Original Article

Quantification of Pre-analytical Quality Indicators in a Clinical Laboratory and Formulating the Lean Six Sigma DMAIC Strategy

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Introduction : Quality control of the laboratory has gained increased importance in the present years. 70 % of the errors in the clinical laboratory occur in the pre-analytical phase. With various guidelines to gauge the quality of the laboratory, Six Sigma Metrics remains by far the most difficult benchmark that a laboratory can achieve. We aimed to quantify the performance of the quality indicators of the routine clinical Biochemistry laboratory in the pre-analytical phase in the form of sigma metrics and devise measures and identify steps to decrease the percentage of errors by defining the DMAIC approach.

Materials and Methods : One year retrospective data was collected from January, 2020 to December, 2020 from the data entry register and pre-analytical variables were quantified. Defects Per Million and sigma metric were calculated for each pre-analytical indicator. DMAIC approach was applied and post intervention sigma scores for the month of Jananuary, 2021, February, 2021 and March, 2021 were calculated.

Results : Postinterventional analysis was done on a month-to-month basis to monitor the trend and also to ensure corrective action can be taken without delay. Out of 5 quality indicators which were quantified, the pre *versus* post sigma scores (March'21) are as follows: missing location of the patient (Sigma 4 *versus* 3.6), missing registration number (Sigma 3.7 *versus* 4.3) and both registration number and location missing (Sigma 3.6 *versus* 4.0), Homolysed sample (4.2 *versus* 4.6), insufficient sample volume (sigma 3.9 *versus* 4.7). Encouraging results in the form of improved Sigma scores were seen in four of the quality indicators except for the fact that the patient location were still missing in the forms and hence warrants continuous monitoring.

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***Key words* : Six sigma metrics, Pre-analytical error, Quality indicators, Quality control, DMAIC, Fishbone, SIPOC.**

Patient safety initiatives across all working areas of the hospitals, which includes the laboratories[1] and technological advances have contributed to substantial decrease of errors in the analytical phase of lab processes. The leading source of errors in laboratory are the pre-analytical work processes and is of major patient safety concern[2]. Increased dependency of clinicians on laboratory results for therapeutic decision making has been observed and Evidence Based Medicine is the new way of clinical practice. Hence, accurate and reliable results are undeniably important. The Total Testing Process (TTP) have been traditionally separated into three phases: pre-analytical, analytical and post-analytical phase[3]. Studies in literature have also reported that the highest error rates are related with the pre-analytical phase and these are mostly generated from mistakes in sample containers, insufficient sample for processing, samplehandling, storage, transportation and wrong identification of sample. Homolysis, unclotted sample, inadequate anticoagulant-sample ratio are other common causes of sample rejections at the pre-analytical stage. With the ongoing expansion of diagnostic laboratory with same working hands and budget constraints, we need to simplify the lab processes and eliminate the waste from pre analytical , analytical and post analytical areas so as to keep up the quality as well as the quantity of work. The lean concept of Quality Improvement Focuses on elimination of the waste which are the processes which do not add value to the

Editor's Comment :

- The pre analytical errors, that comprise 70% of the errors in clinical laboratory, can be monitored as well controlled by applying Six sigma metrics.
- The formulation of DMAIC strategy and implementation of the same can lead to improvement of sigma scores in different work areas of laboratory.

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final outcome of the process and Six Sigma is the Philosophy which focuses on improving the quality of processes and focuses on identification and removal of defects by means of Define Measure Analyze Improvement Control (DMAIC).

In our laboratory we performed a lean mapping exercise to identify the sources of pre analytical errors and to devise appropriate solutions in the laboratory including providing training to the laboratory personnel and other related staff. These areas of pre analytical errors are quality indicators for the laboratory also and were identified in compliance with ISO 15189: 2012 Standard and International Federation of Clinical Chemistry (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) Guidelines.

