Introduction

Clinical medicine has turned out to be progressively subject to the laboratory which has the basic duty of guaranteeing the unwavering quality of its work. Automation and expanding reliance on machines make it fundamental to hold fast to an unbending convention of quality control methodology. The issue of lab quality has advanced over fifty years since the main suggestions for Quality in 1965. Today, Quality control is viewed as just a single piece of the aggregate research centre control program.

Quality additionally incorporates:-

(a) Total Quality Management - an action to enhance patient care by having laboratory screen its work to identify inadequacies and rectify them.

(b) Continuous Quality Improvement (CQI) - It is to enhance the patient care by setting the accentuation on not to commit errors at all.

(c) . Quality Assurance - exercises that guarantee positive patient results. It measures what a research facility can do to enhance unwavering quality.

Quality control alludes to operational systems that must be incorporated to ensure that the necessities for quality are met. While Quality Assurance is worried about all means in the process from sampling to transmission of results to the clinician, Internal Quality control and External Quality control test just the investigative method itself. Yet, these are basic to guarantee that the tests are performed effectively and their outcomes are solid.

It is the obligation of the lab to guarantee that the tests which are performed are applicable and the outcomes dependable, reproducible and as exact as

conceivable as indicated by current ability. Inner Quality control is concerned basically with exactness or reproducibility of results regularly while outside quality control is bothered about similarity of results where-so-ever the test is performed.

Quality assurance alludes to all these arranged and deliberate exercises to give certainty that the outcomes given out by the lab are right. Though the point of quality control is essentially to guarantee that the outcomes created are right, quality assurance is worried about considerably more, that the correct test is done on right example and that correct outcome and right information is conveyed to the individual in time. Along these lines, the reason for Quality assurance is the support of the general nature of patient outcomes. Factors that influence the test result from the time the test starts are:-

(a) Pre analytic - specimen collection, specimen transport, specimen quality.

(b) Analytic- Result accuracy, clerical errors, analytical errors, assay repeat rates.

(c) Post analytic - Result reporting, Record keeping for patient and quality control.

As examined, quality control is a very important portion of quality assurance, all labs gain from quality control regarding certainty and reproducibility of test outcomes. Recording and observing of test factors, for example, temperature, reagents, controls, hardware permits looking impartially and reflectively at parameters essential to exactness and accuracy of the test. Documentation permits predicting a potential issue before the circumstance requires remedial activity and unfavourably impacts outcomes.

Objectives of quality in lab are to help provide quality in health care and along these lines decrease illness , mortality and financial misfortune. It guarantees believability of lab reports and produces trust in lab outcomes, amongst labs and between similar instruments, if possible in agreement with a reference standard on consensus which gives an indication of the "correct" result.

The data obtained from an external quality assurance are intended primarily to access individual laboratory performance, but in addition the data has the value for assessing the validity of the different test procedures-and identifying the faulty types of instrument or kit or a poor method giving rise to poor performance.

Consequences of poor quality are:-

(a) Inappropriate activity - Over examination, over treatment, incorrect treatment.

(b) Inappropriate inaction - Lack of examination, No treatment, Delayed activity, Loss of believability of lab, Legal issues.

Table 1: Hurdles in Quality Control

Process	**Likely Errors**
Test Ordering	Inappropriate test.
	Illegible Handwriting.
	Incorrect Patient identification.
	Special requirements not specified.
Specimen Acquisition	Incorrect tube.
	Incorrect patient identification.
	Insufficient volume.
	Unacceptable specimen (haemolysed or too dilute).
	Collected at wrong time.
Analytical Measurement	Incorrect Instrument Calibration.

	Specimen mix-up.
	Erroneous Quantity of Specimen.
	Presence of Interfering Matter.
Test Reporting	Incorrect Patient ID.
	Illegible Report..
	Delayed Report.
	Error of Transcription.
Test Interpretation	Interfering Matter not recognised.
	Precision limitations.
	Inappropriate Analytical Sensitivity.
	Non availability of Previous values for comparison.

The present study **of the quality of services in the pathology department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi,** was undertaken with this background in mind.

Lal Bahadur Shastri Hospital is an auxiliary level, multi-specialty medical facility with 100 authorized beds (useful 188 beds). It is located at Khichripur, in the Trans Yamuna region of Delhi. It provides medical cover to the East District of Delhi. It was established in December, 1991 with OPD facility. Indoor services were initiated w.e.f 11 Oct 1996 and the Hospital was completely operational w.e.f 22 Jun 1999. All medical cover is given FREE OF COST. The campus is laid out over 10.11 acres and has a floor area of 18,110 Sq. Mtrs.

The Hospital covers entire East Delhi with a population in excess of 15 lacs, Trans Yamuna territories of Delhi, bordering regions of NOIDA, Ghaziabad, Khora and regions of Uttar Pradesh and other connecting states.

The Department Of Pathology of **Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi,** is equipped with many modern automated instruments and a battery of tests is performed daily for outdoor and indoor patients.

It is with this background that the present study on the quality of services in the Pathology Department of **Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi,** has been undertaken.

Objectives

General Objective

To study the quality of services in the Pathology Laboratory at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

Specific Objectives

To analyse the factors affecting the quality services in the Pathology Laboratory of at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

To undertake root cause analysis of the factors affecting the quality services in the Pathology Laboratory of at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

To make recommendations to improve the quality services through data analysis and interpretation of this study.

Review of Literature

To assure the quality of tests, providing high quality laboratory tests is mandatory. To ensure adequate quality assurance in laboratory tests, quality control in the three fields of pre-analytical, analytical and post analytical processes is very important. There are however no formal standardised written requirements concerning specimen collection, handling, preparation, storage and transportation. Most laboratory tests for clinical studies are performed onsite in a local laboratory; however, a part of laboratory tests is done at offsite central laboratories after specimens are transported there. As factors affecting laboratory tests, individual and inter-individual variations are well known. Besides these factors, standardizing the factors of specimen collection, handling, preparation, storage and transportation, may improve and maintain the high quality of clinical studies in general. Thus, to overcome the problems derived from pre analytical processes, it is necessary to standardise specimen handling in a broad sense. (1)

The pre analytical period of the tests demonstrates the most blunders representing 70 % of all errors in lab outcomes. In the study of Davidson et al. They analyzed errors in blood collection , i.e. sample haemolysis, and EDTA pollution. For an aggregate workload of 763577 blood samples, the general haemolysis rate was 3.2%. Significantly higher rates of both sample haemolysis and EDTA pollution were seen when blood was not gathered via qualified phlebotomists. They inferred that better preparation toward professional blood collection will enhance legitimacy of data; lessen dangers of perilous error of results, anemia and needle stick injury as also result in decline in lab supplies costs. They prescribed that labs gather insights on pre-analytical fault rates. (2)

