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ORIGINAL RESEARCH

Evaluation of pre-analytical phase performance of emergency laboratory by harmonized quality indicators and six sigma

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Abstract

Background: Pre-analytical errors account for up to 70% of all the errors made in laboratory diagnostics which are mostly not directly under laboratory control. Laboratories across the world have been using different Quality indicators (QIs) for identifying and quantification of pre-analytical errors. Objective of the present study is to identify the different pre-analytical errors with their frequency and to assess the pre-analytical phase performance of emergency laboratory by using harmonized Quality Indicators and six sigma metrics.

Methods and material: A prospective observational study was conducted from January 2019 to December 2019 to monitor the inappropriateness of samples and test request forms. We have quantified the performance of pre-analytical phase of our emergency laboratory based on the harmonized QIs proposed by The International Federation of Clinical Chemistry Working Group on Laboratory Errors and Patient Safety (IFCC- WGLEPS) and six sigma metrics.

Results: Emergency laboratory received a total of 55431 samples during Jan- 2019 to Dec- 2019. Number of pre-analytical errors were 1089 which accounted for 1.96% of total samples received. Haemolysed samples, clotted samples and samples with insufficient volume were contributed to 37%, 26% and 15% of the total pre-analytical errors respectively.

Conclusions: Pre-analytical phase performance of our emergency laboratory complies with the quality specifications laid by the International Federation of Clinical Chemistry Working Group on Laboratory Errors and Patient Safety (IFCC-WGLEPS). Implementation of harmonised QIs assures the comparability of laboratory findings with different laboratories across the world.

Keywords: pre-analytical errors; harmonized quality indicators; IFCCWG-LEPS

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Introduction

Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process (TTP) is correctly performed, thus assuring valuable medical decision-making and effective patient care [1]. Laboratory total testing process involves pre-analytical, analytical and post-analytical phases. Pre-analytical phase starts from test request to the delivery of the specimen to the laboratory [2, 3].

Pre-analytical errors account for up to 70% of all the errors made in laboratory diagnostics. Most of these are related to, patient preparation, patient identification, sample collection, transportation and storage [4]. These pre-analytical phase procedures of testing process are performed outside the laboratory and are not under direct control of the laboratory.

Pre-analytical errors largely interfere with the test analysis thus affects patient treatment. These errors are proven to be a burden for the laboratory and a serious issue for the hospital administration as sample rejection can leads to loss of critical time and adds to the cost of patient care [5, 6].

Most of the Quality Indicators (QIs) in laboratory medicine tend to focus on the performance and efficiency of analytical processes with less preference to pre-analytical and post-analytical phases [7]. But existing evidence suggests that most errors in the loop actually fall outside the analytical phase, and the pre- and post-analytical steps have been found to be more vulnerable to the risk of error [8]. The lack of attention to extra laboratory factors is the main reason for the multitude of errors that continue to occur in the pre-analytical phase.

Requirements for accreditation against ISO 15189:2012 (Medical laboratories – Requirements for quality and competence) emphasizes that there is a need to evaluate, monitor and improve all the procedures of pre-analytical phase including test requesting, patient and sample identification, sample collection, sample handling, transportation and storage [9].

Identification and effective use of quality indicators of pre-analytical phase is therefore an essential requirement for laboratory accreditation and for useful risk management strategy. In recent years different QIs have been used in different laboratories in order to comply with the requirement of accreditation standards. Due to non-uniformity of methods used by different laboratories for the identification and management of QIs, the results obtained cannot be compared [1].

Standardization in this area of identification and effective use of Quality indicators of pre- analytical phase underpins the effective reporting of errors. This will enable the comparisons between peers and identification of areas for improvements in the TTP. These QIs then provide a harmonized platform for targeted continuous improvement and a means of measuring said improvements [1]. The International Federation of Clinical Chemistry Working Group on Laboratory Errors and Patient Safety (IFCC-WGLEPS) has worked to improve awareness in the field of laboratory errors and patient safety, developed pilot studies to monitor error rates and implemented projects to reduce errors [10, 11]. IFCC-WGLEPS has developed harmonized quality Indicators (QIs) to assess the total testing process of the clinical laboratory (Pre-analytical, analytical and post-analytical). They have also proposed Quality Specifications (QS) for each QI.

A clear definition of how QIs are evaluated and the development of performance levels (e.g., unacceptable, minimum, and desirable) are useful for laboratory performance evaluation, especially in the pre-analytical phase.

