Quality Measures: How we develop them and the science behind it

Matthew A Facktor MD FACS
Geisinger Medical Center
Danville PA

Sandra L Wong MD MS FACS FASCO
Dartmouth-Hitchcock Medical Center
Lebanon NH

OBJECTIVES

• (1) present how/why we develop and report quality measures to CoC-accredited programs

• (2) provide an example of quality measure development, including experience developing melanoma measures
Quality Integration Committee
Chair – Lawrence Shulman, MD
Vice Chair – Mathew Facktor, MD, FACS
Staff Liaison – Ryan McCabe, PhD

- National Cancer Data Base (NCDB)
- Quality measures / reporting tools
- Participant User Files (PUFs)
Measures Reported Over Time

CP^R Reported Measures and Primary Sites

<table>
<thead>
<tr>
<th>Year</th>
<th>Primary Sites</th>
<th>Total Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Spring 2014</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Fall 2014</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Spring 2015</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Fall 2015</td>
<td>10</td>
<td>23</td>
</tr>
<tr>
<td>Spring 2016</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

Types of Quality Measures

- Accountability
- Quality Improvement
- Surveillance
Types of Quality Measures

- **Accountability (A) – Standard 4.4**
  - High level of evidence
    - randomized controlled trials (RCTs)
  - Considered the “gold standard”
    - NQF (National Quality Forum) endorsement
    - Public reporting
    - Payment incentive programs
    - CoC accreditation maintenance

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**STANDARD 4.4**

**Accountability Measures**

Each calendar year, the expected Estimated Performance Rates (EPR) is met for each accountability measure as defined by the Commission on Cancer.

**DEFINITION AND REQUIREMENTS**

The cancer committee is a multidisciplinary forum that provides a platform to evaluate care within and across disciplines to discuss processes that work and to evaluate how processes can be improved to promote evidence-based practice. The CoC requires accredited cancer programs to treat cancer patients according to nationally accepted accountability measures indicated by the CoC quality reporting tool, Cancer Program Practice Profile Reports (CPPR).

Accountability measures promote improvements in care delivery and are the highest standard for measurement. These measures demonstrate provider accountability, influence payment for services, and promote transparency. An accountability measure is the standard of care derived from evidence-based data, including multiple randomized control trials.

If a cancer program is not meeting the EPR of a measure(s), then a corrective action plan is required to be developed and executed in order to improve performance. The corrective action plan must document how the program will investigate the issue for each measure, as needed, with intent of resolving the deficiency and improving compliance.

The cancer committee addresses EPRs and monitoring activity is documented in the cancer committee minutes. The corrective action taken and any required follow-up needed to meet EPRs are included in the documentation.
Types of Quality Measures

- **Quality improvement (QI) – Standard 4.5**
  - Reasonably good evidence (not RCTs)
  - Intended for internal performance monitoring
  - CoC accreditation maintenance

**STANDARD 4.5**

Quality Improvement Measures

Each calendar year, the expected Estimated Performance Rates (EPR) is met for each quality improvement measure as defined by the Commission on Cancer.

**DEFINITION AND REQUIREMENTS**

The CoC requires accredited cancer programs to treat cancer patients according to nationally accepted quality improvement measures indicated by the CoC quality reporting tool, Cancer Program Practice Profile Reports (CPPR). The function of a quality improvement measure is to monitor the need for quality improvement or remediation of treatment provided. Evidence from experimental studies, not randomized control trials, supports these measures. Quality improvement measures are intended for internal monitoring of performance within a cancer program.

If a cancer program is not meeting the EPR of a measure(s), then a corrective action plan is required to be developed and executed in order to improve performance. The corrective action plan must document how the program will investigate the issue for each measure, as needed, with intent of resolving the deficiency and improving compliance.

The cancer committee addresses EPRs and monitoring activity is documented in the cancer committee minutes. The corrective action taken and any required follow-up needed to meet EPRs are included in the documentation.
Types of Quality Measures

• **Surveillance (S)**
  – Limited evidence (but not zero)
  – Help identify the status quo
  – Monitor patterns and trends of care
    • Guide decision making
    • Guide resource allocation
  – May serve as launching pad towards future “A” or “QI”

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Quality Measure Reports – Breast

