Validation of Interfaces: Our Home Grown Approach to Effectively Feed Lab Data into the Myriad of HIS, LIS, EHRs and Mobile Devices in Today’s Connected Healthcare System

Presented by
Hannah Poczter, AVP, Carol Sien and Ed Giugliano, PhD
Goals and Objectives

• To identify common strategies to effectively validate lab interfaces
• To describe the most effective approach and tools to accomplish validations
• To eliminate unnecessary steps in the validation process
• To create a workable plan to validate various electronic laboratory interfaces
NSLIJHS Vital Statistics

2013 Key Facts

- 12 Hospitals (6000 hospital and Long term care beds).
- Owner/operator of North Shore LIJ CareConnect Insurance Company, Inc.
- 3 Skilled Nursing Facilities.
- Nearly 400 ambulatory and physician practices.
- Service area of 7 million people in Long Island, Queens, Manhattan and Staten Island.
- Home of the largest “Corporate University” in the healthcare industry – Center for Learning and Innovation

2013 Economic Impact

- $7 billion operating budget
- More than 48,000 employees – Largest private employer in NYS
- More than 9,400 physicians
- More than 10,000 nurses
- More than 4,725 volunteers
Laboratory Network
NorthShore LIJ

Core Lab

Clinical Trials BARC
Syosset
Southside
Huntington
Staten Island
Plainview
Forest Hills
Franklin
Lenox Hill
Glen Cove
LIJ
Nursing Homes

Non-System Hospital Reference Testing
Physician’s Offices

Outreach
Hospital Lab
RRL
Our Model - Consolidated Laboratory Network

- Central “Core” Laboratory
- 12 Hospital Based Labs
- $300 Million Annual Operating Budget
- 1400 FTEs/ 80+ Pathologists
- 16+ Million Billable Tests
- 180,000 Surgical Specimens
- 30 + Patient Service Centers
- Multiple Ambulatory Sites
Our Model - Consolidated Laboratory Network

- Strategically Located Core Laboratory – 60,000 sq. ft.
- Anatomic Path Subspecialty – 25,000 sq. ft.
- LIS & Billing – 15,000 sq. ft.
- Rapid Response Laboratories (RRL)
- Standardized Test Menu
- Standardized LIS (Cerner)
- Standardized Laboratory Instrumentation
- Standardized Policy and Procedures
Core Laboratory

- Strategically Located – Highly Automated
- 40 - 50 Percent Hospital Lab Tests
- Routine Testing
- Microbiology/Virology
- Esoteric – Molecular, Virology, Special Testing
- Reference Testing – All Send Outs
- Subspecialty / Pathology
- Active Sales Department
## Core Laboratory Business Lines 2013

<table>
<thead>
<tr>
<th>Business Line</th>
<th>Volume</th>
<th>Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>5,813,566</td>
<td>$111,058,701</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>511,102</td>
<td>$4,632,674</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td>150,910</td>
<td>$3,660,636</td>
</tr>
<tr>
<td>Reference</td>
<td>40,062</td>
<td>$890,394</td>
</tr>
<tr>
<td>Total Outreach</td>
<td>6,515,640</td>
<td>$120,242,406</td>
</tr>
<tr>
<td>Hospital</td>
<td>1,737,305</td>
<td>$31,589,143</td>
</tr>
<tr>
<td>TOTAL</td>
<td>8,252,545</td>
<td>$151,831,549</td>
</tr>
</tbody>
</table>
## Find the Right Partner-Alignment

<table>
<thead>
<tr>
<th>NSLIJ</th>
<th>HHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central “Core” Laboratory</td>
<td>4 “Core” Laboratories</td>
</tr>
<tr>
<td>12 Hospital Based Labs</td>
<td>11 Hospital Based Labs</td>
</tr>
<tr>
<td>$260 Million Annual Operating Budget</td>
<td>$260 Million Annual Operating Budget</td>
</tr>
<tr>
<td>Approx. 1400 FTE’s</td>
<td>Approx. 1400 FTE’s</td>
</tr>
<tr>
<td>16 Million Billable Tests/year</td>
<td>16 Million Billable Tests/year</td>
</tr>
<tr>
<td>Not-for-Profit Health System</td>
<td>Public-Benefit Corporation</td>
</tr>
<tr>
<td>Focus on Patients, Community and Education</td>
<td>Focus on Patients, Community and Education</td>
</tr>
</tbody>
</table>
Why Validate?

- Regulatory Requirement
- Patient Safety
- Ensure all elements of a computer system perform as expected
  - Accurately and Reproducibly
- Good business practice
  - Find and Resolve Problems
- Prevent Possible Litigation

HOW MUCH VALIDATION IS NEEDED?
Regulatory and Accrediting Agencies

– FDA - CFR title 21, part 11
– CLIA – 493.1291(a) – Standard: Test Report
– CAP -Gen 48500 – Interface Result Integrity
– ISO 15189 – 5.10.3- Information System Mgmt
– NYS DOH – LIMS S4 – Validation
– CLSI -AUTOo8-A   Managing and Validating Laboratory
  Information Systems
Regulatory and Accrediting Agencies

• FDA/CLIA – 493.1 291(a) – Standard: Test Report
  • The Lab must ensure test results and other patient specific data are accurately and reliably sent from the point of data entry to final report destination.

