Original Article

Undeniable Role of Poor Patient Preparation in the Generation of Preanalytical Errors in Government — Run Tertiary Care Hospital in Eastern India : A Pilot Study

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Abstract

Background : Quality in laboratory medicine ensures the delivery of an accurate, precise, repeatable and reliable report to help patients in diagnosis as well as therapeutic monitoring. Inspite of total lab automation, human involvement cannot be negated and hence errors do occur in every step which may cause unnecessary delay in the final report. Pre analytical errors add upto almost 70% of all errors occurring in laboratory diagnostics. Pre-analytical variables can be divided into two phases-(i) non controllable (ii) controllable. We conducted a pilot study in a tertiary care government run hospital in eastern India to find out the most common cause of preanalytical reason of delayed reporting.

Materials and Methods : For a period of 3 months (June, 2018 - August, 2018), serum samples and requisitions from OPD and from IPD, routinely coming to Department of Biochemistry, Government run Super-speciality Tertiary Care Hospital in Eastern India, were collected and checked for avoidable pre-analytical parameter ie, missing requisitions/ samples, wrong identification, insufficient quantity, lipemia and hemolysis. Such samples were separately tabulated into distinct groups for further analysis. Statistical analysis was done in Microsoft Excel.

Analysis and Result : Out of a total number of 36,515 samples from OPD and 30,395 samples from IPD, the percentage of lipemic samples for 3 months was found to be 0.071%, Hemolyzed samples 0.0259%, insufficient sample 0.0309%, no sample or no requisition amounting to 0.02%, the total pre-analytical controllable errors amounting to 0.208%. Lipemia seemed to be the most significant cause of such preanalytical reason for delay or rejections.

Conclusion : Proper training of personnel involved in sample collection regarding patient preparation, time of sample collection, duration of fasting for patients for collection of samples for certain parameters, requirement of sample quantity for individual parameters to be run in departmental machines would reduce errors, delays in reporting and inappropriate rejection of samples and would give a better Turnaround Time (TAT).

Key words : Quality, Preanalytics, Lipemia, TAT.

It is the necessity in today's universe to talk both in terms of quality and quantity and when we talk about health care, quality is the thing of utmost interest. Quality in laboratory medicine ensures the delivery of an accurate, precise, repeatable and reliable report to help patients in diagnosis as well as therapeutic monitoring. Quality should be guaranteed in all the steps of total testing procedure which starts from ordering of test to delivery of report to the patient. Lundberg introduced the concept of the 'brain-to-brain loop' in laboratory medicine which actually signified the conception of the provisional diagnosis in the minds of the referring clinician and thereby selecting the panel of laboratory tests to confirm the diagnosis for which in turn patients undergo the tests and final step is the delivery of reports to the referring clinician for further management[1,2]. Total Testing Procedure (TTP) may be classified into nine steps as: requisition, collection, identification, transportation,

Editor's Comment :

- This article points out the importance of patient preparation in diagnosis as well therapeutic monitoring of patients from the laboratory Medicine point of view which will definitely play a unprecedented role in patient care and management by the Clinicians .
- The tertiary care government hospital which serves a wide catchment area having a variety of population from both different educational and socio economic strata will be at a position to create awareness amongst the patients about the proper patient care, preparation for different investigation and treatment thereafter.

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preparation, analysis, reporting, and corrective / preventive action, if any required[1,2]. Even after this, samples need to be archived or retained in a proper way for future reference. Every step requires manual interference in one way or the other. Even in this era of Total Laboratory Automation, human involvement cannot be negated altogether, though almost a ten-fold reduction in the analytical error rate has been achieved due to improvements in the standardization and reliability of analytic techniques, reagents, and instrumentation, and advancements in information technology, quality control and quality assurance methods[3]. There lies the importance of source of human errors in every step which may have a great impact at the final delivery of report to the patient.

Evidences have shown that errors in the loop mostly occur outside analytical phase, either in the pre-analytical phase and in some cases in the post analytical phase[4,5]. The Technical Committee of the International Organization for Standardization (ISO/ TC 212) has defined comprehensively the errors occurring in laboratory testing and has given stress on a patient-centered approach and the need for evaluation of all steps of the testing process, irrespective of whether they fall under the direct control of laboratory[6].