Dikman ZG considered sample rejection in labs and noticed a general sample rejection rate of 6% in emergency labs. Rejection proportions were 2.5% for bio chemistry tests, 3.2% for Complete Blood Count (CBC), 9.8% for blood gasses, 9.2 % for urine investigation, 13.3 % for coagulation tests, 12.8% for helpful medication checking, 3.5% for cardiovascular markers and 12% for hormone tests. The most regular rejection reasons were fibrin clumps (28%) and lacking volume (9%) for biochemical tests. Clotted specimens (35%) and lacking volume (13%) were the reasons for coagulation tests, blood gas investigations and CBC. The proportion of rejected samples was higher in the EDs (40%) contrasted with ICUs (30%) and IPD (28%).(3)

Rao etal. examined Quality Measures in Pre-Analytical Phase of Tissue Processing: Understanding Its Value in Histopathology. This investigation was carried out to examine the quality parameters in pre-analytical stage in a histopathology lab registers and records were checked for proficiency and mistakes for pre-analytical quality factors: sample ID, sample in suitable fixatives, lost specimens, every day interior quality control execution on staining, execution in between lab quality appraisal program {External quality confirmation program (EQAS)} and assessment of inward non-congruities (NC) for different blunders. They concluded a low rate of mistakes in pre-ananytical stage signifies that an agreeable level of quality guidelines was being implemented with further scope of enhancement. (4)]

Marques GF underlined to create and actualize an arrangement of interior quality control, intended to distinguish errors, and contrast its information and different lab facilities, through outside quality control. Along these lines it becomes an instrument to recognize the attainment of the targets set, and in the event of

errors, enabling remedial actions to be carried out, and guarantee the quality of the outcomes. They directed an examination to portray the plan and usage of an inward quality control convention, and in addition its periodical appraisal (a half year) to decide consistence with pre-decided details. They accepted that the advancement of an investigative quality control framework is an exceedingly organized process. This ought to be intended to identify mistakes that trade off' the security of the systematic procedure. The research facility should survey its quality markers, precise, irregular and aggregate mistake at normal interims, keeping in mind the end goal to guarantee that they are meeting pre-decided particulars, and if not, take befitting remedial actions.(5)

Internal quality control is intended to distinguish, decrease, and right insufficiencies in a labs internal diagnostic process before the arrival of patient outcomes, keeping in mind the end goal to enhance the nature of the outcomes of the lab. Quality control is a measure of exactness, or how well the estimation framework recreates a similar outcome after some time and under changing working conditions. Lab quality control is normally run toward the start of each shift, after an instrument is maintained, when reagents are changed, after alignment, and at whatever point quiet outcomes appear to be unseemly. Quality control should estimate from an indistinguishable network of patient specimens, considering properties, for example, thickness, turbidity, organization, and shading. It ought to be easy to use, with insignificant vial to vial fluctuation, since changeability could be confounded as deliberate blunder in the technique or instrument. It ought to be steady for drawn out stretches of time, and accessible in sufficiently expansive amounts for a solitary cluster to last no less than one year. Fluid controls are more

helpful than lyophilized controls since they don't need to be reconstituted limiting pipetting blunder. (6)

Interpretation of quality control information includes both graphical and factual techniques. Quality control information is most effortlessly envisioned utilizing a Levy-Jennings diagram. The dates of investigations are plotted along the X-hub and control esteems are plotted on the Y-pivot. The mean and one, two, and three standard deviation limits are additionally set apart on the Y-pivot. Examining the example of plots gives a straightforward method to recognize arbitrary mistakes and shifts or patterns in adjustment. (7)

Levy-Jennings chart plots quality control information to give a visual sign whether a lab test is functioning correctly. The separation from the mean is estimated in standard deviations (SD). On the x-pivot the date and time or the control run are plotted. A tag is made showing how far away the outcome was from the mean (which is the expected outcome). Lines keep running over the diagram at the mean, and in addition one, two and once in a while three standard deviations either side of the mean. This makes it simple to perceive how far the outcome was. (8)

In general use, calibration is often regarded as including the process of adjusting the output or indication on a measurement instrument to agree with value of the applied standard, within a specified accuracy. For the vast majority of calibrations, the calibration process is actually the comparison of an unknown to a known and recording the results. (9)

The term external quality assessment (EQA) is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories

or to the performance of a reference laboratory. EQA is here defined as a system for objectively checking the laboratory's performance using an external agency or facility.

Several EQA methods or processes are commonly used. These include:

(a) Proficiency testing—external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared, and reported to the laboratories.

(b) Rechecking or retelling—slides that have been read are rechecked by a reference laboratory; samples that have been analyzed are retested, allowing for inter-laboratory comparison.

(c) On-site evaluation—usually done when it is difficult to conduct traditional proficiency testing or to use the rechecking/retesting method. Another method of inter-laboratory comparison is the exchange of samples among a set of laboratories, usually reserved for specialized tests for which no proficiency testing is available. This method is used either by very specialized or sophisticated laboratories and therefore will not be discussed further being beyond the scope of this study.

Participation in an outside quality appraisal program gives gainful information and facts which:

(a) Allows correlation of execution and results among various test locations.

(b) Provides early caution about issues related with testing gear or activities.

(c) Provides proof of testing quality.

(d) Indicates aspects that need change.

(e) Identifies skill gaps.

2. EQA assures clients, for example, doctors, patients, and healthcare workers, that the lab can produce consistent outcomes. Every Lab can utilize EQA to distinguish issues in lab work and take remedial action. EQA will help assess dependability of techniques, materials, and hardware, and to assess impact of training.

3. EQA is normally a must for accreditation. Likewise, EQA aids in creating a network, and can be a an excellent device for improving a national lab system. EQA testing, and additionally the data shared by the EQA giver, are helpful for directing further training exercises. (10)

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 programme 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. (11)

Quality improvement (QI) consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups. While each QI program may appear different, a successful program always incorporates the following four key principles. (12).

Methodology

A prospective, observational and analytic study was undertaken to study the quality of services in the Pathology Laboratory at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi. The Hospital covers entire East Delhi with a population in excess of 15 lacs, Trans Yamuna territories of Delhi, bordering regions of NOIDA, Ghaziabad, Khora and regions of Uttar Pradesh and other connecting states. The study was conducted for three months from 01 Feb 2018 to 30 Apr 2018 .Selected outdoor and indoor patients who were referred to the Pathology laboratory for different tests were included in the study by simple random sampling. Sample size of the study was 500.

Pathology laboratory at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi has state of the art, modern, automated equipment where hundreds of sample are run on a regular basis. Qualified technicians handle these instruments and reports are authenticated by qualified doctors. Dr Nakhat Jameel is Head of the Department. The laboratory participates in External Quality Assurance program with All India Institute of Medical Sciences, New Delhi.

