policies and procedures, to reduce risks, and to mitigate or prevent the effects of those risks (7). In line with this information, purpose of our study is to apply a risk management model for examination and prevention of errors occurring in the pre-analytical laboratory phase.

METHODS

In our study, Failure Mode and Effect Analysis (FMEA), which is one of the risk analysis methods, was used to detect types of the errors occurring in the pre-analytical phase and to determine effects and causes of these errors in medical laboratory processes.

The population of the study was determined as all errors occurring in the pre-analytical, analytical and post-analytical phases in Dokuz Eylül University (DEU) Central Laboratory for 2013–2015. The errors occurred in the pre-analytical phase between 2013 and 2015 were selected as sample from the population for this study. The data used in the study were obtained electronically from the "Error Reporting Sheet" coded as MLFR. 409.01 for 2013–2015, prepared by the Quality Management Unit of DEU Hospital Central Laboratory within the scope of the ISO 15189 Medical Laboratory Accreditation Standard.

Permission for the use of the data was obtained from the DEU Central Laboratory Management on 13 March 2014. The study started with the approval of DEU Non-Interventional Research Ethics Committee dated 5 December 2014 and numbered 2014/36–36.

In the pre-analytical laboratory phase, the errors occurred between 2013–2015 were classified according to their types and their frequency, besides their ratio in total errors were calculated in Microsoft Office Excel 2016 program. A pivot table was created by sorting from the most common types of errors to the least common types of errors. The FMEA team, comprising of the principle investigator and co-investigator of study and the laboratory staff assigned by the Central Laboratory Management, determined the causes and effects of the failure modes related to the processes which they identified in the pre-analytical phase, based on their experience.

The severity (S), occurrence (O) and detection (D) values for each failure modes were determined according to Table 1. These values were recorded in the FMEA table and the risk priority number (RPN) values were calculated. Starting from the largest RPN value, preventive actions were planned and a risk management model was created.

RESULTS

Pre-analytical laboratory processes were defined by the FMEA team as "test request", "sampling", "identification", "barcoding" and "transfer".

When the errors occurring in the pre-analytical phase were classified under 9 error types and their total numbers were ranked from large to small, it was observed that errors mostly occurred during the identification process (Table 2). Misidentification was identified as the most common error, and the number and the rate of misidentification in total errors were determined as 71

Table 1. Ranking values for occurrence, severity and detection of failure modes

Occurrence	Severity	Detection
9-10: The failure occurs immediately / in a short time. (one or more times a day)	**9-10:** The failure causes a negative impact on clinical outcomes, serious injury or death.	**9-10:** It is very difficult and sometimes impossible to notice the failure.
7-8: The failure most likely occurs (several times a month).	**7-8:** The failure leads to serious patient dissatisfaction and a negative impact on clinical outcomes.	**7-8:** The failure is probably not noticed.
5-6: The failure likely occurs (several times a year).	**5-6:** A negative impact in the process/service and the probability of creating dissatisfaction is moderate.	**5-6:** The failure may or may not be noticed.
3-4: The failure rarely occurs (once every 5 years).	**3-4:** The failure can be corrected by changes in the process/service.	**3-4:** It is often possible to notice the failure.
2-1: The failure most likely does not occur (sometimes every 5-30 years).	**2-1:** The failure is not noticed and service delivery is not affected.	**1-2:** The failure is obvious, it can be easily detected.

Table 2. Distribution of errors that occurred in the pre-analytical phase of Dokuz Eylul University Hospital Central Laboratory for 2013-2015

