The GRACE Project

GENETIC RISK ASSESSMENT FOR CANCER EDUCATION AND EMPOWERMENT

Tailored Counseling and Navigation Intervention Manual

August 2016

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Study Overview

The Genetic Risk Assessment for Cancer Education and Empowerment (GRACE) Project is a research study that aims to promote risk-appropriate cancer genetic risk assessment (CGRA). The target population is cancer survivors at increased familial risk for hereditary breast and ovarian cancer (HBOC) who have not received genetic counseling or testing. This 3-arm randomized trial will compare an arm that receives a tailored counseling and navigation intervention (TCN) delivered by trained cancer education specialists, an arm that receives a targeted print (TP) in the form of an educational brochure about the risks of HBOC, and an arm that receives usual care (UC). Sixty cancer survivors identified as high risk for HBOC will be contacted through the New Mexico Tumor Registry. Those who are eligible and consent to participate will complete a baseline telephone survey and then will be randomly assigned to one of the three arms. The primary aim is to determine if a high-intensity tailored risk communication intervention (TCN) will be superior to a low-intensity targeted intervention (TP) in promoting CGRA. Secondary aims will be to compare the three study arms with regard to cognitive and emotional outcomes and explore the underlying mechanisms through which the interventions had an impact on CGRA uptake.

The TCN telephone sessions will last approximately 30-45 minutes. Women randomized to the TCN arm will receive a tailored motivational psychoeducational intervention conducted by cancer education specialists trained in behavioral theory and brief motivational interviewing who will:

1. Start with a Greeting and Introduction
   a. Establish rapport
2. Review Medical and Family History
   a. Ask them if they have ever heard about HBOC. Provide a brief definition if they have not.
   b. Ask them what they are already doing (e.g., diet, exercise, screening) to address their cancer risk
   c. Ask them if they have ever thought about CGRA (why or why not?)
   d. Discuss general thoughts and feelings about HBOC and CGRA
3. Identify Participant's Perceptions of Threat
   a. Present visual aids about susceptibility and severity
   b. Use RBD scores to guide time and attention spent on each construct
   c. Use motivational interviewing (MI) strategies to elicit motivational speech
4. Address Response Efficacy
   a. Present visual aids about response efficacy
   b. Use RBD scores to guide time and attention spent on the construct
   c. Benefits to CGRA
   d. Genetic Information Nondiscrimintaion Act (GINA) confidence
   e. Use MI strategies to elicit motivational speech
5. Address Self-Efficacy
   a. Present visual aids about self efficacy
   b. Use RBD scores to guide time and attention spent on the construct
   c. Facilitators and barriers to CGRA
   d. Stage of readiness, using the Readiness Ruler
   e. Use MI strategies to elicit motivational speech
6. Create Action Plan
   a. Give summary of participant's motivation and thoughts about change.

   b. (If appropriate) Help participant complete an action plan, including steps to take, when to take them, and where they could go to get a CGRA; use visual aids
   c. Encourage women to make an appointment with a genetic counselor or cancer genetic risk specialist
   d. Encourage them to talk with their health care provider (and secure a primary care provider if they do not have one) about their risk for HBOC and the recommendations for CGRA
7. Navigate
   a. Help participants overcome specific barriers to CGRA
8. Close
   a. Review and summarize session
   b. Obtain physician contact information, if permitted

Following the TCN session, women will be mailed a tailored follow-up letter summarizing key points from the session (i.e., increased HBOC risk based on their characteristics, CGRA recommendation, importance of provider communication about their HBOC risk, messages about response efficacy and ways to overcome their two most important barriers), and their action plan. With their permission, a cover letter and a copy of the tailored letter summarizing key points of the session will be sent to their primary care provider and/or cancer care provider (ideally both). Women will participate in follow-up surveys 1 month and 6 months following the telephone call. The primary outcome will be CGRA within 6 months of TCN.

Theoretical Background & Rationale

Theory-based interventions addressing multiple determinants of behavior have the highest likelihood of promoting healthy behaviors (Briss et al., 2004). TCN explicitly incorporates health communication and behavioral theories as well as motivational interviewing strategies into the design and implementation of the intervention. Given the complexity of the relationships between risk communication, informed decision making, and health behavior, it is often necessary to judiciously combine constructs from several theories or models that have been validated in prior research (Briss et al., 2004; Irwig et al., 2006; Glanz, et al., 2015). TCN integrates several behavior change theories and conceptual models: **Extended Parallel Process Model (EPPM**; Witte, 1992; Witte & Allen, 2000); **Health Action Planning Approach (HAPA**; Schwarzer, 2008; Schwarzer et al., 2008), and **Ottawa Decision Support Framework** (**ODSF**; O'Connor et al., 2002). The EPPM provides guidance for effective delivery of risk messages, selection of measures, and analysis. The HAPA provides a structure for bridging the motivation/intention-behavior gap. Finally, the ODSF provides a general structure to facilitate informed decision-making and measures HBOC knowledge that are not explicit to the other two models. Together, these theories provide a framework for incorporating both cognitive and emotional factors into the intervention and motivating behavior change.

The EPPM provides a framework for communicating risk messages in a way that helps people channel emotions and cognitions in a positive direction (Witte 1992, 2000). Briefly, EPPM focuses on channeling fear in a positive protective direction aimed at controlling the danger (e.g., getting CGRA) rather than controlling the fear (e.g., derogating the message). Fear is aroused when individuals feel threatened (threat or risk appraisal process); they believe they and/or their family members are at risk for HBOC (perceived susceptibility) and consider it a life-threatening disease (perceived severity). Individuals are more likely to obtain a CGRA if they have high levels of confidence in their own ability (self-efficacy) and believe that CGRA is effective in reducing HBOC risk (response efficacy). One way to bolster self-efficacy is to help

patients overcome barriers. This may include cues to action (provider or other network member recommendation) or other factors (e.g. motivation, demographics, psychosocial and cultural factors) (Murray-Johnson et al., 2001; Maloney et al., 2011). The structure of the intervention is determined by the EPPM as shown in Figure 1. The cancer education specialists will start by presenting information about women's increased risk for HBOC and how serious the disease is in order to heighten perception of threat. After women are made aware of the threat (or threat is reinforced), the cancer education specialists will discuss how they can better understand their and their family's risk for HBOC by addressing the effectiveness of CGRA and their confidence in making an appointment. Barriers counseling is an important way to enhance a woman's self-efficacy regarding CGRA utilization.

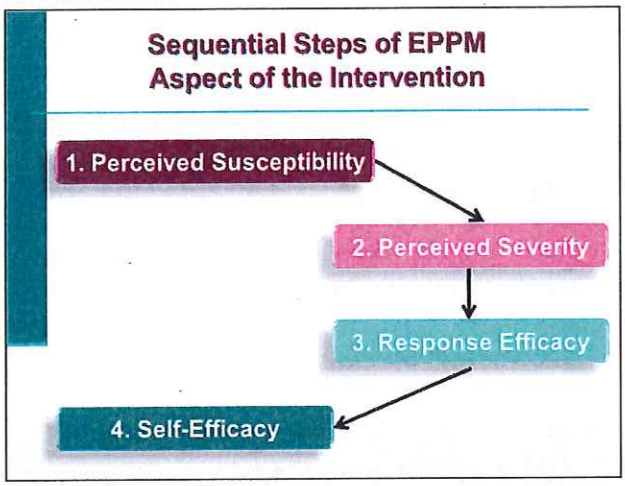


Figure 1. Steps of the intervention according to the EPPM

While the EPPM focuses on strategies to promote motivation and increase intentions to engage in health behavior, the **HAPA** recognizes that a substantial number of individuals are already motivated to engage in the health behavior and form goal intentions, but fail to carry out those intentions (Schwarzer, 2008; Schwarzer et al., 2008). According to the HAPA, successful behavior change involves both a pre-intentional motivational phase in which intention is formed and a post-intentional volitional phase in which intention is translated into action. To this end, the HAPA attempts to bridge the "motivation/intention–behavior gap" with a personalized and engaging action and coping plan component in the form of an implementation intention. **Implementation intention** suggests that patients are more likely to carry out an intended action if they identify specific aspects of the plan such as when, where and how they will do so (Schwarzer et al., 2008; Gollwitzer, 1999; Kwasnicka et al., 2013; Schwarzer, 1999; Sheeran, 2002). The cancer education specialists will elicit readiness to make an action plan and will guide the woman in formulating intentions regarding CGRA.