Data Collection Techniques and Tools

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:

(a) Observation and documentation of the registration process at the laboratory counter with entry of full name, insurance number and issuing of registration number on the requisition and the same number on the vials/ containers of the samples.

(b) Observation and documentation of the sample collection in aseptic procedure, in appropriate vials, in appropriate amount and proper mixing with anticoagulants.

(c) Observation and documentation of timely calibration of the equipment in the Department of Pathology

(d) Observation and documentation of daily running of internal controls prior to sample testing.

(e) Observation and documentation of external quality assurance system (EQUAS) whether followed on a regular basis.

(f) Observation and documentation of the number of samples rejected during the study period to maintain the quality assurance system

Study Variables

No. And percentage of samples accepted/rejected to maintain quality assurance.

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.

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:-

(i) Incomplete requisition.

(ii) Incorrect entry of registration number at the registration counter.

(iii) Incorrect number entry on the sample vials during sample collection.

(iv) Presence of multiple factors.

(b) Aseptic-Sample collection:-

(i) Lack of awareness among the staff

(ii) Lack of compliance among the staff

(iii) Shortage of materials like gloves, spirit etc.

(iv) Presence of multiple factors

(c) Failure of maintenance of pre requisites:-

(i) Lack of proper patient counselling.

(ii) Lack of manpower at help desk.

(iii) Lack of patient compliance.

(iv) Lack of checking of maintenance of pre requisites.

(v) Presence of multiple factors.

(d) Failure of maintenance of sample adequacy:-

(i) Sample collected in inappropriate vials.

(ii) Too less volume.

(iii) Excess volume.

(iv) Improper mixing of samples with anticoagulants in the vials.

(v) Presence of multiple factors.

(e) Failure of maintenance of regular equipment calibration:-

(i) Delay in procurement of calibrators

(ii) Negligence in regular running of calibrators

(iii) Inadequate temperature control of calibrators

(iv) Presence of multiple factors

(f) Failure of maintenance of internal quality control:-

(i) Negligence in running of internal quality control on regular basis.

(ii) Use of out of date controls.

(iii) Lack of temperature maintenance of the controls.

(iv) Lack of knowledge regarding interpretation of Levy Jenning graphs.

(v) Presence of multiple factors.

(g) Failure of maintenance of External Quality Assurance System (EQUAS):-

(i) Negligence in timely reporting of the EQUAS samples.

(ii) Poor communication with the EQUAS laboratory.

(iii) Lack of funding for EQUAS.

(iv) Presence of multiple factors.

Data Analysis and Observation

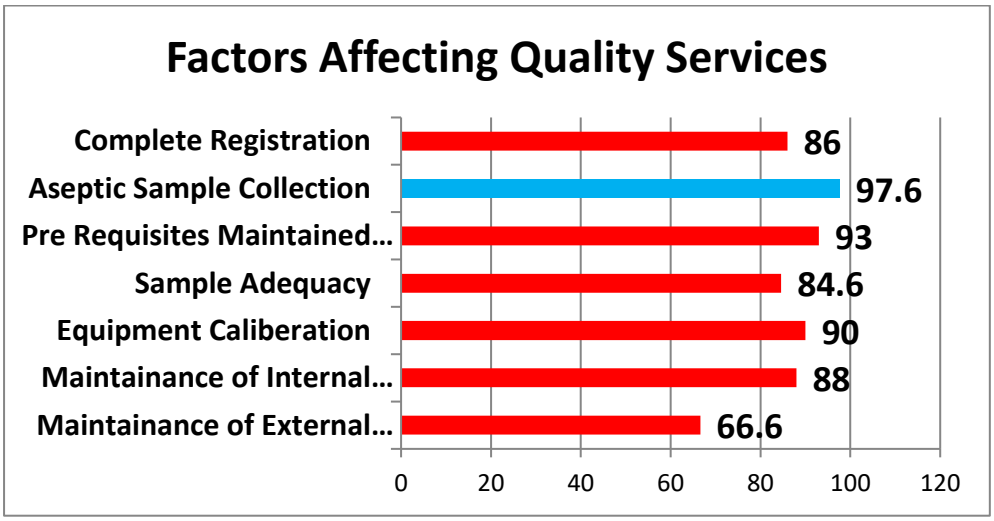
During the study, a total of 500 samples were studied. Number of samples rejected during the study period to maintain quality assurance was estimated and tabulated. 17% of the samples were rejected to maintain quality assurance in the laboratory.

Table 2: Samples accepted/rejected to maintain quality assurance

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

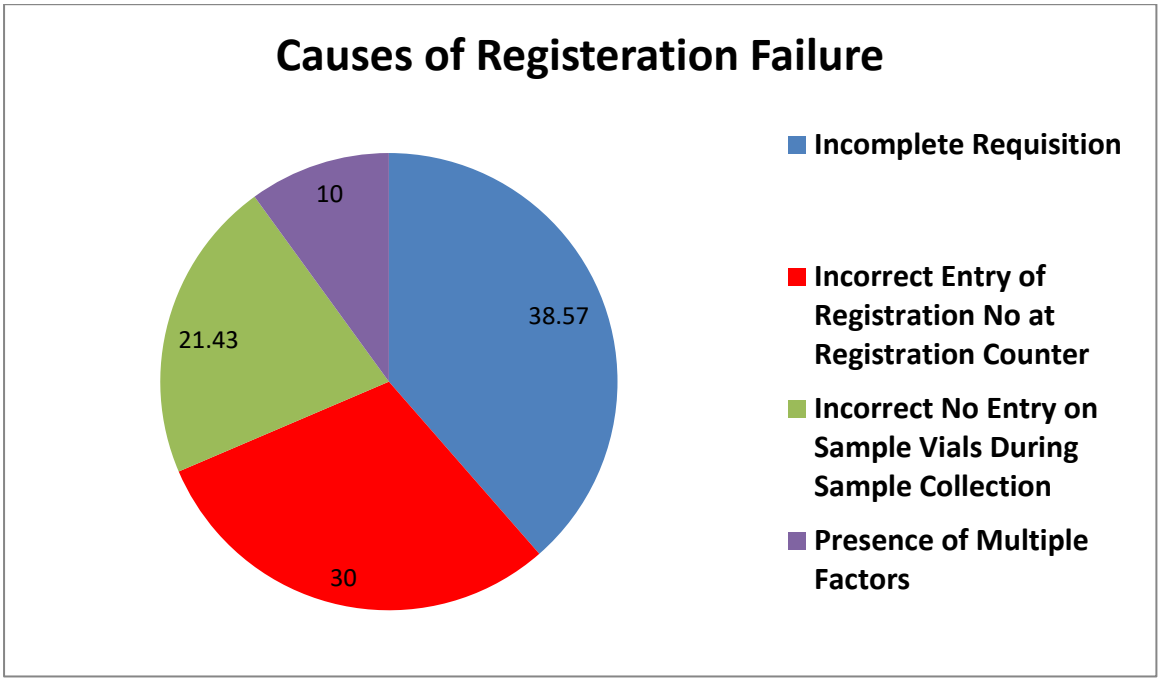
Factors affecting quality of services of the laboratory were determined. The number and percentage of samples possessing each factor were calculated and tabulated. Aseptic sample collection showed the highest percentage (97.6%) whereas maintenance of EQUAS showed lowest percentage (66.6%).The following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

