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Original Research Paper Pathology

The study of the quality services in the Pathology Laboratory of a tertiary care hospital in Eastern region of India

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ABSTRACT In today's scenario of evidence based medicine, maintenance of quality services in the department of Pathology is important to deliver reliable, valid and precise report on the basis of which a patient is put under the treatment plan. A prospective, observational and analytic study was undertaken to study the quality services in the department of Pathology of a tertiary care hospital in Eastern region of India. During the study period, out of 500 samples 17% of the samples were rejected to maintain quality assurance in the laboratory. Factors affecting quality services were studied of which presence of aseptic sample collection showed the highest percentage (97.6%) whereas maintenance of EQUAS showed lowest percentage (66.6%). Root cause analysis of causes of factors affecting quality system were done.Based on the observations certain recommendations were made like training and motivation of staff in various aspects of quality in the Pathology laboratory.

KEYWORDS : Laboratory, Quality Assurance, Quality control

Introduction

Clinical medicine has become an increasingly dependent on the laboratory which thus has the critical responsibility of ensuring the reliability of its work. While Quality Assurance is concerned with all steps in the process from specimen collection to transmission of report to the clinician, Quality control refers to operational techniques that must be included during each assay run to verify that the requirements for quality are met. For providing adequate quality assurance in laboratory tests, quality control in the three fields of pre-analytical, analytical, and post-analytical processes is extremely important 1.The pre-analytical phase of the testing process shows the highest prevalence of errors accounting for 70% of all mistakes in laboratory diagnostics 2. Internal quality control is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory 3. In this background, this is the study of the quality services in the Pathology Laboratory of a tertiary care hospital in Eastern Region of India. Its objectives are to analyse the factors affecting the quality services, to undertake root cause analysis of the factors affecting the quality services and to suggest recommendations to improve the quality services through data analysis and interpretation.

Material and methods

A prospective, observational and analytic study was undertaken to study the quality services in the department of Pathology a tertiary care hospital in Eastern Region of India., Joka. The study was conducted for three months. All the outdoor and indoor patients who were referred to the Pathology laboratory for haematology tests were included in the study. Sample size of the study was 500.
A checklist was prepared which was checked and validated by three experts of the laboratory. On the basis of the checklist following data were collected:

Study Variables included the followings;
1. No. And percentage of samples accepted/rejected to maintain quality assurance.

2. Factors affecting quality assurance
a) Complete registration
b) Aseptic sample collection
c) Pre requisites maintained and checked (fasting/post prandial etc.)
d) Sample adequacy
e) Equipment calibration
f) Maintenance of Internal Quality control
g) Maintenance of External Quality Control

3. Causes of failure of each of the above factors which lead to the deterioration of quality assurance system and percentage of cases under each sub headings:

a) Registration failure
1)Incomplete requisition
2)Incorrect entry of registration number at the registration counter
3)Incorrect number entry on the sample vials during sample collection
4)Presence of multiple factors

b) Aseptic Sample collection
1)Lack of awareness among the staff
2)Lack of compliance among the staff
3)Shortage of materials like gloves, spirit etc.
4)Presence of multiple factors

c) Failure of maintenance of pre requisites
1)Lack of proper patient counselling
2)Lack of manpower at help desk
3)Lack of patient compliance
4)Lack of checking of maintenance of pre requisites
5)Presence of multiple factors

d) Failure of maintenance of sample adequacy
1)Sample collected in inappropriate vials
2)Too less volume
3)Excess volume
4)Improper mixing of samples with anticoagulants in the vials
5)Presence of multiple factors

e) Failure of maintenance of regular equipment calibration
1) Delay in procurement of calibrators
2) Negligence in regular running of calibrators
3) Inadequate temperature control of calibrators
4) Presence of multiple factors

f) Failure of maintenance of internal quality control
1)Negligence in running of internal quality control on regular basis
2)Use of out of date controls
3)Lack of temperature maintenance of the controls
4)Lack of knowledge regarding interpretation of Levey Jenning graphs
5)Presence of multiple factors

g) Failure of maintenance of External Quality Assurance System (EQUAS)
1)Negligence in timely reporting of the EQUAS samples
2)Poor communication with the EQUAS laboratory
3)Lack of funding for EQUAS
4)Presence of multiple factors

Result

During the study period a total of 500 samples were studied. Number of samples rejected during the study period to maintain quality assurance was estimated and tabulated.17% of the samples

were rejected to maintain quality assurance in the laboratory.