Available data suggests that thinking about future behavior in relation to specific environmental cues of when, where, and how to enact a particular behavior increases the frequency of or enactment of that behavior. There is evidence showing that when threatening health messages (e.g., risk communications and fear appeals) are combined with action (implementation plans), the likelihood of the behavior occurring increases (Schweiger & Gollwitzer, 2007). Prior research indicates that action-oriented plans, also known as implementation-intention strategies, that emphasize the action required to meet the goal increase the chances of successfully reaching an intended future goal (i.e., getting CGRA) with minimal effort by making conscious, deliberate behaviors automatic (Gollwitzer & Sheeran, 2006; Sheeran & Orbell, 2000; Sheeran & Silverman, 2003). Participants typically are asked to make their own plan of "when and where" they will implement a given behavior. The cancer education specialist will ask the participant to write down their action plan on the visual aid.

Consistent with **ODSF**'s conceptualization of decision support interventions, a central goal of cancer risk-related communication and behavior change counseling in this study is to facilitate informed decision-making about CGRA and prevent adverse psychosocial outcomes (O'Connor et al., 2002; Quality AfHRa, 2014). Low levels of knowledge and high decisional conflict can serve as impediments to informed decision-making. The ODSF is used in our study to examine the role of cognitive factors (in addition to those that comprise the EPPM), such as knowledge about the disease and recommended behavior and decisional conflict. The intervention will provide women with knowledge about HBOC and CGRA as well as help them in making an informed decision about getting screened that is consistent with their values.

These theories have been used to guide both targeted and tailored (personalized or individualized) interventions, but to our knowledge, no prior studies have tested their effectiveness using a public health approach in ethnically and geographically underserved populations. Tailored and targeted theory-based messages increase the likelihood of engaging audiences with relevant messages and increase motivation to engage in behavior change. Both proposed strategies are feasible and acceptable in the context of CGRA, but little is known about their impact on promoting utilization of genetic services.

The TCN intervention delivery style is based on Motivational Interviewing (MI), an evidence-based behavior change counseling strategy (Miller & Rollnick, 2013; 2014). **The contribution of MI is to encourage the participant to engage and respond more positively to the risk information, rather than to view the participant as a passive recipient of information.** There is evidence that MI reduces defensive responses (message rejection, paralyzing fear, low response efficacy/fatalistic beliefs) after receiving fear-arousing cancer information and effectively motivates people to engage in preventive behavior (Kinney et al, 2014; Miller & Rollnick, 2014; Pengchit, et al., 2011; Hall et al., 2012, 2015; Schwalbe et al., 2014). MI is also culturally responsive because counselors/educators can incorporate the social context into the interaction (Miller & Rose, 2009, 2015). Finally, there is a substantial literature base regarding MI and Hispanic populations suggesting that MI may be particularly well suited to Latinas and other underserved populations (Corsino et al., 2012; Rocha-Goldberg et al., 2010).

Because MI is a communication style, rather than a set of techniques, it is usually introduced in terms of a set of stylistic principles: (1) Express Empathy, which involves a respectful, curious attitude; (2) Roll with Resistance, which emphasizes avoiding arguments whenever possible and finding other ways to respond when challenged; (3) Develop Discrepancy, which means that the provider works to elicit the person's own reasons for change; and (4) Support Self-Efficacy, which emphasizes positive language and an environment that is supportive of change.

Below is a schematic of our study model (Figure 2) that integrates important theoretical constructs which are hypothesized to motivate CGRA uptake.

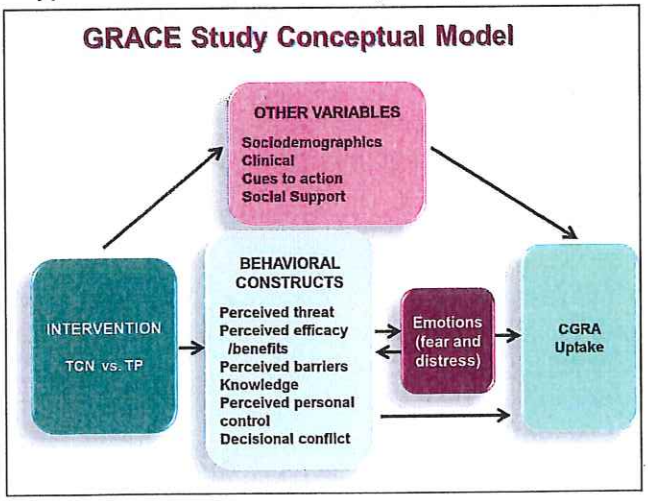


Figure 2. Theoretical framework of the study

Consistent with the study model, the cancer education specialists will need the following data from each woman in order to intervene on the intervention targets (See Apx. A):

1. Age of onset of breast and/or ovarian cancer and presence or absence of other NCCN CGRA referral criteria (e.g., triple negative tumor)
2. Family history of HBOC relevant cancers (breast, ovary, pancreas, prostate – look at NCCN guidelines for list of others)
3. Perceptions of threat including personal risk and family risk (likelihood and comparative risks)
4. Perceptions of threat and efficacy related to HBOC and CGRA, respectively
5. Baseline survey responses to select items: sociodemographic information (age, rural status, etc.), self-reported health status, cancer diagnosis, health literacy, number of living first-degree relatives, cancer worry, perceptions of threat and efficacy, presence of a primary care provider and/or cancer care provider, history of provider CGRA recommendation, CGRA readiness or interest, barriers, and facilitators.

During the TCN session, cancer education specialists will follow an intervention protocol in discussing women's increased risk for HBOC and CGRA as a recommended behavior. The following sections also describe strategies that cancer education specialists will use while communicating with women. Health messages will be personalized with regard to the participant's HBOC risk factor(s) as well as the study's aforementioned key theoretical constructs:

- Stage of change/readiness
- Perceived threat (susceptibility and severity)
- Perceived efficacy (response and self-efficacy)
- Healthcare factors (presence of a primary care provider and/or cancer care provider)
- Social influence (communication with provider about HBOC risk, CGRA recommendation, and family communication about HBOC risk and CGRA)
- Cues to action (action plan and action plan reminder).

Before the session starts, the cancer education specialists will access an electronic folder containing the woman's personal information gathered from the baseline survey and a graph delineating the woman's Risk Behavior Diagnosis Scale RBD scores. The cancer education specialist will review this information prior to the session and use it during the session. The RBD scores will give cancer education specialists an overall idea of what EPPM construct(s) and other factors they should focus on in their discussion with each woman.

Risk Behavior Diagnosis Scale: Assessing Threat and Efficacy

This section describes how to use the Risk Behavior Diagnosis (RBD) scale scores during the session. Specifics examples with more detail about how to address each EPPM key construct during a session will be described in the next section.

According to EPPM, two types of beliefs are identified by participants' scores on the RBD:

Threat is comprised of two cognitive factors:

- Perceived susceptibility
- Perceived severity

Efficacy is comprised of two cognitive factors:

- Response efficacy
- Self-efficacy

Quick Glance: Use participants' RBD scores to get an overall idea of what participants are thinking in terms of threat and efficacy.

Tailored Messages: Use motivational interviewing techniques to focus on the constructs with lower scores. Cancer education specialists can do this by:

1) Asking participants about the reasons why she believes that cancer is threatening or how they can overcome the threat (i.e., why they did not score *lower* in a particular area).
2) Providing information to raise the participants' perception of threat or efficacy.
3) Strategically using the "readiness to get CGRA" ruler (see Section 5) to help identify CGRA readiness.

As aforementioned, participants' scores from the RBD scale will be used to determine what constructs should be emphasized in increasing motivation and ability to get CGRA. Figure 3 provides an example of an individual's RBD subscale scores. **All four constructs should be addressed with ALL participants in the following order: perceived susceptibility, perceived severity, perceived response efficacy, and perceived self-efficacy.** Initially, perceptions of threat should be raised arousing emotions such as fear. This leads to better attention paid to the message. When raised threat perceptions are followed by messages aimed at increasing response efficacy and self-efficacy, fear is more likely to be channeled in a positive direction (e.g., increased likelihood of CGRA).

