How to Cite:
Ojha, V. A., Ranjan, A., Poornima, A. M., & Prashant, A. (2022). Quality indicators to quality reports: Comparative study of two clinical biochemistry laboratories from Southern India, a cross-sectional study. *International Journal of Health Sciences*, *6*(S6), 3262–3277. https://doi.org/10.53730/ijhs.v6nS6.10143

Quality indicators to quality reports: Comparative study of two clinical biochemistry laboratories from Southern India, a cross-sectional study

Vivek Anand Ojha
Department of Biochemistry, ESIC Medical College and Hospital, Bihta, Patna, India

Amit Ranjan
Department of Biochemistry, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India

Poornima A. M.
Department of Biochemistry, Center for Basic Sciences, Kasturba Medical College, Mangalore, Karnataka, India

Akila Prashant
Professor, Department of Biochemistry, JSS Medical College, JSS Academy of Higher Education & Research, Mysuru, India
*Corresponding author email: akilaprashant@jssuni.edu.in

Corresponding Author: Dr. Akila Prashant, Professor, Department of Biochemistry, JSS Medical College, JSS Academy of Higher Education & Research, Mysuru, India
Email:

***Abstract*---**Background - Good laboratory practice is based on the simple doctrine which states, "in a laboratory what moves, needs to be trained, what does not move needs to be calibrated, whatever happens, needs to be documented, and whatever is not documented has never happened'. These principles can be used to improve the quality indicators (QIs) and quality reports (QRs) and can potentiate the total testing process (TTP). Methods – We did a cross-sectional study where annual sample rejection rates from clinical biochemistry laboratories of two quaternary care hospitals in Southern India were compared with similar studies from developing and developed countries. Results – Annual sample rejection rate from laboratory 1

was 0.912%, and 1.69% from laboratory 2. The overall median rejection rate worldwide was 1.3. Hemolysis was the most common cause of rejection from both laboratories. Two criteria, inadequate volume (Quantity not sufficient) and wrong vacutainer, were consistent with 90% of the studies worldwide. Conclusion – To overcome the widespread disparity in sample rejection criteria, this study proposes adopting standard rejection criteria and formulating the national average for rejection.

***Keywords*---**quality indicator, quality report, sample rejection criteria, complete testing process.

Introduction

In the last decade, the concept and definition of clinical empiricism have changed. In the current scenario, clinical empiricism is not mere observation-based but relies heavily on evidence-based medicine[1]. Statistically, more than 80% of evidence-based medicine is directed toward treatment and depends upon diagnostic laboratory services, which come under clinical biochemistry laboratories[2]. These facts highlight the importance and significance of an error-proof total testing process (TTP). TTP covers three very critical phases with precise objectives[3]. The first one is the pre-analytical phase. The second one is the analytical phase which highlights the importance of using specific techniques for biochemical assays and test-run. The last one is the post-analytical phase which involves the net evaluation and delivery of test results, including modifications and revocations.

About 70 to 80 % of the sampling errors fall under the pre-analytical phase [4, 5]. As per National Accreditation Board for Testing and Calibration Laboratories (NABL) [6] and World Health Organization (WHO) guidelines for laboratory safety [7, 8], remarkable improvement has been witnessed in the errors of the analytical phase, owing to the technological advancement in the field of laboratory medicine in the last two decades. But the same magnitude of improvement has not been witnessed in the pre-analytical and post-analytical phases, especially in developing countries [9]. Across the developed and developing countries, there are apparent differences in the clinical biochemistry laboratory operations. Due to automation, accreditation protocols, quality indicators (QI), and the adoption of quality control (QC) measures, developed countries have reduced the error rate considerably. Still, laboratories in developing countries have many disparities in the pre-analytical phase, compromising the integrity of quality reports (QRs)[10, 11].

Defining QR objectively is difficult as there is no universally accepted definition. Subjectively it can be defined as the sample that reflects the closest biological status of the patient's condition when the sample was drawn. Laboratories in developing countries are now adopting accreditation protocols to improve QR [12]. To maintain viable QR, laboratories follow a set of criteria depending on which samples are accepted or rejected. These criteria are crucial for the TTP and serve as the epicentre of any central clinical biochemistry diagnostic laboratory and as

one of the essential QI. Analysing the data retrospectively reveals multiple reasons for rejections. The annual sample rejection rate is a vital statistic that can improve the overall quality continuously in developed countries; accreditation is still in the juvenile phase in developing countries[13]. Most of the developing countries do not follow stringent and structured rejection criteria. Also, there is a lack of a data-based system to analyse their rejection rate against a well-known standard and compare the results[14].

