ACHIEVING TRUE LEAN IN HEMATOLOGY WITH FULL AUTOMATION, INTEGRATION, & PAPERLESS SOLUTIONS

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Who we are: Mercy Medical Center

- 476 bed hospital serving a 5 county area and parts of Southeastern Ohio.
- First in:
  - Angioplasty in an emergency dept (World)
  - Accredited Chest Pain Center (Nation)
  - Cardiac Catheterization in a Community Hospital (Nation)
  - ER use of cardiopulmonary bypass (Nation)
  - Drug-eluting stent Angioplasty (Ohio)
Who we are: Department of pathology and Laboratory Medicine

- Clinical and Anatomic Pathology
  - Main Laboratory
  - 6 offsite StatLabs with drawsites
  - 3 offsite patient service centers
  - Outreach program covering 5 counties
- Early adopter (2004) of Lean practices
  - Chemistry, Hematology, and Phlebotomy
- 2005 Six Sigma introduced
- CAP, AABB, FDA, JCAHO accredited

- 2008 billable tests: 1.47 million
- 2009 projected: over 1.53 million
- Goals:
  - All results to ED within 30 minutes of receipt
  - All stats completed within 1 hour of receipt
  - Improve our LEAN processes
Our journey into innovation......

• 2006 Issues
  – Increased volumes
  – Aging workforce—diminished pool of experienced workers
  – Turn around Time (TAT) a priority
  – Productivity and Budget constraints
  – Increasing volumes of Hgb A₁C
  – Too many differentials
  – Goal to autoverify
  – Need to cross train personnel
  – Process was not fully “Leaned”

Our search began......

• Vendors
  – Who sells Hematology?
  – Reliability, instrument flexibility
• WOULD IT MEET OUR LEAN CRITERIA?
  – Less Hands-on time
  – Personnel could be cross-trained
  – Autoverification
  – Paperless (“GO GREEN”)
  – Minimal downtime
  – What about the A₁c testing?
  – Footprint
Vendor presentations (Dec 06)

- Vendor presentation to
  - COO and Director of Purchasing
  - Lab Administration and Medical Director

- Important points
  - What solution was available for our lab?
    - Volume of CBCs/day:
    - Throughput of instrument
    - If automated line: Time splits at each junction
    - How would this contribute to improvements in TAT?
    - Could we autoverify and go paperless?
    - How big was the configuration

Workflow Assessment

Before
Our choice:

- Combine Hematology with HbA1c testing
  - HbA1c run more frequently
  - Random access
  - Free up tech time
  - Auto-verify
- Middleware
  - Fewer differentials
  - Paperless hematology
- Patient and Physician
  - Faster turn-around-time
  - Earlier Decisions

Preparing for the “blessed event”

- Paperwork
- Homework
- Paperwork
- Paperwork
- Paperwork
  - Oh My, how much is there?
We need a team

- MMC
  - Core Lab Manager
  - Quality Coordinator
  - LIS Coordinator
  - Primary operator

- Vendor
  - Facilitator

Installation

- It took time and resources
  - Laboratory
  - Sysmex
  - BioRad
  - LIS vendor
  - IS department
  - Plant and Engineering
When do we “go live”?

- Testing
  - Emulator
  - Wet testing
- Training
  - Middleware
  - Instrument
  - Line

Instrument & Rules Validation Process
Implementation Process

- Instrument validation- studies performed by Vendor
- Vendor Rules development and testing:
  - Heme and A1c rules template
  - Instrument data emulator for rules testing
  - Guided testing via test plans

Example Hematology Decision Rules

<table>
<thead>
<tr>
<th>Type of Rule</th>
<th>Rule Definition: Criteria for rule</th>
<th>Automated action taken by Automation Line</th>
<th>Operator message to be displayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-level and multi-action</td>
<td>If WBC &lt;2 or &gt;35 and &lt;5 days old then hold CBC/Diff order rerun and smear</td>
<td>Rerun CBC &amp; Diff &amp; make smear</td>
<td>WBC Critical: Call criticals</td>
</tr>
<tr>
<td>Data comparison, multi-parameter</td>
<td>If PLT delta +/- 50% and PLT 0-99</td>
<td>Run for Optical Plt &amp; make smear</td>
<td>PLT Delta failure, Confirm by smear estimate. Check for clumps. Call Criticals</td>
</tr>
</tbody>
</table>
Testing the A1C rules

- Rules Document
  - Emulator
  - Wet testing
- Our current practices
- Rule Example:
  - If Total Area is too high, then dilute sample and rerun