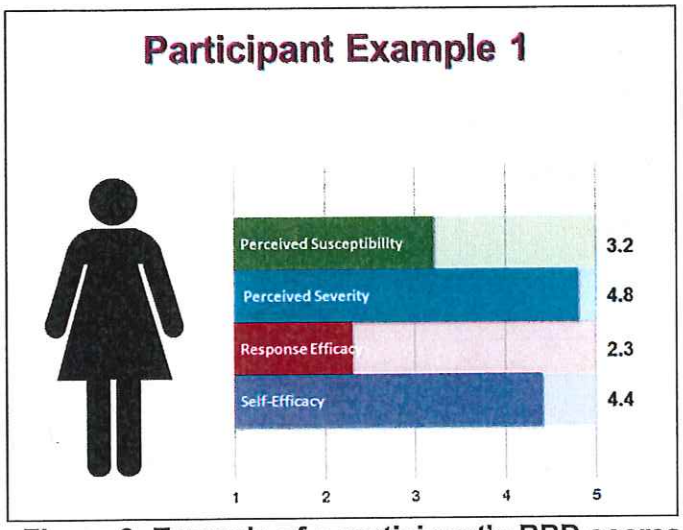


Figure 3. Example of a participant's RBD scores

***Example 1*: Quick glance.** *(For each participant, the participant's RBD scores should be available for use throughout the whole counseling session)* First, examine the participant's combination of scores on the 4 EPPM constructs. Scores are categorized as high, moderate, or low (See Figure 4 for categorization criteria). The purpose of this step is for the cancer education specialists to get a rough idea of what construct(s) they should emphasize in the intervention. In this example, the participant scored lowest on "Perceived Susceptibility" and "Response efficacy." Therefore, greater effort should be put into increasing the participant's perceived risk and beliefs about the effectiveness of having CGRA.

Figure 4. Criteria used to categorize participants according to their RBD scores (score for each construct ranges from 1 to 5).

- Low = 1-2.0
- Moderate = 2.1-3.5
- High = 3.6-5

***Example 1*: Tailored messages.** Cancer education specialists address each EPPM construct, beginning with perceived susceptibility. For example, this participant (Figure 3) will receive a tailored message for moderate perception of risk. She will be given more information about her personal risk due to HBOC risk factors in order to increase her risk perception. Cancer education specialists are not trained cancer genetic risk specialists, thus, participants will only

be informed of other HBOC risk factors they have (e.g., family history, triple negative, two HBOC related cancers). Then, since this woman is already aware of the severity of the cancer, a tailored message for high perception of severity will be provided and the cancer education specialist should spend a short time intervening on this belief. However, because of low response efficacy perceptions, the cancer education specialist will need to correct the participant's belief about the effectiveness and importance of CGRA for their own healthcare and their biological relatives' health. Finally, the cancer education specialist will spend a brief amount of time discussing the participant's self-identified barriers to CGRA and her readiness to get CGRA since she seems ready to obtain a CGRA.

Figure 5 provides an additional example of how to use RBD scores in personalizing the telephone session.

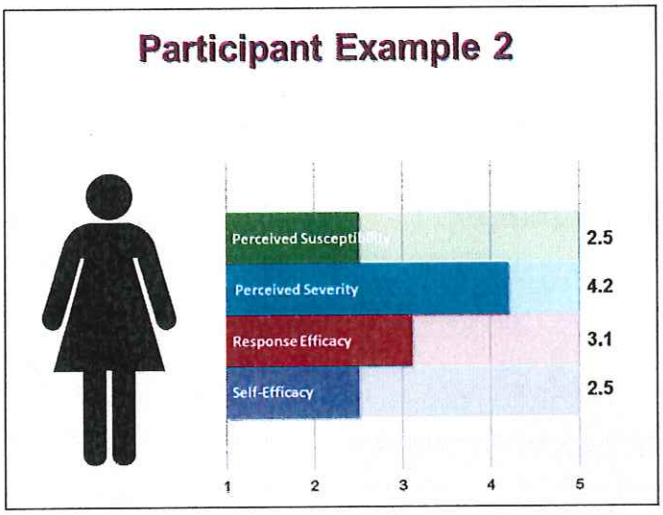


Figure 5. Another example of a participant's RBD scores

***Example 2*: Quick glance.** For this example (Figure 5), the participant has moderate to low perceived risk, high perceived severity, moderate response efficacy, and relatively low self-efficacy. In other words, this person thinks she is not at increased risk for HBOC but she is aware that cancer is dangerous. Although having CGRA seems to be effective in preventing the cancer, the participant believes that it is too difficult to do so. Therefore, the cancer education specialist should put greater effort into discussing the participant's increased risk for HBOC and the effectiveness of CGRA, as well as in helping this person overcome important barriers to getting CGRA. In general, persons with low self-efficacy have more salient barriers and often need navigation.

***Example 2*: Tailored messages.** Cancer education specialist will provide tailored messages regarding participants' personal HBOC risk factors in order to increase risk perception. If the participant has close biological relatives (first and/or second), the cancer education specialist will let the woman know that they may be at increased risk for HBOC and that cancer can be prevented and detected early. Then, since the participant is already aware of the seriousness of HBOC, the cancer education specialist will affirm this belief. Since this participant is not certain about the effectiveness and necessity of having CGRA, the counselor will provide more information about these issues. Finally, it is very important that the cancer education specialist helps this participant brainstorm solutions to obtaining CGRA so that she is more confident in her ability to adhere to the CGRA recommendation. If desired by the client, the counselor will help the participant to create an action plan to schedule a CGRA within the next several weeks.

Intervention Guide for Cancer Education Specialists

1. START WITH A GREETING AND INTRODUCTION

Purpose:

- Orient the woman to the *structure* of the phone call by providing a basic summary of the interaction.
- Orient the woman to the *style* of the interaction, through a warm, friendly attitude.

Steps:

1. Prior to calling, review the Participant Synopsis form (see Appendix A).
2. Make sure your equipment is working properly before calling.
3. Introduce yourself and remind the woman about the GRACE Project.
4. Ascertain that the woman has the desired level of privacy in their location and there is no distraction during the session.
5. Inform the woman that the phone conversation is being recorded for quality control purposes, but that they can refuse recording or stop the conversation at any time.
6. Remind her that all information is confidential.
7. Ask her if she has the sealed envelope that was mailed to her for the TCN session. Give her a moment to locate it if necessary. If she does not have it at the time of the session, check if she is able to receive the visual aid and educational brochure files via email or fax and send her the visual aid file. If she cannot locate the envelope or have the information sent to her electronically then cancel the session, ask a GRACE staff member to resend the envelope via 2-day FedEX, and reschedule the session. If the woman also indicates that she does not have up to 30 minutes or it seems like she may be too distracted, the session should also be rescheduled. If the session gets interrupted in the middle, ask her if it is still a good time to continue the session. If the session has to be stopped in the middle, it should be rescheduled as soon as possible.
   a. If the participant seems distracted or if something happens in the middle of the call, offer to call back at a later time. Try to avoid making the woman feel guilty for the interruption by blaming the study. Ex: "The study requires that this session take place in a quiet environment…"
8. Ask the client what she already knows about the purpose of the session; lay out the basic structure of the session.
   - Goal is to provide information about CGRA so they can make the decision that is right for her.
   - The conversation will last about 30-40 minutes.

Visual aids

Several visual aids will be used to help women follow the discussion with the cancer education specialist regarding their increased HBOC risk and other theoretical constructs. Some visual aids will be tailored for each woman according to her responses on the baseline questionnaire. For example, on the Facilitators and Barriers page (refer to the visual aid packet page 6), it might say "Your most important reported things to address are that you don't have transportation to get CGRA and that the cost of CGRA is too high." There will be seven visual aids that will be sent to participants to be used during the session. They are:

1. Risks of breast and ovarian cancer (2 separate pages)
2. CGRA explanation

3. GINA information
4. Important things to address and facilitators table
5. Readiness ruler
6. Action plan

2. REVIEW MEDICAL AND FAMILY HISTORY

After the introduction, cancer education specialists ask participants what they know about HBOC. Then they move to a discussion with participants about their personal risk factors for HBOC (e.g., young age at diagnosis, triple-negative, family history of HBOC related cancers). These data are obtained from NMTR and the baseline questionnaire.