• CAP -Gen 48500 – Interface Result Integrity
  – There is a procedure to verify that patients results are accurately transmitted from the point of data entry to patient report prior to implementation, every two years thereafter.

• NYS DOH – LIMS S4 – Validation
  • Laboratory shall validate any system changes including new and revised software/hardware changes prior to their use for specimen testing, reporting and report keeping functions. Medical Director and Lab Management must approve any installation validation of new systems.
Pre Lean Validation Team Structure

• Team Lead by LIS Dept Only
  – System Hospital HIS Interfaces
  – EMR Interfaces

• Each LIS Division Developed Own
  • Validation and Post Validation Plans
  • Testing and Approval
  • Documentation
    – Final Documentation and Approvals
    – Maintained by own team

• Minimal Interaction with Lab
NSLIJ Lab Validation Challenges

• Formed alliance with NYC Health and Hospitals
  – Required interfaces between their HIS/LIS and our LIS
  – Involved interfacing 21 HHC sites via middleware to Core Lab LIS in 8 months

• Rapid growth in the number of outreach clients resulted in the need for rapid validation of various new EMRs

• Demand for availability of Laboratory results via high tech electronic handheld devices
Hospital Validation-NYC HHC
Hospital Validation-NYC HHC

• NYC Health and Hospitals Corporation Initiative
• 21 Sites
• 8 Hubs
  – Each Hub Differs from the Others
• Scope of Project required working with IT Consultants
HHC HIS/LIS Data Flow

HHC Hospital → HHC HIS/LIS → Middleware Engine → Lab LIS

Middleware Engine

Receive in Lab

Release result in Lab LIS

Process Sample
HHC/NSLIJ Lab Data Flow
Pre-Lean Initial Validation Plan

• Original HHC HIS/LIS Validation

• Initial Validation Plan Included 6 Phases:
  – Connectivity Testing
  – Sample Testing
  – Unit Testing
  – Scenario and Format Testing
  – Parallel Testing
  – Post Validation Testing
# Pre-Lean Initial Validation

## Initial Validation Plan

<table>
<thead>
<tr>
<th>Phases</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
<th>Step 6</th>
<th>Step 7</th>
<th>Step 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Orders in Quadramed (@HHC IT location)</td>
<td>Review or Orders in Corner (@NSHS)</td>
<td>Resulting Orders - Performed in house (@NSHS)</td>
<td>Result Orders - Sendout tests (@NSHS)</td>
<td>Quadramed (@HHC IT Location)</td>
<td>Quality Management (@NSHS)</td>
<td>Xfin - Billing System</td>
<td>HHC Signoff</td>
</tr>
<tr>
<td>Tasks</td>
<td>Place orders for the requested/tests in Quadramed system. Build and transmit manifest.</td>
<td>Receive the specimen in lab ( scans label) Copy the set of the order in Quadramed and check Quadramed manifest. Check Quadramed label and print Quadramed label.</td>
<td>Enters results. Print screen of results from Corner in Order Result Viewer (DVR). To print patient chart with the results from Corner.</td>
<td>Build transfer list (transmit orders) Contact ref lab. Review results in Corner when provided by ref lab. Print patient chart with the results from Corner.</td>
<td>Print screen of results from Quadramed. Print patient chart with the results from Quadramed. Mach screenshots to packets.</td>
<td>Review Packets. Identify issues. Work with LIS on resolution/refuse. Validation of reports and utilization. TAT, Pending Reports. Final Sign off.</td>
<td>Validate Charging for all tests. Pull billing reports and validate format and accuracy.</td>
<td>Review Packets, Validate result format in Quadramed. Validation of reports and utilization. TAT, Pending Reports. Final Sign off.</td>
</tr>
<tr>
<td>Scope</td>
<td>30 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
<td>30 Orders 10 Orders max per patient 10 Patients max per Manifest</td>
<td>20-30 Orders 1 Patient 3 Patients</td>
<td>20 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
<td>30 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
<td>30 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
<td>30 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
<td>30 Orders 4 Patients 10 Orders max per patient 10 Patients max per Manifest</td>
</tr>
<tr>
<td>Resources</td>
<td>HHC LIS</td>
<td>1NS LIS Analyst</td>
<td>1NS LIS Analyst</td>
<td>1NS LIS Analyst</td>
<td>1NS LIS Analyst</td>
<td>1NS LIS Analyst</td>
<td>1NS QA</td>
<td>1NS Analyst</td>
</tr>
<tr>
<td>Skills</td>
<td>Accessioning Skills, Ordering Experience</td>
<td>Accessioning Skills, Ordering Experience</td>
<td>LIS Analyst</td>
<td>LIS Analyst</td>
<td>Accessioning</td>
<td>1QA</td>
<td>1NW Specialist</td>
<td>Clinical Representative</td>
</tr>
<tr>
<td>Duration</td>
<td>4 Hours</td>
<td>4 Hours</td>
<td>2 hours</td>
<td>4 hours</td>
<td>4 hours</td>
<td>4 hours</td>
<td>4 hours</td>
<td>4 hours</td>
</tr>
<tr>
<td>In Timeline</td>
<td>Day 1</td>
<td>Day 2</td>
<td>Day 3</td>
<td>Day 4</td>
<td>Day 5</td>
<td>Days 6-10</td>
<td>Days 8-10</td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td>Days 1-5 troubleshooting issues</td>
<td>Review script to include name of test in Quadramed and name of test in Corner. Translation of test names between two systems.</td>
<td>Core lab will work with each independent reference lab to coordinate result of orders</td>
<td>Same FTE that has been trained on placing orders.</td>
<td>Need a result example of every test from Quadramed (provided by HHC). The process needs to start at beginning of each testing cycle.</td>
<td>Only performed for the first site.</td>
<td>Performed for each Quadramed hub</td>
<td></td>
</tr>
</tbody>
</table>