Hence, taking into consideration these guidelines, we first quantified the quality indicators in the pre-analytical phase in terms of DPMO (Defects Per million Opportunities) and six sigma metrics and implemented corrective measures by following the DMAIC strategy and installation of LIS (Laboratory Information System) and reassessed the sigma metrics again to see the impact

Aims and Objectives

(1) To quantify the performance of the quality indicators of the Routine Clinical Biochemistry laboratory in the **pre-analytical** phase in the form of Defects Per Million Opportunities (DPMO) and further apply Sigma metrics.

(2) To formulate the DMAIC strategy for the quality indicators

(3) To reassess the DPMO and Sigma Metrics post intervention and see the impact of DMAIC strategy on sigma levels in the next three months

Materials and Methods

This study was designed to observe the before – after analysis of lab processes in the pre- analytical phase in a teaching hospital. A quality improvement team collected the following data: One year retrospective data was collected from January, 2020 to December, 2020 from the data entry register of the In-patient Department and pre-analytical variables was quantified. DPMO and Sigma Metric was calculated using the following formula : DPMO = (number of errors × 1,000,000)/total number of specimens or requests. The DPMO rate was then converted to a Sigma value based on online calculator[4].

DMAIC strategy was formulated by the laboratory team and post training of the Laboratory and Hospital Staff, data was again collected from January, 2021 to March, 2021 and quantified into DPMO and Six Sigma in a month wise manner.

The data was plotted on MS-EXCEL and all the statistical calculations were performed on the same.

Intervention : The intervention was focussed on reorganization of laboratory workflow along with staff training. To see the impact of training after sensitization and explaining the motive of the study, a semi-structured feedback questionnaire having both closed- and open-ended questions, which was validated by 3 Lab Faculty Members, was filled by the laboratory technicians and the Hospital Staff.

Pre-intervention : All samples were received by the Clinical Biochemistry Laboratory from the IPD during January, 2020 to December, 2020 were analyzed for pre analytical errors which were documented in laboratory records. Sample rejection criteria was as follows: unclotted sample, sample contaminated with Ethylenediaminetetraacetic Acid (EDTA), sample for which only the requisition form was received and sample was not received, samples which had been received with wrong test requests or samples which have been received in wrong vials.

Postintervention : DMAIC strategy was formulated and training session were initiated amongst the Laboratory and Hospital Staff. Laboratory Information System (LIS) was installed for the first time in the Clinical Laboratory making a headway for immediate improvements with respect to certain parameters particularly patient identifiers. DPMO and Sigma metrics were calculated again post intervention for the month of January, 2021, February, 2021 and March, 2021.

Results

A total of 26,343 samples were received by the Clinical Biochemistry Laboratory in a period of one year from the IPD during January, 2020 to December, 2020. The total number of pre-analytical errors was 1691 which amounted to 6.4 % of the total of 26,343 collected samples as seen in Table 1.

Preanalytical quality indicators and their DPMO along with Sigma metrics have been tabulated in Table 1.

Amongst the total pre-analytical errors in the pre-interventional period, the most common error, 34.29% (Sigma level=3.6) was unavailibity of both the information about the location as well as registration number of the patient out of which 24.83% (Sigma level=3.7) of the samples had missing registration numbers and 9.46 % (Sigma level=4) of the samples had the IPD location missing. So maximum percentage of error comprised of missing or incomplete patient

Table 1 — *Showing DPMO and six sigma of pre-analytical quality indicators in 26,343 samples from January, 2020 to December, 2020*

Pre-analytical Variables	Frequency of errors	% of total errors	% of total patient samples	DPMO	Six Sigma score
Location/Regn no missing	580	34.29	2.2	22017	3.6(minimum)
Quantity not sufficient	220	13.01	0.838	8351	3.9(minimum)
Regn no missing	420	24.83	1.59	15944	3.7(minimum)
Location missing	160	9.46	0.609	6074	4.0(minimum)
Hemolysed sample	97	5.73	0.3682	3682	4.2(good)
Sample not clotted	47	2.77	0.18	1791	4.5
Contaminated sample	79	4.67	0.299	2999	4.3
Diluted sample	7	0.41	0.0266	267	5
Sample not received	47	2.77	0.1784	1784	4.5
Wrong test	25	1.47	0.094	953	4.7
Wrong vial	6	0.35	0.023	229	5.1
Unlabelled sample	3	0.177	0.011	114	5.2
Empty Vial	2	0.11	0.008	76	5.3
Total	1691(6.4%)				

identifiers. These samples were not rejected but tested and reports were given to the patient based on their demographics wherever possible. Detailed comments were added notifying the clinicians of possible sources of errors and the need to rectify them or repeat the test to avoid identification fallacy.