Fig 1: Bar diagram showing factors affecting quality services



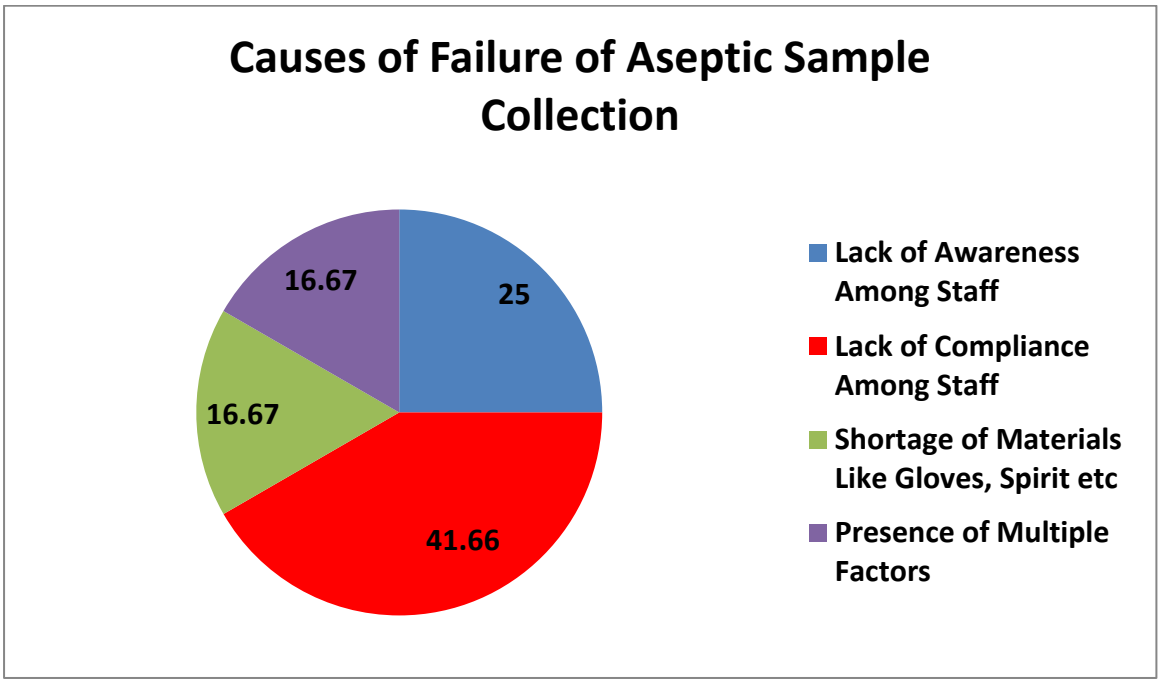
Once the factors affecting quality services and their frequency were determined, the root cause analysis of failure of each factor was done. There were several causes and even sometimes multiple factors were present .The following tables illustrate the various causes of failure of individual factors.

Fig 2: Pie diagram showing distribution of causes of registration failure.



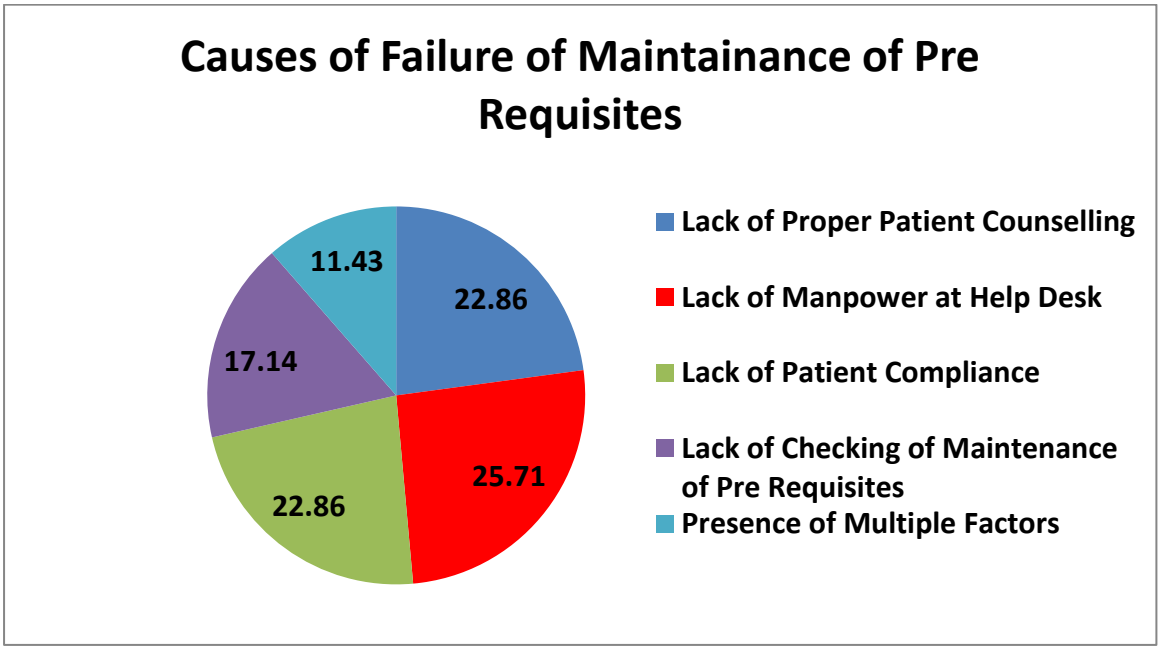
Incomplete requisition was the commonest cause of registration failures- (38.57%).

