International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

An Empirical Study on Laboratory Sample Rejections

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Abstract

Clinical laboratory plays a crucial role in the diagnosis and management of the patients. The increased focus on the patient safety and awareness that the information provided by these laboratories has direct impact on diagnosis and treatment requires that laboratories prioritize reduction in error rates. For patients safety the laboratory has the right to refuse samples that are incompletely, incorrectly labelled because of wrong methods of collection, storage and transportation.

Despite the remarkable advances and the modern innovations which have transformed laboratory diagnostics from manual and labour- intensive service to fully automated process, the clinical laboratory still shows a number of pre-analytical errors that might lead to erroneous patient diagnosis and treatment that follows.

The present study is to analyse the reason for rejections of the tests and lab related incidents. Every sample that reaches the laboratory is considered for the calculation to improve the laboratory practices by using quality indicators. The major findings of the study are that most rejections are happening at pre-analytical phase.

The study suggests several changes in the sample collection and transportation process. Rejections of the samples are high because of human error which can be minimised by training technicians and staff members. Policies and procedures specific to specimen collection, transportation and preparation should be strictly followed.

Keywords: Pre-analytical errors, Patient safety, Quality indicators, Rejections

Introduction

Medical or clinical laboratory is where tests are carried out on clinical specimens to obtain information about the health of a patient to aid in diagnosis, treatment and prevention of disease. Clinical laboratories vary in size and complexity and so offer a variety of testing services. More comprehensive services can be found in acute-care hospitals and medical centres, where 70% of clinical decisions are based on laboratory testing.

Even though automation and standardization technological advances have significantly improved the analytical reliability of laboratory tests, lab errors still do occur in the pre-analytical phase, sample collection and during the analytical phase of the total testing process.

Clinical laboratories have made a series of improvements such as increased automation of manual process and pre analytical quality control programs intended to minimize the mentioned and hence improve patient safety. In order to improve the efficiency, it is very important that the laboratory acknowledge and notify of any error in quality control so as to identify deficiencies in laboratory process that may potentially improve patient care and safety.

The laboratory in most cases has very little control on the collection of specimens for microbiological investigations. The education and awareness of the attendants, technicians, nurses and attending physicians, who are involved in the collection and transport of the specimen to the laboratory is very important. On the other hand, the technicians must confer to the physician before rejecting any valuable specimens.

Clinical laboratories have a direct impact on patient diagnoses and treatments and thus have important roles in patient management and safety. Given that 70–80% of all diagnoses are made, at least in part, based on laboratory tests, laboratory errors have consequences: misdiagnoses, diagnostic delays, and inappropriate therapies, increased risks to patient safety, increased costs, and time lost. The laboratory "total testing process" (TTP) includes three main phases: the pre-analytical, analytical, and post-analytical phases. Approximately 70% of laboratory errors originate in the pre-analytical phase. The pre-analytical phase consists of pre-pre-analytical phase and 'true' pre-analytical phase. The processes of selecting appropriate tests by clinicians, ordering, collecting, identifying and labelling, handling, transporting is known as pre-pre-analytical phase. The processes of accepting samples by the laboratory, centrifuging, aliquoting, diluting, and sorting the biological specimens for analysis are known as 'true' pre-analytical phase. Errors can occur during each step, mostly in processes performed outside the laboratory before the acceptance of biological specimens by the laboratory, referred to as the pre-pre-analytical phase. The processes of 'true' pre-analytical phase which are undertaken within the laboratory are less prone to errors compared with processes performed outside the laboratory.

Sample Rejections

Sample rejections are samples rejected by the laboratory if the sample was not obtained as per technical instruction for the specific specimen. Sample rejection is often regarded as a nuisance by everyone, not just the clinical staffs. For clinical staffs, it means having to redo sample collection and sending it back to the laboratory. This can lead to delay in getting the results for patients and thus, might affect patient management such as decision on treatment and delay of hospital discharge. Laboratory personnel or medical laboratory technologists would have to issue a notice of rejection to the ward or clinic for every rejection. All details regarding the rejection will have to be filled accordingly to allow adequate analysis of the cause of rejection and possible intervention to improve the quality of care for patients.

The role of clinical laboratory continued to grow as the single largest component of objective scientific data within the medical record of patients. The result of any laboratory examination is only as good as the sample received in the laboratory. Some specimens are time-dependent. In order for the laboratory departments to process them correctly, specimens must be collected/received within their time constraints to be accepted by the Laboratory.

In the present medical diagnostic scenario, around 60-70% of medical decisions related to diagnosis and treatment planning are dependent upon the medical laboratory services. This highlights the significance of testing to be done on correct sample (pre-analytical phase) with accurate and precise techniques (analytical phase) at the earliest (post-analytical phase).

"World Health Organization-World Alliance for Patient Safety" states that impressive improvement has occurred in the analytical stage of laboratory medicine, but the pre-analytical and post-analytical phases are still vulnerable to errors.

In the pre-analytical phase, in order to get quality samples (may be defined as the blood samples that are reflecting the actual status of the patient's condition at the time, when the sample is drawn), certain criteria are laid down by the laboratory management system. Thus, laboratories accept only good quality samples. The rate of sample rejection is one of the Quality Indicators and can be used to monitor improvement in the pre-analytical phase. It is measured by the fall in its rate over time, suggesting improvement in pre-analytical phase.

