Cancer Genetics Services Across the Care Delivery Continuum: Challenges and Opportunities

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Vanderbilt-Ingram Cancer Center

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Duke Genomic and Precision Medicine Forum
Durham, NC
CARE DELIVERY CONTINUUM

Identification/Access/Uptake

Delivery of Genetic Counseling and Testing

Delivery of Follow-Up Care

BRCA carriers:
OVER 2 DECADES AFTER DISCOVERING THE \textit{BRCA} GENES, HOW ARE WE DOING?

- Estimate 325,000 women in the US > 25 have a \textit{BRCA} mutation – ~30,000 identified!

Critical areas that need to be addressed:
- raising awareness about inherited breast cancer
- identifying high risk individuals

1994: \textit{BRCA1} discovered

1995: \textit{BRCA2} discovered
RECEIPT OF BRCA TESTING

• Review of >10,000 oncology patient charts across the US (ASCO QOPI Data):
  – Genetic Counseling or Testing recommended in ~50% of breast cancer patients with “hereditary risk”


• Cross-sectional data from 2005, 2010, 2015 NHIS survey from almost 50,000 women
  – Fewer than 20% of high risk individuals with Breast or Ovarian cancer tested
  – Most have never discussed testing with a healthcare provider

Table 5. Referral of Patients With Breast or Colorectal Cancer for Genetic Counseling and/or Testing

<table>
<thead>
<tr>
<th>Referral</th>
<th>Total (N = 10,466)</th>
<th>Breast Cancer (n = 6,569)</th>
<th>Colorectal Cancer (n = 3,897)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral for genetic counseling and/or testing, %</td>
<td>25.6</td>
<td>29.1</td>
<td>19.6</td>
<td>&lt; .001</td>
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<tr>
<td>n = 2,457</td>
<td>n = 1,556</td>
<td>n = 901</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive family history and referred, %</td>
<td>42.7</td>
<td>52.2</td>
<td>26.4</td>
<td>&lt; .001</td>
</tr>
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</table>

*P value corresponds to differences between breast and colorectal cancers.


Childers et al.. J Clin Oncol. 2017 Dec 1;35(34):3800-3806. PMID: 28820644
DISPARITIES IN GENETIC TESTING

• Longstanding disparities in BRCA genetic testing rates...

Among Young Black, Hispanic, and Non-Hispanic White breast cancer survivors, we compared:

- Receipt of BRCA testing
- Uptake of preventive surgery among BRCA mutation carriers

Population-based Cross-sectional Study
Recruited through the Florida State Cancer Registry
Breast cancer survivors
Diagnosed < age 50 between 2009-2012

Blacks
n=440

Hispanics
n=284

Non-Hispanic Whites
n=897
OVERVIEW OF RECRUITMENT

Patient information obtained from FCDS (Florida State Cancer Registry)

Informational/enrollment package sent to potential participants

Secure Informed Consent secured/Questionnaire completed/Medical Record Release signed
BRCA TESTING IN OUR FLORIDA STUDY

- Tested

- p=0.025* controlling for:
  - meeting NCCN criteria
  - SES-related variables
  - provider referral

BRCA TESTING IN OUR FLORIDA STUDY

% Tested

- 36% Black women (n=158 of 440)
- 62% Hispanic women (n=176 of 284)
- 65% White, non-Hispanic (n=583 of 897)

Figure 3. This path model illustrates the factors associated with health care provider discussion and subsequent receipt of breast cancer gene testing. Ca indicates cancer; Hx., history; NHW, non-Hispanic white.
Among Young Black, Hispanic, and Non-Hispanic White breast cancer survivors, we compared:

- Receipt of BRCA testing
- Uptake of preventive surgery among BRCA mutation carriers

Population-based Cross-sectional Study
Recruited through the Florida State Cancer Registry
Breast cancer survivors
Diagnosed ≤ age 50 between 2009-2012

- Blacks
  n=440
- Hispanics
  n=284
- Non-Hispanic Whites
  n=897
BARRIERS (N=412)