Fig 3: Pie diagram showing distribution of causes of failure of aseptic sample collection



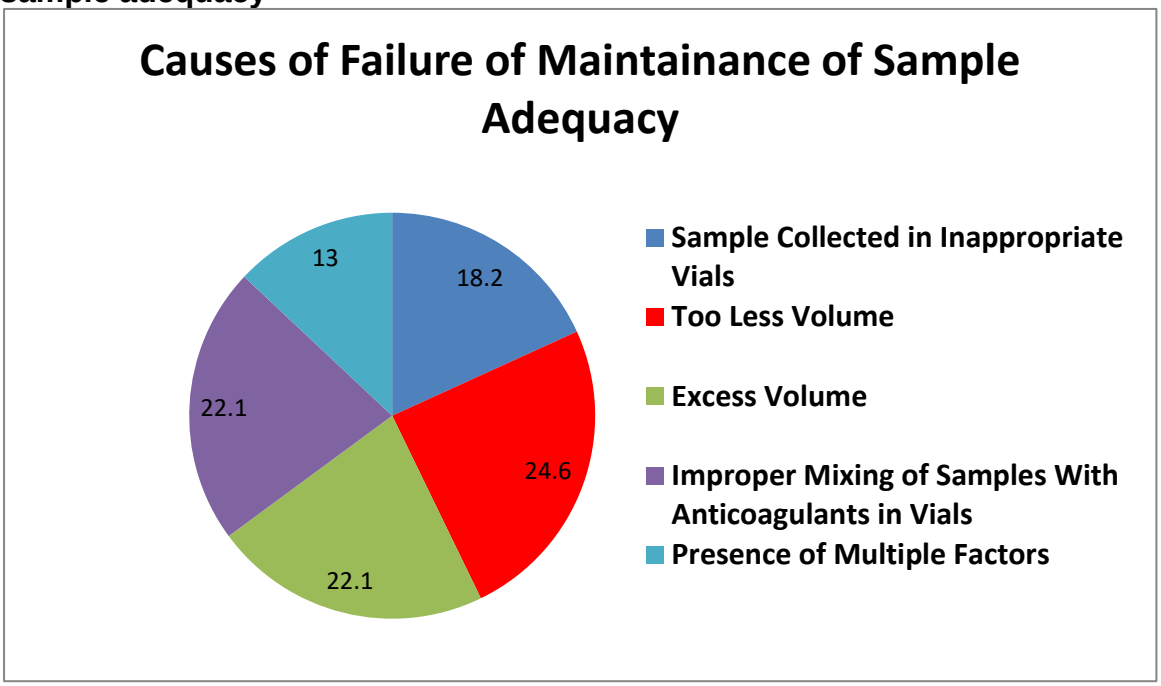
Lack of compliance among staff was the commonest factor causing failure of aseptic sample collection (41.66%).

Fig 4: Pie diagram showing distribution of causes of failure of maintenance of pre requisites before sample collection



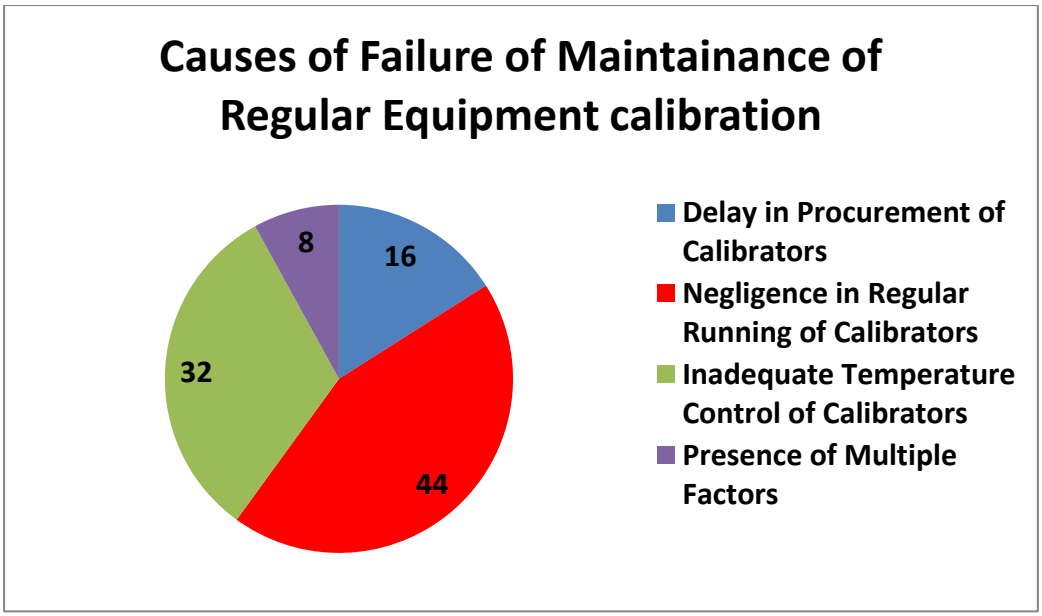
Lack of manpower at help desk was the commonest factor causing failure of maintenance of pre requisites before sample collection (25.71%).

Fig 5: Pie diagram showing distribution of causes of failure of maintenance of sample adequacy



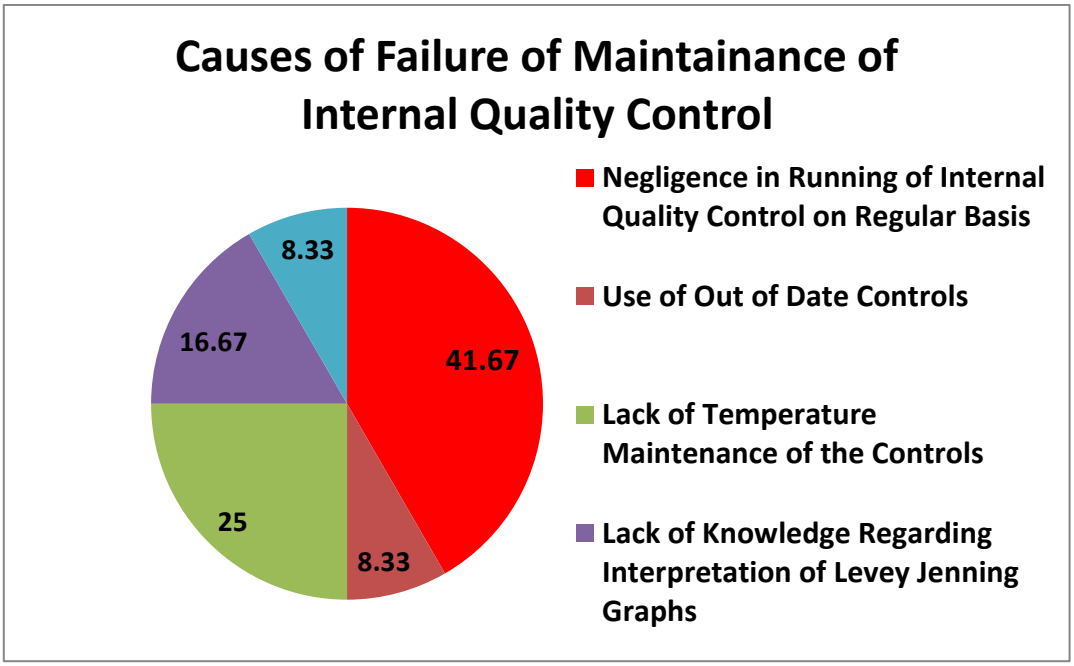
Inadequate volume was the commonest factor causing failure maintenance of sample adequacy (24.6%).

