Quality and Breast Cancer Surgery

BCCA Breast Cancer Update
Vancouver, 2009

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Disclosures

• None
Outline

• Cases

• Quality: Definitions and Background

• North American
  – Data
  – Quality Indicators (not a comprehensive review)
  – Initiatives

• Rethink the cases
Case 1 – 45 y.o. female

- Palpable mass X 8 months, family Dr. reassured by negative MMG, eventually U/S core biopsy - Invasive ductal ca
- Decision for BCS (occurred 5 weeks after diagnosis)
  - MRI performed (indeterminate lesion, cannot biopsy), surgeon discussion
- OR – clinically directed lumpectomy (no frozen section), 1 SLN removed (no frozen/touch prep available)
- Path – 2.4 Gr III ER –ve HER2+’ve, medial and inferior margin < 1mm, SLN +’ve 6mm focus
- Completion MRM 3 weeks later, postop hematoma reop at 12 hours
- No residual ca in breast, 2/7 nodes positive
- Multidisciplinary case conference presentation
  - Adjuvant Rx – postmasteectomy RTx, chemo + herceptin
Case 2 – 75 y.o. female

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- OR – wire localized lumpectomy, 3 SLN removed (touch prep negative), no specimen radiograph
- Path – 0.8 cm Gr. I ER +’ve, closest margin 8 mm, all 3 SLN negative H+E, cytokeratin
- Adjuvant therapy – Whole breast RT, no med onc
62 y.o. female

- Morbidly obese BMI = 52, DM, CAD, sleep apnea, unable to walk 30 m, cannot lie flat
- 3.5 cm breast mass, MMG core – invasive ductal ca
- Lumpectomy under local anesthetic
  - 3.7 cm, gr II, ER –ve, closest margin 1.1 cm
- Multidisciplinary case conference
- Nothing further
Rank Quality

• Which is best?
  – 1
  – 2
  – 3

• Which is worst?
  – 1
  – 2
  – 3

? Clearer at end of presentation?
Access to Care: “Domains”

- Presence
- Quality/appropriateness
- Timeliness → Most important to patients
Access to Care: “Domains”

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Quality: Definition

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge

- Institute of Medicine, 1990

- Quality = doing the right things well most of the time
  - right = appropriateness
  - well = skill
  - Most = observed vs. expected (100% may not be target)
Poor Quality Care

is when “practices of known effectiveness are being underutilized, practices of known ineffectiveness are being over utilized, and services of equivocal effectiveness are being utilized in accordance with provider rather than patient preferences (misuse)”

–National Cancer Policy Board
Access and Quality – The Importance of the 49\textsuperscript{th} Parallel

- **Canada** = Timely access
  - Wait times

- **United States** = Quality
  - Pay for Performance
  - Quality measurement - National Quality Forum and other initiatives
The Ultimate Pay for Performance
Medicare will not pay for:

• Urinary tract infection secondary to catheterization
• Central line infections
• Pressure ulcers occurring in-hospital
• Retained objects after surgery
• Air embolism
• Blood incompatibility reactions
• Sternal wound infection post sternotomy
• In-hospital falls

August 20, 2007
How do we Measure Quality?

• Perspective important – can apply to a patient but most refer to a population

• 3 common aspects of breast cancer care quality
  – Outcomes of care – e.g. disease-free survival, local recurrence
  – Structures of care – presence of organizational components
    • e.g. presence of case conference, pathology protocol for SLN
  – Processes of care – care actually received/considered
    • e.g. use of radiotherapy post BCS, ALND post +’ve SLN
How do we Measure Quality

- Qualitative “was it good care?”
  - gut feeling of patients, physicians, system
- Measure outcomes
  - Not practical
- Quality indicators
- Adherence to guidelines → Canada well positioned?
Canadian Practice Guidelines for the Care and Treatment of Breast Cancer

- Health Canada sponsored
- Steering Committee with rigorous process
- 16 guidelines; 10 in *CMAJ* supplement 1998, 6 new/updates since, all disseminated through *CMAJ*
- No longer operational or funded, last publication 2004
- Implementation and evaluation – little done
- Guideline adherence for 4 surgical measures unchanged over time
  - Latosinsky et al., *CMAJ* 2007
Guidelines – CCO
Staging in Operable Breast Cancer

• ALWAYS post-surgery
• Stage I - No routine bone scans, liver U/S, CXR
• Stage II – bone scan in all, CXR, liver U/S only if \( \geq 1 \) node positive
• Stage III – bone scan, liver U/S, CXR in all
• If Rx options limited to hormonal Rx, or where no Rx due to age/co-morbidities, no baseline staging

2003
How do we Measure Quality

- Qualitative “was it good care?”
  - gut feeling of patients, physicians, system
- Measure outcomes
  - Not practical
- Quality indicators → Most common
- Adherence to guidelines
Quality Indicators in Breast Cancer

• Ideally, a quality indicator should be:
  – Specific
  – Complete
  – Clearly-worded
  – Feasible
  – Reliable
  – Scientifically valid
Quality Indicators in Breast Cancer

