Coordinating Clinical Laboratory and Anatomic Pathology Services in Today’s Integrated Clinical Care Continuum

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Henry Ford Health System, Detroit
Key Learning Objectives

• To learn how an integrated laboratory service can leverage quality management thinking, Lean and ISO to improve testing service levels and capabilities that provide enhanced value to clinician practices

• To understand the critical role of designing and implementing systems and subsystems of management that focus on lab quality and cost control

• To understand the V-(alue) metrics of importance in defining the value of the medical laboratory and the pathologist in the changing clinical care continuum
**Volume Driven Healthcare**

**Incentive: Do More**

- **Efficiency Ranking**
  - High Income nations
  - Increased life expectancy relative to $ spent
  - US ranking = 22 of 27
  - Life expectancy: 15 days/ additional $100 spent


Value Driven Healthcare

Incentive: Do Better

ACA Triple Aim

- Improve Health of INDIVIDUAL
  - Coordinated Care
  - Better Outcomes

- Improve Health of POPULATION
  - Expanded Coverage
  - Chronic Care Mgmt
  - At Risk Mgmt
  - EHR Use

- Spend less on services PER CAPITA
  - Bend the Cost Curve
  - Reduced Reimbursements

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Paradigm Change
Volume $\rightarrow$ Value

• **New** delivery care models
  $\uparrow$ efficiencies, coordination of care, outcomes, satisfaction
  $\downarrow$ spending $$
  – ACA- ACOs, Medical Homes
  – Hospital consolidations & acquisition priv practices
  – Clinically integrated private physician networks

• **New** payment models
  – Pay-for-Value reimbursement
    • PQRS, HCAHPS, Medicare Shared Savings Program

• $\uparrow$ primary care pay and $\downarrow$ specialty care pay
  – PAMA 2014 clinical lab reimbursement reductions
    • 30% 2017-2019 (10%/yr); 45% 2020-2022 (15%/yr)
Survival
Hear the wave before you see it
“If you don’t like change, you will like irrelevance even less”

-Gen. Eric Shinseki
### Problem Background
The Laboratory is unrecognized as an asset to coordinate care, foster health system integration and cost control. More likely seen as cost center.

### Hypothesis
We have either not created systems to do so or articulated the case for high value well.

### Current Condition
- 3% of the cost; 70% of the EMR
- Up to 90% clinical decision-making
- Declining hospital revenue, staff reductions
- Undeveloped lab systems to support call for coordination of care, system integration, cost control

### Problem Analysis WHY?
1. No one asked us to and it’s hard work
2. Hard to quantify clinical and cost success
3. Don’t have good metrics to share
4. Don’t have appropriate management subsystems

### Target Condition
Document & achieve recognition for coordination, care integration & system savings
Obtain support for lab innovation & growth

### Implementation Plan
1. Non-conformance management - Work waste
2. Daily management (QTIPS) - Critical values
3. Test utilization management, Lab Formulary
4. Personalized care management - Molec tests
5. Hospital IPD LOS improvement, MALDI-TOF
6. Pathologists as teachers & consultants

### Results
The Value (V) metrics of lab survival

### Metrics
1. Defect management, Epic errors
   Reduction unacceptable specimens, rework $\$$, patient satisfaction
2. Safety, critical value notification failures
3. The V metrics
   - Test referral utilization control & savings
   - Appropriate therapy guidance & savings
   - IPD episode cost and LOS savings
   - Clinical consultation guidance

### Standardization
Customer focus in consolidated, integrated systems with ISO standardization, Lean leadership and management

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“The business of management is to manage. The thing to be managed is work”

“We still waste more than we use. We waste men, we waste materials, we waste everything, and consequently we have to work too hard and too long to accomplish what in the end amounts to very little.”

