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A Primary Care-Focused, Computer-based Clinical Decision Support Tool to Assess Patients' Risk for Deleterious *BRCA* Mutations

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Research from the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network

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The DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) network is part of AHRQ's Effective Health Care Program. It is a collaborative network of research centers that support the rapid development of new scientific information and analytic tools. The DEcIDE network assists health care providers, patients, and policymakers seeking unbiased information about the outcomes, clinical effectiveness, safety, and appropriateness of health care items and services, particularly prescription medications and medical devices.

This report is based on research conducted by the RTI International DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. HHSA 290-2005-0036-I). The AHRQ Task Order Officer for this project was Gurvaneet Randhawa, M.D.

None of the investigators has any affiliations or financial involvement that conflicts with the materials presented in this report.

The BRCA clinical decision support tool has not undergone a large-scale clinical evaluation. Its ability to protect patient data from Web-based security breach needs to be evaluated. Hence, this first version of the tool is not available for download since it is not considered ready for clinical use. It is available to researchers, upon request, for further evaluation and modification. Individuals who wish to obtain a CD of the tool for evaluation should contact AHRQ program staff using the following email: ProjectManagerCE@ahrq.hhs.gov.

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Contents

Figures

Tables

Appendixes

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Chapter 1. Background

This report summarizes the work completed for the project Computer-based Clinical Decision Support (CDS) Tools for Gene-based Tests Used in Breast Cancer, funded by the Agency for Healthcare Research and Quality (AHRQ) under contract HHSA290-2005-0036-I (Task Order 8). For this project, AHRQ asked for the development and testing of two CDS tools for gene-based tests in breast cancer.

AHRQ envisioned one tool that could be used to screen for risk of *BRCA* mutations in primary care settings and assist in the implementation of the U.S. Preventive Services Task Force (USPSTF) recommendations regarding referrals for genetic counseling and evaluation for *BRCA*1 and *BRCA*2 genes.

The USPSTF recommended in 2005 that physicians refer women who have a family history consistent with hereditary breast and ovarian cancer syndrome (HBOC) for genetic counseling and possible testing. The recommendations are as follows:

> The U.S. Preventive Services Task Force (USPSTF) recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2).
> Grade: D Recommendation.
>
> The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.
> Grade: B Recommendation.

The second tool was to support shared decisionmaking around the use of gene expression profiling (GEP) tests (such as Oncotype DX) used in oncology care for women newly diagnosed with breast cancer (these are recently developed tests with some uncertainty on their proper use). During the initial stages of the project, a large number of information gaps were identified, more so for the GEP tool. Hence, given the resources and timeline, AHRQ focused this project on the *BRCA* tool. The process for developing and testing the *BRCA* tool are detailed in this report. A preliminary workplan can be found in Appendix A.[1]

Purpose of the *BRCA* Tool. HBOC is a familial form of breast and/or ovarian cancer that is inherited as an autosomal dominant condition. In over 90 percent of families who present with both breast and ovarian cancer and 40 percent of those who present with breast cancer alone, the syndrome is the result of a mutation in the *BRCA*1 or *BRCA*2 gene. Women who have a mutation in these genes have up to an 85 percent lifetime risk of breast cancer. The tumors of *BRCA*1 mutation carriers are more likely to be high-grade, estrogen-receptor negative and fatal than those of women without a family history of cancer and are less likely to be associated with survival. Genetic testing for HBOC has been available for several years, and studies have shown that prophylactic measures are effective.

To inform the design and development of the tool we named *Cancer in the Family*, our project team completed the following activities:

- conducted a literature review,

[1] The results of the feasibility assessment with IT specialists at oncology sites are included in Appendix F, which also details findings from the feasibility assessment with IT specialists at primary care sites for the *BRCA* tool.

- obtained input and guidance from our technical expert panel (TEP) members,
- conducted a needs assessment with primary care providers, and
- conducted a feasibility assessment with IT professionals at primary care sites that would be involved in the study.

This report provides an overview of the results of these planning activities and also describes the approach that was used to develop the tool's interface and software. The tool went through a variety of different types of testing, including

- cognitive testing of the educational content for the patient tool,
- internal review by RTI experts,
- usability testing with both patients and providers, and
- 508 compliance testing.

In addition, the tool was field tested with primary care providers and their patients at three primary care settings. Results of this preliminary evaluation are included in this report.

Organization of the Report. This report contains five chapters. Chapter 1, Background, describes the goals and objectives for the tool, findings from our literature review, recommendations from our TEP, results from our needs assessment with physicians, and results from our IT feasibility assessment. Chapter 2, Tool Development, describe the process we used to develop the patient and provider interfaces and provides screenshots of the final tool. In this chapter, results from our cognitive testing of the patient content are presented, as well as results from usability testing with both patients and providers. Chapter 3, Evaluation, provides an overview of our evaluation plan, which includes three types of evaluation: implementation evaluation, outcome evaluation, and a pilot test of evaluation methods and tools. Chapter 4 describes the My Family Health Portrait, the Surgeon General's family history tool, and Chapter 5 summarizes the project and provides recommendations for future development and evaluation of the tool. In addition, appendixes provide our original workplan, the literature review, the list of TEP members and their recommendations, and reports on the results from formative research (e.g., the physician needs and IT feasibility assessments; cognitive testing, usability testing, and results from the accuracy testing we conducted using the BRCAPRO algorithm). We also provide detailed technical documentation of the tool. Finally, our appendices contain our evaluation protocol, surveys, and materials we used to train the evaluation site coordinators and providers who participated in the evaluation.

Goals and Objectives

The goal of the *BRCA*1/2 tool is to facilitate appropriate referral of women for genetic counseling who are at increased risk of having a *BRCA* mutation, as calculated by their family's history of breast and ovarian cancer. The long-term objective is to have a tool that is available to and adopted by clinicians for use in real-time decisionmaking at the point of care and that results in routine screening of women being seen in primary care settings for risk of having a *BRCA* mutation. The tool has the following 10 objectives:

1. Provide patients with a user-friendly computerized tool to record detailed cancer family history data.

2. Empirically assess patients' risk of having a clinically significant *BRCA*1 or *BRCA*2 mutation using cancer family history data and an algorithm accurate for a primary care population.
3. Educate patients about hereditary breast and ovarian cancer, its risks, genetic counseling/testing, and cancer surveillance practices.
4. Encourage women to share their family cancer history and risk with their providers.
5. Educate patients about how to talk to their doctor about their risk for *BRCA* mutations.
6. Support patients' exploration of their values and preferences for involvement in decisionmaking about genetic risk assessment, counseling, and testing.
7. Present providers with patients' risk assessment results and guidelines for referring patients who are at increased risk to a genetic counselor.
8. Offer providers guidance on educating patients about their risk and choice of next steps (e.g., seeing a genetic counselor, regular cancer screenings). Facilitate patient–provider communication about patients' values and preference for involvement in decisionmaking about genetic risk assessment, counseling, and testing.
9. Adhere to all current relevant U.S. Department of Health and Human Services (HHS) requirements, such as compliance with Section 508 of the Americans with Disabilities Act to allow access to disabled persons.
10. Be flexible to allow easy incorporation of new clinical or software knowledge; easy to maintain; capable of working on different IT platforms, systems, and architecture; adaptable to allow different user interfaces and outputs; and easy to modify.

The tool seeks to equip clinicians with the knowledge and skills to effectively and efficiently screen primary care patients and use the U.S. Preventive Services Task Force guidelines to appropriately refer patients for genetic testing based on risk levels. The long-term vision for the tool is to promote and facilitate physicians' adoption of a new practice in primary care: screening for *BRCA*1/2 mutations.

Planning

At the beginning of the project, we reviewed family history collection tools to determine if an existing tool would fit our needs. Our review is included in the workplan (see Appendix A).

We found and reviewed six Web-based and three paper-based tools that were available for collecting family history of cancer. None of the tools were designed for use by both the patient and provider. Instead, they were designed for information to be collected by the patient and brought to an appointment with a physician or other health care provider for discussion. MyGenerations, an online tool designed for patients, provided a personalized risk assessment. A more detailed review of these tools can be found in Appendix A, Section 2.3.

Literature Review

We conducted a literature review to inform the development of the decision aid. The literature review addressed these key questions about CDS tools:

- Are CDS tools effective and how has their effectiveness been assessed?
- What features and functions of a clinical decision tool affect the likelihood that it will be incorporated into routine clinical practice, affect clinic workflow, or affect patient use?

Key questions that guided our review of *BRCA* CDS tools include the following:

1. What family history is needed to classify the likelihood a woman carries a *BRCA*1/2 mutation? Can patients report the needed family history of information? What are the current practices regarding family history collection and pre-cancer identification of *BRCA* mutation carriers? What tools exist to improve family history collection, and how well do they perform?
2. How do we calculate a woman's risk for carrying a *BRCA*1/2 mutation given her family history? What are the screening guidelines from national professional organizations? What risk assessment tools exist for *BRCA* mutations? Which measures are used to assess how the risk assessment tools perform?
3. What information about breast cancer and familial risks should be included in the patient education module of the tool, and how should the information be presented? What do women know about HBOC genetics? What is a woman's understanding of the information provided by the *BRCA* test and her overall perception of cancer risk? What are the issues related to the testing process and results? Are there alternatives to genetic testing?
4. What educational materials on *BRCA*1/2 testing have been developed?
5. What information needs to be included in the followup recommendations for physicians?
6. How good is current communication between patients and providers about genetic risks for breast cancer?
7. What health and psychological outcomes of genetic testing for *BRCA*1/2 mutations have been assessed?
8. How satisfied are patients and providers with patient decisions about *BRCA*1/2 testing?

The complete literature review can be found in Appendix B. Findings from the literature review were used to identify the key characteristics and objectives of our tool.

The literature and practical considerations guided our selection of the BRCAPRO algorithm to assess the risk of having a *BRCA* mutation. The published literature comparing different risk algorithms did not show any single algorithm to perform better than others in all relevant situations. We used BRCAPRO because it performed at least as well as other algorithms; it was developed using U.S. populations to which our tool was targeted, it was freely available, and the developers were willing to assist in adapting it to a primary care population if needed.

Findings from the literature review also guided our selection of evaluation outcomes, the presentation of risk, and key themes required in the educational content. The literature review also contributed to our understanding of providers' information needs around *BRCA* screening and testing.

Technical Expert Panel

We recruited a TEP to advise us on developing the *Cancer in the Family* tool. A list of the TEP members and peer reviewers can be found in Appendix C. We sought input from the TEP in three stages. First, prior to beginning the full literature review, we summarized the information obtained from the relevant evidence-based reviews, the remaining gaps in information needed to develop the tools, and our suggested search terms to fill the identified gaps. We sent this summary to the TEP and our consultants and asked them to review the summary and comment on any information they felt was incorrect, unidentified gaps in

information, and the suggested search terms. These comments were incorporated into the literature search and into the full literature review. Second, we sent the draft literature review to the TEP members and asked them to review sections in which they had expertise and to provide written comments. Third, we scheduled a conference call with the TEP to discuss the literature review and to provide input on specific questions regarding the development of the decision aid. We also shared our draft workplan with the TEP. Their suggestions regarding the tool are summarized below and notes from the TEP conference calls can be found in Appendix D.

TEP Recommendations on Tool Development

The main areas for which the TEP provided recommendations were related to understanding providers' needs, barriers to implementation, patient–provider communication, and integration into the electronic medical record (EMR). Findings from the TEP were used to guide our tool design efforts.

Understanding Providers' Needs. The TEP remarked that providers needed to understand the needs for the tools, how to interpret and discuss the results of the tools, and the use of information in patient care. The TEP recommended we conduct patient and provider focus groups to gather information relevant to the features, design, and content of the tool; however, this type of formative research was not included in the scope of work for this project.

Barriers to Implementation. The TEP described potential barriers to CDS implementation in primary care practices and privacy and security issues, especially with regard to incorporating the CDS information into EMR systems. These issues are discussed in more detail below.

The TEP felt that the *BRCA* tools needed to explain to the providers the goals and function of the tools and the reasons for *BRCA* testing. The TEP felt the tools would need to explicitly inform the provider of when a patient had a cancer family history that put her at risk; how to interpret the information, especially the risk estimates; and how to use the information for patient care. The TEP and AHRQ identified a need for more discussion of the benefits and risks of available preventive measures for women with hereditary breast cancer. The TEP also felt that it was important to address situations where women may have a family history consistent with hereditary breast cancer, yet the affected family members may not have a *BRCA* mutation.

Another concern was how to advise women whose family history was not consistent with hereditary breast and ovarian cancer but who had a more significant number of family members with cancer than would be expected. This challenge is complicated by the lack of clinical guidelines for followup for women whose risk appears to be increased based on family history, but whose family history is not consistent with a known hereditary cancer syndrome. The lack of clear followup action in this situation can be a barrier to tool implementation. Providers can fear liability when information is collected on sensitive issues, but there is no clear action or recommendation to be made, and they can feel they have failed the patient if the family history risks recorded in a patient's record have not been addressed.

The primary barriers to implementing the tools into primary care practices were felt to be the lack of adequate time to collect family history, difficulty in communicating risk information, and privacy and liability issues. Collecting an adequate family history for hereditary cancer risk assessment takes about 30 minutes, far more time than is available in a primary care visit, suggesting it will probably be necessary to collect the information outside of the visit.

Patient–Provider Communication. Given the task of screening for *BRCA* mutations in primary care, a variety of different communication challenges exist. The TEP suggested that providers need help not only in understanding risk information themselves, but also in communicating that information to their patients. The TEP suggested that patients' understanding of risk and preferred messages about health risks differ. Providers will need to tailor messages to patients based on risk status and level of knowledge and understanding of HBOC. The tool could help providers by providing resources, such as built-in prompts for providers to check patients' understanding and to help them assess patients' knowledge and information needs. The TEP recommended that the tool provide a template suggesting how providers present risk information to their patients. The template could be tailored by the clinician during the visit based on the individual patient and circumstances.

The TEP felt communication would be more thorough if patients and providers could exchange some information before the visit. Patients could be prompted to complete their family history, and the provider could review it prior to the appointment. This process would require electronic sharing and storage of information, which raises patient confidentiality and privacy issues and is logistically challenging.

Integration into Electronic Medical Records. The TEP provided input on the feasibility of building the *BRCA* tools to allow incorporation into existing EMRs and confirmed that the tool will probably need to be developed as a standalone tool. EMRs are becoming more widespread, but many providers are still not using them.

Primary Care Physician Needs Assessment

To ensure that the tool addressed the educational and clinical needs of primary care providers, we conducted a needs assessment. Our goals were to explore physicians' current use of decision support tools, current family history collection practices, experience referring patients to genetic counselors, and opinions about patient tool usage. Findings from the needs assessment informed tool development, including workflow, accessibility, and tool features.

The needs assessment comprised 60-minute telephone interviews with primary care physicians (n = 5) employed at the clinics targeted for pilot testing the tool. One interviewer and one dedicated notetaker conducted the interviews using a semistructured interview guide. Once interviews were completed, we assembled responses into a meta-matrix, which displayed participant responses by question and identified trends across respondents.

Key findings from the needs assessment are noted below.

Knowledge of BRCA Mutations, Genetic Testing, and Related Issues

- Interviewees are skeptical of the need for *BRCA* assessment, especially given its rarity. Some are also skeptical of breast cancer screening given its relatively low incidence.
- Interviewees are unfamiliar with *BRCA* screening criteria and USPSTF recommendations. They are unsure when to recommend *BRCA* screening.
- Interviewees are unfamiliar with the genetic counseling and testing referral process. Many are unsure how to locate a genetic counselor and would refer patients to a breast specialist (oncologist) for *BRCA* followup.
- Whether insurance carriers cover the costs of genetic testing and genetic discrimination are seen as barriers.
- Interviewees are unsure how to interpret BRCAPRO risk results and want the tool to provide context.

- If a woman is high risk for a *BRCA* mutation, interviewees are unsure of the next steps and how to counsel patients.
- Patients have trouble distinguishing between *BRCA* mutation risk and cancer risk.
- Interviewees perceive women's inappropriate interest in *BRCA* screening as more common and pertinent than missed screening opportunities.

Family History Collection

- No standard protocol for collecting family history exists. Practices try to collect it at initial visit, then update annually. But no trigger events or reminder systems are in place.
- There is no standard set of family history questions. Some practices use disease-specific forms (e.g., cancer, diabetes); others ask open-ended questions (e.g., list family history of major illnesses).
- Interviewees perceived that patients need substantial time to collect and report an accurate family history. Many have difficulty correctly identifying relatives and types of cancer.
- Most interviewees are unaware of the elements of an appropriate family history.
- The time it takes for physicians to enter family history is perceived as a major barrier.
- Very few interviewees have used (or currently use) an electronic tool to collect family history.
- Family history is regularly captured in EMRs but often stored in open-text fields. Thus, the history is not structured or searchable.
- Despite barriers, physicians believe cancer family history needed for calculating risk of having a *BRCA* mutation has intrinsic value if accurate and timely.

IT Access/Usability

- Interviewees' computer preferences vary. Some interviewees prefer to access computers or EMRs during the visit; others before or after the visit.
- Interviewees identified concerns about the tool, including time, accuracy, complexity, and ownership and maintenance of the tool.
- Privacy and security of patients' health information is a concern. Physicians want the tool to explain to patients how information is protected.
- Interviewees strongly desire a patient-driven tool to minimize physician burden.
- Interviewees expressed concern about patients having access to the Internet and patients' perceptions about whether their information would be kept private. Interviewees also expressed interest in having a Spanish version of the tool and having the reading level of the tool be at the fourth grade or below.

A full report of these findings is included as Appendix E.

Health IT Feasibility Assessment

Prior to tool development, we also conducted an IT feasibility assessment with primary care sites. Our goal was to understand the IT infrastructure of primary care clinics, including operating systems, Internet access, use of EMRs, and physician and patient use of technology. These findings ensured that we developed a tool that was compatible with the sites' technology.

The feasibility assessment comprised 60-minute telephone interviews with IT professionals and informatics experts (n = 3) at the clinics targeted for tool pilot testing. One interviewer and one dedicated notetaker conducted the interviews using a semistructured

interview guide. Once interviews were completed, we assembled responses into a meta-matrix, which displayed participant responses by question and identified trends across respondents.

Major findings from the feasibility assessment are outlined below.

Technology Access and Usability

- Practices have email addresses for fewer than 30 percent of patients, making email connectivity and reminders impractical.
- Navigation and ease of use are critical to patient usage. Some patients have limited experience with computers, limited education, and limited health literacy.
- Computers are available to physicians in every exam room and are connected to the Internet and EMR systems.

Operating Systems and Internet Access

- Practices have restricted access to many outside Web sites (especially those with video).
- Most practices use Windows and Internet Explorer platforms.

Electronic Medical Records (EMRs)

- EMRs cannot be linked to outside tools or systems to protect patient privacy without arduous review and approval.
- Tool–EMR integration is strongly desired by physicians, who want to document patients' *BRCA* risk results within existing medical records.
- Patients cannot access their EMRs to view results or enter/update family history.
- Test results and tool output cannot be sent directly to EMRs. However, staff can manually scan or save visual files into the system.
- Physicians and practices are adverse to the time/cost of maintaining a tool themselves.

These comments reflect challenges for practices that already have functional EMRs. It is important to recognize that many practices have still not adopted EMRs, may have EMRs with limited functionality, or may not have the local informatics support. The full feasibility assessment report is included as Appendix F.

Integrating the *Cancer in the Family* Tool into EMRs

Integrating the tool into EMRs would likely increase utilization of the tool by providers. For providers who currently use EMRs, having a standalone tool that requires a separate login and does not directly transfer results to the EMR may be perceived as cumbersome. Having the tool perceived as being a component of the EMR vs. separate from the EMR is likely to increase both its acceptance and adoption. Although these benefits are important, there are many obstacles to EMR integration.

Objectives for integration have to be clearly defined. If the purpose of integration is to provide a means for launching the tool, then for each specific EMR, it would require the assistance of the EMR vendor to customize the interface of the EMR for a specific practice. This is likely to meet with some resistance since this is not work that is universally applicable for the overall EMR and EMR customer base. However, vendors do customize EMRs for their clients but usually are only more willing to do so at the point of sale and less so after the fact.

As has been determined under other health information exchange-related contracts and grants funded by AHRQ, integrations are not one size fits all. Therefore, each integration would be a custom integration to accommodate the EMR, security configuration, and network configuration of the clinical environment. This is not a scalable model long term and thus would

benefit from the adoption of HIE standards being heavily promoted by AHRQ over the next several years. Experience has determined that EMR vendors presently are at various stages of embracing these standards and have system architectures that are more closed than open.

One significant obstacle to integration in the primary care environment is the deficiency of all current EMRs' ability to store family history information in a way that can be meaningfully used for purposes of preventive screenings and risk assessments such as the BRCAPRO risk calculation. Although some have the ability to discreetly store family history, the family history information is limited and does not provide the level of detail necessary to run a proper analysis. Thus, there is a heavy reliance on keying by the patient, which can fall outside the normal physician workflow. This leads to heavy abandonment rates by patients.

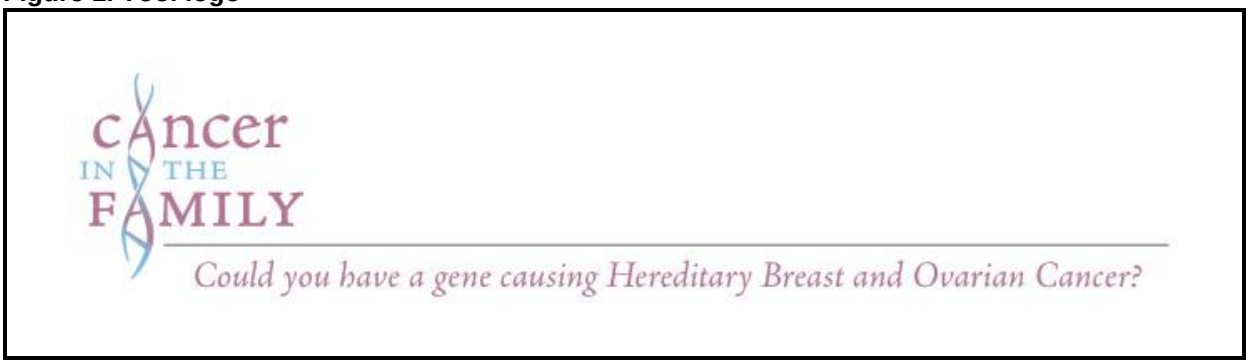
Additionally, once the family history information is captured, we have the capability of sending the information to the physician's EMR; however, because of the aforementioned limitations, storage of this information is relegated to nonpreferred areas such as those for miscellaneous data or scanned documents.

Given these obstacles, EMR integration was not attempted for this project.

Chapter 2. Tool Development

Results from the literature review, TEP meetings, provider needs assessment, and IT feasibility assessment were synthesized and used to design a Web-based tool to screen for *BRCA* mutation in primary care. The tool has both a patient interface and a provider interface. Prior to developing the tool, we developed a theoretical framework to guide our development and evaluation efforts. Chapter 3 of this report contains a detailed discussion of the framework. In addition, we developed a name and logo for the tool (see Figure 1).

Figure 1. Tool logo



Development of Patient Interface

The purpose of the *Cancer in the Family* patient interface is to educate patients about *BRCA* mutations and hereditary breast/ovarian cancer, guide them through the process of gathering family history and calculating their *BRCA* risk, help them interpret their risk result, and prepare them for discussing their risk with a primary care physician.

Development Process

The patient interface was developed in several phases. First, we reviewed results from the physician needs assessment to identify the features, processes, and outcomes they thought would be appropriate for the patient portion of the tool. Finally, we examined the findings of the IT feasibility study to determine what information is regularly captured in EMRs and whether the tool would be able to communicate automatically with clinic EMRs. Based on the findings from these efforts, we designed the tool to be self-navigated and patient driven, to allow physician viewing of patients' family history, and to produce a PDF summarizing each patient's risk result, which can be imported as an attachment into the EMRs at each site.

Next, we used the findings from the literature review and opinions from the TEP to identify key content areas and information that patients should know before and after calculating their *BRCA* risk. Based on these topic areas, we developed the educational content for the patient tool. (See next subsection for more detail.) We then organized the content around key patient tasks, such as deciding whether to learn one's risk, gathering and entering family history information, and preparing an action plan for discussing one's risk with a physician.

Finally, we segmented the content and tasks into the six sequential steps. Thus, the final interface provides a "soft navigation" that guides patients through the six steps yet still allows them the flexibility to explore other features and revisit tasks.

Patient Content Development and Testing

We developed two types of content for the patient interface—educational and instructional. This content helps women learn about hereditary cancer, *BRCA* mutations, and genetic testing and collect and document their family history.

The educational content revolved around the following themes:

- cancer causes and risks, including genetics,
- hereditary breast and ovarian cancer,
- gene mutations, including *BRCA* mutations,
- probability of having a *BRCA* gene mutation,
- probability of developing breast cancer (with and without a *BRCA* mutation),
- probability of developing ovarian cancer (with and without a *BRCA* mutation),
- pros and cons of genetic testing,
- role of a genetic counselor,
- meaning of one's risk result (increased risk vs. not increased risk), and
- recommended cancer screenings.

The instructional content included

- purpose and overview of the tool,
- steps for gathering family history,
- family tree creation,
- how to enter family history into the tool, and
- next steps after learning risk.

Content was adapted from credible existing sources, such as the National Cancer Institute, the American Cancer Society, the American College of Medical Genetics, and the National Society of Genetic Counselors. We tailored the wording for tone and consistency across the tool but did not alter any factual or statistical information.

We also included two separate decision points related to asking women if they wished to proceed with learning their risk of having a *BRCA* mutation. The first decision point asks women if they wish to use the tool to learn their personal risk of having a *BRCA* mutation; it occurs after they learn about *BRCA* mutations but before they enter their cancer family history. The second decision point asks women if they wish to calculate their risk; it occurs after they have entered their cancer family history into the tool. These points were designed to promote informed decisionmaking and to ensure that women understand the pros and cons of learning one's risk.

Once the content was finalized, we cognitively tested it with seven women for clarity and comprehension. We revised the content based on the cognitive testing findings. (See Appendix G for the cognitive testing report.)

