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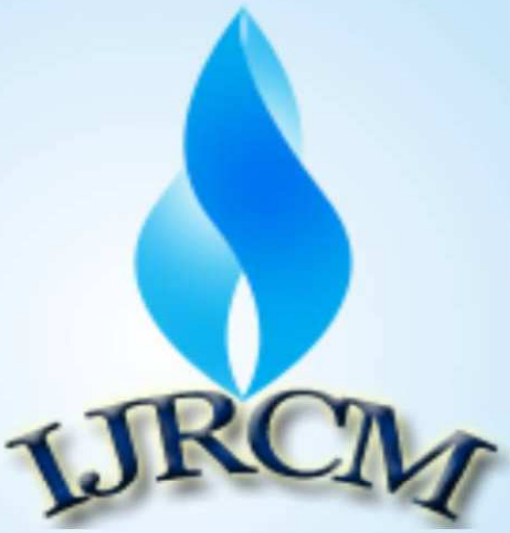

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INTRODUCTION
REVIEW OF LITERATURE
NEED/IMPORTANCE OF THE STUDY
STATEMENT OF THE PROBLEM
OBJECTIVES
HYPOTHESIS (ES)
RESEARCH METHODOLOGY
RESULTS & DISCUSSION
FINDINGS
RECOMMENDATIONS/SUGGESTIONS
CONCLUSIONS
LIMITATIONS
SCOPE FOR FURTHER RESEARCH
REFERENCES
APPENDIX/ANNEXURE

The manuscript should preferably range from ***2000 to 5000 WORDS***.

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BOOKS

- Bowersox, Donald J., Closs, David J., (1996), "Logistical Management." Tata McGraw, Hill, New Delhi.
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- Kumar S. (2011): "Customer Value: A Comparative Study of Rural and Urban Customers," Thesis, Kurukshetra University, Kurukshetra.

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- Garg, Bhavet (2011): Towards a New Gas Policy, Political Weekly, Viewed on January 01, 2012 http://epw.in/user/viewabstract.jsp

A STUDY ON COST OF REJECTION (REJECTED SAMPLES) IN A NABL ACCREDITED LABORATORY AT A POST GRADUATE TEACHING HOSPITAL IN DEHRADUN, UTTARAKHAND

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ABSTRACT

The Laboratories are committed towards providing the highest quality test results. Quality specimens/samples are integral to quality results. By laying down certain quality indicators (QI) for the same, laboratory management system can monitor continual improvement (e.g., pre-analytical, analytical and post-analytical phases) in the laboratory. In order to get quality samples (may be defined as the blood samples that are true reflection of the actual status of the patient's condition at that moment, when the sample is drawn), almost all laboratories opt for rejecting the blood samples which are not the Quality samples. The Aim was to study the Cost of Rejection (Rejected Samples) in a NABL Accredited Lab in a Tertiary Care Hospital. Further objectives were to a) study the reasons for sample rejections b) to prioritize the reason for rejection samples of the lab in a given period of time through ABC Analysis c) To measure the cost of rejection using the costing method and d) Suggesting ways to reduce the rejection so that the percentage of rejection and then overall cost to the patient and hospital can be reduced. Setting and Design : An Observational Cross Sectional Study was done in the NABL accredited lab of a 700 beds Post Graduate teaching Hospital at Dehradun district, in the state of Uttarakhand, from the period of March – May 2013. Methodology: Total rejected samples which were obtained in the three month period of data collection (inclusive of both inpatients and outpatients) were studied. Results: There were various reasons for sample rejections. The largest number of Sample rejections were in Biochemistry (n= 191 of 599 samples obtained, i.e. 32%), followed by Serology (n = 131 of 599 samples, i.e. 22%) and Hematology (n = 92 of 599 samples, i.e. 15 %). Overall the total Rejection rate in the three month period was less than 1% (= .45 %), which amounts to 599 rejections of total 130877 samples obtained in Lab. The maximum contributing factor for sample rejection was a) sample got hemolysed due to large time gap between collection times and processing time (40%), b) sample collected not matching with the Test requisition form (19%) and c) Vacutainers label not matching with the requisition form (12%). The average cost of rejection of a lab sample was Rs 124/sample.

KEYWORDS
Sample rejections in lab, Sample collection guidelines, Process Pathways, Activity based Costing.

