Development of a Decision Aid for Unaffected BRCA Mutation Carriers

Terri Jabaley, PhD, RN
Objectives

- Identify four options for cancer risk management for unaffected BRCA mutation carriers.
- Discuss the challenges that women who are unaffected carriers of BRCA mutations face in the cancer risk management decision making process.
- Recognize the benefits of using a decision aid in the care of those with genetic predisposition for cancer.
Understanding Cancer Risk Management Decision Making for BRCA+ Previvors

- A *Previvor* is a survivor of a predisposition for cancer
- Women with BRCA genetic mutations face up to an 87% lifetime risk for breast cancer and a 63% lifetime risk for ovarian cancer.
- Approximately 1 in 400 individuals in the U.S. carries a BRCA mutation.
- BRCA+ women face complex decisions for cancer risk management, including options for
  - **Prophylactic surgery** (mastectomy/oophorectomy)
  - **Intensive surveillance**
  - **Chemoprevention**

(Chen & Parmigiani, 2007; Mavaddat, et al., 2013)
The Early Previvor Experience
“I was in shock”  Amanda
“It feels like it’s a little bit of cancer” … “I felt like a time bomb”  Heidi

The Decisional Journey
Decisional factors: age, memories of family cancers, fertility, caring for children, intimate relationships, body image changes, ongoing risk and survival

Artist: J.C. Spock
Artist: Jennifer Gooch
The Lack of Knowledge and Experience Among Clinicians

“I need a guiding light ... someone who has experience and knowledge and supports me.” Rory

“... because none of the doctors I went to had any pamphlets on it or anything. No information at all in their offices about it.” Jean

Support for Previvors is Essential

“Don’t go it alone” Cheryl
“I need a sisterhood.” Rory

(Jabaley Leonarczyk & Mawn, 2015)
Cancer risk management decision making is a complex process that challenges both patients and providers.

Internationally accepted clinical guidelines continue to evolve and are limited by:

- Advanced reading levels and complexity
- Length
- Combination of affected and unaffected mutation carriers
- Exclusion of psychosocial issues

(NCCN, 2016; Petrucelli, Daly, & Feldman, 2013; Schackmann, Munoz, Mills, Plevritis, & Kurian, 2013)
Purpose of this Study

➢ To develop an evidence-based, comprehensive decision aid for women who are unaffected BRCA mutation carriers.

➢ Specific aims were
  ✓ to develop an aid based on decisional theory;
  ✓ consistent with internationally accepted clinical guidelines;
  ✓ at a reading level suitable for general population use;
  ✓ and to conduct an analysis of the aid.
Methods

- Development was guided by
  - the Ottawa Decision Support Framework (O’Connor, 2006)
  - the method recommended by Coulter, et al. (2013)

- **Steering committee** of 7 experts
- A **Sample** of 23; 8 experts and 15 end users
- The **Setting**: Facing our Risk of Cancer Empowered (FORCE)
- **Surveys** elicited quantitative and qualitative data
GENERAL INFORMATION: This decision aid is based on internationally accepted guidelines for management of hereditary breast and ovarian cancer (HBOC). The aid is designed to help you evaluate your options as a healthy woman with a BRCA mutation and prepare for a discussion with your health care provider. There may be no easy answers, but this is designed to help you sort out your choices. The following is general information about women’s cancer risks associated with BRCA mutations:

The figure above shows BRCA+ women’s average risks of breast and ovarian cancer by age 70 compared to the general population. Risks for breast cancer: 60% for those who are BRCA 1+, 46% for BRCA 2+, 13% for the general population; risks for ovarian cancer: 39% for BRCA1+, 14% for BRCA 2+, and <2% for the general population.
3rd OPTION: Prophylactic Oophorectomy (Removal of Ovaries and Fallopian Tubes)