Example A1c Decision Rules

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<tr>
<td>Single parameter</td>
<td>If TAREA &lt;1.1</td>
<td>Repeat A1c</td>
<td>HbA1c, Low Total Area: Check sample volume and integrity of aspiration needle. Rerun per lab protocol. Make a 1:100 dilution and repeat test.</td>
</tr>
<tr>
<td>Multi-parameter, multi-level</td>
<td>If LA1c &gt;4.6 and &lt; 6.5 and HbA1c% &lt;8.2</td>
<td>Repeat A1c</td>
<td>HbA1c, Labile too high: Incubate blood for 24 hours at room temperature and rerun. If rule still triggers, sendout.</td>
</tr>
</tbody>
</table>
Weekly conference calls

- Critical to project
- Vendor and Lab team
- As many team members as possible
- Problems brought to surface
- Solutions discussed

When do we “go live”

- Ambitious versus realistic goal
  - Outside forces
    - IS connectivity
    - Staffing
    - Electrical
    - Interface
Implementation Process

• Training
  – Instrument – How does it work?
  – Maintenance – Is it different?
  – Results – Are the printouts the same?
  – Integration with the Line – How many alarms?
  – Sysmex WAM – what?

GO Live?

• Date was postponed
  – Ambitious
  – IS issues not instrument

• May be needed
  – Don’t pressure to move forward
  – Credibility and acceptance at stake
    • Remember your users
**It's not a BED OF ROSES**

- New technology
  - Line versus instrument issues
  - Middleware versus Meditech
  - Where is the specimen?
  - Sorter issues
  - Where is the specimen?

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**Change is always hard**

- Tenured Staff
- This is how we have always done it
- Why do we need to change?
- I am out of my comfort level
- New way of thinking/doing/outcomes
In retrospect……

What could we have done better?

Personnel issues

• Personnel encouragement
• Positive reinforcement
• Numbers
  – TAT for Emergency dept
  – Fewer differentials
Outcomes

Workflow

After
Turn-Around-Time & Review Rate

• Average TAT for CBC: 6.2 minutes
• Differential review rate decreased from 20% to <13%

LEAN Objectives Achieved

• Labor Savings
  – One tube draw for CBC and HBA1c
• TAT average improved 82%
  – from 16.4 hrs to 2.75 hrs (receive to verify)
• Data Review
  – Over 95% of samples are autoverified
• Resource Reallocation
  – 0.5 FTE available for other testing
**A1c Turn-Around-Time Impact**

*Data includes travel time of specimen from offsites*

**Average TAT dropped from 16.4 hours to 2.75 hours**

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**Hematology Automation plus Sysmex**

**WAM - What we gained!**

- Auto-verification
- Paperless environment
- Additional capacity to add new testing without new staff
- Reduce opportunities for error
- Standardized sample and data workflow
- Staff cross-training
- HBA\textsubscript{1} C “on demand”
Hands-Free Repeat/Reflex Testing

"All-in-One" Data Station

Multi-application Sysmex WAM workstation:
- CBC Validation
- Smear review/diff station
- LIS access
Consolidated Data Review & Validation Screen

- No more instrument printouts
- Same review process - all techs, all shifts
- Review by exception - Techs focus on "abnormal" samples
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- Same review process - all techs, all shifts
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Flexible validation options: partial (CBC) and full (CBC+A1c results) validation

"Operator Alert" - displays rule and user-defined instructions for tech.

Visual STAT sample differentiation.

A1C results

CBC, Diff results

Single view of CBC and A1c exception results.

Auto-verification Outcomes

A1c Milestones Achieved:
1. Auto-verification of A1c's
2. 2179 data study - 95% auto-verified
   - 77 (3.5%) flagged by the rules
   - 49 (2.2%) reported after review

Hematology Milestones Achieved:
1. Auto-verification from Day 1 of live
2. Over 85% of samples auto-verify
3. Paperless

Sysmex WAM

www.cantonmercy.com
OUTCOMES—LEAN ACHIEVED

- Standardized workflow
  - One tube for CBC and A1c
- Data Review—auto-verification
  - Over 85% of CBCs
  - Over 95% of A1c
- TAT improvement
- Labor Savings/Resource Reallocation
  - 0.5 FTE (Heme) retired not replaced
  - 0.5 FTE (Chem) available for other testing

Points to remember

It is a team effort

- Laboratory
- Vendor
- LIS vendor
- IS department
- Plant and Engineering

- It will disrupt the lab
- Change is never easy
Take home message

- Time
- Energy
- Teamwork