Table 1: Samples accepted/rejected to maintain quality assurance

Samples	No.	Percentage (%)
Accepted	412	83
Rejected	88	17

Factors affecting quality services of the laboratory were determined. The number and percentage of samples possessing each factor were calculated and tabulated. Aseptic sample collection showed the highest percentage (97.6%) whereas maintenance of EQA showed lowest percentage (66.6%).The following table shows the factors affecting quality assurance and the number and percentage of samples possessing them.

Table 2: Factors affecting quality services

Factors	No./Total Samples	Percentage (%)
Complete registration	430/500	86
Aseptic sample collection	488/500	97.6
Pre requisites maintained & checked	465/500	93
Sample adequacy	423/500	84.6
Equipment calibration	450/500	90
Maintenance of internal quality control	440/500	88
Maintenance of external quality assurance (EQUAS)	2/3	66.6

Once the factors affecting quality services and their frequency were determined, the root cause analysis of failure of each factor was done. There were several causes and even sometimes multiple factors were present .The following tables illustrate the various causes of failure of individual factors.

Table 3: Root cause analysis of causes of registration failure

Causes of registration failure	No.	Percentage (%)
Incomplete requisition	27	38.57
Incorrect entry of registration number at the registration counter	21	30
Incorrect number entry on the sample vials during sample collection	15	21.43
Presence of multiple factors	07	10

Table4: Root cause analysis of causes of failure of aseptic sample collection

Causes of failure of aseptic sample collection	No.	Percentage (%)
Lack of awareness among the staff	03	25
Lack of compliance among the staff	05	41.66
Shortage of materials like gloves, spirit etc	02	16.67
Presence of multiple factors	02	16.67

Table 5: Root cause analysis of causes of failure of maintenance of pre requisites before sample collection

Causes of failure of maintenance of pre requisites	No.	Percentage (%)
Lack of proper patient counselling	08	22.86
Lack of manpower at help desk	09	25.71
Lack of patient compliance	08	22.86
Lack of checking of maintenance of pre requisites	6	17.14
Presence of multiple factors	04	11.43

Table 6: Root cause analysis of causes of failure of maintenance of sample adequacy

Causes of failure of maintenance sample adequacy	No.	Percentage (%)
Sample collected in inappropriate vials	14	18.2
Too less volume	19	24.6
Excess volume	17	22.1
Improper mixing of samples with anticoagulants in the vials	17	22.1
Presence of multiple factors	10	13

Table 7: Root cause analysis of causes of failure of maintenance of regular equipment calibration

Causes of failure of maintenance of regular equipment calibration	No.	Percentage(%)
Delay in procurement of calibrators	8	16
Negligence in regular running of calibrators	22	44
Inadequate temperature control of calibrators	16	32
Presence of multiple factors	4	8

Table 8: Root cause analysis of causes of failure of maintenance of internal quality control

Causes of failure of maintenance of internal quality control	No.	Percentage (%)
Negligence in running of internal quality control on regular basis	25	41.67
Use of out of date controls	05	8.33
Lack of temperature maintenance of the controls	15	25
Lack of knowledge regarding interpretation of Levey Jenning graphs	10	16.67
Presence of multiple factors	05	8.33

Table 9: Root cause analysis of causes of failure of maintenance of External Quality Assurance System (EQA)

Causes of failure of maintenance of EQUAS	No.	Percentage (%)
Negligence in timely reporting of the EQUAS samples	01	100
Poor communication with the EQUAS laboratory	0	0
Lack of funding for EQUAS	0	0
Presence of multiple factors	0	0

Discussion

In the present study, the quality services in the Pathology laboratory were studied. During the study period a total of 500 samples were studied. During the study period, 17% of the samples were rejected to maintain quality assurance in the laboratory.

Dikmen ZG studied specimen rejection in **laboratory** medicine and detected an overall specimen rejection rate of 6% in emergency **laboratory**. Rejection ratios was 2.5% for biochemistry tests, 3.2% for complete blood count, 9.8% for blood gases, 9.2% for urine analysis, 13.3% for coagulation tests, 12.8% for therapeutic drug monitoring, 3.5% for cardiac markers and 12% for hormone tests. The most frequent rejection reasons were fibrin clots (28%) and inadequate volume (9%) for biochemical tests. Clotted samples (35%) and inadequate volume (13%) were the major causes for coagulation tests, blood gas analyses and CBC. The ratio of rejected specimens was higher in the EDs (40%) compared to ICUs (30%) and inpatient services (28%) 4.

