**Implementation of Lean Six Sigma in diagnostic Laboratories with quality standard ISO 15189**

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**Introduction**

Advance diagnostics laboratories have almost replaced manual testing parameter into automated [1]. With high burden of reducing cost with maintaining good quality and turnaround time, Many Clinical laboratories has adapted new approach and modify the procedural system [2][3]. Laboratory Quality management system is one of the main regulatory systems of accreditation. The accreditation is providing by the government based on their scope of testing. There are requirements of different act which need to be complied. It is again based on the specialization of laboratory. i.e., ISO 15189 for diagnostics laboratory [32]. To acquire good quality reports, laboratory needs to emphasize on three important processes of diagnostic laboratory. These are pre-analytical, analytical, and post analytical phases [4]. However, the most common error is pre – analytical errors. As per ISO 15189, The pre-analytical phase includes the steps starts from the patients request form, patient preparation, collection & transportation of primary specimens to laboratory [32].

**Laboratory Quality standard (ISO 15189)**

ISO 15189 is an international standard used by diagnostics laboratories to build their quality management systems and to appraise their competence [32]. Laboratory requires this standard document to propose and implementation of actions to focus risks and opportunities [5]. When laboratory involved to addressing both opportunities and risks, it establishes to increase the validity of the quality management system, improvised results, and preventing adverse effects. This document will accelerate collaboration between laboratories and other organization [6]. It also aids in the commute of information and experience, and in the cooperation between the standards and procedure. This document provides harmonization between standards and procedure [7].

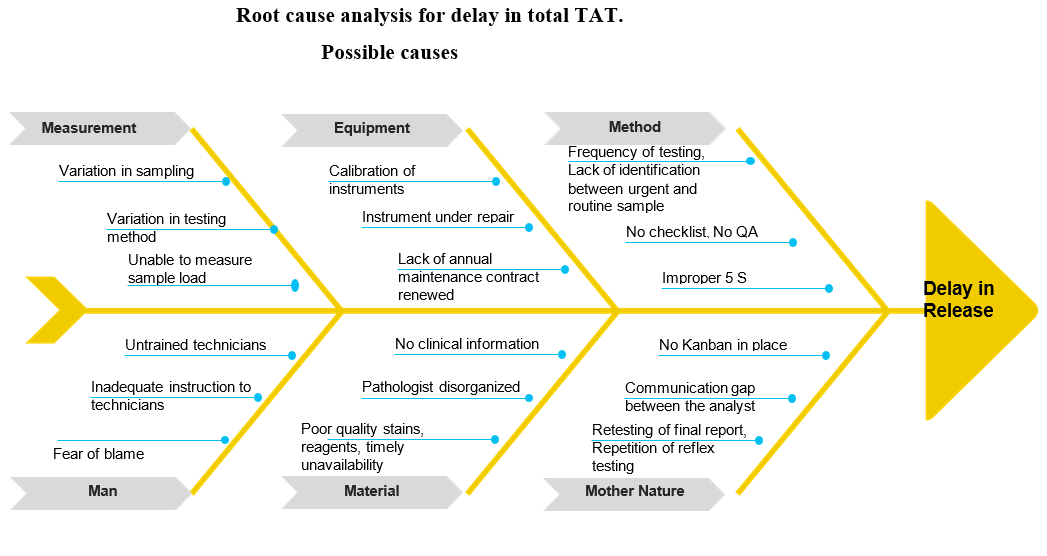


Figure – 1: Possible root cause for delay in repport release in clinical laboratory [12].

**Tools and Techniques of Lean Six Sigma**

The decision of Lean Six Sigma tools and techniques relay on the following:

* Type of service / processes
* Depend on used of approach (DMAIC / DMADV)
* Behaviour of Data (Quantitative/ Qualitative)
* Based on employee’s learning and competency level, which will help to understand and implementation.

Most widely used approach is DMAIC, which stands for Define, Measure, Analyse, Improve & Control while DMADV means Define, Measure, Analyse, Design & Verify. The implementation of DMAIC methodology when a process or results is in existence in a company but it not matching with customer specification [12].

Based of Laboratory case, the below factors can take into consideration in selection and implementation of Six Sigma techniques [14].

