Content available at: iponlinejournal.com

IP Journal of Diagnostic Pathology and Oncology

Journal homepage: www.innovativepublication.com

Original Research Article

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

Shanmugasamy K[1,*], Anandraj Vaithy[1], Venkat Ragavan[1], Sowmya S[1], Sumaty S[2]

[1]*Dept. of Pathology, Mahatma Gandhi Medical College and Research Institute, Puducherry, India*
[2]*Dept. of Biochemistry, Mahatma Gandhi Medical College and Research Institute, Pondicherry, India*

ARTICLE INFO

Article history:
Received 05-11-2019
Accepted 22-11-2019
Available online 29-02-2020

Keywords:
Quality indicators
Turn Around Time
Six sigma
Quality management

ABSTRACT

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 haematologyAutoanalyser. 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) = [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.

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

* *Corresponding author.*
E-mail address: samypatho@gmail.com (Shanmugasamy K).

https://doi.org/10.18231/j.jdpo.2020.013

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.[7] The effects of TAT have been studied to a high extent, with correlations being drawn between emergency department treatment and length of stay.[8] 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.[9]

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.[10] 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.[11]

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.[12] 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.[13]

Six Sigma has been characterized as the latest management fad to repackage old quality management principles, practices, and tools/techniques.[14] Sigma (σ) is the mathematical symbol for Standard Deviation (SD).[15] 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 bench marking. 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 monitorizing the processes.

Six Sigma have 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.[16] 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.[17]

In clinical diagnostic laboratories, the mistakes and blunders contribute primarily to erroneous laboratory

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 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.

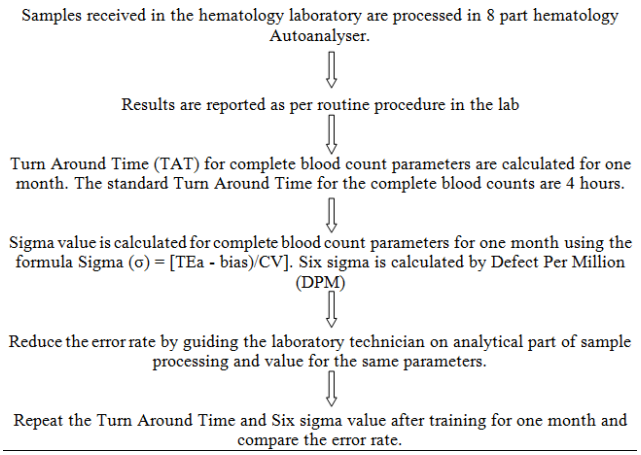

Chart 1: Flow chart

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)

S. No	Parameters	Percentage of test fall within TAT	Percentage of test crossed the TAT
1.	RBC count	86%	14%
2.	Hemoglobin	86%	14%
3.	WBC count	88%	12%
4.	Hematocrit	86%	14%
5.	Platelet count	82%	18%

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

S. No	Parameters	Percentage of test fall within TAT	Percentage of test crossed the TAT
1.	RBC count	92%	08%
2.	Hemoglobin	92%	08%
3.	WBC count	90%	10%
4.	Hematocrit	92%	08%
5.	Platelet count	90%	10%

Table 3: Comparison of TAT before and after training.

S. No	Parameters	TAT before training (April month)	TAT after training (May month)
1.	RBC count	86%	92%
2.	Hemoglobin	86%	92%
3.	WBC count	88%	90%
4.	Hematocrit	86%	92%
5.	Platelet count	82%	90%

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

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

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

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

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

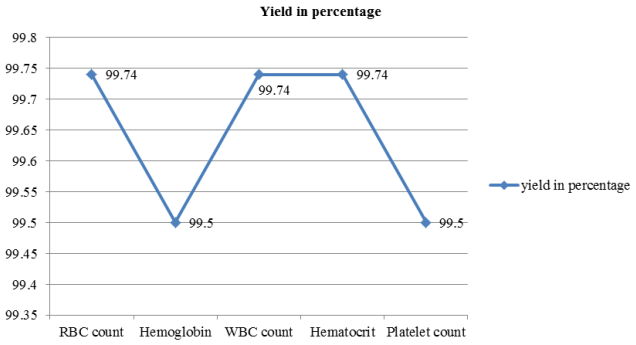

Diagram 1: 1- Yield in percentage from sigma table after training.

QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes."

Statistical analysis was applied for samples taken from ICU departments and Out Patients and In Patients Departments. The average TAT for the samples received from all departments was 4 hours.

A study performed by K. P. Chauhan et al[18] suggested that percentage of specimens exceeding TAT in 2011 was 6.4% which decreased to 4.6% by year 2012. The slightly higher prolonged TAT in our case was due to the registration and billing issues, analyzer errors, inventory of reagent related issues and sample related issues along with reconfirmation and consultation time. In this study, among all factors involved for excessive TAT, pre-analytical factors were responsible for nearly 75% of the delay whereas 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. Similarly, a study done by KN. Desai et al[19] suggests that 74.2% of the samples were delayed due to pre-analytical phase.

