To CAPA or Not To CAPA: Focusing on Error Prevention to Improve Quality and Reduce Cost

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Greetings from the Big Apple

North Shore LIJ
NSLIJHS Vital Statistics

2009 Clinical Statistics
- More than 5,600 hospital and long-term care beds*
- About 4 million patient contacts
- 25,100 babies delivered
- 278,000 inpatients treated
- 137,000 ambulatory surgeries performed
- 605,000 emergency visits
- 817,000 home care visits
- 1,200 clinical research studies
- 3,115 community education programs
- 67,100 ambulance transports

Organizational Statistics
- More than 42,000 employees — the largest employer on Long Island and the ninth-largest in New York City
- More than 9,000 physicians
- More than 10,000 nurses
- 772 medical students
- More than 1,230 medical residents and fellows
- More than 3,900 nursing students
- More than 3,200 volunteers
2010 System Laboratories Network

- Central “Core” Laboratory
- 12 Hospital Based Labs
- $260 Million Annual Operating Budget
- 1400 FTEs/ 70 Pathologists
- 16 Million Billable Tests
- 180,000 Surgical Specimens
- 30+ Patient Service Centers

Consolidated Laboratory Network NS-LIJ HS
Our Model - Consolidated Lab Network

- Strategically Located Core Laboratory – 70,000 sq.ft.
- Integrated Anatomic Pathology -25,000 sq.ft.
- Rapid Response Laboratories (RRL)
- Standardized LIS (Cerner)
- Standardized Laboratory Instrumentation
  - Method Committees
- Standardized Policy and Procedure
  - Quality System Manual

North Shore LIJ Laboratories
North Shore-Long Island Jewish Health System
Core Laboratory Scope of Services

- Routine hospital tests - 30%-50% hospital lab volume
- Large Outreach program
- Clinical Trials
- Highly automated
- Specialized Testing
  – Microbiology, Virology, Molecular, Special Coagulation
- Logistics – 25,000 pick-ups/month
- Phlebotomy - 2,000 patient draws/day
- Reference Testing – 1% of total test volume

Core Lab Business Lines

<table>
<thead>
<tr>
<th>Business Line</th>
<th>$$</th>
<th>Volume (billables)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>$24 M</td>
<td>2.4 M</td>
</tr>
<tr>
<td>Reference</td>
<td>$ 5 M</td>
<td>120 K</td>
</tr>
<tr>
<td>Physician Office</td>
<td>$60 M</td>
<td>4.2M</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>$ 3 M</td>
<td>300 K</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>$ 2 M</td>
<td>200 K</td>
</tr>
<tr>
<td><strong>TOTAL 2010</strong></td>
<td><strong>$94 M</strong></td>
<td><strong>7.2M</strong></td>
</tr>
</tbody>
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Health Care Landscape

- Health Care Initiatives - Government
- Decreasing Reimbursement
- Health System Expansion
- Ambulatory Growth
- Increased Competition
- Limited Access to Capital
- Increasing Difficulty in Staff Recruitment

Health Care Landscape - Long Island

- Increased Competition with Local and National Service Laboratories
- Increasing Difficulty in Laboratory Staff Recruitment
- Economic pressure
- Decreasing Hospital and Outreach Reimbursement
- Limited Access to Capital
What are Labs Facing Today?

- Focus on operational, financial, and service efficiencies
- Declining employee morale
- Outsourcing testing from labs to POCT
- *No money, no time, no staff*
- Continue to maintain and/or improve quality and the big the questions is HOW?