Pre-analytical errors add upto almost 70% of all errors occurring in laboratory diagnostics. Studies have been conducted to find the nature of the error which have revealed that most errors do occur during patient preparation, sample collection, transportation and preparation for analysis and storage, with added weightage on transportation of samples[7].

Pre-analytical variables can be divided into two phases-(i) non controllable, (ii) controllable. Non-controllable variables consist of exercise, stress, age, sex, positional effects, and menstruation. Controllable pre-analytical errors are mostly due to human error related to patient and care- taker's way of understanding and following instruction and also the phlebotomist's particularity in collecting samples following proper guidelines. The most commonly reported types of pre-analytical error are: (a) lost sample and/or inappropriate /no test request, (b) improper /no identification details, (c) contamination from infusion route, (d) hemolyzed, (e) improperly clotted samples due to improper mixing of anticoagulants, (f) insufficient samples, (g) inappropriate vials, (h) inadequate blood to anticoagulant ratio and (i) improper transport, sample spillage and storage conditions, inappropriate temperature monitoring[8]. As per the ISO 15189: 2022 standard for laboratory accreditation, the pre-analytical phase may be defined as the procedures serially starting from the clinician's request, preparing for the examination requisition, patient, preparation, collection of the primary sample, and transportation of the sample/s to and within the laboratory till beginning of the analytical examination. Hence, it is imperative to evaluate, monitor and thus improve all the procedures and processes involved in the preanalytical segment of laboratory medicine.

We conducted a retrospective hospital-based analytical study in a Government run tertiary care 5000 bedded set-up of eastern India to find out the type of pre-analytical error occurring and generate a customized plan to reduce the same for effective maintenance of Turn-around Time (TAT) and delivering error free reports to patients easing early appropriate intervention as required .

Aims and Objective

The study was aimed to evaluate a few controllable pre-analytical variables known to significantly impact the smooth and efficient functioning of the 24x7 laboratory in the Department of Biochemistry in a Government run super-speciality Tertiary Care Hospital in Eastern India.

Settings and Design : The study conducted was a hospital-based retrospective analytical study

Materials and Methods

For a period of 3 months (June 2018-August 2018), serum samples and requisitions from Out-patient Department (OPD) and from In-patient Department (IPD), routinely coming to Department of Biochemistry, Government run Super-speciality Tertiary Care Hospital in Eastern India, were collected and checked for avoidable pre-analytical parameter missing requisitions/samples, wrong identification (samples with name, age, sex, bed no in case of indoor patients, OPD ticket number in outdoor cases, patient identification number / barcode mismatching with the respective test requisition form or TRF provided from indoor departments or phlebotomy area of central laboratory), insufficient quantity, lipemia and hemolysis. Such samples were separately tabulated into distinct groups for further analysis. Statistical analysis was done in Microsoft ExceL (Fig 1).

