Original Article

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Impact of NABL on Quality Indicators of Pre-Analytical Phase of Testing in Tertiary Care Hospital

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ABSTRACT

Introduction: The laboratory's compliance to requirements of the standard and its technical competence are assessed by NABL for accreditation. QIs should be part of a coherent and integrated quality improvement strategy implemented according to the specifically developed International Standard for Medical Laboratories Accreditation (ISO 15189: 2012).Pre-analytical errors account for more than 70% of the total number of laboratory errors.The International Federation of Clinical Chemistry(IFCC) and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety (WG-LEPS) has made an important contribution to developing QIs for the preanalytical phase and specifications for those indicators.We selected following QIs pertaining to the key activities of the pre-analytical phase. These were: Hemolyzed samples (in biochemistry; QI-10b); Samples with inadequate quantity (QI-12).

Material and Method: QI-10b and 12 were recorded from 'Sample rejection register'and 'Sample transport register'. We calculated the sigma metric for these QIs. First, we calculated the Defect Per Million (DPM) then the DPM rate was converted to a sigma value.

Result: After NABL accreditation improvement in six sigma values of QI-10b is 4.0-5.0, suggests 'Good' level of performance and for QI-12 shows between 3.0-4.0, no significant improvement.

Conclusion: NABL accreditation does not make any statement about the technical competence of the laboratory.As continual improvement is necessary for the good laboratory practice, we continue to collect data regarding errors to monitor this critical phase of laboratory testing to ensure ongoing satisfactory performance.

Keywords: *NABL, The International Federation of Clinical Chemistry(IFCC), Quality indicators, Defect per million, Six sigma*

Introduction

Laboratory accreditation activities are administered under the direction of the National Accreditation Board for Testing and Calibration Laboratories (NABL), involving assessment team and accreditation committee as recommending authorities.

The requirements in this document on specific criteria are based on the International Standard, ISO 15189:2012 - "Medical laboratories – Requirements for quality and competence". It specifies requirements for competence and quality that are particular to medical laboratories. The 2012 ISO 15189 standard establishes that the pre analytical phase of the testing process begins with the test request from the healthcare provider and includes the requisition, preparation of the patient, collection of the primary sample and transportation of the sample to and within the laboratory.[1] The pre-analytical phase ends when the analytical examination begins. Clause 4.12.4 of this standard, which used for medical laboratory accreditation, requires the implementation of QIs (Quality Indicators) for systematically monitoring and evaluating the contribution of the laboratory to patient care and the identification of improvement opportunities.[2]

Pre-analytical errors account for more than 70% of the total number of laboratory errors so preanalytical phase of testing is an area of concern for laboratory services.[3]

The International Federation of Clinical Chemistry(IFCC) and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety (WG-LEPS) has made an important contribution to developing QIs for the preanalytical phase and specifications for those indicators.[4-6] Of these, 16 are focused on the preanalytical phase (Table 1).

A method of quality assessment, which is also applicable in the pre-analytical phase, is the use of sigma metrics (i.e., the Six Sigma methodology).Six Sigma provides principles and tools that can be applied to any process to measure the defect and/or error rate.The number of errors, or DPM (Defects per million), is a measure of laboratory performance.[7] The measurement of quality on a sigma scale in the preanalytical phase requires monitoring of outcome process, counting the defects, calculating the DPM and using statistical tables to convert the DPM into sigma metrics.[8] The sigma value indicates the frequency of errors in a process. The higher this value, the less likely the laboratory reports incorrect results.[9] Quality is

assessed on a sigma scale from 3 sigma as the minimum allowed for routine performance to 6 sigma as best-in-class quality. [7] World-class quality processes have a six sigma level, which means around 3.4 errors per million. [9] Average products, regardless of their complexity; have a quality performance value of approximately 4 sigma. [10]

The aim of our study was to quantify performance in the pre-analytical phase of the testing process in Clinical Biochemistry Laboratory using quality indicators and to compare our results (six sigma performance) with before NABL and after NABL accreditation.

Our total no. errors of year 2016 (after NABL Accreditation) are also compared with similar studies.