<table>
<thead>
<tr>
<th>Cost-related concerns</th>
<th>NHW (N=310)</th>
<th>Hispanic (N=102)</th>
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</thead>
<tbody>
<tr>
<td>No one recommended testing</td>
<td>40%</td>
<td>41%</td>
</tr>
<tr>
<td>Never heard of genetic testing</td>
<td>32%</td>
<td>28%</td>
</tr>
<tr>
<td>Did NOT believe testing</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>Testing not right for me</td>
<td>18%</td>
<td>18%</td>
</tr>
<tr>
<td>Doctor advised against testing</td>
<td>11%</td>
<td>12%</td>
</tr>
<tr>
<td>Worried test result could be...</td>
<td>14%</td>
<td>5%</td>
</tr>
</tbody>
</table>

p<0.001  p<0.001

INTERESTED IN GENETIC TESTING RESOURCES / INFORMATION

NHW (n=310 not tested)
- Interested: 80%
- Not interested: 20%

Hispanic (n=102 not tested)
- Interested: 90%
- Not interested: 10%
PROVIDER-LEVEL FACTORS

• Blacks less likely to be referred for genetic counseling (our data)

• Minorities significantly more likely to have unmet need for discussion of genetic testing (LA, Detroit)

• Differences in testing largely attributable to differences in physician recommendation (PA, FL)
DISPARITIES IN ACCESS TO GENETIC TESTING/GENOMIC SERVICES

• Disparities exist across:
  – Racial/ethnic groups
    • Less aware, but interested
  – Geography, SES, etc.

• Provider-level factors
  – Healthcare provider referral (our data and others)

• System-level factors
  – Policies/Insurer Coverage, etc.

• Research Gaps/Solutions
  – Development of multi-level Interventions
  – EMR/automation of identification
  – Access versus Uptake
CARE DELIVERY CONTINUUM

Identification/Access/Uptake

Delivery of Genetic Counseling and Testing

Delivery of Follow-Up Care

BRCA carriers:
“Process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease”

Differences in BRCA counseling and testing practices based on ordering provider type

Deborah Cragun, PhD¹, Lucia Camperlengo, MPH¹, Emily Robinson, MPH¹, Meghan Caldwell, MS, CGC¹, Jongphil Kim, PhD¹, Catherine Phelan, MD, PhD¹, Alvaro N. Monteiro, PhD¹, Susan T. Vadaparampil, PhD, MPH¹, Thomas A. Sellers, PhD, MPH¹ and Tuya Pal, MD¹

137 (31%) no evidence of GHP
276 (58%) GHP involved

80 (41%) No recall
117 (59%) Yes
268 (97%) Yes
8 (3%) No recall

<0.001

## RESULTS:

<table>
<thead>
<tr>
<th>Element of genetic counseling</th>
<th>GHP involved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No ($n = 117)^a$</td>
</tr>
<tr>
<td>Pedigree completed</td>
<td>82 (82.8)</td>
</tr>
<tr>
<td>Discussion of:</td>
<td></td>
</tr>
<tr>
<td>Variants of uncertain significance</td>
<td>72 (72.7)</td>
</tr>
<tr>
<td>Laws protecting against health insurance discrimination</td>
<td>73 (73.7)</td>
</tr>
<tr>
<td>Issues related to disability insurance</td>
<td>57 (57.6)</td>
</tr>
<tr>
<td>Other hereditary cancers</td>
<td>63 (63.9)</td>
</tr>
<tr>
<td>Management recommendations</td>
<td>82 (82.8)</td>
</tr>
<tr>
<td>Family implications</td>
<td>91 (91.9)</td>
</tr>
<tr>
<td>Summary letter received</td>
<td>58 (58.6)</td>
</tr>
</tbody>
</table>
RESULTS FROM PROVIDER-BASED SURVEYS
Surveyed providers across FL who order genetic testing for inherited cancer (n ~100)

Knowledge/Attitudes - gaps: Interpretation of VUS results
Testing Practices
Management practices

Logistics of Service Delivery:
Many providers conducted limited or no pre-test genetic counseling, or discussed most standard pre-test genetic counseling elements.

