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STUDY OF PRE ANALYTICAL ERRORS IN A MEDIUM SIZED PATHOLOGY LABORATORY

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ABSTRACT: Introduction : Pre-analytical errors account for 49% to 68% of the errors in medical Laboratories, which can have a significant impact in patient care. **Material and Methods:** A retrospective analysis was performed on non conformance (NC) data over a 6 month period in a medium sized private Pathology Laboratory . The Laboratory performed all routine tests in the departments of Biochemistry, Hematology, Clinical Pathology, Serology, Cytology and Immunology. All specialized tests were outsourced to a sister concern in the same city. Non conformances were identified by feedback from Referring doctors and patients as well as documented data maintained by the laboratory. **Results:** Data included 11,160 patients during the study period. There were 3644 incidences (32.65%) of NCs. Sample collection reported 1928 (52.9%) incidents of which 1302 were from indoor patients and 626 from outpatient departments. 1716 (47%) incidents were reported from billing / data entry. The most frequent NCs in collection were insufficient sample, less than 2 appropriate identifiers, and sample mislabeling, incomplete data on request forms, hemolysed sample, and wrong vial. In data entry, incorrect / mismatched patient details, incorrect test billing and incorrect Dr Details were commonly found. Causes of recollection were hemolysed sample, insufficient sample and rejection by referral labs. Corrective action was taken to improve non conformances. **Conclusion:** Importance of pre-analytical phase in overall laboratory performance cannot be overemphasized. Monitoring NCs in laboratory is essential to determine areas where further improvements are required. It is a tool of measurement of internal quality assurance as a part of continuous quality improvement.

KEY WORDS: Preanalytical : non conformance; clinical laboratory; internal quality assurance.

INTRODUCTION:

The pre analytical phase is recognized as one of the most vulnerable phase in the diagnostic testing process and accounts for 49% to 68% of errors in a medical laboratory.[1] This not only causes delays / erroneous diagnosis but also adversely impacts patient health and safety. A correct preanalytical phase procedure is critical to get an adequate, representative sample with the aim of achieving the most reliable and reproducible laboratory results thus promoting patient safety.[2] Accreditation of diagnostic services has led to greater awareness not only among healthcare personnel but also the general public. Identification along with documentation of Non Conformances (NC) is essential component required for accreditation to National Accreditation Board of Laboratories (NABL) which emphasizes the importance of total quality management (TQM).

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AIM AND OBJECTIVES

The study was undertaken to evaluate the incidence and type of preanalytical errors in a medium sized diagnostic medical Laboratory in the city of New Delhi. The study also aimed to formulate corrective measures to prevent their recurrences in the future.

MATERIAL AND METHODS

A retrospective analysis was performed on non conformance data over a 6 month period in a medium sized private Pathology Laboratory situated in the premises of a 30 bed Birthing hospital specializing in Gynaec / Neonatal care patronized by patients belonging to the upper and upper middle class strata of society. The Laboratory received samples both from the Wards / Nursery / Outpatient departments.(OPD). Collection was done by laboratory personnel (OPD) and nursing staff (Wards). All routine tests in the departments of Biochemistry, Hematology, Clinical Pathology, Serology, Hormones, Cytology and Immunology were performed in-house. All specialized tests were outsourced to a sister concern in the same city. Non conformances were identified by feedback from Referring doctors, patients as well as documented data maintained by the laboratory. A total of 11,160 patients samples were received during the study period.

OBSERVATION AND RESULTS :

Data included 11,160 patient samples during the study period. There were 3644 incidences (32.65%) of NCs. Sample collection reported 1928 (52.9%) incidents of which 1302 were from indoor patients and 626 from outpatient departments. 1716 (47%) incidents were reported from billing / data entry. The commonest causes of error have been tabulated in Table 1. Table 2 gives the common reasons of recollection of sample.

