A Measure of the Quality and Value of Standardized Genomic Testing in an Integrated Health System

A Review From BayCare Health System

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Shimberg Breast Center
St. Joseph’s Women’s Hospital
BayCare Health System
• Review of healthcare reimbursement evolution
• Review the need and evolution of precision medicine in early stage breast cancer
• Rational for Oncotype DX standardization project
• Design of standardization and metrics
• Standardization study results and impact on metrics
• Future directions
Overview

BayCare
22,900 Employees

7 Medical Groups
- HealthPoint Medical Group
- Morton Plant Mease Immediate care
- Morton Plant Mease Primary Care
- Morton Plant Mease Specialists
- St. Anthony’s Primary Care
- St. Anthony’s Specialists
- Suncoast Medical Clinic

12 Hospitals

3 NAPBC Centers
- St. Joe’s
- Morton Plant
- St. Anthony’s

3,100 Physicians/>200 Locations
The Healthcare Landscape is Changing

Provider Organizational Cultural Shifts

Critical Success Factors for Transformation

<table>
<thead>
<tr>
<th>Now</th>
<th>Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Focus</td>
<td>Value Focus</td>
</tr>
<tr>
<td>Physician Autonomy</td>
<td>Organizational Standards</td>
</tr>
<tr>
<td>Independence</td>
<td>Interdependence</td>
</tr>
<tr>
<td>Physician Captain</td>
<td>Physician Coach &amp; Mgr</td>
</tr>
<tr>
<td>Accountability External</td>
<td>Accountability Internal</td>
</tr>
<tr>
<td>HIT optional</td>
<td>HIT Core to Strategy</td>
</tr>
<tr>
<td>My data is my data</td>
<td>TRANSPARENCY!!</td>
</tr>
</tbody>
</table>
Payment Models are Shifting

Rapidly Changing Reimbursement Landscape for Physicians, Hospitals, and Payers

Fee for Service
- Unit Based
- No Financial Risk

Bundled Payments
- Efficiency Based
- Partial Financial Risk

Global Payment
- Outcome Based
- Full Financial Risk
In Cancer Treatment: One Size Does Not Fit All

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIDEPRESSANTS (SSRIs)</td>
<td>38%</td>
</tr>
<tr>
<td>ASTHMA DRUGS</td>
<td>40%</td>
</tr>
<tr>
<td>DIABETES DRUGS</td>
<td>43%</td>
</tr>
<tr>
<td>ARTHRITIS DRUGS</td>
<td>50%</td>
</tr>
<tr>
<td>ALZHEIMER’S DRUGS</td>
<td>70%</td>
</tr>
<tr>
<td>CANCER DRUGS</td>
<td>75%</td>
</tr>
</tbody>
</table>

Percentage of the Patient Population for Which a Particular Drug Is Ineffective, on Average

Breast Cancer: Facts

100 Women Diagnosed with Early Stage Breast Cancer
Breast Cancer: Facts

Only 4 in 100 patients benefit from chemo*


*Early Stage Invasive Breast Cancer (Stage I & II, ER+, HER2 neg)
Personalized Medicine Has Arrived

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Onco\textsuperscript{type} \textsuperscript{DX\textregistered} Is Changing Clinical Practice

- **Onco\textsuperscript{type} DX** has helped revolutionize the field of molecular diagnostics by providing individualized quantitative risk estimates to improve treatment planning and overall outcomes for patients with early stage ER+ breast cancer

- **The Onco\textsuperscript{type} DX assay for invasive breast cancer**
  - Has been validated to predict chemotherapy benefit in women with ER+, HER2-, early-stage invasive breast cancer who received hormonal therapy
  - Is supported by data from multiple clinical studies with over 5,000 patients, including six validation trials
  - Has a proven 10-year track record with over 500,000 reportable patient results. Estimated that ~70% of all chemo eligible N-, ER+, Her- patients are currently tested.
  - Included as a part of the eligibility criteria of 8 major NCI sponsored trials.
  - Standardized ordering has begun to be implemented at major hospitals around the country


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# Guidelines Support Recurrence Score® Result in Treatment Decision-Making for Early-Stage Breast Cancer