Educational Preferences:
Very interested in education
Format: mix of in person weekend sessions with web-based learning
GENETIC COUNSELING POLICIES

COMPETING FORCES

Shortage of Genetics Professionals

Requirement of genetic counseling prior to testing required by some insurers
• Genetic counseling requirement from an independent genetics professional or other healthcare provider approved by Cigna

• 2013
  – BRCA, colorectal syndromes, long QT

• 2016
  – Expanded to whole exome, hereditary cardiomyopathies, CGH, chromosomal microarray, all other hereditary cancer tests, whole exome testing
CARE DELIVERY CONSIDERATIONS...AND PRE-TEST GC TESTING MANDATE

Disproportionately affected minority populations

Whitworth et al., J Oncol Pract. 2017 Jan;13:e47-e56. PMID 28084878

Low income individuals less likely to complete testing

Stenehjem et al. BMC Health Serv Res. 2018 Mar 7;18(1):165. PMID: 29514700
• Breast Cancer Survivors surveyed (N = 3,672; response rate, 68%)
  – SEER: Georgia and LA

• Treating surgeons surveyed about genetic testing and results management

• Bilateral Mastectomy Rates:
  – Highest among BRCA+, other gene+
  – Also common among VUS+ patients

• Many surgeons managed VUS patients the same as patients with BRCA pathogenic mutations
  – Half of average-risk patients with VUS undergo BLM,
  – Suggesting a limited understanding of results

Genetic Counseling Services

Considerations
• Demand for services exceeds supply
• Need to scale up delivery of services
• Make services widely accessible

Existing gaps
• Develop other evidence-based innovative methods for delivering services
  – Telegenetics
  – Automation of portions of session, with decision support
TELEGENETICS

• Non-inferior to in-person services

Considerations

• State-specific items:  
  – licensure  
  – reimbursement rules

• Institution-specific infrastructure  
  – Software  
  – EMR integration/billing mechanism

APPROACHES

• Utilize genetic professionals where they have potential to have most impact:
  
  – Pre-test: automation
  
  – Post-test: tailored discussion based on results
PRIOR EFFORTS: AUTOMATION OF PRE-TEST GENETIC COUNSELING

Promising data pre-dating panel testing; since introduction of panels:

- Homegrown genetic counseling video + immediate ordering of test by provider
  - Uptake of testing: 55%

- In person genetic counseling through genetic counselor with additional need to schedule provider appointment for testing
  - Uptake of testing: 29%


- Other efforts nationally:
  - E.g., MAGENTA study at MD Anderson using 2-minute COLOR genomics video for pre-test genetic counseling
Developed/validated 14 questions to measure knowledge and elements of informed consent

<table>
<thead>
<tr>
<th>Question</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most cancer is caused by a gene change (mutation) that can be passed on to children.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If a person has a mutation that causes high risks for breast or colon cancer, there is usually nothing they can do about it.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is more common to find variants of uncertain significance (VUS) as more genes are tested.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A change (mutation) in a cancer risk gene can be inherited from a person’s father or mother.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finding a variant of uncertain significance (VUS) in a cancer gene will usually explain why someone got cancer.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic test results in the United States can be used to decide if someone can get health insurance in most cases.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testing can find a gene mutation that is unexpected or does not fit with the pattern of cancers in a person’s family.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In most cases, it is against United States’ law to use a genetic test result to deny life and disability insurance coverage or raise the cost.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowing that a person has inherited a high-risk mutation in a cancer gene can change cancer screening or prevention options.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The sister or brother of a person with an inherited cancer gene mutation usually has a 50% chance of having the same mutation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some people with an inherited cancer gene mutation will never get cancer.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic testing for inherited cancer risk is not usually helpful when a person already has cancer.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutations in some genes raise cancer risks more than mutations in other genes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you are the first person in your family to have genetic testing for inherited cancer risk, there are only two possible test results: положительный - a gene change is found that may increase cancer risk, негативный - no gene changes are found</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CARE DELIVERY-FOCUSED EFFORTS

Administer pre- and post-questionnaire

• 12 minute interactive video

Administer 14-item questionnaire
Collect written feedback about the tool

### Preliminary Data (n=20)

<table>
<thead>
<tr>
<th></th>
<th>#Correct (of 14 questions)</th>
<th>% Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Video</td>
<td>6.2</td>
<td>44%</td>
</tr>
<tr>
<td>Post-Video</td>
<td>11.7</td>
<td>83%</td>
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</table>