INTRODUCTION

Collecting and analysing data consistently are necessary tasks for assessing quality, monitoring standardized key processes, improving performance and patient safety in clinical laboratories. These influences 70% of medical diagnoses. Laboratory testing, commonly known as total testing process (TTP), is generally subdivided as preanalytic, analytical and post analytical phases. Preanalytic phase errors have been found at the majority of the total errors (46-68.2%) in laboratory and research medicine. Unfortunately, according to the literature which comprises the process from the beginning of laboratory test requests to the delivery of specimens in the laboratory, there is no sufficient data on errors during the initial steps of preanalytical phase. However, the error magnitude depends on the capacity of a system of error reporting.

REVIEW OF LITERATURE

Data on rejected samples due to various types of preanalytical errors is one of the laboratory medicine preanalytical quality indicators. There is a set of significant data including various types of errors such as the appropriateness of test order, patient wristband identification error, timing errors in sampling and preparation, haemolytic, lipemic blood samples and inappropriate transport, inadequate and inappropriate tubes portion of the sample. However, the types of error in the preanalytical phase seem to have changed over time, but distribution of errors among other phases of TTP has remained the same as per many studies published .Poor communications among physicians, nurses and phlebotomists involved in the TTP or poorly designed processes are also counted as laboratory errors in preanalytical phase.

Preanalytical phase errors start to occur at the point of entry for laboratory test requests by clinicians. Rejection reasons of test requests generally include requests for wrong tests, missing input of tests, ordering a medically unnecessary tests, over-ordering, erroneous coding or unintelligible requests. In some conditions, test requests were rejected with the whole test panel, while only a few tests were selected to be rejected within the clinicians' request panel. For example: haemolysis interference, one of the most common reasons, especially affects lactate dehydrogenase, aspartate aminotransferase, potassium and total bilirubin concentration, while other tests are not interfered, since it is possible to perform measurement until a severe level of haemolysis . Additionally, if test requests cannot appropriate for calculating, these tests are obliged to rejection.

Personal impact on specimen collection is important factor and the preanalytical error rate is 2 to 4 times higher for non-laboratory phlebotomists than laboratory staff. Inappropriateness of the samples especially due to blood drawing errors generally occurs when the blood samples are drawn by nurses whose experiences and training are not sufficient for blood drawing in clinics comparing to the phlebotomists who are a group of more stable staff.

The reasons for rejection and their high-level rates might gather into certain tests due to the unique operating characteristics of the test groups during routine work. The aim of this study was to better explain the rates and reasons of rejected samples, regarding to the certain test groups in our laboratory. Their respective rates might provide aid for the planning of the preventive and corrective operations in order to reduce the incidence of these errors. In a study published by By Lourens HYPERLINK "http://www.pubfacts.com/author/Lourens+A+Jacobsz" A HYPERLINK "http://www.pubfacts.com/author/Lourens+A+Jacobsz"Jacobsz, Annalise E HYPERLINK "http://www.pubfacts.com/author/Annalise+E+Zemlin"Zemlin, Mark J HYPERLINK "http://www.pubfacts.com/author/MarkJ+Roos"Roos, Rajiv T Erasmus, in internet (PUBFacts); A total of 32,910 specimens were received during the study period, of which 481 were rejected, giving a rejection rate of 1.46%. The main reasons for rejection were inappropriate clotting (30%) and inadequate sample volume (22%). Only 51.7% of rejected samples were repeated and the average time for a repeat sample to reach the laboratory was about 5 days (121 h). Of the repeated samples, 5.1% had results within critical values. Examination of patient folders showed that in 40% of cases the rejection of samples had an impact on patient care. The evaluation of pre-analytical processes in the laboratory, with regard to sample rejection, allowed one to identify problem areas where improvement is necessary. Rejected samples due to factors out of the laboratory's control had a definite impact on patient care and can thus affect customer satisfaction. Clinicians should be aware of these factors to prevent such rejections.

PREANALYTIC STANDARD OPERATING PROCEDURES

Each laboratory accredited by NABL is required to follow written procedures and divisional standard operating procedures (SOP) for:

- Patient preparation, when applicable,
- Specimen/sample collection,
- Specimen/sample labeling, including patient name or unique patient/sample identifier and, when appropriate, specimen source, specimen date,
- Specimen/sample storage and preservation,
- Specimen/sample transport conditions,
- Specimen/sample processing,
- Specimen/sample acceptability and rejection,
- Specimen/sample submission, handling and referral, and
- Acceptance criteria specific to each assay.