The higher rate of sample rejection in the present study was probably due to the fact that failure of maintenance of several factors affecting quality assurance system. Registration failure (14%), sample inadequacy (15.4%), failure to maintain internal quality control (12%) & failure of EQUAS (33.4%) were the important factors which led to sample rejection in the present study. Incomplete requisition (38.57%) & incorrect entry of registration number at the registration counter (30%) were the major cause of registration failure.

The present study showed that the aseptic sample collection was done in 488 out of 500 samples (97.6%) and the sample adequacy was maintained in 423 out of 500 samples (84.6%).

In the study of Davidson et al. they examined some mistakes in blood collection, i.e. specimen haemolysis, and EDTA contamination. For a total workload of 763,577 blood specimens, the overall haemolysis rate was 3.2%. Much higher rates of both specimen haemolysis and EDTA contamination were observed when blood was not collected by trained phlebotomists. They concluded that better training in blood collection, achieving the standard of professional phlebotomists, will improve validity of diagnostic information; reduce risks of dangerous misinterpretation of results, unwanted anaemia and needle stick injury and decrease **laboratory** supplies costs. They recommended that **laboratories** collect statistics on **pre-analytical** error rates 2. In the study by Dikmen ZG, clotted samples (35%) and inadequate volume (13%) were the major causes for failure of coagulation tests, blood gas analyses and CBC 4.

The major causes of failure of aseptic sample collection in the present study were lack of compliance among the staff (41.66%) and lack of awareness among the staff (25%). For sample inadequacy, the present study showed inappropriate volume (46.7%), including too less and excess volume, and improper mixing with anticoagulants were the major factors leading to sample rejection (22.1%). Among the pre analytical factors maintaining the pre requisites was another important factor which was present in 465 out of 500 samples (93%). Major causes of failure of maintenance of pre requisites were lack of manpower at the help desk (25.71%) and lack of proper patient counselling (22.86%).

Equipment calibration was done in 450 out of 500 samples (90%) and internal control was regularly run in 440 out of 500 samples (88%).

Marques GF conducted a study to describe the design and implementation of an internal quality control protocol, as well as its periodical assessment intervals (6 months) to determine compliance with pre-determined specifications. They emphasized that laboratory should review its quality indicators, systematic, random and total error at regular intervals, in order to ensure that they are meeting pre-determined specifications, and if not, apply the appropriate corrective actions 5.

The present study showed that the negligence in running of calibrators on regular basis (44%) was the most important factor in failure of maintenance of calibration of equipments thereby affecting the analytical process. Inadequate temperature control of calibrators lead to rejection of 32% of the samples. Similarly negligence in running of internal quality control on regular basis was the most important factor in failure of maintenance of internal quality control in the laboratory (41.67%). Lack of temperature maintenance of the controls (25%) and lack of knowledge regarding interpretation of Levey Jenning graphs (16.67%) were other contributing factors for sample rejection.

The term external quality assessment (EQA) allows for comparison of a laboratory's testing to a source outside the laboratory. EQA participation is usually required for accreditation. The Pathology laboratory receives unknown samples from external laboratory which are analysed and report sent to same laboratory within due period. In the present study three EQA samples were received during the study period and out of which two were reported (66.67%). Negligence in timely reporting of the EQA samples was the only cause of failure in maintaining of EQA whereas there was no communication gap with the EQA laboratory and adequate funding were available.

Maekawa M conducted a study on intention and current situation of External Quality Assurance Program supervised by the Japan Medical Association and found that the EQA program examines and educates regarding the measurement method, analyzer, reagent, traceability, calibrator, unit, temperature, cut-off value, and lower decision limit, in order to strengthen the foundation of clinical laboratories. Clinical laboratory testing consists of pre-analytical, analytical, post-analytical phases. The EQA program investigates not only the analytical phase but also a part of pre-analytical and post-analytical phases 6.

Conclusion

Based on the observations and data analysis of the present study of quality measures of Pathology laboratory following recommenda tions are made:

Completion of registration forms, maintenance of internal quality control and maintenance of EQA are the areas where more focus has to be drawn for quality improvement. Supervision & monitoring of the registration counter and sample collection counters is recommended.Training program regarding the various aspects of aseptic sample collection ,adequacy of volume, mixing of anticoagulants ,the use of controls and calibrators is necessary. Charts may be displayed with date, time and name of the staff who has run the control and calibrator will help in monitoring the process. Responsibility of timely reporting of EQA samples has to be allotted to a particular doctor and a technician who would ensure the smooth functioning of external quality assurance system. Motivation of the staff regarding towards continuous quality improvement along with periodical in service training in different aspects of quality would bring about an attitude change thereby help in improving quality services of the laboratory.

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