Errors	2013 n (%)	2014 n (%)	2015 n (%)	Total n (%)
Misidentification	71 (29.58)	81 (29.89)	102 (53.97)	254 (36.29)
Wrong transfer of samples to the laboratory	66 (27.50)	70 (25.83)	24 (12.70)	160 (22.86)
Taking samples in inappropriate material	44 (18.33)	47 (17.34)	13 (6.88)	104 (14.86)
Wrong barcode	27 (11.25)	35 (12.92)	26 (13.76)	88 (12.57)
Incorrect test request	9 (3.75)	15 (5.54)	9 (4.76)	33 (4.71)
The incompatibility of the sample and the test request	5 (2.08)	11 (4.06)	10 (5.29)	26 (3.71)
Missing / wrong samples	8 (3.33)	11 (4.06)	2 (1.06)	21 (3.00)
Keeping samples under improper conditions	9 (3.75)	0 (0.00)	1 (0.53)	10 (1.43)
Mixing of samples	1 (0.42)	1 (0.37)	2 (1.06)	4 (0.57)

Table 3. Failure Mode and Effect Analysis: Test Request Process

Process	Potential Failure Modes	Potential effects of failures	Potential causes of failures	S Rating	O Rating	D Rating	RPN	Recommended Actions
Test Request	Inaccurate, incomplete or inappropriate and wrong-time test requests	Delay in the analysis of samples, patient victimization, wrong test result, misleading treatment, re-sampling from the patient, additional material and time cost	the lack of attention and knowledge of physicians	7	6	6	252	1. Ensuring effective communication and regular information between the physicians who request tests in the units and the hospital information system staff regarding the test request method and information management system updates. 2. Reminding physicians who forget the test request by authorized clinical nurse, 3. Training of newly recruited physicians on test request method and information system usage.

S: Severity, **O:** Occurrence, **D:** Detection, **RPN:** Risk Priority Number

Table 4. Failure Mode and Effect Analysis: Sampling Process

Process	Potential Failure Modes	Potential effects of failures	Potential causes of failures	S Rating	O Rating	D Rating	RPN	Recommended Actions
Sampling	Missing / wrong sample, taking samples in inappropriate material, keeping samples under improper conditions	Misleading treatment, rejection of the sample, re-sampling from the patient, patient victimization, additional material and time cost	The lack of knowledge, inattention and control of the health care personnel regarding the sampling procedure for the requested test	7	5	4	140	Providing regular trainings to authorized personnel in the sampling process at the units, and delivery of the basic information about the sampling procedure and the use of appropriate materials in written form
	The incompatibility of the sample and the test request	Incorrect test result, patient victimization and time loss, loss of labor force	Incorrect entering of test request to laboratory information system and wrong barcode on sample	8	6	3	144	Updating the test request module in the information system to be more understandable, informing the responsible health personnel about the update by the information system personnel
	Mixing up the samples	Patient victimization, wrong test result, misleading treatment, re-sampling from the patient, additional material and time cost	Not verifying patient identity	8	4	6	192	Providing regular training to responsible healthcare personnel in the sampling process and delivery of basic information in written form about the sampling procedure and the use of appropriate materials

S: Severity, **O:** Occurrence, **D:** Detection, **RPN:** Risk Priority Number

(29.58%) in 2013, 81 (29.89%) in 2014 and 102 (53.97%) in 2015. The other most common mistake was in the transfer of samples to the laboratory. The number of wrong transfers of samples to the laboratory and the rate of wrong transfers in total errors were 66 (27.50%) in 2013, 70 (25.83%) in 2014 and 24 (12.70%) in 2015. Another common error was taking samples in inappropriate material (tube, container, injector, etc.). It was recognized that the number of errors and the rate of the errors in total errors were 44 (18.33%) in 2013, 47 (17.34%) in 2014 and 13 (6.88%) in 2015.

Failure modes for the test request process of the pre-analytical phase were identified as wrong, incomplete or inappropriate test requests. RPN value was found to be 252 after specifying the S, O and D values of the failure modes by considering the potential effects and causes for these errors. FMEA results of the test request process is presented in Table 3.

The missing/wrong samples, transferring of the samples into wrong container or tube, preserving the samples under improper conditions incompatibility of samples and the test request and mixing up the samples were specified as failure modes related to sampling process of the pre-analytical phase. After deciding the S, O and D values in consideration of potential effects and causes, the RPN value was found as 140 for the error types covering missing/ wrong samples, transferring of the samples into the wrong container or tube, and preserving the sample under improper conditions. The RPN value was 144 for the error types covering incompatibility of samples and the test request. Finally, the RPN value was found to be 192 for the mixing up samples error type. Table 4 shows the FMEA results for sampling process with suggestions for preventive actions.