In the present study TAT for all haematological parameter shows a significant improvement, which is in concordance with the study conducted by K. P. Chauhan et al.[18] In our study 90% of the haematological test falls within TAT time followed in the clinical laboratory after training the laboratory technician.

In our study the Sigma metrics fall in a range of 4.1 to 4.3 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-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 minimal 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

1. Kotlarz VR. Tracing our roots: the broadening horizons of clinical laboratory practice (1945-62). *Clin Lab Sci*. 1998;11:339–345.
2. Plebani M. The Changing Face of Clinical Laboratories. *Clin Chem Lab Med*. 1999;37(7):711–717. doi:10.1515/cclm.1999.109.
3. Levey S, Jennings ER. The use of Control Charts in the Clinical Laboratory*. *Am J Clin Pathol*. 1950;20(11_ts):1059–1066. doi:10.1093/ajcp/20.11_ts.1059.
4. Witte DL, VanNess SA, Angstadt DS, Pennell BJ. Errors, mistakes, blunders, outliers, or unacceptable results: how many? *Clin Chem*. 1997;43(8):1352–1356. doi:10.1093/clinchem/43.8.1352.
5. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clinical Chemistry*. 1997;43(8):1348–1351. doi:10.1093/clinchem/43.8.1348.
6. Hawkins RC. Laboratory turnaround time. *Clin Biochem Rev*. 2007;28(4):179–194.
7. Kilgore ML, Steindel SJ, Smith JA. Evaluating stat testing options in an academic health center: therapeutic turnaround time and staff satisfaction. *Clin Chem*. 1998;44(8):1597–1603. doi:10.1093/clinchem/44.8.1597.
8. Hawkins RC. Laboratory turnaround time. *Clin Biochem Rev*. 2007;28:179–194.
9. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem*. 1997;43(8):1348–1351. doi:10.1093/clinchem/43.8.1348.
10. Steindel SJ. Timeliness of clinical laboratory tests: a discussion based on five college of American pathologist Q-probe studies. *Arch Pathol Lab Med*. 1995;119:952–961.
11. Steindel SJ, Jones BA. Routine outpatient laboratory test turnaround times and practice patterns. *Arch Pathol Lab Med*. 2002;126(1):11–18.

12. Saquib N, Saquib J, Ahmed T, Khanam MA, Cullen MR. Cardiovascular diseases and type 2 diabetes in Bangladesh: A systematic review and meta-analysis of studies between. *BMC Public Health*. 1995;12.
13. Hollensead SC, Lockwood WB, Elin RJ. Errors in pathology and laboratory medicine: Consequences and prevention. *J Surg Oncol*. 2004;88(3):161–181. doi:10.1002/jso.20125.
14. Schroeder RG, Linderman K, Liedtke C, Choo AS. Six Sigma: Definition and underlying theory⋆ ; 2008,.
15. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, et al. Evaluating laboratory performance on quality indicators with six sigma scale. *Arch Pathol Lab Med*. 2000;124(4):516–519.
16. Nakhleh RE. What is quality in surgical pathology? *J Clin Pathol*. 2006;59(7):669–672. doi:10.1136/jcp.2005.031385.
17. Nakhleh RE, Nosé V, Colasacco C, Fatheree LA, Lillemoe TJ, et al. Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology: Guideline From the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. *Arch Pathol Lab Med*. 2016;140(1):29–40. doi:10.5858/arpa.2014-0511-sa.
18. Chauhan KP, Trivedi AP, Patel D, Gami B, Haridas N. Monitoring and Root Cause Analysis of Clinical Biochemistry Turn Around Time at an Academic Hospital. *Indian J Clin Biochemistr*. 2014;29(4):505–509. doi:10.1007/s12291-013-0397-x.
19. Desai KN, Shah M, Patel K, Ranapurwala M, Chaudhari S, et al. Determination of Turn Around Time (TAT) in NABL (National Accredited Board of Laboratory) accredited hematology and clinical pathological laboratory. *Int J Adv Res (Indore)*. 2013;1(6):192–196.
20. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, et al. Evaluating laboratory performance on quality indicators with the six sigma scale. *Arch Pathol Lab Med*. 2000;124:516–519.
21. Morón-Castañeda LH, Useche-Bernal A, Morales-Reyes OL. Impact of Lean methodology to improve care processes and levels of satisfaction in patient care in a clinical laboratory. *Rev Calid Asist*. 2015;30:289–296.

Author biography

Shanmugasamy K Professor

Anandraj Vaithy Associate Professor

Venkat Ragavan Assistant Professor

Sowmya S Professor and HOD

Sumaty S Professor and HOD

Cite this article: Shanmugasamy K , Vaithy A, Ragavan V, Sowmya S , Sumaty S . Impact of intervention on various quality indicators (turn around time and six sigma) in hematology laboratory. *IP J Diagn Pathol Oncol* 2020;5(1):63-68.