

Root Cause Analysis of Patient Samples Rejected by Laboratories: 21-Step Application Example

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ABSTRACT

Aim: Root cause analysis is widely used in healthcare services to analyze the causes of near misses and adverse events with a systematic approach. This study, it is aimed to determine the root causes of rejected samples, define corrective/preventive actions, and create an action plan that will help the implementation of the suggested remedial actions and evaluate their effectiveness.

Material and Methods: For the 21-step methodology, observation, interview, document and record review techniques were applied. The steps of the process were visualized with the flowchart technique and the reasons for rejected samples were analyzed with team members. The identified causes were visualized with the Fishbone Diagram technique, and the risk reduction strategies and improvement actions for rejected samples were determined by the Failure Mode Effect Analysis (FMEA) method. The Action Hierarchy tool was used to evaluate the power of improvement actions.

Results: The root causes of rejected samples were identified as inadequate orientation and training practices, lack of applicability of policies and procedures, lack of monitoring and evaluation, inefficient process flow and lack of equipment. A total of 11 improvement actions were determined and planned for these root causes. It was predicted that there will be an approximately 64.5% decrease in risk scores in general with the basic measures presented in the performed FMEA.

Conclusion: Overall, it was found that the 21-step methodology is suitable for determining root causes by offering detailed guidance.

Keywords: Root cause analysis; 21-step methodology; rejected samples.

Laboratuvarlar Tarafından Reddedilen Hasta Numunelerinin Kök Neden Analizi: 21 Adım Uygulaması Örneği

ÖZ

Amaç: Kök neden analizi, sağlık hizmetlerinde ramak kala ve istenmeyen olayların nedenlerini, sistematik bir yaklaşımla analiz etmek için yaygın olarak kullanılmaktadır. Bu çalışmada, reddedilen numunelerin kök nedenlerinin belirlenmesi, düzeltici/önleyici eylemlerin tanımlanması ve önerilen iyileştirme eylemlerinin uygulanmasına ve etkililiğinin değerlendirilmesine yardımcı olacak bir eylem planının oluşturulması amaçlanmıştır.

Gereç ve Yöntemler: 21 adım uygulaması yönteminde gözlem, görüşme, doküman ve kayıt inceleme teknikleri uygulanmıştır. Akış Şeması tekniği ile süreç adımları görselleştirilmiş ve reddedilen numunelerin nedenleri ekip üyeleri ile analiz edilmiştir. Tespit edilen nedenler, Balık Kılıcı Diyagramı tekniği ile görselleştirilmiş ve reddedilen numuneler için risk azaltma stratejileri ve iyileştirme eylemleri Hata Türleri ve Etkileri Analizi yöntemi ile belirlenmiştir. İyileştirme eylemlerinin gücünü değerlendirmek için Eylem Hiyerarşisi aracı kullanılmıştır.

Bulgular: Reddedilen numunelerin kök nedenleri; oryantasyon ve eğitim uygulamaları yetersizliği, politika ve prosedürlerin uygulanabilirliği, izleme ve değerlendirme eksikliği, verimsiz süreç akışı ve ekipman eksikliği olarak belirlenmiştir. Bu kök nedenlere yönelik toplam 11 iyileştirme eylemi belirlenmiş ve planlanmıştır. Gerçekleştirilen Hata türleri ve Etkileri Analizinde sunulan temel önlemlerle genel olarak risk puanlarında yaklaşık %64,5'lik azalış olacağı öngörülmüştür.

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Sonuç: Genel olarak 21 adım yönteminin ayrıntılı rehberlik sunarak kök nedenleri belirlemede uygun olduğu bulunmuştur.

Anahtar Kelimeler: Kök neden analizi; 21 adım yöntemi; reddedilen numuneler.

INTRODUCTION

Root cause analysis (RCA), which is a risk assessment technique widely used in the industrial sector, has been used frequently in almost every field of healthcare services. This technique is frequently used in imaging, laboratory processes, nursing, care and training processes (1-5). In recent years, the main sub-components or goals of patient safety, such as falls (6), hospital-acquired infection (7,8), adverse event investigation (9) and delay in treatment, have been studied in terms of the RCA technique.

