Original Research Article

Impact of intervention on various quality indicators (turn around time and six sigma) in hematology laboratory

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A R T I C L E  I N F O

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A B S T R A C T

Introduction: The laboratory Turn Around Time (TAT) can be defined differently according to the test type (stat vs. routine), analyte, and institution. It is commonly defined as the time from when a test is ordered until the result is reported. The total TAT for laboratory assays includes the entire interval from ordering of the test to the clinician’s awareness of the result (i.e., “brain-to-brain”). Six Sigma has been characterized as the latest management fad to repackage old quality management principles, practices, and tools/techniques. Sigma methodology can be applied wherever an outcome of a process is be measured. A poor outcome is counted as an error or defect, which is quantified as Defects Per Million (DPM). Six Sigma is a methodology targeting zero error (3.4 errors per million events).

Materials and Methods: Samples received in the haematology laboratory are processed in 8 part haematology Autoanalyser. Results are reported as per routine procedure in the lab. Turn Around Time (TAT) for complete blood count parameters are calculated for one month. The standard Turn Around Time for the complete blood counts are 4 hours. Sigma value is calculated for complete blood count parameters for one month using the formula: $\Sigma = \frac{|TEa - bias|}{CV}$. Six sigma is calculated by Defects Per Million (DPM). Reduce the error rate by guiding the laboratory technician on analytical part of sample processing and value for the same parameters. Repeat the Turn Around Time and Six sigma value after training for one month and compare the error rate.

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1. Introduction

Clinical diagnostic laboratories play a critical role in the diagnosis of many human diseases; it has been doing so for decades now.1 Laboratory testing influences a majority of clinical decision-making. In today’s healthcare environment of managed care and cost containment processes, laboratorians have to work collaboratively with other healthcare professionals, the sole focus being on improvement in medical outcomes. It has been suggested that the importance of laboratorians must have been proven in guaranteeing the quality of tests and improved quality of the services.2

Statistical Quality Control was first introduced in clinical laboratories by Levey and Jennings in 1950.3 The Quality Control gained wide acceptance in later years and most laboratories adopted it as a standard of practice by 1960’s. Laboratory medicine has been at the forefront of many quality improvement initiatives since then. It has been demonstrated previously that modern quality tools and techniques have been applied to improve medical processes by finding the causes as well as solutions to the defects plaguing the system.4,5

The laboratory Turn Around Time can be defined differently according to the test type (stat vs. routine), analyte, and institution. It is commonly defined as the time from when a test is ordered until the result is reported.6 The total TAT for laboratory assays includes the entire interval from ordering of the test to the clinician’s awareness...
of the result (i.e., “brain-to-brain”). It consists of the intervals from order placement to specimen collection, as well as the time necessary for transport to the laboratory, accessioning in the laboratory, centrifugation, aliquoting, additional preanalytic steps if necessary, transport times within and between laboratories, analysis time, the time after completion of analysis until result verification, and the time it takes for the clinical team to be informed of the result. The effects of TAT have been studied to a high extent, with correlations being drawn between emergency department treatment and length of stay. As a result, TAT is often considered the most significant measure of a laboratory’s service and is used by many clinicians to judge its quality. Along with accuracy and reliability, timely reporting of laboratory test results is now considered an important aspect of the services provided by the clinical laboratory. The TAT time for haematological investigation in our lab is 4 hours.

Six sigma is a quality management strategy that makes effort to improve the quality of processes and focuses on identification and removal of defects. A defect is considered to be anything that causes dissatisfaction including unnecessary processes and services. Six sigma uses the structured principles like Define, Measure, Analyze, Improve and Control to solve the defects occurring the laboratory.

Clinical laboratories can measure, monitor, and improve their analytical performances over time thanks to Internal Quality Control (IQC) rules, objective analytical quality specifications, and proficiency testing/External Quality Assessment (EQA) programs, which have provided clinical laboratories with a valuable benchmark based on objective data. IQC procedures and EQA programs have significantly improved the intra-analytical quality of laboratory testing. However, studies on errors in laboratory medicine confirm that most errors occur in the pre-analytical and post-analytical phases of testing.