Apart from this, the Sigma scores for inadequate volume of sample (13.01%) and hemolyzed samples (5.73%) was 3.9 and 4.2 respectively in the pre-intervention period.

After implementation of DMAIC strategy and optimization of work flow, postintervention Sigma metrics was tabulated and can be seen in Table 2.

Discussion

This study was undertaken in the Department of Clinical Biochemistry laboratory for a duration of one year with a view to identify the Sigma Metric Level at which the laboratory was functioning. Following this, DMAIC approach was applied and Six Sigma was reassessed to see improvement in the control processes. The main objective behind this study was to identify indicators which have poor or minimum acceptability and take steps in improvising those areas by careful utilization of the available manpower and resources, optimizing their use and thereby improving upon the Sigma score. Our goal was never to attain a sigma score of 6. However, improvement on the present scores has been the agenda. To attain the present aim, the basic scientific model that we decided to use was the 'DMAIC': Define, Measure, Analyze, Improve and Control approach. *Define* corresponds to the plan step *measure* to the do step, *analyze* to the check step, *improve* to the act step, and *control* to the prevention of the error occurring again. This is a powerful tool because we can plan more effectively until we obtain a desirable degree of quality. The pre-analytical quality indicators for which DMAIC was applied were Hemolysis, incomplete patient identifiers such as location/ward and registration number and insufficient sample volume. Training on sample collection techniques was provided whenever possible via both the online and the offline mode. The DMAIC strategy as applied has been mentioned below:

Define : The main objective in this stage was to identify with the problem areas in the pre-analytical phase. In a Medical Laboratory Six Sigma process focusses on improvement of patient/clinician satisfaction. The Critical to Quality (CTQ) indicators were the quality indicators chosen for this phase. The Suppliers Input Process Output Customers (SIPOC) map helped in defining the problem.

In our hospital, requisition forms received from the IPD are filled up by the Medical Interns and Nurses with patient particulars. Ideally the requisition form should include the patient particulars such as name, age, gender, ward, registration number, test name, sample type, clinical diagnosis and date and time of sample collection. It was noted that the requisition forms were mostly incomplete with details about patient identification such as location/ward and registration number missing. This was an eye-opener as even the WHO recommends that at least two patient identifiers should be present on vacutainers and requisition forms for identification of patient sample and dispatch of reports[5]. Since this study includes population from the IPD, it was deemed necessary to *define* this problem with the help of SIPOC map as shown below in Fig 1.

Table 2 — *Showing comparison of Six sigma metrics of the pre-analytical variables in the pre-intervention and postintervention period spread over a period of three months*

Pre-Analytical Variable	Pre-intervention Jan 2020 to Dec 2020		Postintervention (DMAIC and LIS) Jan 2021	Feb 2021	March 2021
Location/regn No missing	3.6(minimum)	DMAIC & LIS Installation	3.9	4	4(good)
Insufficient volume	3.9(minimum)		4.7	4.4	4.7(good)
Regn no missing	3.7(minimum)		3.9	4.2	4.3(good)
Location missing	4.0(minimum)		3.4	3.4	3.6(minimum)
Hemolysed sample	4.2(good)		4.2	4	4.6(good)