Administer 14-item questionnaire
Collect written feedback about the tool
SUSTAINABILITY CONSIDERATIONS

• Demonstrate value of genetic counseling based on outcomes (cancer risk management, family sharing, mortality)

• CMS recognition of GCs as billing provider

• Downstream revenue considerations
CARE DELIVERY CONTINUUM

Identification/Access/Uptake
Delivery of Genetic Counseling and Testing
Delivery of Follow-Up Care

BRCA carriers:
BRCA CANCER RISKS AND MANAGEMENT

Cancer Risks

- Breast cancer
  - BRCA mutation: Up to 70%
  - General Population: 7%
- Second breast cancer
  - BRCA mutation: Up to 64%
  - General Population: 10%
- Ovarian cancer
  - BRCA mutation: Up to 44%
  - General Population: 2%

Risk Management

- Mastectomy
- Oophorectomy

Cancer Risk Reduction
- Breast Cancer
- Ovarian Cancer
CANCER RISK MANAGEMENT

• Garcia et al, 2014:
  – 305 BRCA carriers in an integrated healthcare system (Kaiser Permanente)
    • RRSO: 74%
    • RRM: 44%

Among those without RRM, Rapid decline in MRI over 5 years:
  ➢ Year 1: 35%
  ➢ Year 5: 3%

CANCER RISK MANAGEMENT AMONG BRCA CARRIERS IN OUR FLORIDA STUDY

¾ still in treatment – too early to have screening

- Black (N=28)
- Hispanic (N=13)
- Non-Hispanic White (N=51)

Bilateral mastectomy

96%
100%
98%

TESTING AND FOLLOW-UP CARE

• Benefit from genetic testing comes from **ACTING** on the test results.

• **BRCA** testing and cancer risk management should be a **CHOICE**
  – Need to understand reasons for disparities:

• Highlights need to ensure access to testing and cancer risk management practices across **ALL** populations.
POLICIES AND COVERAGE

Genetic Testing

Policies to cover genetic testing

Follow-up care

Policies to cover follow-up care

Existing Gaps:

- USPSTF is focused on testing for unaffected individuals
  - NOT follow-up care
- ACA coverage for preventive care based on USPSTF recommendations
IN CONSIDERING FOLLOW-UP CARE

• Important to consider uptake:
  – Initially
  – Over time
  – Across populations

• Delivery of guideline-concordant care:
  – Not OVER and UNDER treatment (access, provider expertise)

• Gaps:
  – Reasons for disparities
  – Development of interventions/decision support tools
  – Policy gaps (access to follow-up care after testing)
Thinking Beyond *BRCA*

Able to test for more and more genes!

- **Considerations…**
  - Increasingly used to guide personalized cancer treatments
  - Makes accessibility across ALL populations even more important
BREAST CANCER RISKS

PARADIGM SHIFT

Conventional Clinical Practice Paradigm

- figure out possible diagnosis “hypothesis” and order test(s)
- Order appropriate test(s) based on “hypothesis”
- Receive result and refine differential diagnosis

“Predictive” Medicine Paradigm

- “test first”
- Generate result and then test hypothesis (diagnosis) based on results
Focus on ‘risk assessment’ rather than cancer treatment at point of care

In addition to ‘risk assessment’, focus now includes cancer treatment implication at point of care
IF WE ARE NOT CAREFUL…

Genomics may widen existing disparities!
WHEN ADDRESSING DISPARITIES...

- Factors at multiple levels impact testing, follow-up care and outcomes

- Genomic advances have great potential to WIDEN existing health disparities if these issues are not addressed

Goal: realize the promise of genomics across ALL populations, regardless of race, ethnicity and ability to pay

Most individuals with inherited cancer tested and treated in community hospitals/practices

Created mechanism to Promote Community-Academic Partnerships

Launched in 2010 to create a registry of individuals with inherited cancer predisposition
• Engage providers and participants, while growing the research registry
• Mechanism to promote Academic-Community Partnerships

Mission Statement:
To end the cycle of inherited cancer through research, education and engagement.
ICARE Overview

- Provide education & resources
- Build partnerships
- Grow registry
- Perform translational studies
ICARE Resources