“It’s the work not the man that manages”
The Value (V) KPI Metric

• The currency of healthcare is now $$ rather than time  -John Waugh

• Are you still pursuing TAT as your lab’s measure of success?
Performance => Productivity => Value $\$\$ Metrics

There's great future in value metrics

Cost per test, cost per episode of care, cost control, cost avoidance
Lab costs per adjusted discharge
The VALUE Metric
Customer Satisfaction in consolidating & integrating systems

Leverage Lean & ISO Management Systems

“Systems don’t produce quality, people do”

But systems provide standardization for people to:

- Deliver high quality consistently
- Focus on specific requirements of new and existing customers
- Identify poor quality rapidly and correct non-conformances
- Engage the workforce in continuous improvement
- Adopt preventive, not just corrective actions
The Processes of Managing for Continuous Improvement

Ongoing PDCA Continuous Improvement

- Identify Defects Non Conformances
- Daily Resolution
- Daily Countermeasure
- PDCA-A3 Resolution
- Customer-Supplier Communication at level of work
- Team Leader Facilitation
- Standard Work, Connections, Pathways
- policy, procedure, document control
- Share the Gain Learnings

Share the Gain Learnings

Learnings

Ongoing PDCA Continuous Improvement

Identify Defects Non Conformances

Daily Resolution

Daily Countermeasure

PDCA-A3 Resolution

Customer-Supplier Communication at level of work

Team Leader Facilitation

Standard Work, Connections, Pathways

policy, procedure, document control

Share the Gain Learnings

Ongoing PDCA Continuous Improvement

Identify Defects Non Conformances

Daily Resolution

Daily Countermeasure

PDCA-A3 Resolution

Customer-Supplier Communication at level of work

Team Leader Facilitation

Standard Work, Connections, Pathways

policy, procedure, document control

Share the Gain Learnings
The Processes of Managing for Continuous Improvement

- Deviation Management
  - Daily Resolution
  - PDCA-A3 Resolution
- Daily Management
  - Daily Countermeasure
- Development System
  - Policy, procedure, document control
- Document Management
  - Standard Work, Connections, Pathways
- Coaching System
  - Team Leader Facilitation
  - Customer-Supplier Communication at level of work
- Team Leader System
  - Share the Gain Learnings
  - Identify Defects Non Conformances

Ongoing PDCA Continuous Improvement

Audit System

LQC 2014

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The Processes of Managing for Continuous Improvement

- Deviation Management
  - Daily Resolution
  - PDCA-A3 Resolution
  - Daily Countermeasure

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  - Standard Work, Connections, Pathways
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- Development System
  - Policy, procedure, document control

- Document Management
  - System Development System
  - Audit System

- Coaching System
  - Team Leader System

- Daily Management
  - System Coaching System
  - Improvement Management

LQC 2014
Slide 17
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Integrated System
Culture of Continuous Improvement

- Standard Work
- 5S
- Visual workplace
- Continuous flow
- Pull production
- Kanban
- Just in Time
- Load leveling
- Batch size
- Mistake proof

Tools of Improvement

- Customer 1st
- Continually develop your most valuable resource, your PEOPLE
- Continuous improvement
- From the level of the work
- Blameless management

Cultural Philosophy

Management Systems

- Hoshin Planning/Policy deployment
- Team leader system
- Improvement management (kata)
- Coaching and development (kata)
- Deviation management
- Daily management
- Document management

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Deviation Management Process

Daily deviations are encountered

All Employees
- Stop
- Record on shared drive spreadsheet
- Classify defect
- Rapid resolution corrective actions

Monthly deviations are tabulated and summarized

Managers and Leaders
- Evaluate trends
- Identify the most common and the critical few
- Prioritize improvements

Monthly PDCA (A3)

The Team
- Problem Background
- Hypothesis
- Current Condition
- Problem Analysis (RCA)
- Target Condition
- Implementation Plan
- Action plan
- Results
- Effectiveness Check (Metrics)

