A novel approach to improving TAT and Quality in the clinical lab

November 16th 2011

Presented by Ralph Millare & Christian Basa
Providence Saint Joseph Medical Center
Burbank, CA

Overview

- Who we are?
  - Presenters
- PSJMC Clinical Laboratory
  - Operations & the Competitive Landscape
  - Journey towards Excellence
- Automation and Batch Processes
  - Advantages, Disadvantages & Risks
  - Queuing Theory and TAT
- Continuous Improvement in the Laboratory
  - Semi-automation
  - Visual controls
  - Business Intelligence
- Lessons Learned

About us

Rafael Millare is the Administrative Director for Laboratory and Pathology Services at Providence Saint Joseph Medical Center in Burbank, California. He has strong leadership qualifications with a successful track record of more than 20 years of hands-on experience in multi-site, multi-department, outreach program and Lab information system. He has an MBA in Health Care and a BS in Microbiology.

Christian Basa is a Lean Six Sigma Black Belt at Providence Saint Joseph Medical Center in Burbank, CA. His projects have focused on test turn-around-times, workflow design, material handling and material usage. Christian has led several successful projects in operations and quality systems and is a major proponent of business analytics and technology integration. Christian has a B.S. in Biomedical Engineering from the University of Southern California.

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Providence Health & Services Southern California

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Providence Saint Joseph Medical Center (PSJMC)

- Providence Health & Services founded in 1943 by the Sisters of Providence
- 431 licensed patient beds
  - Largest hospital serving the San Fernando and Santa Clarita Valleys
- Active medical staff of more than 650 physicians
- More than 2,300 staff members – including 800 RNs
- More than 50,000 patients in the Emergency Department last year
- Recognized leader in excellence:
  - Top 5% in US for Overall Clinical Performance
  - Top 5% in US for Women's Health Services
  - 5 Star rated Cardiac Services
  - Top 10% in US for GI Services and Stroke Care

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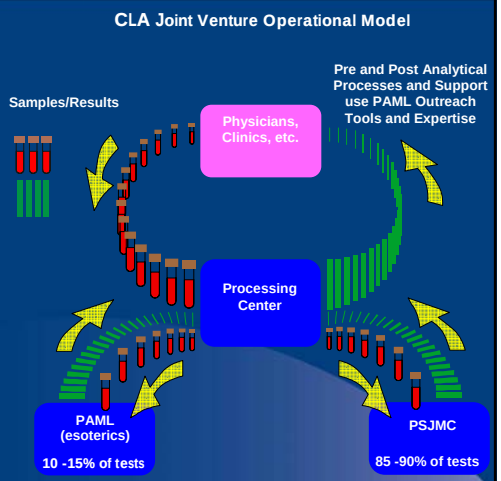
PSJMC Clinical Laboratory

- Profitable outreach lab program servicing 527 providers
- 60 % of testing is from outreach samples
- Chemistry and Immunochemistry Department
  - 2.1 million tests performed annually
  - 88 testing methods
- Joint venture with PAML to create the California Laboratory Association (CLA)



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Competitive Landscape

- High Fixed Costs: Approximately 78%-80% of a laboratory's operating costs are fixed, thus requiring higher volumes to spread the costs.
- Shrinking Profit Margins: A 1.75% cut to the fee schedule from the Centers for Medicare and Medicaid (2011-2016) reduces the average industry profit margin (11.9% in 2011 versus 12.5% in 2006).
- Gain Buying Power: Cost of laboratory-related materials supplies are constantly rising.
- Invest in Technology: Shrinking labor pool results in higher per employee labor cost (32% wages/revenue in 2011). Average firm invests $0.22 of capital to every $1.00 of labor. Alternative technologies such as POCT and Telemedicine (Pathology) challenge the general laboratory business model.

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Diagnostic & Medical Laboratories in the US. IBISWorld Industry Report 62151. July 2011.

