Cancer Care Delivery Research and the SEER Program: Challenges and Opportunities

The Cancer Surveillance and Outcomes Research Team

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Medicine and Health Management and Policy
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Agenda

- Reflect on opportunities and challenges
- Describe illustrative examples of CCDR through CanSORT-SEER partnerships
- Implications for direction of SEER-based population sciences
Unique position to collect comprehensive and standardized information on first course of therapy across providers under state statutes

Trusted data steward and honest broker

Long track record of program productivity and dissemination of results

Opportunities to lead the growth of big data
Partnerships in growing Big Data

- SEER-National System of Vital Statistics (CDC)
- SEER-Medicare (CMS)
- AIDS/HIV Cancer Match Study (NCI)
- Cancer Risk in Organ Transplant Recipients (NCI)
- Oncotype DX Linkage Project (NCI-GHI)
- SEER-Patient Reports
  - NIH-AARP Diet and Health Study
  - ACS Cancer Prevention Study-III
  - Investigator initiated research studies
Challenges

- Funding and infrastructure support
- Data collection
  - Nurturing provider partnerships
  - Technical and logistical barriers
- The courageous quest for missing data and measurement validity
- Rapidly evolving landscape of cancer treatment
- Little surveillance follow-up
- Maximizing the use of the data for research
CanSORT is an interdisciplinary group of investigators dedicated to researching cancer quality of care. We seek to understand and improve how patients and their providers communicate and make decisions about cancer treatments.
A Bird’s Eye View: Partnering with SEER

- Created partnership between SEER registries, investigators, and professional organizations
- Engaged patients & their clinicians across regions
- Promoted use of SEER cancer registries for outcomes research
- Advanced population-based research methods
- Informed clinical & health policy

LA County Cancer Surveillance Program
Georgia Center for Cancer Statistics
Detroit Metro Cancer Surveillance System
Advances in CCDR methodologies with SEER

- Novel approaches to RCA sampling strategies
  - Race/ethnicity
  - Key clinical subgroups
- Developed and validated measures
  - Clinical and treatment information
  - Patient reported experiences measures (PREMs)
  - Survey measures related to attending clinicians
- Advanced techniques in data collection
- Developed fast-forward initiatives to disseminate research results
Cancer Care Quality Gap

- Health outcomes
- Clinical Information
- Patient experiences and appraisal of care
- Use of effective treatment
- Systems
- Community Practice
- Optimal Practice

Quality Gap
CanSORT Research Topics

- **Use of effective treatments**
  - Surgery
  - Radiation
  - Systemic therapies
  - **Patient perspectives**
    - Decision-making
    - Access and coordination
    - Role of significant others
  - **Accuracy of Clinical information**
    - Tumor biology tests

- **Health outcomes**
  - Quality of life
  - Paid work outcomes

- **Focus on Systems**
  - The impact of clinicians and their networks on treatment decision making

- **Interventions**
  - Building and evaluating comprehensive integrated tailored decision tools
Five Things Physicians and Patients Should Question

1. Don’t use PSA screening to detect prostate cancer in men with the following characteristics: low performance status, age 70 or older, a history of prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further aggressive treatment.

2. Don’t perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

3. Don’t perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.

4. Don’t perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.

5. Don’t use white blood cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.
Secular trends in breast cancer stage
Challenges to DM for patients: Ms. Landry

- 60 yr old principal
- Abnormal mammogram
- Core biopsy: invasive breast cancer, low grade tumor, ER/PR positive, HER2 negative;
- Surgical path: 2 cm tumor, SN negative.
The challenge in patients with favorable prognosis

- Net benefit of treatment options is often small and difficult to formulate for individual patients
- Management and treatment options are morbid and burdensome
- Increasing recognition of potential harm if treatment is too aggressive
- Primum non nocere - *First do no harm*
- Studies underway to evaluate strategies to reduce morbidity and burden on patients
Primum non nocere- first do no harm

- Surgery
  - Lumpectomy vs more
  - Axillary node dissection
  - Re-excision after BCS
- Radiation
  - Omit
  - Reduce burden- PBI, HF-WBI
- Chemotherapy
  - Omit
Advances in precision medicine in breast cancer

- Improve quality
- Reduce disparities

Analytic validity
Clinical validity
Clinical utility

ER/PR
HER2
21 gene assay
Sentinel node sampling
Histology
Tumor size
Extent of disease

Improve quality
Reduce disparities
Clinical information that directs recommendations for locoregional treatments