In terms of quality, over time, with the remarkable advances in instrument technology, automation, computer science, reliable quality indicators, internal quality control rules, and external quality assessment programs, in the analytical phase quality is largely assured. Thus, further quality improvements are focused on additional sources of variation, such as pre-analytical errors.

Research Problem Statement

The present study is to reduce the number of specimen rejections drawn by laboratory in a hospital as there are a lot of rejections and patients are suffering a lot by the rejections.

Need for the study

The process of testing the specimen depends on collection, storage, transportation and process to be performed in the laboratory. So, it requires ensuring a high quality process with samples being taken from correctly identified patients, stored and transported and right results being reported to clinical staff by laboratory staff. Specimen rejection has significant consequences including patient discomfort; unnecessary specimen redraws, and delays in diagnosis and treatment of patients. Hence, the present study is needed to know the reasons for rejections.

Significance of the study

Health care costs could decrease when there is a decline in the number of specimens being rejected. The patients would likely have better outcomes because their treatments would be based on more accurate and timelier laboratory testing results due to increased staff awareness. Patient may also benefit by not being subjected to an increased risk of infection caused by excessive needle sticks by staff members who may lack adequate skills. Savings would be increased by healthcare system by having far fewer rejected blood specimens, which would decrease healthcare cost significantly.

Objectives

- To know the reasons behind the rejections of the samples

- To examine root cause of the rejections in the laboratory and suggest measures

Scope

The scope of the study includes the sample rejections by the laboratory at the hospital for a period of six months.

Methodology

Data was collected for six months from November to April and during that period total of 231 samples were rejected. These were the samples collected from various wards and ICUs and also from Day care procedures. And all these are considered for the study. Both Primary and secondary sources are used for collecting the data. The collected and analysed data is represented in the form of bar diagrams and tables. Pareto Charts, Fishbone Analysis, CAPA and FMEA analysis are used to find the root cause for sample rejections.

Review of Literature

A study was done by Dr.Abhineet Mehrotra, Dr.Kanchan Srivastava, Dr.Prabhakar Bais on "An Evaluation of Laboratory Specimen Rejection Rate in a North Indian Setting-A Cross-Sectional Study" in which a total of 2000 sample were studied. A total of 5.3% samples were rejected. The study found that the rejection rate was higher among the hospitals run by trusts than govternment. In all, the rejection rate was higher blood sample (9.1%) as compared to body fluid (8%), urine (6.8%). The main reason of rejection was due to inadequacy of specimen collection by the paramedical staff which concluded that "The rejection rate was higher in trust hospitals due to higher awareness at the analytical level of the sample processing in the lab as compared to government run hospitals where every sample is processed irrespective of its adequacy/inadequacy and the report is provided.

Carraro and Plebani found that 87% of the errors occurred in the pre-analytical phase, which includes proper patient and specimen identification, appropriate and correct test requests, accuracy in blood drawing, specimen handling, and specimen transportation. Furthermore, 73% of all the errors in all phases were classified as being preventable.

University of Porto Alegre conducted a study in which 77,051 blood samples were collected whereof 441 (0.57%) were rejected by some type of pre-analytical error and therefore had to be recollected. Clot was found to be the major cause of rejection of samples, 43.8%, followed by insufficient sample volume, 24%.

Liyun cao and Meng cheon conducted a study in which a total of 837,862 specimens received, 2178 (0.26%) were rejected. The most common reasons for specimen rejection were contamination (35.1%), inappropriate collection container/tube (15.2%), quantity not sufficient (QNS) (15.1%), labelling errors (14.7%), haemolyzed specimen (9.4%), and clotted specimen (9.3%).

Shubhra Jandial and Vasant Gosai conducted a study in a laboratory of a tertiary care centre in which a total 1,57,382 blood samples were received during the period of study (Jan-2015 to Dec-2015). Among these samples, 2315 blood samples were rejected. Total rejection rate was 1.47%. Rejection rates of

blood drawing errors that were quantity not sufficient (78.83%) followed by haemolyzed samples (18.92%), lipemic samples (1.81%) and samples in improper container (0.43%) among all rejected samples in the study.

Rana G Zaini and Haytham a Dahlawi conducted a study at HERA general hospital in which a total of 1,02,197 samples were received by clinical biochemistry laboratory from the patients admitted in the wards as well as outpatient department (OPD) during the period of the study. Venous blood samples were considered unsuitable according to the following accepted criteria: incomplete patient data on request, quantity not sufficient (QNS), clotted sample, visible haemolysis and centrifugation mismatch, wrong tube and others. The overall rejected samples, which were found unsuitable for further processing, were 2116 samples. This accounted for 2.07% of all samples collected in the biochemistry laboratory.

Victor V. Mosha and Claudia Kabanyana conducted a study at KCMC clinical laboratory in which **o**ut of the 1,17,181 samples received from January to December 2016, 234 were rejected, giving a 0.19% rate of rejection. The highest rates of rejection were from haematology section 78 (33.3%). The major type of rejected sample was blood (86.3%) and 20% of the rejected samples came from internal medicine department, mainly from its inpatient department (13.6%).