Purpose:

- Verify participants' HBOC risk factors. See Appendix B for NCCN guidelines for CGRA.
- Use this time as a transition to discussion on risk by asking what they are currently doing.
    - Ex: "What have you already done to reduce your risk of getting cancer again?"
    - "Quitting smoking, increasing screening, and increasing support are a few things some people do to reduce their risk. Are any of these things you could do?"

3. IDENTIFY PARTICIPANTS' PERCEPTIONS OF THREAT

So what I am going to do now is show you some slides about the role of genes in cancer risk

- Explain role of genes and risk
- Ex: "Genes are like the blueprint for how our bodies are built. Genes differ among people, which is how we get different hair colors or eye colors."
- Ex: "Some people carry mutated or changed genes that increase their risk for developing certain diseases, such as cancer. These changed genes means that family members could be at increased risk, too."

Perceived susceptibility

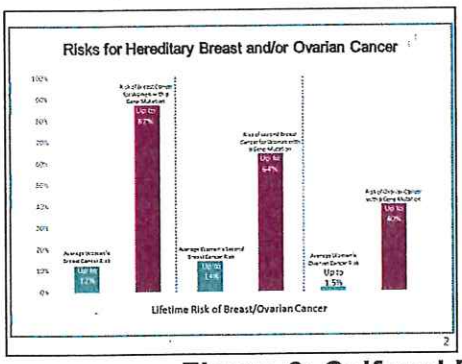
Purpose:

- Ascertain that participants are aware of their increased HBOC risk. Cancer education specialists will provide tailored messages about participants' HBOC risk factors.

Strategies:

- Cancer education specialists use participants' perceived susceptibility score from the RBD scale and their answers to questions from the baseline about their perceived risk (Do you think your chance of developing HBOC is higher/lower/about the same compared to the average woman/man your age?")

- Present tailored risk information based on the participant's risk perceptions (Figure 6; visual aids pages 2 and 3). The following information can be read while the participant is looking at the visual aids:
    - (Visual Aid page 2/3) Women who have been diagnosed with breast cancer may have inherited changes to specific genes (genetic mutation).
        - For breast cancer survivors with a gene mutation, up to 64%, or 64 out of 100, women will get a *second breast cancer*
        - Among this same group, up to 40%, or 40 out of 100, women will get *ovarian cancer*
    - (Visual Aid page 2/3) <u>Relatives</u> of women with a gene mutation may also carry the changed gene.
        - On average, 12% or 12 out of 100 women will get breast cancer in her lifetime
        - For those with a gene mutation, *this number rises* up to 87% or 87 out of 100 women will get breast cancer in her lifetime
- Make sure to mention biological relatives' increased risk. Be sure to include male relatives' increased risk for breast, prostate, and other cancers; especially for those who reported having living, male, first-degree blood relatives (e.g., father, sons and brothers).
    - Summarize the participant's risk assessment.
        - Ex. *"The next section of this call focuses on risk factors for HBOC and how they apply to you and your family. It also focuses on HBOC risks for woman and family members like you. On the survey, you estimated that your risk for HBOC was (lower than, the same as, higher than) the risk for other people of your age and gender. You also indicated that it was (not at all likely, somewhat likely, definitely) that at least one of your close relatives was at risk for HBOC."*
    - Refer to the visual aids and ask the woman about her reaction to the risk comparison chart.
        - Ex. "*On the visual aid, it shows the risk for a second breast cancer or ovarian cancer in women with HBOC. I'm wondering what you make of that."*
          "What do you think about your risk for HBOC?"
          "What concerns you about it?"
          "How does that strike you?"
        - Ex. "*On the visual aid, it shows the risk of breast cancer in relatives of breast cancer patients with HBOC. I'm wondering what you make of that."*
          "What do you think about your family's (both male and female relatives) possible risk for HBOC?"
          "What concerns you about it?"
          "How does that strike you?"



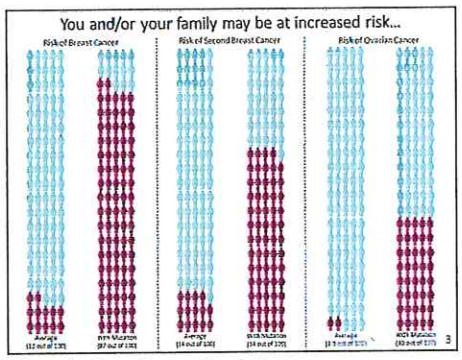


Figure 6: Self and Family risk visual aids

- Clarify and add information as appropriate (but the person's reaction is still most important).
  - "I am at risk":
    - Confirm woman's beliefs and emphasize the role of family history. Ex. *"You said in the survey that you think your risk for HBOC is higher than other people's and that your biological relatives' risk of HBOC is increased. What makes you think that? …You are right that you think your risk for HBOC is higher than other people your age. Because your breast cancer diagnosis (under 50, triple negative,)… Family history is another important risk factor for HBOC [insert personal information about relative(s) diagnosed with HBOC].*
    - Ex. "*You also indicated that you think your biological relatives' risk of HBOC is increased. What makes you think that?"*
  - "I am not at risk":
    - Explore the reasons of belief in low risk, provide more information regarding the influence of family history and elicit participant's response. *Ex. "You may feel that your risk for HBOC is lower than other women your age because you don't have a family history or lead a healthier lifestyle than most people or… However, because your breast cancer diagnosis was (age, type), this puts you at higher risk for having HBOC. Family history is another important risk factors for HBOC [insert personal information about relative(s) diagnosed with HBOC]."*
    - (If participant has indicated that family risk is low) Ex. *"As you can see in the visual aid, a woman's chances of developing cancer in her lifetime increases dramatically if she has a genetic mutation."*

Perceived severity

Purpose:

- To elicit and provide information about the seriousness of HBOC. Cancer education specialists will need to provide information about death rates based on stage, as well as more qualitative information. EPPM studies indicate that statistical information is useful for fear appeals for some people.

Strategies:

- Reflect and provide more information about the severity of HBOC
- Cancer education specialists may discuss the physical effects of advanced disease, treatment and morbidity, and cost of treatment with participants who have low perceived severity.
  - Low perceived severity
    - Reflect and explore reasons
      - Ex. *"So you're not really sure whether HBOC is that serious."*
    - Provide information about severity
      - Ex. *"There may be other things that are more on your mind. Just so you're aware, breast cancer is the leading type of cancer for women in the United States. Every year, over 200,000 women are diagnosed and over 40,000 women will die from breast cancer. Ovarian cancer is rarer, with 22,000 new cases each year, but over 14,000 women die each year from it. As you know,*

cancer causes a lot of pain and suffering, both for the individual and their loved ones. We want to make sure that people understand the risks of HBOC so that they can make a decision that is right for them and their families."

- Encourage participants to think about negative consequences of having HBOC
  - Ex. "*What do you think about this? What would happen to your family members if they got breast or ovarian cancer? What are some of your fears about having a second breast cancer or ovarian cancer? What are some of your fears about your family members getting breast or ovarian cancer?"*

- Moderate perceived severity
  - Reflect and explore reasons
    - Ex. "*So, you think that HBOC is somewhat serious. What are some reasons you think it could be serious?"*
  - Summarize the person's reaction, provide additional information
    - Ex. *"So the reasons you think it could be serious are… You're probably already aware that breast cancer is now the leading type of cancer for women in the United States. Every year, over 200,000 women are diagnosed and over 40,000 women will die from breast cancer. Ovarian cancer is rarer, with 22,000 new cases each year, but over 14,000 women die each year from it. As you know, cancer causes a lot of pain and suffering, both for the individual and their loved ones. We want to make sure that people understand the risks of HBOC so that they can make a decision that is right for them and their families.*
  - Encourage participants to think about negative consequences of having HBOC
    - Ex. "*What do you think about this? What would happen to your family members if they got breast or ovarian cancer? What are some of your fears about having a second breast cancer or ovarian cancer? What are some of your fears about your family members getting breast or ovarian cancer?"*