• **BCSRT**: Breast radiation after breast conserving surgery (NQF 0219 – Accountability)
• **MAC**: Combination chemotherapy for hormone receptor negative breast cancer (NQF 0559 – Accountability)
• **HT**: Adjuvant hormonal therapy for hormone receptor positive breast cancer (NQF 0220 – Accountability)
• **BCS**: Breast conserving surgery rate (Surveillance)
• **MASRT**: Radiation therapy recommended or administered following mastectomy within 1 year of diagnosis for women with 4 or more positive regional lymph nodes (Accountability)
• **nBx**: Image or palpation-guided needle biopsy (core or FNA) is performed for the diagnosis of breast cancer (Quality Improvement)

NQF = National Quality Forum Endorsed Measure
BREAST, 2013, BCSRT: Breast radiation after breast conserving surgery (NQF 0219 - Accountability)

Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer. (CPRD data as of 11/02/2015)

BREAST, 2013, HT: Adjuvant hormonal therapy for hormone receptor positive breast cancer (NQF 0220 - Accountability)

Tamoxifen or third-generation aromatase inhibitor is recommended or administered within 1 year (365 days) of diagnosis for women with an ER+ T1cN0M0, or stage IB - III hormone receptor positive breast cancer. (CPRD data as of 11/02/2015)
Quality Measure Reports - Colon

- **ACT**: Adjuvant chemotherapy for lymph node positive colon cancer (NQF 0223 – Accountability)

- **12RLN**: At least 12 lymph nodes are removed and examined as part of primary colon cancer resection (NQF 0225 – Quality Improvement)

NQF = National Quality Forum Endorsed Measure
Quality Measure Reports - Non-Small Cell Lung

- **10RLN**: At least 10 regional lymph nodes removed and pathologically examined for AJCC stage IA, IB, IIA, and IIB resected NSCLC (Surveillance)

- **LCT**: Systemic chemotherapy is administered or recommended within 4 months prior to surgery or within 6 months postoperatively for surgically resected cases with pathologic, lymph node-positive (pN1) and (pN2) NSCLC (Quality Improvement)

- **LNoSurg**: Surgery is not the first course of treatment for cN2, M0 cases (Quality Improvement)
NSCLC, 2013, 10RLN: At least 10 regional lymph nodes removed and pathologically examined for resected NSCLC (Surveillance)

<table>
<thead>
<tr>
<th>Measure Development Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure Workgroup established</td>
</tr>
<tr>
<td>Measure Workgroup develops measures for consideration</td>
</tr>
<tr>
<td>NCDB statisticians research validity &amp; feasibility of measure(s)</td>
</tr>
<tr>
<td>NCDB statisticians work with clinical group on measure specifications utilizing data in FORDS</td>
</tr>
<tr>
<td>Quality Integration Committee (QIC) Measure Sub-committee recommends measure to QIC</td>
</tr>
<tr>
<td>QIC approves measure</td>
</tr>
</tbody>
</table>
Measure Development Process Cont.

- Business analyst (BA) reviews specifications
- Review issues and questions with Measure development workgroup contact
- BA tests completed measure specifications
- Review data with NCDB statisticians, CTRs & original measure workgroup
- IT adds measure to NCDB application
- Test usability of measure in NCDB test reporting environment
- Develop education materials
- Release measure into production
- Review questions & inquiries on measure specifications with measure subcommittee & measure workgroup
- Maintain and update documentation and NQF submission if applicable

National Quality Forum History of CoC Measures

<table>
<thead>
<tr>
<th>NQF Original Endorsement</th>
<th>Maintenance of Endorsement</th>
</tr>
</thead>
</table>

- Maintenance of Endorsement
  - Submission of Breast Needle biopsy Measure
  - Removal of Breast Needle Biopsy Measure

- Annual updates are performed/submitted each year
- In person review was May 18, 2016
National Quality Forum (NQF)

- Five quality measures were submitted this year to the NQF for “maintenance” of endorsement.
  - Colon:
    - NQF 0223: Adjuvant chemotherapy for LN+ colon cancer
    - NQF 0225: At least 12 regional lymph nodes are removed/examined
  - Breast:
    - NQF 0219: Breast Conservation Surgery Followed by RT
    - NQF 0220: Hormone Therapy for HR+ breast cancer
    - NQF 0559: Chemotherapy for HR- Breast Cancer