Modibo Coulibly and Moussa Diawara conducted a study in which a total of 27,810 venous blood samples were received during the study period; 48% was for biochemistry, 41% for immuno-serology, 9% for blood cell count and 2% for coagulation tests. There were 3,826 instances of pre-analytical non-compliances (13.76%) identified that led to sample rejection. Out of the 11 types of non-compliances investigated, 5 (45.4%) accounted for nearly 91% of the problems: insufficient sample volume (28.9%), haemolyzed samples (20.5%), inappropriate collection time (17.8%), sample clot (12.9%), and inappropriate sample collection tube (10.8%). They observed a significant difference in rates of non-compliance between inpatients and outpatients' samples (44.4%). The proportion of non-compliance has significantly decreased after the two training sessions of hospital staff in phlebotomy and sample handling.

Data Analysis

The study was conducted in a hospital for six months and during that period total rejections amounted to 231. The following figure shows the number of samples rejected and the reasons for the rejection.

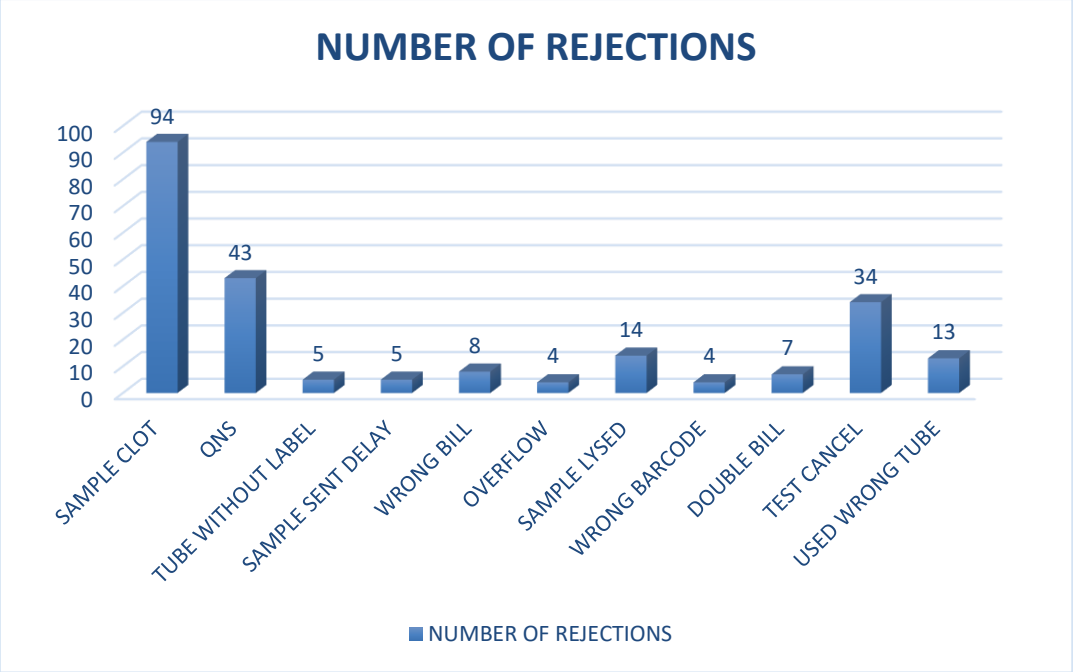


Figure 1

From the above figure it can be analysed that out of 231 samples 94 samples are rejected for sample clot followed by QNS, test cancel and sample lyses. Followed by less number of rejections due to wrong barcode and overflow of sample

The following table represents the rejections based on tests performed

Table 1

TEST NAME	**NO. OF REJECTIONS**
RBS (Random Blood Sugar)	21
CBC (Complete Blood Count)	47
CVE (Cardio vascular event)	19
HBA1C (for diabetic control)	5
EDTA (Ethylene Diamine Tetra Acetic)	8
D-D (D-Dimer)	7
GeneXpert	4
CBP (Complete Blood Picture)	14
TSH (Thyroid Stimulating Hormone)	2
Free PSA (Prostate specific antigen)	4
LFT (Liver function tests)	13
CRP (C-Reactive Protein)	5
RAPID TEST(HIV, HCV, HBSAP)	1
PCT (Procalcitonin)	5
ESR (Erythrocyte Sedimentation Rate)	8

Blood Group	7
WBC count	2
CPK (Creatine phosphokinase)	1
K+ (Potassium)	3
Electrolytes	8
Ammonia	2
RNA (Ribonucleic acid)	2
Lipase	5
Iron	1
PT (Prothrombin time)	16
Urine Culture	2
APTT (Activated partial thromboplastin clotting time)	5
BT CT (Bleeding time and Clotting time)	12
Platelet count	2

The above table is represented in figure 2. It is observed that higher number of rejections is seen for the test CBC and less number of rejections is seen for Iron, CPK and Rapid test