Six sigma methodology is another method of quality assessment, which is applicable in the pre-analytical phase. Six sigma provides principles and tools that can be applied when the outcome of the process can be measured. The number of errors or defects done by the laboratory can be quantified using six sigma metrics. Bill Smith, known colloquially as the father of Six Sigma, decided to measure the defects per million (DPM) instead of defects per thousand. The number of errors, or DPM, is a measure of laboratory performance [12].

In order to measure the quality of pre-analytical phase on six sigma scale, it requires monitoring of outcome process, counting the defects and calculating DPM. By using the statistical tables DPMs can be converted to sigma metrics [13]. Quality is assessed on a sigma scale, from 3 sigma as the minimum allowed for

routine performance to six sigma as best-in-class quality. World-class quality processes have a six sigma level, which means around 3.4 errors per million [12].

Most of the existing studies reported pre-analytical errors by using different QIs which are not harmonized and makes them difficult to compare the results across the different laboratories. On the contrary the present study used harmonized QIs to assess and report the pre-analytical errors.

Objective of the current study is to quantify different pre-analytical errors and to assess the performance of pre-analytical phase of emergency laboratory based on the harmonized QIs proposed by IFCC-WGLEPS and Six sigma metrics.

Materials and methods

A prospective observational study was conducted in Emergency Laboratory, Department of Biochemistry, from January 2019 to December 2019 to monitor the inappropriateness of samples and test request forms (TRFs). We have quantified the performance of pre-analytical phase of our emergency laboratory based on the harmonized QIs proposed by IFCC- WGLEPS and Six sigma metrics.

Laboratory setting: Emergency laboratory is equipped with fully automated Chemistry analysers: Roche Cobas C311, Vitro 350, ABG analysers: Radiometer ABL 80 Flex, Cobas b123, Coagulation analyser: ACL Elite Pro, Fiske Osmometer: Osmolality serum &Urine, Alere Triage meterPro: cardiac markers, Cobas h 232: D-dimer, Beckman Access 2 for analysing Immunoassay parameters.

Path of samples: Samples collected from different ICUs, Casualty and wards are transported to emergency laboratory by nursing staff. Once the samples reaches the laboratory technician will check the TRFs which will be signed and stamped by the clinicians and registers the sample in LIS (SUKRAA), barcode with SID(sample identity number)will be generated for each sample.

Followed by registration in LIS, samples are processed for analysis. After centrifugation Unsuitable samples and inappropriate test requests were recognised and identified by virtual inspection by laboratory staff. The laboratory staff working in emergency laboratory are trained to identify and register all the errors that may affect the total testing process, including those that occur in the pre-analytical phase. All unsuitable samples and inappropriate test requests (as per QIs in the table 1) will be notified in LIS and informed immediately to the concerned department.

Data collection

Harmonized QIs proposed by IFCC-WGLEPS [11] were used to quantify the performance of the emergency laboratory in pre-analytical phase.

The following QIs were used to quantify the errors concerning patient identification, errors concerning physician identification were evaluated by QI 5 & 6 respectively. Errors concerning test input- QI 7, lost-not received Q I8, Inappropriate container QI 9, Haemolysed samples QI10, Clotted samples QI 11, Insufficient sample volume QI 12, Inadequate sample-anticoagulant volume ratio QI 13 and Improperly labelled samples QI 15 (Table 1).

During the study period we have counted the QIs on monthly basis. Descriptions for each QI were mentioned in the Table 1. To assess our performance of pre-analytical phase of our emergency laboratory we have compared our results with the quality specifications (QS) reported by IFCC- WGLEPS [11].

Statistical analysis

Pre-analytical errors were calculated for each month and distribution of inappropriateness among the different ICUs and wards were calculated using Microsoft Excel.

We calculated the sigma metric for 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 https://www.westgard.com/sixsigtable.htm. For example, for the QI involving hemolyzed samples, we calculated the sigma value as follows:

DPM = (number of hemolyzed samples biochemistry × 1,000,000)/total number of samples [12].

Table 1: Quality indicators in the pre-analytic phase proposed by IFCC- WGLEPS [1, 11].

