ORIGINAL RESEARCH PAPER

Volume-8 | Issue-5 | May-2019 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A STUDY TO EVALUATE QUALITY INDICATORS IN PRE ANALYTICAL VARIABLES IN CLINICAL BIOCHEMISTRY LABORATORY IN TERTIARY CARE HOSPITAL OF WEST BENGAL

Biochemistry

Dr. Debasmita Bandyopadhyay Assistant Professor, Department of Biochemistry, Institute of Post Graduate and Medical Research and SSKM Hospital, Kolkata-20.

Dr. Kasturi Mukherjee* Assistant Professor, Department of Biochemistry, Institute of Post Graduate and Medical Research and SSKM Hospital, Kolkata-20. *Corresponding Author

Dr. Santanu Banerjee Professor, Department of Biochemistry, Institute of Post Graduate and Medical Research and SSKM Hospital, Kolkata-20.

ABSTRACT

Aim: To determine the magnitude of quality indicator in clinical chemistry laboratory tests at pre analytical phase of the assay.

Material and method: Hospital based retrospective study, total 236,100 samples were analysed in Department of Biochemistry from inpatient, outpatient and emergency of IPGME & R and SSKM Hospital, West Bengal over a period of one year, April 2018 to March 2019. 10 (ten) IFCC recommended Model Quality Indicator reviewed and frequency of observation analysed.

Results: Highest frequency of occurrence monitored in relation to incomplete patient information and inappropriate container and improper proportion (MQI) in all three divisions of patient care service. (average 20-40 samples per 1000 samples).Higher frequency of occurrence of pre analytical error in the Inpatient department samples than outpatient and emergency samples here observed.

Conclusion: Corrective actions based on the outcome of Pre Analytical Quality Indicators will be beneficial for patient care service. Adequate training is warranted in laboratory service.

KEYWORDS

Model Quality Indicator, Pre analytical errors, Total quality management

INTRODUCTION

Good Laboratory services are the backbone of the modern health care sector and Quality is the core issue for all laboratories. ISO 15189 states that quality indicator (QI) is measure of the degree to which a set of inherent characteristics fulfils requirements. Measure can be expressed in % yield (%within specified requirement) (ISO 15189:2012; 3.19). Any potential quality indicator needs to fulfil primarily two inclusion criteria: it must be an indicator of laboratory functioning and it must cater patient safety, equity, effectiveness, patient centeredness, timeliness, and efficiency (defined as domain by Institute of Medicine). (1) There is stratification of errors in laboratory medicine and they are distributed in three different phases in Total Testing Process (TTP); pre analytical, analytical and post analytical phases. But all the recent studies demonstrate that large percentage of laboratory errors occur in Pre analytical phases. Studies have shown the errors with respect to pre analytical variables to account for more than one third to 50% of all laboratory errors. (2) Many strategies including Quality control, Proficiency testing has been introduced to reduce mainly analytical laboratory errors. But still there is paucity of knowledge of extent of existing errors in pre analytical field in each clinical laboratory. This causes noncompliance for clinicians and patients. The International Federation of Clinical Chemistry (IFCC) Working Group "Laboratory Errors and Patient Safety" has developed a Model of Quality Indicators (MQI). IFCC, being focused on the quality indicators, the pre analytical phase is to assess excellence in current pre analytical practices, identify some of the most critical elements and make recommendations to reduce the impact of the pre analytical phase in laboratory medicine for the most critical segments of this framework. (3) These MQI Data are used to identify of laboratory's own risk level and harmonise the data to compare with global laboratories. Pre Analytical variables in TTP can adversely affect test results in clinical biochemistry laboratory randomly and systematically. IFCC identified 34 MQI among pre analytical variable analysing TTP. These pre analytical MQI, as a tool of Total Quality Management, are used to monitor good pre analytical practice which will improve the overall quality and reliability in the laboratory diagnostic process. In this study MQI data on pre analytical variables has been collected over time to identify, correct, and continuously monitor problems and improve performance and patient safety by identifying and implementing effective interventions and for the purpose of increased consistency and standardization. With this view, we evaluate frequency and magnitude of the benchmark QI in pre analytical variables in our Clinical Biochemistry Laboratory catering both in patient department (IPD) and outpatient department (OPD) in our tertiary care hospital. This study will help us to formulate certain corrective measures that would eliminate these possible pre analytical errors that occur in future.