Figure 2

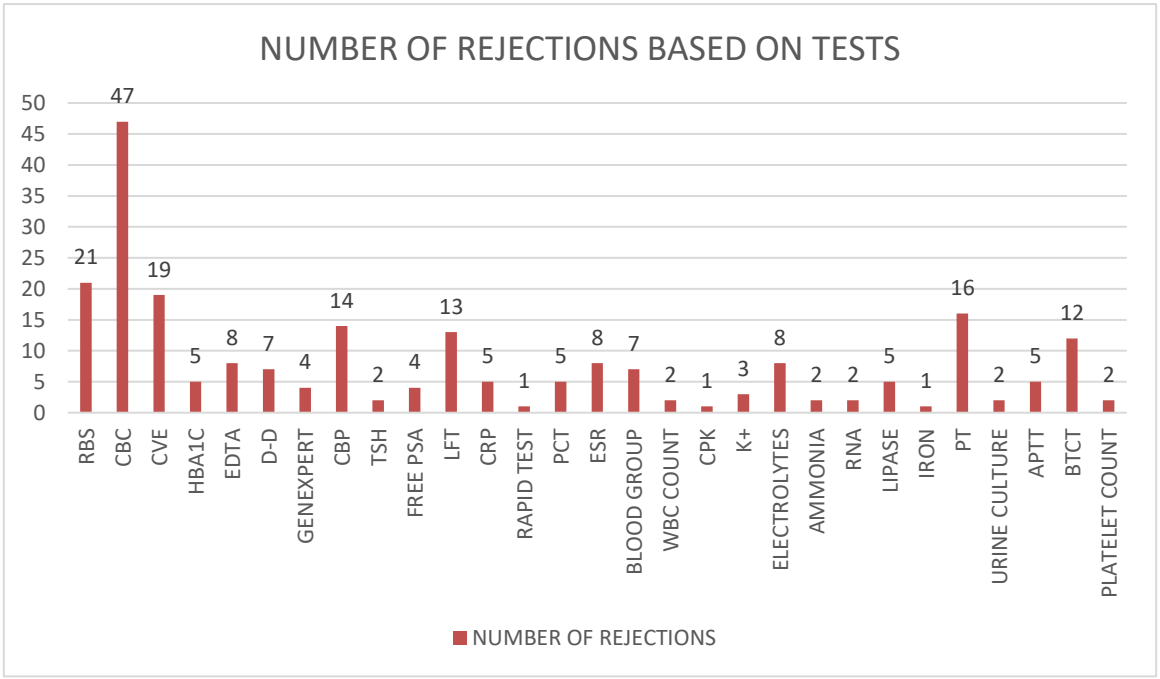
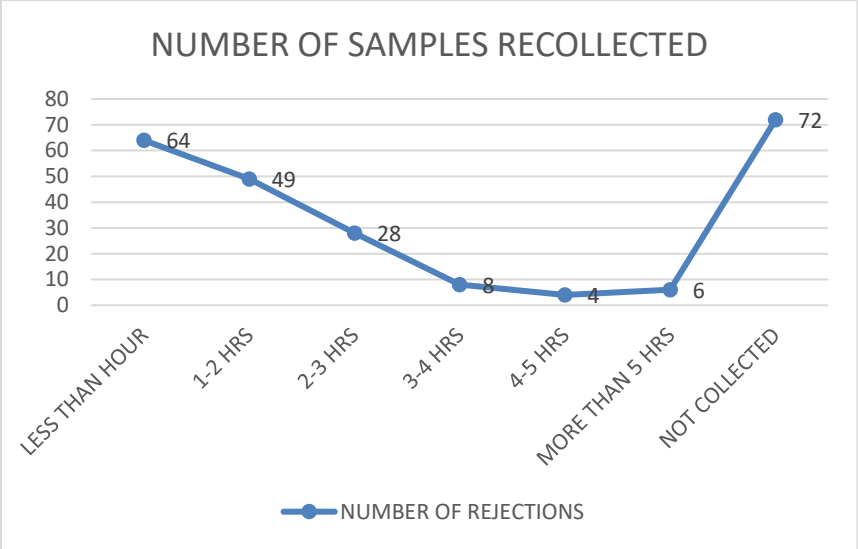


Figure 3 below shows number of samples recollected during different spans of time. Within less than one hour 64 samples are recollected after the samples are rejected

Figure 3



Pareto Charts for the Rejections

For the study Pareto charts are used to find those tests which are contributing for major rejections. Pareto analysis is also called 80/20 rule. This means that 80% of the problems are caused by 20% of the activities and it is this important 20% that should be concentrated on.

A Pareto chart is a series of bars whose heights reflect the frequency or impact of problems. The bars are arranged in descending order of height from left to right. This means the categories represented by the tall bars on the left are relatively more significant than those on the right. The Pareto principle states that a small number of causes accounts for most of the problems. Focusing efforts on the vital few causes is usually a better use of valuable resources.

Figure 4 below shows that sample clot, QNS, test cancel and sample lysed resulted in 80% of the rejections.