Laboratory services, which are an important service unit of healthcare, are also a vital source of error that can affect patient safety (10). Laboratory errors are estimated to contribute about 23% of all errors (11). Laboratory error can be defined as any defect that occurs throughout the entire testing process and any condition that affects the quality of laboratory services. The laboratory process basically consists of 3 parts: the preanalytical phase, analytical phase and post-analytical phase. The preanalytical phase covers the process from requesting the test until the sample is ready for analysis. The analytical phase includes the analysis process of the sample and the post-analytical phase includes the reporting and interpretation of the test result (10).

More than 70% of laboratory errors are preanalytical errors (12,13). Most preanalytical errors are caused by system defects and inadequate supervision by practitioners involved in sample collection and processing. This leads to an unacceptable number of inappropriate samples due to hemolysis, coagulation, insufficient volume, incorrect container, contamination and misidentification (14). Inappropriate sample rejection is an important step for patient safety in the laboratory (15) and is a very common condition (16). Data obtained from rejected samples is a quality indicator of the preanalytical process (17). At this point, for accurate and reliable results, it is necessary to analyze retrospectively, to identify errors, to identify and implement corrective preventive actions, and to constantly evaluate the effectiveness of the measures taken (18).

RCA and its tools are the most widely used comprehensive method of systematic analysis among Joint Commission (JC) accredited organizations (19). The methodology determined for the RCA process in the publication "Root Cause Analysis in Health Care: Tools and Techniques" (2017), which JC has prepared in a workbook format to assist health institutions in the RCA process, consists of 4 chapters and 21 steps (Figure 1). The JC 21- Step Practice is a technique specific to the healthcare industry and incorporates multiple techniques at once (19). There are very few publications showing the results of the technique based on the JC 21 Steps practice (20). This is the first time that this technique has been applied to the root causes of rejected samples and is considered to be a pioneering study for laboratories. The implementation of 21 steps in the laboratory and the

observation of the results constitute the originality of this research.

Root Cause Analysis Preparation	Determine What Happened and Why	Identifying Root Causes	Designing and Implementing a Corrective Action Plan for Improvement
<ul style="list-style-type: none"> • Step 1: Organize a team • Step 2: Define the problem • Step 3: Study the problem 	<ul style="list-style-type: none"> • Step 4: Determine what happened • Step 5: Identify contributing process factors • Step 6: Identify other contributing factors • Step 7: Measure- collect and assess data on proximate and underlying causes • Step 8: Designing and implementing immediate changes 	<ul style="list-style-type: none"> • Step 9: Identify which systems are involved- the root causes • Step 10: Prune the list of root causes • Step 11: Confirm root causes and consider their interrelationships 	<ul style="list-style-type: none"> • Step 12: Explore and identify risk reduction strategies • Step 13: Formulate improvement actions • Step 14: Evaluate proposed improvement actions • Step 15: Design improvements • Step 16: Ensure acceptability of the corrective action plan • Step 17: Implement the improvement plan • Step 18: Develop measures of effectiveness and ensure their success • Step 19: Evaluate implementation of improvement efforts • Step 20: Take additional action • Step 21: Communicate the results

Figure 1. JC root cause analysis steps

In this study, it is aimed to determine the root causes of rejected samples, to define corrective /preventive actions and to create an action plan that will help the implementation of the suggested remedial actions and evaluate their effectiveness.

MATERIAL AND METHODS

RCA can be defined as a research process in which both qualitative and quantitative data are collected systematically and analyzed to identify factors and underlying causes that contribute to an adverse event (21). Therefore, the research is a mixed study in which qualitative and quantitative designs are used together due to the purpose of the researcher and the nature of the subject under investigation.

Retrospective annual data (01.07.2018 - 30.06.2019) for the rejected samples from the Microbiology-Biochemistry Laboratory of the hospital was obtained from the Duzce University Health Research and Application Center automation system in an Excel environment. The data includes the name of the test, the unit that requested the test, the reason for rejection, and the date and time of sample rejection. Analysis of the research data took about four months. Ethics committee approval dated 16.05.2019 and numbered 2019/48 was obtained from Düzce University Scientific Research and Ethics Committee.

In the study, Gantt Chart, Flowchart, Brainstorm, Fishbone Diagram, FMEA and Six Sigma (Calculation of Defects Per Million) techniques and tools were used to assist the team in the 21-step implementation process. In addition, the power of improvement actions was rated using the Action Hierarchy tool developed by the National Patient Safety Center (22). Throughout the research, we adhered to the methods in the 21-step application (19).

RESULTS

The findings regarding the 21-step application performed for the samples rejected in the biochemistry and microbiology laboratory tests of the central-emergency laboratory of the hospital are presented in the four main sub-headings.