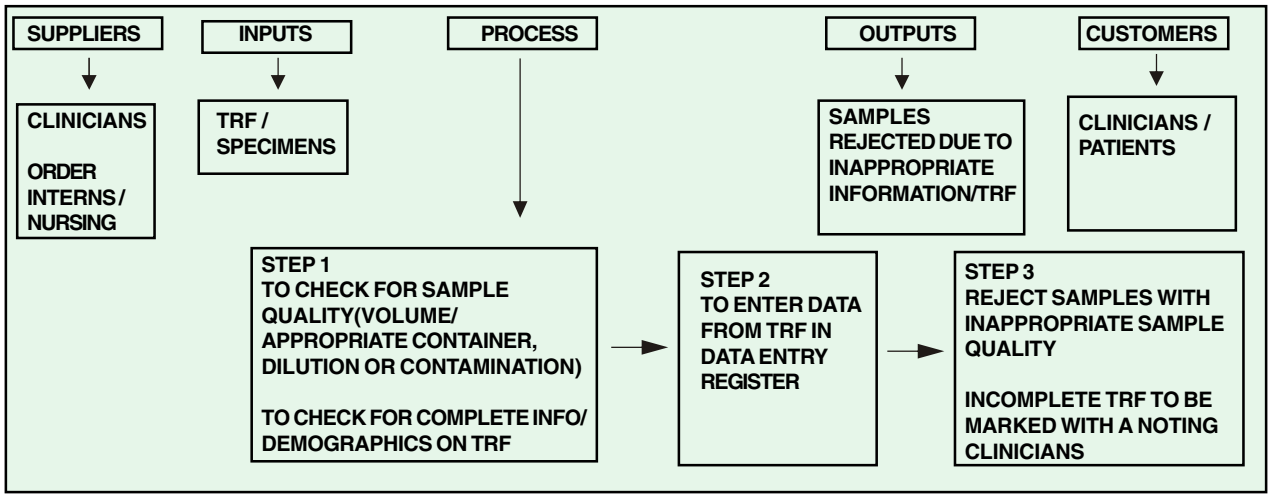

Fig 1 — Showing the SIPOC map for defining the pre-analytical phase of sample collection as a part of process improvement

Measure : In our study in the pre-interventional phase, we measured the DPMO and Six sigma scores. This phase tells us metrically where our lab performs. Hemolysis was seen to be the third most common pre-analytical error with sigma score of 4.2. However, Zaini *et al* in their study mentioned that Hemolysis was the most common error in their setting[6]. Grecu *et al* in their study also mentioned that the hemolysis was the most frequent error in their setting[3]. For Hemolyzed samples, the most recommended provisional specification is 0.6%which is equivalent to sigma value of 4.1 as reported by Gomez *et al*[5]. The most common location from where the Hemolyzed samples were received in our setting was the Hospital Nursery. It is not uncommon for the Sample from Neonates and Children to be hemolyzed . However, due to decreased admission rates in the age group <16 years during the COVID Pandemic, number of such samples received might have been less. However, when we converted our DPMO value into its corresponding Sigma value it turned to be 4.2 on the Sigma Metric Chart which showed an overall acceptable performance. The Sigma score for insufficient sample volume was 3.9 which depicts minimum acceptability. A study done by Alsina *et al* reported a Sigma value of 4.3-5 as specification for insufficient sample[5]. Sigma scores for unavailabity of both the information about the location as well as registration number of the patient, missing registration number and missing information about the ward was 3.6 , 3.7 and 4.1 respectively .

Analyze : By the data measured we tried to find out the root cause analysis of the pre- analytical errors. Qualitative analysis of the preanalytical errors by means of Fish bone diagram was done as shown in Fig 2.

Errors due to Haemolysis and insufficient sample volume demanded resampling and is identified as a non-value-added activity and bottleneck in blood collection in pre-analytical processes[7]. Observations and interviews of the Technical Staff, Nurses and Interns helped us identify error-prone practices and process variation. This needed to be addressed because resampling or double pricks would definitely add to the increase in the turn-around -time for the patient, over and above to the negative feedback and patient dissatisfaction. With regards to patient identifiers, it was observed that the data used to be either missing or incorrect. This would lead to wrong reporting against the sample tube in case the identification particulars are not mentioned on the sample tube and similarly on the requisition form. Maximum number of hemolyzed and insufficient samples mostly came from the Neonatal ICU, Pediatric Wards and Patients of the Geriatric Age Group. Hence, it was found to be pertinent enough to measure these pre-analytical errors, identify the particular ward and the particular phlebotomist.