Figure 4

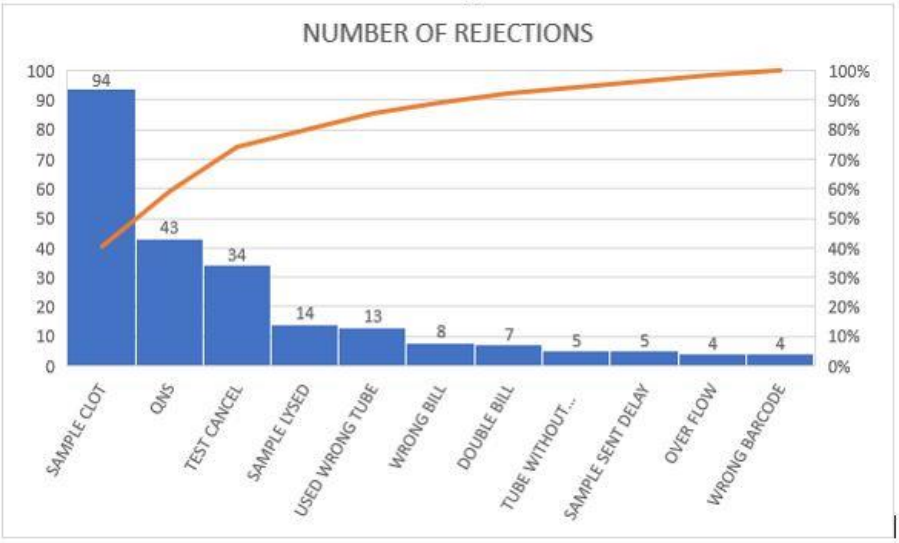
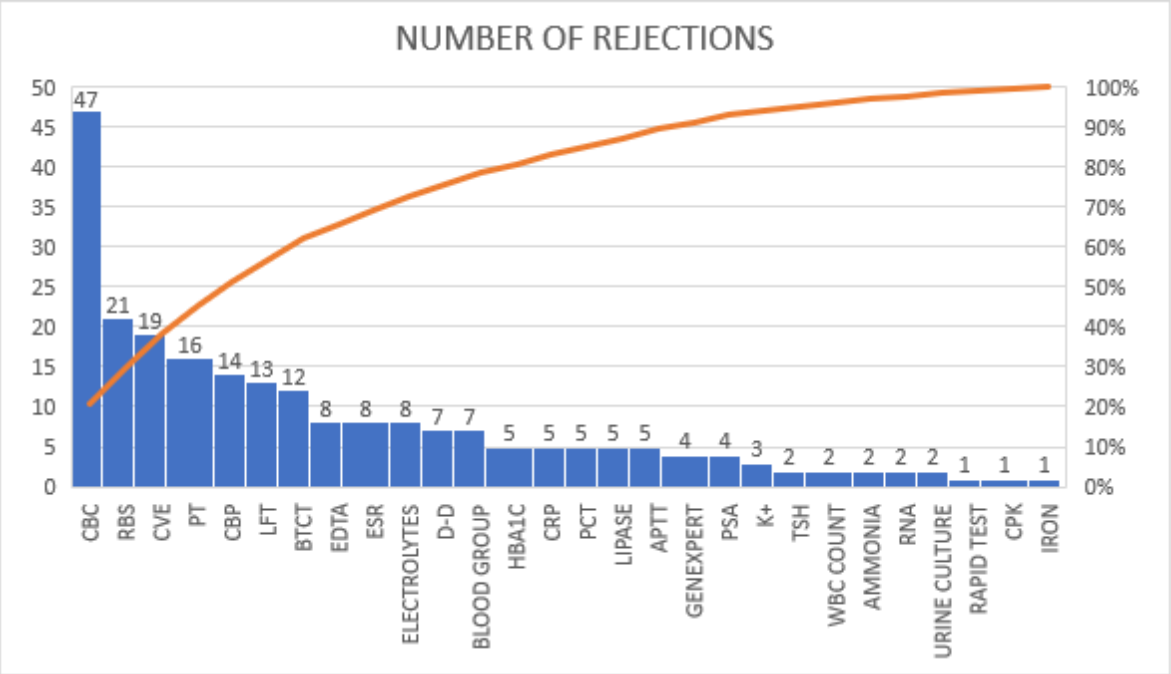


Figure 5 below shows that the tests CBC, RBS, CVE, PT, CBP, LFT, BTCT, EDTA, ESR, Electrolytes, D-D, Blood Group and HBA1C resulted for 80% of total rejections.