Materials and Methods

We performed our study in the Clinical Chemistry Laboratory (NABL accredited, September, 2012), Sir Sayajirao General Hospital (S.S.G.H.), Vadodara, which is major teaching hospital in Government setup in Eastern Gujarat. The laboratory performs emergency and routine tests for the patients attending the hospital.

Blood samples from inpatients and the emergency department are collected by the clinical ward staff whereas outpatient samples are collected at Collection center in the outpatient department (O.P.D.) by the laboratory staff. Venous blood samples are collected in plastic tubes with different additive as per the test requested. All laboratory tests are ordered via the test request form. Request forms are assigned a unique color identification code. (Yellow for Biochemistry, pink for Hematology, white for Serology and green for Microbiology). The request form is duly filled, signed and stamped by the clinician and sent to the laboratory along with the samples. The specimens are transported by the ward staff (in specialized transport boxes to maintain the temperature) to the laboratory reception area. The laboratory staff checks whether the patient's identification data on the sample collection tube match those on the request form.

The laboratory has established acceptance and rejection criteria. In our laboratory, the sample rejection criteria are as follows; wrong, missing patient identification, wrong anticoagulant, too much or not enough sample volume and visible hemolysis. The samples that do not meet the acceptability criteria are rejected; data regarding these samples are recorded in a special register, and the staff members who collected them are notified. The date, a unique identification code, the reason for rejection and the name of the person who rejected the sample are specified in this register. Samples that meet the acceptability criteria are logged in a register that specifies the time the samples were received and the number of tubes collected; all the samples are given specific laboratory identification number to categorize the samples accordingly. Subsequently, the samples are taken for centrifugation. After centrifugation, laboratory personnel visually check the blood samples to detect hemolyzed, lipemic and icteric serum. If hemolyzed, the concerned clinician is informed and sample details are recorded in Hemolyzed sample register. The laboratory personnel receiving the samples maintain this register.

Complying with the ISO 15189:2012 standard that is implemented in the laboratory, the laboratory staff are trained to identify and register all the errors that may affect the testing process, including those that occur in the pre-analytical phase. The collection center staff and clinical staff have been trained to collect specimens. 'Primary sample collection manual', a handbook of instructions on proper techniques of all aspects of sample collection, has been distributed to all wards and OPDs.

We selected following QIs pertaining to the key activities of the pre-analytical phase. These were:

Hemolyzed samples (in biochemistry; QI-10b);

Samples with inadequate quantity (QI-12).

QI-10b and 12 were recorded from 'Sample rejection register' in the Clinical Chemistry Laboratory. Total number of samples being transported from various wards and OPDs, is maintained in the 'Sample transport register'.

Methodology and Calculation

We calculated the sigma metric for these QIs. First, we calculated the DPM rate using the following formula:

DPM = (number of errors × 1,000,000)/total number of specimens or requests.

The DPM rate was converted to a sigma value based on tables available online (http://www.westgard.com/sixsigma- table.htm). For example, for the QI involving hemolyzed samples, we calculated the sigma value as follows:

DPM = (number of hemolyzed samples × 1,000,000)/total number of samples

In our study, the number of hemolyzed biochemistry samples was 266; the total number of samples was 141354 during the period from 1st January to 31st December, 2011.

Therefore, DPM = 266× 1,000,000)/ 141354 =1882. In the statistical tables, the sigma value for 1882 DPM is 4.5.

Sigma score calculators are also available at http://www.westgard.com/six-sigma calculators-2.htm.

Daniela Stefania G. adopted four levels (similar to the WG-LEPS levels) of laboratory performance depending on the sigma values as given below. [11]

1. Very good: ≥ 5 sigma
2. Good: 4- < 5 sigma
3. Minimum: 3 -< 4 sigma
4. Unacceptable: < 3 sigma

These facilitate the identification of opportunities to improve laboratory services.

Result

During the period from 1st January, 2011 to 31st December, 2016, a total of samples and Tests performed were received in the Clinical Chemistry Laboratory are as under.

