

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

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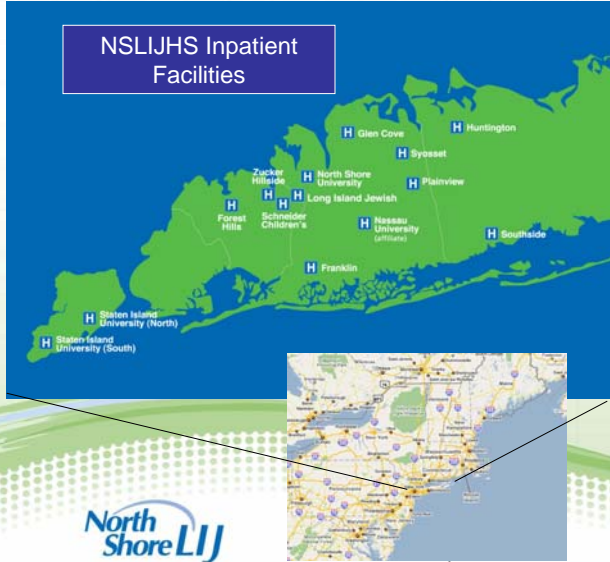
November 16, 2011



Greetings from the Big Apple



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
- 2,115 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

The North Shore-Long Island Jewish Health System

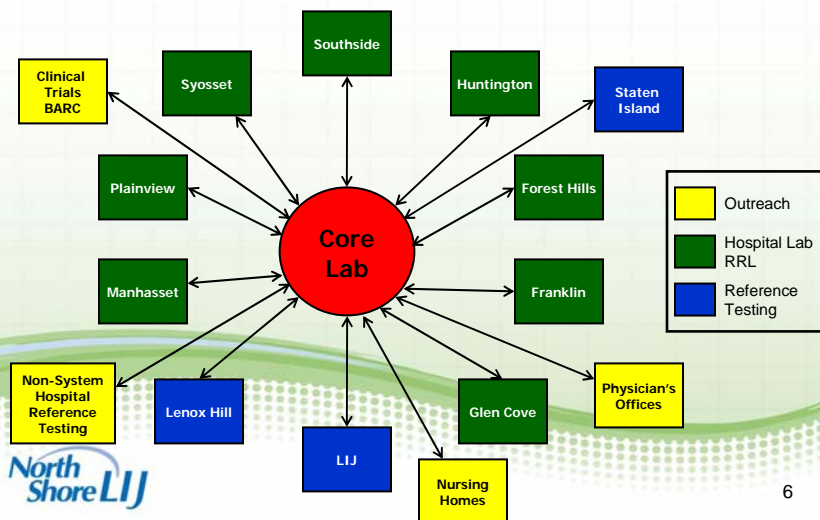


2010 System Laboratories Network

- 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



7



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



9

Core Lab Business Lines

<u>Business Line</u>	<u>\$\$</u>	<u>Volume (billables)</u>
Hospital	\$24 M	2.4 M
Reference	\$ 5 M	120 K
Physician Office	\$60 M	4.2M
Nursing Home	\$ 3 M	300 K
Clinical Trials	\$ 2 M	200 K
TOTAL 2010	\$94 M	7.2M



