International Journal of Advanced Research in Biological Sciences
ISSN : 2348-8069
www.ijarbs.com

Research Article

A Reflection on pre and post Analytical errors in Haematology Laboratories

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Abstract

Objective: To evaluate the leading causes of preanalytical and post analytical errors in a clinical hematology laboratory. **Method:** An analysis of errors obtained in clinical hematology laboratory in the Preanalytical and Postanalytical phase has been carried out over a 1 year period. All pre and post analytical causes for rejection or repeat samples and other errors were registered during this period. **Results:** In the present study the preanalytical errors were found to be more common in both IPD and OPD cases (65.43%) than the postanalytical errors(34.57%) Both pre & post analytical errors were more common in IPD cases (72.40%) than OPD (27.60%) cases. Considering both pre and postanalytical variables leading to a repeat/rejection of sample the overall percentage error out of total(IPD & OPD) cases was found to be 3.73 %. **Conclusion:** By analyzing the rejection percentage of samples over a period of 1 year we found that preanalytical errors were more common than postanalytical errors and were seen more frequently in IPD cases. Amongst the preanalytical errors, clotted samples were the major cause of rejection whereas in the postanalytical category, reports that were misplaced especially in IPD cases caused much inconvenience to the patients and many a times a repeat sample had to be done. The identification of valuable indicators for extra-analytical phases in which most gross errors occur leading at times to adverse events is a fundamental step in assessing and improving laboratory services otherwise we will let the quality control problem fester and grow.

Keywords: Preanalytical Errors (PreAE), Postanalytical Errors (PostAE), quality control(QC)

Introduction

It's said "to err is human" [(1)]

What is medical error? Several definitions exist. "The failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim."[2]

In these modern times with highly sophisticated laboratory equipment, diagnosis is largely dependent upon reliable laboratory data. Although remarkable advances in sample collection, transport, automation and dispatch of reports have greatly minimized errors and have led to drastic improvement in the performance of laboratories[3] yet conformity is still low.

Errors arising in a haematology laboratory sample processing are generally classified into preanalytical, analytical and post analytical [4,5,6,7]

The pre analytical (PreA) and post analytical (PostA) phases of the process account for **0.1-9.3%** of errors influencing outcome and cost of results. [7]

The pre-analytical phase is the most vulnerable part of the total testing process (TTP) and is considered to be among the greatest challenges to laboratory professionals.[8]

The pre analytical phase errors in hematology laboratory include clotting of sample, improper sample collection, whether it is in incorrect vial/ container, inappropriate volume (excess or deficit in volume required for analysis), wrong or missing patient identification or visible hemolysis after centrifugation. Post-analytical Errors include misplacing of reports, printing errors or wrong identification of patient and delay in dispatch of the reports[9]

Materials and Methods

Chatrapati Shivaji Subharti Hospital is a tertiary care centre in Meerut. It is a 750 bedded hospital offering medical and surgical treatment to patients admitted in the general and private wards every year and to outdoor patients. Inpatient phlebotomies are performed by the nursing staff on duty .Blood samples from out patients are collected at a centralized collection centre by laboratory personnel. Samples from IPD are delivered by the paramedical staff from the wards and laboratory support staff from OPD.

A total of 36,200 samples from outpatient department and a total of 28,800 inpatient samples were received during the period from 20/8/12 to 20/8/13.

All the samples from IPD were collected by syringes into vacutainers (Peerless Biotech) whereas OPD samples were mostly collected by vacutainer needles except in few cases where blood was collected by syringes .In these patients the veins were either not clearly visible or the veins were too thin. The laboratory technicians visually checked all samples IPD and OPD for any errors in the preanalytical phase .The samples were considered unsuitable according to these criteria.

- Wrong or missing patient identification.
- Inappropriate container
- Clotted sample
- Haemolysis after centrifugation
- Inadequate sample

The clinical hematology laboratory is equipped with state of the art blood cell counters ABX Pentra XL-80 ,Sysmex and MS-9 and Coagulometer Ca50(Sysmex). The other basic equipment for estimating the ESR and Bleeding Time and Clotting Time are all available in the laboratory.

All samples analyzed and reported were duly dispatched from the laboratory to various wards and the OPD reports were collected by the patients themselves from the central laboratory area

The postanalytical Errors were categorized into:

- Printing errors / wrong identification of patients
- Delay in dispatching report
- Report misplaced

All such problems were entered in the notification log book and records of both Inpatient and Outpatient departments were maintained. Data thus generated was reviewed on weekly basis

Observations

Out of routine indoor samples 28,800 tubes were received from various indoor patients wards. (Gynaecology & Obstetrics, Surgery, Medicine, Paediatrics, Orthopaedics, Skin, Opthalmics, ENT over a period of 1year. Preanalytical errors were observed in 1080 IPD samples

Table 1: Frequency of Different Types of Preanalytical Errors in IPD Patients
(Observed out of a total of 1080 errors)

S.No	Preanalytical Variables	Frequency	Percentage
1	Clotted sample	550	50.92
2	Inadequate sample	180	16.66
3	Hemolyzed sample	130	12.03
4	Improperly filled forms	120	11.14
5	Incorrect sample	100	9.25

A total of 36,200 samples were received from outpatient department, out of these, errors were seen in 510 cases.