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Recurrence Score® Support</th>
<th>Result in Treatment Decision-Making</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCCN Guidelines®</td>
<td>Quantifies risk of recurrence as a continuous variable and predicts responsiveness to both tamoxifen and chemotherapy¹</td>
<td>Node negative, N1mi</td>
</tr>
<tr>
<td>ASCO® Guidelines</td>
<td>Predicts the risk of recurrence and may be used to identify patients likely to benefit from tamoxifen or chemotherapy²</td>
<td>Node negative</td>
</tr>
<tr>
<td>St. Gallen Consensus</td>
<td>Provides not only prognostic but also predictive information regarding the utility of cytotoxic therapy in addition to endocrine therapy³</td>
<td>Node negative, node positive</td>
</tr>
<tr>
<td>ESMO</td>
<td>Provides additional prognostic and/or predictive information to complement pathology assessment and to predict response to adjuvant chemotherapy⁴</td>
<td>Node negative</td>
</tr>
<tr>
<td>BCBS Technology (TEC) Assessment</td>
<td>May be used to determine recurrence risk for women with breast cancer therapy deciding whether to undergo adjuvant chemotherapy⁵</td>
<td>Node negative</td>
</tr>
</tbody>
</table>


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Our Quality Project: Background

Identifying the Problem

• In January of 2013 we assessed our usage of Oncotype DX in the appropriate NCCN eligible patients and identified a need for quality improvement (utilization rate of ~20% in NCCN eligible patients)

• Prior to initiation of the project there was no standardization of any genomic testing

• The level of Oncotype DX consideration and utilization in NCCN eligible patients varied greatly among the downstream providers and was not well documented

• Substantial variability of care of ER+ N- breast cancer patients was noted
Our Quality Project: Background

- The project entailed the development of hospital wide standardization of Oncotype DX utilization and ordering.

- Purpose of the project was to measurement the impact of standardization on quality metrics for the target population.

- The project was developed through the Breast Program Leadership Committee and formally approved by the Cancer Committee, the Quality & Safety Committee and the Medical Executive Committee.

- Targeted June, 2013 as “go live” date for standardization/benchmarking
Why Standardize Oncotype DX Utilization?

**Oncotype DX provides important prognostic and chemotherapy information.**
- Validated estimates of prognosis and the expected benefit of chemotherapy.
- Influences physicians’ treatment recommendations and confidence.
- Influences treatment decisions for the majority of patients. Shown to reduced patient anxiety and improvements in patient quality of life.
- Standardization would likely reduce variability of patient care.

**Assay utilization has been shown to reduces healthcare costs.**
- Chemotherapy and related supportive care costs.
- Reduces “lost work time” related to chemotherapy treatments.
- Standardization would likely reduce healthcare costs.

**Helps meet Accreditation Requirements for COC and NAPBC**
- Both require adherence to nationally accepted guidelines.
- Measurable metric to show quality of care.
Our Goals for Standardization

**Reduce Time-to-Report Delivery (from date of surgery to report date)**
- Speed up delivery of care for ER+ N- breast cancer patients
- Reduce anxiety for patients and improve measures of quality
- A measurable metric that shows quality to payers

**Consistent Patient Management**
- Reduce Variability in Care
- Ensure eligible patients are accessed consistently according to guidelines
- Gain consistency in timing for ordering and decision making

**Develop Measurable Metrics**
- Demonstrate measurable, but simple metrics that shows quality improvements
- Generate potentially useful data for negotiating with payers

**Submit as a Quality Improvement Study for NAPBC Accreditation**
- Part of Quality and Outcomes Standard 6.1
Potential Impact of Standardization on Performance to NAPBC Metrics

**NAPBC accreditation requires compliance with evidence-based guidelines (Standard 1.3)**
Oncotype DX is incorporated into the NCCN and ASCO guidelines.

**Medical Oncology (Standard 2.13)**
Chemotherapy and/or Hormonal therapy is delivered in a timely manner.

**Radiation Oncology (Standard 2.12)**
Radiation therapy is administered within one year of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.

**Quality Improvement (Standard 6.2)**
Annual performance rates are reported for each of the measures identified by the NAPBC, and performance is evaluated annually by the Breast Program Leadership (BPL).

**Quality and Outcomes (Standard 6.1)**
Each year, the breast program leadership conducts or participates in two or more studies that measure quality and/or outcomes.
Standardization Protocol

- **Four different models of standardization were considered.**
  - Pathology initiated ordering
  - Surgeon initiated ordering
  - Nurse Navigator initiated ordering
  - Oncologist initiated ordering

- The Breast Program Leadership Committee reviewed options and decided the Pathology Model was the most efficient and practical for the institution.