QI code	*Description*
QI 1: Appropriateness of test request	Number of requests without clinical question/ Total number of requests
QI 2: Appropriateness of test request	Number of inappropriate requests, with respect to clinical question / Number of requests reporting clinical Question
QI 3: Examination requisition	Number of requests without physician identification / Total number of requests
QI 4: Examination requisition	Number of unintelligible requests / Total number of requests
QI 5: Identification	Number of requests with errors concerning patient identification / Total number of requests
QI 6: Identification	Number of requests with errors concerning physician identification / Total number of requests
QI 7: Test request	Number of requests with errors concerning test input / Total number of requests
QI 8: Samples	Number of samples lost-not received / Total number of samples
QI 9: Samples	Number of samples collected in inappropriate container / Total number of samples
QI 10: Samples	Number of haemolysed samples / Total number of samples
QI 11: Samples	Number of clotted samples / Total number of samples with anticoagulant
QI 12: Samples	Number of samples with insufficient sample volume / Total number of samples
QI 13: Samples	Number of samples with inadequate sample-anticoagulant volume ratio / Total number of samples with anticoagulant
QI 14: Samples	Number of damaged samples / Total number of samples
QI 15: Samples	Number of improperly labelled samples / Total number of samples
QI 16: Samples	Number of improperly stored samples / Total number of samples

Results

Our emergency laboratory has received a total of 55431 samples during the study period. Total test request forms received were 34644. Monthly distribution of total number of samples received, number of pre-analytical errors and pre-analytical error rate were shown in Table 2. Total number of pre-analytical errors were 1089 which accounted for 1.96% of total samples received. Distribution of number of pre-analytical errors from different ICUs and wards during the study period were shown in Table 3.

Haemolysed samples, clotted samples and samples with insufficient volume were contributed to 37%, 26% and 15% of the total pre-analytical errors respectively.

Pre-analytical phase Quality indicators of emergency laboratory as per the IFCC WG-LEPS and performance levels were shown in Table 4.

There were 22 errors related to patient identification (Q I5) with 0.63% of obtained QI and six sigma values of 4.7. Errors concerning physician identification (QI 6) were 11 with 0.31 % of obtained QI and six sigma values of 4.9. Errors concerning test input (QI 7) were 44 with 0.12% of obtained QI and six sigma values of 4.5. There were 22 samples lost-not received (QI 8) with 0.039% of obtained QI and six sigma values of 4.9. Samples collected in inappropriate container (QI 9) were 32 with 0.057% of obtained QI and six sigma values of 4.8.

Haemolysed samples (QI 10) constituted 403 of total pre-analytical errors with 0.72% of obtained QI and six sigma values of 3.9. There were 284 clotted samples (QI 11) with 0.51% of obtained QI and six sigma values of 4.1. Samples with insufficient sample volume (QI 12) were 163 with 0.29% of obtained QI and six sigma values of 4.3. Samples with inadequate sample-anticoagulant volume ratio (QI 13) were 76 with 0.13% of obtained QI and six sigma values of

4.5. Improperly labelled samples (QI 15) were 32 with 0.05% of obtained QI and six sigma values of 4.8. We have observed lowest six sigma value 3.9 for QI 10 and highest value 4.9 for QI 6 & QI 8.

Table 2: Total Number of samples received, number of pre-analytical errors and percentage of Pre-analytical errors during Jan 2019 to Dec 2019.

Month	*Number of samples received*	*Number of pre-analytical errors*	*Pre-analytical errors (%)*
Jan-2019	4378	91	2.07
Feb-2019	4632	98	2.11
Mar-2019	4467	79	1.76
Apr-2019	4298	105	2.44
May-2019	4673	93	1.99
Jun-2019	4574	87	1.90
Jul-2019	4392	91	2.07
Aug-2019	5623	86	1.52
Sep-19	4537	84	1.85
Oct-19	4552	85	1.86
Nov-19	4629	99	2.13
Dec-19	4676	91	1.94
Total	55431	1089	1.96

Discussion

In the present study we have used harmonised QIs to assess pre-analytical phase of emergency laboratory. According to IFCC-WGLEPS, Quality indicator's with 25th percentile value represents the best performance, 50th percentile value represents the most common/frequent performance and 75th percentile value represents the worst performance [11]. Most of our quality indicators showed optimal performance except QI 10 which in desirable range according to specifications laid by IFCC-WGLEPS [11].

Among all the quality indicators we have assessed QI 10, haemolysed samples were 0.72% as compared to 0.4% by Grecu [12], 0.7% by Chawla et al [14] and 0.77%, as reported by Lippi et al [15]. Our study reports 0.51% of clotted samples as compared to 0.77% by Grecu [12] and 0.25% by Lippi et al [15].

Our study reported six sigma metric value for haemolysed samples as 3.9 and clotted samples as 4.1, whereas Grecu et al [12] have reported 4.2 for haemolysed, 4.0 for clotted samples. Sciacovelli et al [11] has reported a six sigma values of 3.6 and 4.4 for Haemolysed and clotted samples respectively.