Table 2 show total number of pre-analytical errors during 2011-2012 (before NABL accreditation) during 2012-2016 (After NABL accreditation) of the total number of samples received during that period.

Table 3 shows the performance levels, based on Sigma value of the QIs for pre-analytical phase of testing in Clinical Chemistry Laboratory after NABL accreditation (2013-2016)

Discussion

Pre-analytical errors account for more than 70% of the total number of laboratory errors and have significant clinical and economic impacts on medical care. [2] QIs are useful performance monitoring tools for the pre-analytical phase of the testing process.

In our study, we selected two quality indicators. Other QIs can also be used; however, we did not examine these in the present study. We recorded data on a daily basis regarding samples that did not meet the acceptance criteria.

Table 3 suggests that after NABL accreditation, continuous monitoring and preventive and corrective action leads to improvement in six sigma value of QI-10b

Most of our results indicated an optimum level of performance; score of sigma value between 4.0-5.0 suggests 'Good' level of performance.

Table 3 suggests that after NABL accreditation, continuous monitoring and preventive and corrective action leads to no significant improvement in six sigma value of QI-12.

Most of our score of sigma value between 3.0-4.0 suggests 'Minimum' level of performance.

The relative total preanalytical error frequency of 2016 in our study is 1.20% and it is in accordance with the international literature. It contrasts with 1.4% of Goswami et al. [12] 0.74% of Stark et al. [13] and 0.25%. of Fabio et al [14]

Table 4 shows comparison of QI performance level value with other studies. From the table it is evident that our QI-10b scores are comparable to **Daniela et al.** [11]and **Chawla et al.** [16]

Performance of QI-12 is in concordance with **Sciacoveli et al.** [15].

Table 5 shows comparison of sigma value with other studies. From the table it is evident that in our study six sigma value of QI-10b is better compared with **Daniela et al.** [11]and **Sciacoveli et al.** [15]whereas six sigma value of QI-12 is lower compared with **Sciacoveli et al.** [15]

Table 1: Quality indicators of the pre-analytical phase.

A) TEST ORDERING
QI-1 Percentage of "Number of requests with clinical question from general practitioners/Total number of requests from general practitioners"
QI-2 Percentage of "Number of appropriate requests, with respect of clinical question from general practitioners/Number of requests that reports clinical question from general practitioners"
B) FORMULATION AND INPUT OF REQUEST
QI-3 Percentage of "Number of requests without physician identification/Total number of requests"
QI-4 Percentage of "Number of unintelligible requests/Total number of requests"
QI-5 Percentage of "Number of requests with errors concerning patient identification/Total number of requests"
QI-6 Percentage of "Number of requests with errors concerning physician identification/Total number of requests"
QI-7a Percentage of "Number of requests with errors concerning input of tests (missing)/Total number of requests"
QI-7b Percentage of "Number of requests with errors concerning input of tests (added)/Total number of requests"
QI-7c Percentage of "Number of requests with errors concerning input of tests (misinterpreted)/Total number of requests"
C) IDENTIFICATION, COLLECTION, HANDLING AND TRANSPORT OF SAMPLES
QI-8 Percentage of "Number of samples lost-not received/Total number of samples"

QI-9 Percentage of "Number of samples collected in inappropriate container/Total number of samples"
QI-10a Percentage of "Number of samples hemolyzed (hematology)/Total number of samples"
QI-10b Percentage of "Number of samples hemolyzed (chemistry)/Total number of samples"
QI-11a Percentage of "Number of samples clotted (hematology)/Total number of samples with anticoagulant"
QI-11b Percentage of "Number of samples clotted (chemistry)/Total number of samples with anticoagulant"
QI-12 Percentage of "Number of samples with insufficient sample volume/Total number of samples"
QI-13 Percentage of "Number of samples with inadequate sample-anticoagulant/Total number of samples with anticoagulant"
QI-14 Percentage of "Number of samples damaged in transport/Total number of samples"
QI-15 Percentage of "Number of samples improperly labeled/Total number of samples"
QI-16 Percentage of "Number of samples improperly stored/Total number of samples"

Table 2: Total no. of Pre-analytical errors during 2011-2016.