*Recommend risk reducing bilateral salpingo-oophorectomy (removal of both ovaries and fallopian tubes) when childbearing is complete: between the ages of 35-40 for women with BRCA 1 mutations; and between the ages of 40-45 for women with BRCA 2 mutations if bilateral mastectomy has been done.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk for ovarian cancer decreases by 80%.</td>
<td>Unable to become pregnant.</td>
</tr>
<tr>
<td>Risk for breast cancer decreases by 50%.</td>
<td>Results in early menopause (natural menopause occurs at about age 50).</td>
</tr>
<tr>
<td>Less anxiety related to ovarian cancer risk.</td>
<td>Long term risks of early menopause are cardiovascular disease and osteoporosis.</td>
</tr>
<tr>
<td>For premenopausal women, risk for breast cancer decreases by 50% and anxiety related to breast cancer risk may lessen.</td>
<td>Menopausal symptoms may include night sweats, hot flashes, sexual discomfort, and a decline in sexual activity, desire and pleasure.</td>
</tr>
<tr>
<td>For premenopausal women, menopausal symptoms and risk for osteoporosis may be lessened with short term hormonal replacement therapy until the natural age of menopause.</td>
<td>May have surgical complications: bleeding, infection, pain, or problems related to anesthesia.</td>
</tr>
<tr>
<td></td>
<td>Up to 2 weeks recovery time.</td>
</tr>
</tbody>
</table>

Personal Values and Other Concerns I Have:
Sample of End users

- all Caucasian women
- all reported some level of college education
- 50% reported a BRCA1 and 50% reported a BRCA2 mutation.
- Age mean was 48.5 years; with an age range of 33-62.
- Time since receiving a positive BRCA mutation testing: mean was 5.2 years, with a range of 1-13 years
## Results

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Experts (N=8)</th>
<th>End Users (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$\bar{X}$</td>
<td>Mode</td>
</tr>
<tr>
<td>Organization</td>
<td>3.88</td>
<td>4.00</td>
</tr>
<tr>
<td>Clarity</td>
<td>3.63</td>
<td>4.00</td>
</tr>
<tr>
<td>Usefulness</td>
<td>4.00</td>
<td>4.00</td>
</tr>
<tr>
<td>Comprehensiveness</td>
<td>3.88</td>
<td>4.00</td>
</tr>
<tr>
<td>Ease of Understanding</td>
<td>3.63</td>
<td>4.00</td>
</tr>
</tbody>
</table>
### Results

<table>
<thead>
<tr>
<th>Relevance (By Section)</th>
<th>Experts (N=8)</th>
<th>End Users (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency of Rating:</td>
<td>Frequency of Rating:</td>
</tr>
<tr>
<td></td>
<td>Quite Relevant or Highly Relevant</td>
<td>Quite Relevant or Highly Relevant</td>
</tr>
<tr>
<td>General Information</td>
<td>4.00 4.00 100%</td>
<td>3.36 3.00 91%</td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Option:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensive Surveillance</td>
<td>4.00 4.00 100%</td>
<td>3.91 4.00 100%</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Option:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prophylactic Mastectomy</td>
<td>4.00 4.00 100%</td>
<td>3.82 4.00 100%</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; Option:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prophylactic Oophorectomy</td>
<td>4.00 4.00 100%</td>
<td>3.64 4.00 91%</td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; Option:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemoprevention</td>
<td>3.88 4.00 100%</td>
<td>3.36 3.00 91%</td>
</tr>
<tr>
<td>Resources</td>
<td>4.00 4.00 100%</td>
<td>3.55 4.00 91%</td>
</tr>
</tbody>
</table>
Conclusions

- Findings suggest that the decision aid is well-organized, clear, comprehensive, and highly relevant to the cancer risk management decision making experience of unaffected BRCA+ women.
- Nurses have an opportunity to facilitate shared decision making through use of the decision aid to
  - Improve the quality and integration of care for unaffected BRCA+ women (previvors)
  - Guide and coach previvors
  - Help previvors clarify values
  - Help to monitor and facilitate the progress of previvors on their decisional journeys


Mavaddat, N., Peock, S., Frost, D., Ellis, S., Platte, R., Fineberg, E., ... Easton, D. F. (2013). Cancer risks for BRCA1 and BRCA2 mutation carriers: Results from prospective analysis of EMBRACE. *Journal of the National Cancer Institute, 105*(11), 812-822. doi: 10.1093/jnci/djt095


References
Questions?

The Decision Aid is available at www.brcadecisionaid.com

Thank You!