Continuous Process
## Taxonomy Deviation Classification Categories

<table>
<thead>
<tr>
<th>Main Categories</th>
<th>Number of Subclassification Categories</th>
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<tbody>
<tr>
<td>Order Defects</td>
<td>36</td>
</tr>
<tr>
<td>Specimen Defects</td>
<td>13</td>
</tr>
<tr>
<td>Testing Defects</td>
<td>38</td>
</tr>
<tr>
<td>Report Defects</td>
<td>12</td>
</tr>
<tr>
<td>System Online Incident Report (RadicaLogic)</td>
<td>3</td>
</tr>
<tr>
<td>Complaints</td>
<td>4</td>
</tr>
<tr>
<td>Safety</td>
<td>2</td>
</tr>
</tbody>
</table>
Deviation Management Progression

Surveillance Events Documented 2012-2014

- Deviation process was piloted
- Roll out to larger sites
- New EMR Implementation
- Roll out to all sites
- Optimization (new subclasses, new graphs, ease of use, new documentation forms)

- 42% Participation in 2012
- 95% Participation in 2013
- 100% Participation in 2014
Deviation Management Surveillance Trending

Time = $$
Redraw = dissatisfaction
Integrity = safety

Top 35 Defects
Daily Management

“A legacy of quality”

Daily Management Board

Q  T  I  P  S
Quality  Time  Inventory (or WIP)  Productivity  Safety

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**Visual Management At-a-Glance**

**DAILY Gemba Rounds with workers**
- Each square has all days of month
- Color each per performance
  - **RED:** METRIC FAILED THRESHOLD
  - **GREEN:** METRIC MET THRESHOLD

**Trendlines**
- Trend challenging metrics
- Day, week, month, year…
  - **BLUE:** THRESHOLD
  - **RED:** TIME OF FAILURE
  - **GREEN:** TIME PASSING THRESHOLD

**Pareto Charts, RCA etc.**

<table>
<thead>
<tr>
<th>What</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Why</th>
<th>How</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

**Countermeasures:**
Corrective & Preventive Actions
Assign responsibility and Accountability for completion

**Associated PDCA - A3 Projects**
### DM Metrics June 2013-2014

<table>
<thead>
<tr>
<th>LAB Division</th>
<th>No. Daily Metrics in 1 yr</th>
<th>No. Long term &gt;6 mo</th>
<th>No. Short term 1-6 mo</th>
<th>No. derived process improvements</th>
<th>Q</th>
<th>T</th>
<th>I</th>
<th>P</th>
<th>S</th>
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<tbody>
<tr>
<td>Core Lab</td>
<td>14</td>
<td>12</td>
<td>2</td>
<td>8</td>
<td>1</td>
<td>5</td>
<td>6</td>
<td>-</td>
<td>2</td>
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<tr>
<td>Lab Support</td>
<td>2</td>
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<td>1</td>
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<td>-</td>
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<td>1</td>
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<tr>
<td>Chemistry</td>
<td>6</td>
<td>6</td>
<td>-</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Micro/Sero</td>
<td>9</td>
<td>9</td>
<td>-</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Transfusion</td>
<td>5</td>
<td>5</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>-</td>
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<tr>
<td>Surgical</td>
<td>19</td>
<td>11</td>
<td>8</td>
<td>17</td>
<td>10</td>
<td>4</td>
<td>4</td>
<td>-</td>
<td>1</td>
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<tr>
<td>Cytology</td>
<td>4</td>
<td>4</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Molecular</td>
<td>5</td>
<td>5</td>
<td>-</td>
<td>3</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>64</strong></td>
<td><strong>53</strong></td>
<td><strong>11</strong></td>
<td><strong>42</strong></td>
<td><strong>22</strong></td>
<td><strong>14</strong></td>
<td><strong>15</strong></td>
<td><strong>8</strong></td>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>

#### No. Unique Metrics/Year

![Bar Chart: No. Unique Metrics/Year](image)

#### QTIPS Domain Usage

![Pie Chart: QTIPS Domain Usage](image)

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Safety

Owners: Jackson/Smothers/Rahman

Month: August 2013

Meeting Time: 11:30

Metric:
All CVs called: green
Any CVs missed: red
Critical Value Defect Rate
First 3 months...