* DMAIC Approach
* Behaviour of Data: qualitative and quantitative
* Education and competency level of employee
* Adaptability with the ISO 15189

**Implementation of Lean Six sigma in diagnostics laboratories with ISO 15189 standard**

To justify the purpose of this chapter which mentioned objective – Implementation of Lean Six sigma in diagnostics laboratories with standard. Some important aspect needs to understand the below requirements:

**A.** ISO 15189 standard specific clause requirements for quality improvement & control of processes: The clauses:

1. The clauses 5.5 which is highlighting the Ensuring the validity of test results,

2. The clauses 4.9 which includes Complaints and

3. The clauses 4.13 which includes non-conforming work.

All these clauses are like the quality control and improvement procedure. Also, these three clauses are very important and fundamental for laboratory accreditation [18].

**B.** One typical clause(4.15.2) says “Data from observation activities should analyzed periodically, used as a control and to improve the laboratory's procedure [20]. If the results of the analysis of data from observed activities are found to be out of pre-defined factor, appropriate action shall be taken to avoid incorrect results from being reported.” Because of this requirement allows the laboratories to implement the quality improvement tools which needed to achieve the performance and this study proves worth.

**C.** Diagnostics laboratory process needs: Most of the diagnostics laboratories will carry out the procedure either by instrumental or through wet laboratory procedure and sometimes combination of both [21].

**Lean Microbiology:**

In today’s world of health care, the laboratory is position of aggressively change of new disease, new technologies, new health care delivery techniques, a changing work area, economical pressure, and evolving reimbursement combine to challenge the; laboratory in ways that were unimaginable even decades ago. Lean management procedure within the clinical microbiology laboratory can help to focus these challenges both today and in future.

**Examples of Lean initiatives:**

Microbiology laboratory involves the integration of pre – and post analytical processes through incorporation of multiple, modular systems to perform different tests which involves manual plating, incubation, reading and processing of specimens. Through reduced manual processing of specimen, standardization can be established to minimize the human error. Implementation of Lean techniques especially 5 S helps to enhance improve quality of microbiological workflow including enhanced microbial growth, better colony isolation, reduced requirements for bacterial subculture, and reduced time to result [28].

Process involved and improvements:

1. Review of SOPS
2. Staff education
3. Streamlined culture reading with standardized follow-up protocol
4. A pending of specimen’s process at end of second shift by assessment and plating for expansion to 16 hours’ operation. so, technologist significantly reduce the extend of the backlog without the intervention of higher management authority or the need of additional staffing. They were able to accomplish this by identify key barriers in specimen processing time and its peak hours for specimen receiving.
5. To apply on First –in, first- out approach to specimen processing and associated with other department to reduce batch sizes of samples through more frequent specimen pickups.
6. Application of evidence-based decision making, which is core concept of Lean. When resources are limited, the natural tendency is to provide a simple fix to a problem.
7. Standardization of work process by standard work document to visual aid and for reading and reporting of different specimen types.
8. Physical redesigned of work benches including storage and clear labelling of all items. By standardizing each workstation, there was reduced room for error and reduce time for search of reagents and materials.
9. Kanban used for inventory management of laboratory resources allowed for reduced need for extra storage space and waste due to unnecessary inventory by more usage pattern and ordering.
10. Routine analysis over time allowed the department to adjust the timing of negative-preliminary results reporting to reduce the number of amended reports.
11. Despite multiple use of PDCA cycle, all microbiological sample’s culture reports like pus, urine, blood, respiratory, fluids, no improvements were noted. So as a part of process of continuous improvement, all culture reports were started released in form of preliminary and final. This approach immediately shortens TATs (Turnaround time) of report.
12. Most challenging part in microbiology lab. was staff motivation. That had been improved by conducting individual opportunity to demonstrate their organization skill.

**Conclusion**

This chapter is an attempt to understand the key parameter of application of Lean Six sigma in the clinical laboratories. Implementation of Lean Six sigma in the Laboratory Quality standard (ISO 15189), the important results are,

1. Identify and application of proper Lean Six sigma tools and techniques like the clinical laboratory.
2. Selection suitable DMAIC method.
3. To understand the importance of Lean Six sigma in quality control management & improvement of the diagnostics laboratory.
4. Develop framework of Lean Six sigma along with the method and tools & techniques which would be appropriate to the Laboratory standard (ISO 15189) collabration.

So Lean practice within diagnostics laboratory & in Microbiology testing can help to attend many challenges for today and for future.

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