The failure mode in the identification process of the pre-analytical phase was determined as the misidentification of patients. The

Table 5. Failure Mode and Effect Analysis: Identification Process

Process	Potential Failure Modes	Potential effects of failures	Potential causes of failures	S Rating	O Rating	D Rating	RPN	Recommended Actions
Identification	Misidentification	Patient victimization, misleading treatment, re-sampling from the patient, additional material and time cost, loss of labor force	Sticking the wrong barcode label on the sample, patients with the same name, printing the barcode after taking the sample, personnel shift, lack of knowledge of the personnel	8	8	9	576	Taking samples after the barcode is printed on the tube, verifying the identity information on the barcode to the patient, checking the patient wristband, ensuring that the flow of the barcoding and identification processes is visible in the physical working environment

S: Severity, **O:** Occurrence, **D:** Detection, **RPN:** Risk Priority Number

Table 6. Failure Mode and Effect Analysis: Barcoding Process

Process	Potential Failure Modes	Potential effects of failures	Potential causes of failures	S Rating	O Rating	D Rating	RPN	Recommended Actions
Barcoding	Wrong barcode (mixing the barcodes of samples, placing the barcodes of different patients on a sample, re-sending samples with the same barcode, slipping and exiting the barcode label and sending samples without barcode.)	Misleading treatment, patient victimization, re-sampling, re-barcoding, additional material and time costs, loss of labor	**1.** Lack of information or inattention of the responsible secretary, sampling and barcoding are done by different personnel, not verifying patient identity. **2.** Incorrect patient registration sampling and barcoding are done by different personnel, not verifying patient identity **3.** Not sticking the barcode carefully and using quality labels	8	7	6	336	**1.** Taking samples from patients after the barcode label is stuck on the sample materials, the obligatory training of the responsible health personnel about the barcoding process, ensuring that the flow of the barcoding processes is visible in the physical working environment **2.** Taking samples from patients after the barcode label is stuck on the sample materials, verifying the identity information on the barcode to the patient, checking the patient wristband, ensuring that the flow of the barcoding and identification processes is visible in the physical working environment **3.** Using quality labels, using latex gloves while sticking barcode labels, checking barcodes before transfer of samples.

S: Severity, **O:** Occurrence, **D:** Detection, **RPN:** Risk Priority Number

Table 7. Failure Mode and Effect Analysis: Transfer Process

Process	Potential Failure Modes	Potential effects of failures	Potential causes of failures	S Rating	O Rating	D Rating	RPN	Recommended Actions
Transfer	Wrong transfer of samples to the laboratory (transport of samples under improper conditions, without a record, in unsuitable material and by the patient's relative and the left of samples to the wrong laboratory unit)	Delay and negative impact in the treatment process, rejection of samples, re-sampling, additional time and material cost	Losing of samples, using incorrect sample material, lack of transport staff, noncompliance with cold chain transport procedure	8	7	6	336	1. Employing personnel only for the sample transfer process, clarifying the task definition, providing the necessary training for the transfer process, and ensuring that the flow of the transfer processes is visible in the physical working environment, providing the pneumatic system throughout the hospital 2. Identification of whether it is urgent when requesting tests from diagnostic units, using methods such as colored labeling indicating urgent samples, defining the process to be followed in urgent samples

S, O and D values were identified in consideration of potential effects and causes, the RPN value of this failure mode was found to be the highest value in FMEA analysis as 576. The analysis of the identification process was presented in Table 5.

Regarding the barcoding process of the pre-analytical phase, failure modes were specified as mixing up the barcodes of samples, placing the barcodes of different patients on a sample, re-sending samples with the same barcode, slipping and exiting the barcode label and sending samples without barcode. RPN value of this failure mode was found to be 336 after indicating the S, O and D values considering potential effects and causes. The FMEA results of the barcoding process were showed in Table 6.