Interface Description and Screenshots. The final patient interface is organized around the six sequential steps and incorporates the key educational and instructional content:

- **Introduction** to the tool
- **Step 1: Learn** about hereditary breast and ovarian cancer
- **Step 2: Decide** if you want to know your risk
- **Step 3: Gather** your family history of cancer
- **Step 4: Calculate** your risk

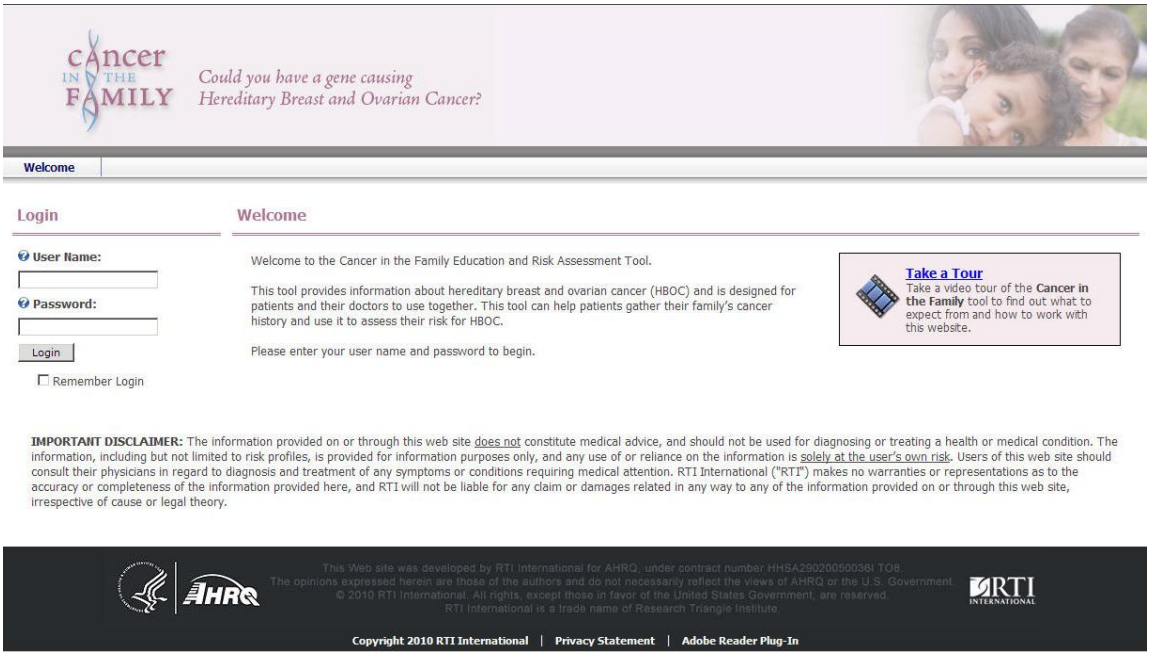
- **Step 5: Know** what your risk means
- **Step 6: Plan** for your clinic visit

The interface also includes a glossary of medical terms and a list of additional resources (e.g., AHRQ and NCI factsheets, USPSTF screening guidelines).

The patient interface ultimately produces one of two risk results—"Increased risk" or "Not at increased risk" of having a *BRCA* mutation. The names of these categories were based on cognitive testing with women.

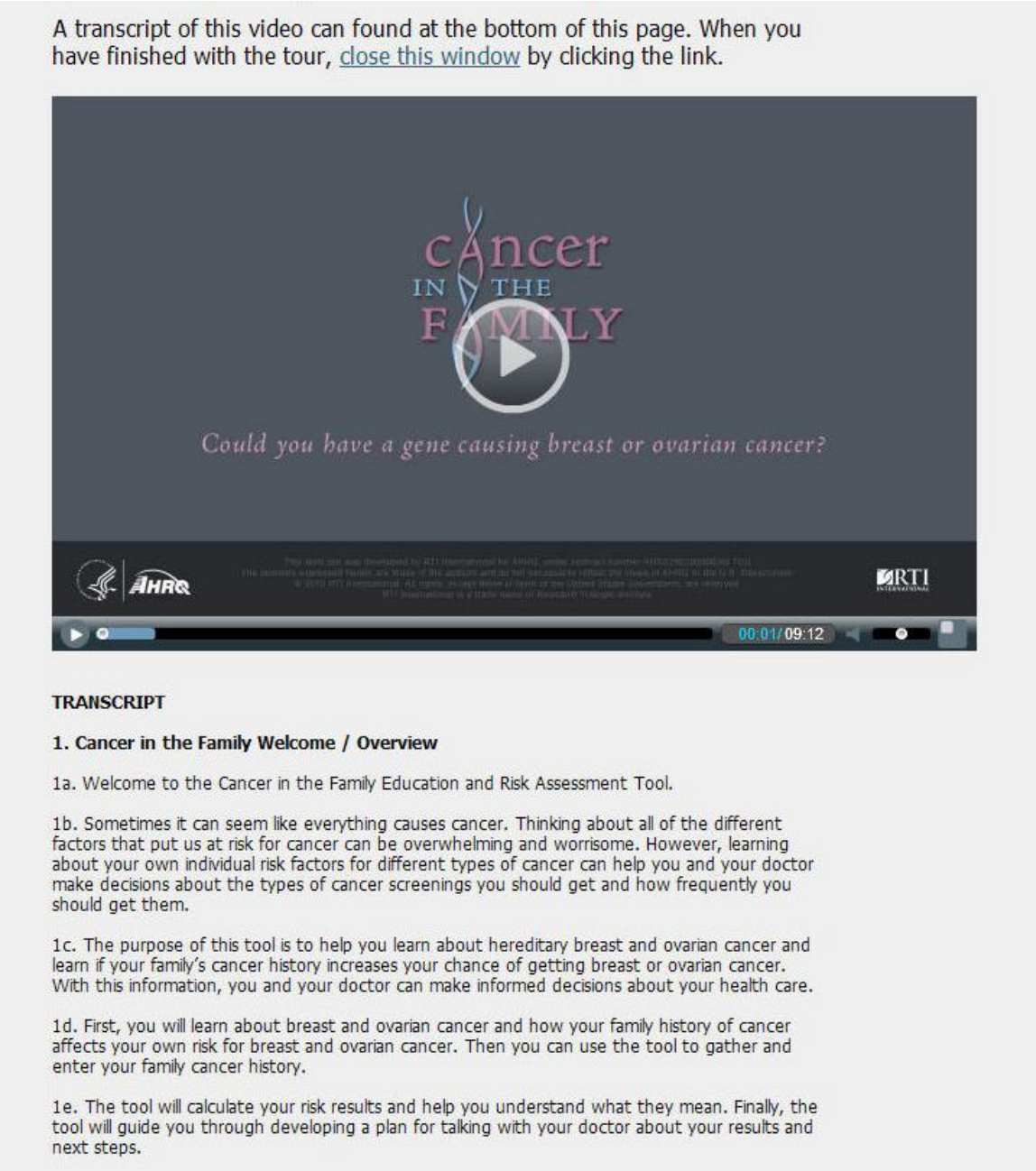
Figures 2–20 contain screenshots that highlight the essential sections and features of the interface.

Figure 2. Screenshot 1



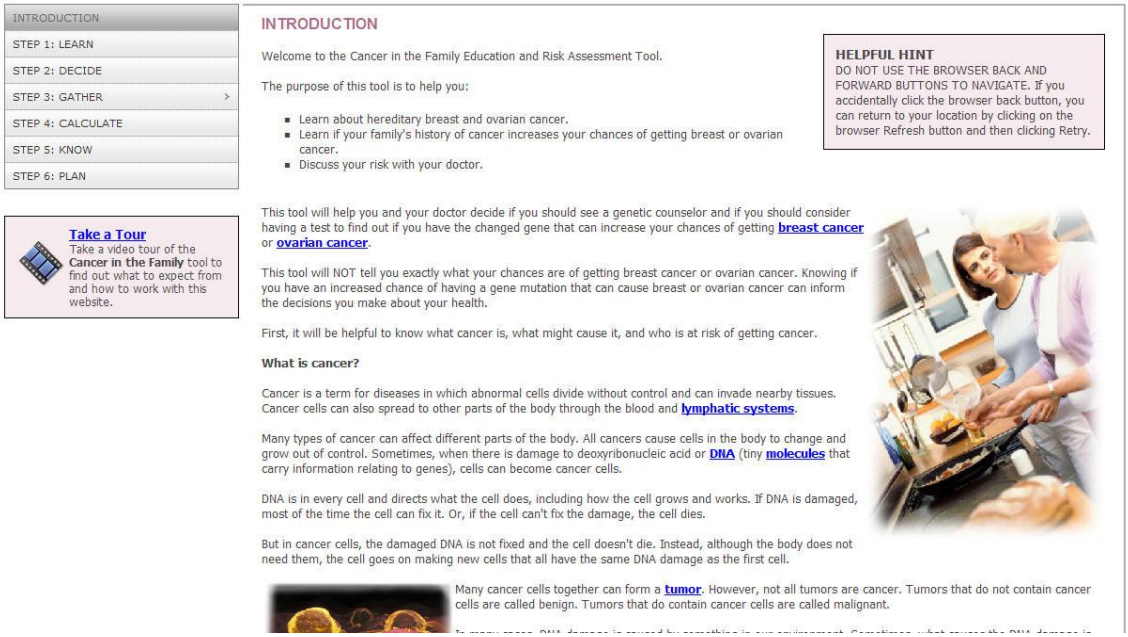
This is a screenshot of the login page for the tool. Patients are provided login and passwords by the study sites.

Figure 3. Screenshot 2



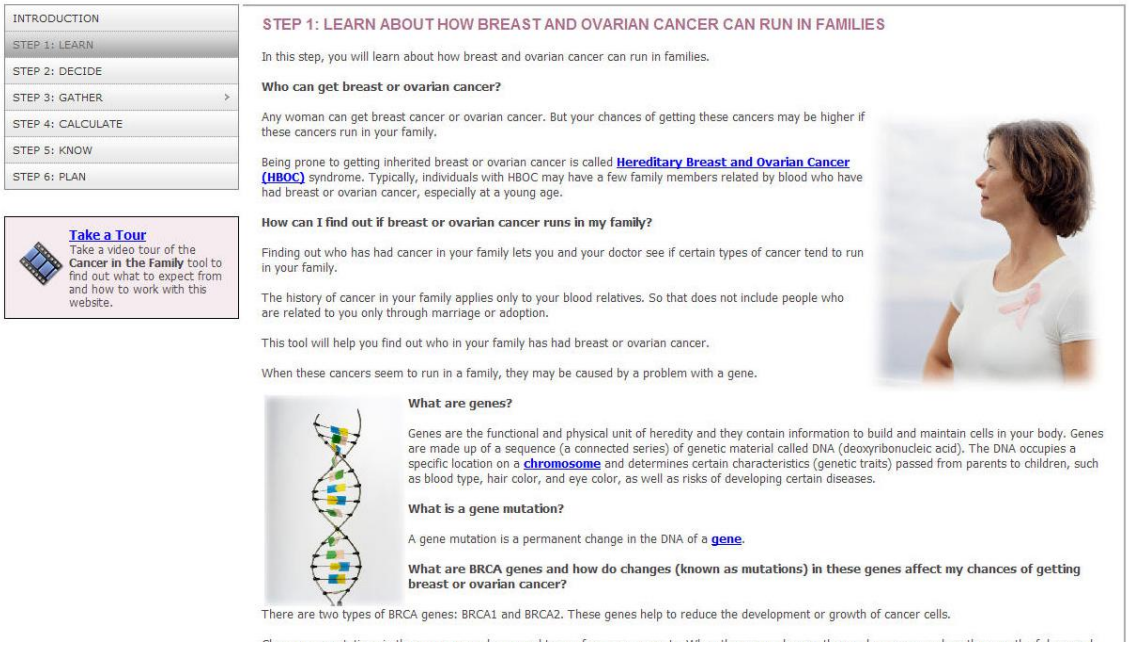
This is a screenshot of the Take a Tour video page that teaches users how to use the tool.

Figure 4. Screenshot 3



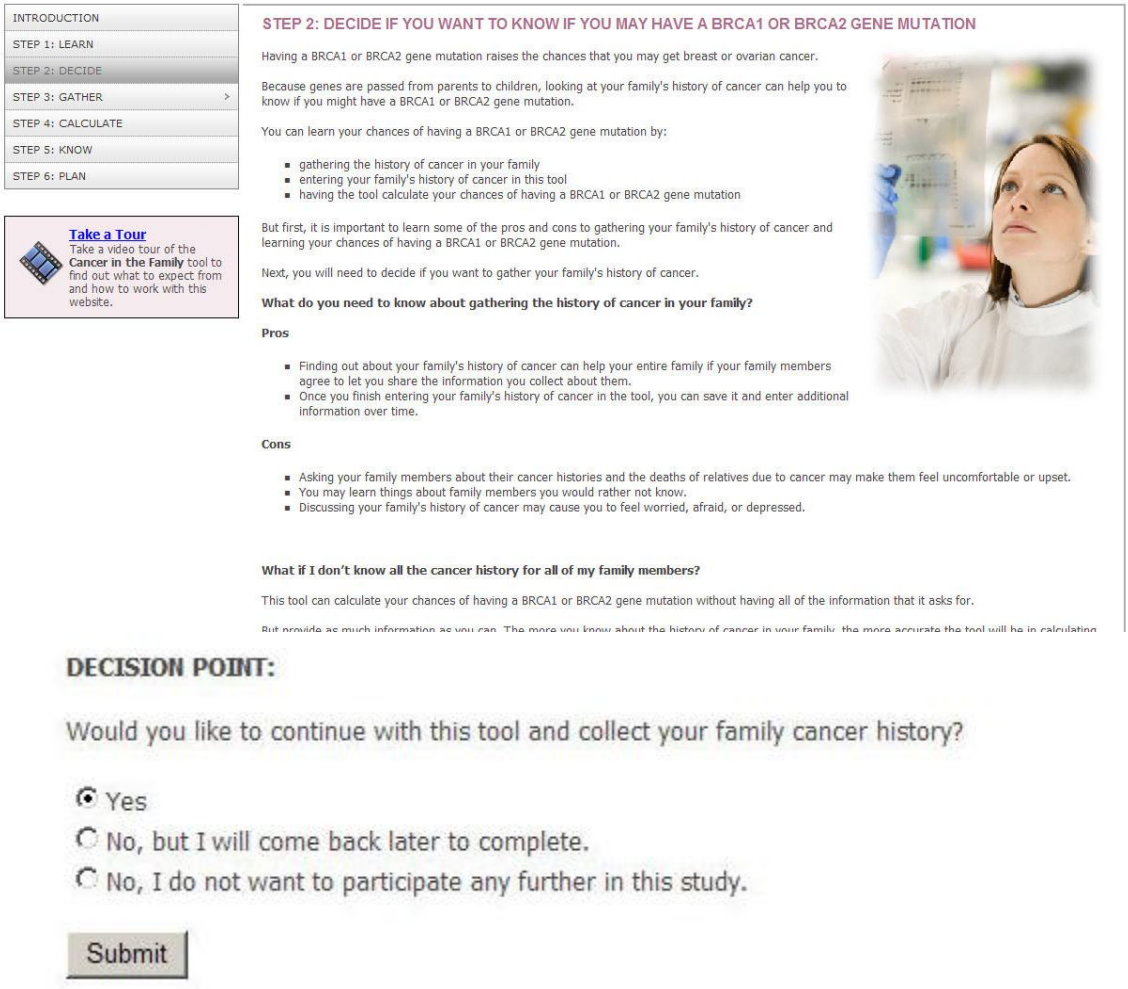
This is a screenshot of the Introduction page, which is the first page users see after logging in to the tool and which provides information on cancer.

Figure 5. Screenshot 4



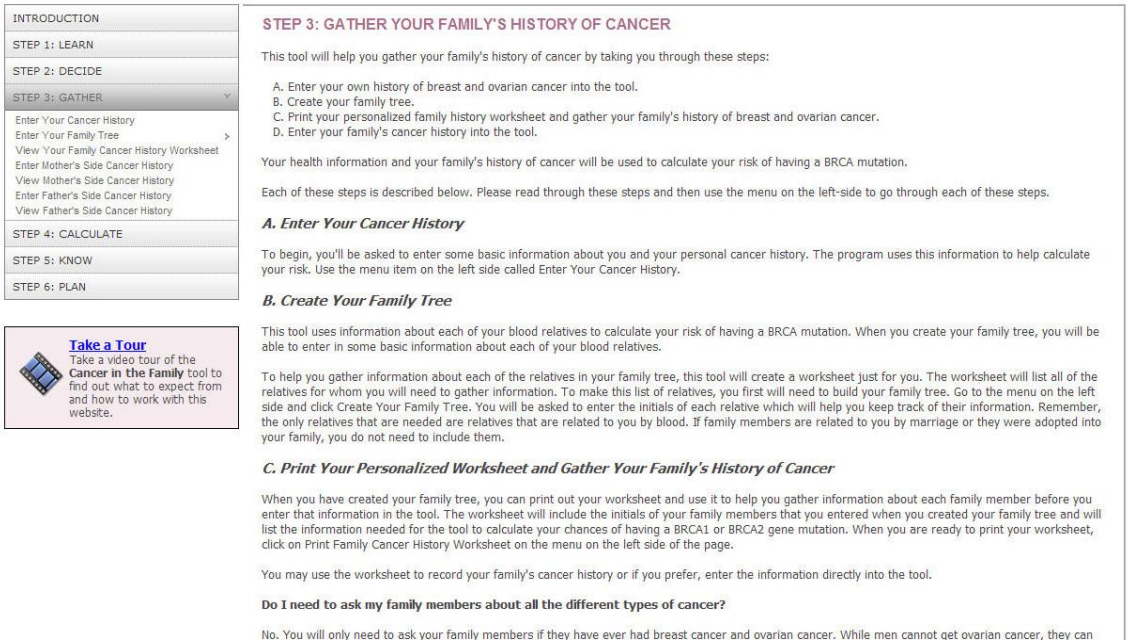
This is a screenshot of Step 1: Learn. The page provides background information on hereditary breast and ovarian cancer and *BRCA* genes.

Figure 6. Screenshot 5



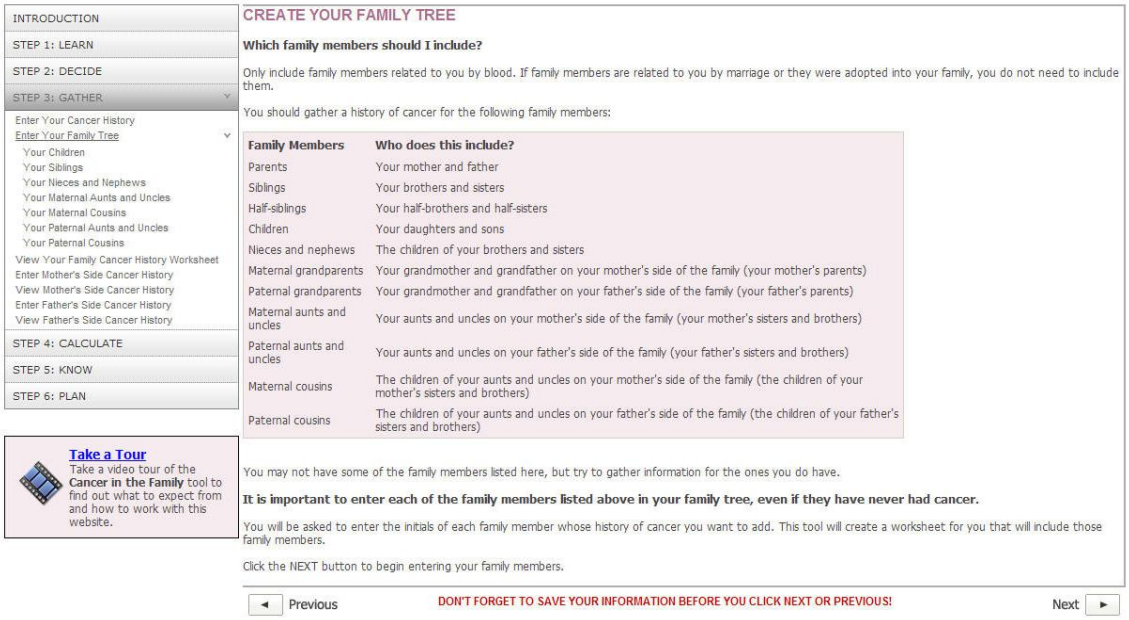
This is a screenshot of Step 2: Decide. This page discusses the pros and cons of gathering family history to learn one's risk of having a *BRCA* mutation.

Figure 7. Screenshot 6



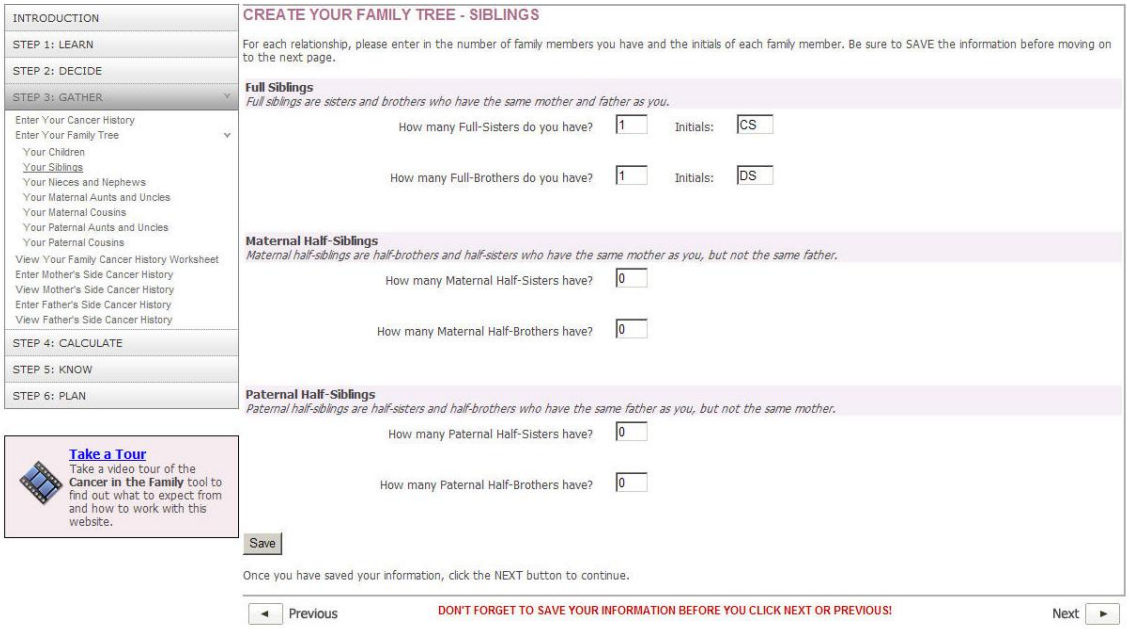
This is a screenshot of Step 3: Gather. This page describes the steps users need to take to use the tool to calculate their risk. They first enter their own cancer history. Next, they create their family tree and print a personalized worksheet they can use to record their family history when talking to relatives.

Figure 8. Screenshot 7



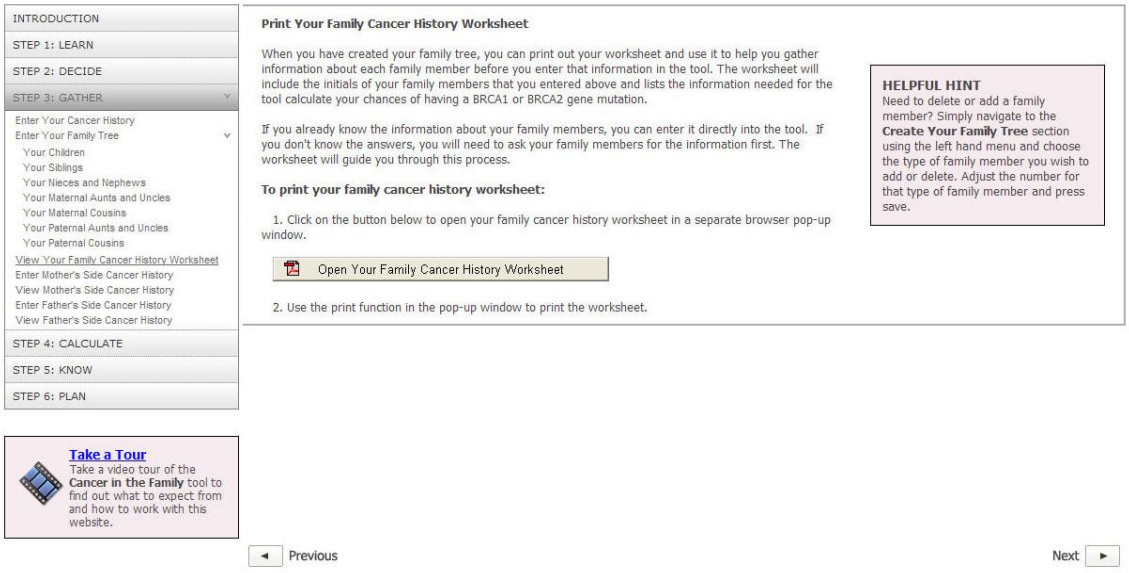
This is a screenshot of the page within Step 3 that defines which relatives should be included in the cancer family history.

Figure 9. Screenshot 8



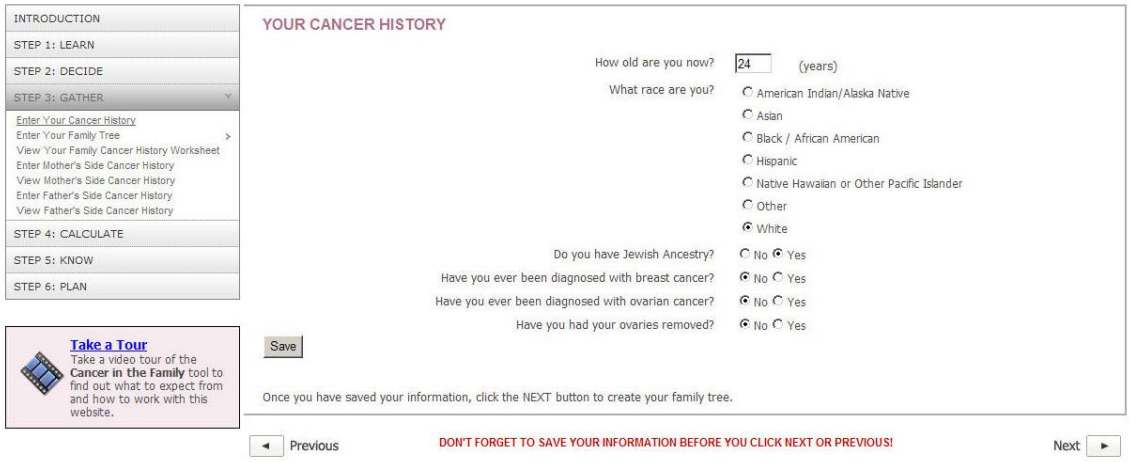
This is a screenshot of this page within Step 3 that shows how users enter their family history information.