Root Cause Analysis Preparation

In the study, a multidisciplinary team was formed. In this context, the working team consists of 5 people: "Assistant Hospital Manager", "Quality Unit Employee", "Laboratory Supervisor", "Microbiology Laboratory Technician" and "Biochemistry Laboratory Technician". The mission, values and basic rules of the team were determined with the participation of the whole team.

In terms of defining the problem, the problem sentence (What is wrong? What's the result?) that clarified the questions was determined with the help of the data obtained from the hospital's automation system. In this context, it was determined that 21.297 out of 978.506 samples were rejected in a 1-year period, and 31% of the rejected 21.297 samples were defined as hemolysis, 18.5% insufficient, 15.7% clotted in the Biochemistry and Microbiology Laboratory tests. Later, the preliminary work plan created by determining the activities, the people involved, the start date and the duration, and the 21-step implementation were integrated into the problem.

Within the scope of the study, 25 interviews were carried out regarding the observations and comments of the people directly or indirectly involved in the process about the functioning of the process, the reasons for sample rejection and the solution proposals. Interviews were held with the microbiology laboratory, biochemistry laboratory, polyclinic blood collection, emergency service, intensive care, technical service, training unit and 8 service units. The policies, procedures and rules of the hospital regarding the subject were taken from the quality unit and examined. One-year retrospective data for rejected samples from the hospital's microbiology-biochemistry laboratories were obtained from the hospital automation system. During the preanalytical process, the process was observed in places such as polyclinic blood collection, emergency service, pneumatic transport system, laboratory sample acceptance, biochemistry laboratory, and microbiology laboratory. As a result of the interviews and observations, the process steps were determined and recorded. Equipment and instruments such as injectors, needle tips, tubes, vacutainers, tourniquets used during sampling, the pneumatic conveying system used in sample transfer, laboratory analysis and centrifugal devices were recognized, examined, information about their use and effects on sample rejection was collected.

Determining What Happened and Why

In the stage of determining what happened and why, the problem was defined in more detail by determining when, where and how the incident occurred and the service areas affected by the incident. The laboratory test request - result process was visualized with the help of a flow chart.

- In the one-year period, the maximum number of samples was rejected in April, May and January, respectively.
- In the distribution of rejected samples by rejection time, the first three times in which the samples are rejected are 13:00, 11:00 and 12:00, respectively.

- According to the rejection rate, the affected service areas are as follows: intensive care units (4.2%), services (3.5%), emergencies (3.0%), and outpatient clinics (1.2%).
- The most common reasons for rejection in rejected samples are; hemolyzed sample (31.0%), insufficient sample (18.5%) and clotted sample (15.7%).

In the study conducted to examine the problem in-depth, it is seen that the factors that make up 65.2% of the rejected samples are as follows; Process factors, human factors, equipment factors, information factors, controllable or uncontrollable environmental factors and other factors (procedure, education, communication, patient structure, etc.) that may contribute to the occurrence of hemolyzed, insufficient and clotted sample rejection reasons.

To evaluate hemolyzed, insufficient and clotted samples, rejection rates by service areas and distributions by test type were examined. The data were evaluated in the light of the answers, observations, knowledge and experiences of the team members during the interviews.

98% of the hemolyzed sample is of the biochemistry test type. The distribution of the hemolyzed sample according to the service area is as follows; emergency (1.27%), intensive care (1.12%), service (1.07%), and outpatient clinic (0.22%).

The most common types of tests where insufficient samples are encountered are hematology, blood gas, biochemistry, coagulation, hormone and urine tests. The distribution of insufficient samples by service units is as follows; Service (0.83%), Intensive Care (0.73%), Emergency (0.64%), Outpatient Clinic (0.12%).

When the distribution of clotted samples are examined according to test types, it is mostly encountered in blood gas samples. The service areas from which the samples came are as follows, respectively, according to the coagulated sample rejection rate; Intensive care (0.65%), Service (0.63%), Emergency (0.47%), and Outpatient Clinic (0.16%).

Generally, it was observed that rejection rates were higher in units with a patient profile having difficulty in blood collection. A high staff rotation is an expected condition of the teaching hospital. It includes inexperienced (newcomers) employees. Intern doctor-nurses can perform sampling. Increasing the knowledge and competence of the personnel was determined as an urgent change and planned with the help of the Gantt chart because of the lack of knowledge and competence in proper sampling, the difficulty in taking blood and progressing the process appropriately.