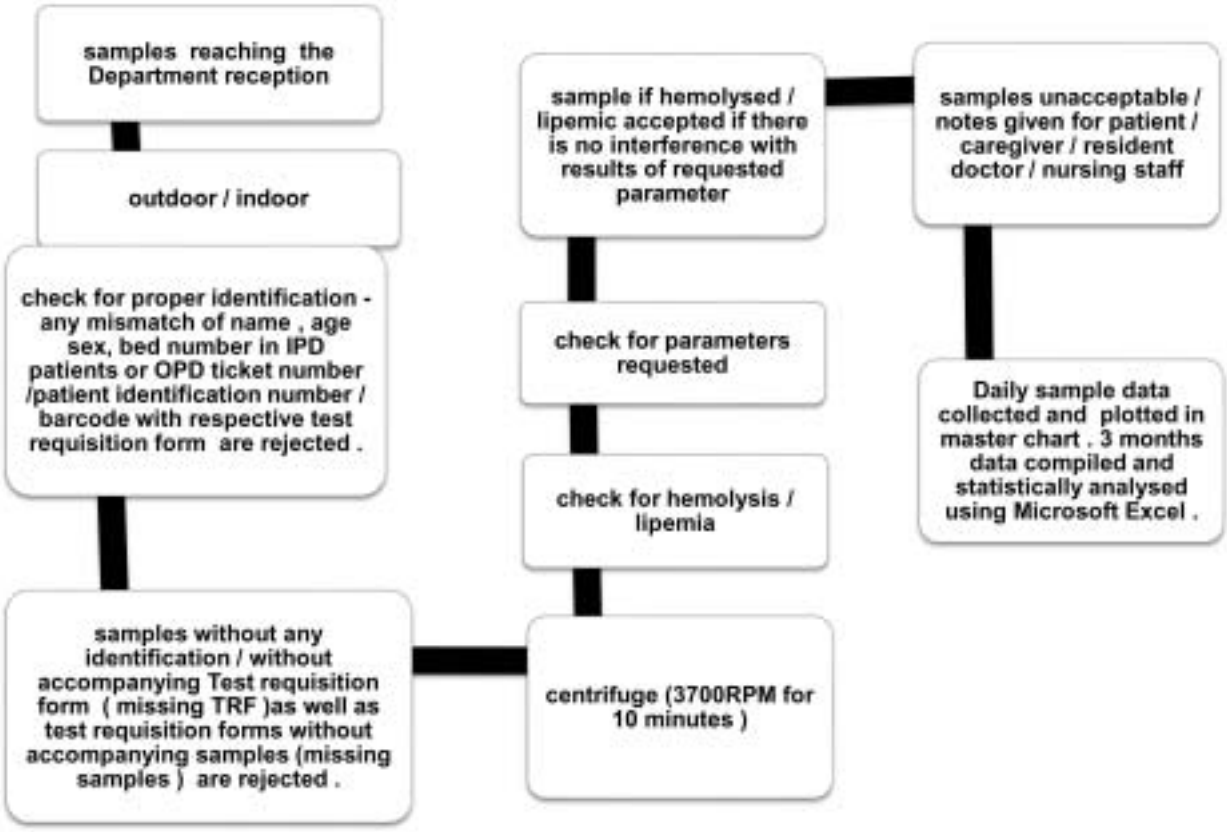

Fig 1 — Methodology followed for data collection

Results

Over a period of 3 months (June, 2018 - August, 2018) from OPD a total number of 36,515 serum samples and requisitions from Out-patient Department (OPD) and 30,395 samples from In-patient Department (IPD), routinely coming to Department of Biochemistry, Government run Super-speciality Tertiary Care Hospital in Eastern India were collected. Number of lipemic samples was 4792, hemolyzed samples were 1748, insufficient samples was 2085 in number, total number of parameters ordered being 2,90,274. The percentage of lipemic samples for 3months was found to be 0.071%. Hemolyzed samples for the month 0.0259%, insufficient sample 0.0309%, no sample or no requisition amounting to 0.02%, the total pre-analytical controllable errors amounting to 0.208%. Lipemic samples comprised of the most significant part in the controllable pre-analytical error which is attributed to the faulty patient preparation. Lipemic samples were identified and patients were notified for repeat sampling with proper instructions and proper preparation.

Pre-analytical errors from the indoor and outdoor patients are not similar. Out of the total number of hemolysed samples, 50% come from indoor and 50% from outdoor patients, however for lipemia number of error samples are more from Outdoor (33%) than from Indoor (77%). Insufficient sample volume are more from indoor (60%) than from outdoor (40%), while no requisition, wrong identification and wrong vial are more from outdoor samples than from indoor samples.

Discussion

The IFCC working group on laboratory errors and patients safety was launched with the primary goal of identifying and evaluating Quality Indicators and related quality specifications in order to address all the stages of the TTP. This was in compliance with Standard UNI 11097, according to which a quality indicator is, 'the information, qualitative or quantitative, that is able to evaluate its change during the time and to verify the defined quality goals, in order to take the correct decisions and choices' 'the information, qualitative or quantitative, that is able to evaluate its

change during the time and to verify the defined quality goals, in order to take the correct decisions and choices'[10-12]. Quality indicators should be selected in a way for each lab with the prerequisites fulfilled namely (a) relevance and applicability to the clinical laboratory; (b) scientific soundness, with a focus on assuring quality in laboratory reporting; (c) feasibility, both regarding the availability of data and the definition of thresholds for acceptable performance; (d) timeliness.

