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

## PATRICIA HUNT

V. Telles, T. Odoms, P. Trevino Gonzales, A. Vinyard, L. Cao, S. Tupy, B. Reilly, P. Hunt, R. Lee
Texas Department of State Health Services, Austin, TX

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# OVERVIEW OF CQI PROJECTS AT DSHS

- 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

# OVERVIEW OF THE GREEN BELT PROJECTS

- 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.

# ESTABLISHING A BASELINE

- 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
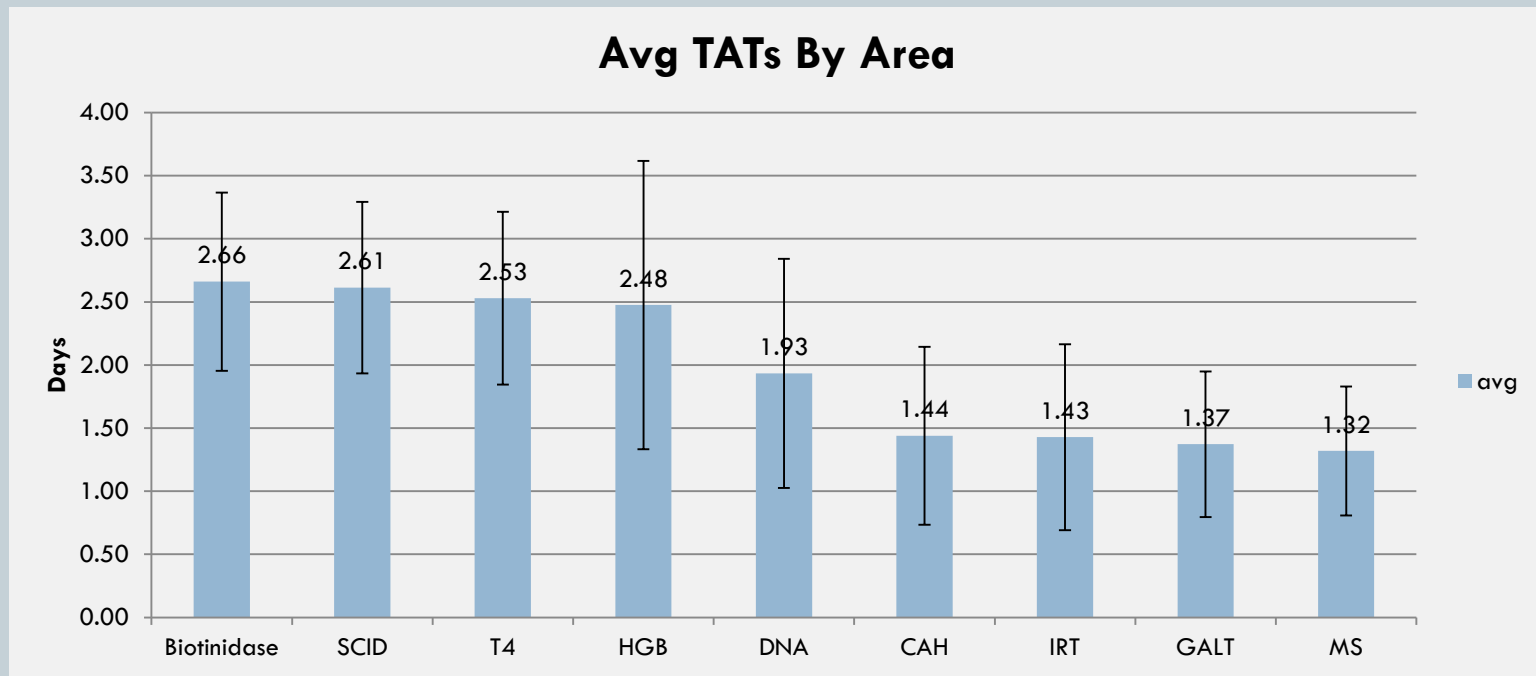