Identifying Root Causes

The factors contributing to the formation of hemolyzed, insufficient and clotted samples were examined in depth. The underlying system and process reasons were determined and a fishbone diagram of rejected samples was created. The underlying system and process reasons in the diagram were detailed under the main categories of management, workforce, procedure and method/process (Figure 2).

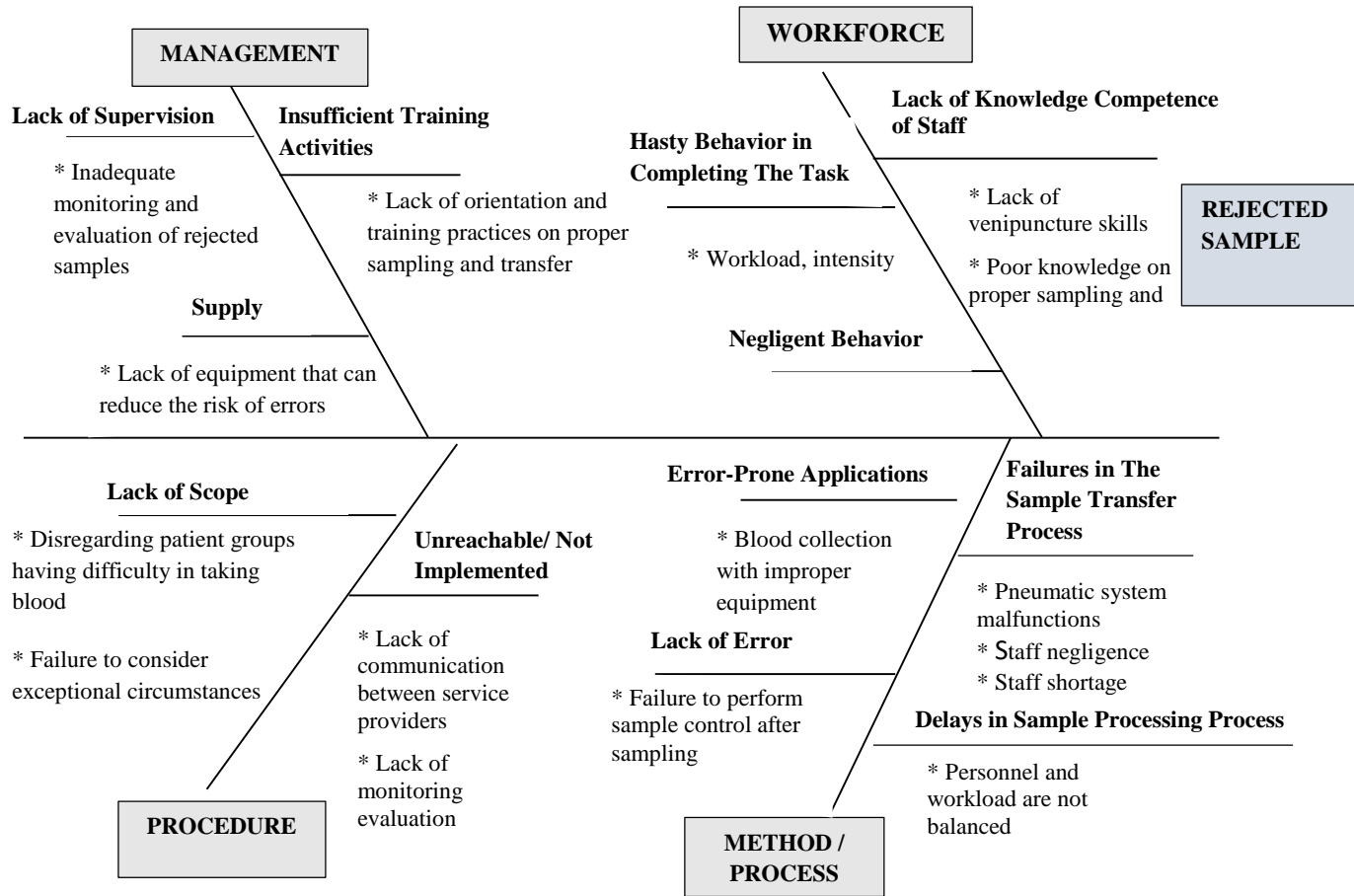


Figure 2. Fishbone diagram of rejected sample

The team evaluated the root causes of the identified system problems for hemolyzed samples, insufficient samples, and clotted samples using logic-based reasoning. The root causes of the causal factors such as lack of staff knowledge and competence, rushing to complete the task, negligence were identified as the lack of orientation and training practices and the lack of monitoring and evaluation of the process by the management. The root causes of failure to comply with policies and procedures were identified as the inadequate scope of existing policies and procedures, procedural factors such as inaccessibility and non-implementation, lack of monitoring and evaluation, and inadequate orientation and training practices. The root cause of causal factors such as error-prone applications, lack of error correction, and delays in the process has been identified as inefficient process flow. The root cause of the lack of widespread use of the vacuum system, the absence of a vein finding device, the lack of a laboratory device in which pediatric blood tubes can be operated, the lack of a mechanism to prevent the severity of impact in the pneumatic system and the absence/insufficiency of

equipment that could reduce the risk of error were identified as lack of equipment. The root causes were identified as lack of orientation and training practices, policy and procedural factors, lack of monitoring and evaluation, inefficient process flow with error-prone applications/lack of error correction, and widespread/unavailability of equipment to reduce the frequency of error occurrence. Within the scope of the root causes verification and evaluation of their relationships, it is stated that assistance can be obtained by examining the sentinel event data, root cause data, and risk reduction data related to the event in the JC Sentinel Event Database. In the database in question, no data on the subject of the study could be reached (23). At this point, the root causes mentioned in the relevant literature were examined and confirmed. In order to effectively define the identified root causes and to understand their interactions, discussions were opened with the team members and their relations with each other were evaluated. In this evaluation, it was concluded that each root cause can interact with other root causes and create an undesirable event scene.

Table 1. Recommended improvement actions

Root Cause Type	Root Cause Detail	Improvement Action	Weak Action	Mid-Level Action	Strong Action	Success Measurement
Management / Control	Failure to comply with policies and procedures; The need for monitoring and evaluation	Performance evaluation of the process, monitoring with statistical process control and establishment of a feedback mechanism		X		Number of Rejected Samples/ Total Number of Samples