- Specifications harmonized with ASCO and NCCN

### NQF Evaluation Criteria

<table>
<thead>
<tr>
<th>CURRENT MAINTENANCE PROCESS</th>
<th>NEW MAINTENANCE PROCESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IMPORTANCE TO MEASURE AND REPORT</strong></td>
<td></td>
</tr>
<tr>
<td>• Gap — opportunity for improvement, variation, quality of care across providers</td>
<td>INCREASED EMPHASIS: gap in care and variation</td>
</tr>
<tr>
<td>• Evidence — Quantity, quality, consistency (QOC)</td>
<td>DECREASED EMPHASIS: Require measure developer to attest to current evidence, Standing Committee to affirm no change in evidence</td>
</tr>
<tr>
<td>• Established link for process measures with outcomes</td>
<td></td>
</tr>
<tr>
<td><strong>SCIENTIFIC ACCURACY</strong></td>
<td></td>
</tr>
<tr>
<td>• Measure specifications</td>
<td></td>
</tr>
<tr>
<td>• Reliability of measurement</td>
<td>DECREASED EMPHASIS: Require measure developer to attest to testing adequate, Standing Committee to affirm no change in evidence</td>
</tr>
<tr>
<td>• Validity (including external validation)</td>
<td></td>
</tr>
<tr>
<td><strong>USABILITY AND USE</strong></td>
<td></td>
</tr>
<tr>
<td>• Used in accountability applications and public reporting</td>
<td>DECREASED EMPHASIS: Much greater focus on measure use and usefulness, including both impact and unintended consequences</td>
</tr>
<tr>
<td>• Usability: impact and unintended consequences</td>
<td></td>
</tr>
<tr>
<td><strong>FEASIBILITY</strong></td>
<td></td>
</tr>
<tr>
<td>• Measure feasible, including measure feasibility</td>
<td>NO CHANGE: Implementation issues may be more prominent</td>
</tr>
</tbody>
</table>

**Final Board Vote:**

October 2016
Plans for new measures

- National Accreditation Program for Rectal Cancer (NAPRC)
  - In beginning stages of review of quality measures

- Alliance Collaboration
  - Vol. 2 Operative Standards Manual

- Site Specific Leaders Integration

- Collaboration with specialty societies (e.g., SSO, AUA)

- Must balance total # reportable measures with everyone’s workload – NCDB/CoC staff, cancer registrars, & clinicians

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OBJECTIVES

(1) present how/why we develop and report quality measures to CoC-accredited programs

(2) provide an example of quality measure development, including experience developing melanoma measures

Quality Measures: How we develop them and the science behind it

Sandra L Wong MD MS FACS FASCO
Dartmouth-Hitchcock Medical Center
Lebanon NH
Objectives:

1. present how and why we develop and report quality measures to CoC-accredited programs and the future direction of the Measures Subcommittee, and
2. provide an example of quality measure development, including experience developing melanoma measures

Patients undergoing colon cancer resections should have > 12 regional lymph nodes removed
Colon Ca Resection - Compliance with 12+ nodes 2003-2013

Significant increase in compliance over time (p<0.0001)

Colon Ca Resection - Compliance with 12+ nodes 2003-2013
Stage III is the only stage that saw a statistically significant increase in survival from 2003 to 2008.

Compliant cases have greater 5-year survival than non-compliant cases. This holds true in 2003 and in 2008.
Colon Ca Risk-adjusted survival 2003 and 2008 by compliance

Breast Ca Stage III Adjusted Hazard Ratios by Significance
Breast Ca Stage III - Un-adjusted survival by hospital type

Distribution of Survival Change for Breast Cancer Stage III

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Un-adjusted High</th>
<th>Risk-Adjusted High</th>
<th>Un-adjusted Low</th>
<th>Risk-adjusted Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community</td>
<td>34/486</td>
<td>0/486</td>
<td>6/486</td>
<td>0/486</td>
</tr>
<tr>
<td>Comprehensive Community</td>
<td>53/636</td>
<td>3/636</td>
<td>16/636</td>
<td>2/636</td>
</tr>
<tr>
<td>NCI</td>
<td>12/40</td>
<td>3/40</td>
<td>0/40</td>
<td>2/40</td>
</tr>
</tbody>
</table>
Stage III Breast Cancer – Risk-Adjusted Survival by Hospital Type

Unadjusted 5 Year Survival Rates 2006 - 2008: Breast Cancer Stages III, IV
Risk-Adjusted Survival Breast Cancer
Stage Stratified Hazard Ratios 2006 - 2008

BREAST, 2013, MASRT: Post-mastectomy radiation for women with 4 or more positive regional lymph nodes (Accountability)
Breast cancer patients with > 4 positive axillary nodes should receive post-mastectomy radiation

CoC wide compliance rates

2005 = 69%
2012 = 86%

Denominator = 64,556 patients
Unadjusted Survival Rates for Administration of Post-Mastectomy Radiation for Breast Ca Patients with ≥ 4+ Nodes

