The LEAN Transformation of the Molecular Diagnostics Laboratory

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“I Wasted Time, and Now Doth Time Waste Me”

William Shakespeare – Richard II, Act 5, Scene 5
Disclosures

• Lecture honoraria received during the past 12 months
  – American Society of Clinical Pathology
  – Bionuclear
  – Cepheid
  – Qiagen
  – Siemens

• Service on advisory boards
  – Sunquest
What’s Wrong with the Way We’ve Been Doing Things Up to Now?

• Nothing – it’s just that new technology is available that increases the utility of laboratory testing
• The area of infectious disease diagnostics is evolving right before our very eyes
• Laboratories should embrace changes that lead to better patient outcomes
• LEAN methodology improves testing processes by eliminating wasteful activity and inactivity

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Laboratory Testing and LEAN

• In a sentence, the objectives of a LEAN laboratory reorganization are to deliver higher quality test results, at a lower cost, within a shorter time frame, while improving physician/patient satisfaction with their laboratory experience.

• A LEAN overhaul of a hospital laboratory achieves these objectives largely by eliminating wasteful activity and inactivity.
Five LEAN Targets That Are Appropriate to the Laboratory Setting

- **Value**: We wish to increase the clinical utility of test results
- **Value Stream**: We wish to analyze the steps of our testing processes to eliminate wasteful activity and inactivity
- **Flow**: We wish to level off workload peaks and valleys
- **Pull**: We wish to maintain a “just-in-time” supply inventory
- **Continuous Improvement**: We wish to strive for perfection by diligently enhancing the steps of our testing processes
Implementation of LEAN in Our Infectious Diseases Diagnostic Laboratories

• Between November 2009 and October 2010, our Microbiology Laboratory underwent a 12 month LEAN transformation with a “live date” of November 1, 2010.

• The Molecular Laboratory has been the focus of a similar undertaking since January 2011.

• Rules imposed by our Chair
  – No new laboratory space is available
  – Additional laboratory staffing is “off the table”
  – The costs of renovating either laboratory must be minimal.
Major Microbiology LEAN Recommendation

- Move staff from the day shift to the evening and night shifts to enable 24-hour specimen processing and culture reading
  - ~25% of our specimens were waiting 1-10 hours for processing
  - Cultures that became positive during the late day, evening or night shifts were waiting 1-20 hours for the initiation of workups
Traditional versus LEAN Microbiology

• In the traditional scenario, work is performed when the laboratory staff is ready – organisms wait for the staff to be available on the next day shift.

• In the LEAN scenario, work is performed when the organisms are ready – staff is always available to begin work on positive cultures.

• In the traditional scenario, final results of uncomplicated positive cultures are available in 40-64 hours.

• In the LEAN scenario, final results of uncomplicated positive cultures are available in 34-40 hours.
Waste Identified in Our Pre-LEAN Molecular Laboratory During a Kaizen Event

- The floor plan of the laboratory led to unnecessary personnel movement
- Staffing was day shift only so that testing of specimens collected during that shift was delayed by at least 16-24 hours
- Specimens were stored in too many places leading to time-wasting efforts in gathering specimens for testing
- Batching of rapid molecular tests was beset with wasteful inactivity
Laboratory Floor Plan

• Allocating space for a Molecular Laboratory was not a consideration when our hospital was built in 1974

• Squeezing the initial laboratory into a “land-locked” floor plan was a haphazard endeavor at best

• As the Laboratory expanded its scope of activity, distances between its work areas increased

• Addressing this problem was first tackled as a corollary to our 2010 Microbiology LEAN project

• The eventual reorganized floor plan provided 38% more space and much less walking for our staff

“Spaghetti Diagram”
Microbiology and Molecular Diagnostics

Post-LEAN Floor Plan

Microbiology Total 1550 sq ft

Molecular Diagnostics Total 825 sq ft
Recent Developments

• The scope of our Molecular Laboratory was broadened in July 2012 with the hiring of a new faculty member to expand our human genetic testing menu

• We merged the infectious disease and human genetic molecular laboratories to eliminate wasteful redundancy

• Replacement of archaic methods and consolidation of testing on fewer, more automated platforms will further increase laboratory efficiency
Laboratory Staffing Plan

• The current molecular laboratory staff consists of six medical technologists and a Supervisor
• Currently the lab operates seven days per week, day shift only
• Extending the workdays to include weekday evening shifts will eliminate a good deal of wasted inactivity
• The turnaround time for batched test results will be significantly reduced
Automation of Batched Molecular Testing

• The model molecular laboratory is able to replace mindless, repetitive, manual activities with hands-free, automated instrumentation