YEAR	TOTAL NO. OF SAMPLE	HEMOLYZED SAMPLE (QI-10b) (%)	QNS SAMPLE (QI-12) (%)
2011	141354	266 (0.19%)	1739 (1.23%)
2012	151621	301 (0.20%)	1689 (1.11%)
2013	170411	356 (0.21%)	2212 (1.30%)
2014	184020	392 (0.21%)	2296 (1.25%)
2015	157382	286 (0.18%)	1857 (1.18%)
2016	146478	242 (0.17%)	1505 (1.03%)

Table 3: Type and Number of Errors in Pre-analytical and Performance Levels obtained for Quality Indicators before NABL accreditation(2011-2012) and after NABL accreditation (2011-2016).

QI code and meaning and Descriptor	DPM Sigma Value Sigma based Performance Level [A]					
	2011	2012	2013	2014	2015	2016
(QI-10b) Hemolyzed samples Hemolyzed samples/ Total no. of samples	1882 4.3 Good	1985 4.3 Good	2089 4.4 Good	2130 4.4 Good	1817 4.5 Good	1652 4.5 Good
(QI-12) Samples with inadequate Quantity Samples with inadequate Quantity/ Total no. of samples	12302 3.8 Minimum	11140 3.8 Minimum	12980 3.8 Minimum	12476 3.8 Minimum	11799 3.8 Minimum	10274 3.9 Minimum
	DPM, defects per million; QI, Quality Indicator [A] Based on the sigma level for the pre analytical phase in the Laboratory					

Table 4: Comparison of Performance level (%) value of QI 10b and QI 12 with other studies.

Quality Indiacators (QIs)	Daniela et al. [11]	Sciacoveli et al. [15]	Chawla et al. [16]	Present study (Year 2016)
(QI-10b) Hemolyzed samples	0.4%	2.2%	0.74%	0.17%
(QI-12) Samples with inadequate Quantity	-	0.99%	0.23%	1.03%

Table 5: Comparison of six sigma value with other studies.

Quality Indiacators (QIs)	Daniela et al. [11]	Sciacoveli et al. [15]	Present study (Year 2016)
(QI-10b) Hemolyzed samples	4.2	3.6	4.5
(QI-12) Samples with inadequate Quantity	-	4.8	3.9

The reason for more frequent errors in quantity of samples could be that in our institute, the personnel collecting samples change often. Ours being a teaching institute, new batch of interns and Post Graduate students are assigned the work of sample collection on rotational basis. They might not be able to learn the importance of proper quantity of samples in a short of period of their posting. The error of 'Inadequate quantity' mainly observed with Serum Electrolyte test, which required more amount of serum. Difficulty in sample collection of the pediatric patients is another major cause of insufficient quantity. Hemolysis is responsible for the rejection of countless exams, like lactate dehydrogenase (LDH), acid phosphatase, and potassium tests, aspartate transaminase (AST), alanine transaminase (ALT). [17-20]

Hemolysis leads to test rerun which adds on cost, time and usage of equipments.

Limitations of this study are, (1) We have not included all QIs and set of the QIs selected partly reflects internal experiences in accreditation program (2) In data collection, some errors might have been missed out from recording because the way data were collected by us changed over a time: initially they were collected manually, printed worksheet being used, whereas now they are collected by laboratory information system.

Conclusion

NABL accreditation does not make any statement about the technical competence of the laboratory. Each laboratory uses criteria specifically developed to determine technical competence of the laboratory. To minimize Pre-analytical error, regular training of the technical staff, retraining and evaluation program should be organized for laboratory staff and induction training should be organize for newly posted interns and postgraduates. As continual improvement is necessary for the good laboratory practice, we continue to collect data regarding errors to monitor this critical phase of laboratory testing to ensure ongoing satisfactory performance.

Further study can be done to include monitoring of other QIs of the Pre-analytical, Analytical and Post analytical phase of testing in the Clinical Chemistry Laboratory.

Declarations

Conflict of interest**:** The author stat that there are no conflicts of interest regarding the publication of this article.

Ethical approval: not required, as it was retrospective analysis of the data.

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