10

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

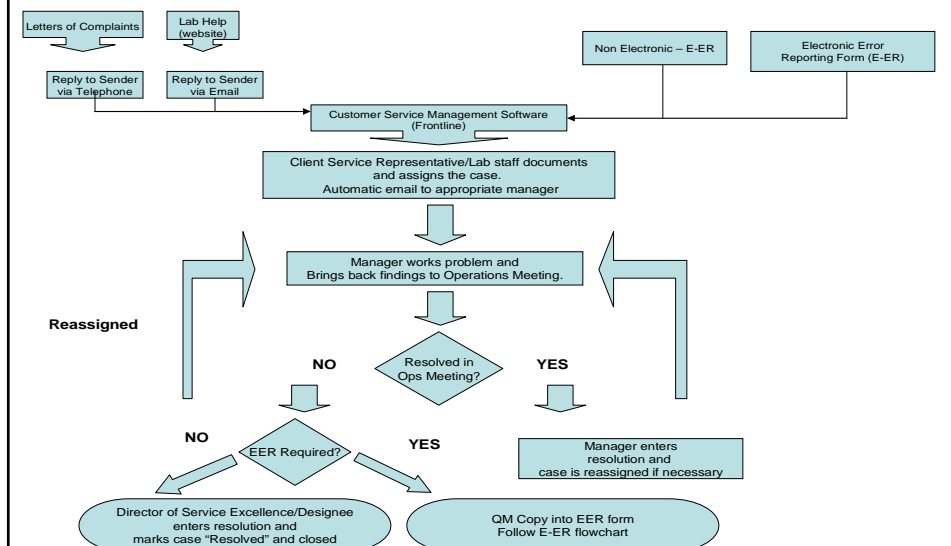
Complaints: Who, How and When

- 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



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-ERROR REPORTING INSTRUCTIONS

Please complete all three pages of the E-Error Reporting Form.

Originating Facility

Page 1:
Fill in all information including either Client Number with patient ID number or Accession number.
For Client number, patient ID number or Accession number do not use any Parenthesis or Dashes. Example: Client Number= 10000, ID number= 123 40 6789, Acc. Number= 10 03 000 00000
The date on Page 1 is categorized into Today's date (date the form is filed out) and Occur date (date occurrence happened)

Page 2:
Please click the toggle button with reason for E-Error Report Form
More than one reason may be chosen.

Page 3:
FACTS:
Explain Concern/Issue. Be very specific. Sign and date.

Responding Facility

Page 3:
FOLLOW UP:
Endlog/Investigation must be completed by Responding Facility. Sign and date.


CAPA (Corrective Action/Preventive Action)
Corrective Action: Explain cause of problem/error and corrective action. Sign and date.
Preventive Action: Explain opportunities and action plan for improvements to prevent likelihood of the recurrence. Sign and date.


Error Code Explanation:
Category A: Any error that caused the primary care provider to take action ordering another test, providing, withholding or changing treatment, modifying a diagnosis, or informing the patient or family.
For A Only: State if the adverse event is potential or actual.
Potential: Adverse event is an error or incident that produce no injury but had clear potential to do so. Example: Inocured result. Patient not treated - Potential.
Actual: Adverse event in an error or incident that caused the provider to take action providing or changing treatment to patient. Example: Inocured result. Patient treated - Actual.

Category B: A serious error, but one unlikely to affect patient care because the error did not cause the primary care provider to take action.

Category C: Minor clerical errors in reporting and "format" corrections to the report, misspelling of the patient name, improvement in wording of the report, etc.
Sign and Date.

The information in this message may be privileged and confidential information intended only for the use of the intended recipient. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error please immediately notify Quality Management by telephone. Receipt by anyone other than the intended recipient is not a waiver of any attorney-client, physician-patient or other privilege. Thank you.





E-Error Reporting Form

Patient Name: _____ Client Number: _____ Floor: _____
 Person Completing This Form: _____ Today's Date: _____ Occur Date: _____
 Client Number: _____ Specimen Num: _____ M/N: _____


Please enter the appropriate code from the list below:

Originating Facility: _____
 TO: _____

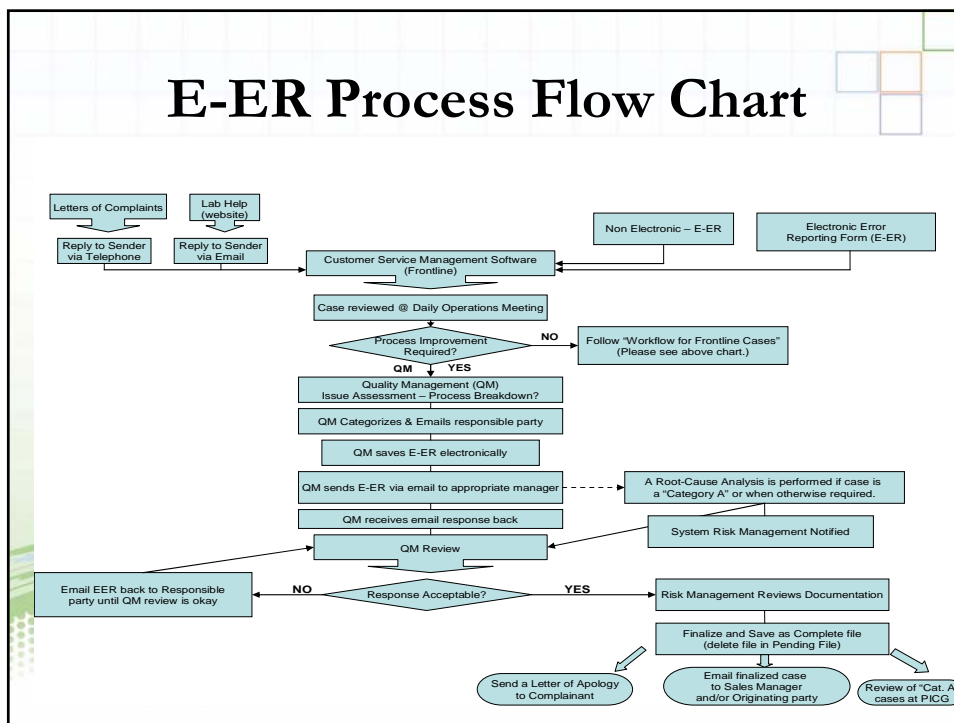
FACILITY	CODE
CORE	= CORE
Northshore	= NMS
LIJ	= LIJ
Huntington	= HUN
Spine Care	= SC
Franklin	= FRM
Joseph-Hills	= JSH
Palmyra	= PLM
Sydney	= SYD
Southside	= SS
SPARC	= SPARC
Hunting Home	= HH
Outreach	= OUT
New Island Hospital	= NIH
Patient Services Center	= PSC
Morton Cancer Center	= MCC

Sent to: _____ Date: _____
 2nd Notice: _____ Date: _____
 3rd Notice: _____ Date: _____
 Final Notice: _____ Date: _____

CONFIDENTIAL



The image displays two versions of the North Shore LIJ E-Error Reporting Form. The left version is the full form, featuring a header with the North Shore LIJ logo and the title 'E-Error Reporting Form'. Below the header is a grid of checkboxes organized into several sections: 'Prevalence', 'Reproduction', 'Patient Service Center', 'Legality', 'Misdiagnosis', 'Miscommunication', 'Misinformation', 'Mismanagement', 'Misuse of equipment', 'Misuse of information', 'Misuse of resources', 'Misuse of time', 'Misuse of space', 'Misuse of personnel', 'Misuse of materials', 'Misuse of equipment', 'Misuse of information', 'Misuse of resources', 'Misuse of time', 'Misuse of space', 'Misuse of personnel', 'Misuse of materials'. The right version is a simplified view of the form, showing the header and several large text input fields for reporting details, including 'Patient Complaint', 'Investigation', 'Corrective Action', and 'Preventive Action'. Both versions include a 'Name' and 'Date' field at the bottom.