Error Bars Illustrate One Standard Deviation Above and Below the Averages

# PROJECT SELECTION

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

# CHECK-IN

- 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
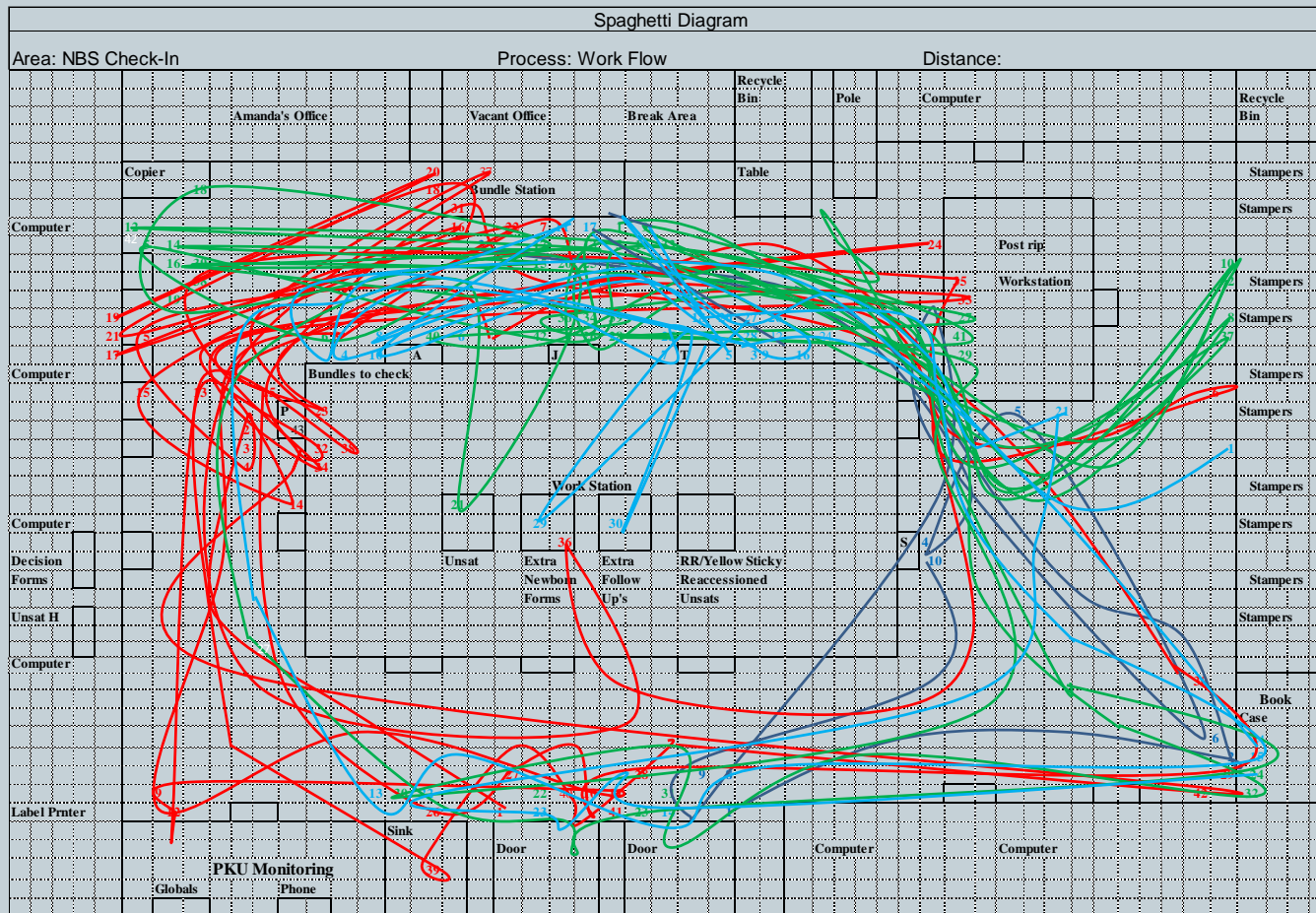
# CHECK-IN PROJECT UPDATE

- 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.

# CONGENITAL HYPOTHYROIDISM (T4)

- 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%.

# GALACTOSEMIA

- **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.

# TANDEM MASS SPECTROMETRY

- 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.

# MS/MS VALUE STREAM MAPPING



Current State Value Stream Map: Tandem MS Abnormals
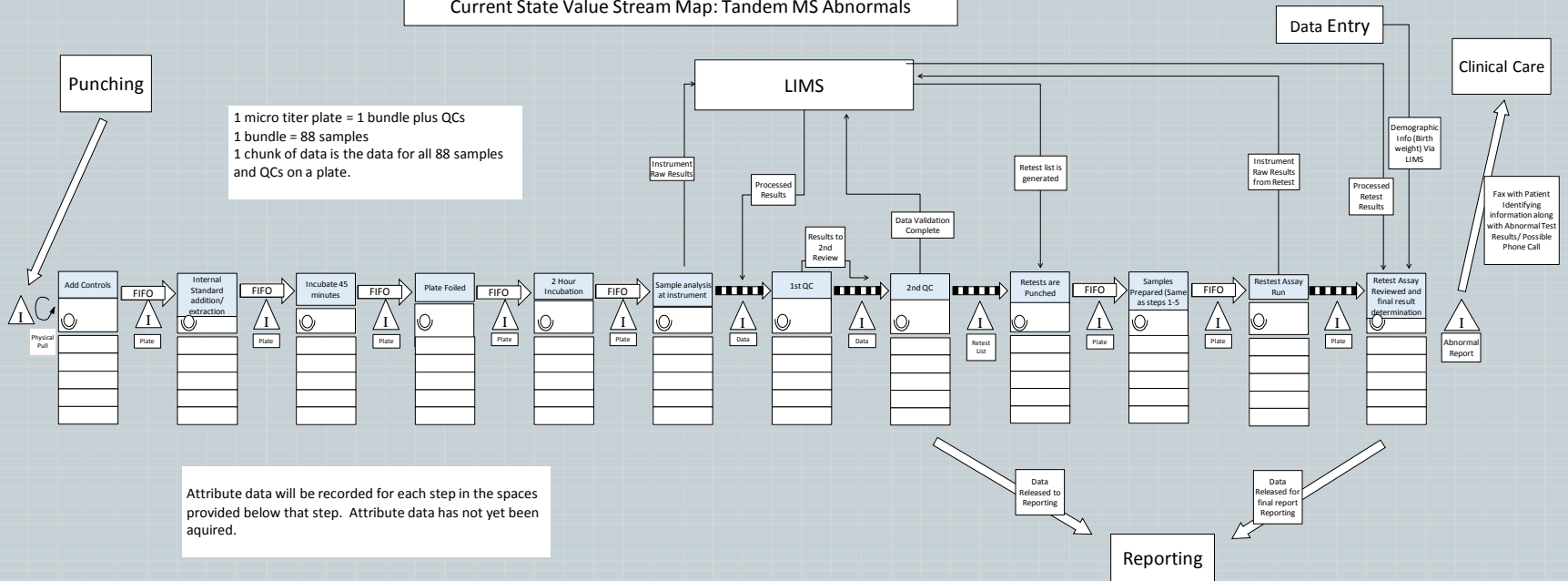
# TANDEM MASS SPECTROMETRY

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.

# RESULTS

- 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!

# LESSON LEARNED

- 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.