In the light of these observations, we conducted a retrospective and comparative cross-sectional study based on data from clinical biochemistry laboratories of two quaternary care hospitals from Southern India. We have evaluated the reasons for sample rejection by different criteria and departments, in-patient, out-patient, intensive care unit (ICU), and emergency. This is the first study where data was comprehensively analyzed from two laboratories[15]. Rejection patterns, types of error, and comparison of the results with other national and international studies were also performed [16]. The main objective of this study was to critically compare the data from two laboratories of a similar line of setup and subjective comparison with other laboratories worldwide. We wanted to check the validity of multiple categories of sample rejection and whether it is technically correct to choose a universal, national, or multiple rejection criteria. We also we have considered generating a national average sample rejection rate and its applicability.

Graphical abstract

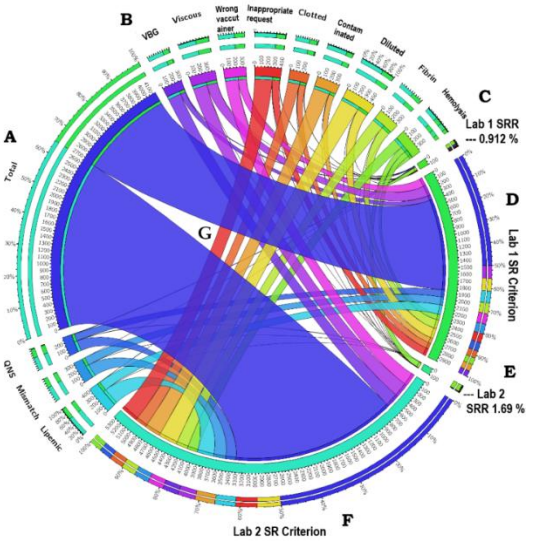

Fig.1.

Circos plot depicting a graphical representation of the comparative analysis of the various determinants of the two clinical biochemistry laboratories in Southern India. A represents the cumulative number of samples from two laboratories; light green colour represents Lab. 1, and light blue colour represents Lab. 2. B represents the individual common criterion for sample rejection followed by the two laboratories. C and E represent the sample rejection rate of Lab. 1. & Lab. 2.

D and F represent the criterion and their proportion in the total sample rejection rates for Lab. 1. 2. G represents the inside strings of the circular plot communicate the relation between total samples, total rejection, and different criteria with their percentage, compared and defined between two laboratories.
Lab.: Laboratory; QNS: Quantity not sufficient; VBG – Venous blood gas

Materials and Methods

Study Site

This study included laboratories from two quaternary care hospitals in Southern India. Laboratory 1 belongs to JSS Medical College & Hospital, Mysore, Karnataka, an 1800 bedded hospital. National Accreditation Board accredits its Hospitals and Healthcare Providers (NABH). Laboratory 2 belongs to Kasturba Medical College & Hospital, Mangalore, Karnataka, an 850 bedded hospital. It is ISO 9001:2008 certified and accredited by NABL. Institutional ethical clearance was taken from both institutes for conducting this study (JSSMC/IEC/1107/15 NCT/2019-20; IEC KMC MLR 01-19/36).

Study design

This study was conducted between January 1st 2018 to 31st December 2018. Laboratory used Cobas e411 for immunoassay, ABL 800 Flex for arterial blood gas analysis, Toshiba Accute TBA - 40 FR & TBA - 120 FR for chemistry, Bio Rad D 10 for HbA1C, Prolyte IL – 2121D and Diestro Autosampler for electrolytes. Laboratory 2 used Cobas e411 for immunoassay, Cobas 6000 for chemistry, ABL 800 Basic for arterial blood gas analysis, Bio Rad D 10 for HbA1C, and Osmomet 300 for urine analysis. This study was a data-based retrospective cross-sectional comparative analysis of types of sampling errors and rejection criteria.

Life path of samples

To troubleshoot the problems during the labelling and drawing of the samples, it was essential to do a network analysis of the sample pathway. Through HIS and LIS, the barcoding system was used in both hospitals. For in-patients, once the clinician raises a test request electronically for a patient in the HIS, the phlebotomist answers the requisition by generating barcode labels from the system, to be labelled on specific tubes and cross-checked with the patient's identification at the bedside. The phlebotomist attended to outpatients holding the written requests of the tests from the concerned clinician after generating the bar code. The methodology for data segregation and cleaning is shown in Fig.2.