Figure 10. Screenshot 9



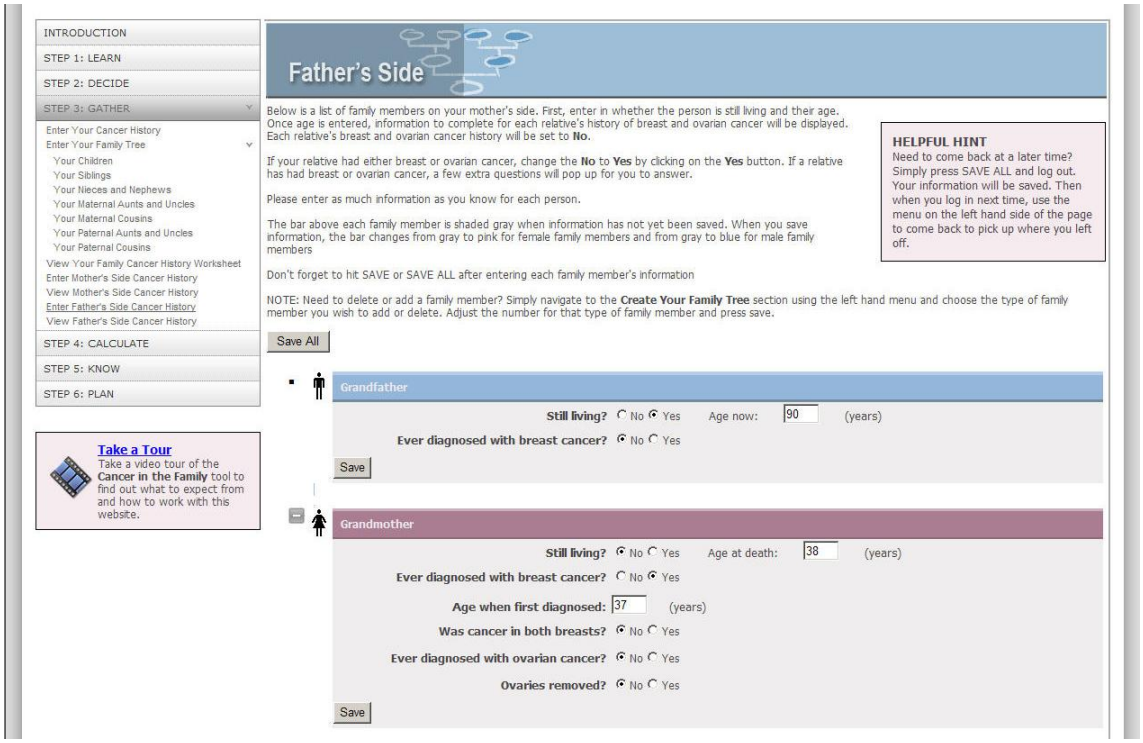
This is a screenshot of the page within Step 3 that allows users to print their personalized worksheet they can use to record their family history when talking with relatives.

Figure 11. Screenshot 10



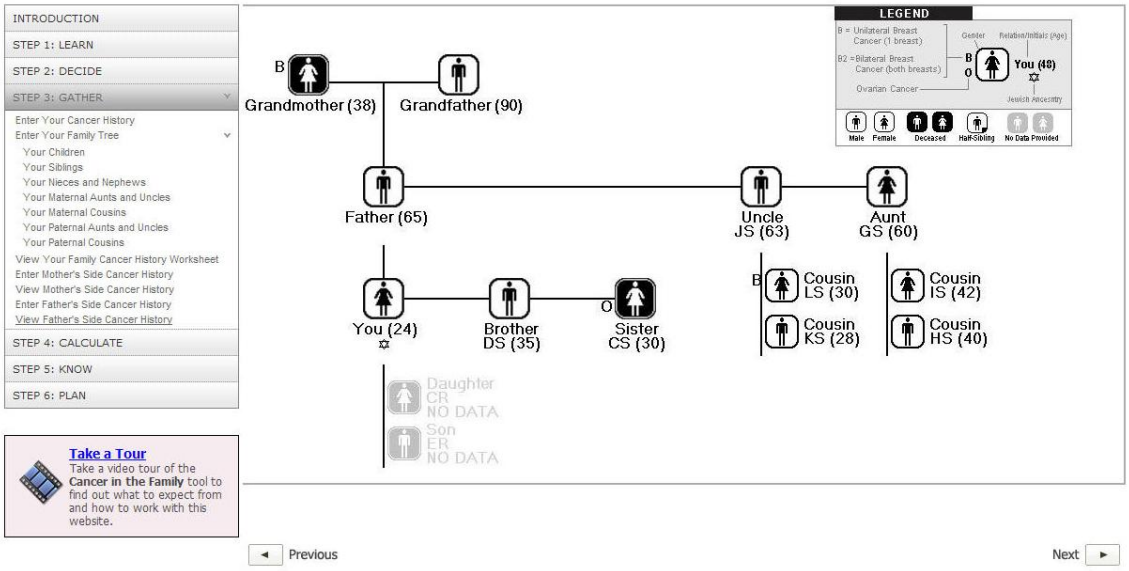
This is a screenshot of where the user enters her own cancer history.

Figure 12. Screenshot 11



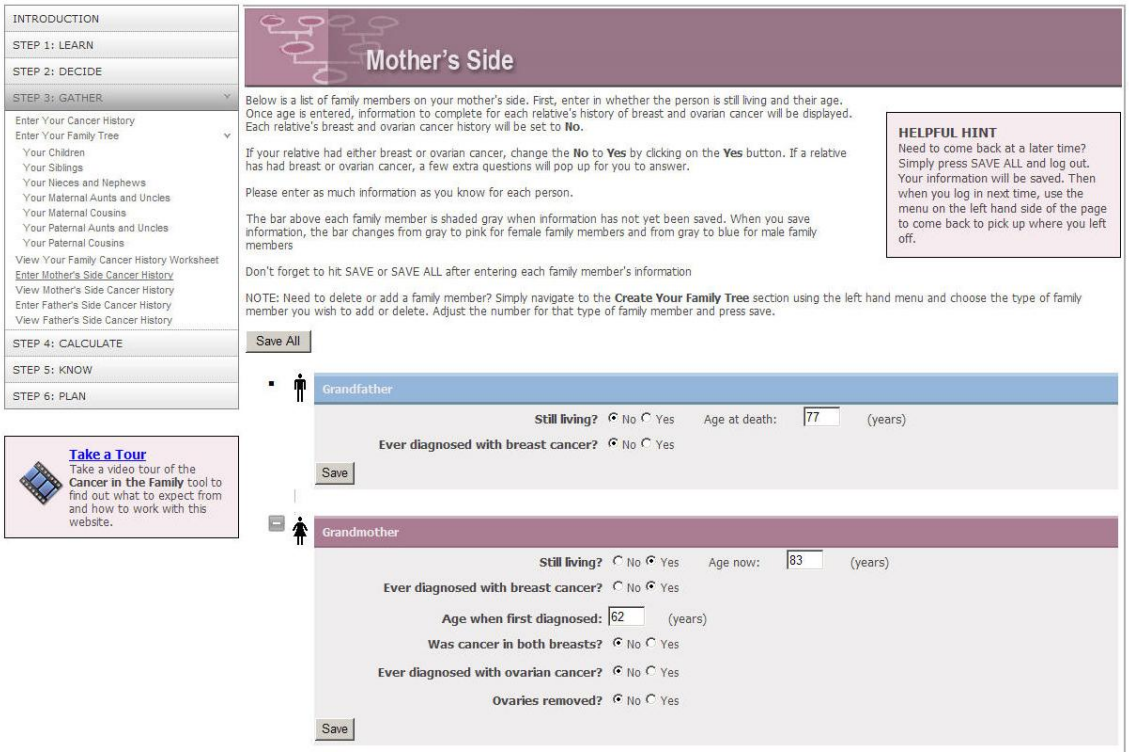
This is a screenshot of the page that allows the user to build her family tree on her father's side.

Figure 13. Screenshot 12



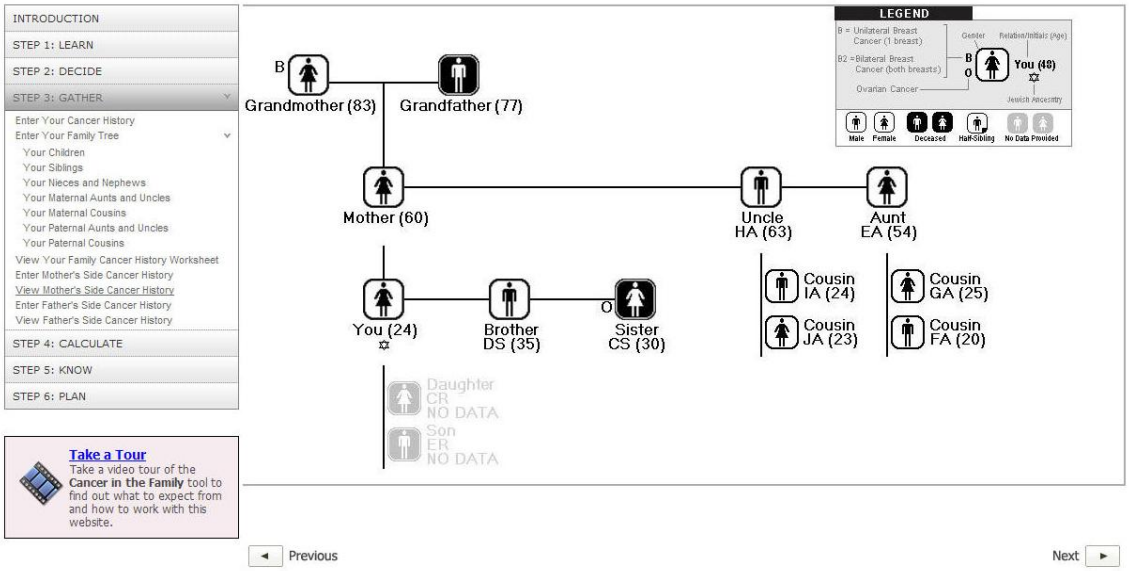
This screenshot displays the pedigree that the tool produces after the user's cancer family history is entered.

Figure 14. Screenshot 13



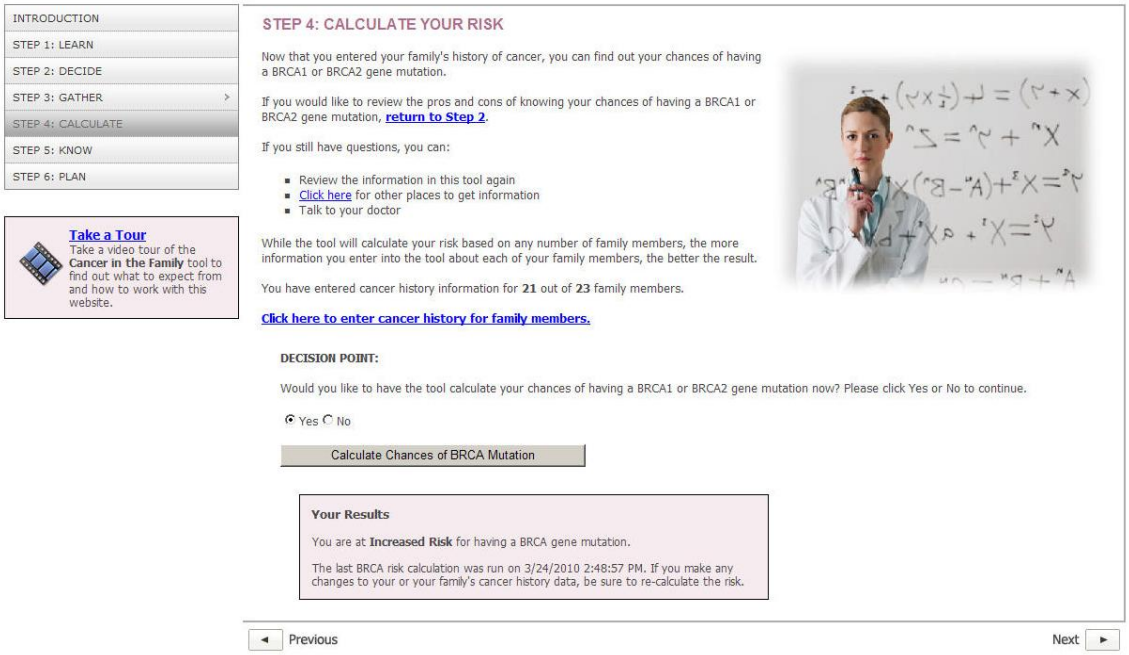
This screenshot displays the data-entry form for entering the user's cancer family history on her mother's side.

Figure 15. Screenshot 14



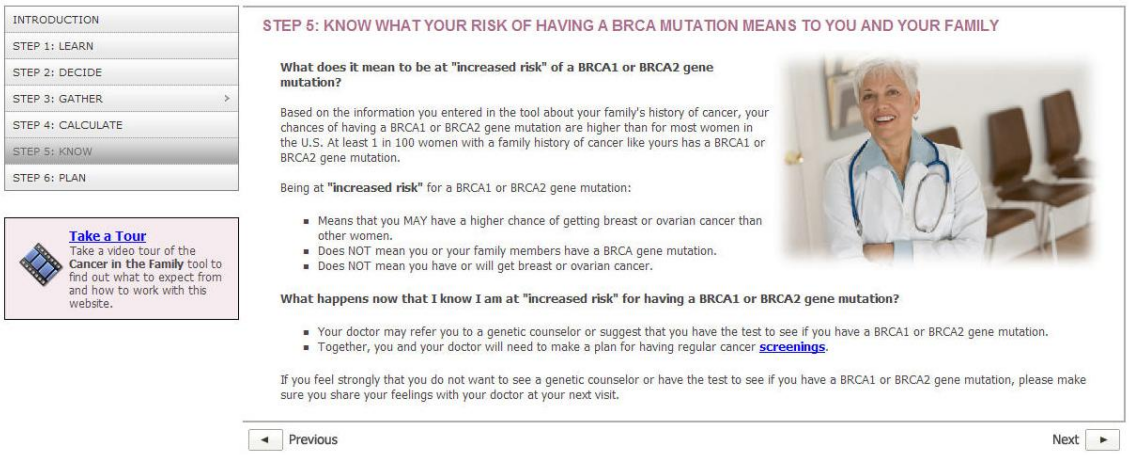
This screenshot displays the pedigree that the tool produces for the mother's side of the family.

Figure 16. Screenshot 15



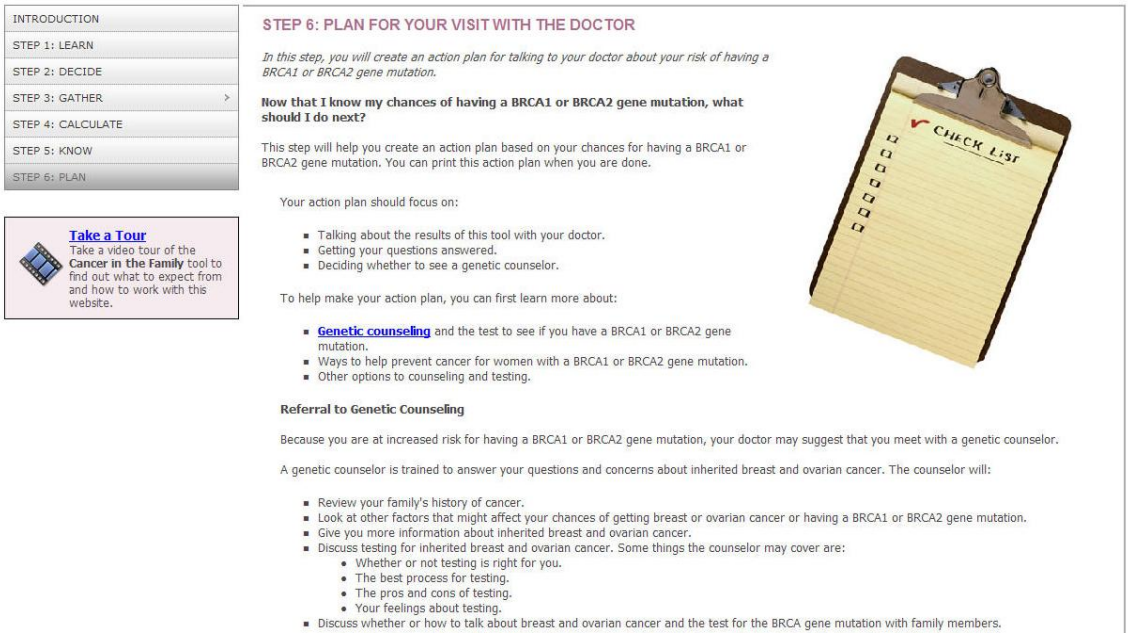
This is a screenshot of Step 4: Calculate. This page provides users with a decision point. To have the user's risk of having a *BRCA* mutation calculated, the user must select Yes.

Figure 17. Screenshot 16



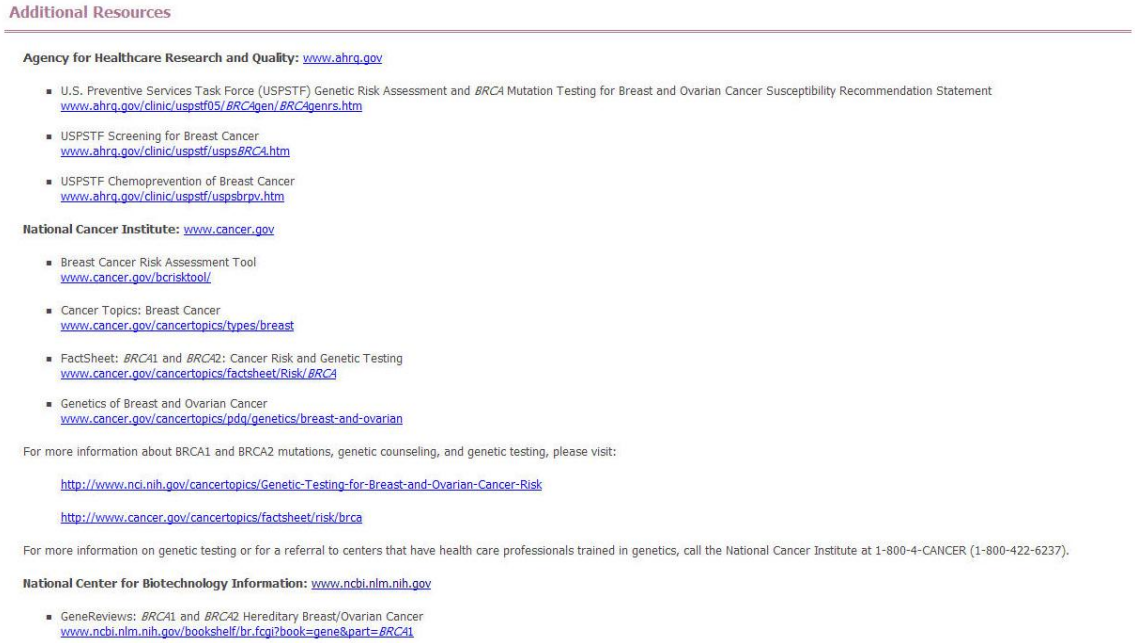
This is a screenshot of Step 5: Know. This page helps users interpret what their results mean.

Figure 18. Screenshot 17



This is a screenshot of Step 6: Plan. In this step, users are walked through what the next steps will be and offered a list of questions they can select to develop a personalized printout of their results and the questions they would like to ask their doctor. The tool asks them to take the printout to their appointment with their doctor.

Figure 19. Screenshot 18



Additional Resources

Agency for Healthcare Research and Quality: www.ahrq.gov

- U.S. Preventive Services Task Force (USPSTF) Genetic Risk Assessment and *BRCA* Mutation Testing for Breast and Ovarian Cancer Susceptibility Recommendation Statement
  www.ahrq.gov/clinic/uspstf05/*BRCA*gen/*BRCA*genrs.htm
- USPSTF Screening for Breast Cancer
  www.ahrq.gov/clinic/uspstf/usps*BRCA*.htm
- USPSTF Chemoprevention of Breast Cancer
  www.ahrq.gov/clinic/uspstf/uspsbrpv.htm

National Cancer Institute: www.cancer.gov

- Breast Cancer Risk Assessment Tool
  www.cancer.gov/bcrisktool/
- Cancer Topics: Breast Cancer
  www.cancer.gov/cancertopics/types/breast
- FactSheet: *BRCA*1 and *BRCA*2: Cancer Risk and Genetic Testing
  www.cancer.gov/cancertopics/factsheet/Risk/*BRCA*
- Genetics of Breast and Ovarian Cancer
  www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian

For more information about BRCA1 and BRCA2 mutations, genetic counseling, and genetic testing, please visit:

http://www.nci.nih.gov/cancertopics/Genetic-Testing-for-Breast-and-Ovarian-Cancer-Risk

http://www.cancer.gov/cancertopics/factsheet/risk/brca

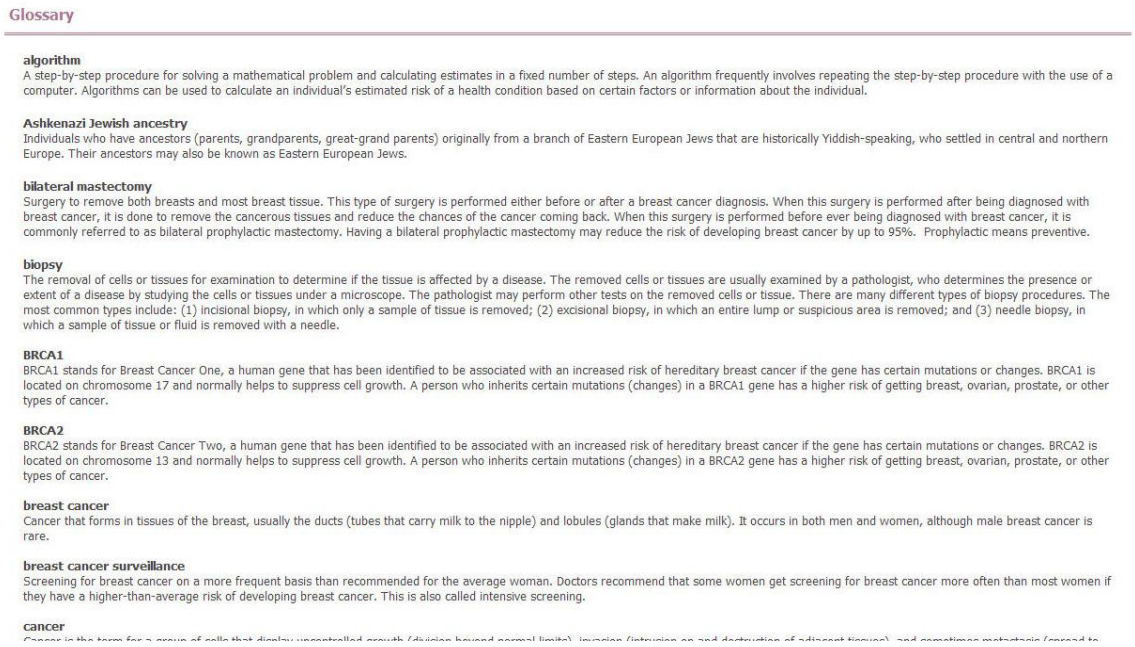
For more information on genetic testing or for a referral to centers that have health care professionals trained in genetics, call the National Cancer Institute at 1-800-4-CANCER (1-800-422-6237).

National Center for Biotechnology Information: www.ncbi.nlm.nih.gov

- GeneReviews: *BRCA*1 and *BRCA*2 Hereditary Breast/Ovarian Cancer
  www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=gene&part=*BRCA*1

This is a screenshot of the links to the additional resources provided for users.

Figure 20. Screenshot 19



Glossary

algorithm
A step-by-step procedure for solving a mathematical problem and calculating estimates in a fixed number of steps. An algorithm frequently involves repeating the step-by-step procedure with the use of a computer. Algorithms can be used to calculate an individual's estimated risk of a health condition based on certain factors or information about the individual.

Ashkenazi Jewish ancestry
Individuals who have ancestors (parents, grandparents, great-grand parents) originally from a branch of Eastern European Jews that are historically Yiddish-speaking, who settled in central and northern Europe. Their ancestors may also be known as Eastern European Jews.

bilateral mastectomy
Surgery to remove both breasts and most breast tissue. This type of surgery is performed either before or after a breast cancer diagnosis. When this surgery is performed after being diagnosed with breast cancer, it is done to remove the cancerous tissues and reduce the chances of the cancer coming back. When this surgery is performed before ever being diagnosed with breast cancer, it is commonly referred to as bilateral prophylactic mastectomy. Having a bilateral prophylactic mastectomy may reduce the risk of developing breast cancer by up to 95%. Prophylactic means preventive.

biopsy
The removal of cells or tissues for examination to determine if the tissue is affected by a disease. The removed cells or tissues are usually examined by a pathologist, who determines the presence or extent of a disease by studying the cells or tissues under a microscope. The pathologist may perform other tests on the removed cells or tissue. There are many different types of biopsy procedures. The most common types include: (1) incisional biopsy, in which only a sample of tissue is removed; (2) excisional biopsy, in which an entire lump or suspicious area is removed; and (3) needle biopsy, in which a sample of tissue or fluid is removed with a needle.

BRCA1
BRCA1 stands for Breast Cancer One, a human gene that has been identified to be associated with an increased risk of hereditary breast cancer if the gene has certain mutations or changes. BRCA1 is located on chromosome 17 and normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a BRCA1 gene has a higher risk of getting breast, ovarian, prostate, or other types of cancer.

BRCA2
BRCA2 stands for Breast Cancer Two, a human gene that has been identified to be associated with an increased risk of hereditary breast cancer if the gene has certain mutations or changes. BRCA2 is located on chromosome 13 and normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a BRCA2 gene has a higher risk of getting breast, ovarian, prostate, or other types of cancer.

breast cancer
Cancer that forms in tissues of the breast, usually the ducts (tubes that carry milk to the nipple) and lobules (glands that make milk). It occurs in both men and women, although male breast cancer is rare.

breast cancer surveillance
Screening for breast cancer on a more frequent basis than recommended for the average woman. Doctors recommend that some women get screening for breast cancer more often than most women if they have a higher-than-average risk of developing breast cancer. This is also called intensive screening.

cancer

This is a screenshot of the links to the glossary page.

Patient Usability Testing

To test the usability of the *Cancer in the Family* Web tool, RTI conducted eight usability interviews at RTI's office in Research Triangle Park, North Carolina. Interviews were conducted in two rounds of four people. We changed the patient Web site between rounds based on the first

set of interviews. A trained interviewer conducted the interviews using a semistructured interview guide developed by RTI. Each interview lasted approximately 90 minutes. After the interview, respondents received an honorarium of $75.

In this section, we present major findings from the usability testing with patients. Appendix H provides the full report. In general, users found the site to be interesting and informative. Users with a family history of breast or ovarian cancer were especially interested in learning about their risk of having a *BRCA* mutation. Participants expressed concern about storing their medical data on the Internet. To address these concerns about privacy, RTI worked with its legal consultants and Institutional Review Board to include a link to RTI's privacy policy at the bottom of the page.

Patients needed additional instructions or clarification in several places in the tool. For example, the first version of Step 3 was confusing and difficult for participants. After debating several options, RTI adopted a new process by which the steps of gathering family history were broken down into four smaller steps ("substeps"). The left panel menu was modified to include the substeps under Step 3. A start page was added to this step with an overview of how the steps would work. To address these issues, RTI developed a Take a Tour tutorial to provide specific step-by-step instructions on using the tool, including how to enter data and how data are stored (see Take a Tour Section).