		Appointment of an assistant chief physician for the performance evaluation of the process, monitoring with statistical process control and establishing a feedback mechanism. Granting the necessary authority and responsibility in providing finance and human resources.			X	
Management / Policy and Procedure	Deficiencies in existing policies and procedures for appropriate sampling and transfer	Developing policies and procedures by considering exceptional cases and alternatives for proper sampling and transfer process.	X			Number of Rejected Samples/ Total Number of Samples
		Using a standardized format for blood collection that takes into account the most internationally accepted recommendations and guidelines.		X		
Process	Inefficient process flow	Simplify the process by removing inefficient steps: sample rejection can be carried out in 5 different stages. Reducing these rejection stages to 2 stages as the sample acceptance and after centrifugation. Providing the necessary human resources and financing for this. (Employment of competent personnel in the sample acceptance unit to detect sample nonconformities)			X	Number of Rejected Samples/ Total Number of Samples
		Conducting work studies and providing the necessary workforce resource in order to eliminate personnel workload imbalances that cause delays in the process			X	
		To eliminate the error correction deficiency in the process by adding the step of checking the conformity of the sample before sending the sample to the laboratory during the sampling process and after the sample is taken.	X			
Management / Workforce	Personnel training; lack of orientation and training practices on proper collection and transfer of samples	Periodic and systematic renewal of training and orientation activities on proper sampling and transfer.	X			Number of Rejected Samples/ Total Number of Samples
		Conducting simulation-based trainings with periodic refresher sessions and surveillance on appropriate sampling.		X		
		Appointment of a deputy chief physician for the monitoring and tracking of sample rejection rates and authorization of expenditure for the necessary training and orientation activities.			X	
Equipment	Lack of equipment to reduce the risk of error occurrence	Purchasing equipment that will reduce the risk of error occurrence; * Spreading the use of vacutainers, which reduces the risk of hemolyzed samples by removing the activity of insufficient sample, clotted sample, discharge from the syringe to the tubes by taking the blood to a sufficient level. In this regard, considering the patient structure and giving priority to the units where laboratory test requests are made the most. * To purchase a vein finder device in the units where the patient groups have difficulty in finding the vein. * Pediatrics laboratory device (where the pediatric tube can be operated) * Providing a mechanism to prevent the severity of impact in the pneumatic system.			X	Number of Rejected Samples/ Total Number of Samples

Designing the Improvement Action Plan

FMEA was conducted in order to conduct research on risk reduction strategies, define prevention strategies and evaluate their effects. The scale, which was used as a probability scale in a similar study in calculating the risk score, was modified and used in a way that was statistically appropriate to the nature of the process (24). Scales available in the literature were used as severity and detectability scales (25). The second scoring of FMEA was scored by team members based on the assumption that the proposed basic measures were implemented.