Sigma values for inadequate sample-anticoagulant volume ratio and samples with insufficient sample volume were 4.5 and 4.3 against values reported

Table 3: Distribution of number of pre-analytical errors from different ICUs and wards from Jan-2019 to Dec-2019.

Month	*Casualty*	*ICU*	*SICU*	*NICU*	*MMWD*	*FMWD*	*MSWD*	*FSWD*	*PWD*	*OGWD*	*Chest WD*	*Total*
Jan-2019	17	12	6	8	7	5	9	3	8	10	6	91
Feb-2019	26	14	10	9	6	9	4	5	6	7	2	98
Mar-2019	18	8	8	10	12	4	3	4	4	5	3	79
Apr-2019	23	11	14	12	8	7	7	3	7	11	2	105
May-2019	14	17	8	14	10	5	5	2	10	5	3	93
Jun-2019	23	9	12	11	7	3	8	3	4	6	1	87
Jul-2019	23	16	13	9	5	4	3	5	6	5	2	91
Aug-2019	17	15	9	13	6	3	6	2	5	7	3	86
Sep-2019	16	12	7	8	8	7	5	2	8	9	2	84
Oct-2019	24	9	8	9	11	2	3	7	4	6	2	85
Nov-2019	18	11	12	15	8	4	5	4	9	9	4	99
Dec-2019	21	8	13	12	10	2	7	3	5	7	3	91
Total	240	142	120	130	98	55	65	43	76	87	33	1089

Abbreviations: MMWD=Male Medical Ward, FMWD=Female Medical ward, MSWD=male surgical ward, FSWD=Female surgical ward, PWD=Paediatric ward, OGWD=Obstetrics & Gynaecology ward.

by Grecu et.al [12] 5.6,4.8 and Sciacovelli et al [11] 5.0,3.9 respectively.

In the current study we have made efforts to use harmonised QIs to monitor and quantify the performance of several steps of pre-analytical phase of our laboratory. These QIs are comparable with Quality specifications laid by IFCC-WGLEPS [11].

The present study showed most common pre-analytical errors are related to haemolysed samples followed by inadequate sample-anticoagulant volume ratio and samples with insufficient sample volume. None of our QIs showed unacceptable performances according to six sigma metrics in our study.

Table 4: Assessment of pre-analytical phase quality indicators of emergency laboratory as per the IFCC WG-LEPS and six sigma.

QI code	*Description*	*No of errors*	*QI obtained value as per description (%)*	*IFCC-based performance level [11]*	*DPM*	*Sigma value*
QI 5: Identification	Number of requests with errors concerning patient identification / Total number of requests	22	0.063	Optimal	635	4.7
QI 6: Identification	Number of requests with errors concerning physician identification / Total number of requests	11	0.03	Optimal	317	4.9
QI 7: Test request	Number of requests with errors concerning test input / Total number of requests	44	0.127	Optimal	1270	4.5
QI 8: Samples	Number of samples lost-not received / Total number of samples	22	0.039	Optimal	397	4.9
QI 9: Samples	Number of samples collected in inappropriate container / Total number of samples	32	0.057	Optimal	577	4.8
QI 10: Samples	Number of haemolysed samples / Total number of samples	403	0.72	Desirable	7270	3.9
QI 11: Samples	Number of clotted samples / Total number of samples with anticoagulant	284	0.51	Optimal	5123	4.1
QI 12: Samples	Number of samples with insufficient sample volume / Total number of samples	163	0.29	Optimal	2940	4.3
QI 13: Samples	Number of samples with inadequate sample-anticoagulant volume ratio / Total number of samples with anticoagulant	76	0.137	Optimal	1371	4.5
QI 15: Samples	Number of improperly labelled samples / Total number of samples	32	0.057	Optimal	577	4.8

Limitations

We have examined the QIs which are more suitable to our quality program, however the present study did not examine QI 1-4, QI 14 and QI 16. Identifying and recording of all QIs require lots of time efforts by the laboratory staff which may not be feasible during night shifts in emergency laboratory.

Conclusion

The present study showed haemolysed samples followed by inadequate sample-anticoagulant volume ratio and samples with insufficient sample volume were most common pre-analytical phase errors. Pre-analytical phase performance of our emergency laboratory complies with the quality specifications laid by IFCC- WGLEPS. Implementation of harmonised QIs assures the comparability of laboratory findings with different laboratories across the world. Harmonised QIs also play a key role in ensuring the targeted continuous improvement activities aiming to reduce the risk of errors.

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Conflicts of interest

Authors declare no conflicts of interest.

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