**Surgery**
- Extent of disease: PE, imaging of the breast region, margin status after BCS
- Tumor biology: None
- Host factors: Comorbidity; Genetic testing

**Radiation**
- Extent of disease: Surgery option; tumor behavior and size; node status
- Tumor biology: grade
- Host factors: Comorbidity
Clinical information that directs recommendation for systemic treatments

**Endocrine**
- Extent of disease: Tumor behavior
- Tumor biology: ER/PR status
- Host factors: menopause status, vascular disease

**Chemotherapy**
- Extent of disease: Tumor behavior and size, node status
- Tumor biology: ER/PR, HER2, 21-gene assay, grade
- Host factors: Comorbidity
Timing of tests and treatment decisions

- Diagnosis confirmed by biopsy
- History, PE, Imaging
- Initial locoreg therapy decisions
- Final locoreg therapy decisions
- Systemic treatment decisions

- Path node and margin status
- 21 gene assay

- Est tumor size
- Clinical nodes
- Comorbidity

- Tumor behavior
  - ER/HER2

- Tumor biology
- Extent of disease
- Host factors
### iCanCare Study

<table>
<thead>
<tr>
<th>Survey of 5200 women newly diagnosed with breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Population-based sample from Georgia and LA county SEER; began treatment 2013-15</td>
</tr>
<tr>
<td>- Oversampled African Americans and Latinas</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Surveys linked to clinical and treatment information</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Pathology, medical record data from SEER</td>
</tr>
<tr>
<td>- Genomic and genetic test results from industry partners</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Survey of attending surgeons, medical and radiation oncologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Clinicians linked to patients</td>
</tr>
<tr>
<td>- Clinician networks mapped</td>
</tr>
</tbody>
</table>
Rates of CPM have markedly increased
CPM does not confer additional benefit in DDFS in patients at average risk for 2\textsuperscript{nd} primary
Most women who get CPM are at average risk
Surgery option

N=1982; women with bilateral cancer excluded

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Reasons got CPM among average risk patients

- Family history  28%
- Age            46%
- Cosmesis       45%
- Peace of mind  92%

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Knowledge among patients at average risk who received CPM n=235

- Survival higher for mastectomy vs BCS w/rads
  - Yes 62%; No 22%; Don’t know 16%
- Survival after CPM is higher in all women
  - Yes 38%; No 34%; Don’t know 28%
- My doctors told me that having CPM would:
  - Increase survival: 31%
  - Reduce recurrence of the cancer I have: 49%
When it came to getting treatment for breast cancer, I wanted my doctor to tell me what to do

- Always
- Quite a bit
- Some of the time
- A little or none of the time

What % of patients selected “Always”

A. 10%  B. 30%  C. 50%  D. 80%

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Decision Style: Decision Control

When it came to getting treatment for breast cancer, I wanted my doctor to tell me what to do

- Always 29%
- Quite a bit 29%
- Some of the time 24%
- A little or none of the time 18%
Decision style and receipt of CPM

<table>
<thead>
<tr>
<th>Wanted Drs to tell me what to do</th>
<th>%</th>
<th>CPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>29</td>
<td>13</td>
</tr>
<tr>
<td>Quite a bit</td>
<td>29</td>
<td>20</td>
</tr>
<tr>
<td>Sometimes</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Not at all or little</td>
<td>18</td>
<td>27</td>
</tr>
</tbody>
</table>

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
THE PRECISION MEDICINE INITIATIVE
2014: Rapid Change in Cancer Genetics

Clinical genetic testing is advancing rapidly

But how does this technologic progress affect patient care?
Germline Genetic testing and Breast cancer

- Rates are soaring
- Test results primarily inform risk of future cancer
- Patients must juggle two different schemas: secondary prevention of new cancers vs primary treatment for the one they have
- Primary prevention strategy is contralateral prophylactic mastectomy
- Wide variability in prognostic value and risk implications of mutations
# Breast Cancer Genes