REQUIRED ACCEPTABILITY CRITERIA FOR SPECIMEN/SAMPLES

A. **Test Requisition (or Electronic Test Order)**

1. The approved test requisition must have the following information:

a. The name and address or other suitable identifiers of the authorized person(s), or laboratory requesting the test and, if appropriate, the name and address of the individual responsible for using the test results,

b. The patient's name or unique patient/sample identifier matching what is labeled on the specimen/sample,

c. The test(s) to be performed, and

d. The date of specimen/sample collection

2. When appropriate to the testing system, the following may be required:

a. The source of the specimen/sample,

b. The sex and age or date of birth of the patient,

c. The time of specimen/sample collection, and

d. Any additional information relevant and necessary for a specific test.

SPECIMEN/SAMPLE LABELING

The specimen/sample must be properly labeled and include

1. The patient's name or unique patient/sample identifier matching the test requisition or electronic test order,
2. If appropriate, the date and time of specimen/sample collection, and
3. Any additional information relevant and necessary for a specific test.

SPECIMEN/SAMPLE INTEGRITY

The specimen/sample must be:

1. Collected in the correct, non-expired, intact, container, device or transport media,
2. Transported under the correct conditions,
3. Processed/handled according to approved laboratory procedure,
4. Sufficient quantity to perform testing (includes no specimen/sample received),
5. Received within acceptable time limitation; specific criteria to be determined by each lab.

EXCEPTIONS

1. All requests for exceptions shall be referred up the chain of command to the Supervisor, Division Chief, Deputy Director, and/or Director.
2. Potential exceptions may include but are not limited to:

a. Outbreak investigations,

b. Specimens from deceased patients, or other extenuating circumstances

PROCEDURE FOR REJECTION OF SPECIMENS/SAMPLES

- Evaluate specimens/samples for acceptability,
- Document the reason(s) for rejecting a specimen/sample,
- Maintain records of efforts to resolve problems and all associated documents,
- Maintain a written or electronic specimen/sample rejection log (refer to Section IX),

- Store rejected specimens/samples properly prior to problem resolution/rejection/disposal,
- Hold specimens/samples for a minimum of seven (7) working days following the
- Rejection report.

NEED AND IMPORTANCE OF STUDY

This study shows that it is essential to keep a track of the sample rejection rate in various Sub Units of Laboratory of a hospital. It shows a method to quantify financially the cost of processing and re-processing patient sample in a Lab. Also it brings out the fact that there is a incidence of higher rejections in Biochemistry followed with Microbiology. Also the contributing factors to these rejections has been analysed. The management can take a guidance from this study to bring out salient interventions both at a systemic level in the Lab as well as logistics and training of the Laboratory staff in the NABL guidelines.

STATEMENT OF THE PROBLEM

A Study on Cost of Rejection (Rejected Samples) in a NABL Accredited Lab Of A Tertiary Care Hospital"

OBJECTIVES

- To study the reasons for sample rejections.
- To prioritize the reason for rejection samples of the lab in a given period.
- To measure the cost of rejection using the costing method.
- Suggesting ways to reduce the rejection so that the percentage of rejection and then overall cost to the patient and hospital can be reduced.

RESEARCH METHODOLOGY

The hospital has a Bed Strength of 750 beds commissioned along with a Cancer Research Institute of 150 beds supported under the same banner.
A cross sectional study was conducted in March 2013 using the following tools/Data Sources:

- Review of Process document of NABL and actual observation on sampled cases.
- Internal Departmental Audit & Quality assessment
- Sample Collection procedure
- Checklist tallying and review of Laboratory & Biomedical equipments
- Results Reporting Protocol –Actual & Prescribed
- Records of number of rejected sample per day
- Records of number of sample collected per day.
- Review of Laboratory policy
- Number of staffs
- Working hours in the laboratory
- Number of operational hours (overall each sample on an average)
- Time gap between sample collections to report distribution
- Activities for lab staff for entering the laboratory (universal precautions followed)
- Activities Involved in the Act of rejection samples in lab
- Activities after sample test
- Nursing Activities
- Clerical Procedures
- Log book reading for electrical and water department
- Laboratory indent record from Materials and Maintenance

SAMPLING

This was an cross sectional study which was done on all the rejected requests pertaining to the laboratory in various sections of biochemistry, hematology, clinical pathology, cytology, microbiology, immunology histopathology and serology samples from the inpatient departments of all the specialties and super specialties. In order to establish the system of rejecting inappropriate requests and samples, the laboratory had designed a Rejection Format that had fifteen pre-defined criteria (Table 1.1). Each request and sample sent to the laboratory was scrutinized against these criteria by the staff at the collection room. If any of the request or the sample met any of these rejection criteria, the same was rejected and a record was kept.