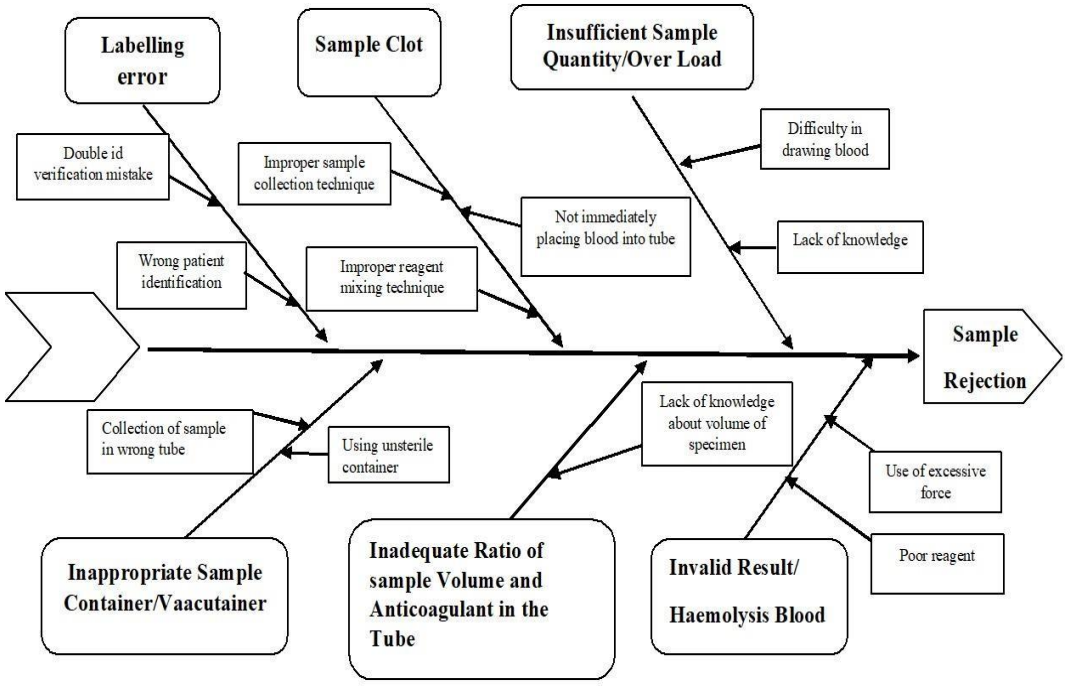
Figure 5



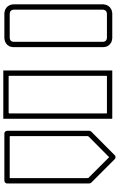
Fish Bone Analysis

In the study, Ishikawa diagrams or fish bone analysis is done to know the causes for rejections. This is a quality tool and causal diagrams created by Kaoru Ishikawa that show the potential causes of a specific problem. The figure 6 below shows the potential causes for the various tests of rejected samples. Figure 7 is the standard format of the fish bone analysis for sample rejections using man, material, method and machine

Fish Bone Analysis for Rejections Figure 6



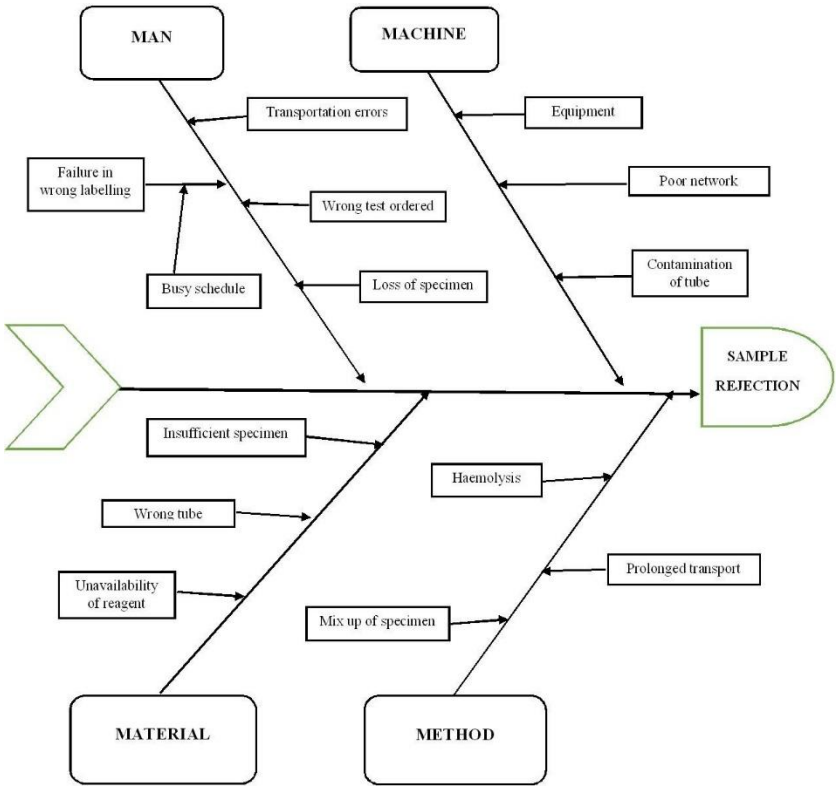
The symbols used in fishbone analysis are as follows



Represents –causes Represents –sub causes

Represents - problem

Fish Bone Analysis for Rejections in Standard Format Figure 7



For the current study Corrective and Preventive Action (CAPA) is also used. CAPA tool is applied for process failures and are investigated to determine their root cause in an effort to eliminate occurrences of nonconformity (corrective action) and prevent similar occurrences from happening in the future (preventive action). In the following table CAPA analysis is applied on typing and processing errors, missing results, auto approvals and wrong sample collection and results are shown in table 2.

Table 2

CAPA ANALYSIS (CORRECTIVE AND PREVENTIVE ACTION ANALYSIS)

ROOT CAUSE	CORRECTIVE ACTION	PREVENTIVE ACTION
CAPA Analysis for typing errors.	Check the report and retype the results again and issue the report	Recheck the results before entering into the system. If there is any doubt on results repeat the test again.
CAPA Analysis for processing errors	Reprocessed and reported sample	Checking the sample twice before the processing so that there is a chance of decreasing the errors. Checking the machine before starting the sample processing

CAPA Analysis for missing some results in the report	If the incident happened after issuing the report check the details and correct it and inform the patient and give the correct report to the patient	Check the details before and after entering in to the system. If it is because of the software problem inform to the IT department once before typing and correct it.
CAPA Analysis for auto approvals with doctor signature	Check the details how the report got auto approval if its IT issue inform the IT department and correct the report and re-report to the patient	Check the report before dispatch whether the report approved by the doctor or not.
CAPA Analysis for wrong sample collection	Ask the nurse to collect correct sample and do the test	Educating the nurses regularly by conducting classes.