Steady Drop in Critical Value Callback Failures
Critical Value Defect Rate
First 8 months...

Dec 12
0.7/day

Aug 13
0.3/day

Improvement!
Reduction in Critical Value Defects. This graph represents the improvement in the performance of our laboratory’s safety (S) metric related to notification and documentation of a critical value notification to an ordering provider. It represents the initial gains in performance during deployment (December 2012-May 2013), subsequent monitoring of performance (April 2013-August 2014) impacted by varied root-causes (↑) and improvements through countermeasures (↓).
## Personalized Cancer Care Management

<table>
<thead>
<tr>
<th>Molecular Profile</th>
<th>Targeted Therapeutic</th>
<th>Cost of Treatment</th>
<th>Pharma Cost Savings 2012</th>
<th>Pharma Cost Savings 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR (Gefitinib)</td>
<td>lung</td>
<td>$72,000</td>
<td>$14,184,000</td>
<td>$14,832,000</td>
</tr>
<tr>
<td>ALK FISH (Crizotinib)</td>
<td>lung</td>
<td>$72,000</td>
<td>$12,600,000</td>
<td>$13,248,000</td>
</tr>
<tr>
<td>BRAF (Ipilimumab)</td>
<td>melanoma</td>
<td>$120,000</td>
<td>$1,560,000</td>
<td>$2,880,000</td>
</tr>
<tr>
<td>Her2 FISH (Herceptin)</td>
<td>breast</td>
<td>$70,000</td>
<td>$12,180,000</td>
<td>$14,560,000</td>
</tr>
<tr>
<td>KRAS (Cetuximab)</td>
<td>colon</td>
<td>$125,000</td>
<td>$5,750,000</td>
<td>$4,750,000</td>
</tr>
<tr>
<td>Testing cost</td>
<td>--</td>
<td>--</td>
<td>($253,994)</td>
<td>($243,551)</td>
</tr>
<tr>
<td>Reimburse</td>
<td></td>
<td></td>
<td>$173,881</td>
<td>$176,796</td>
</tr>
</tbody>
</table>

**Pharma cost savings** (Neg tests X cost Rx) $46,274,000 $50,270,000
Hospital LOS Improvement
Infectious Disease Episode of Care

Performance Metric TAT Blood Culture
Pre & Post MALDI-TOF

• ~33% decrease overall TAT ID reporting
• Annual lab testing cost savings = $115,000
• ~33% decrease in overall TAT ID report translates to:
• ~33% decrease LOS (~14 to 9 days)
• LOS = $4147/day
Cost savings associated with LOS

- Average reduction LOS = 4.78 days
- Average reduction Costs/LOS = $19,822.66 per Candida sepsis episode
- Projected annualized LOS cost savings = $1,110,069.00
- Plus annual lab savings = $1,225,069.00
Test Utilization Management

Without Formulary

Provider Request for Esoteric Tests

Reference Laboratory Marketing

Pathologist Review for appropriateness

Reference Laboratory

High $$ : Low Standardization → Chaos
Test Utilization Management

Without Formulary:
- Provider Request for Esoteric Tests
- Reference Laboratory Marketing
- Pathologist Review for appropriateness
- Reference Laboratory

High $$ : Low Standardization → Chaos

With Formulary:
- Provider Request for Esoteric Tests
- Pathologist Review
- CETAC Review
- MLFC Review
- Reference Laboratory Marketing
- Reference Laboratory

Low $$ : Standardization → Better Utilization
Test Utilization Management

Lab CETAC
11 Voting
5 Non voting

- Anatomic Pathology
- Clinical Pathology
- Molecular Genetic Pathology
- Support Services

Receive New Test Service Request
Identify Leads: Pathology & Clinician
Gather Information on Lab and Charges
Medical and Financial Impact Analysis
Discuss at CETAC Meeting, make determination
Memorandum and notification to Med. Lab Formulary Committee