Journey Towards Excellence

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Fall 2008	Spring 2009	Summer 2010	Winter 2010	Fall 2011
Technology Integration Roche's cobas introduces high accuracy specimen analysis	**Automation Expansion** Roche MPA streamlines pre-analytical operation	**Business Growth** Joint-venture w/ PAML increases laboratory test volume	**Continuous Improvement** Regional Lab Excellence Council facilitates the spread of learning	**Business Intelligence** Real-time data reporting allows proactive operational management



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Before

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Pre-Implementation
Abbott Aeroset (2)
Abbott Axysym (2)
Roche Elecsys 2010 (2)
Bayer Centaur

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After

Post-Implementation
cobas® 6000 analyzer series (2)
MODULAR PRE-ANALYTICS (MPA) and middleware

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Advantages, Disadvantages & Risks

Advantages

- Increase capacity without additional labor cost
- Improve accuracy through standardized test methods
- Reduce identification errors and searching (bar-code system and auto-verification)
- Improve operator safety through minimal specimen handling (de-capping and aliquoting)
- Improve specimen storage and archiving process

Disadvantages & Risks

- Capital intensive and recurring maintenance costs
- Fluctuating volumes (revenue-driver) may not offset high fixed costs
- Equipment downtime (planned vs. unplanned)
- Technical expertise may be limited to only a few employees

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Automation Process Overview

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= 5 Specimen Rack

Loader | x2 Centrifuge | De-stopper | Aliquot | Barcode Label | Re-stopper | Sorter → To Analyzer

Rejected Units (~145/month or 1.9% defect rate)

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Initial results

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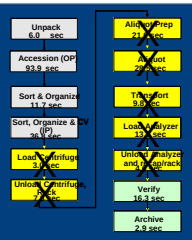

- 7 of 13 steps eliminated
- Improved flow
- Safer operation
- Fewer errors

Launch of Roche MPA + COBAS
Before: 06/01/08 - 08/31/08
After: 01/27/11 - 02/07/11
Mood's Median Test, 95% CI

Test	Before TAT, minutes (Receive-Result, median)	After TAT, minutes (Receive-Result, median)	% Change
Troponin	27 n=1802	34 n=726	**25.9%**

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Detailed Process Overview

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1st = 08:52
2nd = 09:22
3rd = 12:52
21st = 17:22
29th = 19:22

00:08:52

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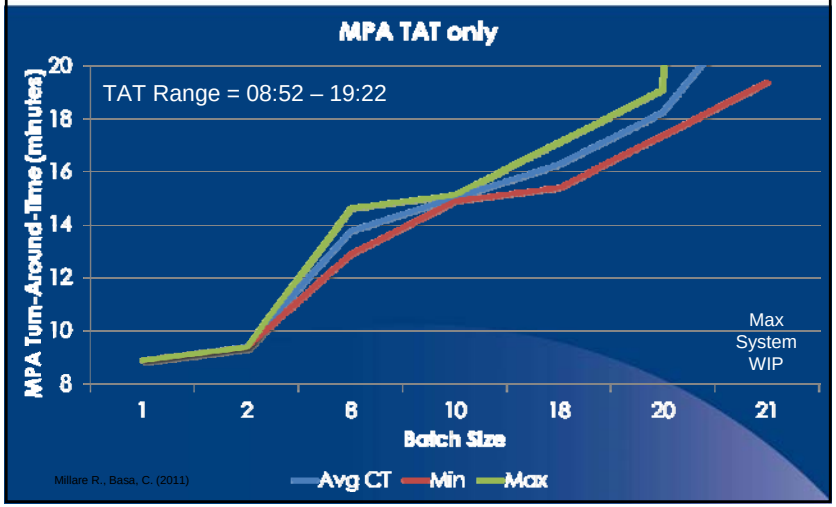
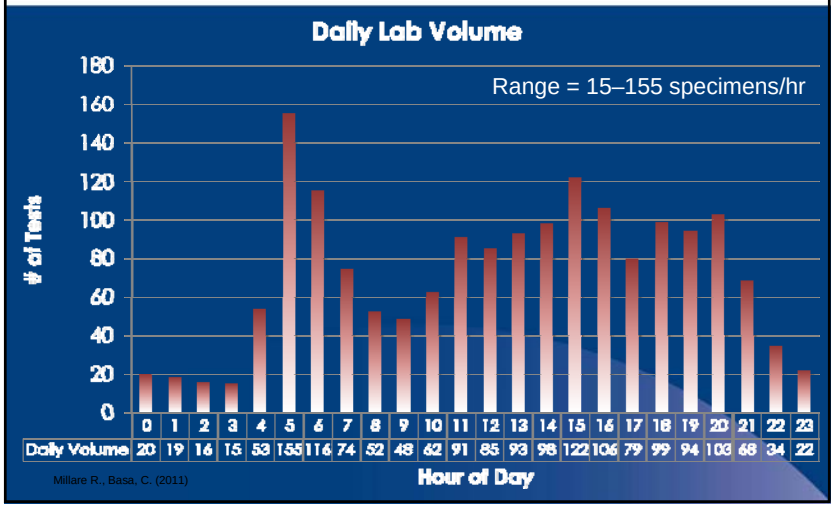
TAT increases as batch size increases