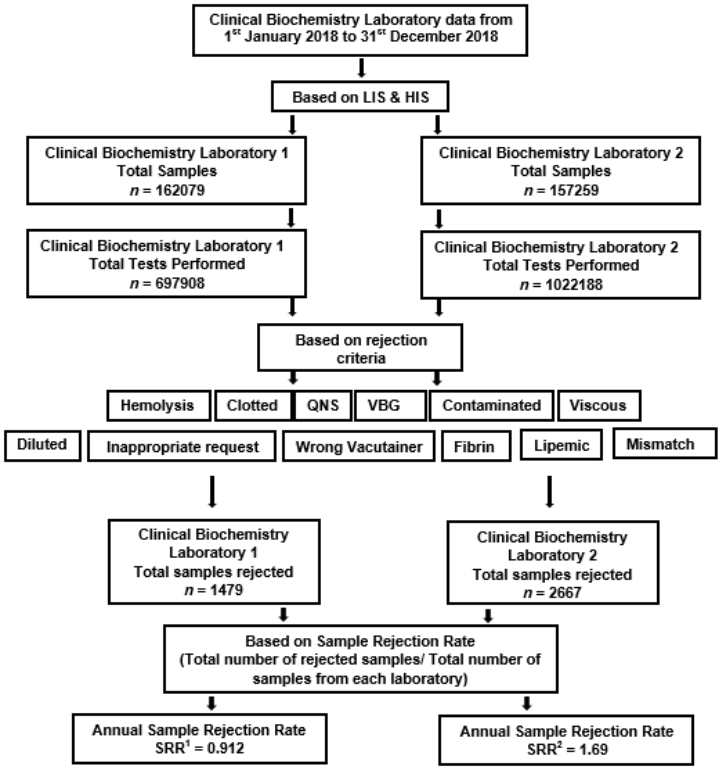

Fig.2.

Sample collection tubes

Both the laboratories followed Clinical and Laboratory Standards Institute protocols for drawing samples. In this study, K2EDTA and plain tubes were used by both laboratories. The pneumatic tube system transported the vacutainer tubes in the laboratory 1. Manual transport was used for special specimens like urine, cerebrospinal fluid, and arterial blood gas analysis. Laboratory 2 has used dedicated staff for sample transport. Besides the automated barcoding system, technicians manually checked the samples for suitable volume, clotting, and haemolysis at the time of sample receipt and simultaneously matched labels with those on the accompanying requisition forms and accepted them accordingly. Any inappropriateness was recorded in LIS. The specimens were allowed to clot, centrifuged at 3000 x g for 5 minutes in laboratory 1 and 1500 x g for 10 minutes in laboratory 2, and then delivered to the respective analysers.

Methods

As routine work, monthly data were obtained from LIS and HIS. Laboratory 1 has used Backbone (Aosta Software Technologies India Ltd.) to manage laboratory data as part of the hospital management system. Laboratory 2 has used TrakCare (InterSystems Corporation, Cambridge, MA.) and Cobas® Infinity Laboratory Solution (Hoffmann-La Roche Ltd.) to manage laboratory information systems and

data. Twelve-month data were segregated. Percentage calculations were obtained by the number of rejected samples/ total number of samples formula for each laboratory test unit.

Types of errors

Both the laboratories have used set categories of sample rejection criteria, summarised in Table 1. Based on the proportion of occurrence, the bar was divided into major and minor criteria.

Table 1

Rejected samples belonging to each criterion from the clinical biochemistry laboratory of the two hospitals in Southern India ([a]n_1 =1479, [b]$n2$ = 2667)

Sample rejection criteria	n (%)	
	n_1 (%)	n_2 (%)
[c]Major criterion		
Haemolysis	763 (51.58)	2344 (87.88)
Clotted	124 (8.38)	112 (4.19)
Quantity not sufficient	125 (8.45)	98 (3.67)
Venous blood gas (VBG)	175 (11.83)	-
Contaminated	-	58 (2.17)
[d]Minor criterion		
Inappropriate request	70 (4.73)	6 (0.22)
Diluted	55 (3.71)	7 (0.26)
Lipemic	52 (3.51)	11 (0.41)
Viscous	47 (3.17)	3 (0.11)
Fibrin	46 (3.11)	5 (0.18)
Mismatch	11 (0.74)	6 (0.22)
Wrong vacutainer	11 (0.74)	21 (0.78)

[a] Represents the total number of rejected samples from Lab. 1 (Laboratory 1), from 1st January 2018 to 31st December 2018.
[b] Represents the total number of rejected samples from Lab. 2 (Laboratory 2) from 1st January 2018 to 31st December 2018.
[C] Major criterion - Five criteria having sample rejection rates in the range of 8.38 to 51.58 % for Lab. 1 and 2.17 to 87.88 % for Lab. 2
[d] Minor criterion - Seven criteria have sample rejection rates in the range of 0.74 to 4.73 % for Lab. 1 and 0.07 to 0.78 % for Lab. 2.

Statistical analysis

Rejected samples for each test group were calculated as rates and percentages. Windows, Version 25.0, SPSS Inc. (Chicago, IL, USA) was used for statistical analysis. Two-way ANOVA for grouped analysis of the data from the two laboratories was performed. *P*-value < 0.05 was considered statistically significant.