• Systematic review: Schacter et al. BMC Cancer 2006
  – 143 indicators, 58 studies
  – Most indicators related to pathology (42) and appropriate use of chemotherapy (23)
  – Only QOL/ patient satisfaction indicators met scientific rigor
Table 1: Quality Indicators Used to Measure Adherence to Standards of Breast Cancer Care

<table>
<thead>
<tr>
<th>Type of Quality Indicator</th>
<th>n</th>
<th>Extent of scientific development as a quality measure*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate use of imaging, sampling (fine-needle or biopsy) within given time-frame</td>
<td>8</td>
<td>N</td>
</tr>
<tr>
<td>Adequacy of fine-needle biopsy samples</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Receipt of frozen section of primary operable BC</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Quality of surgical technique, sampling nodes</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Quality of hormone receptor assay</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Quality of life and patient satisfaction relating to diagnosis</td>
<td>2</td>
<td>lac</td>
</tr>
<tr>
<td>Appropriate referral to surgeon</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate (timely) attendance at assessment centre, specialist appointment, surgery, receipt of information by patient</td>
<td>5</td>
<td>N</td>
</tr>
<tr>
<td>Efficient diagnosis (few visits to hospital)</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate evaluation via care guidelines, or at first visit</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate specialist knowledge of surgeons</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate surgical choices – breast conserving, mastectomy, lymph node dissection</td>
<td>7</td>
<td>N</td>
</tr>
<tr>
<td>Timely admission for therapeutic surgery</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>&lt; 3 operations for breast-conserving surgery</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Evidence of discussion of surgical options</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate use, timeliness of initial radiotherapy</td>
<td>6</td>
<td>N</td>
</tr>
<tr>
<td>Quality of radiotherapy, planning, fractionation, radiation field distribution</td>
<td>7</td>
<td>N</td>
</tr>
<tr>
<td>Regional recurrence</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate use of radiotherapy for regional recurrence, palliation</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate use (or not) of adjuvant systemic therapy</td>
<td>23</td>
<td>N</td>
</tr>
<tr>
<td>Chemotherapy quality of administration – dosages and availability of procedure manual</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Quality of life, satisfaction with treatment</td>
<td>6</td>
<td>la, lac</td>
</tr>
<tr>
<td>Participation in decision-making, receipt of sufficient information re. treatment</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Qualifications of doctors</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate referrals to specialists</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate treatment choices, sequences</td>
<td>5</td>
<td>N</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate followup mammography, use of guidelines</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Recurrence within 5 years</td>
<td>2</td>
<td>N</td>
</tr>
<tr>
<td>Appropriate use of prophylactic radiotherapy in woman with high risk of flap recurrence</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Reporting/Documentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology reporting/documentation</td>
<td>42</td>
<td>N</td>
</tr>
<tr>
<td>Imaging reporting/documentation – size of mammographic abnormality</td>
<td>1</td>
<td>N</td>
</tr>
<tr>
<td>Chemotherapy reporting/documentation</td>
<td>2</td>
<td>N</td>
</tr>
</tbody>
</table>

n = number of different quality indicators regarding this type; *extent of scientific development of quality indicator: Level la = pre-study data indicating consistently sound psychometric properties; lac = pre- and on-study data indicating consistently sound psychometric properties; IV = no pre- or on-study psychometric data
Breast Cancer Quality Indicators - Surgery

• 8 measures – unclear selection criteria
  – Mastectomy rate (proposed rate 15%-35%)
  – Positive and < 1 mm margin in BCS (proposed rate 10%-30%)
  – Reoperation for BCS (proposed 10%-20%)
  – Number SLN (most 2-4)
  – Number nodes in ALND (12-15)
  – Proportion SLN +’ve undergoing ALND (?)
  – Intraop SLN assessment % (available)
  – Time for Dx to surgery (85%-100% within 4 weeks)

• Meaningful conclusion: Measures assessable, even retrospectively

McCahill et al Arch Surg 2009
National Quality Forum (NQF)

- Non-profit U.S. organization created to develop and implement a national strategy for healthcare quality measurement and reporting

- Goals
  - Principal body to endorse performance measures and quality indicators
  - NQF-endorsed are THE primary standards to measure quality of healthcare in U.S.
  - Increase the demand for high quality healthcare
  - Major driver of quality improvement
National Quality Forum – ASCO/NCCN/ACS CoC

- Measures for Breast Cancer - *proposed*
  - RadioRx within 1 year of date of Dx for women < 70 undergoing breast conserving surgery
  - ChemoRx considered within 4/12 of Dx for women < 70; AJCC T1c, stage II or stage III
  - Tamoxifen/AA considered within 1 year of Dx for women < 70; AJCC T1c, stage II or stage III
  - Pre-resection needle biopsy
  - SLN Bx or ALND at time of resection for stage I-IIb
  - Use of College of American Pathologists Breast Cancer Protocol
National Quality Forum

• Measures for Breast Cancer - final
  – RadioRx within 1 year of date of Dx for women < 70 undergoing breast conserving surgery
  – ChemoRx considered within 4/12 of Dx for women < 70; AJCC T1c, stage II or stage III
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All intended to be applied at hospital level
Breast Cancer Quality Indicators – SLN Surgery