- High perceived severity
  - Reflect, affirm, and provide the statistical information
    - Ex. "*So, you think that HBOC is a serious disease. You're probably already aware that breast cancer is now the leading type of cancer for women in the United States. Every year, over 200,000 women are diagnosed and over 40,000 women will die from breast cancer. Ovarian cancer is rarer, with 22,000 new cases each year, but over 14,000 women die each year from it. As you know, cancer causes a lot of pain and suffering, both for the individual and their loved ones. We want to make sure that people understand the risks of HBOC so that they can make a decision that is right for them and their families.*

- Information for all levels:
  - Ex. "*The good news is that the severity of both breast and ovarian cancer depends on when it is detected or if risk reducing surgery is performed (e.g. preventive removal of the breasts and ovaries. Prophylactic mastectomy refers to the removal of healthy breasts to reduce a woman's risk of developing breast cancer. Prophylactic mastectomy is the most effective means of decreasing a woman's risk; however, the benefits of this surgery depend on a woman's individual risk. For women who have HBOC but choose not to have this type of surgery, breast cancer screening (e.g., mammograms and MRIs) can help detect cancer early. The survival rate is much higher if breast cancer is detected earlier."*
  - Ex. *"Ovarian cancer screening is not effective. Therefore, it is recommended that women with HBOC have their ovaries removed after they complete*

childbearing. This type of surgery is called prophylactic oophorectomy. It is a very effective tool to reduce the risk of ovarian cancer and also reduce the risk of breast cancer and risk of a second breast cancer in women who have already had the disease. Both breast and ovarian cancer have high survival rates if the cancer is found early."

- Ex. *"Additionally, breast or ovarian cancer that is detected early can be treated in a much less aggressive way, for example, less likely to need chemotherapy, less likely to need mastectomy. However, most ovarian cancers are detected at later stages because there is no effective screening method. What do you think about that?"*

- Introduce CGRA as one way to reduce risk of developing HBOC.
  - Ex: *"When we talk about ways to learn about and manage risk, one thing we usually talk about is CGRA. During this session, a cancer genetic risk specialist will discuss if you and your family are at increased risk for HBOC and possibly recommend genetic testing. Once you know more about your risk for HBOC, you and your family can begin taking measures to reduce this risk. CGRA is especially recommended (breast cancer under 50, ovarian/fallopian/peritoneal cancer at any age…)"*
- Elicit information about what the woman already knows about CGRA (Ex. "*What do you know about CGRA?*"). Add information as appropriate.

4. ADDRESS RESPONSE EFFICACY

Response efficacy regarding CGRA

Purpose:

- Participants believe that CGRA is the best way to understand their risk for HBOC.

Strategies:

- Elicit what participants already know about CGRA.
  - *"What do you know about CGRA?"*
  - *"What are your plans to get CGRA in the next 6 months?"*
- Cancer education specialists provide information about CGRA, how it works, and its effectiveness in determining risk for HBOC based on what participants know about it. (use visual aid 4, Figure 7)
- Check if participants understand what happens during a CGRA session.
- Recommend or reinforce getting CGRA, bringing up family history if applicable.
- Reassure any fears about discrimination due to genetic testing.

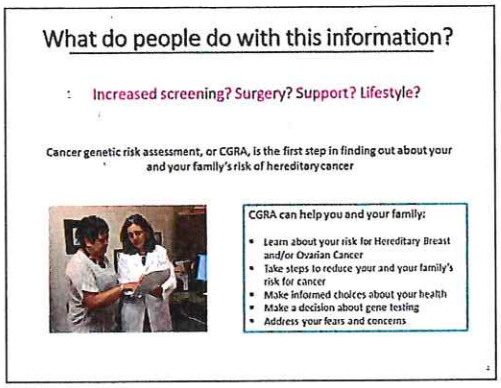


Figure 7: Introduction to CGRA

- Low perceived response efficacy
  - Reflect and ask the reason for their belief.
    - Ex. *"Prior to our discussion today, you indicated that you thought CGRA was not very effective in helping you understand you and your relatives' risk for HBOC. What are some of the reasons you think this?"*
  - Then, reflect and provide more information.
    - Ex. *"CGRA is very effective to better understand you and your family's risk for HBOC. The cancer genetic risk specialist analyzes your personal and family cancer history to determine the risk of a genetic cause. As we discussed, surgery can be a very effective way to reduce the risk of breast and ovarian cancer and risk of second breast cancers in women who are at high risk for HBOC. When breast and ovarian cancer are detected and treated early, the survival rates are much higher than if the cancer is found later. If you and your family know your risk for HBOC, you can begin to take preventative measures to reduce that risk."*
- Moderate perceived response efficacy
  - Reflect and ask the reason for their belief.
    - Ex. *"Prior to our discussion today, you indicated that you thought CGRA was somewhat effective in helping you understand your risk for HBOC. What are some of the reasons you think this?"*
  - Then, reflect and provide more information.
    - Ex. *"CGRA is very effective to better understand you and your family's risk for HBOC, including your male blood relatives such as sons and brothers. The cancer genetic risk specialist analyzes your family's cancer history in order to determine the likelihood of a genetic cause. As we discussed earlier, when breast and ovarian cancer are detected and treated early, the survival rates are much higher than if the cancer is found later. If you and your family know your risk for HBOC, you can begin to take preventative measures to reduce that risk."*
- High perceived response efficacy
  - Affirm their belief that CGRA may be effective in helping them understand their risk for HBOC.
    - Ex. *"You are right. CGRA is very effective to better understand you and your family's risk for HBOC. The cancer genetic risk specialist analyzes your family's cancer history in order to determine the likelihood of a genetic cause. As we discussed earlier, when breast and ovarian cancer are detected and treated early, the survival rates are much higher than if the cancer is found*

later. If you and your family know your risk for HBOC, you can begin to take preventative measures to reduce that risk."

- Referring to visual aid 5, Figure 8, remind the participant about GINA. They cannot be discriminated against by employers or health insurance companies based on their genetic information.

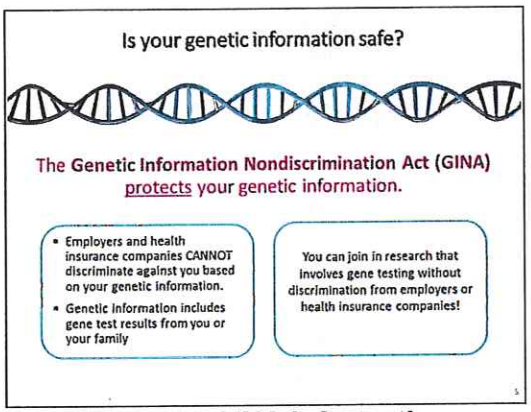


Figure 8: GINA information

5. ADDRESS SELF-EFFICACY

After addressing perceived susceptibility, perceived severity, and response efficacy, in this section, cancer education specialists will reevaluate the participants' readiness to change using a readiness ruler that will help determine if participants have adequate motivation to change and if they have the confidence and ability (self-efficacy) to do so.

Purpose:

- The primary goal is to elicit participants' readiness to get CGRA (e.g., to focus on the motivation the person *already* has). Using information from the previous two sections, as well as the participant's own responses in this section, the goal is to help the person voice the reasons for change and some possible ideas around change.

Strategies:

- Address barriers and facilitators to encourage participants to seek CGRA services
- Use the "readiness" ruler to elicit the participants' own reasons for wanting to get CGRA and thoughts about how they could accomplish this.

Steps:

1. Refer to visual aid 6, Figure 9 to discuss the two most important facilitators for getting CGRA.
    - Stress the importance of understanding risk for HBOC in preventing cancer in family members
        - Ex. *"In the survey, you indicated that the two most important facilitators to you getting CGRA are… These are great reasons to seek CGRA services.*

Remember, through CGRA, you can not only learn about your risk for HBOC, but your family members' risk, as well. Understanding your risk is an important step in preventing cancer."

