Original Research Article

Study of pre analytical variables in clinical biochemsitry laboratory

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ABSTRACT

Introduction: Advances in science and Technology have led to transformation of laboratory diagnostics from manual, clumsy testing methods to fully automated science, ensuring accuracy and speed. Pre analytical errors have a major impact on diagnostic accuracy of laboratory results. There have been tremendous work and established quality control criteria for analytical phase of testing however there is paucity of standards for pre analytical phase. Quality indicators (QIs) should therefore cover all the steps involved in the pre-analytical phase, from test requesting, transport to sample storage.

Objectives: The following were the objectives for the study: 1. To discern the percent age of pre-analytical errors in our central clinical biochemistry Laboratory (CCL); 2. To stratify the pre-analytical errors documented at CCL; 3. To formulate the possible corrective measures to be taken to minimise such errors.

Materials and Methods: In patients (IPD) 18,982 blood specimens requested and received at CCL for various biochemical investigations during November 2018 to May 2019 (6 months) were first sorted out for pre analytical errors. And n= 1907 blood specimens were identified with pre analytical errors were further stratified and categorised according to the error contributing and expressed in percentage.

Result: Total 1907 blood specimens were documented and grouped under pre analytical phase errors out of 18,982 total samples received at CCL. When sorted for individual pre-analytical error, out of total n= 1907; Improper request form (n= 107), incorrect timing of sample (n=37), improper labelling (n=65); improper tube collection (n=67) ; insufficient sample (n=228) and in-vitro haemolysis (n=251), sample not received (SNR) (n=1142) of samples amounted to be the major proportion of errors.

Conclusion: Pre-analytical errors are not inevitable and can be avoided with a diligent application of proper quality control, proper education of phlebotomist about the errors and effective collection systems to improve the total quality management of laboratory so as to ensure total quality patient care.

1. Introduction

Quality indicator (QI) is a quality tool enabling laboratories seeking improvement to quantify the laboratory's performance by selecting a certain comparative criterion; its aim is to appraise the performance and initiate corrective measures to ensure continual improvement in patients care. The acronym SMART is often applied hen identifying the QIs, where SMART denotes selected goals that should be specific, measurable, achievable, realistic, and time bound. QIs were broadly categorised as pre analytical, analytical, and post analytical accordingly as per the phase of the laboratory process they processed and estimate. [1]

The major 5 key components for the establishment of quality and reliability in the laboratory diagnostics of health care systems include (a) Quality laboratory process (QLPs), (b) Quality control(QC), (c) Quality Assurance/Assessment (QA), (d) Quality Improvement (QI) and (e) Quality policy (QP). [2]

The pre analytical phase is an important component of laboratory medicine. It includes the time from the order of test by the clinician until the sample is ready for analysis - it can account up to 70% of errors during the total diagnostic

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process.[3]

1.1. Errors in the pre-analytical phase

Currently, pre-analytical errors contributes up to 70% of all mistakes made in laboratory diagnostics, most of which arise from p roblems in patient preparation and sample collection,

Transportation and preparation for analysis and storage. However, patient preparation and sample collection (including patient and sample identification, and specimen handling) are widely recognised as frequent sources of errors, thus greater emphasis and attention should be paid towards sample transportation. This area needs improvement initiatives, as there is an increasing trend towards consolidation of laboratory facilities, with a consequent need for long-distance sample transportation.

The most commonly reported types of pre-analytical error are: a) missing sample and/or improper test request, b) wrong or missing identification, c) contamination from infusion route, d) haemolysed, clotted, and insufficient samples, e) inappropriate use of containers, f) inappropriate blood to anticoagulant ratio, and g) inappropriate transport and storage conditions.

Taking these issues into consideration, the present study has been planned with following

2. Objectives

1. To discern the percentage of pre-analytical errors in our central clinical biochemistry Laboratory (CCL).
2. To stratify the pre-analytical errors documented and evaluate the types, frequency and Extent of errors occurred in our tertiary health care clinical biochemistry laboratory during pre-analytical testing process.
3. To formulate the possible corrective measures to be taken to minimise such errors.

3. Materials and Methods

A prospective study was done for a period of 6 months from 1st November 2018 to 30th May 2019 in Central Clinical Biochemistry laboratory of Government Medical College Akola, Maharashtra. We monitored the frequency and type of pre-analytical errors by screening all the inpatient venous blood samples received from the wards collected by the nurses/interns before the analytical phase was undertaken. All types of pre-analytical errors were documented by technical assistants and later verifi ed by laboratory in-charge for final decision making. 'Pre-analytical variables' were recorded systematically under the following categories:

1. Improper request forms (sample requisition)
2. Incorrect identification/Improper labelling

3. Timing of sample (correction to transport)
4. Insufficient volume (quantity of sample collected)
5. In-vitro haemolysis
6. Improper tube (usage for sample collection)
7. Specimen handling

The analysis of such errors was done by calcu=lating the percentage and of each category.

Percentage calculations of samples rejected for each month and the sample rejection rate was calculated by number of samples rejected / to total number of samples analyzed X 100.

4. Observation & Result

Table 1 pre-analytical errors among 1907 samples out of total sample documented (i.e 18,982) over a period of 6 months. Pre-analytical errors happening at various levels of sampling namely at the level of patient identifi cation, sample collection and sample transport were investigated as mentioned in above table.

5. Discussion

Quality in general means conformance to the requirement of users or customers, with respect to health care systems, the users of health care laboratories are doctors, nurses and their customers are the patients.[2]

Pre analytical errors have a major impact on diagnostic accuracy of laboratory results. There have been tremendous work and established quality control criteria for analytical phase of testing but there is paucity of standards for pre analytical phase.