Working principle

To systematically rule out the reasons for sample rejection, both the laboratories have adopted a precise format based on the guidelines for operating a clinical biochemistry laboratory by National Accreditation Board for Testing and Calibration Laboratories (NABL -112)[17]. Based on their observations, each had 11 criteria for rejection. They excluded those criteria that were objectively specific to microbiology, pathology, and clinical haematology (Table 1).

Results: Annual sample rejection rate

The sample collection methodology and the total number of samples in one year from both the laboratories have been explained in Fig.2. The formula calculated annual sample rejection, the number of rejected samples/ total number of samples of each laboratory test unit for one year. The yearly sample rejection rate for the lab. 1 was 0.912 and for lab. 2 it was 1.69. 'Hemolysis' was the most common reason for rejection for both the laboratories among major criteria. Among minor criteria, 'inappropriate request' was the most common criteria for the lab. 1 and 'wrong vaccutainer' was the most common criteria for lab. 2 for sample rejection (Table 1).

Major and minor criteria

The major criteria were those whose rejection rate was equal to or more than 5 % and for minor criteria it was less than 5%. Among the five major criteria, 'hemolysis', 'clotted', and 'quantity not sufficient' were common for both the laboratories. 'Venous blood gas' (VBG) was used as rejection criteria for blood gas analysis in laboratory 1 for that period for which the study was conducted whereas, in laboratory 2 the reports were released baring a comment that the sample was venous blood. 'Contaminated' as a rejection criterion was used by laboratory 2 but not by laboratory 1. Among the major criteria, 'hemolysis' was the most common, 51.58% for the lab. 1 and 87.88% for the lab. 2. Among minor criteria, 'mismatch' and 'wrong vacutainer' had the lowest rejection rate of 0.74% in lab.1, while 'viscous' had the lowest rate of 0.11% in lab.2.(Table 1). Department wise percentage of sample rejection was calculated for the all-individual criterion, for major criteria (Table 2) and minor criteria (Table 3). In-patient and out-patient were clubbed together, as the sample collection methodology was the same for both types of patients.

Table 2
Sample rejection rates for major criterion as per the different departments

Department	Hemolysis %		Clotted %		QNS %		[a]VBG/[b]Contaminated %	
	Lab 1	Lab 2	Lab 1	Lab 2	Lab 1	Lab 2	[a]Lab 1	[b]Lab 2
Medicine	40.89	61.39	15.32	73.21	28	46.93	28	60.34
Surgery	16.67	14.63	4.03	11.6	11.2	15.3	5.14	15.51
Pediatrics	0	0.59	2.41	1.78	1.6	1.02	0	0
Emergency	10.61	3.02	9.67	3.57	12.8	23.46	10.28	6.89
NICU	6.81	0.46	31.45	0	28	4.08	5.14	6.89
ICU	24.90	19.88	37.09	9.82	18.4	9.18	51.42	10.34
SRR (%)	51.58	87.88	8.38	4.19	8.45	3.67	11.83	2.17

The sample rejection rate (%) of major criteria were calculated for each criterion for the respected department, the number of rejected samples/ total number of samples of each laboratory test unit for 1 year. The row factor accounts for a significant variance with $P < 0.0001$.

QNS – Quantity not sufficient
[a]VBG – Venous blood gas, used by laboratory 1.
[b]Contaminated – Criterion was used by laboratory 2.
NICU – Neonatal intensive care unit.
ICU – Intensive care unit.
SRR – Sample rejection rate.

Table 3
Sample rejection rates for minor criterion as per the different departments

Department	Inappropriate request		Diluted		Lipemic		Viscous		Fibrin		Mismatch		Wrong Vacutainer	
	Lab 1	Lab 2	Lab 1	Lab 2	Lab 1	Lab 2	Lab 1	Lab 2	Lab 1	Lab2	Lab 1	Lab 2	Lab 1	Lab 2
Medicine	38.57	52.38	60	28.57	50	36.36	40.42	38.46	67.39	60	54.54	33.33	54.54	0
Surgery	10	28.57	9.09	42.85	21.15	0	34.04	23.07	17.39	40	9.09	16.66	9.09	0
Pediatrics	2.85	4.76	1.81	28.57	3.84	18.18	2.12	15.38	4.34	0	0	0	0	0
Emergency	17.14	4.76	16.36	0	13.46	9.09	12.76	7.69	4.34	0	27.27	0	27.27	100
NICU	14.28	4.76	5.45	0	1.92	9.09	6.38	7.69	4.34	0	0	16.66	9.09	0