---

*North Shore LIJ Laboratories*
### Pre-Lean Initial Validation

**Test Script Checklist**

<table>
<thead>
<tr>
<th>A</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Name</strong></td>
<td>TestHLM, UnitNine</td>
<td>TestHLM, UnitNine</td>
<td>TestHLM, UnitNine</td>
<td>TestHLM, UnitNine</td>
<td>TestHLM, UnitNine</td>
</tr>
<tr>
<td><strong>Quadramed MRN</strong></td>
<td>73</td>
<td>73</td>
<td>73</td>
<td>73</td>
<td>73</td>
</tr>
<tr>
<td><strong>QUADRAMED ORDER DESCRIPTION</strong></td>
<td>CI Inhibitor Functional (Send Out)</td>
<td>Amylase Isoenzymes, Serum (Send Out)</td>
<td>Hepatitis D Ab Total (Send Out)</td>
<td>Polio (Type 1,2,3) Ab, CF, Serum (for recent infection) (Send Out)</td>
<td>Haloperidol, Serum (Send Out)</td>
</tr>
<tr>
<td>Quadramed Accession Number</td>
<td>2000152-1</td>
<td>2000152-1</td>
<td>2000152-1</td>
<td>2000152-1</td>
<td>2000152-1</td>
</tr>
<tr>
<td>Quadramed Ordered Date/Time</td>
<td>12/18/2013</td>
<td>12/18/2013</td>
<td>12/18/2013</td>
<td>12/18/2013</td>
<td>12/18/2013</td>
</tr>
<tr>
<td>Quadramed Manifest Number</td>
<td>85</td>
<td>85</td>
<td>85</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>NSLIJ Core Lab Received By</td>
<td>sriley2</td>
<td>sriley2</td>
<td>sriley2</td>
<td>sriley2</td>
<td>sriley2</td>
</tr>
<tr>
<td>Center Financial Number</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CENTER ORDER DESCRIPTION</td>
<td>CI Esterase Inhibitor</td>
<td>Amylase Isoenzyme</td>
<td>Hepatitis Delta Antibodies</td>
<td>Polio Virus Antibodies</td>
<td>Haloperidol</td>
</tr>
<tr>
<td>Center Packing List (if send out)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>in front of Manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results from Center Posted (Pass/Fail)</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Fail</td>
<td>Pass</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VALIDATION DOCUMENTATION RECEIVED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HHC Order</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HHC Manifest</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Center Order</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Center Results</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Center Chart</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Screenshots of results in Cmsed EMR/HIS</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>HHC Chart</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Reference Lab Chart</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Xfiffi Charge</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Verified By</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Completed Testing Script Spreadsheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviewed / Approved By</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

North Shore LIJ Laboratories
Pre-Lean Validation Plan/Checklist Issues

– Too many tests validated per patient causing high rate of script failure

– Documentation was difficult to obtain from all parties involved (HHC/NSLIJ/Reference Labs)

– Validation test plan/test script checklist were difficult to follow

– Lack of communication
  
  • Many different people involved at many different locations (HHC LIS/Consultants/NSLIJ LIS/Middleware LIS/ Lab Operations/Quality Management
  
  • Misunderstanding of roles and responsibilities of each person
Pre-Lean Validation Plan/Checklist Issues

– Tracking of Issues
  • Many versions of issue logs
  • Poor documentation on logs
  • Lack of consolidation of issues

– Documentation of validation performed by LIS and not communicated to QM
  • Unable to tell which tests failed and which passed
  • If failed, where was documentation of retest?

