Building the right esoteric testing laboratory for Cleveland Clinic: Successes and Lessons Learned

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Executive War College, 5/4/2011

Objectives

• Cleveland Clinic
  • Health System, Lab

• Esoteric lab initiatives
  • Molecular department
  • Test Development
  • Test Utilization
Cleveland Clinic

- Founded in 1921 by four physicians: “To Act as a Unit”
- A nonprofit multispecialty academic medical center
- 2,000 employed physicians and scientists
- 4.2 million patient visits/year.
- Institute Model: centered on organ system and disease type

Cleveland Clinic Organization – Regional

- Main Campus Hospital, Cleveland, Ohio
  - 180 acres, 50 buildings
- Family Health Centers
  - 17 centers across Northeast Ohio
- Nine Regional Hospitals
Cleveland Clinic Organization – Beyond

- Cleveland Clinic Florida
  - Weston and West Palm Beach
- Lou Ruvo Center for Brain Health
  - Co-located in Las Vegas and Cleveland
- Cleveland Clinic Abu Dhabi
  - Under construction, scheduled completion: end 2012

Cleveland Clinic’s Pathology and Laboratory Medicine Institute

- Chair: Kandice Kottke-Marchant, MD, PhD
- 70+ pathologists, complete subspecialty-based practice
- Approx. 2,000 employees
- Approx. 20 million test results generated each year
- Departments
  - Main campus
    - Anatomic Pathology
    - Clinical Pathology
    - Molecular Pathology
  - Regional Pathology
  - Cleveland Clinic Florida
  - Cleveland Clinic Laboratories
Cleveland Clinic Laboratories (Reference Lab)

• Expanding menu of routine and esoteric tests
• Mixture of regional physician outreach and hospital clients
• New building
  • 136,000 square feet
  • “Green” building, targeting LEED Silver
  • Designed “from the bench out” to support optimal laboratory work flow

Cleveland Clinic Laboratories (Reference Lab)

• Growth Plan
  • Leverage our core strengths
    – Comprehensive subspecialty expertise
    – Breadth of test offerings in Clinical, Molecular and Anatomic Pathology
  • Expand into key market of hospital referrals, value added niche
  • Integrated hospital-level affiliations

• Key Challenge
  • How to continue what we do well for our clients “across the street”, and translate into successful service for referral clients nationally and internationally
Creating a Department of Molecular Pathology

• Chair: Gary Procop, MD, MS

• Why a Molecular Department?
  – Fosters growth of in-depth knowledge and expertise in all areas that require molecular testing
  – Furthers medical investigation/innovation and education

Creating a Department of Molecular Pathology

• Design Philosophy
  – Centralized technical cores ensure quality and operational efficiency
  – Disease and expertise-based professional interpretation optimizes value to patient care
Department of Molecular Pathology

Clinical Sections

- Cytogenetics
- Molecular Genetic Pathology
- Molecular Hematopathology
- Molecular Oncologic Pathology
- Molecular Microbiology

Department of Molecular Pathology

Operational Cores

- Polymerase chain reaction (PCR)
- Sequencing
- Microarray
- Epigenetics
- Commercial assays
- Cytogenetics
- Fluorescence in situ hybridization (FISH)
- Materials handling
- Extraction
Department of Molecular Pathology

Operational Cores Concept
Yields Efficiencies:

• Commercial assays core
  – Kit based assays allow step-wise development of technologists’ expertise
  – Accommodates staffing growth
• Materials handling core
  – Dedicated reagent preparation and QC improves efficiency in other cores
  – In-house production of control materials lowers materials cost

Lessons Learned:

Career pathways for technologists improve satisfaction and retention
Cross training is a vital part of maintaining optimal staffing levels in each core

Focus on Test Development

Translating what we already do well to a growing reference laboratory mission:

• 2200+ tests
  – Extensive menu for hospital lab
  – Increased expectations for reference lab
• Ever increasing send out volumes and costs
  – CC physicians: increased utilization of high cost esoteric testing
  – Reference work: sending out tests increases turn around time, unfavorable finance, and puts our reputation in the hands of others

Solution: Dedicated test development resources
Center for Test Development

• Director: Tom Daly, MD
  • Purpose: pooled resource dedicated to test development
  • Staffing
    – 2 PhDs, 5 Technical
    – "Embedded" Development Techs outside CTD
      • 4 in Chemistry
      • 5 in Molecular

Center for Test Development

• Equipment
  • Used for a variety of protein and molecular assay development including:
    – PCR
    – Sequencing
    – IHC
    – ELISA
    – FISH
How are projects selected for development?