ICU	17.14	4.76	7.27	0	9.61	27.27	4.25	7.69	2.17	0	9.09	33.33	0	0
SRR	4.73	0.78	3.71	0.26	3.51	0.41	3.17	0.48	3.11	0.18	0.74	0.22	0.74	0.07

The sample rejection rate (%) of the minor criterion was calculated for each criterion for the respected department, the number of rejected samples/ total number of samples of each laboratory test unit for 1 year. The row factor accounts for a significant variance with $P < 0.0001$. Comparison of sample rejection criteria across different Indian and global [18] studies. To critically review the different rejection criteria adopted across developing[19] and developed [20] countries, we did a comparative analysis. Analysis for the developing country had shown that out of the 19 criteria only 2, 'mismatch' and 'lipemic', were common to all the studies. Compared to studies for developed countries,[21] the current study had 42.1% of common criteria, 8 out of 19 (Table 4).

Table 4
Comparison of sample rejection criteria across different Indian studies

Criteria	Chawala *et al.*	Agarwal *et al.*	Chhillar *et al.*	Agarwal *et al.*	Current study
Clotted sample		Yes		Yes	Yes
Inadequate volume/QNS	Yes	Yes		Yes	Yes
Wrong vacutainer	Yes	Yes	Yes		Yes
Hemolyzed sample		Yes	Yes	Yes	Yes
Mislabeled specimen/Inappropriate request	Yes	Yes	Yes		Yes
Incomplete request forms		Yes	Yes		
Patient identification wrong/Mismatch	Yes	Yes	Yes	Yes	Yes
Lipemic sample	Yes	Yes	Yes	Yes	Yes
Sample collection from infusion set		Yes			
Illegible handwriting	Yes		Yes		
Unlabeled specimen	Yes	Yes			
Doctor identification absent		Yes	Yes	Yes	
From where sample send (ER/ward/other) – Inadequate		Yes	Yes	Yes	
Hemolyzed after centrifugation	Yes				Yes
Date and time of collection absent		Yes	Yes		
Clinical diagnosis not written		Yes	Yes		
Sample not transported in closed box					
Test not mentioned on request form					
Wrong billing				Yes	
[a] Sample rejection rate (%)	1.9	16.27	28	10.5	[b]0.912; [c]1.69
Most common cause	Hemolysis after centrifugation	Incomplete requisition	Illegible handwriting	Incomplete requisition	Hemolysis

[a] Sample rejection rate (%) was calculated by using the formula, Total samples rejected/Total number of the samples in one year.
[b] Sample rejection rate from the lab. 1.
[C] Sample rejection rate from the lab. 2.
QNS – Quantity not sufficient.

For developed countries, out of 30 criteria only 2, 'inadequate volume' and 'wrong vacutainer' were common to all the studies. The current study had 30% of common criteria across the studies in developed countries (Table 5).

Table 5
Comparison of sample rejection criteria across different Global studies

Criteria	Carraro *et al.*	Stark *al.*	*et*Lippi *et al.*	Bonini *al.*	*et*Zarbo *al.*	*et*Current study
Clotted sample		Yes	Yes	Yes	Yes	Yes
Inadequate volume/QNS	Yes	Yes	Yes	Yes	Yes	Yes
Wrong vacutainer	Yes	Yes	Yes	Yes	Yes	Yes
Hemolyzed sample		Yes		Yes	Yes	Yes
Empty tubes	Yes	Yes		Yes		
Mislabeled specimen/ Inappropriate request		Yes		Yes	Yes	Yes
Incomplete request forms		Yes		Yes	Yes	
Patient identification wrong/Mismatch	Yes		Yes	Yes		Yes
Lipemic sample			Yes		Yes	Yes
Significant platelet clump		Yes				
Sample collection from infusion set	Yes		Yes			
Illegible handwriting						
Unlabeled specimen					Yes	
Doctor identification absent				Yes		
From where sample send (ER/ward/other) – Inadequate						

Hemolyzed after centrifugation			Yes			Yes
Test tube broken in centrifuge				Yes	Yes	
Open vacutainer				Yes		
Non refrigerated samples	Yes			Yes		
Missing tubes	Yes				Yes	
Samples contaminated	Yes					[a]Yes
Date and time of collection absent						
Clinical diagnosis not written						
Delta check not done					Yes	
Specimen lost			Yes		Yes	
Delay in transport		Yes				
Sample not transported in closed box	Yes	Yes	Yes	Yes	Yes	
Test not mentioned on request form						
Wrist band error rate					Yes	
Wrong billing						
[b]Sample rejection rate (%)	1.3	0.74	0.74	0.64	0.62	[c]0.912; [d]1.69
Most common cause	Hemolysis	Hemolysis	Inadequate volume	OPD: Wrong Vacutainer IPD: Hemolysis	Inadequate volume	Hemolysis

[a]Criterion was used only by lab. 2 in this study
[b]Sample rejection rate (%) was calculated by using the formula, Total samples rejected/Total number of the samples in one year.
[c] Sample rejection rate from the lab. 1.
[d]Sample rejection rate from the lab. 2.; QNS – Quantity not sufficient.