Table 2: Frequency of different types of Preanalytical errors in OPD patients
(Observed out of a total of 510 errors)

S.No	Preanalytical Variables	Frequency	Percentage
1	Clotted sample	140	27.45
2	Inadequate sample	130	25.49
3	Hemolyzed sample	110	21.56
4	Improperly filled forms	70	13.72
5	Incorrect sample	60	11.78

Table 3: Frequency of different type of PostAE in IPD
(Observed out of a total of 680 errors)

S.N	Postanalytical Variables	Frequency	Percentage
1.	Reports misplaced	470	69.11
2	Reports dispatched late	180	26.47
3	Printing Error	030	4.42

Table 4: Frequency of different type of PostAE in OPD
(Observed out of a total of 160 errors)

S.No	Postanalytical Variants	Frequency	Percentage
1	Report dispatched late	100	62.50
2	Report misplaced	40	25.00
3	Printing Error	20	12.50

Table 5: Percentage of IPD and OPD
(Observed out of total of 2430 errors)

Cases	PreAE	PostAE	TOTAL	Percentage
IPD	1080	680	1760	72.40
OPD	510	160	670	27.60

Above table shows that percentage of errors were more common in IPD than OPD cases

Table 6: Percentage Errors PreA & PostA out of total IPD and OPD
(Observed out of total of 2430 errors)

Errors	(IPD&OPD)	Percentage
PreAE	1590	65.43
PostAE	840	34.57

If we consider the percentage of rejection /repeat sample due to both pre and post analytical errors, it was found to be **3.73 %** out of the total cases received in both IPD & OPD (65,000 samples) during 1 year.

Discussion

The Institute of Medicine report *To Err Is Human: Building a Safer Health System* 10) and other reports [11,12,13,14] have increased concern over the negative

impact of medical errors on public health and patient care.

The total testing procedure (TTP) starts and ends with the **patient.**

Pre-analytical and Post-analytical errors tend to fall into the "obvious" categories.

We should unify the pre-analytical and post-analytical error categories as suggested by David PLAUT.[8] They fall into one bigger, more important category.[15,16,17,18] It's the "This Error Makes the Doctors Angry" category. Kalra J ,Da Rin G and McCayL [19], [20, 21] too emphasized that pre- and post-analytical processes are more vulnerable to errors than analytical processes.

In our study in both IPD & OPD, PreAE errors accounted for 65.43% and PostAE accounted for 34.57 % cases out of total errors.

Clotting of sample constituted 50.92 % of IPD samples errors.Inversion of citrated and EDTA containing vacutainers is recommended to adequately mix blood with the anticoagulant. Inadequate or delay in inversion and mixing of blood with the anticoagulant constitute an important part of the preanalytical errors inVenous Blood Sample (VBS).Samples in which the blood is slow to fill the collection container, where there is prolonged use of a tourniquet, or considerable manipulation of the vein by the needle may be prone to develop a clot *in vitro*.[9] This could be the plausible reason for the large frequency of clotted samples found in our study where the majority of such samples were from the various IPD and the staff on duty was not proficient enough and aware of the intricacies and aftermaths of a seemingly simple procedure. In many cases on careful examination of the vacutainers, blood was drawn beyond the required quantity mark on the tube. Carelessness of the staff while drawing the sample led to such mistakes.

The data in our study are comparable to those provided by similar studies done by Romero et al and Jones et al which confirm that problems directly related to specimen collection are the first causes of preanalytic errors, especially hemolyzed, clotted, insufficient, and incorrect samples,[22,23 24, 25]

Based on these observations in our set up, the use of the evacuated blood collection system resulted in better preanalytical specimen quality as compared with needle and syringe collection. The findings also showed an approximately reduction in the incidence of clotting as also observed by many other studies [26,27,28]