Identified failure modes of transfer process in pre-analytical phase were the transport of the samples under improper conditions, without a record, by using an unsuitable material, with help of patient's relative and delivery of the samples to the wrong laboratory unit. RPN value of this failure mode was found to be 336 after deciding the S, O and D values considering potential effects and causes. The Table 7 provides the results of FMEA for the transfer process.

DISCUSSION

Our results demonstrated that the most common type of error in the pre-analytical phase of DEU Hospital Central Laboratory for 2013–2015 and that the highest RPN value was related to misidentification of patients and this failure mode occurred during the identification process. It was also seen that this error increased over the years. The standard of the Joint Commission on Accreditation of Healthcare Organizations to improve the accuracy of patient identification was adopted as one of the six national patient safety objectives for 2003 (8). Subsequently, the issue of patient identification has continued as a priority among the Joint Commission's patient safety objectives (9). It is known that errors occurring in patient identification in the pre-analytical process of medical laboratories may have potential serious effects on the patient. Reasons of misidentification of patients or samples according to the study of Lippi et all, referral of patients with the identical name, incorrect patient registration, incorrect or incomplete test request, collection of biological samples from the wrong patient, improper labeling of samples, incorrectly labeled samples, unlabeled or unreadable labeled samples, and wrong data entry to the laboratory information system (10). The study of Lippi et all that implements a risk management in the pre-analytical laboratory phase suggested corrective and preventive actions in line with our results to the misidentification of patients. It had also been recommended in the study to use information technologies to prevent errors and evaluate the reliability of the results. In order to correct errors, it is recommended to report suspicious results, take samples again and report errors (11). Najafpour et al. aimed at completely eliminating human errors in patient identification suggested an automatic sample labeling application combined with patient identification procedure and electronic identification systems in their study. It had also been specified that this system reduced errors related to the test request and the use of wrong sample container or tubes and the sample without barcode. Both studies of Lippi et all and Wallin et al. had emphasized the need to use at least two identifiers also had stated that nurses and other health care professionals should be trained periodically to use reliable methods to identify samples and control patient medical records. In line with the FMEA recommendations in our study results, the knowledge of health care professionals about safe and correct patient identification should be kept up-to-date. In addition, it was suggested in the three studies mentioned above that organization of the working plans of the health care personnel could greatly reduce the misidentification of the patient (12–14).

The forth most common failure mode in the pre-analytical phase of DEU Hospital Central Laboratory occurred in barcoding process and had the third-highest RPN value. The study of Antonia et all claimed that to scan the patient's barcoded wristband by nurses before taking a sample from the patient. This control procedure was carried out on the mobile computer to verify the requirements of the test for the patient and that the sample had not yet been taken. Then, the printed barcode label was affixed on the sample material. Two-dimensional barcode technology can be used to eliminate the possibility of confusion about which tests should be performed. At the same time, this barcode technology helps record the test result, improves patient identification accuracy and provides measurable process improvements and time savings for laboratory staff. The study mentioned above emphasized the necessity of continuing training of health personnel on the sampling procedure for the correct labeling of the barcode in line with the FMEA results of our study. Labeling by the health care staff without leaving the patient and minimizing re-labeling was also suggested in the study (15).

The second most common failure mode in the pre-analytical phase was the wrong transfer of samples to the laboratory and had the third-highest RPN value. With regard to sample transfer, the ISO 15189 standard defined that the transport of samples to the laboratory should be at a suitable time and temperature, ensuring the safety of all personnel involved in the transfer process and in accordance with all national and international standards (16). The main variables to be considered during the transfer process were shaking, exposure to light, temperature, transfer time, placing samples in the container, type of packaging and label were specified in the study of Antonia et all. In addition, medical laboratories should document the conditions and requirements that must be followed during the transfer process to protect samples with a standard operating procedure and define the duties, responsibilities and authorities of the relevant staff (15).

