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Original Research Paper

Pathology

DETECTION AND LEARNING FROM CLINICAL LABORATORY ERRORS: A PERFORMANCE IMPROVEMENT METHODOLOGY.

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ABSTRACT

Introduction : Mistakes in the "Total Testing Process" are called "Laboratory Errors."
Laboratory services have a great influence on clinical decision making, hence there is a need to investigate any possible error in the "Total Testing Process."
Errors are broadly divided into preanalytical, analytical & postanalytical categories.
A simple practice of maintaining "Error Register" and analyzing the reported errors can pin point at the probable modification required in the process design.
Methods : All errors were recorded in a register. The root cause analysis was carried out for each error reported for six months.The necessary corrective action was decided to avoid future errors.
In order to know the trend a bar graph was plotted for number of errors per month.
Percentage of pre analytical, analytical and post analytical errors was calculated.
Results : Among the total errors 75% are pre-analytical, 7.1% are analytical and 17.9% are post-analytical errors. Phlebotomy training for staff & bidirectional interphasing of instruments are most important corrections required.
Conclusion : Maintaining an error reporting register is very simple, cost effective and performance improving method.

KEYWORDS : Error register, Pre analytical, Analytical, Post analytical

Introduction –

The Institute of Medicine (IOM) report -- 'To Err Is Human: Building a Safer Health System,'(1) Since the release of this report, error detection and prevention gained importance in the health care system.

Laboratory services have a great influence on clinical decision making, like admission, discharge, and medication.Hence there is a need to investigate any possible error in the "Total Testing Process." Traditionally, laboratory practice can be divided into 3 phases (pre-analytical, analytical, and post-analytical). (2)

All 3 phases do not fall under laboratory control, the pre- and post-analytic phases are the responsibility of stakeholders other than the laboratory such as the clinician, the nurse, the patient and others involved in patient identification, data entry, specimen collection and transport.

As per Technical Specification (ISO/TS 22367) 2008, any clinical laboratory should employ processes for: a) identifying high risk processes where the potential error could lead to a safety risk for patients; b) detecting actual incidents associated with deviations from standard requirements; c) estimating and evaluating the associated risks to patient safety; d) controlling the risks; and e) monitoring the effectiveness of the measure taken. (3)

The frequency of laboratory errors varies greatly, depending on the study design and steps of the total testing process (TTP) investigated (3)

Literature clearly demonstrate that different data collection methods, different time spans, different laboratory sections investigated, has an important influence on error types and their prevalence (4)

Root Cause Analysis (RCA) is based on a retrospective analytical approach. RCA focuses on identifying the latent conditions underlying variation in medical performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.(5)

A simple practice of maintaining "Error Register" and analyzing the reported errors can notify the modification required in the process design so as to minimize future similar errors.

Material and Method –

The format for error register was decided as follows.
The columns prepared in the error register are as under.

1. Date
2. Department
3. Error details
4. Error type - pre-analytical, analytical, and post-analytical.
5. Error identification phase
6. Name & signature of the reporting technician
7. Action taken
8. Error impact
9. Outcome from root cause analysis.

Reporting of errors in the above-mentioned format was established as a routine practice.

The errors reported from Jan 2018 to July 2018 are included in the study.

The columns 1. to 6. were entered by the technicians and columns 7,8,9 by the quality manager on duty.

The error data captured in the register led to the following steps.

1. The root cause analysis was carried out for each error reported during study duration.
2. The analysis was done to understand whether the error affected clinical decision making.
3. The necessary corrective action was decided to avoid future errors.
4. In order to know the trend a bar graph was plotted for number of errors per month.
5. Percentage of pre-analytical, analytical and post-analytical errors was calculated.

The outcome was reported to the concerned personnel to avoid similar future errors.

Results –
Mainly seven types of pre-analytical and two each of analytical and post-analytical causes of errors are identified.

PRE-ANALYTICAL PHASE –
1. Collection error – Low calcium value / high potassium value, not co-relating with patient's clinical condition or previously delivered report.
2. Interchanging of label / barcode.
3. Wrong labelling of mother and baby's sample.
4. Venous blood collected for blood gas analysis instead of arterial blood sample.
5. Sample clotted – inappropriate ratio of blood volume to anticoagulant.
6. Diluted sample – sample collected from IV line.
7. Wrong time of collection.

Inference –
These errors lead to increased TAT, as a result, there could be delay in patient management. Collection of repeat sample causes inconvenience to patient, which can affect image of the lab & hospital. Most (93.7%) of the pre-analytical errors occurred during sample collection for IPD patients.