Table 1. pre analytical non conformances in specimen collection / data entry

SAMPLE COLLECTION (n=1928) (52.9%)	
Insufficient sample	848
Less than 2 appropriate identifiers	342
Sample mislabeling	82
Incomplete clinical data like time of collection	143
Hemolysed sample	476
Wrong vial / fixative	35
Wrong patient	2
DATA ENTRY / BILLING (n=1716) (47%)	
Incorrect / mismatched patient details (Name, age , gender)	847
Incorrect test billed (Prothrombin time (PT) mistaken for SGPT	56
Incorrect referring Dr. details	215
Incomplete patient demographic details	598

Table 2. Causes of recollection of sample (department wise break up)

Hemolysed sample	NICU / Nursery
Insufficient sample	NICU / Nursery
Rejection of sample by referral lab	OPD / Wards
Mislabeled sample	Urine (Ward, OPD collection area)
Incorrect specimen type / dedicated sample not collected.	NICU

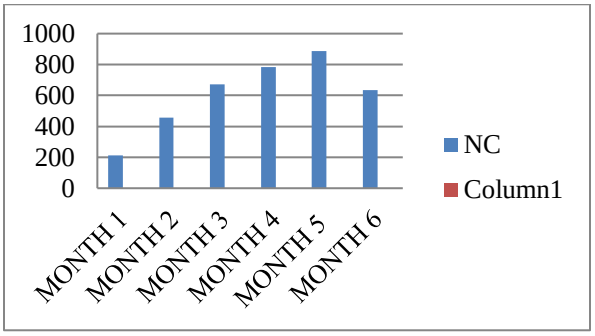

Figure 1. Month –wise distribution of NCs over a 6 month period

Figure 1. highlights the distribution of non-conformances over a 6 month period, with the first month recording the lowest incidences of NCs (211) whereas the 5th month recorded the highest (886) in the 6 month study period.

On the basis of the data obtained over this time period, strategy for corrective action was formulated as detailed below.

Corrective and Preventive Action (CAPA)

1. Education and training was imparted to laboratory staff to improve systems and processes, rather than "fix a blame," which made them more cooperative and open for correction. It also encouraged a non-judgmental work environment.
2. Manual labeling of sample vials was discontinued. Printed stickers with patient details generated at the time of Registration were affixed on sample vials. This reduced staff fatigue and obviated the need to do repetitive manual entries increasing the chances of error.
3. Data entry billing executives were given vigorous training on common test requests. A mini- test at end of each session ensured retention of learnt material.
4. Fortnightly trainings were held on the commonly found deficiencies. Attendance was made compulsory and was documented. This ensured participation by maximum staff members which was reflected in the Yearly performance appraisals of each employee.
5. Laboratory training / rotation was made compulsory for a minimum of 2 weeks for all new employees as a part of employee induction programme. The programme Included nursing staff, data entry personnel, junior doctors and housekeeping staff.
6. Training on sample collection techniques by evacuated blood collection systems organized every month for all new laboratory personnel and nursing staff to reduce the number of hemolysed samples.
7. Facility specific detailed documented Standard Operating Procedures (SOPs) for sample collection, information regarding appropriate vials for common specialized tests, including relevant clinical history and transporation requirements handed over to all Wards / OT / NICU . This replaced the Directory of services (DOS) which being huge and exhaustive was never referred to.
8. Identification wrist bands for all indoor patients including infants. These bands mentioned all the details and were only removed after the patients' discharge.
9. A 2 tier supervisory system introduced in OT for test requests on tissue samples. Nursing staff assigned with duty of labeling the sample bottles before collection whereas Resident Doctors responsible for the choice of fixative (normal saline / 10% buffered formalin) and completed the clinical details on test request forms. This decreased the rate of sample rejections dramatically and also the turnaround time for generating reports.
10. Weekly meeting Convened by Facility Director attended by Heads and a single senior staff of all Sections including

Referring Doctors (when available) where weekly metrics of each department displayed and discussed. Led to sense of ownership. Under no circumstances were weekly meetings cancelled. Commitment to quality reiterated at all levels in Organizational heirachy.

11. Monthly performance assessed not only by documented metrics but also 'Customer Satisfaction scores"given by Users of that service. For laboratory services both doctors and patients were encouraged to give feedback including positive and negative experiences.
12. Award and certificate of appreciation instituted every month for a department with the best improvement in metrics. Fostered a sense of competiveness among departments and a positive willingness to improve among employees.

DISCUSSION:

The total testing process (TTP) has been traditionally divided into three phases namely pre analytical , analytical and post analytical. [3-6]

Errors in laboratory medicine are difficult to identify and are less understood than other types of medical error. This may be due to their insidious nature and the multiple complex processes which are involved in the laboratory. [1] The pre analytical phase encompasses numerous tasks and begins from the Clinicians request and includes the examination request, preparation and identification of the patient, collection of the sample, transportation to and within the laboratory and ends when the analysis of sample begins. [2] This phase moreover does not fall directly under laboratory control as it involves different stakeholders who may / may not be directly related to the Laboratory.