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

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

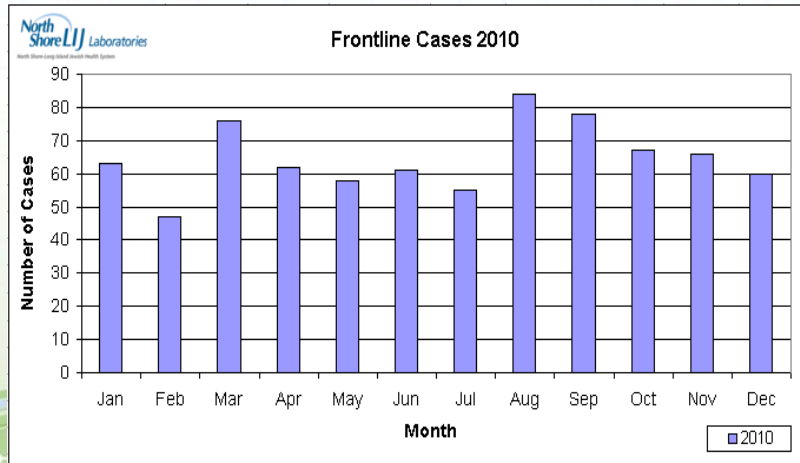
Total Cost of Failure in 2010

- **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



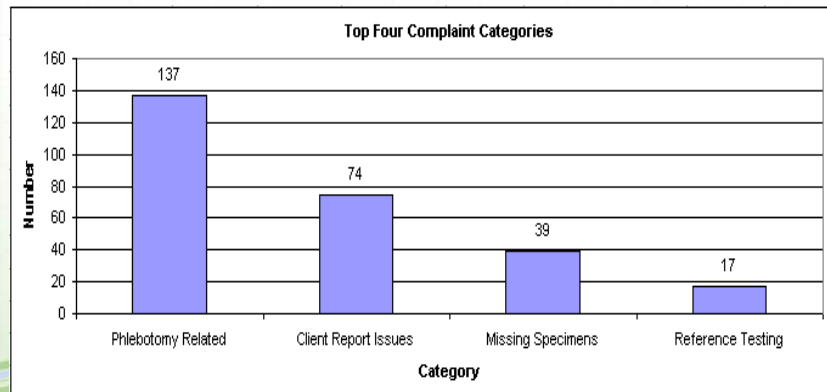
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Why Focus on Preventative Action?

- **NO TIME! NO STAFF! NO MONEY!**
- Efforts Spent on Corrective Action Could Translate to additional FTEs/Revenue

North
Shore LIJ

Top Four Complaint Categories in 2010

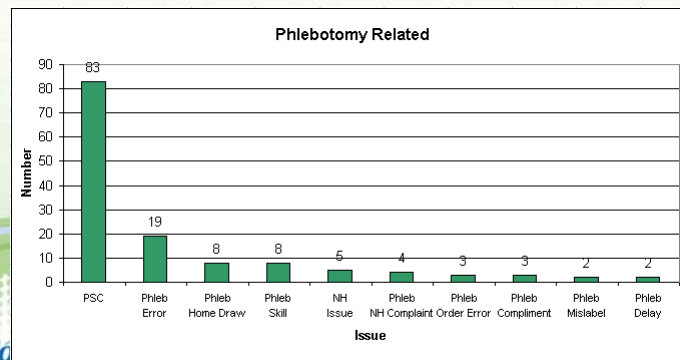
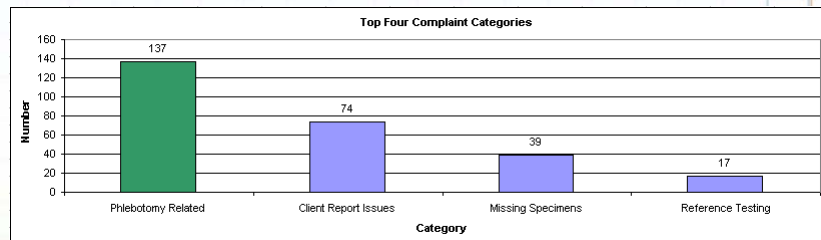


Preventive Actions Initiatives in 2011

- 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

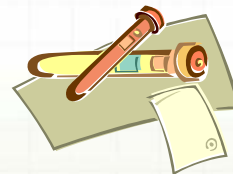


Phlebotomy Preventive Actions Initiatives


- Specimen collection
 - Phlebotomy Skill
 - Patient Identification
 - Specimen labeling
 - Patient Restrictions
- Computer skills
 - Order entry errors
 - Transfer List
- SOPs
 - Training
 - Competency
- Courtesy
 - Language barriers
 - Body language
 - Greetings

Phlebotomy – Preventive Actions *Specimen Collection*

- Phlebotomy Skill
 - Removal/Disposal of phlebotomy apparatus
 - Patient Restrictions
 - Nursing notification