Among all the 49 criteria (developing and developed), none of the criteria had shown any consistency. Two criteria, 'inadequate volume' (Quantity not sufficient) and 'wrong vacutainer' were found to be consistent with 90% of the studies throughout the world (developing countries study data mostly based on Indian studies) (Table 4, 5)[22, 23]. Similar results were shown in the study performed by Gupta *et al*[24].

Discussion

Identification and documentation of an error is the critical step in the complex process of troubleshooting problems. Improving the total testing process in an environment which is governed by automated machines and commanded by humans is always challenging. In this study, we analyzed and compared the annual sample rejection rates from two laboratories and also compared the results with other national and international studies. The annual sample rejection rate of laboratory 1 was 0.912% and 1.69% of laboratory 2. The median rejection rate across the studies in developing countries was found to be 6.2% and among developed countries, it was 0.74%. Overall median rejection throughout similar studies was 1.3%. In this study, the rejection rate was 5% to 6% lower than the median rejection rate of developing countries. Laboratory 1 had shown 'hemolysis' with 51.58%, as the most common rejection criterion and 'mismatch', 'wrong vacutainer' with 0.74% as the least common criteria.

In this study, we have compared the data from 11 different laboratories, including the 2 laboratories from the present study. The average rejection rate based on the annual sample rejection rate was 5.75%. Out of total 11, 6 were from developing countries (primarily Indian studies) and 5 were from developed (Western) countries. As the study objective was to first compare and analyze the data from the two laboratories from Southern India, and compare the pattern with other studies, we performed grouped analysis for the two laboratories. While looking into the common variables we found the following points, both were quaternary care hospitals, catering to similar demographic populations, strict quality control protocols in place, almost similar types of instruments used for analytical phase, integrated laboratory information system, and hospital information system. There were some major differences also, laboratory 1 was receiving samples mostly from one hospital, and laboratory 2 was receiving samples from multiple affiliated hospitals including two government hospitals (a public-Private partnership initiative). Further, laboratory 1 was using pneumatic tube, while laboratory 2, manually transported the samples from the area of collection to the laboratory, owing to the disperse hospital setting. This explains the fact that laboratory 2 rejection due to hemolysis was 87.88%, much higher than the laboratory 1, which was 51.58%. Some studies support the use of pneumatic chute system for checking the pre-analytical phase of errors, limited by para-medic staff training for operational sufficiency. The rejection criterion, 'venous blood for blood gas analysis' was used by laboratory 1 but not by laboratory 2, instead the laboratory 2 released the report baring the comment that the analyzed sample was venous blood. VBG rejection rate for laboratory 1 was 11.83%, which was the second-highest after hemolysis.

Unlike many other studies, we have included data from both in-patient and out-patient departments. The reason for this was the associated hospitals with laboratory 1 and laboratory 2 had in-house training modules for phlebotomist and paramedical staff about the sample collection, storage, and transportation. Several studies from the developed and developing countries have not mentioned the status of on-duty staff training and this conditional clause could be a reason for the high rejection rates found in those studies[25]. In some of the studies from developed countries, in the OPD, patient requisition form for laboratory tests were

filled up by doctors and paramedics, who were not specifically trained, and that was taken up as the primary source for data input for test name and other commands, we found that this could be a reason for high rejection rate in the pre-analytical phase.

Q-Probe program of Continuous Laboratory Monitoring (CLM)[22], provides the details about the total testing process in the developing countries, and how they were able to contain rejection rates below 0.83%. Diagnostic laboratories in developed countries adopted barcoding, hospital information system (HIS), laboratory information system (LIS), wrist band identification technique, and pneumatic tube system even before the year 2007. Few laboratories in developing countries have adopted these measures, which justifies the high rejection rates across various studies in developing countries. The very important and less appreciated fact is laboratories in the developing countries are bound to serve a large number of patients in a short stipulated time frame, at a pocket-friendly price. Sometimes, the larger good becomes the priority, which jeopardizes quality.

The directives laid down by the accreditation council ISO 15189, declares that each laboratory should identify and postulate its quality indicators (QI), these QIs should be regularly monitored. Unfortunately, the accreditation council does not define rejection criteria, which has caused a distinct variation in the criteria followed across different countries. Based on the observations of this study we would like to recommend development of a strategy to define the ergonomics and specific criteria that can be adopted by any laboratory, at the same time negating the absence of universally viable QI. This approach could be a landmark in enhancing the performance of laboratories in the context of total quality management (TQM). Laboratories can improve their performance by adopting the recommendations with suitable modifications, which can improve their overall performance.