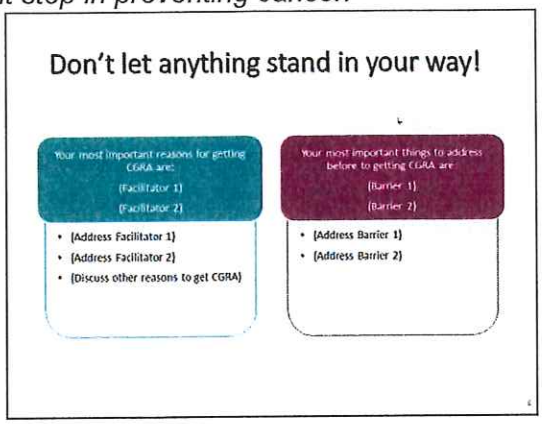


Figure 9: Facilitators and Barriers

2. Still using visual aid 7, Figure 9, address the two most important things to address before getting CGRA
   - Discuss and address the things preventing participant from CGRA (see Apx C)
     - Ex. *"In the survey, you indicated that the two most important things to address before getting CGRA are… While we understand these are difficult, we encourage you to… Remember, through CGRA, you can not only learn about your risk for HBOC, but your family members' risk, as well. Understanding your risk is an important step in preventing cancer."*
3. *Summarize what was discussed concerning facilitators and barriers.*
4. Ask about readiness in getting CGRA in the next 6 months, referring to visual aid 7, Figure 10. *On a scale from 1-10, how ready are you to get CGRA in the next 6 months, when 1 is not at all ready and 10 is very ready?"* Record readiness.

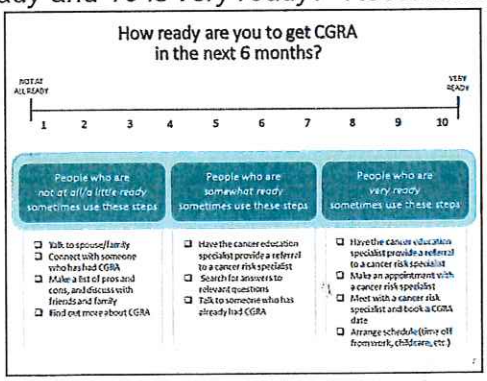


Figure 10: Readiness Ruler

   - o <u>If high level of readiness</u> (e.g., 5-10)
     - Reflect
       - *"So you are very/pretty ready to get CGRA."*
     - Ask for elaboration:
       - *"Why is that?"*
       - *"How would you go about it?"*
       - *"Who would be helpful to you?"*
       - *"Who would this be helpful for?"*
     - Try to elicit and reflect on 2-3 reasons why the participant is ready.

- If readiness is medium/high, cancer education specialists ask about any other things to address before getting CGRA, how important these things are to participants, and if they already have a plan to deal with them.
- Discuss possible things to address and how to resolve them (see Appendix C for details of strategies to overcome specifics).

- If low level of readiness (e.g., 2-4)
  - Reflect on answer and ask why they did not choose an even lower number. Focus on the readiness they do have, rather than what they lack.
    - *"I see you chose a 3. Why not a 1? What else"?*
    - *"What would it take to raise your readiness to a 4 [one number higher]?"*
    - *"How would you go about that?"*
    - *"Who would be helpful to you?"*
  - Try to elicit and reflect 2-3 reasons why the participant is not so ready.
  - Discuss any other things to address and ambivalence about moving ahead with CGRA. Ask why they are not sure if they can have CGRA.
  - Discuss family influence to encourage participants to seek help from other family members and to help other members to get CGRA.
- If a one (e.g., not confident at all)
  - Ask **what it would take to raise their level** of readiness.
    - *"What would it take to get you to a little higher readiness level?"*
    - *"How would you go about that?"*
    - *"What things have been helpful to you in the past?"*
  - Discuss any other things that need addressing and ambivalence about moving ahead with CGRA. Ask why they are not sure if they can have CGRA.
  - Discuss family influence to encourage participants to seek help from other family members and to help other members to get CGRA.
- For all levels
  - Present the participant with options that other people have considered, using the visual aid examples as a guide
  - These options should be emphasized as easy to be adopted and presented as ways to get more information
  - Ex. "*When some people are unsure about whether or not they want to go about getting CGRA, they may try calling their insurance company to see if the procedure would be covered or talk to their doctor about getting a referral or talk to a friend or family member. Do you think any of those things would be helpful for you?*"
  - Make sure to discuss the important things to address given during the baseline survey. Only directly mention these if the participant has already done so herself. Otherwise, introduce the idea using a hypothetical, like the above example.

6. CREATE ACTION PLAN

Purpose:

- Assist participants in constructing their action plan for having CGRA.
- Provide a quick summary of the previous sections, especially people's stated reasons for wanting to get CGRA, and perceptions of readiness.

- If it is unclear whether the person wants to develop a plan, ask a question to determine readiness to proceed to planning.
  - Ex: "*So what would you like to do about this?*"
  - If the person doesn't want to proceed, skip this section (move to closing).
  - If the person would like to proceed, continue this section:

Strategies:

- Ask about their plan.
  - Reflect and summarize.
    - *"If you were to get CGRA, how would you go about it? What would be the first step?"*
    - *"For most people, the first step involves making an appointment with their doctor."*
    - *"What would that look like for you?"; "What's the next step for you?"*
    - *"What's your plan?"; "How will you do that?"; "Who would help you?"*
- Create Action Plan. (visual aid 8, Figure 11)
  - Cancer education specialists will refer to the visual aid that has an action plan table (it should be noted that the participant will not have a date but that CGRA should be done within the next 6 months). Encourage participants who are ready, to make a plan by saying things like *"If you do not have an appointment to have the CGRA and you want to have it, you are more likely to have it if you decide now on the steps you need to make to get an appointment."*
  - If they are ready, the best solution is to have them call for an appointment and identify where. Let them know that UNMCCC is the only place that has board certified risk specialists/genetic counselors but if travel is burdensome, they can go somewhere else and work with them to identify where (See list of places to CGRA in New Mexico). Have the patient write on the visual aid the steps including the place and phone number.

Figure 11: Action Plan

  - Use implementation intention strategy to construct the action plan: ask patient to specify when, where, and how they will implement each step that is necessary to get CGRA.
  - For participants who are not ready to create an action plan (e.g., those who are ambivalent or resistant about getting CGRA), the following strategies may be used.
    - Ambivalent participants: For participants who have mixed feelings about having a CGRA (e.g., "I know I should get one but…"), the cancer education specialist might focus on reflecting on reasons they should have CGRA and encourage the participant to talk more about the reasons they should get or benefits of CGRA.

- If participant agrees to make a plan: Encourage the participant to identify their own solutions to their self-reported barriers. This could include asking them to think hypothetically about how they would go about getting CGRA if they wanted to. Depending on how ready participants are, ambivalent participants may or may not be ready to commit to a plan to get CGRA.
- If participant does not want to make a plan: The cancer education specialist may explain the visual aid on page 9 and discuss some options that other people have considered, "*When some people are unsure about whether or not they want to go about getting CGRA they may try calling their insurance company to see if the procedure would be covered or talk to their doctor about getting a referral or talk to a friend or family member to see what it was like for them. We hope this information would be useful to you when you decide to make your own plan to get CGRA. I'm wondering when the time is right, how would you go about it? Give me some examples of what you would do.*" The cancer education specialist then supports their rough plan by emphasizing benefits and ease of performing the behavior (e.g., calling their physician or talking to their family member is an easy way to start it).

- Resistant participants: These are participants who are not ready to change either because they think getting CGRA is not important, CGRA is not effective in understanding risk of HBOC (issues of importance), or because they are not able to get it (confidence issue). Therefore, asking them to commit to an action plan may not be practical or appropriate.
  - If the resistance comes from low readiness. If it's clear that participants cannot get CGRA because they have some important barriers that they cannot overcome (most likely, the cost of CGRA), see Appendix C.

7. NAVIGATE

This section will be highly personalized to each participant, based on how the session has gone so far.

Purpose:

- To provide direction for participants based on barriers and readiness for CGRA.

