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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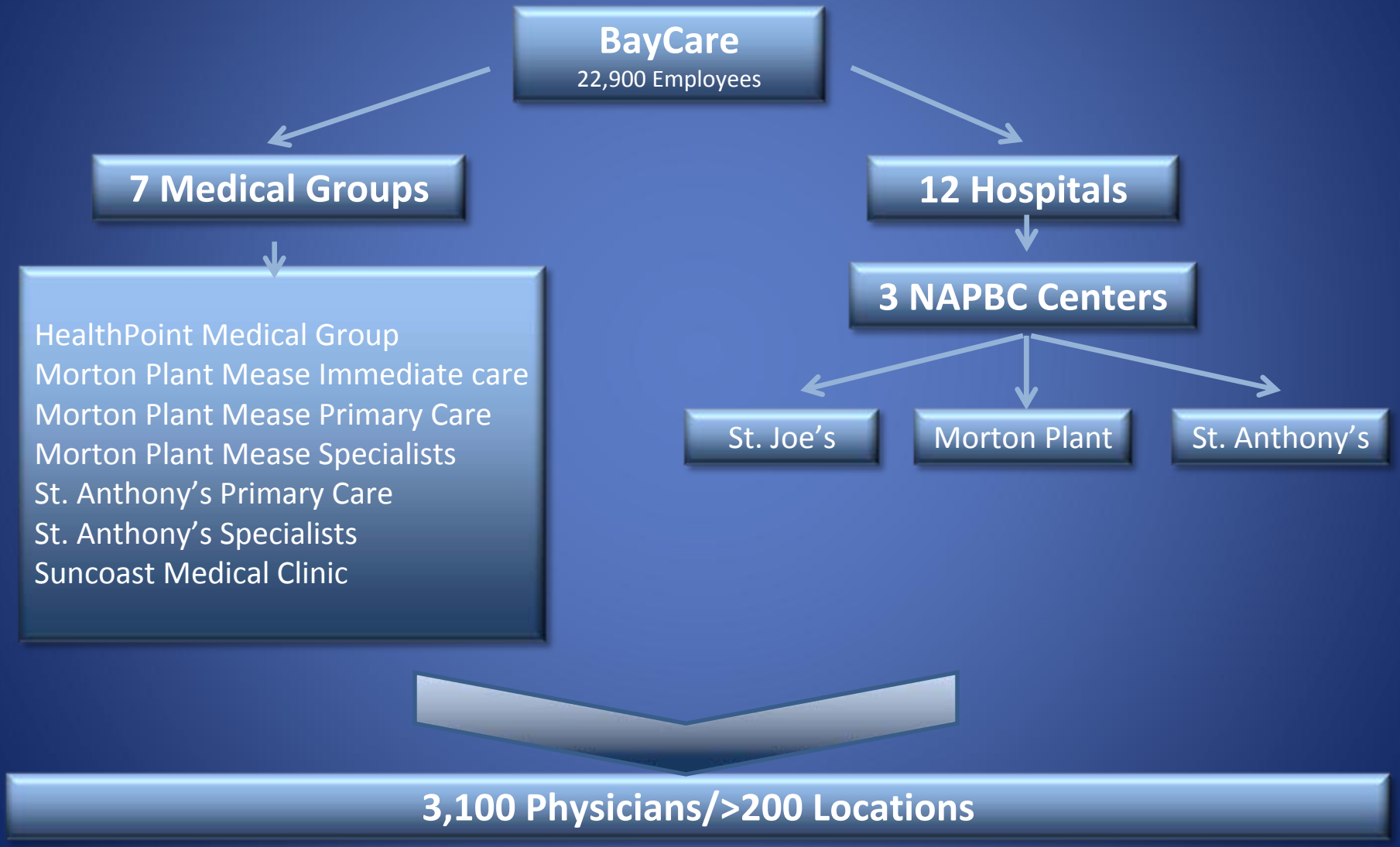
St. Joseph's Women's Hospital