The laboratory till prior to the commencement of this study had a knee-jerk reaction policy to addressing Referring doctor / patient complaints. Redressal was done on "case to case" basis with no mechanism for follow up to prevent recurrences. All feedback was perceived to be negative and hence there was resistance among laboratory personnel at the commencement of the study. It was felt to be a non productive, wasteful exercise which would unnecessarily overburden the lab staff with additional documentation leading to further delays in the commencement of the analytical process. Also, it was thought to be a a tool for instituting disciplinary and punitive action for errant employees. This is corroborated by the lowest error reporting in the first month of the study (Figure1.). This behavior has been documented in another study and the author cites fear of sense of blame and individual failure among laboratory personnel as well as culpability associated with these events for the same[7]. As detailed in the above figure, the number of documented NCs showed a steady increase for a period of 5 months and only in the 6th month started to decline till the corrective measures bore results. Also a high turnover of hospital staff was observed in the 4th and 5th months of study. Rapid employee turnover has been cited as one of the reasons for pre analytical non conformances. In one study the association between new employees and non conformances per month approached statistical significance. [8] We however, could not assess the same in our study.

The commonest reason for preanalytical non conformance was insufficient and hemolysed samples. This was mainly observed in neonate samples where sampling can sometimes be very difficult and the physiological high hematocrit does not allow for sufficient quantity of serum to be obtained. Hemolysed samples were observed when the staff deviated from the standard guidelines laid down for sample collection and collected the samples via a syringe and needle. This technique followed was mainly due to lack of experience. Though collection from wrong patient formed a small proportion of sample collection NCs it was an area of huge concern for us. This

was also observed in samples from newborn babies where the neonate was just identified by the cot number and mothers name. The NCs were observed when the sample was collected in the feeding room, changing room etc. The introduction of identification wrist bands as detailed in CAPA 6 above enabled the elimination of this error.

Data entry non conformances (Table 2) occurred primarily in the Outpatient department where billing and customer care executives were entrusted with the task. Incorrect spelling of name / age as well as incomplete demographic details like contact information was commonly deficient. This was due to oversight and also the common perception that it did not have much bearing on the analytical process. Incorrect test requests (56/1716) occurred due to illegible handwriting on request slips as also lack of background medical knowledge coupled with inadequate training.

Studies worldwide have documented a pre analytical conformance ranging from 0.56% to 0.6% of tests done.[9-10]

The rate of non conformances in this study which was measured according to patient episodes and cannot be directly compared with other studies which measured the rate of non conformance based on the number of tests. Our data of 32.65 % NCs in the pre-analytical phase may be lower when based on the number of tests.

Studies conducted in a laboratory in a public hospital In India documented an error rate ranging from 44.7% to 61% in the pre-analytical phase. [11,12] This is possibly due to lack of motivated staff in government hospitals due to high volumes of workload as patients' availing these services are generally very poor and thus believed to have no consumer rights as the services availed are not paid for. Also, the staff employed is permanent with greater job security as regards to employment status with no fear of negative appraisals due to deficient performance. This is thankfully not the case in private hospitals where the patients actually "pays" for the services he avails and thus expects a minimum standard of service.

Failures that occur early on in the analytical process like the pre analytical phase are more likely to result in process disruption but introduction of active and passive defence barriers in this phase akin to a Swiss cheese model involving personnel, technology, procedures and administrative control may mitigate the incidence and impact of these errors. [13]

Introduction of specific software for recording of preanalytical errors needs to be introduced as it enables harmonization of incident reporting in laboratories within same laboratory and also across different laboratories. This is important as preanalytical non conformances are generally under reported. [14,15]

The study was limited by its retrospective nature and that we were unable to determine the rate of non conformances as a percentage of tests performed for comparison with other studies. Non conformances assessed were based on patient episodes.

System relied on the accurate and honest reporting by staff concerned. Documentation of the same done manually in Lab Registers.

CONCLUSION:

The importance of the pre analytical phase in the total testing process cannot be understated. Monitoring non conformances is paramount to determine areas where further improvements can be made. Studies such as these can serve as a tool for internal quality assurance, and act as a measurable benchmark for comparison with future studies as a part of continuous quality improvement and total quality management.

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