Lab samples arrive in large batches



Paradigm Shift

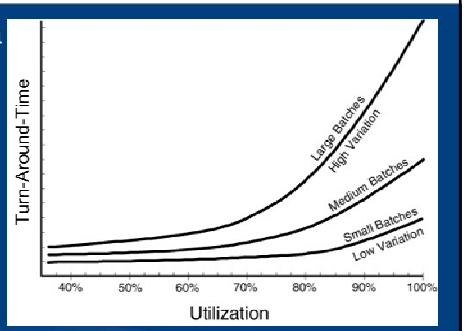
We have **higher** volumes of tests
AND
We have **better** equipment utilization rates…

…Shouldn't this be a **GOOD** thing?

Queuing theory and TAT

- Queuing theory offers a mathematical approach to studying the effects of batch size, cycle time and arrival rate.

↑ Utilization = ↑ Delay



- Restaurants

Reference: 1) Implementing Lean Software Development from Concept to Cash. Poppendieck et. al. Sept 2006
2) MPA Simulation Run.xls. C.Basa, October 2011.

Continuous improvement approach

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Key Findings

- **Automation-Dependent:** Roche machine (MPA and COBAS) used for 100% of Troponin tests
- **Fast-Track:** Stat priority allows specimens to be expedited through different modules in the MPA
- **Delay for Stat Tests:** Expedited process can be delayed due to large WIP in MPA leading to longer cycle times and high variation
- **Delay in Quality Check:** Specimens that are rejected are segregated in a bin and will wait for analyst, thus leading to longer cycle times and high variation for failed units. Hemolyzed specimens will require a re-draw and will further delay the overall test.

Improvement

- **Semi-Automation:** Externalized a process and introduced an early quality check.
- New process is as follow:
  1. Receive specimens
  2. Pre-Inspect
  3. Centrifuge (3-min)
  4. Inspect
  5. Load into MPA
     - Time-stamp
     - Fast-track to COBAS
     - Results in COBAS
  6. Enter test Results

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New Improved Process

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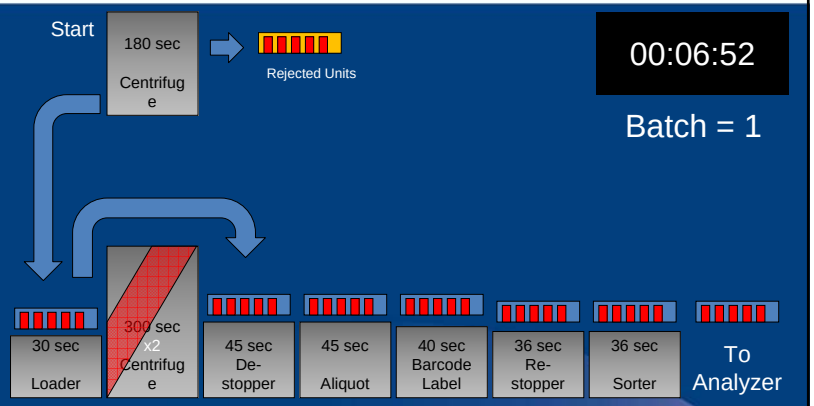

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Optimizing Automation:
TAT Results

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Test	Before TAT, minutes (Receive-Result, median)	After TAT, minutes (Receive-Result, median)	%
Troponin	34 n=726	26 n=509	-23.5%

No additional FTE required to achieve results

New Pre-Analytic Process
Before: 01/27/11 - 02/07/11
After: 07/01/11 - 07/21/11
Mood's Median Test, 95% CI

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How do we improve the process **UP**-stream?

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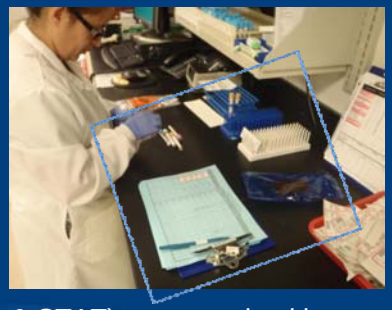
Implementing Visual Controls



Before: All specimens (Routine & STAT) were received in clear/orange bags. No differentiation = Incidental delays

After: STAT specimens are received in blue bags and are expedited at Pre-Analytical.