BayCare Health System

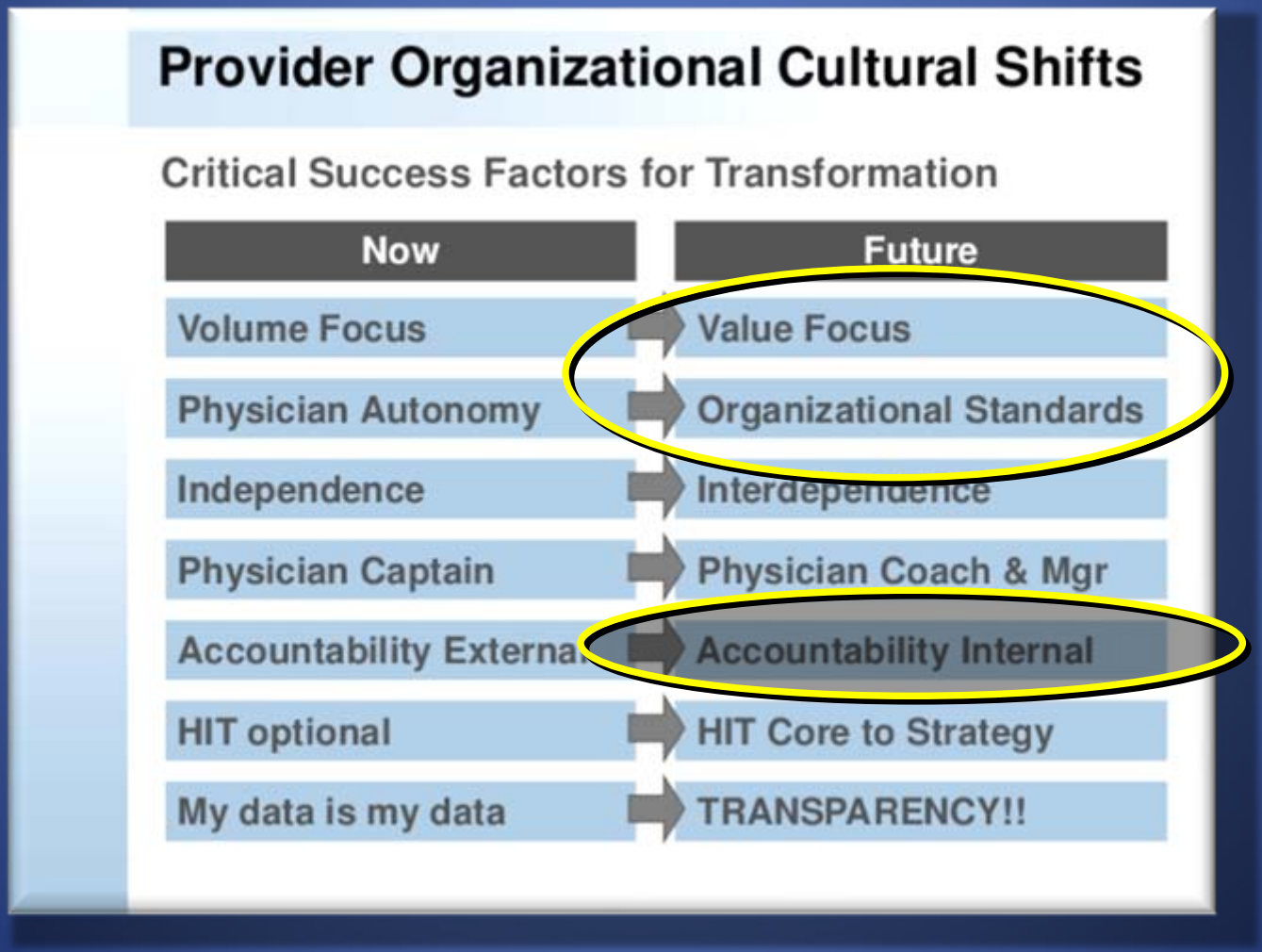
Agenda

- 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



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

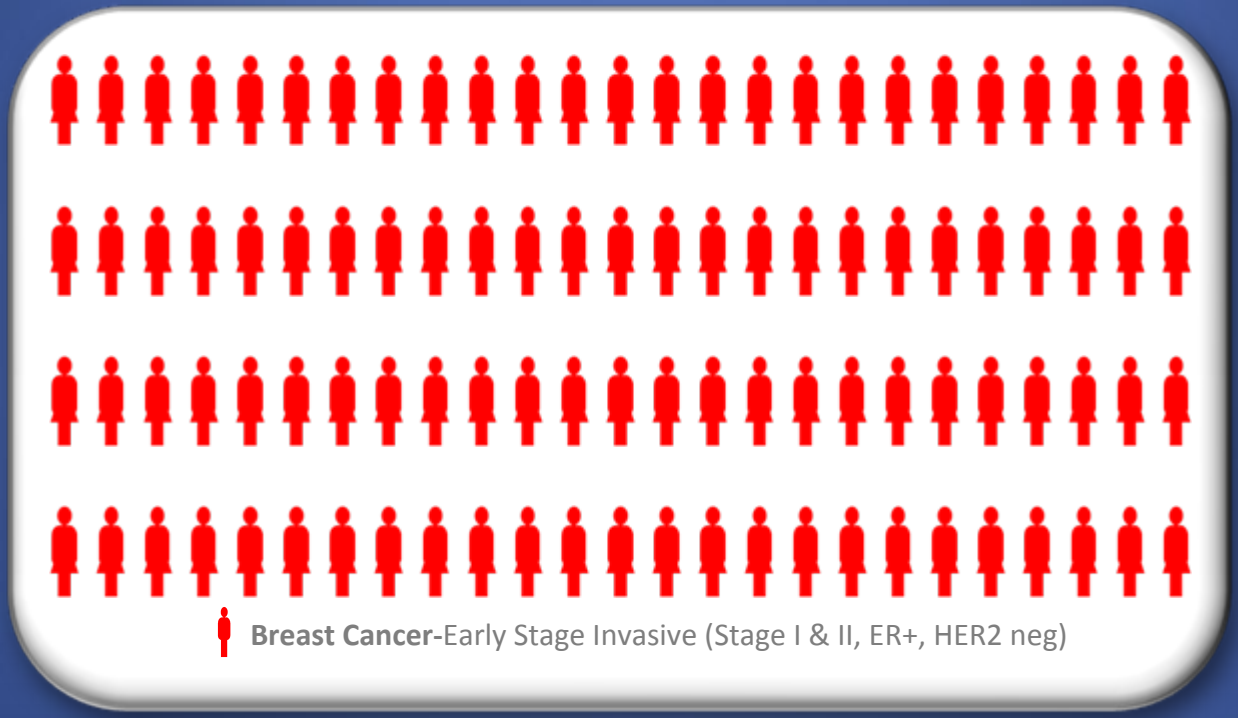
Percentage of the Patient Population for Which a Particular Drug Is Ineffective, on Average

ANTIDEPRESSANTS (SSRIs)	38%
ASTHMA DRUGS	40%
DIABETES DRUGS	43%
ARTHRITIS DRUGS	50%
ALZHEIMER'S DRUGS	70%
CANCER DRUGS	75%

Spear et al. Trends Mol Med. *2001.*

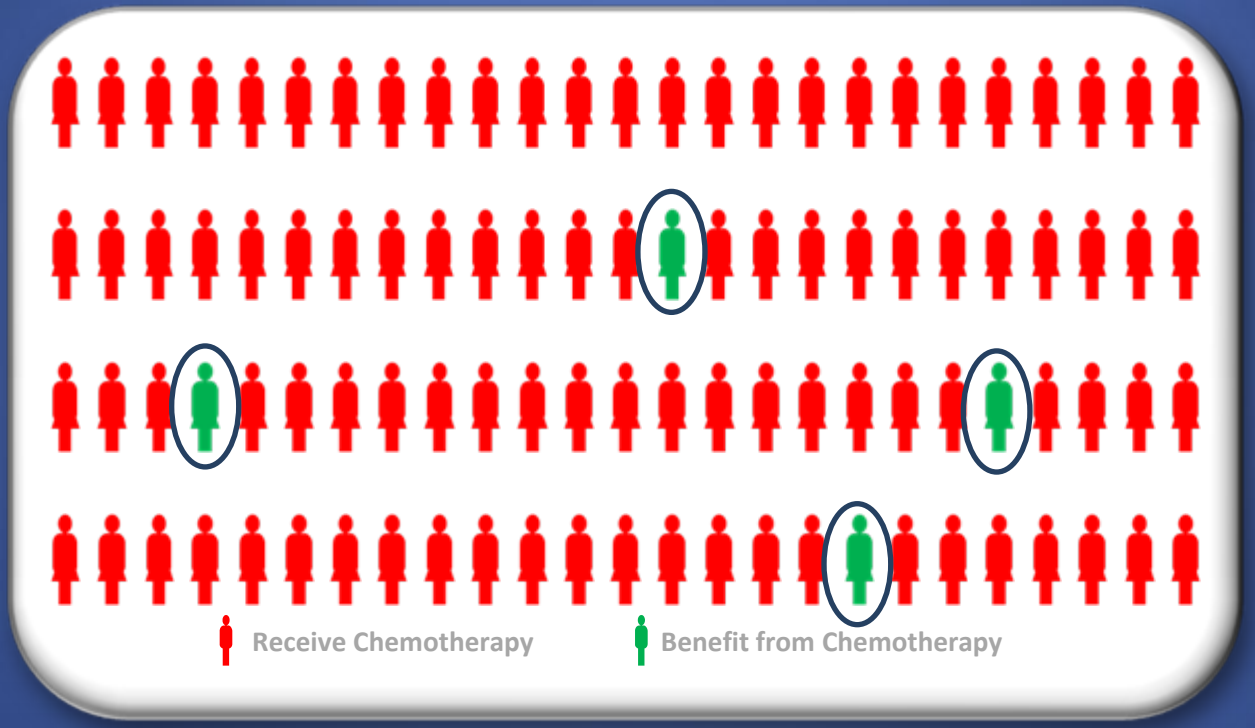
Breast Cancer: Facts

100 Women Diagnosed with Early Stage Breast Cancer



Breast Cancer: Facts

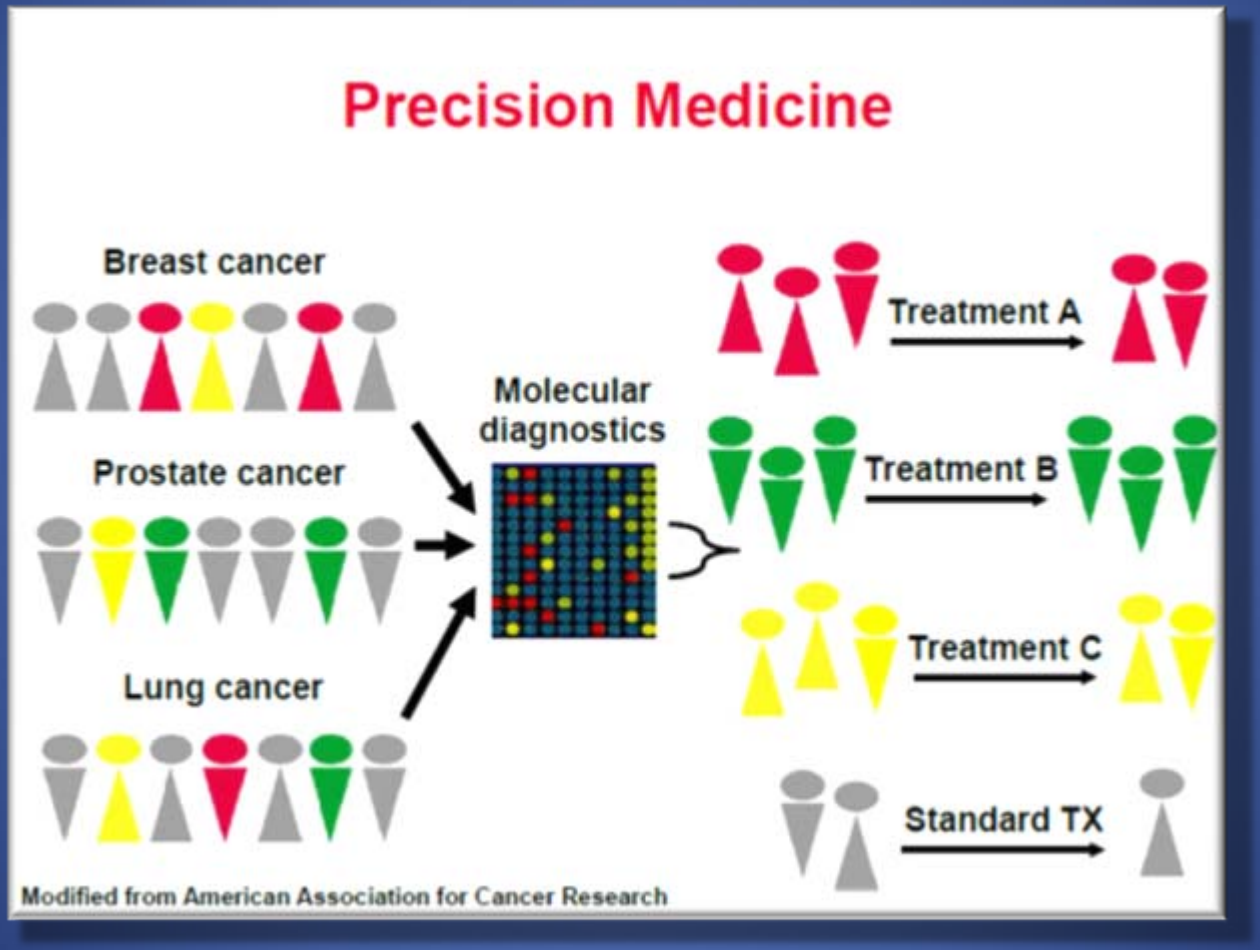
Only 4 in 100 patients benefit from chemo*