CRITERIONS FOR SAMPLE REJECTIONS IN THE LABORATORY UNDER STUDY

TABLE 1.1: CRITERIA UNDER WHICH ALL SECTIONS OF LABORATORY REQUESTS AND SAMPLES WERE SCRUTINIZED IN PRESENT STUDY

S.NO.	CRITERIA FOR REJECTIONS
1	Test marked in requisition form not matching with the test billed in the software
2	Sample is collected in a wrong container
3	Underfilled / overfilled Vacutainers
4	Leaking container
5	Requisition form stained with blood or body fluids
6	Long time gap between collection and submission to lab
7	Dried swabs
8	Sample clotted or sample hemolysed
9	Name of the patient on the label not matching with the requisition form
10	UHID of the patient on the label not matching with the requisition form
11	Name of phlebotomist not mentioned on Vacutainers
12	Name of phlebotomist not mentioned on requisition form
13	Time of sample collection not mentioned on sample container
14	Time of sample collection not mentioned on requisition form
15	Sample not transported in closed box

THE PROCESS PATHWAY FOR LABORATORY FOR ACTIVITY BASED COSTING (ABC) OF SAMPLE RE-RUN IN CASE OF REJECTION

The following protocol is followed by the Laboratory for collection, storage and Processing of samples

- Patient/ Part preparation, when applicable,
- Validation of Requisition form with payment details and samples to be collected

- Specimen/sample collection,
- Specimen/sample labeling, including patient name or unique patient/sample identifier and, when appropriate, specimen source, specimen date,
- Specimen/sample storage and preservation,
- Specimen/sample transport
- Specimen/sample processing,
- Specimen/sample acceptability and rejection,
- Specimen/sample submission, handling and referral, and

COSTING OF SAMPLE – REPEAT PROCESSING

Costing:-Costing in Healthcare is defined as 'the technique and process of ascertaining costs' in providing a comprehensive spectrum of healthcare service or a component of a service. Costing is classifying, recording, allocation and appropriation of expenses for the determination of cost of products or services and for the presentation of suitably arranged data for the purpose of control and guidance of management. It includes the ascertainment of every order, job, contract, process, service units as may be appropriate

There are different costing systems used in practice.

Historical Costing:-In this system, costs are ascertained only after they are incurred and that is why it is called as historical costing system. For example, costs incurred in the month of April 2007 may be ascertained and collected in the month of May. Such type of costing system is extremely useful for conducting post-mortem examination of costs, i.e. analysis of the costs Incurred in the past. Historical costing system may not be useful from cost control point of view but it certainly indicates a trend in the behavior of costs and is useful for estimation of costs in future.

Absorption Costing:-In this type of costing system, costs are absorbed in the product units irrespective of their nature. In other words, all fixed and variable costs are absorbed in the products. It is based on the principle that costs should be charged or absorbed to whatever is being costed, whether it is a cost unit, cost center.

Marginal Costing:-In Marginal Costing, only variable costs are charged to the products and fixed costs are written off to the Costing Profit and Loss A/c. The principle followed in this case is that since fixed costs are largely period costs, they should not enter into the production units. Naturally, the fixed costs will not enter into the inventories and they will be valued at marginal costs only.

Uniform Costing:-This is not a distinct method of costing but is the adoption of identical costing principles and procedures by several units of the same industry or by several undertakings by mutual agreement. Uniform costing facilitates valid comparisons between organizations and helps in eliminating inefficiencies.

CLASSIFICATION OF COSTS

An important step in computation and analysis of cost is the classification action of costs into different classify action helps in better control of the costs and also helps considerably in decision making. Classify action of costs can be made according to the following basis.

***A.* Classification according to elements:-** Costs can be classified according to the elements. There are three elements of costing, viz. material, labor and expenses. Total cost of services can be divided into the three elements to find out the contribution of each element in the total costs.

***B*. Classification according to nature:-** As per this classification, costs can be classified into Direct and Indirect. Direct costs are the costs which are identifiable with the product unit or cost center while indirect costs are not identifiable with the product unit or cost center and hence they are to be allocated, apportioned and then absorb in the production units. All elements of costs like material, labor and expenses can be classified into direct and indirect. They are mentioned below.