Improve : The labelling errors in the pre-intervention phase were best solved by the installation of Laboratory Information System (LIS). The laboratory earlier did not have the facility of LIS and hence, installation of LIS along with proper training of the Hospital Staff reinforcing the importance of patient identifiers appeared to be the most common solution. Presence of LIS facilitated in data management and tracking. LIS can help us correctly identify the patient, the location where the patient is admitted, the treating physician, the name, age and gender of the patient. With this myriad of information which can be correctly obtained through the LIS and that too in an organized

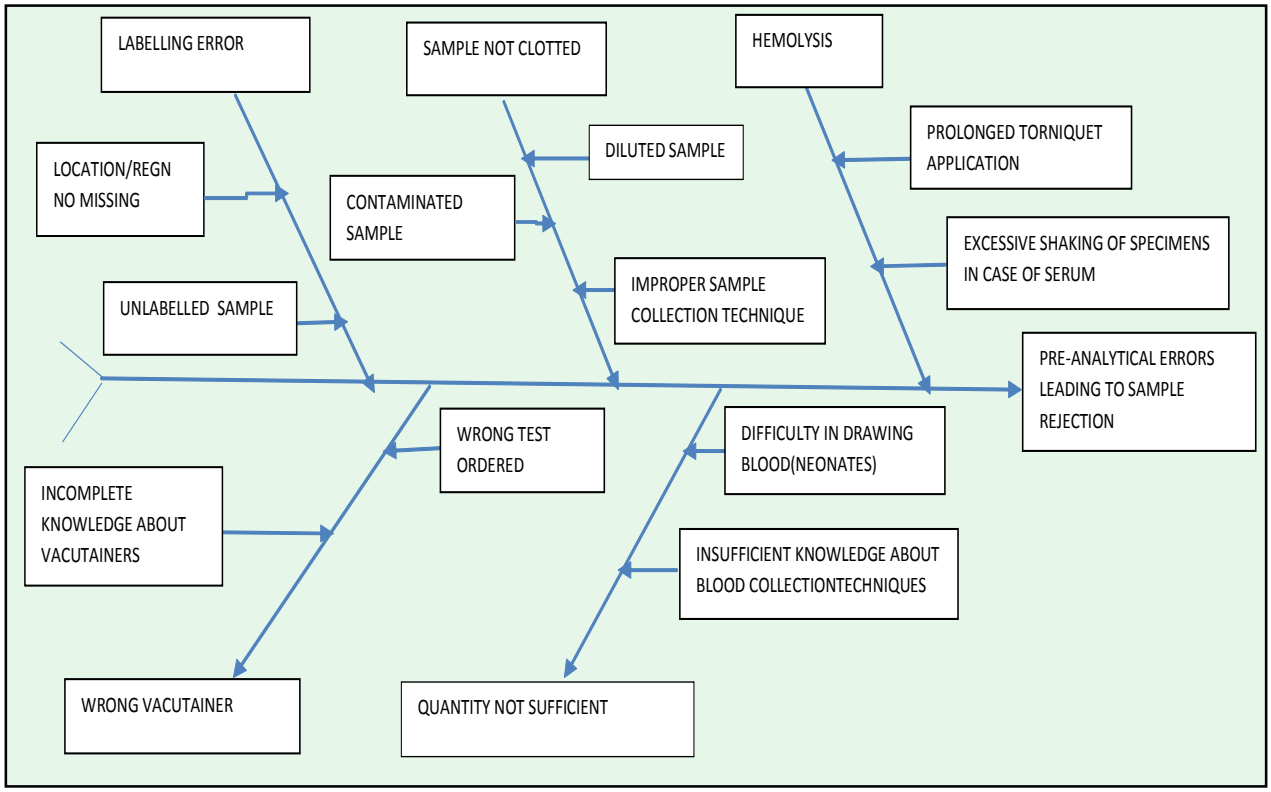

Fig 2 — Showing Root Cause Analysis using Fishbone Diagram/Ishikawa Technique as Part of the Analyze Phase of the DMAIC Strategy

manner, definitely warrants the installation of such a system in the laboratory. The benefits of the LIS further outweigh its cost. Hence, after installing the LIS in the month of January, 2021, a follow-up study was planned to validate the solution by comparing the pre- and postintervention DPMO and Sigma score.