Fig 6: Pie diagram showing distribution of causes of Failure of maintenance of regular equipment calibration



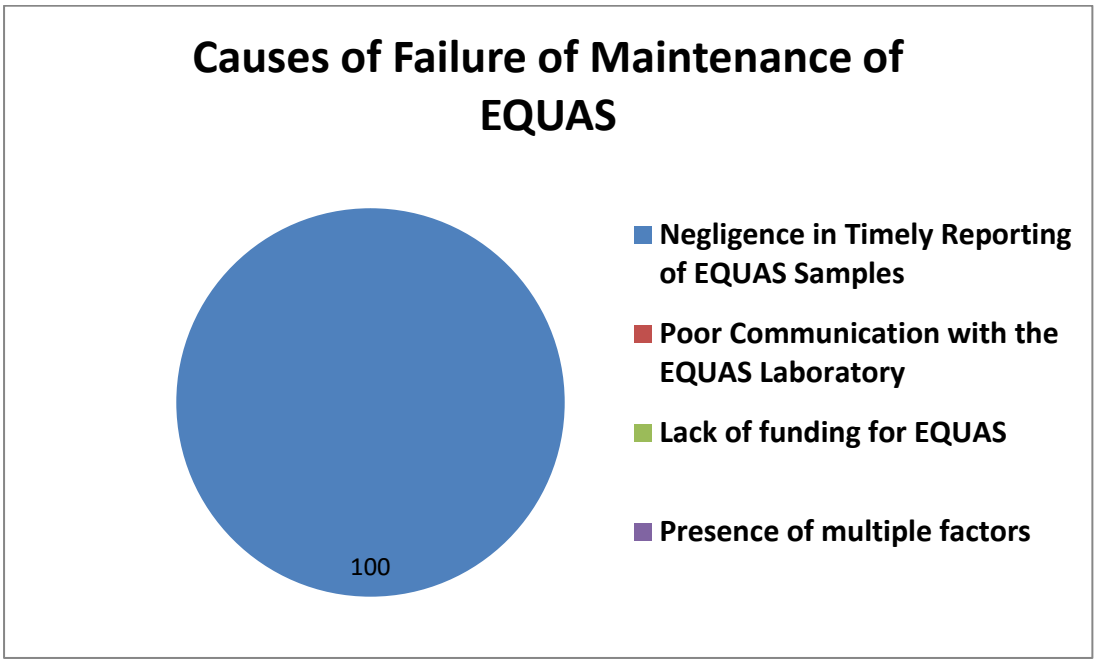
Negligence in regular running of calibrators was the commonest factor causing failure of maintenance of regular equipment calibration (44%).

Fig 7: Pie diagram showing distribution of causes of failure of maintenance of internal quality control



Negligence in running of internal quality control on regular basis was the commonest factor causing of failure of maintenance of internal quality control (41.67%).

Fig 8: Bar diagram showing distribution of causes of failure of maintenance of EQUAS



Negligence in timely reporting of the EQUAS samples was the only factor causing failure of maintenance of External Quality Assurance System (EQUAS) (100%).

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 considered sample dismissal in labs and identified a general sample dismissal rate of 6% in emergency lab. Dismissal proportion was 2.5% for bio chemistry tests, 3.2% for finish blood check, 9.8% for blood gases, 9.2% for urine examination, 13.3% for coagulation tests, 12.8% for restorative medication observing, 3.5% for heart markers and 12% for hormone tests. The most successive dismissal reasons were fibrin clusters (28%) and insufficient volume (9%) for biochemical tests. Thickened samples (35%) and lacking volume (13%) were the reasons for coagulation tests, blood gas investigations and CBC. The proportion of rejected specimens was higher in the EDs (40%) contrasted with ICUs (30%) and IPDs (28%).(3)

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. Incomplete requisition (38.57%) and 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 analyzed errors in blood collection , i.e. sample haemolysis, and EDTA pollution. For an aggregate workload of 763577 blood samples, the general haemolysis rate was 3.2%. Significantly higher rates of both sample haemolysis and EDTA pollution were seen when blood was not gathered via qualified phlebotomists. They inferred that better preparation toward professional blood collection will enhance legitimacy of data; lessen dangers of perilous error of results, anemia and needle stick injury as also result in decline in lab supplies costs. They prescribed that labs gather insights on pre-analytical fault rates. (2) In the investigation by Dikmen ZG, thickened examples (35%) and lacking volume (13%) were the reasons for unsuccessful coagulation tests, blood gas examinations and CBC.(3)

Major causes for 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 underlined to create and actualize an arrangement of interior quality control, intended to distinguish errors, and contrast its information and different lab facilities, through outside quality control. Along these lines it becomes an instrument to recognize the attainment of the targets set, and in the event of errors, enabling remedial actions to be carried out, and guarantee the quality of the outcomes. They directed an examination to portray the plan and usage of an inward quality control convention, and in addition its periodical appraisal (a half year) to decide consistence with pre-decided details. They accepted that the advancement of an investigative quality control framework is an exceedingly organized process. This ought to be intended to identify mistakes that trade off' the security of the systematic procedure. The research facility should survey its quality markers, precise, irregular and aggregate mistake at normal interims, keeping in mind the end goal to guarantee that they are meeting pre-decided particulars, and if not, take befitting remedial 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 Levy Jenning graphs (16.67%) were other contributing factors for sample rejection.

The term External Quality Assessment (EQUAS) implies correlation of a lab to a source outside the lab EQUAS participation is usually required for accreditation.

The Pathology laboratory of Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi participated in EQUAS program with All India Institute of Medical Sciences, New Delhi. The Pathology laboratory receives unknown samples from AIIMS which are analysed and report sent to AIIMS within due period. In the present study three EQUAS samples were received during the study period and out of which two were reported (66.67%). Negligence in timely reporting of the EQUAS samples was the only cause of failure in maintaining of EQUAS whereas there was no communication gap with the EQUAS 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 programme 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. (11)

Conclusion

The study was conducted on the **quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi**. The study revealed the following facts:

(a) 17% of the samples were rejected to maintain quality assurance in the laboratory.

(b) 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%).

(c) Root cause analysis of causes of registration failure showed incomplete requisition was the commonest cause of registration failure (38.57%).

(d) Root cause analysis of causes of failure of aseptic sample collection revealed that lack of compliance among staff was the commonest factor causing failure of aseptic sample collection (41.66%).

(e) Root cause analysis of causes of failure of maintenance of pre requisites before sample collection identified that lack of manpower at help desk for patient counselling was the commonest factor causing failure maintenance of pre requisites before sample collection (25.71%).