FMEA Analysis (Failure Mode and Effect Analysis)

FMEA stands for Failure Modes and Effects Analysis. It is a step-by-step method for identifying and analyzing all possible ways a process could fail and designing a strategy to prioritize and mitigate the biggest risks.

Criteria for FMEA analysis

Criteria	Rating	Description
SEVERITY		
Negligible	1	Temporary discomfort
Minor	2	Harm that does not require medical intervention
Moderate	3	Harm that requires medical intervention
Critical	4	Harm that damages the quality of life
Catastrophic	5	Permanent harm.
OCCURRENCE		
Remote	1	Occurs annually
Uncommon	2	Occurs within 2-6 months
Occasional	3	Occurs monthly
Frequent	4	Occurs weekly
Continuous	5	Occurs daily
DETECTION		
High	1	Control measures can detect errors
Occasional	2	Control measures almost detect the errors
Moderate	3	Control measures may or may not detect the errors
Low	4	Control measures unlikely detect the errors
Nil	5	Control measures are ineffective

Table 3 Initial FMEA analysis with highest risk failure modes (before action plan)

FAILURE MODE	POTENTIAL EFFECT	POTENTIAL CAUSE	SI	OI	DI	RPN	CONTROL MEASURE	ACTION TO TAKE
Sample clot	Repeat of sample collection and delay in treatment	Improper sample collection technique	3	5	4	60	Proper staff training for collection like use of closed system for collection	Regular training for nurses and also maintaining hygienic environment
QNS(Quantity not sufficient)	Double injury to the patient due to collection of sample twice	Lack of awareness to the staff about the volume required for the test	3	5	4	60	Developing awareness among the nurses about the volume required	Proper training and develop awareness among the staff.
Transcription error(wrong entry of result)	Effects patient treatment	Inefficient and untrained staff	5	5	4	100	Efficient staff training	Training to staff given regularly
Malfunction of reagent	Effects wrong test result(unexpected results may occur)	Contamination	5	3	5	75	IQC before sample analysis (incoming quality control)	IQC before and after run
Malfunction of calibrator	Calibration failure	Storage temperature	4	3	4	48	Visual check of calibrator	Continuous temperature monitoring of refrigerator
Sample was taken in wrong tube	Wrong result	Inefficient staff	3	4	3	36	Efficient staff training	Regular training to staff
Sample misplaced in laboratory	Delayed reports	Inefficient and less manpower	3	3	4	36	Efficient staff training and recruiting enough man	Regular training to staff and also checking and recruiting staff wherever and whenever is required

SI-Severity Index OI-Occurrence Index DI-Detective Index RPN-Risk priority number

Table 4

FMEA analysis after implementing the action plan with highest risk failure modes (Expected)

FAILURE MODE	POTENTIAL EFFECT	POTENTIAL CAUSE	SI	OI	DI	RPN	ACTION TAKEN
Sample clot	Repeat of sample collection and delay in treatment	Improper sample collection technique	3	3	1	9	Regular training for nurses and also maintaining hygienic environment
QNS(Quantity not sufficient)	Double injury to the patient due to collection of sample twice	Lack of awareness to the staff about the volume required for the test	3	3	1	9	Proper training and develop awareness among the staff.
Transcription error(wrong entry of result)	Effects patient treatment	Inefficient and untrained staff	5	2	1	10	Training to staff given regularly
Malfunction of reagent	Effects wrong test result(unexpected results may occur)	Contamination	5	1	2	10	IQC before and after run
Malfunction of calibrator	Calibration failure	Storage temperature	4	1	1	4	Continuous temperature monitoring of refrigerator
Sample was taken in wrong tube	Wrong result	Inefficient staff	3	2	2	12	Regular training to staff
Sample misplaced in laboratory	Delayed reports	Inefficient and less manpower power	3	1	1	3	Regular training to staff and also checking and recruiting staff wherever and whenever is required