28 Tests [$85 - $5800]
2 Unrestricted [$55-$140]
19 Restricted [$84-$2500]
7 Not Available [$93-$5800]
<table>
<thead>
<tr>
<th>Test</th>
<th>Vendor Claim</th>
<th>CETAC Determination</th>
<th>Cost and Reimbursement</th>
<th>Potential Cost Avoidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay 1</td>
<td>A genomic profile that helps physicians make treatment decisions.</td>
<td>NOT AVAILABLE</td>
<td>Cost: $5800 and $7500 Reimbursement: $0 LOSS: $5800-$7500/test</td>
<td>&gt;$10 million/year</td>
</tr>
</tbody>
</table>
|       | - No FDA approval  
- Not in NCCN guidelines  
- Not for HFHS Trials | | | In HFHS, 2000 cases/year will qualify for ‘genomic testing for potential targets’. This will be in addition to routine pathological diagnostic work-up. |
| Assay 2 | Quantitative assessment of the likelihood of distant recurrence in patients diagnosed with ER+ node-negative breast cancer. | NOT AVAILABLE | Cost: $3500  
Reimbursement $150 LOSS: $3350/test | > $3.5 million |
|       | - No FDA approval  
- Not in NCCN guidelines | | | > 300 cases/y of breast carcinoma are diagnosed in HFHS. A cohort of >1000 patients may qualify per vendor claim. |
| Assay 3 | Aid in the classification of the tissue of origin and tumor subtype in conjunction with standard clinical and pathological assessment by a qualified physician. | NOT AVAILABLE | Cost: $4750  
Reimbursement: $0 LOSS: $4750/test | >$1.4 million/year |
|       | - No FDA approval  
- Not in NCCN guidelines | | | Per vendor claim, test is to be used in 30 % of metastatic cases that remain unclear.  
If we assume 30% malignancies are metastatic at diagnosis then HFHS has 300 cases/y (i.e. 10% of the total 3000) that may qualify per vendor criteria. |
| Assay 4 | Tests for *** protein and **** may be used as supplemental tests to help establish a diagnosis of Alzheimer Disease. | NOT AVAILABLE | Cost: $1160  
Reimbursement: $52 LOSS: $1108/test | >$110,000/year |
|       | - No FDA approval  
- Not required for diagnosis | | | Per clinical expert, the utilization of this test is expected to be be around 100 cases/year. |
Test Utilization Management
The Path Forward….

- Formulary
- Esoteric Testing
- EMR Tools
- Inpatient Testing
- Protocols
- Outpatient Testing

2014  2015  2016
Value of Clinical Consultant

What pathologists bring to the table:

- Physician who can interface with other physicians
- Understands the medical implications and technical limitations
- Can suggest and provide rationale for alternative testing modalities

What pathologists need from the administration:

- Medical laboratory has to be visible and involved in decision making
- A mechanism must exist for interaction and exchange of information
- Must be recognized and incentivized for improving lab utilization

What pathologists bring to the table...

What pathologists need from the administration....
Value Metrics

Won’t always be cost and productivity but…..

Downstream episode of care efficiencies and clinical outcomes
Relating to Value Metrics

The language of the hospital C-Suite

• Risk Adjusted LOS (case type and severity)
• Emergency Room LOS
• Case Mix Adjusted Episode Costs
• Risk Adjusted Early Readmission Rate
• Average Time Emergency Department (ED) Door to Bed Average Time
• ED Treatment to Release
• Divert Hours for ED
• Pharmacy cost/DRG
• RVUs/DRG
• Cost per unit of service
• Salary Expense per Adjusted Patient Day
• Full Time Equivalents (FTE) per Adjusted Patient Day
• Supply Expense per Adjusted Patient Day
Are You Ready to Unleash the Power of Pathology’s V-Man?
“Improved efficiency is only meaningful when it leads to **cost reduction**. This requires producing the required amount with the least resource.”

“Efficiency improvement must be looked at not only at the level of individual people, lines staffed by teams of people, and groups of these lines but as efficiency of the **entire system**.”

-Taiichi Ohno