***C.* Direct and Indirect Material:-** Direct material is the material which is identifiable with the product. For example, in a cup of tea, quantity of milk consumed can be identified, quantity of glass in a glass bottle can be identified and so these will be direct materials for these products. Indirect material cannot be identified with the product, for example lubricants, fuel, oil, cotton wastes etc cannot be identified with a given unit of product and hence these are the examples of indirect materials.

***D.* Direct and Indirect Labor:-** Direct labor can be identified with a given unit of product, for example, when wages are paid according to the piece rate, wages per unit can be identified. Similarly wages paid to workers who are directly engaged in the providing the service (such as Nursing, Medical, Paramedical staff) is identified and hence they are direct wages. On the other hand, wages paid to workers like Hospital administrators, Marketing & HR managers, Security, Housekeeping staff and Maintenance Engineering workers etc. are indirect wages as they cannot be identified with the given unit of production.

***E.* Direct and Indirect Expenses :-**Direct expenses refers to expenses that are specifically incurred and charged for specific or particular job, process, service, cost center or cost unit. These expenses are also called as chargeable expenses. Examples of these expenses are cost of drawing, design and layout, royalties payable on use of patents, copyrights etc., consultation fees paid to architects, surveyors etc. Indirect expenses on the other Hand cannot be traced to specific product, job, process, service or cost center or cost unit. Several examples of indirect expenses can be given like insurance, electricity, rent, salaries, advertising etc. It should be noted that the total of direct expenses is known as 'Prime Cost' while the total of all indirect expenses is known as **'Overheads'**.

ACTIVITY BASED COSTING

The main objective of any costing system is to determine scientifically the cost of a product or service. For facilitating the calculation, costs are divided into direct and indirect. Direct costs are the costs which are traceable to the products/ services offered. On the other hand, indirect costs which are also called as 'overheads' are not traceable to the products/services. Hence these costs are first identified, classified, allocated, apportioned wherever allocation is not possible, reapportioned and finally absorbed in the products/services. Charging the direct costs to the products is comparatively a simple procedure and can be done with remarkable accuracy. However, the indirect costs present problems in charging them to the products and there is a possibility of distortion of costs though the basis of charging them is quite logical. This is one of the limitations of the traditional costing system. For example, one of the methods of absorption of overheads is direct labor cost and this method is quite satisfactory when the overhead costs of indirect activities is a small percentage compared to direct labor component in actual making of products. However, the increased technology and automation has reduced the direct labor considerably and so the indirect activities have assumed greater importance. Therefore, using the direct labor as a basis for absorbing the overheads can lead to distortions in the costs. Distortions in the costs resulting into incorrect cost calculations may lead to following wrong decisions.

- Errors in fixation of selling prices.
- Wrong decisions regarding deciding of product mix.
- Ignoring customer orientation.
- Missing of profitable opportunities

MERITS OF ESTIMATING THE ACTIVITY BASED COST IN LABORATORY

The objectives of Activity Based Costing are

- To remove the distortions in computation of total costs as seen in the traditional costing system and bring more accuracy in the computation of costs of products and services.
- To help in decision making by accurately computing the costs of products and services.
- To identify various activities in the production process and further identify the value adding activities.
- To distribute overheads on the basis of activities.
- To focus on high cost activities.

- To identify the opportunities for improvement and reduction of costs.
- To eliminate non-value adding activities.

RESULTS

The total rejection rate found over the study period was *.45 %* only, i.e. 599 samples were rejected out of 130877 samples processed. The highest number of rejections were in the Department of Biochemistry, followed with Serology and Hematology, of the gross Rejections.

TABLE 1.2: REJECTION RATE DEPARTMENT WISE

S. No.	Department	Total Number of samples Received	Total Number of Patients (Inclusive of Inpatients and Outpatients)	Rejected Samples Count	Department Rejection Rate
1	**Biochemistry**	**73240**	**28548**	**191**	**32%**
2	**Clinical Pathology**	**7064**	**6649**	**39**	**7%**
3	**Hematology**	**29458**	**18334**	**92**	**15%**
4	**Microbiology**	**3182**	**3851**	**37**	**6%**
5	**Cytology**	**1389**	**925**	**25**	**4%**
6	**Immunology**	**1804**	**1227**	**84**	**14%**
7	**Histopathology**	**4104**	**1704**	**0**	**0%**
8	**Serology**	**10546**	**3351**	**131**	**22%**
		130877		**599 (. 45 %)**	