Hence expert phlebotomists from the laboratory were assigned two rounds per day to the wards for sample collection.

A training in phlebotomy was arranged for nursing staff and technicians.

ANALYTICAL PHASE –
1. Calculation error – non-consideration of dilution factor / volume of 24 hr. urine sample.
2. Interchanging of samples, while loading on the autoanalyzer.

Inference –
There is a need for creating more awareness and alertness amongst the lab technicians, so continuous training sessions were arranged.
IQC and EQAS help to identify analytical errors, hence analytical quality can be maintained by keeping 'Total Allowable Errors'within limit as per CLIA guidelines.

Use of barcode system was implemented, which helped autoanalyzer to identify correct sample.

POST ANALYTICAL PHASE –
1. Values informed telephonically, does not match with the report delivered. Error is incorporated during verbal communication.
2. Values of one patient given to another patient / or value of one parameter reported for another parameter of the same patient.

Inference –
Error is detected by the treating doctor, which leaves bitter impression. Changes were made in the software by introducing additional level of authentication of reports before delivery.

Similar errors occurred repeatedly, with a frequency of once in a month but they were detected during 2nd level of authentication and corrected reports were dispatched.

A process was initiated for bidirectional interphasing of the autoanalyzer.

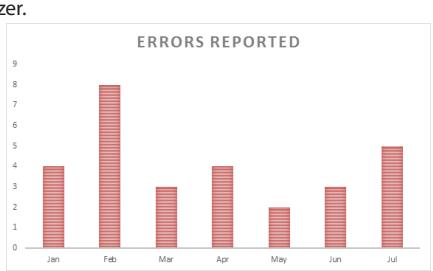

Figure 1. No. of errors reported per month

The number of errors reported, does not depend upon sample size as maximum no. of samples were processed in the month of July (13215) followed by March (10112) and minimum no. of samples in February (8471)

Among the total errors 75% are Preanalytical, 7.1% are analytical and 17.9% are post analytical errors.

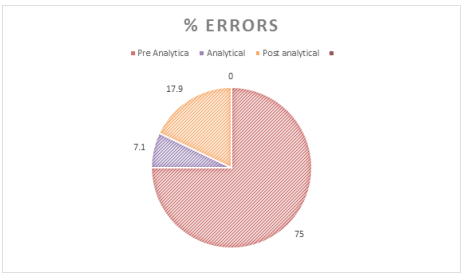

Figure 2. Percentage of type of errors

Discussion –
The study design chosen by Paolo Carraro and Mario Plebani was to monitor the error rates for laboratory testing in 4 different departments (internal medicine, nephrology, surgery, and intensive care). For 3 months (6)

According to Goldschmidt HM, Lent RW, Data collection based upon complaints has reported very few errors.(7)

As per Julie A. Hammerling, laboratory errors are being underreported, & there is an urgent need to establish a reliable policy of error recording.(2)

The methodology of error data collection used in the present study is different from that reported in the above studies.

Over the past decades, a ten-fold reduction in the analytical error rate has been achieved, thanks to improvements in the reliability and standardization of analytical techniques, reagents, and instrumentation. In addition, advances in information technology, quality control and quality assurance methods have made a valuable contribution to error reduction. (3)

Julie A. Hammerling(2) reported, Pre-analytical errors 46%-68.2%, Analytical errors 7%-13% and Post-analytical errors18.5%-47%.

A study by Mario Plebani demonstrates that pre-analytical errors are estimated to account for up to 70% of all mistakes made in laboratory diagnostics(3)

A report by Bonini and colleagues found that preanalytical errors predominated in the laboratory, ranging from 31.6% to 75%.(8)
This corroborates with present study.

According to the study by Julie A. Hammerling(2), a comprehensive plan to prevent pre-analytical errors has 5 interrelated steps: 1. Developing clear written procedures. 2. Enhancing health care professional training. 3. Automating functions, both for support operations and for executive operations. 4. Monitoring quality indicators. 5. Improving communication among health care professionals and fostering interdepartmental cooperation.

The above comprehensive plan is aligned with the inferences of the present study.

So, errors can no longer be seen as inevitable, but as something that can be actively streamlined and prevented. (9)

Conclusion –
1. Maintaining an error reporting register is very simple, cost effective and performance improving method.
2. It provides evidence to convince the higher authorities to bring change in the existing process design.

3. It increases awareness among the technicians and other laboratory staff so as to avoid future errors.

Scope –

1. Separate error register to capture data during shifts to identify frequency and type of errors occurring in various shifts.
2. Study of appropriate diagnostic test order and inappropriate response or follow up of lab results.

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