Risk-Adjusted hazard for Administration of Post-Mastectomy Radiation for Breast Ca Patients with ≥ 4+ Nodes

<table>
<thead>
<tr>
<th>2005-2012 Diagnoses</th>
<th>Non-Compliant</th>
<th>Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference</td>
<td>0.67 [0.65-0.70]</td>
</tr>
</tbody>
</table>
Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis for patients with Stage III (lymph node positive) colon cancer. (NQF #0223)

Volume and Unadjusted 30, 90 Day Mortality After Selected Complex Cancer Operations

- Cystectomy
- Esophagectomy
- Gastrectomy
- Pancreatectomy
- Rectal resection
- Non–Small-Cell Lung Cancer (NSCLC) resection
Gastrectomies, Unadjusted 30, 90 Day Mortality, 95% CI, 2011 - 2013 My Facility vs. All CoC and CoC High Volume

<table>
<thead>
<tr>
<th></th>
<th>My Facility</th>
<th>All CoC</th>
<th>CoC High Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Day Mortality</td>
<td>30.0%</td>
<td>1.6%</td>
<td>0.1%</td>
</tr>
<tr>
<td>90 Day Mortality</td>
<td>9.7%</td>
<td>7.2%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

Deaths
- My Facility: 0
- All CoC: 1
- CoC High Volume: 1

Resections
- My Facility: 100
- All CoC: 96
- CoC High Volume: 18,412

*NA No resections, or < 30 or < 90 days of follow up for alive patients
Learning objectives

- Why measure quality?
- What is a good quality measure?
- Types of measures
- Quality measures for melanoma
  How are we doing with providing high quality melanoma care?

Why measure?

- Intent of quality measurement \(\rightarrow\) improve patient care
  - Standardized data capture
  - Required participation in reporting
  - Benchmarking
  - Quality improvement

  - Financial rewards or penalties?
  - Public reporting?
Targeting what to measure

- **Characteristics of a good quality measure**
  - Solid evidence base supports that the metric leads to an improved outcome
  - The measure actually captures whether care was delivered
  - The process is in the direct causal pathway of the outcome
  - No unintended consequences as a result of the metric


Targeting what to measure

- **Pitfalls of measurement**
  - Analytics must be rigorous
  - Can be costly
  - Measurement may not actually be related to improvement
  - Success requires ongoing vigilance

Evidence-based guidelines for melanoma

- SSO-ASCO joint guidelines
- Sentinel node biopsy for \( \geq 1 \) mm tumors
- Completion lymph node biopsy when SLNB (+)

Sentinel Lymph Node Biopsy for Melanoma: American Society of Clinical Oncology and Society of Surgical Oncology Joint Clinical Practice Guideline

Commission on Cancer and SSO leadership – Ned Carp, Chris Pezzi, Sandra Wong

SSO Melanoma Disease Site WorkGroup – Co-chairs Doug Tyler & Jon Zager
Measure: Sentinel lymph node biopsy

- **Measure 1:** Appropriate use of sentinel lymph node biopsy (SLNB)

  - Sentinel lymph node biopsy for nodal staging of clinically node negative patients with intermediate thickness melanoma (1.0 to 4.0 mm)
  - Concern for overuse of the procedure when patients have <0.75 mm

Measure: Sentinel lymph node biopsy

- Does not account for quality of SLNB
  - Identification rate
  - False negative biopsy
- Cannot completely account for referral to surgeon after diagnosis
- May not completely exclude patients based on comorbid conditions or decision to decline SLNB
Baseline data from NCDB

- 2011-2012
- Melanoma diagnoses (C44.0-44.9; C51.0-51.2; C51.8-51.9; C60.0; C60.2; C60.8; C60.9; C63.2)
- N=50,031 after exclusions
  - Primary disease only
  - Age 18-80

How are we doing?

| Sentinel node biopsy performed |  
|-------------------------------|---
| Tumor thickness <0.75 mm      | 17.9%
| Tumor thickness >1.0 mm       | 83.5%
Measure: Completion lymph node dissection

- Measure 2: Appropriate use of completion lymph node dissection (CLND)

Patients identified as having a positive SLNB (without evidence of distant metastases) should have a CLND.

Pending results of MSLT-II
- Randomized clinical trial comparing CLND to surveillance when SLNB is positive.
### How are we doing?