– Writing of new scripts while running of retests
  • Became disorganized and confusing
Pre-Lean Validation Process Flow

HHC Analyst
- Submit test orders and create manifest
- Notify S&P Analyst that test orders are ready

Consultant Analyst
- Orders and manifest complete?
  - Yes
    - Did Middleware transfer results correctly?
      - No
        - Contact reference lab to result test orders
      - Yes
        - Compile the test packet containing 10 tests on each script
            - Does packet have all necessary documentation?
              - Yes
                - Record in Analyst excel spreadsheet
              - No
                - Make necessary corrections to script
            - No
              - Is it a send out test?
                - Yes
                  - Record as FAIL on QM excel spreadsheet
                - No
                  - Result in house test orders
          - No
            - Result in house test orders

Lab Personnel

QA Specialist
- Pass script and send test into production
- Received completed test packets?
  - Yes
    - Can we make the deadline?
      - Yes
        - Continue with one QM staff member
      - No
        - Send entire QM department for assistance
  - No
    - All tests and scripts validated?
      - Yes
        - Record as PASS on QM excel spreadsheet
      - No
        - Record as FAIL on QM excel spreadsheet

Lean Process

• Took 3 months of weekly meetings
• Engaged Laboratory Operations, LIS and Quality Management
• Identified Non-Value Added Steps and removed from the validation plan
• Identified Process Improvements and implemented them
Post Lean Validation Team Structure

• NSLIJ Laboratories Validation Structure
  – LIS Department - Hospital Group
  – Lab Operations
  – Lab Technical Personnel
  – Quality Management
Post Lean Validation Plan

• Streamlined Validation Plan
  – Combined connectivity and sample testing
  – Combined unit testing and scenario/format testing
Post Lean Validation Plan

• Changes included:
  – Reduction in the number of documents required by the test script.
  – Streamlined script to include only one test / test patient to allow for completion of the script from beginning to end and facilitate tracking of failures/issues.
  – Use of a shared test script tracking spreadsheet by LIS and QM called the “SMART SHEET”
  – Obtain and review test compendium for each site and prioritize test scripts
  – Improved communication through the implementation of “touch point” meetings
  – Assignment of outstanding test scripts to a designated person
Post-Lean Validation

• Test Script Checklist
  – Patient Demographics
  – Test Name
  – Result Value or Text
  – Result Review
    • UOM
    • Reference Range
    • Critical Flagging
    • Abnormal Alphas
    • Calculations
    • Interpretive Data
    • Reflex Orders
    • Comments
  – Corrected Results
Post-Lean Validation

• Test Script Tracking Status
HHC Common Validation Errors

• Truncation of Textual Test Results/Comments
• Report Formatting Issues
• Logical Display of Results
• Flagging of Abnormal Result
• Accurate Reference Ranges/Units of Measure
• Validation of User Display of Results
• Handling of Complex Reports Containing an Abundance of Text and Tables which can Become Scrambled
Validation Documentation

• Hard or Electronic Copy Acceptable
  – Interface Implementation Test Plan Overview Approval Page
  – Interface Test Script Validation Approval Page
    • IT Director and AVP Labs – NSLIJ Labs
    • Medical Directors - NSLIJ Labs and HHC Site
  – Table of Contents
  – Test Plan Overview Process Document
  – Manifests with Test Orders
  – Test Scripts
  – Scenario
Validation Statistics/Metrics

• To Date there were
  – Thirteen sites validated
  – Approximately 3000 test results validated
  – Approximately 400 UNIQUE tests validated

• Lean Metrics
  – Pre-Lean Resources Metrics—Approx 15 FTE
  – Post-Lean Resources Metrics—Approx 5 FTE
    • Approximately 67% Reduction in Resources!
    • Or Savings of $430,125 per hub
Validation Statistics/Metrics

- Lean Metrics-Cont
  - Average Turn Around Time (TAT) per HHC hub
    - Pre-Lean = Approximately 3 months
    - Post-Lean = Approximately 1 month
  - Average Volume of Failed Scripts
    - Pre-Lean = 69 out of 196 test scripts (35%)
    - Post-Lean = 6 out of 229 test scripts (3%)
Hospital Validation Summary

• Test Compendiums, Test Definitions and Test Nomenclature Should Be Compared and Standardized prior to performing validations
• Make the test validation plan flexible enough to handle situations that come up
• Perform trial run of the process from start to finish to get out all of the kinks and the process of passing data around
• Organization of binders for presentation to the client makes all the difference!
Hospital Validation Outcome

From:
- Chaos
- Stress
- Long Hours
- Excessive Rework
- Poor Communication

To:
- Cohesive Teamwork
- Calm
- Efficient Validation Team
- Correct the First Time
- Daily Touch Point Meetings

