Universal *BRCA1* and *BRCA2* Genetic Testing for Ovarian Cancer Patients

An initiative to improve genetic counseling and genetic testing rates among patients with high grade, non-mucinous epithelial ovarian cancer

**Erica Bednar, MS, CGC**

Clinical Cancer Genetics and Flagship 1A Breast and Ovarian Cancers Moonshot
embednar@mdanderson.org
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• I have no conflicts of interest to disclose

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Outline

1  BACKGROUND
   • Hereditary ovarian cancer
   • National guidelines

2  UNIVERSAL TESTING
   • Preliminary results

3  DISCUSSION
   • Future Plans
Background
Background

All Cancers

Sporadic 70-85%

Familial 10-20%

Hereditary 5-10%
Background

Epithelial Ovarian Cancers

Sporadic 80-90%

Hereditary 10-20%

Walsh et al. “Mutations in 12 genes for inherited ovarian, fallopian tube, and peritoneal carcinoma identified by massively parallel sequencing.” PNAS 108.44 (2011):18032
Background

Examples of Epithelial Ovarian Cancer Histology Types:

• Serous
• Endometrioid
• Clear cell
## Background

### Hereditary Ovarian Cancer

<table>
<thead>
<tr>
<th>Hereditary Breast and Ovarian Cancer syndrome (HBOC)</th>
<th>Lynch syndrome/Hereditary Non-polyposis Colorectal Cancer (HNPCC)</th>
<th>Moderate Penetrant Genes</th>
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- **Hereditary Breast and Ovarian Cancer syndrome (HBOC)**
- **Lynch syndrome/Hereditary Non-polyposis Colorectal Cancer (HNPCC)**
- **Moderate Penetrant Genes**
Background

Hereditary Breast and Ovarian Cancer Syndrome
The University of Texas MD Anderson Cancer Center ©2006
Revised 09/2013, Patient Education 2361
Background

- Increased lifetime risk for cancer
- Guidelines for screening and risk reducing options
- General population cancer risks and screening recommendations
Background

National Guidelines for *BRCA1* and *BRCA2* Genetic Testing

**National Comprehensive Cancer Network (NCCN)**
- v.1.2008
- “Personal history of epithelial ovarian cancer”

**Medicare (CMS) Guidelines**
- Original effective date: 12/1/2006
- “Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer”

Background

Consensus Statements for \textit{BRCA1} and \textit{BRCA2} Genetic Testing

2009

- American Congress of Obstetrics and Gynecologists (ACOG)\textsuperscript{1}

2014

- Society of Gynecologic Oncology (SGO)
- American Society of Clinical Oncology (ASCO)
- American College of Medical Genetics (ACMG)


Background

Adherence to guidelines and recommendations?

Reported genetic counseling recommendation and referral rates for epithelial ovarian, fallopian tube, and primary peritoneal cancers between 11% and 49.3%.

Backman et al. "Referrals to Genetic Counseling in Patients with Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, an Institutional Review." Gynecologic Oncology 139.3 (2015): 586.
Background

MD Anderson Gyn Onc referral rates of ovarian cancer patients (1999-2007)

- “High Risk” criteria used:
  - Breast and ovarian cancer
  - Ovarian cancer and Ashkenazi Jewish ancestry
  - Ovarian cancer and blood relative with breast cancer <50 or ovarian cancer

- 1999: ~12% Referred
- 2007: ~48% Referred

- Median time to referral was >3 years

- African American patients were less likely to be referred than White or Hispanic patients

Universal Testing Initiative
Universal Testing

A moon shot for cancer

Inspired by America’s drive a generation ago to put a man on the moon, The University of Texas MD Anderson Cancer Center has an ambitious and comprehensive action plan to make a giant leap for patients — to rapidly and dramatically reduce mortality and suffering in cancer.
Universal Testing

Aim

• At least 80% of patients with high grade, non-mucinous epithelial ovarian cancer (HGOC) will be offered standard of care genetic counseling and/or genetic testing for BRCA1/2
Universal Testing