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How do we improve the process **DOWN**-stream?

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Leveraging Information Technology

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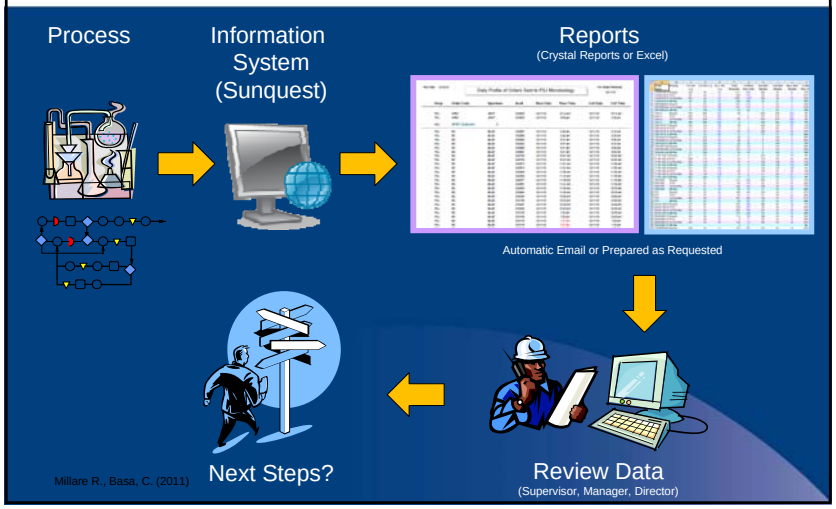

Integrating Business Intelligence

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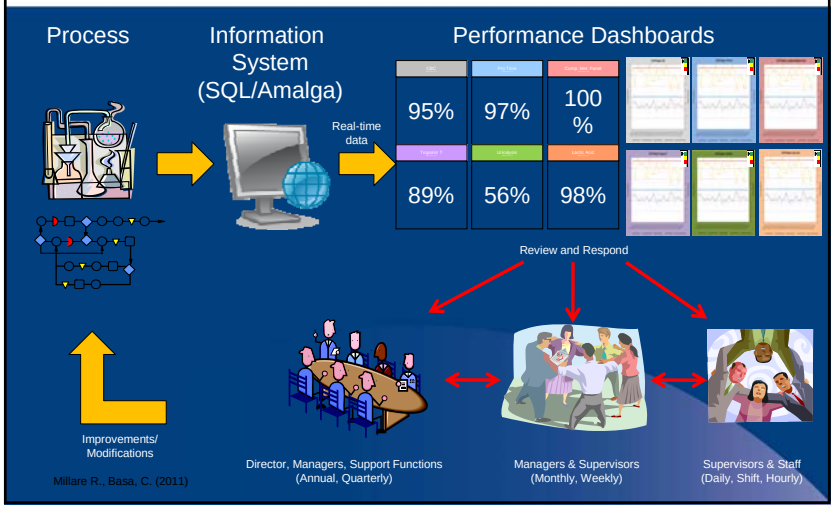

Real-Time Dashboard

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Real-Time Dashboards

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Results

Test	Before TAT, minutes (Receive-Result, median)	After TAT, minutes (Receive-Result, median)	%
Troponin	34 n=726	26 n=509	-23.5%
Complete Metabolic Panel	35 n=351	33 n=538	-5.7%
Basic Metabolic Panel	33 n=675	32 n=856	-3.0%

Additional Improvements
Before: 01/27/11 - 02/07/11
After: 07/01/11 - 07/21/11
Mood's Median Test, 95% CI

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User Feedback

August 1, 2011

"At first I didn't think [the new process] was going to be faster. I just gave it a try. Sometimes, we just have to try anything to make things better. I was really surprised to see the results!

It's rewarding to get patient test results faster. The faster you get it out, the faster [the patient] receives the right care. I can help make that difference."

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David Gamboa
Pre-Analytical
6 yrs at PSJMC

Lessons Learned

- Follow the product (value-driver)
- Wait times can be disguised as equipment time—know your equipment sub-processes in detail (e.g. cycle times, batch sizes, queue sizes, etc.)
- Choose the best metric to measure performance and be consistent
- Challenge the status quo—if you fail, it's better (and cheaper) to fail earlier rather than later
- Celebrate quick wins with your customers and suppliers. Then get them involved in future improvement activities.

Acknowledgment

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Thank you!!!

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Questions?