The best possible way to improve the sample collection technique thereby controlling the rate of Haemolysis or inadequate sample volume, was training the phlebotomist, the nurses in the IPD and the Interns. Before starting the training process, we decided on assessing them via a pre-test with regards to their knowledge on sample collection techniques. Based upon their test scores problem areas were defined and identified with. It was important to put across the impact of Homolysed sample on patient results and the treatment that follows based on those results to make the workforce realise the impact of correct techniques. Study materials were prepared which included various causes of Haemolysis, appropriate sample collection techniques were dealt in details and included in the SOP of the sample collection centre and also circulated amongst the Nurses and the Interns via face-to -face classes and also via the online mode. Continuous training was provided and the work was properly monitored. A post- test assessment was then done to identify the improvement. We decided to calculate the Sigma Metric value post intervention to get a real time idea about the performance of the indicators. Overall increase in the Sigma score was seen for Haemolysis in the month of March with a Sigma score of 4.6 against 4.2 in the pre-interventional period as seen in Table 2.

Samples from Neonates, Geriatric, Pediatric population group, Ignorance amongst phlebotomist, samples from patients on chemotherapy, patients with Chronic disease are other causes for insufficient sample volume. Hence, this group was given special attention and training initiated according to the SOPs. The sigma scores in the pre-interventional period were 3.9 which improved to 4.7 in the month of March in the postinterventional phase.

The advantages of LIS were tapped in after its implementation. Postintervention in the period from January, 2021-March, 2021the Sigma value for the missing registration number, for missing location and for both the location and registration no missing was 4.3, 3.6 (minimum acceptability) and 4 respectively. This showed an improved performance and acceptability than the pre-intervention values.

Control : Our objective in the last stage was to develop metrics that would help monitor and document continued improvement. Six Sigma strategies are adaptive and ongoing. Adjustments can be made and new changes may be implemented as a result of the completion of this first cycle of the process. The performance of the quality indicators after improvement has to be measured routinely and accordingly adjustments have to be made in operations. If the Control phase is not implemented, the processes may revert the project to its previous state[7].

The DMAIC approach led to the improvement in the Sigma scores of patient identifiers, Hemolysis and insufficient sample volume. However, the Sigma scores for registering the location/ward showed a downtrend. Further training, optimization of resources, changes in the present techniques and adaptability of the workforce to these changes will be required.

Limitation :

The most important limitation of the present study was that the retrospective data was that of during the First wave of COVID in India. The number of samples received were less compared to Non-COVID times. However, we may assume that since the results were quantified in terms of percentage of defects and DPMO, it may help us in adjusting the biasness due to reduced sampling.

Conflicts of Interest : None declared.

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References

1 https://www.who.int/teams/integrated-health-services/patient-safety/about
2 Lippi G, Plebani M — Identification errors in the blood transfusion laboratory: A still relevant issue for patient safety, *Transfusion and Apheresis Science* 2011; **44(2):** 231-3.
3 Grecu DS, Vlad DC, Dumitrascu V — Quality indicators in the preanalytical phase of testing in a stat laboratory. *Lab Med* 2014; **45(1):** 74-81. Available from: doi:10.1309/lm9zy92ybzrfpfqy. PMID: 24719991
4 http://www.westgard.com/sixsigma-table.htm
5 www.melap15189.com/pdf/SIX SIGMA IN MEDICAL LABORATORIES.pdf
6 Zaini RG, Dahlawi HA, Abdullah S — Identification of the types and frequencies of Pre-analytical Errors in the clinical biochemistry Laboratory: 1-year Study at Hera'a General Hospital Clinical Biochemistry Laboratory, *Archives of medicine* 2016; **8(4):** 8. doi:10.21767/1989-5216.1000152
7 Patil B — Alok, Inamdar KH. Process improvement using DMAIC Approach: Case study in Downtime Reduction. *International Journal of Engineering Research &Technology (IJERT)*, 2014; 3(3).