MATERIAL AND METHODS:

STUDY DESIGN AND SETTINGS

This hospital based retrospective study was done in Department of Biochemistry in Institute of Post Graduate and Medical Research (IPGME&R) and SSKM Hospital, West Bengal from April 2018 to March 2019, over a period of one year.

STUDY POPULATION

IPGME&R is the busiest tertiary care hospital, having 2000 beds in West Bengal providing super speciality service over years. Relevant data regarding ten pre analytical quality indicators are generated on blood samples reviewed on a weekly basis from departmental documents of patients which is evidence based. Overall 236,100 samples are analysed for a period of one year. Venous blood sample (serum, plasma sample) was included in the study. Urine and other body fluids such as serous fluid, synovial fluid and cerebrospinal fluid were not included in this study. Moreover, test requests ordered for Clinical Chemistry tests only were included.

DATA COLLECTION

Clinical biochemistry laboratory is equipped with four auto analysers, two chemiluminiscence analysers, four ISEs and other ancillaries for sample processing. Routine IPD and emergency samples are drawn by the clinical personnel in wards and emergency, are brought in the department by the ward personnel of respective clinical departments. Those IPD and emergency samples are received by departmental technologists from 9 A.M to 12 noon(for IPD) and 24X7 (for emergency).The OPD samples are collected at the centralized collection centre during the day as per prior given dates. Those OPD samples are sent to laboratory by the staff of Central laboratory. Samples are numbered at the reception counter with separate IPD, OPD and emergency identifications and labelled with order information, are processed accordingly and a receipt is formed simultaneously. A laboratory log book is simultaneously maintained to keep the details of patient information and sample collection both IPD, emergency and OPD. Laboratory personnel screen specimens for pre analytical errors before processing those specimens, though they are not aware of the present study. We have scrutinised our observation randomly and root cause analysis done from laboratory data over ten pre analytical QI over a stipulated time of one year. Samples were considered unsuitable for processing according to the following IFCC MQI and reviewing similar literatures: 1. Missing requisition, 2.

Wrong labelling/unlabelled sample/mismatched registration, 3. Illegible handwriting, 4. Incomplete Patient Information, 5.Inappropriate container and incorrect proportion, 6. Visible haemolysis, 7. Lipemia 8. Insufficient quantity, 9.Clotted sample (EDTA) 10. Increased glycolysis as sample left for 4-6 hours (delay in sample transportation). All the above parameters were considered and viewed as quality indicators in pre analytical variables as per ISO recommendation.

STATISTICAL ANALYSIS AND ETHICS CLEARANCE

Necessary approval from Institutional Ethics Committee and Departmental authority has taken for handling of clinical laboratory data. Frequency of occurrence of QI in pre analytical errors observed in our clinical biochemistry laboratory are entered in Microsoft excels and statistically analysed.

RESULT ANALYSIS

In this study 236, 100 samples are analysed for a period of April 2018 to March 2019.

95472 (IPD), 1, 07340 (OPD) and 33,288 (emergency) were analysed.

We have noticed that frequency of missing requisition in IPD is 28 among 1000 samples, in OPD 15 per 1000samples, in Emergency 3 in 1000 samples. We have found that wrong labelling, unlabelled samples, mismatched registration 11 among 1000 IPD samples, whereas 0.4 in 1000 OPD and 0.1 per 1000 emergency samples. But illegible handwriting over samples is observed to be 8 per 1000 Emergency samples and 1 per 1000 IPD sample. We have not received any samples with such pre analytical error from OPD. Incomplete patient information has huge burden, having 34(IPD), 21(OPD) and 19(Emergency) samples per 1000 samples. Visible haemolysis is found in 9(IPD), 6(OPD) and 7(Emergency) samples among 1000 samples. Lipemic samples are observed in 0.2 (IPD), 0.2(OPD) and 1(Emergency) in 1000 samples. Insufficient quantity has been found in 2(IPD), 5(OPD), 1(Emergency) per 1000samples.Clotted sample (EDTA) is found in 11 per 1000 samples,7 per 1000 samples but emergency sample showing 0.8 per 1000 samples. Increased glycolysis as sample left for 4-6 hours (delay in sample transportation) are also showing significant pre analytical error as 6.6(IPD), 8(OPD), 5 (Emergency) in 1000 samples. All have been given in **TABLE 1**. The total IPD, OPD and Emergency samples are analysed showing the frequency of MQI over a period of one year in **DIAGRAM 1, 2, 3** respectively.