Several participants found the pedigree confusing, too small, or unnoticeable. The pedigree was modified with new symbols indicating breast or ovarian cancer (B1, B2, and O replaced the dots), age of diagnosis was dropped to make the pedigree more streamlined, and the size of the legend was increased so that it was easier to read. Because several participants did not understand the term "pedigree," the term pedigree was changed to "family tree" and "health history."

Participants identified several issues related to navigating the tool.

- Some participants tried to use their browser's forward and back buttons to navigate and were unable to get back into the tool without assistance.
- A few respondents did not notice the top menu because the words were too small or blended in. Top menu items were made larger and darker.
- Participants were also confused in Step 3: Submit when they were asked whether they wanted to continue to calculate their risk after learning about *BRCA* mutations and hereditary breast and ovarian cancer. After clicking yes, participants expected to be routed to the next page, but they were not. They found this confusing.

Although all participants understood the sidebar navigation, a recommendation was made to number the steps on the sidebar (Step 1: Introduction, Step 2: Learn) to provide further clarification. To address these navigation issues, additional instructions on how to move through and within the tool were included in the Introduction section. In addition, a Take a Tour video was developed as a tutorial.

Take a Tour

The Take a Tour feature was developed to provide potential users with an overview of the tool and to address many of the instructional needs identified by patients during usability testing. Our video production followed the process illustrated in Table 1.

Table 1. Process for developing the take a tour feature

Process
Write the script
Select images that match the text
Record rough draft audio clips
Produce a rough draft video and share with team for review
Incorporate review comments
Record final audio in sound booth
Make final video edits
Render video to suitable format
Post video to Web site

We began by convening a subset of the project team, including content developers and programmers, to define the objectives of the Take a Tour feature. Our intent was to develop a brief, persuasive, and engaging multimedia asset that effectively communicates the purpose of the tool, the importance of *BRCA* screening, and the estimated burden associated with using the tool. An outline was developed for each section of the tour, including bulleted descriptions of major topic areas and anticipated runtime for each section. We wanted to have sufficiently helpful content but wanted to keep the file size down, for faster downloads, so we decided on a total runtime target of 7 to 8 minutes. This outline was reviewed by the project team, was edited based on the feedback that was received, and served as the core for developing the script. After completing a draft script, soliciting feedback, and editing the narrative, we incorporated a collection of screen captures and stock photos to create a storyboard.

The next step was to record a rough draft version of the voiceover audio (narration). Again, project staff reviewed and provided feedback on the script prior to moving into production.

The final female voiceover was done by an RTI in-house "voice talent" person in a professional sound booth, but the rough draft recording was done by a project team member to reduce time and costs. The rough draft audio was recorded using a PC microphone and the Windows Sound Recorder application (built in to Windows). Record quality was set low to keep file sizes small during the rough edit phase.

Draft voiceover audio files were created and photos were selected to match the audio, and a rough draft video was produced. The video was edited using Sony Vegas Movie Studio Platinum, version 9. The rough draft video was rendered and shared with the team, and after the team's comments were incorporated, the final voiceover audio files were recorded in RTI's internal sound recording studio using RTI's "voice talent" person. The rough draft audio files were replaced with the final recordings, titling and other video enhancements were added, and the final video was rendered. Although the native resolution of the video is in high definition (HD), we reduced the size by one-quarter to reduce the size of the video file. The final render is in Flash (FLV) format.

Development of Provider Interface

Design of the provider interface focused on taking steps to create a streamlined user experience. Our objective was to create a tool that physicians could access in their home or office to review learning material and could also use with patients at the point of care.

Development Process

In addition to the formative research and resources previously described, the layout of the provider interface was driven largely by the flow of the learning material that was created as a refresher on cancer genetics for primary care clinicians. Our development team began by reviewing the features and functionality of various CDS tools and discussing with primary care physicians how they might use such a resource at the point of care. Interim feedback on our content and design concepts was provided by a panel of primary care physicians. Once completed, usability testing among a sample of primary care physicians who were naive to the tool provided actionable feedback for finalizing changes to the evaluation version of the Web tool.

Interface Description and Screenshots. All physicians who provided input to the design of the *Cancer in the Family* Web tool reported that the resource must be easy to use, be easy to navigate, and not require too many mouse clicks to access information, particularly for content intended for use at the point of care. For that reason, navigation within the provider site is based on tabbed document interface design principles that allow multiple documents to be contained within a single window, using tabs as a navigational widget for switching between sets of documents.

The Patient List is the centerpiece of the provider site and was designed and optimized for ease of use during the clinic encounter. This matrix provides clinicians with a method to identify their patient's record in the Web tool, a simplified risk result flag for each record, access to the detailed risk results data in PDF format, the patient data entry forms, and the provider checklist on a single page.

A header spans across each page of the Web tool that includes eight tabs for browsing from the Patient List to the educational content, tips on discussing risk results, references, additional resources, and a glossary.

Background educational information on HBOC and *BRCA* screening for physicians is found on the first two tabs, which are located at the top of the Web site and called *BRCA* Basics and Beyond Basics. *BRCA* Basics provides a rationale for *BRCA* screening in primary care, describes the primary care provider's role in screening, and provides an overview of the *Cancer in the Family* tool. Beyond Basics provides more detailed information on the following:

- the genetics of breast and ovarian cancer,
- how the tool calculates risk,
- genetic discrimination,
- the role of the genetic counselor,
- the shared decisionmaking process, and
- preventive treatments available for *BRCA* mutation carriers.

The instructional design principles relied on the assumption that physicians are self-motivated learners who prefer self-directed content. Both sections applied the same approach to navigation and content presentation in which bulleted, topical headers expand and collapse to reveal the subject matter in each area. References to additional resources and links to external Web sites to complement the learning material were used throughout the educational component of the Web tool.

The provider interface was also designed to be used by providers during the clinical encounter and has a tab that walks through the steps that a provider should use when discussing a

patient's risk assessment results. The tab Sharing Results—Increased Risk walks providers through seven communication tasks that providers should complete with patients whose risk assessment results indicate they are at increased risk. The tab Sharing Results—Not at Increased Risk provides primary care providers with the six communication tasks for patients whose risk-assessment results indicate they are not at increased risk.

Providers' communication tasks for patients who are at increased risk are to:

1. Review your patient's family history and confirm it is complete and accurate
2. Explain what it means to be at "increased risk"
3. Discuss recommendations and next steps
4. Referto genetic counseling
5. Review your patient's medical record
6. Address questions from your patient
7. Check patient understanding

Providers' communication tasks for patients who are not at increased risk are to:

1. Review your patient's family history and confirm it is complete and accurate
2. Explain what it means to be "not at increased risk"
3. Discuss recommendations
4. Address questions from your patient
5. Patients may wish to seek counseling despite being "not at increased risk"
6. Check patient understanding

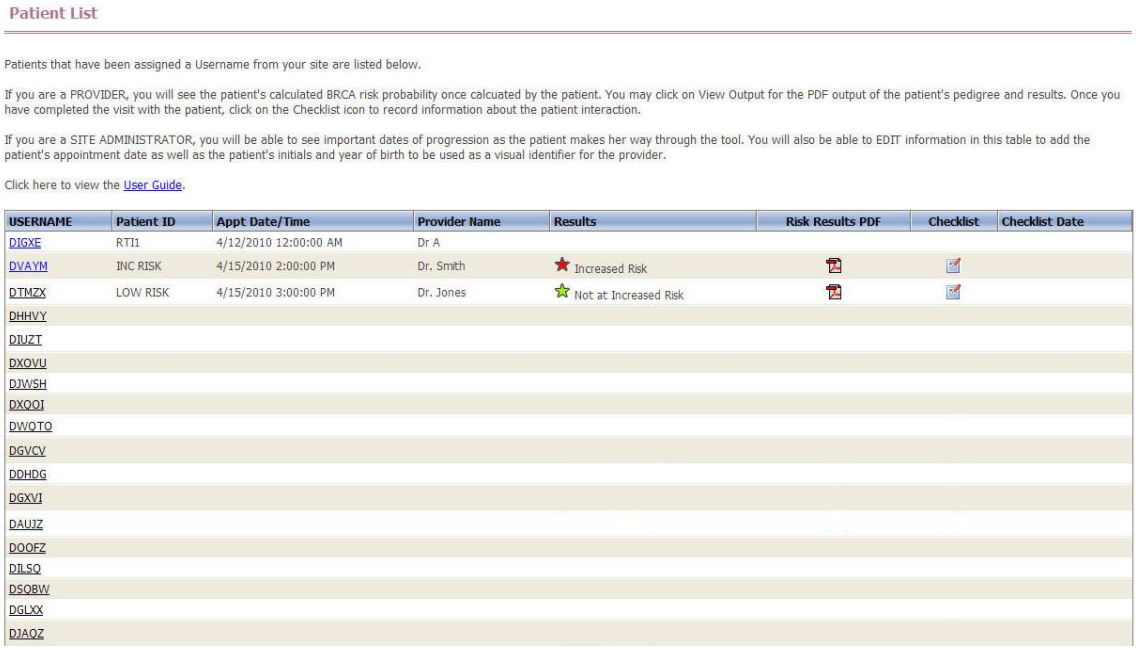
Finally, the tool provides three additional tabs that contain References, Additional Resources, and a Glossary of terms. Although inline references are used throughout the text and point users to external Web sites, including additional resources and source recommendations we present all of these resources, in aggregate, under the References, Additional Resources, and Glossary tabs. This approach allows returning users to navigate directly to these and access an item they may have been introduced to in the didactic section but did not have time to fully explore in a prior session.

Detailed risk results are available for providers in an individualized PDF document that can be reviewed during the clinical session and then saved for upload to an EHR as a patient care record attachment. Each PDF contains the following elements:

1. The patient's risk score as shown as a numerical value on a scale of 0 to 1. Patients are categorized as being at increased risk when their score is above 0.010.
2. Quick reference tips for talking to patients about their risk that reinforces the more detailed content from the Sharing Results tabs.
3. A table view of the patient's family history data that were used to produce the risk results are also provided as an alternative visualization of the data.
4. A family history pedigree chart that highlights the incidence of maternal and paternal breast and ovarian cancer across four generations.

Additional screenshots of the provider interface follow in Figures 21–30. Samples of the patient and provider output from the tool (e.g., risk results and cancer family history in pedigree and table formats) can be found in Appendix I.

Figure 21. Screenshot 20



Patient List

Patients that have been assigned a Username from your site are listed below.

If you are a PROVIDER, you will see the patient's calculated BRCA risk probability once calcuated by the patient. You may click on View Output for the PDF output of the patient's pedigree and results. Once you have completed the visit with the patient, click on the Checklist icon to record information about the patient interaction.

If you are a SITE ADMINISTRATOR, you will be able to see important dates of progression as the patient makes her way through the tool. You will also be able to EDIT information in this table to add the patient's appointment date as well as the patient's initials and year of birth to be used as a visual identifier for the provider.

Click here to view the User Guide.

USERNAME	Patient ID	Appt Date/Time	Provider Name	Results	Risk Results PDF	Checklist	Checklist Date
DIGXE	RTI1	4/12/2010 12:00:00 AM	Dr A				
DVAYM	INC RISK	4/15/2010 2:00:00 PM	Dr. Smith	Increased Risk			
DTMZX	LOW RISK	4/15/2010 3:00:00 PM	Dr. Jones	Not at Increased Risk			
DHHVY							
DIUZT							
DXOVU							
DJWSH							
DXQOI							
DWQTO							
DGVCV							
DDHDG							
DGXVI							
DAUJZ							
DOOFZ							
DJLSQ							
DSQBW							
DGLXX							
DJAQZ							

This is a screenshot of the landing page for providers.

After logging in, this "landing page" is what providers see first. Patients are identified by a username, appointment date and time, and provider. At a glance, providers are able to see the risk calculation result and click on the risk results. The checklist is used in the evaluation to document the interaction between patient and provider and whether the provider referred the patient to genetic counseling.

Figure 22. Screenshot 21

BRCA Basics

Click on each heading to learn more.

Importance of BRCA Screening in Primary Care

Primary Care Provider's Role

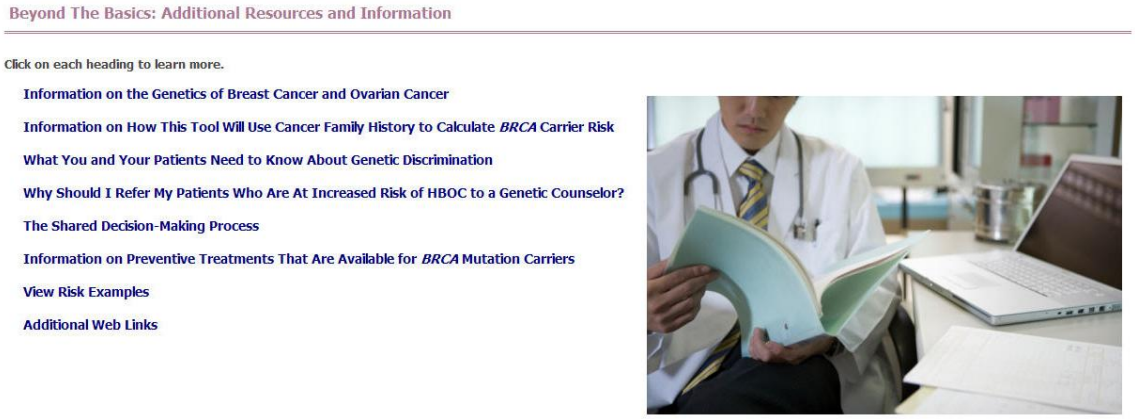
How this Tool Uses Cancer Family History to Calculate *BRCA* Carrier Risk

Next Steps for Cancer Screening After Risk Is Calculated

This is a screenshot of the links the information found in the *BRCA* Basics section on the provider interface.

BRCA Basics gives providers background information on hereditary breast and ovarian cancer, the provider's role in *BRCA* screening, and the purpose of the *Cancer in the Family* tool. To get more detailed information on these topics, providers click on the titles above.

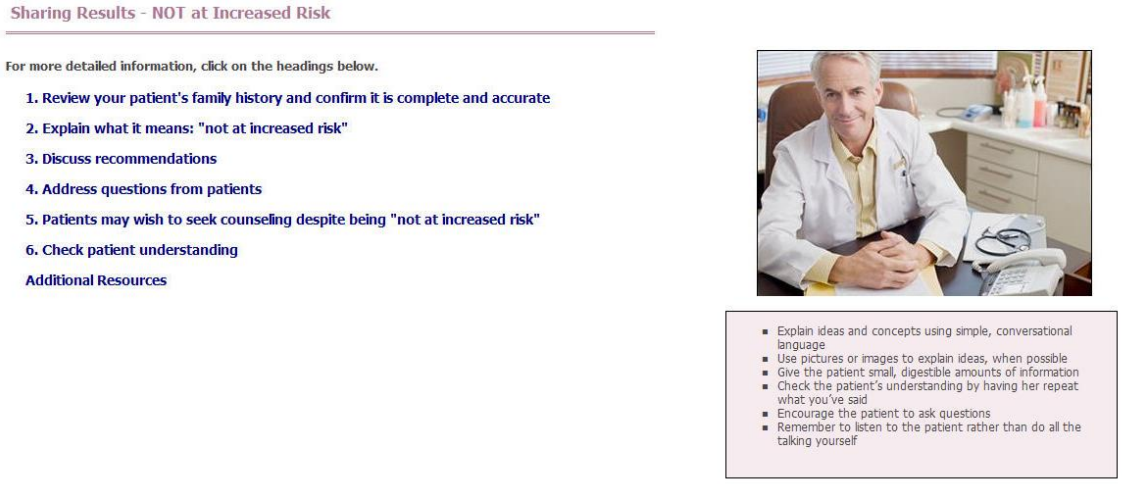
Figure 23. Screenshot 22



This is a screenshot of Beyond the Basics section on the provider interface.

Beyond The Basics gives providers more detailed information about the genetics of breast and ovarian cancer, how the tool calculates the risk of a patient having a *BRCA* mutation, and information on the following: genetic discrimination, genetic counseling, shared decisionmaking, and preventive treatments for *BRCA* mutation carriers.

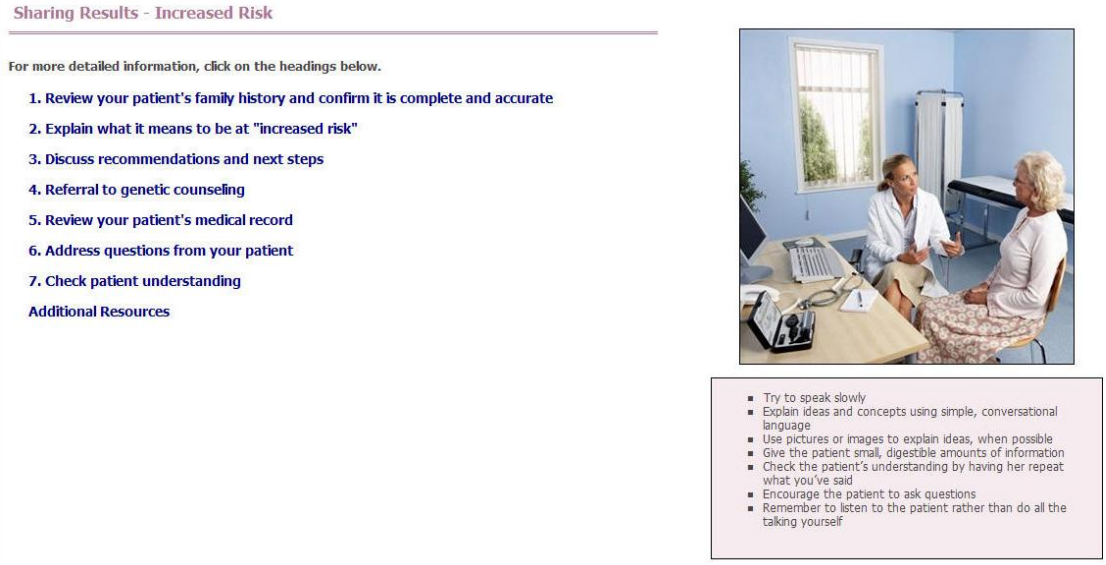
Figure 24. Screenshot 23



This is a screenshot of the Sharing Results—NOT at Increased Risk page.

Providers click on the tab Sharing Results—NOT at Increased Risk to get to this page, which provides them with six steps to walk through with a patient. Providers can click on each heading to get more detailed information and suggestions on how to discuss each topic with the patient.

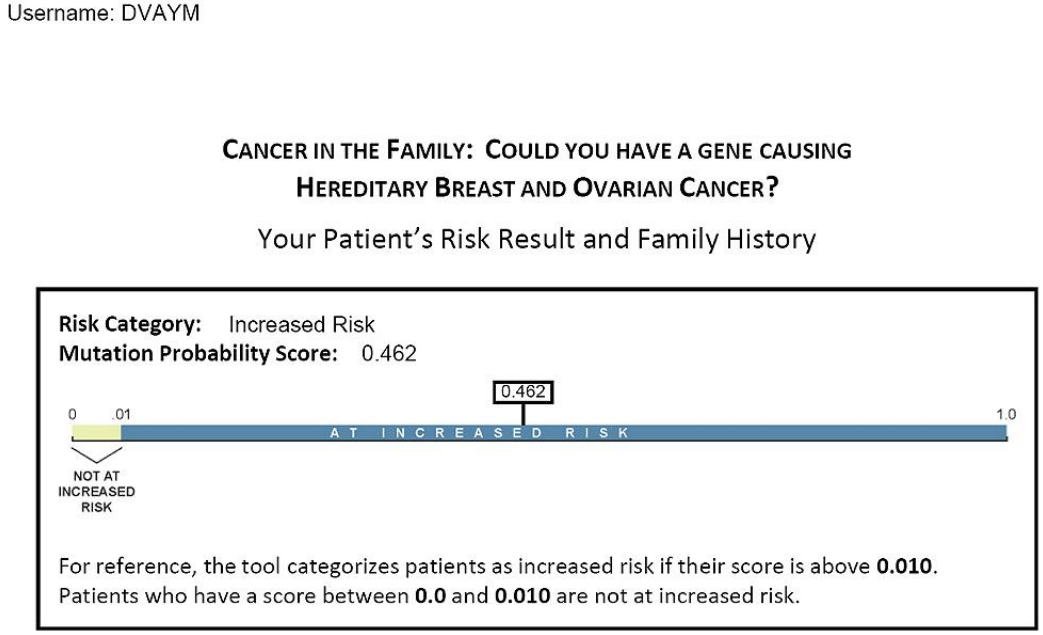
Figure 25. Screenshot 24



This is a screenshot of the Sharing Results—Increased Risk page.

Providers click on the tab Sharing Results—Increased Risk to get to this page, which provides them with seven steps to walk through with a patient. Providers can click on each heading to get more detailed information and suggestions on how to discuss each topic with the patient.

Figure 26. Screenshot 25



This screenshot provides a sample of how the risk results are presented to providers.

Figure 27. Screenshot 26

Username: DVAYM

Family History Summary – Data Supplied

Relationship to Patient	Initials	Gender	Age (now or at death)	Breast Cancer	Age at Diagnosis	Ovarian Cancer	Age at Diagnosis	Ovaries Removed	Age Ovaries Removed
Paternal Grandfather		Male	90						
Paternal Grandmother		Female	38	uni	37				
Maternal Grandfather		Male	77						
Maternal Grandmother		Female	83	uni	62				
Father		Male	65						
Mother		Female	60					Yes	45
You		Female	24						
Sister	CS	Female	30			Yes	28		
Brother	DS	Male	35						
Maternal Aunt	EA	Female	54						
Maternal Uncle	HA	Male	63						
Maternal Female Cousin	GA	Female	25						
Maternal Male Cousin	FA	Male	20						
Maternal Female Cousin	JA	Female	23						
Maternal Male Cousin	IA	Male	24						
Paternal Aunt	GS	Female	60					Yes	36
Paternal Uncle	JS	Male	63						
Paternal Female Cousin	IS	Female	42						
Paternal Male Cousin	HS	Male	40						
Paternal Female Cousin	LS	Female	30	uni	30				
Paternal Male Cousin	KS	Male	28						

This screenshot presents a table that gives providers an alternative view of the patient's cancer family history. They also are provided with the pedigree that was previously presented in the description of the patient tool.

Figure 28. Screenshot 27

Glossary

Ashkenazi Jewish ancestry Jewish individuals of Eastern European descent, primarily Hungary, Poland, Lithuania, and Russia.

Autosomal dominant inheritance means that the gene carrying a mutation is located on one of the autosomes (chromosome pairs 1 through 22). This means that males and females are equally likely to inherit the mutation. Dominant means that having a mutation in just one of the two copies of a particular gene is all that is needed for a person to have a trait, such as an increased risk of developing cancer. When a parent has a dominant gene mutation, there is a 50% chance that any child he or she has will also inherit the mutation.

Bayes' rules In probability theory, shows how one conditional probability, such as the probability of a hypothesis given observed evidence, depends on its inverse, the probability of that evidence given the hypothesis. It implies that evidence has a stronger confirming effect if it was more unlikely before being observed.

***BRCA*1** A gene on chromosome 17 that normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a *BRCA*1 gene has a higher risk of getting breast, ovarian, prostate, or other types of cancer.

***BRCA*2** A gene on chromosome 13 that normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a *BRCA*2 gene has a higher risk of getting breast, ovarian, prostate, or other types of cancer.

***BRCA* mutation carrier** A person that has one *BRCA* gene that has a mutation and one *BRCA* gene that does not have a mutation. This means that a *BRCA*1 carrier has one mutated gene on chromosome 17 and one non-mutated gene; whereas a *BRCA*2 carrier has one mutated gene on chromosome 13 and one non-mutated gene.

***BRCA*PRO probability model** A statistical model for assessing the probability that an individual carries a deleterious mutation of the *BRCA*1 and/or *BRCA*2 genes, based on family history of breast and ovarian cancer, based on his or her family's history of breast and ovarian cancer, including male breast cancer and bilateral synchronous and asynchronous diagnoses. BRCAPRO uses a Mendelian approach that assumes autosomal dominant inheritance, based on previous linkage and based on a systematic review of the literature.

Gene sequencing A combination of laboratory procedures used on a segment(s) of DNA to identify the nucleotide sequence.

Genetic counselors Professionals with specialized graduate degrees and experience in medical genetics and counseling. Genetic counselors work as members of a healthcare team and act as a patient advocate as well as a genetic resource to primary care physicians, other clinicians, and families. Counselors assist in the identification of families at risk for birth defects, or a genetic condition, disorder, or syndrome. Additionally counselors investigate the problems present in the family, interpret genetic information, analyze inheritance patterns and risks of recurrence, and review with families the available testing options.

HBOC Hereditary breast and ovarian cancer.

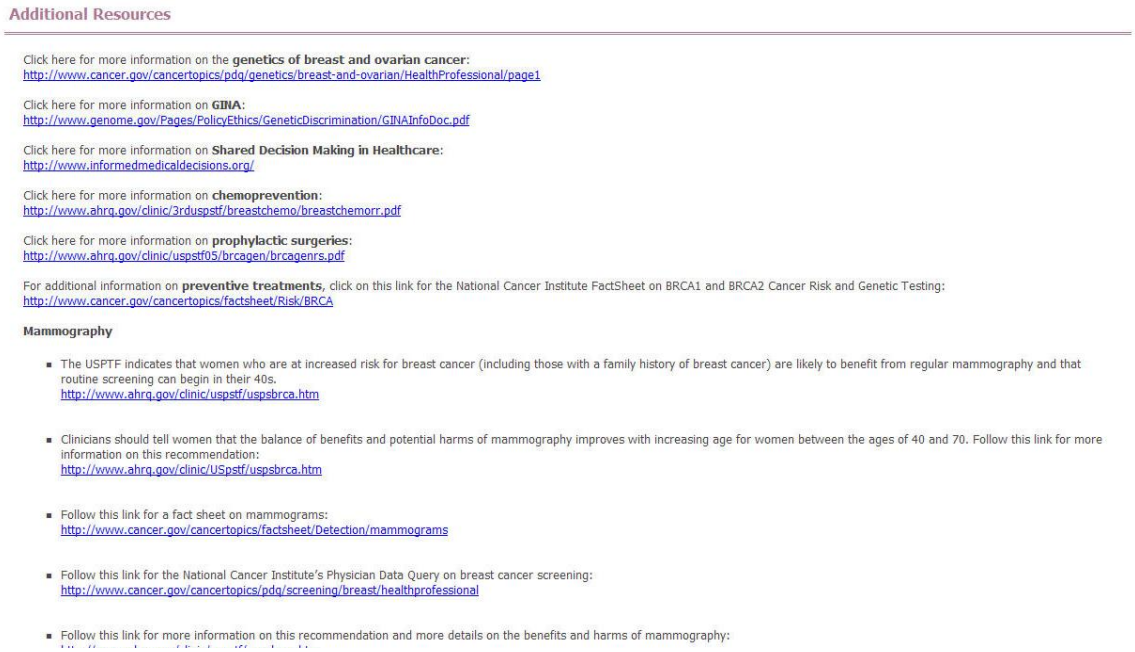
Mutation analysis Testing for a specific mutation within a gene, such as a deletion or insertion of a nucleotide.