Turn Around Time is often considered the most significant measure of a laboratory’s service and is used by many clinicians to judge its quality. Along with accuracy and reliability, timely reporting of laboratory test results is now considered an important aspect of the services provided by the clinical laboratory. Whether or not, faster Turn Around Time can make any medical difference, patients and their physicians want reports as rapid as possible. Also it has been shown that outcomes in certain situations such as operation theatres and in emergency departments have been affected by timely reporting of lab tests results. Hence, rapid laboratory Turn Around Time is important both from a medical and commercial point of view.

Total laboratory testing process is divided into three phases, namely: pre-analytical, analytical and post-analytical, and TAT depends on these three phases. The pre-analytical phase refers to the period between requisition of test to the sample being reached to the hands of professionals and prepared for analysis. The analytical phase is the period of measurement: this is the interval between the beginning of the measurement (actual testing) and the confirmation of the test results. The post-analytical period indicates the time from result verification or printing to the time when the physician actually observes the results.

The “quality system” terminology originates from ISO 9000 Quality Standards that have been used in business life and industry. A Quality system comprises organizational structure, liabilities, procedures, operations and sources that are required for quality management. This system has also been modified for medical sciences. Laboratory medicine specialists emphasized the quality control model in daily operations such as instrument calibration and validation, reagent performance, linearity measurements, and result output. Total quality management including policies, written documents, organization, personnel, equipment and safety has been applied in pathology laboratories worldwide.

Six Sigma has been characterized as the latest management fad to repackage old quality management principles, practices, and tools/techniques. Sigma (σ) is the mathematical symbol for Standard Deviation (SD). Six Sigma was developed at Motorola by an engineer Bill Smith in the mid 1980s. It was proclaimed as a new approach to improving quality through statistical measurements and benchmarking. Sigma methodology can be applied wherever an outcome of a process is be measured. A poor outcome is counted as an error or defect, which is quantified as Defects Per Million (DPM). Six Sigma is a methodology targeting zero error (3.4 errors per million events). This method has also been used as a statistical term demonstrating a process’ degree of deviation from excellence. Six Sigma enables the determination of the number of defects per million events via monitoring the processes.

Six Sigma has been used in industrial sciences for regulating validity according to statistical analyses and improving quality and minimizing errors in operation processes. Six Sigma was first used by a Japanese company in the 70s for decreasing the error rate. The five main principles of Six Sigma are: 1. Defining, 2. Measuring, 3. Analysis, 4. Improving, and 5. Control. It is suggested that Six Sigma can have positive impacts on efficiency of laboratory safety. Six Sigma approach in laboratory medicine was first tested in pathology, and the data of Q-Probes Program created by College of American Pathologists are present in literature. Six Sigma is a procedure of detecting errors used for the purpose of improvement under the roof of total quality management.

In clinical diagnostic laboratories, the mistakes and blunders contribute primarily to erroneous laboratory
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results. The precise magnitude of the error rate is difficult
to determine for two important reasons, under-reporting or a
complete lack of feedback and difficulty in error detection.
It is in such instances that the true value of adopting six
sigma quality initiatives can be appreciated. It should also
be noted that in the six sigma methodology, the errors are
expressed as rates and not as absolute numbers. So it is
essential to estimate the turn around time and six sigma in
Hematology laboratory. The aim of the study the impact
of intervention on various quality indicators (Turn Around
Time and six sigma) in Hematology laboratory.

2. Material and Methods

The study was conducted in the Hematology Laboratory
at Department of Pathology, Mahatma Gandhi Medical
College & Research Institute during the time period
between April 2019 and May 2019. The blood samples
received in the hematology laboratory during this time
period were included for the study.

2.1. Type of study

Descriptive study.

2.2. Sample size

2400

2.3. Inclusion criteria

The study includes all blood samples received for Complete
blood counts in the Hematology laboratory.

2.4. Exclusion criteria

Clotted samples

Blood sample received only for peripheral smear.

The study involves calculation of Turn Around Time and
Six Sigma for various haematological parameters like RBC
count, Hemoglobin, Hematocrit, WBC count and Platelet
count in the hematology laboratory for one month. Then
the laboratory technicians were trained further in the Pre
analytical and analytical part about the sample processing
for next one month and again the Turn Around Time and
Six Sigma are calculated and compared with previous month
value.

3. Results

The present study is conducted in the Hematology
Laboratory at Department of Pathology, Mahatma Gandhi
Medical College & Research Institute during the time period
between April 2019 and May 2019. A total of 2540 samples
were received in the month of April 2019 and 2600 samples
in the month of May 2019. The blood samples received in
the hematology laboratory during this time period were

Samples received in the hematology laboratory are processed in 8 part hematology
Automounter.