(f) Root cause analysis of causes of failure of maintenance of sample adequacy showed that inadequate volume was the commonest factor causing failure of maintenance of sample adequacy (24.6%).

(g) Root cause analysis of causes of failure of maintenance of regular

equipment calibration revealed that negligence in regular running of calibrators was the commonest factor causing of failure of maintenance of regular equipment calibration (44%).

(h) Root cause analysis of causes of failure of maintenance of internal quality control identified that negligence in running of internal quality control on regular basis was the commonest factor causing failure of maintenance of internal quality control (41.67%).

(i) Root cause analysis of causes of failure of maintenance of External Quality Assurance System (EQUAS) showed that negligence in timely reporting of the EQUAS samples was the only factor causing of failure of maintenance External Quality Assurance System (EQUAS) (100%).

Recommendations

Based on the observations and data analysis of the present study **quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi**, following recommendations are made:

(a) Strict adherence to SOPs is advised.

(b) Completion of registration forms, maintenance of internal quality controls and maintenance of EQUAS are areas requiring greater focus for quality improvement.

(c) Supervision and monitoring of the registration counter and sample collection counters is recommended to avoid sample registration errors.

(d) Preparation of duty rosters for manning the help desk and monitoring the adherence to the duty roster is required so that proper patient counselling is done regarding the pre requisites before sample collection. The staff attending the help desk should undergo regular training regarding the various tests done in the laboratory so that they can help the patients adequately.

(e) **Training**

(i) Create awareness among staff regarding aspects of aseptic sample collection would decrease the frequency of aseptic sample collection.

(ii) Training of the staff as well as supervision regarding sample collection in adequate volume both for indoor and outdoor samples as

well as importance of proper mixing of the samples with anticoagulants..

(iii) Training about use of controls and calibrators and allotment of duties for regular running of controls and calibrators before sample testing.

(f) 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.

(g) Responsibility of timely reporting of EQUAS samples has to be allotted to a particular doctor and a technician who would ensure the smooth functioning of external quality assurance system.

(h) Motivation of the staff towards continuous quality improvement along with periodic in service training in different aspects of quality would bring about an attitude change thereby help in improving quality services of the laboratory.

(i) Some sort of incentives like chance of promotion to quality manager could act as a motivating factor among the staff.

Summary

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 quality assurance system guarantees that quality control measures are being carried out in the laboratory and the results are reliable. Quality control refers to the system of processes and procedures of the laboratory so as to generate a reliable report. The performance of the laboratory may also be monitored using samples of known composition supplied for testing by an external organisation (EQUAS).

With this background, the aim of the study was to study the quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi. The objectives were to:

(a) To analyse the factors affecting the quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

(b) To undertake root cause analysis of the factors affecting the quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

(c) To suggest recommendations to improve the quality services through data analysis and interpretation of this project.

A prospective, observational and analytic study was undertaken to study the quality of services in the Pathology Department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi. The study was conducted for three months from 1 Feb 2018 to 30

Apr 2018. Selected outdoor and indoor patients who were referred to the Pathology laboratory for different tests were included in the study by simple random sampling. 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 data were collected. After observation and data collection of the various variables of the quality services, the data was tabulated and analysed statistically.

During the study period, 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 registration failure showed incomplete requisition was the commonest cause of registration failure (38.57%). Root cause analysis of causes of failure of aseptic sample collection revealed that lack of compliance among staff was the commonest factor causing failure of aseptic sample collection (41.66%). Root cause analysis of causes of failure of maintenance of pre requisites before sample collection identified that lack of manpower at help desk for patient counselling was the commonest factor causing failure maintenance of pre requisites, before sample collection (25.71%). Root cause analysis of causes of failure of maintenance of sample adequacy showed that inadequate volume was the commonest factor causing failure maintenance of sample adequacy (24.6%). Root cause analysis of causes of failure of maintenance of regular equipment calibration revealed that negligence in regular running of calibrators was the commonest factor causing of failure of maintenance of regular equipment calibration (44%). Root cause analysis of causes of failure of maintenance of internal quality control identified that negligence in running of internal quality control on regular basis was the commonest factor causing of failure of maintenance of internal quality

control (4I.67%).Root cause analysis of causes of failure of maintenance of External Quality Assurance System (EQUAS) showed that negligence in timely reporting of the EQUAS samples was the only factor causing of failure of maintenance External Quality Assurance System (EQUAS) (100%).

Based on the observations and data analysis of the present study of quality services of Pathology laboratory of Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi, following recommendations are made:

(a) Completion of registration forms, maintenance of internal quality control and maintenance of EQUAS 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 to avoid sample registration errors. Training program to create awareness among the staff regarding the various aspects of aseptic sample collection would decrease the frequency of aseptic sample collection.

(b) Preparation of duty rosters for manning the help desk and monitoring the adherence to the duty roster is required so that proper patient counselling is done regarding the pre requisites before sample collection. The staff attending the help desk should undergo regular training regarding the various tests done in the laboratory so that they can help the patients adequately.

(c) Training of the staff as well as supervision regarding sample collection in adequate volume both for indoor and outdoor samples is recommended. Importance of proper mixing of the samples with anticoagulants has to be emphasized too.

(d) Training about the use of controls and calibrators and allotment of duties for regular running of controls and calibrators before sample testing is advised. Charts may be displayed with date, time and name of the staff who have run the control and calibrator will help in monitoring the process.

(e) Responsibility of timely reporting of EQUAS samples has to be allotted to a particular doctor and a technician who would ensure the smooth functioning of external quality assurance system.

(f) 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. Some sort of incentives like chance of promotion to quality manager could act as a motivating factor among the staff.

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Annexure I

Checklist

1. Sample No.:

2. Complete registration present including followings: Yes/ No

   (a) Full Name

   (b) Age

   (c) Sex

   (d) Department

   (e) Bed No.