The graph shows the total number of samples collected out of total number of patients in various departments of laboratory. The Department of biochemistry received 73240 samples from 28548 patients and department of hematology received 29458 samples from 18334 patients. Department of clinical pathology, histopathology & microbiology is moderate which is 7064 , 10546,4104 ,3182 samples out of 6649, 3351, 1704, 3851 no. of patients respectively . Other two departments of cytology and Serology received very less number of samples along with patients which is 1389, 1804 number of samples from 925 &1227 number of patients.

COSTING OF EACH SAMPLE PROCESSING IN A HOSPITAL LABORATORY

For estimating the operating cost (direct expenses) for processing each sample till results, all the Cost heads have been derived on basis of actual expenses incurred. For example the electricity cost, Water expenses and the Manpower cost (based on their salaries) of the total study period (3 months) was taken as on actuals. This was then apportioned on the basis of the total number of working hours in a lab, deducting the calibration, control, inspection, audit and lean timings of the lab.

Thereby the average time taken in processing a sample (leaving out Culture and Histopathology) was estimated. The total cost per sample was hence derived as follows:

TABLE 1.3: ESTIMATING DIRECT COST OF SAMPLE PROCESSING IN LAB

Cost Head	**Gross Cost in Three Months (Rs.)**	**Average Cost per Month (Rs.)**	**Apportioned Cost / Sample (Rs.)**
Electricity Cost	72028	24009	0.562
Water Cost	5040	1680	0.04
Manpower Cost	8724000	2908000	68.2
Equipment Depreciation Cost	1853832	617944	15
Consumable cost	5162296	1720765	40
Total cost for running per sample in the Lab (in rupee)	15817189	5272398	124

DISCUSSIONS

The study showed that in the 8 Subunits of the Laboratory consolidated, the average rejection rate of all Outpatients and Inpatients of this NABL accredited Laboratory was less than 1%. Effectively 599 samples out of 130787 were rejected and had to be redone. The major causes of these rejections were attributed to Hemolysed Samples (40% of total Rejections), and Discrepancies in the Requisition form and sample collected (19 %), followed with leaky containers (19 %). Also the largest rate in rejections was found in the Biochemistry Unit (32%), followed with Microbiology (22%). Hematology & Immuno-Molecular Biology had rejection rate of 15 % and 14 % respectively. This can also be correspondingly mapped with their Volume levels , as higher volumes means a higher chance of sample collection, and a greater probability of sample rejections.

In terms of Cost, though the incidence of rejection rate was quite low, the direct cost of reprocessing each sample is around Rs 124. However the cost of reprocessing cannot be measured in financial terms alone. It needs to be seen that in how many of these rejected samples, critical values get reported. In case any of these rejected samples, had critical values result, then the delay in redoing will impact the Morbidity and the length of stay and may impact the clinical outcome quality probability as well.

FINDINGS & CONCLUSIONS

This study shows that it is essential to keep a track of the sample rejection rate in various Sub Units of Laboratory of a hospital. It shows a method to quantify financially the cost of processing and re-processing patient sample in a Lab. Also it brings out the fact that there is a incidence of higher rejections in Biochemistry followed with Microbiology. Also the contributing factors to these rejections has been analysed. The management can take guidance from this study to bring out salient interventions both at a systemic level in the Lab as well as logistics and training of the Laboratory staff in the NABL guidelines.

LIMITATIONS

The sample processing costing took into consideration only the direct recurring cost with respect to the department, other indirect cost are not considered due to the dual role of most of the cost heads. Indirect costs are such that administrative, Housekeeping, security expenses, which are not revenue generating heads and whose costs have to be apportioned suitably across all the processes in a Hospital. Also in a Medical Teaching Hospital Staff, infrastructure, and resources are used both for patient care and teaching purposes; so the direct cost of laboratory staff is being utilized both for Post graduate and graduate students as well as in Laboratory. A time motion study can best derive the % of time or weightage in allocation of resources to Medical College and Hospital.

SCOPE FOR FURTHER RESEARCH

A further study can be done from here to ascertain how many of the rejected samples had critical values reported and if it had any impact on the Clinical morbidity and length of stay (LOS) in the hospital because of time delay in the reporting the results and start of clinical interventions on the patients.

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