In a Government run tertiary health care set up , the pre-analytical phase can be further classified as a'pre-pre-analytical phase' and a 'true' pre-analytical phase. The true pre-analytical phase starts within the laboratory when the lab receives the specimen. The former phase, which comprises initial procedures usually performed in the clinical departments at the bedside or at the collection centre of the Central laboratory of the hospital, mostly not under the control of laboratory personnel, includes test requesting, patient and sample identification, patient preparation / instructions to the patients / counseling the patients regarding some procedures and sample collection. The latter involves the steps required to prepare samples for analysis (centrifugation, aliquoting, sorting and transportation).

The result of our study clearly indicated that hemolysis and lipemia are the two major pre analytics in the laboratory with significant effects. The data clearly indicates that the lipemic sample load from outdoor cases are mostly due to improper patient preparation which on investigation pointed towards very important facts .In government run tertiary care hospital with a huge out patient load and limited man power patients avoid standing in queue for requisition and instruction for patient preparation which are often not the same . Moreover language and communication skill of the personnel counseling the patient and patient party is not up to the mark. It is often difficult for the treating physician to counsel and instruct every individual patient for individual parameter in the outdoor setting where the patient load is almost 240-260 patients per doctor . It has also been pointed out that patient standing for long in the queue often for more than 4-5 hours for their turn for sample collection violate the guideline.

Insufficient sample volume from indoor samples point out to the fact of requesting for panel of test without clinical history to guide the laboratory for the urgency of certain parameters over others. This results in unavoidable delay of reports and repeat sampling.

Analytic hemolysis interfere when the constituents in erythrocytes are more than that in plasma. The release of erythrocyte constituents can result in increased values for serum concentrations of parameters like potassium, phosphate AST, LDH etc. Dilution is another possible cause especially for grossly hemolyzed samples, and may result in decreased values. Hb absorbance peak occur at ~417, 540, and 575 nm and at 415 nm (Soret wave), therefore at these wavelengths, spectrophotometric interference occurs due to an increase in the optical absorbance or a change in the blank value. Free hemoglobin also has pseudo-peroxidase activity which interferes in the bilirubin estimation by inhibiting the diazonium color formation[13-15]. Sample collection in pediatric patient population being very challenging with a large percentage of hemolysis occurring during sample collection by heal prick method often leads to sample rejection / faulty reporting. A slight decrease in glucose and uric acid can be seen which may be due to a premature decomposition of hydrogen peroxide by Hb. Dilutional effect may even be caused by the leakage of intracellular components in the surrounding fluid especially in case of severe hemolysis which may cause lower values for glucose, sodium and calcium[16]. CK is not a constituent of erythrocytes; however, intracellular adenylate kinase may cause interference in the CK assay. Correction can be done by adding inhibitors such as adenosine monophosphate and diadenosine pentaphosphate, or by substracting the activity measured in the absence of creatine phosphate[17]. Routine free Hb level determination in serum or plasma, or any other automated detection of the degree of hemolysis although recommended, yet it is not feasible on part of a government run set up with continuously increasing load, constraint in manpower and financial resources[18].

Lipemia is a turbidity of the sample caused by accumulation of lipoprotein particles. Lipemia is the leading cause of rejected samples with the frequency almost 4-fold higher in outdoor patients than in hospital patients. Not only pre-analytical conditions but also certain pathological conditions (multiple myeloma, diabetes mellitus, acute pancreatitis, kidney failure or hypothyreosis) do result in lipemic samples. The largest particles, chylomicrons (particle size of 70-1000 nm), have the greatest potential cause of sample turbidity.

The most common cause of lipemic sample is improper patient preparation, mostly due to inadequate interval between meals and sample collection. Another cause of lipemia in indoor patients may be parenteral administration of synthetic lipid emulsions. It is a practical difficulty in emergency patients to allow for adequate interval between meals and sample collection leading to lipemic samples which may have interference on different parameter relevant for patient management.