   (f) Registration No. on the requisition is matching with the sample requisition No.: Yes/No

3. Aseptic sample collection present: Yes/ No

   (a) Use of gloves by phlebotomist: Yes/ No

   (b) Cleaning with spirit before collection of blood Yes/ No

   (c) Use of disposable syringes Yes/ No

   (d) Awareness of the staff about aseptic sample collection Yes/ No

4. Pre requisites maintained and checked: Yes/ No

   (a) Patient properly explained about the pre requisites of sample collection: Yes/ No

   (b) Patient complied to the advice of pre requisites of sample collection :

Yes/ No

(c) Checking of maintenance of pre requisites done before sample collection : Yes/ No

(d) Staff was available to explain about the pre requisites before sample collection : Yes/ No

5. Maintenance of sample adequacy: Yes/No.

(a) Sample collected in inappropriate vials : Yes/ No

(b) Sample collected in appropriate volume : Yes/No

(c) Proper mixing of sample with anticoagulants in the vials : Yes/ No

6. Maintenance of regular equipment calibration: Yes/No

(a) Timely procurement of calibrators : Yes/ No

(b) Regular running of calibrators; Yes/ No

(c) Adequate temperature control of calibrators: Yes/ No

7. Maintenance of internal quality control

(a) Running of internal quality control before sample testing: Yes/ No

(b) Use of controls within expiry date: Yes/ No

(c) Presence of knowledge regarding interpretation of Levy Jenning graphs: Yes/ No

(d) Maintenance of temperature the controls: Yes/ No

8. Maintenance of External Quality Assurance System (EQUAS): Yes/ No

(a) Timely reporting of the EQUAS samples: Yes/No

(b) Communication with the EQUAS laboratory maintained

(c) Funding for EQUAS available : Yes/ No

Annexure II

Approved Synopsis

SYNOPSIS FOR THE DISSERTATION

Background

As part of the PGDM curriculum at IIHMR, I am doing my internship cum dissertation under the **Ministry of Health and Family Welfare** (MOHFW) wef 01Feb 2018. The MOHFW has further attached me with **Lal Bahadur Shastri Hospital** (LBSH), Mayur Vihar, Delhi through **National Institute of Health and Family Welfare** (NIHFW) for the Internship and Dissertation during the internship period.

The NIHFW has allotted me the task **to study the quality of services in the pathology department at the Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi**.

Background of the Study

Hospital. Lal Bahadur Shastri Hospital is a secondary level multi-specialty hospital with 100 sanctioned beds (functional 188 beds). It is situated at Khichripur, in the Trans Yamuna area of Delhi. It caters to the East District of Delhi. It was commissioned in December, 1991 with OPD services only. Indoor services commenced w.e.f 11 Oct 1996 and the Hospital became fully functional w.e.f 22 Jun 1999. All the health services are provided **FREE OF COST.** Hospital campus is spread over 10.11 acres of land and has a floor area of 18,110 Sq. Mtrs.

The Hospital caters to the whole of East Delhi with more than 15 lacs population, other Trans Yamuna areas of Delhi, adjoining areas of NOIDA, Ghaziabad, Khora and areas of Uttar Pradesh and other adjoining states.

The Study. Clinical medicine is increasingly dependent on laboratory test results for correct diagnosis. The laboratory therefore has the critical responsibility of ensuring the quality and reliability of its work. The advent of automation and increasing dependence on machine generated results for analytic tests in the diagnostic laboratory, make it essential to adhere to a rigid protocol of quality control. The issue of laboratory quality has evolved over more than four decades since the first recommendations for Quality in 1965. Now, Quality control is seen only as one part of total laboratory control program. Quality includes within its ambit **Total Quality Management** - an activity to improve patient care by having laboratory monitor, its work to detect deficiencies and subsequently correct them, **Continuous Quality Improvement** (CQI) - to improve patient care by placing emphasis on not making mistakes in the first place and **Quality Assurance** - activities that ensure positive patient outcomes and measures what a laboratory can do to improve reliability. The consequences of poor quality are many however to name a few these would include issues such as inappropriate action - Over investigation, over treatment, mistreatment; Inappropriate inaction - Lack of investigation, No treatment, delayed action, loss of credibility of laboratory and legal action. Objectives of quality in the laboratory are to support provision of high quality health care and thereby reduce morbidity, mortality and economic loss. It ensures credibility of laboratory and generates confidence in laboratory results, between laboratories and between instrument comparability, if possible in agreement with a reference standard on consensus which gives an indication of the "correct" result. **LBSH, Mayur Vihar, Delhi** is equipped with modern automated instruments and a battery of tests is performed regularly on a daily basis for outdoor and indoor patients. It is with this background that the present study on the Department of Pathology at **LBSH, Mayur**

Vihar, Delhi has been undertaken. The study is designed to assess the prevailing quality services in the laboratory of the Pathology Department.

Objectives

General Objective To study the quality services in the Pathology Laboratory at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

Specific Objectives

(a) To analyse the factors affecting the quality services in the Pathology Laboratory of at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

(b) To undertake root cause analysis of the factors affecting the quality services in the Pathology Laboratory of at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

(c) To make recommendations to improve the quality services through data analysis and interpretation of this study.

Methodology

The study will be carried out as per the following methodology/ procedures:

(a) Review of literature

(b) Study the Layout and Functioning of the laboratory at the Pathology Department in LBSH.

(c) Study the sample collection and testing procedures of the laboratory.

(i) Observation and documentation of the registration process at the laboratory counter with entry of full name and particulars and issuing of registration number on the requisition and the same number on the vials/ containers of the samples.

(ii) Observation and documentation of the sample collection in aseptic procedure, in appropriate vials, in appropriate amount and proper mixing with anticoagulants.

(iii) Observation and documentation of timely calibration of the equipment in the Department of Pathology

(iv) Observation and documentation of daily running of internal controls prior to sample testing.

(v) Observation and documentation of external quality assurance system (EQUAS) whether followed on a regular basis.

(vi) Observation and documentation of the number of samples rejected during the study period to maintain the quality assurance system

(d) **Study**

(i) **Study Design**: Descriptive Analytic Study

(ii) **Study Area**: The Laboratory Pathology Department at Lal Bahadur Shastri Hospital, Mayur Vihar, Delhi.

(iii) **Study Population**: Selected Outdoor and Indoor patients who are referred to the pathology department for different tests.

(iv) **Data Collection**: Prospective Observational Study with the help of a Check list.

(v) **Study Period**: 01 Feb to 30 Apr 2018.

(vi) **Sample Size**: 500

(vii) **Sampling Technique**: Simple Random Sampling.

(e) **Data Analysis Plan:** After observation and data collection of the various variables of the quality services, the data will be tabulated and analysed statistically.

(f) Find out the gaps in the laboratory procedures being followed at LBSH in comparison with the **Essential Standards for Medical Laboratories** as stipulated by NABH Standards for medical laboratory certification. Based on the results and data analysis of the project, recommendations would be suggested to improve the quality assurance system of the Pathology Laboratory.

Expected Outcome

The study is intended to bring out the following outcome:

(a) Find out the gaps in the laboratory procedures being followed at LBSH.

(b) Make Recommendations to update the procedures in tune with the NABH standards based on findings of the study.

Time Frame

The study will be carried out over a period of three months from 01 Feb to 30 Apr 2018.

References

The study will be carried out by referring to the following:

(a) Recommended guidelines for Quality Assurance and Good Laboratory Practices. United Nations. New York.1995.

(b) Cushman M, Cornell ES, Howard PR, Bovill EG, Tracy RP. Laboratory Methods and Quality Assurance. Clin. Chem. 1995^41 (2):264

(c) **Essential Standards for Medical Laboratories** as stipulated by NABH Standards for medical laboratory certification.