Results are reported as per routine procedure in the lab

Turn Around Time (TAT) for complete blood count parameters are calculated for one
month. The standard Turn Around Time for the complete blood counts are 4 hours.

Sigma value is calculated for complete blood count parameters for one month using the
formula Sigma (σ) = [TTR - bias] / CV. Six sigma is calculated by Defect Per Million
(DPM)

Reduce the error rate by guiding the laboratory technician on analytical part of sample
processing and value for the same parameters.

Repeat the Turn Around Time and Six sigma value after training for one month and
compare the error rate.

Chart 1: Flow chart

included for the study. The test parameter includes RBC
count, haemoglobin, WBC count, Hematocrit and Platelet
count. The test results were reported and updated in the
AOSTA software and the TAT for the RBC count, haemoglobin, WBC count, Hematocrit and Platelet
count were studied.

Before training during the month of April out of 2540
samples 86% of RBC count, Hemoglobin and Hematocrit
were with prescribed TAT. 88% of WBC count and 82% of
platelet count are within prescribed TAT.

After training during the month of May out of 2600
samples 92% of RBC count, Hemoglobin and Hematocrit
were with prescribed TAT. 90% of WBC count and Platelet
count are within prescribed TAT.

After training there is increase in the percentage of
test falling within the prescribed TAT. So after training
additional 5% of RBC count, Hemoglobin and Hematocrit
test were falling within prescribed TAT and overall
percentage reaches about 92%.

The Defects Per Million (DPM) before training for RBC
count is 3937, Hemoglobin is 8268, WBC count is 4724,
Hematocrit is 3937 and Platelet count is 10236. The sigma
metrics depicted in the sigma table for RBC count is 4.2,
Hemoglobin is 3.9, WBC count is 4.1, Hematocrit is 4.2
and Platelet count is 3.9.

The Defects Per Million (DPM) after training for RBC
count is 3077, Hemoglobin is 4615, WBC count is 3077,
Hematocrit is 3462 and Platelet count is 5000. The sigma
metrics depicted in the sigma table for RBC count is 4.3,
Hemoglobin is 4.2, WBC count is 4.3, Hematocrit is 4.3
and Platelet count is 4.1.

4. Discussion

The laboratory quality objectives should be measurable.
The quality indicators must be quantifiable or otherwise
capable of analysis, allowing for an assessment of the
success of the quality system. The quality indicator
Table 1: Percentage of the test reported within given Turn Around Time before training. (April month)

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>Percentage of test fall within TAT</th>
<th>Percentage of test crossed the TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>RBC count</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>2.</td>
<td>Hemoglobin</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>3.</td>
<td>WBC count</td>
<td>88%</td>
<td>12%</td>
</tr>
<tr>
<td>4.</td>
<td>Hematocrit</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>5.</td>
<td>Platelet count</td>
<td>82%</td>
<td>18%</td>
</tr>
</tbody>
</table>

Table 2: Percentage of the test reported within given Turn Around Time after training. (May month)

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>Percentage of test fall within TAT</th>
<th>Percentage of test crossed the TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>RBC count</td>
<td>92%</td>
<td>08%</td>
</tr>
<tr>
<td>2.</td>
<td>Hemoglobin</td>
<td>92%</td>
<td>08%</td>
</tr>
<tr>
<td>3.</td>
<td>WBC count</td>
<td>90%</td>
<td>10%</td>
</tr>
<tr>
<td>4.</td>
<td>Hematocrit</td>
<td>92%</td>
<td>08%</td>
</tr>
<tr>
<td>5.</td>
<td>Platelet count</td>
<td>90%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Table 3: Comparison of TAT before and after training.