- The Breast Program Leadership Committee after consultation with all stakeholders developed a ordering criteria based the NCCN criteria.

- The Manager of Breast Services and the Pathology Lab Manager in conjunction with Genomic Health developed the final processes.
Oncotype DX Protocol

- Standing Order Letter (signed by all surgeons in breast program & kept on file in pathology)
  - Pathology Identifies NCCN pts for Testing (Online portal accounts created for all pathologists and selected delegates)
  - Delegates Place Orders (Delegates place order on Surgeon’s behalf per standing order)
  - GHI Receives Order

Questions?
- Insurance (PreAuth’s, Hardships, etc)
- Other

Contact:
- Manager of Breast Services (eliminates contacting Pathology or Surgeons)

No Questions

Process Order

Report Delivered to Surgeon & Pathologist (by Fax or Portal) in 7-10 Days
**Measurable Metrics:**

1. **Utilization Rate in NCCN eligible patients**
   Measure appropriate testing in NCCN Guideline eligible patients

2. **Surgery to Oncotype DX Order**
   Measure of time from surgery to the order of the test

3. **Pathology Process Time**
   Measure of time from order date until Genomic Health receives the tissue

4. **Genomic Health Process Time**
   Measures time from receipt of tissue to report date

5. **Measured Time from Surgery to Report Date**
   Measure of time for entire process of ordering and delivery of results
Our Performance vs NCCN Eligible Pts

(NCCN Guideline Criteria for 21 Gene Assay: ER+, Node -, Her2neg, micromets)

• **Results:** Major improvement in percentage of patients with documented consideration of testing
Results: Time from Surgery to Oncotype DX Order

Time from Surgery to Oncotype DX Order improved by 10 days.
Results: *Time from Surgery to Oncotype DX Order*

Pre-Standardization

Post-Standardization

18 Months

#Days: Surgery to Order

June, 2013

18 Months

# Days-Surgery to Order

Consecutive Oncotype Patients

Consecutive Oncotype Patients

Results: Improvement seen at the individual patient level
Results: **Pathology Processing Time**

~Time from pathology order to GHI receiving tissue

- **Surgery to Oncotype DX Order**
- **Pathology Process Time**
- **Genomic Health Process Time**

![Graph showing Pathology Processing Time](image)

Results:
Pathology processing time cut by approx 50% w/standardization
Results: Pathology Processing Time

**Pre-Standardization**

18 Months

**Post-Standardization**

18 Months

Pathology Process Time

Results: Improvement seen at the individual patient level
Results: **Genomic Health Process Time**

*From receipt of the tissue to issuing report*

- **Surgery to Oncotype DX Order**
- **Pathology Process Time**
- **Genomic Health Process Time**

Results: Genomic Health’s process time remains steady
Results: Genomic Health Process Time
~Days in the lab process from receipt of specimen to report

Pre-Standardization

Post-Standardization

Results: GHI processing time remains consistent
Results: *Time to Treatment Decision*

*T~Total Days between Surgery and Oncotype DX Report*

- **Surgery to Oncotype DX Order**
- **Pathology Process Time**
- **Genomic Health Process Time**

**Time to Treatment Decision**

Results:

- Time from Surgery to report was reduced by 11 days.
Results: **Time to Treatment Decision (report)**

~Total Days between Surgery and Oncotype DX Report

**Pre-Standardization**

18 Months

# Days: Surgery to Oncotype Report

**Post-Standardization**

18 Months

# Days: Surgery to Oncotype Report

Results: Improvement seen at the individual patient level
Results: Age Distribution

Pre-Standardization vs. Post-Standardization

Oncotype DX Age Distribution

- Pre-Standardization:
  - 0-39 years: 1.3%
  - 40-49 years: 8.9%
  - 50-59 years: 22.8%
  - 60-69 years: 26.6%
  - 70+ years: 31.6%

- Post-Standardization:
  - 0-39 years: 1.6%
  - 40-49 years: 18.1%
  - 50-59 years: 29.5%
  - 60-69 years: 31.1%
  - 70+ years: 19.7%

June, 2013
Results: **Online vs Paper**

~Conversion to online ordering saves time, increases efficiency and prevents errors