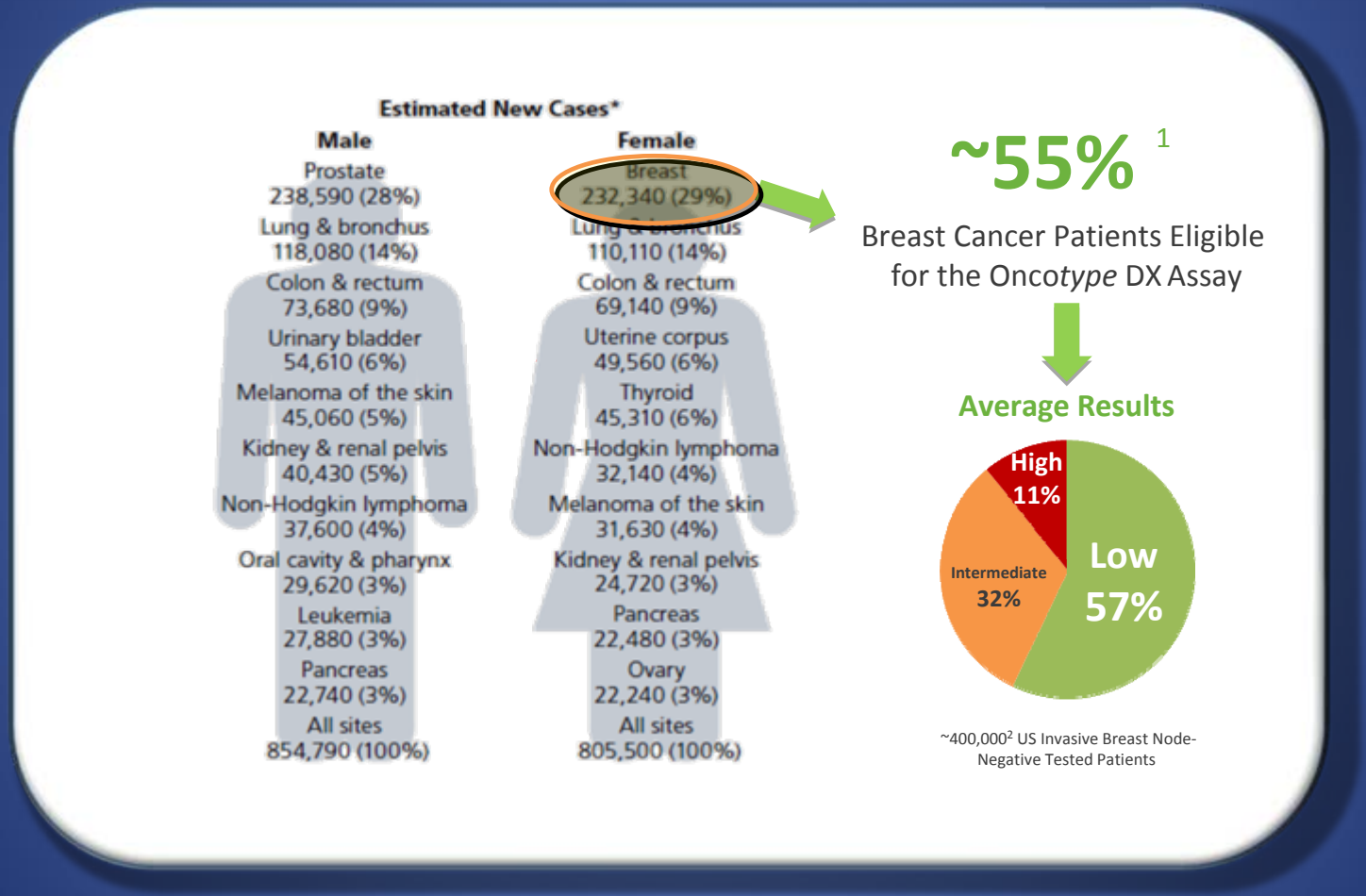
Fisher B, Dignam J, Womark N, et al: Tamoxifen and chemotherapy for lymph node-negative, estrogen receptor-positive breast cancer. J Natl Cancer Inst 89:1673-1682, 1997

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

Personalized Medicine Has Arrived



High Percentage of Breast Cancer Patients May Benefit from the Oncotype DX® Assay



Genomic Health, Inc. 2013. Updated St. Gallen International Breast Cancer Guidelines, for the Second Time, Recognize Oncotype DX® as the Only Validated Multi-Gene Test Able to Predict Chemotherapy Benefit. [press release] August 22, 2013.

ASCO is a trademark of the American Society of Clinical Oncology. NCCN and NCCN Guidelines are trademarks of the National Comprehensive Cancer Network. The guidelines do not endorse products or therapies.

Oncotype DX® Is Changing Clinical Practice

- **Oncotype 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 Oncotype 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

Genomic Health, Inc. 2013. Updated St. Gallen International Breast Cancer Guidelines, for the Second Time, Recognize Oncotype DX® as the Only Validated Multi-Gene Test Able to Predict Chemotherapy Benefit. [press release] August 22, 2013.
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Guidelines Support Recurrence Score® Result in Treatment Decision-Making for Early-Stage Breast Cancer

NCCN Guidelines® **> 0.5 cm, node negative, N1mi**	**Quantifies risk of recurrence as a continuous variable and predicts responsiveness to both tamoxifen and chemotherapy[1]**
ASCO® Guidelines **Node negative**	**Predicts the risk of recurrence and may be used to identify patients likely to benefit from tamoxifen or chemotherapy[2]**
St. Gallen Consensus **Node negative, node positive**	**Provides not only prognostic but also predictive information regarding the utility of cytotoxic therapy in addition to endocrine therapy[3]**
ESMO **Node negative**	**Provides additional prognostic and/or predictive information to complement pathology assessment and to predict response to adjuvant chemotherapy[4]**
BCBS Technology (TEC) Assessment **Node negative**	**May be used to determine recurrence risk for women with breast cancer therapy deciding whether to undergo adjuvant chemotherapy[5]**

1. Harris et al. JCO. *2007.; 2. NCCN Practice Guidelines in Oncology. V.3.2013.; 3. Goldhirsch et al.* Ann Oncol. *2013.; 4. Aebi et al.* Ann Oncol. *2010.; 5. Blue Cross Blue Shield. Gene expression profiling in women with lymph node-negative breast cancer to select adjuvant chemotherapy.*

ASCO is a trademark of the American Society of Clinical Oncology. NCCN and NCCN Guidelines are registered trademarks of the National Comprehensive Cancer Network. ESMO is the European Society of Medical Oncology. The guidelines do not endorse products or therapies.

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

Approval Process

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).

