A LEAN SIX SIGMA APPROACH TO CONTINUOUS QUALITY IMPROVEMENT IN THE TEXAS NEWBORN SCREENING PROGRAM

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Lean Six Sigma process in DSHS Laboratory started with Yellow Belt Training (40 staff). Continued with Green Belt (8 staff) and Black Belt Training (4 staff). Currently includes a new level provided in-house, White Belt Training.

Led to:

- Black Belt Project – Improve Space Utilization in the Laboratory – may impact NBS Molecular Testing.
- Yellow Belt Projects – 5S each testing area in NBS – basically clean up, get rid of obsolete consumables.
- Green Belt Projects – Improve NBS Turn Around Times.
- Green Belt Project – (Ch-IP) Improve time from NBS specimen accessioning (Check-In) to punching.
  - See Poster #33 presented by Brendan Reilly.
METHODOLOGY

- Lean Six Sigma
  - Managerial approach
  - Combines Six Sigma methods and tools and the lean manufacturing/lean enterprise philosophy
    - Eliminate waste of physical resources, time, effort and talent
    - Assure quality in production and organizational processes

- The Theory of Constraints
  - Methodology used in Lean Six Sigma
  - Identify the most important limiting factor (i.e. constraint) that stands in the way of achieving a goal
  - Systematically improve that constraint until it is no longer the limiting factor
  - In manufacturing, the constraint is often referred to as a bottleneck
THE APPROACH - DMAIC

- **Define** – define the problem and the project goals
- **Measure** – identify the baseline and key metrics
- **Analyze** – the data and the processes
- **Improve** – implement improvements
- **Control** – maintain and sustain the improvements
Lean Six Sigma and Theory of Constraints concepts were used to analyze the system timeliness and efficiency in the Texas Newborn Screening (NBS) Laboratory.

The Lean Six Sigma Green Belt Team
- 4 Individuals working on Lean Six Sigma Green Belt certification
- Assistance from a Yellow Belt

Goals:
- Examine processes from the arrival of specimens in the laboratory to the final reporting step in an effort to remove delays, duplications and bottlenecks.
- Improve the average overall NBS turn-around-time by 10%, from 5.26 days to 4.73 days, in a way that prioritized the turn-around-time of abnormal results for the most crucial NBS tests.
Data collection
- Forms were created for each area to capture major time points in the process
- 3 bundles/day over a period of 2 weeks
- Data collected was compared to the LIMS data

Data Analysis
- Overall TAT is meeting established expectations.
- The current process flow appears predictable and stable.

Based on data analysis, initiated a series of projects to minimize the time from receipt of the specimen to:
- Release of presumptive positive results for critical disorders
- Release of presumptive positive results for non-critical disorders
- Reporting of complete test result
30,000 Foot Assessment of the DSHS NBS Lab

Error Bars Illustrate One Standard Deviation Above and Below the Averages
Based on results from data analysis and criticality of disorders, 5 projects were selected:

- Check in (Specimen Receiving/Accessioning) and Punching
- Data Entry and Logistics – plan to reassign and reinitiate in near future
- Congenital Hypothyroidism
- Galactosemia
- Tandem Mass Spectrometry
Green belt: Tiffunee Odoms

Goal:
- Initial: To reduce the amount of time specimens spend in the check-in and punching areas.
- Final: To reduce the amount of time specimens spend in the check-in area.
  - Analysis of punching process moved to a new Green Belt Project – Ch-IP (see poster #33)
- Reviewed processes and Standard Operating Procedures (SOPs) for the area
- Evaluate process flow using spaghetti diagram and a modified value stream map
CHECK-IN SPAGHETTI DIAGRAM
After **Measure** and **Analysis** step, recommendation was to adjust to a ‘1 to 1’ or continuous flow process.

- **Check-in Group** implemented the new ‘1 to 1’ process in the **Improve** phase.
  - This allows bundles of specimens to be available for testing throughout the day rather than previous goal of all bundles available by 5 pm daily.

- Allowed the testing areas to model some new punching workflows during 2015 Christmas Holiday for Ch-IP project.
Green belt: Linda Cao

Goal:
- Reduce turn around time with a focus on abnormal results

A workflow diagram of the current process was created, also utilized SIPOC, Fish Diagram, Spaghetti Diagram, and Value Stream Mapping.
- Met with team members to get input on process change ideas
- Currently evaluating SOPs to focus on best areas for improvement
GALACTOSEMIA

- Green belt: Shawn Tupy

- Goal:
  - Reduce the TAT notification for abnormal results

- Measured the current process and theorized the impact if the process were changed from reporting preliminary results on Friday to reporting preliminary results daily.

- Pulled reporting data for abnormal test results.

- Average turn around time (TAT) in a 15-month period from initial abnormal result to notification of Clinical Care Coordination (CCC) is 35 hours and 21 minutes. Goal is to improve TAT by at least 10%.
Results of Analysis Phase

- 17 results met preliminary reporting criteria.
  - 7 samples confirmed with abnormal results
  - 5 samples were borderline abnormal
  - 4 samples were normal
  - 1 sample recovered inconsistent results

Improvement phase recommendation: Notify CCC of abnormal results based upon initial testing results (i.e. a preliminary report).

- 4 out of 17 patients would receive unnecessary treatment for up to 48 hours until the repeat testing is complete.
- 12 out of 13 patients with abnormal or borderline results could be started on treatment the same day as the initial abnormal result was obtained.

Improvement Phase Final Outcome

- Input from Clinical Care Coordination – prefer to minimize parental anxiety by not increasing the amount of preliminary reports.
Green belt: Andrew Vinyard

Goal:
- Reduce TAT for abnormal specimens with an impact on the process as a whole to ensure the overall goal is accomplished

Collected baseline metrics for the area for Measure Phase, completed value stream mapping, held meeting with MS/MS staff for ideas for more effective process, held Wisdom of the Org meeting with team leads and supervisor.
1 micro titer plate = 1 bundle plus QCs  
1 bundle = 88 samples  
1 chunk of data is the data for all 88 samples and QCs on a plate.

Attribute data will be recorded for each step in the spaces provided below that step. Attribute data has not yet been acquired.
During Measure phase, the MS/MS abnormals had a turn-around-time of 1.19 days after punching step, hoped to improve turn-around-time to 1.07 days (10% improvement).

After Analysis phase:

- Some recommendation included: modifying the FDA approved kit to shorten incubation step, working on Sunday, adjusting staff schedules to add an evening or late shift to lab.
- Recommendation selected: Automate 1st Worklist steps. Currently process is very manual and involves handwriting final results.
- Next step is Improve phase.
  - Developed new report in LIMS to replace manual record.
  - Working on updating the SOP.
The baseline data indicated that overall turnaround time met DSHS previously established expectations and process flow appeared predictable and stable.

Check-in project near completion, the impact of the improvement has been positive and will help prepare the laboratory for the next phase – Ch-IP project.

MS/MS project recommendation, although not implemented, is expected to positively impact Texas’s ability to meet timeliness measures.

Overall improvement data will not be available until all projects are completed.

These project will help DSHS meet timeliness measures in future!
Lean Six Sigma approach is suitable for the NBS process to identify bottlenecks and improvement opportunities.

- Data is important. Some data isn’t captured in LIMS (ie. Preliminary Result Reporting).
- Managerial support and guidance is essential – Establish a QI Advisory Committee
- Require resources, time, and collaboration – Persistence is a must!
- Communicate with staff early and often.
- Sequential projects, not in parallel. Focus one at a time.
- Not all recommendations are feasible.