• Host monthly VIRTUAL Genetic Case Conferences

• Develop and disseminate bi-yearly newsletters (English & Spanish)

• Provide information to patients on continued updates and additional research opportunities

• Centralized contact:
  – Email: ICARE@inheritedcancer.net
  – Phone: 615-875-2444
  – Website: www.InheritedCancer.net
Secure Informed Consent:
- Baseline questionnaire
- MR release
- Tissue release
- Use of existing samples
- Sample collection/banking
- Secure permission for f/u

Additional targeted correspondence:
- Research opportunities for which they are eligible
- Clinical advances with direct impact

Clinic
Website
ICARE Partners

1  2  3  4

Follow-up Q

Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Newsletter
Inherited Cancer Registry (ICARE)

Healthcare providers from across the country refer their high risk patients

Developed partnerships with >200 providers

Amongst the largest inherited cancer registries in the US

Almost 3000 participants:
- >1100 BRCA carriers
- >600 other carriers
ICARE RECRUITMENT

Figure 1. ICARE Provider Partner Recruitment by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Total patients recruited by external providers</th>
<th>Total unique recruiting provider sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>0</td>
<td>0</td>
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<tr>
<td>2011</td>
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<td>2012</td>
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<td>2016</td>
<td>300</td>
<td>300</td>
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<tr>
<td>2017</td>
<td>350</td>
<td>350</td>
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</table>

## ICARE: Carriers

<table>
<thead>
<tr>
<th>Gene</th>
<th>Total</th>
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<tr>
<td>APC</td>
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<tr>
<td>ATM</td>
<td>79</td>
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<tr>
<td>ATP2A2</td>
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<td>BLM</td>
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<td>BARD1</td>
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<td>BMPR1A</td>
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<td>BRCA1/2</td>
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<td>BRIP1</td>
<td>20</td>
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<tr>
<td>CDH1</td>
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<td>VHL</td>
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<tr>
<td>XRCC2</td>
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</table>
Purpose: To identify and follow 500 women with breast cancer and a \textit{PALB2} mutation to:

- establish the five-year survival rate and predictors of survival
- Findings will help us refine breast cancer treatment and help to develop strategies to improve outcomes

Eligibility criteria:
- Woman diagnosed with breast cancer in 2000 or later
- Pathogenic or likely pathogenic \textit{PALB2} mutation
- Can read and understand English

- Almost 200 participants recruited to date
  - Facilitated through ICARE...
GENECARE STUDY

Objective:

- Explore cancer risk management and family sharing among
  - BRCA carriers
  - Other carriers
  - BRCA VUS patients
- Collect quantitative and qualitative data

Study Progress:
- Recruited through:
  - ICARE, BEST, YouGRADE (existing cohorts)
- Since July:
  - ~300 carriers enrolled
  - ~20 in-depth interviews complete

Preliminary Data:

<table>
<thead>
<tr>
<th>Relatives</th>
<th>Proportion of relatives who know result</th>
<th>Proportion of relatives tested</th>
<th>Proportion of relatives tested w/ positive result</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-degree</td>
<td>81.40%</td>
<td>38.90%</td>
<td>53.10%</td>
</tr>
<tr>
<td>Second-degree</td>
<td>52.10%</td>
<td>7.40%</td>
<td>55.30%</td>
</tr>
<tr>
<td>Third-degree</td>
<td>53.10%</td>
<td>8.90%</td>
<td>41.10%</td>
</tr>
<tr>
<td>Females</td>
<td>66.50%</td>
<td>26.10%</td>
<td>52.40%</td>
</tr>
<tr>
<td>Males</td>
<td>55.30%</td>
<td>7.90%</td>
<td>43.40%</td>
</tr>
</tbody>
</table>
OPPORTUNITIES/NEXT STEPS

Identification/Access/Uptake
- EMR
- Automation
- Education
- Access vs uptake
- Interventions

Delivery of Genetic Counseling and Testing
- Streamline Services
- Triage Systems
- Automation of components

Delivery of Follow-Up Care
Develop Interventions focused on:
- guideline-concordant cancer risk management
- family sharing
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THANK YOU FOR YOUR ATTENTION!

QUESTIONS?