As an example, the risk score calculated after FMEA and recommended basic measures are as follows; The risk score of the risk factor of not performing the blood collection process appropriately, which causes hemolyzed sample formation, is 600 and it has the highest risk score. This high risk was greatly reduced by carrying out training and orientation activities regarding proper sampling and transfer, and their periodic and systematic renewal, creating exceptional cases/alternatives for applications that increase the risk of hemolysis (blood sampling from the catheter, use of fine-tipped needles) and following consistent methods and expanding the use of equipment that will reduce the risk of error (such as vacutainer, vein finder) throughout the hospital (RP: 180). Thanks to the basic measures, a decrease of approximately 64.5% in overall risk scores was calculated.

In this context, a total of 11 improvement actions have been identified, with at least one strong or medium-level action for each root cause. Of these, 5 (45.5%) are strong, 3 (27.3%) are moderate and 3 (27.3%) are weak actions. The determined improvement actions are shown in Table 1 in detail.

The plan for the implementation process of the improvement actions was prepared. The evaluation of the acceptability of the plan was carried out, and as the last step, a summary report of these 21 steps of implementation on rejected samples was prepared and the results were transmitted to the management (as of the period in which the study was conducted, the action plan could not be implemented. Therefore, steps 17 and 18-20 could not be carried out).

DISCUSSION

In the study, the sample rejection rate that occurred during a one-year period at a University Hospital was found to be 2%. In most studies evaluating the rejected sample rate, the sample rejection rate was reported as 0.1% to 3.49%. Although there is no threshold for an acceptable sample rejection rate, the CAP - College of American Pathologists recommends that each institution compare its own rejected sample rates with references from multiple institutional studies (26). As part of providing this benchmarking opportunity, a median rejection rate of 0.31% was reported in a study conducted by collecting corporate data from numerous laboratories (27). In another study conducted for the same purpose, the best performance indicator target was highlighted as 0.28 % (28).

Regarding the "Rejected Sample Rate In Clinical Laboratory Tests" monitored monthly within the scope of quality indicators in Turkey, the institution itself is asked

to determine the target value, which is the estimated indicator that was determined and aimed to be reached, considering the current situation and improvement potential (29).

In studies conducted in Turkey, there are studies in which the sample rejection rate ranges from 1 to 1.30% (17,18,30,31). There are also studies where the rejection rate is between 0.3% and 0.7% (32–36). Korkmaz (2020) calculated the average sample rejection rate in the six-month process in his study as 2.08%, similar to the results obtained in this study (37).

Hemolyzed, insufficient and clotted sample rejection reasons, which constitute 65.2% of the 2% sample rejection rate obtained in this study, stand out as the first three reasons for rejection. The most common reasons for rejection are consistent with other study results (18,34,36–38).

In this study, the frequency of rejection was evaluated according to the distinction between intensive care, inpatient service units, emergency (pediatric and adult emergency) and outpatient clinic service units. In inpatient and emergency patients, the frequency of rejected samples was higher than in outpatient clinics (outpatient and routine patients). Similarly, higher rejection rates were reported in inpatients (34,39) and emergency patients (40) in previous studies. It is believed that this increase in rejection rates in inpatient and emergency patients is caused by failures in the implementation of standard sampling procedures due to the presence of complex clinical conditions in these patient groups and omissions in compliance with defined standard operating procedures (41).

In this study, the six sigma approach was used as an alternative for the sample rejection rate in the context of performance evaluation. This approach involves converting the number of errors experienced in any process first to the number of errors per million and then to six sigma values through a statistical table (41,42). The six sigma scale ranges from 0 to 6, and the smallest sigma value for adequate performance in laboratory processes is considered to be 4 (43). In this study, the six sigma values calculated for the number of rejected samples were determined as 3.6 (Defects Per Million: 21765). Accordingly, the result was reinforced that any corrective and preventive action was needed to reduce the number of rejected samples.