Phlebotomy Preventive Actions



NURSING HOME GENERAL
10 NEVADA DRIVE, LAKE SUCCESS, NY 11042
(516) 719-1000 • 1-800-472-5757

PHLEBOTOMIST 1:
 1st Draw Attempt- Right Left
 2nd Draw Attempt- Right Left
 Unsuccessful
 Spoke to: _____

PHLEBOTOMIST 2:
 1st Draw Attempt- Right Left
 2nd Draw Attempt- Right Left
 Unsuccessful
 Spoke to: _____

SPECIMEN INFORMATION: Fasting Non-Fasting

DRAWN BY: _____ DATE: _____ PHYSICIAN SIGNATURE: _____ ID BAND: _____
 Left Arm Right Arm

STAT

Right Arm Left Arm Tourniquet Removed NURSE SIGNATURE: _____

CHECK ALL TESTS		CHECK ALL TESTS		STAT	
GENERAL LAB					
11	Basic Metabolic	S	79	Amylase	S
16	Comp. Metabolic	S	69	Lipase	S
13	Hepatic Profile	S	100	Potassium	S
22	Serum Prot. Electro.	S	46	Uric Acid	S
HEMATOLOGY					
2	CBC	L	79	D 12	S
3	CBC with Diff	L	76	Folate	S
96	Iron	S	84	Reticulocyte Count	L
45	TIBC	S	HH	HGB & HCT	L
34	Ferritin	S			
COAGULATION					
1	PT / INR	B			
19	APTT	B			
00	D-Dimer	B			
OTHER					

STAT

CODES - PLEASE CHECK CODE(S) OR INDICATE "OTHER" CODE

<input type="checkbox"/> 789.00 Abdominal Pain	<input type="checkbox"/> 250.01 Diabetes Mellitus, IDDM	<input type="checkbox"/> 791.0 Proteinuria
<input type="checkbox"/> 790.6 Abnormal Blood Chemistry	<input type="checkbox"/> 599.70 Hematuria	<input type="checkbox"/> 780.2 Syncope
<input type="checkbox"/> 794.6 Abnormal LFT	<input type="checkbox"/> 573.3 Hepatitis, NOS	<input type="checkbox"/> 599.0 UTI
<input type="checkbox"/> 428.0 Congestive Heart Failure	<input type="checkbox"/> 276.7 Hyperkalemia	<input type="checkbox"/> 783.21 Weight Loss
<input type="checkbox"/> 585.9 Chronic Renal Failure	<input type="checkbox"/> 276.8 Hypokalemia	<input type="checkbox"/> V58.69 Long Term Med. Use
<input type="checkbox"/> 785.1 Dysuria	<input type="checkbox"/> 272.4 Hyperhidrosis	
<input type="checkbox"/> 250.00 Diabetes Mellitus, NIDDM	<input type="checkbox"/> 401.9 Hypertension, NOS	Other: _____
<input type="checkbox"/> 790.6 Abnormal Blood Chemistry	<input type="checkbox"/> 780.60 Fever, NOS	
<input type="checkbox"/> 285.9 Anemia, NOS	<input type="checkbox"/> 573.3 Hepatitis, NOS	
<input type="checkbox"/> 041.9 Bacterial Infection	<input type="checkbox"/> 280.9 Iron Deficiency Anemia	
<input type="checkbox"/> 006.2 Diarrhea, Infectious	<input type="checkbox"/> 780.79 Malaise and Fatigue	
<input type="checkbox"/> 786.05 Dyspnea	<input type="checkbox"/> 486 Pneumonia	
<input type="checkbox"/> 250.00 Diabetes Mellitus, IDDM	<input type="checkbox"/> 079.99 Vital Infection	
<input type="checkbox"/> 250.01 Diabetes Mellitus, IDDM		Other: _____
<input type="checkbox"/> 427.31 Atrial Fibrillation	<input type="checkbox"/> 415.19 Other Pulmonary Embolism	<input type="checkbox"/> V43.3 Mechanical Heart Valve
<input type="checkbox"/> 571.5 Cirrhosis	<input type="checkbox"/> 287.5 Thrombocytopenia	<input type="checkbox"/> V58.61 Long Term Anticoagulants
<input type="checkbox"/> 573.9 Liver Disorder	<input type="checkbox"/> 453.9 Thrombosis	
<input type="checkbox"/> 415.12 Septic Pulmonary Embolism		Other: _____