Another suggestion of our study regarding the transfer process is related to the expansion of the pneumatic system throughout the hospital. The pneumatic transfer system has become a common method for transporting samples in hospitals and is considered to be effective due to the speed and efficient use of the system. However, it has been noted that this type of transport method may affect some laboratory measurements, and although abnormal analytical results have been observed due to the pneumatic transfer method, the factors that directly cause this condition cannot be measured. For all that, the latest technological developments have made it possible to measure the environmental factors affecting samples while reaching the laboratory in the pneumatic tube carrier (15).

The fifth most common failure mode in the pre-analytical phase was the wrong test request and had the fourth-highest RPN value. In this process, tests were requested by the physician over the Hospital Information Management System and transmitted to the Laboratory Information System. It had been determined that errors such as wrong, incomplete or inappropriate, wrong-time test requests occurred during the test request process. The potential causes of these failure modes were especially the lack of attention and knowledge of physicians who requested tests. In a study, it was stated that the electronic test request system in hospitals reduced possible undesirable errors as much as possible but did not completely eliminate them. The source of these errors was seen as the authorized persons using the system did not comply with the written procedures. Preventive actions for these errors were specified as, development of written procedures for the use of electronic test system, improving vocational training, automating the functions required for both technical support

and administrative activities in hospitals, monitoring quality indicators, and promoting inter-departmental cooperation by improving communication among health care professionals in both studies of Lippi et all and Najafpour et al. Suggestions of the two studies mentioned above are in line with the preventive actions in our FMEA results. The development and dissemination of the quality management system is the most effective strategy to minimize uncertainty in laboratory diagnostics (12–13).

The last most common failure mode in the pre-analytical phase was the wrong sampling and had the lowest RPN value. Failure modes of this process were missing/wrong samples, taking samples in the wrong container or tube, keeping samples under improper conditions, the incompatibility of samples and the test request and mixing up of samples. The results of our study showed that the causes of these failure modes were the wrong entry of samples into the laboratory information system, incorrect barcode sticking on the sample materials and the inadequate patient identification due to the lack of knowledge, inattention and control of the health care personnel regarding the sampling procedure for the requested test. The study of Sholadem suggested two improvement plans for wrong sample collection. The first was an information brochure for nurses. The sampling procedure was explained by the head nurse to each nurse who took part in the sampling process. After checking that the procedure was effectively learned by nurses, their working system was followed for a month. When it was detected that an inappropriate sample was taken, a separate field was created in the laboratory information system to report this inappropriate sample and request a new sample. Errors reported to the separate field in the laboratory information system were defined as pre-analytical error. Later on, indicators were created on a monthly basis to identify improvement strategies for these errors. In the study, which offers suggestions in line with our FMEA results, it was emphasized that pre-analytical errors caused by taking wrong sample may have serious consequences and cause incomplete/wrong results in diagnosis, treatment or disease prevention and eventually cause patient victimization. The second improvement plan of the study was to create a special label system for each test request. Each laboratory test registered in the laboratory information system was matched with the sample material thus labels could be automatically printed according to the requested tests with this system. In the results of the study, it was observed that both improvement suggestions prevented taking incorrect samples (17).

The errors, potential causes, and especially their effects on patient safety during the pre-analytical phase of DEU Hospital Central Laboratory were examined in detail with the FMEA application of our study. As a result of our study, it was determined that pre-analytical phase errors primarily caused the wrong treatment of the patients, the misdirection of the treatment and the patient's victimization. Furthermore, additional material and time costs for hospital resources and loss of labor force were identified as the effects of errors. Therefore, in a university hospital central laboratory that meets the requirements of the ISO 15189 standard, it is recommended to apply a risk management model in order to identify and eliminate errors in the pre-analytical phase. With a FMEA procedure that can be included in the laboratory's quality management system, it is expected to minimize the possibility of errors in the pre-analytical phase and improve the quality of laboratory tests. It will effectively reduce pre-analytical errors and improve clinical outcomes by improving patient safety. It will also improve clinical outcomes by effectively reducing pre-analytical stage errors and improving patient safety.

Compliance with Ethical Standards: DEU Non-Interventional Research Ethics Committee (No: 2014/36-36, Date: 5.12.2014)

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