In our study, out of total blood specimens received during Nov 2018 to May 2019 were 18,982 out of which 1907 specimens were sorted with pre analytical errors, leading aspect to enhance the overall susceptibility in pre analytical phase include Sample Not Received (60%), hemolysis (13.1%), insufficient sample (12%), improper request (5.6%),improper tube collection (3.6%), improper labelling (3.4%), incorrect timing of sample (1.9%). The reason for being 60% SNR would be lack of man power in govt set up would adversely affects lack of standardization of different practises for collecting managing transporting speciemen. Our study are ler (Asha kiran et al (by Pal Bela Szecsi and Lars Ødum), (lipppi G.) 3 months study of pre analytical varations was carried out by Asha Kiran where she demonstrated that average 44.7/day as pre analytical errors observed.

In addition Sezeci BP and Odum L observed 81% pre analytical errors and stated that each laboratory should record their errors in a structured manner. The issue of identifying hemolysis in whole blood specially concerning the rate of hemolysis in the present study (13.1%) which is pretty high when compared with study conducted by Salvagno GL et al 2012 where they observed 4% in the

Table 1: Distribution of pre analytical errors variables

Months	Improper Request	Improper Labelling	Incorrect timing of Sample	Insufficient Sample	Improper tube Collection	Haemolysis	Sample Not Received	Errors	Total IPD
	Number of samples (n) & Percentage (%)								
Nov 2018	13 (0.46%)	16 (0.56%)	0 (0%)	26 (0.91%)	02 (0.07%)	19 (0.66%)	100 (3.5%)	176 (6.5%)	2857
Dec 2018	18 (0.66%)	19 (0.70%)	04 (0.14%)	26 (0.95%)	43 (1.58%)	27 (0.99%)	111 (4.09%)	248 (9.15%)	2709
Jan 2019	08 (0.28%)	14 (0.49%)	16 (0.57%)	53 (1.88%)	05 (0.17%)	45 (1.60%)	156 (5.56%)	297 (10.5%)	2805
Feb 2019	15 (0.51%)	03 (0.10%)	00	90 (3.09%)	07 (0.24%)	60 (2.06%)	265 (9.11%)	440 (15.1%)	2906
March 2019	18 (0.68%)	04 (0.15%)	08 (0.30%)	08 (0.30%)	02 (0.07%)	25 (0.95%)	200 (7.61%)	265 (10.08%)	2627
April 2019	20 (0.8%)	06 (0.24%	07 (0.28%)	10 (0.40%)	05 (0.20%)	30 (1.22%)	150 (6.12%)	238 (9.72%)	2447
May 2019	15 (0.57%)	03 (0.11%)	02 (0.07%)	15 (0.57%)	03 (0.11%)	45 (1.7%)	160 (6.08%)	243 (9.23%)	2631
Total	107 (5.6%)	65 (3.4%)	37 (1.9%)	228 (12%)	67 (3.6%)	251 (13.1%)	1142 (60%)	1907 (10.04%)	18,982

whole blood samples collected for blood gas analysis.[4]

Binita Gosw ami et al scrutinized data for 67438 routine venous blood specimens and errors were documented over a period of 1 year and they found that pre analytical errors were most common with 77.1% followed by post analytical 15% and analytical 7.9%, respectively indicates the urgent need of close inter-departmental cooperation to meet the goal of ensuring patient well being.[5]

Laboratory errors have significantly decreased in the last four decades with advances in technology such as automation, lab lean process and application of six sigma, analytical errors but related errors still remains to be the major problem faced routinely in laboratory.[2]

Elimination of such errors can be done by taking certain proactive steps and is must for good laboratory practice. Lippi & Guidi emphasized to develop a reliable approach to overcome this problem entails prediction of accidental events, an increase in and diversification of defences and a decrease in vulnerability to overcome such pre-analytical variations.[3]

To overcome pre - analytical errors, the following correcti ve measures have been recommended: (Lippi G et al, Sciacovellia L et al, Jo Gile T)

1. Skilled staff: skilled and adequate staff to maintain collection standards, which give an extra verge of expertise.[6]
2. Phlebotomists : with proper knowledge pertaining to phlebotomy (trained personnel)
3. Regular educational competency assessments should be encouraged to allow (new and old personal) an opportunity to recognize and manage errors.
4. Vacutainers: Proper knowledge regarding use of evacuated tube system to the lab personal pertaining to sample volume and use of anti- coagulants.[7]
5. Transport : laboratory personnel guided regarding importance of transport the specimens promptly to the laboratory at the earliest after collection to avoid errors related to delay.
6. Advanced Technology : Usefulness of barcode scanners system for individual sample recognition.[8]

6. Conclusion

Now a day, pre-eminent advances in laboratory automation, sample collection, transport, and report dispatch leads to an utmost improvement in laboratories performance. But still there is long path to pace before we achieve 100% accuracy and precision. Pre-analytical errors are not unavoidable, but we can minimize or eliminate it by improving laboratory testing. Promoting quality control and systemic monitoring, will help to improve test reliability and thus enable physicians to have optimal clinical management for patient care.

Laboratory experts should implement continuous internal programs not only for detection of analytical errors but for overall quality management & improvement in laboratories. Proper exhaustive program should be silhouette for laboratory personnel like orientation program regarding total quality management to attain better laboratory testing, monitoring, reporting and performance in terms of accuracy, precision and will eventually assists physicians to have favourable insights in patients care.

7. Summary

Monitoring pre-analytical variables require coordinated effort of many individuals, each one of which must

recognise the importance of these efforts in maintaining a high quality service.

8. Source of funding

None.

9. Conflict of interest

None.

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