Strategies:

- Ready for CGRA and have overcome the important things to address
  - Provide resources for where to seek CGRA services nearby or on the phone
- Not that ready for CGRA due to important things to address
  - Address these as much as possible, using Appendix C for help
  - List nearby or phone resources for CGRA services, if distance is the issue
  - Provide insurance / low-cost resources if money is the issue
  - Offer to call back in a week if participant needs time to think or talk with friends or family

- Not ready at all for CGRA
  - Offer to call back in a week if participant needs time to think or to talk with friends and family
  - Offer to connect with state Community Health Workers or other services to help obtain health insurance
  - Offer help with travel barriers
  - Provide insurance / low cost resources if money is an issue
  - Address issues as much as possible, using Appendix C for help

8. CLOSE

At this final step, cancer education specialists will:

- Review and summarize the participants' important reasons to get CGRA, their readiness, and action plan for getting CGRA.
- Obtain permission from participant to allow study staff to send their physician(s) the tailored letter that contains their personal cancer history and family history and risk information, action plan, and CGRA recommendation.
  - Get information about oncologist or PCP (whichever the patient sees most concerning their care): name, possible address, city
- Inform participants that they will receive a personalized follow-up letter and written action plan that they just developed within a week. Remind participants of their appointment for the upcoming 1-month survey.
- Ask if they have any questions or concerns.
- Emphasize personal responsibility and thank the participant for speaking with you. If appropriate, restate that CGRA can save lives.
  - If the participant has already made an action plan to get CGRA: Ex. *"We are glad that you've taken a great step for you and your family to manage your cancer risks. We hope that you will follow the plan to get CGRA. Remember that CGRA can save lives, and the next move is yours. I appreciate you speaking with me, and I wish you well."*
  - If participants do not create an action plan: Ex. *"It's clear you've thought a lot about this, so I hope you will make the decision that is right for you and your family. I appreciate you speaking with me, and I wish you well."*

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Appendix A: Pre-Intervention Patient Synopsis

General Information	
Age	
Residence	• Urban • Rural
General Health	
Health literacy	• Score=
HBOC Knowledge	• Score=
Cancer	• Type= • Age of diagnosis=
Cancer Worry	• Frequency= • Intensity=

RBD Score	• Perceived severity=
	• Perceived susceptibility=
	  • Self=
	  • Family=
	• Perceived severity=
	• Response efficacy=
	• Self-efficacy=

Family Cancer History	
Breast Cancer?	Yes or No (triple negative / under 50 / 2+ BCs)
Ovarian Cancer?	Yes or No
P/HCP CGRA Recommendation	
CGRA Readiness/Interest	
Things to address before getting CGRA	1. 2. Other things to address: •
Facilitators	1. 2. Other facilitators: •

Sociodemographics	• Hispanic=
	• Race=
	• Ashkenazi Jewish=
	• Education=
	• Income=
	• Marital status=
	• Living first degree relatives:
	  • Children – #Male= #Female=
	  • Siblings – #Male= #Female=
	  • Other – #Male= #Female=

Insurance	
Type of insurance	Primary: Secondary:
Coverage of CGRA?	
PCP (Main health care provider)	
Nearest CGRA resource (make sure	

to emphasize that only those at UNM are board certified)	
Contact Preference	Mail Call Email Text Contact Info:
Appointment Time Frame	

Appendix B: NCCN Guidelines for CGRA

NCCN Guidelines Version 2.2016

Breast and/or Ovarian Cancer Genetic Assessment

CRITERIA FOR FURTHER GENETIC RISK EVALUATION

- An individual with a breast cancer diagnosis meeting any of the following:
  - A known mutation in a cancer susceptibility gene within the family
  - Early-age-onset breast cancer
  - Triple negative (ER-, PR-, HER2-) breast cancer diagnosed ≤60 y
  - Two breast cancer primaries in a single individual
  - Breast cancer at any age, and
    - ≥1 close blood relative with breast cancer ≤50 y, or
    - ≥1 close blood relative with invasive ovarian cancer at any age, or
    - ≥2 close blood relatives with breast cancer and/or pancreatic cancer at any age, or
    - From a population at increased risk
  - Male breast cancer
- An individual of Ashkenazi Jewish descent with breast, ovarian, or pancreatic cancer at any age
- An individual with a personal and/or family history of three or more of the following (especially if early onset and can include multiple primary cancers in the same individual): breast, pancreatic cancer, prostate cancer (Gleason score ≥7), melanoma, sarcoma, adrenocortical carcinoma, brain tumors, leukemia, diffuse gastric cancer, colon cancer, endometrial cancer, thyroid cancer, kidney cancer, dermatologic manifestations and/or macrocephaly, hamartomatous polyps of gastrointestinal (GI) tract
- An individual with an ovarian cancer

Appendix C: Specific Strategies to Overcome Important Things to Address

Things to Address that Still Exist or have Changed After the Counseling Session	Personalized Messages Associated with Thing to Address, to be Inserted in the Tailored Letter
Health Care Provider	
1. My health care provider has not recommended CGRA services *(No one ever recommended it)*	If your health care provider is trained in genetics, we encourage you to talk with them about your risk of HBOC. Otherwise, ask your health care provider if they can refer you to someone trained in genetics, or you can call a genetic risk specialist near you [list local resources/organizations]. Learning about your risk of HBOC is an important step in preventing cancer in both you and your family.
2. A health care provider told me not to go *(A doctor told me not to go)*	We encourage you to speak to your health care provider about the factors that contribute to your increased risk of HBOC. A genetic risk specialist will help you understand you and your family's risk of developing HBOC and will provide information on preventative measure you can take, if necessary.
3. I don't have a health care provider	Fortunately, you can see a genetic risk specialist without the referral of a health care provider. Call a genetic risk specialist near you [list local resources/organizations]
4. My health care provider is not trained in cancer genetics	In this letter, we have provided you with a list of resources where you can seek CGRA.
Busy	
1. I have a busy schedule and don't have time *(Too busy)*	Calling to make an appointment with a genetic risk specialist will only take a few minutes, and the CGRA session itself will last [a couple hours, at most]. It is well worth working this into your busy schedule to determine you and your family's risk of HBOC.

2. I cannot get time off from work *(Cannot get time off from work)*	We encourage you to call a genetic risk specialist near you to find out if you can make an appointment either before or after work, as many clinics have flexible hours.
3. I would not be able to find someone to watch my children during my appointment *(Lack of childcare)*	We encourage you to find a family member or close friend who would be available to babysit, or to call a genetic risk specialist to find out if their clinic offers childcare.
4. Clinical hours do not fit my schedule *(Clinical hours do not fit my schedule)*	Some clinics have more flexible hours than others, so we encourage you to call other nearby organizations to make an appointment to see a genetic risk specialist that will fit into your busy schedule.
5. My other responsibilities take precedence over CGRA *(Other life issues that come up are more important that an appointment)*	We encourage you to talk to a healthcare professional about the importance of CGRA. A genetic risk specialist will help identify not only your risk of HBOC, but your family's risk, as well. If necessary, you and your family can begin preventative measures to manage your risk or minimize your chances of getting HBOC.
6. I have too many other things to worry about other than CGRA *(I have too many other things to worry about other than cancer screening)*	We encourage you to talk to a healthcare professional about the importance of CGRA. A genetic risk specialist will help identify not only your risk of HBOC, but your family's risk, as well. If necessary, you and your family can begin preventative measures to manage your risk or minimize your chances of getting HBOC.
7. I am more concerned with taking care of other's health than my own health *(I am more concerned with taking care of other's health than my own health)*	CGRA will determine not only your risk of HBOC, but your family members' risk, as well. With this knowledge, you and your family can begin taking the necessary steps to prevent the development of HBOC.
<u>Transportation</u>	

1. I don't have transportation to get to a cancer genetic risk specialist *(Lack of transportation)*	We encourage you to utilize public transportation options or to find a friend or family member to drive you. It is possible to speak to a genetic risk specialist over the phone, as well. [list of local resources/organizations]
2. I would have to travel too far to see a genetic risk specialist *(Clinics are too far away)*	We encourage you to utilize public transportation options or to find a friend or family member to drive with you. It is possible to speak to a genetic risk specialist over the phone, as well. [list of local resources/organizations]
Cost / Insurance	
1. The cost of CGRA is too high *[Medical insurance coverage issues (no coverage or out of pocket cost is too high)]*	Understanding your risk of HBOC and taking the necessary preventative actions is much less expensive than treating cancer. In addition, most health insurances cover the cost of seeing a genetic risk specialist, especially for high risk individuals. CGRA is also available for free or at a lower cost for individuals that qualify.
2. My health insurance doesn't cover CGRA, or I am not sure if it does *[Medical insurance coverage issues (no coverage or out of pocket cost is too high)]*	We encourage you to call your insurance company to ask or to call a clinic to ask them for help in determining your coverage. Most insurance companies do cover the cost of seeing a genetic risk specialist. It is important to state that this service has been recommended to you due to your increased risk for HBOC. If it is not covered by your insurance, free or low cost CGRA is available for individuals who qualify.
3. I don't have health insurance *[Medical insurance coverage issues (no coverage or out of pocket cost is too high)]*	Free or low cost CGRA is available for individuals who qualify.
4. I am not in a financial position to get CGRA right now	Free or low cost CGRA is available for individuals who qualify.