Phlebotomy – Preventive Actions *Courtesy*

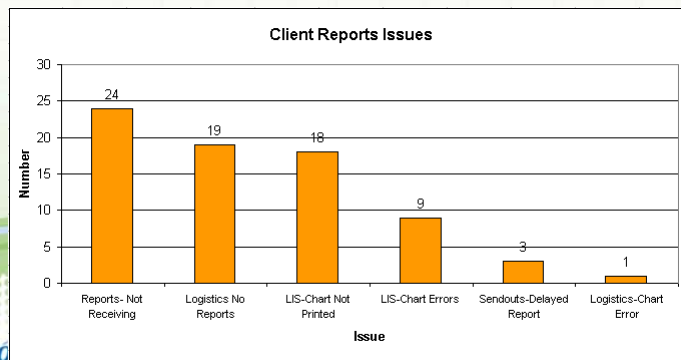
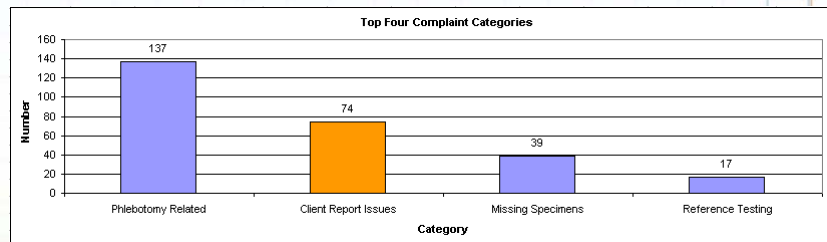


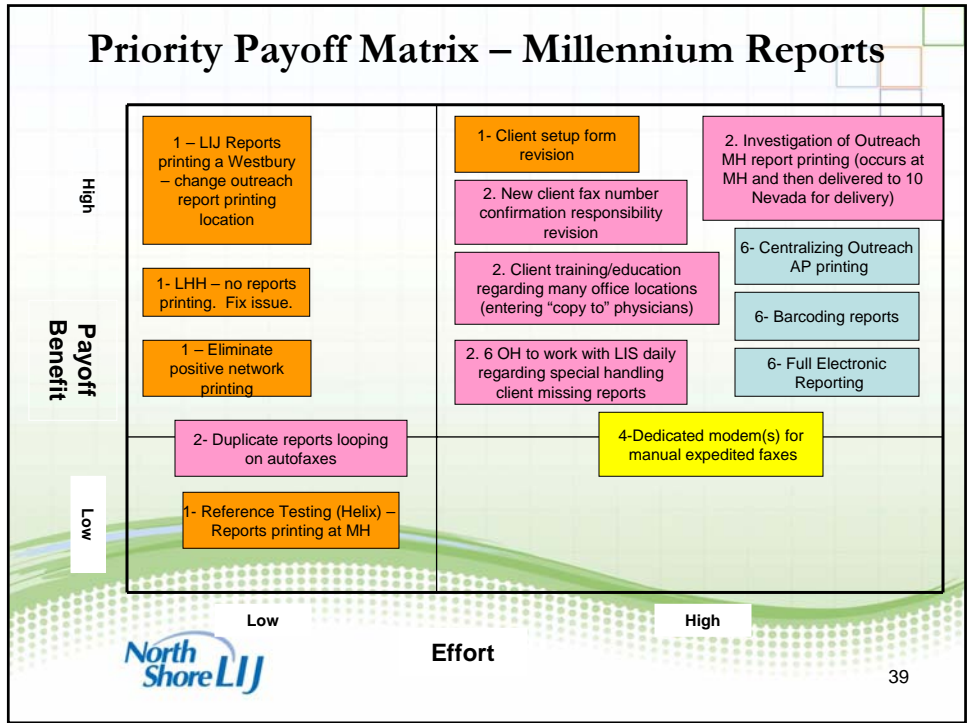
- Patient Sensitivity
- Service Excellence