**Results:**
- Standardization had a major impact on the utilization of online ordering
- Improved efficiency by eliminating call backs for missing or illegible data
Results: RS Score Pre & Post

**Pre-Standardization**
18 Months

**Recurrence Score Distribution**
N=97

- 33% RS 18-30
- 60% RS < 18
- 7% RS ≥ 31

**Post-Standardization**
18 Months

**Recurrence Score Distribution**
N=250

- 35% RS 18-30
- 56% RS < 18
- 9% RS ≥ 31

June, 2013

Results: Recurrence Score remained consistent pre & post
Results: St. Joe’s vs. Local & State

Time from Surgery to Report

St. Joe’s

Tampa

Florida

Tampa—All Hospitals (Excluding St. Joe’s)

All Hospitals in Florida
Turnaround Time Analysis

Definitions:
- Surgery to MD's Signature: Surgery date to when the physician signs the requisition form.
- TAT Specimen Retrieval: TAT from specimen request date to specimen receipt.
- TAT Specimen Processing: Specimen receipt at GHI to test delivered date.
- Overall GHI TAT: Requisition created to test delivered date.

St. Joe's

- Avg TAT Analysis

Tampa

All Tampa Hospitals (Excluding St. Joe's)

Florida

All Hospitals in Florida
Key findings

Standardization of Oncotype DX utilization and ordering:

• The average time after standardization for all phases of test delivery is substantially shorter than other hospitals in Tampa and across Florida.

• Implementing standardization shortened the “Time to Report” by almost 11 days for all patients.

• Standardization increased pathology efficiency.

• Improved performance and measurement to key quality metrics.

• Submitted for quality improvement project to meet NAPBC accreditation requirement.
### Chapter 6 - Quality Improvement

<table>
<thead>
<tr>
<th>6.1 Quality and Outcomes</th>
<th>Compliant</th>
<th>Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encouraged participation in NQMBC as a resource for finding problematic issues to study for this standard.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Accreditation Award

| Total number of standards rated - Compliant | 27 |
| Total number of standards rated - Non-compliant | 0 |

#### Accreditation Award*

Three-Year Full Accreditation

#### Final Comments

This is an excellent program with a moderate breast cancer caseload volume. There have been substantial improvements in many aspects of breast care during the survey cycle. The new chair is a physician champion for the breast patient and will guide the program to more improvements during the coming survey cycle. There is excellent support from administration. The breast cancer conference was excellent. All disciplines were present. Eight cases were comprehensively presented in 45 minutes with careful staging, guideline and trial opportunity discussion. Tour the in-patient med onc unit, the infusion center, radiation facility and the very comprehensive Shimberg breast diagnostic center. Patient support and resources were noted as well during the tour.
Conclusions

• Standardization of Oncotype DX utilization and ordering is feasible in a large clinically integrated organization.

• Standardization dramatically increases process efficiency leading to measurable and meaningful improvements in quality of care.

• Standardization allows for Identification of sources of delays and inefficiency within the process thereby improving efficiency.

• Standardization has a favorable effect on consistency of patient management across the organization.
Future Directions

• Expand standardization protocol to other BayCare facilities.

• Examine the feasibility of formalizing the utilization and ordering of other genetic and genomic tests.

• Develop a formal protocol to estimate economic impact based on the data examining chemotherapy utilization and healthcare costs vs. the historical control group.
Moving Forward: Our Research Protocol

Economic Impact of Oncotype DX Standardization

**Pre-Standardization** vs **Post-Standardization**

- **NCCN Elig**
  - ER+, Node(-), HER2(-) micromets
  - NCCN Compliance %

- **Oncotype DX**
  - Low %
  - Int %
  - High %
  - Oncotype DX Group Results
  - Chemo %
  - Days from Surg-Report (Time-to-Tx)
  - Chemo % (Chemo % by Low/Int/High)

- **No Oncotype DX**
  - ER Visits %
  - Hospitalizations %
  - Chemo Cost $
  - Non-Oncotype DX Group Results

**Total Group Costs**

Before June 1st, 2013 vs After June 1st, 2013

Pre-Standardization Total Costs vs Post-Standardization Total Costs

Moving Forward:
Our Research Protocol

Economic Impact of Oncotype DX Standardization

- Before June 1st, 2013
- After June 1st, 2013

- Pre-Standardization Total Costs
- Post-Standardization Total Costs