TABLE 1:

MQI	IPD(%N), (N=95472)	OPD(%N) (N=1, 07340)	Emergency(%N) (N=33288)
1.Missing requisition	2.8%(28/1000)	1.5%(15/1000)	0.3%(3/1000)
2. wrong labelling/unlabelled sample/ mismatched registration,	1.1%(11/1000)	0.04%(0.4/1000)	0.01%(0.1/1000)
3. illegible handwriting,	0.1%(1/1000)	0	0.8%(8/1000)
4. Incomplete Patient Information	3.4%(34/1000)	2.1%(21/1000)	1.9%(19/1000)
5.Inappropriate container and incorrect proportion	3.9%(39/1000)	3.1%(31/1000)	4.1%(41/1000)
6. visible haemolysis	0.9%(9/1000)	0.6%(6/1000)	0.7%(7/1000)
7. Lipemia	0.02%(0.2/1000)	0.02%(0.2/1000)	0.1%(1/1000)
8. Insufficient quantity	0.2%(2/1000)	0.5%(5/1000)	0.1%(1/1000)
9.clotted sample (EDTA)	1.1%(11/1000)	0.7%(7/1000)	0.08%(0.8/1000)
10. Increased glycolysis as sample left for 4-6 hours (delay in sample transportation)	0.66%(6.6/1000)	0.8%(8/1000)	0.5%(5/1000)