Multifocal disease Breast cancers with two or more centers (foci) of disease appearing in different areas of the same breast.

Tumor suppressor genes Genes whose protein products are involved with the rate of cell division, cell death, and DNA repair processes. When these genes are mutated, cells can grow out of control, which can lead to the presence of various types of cancer.

This is a screenshot of the glossary available to providers.

Figure 29. Screenshot 28



Additional Resources

Click here for more information on the **genetics of breast and ovarian cancer**:
http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page1

Click here for more information on **GINA**:
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf

Click here for more information on **Shared Decision Making in Healthcare**:
http://www.informedmedicaldecisions.org/

Click here for more information on **chemoprevention**:
http://www.ahrq.gov/clinic/3rduspstf/breastchemo/breastchemorr.pdf

Click here for more information on **prophylactic surgeries**:
http://www.ahrq.gov/clinic/uspstf05/brcagen/brcagenrs.pdf

For additional information on **preventive treatments**, click on this link for the National Cancer Institute FactSheet on BRCA1 and BRCA2 Cancer Risk and Genetic Testing:
http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA

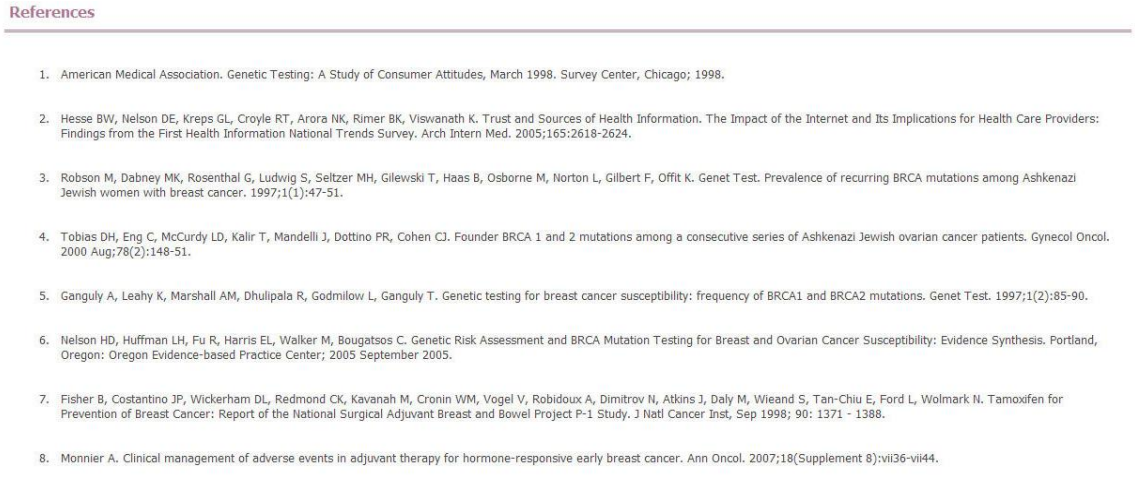
Mammography

- The USPTF indicates that women who are at increased risk for breast cancer (including those with a family history of breast cancer) are likely to benefit from regular mammography and that routine screening can begin in their 40s.
  http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm
- Clinicians should tell women that the balance of benefits and potential harms of mammography improves with increasing age for women between the ages of 40 and 70. Follow this link for more information on this recommendation:
  http://www.ahrq.gov/clinic/USpstf/uspsbrca.htm
- Follow this link for a fact sheet on mammograms:
  http://www.cancer.gov/cancertopics/factsheet/Detection/mammograms
- Follow this link for the National Cancer Institute's Physician Data Query on breast cancer screening:
  http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional
- Follow this link for more information on this recommendation and more details on the benefits and harms of mammography:

This is a screenshot of the additional Web links to resources available to providers.

Providers are able to click on these pages to get definitions of terms used in the tool and to obtain additional information.

Figure 30. Screenshot 29



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This is a screenshot of the references that are cited in the provider interface.

Internal Review from RTI Experts

We employed an iterative, two-stage review process using a panel of internal and external subject matter experts. Through the use of a three-round review and edit cycle, the panel was instrumental in providing final vetting of the learning material, ensuring its accuracy, readability, and appropriateness for the physician audience.

The RTI reviewers who were recruited to support this project included three primary care physicians and a genetic epidemiologist. The panel represented various perspectives of expertise, including genetic counseling, epidemiology, guideline implementation, CDS, and preventive medicine. All reviewers agreed to provide iterative feedback on the learning material as well as basic design and navigation concepts. Revisions were made to the tool based on three rounds of review.

We sent the fourth iteration of the provider content to all members of the *BRCA* TEP and our AHRQ Project Officer, Dr. Gurvaneet Randhawa, requesting their review. Written comments were received from three TEP members and Dr. Randhawa.

To ensure that all of the feedback we received was reviewed and accounted for, we created a Provider Content Compliance Matrix. All internal and external comments were systematically cataloged, including fields for section, original text, reviewers' comment, and solution. Entries to the Solution field indicated how text was changed to reflect the feedback we received, or if it was not, the rationale supporting the decision not to make changes based on the reviewer's input.

The changes made to the provider content from the first draft to the final production material were significant. In general, reviewers verified that the educational material was written and formatted appropriately for a physician audience; various subject matter experts confirmed that the references used were appropriate and the statements made throughout the course are accurate. Based on the feedback, the overall length of the content in Word format was reduced by approximately four pages; portions of the text were edited and reworded to improve readability. Additional references and resource materials were also incorporated.

Provider Usability Testing

The purpose of this task was to conduct a set of interviews to test the usability of the *Cancer in the Family* provider Web site, specifically to characterize users' experiences with navigating the site, their reactions to the site layout and content, and their reactions to the prospect of integrating the provider tool within their clinical workflow.

We conducted five usability interviews that lasted 90 minutes. We completed one round of interviews over a period of 3 weeks in December 2009. No changes were made to the Web site during the testing period so all physicians provided feedback on the same content. Providers were sent a link to the *Cancer in the Family* Web site and instructions 1 week before the interview. Participants were asked to review the Web site and complete a worksheet to provide feedback. A trained interviewer conducted the interviews using a semistructured interview guide developed by RTI, beginning with a discussion of the review worksheet.

The clinicians interviewed for this task all responded favorably to the tool. According to respondents, the two areas of interest were the primary care physician's role in discussing a patient's risk and the physician's responsibility to recommend screening for *BRCA* mutations. Clinicians provided recommendations on the general characteristics of the tool, the educational content, the risk results produced by the tool, and terminology.

Some respondents raised concerns about images of a male mammography technician and male physicians, so a decision was made to review all images.

Participants provided two suggestions to make the educational content more concise and organized. Respondents preferred using succinct, bulleted content, collapsed beneath each subject heading. Thus, all education content was modified to this format. Participants also indicated that the Beyond Basics section was less organized and was redundant with the Basics

section. In response, RTI reviewed and eliminated material from certain sections. Respondents also liked having links embedded within the text as well as available in a separate section. An additional tab on the top menu was created labeled Additional Resources. For the glossary, hover definitions were added, at the suggestion of several participants. Overall, respondents found the Patient List to be useful, but some aspects of navigation, layout, and functionality were confusing. In response, a patient username convention was adopted that consisted of the first three letters of the last name and birth year. The list was made sortable alphabetically by name and by appointment date. The View Output column was renamed the View Risk Results.

Several respondents indicated the talking points in the Sharing Results page (for increased and not increased risk) were helpful and expressed a desire for a handout to give to their patients. RTI proposed a Visit Summary PDF that the physician could tailor to include key pieces of information about an individual's *BRCA* risk and general information on HBOC. Although this recommendation was not implemented for the pilot phase, it is being considered for future modifications of the tool. Respondents liked that the output PDF was printable and savable, and they preferred having both the family history table and pedigree chart available. Based on provider feedback, the Risk Results PDF was revised to be more physician focused, and to include patients' customized risk results, the family history table was modified so that rows of family members with breast or ovarian cancer were highlighted.

Project staff with experience in instructional design formatted the provider material and created a bulleted outline of the *BRCA* Basics and Beyond Basics sections. Additional narrative content was written, based on a collection of references and a synthesis of the literature review. Additional resources, including further reading on clinical guidelines, and credible, complementary Web sites were also included in the material.

Summary

To guide the development of the *Cancer in the Family* tool, we used results from formative research conducted with providers, patients, and IT professionals; numerous sources and resources; input from the TEP; and findings from a literature review. The tool has both patient and provider interfaces that have undergone usability testing with their respective audiences. Specific challenges were identified through this formative research. The following features of the tool were developed to address these challenges.

- Patient-Driven Tool—Providers strongly advocated for a patient-driven tool. They emphasized that breast and ovarian cancer were rare illnesses (in primary care) and that they would not support a tool that required providers or clinic staff to enter patients' family history. Consequently, we created a patient-driven tool; providers need only to review patients' family history and risk results during the appointment.
- Security Features—Patients and providers both voiced concerns about protected health information (PHI) being stored in a Web-based tool. We addressed this challenge by creating password-protected accounts (patients and providers), segmenting patients by clinical site, eliminating full names from family history, and storing data on RTI's secure server (rather than clinic servers or online).
- Step-by-Step Navigation—Patients need to learn about *BRCA* mutations and understand the tool's purpose before they document family history. Patients and providers also voiced concern about the tool's length/involvement. We addressed these challenges by dividing the tool into six linear steps. The step-by-step approach ensured that patients

moved through each section in order and had an appropriate understanding of each step. The left navigation menu also provided a roadmap of the tool for patients.

- *BRCA* Risk vs. Cancer Risk—In cognitive testing, patients sometimes conflated the risk of having a *BRCA* mutation (which the tool calculates) and the risk of having cancer (which the tool does not calculate). We explicitly explained the difference in the education module (Step 1).
- Web-Based Tool—One of the tool's first challenges was accessibility. Patients and providers both needed to access accounts from multiple locations on multiple occasions. By creating a Web-based tool (vs. a CD-ROM tool or a clinic computer tool), we overcame these challenges. We ensured patients and providers could seamlessly share family history, update accounts, and review *BRCA* risk results. Providers could also access the tool from each exam room, which encouraged integrating the tool into clinical workflow.
- Family Tree Builder—Providers and patients were both unsure what a "complete family history" should entail. The family tree builder asks step-by-step questions about a patient's relatives, thus ensuring that the family history includes all relevant individuals.
- Family History Collection—Patients flagged other challenges to collecting family history—difficulty tracking down relatives and their cancer history, concern about awkward conversations with relatives, sporadic computer access, etc. We addressed these challenges by providing tips on discussing family history, creating a customized and printable worksheet that enables offline family history collection, and allowing individuals to enter family history over time, relative by relative.
- Limited Family History Entry—To minimize the burden on patients, the tool asks only for the elements necessary to calculate one's *BRCA* mutation risk. Family history fields are limited to life status (e.g., currently living/dead), breast cancer history, age at diagnosis, ovarian cancer history, and ovary removal history.
- Pedigree Graphics—In addition to calculating one's *BRCA* risk, the tool creates a graphic ("pedigree") of each patient's family history. The pedigree graphic is a simple, straightforward way for patients to view their family history. Providers can also scan the pedigree graphic quickly and can use it to educate patients about their family history during appointments.
- Risk Result Display—Providers voiced concern about high-risk patients overreacting and misinterpreting their risk result. Consequently, we created two dichotomous risk categories for patients—"increased risk" and "not at increased risk." This eliminated trigger words like "high risk" and provided clear categories for patients. Conversely, providers wanted more detail for themselves about patient risk results. Thus, the tool depicts a numerical risk result on the provider printout.
- Patient Action Plan—Providers wanted an opportunity to discuss family history with patients and to help them interpret their risk result. Consequently, the tool directs patients to create a Patient Action Plan (Step 6). The action plan discusses next steps, encourages patients to speak with their primary care provider, and suggests questions/topics for the discussion.

Once all components of the tool were developed, the tool underwent both systems and accuracy testing. Appendix J provides detailed specifications for the tool and results of systems

testing, including 508 compliance testing. Appendix K provides details about the risk-assessment procedures and accuracy testing.

Following this testing, we evaluated the *Cancer in the Family* tool at three clinical sites. Chapter 3 describes the evaluation study and results. As the Surgeon General's Office updated their family history tool, My Family Health Portrait, after our literature review had been completed, Chapter 4 provides a brief review of this new and improved tool. Finally, Chapter 5 summarizes the issues still to be addressed in tool development and recommendations for enhancements to the *Cancer in the Family* tool.

Chapter 3. Evaluation

Introduction

The goal of this pilot evaluation was to conduct a preliminary assessment of the tool within a clinical setting. Details of our evaluation plan can be found in Appendix A.

Our preliminary pilot evaluation focused on three objectives:

1. Assess the degree to which the CDS tool is used as designed in three clinical settings and explore the characteristics of the tool that influence adoption (**Implementation Evaluation)**.
2. Use the data from this pilot outcome evaluation to examine potential effects of the CDS tool on both patient and provider outcomes (**Outcome Evaluation**).
3. Pilot evaluation procedures, instruments, and processes to inform the development of a larger outcome evaluation postcontract (**Pilot Evaluation Procedures, Instruments, and Processes)**.

Theoretical Framework for the Evaluation

Our theoretical framework for the evaluation is based on the Health Belief Model (HBM) as well as concepts from other behavioral theories appropriate to this intervention and can be found in the workplan in Appendix A. In considering the utilization of this tool, particularly by providers, we added constructs from the Diffusion of Innovation (DOI) theory (Rogers, 1995), which describes the process through which an innovation spreads via communication channels over time among the members of a social system.

For this evaluation, the "innovation" would be our core intervention of the *Cancer in the Family* tool plus the patient–provider communication.

Individual characteristics of patients and providers that we believe would influence use of the *Cancer in the Family* tool and patient–provider communication are further described in the sections below.

Evaluation Design

Patient outcomes were assessed at baseline, after patients used the *Cancer in the Family* tool at home and prior to seeing their primary care provider, and then again directly after their clinic/doctor's office visit. Provider outcomes were assessed at four points: (1) at baseline (pretest), (2) directly after receiving training on the tool and evaluation from the study team (post-training survey), (3) after having a week to explore the tool to review *BRCA* Basics and Beyond Basics (the postexploration/education survey), and (4) within 1 week after seeing all study patients during the 8-week field period (April 19 to June 11, 2010) (poststudy survey).

Study Sites

Baylor Health Care System. Baylor Health Care System (BHCS) is a multisite health system based in Dallas-Ft. Worth, TX. Two BHCS primary care clinics were recruited to participate in the study—Family Medical Center of North Garland and Southlake Family Medicine. Three physicians from each site were enrolled in the study. Table 2 provides a summary of the sites' characteristics and patient populations.

Fairfax Family Practice. Fairfax Family Practice (FFP) is a primary care clinic based in Fairfax, VA. FFP is a member of the Fairfax Family Practice Centers, which has 10 locations throughout northern Virginia, and is associated with the Department of Family Medicine at Virginia Commonwealth University. Table 2 provides a summary of the site's characteristics and patient population.

Table 2. Evaluation site characteristics and patient populations[a]

Characteristic	BHCS—North Garland	BHCS—Southlake	Fairfax
Type of practice	*Medical group/ health care system*	*Medical group/ health care system*	*Physician-owned practice*
Physicians on site	6–15	6–15	16–49
Nurse practitioners	3	2	2
Medical assistants	4	20	0
Patients seen per week	126 or more	126 or more	126 or more
Sex (patients)			
Female	54%	60%	65%
Male	56%	40%	NA
Age (female pages)			
18 years or younger	15%	30%	15%
18–39 years	35%	30%	35%
40–64 years	40%	20%	30%
65 years or older	10%	20%	20%
Insurance coverage (patients)			
Medicaid	0–5%	0–5%	26–50%
No coverage	0–5%	0–5%	0–5%
Race (patients)			
White	51-75%	76–100%	26–50%
Black/African American	6–25%	0–5%	6–25%
Asian	0–5%	0–5%	6–25%
Native Hawaiian/Pacific Islander	0–5%	0–5%	6–25%
Hispanic/Latino	6–25%	0–5%	6–25%
American Indian/Alaska Native	0–5%	0–5%	0–5%

[a]Data are from a survey that evaluation site coordinators completed to document the characteristics of their site. Response options for questions included a range of numbers or percentages (e.g., for uninsured, percentage ranges were 0 to 5 percent, 6 to 25 percent, 26 to 50 percent, 51 to 75 percent, and 76 to 100 percent).

OMB and IRB

An OMB clearance package was prepared and submitted to the ARHQ OMB liaison who determined it met the criteria for clinical exemption for patient evaluation.

The study was also reviewed and approved by RTI's IRB. The original study application was reviewed on April 22, 2009, and the IRB requested minor revisions to more clearly explain the study design and analysis. The IRB granted final approval on May 11, 2009.

Several study amendments also were submitted and approved by the RTI IRB over the course of evaluation planning:

- Cognitive Testing—Amended the study to include cognitive testing of patient surveys and patient educational content.
- Patient/Provider Incentives—Amended the study by adding survey completion incentives for patients ($10 per survey) and providers ($25 per survey).
- Provider Surveys—Revised several questions on provider surveys to more accurately reflect final tool content.
- Privacy Language—Added a disclaimer to the tool that described how patient information is protected and kept confidential.
- Provider Consent Form—Revised provider informed consent form to more accurately describe study workflow.

One exemption was also submitted and approved by the RTI IRB:

- Usability Testing—Amended the study to include tool usability testing with patients and providers.

In addition, BHCS has an independent IRB that reviewed and approved the study on September 11, 2009. FFP does not have an independent review board and was covered by the RTI IRB approval.

Implementation Evaluation

Implementation evaluation focuses on assessing the degree to which an intervention has been implemented as planned, which is also referred to as fidelity. Although both patients and providers received training and educational materials to prepare them to use the CDS tool, we consider the core intervention components to be the following:

- use of the tool by patients
- use of the tool by providers
- patient–provider discussion of the risk classification and next steps

All three of these core intervention components could be either adopted or rejected by the intended user groups.

The constructs and evaluation questions that were addressed in the implementation evaluation for patients are listed below.

Patients

Relative advantage of the innovation

- Do patients perceive the tool to be effective in learning about *BRCA* screening and genetic testing compared to other methods they would likely use?
- Does the CDS stimulate better quality patient–provider communication than that which takes place without using the CDS tool?

Compatibility of the innovation

- Is use of the tool compatible with patients' computer use? Were patients able to remember to complete the tool prior to their visit?

Complexity of the innovation

- How easy or difficult do patients find the tool?

- Are there particular aspects of the tool that patients find problematic or too complex/difficult? How should they be adjusted?

Trialability or flexibility of the innovation

- How easy or difficult was it for patients to use the tool prior to the visit?
- How easy or difficult was it for patients to contact their family members to gather their cancer history?
- Did patients use the worksheet to record family history prior to entry into the tool? Was the worksheet an effective way to record the information?
- How easy or difficult was it for patients to enter family cancer history information into the tool?

Observability of the innovation

- Do patients perceive that their provider will review the cancer family history they record in the tool? What do they perceive to be the consequences if they do not complete this task?

Perception of patient–provider interaction

- Was the patient satisfied with the information related to *BRCA* risk and genetic testing discussed in the interaction?
- How does the patient rate the quality of the interaction?
- How effective does the patient perceive the provider to be in providing information about risk of *BRCA* mutations?

Overall satisfaction with the tool

- Overall, how satisfied were patients with the tool? What recommendations do they have for improving the tool's functionality or content?

Use of the tool

- Did patients use the tool as designed? Why or why not?

The constructs and evaluation questions that were addressed in the implementation evaluation for providers are as follows:

Providers

Relative advantage of the innovation

- Is using the CDS tool to gather a patient's family history of cancer better than previous practices (which may be not gathering the family history?)
- Is using the CDS tool to screen women for risk of having a *BRCA* mutation better than not screening women at all?
- How much time does it take for providers to use the tool prior to a patient's visit? Is this time (cost) worth the benefit (screening women or having a patients' family history of cancer available)?
- Does the CDS stimulate better quality patient-provider communication than that which takes place without using the CDS tool?

Compatibility of the innovation

- Is use of the tool compatible with providers' current practices and procedures? If not, what could make it more compatible?

- Or did providers have to alter current practices to use the tools? Were those alterations acceptable?

Complexity of the innovation

- How easy or difficult do providers and patients find the tool? Are the messages and information presented easily understood?
- Are there particular aspects of the tool that providers find problematic or too complex/difficult? How should they be adjusted?

Trialability or flexibility of the innovation

- How and why does implementation of the CDS tool vary at each site? Do providers use the tool as designed? Do clinics adjust implementation procedures? If so, how and why do they adjust? Does use change over time?
- Do providers perceive the tool to be flexible? Do providers use the tool prior to the patient's visit, during the patient's visit, or both?
- Do providers perceive that the tool can be incorporated into practice? Why or why not? What are the barriers to implementation? What would facilitate implementation?

Observability of the innovation

- Do providers perceive that others in their practice are using the tool? Do they perceive that other providers would believe they should use the tool? Do they discuss their use with others? What do they say? What do their colleagues say? Do providers believe that their physicians are assessing whether or not they are using the tool correctly?
- Do providers perceive that their peers at their site will know whether they are using the tool?

Overall satisfaction with the tool

- Overall, how satisfied were providers with the tool? What recommendations do they have for improving the tool's functionality or content? What parts of the tool were most and least useful?

Use of the tool

- Did providers use the tool with each patient in the study? Why or why not?

Content of tool used

- What parts of the tool were most used?

Efficacy of the tool

- Do providers believe that the tool provides accurate risk assessments for their patients? Do providers perceive that the tool effectively educates patients about *BRCA* risk? Do providers believe that the information support provided in the tool is credible and accurate? Do providers believe that the tool helps them better communicate with their patients about the risk of *BRCA* mutations?

Tool vs. provider recommendations

- Did providers refer high-risk patients for genetic counseling? Why or why not?

Evaluation fidelity

- Did providers follow the evaluation protocol? Why or why not?

Perceptions of evaluation

- What do providers perceive were barriers to participating in the evaluation? Do providers perceive the data collection to be burdensome? What alternate methods or procedures would they prefer?
- What do providers believe would improve evaluation procedures or instruments? What would be needed for their clinic to participate in a longer and larger evaluation?

Effectiveness of data collection tools and procedures

- Did providers understand the questions asked on the prestudy and poststudy assessment? Were data gathered from them complete?

Outcome Evaluation

Based on our conceptual framework, our evaluation focused on measuring patient- and provider-level outcomes using a pre-post study design. In addition to these outcomes, we also assessed patients' and providers' reactions to the tools, including whether they found them easy or hard to use, whether they found them helpful, and the extent to which they felt the tools facilitated obtaining and presenting accurate family history information.

The short field period for this study precluded us from gathering the longer-term outcomes. For example, outcomes that are key to determining the effectiveness of the tool include referral to a genetic counselor and receiving a *BRCA* test for high-risk women. For women who are not at high risk, desirable outcomes include continuing to use the family history tool (e.g., updating cancer history as it changes within the family) and following cancer screening recommendations.

Constructs and evaluation questions for the outcome evaluation for patients can be found below.

Patients

Demographics/characteristics: age, race/ethnicity, marital status, children

- What are the demographics characteristics of the patients in the study?

Length of time with provider

- How long has the patient been a patient of the practice?

Comfort with computers

- Does the patient regularly use a computer? How comfortable is she in using one?
- Trust in provider
- To what degree does the patient trust the provider or practice?

Health status

- How does the patient perceive her health status?

Close friends/family with cancer

- Does the patient have any close friends or family members with cancer?

Knowledge of CDS tools, hereditary breast cancer, genetic testing, and BRCA screening

- How much do patients know about CDS tools, hereditary breast cancer, genetic testing, and *BRCA* screening?

Previous use of CDS tools or experience in genetic testing

- Have patients used any type of CDS tool in the past? What type of experience do patients have with genetic testing?

Perceived risk of patient seen at clinic

- Do patients perceive they are at risk for *BRCA* mutations?

Perceived severity of hereditary breast cancer

- How severe do patients feel hereditary breast cancer is?

Perceived benefits of risk assessment

- Do patients perceive that learning their risk of *BRCA* mutations would be beneficial to them?

Perceived barriers/costs of gathering cancer family history and risk assessment

- What do patients perceive to be the barriers to gathering their family's cancer history? What do patients perceive to be the barriers to learning their risk?

Decision recognition

- Do high-risk patients recognize that they need to make a decision about whether or not to (1) see a genetic counselor, (2) be tested for *BRCA* mutations, and (3) discuss their risk status with family members?

Patient–provider communication about risk status

- How frequently did providers discuss patients' risk status with them during the clinical encounter? What content and messages were included in that discussion?

Self-efficacy in communicating with provider

- How confident are patients in their ability to ask their provider questions? How confident are patients in their ability to providers to clarify information they don't understand?

Perceptions of patient-centered communication

- Do patients feel their provider exchanged information with them, answered questions and managed their uncertainty, supported a healing relationship, and made decisions with them?

Perception of patient-provider interaction

- Was the patient satisfied with the information related to *BRCA* risk and genetic testing discussed in the interaction?
- How does the patient rate the quality of the interaction?
- How well does the patient perceive the provider did in helping her understand her risk of *BRCA* mutations?

Intention to use the CDS tool

- Do patients intend to use the CDS tool after the study if their cancer family history changes?

Use of the tool

- Do patients report they used the tool? Do patients report that their provider used the tool?

Decision to gather family history

- What proportion of patients decides to gather their family history? What reasons do patients who chose not to gather their family history give?

Decision to learn risk

- What proportion of patients decides to learn their risk of having a *BRCA* mutation? What reasons do patients who chose not to learn their risk give?

Delivery of tool output

- Do patients bring the printed output from the CDS tool to their provider? Why or why not?
- Do patients comprehend of the term "risk result"?
- Do patients understand the result of their risk assessment?

Referral

- Were patients at high risk referred for genetic counseling? Why or why not? Were patients who were not at high risk referred? Why?

Intent to follow provider's recommendation

- Do patients intend to follow the recommendations concerning screening and referral, if given? Why or why not?

Constructs and evaluation questions for the outcome evaluation for providers can be found below.

Providers

Demographics: Type of primary care provider, age, length of time in practice

- What are the demographic characteristics of the providers in the study?

Knowledge of CDS tools, hereditary breast cancer, genetic testing, and BRCA screening

- How much do providers know about CDS tools, hereditary breast cancer, genetic testing, and *BRCA* screening?

Attitudes toward CDS tools, hereditary breast cancer, and BRCA screening

- What are providers' attitudes toward CDS tools, hereditary breast cancer, genetic testing, and *BRCA* screening?

Previous use of CDS tools or experience in genetic testing

- Have providers used any type of CDS tool in the past? What type of experience do providers have with genetic testing?

Patient–provider communication about risk status

- How frequently did providers discuss patients' risk status with them during the clinical encounter? What content and messages were included in that discussion?