• Modified Delphi approach to select QI
• Retrospective chart review of final QI to assess feasibility of measurement.
• Initial 25 potential QI
• 11 prioritized by panel
  – feasibility assessment based of reporting on these 11 based on 1 year consecutive cohort

Quan et al., Ann Surg Onc 2009
Final SLN Quality Indicators
All based on % of patients

Structure
• Serial section path protocol used
• Path report of SLN AJCC-compliant
• Nuclear medicine protocol for colloid injection

Process
• Proper SLN ID (hot/blue/suspicious)
• SLN Bx in T1 undergoing BCS
• SLN Bx concurrent with lumpectomy
• +’ve SLN undergoing ALND
• Inappropriate SLN Bx (e.g. previous inflammatory BC)

Outcome
• SLN Bx +’ve rate
• > 1 SLN removed
• -’ve SLN axillary recurrence

Quan et al., Ann Surg Onc 2009
Breast Cancer Quality Indicators – SLN Surgery

• For each final QI, authors assigned potential target

• Most (but not all) QI measurable via chart or institutional level data

*Quan et al., Ann Surg Onc 2009*
Quality in Breast Cancer Care
The Next Step – Validation Programs

National Consortium of Breast Centers (NCBC)

- Type of center (screening, diagnosis, treatment, combo)
- Type-specific Web questionnaire, must be able to verify responses
  - mostly process measures (e.g. mammography call-back rate, BCS rates)
- Confidential comparison to similar centers
- Based on responses, may qualify as
  - Participant
  - Quality breast center
  - Certified breast center of excellence
Quality in Breast Cancer Care
The Next Step – Validation Programs

National Accreditation Program for Breast Care (NAPBC)

- ACS-initiated, 15 breast cancer organizations involved in development
- On-site survey
- Mostly structure measures (e.g. case conferences, presence of guidelines, >4% patients on trials)
- Started late 2007
- June 2009 – 51 accredited centers
- 17 required components – 3 “critical”
  - Program leader with authority and responsibility
  - Interdisciplinary care team
  - Interdisciplinary case conferences
Quality in Breast Cancer Care
The Next Step – Validation Programs

American Society of Breast Surgeons Quality Program

- “Mastery of Breast Surgery”
- Surgery focused based on ASBS quality indicators
- Individual surgeon focused
- Requires > 3 months all breast OR cases for 3 element:
  - Was pre-OR needle biopsy performed
  - Was surgical specimen oriented for pathology
  - Was confirmation of presence of lesion undertaken before leaving OR
- Confidential peer comparison
  - Expectation of non-threatening environment makes behavioral change more likely
Breast Cancer Quality Indicators – Surgery (Canada)

• Modified Delphi approach
  – Panel 10 surgeons, med onc, rad onc, nurse, pathologist
• 15 final QI prioritized
• Improved Canadian breast cancer health services research
  – Decision-making and supportive care
• Gaps in knowledge about quality of breast cancer care in Canada identified
  – Complications, recurrence, diagnostic work-up, accuracy and completion of pathology reports etc…..

Gagliardi et al., Breast Cancer Res Treat 2007
Quality of Breast Cancer Surgery in Canada

• Much work to do

• Limitation
  – Level of evidence for outcome impact of what we do (or do not) think is important

• Details are daunting
  – Data/information sources
  – Surgeon buy-in
  – What is target?
  – Heterogeneous clinical care environments
  – Ever changing clinical landscape
Case 1 – 45 y.o. female

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Quality issues with all
Difficult to quantify quality at the patient level
Conclusions: Quality of Breast Cancer Care

- This is not simple
- This is increasingly important
  - We are behind USA, but can do this better
- No single quality measure
- Start somewhere
- Major focus must be on *seamless* data gathering techniques
  - Needs to be built into what we do, how we think
Thank you
Quality Indicators in Breast Cancer

1. Staging (n=519)

2. RadioRx within 1 year of date of Dx for women < 70 yrs undergoing BCS
   158/185 = 84%

3. Consider Chemo within 4/12 if ER –ve, T1c/Stage II/III, < 70 yrs
   66/90= 73%

4. Tamoxifen/AA considered within 1 year of Dx for women < 70; AJCC T1c, stage II or stage III
   Not assessable

No associations with any time interval benchmark

Porter et al., Submitted
Quality Indicator: RTx in BCS within 1 year (N=185)

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pres to Dx &lt;4 weeks</td>
<td>80</td>
<td>20</td>
<td>0.09*</td>
</tr>
<tr>
<td>Dx to Surg &lt;4 weeks</td>
<td>70</td>
<td>30</td>
<td>0.48*</td>
</tr>
<tr>
<td>Surg to Chemo &lt;12 weeks</td>
<td>90</td>
<td>10</td>
<td>0.2*</td>
</tr>
<tr>
<td>Surg to RTx &lt;8 weeks</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Adjusted for significant clinicodemographic factors.
Quality Indic. Consider Chemo for ER –’ve
N=90

P=0.05*  P<0.001*

* Adjusted for significant clinicodemographic factors