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>TAT before training (April month)</th>
<th>TAT after training (May month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>RBC count</td>
<td>86%</td>
<td>92%</td>
</tr>
<tr>
<td>2.</td>
<td>Hemoglobin</td>
<td>86%</td>
<td>92%</td>
</tr>
<tr>
<td>3.</td>
<td>WBC count</td>
<td>88%</td>
<td>90%</td>
</tr>
<tr>
<td>4.</td>
<td>Hematocrit</td>
<td>86%</td>
<td>92%</td>
</tr>
<tr>
<td>5.</td>
<td>Platelet count</td>
<td>82%</td>
<td>90%</td>
</tr>
</tbody>
</table>

Table 4: Six Sigma value before training (April month)

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>Number of defects/ Errors</th>
<th>Six sigma (Defects per million)</th>
<th>Sigma metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>RBC count</td>
<td>10/2540</td>
<td>3937</td>
<td>4.2</td>
</tr>
<tr>
<td>2.</td>
<td>Hemoglobin</td>
<td>21/2540</td>
<td>8268</td>
<td>3.9</td>
</tr>
<tr>
<td>3.</td>
<td>WBC count</td>
<td>12/2540</td>
<td>4724</td>
<td>4.1</td>
</tr>
<tr>
<td>4.</td>
<td>Hematocrit</td>
<td>10/2540</td>
<td>3937</td>
<td>4.2</td>
</tr>
<tr>
<td>5.</td>
<td>Platelet count</td>
<td>26/2540</td>
<td>10236</td>
<td>3.9</td>
</tr>
</tbody>
</table>

Table 5: Six Sigma value after training (May month)

<table>
<thead>
<tr>
<th>S. No</th>
<th>Parameters</th>
<th>Number of defects/ Errors</th>
<th>Six sigma (Defects per million)</th>
<th>Sigma metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>RBC count</td>
<td>08/2600</td>
<td>3077</td>
<td>4.3</td>
</tr>
<tr>
<td>2.</td>
<td>Hemoglobin</td>
<td>12/2600</td>
<td>4615</td>
<td>4.2</td>
</tr>
<tr>
<td>3.</td>
<td>WBC count</td>
<td>08/2600</td>
<td>3077</td>
<td>4.3</td>
</tr>
<tr>
<td>4.</td>
<td>Hematocrit</td>
<td>09/2600</td>
<td>3462</td>
<td>4.3</td>
</tr>
<tr>
<td>5.</td>
<td>Platelet count</td>
<td>13/2600</td>
<td>5000</td>
<td>4.1</td>
</tr>
</tbody>
</table>

Specifically requires collecting and analyzing specific information or data upon which one can determine effectiveness and continual improvement of performance of the laboratory.

ISO 15189-2012 [4.12.4] states that the laboratory shall implement quality indicators to systematically monitor and evaluate the laboratory’s contribution to patient care. When the programme identifies opportunities for improvement, the laboratory management shall address them, regardless of where they occur. Also, it is stated that laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

ISO 15189: 2012- Clause 3.19: “Quality Indicators (QIs) can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.” Clause 4.14.7: In addition, the document specifies that “the laboratory shall establish...”
74.2% of the samples were delayed due to pre-analytical factors. Similarly, a study done by KN. Desai et al.19 suggests that around 24% of the delay was due to analytical factors. So the technicians were given orientation and re-emphasizing the factors involved in pre-analytical part of evaluation. In the present study TAT for all haematological test falls within 4.1 to 4.3 range after training which was in range of 3.9 to 4.2 before training the technical personnel, this findings are similar to the study conducted by the Nevalainen D et al.20

Also there was a remarkable change in the Six sigma value (Defects Per Million) and error rate which again stress upon the fact that continuous and periodic training is mandatory for the technical personnel in the laboratory.

In the present study the yield in percentage for the various haematological parameter ranges from 99.5% to 99.8%, which is similar to study conducted by Moron-Hawkins RC. Laboratory turnaround time. 2002;126(1):11–18. Castaneda LH et al.21

Yield in percentage indirectly depicts the clear view of the percentage of error occurs in a clinical laboratory.

As a part of continuous quality improvement in the laboratory, periodic training and monitoring the laboratory technician is an essential criteria. Apart from this training, they are also sponsored to attend the Conferences and CME programme which further enrich their knowledge and motivate them.

5. Conclusion

Successful implementation of the various quality indicators like Turn Around Time and Six sigma significantly improves the performance in the clinical laboratories. It also further improves the efficiency and promote user satisfaction by ensuring the quality in the laboratory management system. As a part of continuous quality improvement strategies minimum number of quality indicators should be implemented and monitored periodically showed significant improvements and sustainability in the healthcare laboratories.

6. Source of funding

None.

7. Conflict of interest

None.

References


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Sumaty S Professor and HOD

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