Perception of patient–provider interaction

- How well does the provider perceive that the patient understood her risk of *BRCA* mutations?

Intention to use the CDS tool

- Do providers intend to use the CDS tool in their practice after the study ends?

Use of the tool

- Do providers report that they used the tool? How often do they report using the tool? When do they report using the tool (i.e., before or during a patient visit)?

Referral and referral alignment

- Do providers refer patients who were at high risk for genetic counseling? Why or why not? Do they refer patients who were not high risk? Why? Do providers' referrals match what was suggested by the tool?

Piloting Evaluation Methods and Tools

One of the objectives of our evaluation was to pilot our evaluation procedures, instruments, and processes to inform the development of a larger outcome evaluation postcontract. For a scaled-up evaluation to be successful, the evaluation procedures need to be as nonburdensome as possible for both patients and providers. We will seek to answer the following questions regarding the implementation of the evaluation:

- How does implementation of the evaluation protocol vary in each clinic? Are patients and providers compliant with the evaluation protocol? Why or why not?
- What are the barriers and facilitators toward implementing the evaluation at each site? What would need to be put in place at each site to support a scaled-up outcome and implementation evaluation?
- Are the data gathered on the surveys complete? Are questions working as intended? Are there any questions that are not producing variability in responses? Which ones and why?
- Do patients and providers perceive the data collection to be burdensome? What alternate methods would they prefer?

These questions were included in post-test 2 for the patient and in the poststudy interview for the providers.

Instrument Development

Seven surveys and one checklist were developed for the evaluation. For patients, we developed three surveys: (1) a baseline survey, (2) a survey to be completed after they used the tool and calculated their risk of having a *BRCA* mutation and before their scheduled visit with their provider, and (3) a survey to be completed after they finished their appointment with their provider. Patient surveys underwent cognitive testing. A summary of the results of this cognitive testing can be found in Appendix L. Findings were used to revise the patient surveys. The final protocol and patient surveys used in the evaluation can be found in Appendix M. All surveys were administered via the study Web site, which also housed the *Cancer in the Family* tool.

For providers, four Web surveys were developed: (1) a baseline survey, (2) a post-training survey that launched after the providers completed the study training, (3) a posteducation survey that launched approximately 1 week post-training, and (4) a poststudy survey that was made available after providers finished seeing all study patients. A postencounter checklist was also developed for providers to document for each patient in the study their use of the tool during the clinical encounter, the patient's risk assessment results, and whether they provided a referral to a genetic counselor. Given the resources of the project and the anticipated number of providers in the study, we did not conduct cognitive testing of the provider surveys; however, most survey questions were adapted from an existing instrument by Moore and Benbasat (2001) that had been assessed for validity and reliability. Moore and Benbasat's instrument was based on Roger's Diffusion of Innovation theory and was designed to assess the adoption of an information technology innovation. We used items from this scale to assess the

following domains: relative advantage, compatibility, ease of use, trailability, and image. Cronbach's alphas for Moore and Benbasat's subscales for these items ranged from 0.71 to 0.90. We revised the wording of some questions slightly for the purposes of making items applicable to this evaluation. The provider surveys and the checklist can be found in Appendix M.

Site Training

Site training took place through a series of informal conference calls between site coordinators and RTI staff members. RTI created a protocol guide ("tip sheets") that outlined the site coordinator's responsibilities for both the patient and the provider (see Appendix N). In addition, flowcharts for both the patient and provider outlined the site coordinator's role during the various steps of the evaluation (see Appendix N).

The tip sheet for patients delineated approximate points during the study when site coordinators needed to place reminder calls, outlined the steps that the patient needed to go through during the study, and provided guidance for anticipated problems that could arise (e.g., a patient lost a username or password). The tip sheet for providers provided similar information on steps providers needed to take throughout the study, approximate points during the study when site coordinators should place reminder calls, and guidance for anticipated problems that might occur.

Sites also received a separate instruction sheet on the patient enrollment database that outlined what information should be recorded and how it should be recorded. Once RTI had developed these materials, they were forwarded to the site coordinators, along with a sample patient and provider enrollment packet, provider and patient informed consent forms, and an enrollment screener for the sites to review.

Site Monitoring. After sites reviewed the documents, RTI conducted a semistructured training in which the site coordinator's role throughout the study was discussed and sites were offered the chance to ask questions about how the study progressed. Once recruitment for the study began, sites met weekly with an RTI staff member to discuss problems or issues that arose. Outstanding concerns were passed onto the RTI research team for further discussion. During recruitment, sites completed a weekly recruitment report that provided information on how many times potential participants had been contacted, how many patients had been recruited, and how many had refused participation and the reason for refusal.

RTI could access a separate interface of the tool that generated a report that monitored patients' progress in the study. These reports provided information such as the date patients completed the surveys, the last time the patient logged on to the tool, and the patient's appointment date. On the weekly conference calls, RTI discussed any patients that needed additional reminders or attention (e.g., if a patient who had an upcoming appointment within a week and had not yet logged on to the tool) as well as any global issues that arose with sites (e.g., if one site was struggling to get providers to complete the checklist during the visit). RTI was also able to monitor the disbursement of incentives through these reports.

Provider Training

Because the RTI Project Director for the study lived in close proximity to FFP, she conducted an in-person training for physicians at this site. The training was conducted via Webinar for physicians at the two BHCS sites.

The training consisted of a PowerPoint presentation (see Appendix O) that outlined the purpose of the study, outlined the tool components for both patients and providers, provided background on the evaluation study, and provided detailed instructions on the physician responsibilities in the study. The training provided detailed information on tool usage, such as how to log on, change their password, review and edit a patient's family history, and review or rerun a patient's risk results. The training also provided information and guidance on the provider's interaction with the patient, such as how to discuss the risk results, offer screening and/or referral to a genetic counselor for a patient, complete the visit checklist, and save the patient's record in the EMR. After the training, providers were given several weeks to independently explore the tool and its educational modules before using the tool in patient appointments.

Data Analysis

Given the small sample size for both patients and providers, only descriptive analyses were conducted.

Sites

We conducted the field test of the *Cancer in the Family* tool over 8 weeks (April 19 to June 11, 2010). Three providers participated at each site for a total of nine providers. The goal for each clinic was to have 40 patients complete the study. A total of 48 patients completed the full study protocol (e.g., the baseline survey and two post-tests). Nineteen patients completed the study at Southlake, 17 at Garland, and 12 at Fairfax. (Note: one patient only completed a few questions on post-test 2. These data are included in the analysis, and the case was still deemed to be "complete.")

Fifteen patients who initially enrolled in the study and completed the online consent form withdrew from the study (seven from North Garland, four from Southlake, and four from Fairfax). Of those 15 patients, 14 completed the baseline survey and 1 also completed the risk assessment in the tool. None completed either of the two post-tests. The demographic characteristics of those who completed all the surveys were compared to those who had completed the baseline survey and withdrew. No significant differences were found. Data from participants who withdrew from the study were excluded from the following analyses.

Patient Characteristics

Demographic characteristics of patients who completed all three surveys (baseline, post-test1, and post-test 2) are included in Table 3. The majority (90 percent) of patients were White and ranged in age from 22 to 59. Most were married or living as married (81 percent) and reported family incomes of $40,000 or greater (94 percent). Nearly all (98 percent) reported having insurance and reported their health status as good, very good, or excellent. Three-quarters indicated they have a family member or close friend who has had breast cancer, with a very small percentage of those (3 percent) reporting the person had died of breast cancer. About one-third of participants reported having a family member or close friend who has had ovarian cancer, with less than half (40 percent) reporting the person had died from ovarian cancer. About 10 percent indicated that they have had a genetic test in the past.

Patients' Perceptions and Use of the *Cancer in the Family* Tool

During the study period, there were 250 logins to the tool from patients. The number of times patients logged on to the tool ranged from 2 to 13 times, with a mean of 5.21 times (SD = 3.01), a median of 4.00, and a mode of 3.00. Ten percent of patients logged on to the tool two times, 46 percent logged on three to four times, and 44 percent logged on five or more times (see Table 4).

At post-test 1, which was administered prior to patients' appointment with their provider, patients were asked about their use of the tool. Almost all patients reported calculating their risk. The majority believed their result to be accurate, and three quarters were satisfied or very satisfied with their decision to learn their risk of having a *BRCA* mutation. The majority of patients printed out the results of their risk assessment and reported bringing it to their doctor's visit.

At post-test 1, patients were asked about their experience using the *Cancer in the Family* tool to gather their family's cancer history (see Table 5). The majority of patients asked their family members about their cancer family history and reported that doing so was easy or very easy. Half used the personalized worksheet generated by the tool to gather their family's cancer history and found it to be very easy to use and useful. Patients also reported that entering their family history into the tool was easy or very easy.

Table 3. Patient background and demographics (n = 48)

Item	Baseline
Age	
22–40	10 (20.8%)
41–50	21 (43.8%)
51 and older	17 (35.4%)
Race	
White	43 (89.6%)
Black	1 (02.1%)
Native Hawaiian	1 (02.1%)
Hispanic	2 (04.2%)
Multiple races	1 (02.1%)
Education	
High school	3 (06.3%)
Some college or technical school	16 (33.3%)
Bachelor's degree	20 (41.7%)
Graduate degree	9 (18.8%)
Marital status	
Married or living as married	39 (81.2%)
Not married	9 (18.8%)
Income	
Less than $20K	1 (02.1%)
$20K to less than $40K	1 (02.1%)
$40K to less than $60K	2 (04.2%)
$60K to less than $80K	3 (06.3%)
$80K to less than $100K	8 (16.7%)
$100K or more	32 (66.7%)
Don't know	1 (02.1%)
Number of dependents	
1 to 2	23 (47.9%)
3 to 4	23 (47.9%)
5 to 6	1 (02.1%)
Missing	1 (02.1%)

Table 3. Patient background and demographics (n = 48) (continued)

Item	Baseline
How long have you been a patient at [CLINIC NAME]?	
Less than 1 year	1 (02.1%)
1 to 2 years	4 (08.3%)
3 to 4 years	4 (08.3%)
5 or more years	39 (81.3%)
Health insurance[a]	
Private or employer	47(97.9%)
Medicaid	0 (00.0%)
Medicare	0 (00.0%)
Military health care/VA	1 (2.1%)
Other	0 (0.0%)
In general, would you say your health is…	
Excellent	8 (16.7%)
Very good	23 (47.9%)
Good	16 (33.3%)
Fair	1 (02.1%)
Poor	0 (00.0%)
Do you have any family members or close friends who ever had breast cancer?	
Yes	36 (75.0%)
No	12 (25.0%)
Do you have any family members or close friends who have died from breast cancer?	
Yes	1 (02.1%)
No	18 (37.5%)
Not applicable	12 (25.0%)
Don't know	17 (35.4%)
Do you have any family members or close friends who ever had ovarian cancer?	
Yes	15 (31.3%)
No	25 (52.1%)
Don't know	8 (16.7%)
Do you have any family members or close friends who have died from ovarian cancer?	
Yes	6 (12.5%)
No	13 (27.1%)
Not applicable	25 (52.1%)
Missing	4 (08.3%)
Have you ever had a genetic test for any reason?	
Yes	5 (10.4%)
No	41 (85.4%)
Don't know	2 (04.2%)

[a]Percentages across patients are greater than 100 because one patient reported having both private/employer and "other" health insurance.

Table 4. Patient use of the *BRCA* decision aid tool (n = 48)

Item	Post-test 1	Post-test 2
According to the tool, what is your risk of having a *BRCA* mutation?		
Increased risk	2 (04.2%)	a
Average risk[b]	44 (91.6%)	a
Don't remember/missing	2 (04.2%)	a
How accurate do you think your *BRCA* risk assessment results are?		
1 Not at all accurate	1 (02.1%)	a
2	2 (04.2%)	a
3	5 (10.4%)	a
4	18 (37.5%)	a
5 Very accurate	18 (37.5%)	a
Missing	4 (08.3%)	a
How satisfied are you with your decision to learn your risk of having a *BRCA* mutation?		
1 Not at all satisfied	0 (00.0%)	a
2	2 (04.2%)	a
3	4 (08.3%)	a
4	10 (20.8%)	a
5 Very satisfied	27 (56.3%)	a
Missing	4 (08.3%)	a
Did you print out the results of your risk assessment?		
Yes	c	35 (72.9%)
No	c	11 (22.9%)
Don't remember	c	1 (02.1%)
Missing	c	1 (02.1%)
Did you bring a printout of the risk assessment results to your doctor's visit?		
Yes	c	31(64.6%)
No	c	4 (08.3%)
Not applicable	c	12 (25.0%)
Missing	c	1 (02.1%)

[a]This question was not asked in post-test 2.
[b]The questionnaires for the evaluation were developed before the tool content was final. Thus, the term "average risk" was used in the evaluation; however the term "not at increased risk" was used in the tool.
[c]This question was not asked in post-test 1.

Table 5. Patient use of the *BRCA* decision aid tool to gather family cancer history (n = 48)

Item	Post-test 1
Did you ask any of your family members about their cancer history?	
Yes	37 (77.1%)
No	10 (20.8%)
Missing	1 (02.1%)
How easy or difficult was it to ask your family members about their history of cancer?	
1 Very easy	16 (33.3%)
2	5 (10.4%)
3	1 (02.1%)
4	2 (04.2%)
5 Very difficult	0 (00.0%)
Not applicable	10 (20.8%)
Missing	14 (29.2%)
How effective was the tool at helping you understand how to gather your family's cancer history?	
1 Not at all effective	2 (04.2%)
2	2 (04.2%)
3	2 (04.2%)
4	10 (20.8%)
5 Very effective	31 (64.5%)
Missing	1 (02.1%)
Did you use the worksheet provided by the tool for collecting your family history?	
Yes	25 (52.1%)
No	12 (25.0%)
Missing	11 (22.9%)
In your opinion, how useful was the worksheet for collecting your family's cancer history?	
1 Not at all useful	0 (00.0%)
2	3 (06.3%)
3	3 (06.3%)
4	6 (12.5%)
5 Very useful	13 (27.0%)
Missing	23 (47.9%)
How easy or difficult was it to use the worksheet?	
1 Very easy	15 (31.3%)
2	3 (06.3%)
3	4 (08.3%)
4	3 (06.3%)
5 Very difficult	0 (00.0%)
Missing	23 (47.9%)
Did you enter your family's cancer history into the tool?	
Entered family's complete cancer history	32 (66.7%)
Entered some or most of family's cancer history	4 (08.3%)
Did not enter any history	1 (02.1%)
Missing	11 (22.9%)
How easy or difficult was it to enter your family history into the tool?	
1 Very easy	23 (47.9%)
2	11 (22.9%)
3	1 (02.1%)
4	1 (02.1%)
5 Very difficult	0 (00.0%)
Missing	12 (25.0%)

At post-test 1, patients were also asked about their perceptions of the effectiveness of the educational content of the *Cancer in the Family* tool (see Table 6). Perceived effectiveness was high as was satisfaction with the tool.

Table 6. Patients' perceived effectiveness of the educational content in the tool at post-test 1 (n = 48)

Item	Post-test 1
How effective was the tool in helping you understand what *BRCA* mutations are?	
1 Not at all effective	2 (04.2%)
2	2 (04.2%)
3	5 (10.4%)
4	13 (27.1%)
5 Very effective	25 (52.1%)
Missing	1 (02.1%)
How effective was the tool in helping you understand the advantages and disadvantages of learning your risk for *BRCA* mutations?	
1 Not at all effective	1 (02.1%)
2	3 (06.2%)
3	5 (10.4%)
4	12 (25.0%)
5 Very effective	26 (54.2%)
Missing	1 (02.1%)
How effective was the tool in helping you understand the results of your *BRCA* risk assessment?	
1 Not at all effective	2 (04.2%)
2	2 (04.2%)
3	3 (06.2%)
4	13 (27.1%)
5 Very effective	23 (47.9%)
Missing	4 (08.3%)
Overall, how satisfied were you with the tool?	
1 Not at all satisfied	0 (00.0%)
2	2 (04.2%)
3	4 (08.3%)
4	11 (22.9%)
5 Very satisfied	27 (56.3%)
Missing	4 (08.3%)

One of the main goals of the tool was to help stimulate and improve patient–provider communication. At post-test 2, which was administered after their visit with their physician, patients were asked to rate, on a scale from 1 (not at all effective) to 5 (very effective), the effectiveness of the tool in preparing them to talk with their doctor. Fifty-four percent of patients (n = 26) said the tool was very effective (5), 25 percent (n = 12) said "4," and 19 percent (n = 9) said "3." No respondents indicated the tool was a "2" or a "1" (not at all effective).

Table 7 displays the results from questions about patient–provider communication asked on post-test 2, which was administered after the patients' appointments with their providers. Overall, patients were very satisfied with the conversation they had with their provider.

Table 7. Patients' conversations with the doctor at post-test 2 (n = 48)

Item	Post-test 2
Overall, how satisfied were you with the conversation you had with your doctor?	
1 Not at all satisfied	0 (00.0%)
2	1 (02.1%)
3	0 (00.0%)
4	6 (12.5%)
5 Very satisfied	39 (81.3%)
Missing	2 (04.2%)
Which of the following did you do during your conversation with the doctor?	
Asked about my chances of getting breast or ovarian cancer	12 (25.0%)
Asked about genetic counseling and genetic testing	4 (08.3%)
Asked doctor to explain something I did not understand	10 (20.8%)
Shared my opinion about whether or not I should see a genetic counselor	10 (20.8%)
Shared my opinion about whether or not I should get tested for a *BRCA* mutation	20 (41.7%)
I decided whether or not I will go see a genetic counselor	8 (16.7%)
I decided whether or not I will get a test for *BRCA* mutations	13 (27.1%)
Other	8 (16.7%)
Asked why I was chosen for the study	1 (02.1%)
Discussed ongoing preventative screening	2 (04.2%)
Discussed research about breast cancer and prevention	1 (02.1%)
Discussed options if I were to test positive	2 (04.2%)
Discussed past screenings for *BRCA* mutations	1 (02.1%)
Discussed risks of cancer if no family history of cancer	1 (02.1%)
Discussed other family health history	1 (02.1%)

Patient Outcomes

Patients were asked survey questions that assessed their perceived risk of breast and ovarian cancer and desire to learn about their risk based on a more objective assessment at baseline and one or both post-tests. As shown in Table 8, participants' perceived risk of breast cancer decreased significantly from baseline ($\times$ = 2.50) to the first followup ($\times$ = 2.17). Perceived risk for ovarian cancer did not change over time. The extent to which participants were worried about getting breast cancer decreased significantly from baseline ($\times$ = 2.66) and post-test 1 ($\times$ = 2.44) to post-test 2 ($\times$ = 1.81). The extent to which participants were worried about getting ovarian cancer decreased significantly from post-test 1 ($\times$ = 2.20) to post-test 2 ($\times$ = 1.63). Participants were also more likely to disagree with the statement that all women who get ovarian cancer die at post-test 1 ($\times$ = 2.38) as compared to baseline ($\times$ = 2.77).

Table 8. Average pre- and post-test patient perceived risk of breast and ovarian cancer and desire to learn risk (n = 48)

Item	Baseline	Post-test 1	Post-test 2
Would you say your chance of getting breast cancer in your lifetime is… (1-Very low to 5-Very high)	2.50*	2.17*	a
Would you say your chance of getting ovarian cancer in your lifetime is… (1-Very low to 5-Very high)	2.04	1.79	a
How worried are you about getting breast cancer? (1-Not worried at all to 5-Very worried)	2.66*	2.44*	1.81*
How worried are you about getting ovarian cancer? (1-Not worried at all to 5-Very worried)	2.07	2.20*	1.63*
Almost all women who get breast cancer die from the disease. (1-Strongly disagree to 5-Strongly agree)	1.87	1.79	a
Almost all women who get ovarian cancer die from the disease. (1-Strongly disagree to 5-Strongly agree)	2.77*	2.38*	a
I would like to know my chances of getting breast cancer. (1-Strongly disagree to 5-Strongly agree)	4.49	4.26	a
I would like to know my chances of getting ovarian cancer. (1-Strongly disagree to 5-Strongly agree)	4.53	4.11	a

* $p < .05$

[a] Question not asked in post-test 2.

Patients were also asked several items to assess current knowledge about breast and ovarian cancer, genetic testing, *BRCA* screening, and factors related to increased risk of *BRCA* mutations. Table 9 shows the number and percentage for responses to each of the items.

Table 9. Patient knowledge about risks of breast and ovarian cancer (n = 48)

Item	Baseline	Post-test 1
Breast cancer is more common than ovarian cancer		
True[a]	32 (66.7%)	34 (70.8%)
False	1 (02.1%)	2 (04.2%)
Don't know	15 (31.3%)	11 (22.9%)
Missing	0 (00.0%)	1 (02.1%)
Who can get breast cancer?		
All women[a]	41 (85.4%)	47 (97.9%)
Only women who have a *BRCA* mutation	1 (02.1%)	0 (00.0%)
Only women with a mother who had breast cancer	0 (00.0%)	0 (00.0%)
Don't know	6 (12.5%)	0 (00.0%)
Missing	0 (00.0%)	1 (02.1%)
Who can get ovarian cancer?		
All women[a]	41 (85.4%)	46 (95.8%)
Only women who have a *BRCA* mutation	0 (00.0%)	0 (00.0%)
Only women with a mother who had ovarian cancer	0 (00.0%)	0 (00.0%)
Don't know	7 (14.6%)	1 (02.1%)
Missing	0 (00.0%)	1 (02.1%)

Table 9. Patient knowledge about risks of breast and ovarian cancer (n = 48) (continued)

Item	Baseline	Post-test 1
A woman who does not have a *BRCA*1 or *BRCA*2 gene mutation can still get cancer.		
True[a]	27 (43.8%)	43 (89.6%)
False	0 (00.0%)	0 (00.0%)
Don't know	21 (43.8%)	4 (08.3%)
Missing	0 (00.0%)	1 (02.1%)
A woman who has a *BRCA*1 or *BRCA*2 gene mutation…		
Will definitely get breast or ovarian cancer	0 (00.0%)	1 (02.1%)
Is at lower risk for breast or ovarian cancer	0 (00.0%)	0 (00.0%)
Is at greater risk for breast and/or ovarian cancer[a]	26 (54.2%)	45 (93.8%)
Don't know	22 (45.8%)	0 (00.0%)
Missing	0 (00.0%)	1 (02.1%)
Your chances of having a *BRCA*1 or *BRCA*2 gene mutation is based on…		
Whether your mother had breast and/or ovarian cancer	2 (04.2%)	0 (00.0%)
Your entire family history of all diseases	7 (14.6%)	1 (02.1%)
Your entire family history of breast and ovarian cancer[a]	17 (35.4%)	44 (91.7%)
Don't know	22 (45.8%)	0 (00.0%)
Missing	0 (00.0%)	1 (02.1%)
A family cancer history should include…		
All of your relatives	7 (14.6%)	2 (04.2%)
Only blood relatives[a]	41 (85.4%)	45 (93.8%)
Only relatives that are alive	0 (00.0%)	0 (00.0%)
Don't know	0 (00.0%)	0 (00.0%)
Missing	0 (00.0%)	1 (02.1%)
About 1 in 10 women have a *BRCA*1 or *BRCA*2 gene mutation		
True	4 (08.3%)	16 (33.3%)
False[a]	0 (00.0%)	20 (41.7%)
Don't know	43 (89.6%)	11 (22.9%)
Missing	1 (02.1%)	1 (02.1%)
A *BRCA* genetic test cannot tell you…		
If you have a *BRCA*1 or *BRCA*2 mutation	2 (04.2%)	0 (00.0%)
If you will get breast and/or ovarian cancer[a]	25 (52.1%)	42 (87.5%)
If you have a greater chance of breast and ovarian cancer	0 (00.0%)	1 (02.1%)
Don't know	21 (43.8%)	4 (08.3%)
Missing	0 (00.0%)	0 (00.0%)
If you see a genetic counselor, you must get a genetic test.		
True	5 (10.4%)	4 (08.3%)
False[a]	29 (60.4%)	37 (77.1%)
Don't know	14 (29.2%)	6 (12.5%)
Missing	0 (00.0%)	1 (02.1%)

[a]Correct answer

Patients were also asked to respond to items aimed at assessing their perceived severity of risk, benefits, and costs of assessing one's risk. As shown in Table 10, patients were significantly more likely to agree that having a *BRCA*1 or *BRCA*2 gene mutation would be no big deal at post-test 1 ($\times$ = 2.30) compared to baseline ($\times$ = 1.34). They were also significantly more likely to agree that there is no reason for them to get any type of genetic test at post-test 1 ($\times$ = 2.75) than at baseline ($\times$ =1.53).

Table 10. Average pre- and post-test perceived severity of risk, benefits, and costs of risk assessment (n = 48)

Item	Baseline	Post-test 1	Post-test 2
To me, having a *BRCA*1 or *BRCA*2 gene mutation would be no big deal. (1-Strongly disagree to 5-Strongly agree)	1.34*	2.30*	a
For me, there is no reason to get any type of genetic test. (1-Strongly disagree to 5-Strongly agree)	1.53*	2.75*	a
If I could get a genetic test to learn whether I have a gene that causes a serious disease, I would get it. (1-Strongly disagree to 5-Strongly agree)	3.66	3.83	a
Knowing whether or not I have a greater chance of getting breast or ovarian cancer would help me make decisions about my medical care. (1-Strongly disagree to 5-Strongly agree)	4.51	4.38	a
How easy or difficult would it be to handle learning you had a greater chance of having a *BRCA*1 or *BRCA*2 gene mutation? (1-Very difficult to 5-Very easy)	2.30	2.53	a
How easy or difficult would it be to handle learning you had a greater chance of getting breast or ovarian cancer? (1-Very difficult to 5-Very easy)	2.30	2.66	a
The advantages of knowing whether my genes give me a greater chance of getting breast or ovarian cancer outweigh the disadvantages. (1-Strongly disagree to 5-Strongly agree)	3.79	4.06	a
I am concerned that if I were to get a genetic test that my health insurance coverage would not cover the genetic test. (1-Strongly disagree to 5-Strongly agree)	3.92*	3.57*	2.17*

* $p < .05$

[a]Question not asked in post-test 2.

Patients' level of self-efficacy in communicating with their provider was assessed at baseline and post-test 1. Patients were more likely to report that they would feel confident asking their provider about genetic testing at post-test 1 ($\times = 4.81$) than at baseline ($\times = 4.47$) (see Table 11).

Table 11. Average pre- and post-test patient self-efficacy in communicating with provider (n = 48)

Item	Baseline	Post-test 1
Ask your doctor questions? (1-Not at all confident to 5-Very confident)	4.77	4.81
Ask your doctor questions about genetic testing? (1-Not at all confident to 5-Very confident)	4.47*	4.81*
Make decisions about your medical care with your doctor? (1-Not at all confident to 5-Very confident)	4.81	4.81

* $p < .05$

We also assessed whether number of patient logins was related to outcomes. No statistically significant differences were found.