Out of total errors, due to inadequate sampling, were 16.66%in IPD and 25.49% in OPD cases. In this study the various causes were difficult veins in children, patients with chronic debilitating diseases and some patients had veins which were too thin to localize. Few patients especially children were uncooperative and did not allow a second time prick. Also since ours is a common collection centre where samples have to be collected for microbiology, haemotology and biochemistry ,if the number of investigations are too many, the quantity of sample drawn amply in each vacutainer becomes difficult . Sometimes ignorance of the staff about the basic quantity of sample required for analysis for particular set of tests seemed to be the reason for inadequate sampling,especially from indoor patients .Similar findings of inadequacy of sample from indoor patients prevailed in the 1 year study done by Lippi et al [29]
Mixing procedure of tubes after blood withdrawal is also crucial for obtaining correct analytical results.Venous Blood Sample from peripheral venous catheter is known to be prone to hemolysis[9]. In this study hemolysed samples led to 21.56% errors especially Prothrombin time (PT)samples from IPD patients. Exposure to extremes of temperature and physical forces during transportation could also be the cause of hemolysis.

Labeling of test tubes after blood collection lead to an increased risk of collection of blood from wrong patient .In this study such mistakes were more often found in IPD samples than in OPD patients where the patient too keeps an eye on his own sample identification number during phlebotomy . Similar findings were seen in a study done at GB Pant Hospital[3].Correct patient identification and test tube labeling are therefore of utmost importance for patient safety in TTP.
Another question raised by the coexistence of pre, post and analytical errors is this: which ones affect the patients the most? It is a triple dead heat. If you can't get the patient specimen to the lab, if you can't perform the test correctly, and if you can't deliver the

results back to the patient, the consequence is the same: poor patient care. No error is worse than the other. They are all equally terrible as Westguard puts, in his extensive studies [30]

Illegible writing especially pertaining to the test name and spelling are often a source of incorrect samplingComputerised test order entry connected to patient medical record should be the ideal method to minimize such errors.

Improper filling of requisition forms whether it was wrong patient identification or wrong tests being entered led to repeat sample which involved an extra cost burden to the institute as well as caused much inconvenience to the patient and a delay in the reports. At times an emergency investigation repeat sample due to such negligence may delay the reporting and required urgent treatment .This in turn deprives the patient from critical care which could prove fatal/life threatening. In our study such errors comprised 11.14 % errors in IPD and 13.72 % errors in OPD forms. Post-analytical errors were mostly found in IPD cases. Very often the reports were misplaced because of reports being delivered in the wrong wards or the staff on duty did not attach the reports in the proper file. This eventually delayed the treatment process.

In our study printing errors in the final report were mostly due to illegible writing on the forms in the preanalytical phase.

Delay in dispatch was at times due to delay in the analysis of the sample due to reasons like a repeat sample / or system failure. At other times delay in the reports was due to inefficient or new staff which was deputed on the duty and probably did not execute his/her duty on time .Sometimes a repeat sample was required because there was insufficient clinical data which was essential to correlate with certain abnormal hematological results.

Similar lacunae in the pre and post analytical phases as in our set up have been discussed by Robert Hawkins[9] The present study should be of interest to both laboratory personnel and pathologists working in hematology laboratory and the clinicians that request such tests. The former, because they are ultimately responsible for the test results they provide to clinicians, and there is a duty of care to provide both accurate and precise results and to avoid the need to recollect and retest. The latter because unless clinicians gain an appreciation of these issues, they will not be in a position to best manage their patients as . Emmanuel Giuseppe Lippi put their view on PreAE and postAE[29]

In contrast, analytical errors fall into the "This Error CAN'T readily be detected by the Doctor"[30] The doctor simply gets numbers and there is no way of checking these numbers unless they are completely divergent from the patients clinical condition, in that case the doctor orders for another battery of tests much to the agony of the patient.

The aim for investigating the pre and post analytical errors is to search whether it is human error or lack of routines or both. Most often it is a combination of both leading to an error .

Conclusion

This study has been undertaken since it is important to reflect and act on laboratory errors in daily work. In this study PreAE & PostAE together accounted for 3.73% of total cases, out of which preanalytical errors were more and were seen mostly in Indoor patient samples. Significant difference in the error rate were found between inpatients and outpatients $P<0.001$ in conformity with studies done by Guiseppi et al[29] (0.82% vs 0.37%; χ^2 test, P <0.001).

So in the interest of the patients a more efficient and sincere staff should be employed especially in wards ,also it is of utmost importance that all test results are judged and correlated with the clinical picture of the patient since erroneous results otherwise can lead to serious consequences. In CSSH, HIS &LIS system is the need of the hour which is being introduced to minimize errors in pre, analytical, analytical and post-analytical phases.

References

1. Kohn KT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System 1999:287pp National Academy Press Washington, DC

2.. Institute of Medicine. Crossing the Quality Chasm: A New Health Care System for the 21st Century 2001:387pp National Academy Press Washington, DC.