Looking Forward to the Next Challenge of Implementing a New HIS System for HHC and Other Hospitals Joining the NSLIJ Team!
EMR Validation-Outreach Clients

• Faced with an Ever Growing Number of Outreach clients with a myriad of EMRs requiring interface validations to our LIS simultaneously
  – 100s of sites
  – Number of different EMRs – A LOT!
    • Allscripts, Atlas, Comtron, i-Patient, Epic, etc
• To Perform Validation Must Engage EMR Vendors, LIS Outreach Team and Clients
EMR Data Flow

1. Clinician’s EMR
2. Lab LIS
3. Receive in Lab
4. Process Sample
5. Release Result in Lab LIS

Flow:
- Clinician’s EMR → Lab LIS
- Lab LIS → Receive in Lab
- Receive in Lab → Process Sample
- Process Sample → Release Result in Lab LIS
- Release Result in Lab LIS → Clinician’s EMR
EMR Lean Validation Structure

– We Learned Many Lessons from HHC HIS/LIS Validation Lean Process. These were adapted for use in Outreach EMR Validations
– Streamlined Validation Plan and Test Script Checklist based on HHC Lean Process
– Streamlined Team Approach Incorporating LIS, QM, Lab Operations, Sales, Client and/or Vendor.
EMR Lean Validation Plan

• Streamlined Outreach Client Validation Plan

• Validation Plan Includes 3 Phases:
  – Connectivity Testing (Combined with Sample Testing)
  – Unit, Scenario and Format Testing (Combined)
  – Post Validation Testing
    • Parallel Testing Eliminated – “Dry Run”
### Lean Validation Plan

- **Streamlined Outreach Client Test Script Checklist**

<table>
<thead>
<tr>
<th>Step</th>
<th>System</th>
<th>Step</th>
<th>Expected Outcome</th>
<th>Documentation</th>
<th>Pass/Fail</th>
<th>Issue</th>
<th>Resolution</th>
<th>Date/Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Client</td>
<td>Register AllscriptPro, Test2</td>
<td>Patient is registered</td>
<td>Req</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>NAME: AllscriptPro, Test2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>GENDER: Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>MRN: Please provide</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>Insurance Primary: MEDICARE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>Insurance Secondary: MEDICARE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>Relationship Type: Self for Primary/Self for Secondary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>Requisition #: 1533-00655</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Client</td>
<td>Place ROUTINE order for</td>
<td>Orders are placed</td>
<td>Req</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300000 - METABOLIC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300145 - LDH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300437 - TSHX</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300211 - GLY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300110 - UA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300102 - UREA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5500190 - CBC/DIFF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300110 - URIC4 [ACF Refer to ACF sheet]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Client</td>
<td>5300520 - CRLEAR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Client</td>
<td>Verify Request and labels printed</td>
<td>Requisition and labels printed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>LIS</td>
<td>Verify Patient registration</td>
<td>Patient registration is correct in HNAM</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>5</td>
<td>LIS</td>
<td>Verify order display</td>
<td>Orders display in HNAM with correct priority and route to appropriate collection list</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>6</td>
<td>LIS</td>
<td>Receive orders into HNAM</td>
<td>Status updates in HNAM to “In Lab”</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>7</td>
<td>Client</td>
<td>Verify status update of orders/in Lab/in Process</td>
<td>Status is updated to complete/in process for micro’s</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>8</td>
<td>LIS</td>
<td>Lab to result orders with a combination of Low, Normal, High and Critical. Micro’s can be resulted as pending’s. RESULT TSH AS ABNORMAL &gt;20, RESULT UAC AS ABNORMAL FOR</td>
<td></td>
<td></td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>9</td>
<td>Client</td>
<td>Verify status update of orders</td>
<td>Status is updated</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>10</td>
<td>LIS</td>
<td>Verify status update of orders</td>
<td>Status is updated</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>11</td>
<td>Client</td>
<td>Verify status update of orders/in Lab/in Process</td>
<td>Status is updated</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>12</td>
<td>Client</td>
<td>Lab to result orders with a combination of Low, Normal, High and Critical. Lab to finalize any pending</td>
<td>Expect finals across the board</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
<tr>
<td>13</td>
<td>LIS</td>
<td>Verify all orders are complete</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Client</td>
<td>Send final documentation of script to LIS</td>
<td>Final Report</td>
<td>Screen Print</td>
<td>PASS</td>
<td></td>
<td></td>
<td>4/24/2014</td>
</tr>
</tbody>
</table>
New Streamlined EMR Validation Plan

• Patients and Tests to Validate Included:
  – Performed in Test Environment
  – Approx 10 Test Patients
  – Primarily High Volume and Esoteric Tests
  – Approx 1 – 15 Tests/ Test Patient

  • Various Areas of Lab
    – Chem, Special Chem, Serology, Hematology, Coagulation, UA
    – Blood Bank, Microbiology, Anatomic Pathology
    – Cytogenetics, Molecular Genetics
    – Reference Testing