Conclusion

The annual sample rejection rate for the lab. 1 was 0.912 and for lab. 2 it was 1.69. 'Hemolysis' was the most common reason for rejection for both the laboratories among major criteria. Among minor criteria, 'inappropriate request' was the most common criteria for the lab. 1 and 'wrong vaccutainer' was the most common criteria for lab. 2 for sample rejection. Our study has some singular technical limitations common to both the laboratories involved. Customized training was provided to the phlebotomists, paramedics, and nursing staff responsible for drawing the samples, documentation, storage, and transportation. But the commitment and motivational factor have never been assessed or it can be said there is no scientific methodology in place to perform that. More than just a superlative remark, it is an important parameter that determines the productivity of the procedure like sample drawing. We suggest that researchers should follow a methodology for this assessment in other similar studies. The second limitation is, we were not able to systematically retrieve the annual data from the two laboratories before the implementation of LIS, as it could have provided other determinants in terms of sample rejection pattern prior to the integration of LIS. Finally, we would like to conclude by proposing the formulation of national sample rejection criteria which can also answer the national average

or median rejection rate, and serves as a standard benchmark for any laboratory. Further, the national sample rejection criteria can be compared with other international criteria and can be modified accordingly.

Acknowledgment

For the accomplishment of this study, we would like to express our gratitude to the staff of the department of biochemistry, JSS Medical College, Mysuru, and Kasturba Medical College, Mangalore, Karnataka, India.

References

1. M. Plebani, Towards a new paradigm in laboratory medicine: the five rights, Clin Chem Lab Med 54(12) (2016) 1881-1891.
2. L. Sciacovelli, M. O'Kane, Y.A. Skaik, P. Caciagli, C. Pellegrini, G. Da Rin, A. Ivanov, T. Ghys, M. Plebani, W.-L. Ifcc, Quality Indicators in Laboratory Medicine: from theory to practice. Preliminary data from the IFCC Working Group Project "Laboratory Errors and Patient Safety", Clin Chem Lab Med 49(5) (2011) 835-44.
3. M.P. Cornes, J. Atherton, G. Pourmahram, H. Borthwick, B. Kyle, J. West, S.J. Costelloe, Monitoring and reporting of preanalytical errors in laboratory medicine: the UK situation, Ann Clin Biochem 53(Pt 2) (2016) 279-84.
4. M. Salinas, M. Lopez-Garrigos, E. Flores, A. Santo-Quiles, M. Gutierrez, J. Lugo, R. Lillo, C. Leiva-Salinas, Ten years of preanalytical monitoring and control: Synthetic Balanced Score Card Indicator, Biochem Med (Zagreb) 25(1) (2015) 49-56.
5. M.P. Cornes, S. Church, E. van Dongen-Lases, K. Grankvist, J.T. Guimaraes, M. Ibarz, S. Kovalevskaya, G.B. Kristensen, G. Lippi, M. Nybo, L. Sprongl, Z. Sumarac, A.M. Simundic, P. Working Group for Preanalytical, C. European Federation of Clinical, M. Laboratory, The role of European Federation of Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase in standardization and harmonization of the preanalytical phase in Europe, Ann Clin Biochem 53(Pt 5) (2016) 539-47.
6. M. Verma, K. Dahiya, V.S. Ghalaut, V. Dhupper, Assessment of quality control system by sigma metrics and quality goal index ratio: A roadmap towards preparation for NABL, World J Methodol 8(3) (2018) 44-50.
7. K.P. Eaton, K. Levy, C. Soong, A.K. Pahwa, C. Petrilli, J.B. Ziemba, H.J. Cho, R. Alban, J.F. Blanck, A.S. Parsons, Evidence-Based Guidelines to Eliminate Repetitive Laboratory Testing, JAMA Intern Med 177(12) (2017) 1833-1839.
8. L. McCay, C. Lemer, A.W. Wu, Laboratory safety and the WHO World Alliance for Patient Safety, Clin Chim Acta 404(1) (2009) 6-11.
9. G. Da Rin, Pre-analytical workstations: a tool for reducing laboratory errors, Clin Chim Acta 404(1) (2009) 68-74.
10. O. Dauwalder, L. Landrieve, F. Laurent, M. de Montclos, F. Vandenesch, G. Lina, Does bacteriology laboratory automation reduce time to results and increase quality management?, Clin Microbiol Infect 22(3) (2016) 236-43.
11. J.R. Genzen, C.D. Burnham, R.A. Felder, C.D. Hawker, G. Lippi, O.M. Peck Palmer, Challenges and Opportunities in Implementing Total Laboratory Automation, Clin Chem 64(2) (2018) 259-264.