<table>
<thead>
<tr>
<th>Gene</th>
<th>Relative BC Risk</th>
<th>Population Prevalence</th>
<th>Gene-Specific Practice Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>TP53</td>
<td>Up to 100-fold</td>
<td>~ 1/50,000</td>
<td>Breast MRI, whole body MRI</td>
</tr>
<tr>
<td>BRCA1</td>
<td>10-fold</td>
<td>1/400 – 1/800</td>
<td>Breast MRI, discuss mastectomy</td>
</tr>
<tr>
<td>BRCA2</td>
<td>10-fold</td>
<td>1/400 – 1/800</td>
<td>Breast MRI, discuss mastectomy</td>
</tr>
<tr>
<td>CDH1</td>
<td>6-fold</td>
<td>~ 1/200,000</td>
<td>Breast MRI, discuss mastectomy</td>
</tr>
<tr>
<td>PTEN</td>
<td>5 to 10-fold</td>
<td>~ 1/200,000</td>
<td>Breast MRI, discuss mastectomy</td>
</tr>
<tr>
<td>STK11</td>
<td>5 to 10-fold</td>
<td>Unknown</td>
<td>Breast MRI</td>
</tr>
<tr>
<td>PALB2</td>
<td>5-fold</td>
<td>Unknown</td>
<td>Breast MRI</td>
</tr>
<tr>
<td>CHEK2</td>
<td>3-fold</td>
<td>Unknown</td>
<td>Breast MRI</td>
</tr>
<tr>
<td>ATM</td>
<td>2 to 3-fold</td>
<td>1/100 – 1/200</td>
<td>Breast MRI</td>
</tr>
<tr>
<td>NF1</td>
<td>2-fold</td>
<td>~ 1/3000</td>
<td>None to date</td>
</tr>
<tr>
<td>NBN</td>
<td>2-fold</td>
<td>~ 1/500 – 1/1000</td>
<td>None to date</td>
</tr>
</tbody>
</table>
Risk with a Mutation Can Vary Greatly

A Mutation in *PALB2*

- **Upper limit of ** *PALB2* **risk**
- **PALB2 BC risk**
- **Lower limit**
- **Average BC risk**

Wanted genetic testing quite a bit/very much

What % of patients at avg risk of 2nd primary wanted testing
A. 10%  B. 30%  C. 50%  D. 80%

N=1922

Average (n=1481)
Intermediate (n=153)
High risk (n=288)

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Wanted genetic testing quite a bit/very much

- Average (n=1481)
- Intermediate (n=153)
- High risk (n=288)

N=1922

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Received genetic test

Genetic Testing

- Average (n=1481)
- Intermediate (n=153)
- High risk (n=288)

N=1922
Genetic counseling

The iCan Care Study P01CA163233
Preliminary data only – not for reproduction or distribution
Decision satisfaction among patients who wanted genetic testing (n=834)

- No talk (n=137)
- Doctor only (n=319)
- Genetic counselor (n=378)

not satisfied with decision process
Essential Questions for Practice and Policy

- What are the trends in test use (BRCA1/2 and multi-gene panels) across different patient subgroups?
- What is the distribution of results among breast cancer patients in the community?
- What do patients understand about their test results and cancer risks?
- What are the clinician factors that influence test use?
- How do test results influence treatment decisions?
Genetic and genomic testing has already emerged as key evaluative tests that direct initial course of treatment of cancer

Barriers to collecting data through providers

Essential to partner with industry to link data

Need demonstration projects

• Establish relationships with industry partners
• Assess most efficient and effective approaches to linkage
• Address challenges in scalability in a rapidly evolving business environment
• Demonstrate how the results will be used to advance science and improve public health
PRIMUM
NON
NOCERE
## 2nd Primary Breast Cancer Risk Groups

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Average Risk</strong></td>
<td>No relatives(^1) diagnosed with BC, Ovarian Cancer, and/or Sarcoma (n=655)</td>
</tr>
<tr>
<td>(n= 1538, 77%)</td>
<td>1 relative with BC at age &gt;50 and pt aged &gt;50 (n=125)</td>
</tr>
<tr>
<td></td>
<td>1 relative with BC at age &gt;50 and pt aged 40-49 (n=22)</td>
</tr>
<tr>
<td></td>
<td>1 relative with BC at age &lt;50, pt aged 40+ (n=54)</td>
</tr>
<tr>
<td><strong>Intermediate Risk</strong></td>
<td>1 relative with BC at age &gt;50 and pt aged 40-49 (n=22)</td>
</tr>
<tr>
<td>(n= 158, 8%)</td>
<td>1 relative with BC at age &lt;50, pt aged 40+ (n=54)</td>
</tr>
<tr>
<td><strong>High Risk</strong></td>
<td>Any relatives diagnosed with male breast cancer, ovarian cancer, and/or sarcoma (n=76)</td>
</tr>
<tr>
<td>(n= 298, 15%)</td>
<td>2 or more relatives diagnosed with BC (n=34)</td>
</tr>
<tr>
<td></td>
<td>pt aged &lt;40 (n=38)</td>
</tr>
</tbody>
</table>

1. 1\(^{st}\) degree relative