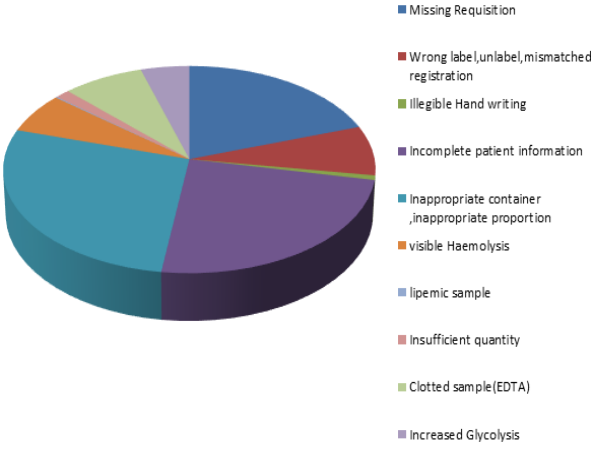

DIAGRAM 1 Frequency of pre analytical MQI observed in IPD (95472) samples

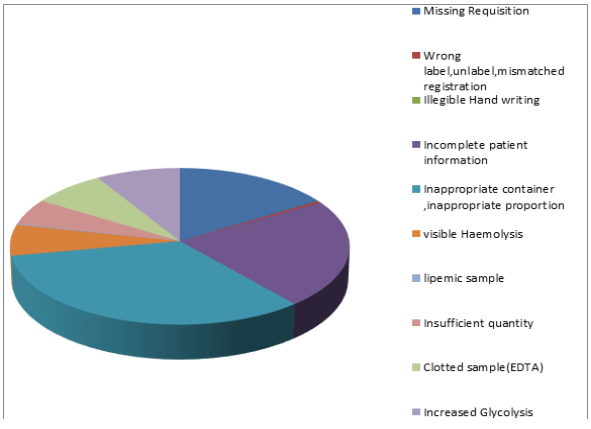

DIAGRAM 2 Frequency of pre analytical MQI observed in OPD (1, 07340) samples

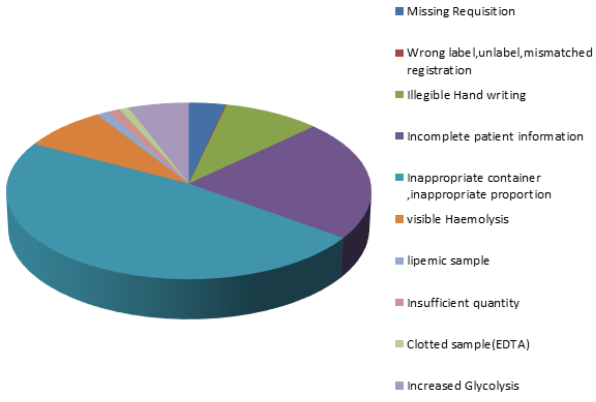

DIAGRAM 3: Frequency of pre analytical MQI observed in Emergency (33288) samples

DISCUSSION

Automation in laboratory practice helps us to provide proficient laboratory service though there is a huge burden of errors in pre analytical side. This ultimately leads to inappropriate patient care decisions. In this study, 95472 (IPD), 1, 07340 (OPD) and 33,288 (emergency) were analysed. In this study, visible haemolysis is observed 6-9% samples whereas 3-5% pre-analytical errors in haemolysed sample observed by Hawkins (4) in his review. Increased hemolysis observed from this study was mainly due to the increased pressure with which blood was dispensed from syringes into sample tubes in most wards by nurses. Other causes for this pre analytical error could be due to venipuncture site other than anti cubital fossa i.e. from forearm where veins are small, tortuous and has shown increased incidence of haemolysis, use of antiseptics like alcohol as disinfectant if not dried properly or dried manually, longer duration of application of tourniquet, traumatic venipuncture or double puncture of veins can also result in hemolysis of the sample. Therefore in order to avoid obtaining hemolysed sample the staff involved in collecting samples must be trained appropriately to maintain collection standards and the laboratory has to establish training curricula for all staff involved in phlebotomy.(5)Periodic training and revision training,

standard operating procedures for venipuncture are required to avoid hemolysis of the patient sample.(6,7)

In our study we observed that there is highest frequency of error in the MQI of Incomplete Patient Information and Inappropriate container and incorrect proportion in all three divisions of patient care service like IPD, OPD and Emergency .Increased frequency of Missing requisition also been found in IPD and OPD whereas Emergency samples are showing improved percentage. Overall sample load is much less in Emergency that would be one reason. These are the major cause in sample rejection in laboratory part and non compliance in patient side. This result was in line with findings from Ethiopia (8), Pakistan (9). Frequent changes of health care assistants, nurses and periodic influx of students from various training institutions was found to be the cause. All MQI here, are having increased frequency in IPD samples. This variation could be attributed to the workload on physicians, attitudinal difference and negligence among physicians, lack of monitoring by the concerned body or improper orientation about the impact of incomplete Patient Information and Inappropriate container and incorrect proportion on the quality of patient care. The scenario of Missing Requisition is going with Ehiopian study (10). This could be due to excessive patient load (disproportionate of patients to phlebotomists), the absence of functional LIS. Loss of attention and poor communication between staffs might further aggravate the problem. To bring down the frequency of this commonest pre analytical error, laboratory professionals should provide proper training or information to the treating physician and to insist upon the bedside phlebotomist to take care of proper filling of test request forms. This helps laboratory personnel for better biological validation and also important for the clinicians perspective to understand the concept of biological variations that may arise.

Increased Glycolysis has been observed 5-9% among all laboratory samples coming from IPD, OPD and Emergency. Plasma Glucose level has been found to be less than 60mg/dl which was not correlated with the respective patient health. It is the cause of non compliance in clinician's part regarding Glucose estimation. The cause behind this MQI is delayed specimen transport to the laboratory and many corrective actions are needed to minimize this type of error. Some of the wards at our hospitals are located further from Biochemistry laboratory; the samples frequently underwent various temperature fluctuations before reaching the lab for analysis. Some of the samples were transported from the phlebotomy area, which is not properly air-conditioned, and ambient temperatures typically range from 30-36 degree centigrade from May-October. Notably, untrained hospital staff was transporting the samples. (11)