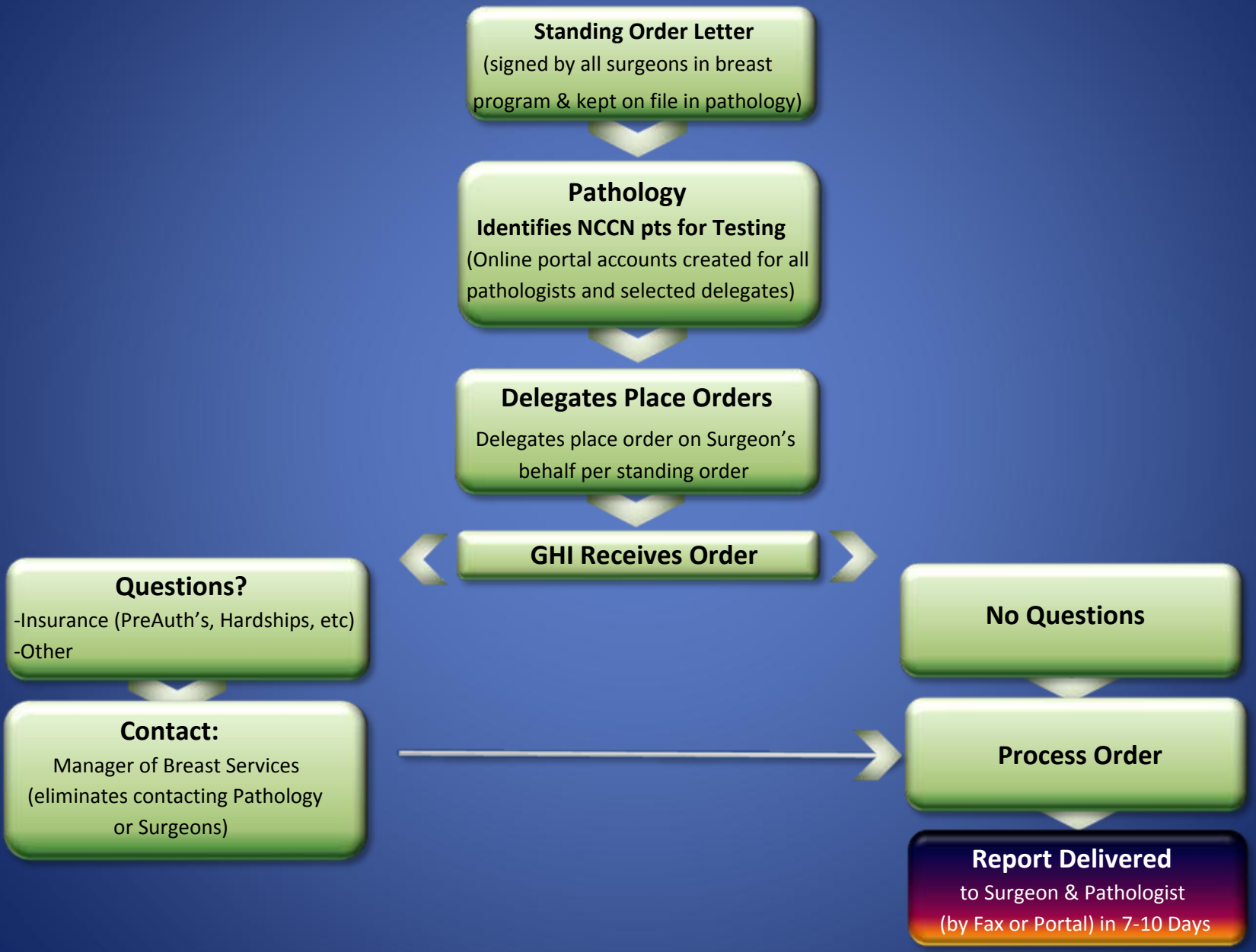
Quality and Outcomes (Standard 6.1)
Each year, the breast program leadership conducts or participates in two or more studies that measure quality and/or outcomes.

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 stake holders 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



Project Measured Metrics

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***

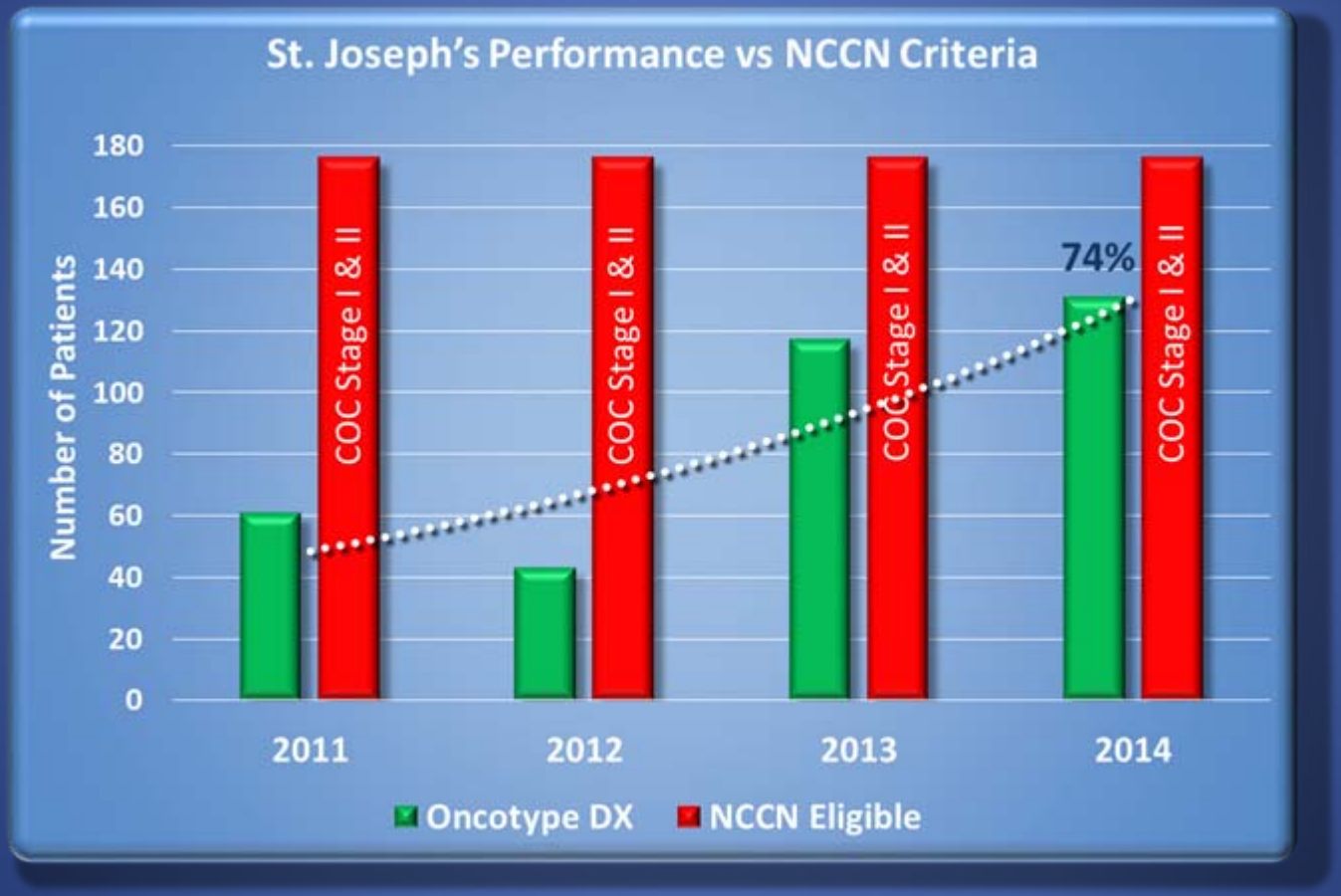
   Measures time from receipt of tissue to report date

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)



- **<u>Results</u>: Major improvement in percentage of patients with documented consideration of testing**