  – Post Validation Testing
    • Occurs After Go-Live Using Same Validation Plan Criteria
New Streamlined EMR Validation Plan

• Fields to Validate Included:
  – Patient Demographics
  – Billing and Insurance Information
  – Test Name
  – Result Review
  – Comments
  – Reflex Order
  – Corrected/Amended/Appended Results
EMR Validation Errors

• Performing Facility Issues
  – Duplicate Listings

• Incomplete Order Comments
  – Gestation Age Missing Units
  – Weeks vs Days

• Missing Reference Ranges and Units
  – Vitamin D and K

• Calculation Issue
  – Creatinine Clearance and Uric Acid Blended as One Test

• Collection and Report Time Discrepancies
EMR Validation - What Worked Well

- Issues Faced Previously During the HHC Validation are No Longer Problematic
  - Electronic communication of validation documents from one person to another worked well
  - Documentation of validation steps performed by LIS and communicated to QM via spreadsheet worked well
  - Running of retests and subsequent documentation was more organized
  - Good documentation on the issue log was noted
EMR Validation - What Didn’t

• Unanticipated Billing Issue Arose
  – 1° and 2° Insurance data transposed in Billing System

• Obstacles Faced During the Validation Process
  – EMR Vendors
    • Can be Very Uncooperative
  – Clients
    • Oftentimes Lack IT Support, Knowledge and Resources
    • Do Not Truly Understand the Importance of Lab Data Integrity
    • Not enough lead time to perform validation
    • Tend to be Reactive Rather Than Proactive

• However, the overall EMR Validation Process Worked Very Well!
EMR Validation Outcome

From:
- Unilateral LIS Approach
- Limited Expertise
- Missed Errors
- Working in Silos
- Complex Broken Process

To:
- Multidisciplinary Approach
- Benefits of Technical, QM, Operations, Sales Expertise
- Quality Validation
- Benefits of Collaboration
- Streamlined Process that WORKS!

Armed and Ready for the Multitudes of EMR Validations to Come!
Mobile Device Validation

• Demand for rapid laboratory result data availability was fueled by advent of various high tech electronic handheld solutions

• Number of different Devices
  – iPhone
  – Androids

• Yes... the NSLIJ Laboratories now have an “App” for that!
Mobile Device Validation

[Image of a smartphone interface with an app named North Shore LIJ Labs highlighted.]

[Image of a login screen for North Shore LIJ Laboratories with fields for Username and Password, and a Login button.]
Mobile Device Validation
Mobile Device Validation

MPC

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALK PHOS</td>
<td>48</td>
</tr>
<tr>
<td>Glucose, Serum</td>
<td>123 (in mg/dL)</td>
</tr>
<tr>
<td>Total Bilirubin</td>
<td>0.1 (in mg/dL)</td>
</tr>
<tr>
<td>CO2</td>
<td>21 (in mmol/l)</td>
</tr>
<tr>
<td>Chloride</td>
<td>106 (in mmol/L)</td>
</tr>
<tr>
<td>Albumin</td>
<td>3.7 (in g/dL)</td>
</tr>
</tbody>
</table>

Parameter History

<table>
<thead>
<tr>
<th>Date</th>
<th>Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/03/2013</td>
<td>101</td>
<td>(96-108)</td>
</tr>
<tr>
<td>04/19/2013</td>
<td>102</td>
<td>(96-108)</td>
</tr>
<tr>
<td>06/06/2013</td>
<td>103</td>
<td>(96-108)</td>
</tr>
<tr>
<td>09/06/2013</td>
<td>100</td>
<td>(96-108)</td>
</tr>
<tr>
<td>10/04/2013</td>
<td>95</td>
<td>(96-108)</td>
</tr>
</tbody>
</table>
Mobile Device Data Flow

1. Lab Order Placed
2. Lab LIS
3. Receive in Lab
4. Process Sample
5. Release result in Lab LIS
6. Mobile EMR Software
7. ATLAS
Mobile App/NSLIJ Lab Data Flow
Mobile Device Validation

• Scope of the project required working with the Application vendor, LIS and QM Departments and Sales

• Three Lab Result formats requiring validation:
  – Application Website – “Hard Copy”
  – iPhone App Display
  – Android App Display

• In the case of Smart Phone apps, security validations were also required
Mobile Device Validation

- Validation plan was formatted from prior LIS interface validation plans.
- The Validation Team included QM working together with LIS, the App vendors as well as Sales and a “Beta-Test” Physician Client.
Mobile Device Validation Plan

Verification of Transmitted Results Form for iPhone and Android App

North Shore Long Island Jewish Health System Laboratories
10 Nevada Drive, Lake Success, NY 11042