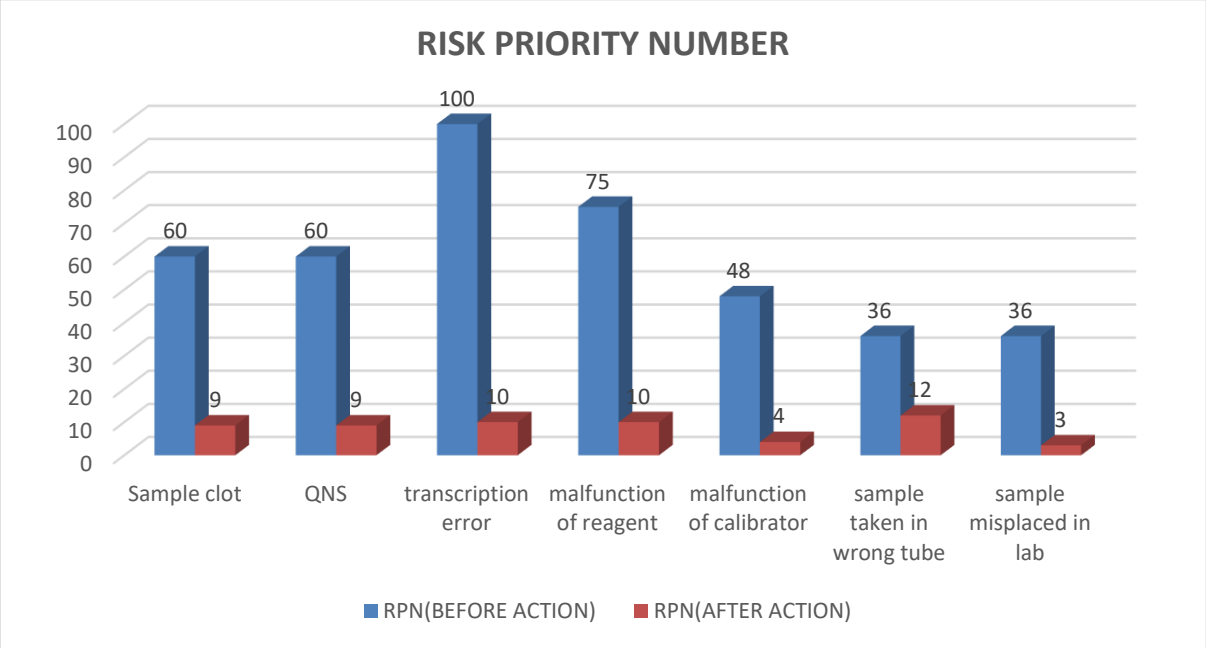
Table 5

The following table represents the RPN Values before and after action

REASON	RPN(BEFORE ACTION)	RPN(AFTER ACTION)
Sample clot	60	9
QNS	60	9
Transcription error	100	10
Malfunction of reagent	75	10
Malfunction of calibrator	48	4

Sample taken in wrong tube	36	12
Sample misplaced in lab	36	3

Figure 8



The above figure shows that there is fall of RPN after using FMEA analysis, which shows that if any lab or hospital strictly follows the actions given by using FMEA analysis, RPN decreases, therefore, rejections rates will also reduce. The study clearly shows that that majority of rejections are manmade which can be reduced if correct action can be taken and monitored regularly.

Observations

- Mostly the rejections of samples are happening due to busy schedule of the nurses which causes ignorance of the proper process flow of taking the specimens.
- One of the reasons for rejection of tests is the inexperience of new nurses who are not fully trained.
- The common reason of repeated tests at entry level is wrong labelling of samples.
- Manual transporting of the samples is resulting in delaying of the investigation and generation of reports.
- Sometimes the requisition for the test was raised by one nurse and sample was collected by another nurse which also causes inter changing of specimens.
- The main reason of occurrence of lab related incidents are improper preparation of the lab specimen and the specimen container.
- Insufficient manpower leading to delay in transportation of the sample.
- Lack of proper training to the nursing staff on laboratory software how to put the incidents for lab test as well as the radiology test.

Summary

The study laboratory sample rejections are done by primary observation and collected secondary data from laboratory register. A total of 231 rejected samples over a period of six months were analysed. It

has been observed that most of the rejections are happening in pre-analytical stage, due to the sample clotting and also due to the delayed dispatch of samples due to less manpower. The rejections are also caused due to newly joined nurses who lack proper training. To know the root cause of rejections Pareto and fish bone analysis is also done

To reduce the rejections, regular training and education to the nursing staff and laboratory technicians and also maintaining sufficient manpower to dispatch the samples is required. Proper orientation regarding the organisation and working area and giving training to the newly joined nurses will also reduce the rejections and also reduce the wastage of the organisation resources and improves the quality services of the laboratory.

Conclusion

From this study, we can conclude that most of errors are occurring in pre analytic phase. The reporting system for the sample rejections is not satisfactory due to improper process and lack of communication between nursing staff and lab technicians. The Hospital needs to customize its Laboratory information system to identify the significant gaps in sample collection process.

It can be concluded that staff training takes a very important place in preventing these rejections, as it can be seen from the study, training helps in decreasing rejection rates.

Recommendations

To organize a team of nursing as well as laboratory staff in conjunction with the quality department with the target of creating a procedure manual to provide health care personnel with concise information on the proper techniques to collect quality blood specimens with minimal patient discomfort. So as to minimize the errors encountered in blood collection that can lead to unsuitable specimens eventually rejected when received in the medical laboratory.

The sample dispatch person who takes the specimen to the lab should be trained properly for proper transportation of sample, the bio-hazard box in which the sample is taken should always have an ice pack so that the sample is protected, by maintaining sufficient manpower prevents the delays in the dispatch of the sample.

Other measures of improvement include the use of better phlebotomy equipment such as using straight needles rather than butterfly devices or syringes. Also to use a dedicated phlebotomist or technician for blood draws instead of registered nurses. Considering the effect of laboratory rejections on efficient care delivery, healthcare costs, and patient satisfaction, reducing the blood sample rejection rate should be prioritized.

Scope for Further Research

However, this study has few methodological limitations. First of all, although the intensive regular trainings were provided to the nursing staff responsible to for drawing the samples and filling the requisition forms and laboratory technician at collection room scrutinizing each request and sample send with it, their motivation was not assessed. This factor is important as this can confound the results as

although a person may be trained for the job, but to implement that training on continuous basis needs staff's motivation toward quality work. This can be assessed in future studies. Further studies should be performed after preventive and corrective actions for rejecting samples.

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