Enhancing laboratory turnaround time performance by combining the implementation of a laboratory instrumentation interfacing solution with six sigma methodology

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ABSTRACT
Objective: Six Sigma is considered to be an important quality improvement tool in the industry. This paper outlines the application of six sigma methodology along with the implementation of a laboratory instrumentation interfacing solution in bringing down turnaround time (TAT) failures in the hospital laboratory sample collection, testing and reporting cycle at GMC Hospital Ajman. This was implemented since the GMC Hospital laboratory was facing numerous client complaints due to TAT failure in reporting of diagnostic test results.

Materials and Methods: To address the problem of high TAT failures the following steps were taken
1. Bar coding of all samples was facilitated and all samples barcoded
2. Random access analyzers interfaced through RS232 ports with HIMS
3. TAT defined for all in-house tests
4. Barcoded samples were scanned and time points noted automatically at collection, receipt in lab, testing on bench, initial technical verification, secondary verification and printing of report. This data was monitored for adherence to the pre-analytical, analytical and post analytical phases.
5. Three cycles of the DMAIC process was used to decrease defect rate and enhance adherence to TAT.
   a. In the first cycle analytical Issues,
   b. In the second cycle pre-analytical issues and
   c. In the third cycle post-analytical issues
      were defined, measured, analyzed, intervention carried out and changes consolidated (DMAIC).

Results: The interventions in three phases of two months each, over a six months period, sequentially brought down TAT failures 45% (pre-intervention) to 33%, 13%, 11%, 4%, 3% and 1% (post-intervention) respectively.

Conclusion: A barcode enabled laboratory equipment interfaced HIMS system combined with Six Sigma Tools was able to significantly enhance adherence to TAT, improve services to physician, resulted in better staff utilization and improve the quality and value of the report by ensuring timely reporting. To consolidate gains and for continual improvement it is now proposed to improve performance by further reduction of TAT by introducing POCT, introducing a dedicated LIMS and auto-verification of samples.

Keywords: sigma six, TAT, laboratory errors

INTRODUCTION
This paper outlines the application of Six Sigma processes in conjunction with information technology processes in a busy hospital laboratory to enhance performance and reduce clinical errors. The patients and physicians using laboratory services had complained of inordinate turnaround time (TAT) delays, lost samples, leading to a direct impact on early diagnosis, delay in the start of early appropriate treatment, patient dissatisfaction, physician dissatisfaction and revenue loss.

Six Sigma is considered to be an important quality improvement tool in the industry. Six Sigma methodologies involve implementing a strategy based on
measurement and data collection focusing on improvement of process and defect reduction developed initially by Motorola in 19811. Two Six Sigma sub-methodologies DMAIC (define, measure, analyze, improve, control) and DMADV (define, measure, analyze, design, verify) are for existing processes and developing new processes respectively so as to perform at Six Sigma quality levels i.e., 3.4 defects per million opportunities. In Six Sigma programs, the PDCA, plan–do–check / study–act (or PDSA) cycle, popularly also known as the Deming cycle or Shewhart cycle is a four–step model for carrying out change. The PDCA cycle should be repeated for continuous improvement.

This paper describes the authors experience in the application of six sigma methodology along with the implementation of a laboratory instrumentation interfacing solution in bringing down TAT failures in the sample collection, testing and reporting cycle2 at a busy hospital laboratory.

**MATERIALS AND METHODS**

The necessity of modifying process in a busy lab required a slight modification of the conventional DMAIC process to the following cycle: Define, Observe, Analyze, Intervene, Measure and finally Consolidate or control (DOAIMC). It also required that the processes of implementation were not disruptive. With this aim following a one month pre-intervention period where detailed observations and technology modifications were carried out, three cycles of two months each of the DOAIMC process were run to address respectively

a. First cycle: analytical issues,

b. Second cycle: pre-analytical issues

c. Third cycle: **post–analytical** issues

The Pre-intervention phase was marked by observation and identification of the problematic issues into pre-analytical, analytical and post analytical areas. Some of the opportunities for improvement identified were:

- **LIMS and QMS**
  - No inter-phasing of equipment with the Laboratory Information Management System (LIMS)
  - No data points available for analysis
  - No documented External Quality Assurance Scheme (EQAS) participation or any outlier corrective action
  - TAT not defined for all in-house tests
  - Bar coding of samples not done
- **Pre-analytical**
  - Missing samples
  - Multiple repeat sample collections
  - Frequent test downs due to kit stock-outs
  - Anecdotal issue reporting
  - Shortage of staff
  - Phlebotomy services also provided by lab staff
  - Staff training inadequate
  - No accreditation or standardization
- **Analytical**
  - Repeat testing leading to loss of revenue
  - Non usage of daily controls
  - Masking instead of calibrator use
  - Manual data entry and typographical errors
- **Post analytical**
  - Delayed reports
  - Random access analyzers interfaced HIMS

To address the identified issues and ensure data based intervention is carried out a system of barcoding of samples was implemented. Barcoded samples were scanned and time points noted automatically at collection, receipt in lab, testing on bench, initial technical verification, secondary verification and printing of report. TAT for each time point for each test was defined. Data was continuously monitored electronically for laboratory adherence to the pre-analytical, analytical and post analytical timelines.
The Random access analyzers were inter-phased through RS232 ports with the LIMS and a bidirectional data flow between the equipment ensured that the appropriate tests were being carried out on the samples sent to the lab obviating data entry errors.