<table>
<thead>
<tr>
<th>Year</th>
<th>SLNB done</th>
<th>(+) SLNB (in %)</th>
<th>CLND performed (in %)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004-2005</td>
<td>17524</td>
<td>2942 (16.8%)</td>
<td>1470 (50%)</td>
<td>Bilimoria, Ann Surg Oncol 2008;15:1566-78</td>
</tr>
<tr>
<td>2011-2012</td>
<td></td>
<td></td>
<td>59.7%</td>
<td>NCDB (unpublished)</td>
</tr>
</tbody>
</table>

### Measure: adequacy of CLND

- **Measure 3: Adequacy of a completion lymph node dissection**
  - **Cervical** lymph node dissection → **at least 15** regional lymph nodes are removed and examined
  - **Axillary** lymph node dissection → **at least 10** regional lymph nodes are removed and examined
  - **Inguinal** lymph node dissection → **at least 5** regional lymph nodes are removed and examined
**Measure: adequacy of CLND**

- Proxy for anatomic extent of node dissection
  - Node basins are not completely captured
- Minimum threshold number of nodes in a dissection specimen
- Must include number of sentinel nodes for accurate count
- More than one responsible party for quantifying node counts

### Adequacy of neck dissection—15 nodes

<table>
<thead>
<tr>
<th>Source</th>
<th>Patients (N)</th>
<th>Mean # nodes</th>
<th>Median # nodes</th>
<th>% over 15 nodes</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCDB</td>
<td>2185</td>
<td></td>
<td></td>
<td>28.6%</td>
<td>1</td>
</tr>
<tr>
<td>SEER</td>
<td>1468</td>
<td>13</td>
<td>5</td>
<td>28.9%</td>
<td>2</td>
</tr>
<tr>
<td>Italian Melanoma Intergroup</td>
<td>135 (≥4 levels)</td>
<td>31</td>
<td>29</td>
<td>(10th percentile count is 14)</td>
<td>3</td>
</tr>
<tr>
<td>Melanoma Institute of Australia</td>
<td>86 (≥4 levels dissected)</td>
<td>45.4</td>
<td>41</td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

4. Reed, et al. ESJO 2014
### Adequacy of ALND—10 nodes

<table>
<thead>
<tr>
<th>Source</th>
<th>Patients (N)</th>
<th>Mean # nodes</th>
<th>Median # nodes</th>
<th>% over 10 nodes</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCDB</td>
<td>2690</td>
<td>27.1%</td>
<td>63.8%</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SEER</td>
<td>1888</td>
<td>9</td>
<td>5</td>
<td>32.9%</td>
<td>2</td>
</tr>
<tr>
<td>Italian Melanoma Intergroup</td>
<td>1150</td>
<td>22</td>
<td>20</td>
<td>(10th percentile count is 12)</td>
<td>3</td>
</tr>
<tr>
<td>Melanoma Institute of Australia</td>
<td>152</td>
<td>25.4</td>
<td>23</td>
<td>100%</td>
<td>4</td>
</tr>
</tbody>
</table>

4. Reed, et al. ESJO 2014

### Adequacy of ILND—5 nodes

<table>
<thead>
<tr>
<th>Source</th>
<th>Patients (N)</th>
<th>Mean # nodes</th>
<th>Median # nodes</th>
<th>% over 5 nodes</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCDB</td>
<td>2029</td>
<td>45.0%</td>
<td>61.4%</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SEER</td>
<td>1349</td>
<td>8</td>
<td>5</td>
<td>52.2%</td>
<td>2</td>
</tr>
<tr>
<td>Italian Melanoma Intergroup</td>
<td>290 (superficial ILND)</td>
<td>12</td>
<td>11</td>
<td>(10th percentile count is 6)</td>
<td>3</td>
</tr>
<tr>
<td>Melanoma Institute of Australia</td>
<td>55</td>
<td>12.3</td>
<td>11</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

4. Reed, et al. ESJO 2014
Benchmarks/reporting

- Exclusions
  - Contraindications
  - Patient decision making
- Dichotomous
  - Yes/no
  - Usually used if expect full compliance (0% or 100%)
- Targets/thresholds
  - “In ≥90% of cases...”

Attribution of melanoma measures

- Use of SLNB and CLND could be measured by surgeon and/or hospital
  - Physician reports subject to small samples
  - Hospital reports demand a collaborative approach
- Adequacy of CLND should be measured by the hospital
  - Role of pathology in identifying nodes
Conclusions

- We should continue to develop and implement quality measures
- Quality measures can be used to inform ongoing quality improvement
  - May have public reporting and reimbursement implications
- Achieving goals of high quality care is a continual process