Lipemia may cause interference in capillary electrophoresis of serum proteins. When analyzing patient samples with increased concentration of triglycerides, an abnormal morphology of the alpha-2-globulin fraction has been detected. This finding has been replicated when spiking native samples with sample containing high concentration of triglycerides. The peak height is correlated with the triglyceride concentration which suggested interference in a dose-dependent manner[19]. Lipemia can also non-specifically interfere in various immuno-assays. Lipoproteins may interfere with antigen-antibody reaction by blocking the binding sites on antibodies even when antibodies are bound to a solid surface. Depending on the nature of the reaction, the interference may cause either, falsely elevated or falsely decreased result[20].

The amount of absorbance of light by lipoprotein particles is inversely proportional to the wavelength and decreases from 300 to 700 nm, without any specific absorption peaks. Therefore, methods that use lower wavelengths are affected more by lipemia, as the absorbance is highest in that part of the spectra[21].

Many clinical chemistry methods (like alanine aminotransferase, ALT; aspartate aminotransferase, AST; glucose) use reaction NAD(P)+ ”! NAD(P)H + H+ as an indicator reaction for determining concentration or activity of the analyte. Since the change of absorbance is measured at 340 nm, most of these methods are strongly affected by lipemia giving falsely high results.

Plasma consists of approximately 92% of water and 8% of lipids. In lipemic samples, the proportion of lipid phase increases and can be up to 25%. Analytes, distributed in the aqueous part, now actually distributed in only 75% of the sample, (eg electrolytes) hence, measurement if these analytes get affected especially when the methodology used measure concentration of electrolytes in the total plasma volume (including the lipid phase), as in case of flame photometry or indirect potentiometry[22-24]. The result will show falsely decreased concentration of electrolytes because of the high dilution prior to analysis. Thus, this gives an erroneous calculation of the measured analyte concentration. This effect is noticed at grossly lipemic samples (over 17 mmol/L of triglycerides).

After procuring the sample, the most common practice before analyte measurement is centrifugation for obtaining serum or plasma. Centrifugation causes the particles to distribute according to their density: chylomicrons and VLDL particles having low density will form the topmost layer in the tube, distinctly while the constituents in the plasma get distributed depending on their polarity: thus, hydrophobic analytes are found to be distributed in the lipid phase whereas the hydrophilic/ polar analytes are found to be distributed in the aqueous phase (small molecules, electrolytes). When aspirated by the probe of the instrument, for measurement, most analyzers obtain sample from the upper part of the tube, due to the presence of sensors preventing the probe from going too deep into the tube. This can result in falsely decreased concentration of electrolytes and metabolites. The opposite is valid for non-polar substances (some drugs, like valproic acid or steroid hormones). The non-polar analytes will accumulate in the upper lipid layer, and their concentration will be falsely decreased in the lower part of the tube.

Errors like insufficient sampling; wrong vials can be rectified with proper training to the respective personnel involved in the activity regarding the requirement of volume of sample for each parameter to be tested by the instrument in the laboratory. Also measures can be taken by the clinician in mentioning the urgency in the requirement of relevant parameters for patient treatment while the’ not so important parameters’ can be taken care of with subsequent samples on intimation. Transcription errors can again be subdivided into (a) ‘true’ misidentification of patients and/or mismatch and (b) nominal identification errors (eg, age, gender etc) that do not ‘significantly’ compromise patient safety. Proper training and careful handling can effectively decrease such errors to a large extent though can’t be completely negated.

Limitation :

The samples reaching the receiving section of the

Department were only taken into account. Samples lost during transportation, from respective departments and outdoor collection site to the department, were not taken into acount.

Conclusion

The study concluded that a large number of patients are improperly instructed or lack proper understanding of instruction which leads to faulty patient preparation and hence affects the sample quality often to the level of not being able to report or even generate faulty reports if the technologists are not careful enough. This leads to wastage of man power and resource as well as delay in reports which can cause delay in patient management. The phlebotomists/ technologists as well as resident doctors and nursing staffs who are entitled for collection of samples from outdoor and indoor patients need to be trained in proper technique of sample collection, usage of tourniquets. They need to be trained about proper patient preparation, time of sample collection, duration of fasting in patients for collection of samples, requirement of sample quantity for individual parameters to be run in the machines as well as commonly encountered interferences for reporting of samples.

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Conflict of interest : The authors declare that they have no conflict of interest.

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