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



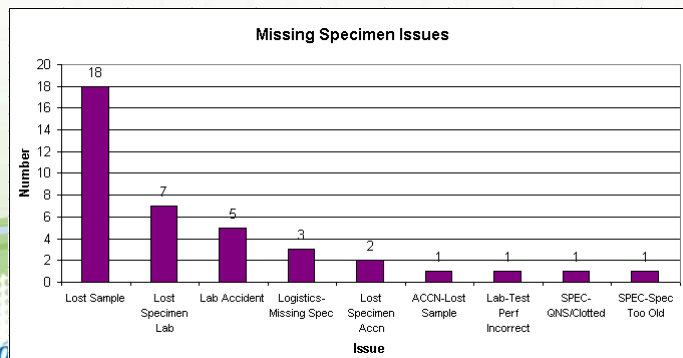
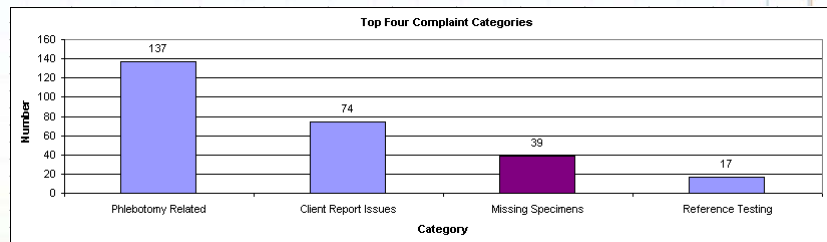


- ## Client Patient Reports Preventive Actions Initiatives – Mini-Lean
- Preventive Actions
 - Reschedule and Relocate Print Jobs
 - Monitor Technical Resulting Cut-off Time of 6am
 - Monitor Print-job Initiation on Daily Basis
 - Adjusted Logistics Staffing and Route Start Times
 - Review and Update Data Base
 - Improving Hardware
 - Enable Bar-coding of Charts for Tracking – In Progress
- North Shore LIJ**
- 40

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



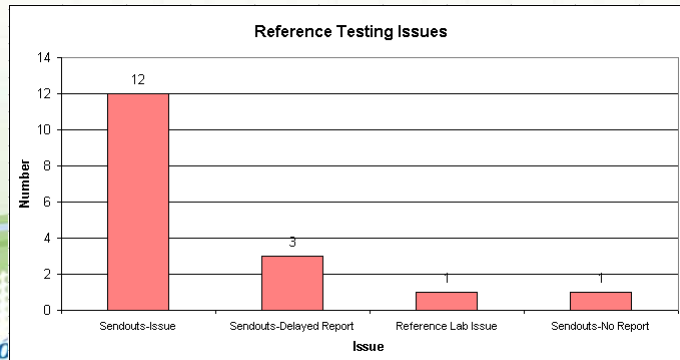
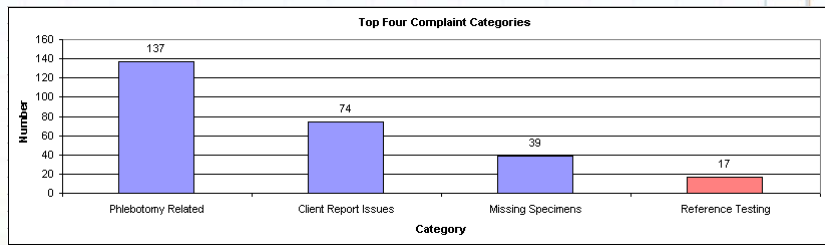
Missing Specimens Preventive Actions Initiatives

- 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 though out 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



THANK YOU!

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