Results: *Time from Surgery to Oncotype DX Order*

Surgery

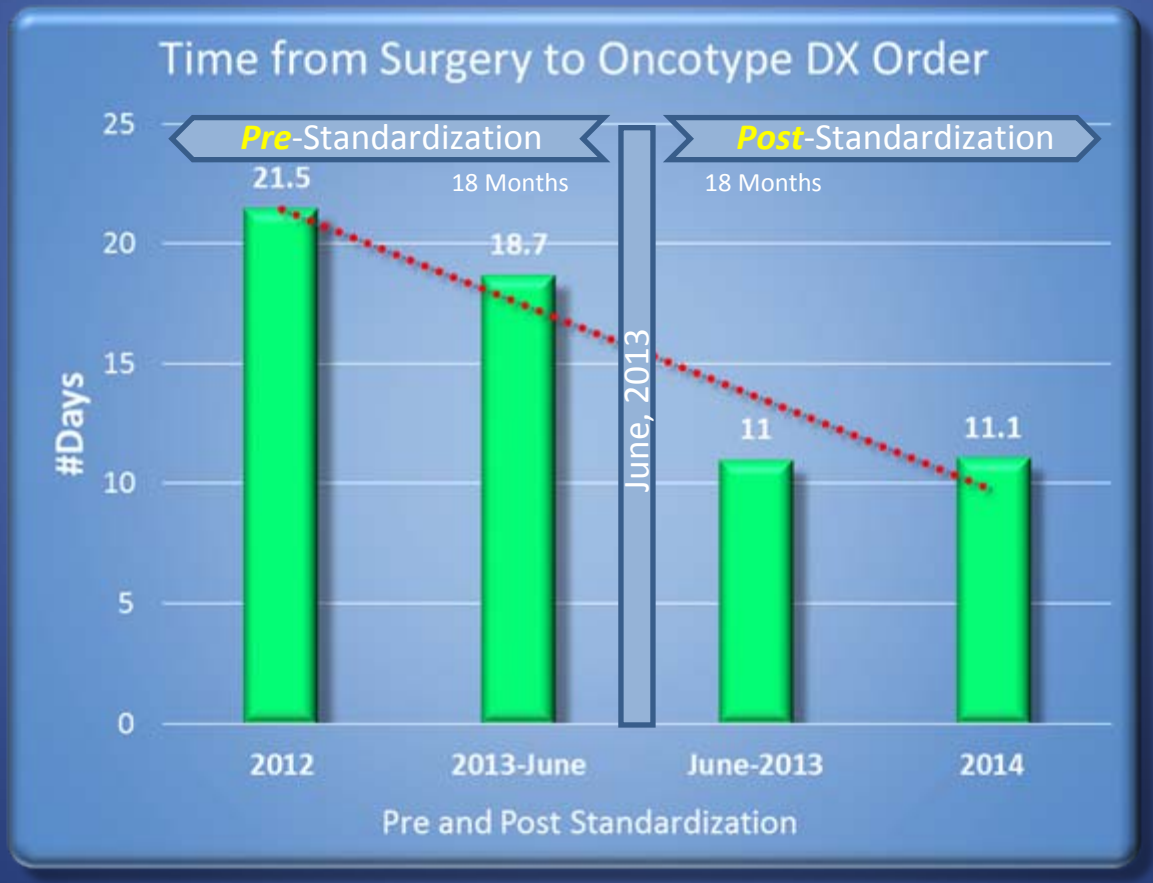
Surgery to Oncotype DX Order

Pathology Process Time

Genomic Health Process Time

Time to Treatment Decision

Oncotype DX Report

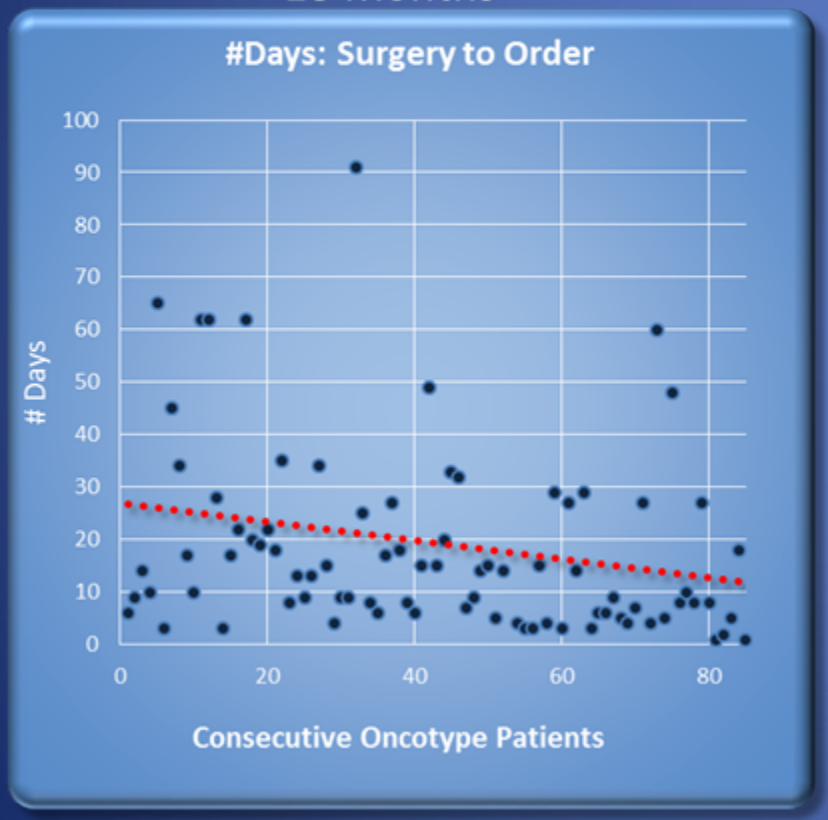


Results:
Time from Surgery to assay order improved by 10 days

Results: *Time from Surgery to Oncotype DX Order*

Pre-Standardization

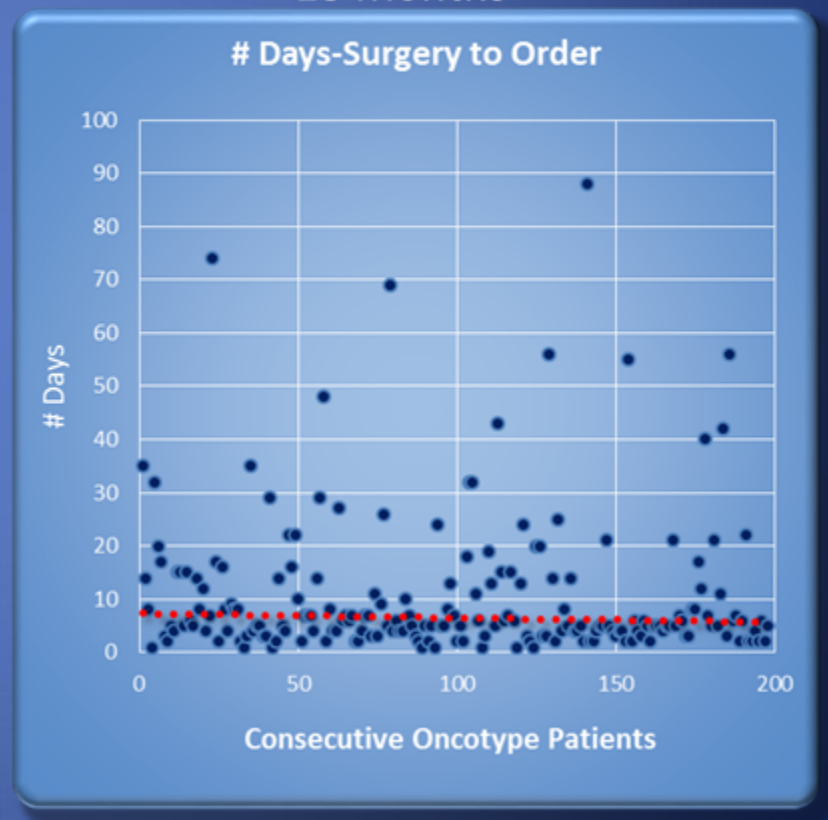
18 Months



June, 2013

Post-Standardization

18 Months



Results: Improvement seen at the individual patient level

Results: *Pathology Processing Time*

~Time from pathology order to GHI receiving tissue

Surgery

Surgery to Oncotype DX Order

Pathology Process Time

Genomic Health Process Time

Time to Treatment Decision

Oncotype DX Report

<u>Results:</u>

Pathology processing time cut by apprx 50% w/standardization

Results: *Pathology Processing Time*

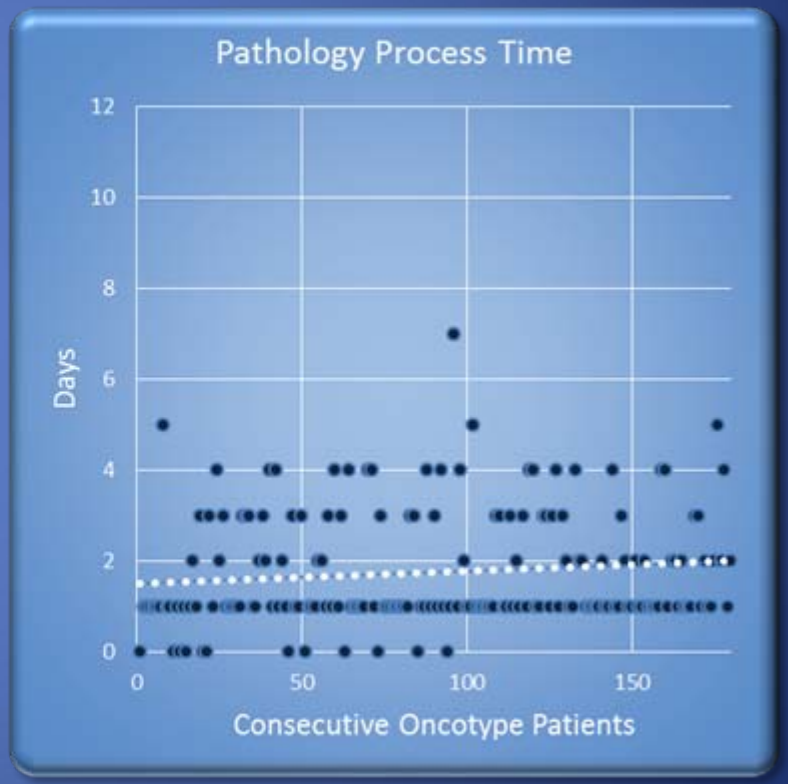