3. Chawla R, Goswami B, Tayal D, Mallika V. Identification of the Types of Preanalytical Errors in

the Clinical Chemistry Laboratory: 1-Year Study at G.B. Pant Hospital. Lab Medicine 2010;41:89-92.
4. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem Lab Med 1997;43:1348-1351.
5. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. Clin Chem Lab Med 2002;48:691-698.
6. Plebani M. Errors in clinical laboratories or errors in laboratory medicine?. Clin Chem Lab Med 2006;44:750-759.
7. Patra S, Mukherjee B, Das Kumar A. Pre-analytical Errors In The Clinical Laboratory And How To Minimize Them.International Journal of Bioassays 2013;2(3):551-553
8. Plaut David. Preventing Pre-analytical Errors. Advance Health Care Network 2013;22(5):24
9. Hawkins Robert. Managing the Pre- and Post-analytical Phases of the Total Testing Process. Ann Lab Med. 2012 January; 32(1):5–16.
10. The Institute of Medicine report To Err Is Human: Building a Safer Health System 10) o Err Is Human: Building a Safer Health System Linda T. Kohn, Janet M. Corrigan, M. Donaldson Published in 2000.
11 Institute of Medicine. Crossing the Quality Chasm: A New Health Care System for the 21st Century 2001:387pp National Academy Press Washington, DC.
12. Aspden P, Corrigan JM, Walcott J, Erikson SM. Patient safety. Achieving a new standard for care. Washington, DC. National Academy Press 2004:528pp
13. Brennan TA, Gawande A, Thomas E, Studdert D. Accidental deaths, saved lives, and improved quality. N Engl J Med 2005;353:1405-1409.
14. Bell D, McNaney N, Jones M. Improving health care through redesign. BMJ 2006;332:1286-1287.
15. Sandra C Hollensead, William B Lockwood, Ronald J Elin. Errors in pathology and laboratory medicine: consequences and prevention. Mikrobik.net 2008;10:11.
16. Astion ML, Shojana KG, Hamil TR, Kim S, Ng VL. Classifying laboratory incidents reports to identify problems that jeopardize patient safety. Am J Clin Pathol 2003;120:18-26.
17. Laposata M, Dighe A. "Pre-pre" and "post-post" analytical error: high-incidence patient safety hazards involving the clinical laboratory. Clin Chem Lab Med 2007;45:712–719.
18. Stankovic AK. The laboratory is a key partner in assuring patient safety. Clin Lab Med. 2004Dec;24(4):1023-35.
19. Da Rin G. Pre-analytical workstations: A tool for reducing laboratory errors. Clin Chem Acta 2009 Jun;404(1):68-74.
20. Kalra J. Medical errors: impact on clinical laboratories and other critical areas. Pub Med.gov 2004 Dec;37(12):1052-62.
21. McCay L, Lemer C, Wu AW. Laboratory safety and the WHO World Alliance for Patient Safety. Clin Chem Acta 2009 Jun; 404(1):6-11.
22. Manochiopinij S, Sirisali K, Leelahakul P. Effects of non-analytical factors on the quality of laboratory results. Southeast Asian J Trop Med Public Health 1999;30(3):50-3.
23. Paolo Carraro, Mario Plebani. Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clinical Chemistry 2007July;53(7):1338-1342.
24. Romero A, Munoz M, Ramos JR, Campos A, Ramirez G. Identification of preanalytical mistakes in the stat section of the clinical laboratory. Clin Chem Lab Med 2005;43:974-975.
25. Jones BA, Meier F, Howanitz PJ. Complete blood count specimen acceptability: a College of American Pathologists Q-Probes study of 703 laboratories. Arch Pathol Lab Med 1995;119:203-208.26.
26. Mario Plebani. Laboratory errors: How to improve pre- and post-analytical phases? Biochemia Medica 2007;17(1):5-9.
27. Ashavaid TF, Dandekar SP, Khodiji S, Ansari MH, Singh AP. Influence of method of specimen collection on various preanalytical sample quality indicators in EDTA blood collected for cell counting. Indian J Clin Biochem 2009 October;24(4):356-360.
28. Michael Astion. 10 (or more) Annoying Pre and Post Analytical Problems and how to Eliminate Them. Clinical Toxicology, Clinical in Professional Opinions, Recent Developments with 0 Comments, Patient Safety Focus Section of Clinical Laboratory News, July 31, 2012.
29. Emmanuel J. Favaloro, Giuseppe Lippi, Dorothy M. Adcock. Preanalytical and Postanalytical Variables: The Leading Causes of Diagnostic Error in Hemostasis? Pub Med.Com 2008 Oct;34(7):612-34.
30. Plaut David, Westgard Sten, Westgard James O. PRE, POST- ANALYTICAL ERRORS 2013. www.westgard.com.