Verification of Transmitted Results Form for iPhone and Android App

<table>
<thead>
<tr>
<th>Verification of Transmitted Results Form for iPhone and Android App</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Identification:</td>
</tr>
</tbody>
</table>

1. Patient Chart (request a chart in Millennium) with patient demographics vs. Malignant patient demographics in Patient Chart (Hard copy vs. Hard Copy)

2. Patient Chart (request a chart in Millennium) with NORMAL results vs. Malignant result in Cell Phone Screen including Reference Range and units (Hard copy vs. Hard Copy)

3. Patient Chart (request a chart in Millennium) with ABNORMAL results vs. Malignant result in Cell Phone Screen (Hard copy vs. Hard Copy)

4. Patient Chart (request a chart in Millennium) with CRITICAL results vs. Malignant result in Cell Phone Screen (Hard copy vs. Hard Copy)

5. Patient Chart (request a chart in Millennium) with a CHANGED result vs. Malignant result in Cell Phone Screen

6. Patient Chart (request a chart in Millennium) with INTERPRETATION vs. Malignant result in Cell Phone Screen

7. Patient Chart (request a chart in Millennium) with CHARGABLE COMMENTS vs. Malignant result in Cell Phone Screen

<table>
<thead>
<tr>
<th>Review</th>
<th>Date</th>
<th>Initial</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewers: (Hard Copy): Date: Date: Phone Type: Date: Phone: Date:

Reviewed by QA: Date: Date:

Summary of Review:
- Acceptably; no errors found
- Not acceptable, requires follow up
- Comment: 

Approved by: Date: Date:

North Shore LIJ Laboratories
Mobile Device Validation Plan

- Scope limited to primarily outreach patients
- Included approximately 50 different patients
- Approximately 85 different tests validated
- These tests were from all areas of the Lab
  - Main Automated Lab
  - Specialty Lab Sections
  - Reference Section
- Focused on High Volume Tests
Mobile Device Validation Plan

• Fields to Validate Included:
  – Patient Demographics
  – Test Name
  – Result Review
  – Comments
  – Reflex Order
  – Corrected/Amended/Appended Results
Mobile Device Validation Findings

• General Issues
  – Initially, App was running too slow
  – Physicians needed patient phone link

• Specific Lab Result Issues
  – Pediatric Ages <1 year rounded to 1 year
  – “+” signs did not cross as alpha-numeric characters and hence did not appear in Molecular Genetic karyotype results
  – Text alignment issues making results difficult to read
  – Patient Demographic Issue – Phone numbers missing
  – Report Subsection Order was Different than Chart Copy
  – Corrected Report did not show prior result
  – Reference Lab report had green dot on phone display indicating a normal result when it was actually abnormal
Mobile Device Validation Findings

• A number of issues were identified pertaining to the data feed which related to patient care. These required an LIS fix of the Cerner output feed.
  • Extraneous comments and page numbers present
  • Missing Disclaimers /Performing Lab/ Pt Phone Number
• Website “hard copy” and phone displays reflected similar information and was dependent on the integrity of the data feed
• Most issues were addressed and revalidated
• Some compromises made regarding:
  • Report subsection order
  • Placement of footnotes
Mobile Device Security Validation Plan

Verification of Security Form
for iPhone and Android App

Choose Phone: iPhone

1. New Account Creation
   - Create a new account
   - Take screenshot of home page with account name
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

2. Password Validation
   - At least 8 characters long
   - Must include at least one numeric character
   - Demonstrate out of compliance:
     - Write compliant Password Here:
     - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

3. Validation of Automatic Logout
   - At 5 minutes
   - Record actual Log-out time:
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

4. Ability to Revise User Access
   - Revise Access Prior to Log-on
   - Attempt to log-on
   - Print Screen of result
   - Revise Access After Log-on
   - Time to remove privileges
   - Record action time to revoke here:
   - Print Screen of results
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

5. Password Reset Process
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

6. Access Control Automation Validation (Core Lab User)
   - Create Account for Limited Patient Access - Limited Features and Limited Database Access
   - Print Screen
   - Access limited features and limited patient result
   - Print screen
   - Access other than limited features and limited patient result
   - Print screen
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

7. Access Control Automation Validation (Core Lab User)
   - Create Account for Operational Administrator Access - Most Features and All Database Access
   - Print Screen
   - Access any patient results (Any L, J, or M, etc., patient result)
   - Print screen
   - Access features other than Operational Administrator
   - Print screen
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

8. Access Control Automation Validation (Core Lab User)
   - Create Account for Super User Access - All Features and All Database Access
   - Print Screen
   - Access All Features and All Database patient results
   - Print screen
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

9. Access to Specific Patient Populations Validation (Physician User)
   - Create Account for Internal Physician Access
   - Print Screen
   - Access Full Patient Database patient results
   - Print screen
   - [Table with columns for Reviewed, Date, Criteria Met?, Comment]