Pre-Standardization

18 Months

June, 2013

Post-Standardization

18 Months



Results: Improvement seen at the individual patient level

Results: *Genomic Health Process Time*

~From receipt of the tissue to issuing report

Surgery

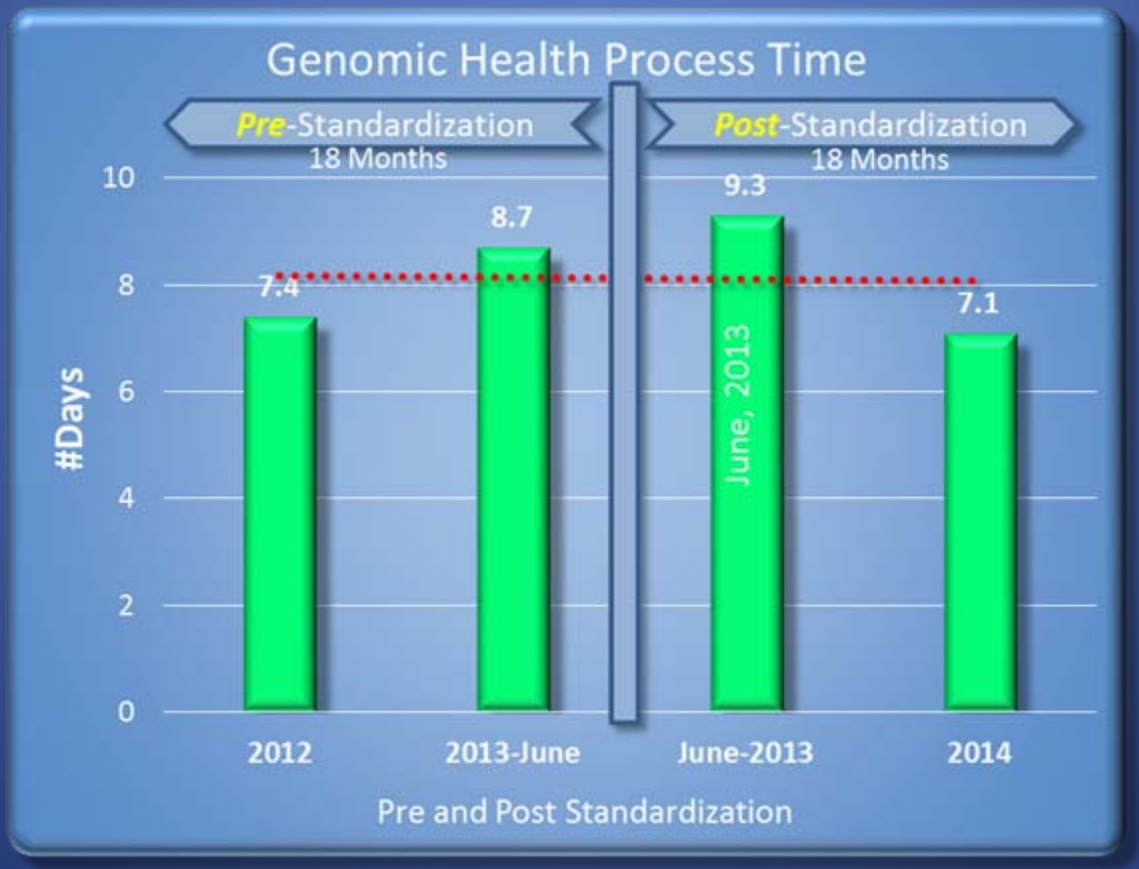
Surgery to Oncotype DX Order

Pathology Process Time

Genomic Health Process Time

Time to Treatment Decision

Oncotype DX Report



Results:

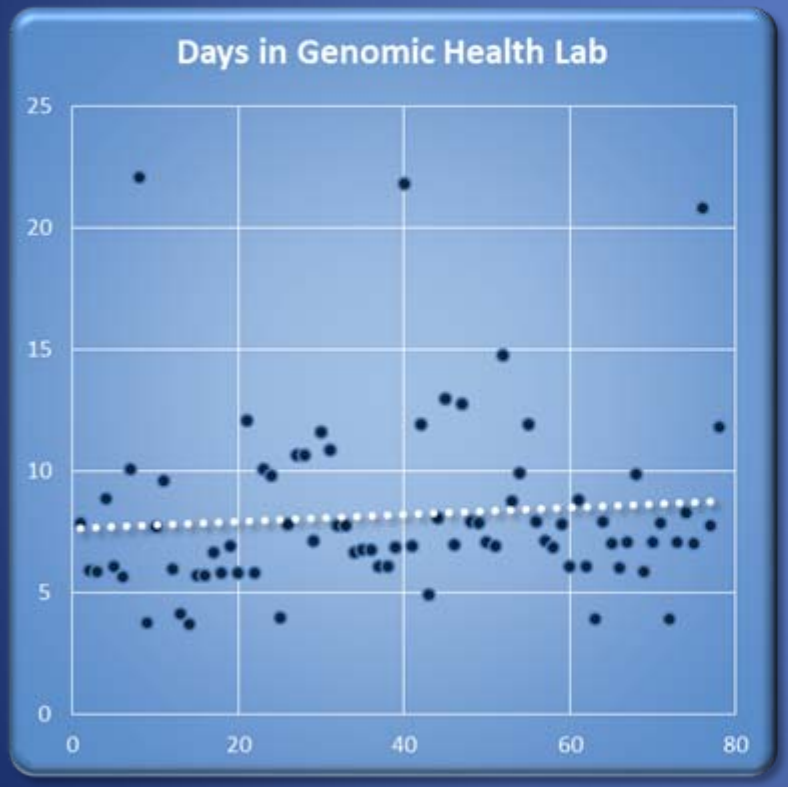
Genomic Health's process time remains steady

Results: *Genomic Health Process Time*

~Days in the lab process from receipt of specimen to report

Pre-Standardization

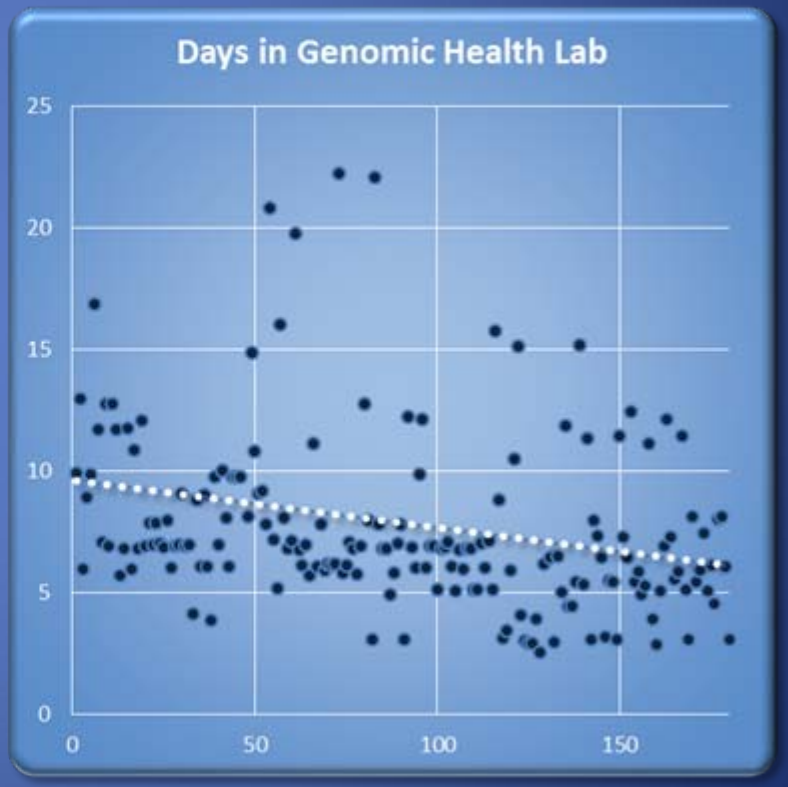
18 Months



June, 2013

Post-Standardization

18 Months



Results: GHI processing time remains consistent

Results: *Time to Treatment Decision*

~Total Days between Surgery and Oncotype DX Report

Surgery

Surgery to Oncotype DX Order | Pathology Process Time | Genomic Health Process Time