Health	
1. I have a disability or health condition that makes daily activities difficult *(Disability makes it difficult to carry out daily activities)*	We encourage you to schedule your CGRA at a time that you'd be most comfortable, and perhaps find a friend or family member to take you to your appointment. You may also want to call a genetic risk specialist to determine if their clinic has accommodations available to make your visit easier and more comfortable.
2. I'm feeling too sick from cancer treatments *(Feeling sick from cancer treatments)*	We encourage you to schedule your CGRA at a time that you'd be most comfortable, and perhaps find a friend or family member to take you to your appointment.
3. I believe I am healthy so CGRA is unnecessary	Even though it's wonderful that you are healthy now, you have been identified as being at increased risk for HBOC. Understanding you and your family's risk for this disease now allows you to begin preventative measures, if necessary.
4. I'm not at risk for HBOC	Based on several factors, you have already been identified as being at high risk for HCOB. Speaking to a genetic risk specialist will help you learn more about the risk you and your family have of developing HBOC.
5. I don't have any symptoms of HBOC	A genetic risk specialist will help you understand you and your family's risk of developing HBOC, and will allow you take the necessary preventative measures.
6. I already had/have cancer, so I don't need CGRA	Hereditary cancers can lead to the development of second cancers or other types of cancers. Speaking to a genetic risk specialist will help you understand you and your family's risk of HBOC, and will provide you with preventive measures you can take.

7. I'm too young for CGRA	One of the risk factors of hereditary cancers is being diagnosed at a young age. In addition, it is important to understand your risk for HBOC now to begin prevention measures, if necessary.
8. I'm too old for CGRA	Hereditary cancers can affect people of any age. In addition, a genetic risk specialist can identify your family members' risk of inheriting HBOC.
Worry	
1. I am worried that the results will be used against me by health insurance companies *[Worried a genetic test could be used against me (i.e. by an employer or for future health insurance, etc.)]*	The Genetic Information Non-discrimination Act of 2008 prevents health insurance companies from using your genetic information to determine your eligibility, coverage, and how much you pay.
2. I am worried that the results will be used against me by employers *[Worried a genetic test could be used against me (i.e. by an employer or for future health insurance, etc.)]*	The Genetic Information Non-discrimination Act of 2008 prevents employers from using your genetic information in decisions concerning hiring, firing, promotion, or salary, nor are they allowed to mistreat you in any way.
3. I'm nervous/anxious about the possible results *[Too nervous (i.e. I don't want to know the risk of inherited cancer)]*	Understanding your risk and your family's risk of HBOC will help you take the preventative measures to manage your risk or minimize your chances of developing cancer, if necessary. Genetic risk specialists are also available for support, both in learning the results and in deciding what steps to take next.
4. "I am afraid of being alienated if my results are positive for a mutation..." Stigma (fear of being stigmatized)	You are not alone. Familial cancer affects many families and there are a variety of support resources that might be helpful for you in coping with familial cancer risk. Psychosocial counseling available Provide list of resources of support

Family	
1. My family does not want me to get CGRA *(Family members would not want me to go)*	We encourage you to talk to your family members about the importance of speaking to a genetic risk specialist. By understanding both you and your family's risk of HBOC, you can begin the preventative measures to reduce your chances of developing cancer, if necessary.
2. I don't need to worry about my risk for HBOC because I only have sons	Breast cancer can affect both women and men, and even if your sons or brothers never develop cancer, they could end up passing it on to their children in the future. HBOC also puts you at a higher risk for developing a second cancer or another type of cancer.
3. Because I am the first one in my family to be diagnosed with breast cancer, I do not believe my cancer is hereditary	Even if you are the first member of your family to be diagnosed, this does not necessarily mean you are not at risk for familial cancer. Your family size may be too small or there may not be enough women to rule out the possibility of hereditary breast and ovarian cancer, or you may be the first member of your family to develop the genetic change. CGRA will help you determine if you are at risk for HBOC and will help you take the next steps in managing your risk, if necessary.
4. I am worried that my test results will negatively impact my children, or other family members. Worried that test results will negatively impact children, other family members (siblings, nieces/nephews, etc.)	Similar to your own genetic information, family history of genetic information of the family is also protected by law. The Genetic Information Non-discrimination Act of 2008 prevents the misuse of genetic information, which includes the results of genetic testing of family members.
Cultural Concerns / Personal Beliefs	

1. My culture and/or religious beliefs do not support genetic testing *(Cultural and/or religious beliefs do not support genetic testing)*	While we respect your beliefs, it is important to understand the CGRA does not involve genetic testing. Rather, CGRA is simply to help you understand you and your family's risk of HBOC and what preventative measures you can take, if necessary.
2. I have trouble understanding English	We encourage you to check whether a translator may be provided for you during your appointment.
3. Citizenship status concerns (undocumented patients)	You are not required to disclose your citizenship status to receive CGRA, just as your citizenship status is not necessary for your cancer treatment. There may also be free or low-cost genetic testing program that you can apply for, regardless of your citizenship status.
4. I believe that if I am at risk of HBOC, there is nothing I can do to change it *(One cannot do much to lower his or her chances of getting cancer)*	Just because someone has inherited a mutated gene does not mean they are guaranteed to develop cancer. CGRA will help you understand your risk for HBOC and the preventative measures you can take to manage your risk or minimize your chances of developing cancer.
5. I don't think that knowing my risk will help prevent HBOC *(One cannot do much to lower his or her chances of getting a second cancer)*	By knowing your level of risk, there are a number of preventative measures that can be taken, by both you and your family members, in order to manage your risk or minimize your chances of developing HBOC.
6. Thinking about cancer makes one automatically think about death *(Thinking about cancer makes one automatically think about death)*	Just because someone has inherited a mutated gene does not mean they are guaranteed to have cancer. CGRA will help you understand your risk for HBOC and the preventative measures you can take to manage your risk or minimize your chances of developing cancer.
7. I don't feel comfortable talking to a genetic risk specialist alone	Perhaps a family member or close friend would be available to be with you during your

	appointment with a genetic risk specialist.
8. "I don't trust medical providers…" Medical mistrust Perceived discrimination/mistreatment e.g. fear of information abuse or lack of confidentiality	We encourage you to call a local genetic risk specialist to learn more about what will be discussed and uncovered during a session. Genetic risk specialists are here to help you determine you and your family's risk for HBOC and provide direction for what steps you can take to manage your risk. Everything discussed is entirely confidential and, by law, cannot be used against you by health insurance companies or employers.
9. Perceived disadvantages of CGRA/No perceived advantages of CGRA This is general, but if negative perspectives/attitudes are present, it could be a barrier	We encourage you to call a local genetic risk specialist for more information concerning the advantages of CGRA. Genetic risk specialists are here to help you determine you and your family's risk for HBOC and provide direction for what steps you can take to manage your risk.
<u>Education / Knowledge</u>	
1. I didn't know that CGRA services existed *(Did not know they existed)*	CGRA is a conversation with a genetic risk specialist. Through this conversation, the genetic risk specialist will determine if you are at risk for having HBOC and help you decide what to do next. If you have any further questions, we encourage you to speak to your health care provider or call a genetic risk specialist near you. [list of local resources/organizations]
2. I don't know where I can seek CGRA services	We encourage you to talk to your health care provider about a referral, or you can call a genetic risk specialist near you. [list of local resources/organizations]
3. I still don't understand what CGRA is	CGRA is a conversation with a genetic risk specialist. Through this conversation, the genetic risk specialist will explain factors that may or may not put you at higher risk of

	HBOC. They will help you decide what to do next. If you have any further questions, we encourage you to speak to your health care provider or call a genetic risk specialist near you. [list of local resources/organizations]