The Road to Success
NSLIJHS Labs Objectives

- Increase the number tests and decrease the number of errors
- Create a new culture of quality
  - streamline error reporting processes
  - focus on prevention rather than correction
- Partner with stakeholders in prevention awareness
- Develop new techniques for error reduction and error prevention
- Encourage awareness of the prevention process

Complaints: Who, How and When

- Who
  - Physicians, Patients, Medical Staff, Laboratory staff, others
- How
  - Verbal, phone, website, emails letters, sales representative, anonymous, physician and patient satisfaction surveys, walk-ins
- When to Follow-up
  - Written complaints must be responded within 48hrs
  - All complaints must be followed up and documentation completed within 30 days
Occurrence Documentation and Follow Up

- Complaint Management Software (Frontline) is being utilized to initiate all complaint (case) documentation
- Case assigned to appropriate manager for immediate follow up
- All cases discussed at daily operations meeting
  - Complaint resolved and closed
  - Complaint escalated to an Occurrence Form (E-ER) and QM follow up

Workflow for Frontline Cases

Client Service Representative/Lab staff documents and assigns the case. Automatic email to appropriate manager.

Manager works problem and brings back findings to Operations Meeting.

Resolved in Ops Meeting?

YES

Manager enters resolution and case is reassigned if necessary.

Non Electronic – E-ER

Electronic Error Reporting Form (E-ER)

NO

EER Required?

YES

Director of Service Excellence/Designee enters resolution and marks case “Resolved” and closed.

QM Copy into EER form Follow E-ER flowchart

NO

Reassigned
Electronic Error Reporting (E-ER)

- Process Improvement necessary
- Patient Safety Issue
- Re-occurring Issues
- Serious errors
  - Irretrievable specimens
  - Lost Specimens
  - Time sensitive specimens
- Client at Risk
E-ER Process Flow Chart

Letters of Complaints

Lab Help (website)  

Reply to Sender via Telephone

QM Receives email response back

GM Receives email response back

A Root-Cause Analysis is performed if case is a "Category A" or when otherwise required.

Follow "Workflow for Frontline Cases" (please see above chart.)

YES

Risk Management Reviews Documentation

Flexible and Secure Complete file (Make file in Pending File)

Send a Letter of Apology to Complainant

Send a Letter of Apology to Sales Manager and/or Originating party

Review of "Cat. A" cases at PICG

GM Reviews

GM Sends E-ER via email to appropriate manager

GM Sends E-ER Electronically

QM Categorizes & Emails responsible party

QM Reviews E-ER electronically

NO

Process Improvement Required?  

 Iso QM

Is Issue Assessment: Process Breakdown?  

QM Reviews E-ER via email to appropriate manager

QM Serves E-ER electronically

QM Receives email response back

NO

Customer Service Management Software (Frontline)

Electronic Error Reporting Form (E-ER)

Plan Electronic – E-ER

Finalize and Save as Complete file (delete file in Pending File)

Email EER back to Responsible party until QM review is okay

YES

Send a Letter of Apology to Complainant

Send a Letter of Apology to Sales Manager and/or Originating party

Review of "Cat. A" cases at PICG

System Risk Management Notified

NO

Letters of Complaints

Lab Help (website)  

Reply to Sender via Telephone

QM Receives email response back
**Average Cost of a Frontline Case 2010**

- **Average cost/case:** $83
  - Client Service: $4.00/case
  - Appropriate Managers follow up: $25/case
  - Daily Operations: - $50/case
  - Other – $4.00/case

- **Average Cost of all cases:** $64,491
  - Number of Frontline cases: 777 cases
  - Cost per Frontline case: $83/case

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**Average Cost of an E-ER 2010**

- **Average cost/E-ER:** $247
  - Quality Management cost/case: $172.50
  - Service Recovery: $75

- **Average cost of all E-ERs = $72,371**
  - Number of E-ERs: 293
  - Cost per E-ER: $247
Total Cost of Failure in 2010

- **Total Cost of Failure: $136,862**
  - Average cost of all Frontline cases: $64,491
  - Cost of all cases requiring E-ERs: $72,371

- **What about cost of losing a client?**
  - Contribute to substantial loss in revenue
  - Prevent on-boarding of future clients

To CAPA OR NOT?
Number of Frontline Cases 2010 = 777

Why Focus on Preventative Action?

• NO TIME! NO STAFF! NO MONEY!