Conclusions about the results of qualitative analysis are as follows: In the study, it was observed that negligent behavior was involved in providing the necessary conditions for proper sampling and transfer. In order to ensure compliance with policies and procedures, it was determined that the institution needs monitoring and evaluation regarding the issue. Performance must be continuously monitored to verify the extent to which procedures comply with their requirements and in which service units the intended results are achieved (44). Improvements to this in our study are presented in Table 1.

It was observed that the current policies and procedures of the hospital for proper sampling and transfer do not clarify some exceptional situations and alternatives, which makes

it difficult to comply with policies and procedures. Procedures should clearly state how to reliably identify a patient, how to collect and label a sample, and then how to transport the sample and prepare it for analysis (45). Da Rin (2009) cited the development of clear/clear written procedures as a step in a comprehensive plan to prevent errors before analysis (45). Lippi and Guidi (2007) referred to the publication of guidelines or best practice recommendations for the collection and processing of samples as an activity to prevent improper sampling (14). Improvements to this in our study are presented in Table 1.

When the sample rejection process of the hospital was examined, it was observed that there were situations that caused the inefficiency of the process, such as the presence of error-prone applications, the lack of error correction in the process, and the experience of delays. In the hospital where the study was carried out, sample rejection can be performed in 5 different stages. These rejection stages are planned to be reduced to 2 stages: during sample acceptance and after centrifugation. Thus, it is aimed to simplify the process by removing inefficient steps. Also it was observed that there was a lack of error correction in the process. The improvement activities identified for these situations in the study are presented in Table 1.

When the interviews and observations in the study were evaluated, it was concluded that the personnel had a lack of knowledge on the issues such as what hemolysis is and which conditions affect hemolysis and clot formation. It was observed that a 1-hour training was provided for proper sampling and transfer in the hospital during the year and a limited number of people were included in the training. At this point, it was determined that the training and orientation activities of the institution were insufficient. In the study conducted by Güvenç (2017) in order to evaluate the effectiveness of the training in reducing the rejection rates, it was determined that there was a statistically significant decrease in the sample rejection rate between pre-training and post-training (18). In Aykal's et al. (2014) study aiming to evaluate the effects of corrective and preventive actions to reduce rejection rates, they stated that sample rejection rates can be reduced with training and close follow-up is required on this issue (46). The improvement activities identified for this situation in our study are presented in Table 1.

In the study, it was observed that the vacuum system, which draws blood to a sufficient level, is not common, especially in services. It is known that the risk of hemolysis also increases, as the risk of blood entering the injector hitting the wall of the tube with pressure increases due to the absence of a vacuum system (17). In this context, the identified improvement activities are presented in Table 1. The difficulty of getting enough volume of blood from patients treated in premature babies, newborns, oncology and intensive care units is known. The use of microtubules produced for such patients can ensure that the correct test result is achieved with a small sample volume (31). In our study, it was observed that the staff had difficulties in taking blood in these patient groups. In this context, the identified improvement activities are presented in Table 1. The National Patient Safety Foundation noted that 'weaker' actions, such as education and policy changes, are often required in remediation actions to ensure competence and

expectations, but when used alone would not be sufficient to provide continuous improvements in patient safety. At this point, it is recommended to identify at least one strong or medium level action (22,47). In our study, a total of 11 healing actions were determined, with at least one strong or moderate action for each root cause that can be performed to reduce and prevent the likelihood of similar events repeating. Of the 11 determined improvement actions, 5 are strong, 3 are medium level and 3 are weak actions. Thus, it is thought that sustainable improvement can be achieved by reducing and preventing similar events in the future.

CONCLUSION

In our study, with the 21-step application, the root causes of the rejected samples were determined, corrective / preventive actions were defined, and an action plan was created to help the implementation of the suggested improvement actions and evaluate their effectiveness. The root causes of rejected samples were identified as inadequate orientation and training practices, applicability of policies and procedures, lack of monitoring and evaluation, inefficient process flow and lack of equipment. A total of 11 remedial actions were identified and planned for these root causes, of which 5 (45.5%) were strong, 3 (27.3%) were moderate, and 3 (27.3%) were weak. Shojania et al. (2001) stated that root cause analysis is a time-consuming and labor-intensive method (48). The experience gained in this study also supports this. In addition, it was found that the overall 21-step methodology can assist in identifying the direct, contributing, underlying and root causes of rejected samples and in planning remediation actions for root causes by providing detailed guidance.

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