Interventions

**Physician Level**
- Education and engagement
- Physician-coordinated genetic testing

**Clinic Level**
- Improved new-patient screening forms
- Genetic counseling appointments coincide with other departmental visits
- Optimized genetic counseling scheduling template

**Supportive**
- Created patient education document
- Group email for urgent genetic counseling appointment requests
- Patient/clinic tracking and assisted genetic counseling referral placement
Universal Testing

Preliminary outcomes presented at SGO and ASCO meetings 2016

- All patients presenting to MD Anderson Gynecologic Oncology department for HGOC:
  - Includes cases of newly diagnosed and recurrent ovarian cancer.
  - Visit types: new diagnosis and treatment, treatment planning and coordination, and second opinions
- Initial appointments occurred between 9/1/2012 and 8/31/2015 (3 years)
- Data collection through 8/31/2016
- Collected: documentation of genetic counseling (GC) and/or genetic testing (GT), documented referrals/recommendations, results of genetic testing, and treatment implications (PARP inhibitor)
Universal Testing

- Preliminary data not available for archived slides
Universal Testing

Core Interventions:

**Physician-Coordinated Genetic Testing**

- Gyn Onc physician completes pre-test counseling and coordination genetic testing per national guidelines

- Referral to Genetic Counselor made if:
  - Patient has BRCA+/VUS result
  - Physician chooses to have Genetic Counselor coordinate testing
  - Patient requests genetic counseling, or has additional questions or needs
Universal Testing

Core Interventions:

**Integrated Genetic Counseling Services**

- 2.5 FTE Genetic Counselors in the Gyn Onc Department
- 4-5 Appointments available daily, Monday-Friday
- Appointments often available for same/next day requests
- Genetic counseling schedule optimization
Core Interventions:

**Assisted Genetic Counseling Referrals**

- Staff screen clinic schedules for HGOC patients, genetic counseling, and genetic testing status
- If no documented genetic counseling or testing, the patient care team is notified, and a referral to genetic counseling is drafted, pending physician signature
Discussion
Discussion

What worked well

- Three core interventions:
  - Physician coordinated GT at Houston-area Locations
  - Integrated Genetic Counseling Services
  - Assisted Genetic Counseling Referrals

- Institution and department-wide effort (Moon shot)

What didn’t work well

- Texas Medical Center campus physician coordinated testing

- Occasional physician coordinated testing issues at Houston-area locations

- Clinic tracking has been time and labor intensive
### Limitations of our study

- **Unique patient population?**
- **Patients with outside testing and incomplete clinical documentation**
- **How to account for the “Jolie Effect,” availability of gene panels, FDA approval of Lynparza™ (PARP inhibitor)?**
- **Implemented more than one intervention at one time, rather than discrete studies**
Discussion

Areas for future research

• Combining additional interventions

• Determining patient perception, understanding, satisfaction

• Replicating results in other care settings

• IT or EMR interventions (sustainability?)

• Implications for families

Dissemination

Flagship 1A has partnered with MD Anderson Cancer Prevention and Control Platform.

CPCP develops, tailors, implements and disseminates evidence-based, community-focused programs involving public policy, public/professional education, or service delivery to advance cancer prevention, screening, early detection and survivorship. The goal is to achieve a measurable and sustainable reduction in the cancer burden, especially in the underserved in whom cancer and cancer risk factors predominate.
Dissemination
Dissemination

Dissemination Goals:

• Increase standard of care HBOC associated genetic counseling and genetic testing referrals, and improve adherence to guidelines

• Improve access to genetics services for cancer patients by anticipating and identifying barriers at each site

• Use insights gained at MD Anderson and Physician Network sites to help guide national recommendations and/or policy development
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Questions?
Contact

Erica Bednar, MS, CGC
Certified Genetic Counselor
Clinical Cancer Genetics, Gynecologic Oncology
EMBednar@mdanderson.org