• Efforts Spent on Corrective Action Could Translate to additional FTEs/Revenue
Top Four Complaint Categories in 2010

Preventive Actions Initiatives in 2011

- Phlebotomy related issues
- Clients Reports Issues
- Missing Specimens
- Reference Testing
Approaches to Preventive Actions

• FTD (Fast Track Decision Making)
• Mini-Lean
• Focus Groups
• Rounding (staff and management)
• Client engagement
  – Medical Advisory Committee
• Adopting Best Practices System wide
• Creating a Future Initiative – Process engineering
Phlebotomy Preventive Actions

Initiatives

• Specimen collection
  – Phlebotomy Skill
  – Patient Identification
  – Specimen labeling
  – Patient Restrictions

• Courtesy
  – Language barriers
  – Body language
  – Greetings

• Computer skills
  – Order entry errors
  – Transfer List

• SOPs
  – Training
  – Competency

Phlebotomy – Preventive Actions

Specimen Collection

• Phlebotomy Skill
  – Removal/Disposal of phlebotomy apparatus
  – Patient Restrictions
  – Nursing notification
Phlebotomy Preventive Actions

Phlebotomy is both a technical and people orientated profession

Courtes  

- Patient Sensitivity  
- Service Excellence  

Phlebotomy is both a technical and people orientated profession
Phlebotomy Preventive Actions

Accomplishments

- Number of complaints in Phlebotomy Skill and Phlebotomy Courtesy decreased in 2011(YTD) by 33%

- Which equates to $15,000 savings for 2011(YTD)

- Increase compliments received
### Priority Payoff Matrix – Millennium Reports

<table>
<thead>
<tr>
<th>Payoff</th>
<th>Benefit</th>
<th>Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>1- LHH – no reports printing. Fix issue.</td>
</tr>
<tr>
<td>High</td>
<td>Low</td>
<td>2- Dedicated modem(s) for manual expedited faxes</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>1- Eliminate positive network printing</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>2- Duplicate reports looping on autofaxes</td>
</tr>
<tr>
<td>Low</td>
<td>High</td>
<td>4- Dedicated modem(s) for manual expedited faxes</td>
</tr>
</tbody>
</table>

### Client Patient Reports Preventive Actions Initiatives – Mini-Lean

- **Preventive Actions**
  - Reschedule and Relocate Print Jobs
  - Monitor Technical Resulting Cut-off Time of 6am
  - Monitor Print-job Initiation on Daily Basis
  - Adjusted Logistics Staffing and Route Start Times
  - Review and Update Data Base
  - Improving Hardware
  - Enable Bar-coding of Charts for Tracking – In Progress
Client Patient Reports
Preventive Action Accomplishments

• 31% decreased in complaints 3 months following the mini-lean

• Savings based on the decrease for 2011 = $7,000
Missing Specimens Preventive Actions Initiatives

• Improved laboratory tracking into the laboratory departments
• Provide better TAT (turn around time)
• Decrease in pending tests by 6am
• Creation of a process engineering team

Missing Specimens Preventive Actions Initiatives

• Engineering Team focus on:
  ➢ Decrease the number missing specimen issues related to “Shared” specimens
  ➢ Decrease the number of specimens requiring manual aliquots
  ➢ Expand electronic tracking and movement of shared specimens throughout the laboratory.
Reference Testing Issues

- Specimen/Preparation - Integrity Issues
- Delay in Testing
- Cancel Test issues
  - Test not performed
  - Delay in notification
- Transcription errors in result reporting
- Incorrect test ordered or test not ordered
Reference Testing Preventive Actions Initiatives

- Multiple errors evident from a particular provider
  - Customize requisition
  - Laminate cheat sheet
- Multiple errors evident from a particular patient service center
- Electronic ordering of tests

Lessons Learned

- Change the culture from Reactive (corrective) to Proactive (preventive) Approach to Quality
  - “CAPA to PACA”
- Increase Patient Safety Awareness
- Gain respect of MDs, Medical Staff, Patients, Administration
WORDS OF WISDOM

• When you are out of quality, you are out of business!
• If you don’t have time to do it right, you must have time to do it over.
• Average Quality produces Average Results.
• No Quality…. No Money…. 

The Road to Success

EXCELLENCE AHEAD
THANK YOU!

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