**Phase I: Addressing Analytical issues.**
The following interventions were carried out in this phase. Process of daily equipment maintenance and regular calibration initiated and instrument function improved. EQAS started for all tests from using material supplied by the College of American Pathologists (CAP). Regular calibration and Running controls and good EQAS results gave staff more confidence in reports. Daily Lab stock verification was carried out. Purchase and stores departments set up fresh reorder levels. Kit availability improved with rare stock outs. Staff training on all instruments was carried out. Lab SOPs were written and staff trained on SOPs and documentation. Nursing staff recruited for providing Phlebotomy services freeing laboratory staff for technical duties. Inter-phasing of equipment ensured the ability to follow sample time points through the lab, no manual data entry for majority of samples, no typographical errors and releasing technicians to do another jobs.

**Phase II: Pre-analytical issues**
Patient waiting time was found to be high both for registering the tests, payment and printing of results. The process was streamlined with an electronic queue system and sign boards for separating the cash counter and report receiving. Peak rush hours of lab were identified: manning of phlebotomy stations adjusted to account for patient flow. The time lapse between sample collection and arrival at the testing bench was decreased by ensuring a Lab orderly went to collect sample every 15 minutes and delivered it at the accessioning counter.

**Phase III: Post analytical issues**
With the aim that the time lag between result approval and verification be not be more than 15 minutes the technicians responsible for verification were asked to check every 15 minutes for any pending results. To ensure this the LIMS was configured so as to display verification pending samples by a different color code. A Quality Management System was implemented to align with ISO 15189 and CAP requirements and staff trained on incident reporting an CAPA analysis.

**RESULTS**
The interventions in phases, over an eight months period, sequentially brought down TAT failures 45% (pre-intervention) to 33%, 13%, 11%, 4%,3% and 1% (post-intervention) respectively. The results were noted are displayed in Graph No. 1 and table no 1.

![Graph No1: TAT Failure](image_url)

**DISCUSSION**
Causes of errors in the total testing process described by Plebani\(^3\) are Pre-pre-analytical (46-68%), Pre-analytical (3-5%), Analytical (7-13%), Post-analytical (13-20%) and Post-post-analytical (25-46%). On time and accurate laboratory test results are a cornerstone of effective diagnosis and treatment of patients\(^4\). This study only examined TAT as an index of laboratory performance primarily because of the broad range of issues which needed to be addressed. TAT primarily is an index of overall laboratory performance predominantly since it affects the availability of clinically useable results on time, leading to effective intervention by the physician and early recovery by
the patient. Pre-analytical, Analytical and Post-analytical issues were serially assessed as described above. TAT showed remarkable improvement month on month as evidenced by the data presented. Hawkins states that “For many years, the clinical laboratory has been at the forefront of quality improvement activities in the healthcare sector. Its focus on analytical quality has resulted in an error rate of 4-5 sigma which surpasses most other areas in healthcare”2.

However definitions of areas outside the immediate laboratory environment and its distinct division into five areas has led to effective interventions leading to better management of the extra-analytical phase of laboratory testing. The Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has a Working Group on “Laboratory errors and patient safety” (WG-LEPS). Quality indicators proposed by IFCC and WG-LEPS help benchmarking data for laboratories. Managing the Brain to Brain phases of the total testing cycle is the next challenge for laboratory medicine concept described by Lundberg3,6. Using existing quality management expertise, and conjuction with information technology, the clinical laboratory will have an important role in reducing clinical errors and improving patient safety

### Table 1: TAT failures

<table>
<thead>
<tr>
<th>Phases</th>
<th>Month/ 2013</th>
<th>No of tests done</th>
<th>No of TAT failures</th>
<th>% TAT Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Define and Measure)</td>
<td>January</td>
<td>12515</td>
<td>5907</td>
<td>47.20%</td>
</tr>
<tr>
<td>Phase I (Analyse &amp; Intervene)</td>
<td>February</td>
<td>14678</td>
<td>4985</td>
<td>33.96%</td>
</tr>
<tr>
<td>Phase II(Analyse &amp; Intervene)</td>
<td>March</td>
<td>20684</td>
<td>2903</td>
<td>14.04%</td>
</tr>
<tr>
<td>Phase III(Analyse &amp; Intervene)</td>
<td>April</td>
<td>20596</td>
<td>2310</td>
<td>11.22%</td>
</tr>
<tr>
<td>Control Month1</td>
<td>August</td>
<td>16738</td>
<td>158</td>
<td>0.94%</td>
</tr>
<tr>
<td>Control Month2</td>
<td>September</td>
<td>20459</td>
<td>344</td>
<td>1.68%</td>
</tr>
</tbody>
</table>

### CONCLUSION

A barcode enabled laboratory equipment interfaced HIMS system combined with Six Sigma Tools was able to significantly enhance adherence to TAT, improve services to physician, resulted in better staff utilization and improvement in the quality and value of the report by ensuring timely reporting. To consolidate gains and for continual improvement it is now proposed to improve performance by further reduction of TAT by introducing POCT, introducing a dedicated LIMS and auto-verification of samples.

### REFERENCES