• Once implemented, the technologist time spent on laborious, time-consuming processes can be redeployed

• We are using the QIASymphony RGQ™ automated platform to successfully achieve this goal

• As more testing is moved to this platform, the return on our investment grows larger
Batched to STAT Test Conversion

- Because of its ease of use and rapid availability of test results, we moved the Cepheid GeneXpert™ to the 24 hour microbiology laboratory for STAT MRSA, enterovirus, and *Clostridium difficile* testing
- Similarly, a Focus Simplexa™ was placed in the same laboratory for STAT influenza A/B and RSV testing
- The next slide illustrates the dramatic decrease in GeneXpert™ testing turnaround time that has resulted
Impact of LEAN on Turnaround Time

Six Month Period Post-LEAN versus the Same Six Month Period Pre-LEAN
Evidence of the Benefits of Our LEAN Efforts

- We wished to document that the intuitive benefits of a LEAN transformation could be verified in a manner that would impress hospital leadership.
- The following three slides are an attempt to do so by comparing workload and financial data from the two laboratories for FY 2010 (pre-LEAN), FY 2011 (transition year), and FY 2012 (post-LEAN).
Comparability of Workload Complexity

Microbiology + Molecular Laboratories
Worked Hours per Unit of Service

- Pre-LEAN
- Transition
- Post-LEAN

FY 2010 FY 2011 FY 2012
Impact of LEAN on Staff Efficiency

Microbiology + Molecular Laboratories
Salary Dollars per Unit of Service

Expected figure due to 4% salary increase per year

FY 2010
Pre-LEAN
FY 2011
Transition
FY 2012
Post-LEAN
Impact of LEAN on Supply Expenses

Microbiology + Molecular Laboratories
Supply Dollars per Unit of Service

Expected figure due to 4% expense increase per year

Pre-LEAN
FY 2010

Transition
FY 2011

Post-LEAN
FY 2012
Organized Storage of Specimens

• Our pre-LEAN analysis had identified hunting for specimens on the daily Molecular Diagnostics worksheets as a waste of valuable technologist time that delayed testing

• Because the Microbiology Laboratory incoming bench is staffed around the clock, receiving and organized storage of Molecular Diagnostics specimens could become the responsibility of Microbiology personnel
Streamlining the Workflow

• Pre-analytical phase
  – Downloading of worklists from the laboratory information system to the testing platforms via computer interfaces
  – Automation of DNA/RNA extraction from specimens
    • Abbott m2000™
    • Qiagen Biorobot EZ1™
    • Qiagen EZ1 Advanced XL™
    • Qiagen QIAsymphony™
    • Roche COBAS AmpliPrep™
  – Use of assays that do not require DNA/RNA extraction
    • Focus Simplexa™
Streamlining the Workflow

• Analytical phase
  – Automation of DNA/RNA amplification and results reading
    • Abbott m2000™
    • Cepheid GeneXpert™
    • Cepheid SmartCycler™
    • Eppendorf Mastercycler EP™
    • Focus Simplexa™
    • Luminex xTAG™
    • QIAsymphony™
    • Qiagen Rotor-Gene Q™
    • Roche COBAS TaqMan™

Qiagen Rotor-Gene Q™
Streamlining the Workflow

• Post-analytical phase
  – Uploading of results from the testing platforms to the laboratory information system via computer interfaces
  – Use of delta checking capabilities on the laboratory information system to identify test results requiring verification
  – Single keystroke insertion of composed text comments to aid clinicians in interpreting test results

Development and implementation of an electronic interface for complex clinical laboratory instruments without a vendor-provided data transfer interface

Gary E. Blank, Mohamed A. Virji

J Pathol Inform 2011, 2:14

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Summary (1)

• We need to creatively reevaluate our practice of infectious disease testing.
• Because of technological advances and a shrinking workforce, our laboratories should implement operational changes that promote more efficient work practices.
• We ought to leverage automation to eliminate errors, enhance quality, reduce test result turnaround times, and improve patient outcomes.
• Relatively few infectious disease diagnostic laboratories have embarked on this road so far – it’s time to get moving!
Summary (2)

• The LEAN-based reorganization of our laboratories has eliminated a great deal of wasted time and effort.
• The changes to our laboratories have been achieved without increasing our space nor the number of our staff.
• Most importantly, the clinical utility of our test results is improved because they are less prone to human error and are available on a more timely basis.
• The morale of the staff is higher than ever, as evidenced by the following question asked at a recent Microbiology Laboratory meeting: “Why didn’t we do this a long time ago?”

Mission Accomplished!