Provider Characteristics

Demographic characteristics and background information for the providers are included in Table 12. All providers were White and ranged in age from 32 to 59. Only one of the nine providers was male. The majority identified themselves as primary care physicians for about 10 to 20 years with no specialties. Most have not had any training on hereditary breast and ovarian cancer or *BRCA* testing. About half have used decision aids in their practice, and those who have used decision aids rated their experience as more positive than negative.

Table 12. Provider background (n = 9)

Item	Baseline
Age	
30 to 39	2 (22.2%)
40 to 49	4 (44.4%)
50 to 59	3 (33.3%)
Gender	
Male	1 (11.1%)
Female	8 (88.9%)
Race	
White	9 (100.0%)
Black	0 (00.0%)
Native Hawaiian	0 (00.0%)
Hispanic	0 (00.0%)
Multiple races	0 (00.0%)
What kind of primary care provider are you?	
Primary care physician	7 (77.8%)
Obstetrician/gynecologist	0 (00.0%)
Physician's assistant	0 (00.0%)
Internal medicine	1 (11.1%)
Other	1 (11.1%)
Nurse practitioner	1 (11.1%)
Do you have any specialties?	
Yes	1 (11.1%)
Family medicine	1 (11.1%)
No	8 (88.9%)
How long have you been a primary care physician?	
Less than 10 years	1 (11.1%)
10 to 15 years	4 (44.4%)
16 to 20 years	2 (22.2%)
21 to 25 years	1 (11.1%)
26 or more years	1 (11.1%)
How long have you been with your current employer?	
Less than 10 years	1 (11.1%)
10 to 15 years	6 (66.7%)
16 to 20 years	1 (11.1%)
21 to 25 years	0 (00.0%)
26 or more years	1 (11.1%)
How long have you been with your current clinic?	
Less than 10 years	2 (22.2%)
10 to 15 years	5 (55.6%)
16 to 20 years	1 (11.1%)
21 to 25 years	1 (11.1%)
26 or more years	0 (00.1%)

Table 12. Provider background (n = 9) (continued)

Item	Baseline
Have you ever had any type of training (including CME courses) on hereditary breast and ovarian cancer or *BRCA* testing? If yes, how long ago did you participate?	
Yes	1 (11.1%)
5 years ago	1 (11.1%)
No	8 (88.9%)
Have you ever used a decision aid in your practice?	
Yes	5 (55.6%)
No	4 (44.4%)
Description of decision aid(s) used	
Protocols through the AAFP	1 (11.1%)
We utilize Up to Date, MD Consult	1 (11.1%)
EHR helps to factor risks of heart disease	1 (11.1%)
EHR with prompts and protocols, flowsheets	1 (11.1%)
Framingham Risk Assessment	1 (11.1%)
Breast Cancer Risk Calculator	1 (11.1%)
Aids regarding dementia or depression	1 (11.1%)
If Yes: Please rate your overall experience with decision aid(s).	
1 Extremely negative	0 (00.0%)
2	1 (11.1%)
3	1 (11.1%)
4	1 (11.1%)
5 Extremely positive	2 (22.2%)
Not applicable	4 (44.4%)

Providers' Use and Perceptions of the Tool

During the study period, there were 128 logins to the tool from providers. The number of times providers logged on to the tool ranged from 7 to 25 times, with a mean of 14.22 times (SD = 5.54), a median of 15, and a mode of 7. Twenty-two percent of providers logged on to 5 to 10 times; 44 percent logged on 11 to 15 times; and 33 percent logged on 16 or more times.

Providers were asked to complete a checklist documenting their clinical encounter with each study patient (see Table 13). Of the 48 patients in the study, only 2 were at increased risk for having a *BRCA* mutation and were referred to genetic counseling. Forty-six percent of providers reported using the tool during the patient's appointment, and 33 percent reported using it before patients' appointments. Four providers indicated they did not use the tool, which may be because site coordinators often printed out the risk results for each patient and provided the printout to the provider, thus making it less important, perhaps, for the provider to actually log into the tool and use it during the clinical encounter.

During the patient's visit, providers reported reviewing patients' cancer family history (88 percent), updating the patient's cancer family history (67 percent), explaining the risk results (88 percent), addressing questions (83 percent), and checking patients' understanding (60 percent). Providers documented other referrals that they made during the clinical visit (see Table 13).

Table 13. Provider checklist responses following visit with patient (n = 9)

Item	Postpatient Visit
This patient's risk for having a *BRCA* mutation was…	
Not at increased risk	44 (91.6%)
Increased risk	2 (04.2%)
Missing	2 (04.2%)
When did you use the tool to review this patient's risk results	
Before patient's appointment	16 (33.3%)
During patient's appointment	22 (45.8%)
Both before and during patient's appointment	4 (08.3%)
Did not use tool	4 (08.3%)
Missing	2 (04.2%)
Did you refer this patient for genetic counseling?	
Yes	2 (04.2%)
No	44 (91.7%)
Missing	2 (04.2%)
What other referrals did you provide to this patient?	
Mammography	29 (60.4%)
Pap test	21 (43.8%)
Colorectal cancer screening	0 (00.0%)
Other	2 (04.2%)
Blood pressure treatment	1 (02.1%)
Cholesterol	1 (02.1%)
During the patient's visit, which of the following did you do with the patient?	
Reviewed cancer family history	42 (87.5%)
Updated cancer family history after review	32 (66.7%)
Explained risk result	42 (87.5%)
Addressed questions	40 (83.3%)
Checked understanding	29 (60.4%)

Providers' Perceptions of Tool. After providers were trained on the tool and prior to seeing patients, they were encouraged to explore the tool, especially the background educational information (module). Before the field period began, providers were asked for their opinion about the information in the educational module. Results can be found in Table 14. Providers rated the quality of the information as being good, influential, and easy to navigate. They also indicated that they learned a great deal from the educational module and that it helped them feel better prepared to answer patients' questions on *BRCA* screening. Providers' satisfaction with the educational content was high.

Table 14. Provider responses following education module (n = 9)

Item	Posteducation
How would you rate the quality of the information in the educational module?	
1 Extremely low quality	0 (00.0%)
2	0 (00.0%)
3	1 (11.1%)
4	3 (33.3%)
5 Extremely high quality	5 (55.6%)
How much did the information in the educational module change your opinion of *BRCA* testing?	
1 Not at all	0 (00.0%)
2	1 (11.1%)
3	1 (11.1%)
4	5 (55.6%)
5 A lot	2 (22.2%)
The educational module made me feel more confident in my knowledge about *BRCA* screening and testing.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	4 (44.4%)
5 Strongly agree	5 (55.6%)
I learned a great deal from the educational module.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	2 (22.2%)
4	5 (55.6%)
5 Strongly agree	2 (22.2%)
Most of the information in the educational module was new to me.	
1 Strongly disagree	0 (00.0%)
2	2 (22.2%)
3	3 (33.3%)
4	4 (44.4%)
5 Strongly agree	0 (00.0%)
The educational module helped me feel better prepared to answer my patients' questions on *BRCA* screening.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	3 (33.3%)
5 Strongly agree	6 (66.7%)
The educational module helped me feel better prepared to answer my patients' questions about their risk for having a *BRCA* mutation.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	2 (22.2%)
5 Strongly agree	7 (77.8%)

Table 14. Provider responses following education module (n = 9) (continued)

Item	Posteducation
The educational module helped me feel better prepared to ask about my patients' cancer family history.	
1 Strongly disagree	0 (00.0%)
2	1 (11.1%)
3	1 (11.1%)
4	4 (44.4%)
5 Strongly agree	3 (33.3%)
The educational module was very difficult to navigate.	
1 strongly disagree	7 (77.8%)
2	2 (22.2%)
3	0 (00.0%)
4	0 (00.0%)
5 Strongly agree	0 (00.0%)
I would recommend the educational module to my colleagues.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	5 (55.6%)
5 Strongly agree	4 (44.4%)
Overall, how satisfied were you with the educational module.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	6 (66.7%)
5 Strongly agree	3 (33.3%)

Quality of Care. One of the study's goals was to evaluate how the tool could affect health care delivery, including the quality of care. In general, providers enrolled in the study with positive expectations for how the tool would affect quality of care, and these expectations increased after the study training (Table 15). However, after using the tool during the evaluation, providers held slightly lower expectations on this topic.

At the end of the study, providers were split on whether the tool would improve care quality or enhance their effectiveness in clinical work. They were more likely to think that the tool would improve the quality of information they provided to their patients. During the debriefing, providers echoed these expectations by saying that the tool, although valuable, would not necessarily affect the care of most patients who were not at increased risk.

Table 15. Provider perceptions—tool's effect on quality of care (n = 9)

Item	Baseline	Post-training	Poststudy
Using the *BRCA* decision aid will improve the quality of the care I provide to my patients.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	1 (11.1%)
2	0 (00.0%)	0 (00.0%)	1 (11.1%)
3	0 (00.0%)	0 (00.0%)	1 (11.1%)
4	5 (55.6%)	6 (66.7%)	2 (22.2%)
5 Strongly agree	4 (44.4%)	3 (33.3%)	4 (44.4%)
Average Response	***4.4***	***4.3***	***3.7***
Using the *BRCA* decision aid will improve the quality of the information I provide to my patients.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	0 (00.0%)	0 (00.0%)	0 (00.0%)
3	0 (00.0%)	1 (11.1%)	1 (11.1%)
4	6 (66.7%)	3 (33.3%)	5 (55.6%)
5 Strongly agree	3 (33.3%)	5 (55.6%)	3 (33.3%)
Average Response	***4.3***	***4.4***	***4.2***
Using the *BRCA* decision aid will enhance my effectiveness on the job.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	0 (00.0%)	0 (00.0%)	1 (11.1%)
3	2 (22.2%)	2 (22.2%)	1 (11.1%)
4	5 (55.6%)	4 (44.4%)	6 (66.7%)
5 Strongly agree	2 (22.2%)	3 (33.3%)	1 (11.1%)
Average Response	***4.0***	***4.1***	***3.7***

Clinical Workflow and Compatibility. A second goal of the study was to assess the tool's compatibility with current clinical practices. In particular, the study explored how easily the tool could be integrated into providers' workflow without major disruptions. In most cases, providers' perceptions of tool compatibility improved after they participated in the study (Table 16), and some providers agreed that the tool was compatible with their workflow (Table 16 and Table 17). At the end of the study, most providers (56 percent) held a neutral opinion of the tool's compatibility, and some (33 percent) agreed or strongly agreed that the tool was compatible with their clinic's workflow.

Providers also tended to believe that the tool fit well with their work style (Table 16). Most (78 percent) agreed or strongly agreed with this statement, a noticeable improvement from the 44 percent who agreed on the baseline survey. By the end of the study, fewer providers (33 percent) thought that the tool would interrupt the clinical workflow than at baseline (56 percent).

Providers were less likely to believe that the tool was easy to use or could be used quickly in a clinical setting (Table 16). Specifically, providers were split on whether the tool would make their job easier. Some (22 percent) agreed that it would; others (22 percent) disagreed. The majority (56 percent) neither agreed nor disagreed. Likewise, most providers (67 percent) did not agree that the tool would enable them to accomplish tasks more quickly.

Table 16. Provider perceptions—tool's effect on workflow (n = 9)

Item	Baseline	Post-training	Poststudy
Using the *BRCA* decision aid will allow me to accomplish tasks more quickly.			
1 Strongly disagree	3 (33.3%)	0 (00.0%)	1 (11.1%)
2	4 (44.4%)	3 (33.3%)	3 (33.3%)
3	2 (22.2%)	4 (44.4%)	2 (22.2%)
4	0 (00.0%)	2 (22.2%)	2 (22.2%)
5 Strongly agree	0 (00.0%)	0 (00.0%)	1 (11.1%)
Average Response	***1.8***	***2.8***	***2.8***
Using the *BRCA* decision aid will make it easier to do my job.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (0.00%)
2	2 (22.2%)	1 (11.1%)	2 (22.2%)
3	4 (44.4%)	5 (55.6%)	5 (55.6%)
4	2 (22.2%)	1 (11.1%)	2 (22.2%)
5 Strongly agree	1 (11.1%)	2 (22.2%)	0 (00.0%)
Average Response	***3.2***	***3.4***	***3.0***
Using the *BRCA* decision aid will be compatible with the workflow in our clinic.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	4 (44.4%)	4 (44.4%)	1 (11.1%)
3	3 (33.3%)	1 (11.1%)	5 (55.6%)
4	1 (11.1%)	3 (33.3%)	2 (22.2%)
5 Strongly agree	1 (11.1%)	1 (11.1%)	1 (11.1%)
Average Response	***2.8***	***3.1***	***3.3***
Using the *BRCA* decision aid will fit well with the way I like to work.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	2 (22.2%)	4 (44.4%)	2 (22.2%)
3	3 (33.3%)	2 (22.2%)	0 (00.0%)
4	3 (33.3%)	2 (22.2%)	4 (44.4%)
5 Strongly agree	1 (11.1%)	1 (11.1%)	3 (33.3%)
Average Response	***3.3***	***3.0***	***3.8***
The *BRCA* decision aid is going to interrupt the clinical workflow.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	1 (11.1%)
2	1 (11.1%)	1 (11.1%)	2 (22.2%)
3	3 (33.3%)	3 (33.3%)	3 (33.3%)
4	5 (55.6%)	4 (44.4%)	3 (33.0%)
5 Strongly agree	0 (00.0%)	1 (11.1%)	0 (00.0%)
Average Response	***3.4***	***3.5***	***2.8***

Table 17. Provider perceptions—tool's compatibility (n = 9)

Item	Post-training
Using the *BRCA* decision aid will be compatible with many aspects of my work.	
1 Strongly Disagree	0 (00.0%)
2	1 (11.1%)
3	5 (55.6%)
4	2 (22.2%)
5 Strongly agree	1 (11.1%)
Average Response	***3.3***

Tool Adopters. Theories of health behavior have demonstrated that individuals are more likely to adopt a tool or process if they believe that others like them have adopted it (Moore and Benbasat, 2001). Thus, the study assessed providers' perceptions of who in their practice would adopt the tool if it were made available.

Providers were mostly split on whether those who adopted the tool would be prestigious or have a high profile (Table 18). Interestingly, the belief that adopters would be prestigious decreased by the end of the study, yet the belief that adopters would have a high profile increased over the same period.

Table 18. Provider perceptions—tool adoption (n = 9)

Item	Baseline	Post-training	Poststudy
The people in my practice or clinic who are likely to use the *BRCA* decision aid have more prestige than those who are unlikely to use it.			
1 Strongly disagree	0 (00.0%)	1 (11.1%)	1 (11.1%)
2	4 (44.4%)	1 (11.1%)	1 (11.1%)
3	1 (11.1%)	1 (11.1%)	5 (5.56%)
4	3 (33.3%)	5 (55.6%)	2 (22.2%)
5 Strongly agree	1 (11.1%)	1 (11.1%)	0 (00.0%)
Average Response	***3.1***	***3.4***	***2.8***
The people in my practice or clinic who are likely to use the *BRCA* decision aids have a high profile.			
1 Strongly disagree	0 (00.0%)	1 (11.1%)	1 (11.1%)
2	2 (22.2%)	0 (00.0%)	0 (00.0%)
3	4 (44.4%)	2 (22.2%)	3 (33.3%)
4	3 (33.3%)	6 (66.7%)	5 (55.6%)
5 Strongly agree	0 (00.0%)	0 (00.0%)	0 (00.0%)
Average Response	***3.1***	***3.4***	***3.3***

Ease of Use and Trialability. Diffusion of Innovation theory suggests that a number of factors influence whether individuals ultimately adopt a tool or process (Rogers, 1995). Two of those factors are the ease of using the tool and the ability to try the tool before fully committing to it.

Provider perceptions of the tool's ease increased dramatically throughout the study (Table 19). At baseline, most providers did not agree that the tool would be clear, understandable, or easy to use. However, by the end of the study, almost all providers felt that the tool was clear, understandable, and easy to use and that it worked as intended. Despite providers' mixed feedback on compatibility and quality of care, these findings suggest that providers found the tool very easy to use and that it exceeded their usability expectations.

Table 19. Provider perceptions—tool ease of use (n = 9)

Item	Baseline	Post-training	Poststudy
The *BRCA* decision aid seems to be clear and understandable.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	1 (11.1%)	0 (00.0%)	0 (00.0%)
3	3 (33.3%)	0 (00.0%)	0 (00.0%)
4	1 (11.1%)	4 (44.4%)	6 (66.7%)
5 Strongly agree	0 (00.0%)	5 (55.6%)	3 (33.3%)
Missing	4 (44.4%)	0 (00.0%)	0 (00.0%)
Average Response	***3.0***	***4.5***	***4.3***
It is going to be easy to get the *BRCA* decision aid to work the way it should.			
1 Strongly disagree	a	0 (00.0%)	0 (00.0%)
2	a	0 (00.0%)	0 (00.0%)
3	a	3 (33.3%)	2 (22.2%)
4	a	4 (44.4%)	5 (55.6%)
5 Strongly agree	a	2 (22.2%)	2 (22.2%)
Average Response	a	***3.8***	***4.0***
I believe that the *BRCA* decision aids will be easy to use.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	6 (66.7%)	0 (00.0%)	0 (00.0%)
3	3 (33.3%)	2 (22.2%)	2 (22.2%)
4	0 (00.0%)	6 (66.7%)	3 (33.3%)
5 Strongly agree	0 (00.0%)	1 (11.1%)	4 (44.4%)
Average Response	***2.3***	***3.8***	***4.2***

[a]Not asked at baseline.

Likewise, providers' perceptions of the tool's trialability—or the ability to try the tool before committing to it—increased dramatically throughout the study (Table 20). At baseline, few providers thought they would have enough time to try or experiment with the tool before using it with patients. However, by the end of the study, almost all providers agreed or strongly agreed that they were able to test the tool before using it in practice and that they were able to learn the tool quickly.

These findings might reflect providers' growing comfort and familiarity with the tool. The longer providers use a tool—and the more proficient they become at using it—the more likely they might be to believe that the trial period was adequate.

Table 20. Provider perceptions—tool trialability (n = 9)

Item	Baseline	Post-training	Poststudy
I am going to have enough time to properly try out the *BRCA* decision aid before I use it in my practice.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	2 (22.2%)	1 (11.1%)	0 (00.0%)
3	1 (11.1%)	3 (33.3%)	0 (00.0%)
4	2 (22.2%)	3 (33.3%)	4 (44.4%)
5 Strongly agree	0 (00.0%)	2 (22.2%)	5 (55.6%)
Missing	4 (44.4%)	0 (00.0%)	0 (00.0%)
Average Response	***3.0***	***3.6***	***4.5***
I am going to have access to the *BRCA* decision aid for a long enough time to see what it can do.			
1 Strongly disagree	1 (11.1%)	a	b
2	1 (11.1%)	a	b
3	2 (22.2%)	a	b
4	1 (11.1%)	a	b
5 Strongly agree	0 (00.0%)	a	b
Missing	4 (44.4%)	a	b
Average Response	***2.6***	***a***	***b***
I am going to be able to experiment with the *BRCA* decision aid as necessary.			
1 Strongly disagree	1 (11.1%)	0 (00.0%)	0 (00.0%)
2	1 (11.1%)	0 (00.0%)	0 (00.0%)
3	2 (22.2%)	2 (22.2%)	2 (22.2%)
4	1 (11.1%)	5 (55.6%)	4 (44.4%)
5 Strongly agree	4 (44.4%)	2 (22.2%)	2 (22.2%)
Missing	0 (00.0%)	0 (00.0%)	1 (11.1%)
Average Response	***3.6***	***4.0***	***4.0***
The *BRCA* decision aid is going to take too long to learn.			
1 Strongly disagree	0 (00.0%)	1 (11.1%)	3 (33.3%)
2	3 (33.3%)	4 (44.4%)	5 (55.6%)
3	5 (55.6%)	4 (44.4%)	0 (00.0%)
4	1 (11.1%)	0 (00.0%)	1 (11.1%)
5 Strongly agree	0 (00.0%)	0 (00.0%)	0 (00.0%)
Average Response	***2.7***	***2.3***	***1.8***

[a]Not asked on post-training survey.
[b]Not asked on poststudy survey.

Overall Value. Finally, providers rated the tool high on its overall value (Table 21). First, almost all providers agreed that the tool was likely to improve clinical care and that the tool would be useful for patients. Second, providers disagreed with the statement that the tool was more trouble than it was worth, especially after piloting the tool in clinical practice. These perceptions held relatively steady throughout the study or, in some cases, improved as the study progressed.

Table 21. Overall provider perceptions of the tool (n = 9)

Item	Baseline	Post-training	Poststudy
The *BRCA* decision aid is likely to improve clinical care.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (0.00%)
2	0 (00.0%)	0 (00.0%)	1 (11.1%)
3	0 (00.0%)	0 (00.0%)	1 (11.1%)
4	5 (55.6%)	3 (33.3%)	4 (44.4%)
5 Strongly agree	4 (44.4%)	5 (55.6%)	3 (33.3%)
Missing	0 (00.0%)	1 (11.1%)	0 (00.0%)
Average Response	***4.4***	***4.6***	***4.0***
The *BRCA* decision aid seems like it's going to be more trouble than it is worth			
1 Strongly disagree	a	0 (00.0%)	3 (33.3%)
2	a	6 (66.7%)	4 (44.4%)
3	a	1 (11.1%)	1 (11.1%)
4	a	2 (22.2%)	1 (11.1%)
5 Strongly agree	a	0 (00.0%)	0 (00.0%)
Average Response	***a***	***2.5***	***2.0***
The *BRCA* decision aid will be useful for patients.			
1 Strongly disagree	0 (00.0%)	0 (00.0%)	0 (00.0%)
2	0 (00.0%)	0 (00.0%)	0 (00.0%)
3	0 (00.0%)	1 (11.1%)	0 (00.0%)
4	6 (66.7%)	5 (55.6%)	5 (55.6%)
5 Strongly agree	3 (33.3%)	3 (33.3%)	4 (44.4%)
Average Response	***4.3***	***4.2***	***4.4***

[a]Not asked at baseline.

Providers were asked on the poststudy survey about their level of satisfaction, intention to use the tool, and perceived effectiveness of the tool. Results are presented in Table 22. Providers were highly satisfied with the tool and perceived it to be effective, accurate, and easy to use. Of the nine providers, one indicated that she would be extremely unlikely to use it poststudy, while the remaining eight indicated they were likely or extremely likely to use it.

Table 22. Provider satisfaction, expected continuation, and effectiveness of *BRCA* decision aid tool (n = 9)

Item	Poststudy
In general, how satisfied were you with the *BRCA* decision aid?	
1 Not at all satisfied	0 (00.0%)
2	0 (00.0%)
3	3 (33.3%)
4	2 (22.2%)
5 Extremely satisfied	4 (44.4%)
If the *BRCA* decision aid was to continue to be available after this study, how likely would you be to use this tool?	
1 Extremely unlikely	1 (11.1%)
2	0 (00.0%)
3	0 (00.0%)
4	6 (66.7%)
5 Extremely likely	2 (22.2%)
How effective was the *BRCA* decision aid in helping you educate your patients?	
1 Not at all effective	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	6 (66.7%)
5 Very effective	3 (33.3%)
How effective was the *BRCA* decision aid in preparing your patients to discuss their risk result with you?	
1 Not at all effective	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	5 (55.6%)
5 Very effective	4 (44.4%)
How accurate were the risk assessment results produced by the *BRCA* decision aid?	
1 Not at all accurate	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	2 (22.2%)
5 Extremely accurate	7 (77.8%)
How easy was it to review your patients' cancer family history using the tool?	
1 Extremely difficult	0 (00.0%)
2	0 (00.0%)
3	1 (11.1%)
4	2 (22.2%)
5 Extremely easy	6 (66.7%)

Provider Outcomes

Providers were also asked about their experiences and preferences for changes in their practice, including those technological in nature. As shown in Table 23, most indicated that they do not tend to resist changes and consider themselves early adopters of new technology. Most also noted that they have recommended that about one to six patients get some type of genetic testing and have referred a similar number to a genetic counselor within the previous 12 months. Four of the nine providers indicated having ordered a *BRCA* test for between one and four patients. Two providers reported that they have not gathered a complete cancer family history from any patients, while 6 of the remaining 7 have gathered such history from between 500 and 2,000 patients within the past 12 months.

Table 23. Provider experience with changes, technology, and screenings (n = 9)

Item	Baseline
I tend to resist changing my practice routine.	
1 Strongly disagree	4 (44.4%)
2	2 (22.2%)
3	1 (11.1%)
4	1 (11.1%)
5 Strongly agree	1 (11.1%)
Do you consider yourself to be an early adopter, late adopter, or somewhere in between when it comes to incorporating new technology into your practice?	
1 Early adopter	6 (66.7%)
2	2 (22.2%)
3 Late adopter	1 (11.1%)
In the past 12 months, how many patients did you recommend get any type of genetic testing?	
0	1 (11.1%)
1–2	4 (44.4%)
3–4	1 (11.1%)
5–6	2 (22.2%)
8–10	0 (00.0%)
10 or more	1 (11.1%)
In the past 12 months, how many patients did you refer to a genetic counselor for any reason?	
0	3 (33.3%)
1–2	3 (33.3%)
3–4	1 (11.1%)
5–6	2 (22.2%)
8–10	0 (00.0%)
10 or more	0 (00.0%)
In the past 12 months, for how many patients did you order a *BRCA* genetic test?	
0	5 (55.6%)
1–2	1 (11.1%)
3–4	3 (33.3%)
5 or more	0 (00.0%)
In the past 12 months, from how many patients did you gather a complete cancer family history?	
0	2 (22.2%)
Less than 100	1 (11.1%)
100 to 500	0 (00.0%)
501 to 1000	5 (55.6%)
1001 to 2000	1 (11.1%)

To assess attitudes and beliefs about *BRCA* screening, providers were asked to indicate how important they believe it is to screen all women and how much of a priority they believe it is to screen any patients for *BRCA* mutations at baseline and after the study ended. As shown in Table 24, providers were significantly more likely to believe it is important to screen all women and that screening for *BRCA* mutations is a priority after the study (4.00 and 3.67, respectively) than at baseline (2.78 and 2.78, respectively). This suggests that the training and experience with the *BRCA* decision aid tool had an effect on providers' beliefs. Providers were also less likely to believe that patients would not see a genetic counselor if they were to give them a referral based on screening for *BRCA* mutations after the study than at baseline (1.33 vs. 1.78).

Table 24. Average ratings of provider attitudes and beliefs about screening patients for *BRCA* mutations (n = 9)

Item	Baseline	Poststudy
In a primary care setting such as yours, how important do you think it is to screen all women for *BRCA* mutations? (1-Not at all important to 5-Extremely important)	2.78	4.00
In primary care, how low or high a priority is screening patients for *BRCA* mutations? (1-Extremely low priority to 5-Extremely high priority)	2.78	3.67
It is not worth screening or testing women for *BRCA* mutations unless they have had a cancer diagnosis. (1-Strongly disagree to 5-Strongly agree)	1.56	1.22
Even if I did screen patients for *BRCA* mutations, they probably would not see a genetic counselor if I gave them a referral. (1-Strongly disagree to 5-Strongly agree)	1.78	1.33

Providers were also asked several items to assess current knowledge about breast and ovarian cancer, genetic testing, *BRCA* screening, and factors related to increased risk of *BRCA* mutations. Table 25 shows the number and percentage for responses to each of the items. The proportion of providers who gave correct responses increased from baseline to posteducation on almost all items.