Standardized RFP
Prioritization
TDSC Progress oversight

Center for Test Development

CTD Development Phases
- Feasibility
- Validation
- Transfer
Center for Test Development

- **Feasibility**
  - CTD staff partners with laboratory medical director
  - Platform selection
  - Assay design & Development
- **Transfer**
  - Transfer packet
  - Observation of procedure in CTD by clinical lab
  - CTD available for trouble shooting prior to “go live”

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**Center for Test Development**

**Benefits of Design**

- **Operational efficiency**
  - Specialized skill sets
  - Lack of clinical responsibilities eliminates conflict of priorities
- **Strategic focus**
  - Opportunity for institute level prioritization and tracking
  - Promotes coordination with reference laboratory efforts
Impact of Development Efforts

- CTD Developed, Launched

Sendout Test Volumes: 2008-2010

Focus on sendout testing yielded results in 2010:
- 3-fold increase in the # of sendout tests brought in vs. 2009
- Initial focus on high-impact sendouts

Implemented tests as % of prior year sendout volume:
- 2009 = 0.9%
- 2010 = 17.2%
Sendout Test Costs: 2008-2010

Implemented tests as % of prior year sendout costs
- 2009 = 0.3%
- 2010 = 10.5%

Molecular testing is greater percentage of costs than of volume

Sendouts: Progress against the “top of the curve”

Tests with volumes > 1000/yr

Tests with costs > $100K/yr

Gray = brought in-house
Yellow = in active development
Center for Test Development

Lessons Learned

- Buy-in to community resource concept
  - Overcome culture of development “silos”
  - Foster trust in process
    - No loss of medical control over assay
    - Communicate along the way
    - Celebrate successes
- Plan resources for implementation
  - “Throughput” limited by staffing of clinical lab
  - Increasing clinical lab head count can be difficult in resource constrained environment
Test Development Status

Center for Test Development

Next Steps
- How to approach the “tail” of the send out curve?
- Laboratory “Centers of Excellence”
  - Comprehensive offerings in focused areas, building on strengths
  - Engage CC clinical faculty
    - Ensures needs are met
    - Improves clinical utility of diagnostic algorithms
Test Utilization Review

Before…
• “If one of our docs orders it, run it!”

Now…
• Service line cost initiatives
  – Mandates to reduce cost, recognition for savings
  – Driving efficiency and cost throughout the enterprise
  – Cultural shift makes timing right for test utilization review

Test Utilization Committee
• Chair: Gary Procop, MD, MS
  – Inclusive membership
    • Wrote letter of invitation to each Department Chair
    • Interdisciplinary members
    • High-level leadership

Initial Steps: Inpatient “Hard Stops”
• 10 tests identified for limitation based on frequency (no more than 1 per 24 hours)
  – Medical Leadership, staff engaged
  – Implemented trial as “soft stops” (could push through)
  – Converted to hard stops 08/2010
• 78 additional hard stops implemented 11/2010
Test Utilization Review: Calls to Client Services Regarding Hard Stops

Lab Client Services EPIC Hardstop Calls
September 2010 to March 2011

<table>
<thead>
<tr>
<th>Month</th>
<th>Volume</th>
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<tbody>
<tr>
<td>Sept 10</td>
<td>5</td>
</tr>
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<td>Oct 10</td>
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</tr>
<tr>
<td>Dec 10</td>
<td>6</td>
</tr>
<tr>
<td>Jan 11</td>
<td>5.9</td>
</tr>
<tr>
<td>Feb 11</td>
<td>6</td>
</tr>
<tr>
<td>Mar 11</td>
<td>6</td>
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10 Hard Stops 8/24/2010
+78 Hard Stops 11/16/2010

Reduced Laboratory Test Orders

Completed Laboratory Test Orders per Patient Day

<table>
<thead>
<tr>
<th>Month</th>
<th># per patient day</th>
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<td>Feb-11</td>
<td>5.3</td>
</tr>
</tbody>
</table>

Data from 4 inpatient floors
9% reduction in completed orders/patient day
Estimated at $670K annualized savings
Hard Stop Fire “Revenue Avoidance”

Less inpatient “revenue” for lab medicine after hard stops initiated
This is a good thing! Lab realization rate being remodeled to account for this changed practice

Test Utilization Review

Lessons Learned
• Be aware of institutional trends and tie initiatives to them
• Foster inclusive membership in utilization review committee
• Engage ordering physicians early and often
• Target early “wins” by building consensus on non-controversial items
• Track progress and use metrics to showcase successes
Test Utilization Review

Next Steps Underway:
• Once daily limitation for broader portion of menu (~1000 tests approved, awaiting implementation)
• Extend duration of hard stop interval for certain tests based on established guidelines (eg HbA1c)
• Implement consideration of utilization limits as part of new test implementation

Top 10 most expensive genetics tests
• Applies to inpatient and outpatient
• Make “Lab order” only
• Deemed users list
• Non-deemed users must
  – Obtain a consult from deemed user
  – Contact Laboratory Genetics Counselor
  – Contact designated Laboratory Faculty

Building the right esoteric testing lab…

What has helped us:
• Molecular Department
  – “Critical mass”
  – Expansion in growing area
• Dedicated development resources
  – Creates efficiencies
  – Allows strategic input
• Utilization Review
  – Capitalizes on cost focus
  – Bridge building yields results
Cleveland Clinic

Every life deserves world class care.