12. G. Boursier, I. Vukasovic, P.M. Brguljan, M. Lohmander, I. Ghita, F.A. Bernabeu Andreu, E. Barrett, D. Brugnoni, C. Kroupis, L. Sprongl, M.H. Thelen, F. Vanstapel, T. Vodnik, W. Huisman, M. Vaubourdolle, A. Working Group, I.C.s.o.t. EFLM, Accreditation process in European countries - an EFLM survey, Clin Chem Lab Med 54(4) (2016) 545-51.
13. S. Sayed, W. Cherniak, M. Lawler, S.Y. Tan, W. El Sadr, N. Wolf, S. Silkensen, N. Brand, L.M. Looi, S.A. Pai, M.L. Wilson, D. Milner, J. Flanigan, K.A. Fleming, Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions, Lancet 391(10133) (2018) 1939-1952.
14. L. Sciacovelli, G. Lippi, Z. Sumarac, J. West, I. Garcia Del Pino Castro, K. Furtado Vieira, A. Ivanov, M. Plebani, E. Working Group "Laboratory, C. Patient Safety" of International Federation of Clinical, M. Laboratory, Quality Indicators in Laboratory Medicine: the status of the progress of IFCC Working Group "Laboratory Errors and Patient Safety" project, Clin Chem Lab Med 55(3) (2017) 348-357.
15. L. Rooper, J. Carter, J. Hargrove, S. Hoffmann, S. Riedel, Targeting Rejection: Analysis of Specimen Acceptability and Rejection, and Framework for Identifying Interventions in a Single Tertiary Healthcare Facility, J Clin Lab Anal 31(3) (2017).
16. R.L. Fitzgerald, J.E. Hollander, W.F. Peacock, A.T. Limkakeng, N. Breitenbeck, K. Blechschmidt, M. Laimighofer, C. deFilippi, Analytical performance evaluation of the Elecsys(R) Troponin T Gen 5 STAT assay, Clin Chim Acta 495 (2019) 522-528.
17. V. Wadhwa, S. Rai, T. Thukral, M. Chopra, Laboratory quality management system: road to accreditation and beyond, Indian J Med Microbiol 30(2) (2012) 131-40.
18. P. Bonini, M. Plebani, F. Ceriotti, F. Rubboli, Errors in laboratory medicine, Clin Chem 48(5) (2002) 691-8.
19. N. Chhillar, S. Khurana, R. Agarwal, N.K. Singh, Effect of pre-analytical errors on quality of laboratory medicine at a neuropsychiatry institute in north India, Indian J Clin Biochem 26(1) (2011) 46-9.
20. G. Lippi, A. Bassi, G. Brocco, M. Montagnana, G.L. Salvagno, G.C. Guidi, Preanalytic error tracking in a laboratory medicine department: results of a 1-year experience, Clin Chem 52(7) (2006) 1442-3.
21. A. Stark, B.A. Jones, D. Chapman, K. Well, R. Krajenta, F.A. Meier, R.J. Zarbo, Clinical laboratory specimen rejection--association with the site of patient care and patients' characteristics: findings from a single health care organization, Arch Pathol Lab Med 131(4) (2007) 588-92.
22. R.J. Zarbo, B.A. Jones, R.C. Friedberg, P.N. Valenstein, S.W. Renner, R.B. Schifman, M.K. Walsh, P.J. Howanitz, Q-tracks: a College of American Pathologists program of continuous laboratory monitoring and longitudinal tracking, Arch Pathol Lab Med 126(9) (2002) 1036-44.
23. P. Carraro, T. Zago, M. Plebani, Exploring the initial steps of the testing process: frequency and nature of pre-preanalytic errors, Clin Chem 58(3) (2012) 638-42.
24. N.G. Gupta V, Harsh M, Chandra H, Agarwal A, Shrivastava V., Utility of sample rejection rate as a quality indicator in developing countries. , J Nat Accred Board Hosp Healthcare Providers 2 (2015) 30-35.

25. M.L. Wilson, K.A. Fleming, M.A. Kuti, L.M. Looi, N. Lago, K. Ru, Access to pathology and laboratory medicine services: a crucial gap, Lancet 391(10133) (2018) 1927-1938.
26. Nyandra, M., Kartiko, B.H., Susanto, P.C., Supriyati, A., Suryasa, W. (2018). Education and training improve quality of life and decrease depression score in elderly population. *Eurasian Journal of Analytical Chemistry*, *13*(2), 371-377.
27. Sarada, V., & Mallikarjuna, T. (2018). Socio-economic and psychological problems of third gender people living with HIV/AIDS: A study in A.P. International Journal of Health & Medical Sciences, 1(1), 10-17. https://doi.org/10.31295/ijhms.v1n1.34