10. Create Account for Referring Physician Organization (Physician User)
    - [Table with columns for Reviewed, Date, Criteria Met?, Comment]
Mobile Device Security Validation Plan

<table>
<thead>
<tr>
<th>Verification of Transmitted Results Form for iPhone and Android App</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Shore Long Island Jewish Health System Laboratories</td>
</tr>
<tr>
<td>10 Nevada Drive, Lake Success, NY 11042</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patient Security</td>
<td></td>
</tr>
<tr>
<td>- Access Referring Physician Organization patient record</td>
<td></td>
</tr>
<tr>
<td>- Patient Medical</td>
<td></td>
</tr>
<tr>
<td>- Access other than Referring Physician Organization patient record</td>
<td></td>
</tr>
<tr>
<td>- Patient Medical</td>
<td></td>
</tr>
<tr>
<td>- Access Individual Record Search</td>
<td></td>
</tr>
<tr>
<td>- Patient Medical</td>
<td></td>
</tr>
<tr>
<td>- Access Individual Patient record search</td>
<td></td>
</tr>
<tr>
<td>- Patient Medical</td>
<td></td>
</tr>
<tr>
<td>- Audit Trail Validation</td>
<td></td>
</tr>
<tr>
<td>- Integrity of the above patient records</td>
<td></td>
</tr>
<tr>
<td>- Confirm Activity: Time stamp</td>
<td></td>
</tr>
<tr>
<td>- Confirm Logon User</td>
<td></td>
</tr>
<tr>
<td>- Confirm Activity: Type</td>
<td></td>
</tr>
<tr>
<td>- Confirm Activity: Details</td>
<td></td>
</tr>
<tr>
<td>- Non Audit Trail Using CV</td>
<td></td>
</tr>
</tbody>
</table>

Reviewer: ___________________________ Phone Type: _____ Date: ________________

Reviewed by QA: ___________________ Date: __________________

Summary of Review:
- Acceptable, no errors found
- Not acceptable, requires follow up
  Comment: ____________________________

Approved by: ______________________ Date: ________________
Mobile Device Security Validation Plan

• For Both iPhone and Android
• Creation of Account
• Password Validation
  – 6 alphanumeric and one numeric
  – Demonstrate compliance and Non-Compliance
• Automatic Logout Validation
  – At 3 minutes
Mobile Device Security Validation Plan

• Ability to Revoke User Access
  – Validate Privilege Revocation and Time

• Password Reset Validation

• Access Control
  – Limited Patient access – NSLIJ Lab
    • Limited Features/Limited Patients
  – Patient Result Access by Individual Patient
    • Access only individual patient results

• Audit Trail Validation
Mobile Device Security Validation Plan Findings

• There were NO Major Security Issues
• There were minor security enhancements
  – Password security level raised from Low to Moderate
  – HIPAA Attestation Required
    • to obtain a user ID and Password
    • with a strong recommendation to lock Smart Phones
  – Confidential Fax Coversheet Developed
Mobile Device Validation Plan Review

• Levels of Review for Both Testing and Security Validations
  – Sales
  – LIS Liaison
  – Quality Management
  – Medical Director
Mobile Device Validation Summary

• Unexpected issues occur and may be found in downstream data flow processes and interfaces
• Differences existed between the iPhone and Android display of results
  – Validated each platform individually
• Visual displays of data on handheld devices can be misleading
  – Green to Gray Dot Issue
• Special characters in result fields require special consideration during validations
• Age calculations as well as result calculations are important
• Smart phone device app displayed a high level of security
Mobile Device Validation Outcome

From:
- Out of the Box Solution
- Misleading Display of Results
- Slower Product
- Relatively Secure App

To:
- Customized App
- Accurate Depiction of Laboratory Data
- Rapid App
- Enhanced Security

Approximately 576 NSLIJ App Users and Counting....
Elements for Successful Interface Validations

– Creation of a New Section within the QM Department to Lead Validation Efforts
– Selection of the Right Validation Team including the Right Stakeholders
– Creation of a Comprehensive Validation Plan
– Developing Effective Communication Tools for Team Members
– Ensuring Ample Time for the Validation to be Properly Performed
Elements for Successful Interface Validations

– Careful initial planning may still require lean engineering to streamline processes especially when processes are complex.

– Validation processes can reveal issues with your own host LIS environment.

– A Well Thought Out and Piloted Validation Plan will Streamline Current and Subsequent Validations.
Concluding Remarks

• With the advent of the CMS EHR Incentive Programs the Laboratory Will be Required to Establish and Maintain Even More Interface Connections in the future.

• Having Knowledge of Issues that We Encountered will May help You with your Own Validation Processes

• The Ultimate Goal Being the Provision of Accurate, Readable, Understandable Laboratory Reports for Clinicians to Properly and Safely Treat Their Patients.
THANK YOU!

- csien@nshs.edu
- hpoczter@nshs.edu
- egiuglia@nshs.edu