Time to Treatment Decision

Oncotype DX Report

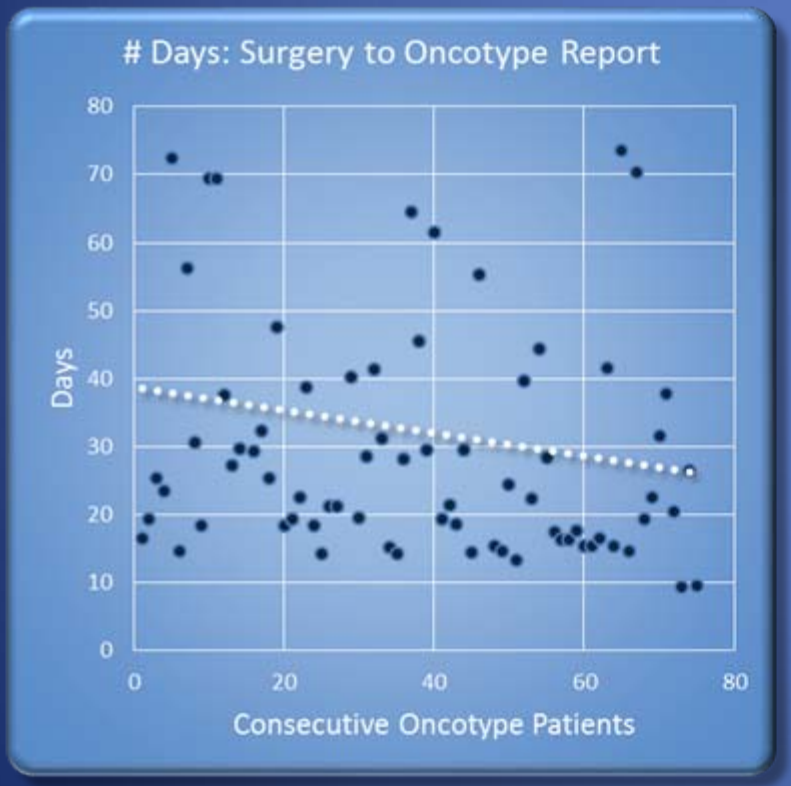
Results:
Time from Surgery to report was reduced by 11 days