We have observed increased frequency of Lipemia MQI in emergency samples which is obvious. But this MQI in IPD and OPD indicates that patient preparation was inadequate for the required test, which might lead to spectral interference during the process of sample assay. In our study Insufficient quantity MQI observation is less (0.1-0.5) % in inpatient, outpatient and emergency similar to was 0.53% and 0.70% from samples received from inpatient and outpatients respectively (12). The laboratory should document periodically and review the requirements regarding sample volume needed for various tests including the dead volume required in analyzer and serum blank in order to avoid collecting insufficient quantities and also considering the repetition of the test. MQIs like Wrong labelling or unlabelled sample/mismatched registration, illegible handwriting and incidence of clotted sample have been noticed to be less in Outpatient samples where the phlebotomists are dedicated laboratory personnel. Clinical personnel are showing indifference towards laboratory work can be overcome by repeated clinical meetings. The impact of those pre analytical MQI on laboratory reports should be regularly communicated with proper document. Introduction of Laboratory information system (LIS) will improve the MQI monitored(13). There is a limitation of analysis of this study that the impact following interventions likes frequent training of hospital personnel and laboratory staff with competency evaluation. Constant working in this field will reduce the incidence of huge burden of pre analytical errors and improve TQM.

CONCLUSION

The concept of quality indicators has revolutionised the laboratory service. The close monitoring of these QI improved our laboratory service and helped us to produce valid document to convince the clinical side of busy hospital to give special attention in pre analytical aspects. Pre Analytical QI has impacted on sample quality, laboratory efficiency and patient care. Recommendations should hence be issued and followed to support strategies and practical policies that laboratories can implement, to reduce the impact of the preanalytical errors, and thereby increase laboratory efficiencies and reduce the potential threat of inappropriate patient care.

ACKNOWLEDGEMENT

This study is materially supported by Department of Biochemistry, IPGMER and SSKM Hospital, Kolkata, West Bengal.

REFERENCES

1. Chawla R, Goswami B, Tayal. D, Mallika. V; 2010. Identification of the Types of Preanalytical Errors in the Clinical Chemistry Laboratory: 1-Year Study at G.B. Pant Hospital Lab Medicine,41(2):89-92.
2. Lippi G, Banfi G, Buttarello M, Ceriotti F, daves M, Caputo M, et.al;2007. Recommendations for detection and management of unsuitable samples in clinical laboratories. Clin Chem Lab Med: 45(6):728-736.
3. Simundic AM, Lippi G. Preanalytical phase – a continuous challenge for laboratory professionals. 2012 Biochem Med (Zagreb):22:145 – 9.
4. Hawkins R.2012 Managing the pre- and post-analytical phases of the total testing process. Ann Lab Med.;32:5–16
5. Westgard JO, Barry PL, Tomar RH. Implementing total quality management (TQM) in health care laboratories. 1991 Clin lab Mange Rev;353-370.
6. Jones BA, Calam RR, Howanitz PJ. 1997;Chemistry specimen acceptability: A college of American Pathologists QProbes study of 453 Laboratories. Arch Pathol Lab Med ;121: 19-26.
7. Firdashi B. 2014.A study of preanalytical errors in a hospital based clinical biochemistry laboratory and formulation of measures for correction. International journal of Bioassays;3(9):3270-3275.
8. Addis Z, Wondimagegn T, Tachebele B. 2015. Types and frequency of pre-analytical errors at University of Gondar hospital laboratory. Elective Medicine Journal;2 (4): 363– 365
9. Malik MF, Khan DA, Ansari WM, Khan FA. 2013Injudicious use of laboratory facilities in tertiary care hospitals at rawalpindi, pakistan: a cross-sectional descriptive study. BMC health services research;13(1):1.
10. Sintayehu Ambachew, Kasaw Adane,Abebaw Worede, et.al. Mar,2018Errors in the Total Testing Process in the Clinical Chemistry Laboratory at the University of Gondar Hospital, Northwest Ethiopia Ethiopian journal of Health Science;(28)2
11. Dereen Najat* January 20, 2017 Prevalence of Pre-Analytical Errors in Clinical Chemistry Diagnostic Labs in Sulaimani City of Iraqi Kurdistan Department of Chemistry, College of Science, University of Sulaimani, Sulaimani, Iraq DOI:10.1371/journal.pone.0170211
12. Munilakshmi, Shashidhar K. Susanna T. July-September, 2018. Preanalytical variables and its impact on total quality management of clinical biochemistry laboratory- A tertiary referral rural hospital study.International Journal of Clinical Biochemistry and Research;5(3):467-472
13. Guzel O, Guner.EI. 2009. ISO 15189 accrediation: Requirements for quality and competence of medical laboratories, experience of a laboratory I. Clin Biochem;42:274-278.