Results: *Time to Treatment Decision (report)*

~Total Days between Surgery and Oncotype DX Report

Pre-Standardization

18 Months



June, 2013

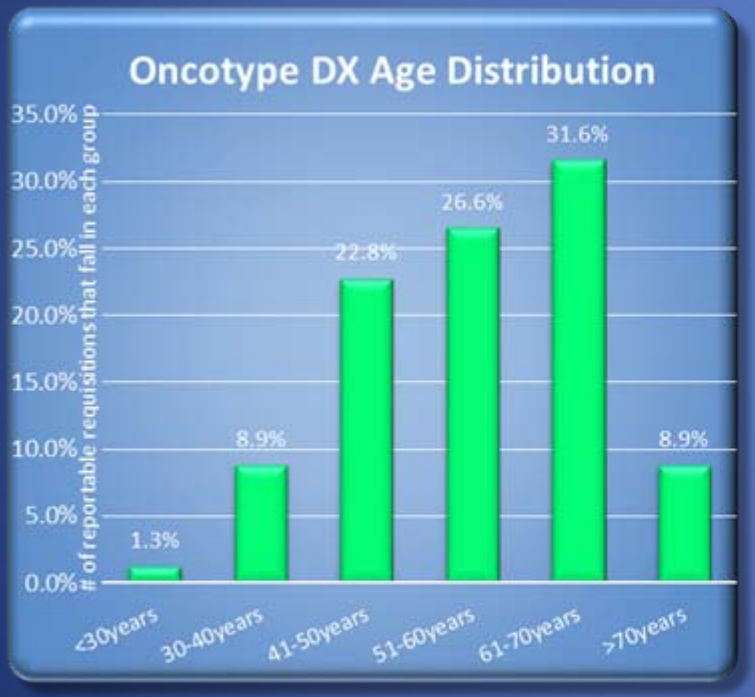
Post-Standardization

18 Months

Results: Improvement seen at the individual patient level

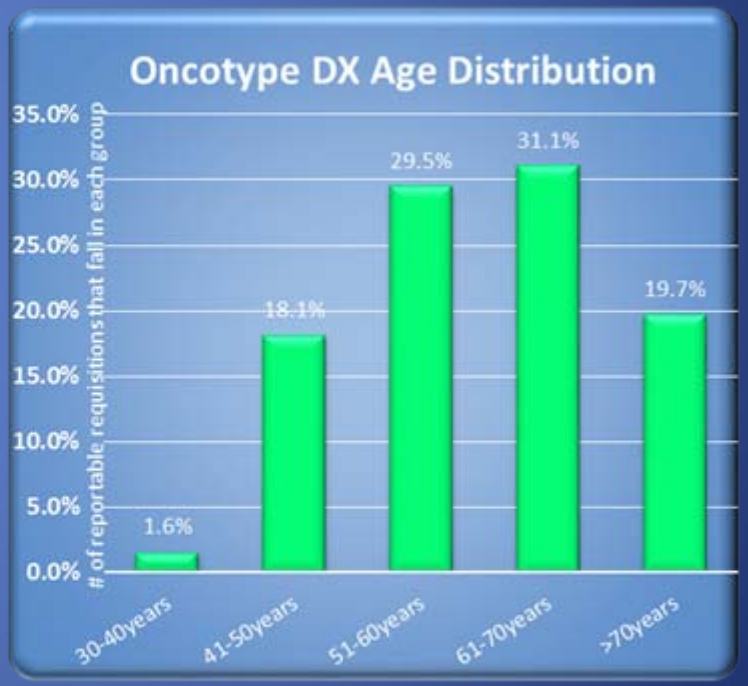
Results: *Age Distribution*

Pre-Standardization



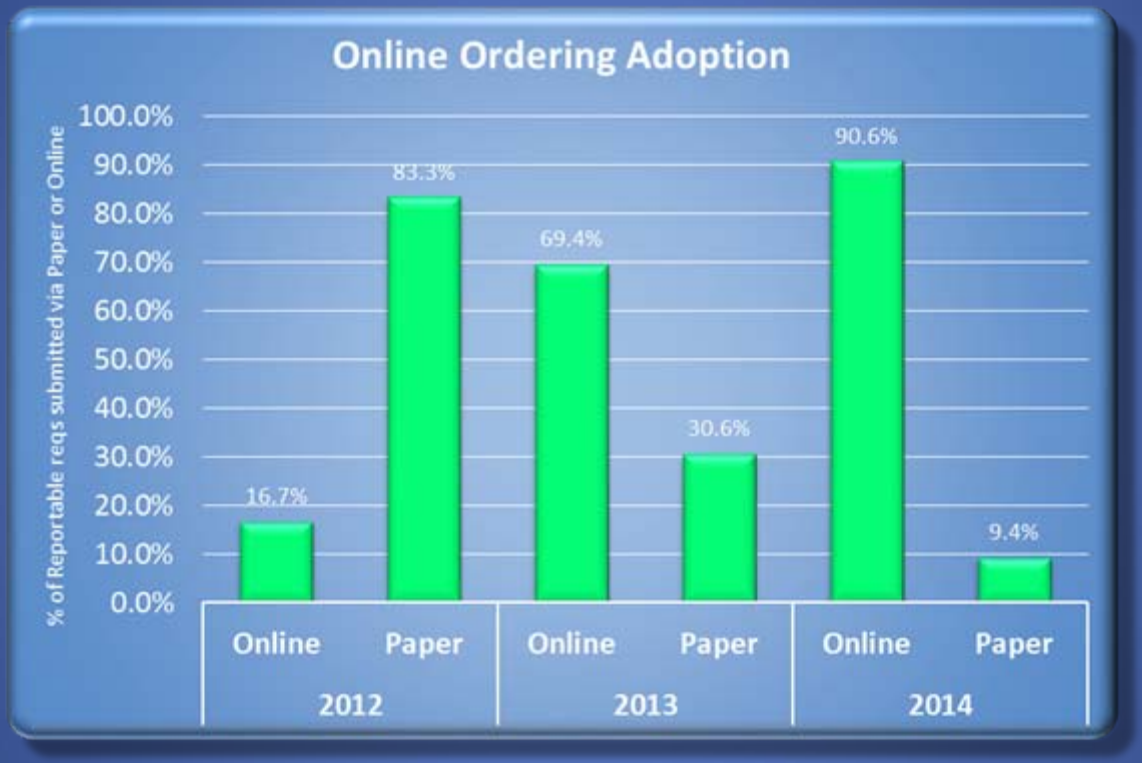
June, 2013

Post-Standardization



Results: *Online vs Paper*

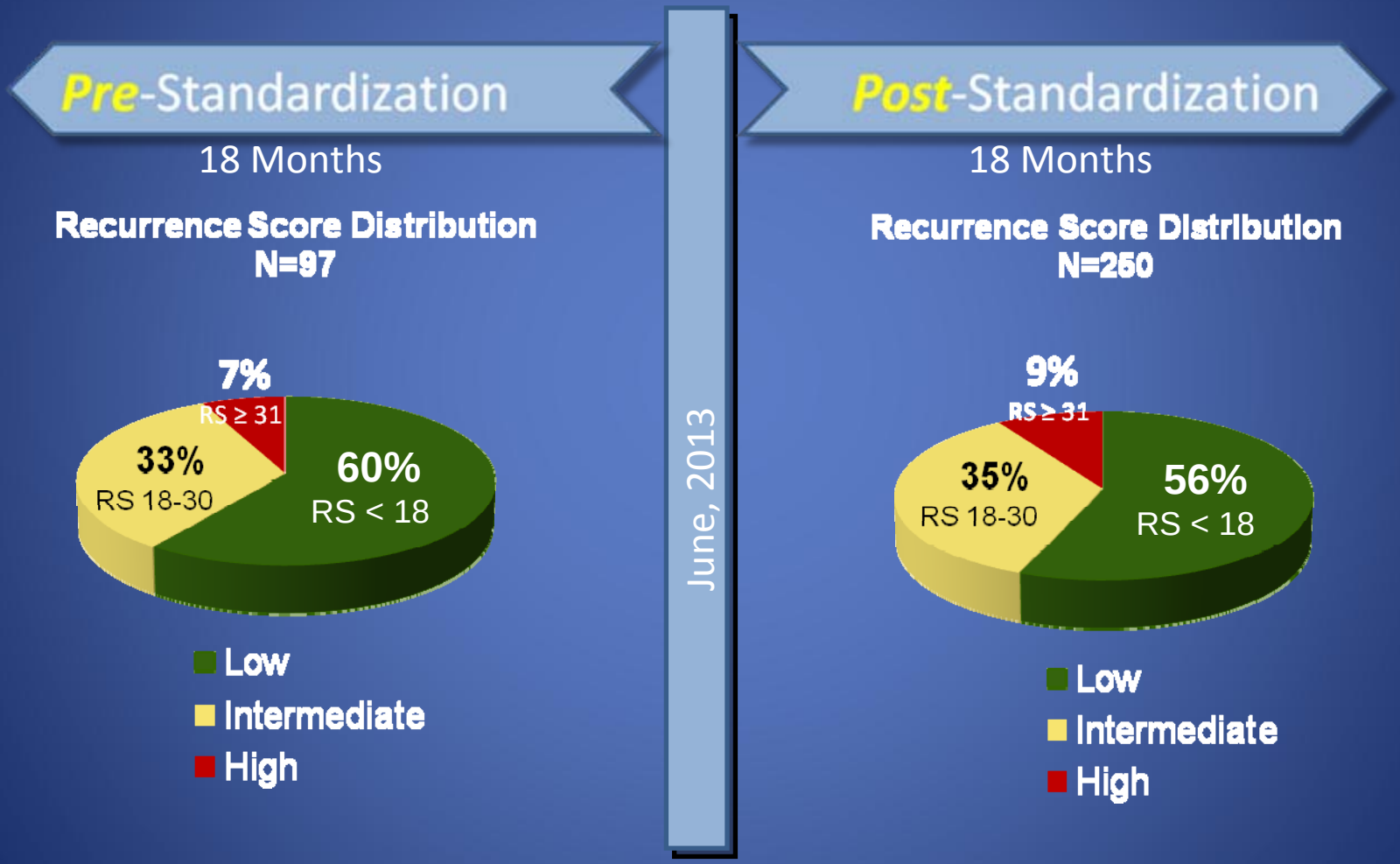
~Conversion to online ordering saves time, increases efficiency and prevents errors



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



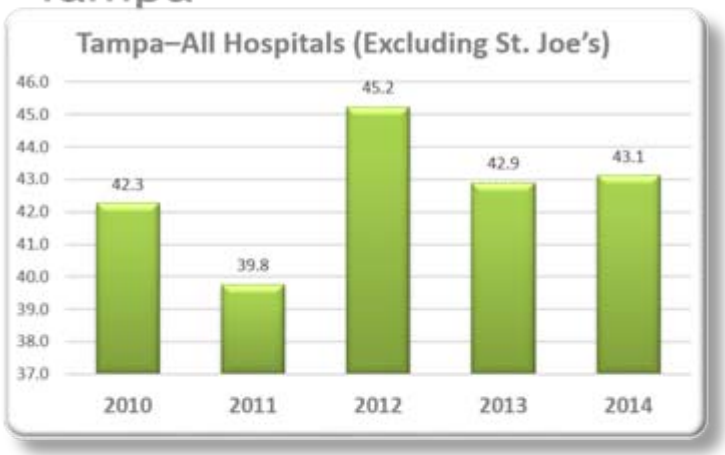
Results: Recurrence Score remained consistent pre & post

Results: St. Joe's vs. Local & State

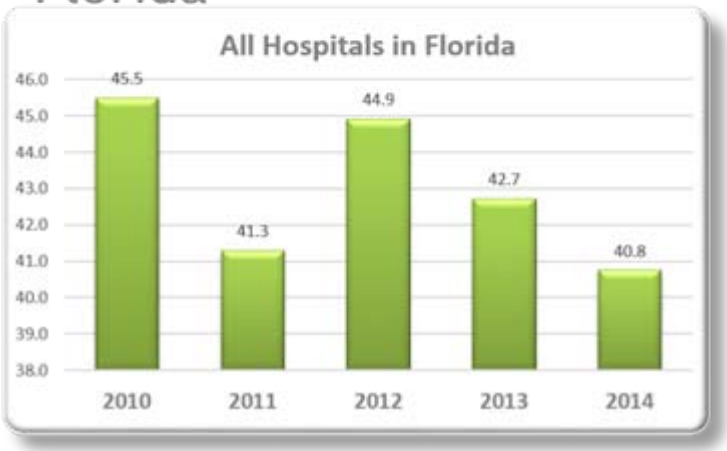
Time from Surgery to Report

St. Joe's

Tampa

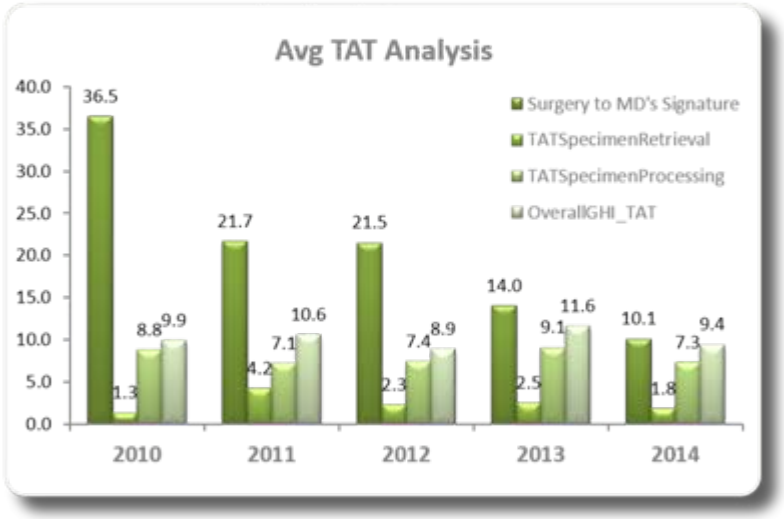


Florida



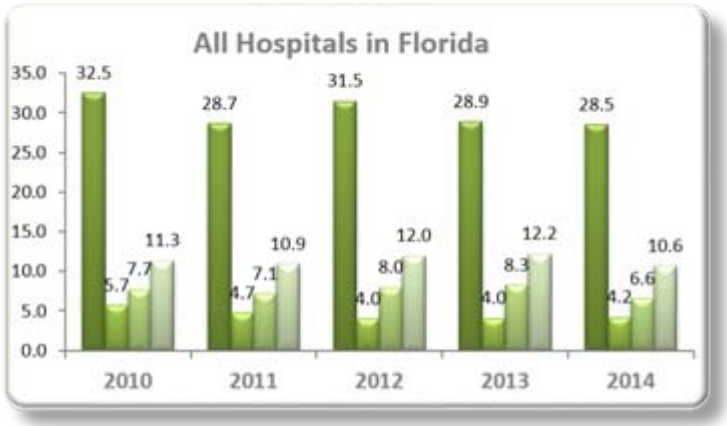
Turnaround Time Analysis

St. Joe's



Tampa

Florida



Definitions:

Surgery to MD's Signature - Surgery date to when the physician signs the req 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

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.

NAPBC Post Survey Report

Chapter 6 - Quality Improvement			
6.1 Quality and Outcomes	Compliant	Compliant	Encouraged participation in NQMBC as a resource for finding problematic issues to study for this standard. [redacted]

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

Surveyor Remarks

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. Toured the in-patient medonc 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