Table 25. Provider knowledge of breast cancer and ovarian cancer (n = 9)

Item	Baseline	Posteducation
Specific gene alterations have been identified in different ethnic groups. Which of the following groups has a higher frequency of *BRCA* mutations?		
Hispanic women	0 (00.0%)	0 (00.0%)
African American women	3 (33.3%)	0 (00.0%)
Ashkenazi Jewish women[a]	6 (66.7%)	9 (100.0%)
Indo-European women	3 (33.3%)	0 (00.0%)
Hereditary breast and ovarian cancer (HBOC) syndrome is characterized by which of the following features in a family.		
An early age of onset of breast cancer[a]	9 (100.0%)	9 (100.0%)
Family history of both breast and ovarian cancer[a]	7 (77.8%)	8 (88.9%)
An autosomal dominant pattern of inheritance[a]	4 (44.4%)	9 (100.0%)
More aggressive tumor growth[a]	7 (77.8%)	9 (100.0%)
Based on the U.S. Preventive Services Task Force (USPSTF) recommendations, which one of the following groups should be referred for genetic counseling and possible *BRCA* testing?		
All women with a first-degree female relative with breast cancer	3 (33.3%)	3 (33.3%)
All women older than 40 years	0 (00.0%)	0 (00.0%)
Women of Ashkenazi Jewish origin	4 (44.4%)	4 (44.4%)
Women with a strong family history of breast or ovarian cancer[a]	9 (100.0%)	9 (100.0%)
In order to assess a patient's risk of having a *BRCA* mutation, physicians should document family history of which cancer types?		
Breast cancer[a]	9 (100.0%)	9 (100.0%)
Ovarian cancer[a]	9 (100.0%)	9 (100.0%)
Colorectal cancer	5 (55.6%)	3 (33.3%)
Pancreatic cancer	2 (22.2%)	1 (11.1%)

Table 25. Provider knowledge of breast cancer and ovarian cancer (n = 9) (continued)

Item	Baseline	Posteducation
Each offspring of an individual with a *BRCA*1 or *BRCA*2 mutation has what percentage chance of inheriting the mutation?		
25%	3 (33.3%)	0 (00.0%)
50%[a]	6 (66.7%)	9 (100.0%)
75%	0 (00.0%)	0 (00.0%)
100%	0 (00.0%)	0 (00.0%)
For every 100 women with a *BRCA* mutation, ___ will develop breast cancer and ____ will develop ovarian cancer by the age of 70.		
30, 50	1 (11.1%)	0 (00.0%)
50, 30[a]	5 (55.6%)	8 (88.9%)
80, 50	1 (11.1%)	0 (00.0%)
90, 40	0 (00.0%)	0 (00.0%)
7, 1	2 (22.2%)	1 (11.1%)
***BRCA* mutations can be inherited from *both* the mother and the father's side of the family.**		
True[a]	7 (77.8%)	8 (88.9%)
False	2 (22.2%)	1 (11.1%)
The USPSTF recommends that women with an increased risk for *BRCA* mutations, based on family history, be referred for genetic counseling and possible *BRCA* testing.		
True[a]	9 (100.0%)	8 (88.9%)
False	0 (00.0%)	1 (11.1%)
The USPSTF recommends that women with an increased risk for *BRCA* mutations, based on family history, receive a mammogram every three years.		
True	0 (00.0%)	0 (00.0%)
False[a]	9 (100.0%)	8 (88.9%)
Don't know	0 (00.0%)	1 (11.1%)
The USPSTF recommends that women with an increased risk for *BRCA* mutations, based on family history, be routinely screened for ovarian cancer.		
True	2 (22.2%)	0 (00.0%)
False[a]	4 (44.4%)	8 (88.9%)
Don't know	1 (11.1%)	1 (11.1%)

[a]Correct response

To assess beliefs about decision aids prior to and after the training, providers were asked a series of questions (see Table 26). More specifically, they were asked to indicate how decision aids affect the efficiency, quality, and effectiveness of their work. Interestingly, few significant differences between baseline and post-training were found, suggesting that the training did not influence general beliefs about decision aids.

Table 26. Average ratings of provider attitudes and beliefs about decision aids (n = 9)

Items[a]	Baseline	Post-training
Using a decision aid will allow me to accomplish tasks more quickly.	2.89	3.33
Using a decision aid will improve the quality of the care I provide to my patients.	4.44	4.33
Using a decision aid will improve the quality of the information I provide to my patients.	4.33	4.44
Using a decision aid will make it easier to do my job.	3.22	3.44
Using a decision aid will enhance my effectiveness on the job.	4.00	4.11
Using a decision aid is compatible with improving the workflow in our clinic.	2.89	3.11
Using a decision aid fits well with the way I like to work.	3.33	3.22
People in my practice or clinic who use decision aids have more prestige than those who do not.	3.11	3.44
The people in my practice or clinic who use decision aids have a high profile.	3.11	3.44
Based on past experience, I believe that decision aids are easy to use.	2.33*	3.89*
The decision aids I have used were clear and understandable.	3.00*	4.40*
When I used a decision aid in the past, I was able to try it out before using it in my practice.	3.00	3.20
I was able to use a decision aid on a trial basis long enough to see what it could do.	2.60	3.60
I was able to experiment with the decision aid as necessary.	2.60	3.60

* $p < .05$

[a]Items range from 1-Strongly disagree to 5-Strongly agree.

Assessment of the Evaluation Protocol

To assess how easy or difficult it was for providers to implement the study protocol, providers were asked a series of questions on the poststudy survey about the evaluation. The following sections describe the results.

Visit Checklists. Almost all providers (89 percent) found it easy or extremely easy to complete the visit checklists for each patient (Table 27). These checklists asked the provider to document each patient's risk result (i.e., increased risk, not increased risk), whether a patient was referred for genetic counseling or other screenings, and what activities occurred during the appointment (i.e., updated family history, explained risk result, addressed questions, checked understanding). Most providers (90 percent) also found the checklists to be brief, stating they did not require too much time (Table 27).

Table 27. Provider use of the tool checklist (n = 9)

Item	Poststudy
During the evaluation, how easy or difficult was it to answer the questions on the checklist that you completed after seeing each patient?	
1 Extremely easy	6 (66.7%)
2	2 (22.2%)
3	1 (11.1%)
4	0 (00.0%)
5 Extremely difficult	0 (00.0%)
Completing the checklist after each patient took too much time.	
1 Strongly disagree	3 (33.3%)
2	5 (56.6%)
3	1 (11.1%)
4	0 (00.0%)
5 Strongly agree	0 (00.0%)

Provider Protocol. RTI hosted three informal phone-based study debriefings (one for each site) with providers at the end of the study. The research team used a semistructured interview guide to ask providers about their experience participating in the study and their recommendations for improving the protocol. In general, providers expressed satisfaction with and enthusiasm for the study, and most expressed interest in joining future evaluations of the tool.

Nevertheless, providers cited several challenges to the current protocol both in the debriefings and on their surveys (Table 28). The most common challenge was the time required to discuss *BRCA* risk during a well-woman appointment, especially with increased-risk patients. The second most common challenge was occasionally not having patients' risk results available (i.e., patient did not finish tool, site coordinator did not print results for provider in advance). Other challenges included incorporating the study into clinical workflow, identifying which patients were enrolled in the study, recruiting patients for the study, and not having an on-site study contact.

Providers also offered several recommendations for improving the study protocol (Table 29). The most common recommendation was to have a larger patient sample. (Two providers saw only two to three patients during the study, which limited their exposure to the tool and their ability to judge its value.) Others recommended providing technical assistance for patients who are using the tool, receiving information more rapidly (including via email to the office manager), and designing the study to allot more time for patient appointments.

Table 28. Provider challenges on the study protocol (n = 9)

Item	Poststudy
What were the challenges to participating in the evaluation?	
Time	3 (33.3%)
Workflow	2 (22.2%)
Not having patient data/results available for visit	3 (33.3%)
Recruiting patients	1 (11.1%)
Remembering which patients involved in the study	1 (11.1%)
Not having a "go to" person in the clinic when started the using the program	1 (11.1%)

Table 29. Provider recommendations for improving the study protocol (n = 9)

Item	Poststudy
What changes to the evaluation protocol would be needed for your clinic to participate in a longer and larger evaluation?	
None	3 (33.3%)
More patients participating (e.g., not restricting to patients coming for wellness exams)	3 (33.3%)
More time with PEs	1 (11.1%)
Receiving information in timely manner	1 (11.1%)
Having patient results available (e.g., email to office after patient completes the assessment)	1 (11.1%)
Having someone available to help patients use the tool	1 (11.1%)

At one of the clinics, the site coordinator routinely printed each patient's risk result summary prior to her appointment and added it to the patient's file. Providers found this extremely helpful, because it minimized their need to log on to the tool prior to the appointment. Providers recommended including, even boosting, this type of onsite staff support for future studies.

Most providers (67%) found the surveys relatively painless to complete, but the remaining third felt the surveys were somewhat burdensome (Table 30). In general, providers

stated that the surveys were lengthy and that the initial surveys (baseline, post-training, posteducation) were clustered too closely together.

Most providers were also late in completing the initial surveys. Sixty-seven percent of providers completed the baseline survey by the official deadline; however, only 33 percent and 22 percent completed the post-training and posteducation surveys, respectively, by the deadline (not shown). After the deadlines, the site coordinators continually nudged providers to complete their surveys, which may have contributed to the perception of burden.

Table 30. Provider perception of study surveys (n = 9)

Item	Poststudy
Completing the online pre- and post-tests was burdensome.	
1 Strongly disagree	1 (11.1%)
2	5 (55.6%)
3	2 (22.2%)
4	1 (11.1%)
5 Strongly agree	0 (00.0%)

Provider Study Training. Prior to seeing patients or using the tool, providers participated in a 60-minute study training Webinar. The training introduced the tool's patient and provider interfaces, discussed the tool's workflow, reviewed the study's purpose, and outlined providers' study responsibilities. The training ended with a Q&A session in which providers could ask questions about the tool and the study protocol.

Providers responded positively to the training (Table 31). Every provider agreed or strongly agreed that the training helped them understand both their role in the study and the surveys/checklists they needed to complete. The training also helped most providers (89 percent) feel confident in their ability to use the tool.

Table 31. Provider-reported outcomes of study training (n = 9)

Item	Post-training
As a result of participating in the study training, I feel confident in my ability to use the *BRCA* decision aid.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	1 (11.1%)
4	4 (44.4%)
5 Strongly agree	4 (44.4%)
As a result of participating in the study training, I understand my role in this study.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	4 (44.4%)
5 Strongly agree	5 (55.6%)
As a result of participating in the study training, I understand what surveys and forms I need to complete.	
1 Strongly disagree	0 (00.0%)
2	0 (00.0%)
3	0 (00.0%)
4	5 (55.6%)
5 Strongly agree	4 (44.4%)

Patient Protocol. *Study completion.* Of the 106 patients who initially enrolled, 48 participants ultimately completed the study (Table 32). One participant completed one question on the second post-test, but none of the others did. Almost all of the remaining participants passively withdrew

without alerting the study coordinator or their provider. These patients generally fell into two categories: (1) patients who completed the consent form and baseline survey then stopped participating or (2) patients who never logged on to the tool. In addition, a few patients rescheduled appointments for a date after the evaluation period.

Site coordinators called such patients four to five times to either urge completion or clarify their desire to withdraw from the study. In most cases, site coordinators did not reach live participants and left voice mail messages. Very few participants returned these calls. When coordinators did reach these patients, most indicated they no longer had time for the study and wished to withdraw.

Table 32. Patient enrollment and completion by site (n = 48)

Site	Enrolled	Completed Study	Completed All Surveys
Baylor—North Garland	41	18	17
Baylor—Southlake	38	22	19
Fairfax	27	15	11
TOTAL	**106**	**55**	**47**

Survey Completion. Most patients (85 percent) who completed the study finished all three surveys—baseline, post-test 1, and post-test 2 (Table 32). The remaining participants failed to complete either post-test 1 or post-test 2, although one participant failed to complete either of the postsurveys. Every patient completed the baseline survey.

Patients reported little need for assistance in completing the evaluation surveys (Table 33). Only two patients (4 percent) said that someone helped them complete the surveys. This help entailed reading the questions aloud and entering the patient's answers into the survey.

Table 33. Assistance with responding to baseline survey (n = 48)

Item	Yes	No
Did someone help you complete this survey?	2 (4.2%)	46 (95.8%)
How did that person help you?		
Read the questions to me	1 (2.1%)	1 (2.1%)
Explained the questions to me	0 (0.0%)	2 (4.2%)
Entered the answers I gave	1 (2.1%)	1 (2.1%)
Translated the questions into my language	0 (0.0%)	2 (4.2%)

Limitations. Numerous limitations to this pilot evaluation should be noted. First, both patient and provider samples are not representative. Patients were mostly white, highly educated, had private insurance, and high income levels. We only were able to include a small number of providers in the study (n = 9). All were all white and almost all had worked in primary care and been with their current employer 10 years or longer.

As this study was a pilot evaluation assessing initial feedback on the tool and on its use by patients and providers, we did not have a control or comparison group for the study. Although we used cognitive testing to ensure that patients understood the questions being asked on the baseline survey and provider questionnaire items were adapted from an existing scale that assessed diffusion of a technological innovation, due to resource constraints and small sample sizes, we have not thoroughly assessed each questionnaire item for validity, and we have not yet developed scales and assessed their internal consistency. For this report, we are presenting only descriptive findings.

The evaluation was only in the field for 8 weeks. Providers and site coordinators indicated that a longer field period would have been very beneficial as they would have refined their recruitment strategies and been able to see more patients and thus use the tool itself more.

Chapter 4. My Family Health Portrait

At the time of our review, the Surgeon General's family history tool, My Family Health Portrait (MFHP), did not collect sufficient information based on the American College of Medical Genetics guidelines to accurately calculate the probability that a person may have a *BRCA*1 or *BRCA*2 mutation. MFHP was revised and the new version released in January 2009. For this final report, we reviewed the new version and publications about either version of MFHP. The new version is improved in several ways.

- The tool is Web based. The completed family history can be downloaded to an individual's computer. Because the family history is electronic, it can be shared easily with family members or health care providers.
- It is standards based, customizable, and open source, allowing its incorporation into electronic health records or clinical decision tools.
- It includes a list of 15 common diseases and allows other diseases to be added for any family member.
- The tool now allows the addition of family members beyond first and second degree relatives.

MFHP has some limitations that affect its usefulness for clinical decision tools in general and for our tool in particular. These limitations include the following:

- Age at diagnosis is collected by category (prebirth, in infancy, in childhood, in adolescence, by decade of adult life between the ages of 20 and 60, and 60 or older). Such broad age categories would introduce considerable imprecision into calculations of the probability of an individual having a *BRCA*1 or *BRCA*2 mutation. Our tool needs to collect the actual age at diagnosis if known.
- The tool does not ask if breast cancer was unilateral or bilateral or if a woman's ovaries have been removed. Thus, this tool would not produce the specific data needed to run the BRCAPRO algorithm.
- The drop-down menu-driven decision is time consuming to navigate. Although the introduction says it should take about 15 to 20 minutes to enter a family history, our staff member who reviewed the tool found that entering data for her immediate family required approximately 15 minutes. Third-degree relatives must be added individually, which would increase the time required to enter the data even further.

MFHP has been used in two studies of family history and disease. Vanderhoof et al. (2007) asked women recruited into a study of premature ovarian failure to use the original version of MFHP to provide their family history of related conditions, such as Fragile X syndrome. In 2007, 50 patients had provided family histories. The researchers had received no complaints regarding MFHP, and their clinical experience with the tool was favorable. They found that using MFHP improved the quality and completeness of family history data provided by their patients. Au et al. (2010) reported on the experience of six community organizations in conducting educational workshops regarding family history in health care among urban Appalachian women. They found most participants intended to share their family history results with their health care providers. These studies suggest the MFHP is acceptable to study participants; however, its use and acceptance in routine clinical practice have not been examined.

These studies used the previous version of the tool; studies using the new version have not yet been published, although it would be expected to be at least as acceptable as the first version. Limited cognitive testing and usability testing were conducted prior to its release in early 2009. Such testing is important to ensure that participants with varying levels of health literacy can accurately understand and enter information.

Chapter 5. Conclusions and Summary

To inform the design and development of the *Cancer in the Family* tool, our project team completed the following activities:

- conducted a literature review,
- obtained input and guidance from our technical expert panel (TEP) members,
- conducted a needs assessment with primary care providers, and
- conducted a feasibility assessment with IT professionals at primary care sites that would be involved in the study.

The tool went through a variety of different types of testing, including

- cognitive testing of the educational content for the patient tool,
- internal review by RTI experts,
- usability testing with both patients and providers, and
- 508 compliance testing.

In addition, the tool was field tested with primary care providers and their patients at three primary care settings. Some of the key issues we faced in designing the tool are described below. Suggestions for enhancements to the tool are also discussed.

Tool Design. Feedback from patients and providers throughout the development phase indicated that designing the tool to be patient driven was acceptable and time efficient for both user groups. Debriefing interviews with providers indicated that most study patients brought their printouts with the risk assessment results to the clinic visit and were ready to discuss them with the provider. Thus, early results indicated that this design empowers the patient and stimulates patient–provider discussion of *BRCA* screening results.

To ensure that patient and provider information was secure, it was necessary to have users log on to the tool with both a user name and password. In addition, to ensure privacy, we were unable to use patients' names within the tool itself. This limitation did affect the providers' perceptions about how easy it was to use the tool. Hopefully, if health care practices or systems adopt the tool, they will be able to develop ways to link patient contact information to the tool and make locating risk results for an individual patient easier. In addition, future applications of the tool outside a study scenario would perhaps allow for providers to more easily access the tool without a login.

Feedback and evaluation results do not indicate a need for any major redesign of the structure, functionality, or navigation of the tool. However, we would like to make a variety of enhancements and tweaks to the tool itself and to the printouts produced by the tool (e.g., family history worksheet, results printout with pedigree and table), including a more thorough assessment of how well patients and providers understand the risk results and their implications. In addition, providers who completed usability testing indicated that an appointment summary, similar to discharge instructions, may be beneficial. Additional usability testing could help identify best solutions. Reviewers also identified additional references and resources that could be added.

An ongoing challenge for the tool is to keep abreast of updates to the R software that is used to run the risk calculation. During development, the software was updated and it is likely that it will continue to be enhanced. Ensuring that links to other resources, references, and

support materials remain up to date will be important to ensuring that the tool contains the most scientifically accurate information and resources.

Evaluation of the Tool. The pilot evaluation provided initial feedback regarding patients' and providers' use and perceptions of the *Cancer in the Family* tool. In addition, the evaluation examined whether the use of the tool affected knowledge, attitudes, and patient–provider communication. The list below provides an overview of the results from the pilot evaluation. A more detailed discussion of the findings follows.

Patient Characteristics

- Forty-eight patients completed full protocol (baseline survey, post-test 1, and post-test 2)
- Demographic profile of patients who participated in the study was skewed

Patients' Use of Tool

- Patients used tool an average of five times
- Almost all patients reported calculating their risk
- Two patients were identified by the tool as being at increased risk and referred to a genetic counselor

Patients' Perceptions of Tool

- Educational content perceived to be effective or very effective in helping patients understand:
  - → *BRCA* mutations (80 percent)
  - → advantages/disadvantages of learning risk (79 percent)
  - → results of *BRCA* risk assessment (70 percent)
- 38 percent said tool produces very accurate risk results
- 71 percent said very easy or easy to enter family history
- 75 percent found worksheet very useful or useful
- 73 percent printed results of risk assessment
- 65 percent brought printed risk assessment results to provider
- 79 percent satisfied or very satisfied with tool

Patient Outcomes

- Outcomes changed in the anticipated direction
- Perceived risk decreased from baseline to post-test
- Knowledge and self-efficacy in communicating with provider increased from baseline to post-test

Provider Characteristics

- Nine providers participated in study
- Nine white, eight female
- 8 had practiced medicine for 10 or more years
- Five had used decision aids in the past

Providers' Use of the Tool

- Most providers used tool before and during patient appointments
- 88 percent reviewed patients' family history
- 67 percent updated patients' family history
- 88 percent explained risk result
- 83 percent addressed questions about risk

Providers' Perceptions of Educational Module

- 89 percent said quality of information was high or extremely high
- 100 percent said they agreed or strongly agreed that tool made them feel more confident in educating patients
- 78 percent agreed or strongly agreed they learned a great deal

Providers' Perceptions of the Tool

- Attitudes toward tool were more positive at post-test than at baseline
- However, providers were less likely at post-test to say that the tool will likely improve clinical care
- The tool was perceived to be compatible with their current workflow, easy to learn, easy to use, and effective in helping providers educate patients
- Perceived risk results to be very accurate
- Attitudes toward the tool were positive at post-test
- Overall satisfaction ratings were positive
- Printouts of patients' risk results viewed very favorably

Evaluation Protocol

- Evaluation protocol worked well
  - → Recruiting participants was challenging. Getting through to participants via phone was difficult.
  - → Email and/or texting may help.
- Future evaluations
  - → Use a control or comparison group.
  - → Randomly select clinical sites.
  - → Ensure more representative patient and provider populations.
- Alternate ways of using the tool
  - → Providers could discuss results with patients by phone.
  - → Patient tool could be standalone tool.
  - → Develop the current tool to transfer risk results to EMR.

Patient Results. The demographic profile of patients who participated in the study was skewed. Patients were predominantly white, had college degrees or higher, made over $100,000, and were married.

All patients in the study used the tool two or more times. On average, patients used it five times. Almost all patients reported calculating their risk. Of the 48 patients who completed the

full protocol, two were identified by the tool as being at increased risk and were referred to a genetic counselor.

Patients perceived the educational content to be effective in helping them understand *BRCA* mutations, learning their risk, and understanding their results. They also perceived the tool to be accurate, said that using the tool was relatively easy, and found resources such as the personalized cancer family history worksheet useful. Patients reported high levels of overall satisfaction with the tool.

Although the patient sample size was too small to fully test for differences in outcomes from baseline to post-test, outcomes generally changed in the anticipated direction. Patients' perceived risk went down from baseline to post-test, and the proportion of correct responses to knowledge items increased. Patients' self-efficacy in communicating with their provider also increased from baseline to post-test.

Provider Results. Nine providers participated in the study across three sites. All providers were White, eight were female, five had used decision aids in the past, and eight had been practicing medicine for 10 years or more. Thus, the demographic profile of providers is not representative of all providers in primary care.

Most providers reported using the tool before and during their patients' appointments. The tool identified two patients as being at increased risk for having a *BRCA* mutation; both were referred to genetic counseling. This number is higher than anticipated.

Providers rated the educational content for clinicians within the tool positively. Providers rated the perceived compatibility of the tool with their current workflow and the effect of the tool on the quality of care they provided lower than they rated the tool's effectiveness. Most providers indicated that the *BRCA* tool was easy to learn and disagreed that the tool was going to be more trouble than it is worth. Overall satisfaction ratings were positive, and all providers indicated that the tool was effective in helping them educate their patients and preparing patients to discuss their risk results. They also indicated that the tool was easy to use when reviewing patients' cancer family history and that the tool produced risk results that were very accurate.

On the poststudy survey, providers reported positive attitudes toward the tool in general. Feedback from providers indicated that taking time to discuss the results of the *BRCA* screening was a challenge as was incorporating the study into the clinical workflow. Debriefing interviews with providers revealed that providers appreciated having the patients' risk results printed out for them prior to the appointment, and many recommended having additional onsite support for future evaluations.

Evaluation Protocol. Overall, the evaluation protocol worked well. Providers rated the study training very positively and indicated that it helped them feel more confident in their ability to use the tool. Providers generally found the checklist easy to use and did not find the four surveys burdensome. Most providers did not complete their surveys on time and had to be reminded by the site coordinators to finish them.

Recruitment was a challenge because it was difficult to reach potential participants by phone. Future studies should plan to overrecruit and explore using email or texting to communicate with study participants.

Overall, the evaluation protocol could be refined, adapted, and used for a larger evaluation of the tool. We recommend that future evaluations include a comparison or control group. However, because most primary care practices do not currently screen women for *BRCA*

mutations, designing a control condition may be challenging. By using such a design, we would be able to determine the proportion of patients who are identified as being at increased risk for *BRCA* mutations by the tool compared to usual care. The *Cancer in the Family* tool could also be compared to other decision aids for *BRCA* screening. Thus, a future study design might randomize sites into a control arm and multiple experimental arms testing different decision aids or educational materials on *BRCA* screening. Alternatively, a scaled-up evaluation might also match sites on particular characteristics (e.g., the size, age, and race/ethnicity, including Jewish ancestry of the patient population).

Because the time period for this pilot evaluation was 8 weeks, the outcomes that we could measure were only short term. We were unable to measure additional outcomes such as whether those who were referred to a genetic counselor made and kept an appointment, whether they received genetic counseling and testing, and what their result from *BRCA* testing was if it was conducted. The true utility of the tool cannot be realized without further assessing these outcomes. Whether and how patients use the cancer family history information (e.g., do they share it with family members) would also be an important outcome to measure in future studies.

To obtain estimates of the proportion of patients in primary care settings who are at increased risk of having a *BRCA* mutation, future studies should include a much larger and more representative patient sample and include reimbursement for *BRCA* testing for all patients in the study, regardless of their risk status. Doing so would help validate the accuracy of the BRCAPRO algorithm in identifying patients with *BRCA* mutations. In our preliminary testing and evaluation of the tool, we used a high-risk cutoff value of 0.01. This value has a very high sensitivity, 0.97, but has a low specificity, 0.18. Based on the results of the analyses discussed above, we should consider using a risk cutoff value of 0.02. This value results in a slightly lower sensitivity, 0.95, but much better specificity, 0.48. At this level, approximately 1 in 143 primary care patients would be referred for genetic counseling. Further evaluation of the performance of this tool in primary care is needed. We need a sample of primary care patients to complete the tool and have genetic testing to determine how accurately the tool classifies primary care patients by their risk status.

Future studies could also compare different versions of the *Cancer in the Family* tool. For example, a standalone, Web version could be compared to a version that is integrated into an EMR, or a patient-only version could be compared to the current version of the tool that has both patient and provider interfaces. In addition, studies could assess different ways for health care practices to deliver or discuss the risk results with the patient (e.g., in-person appointment vs. telephone appointment, physician vs. nurse). Clinical sites could also explore different strategies of introducing the tool to patients (e.g., prior to an office visit, at an office visit) and encouraging patients to use the tool (e.g., email, phone or text messaging reminders).

We still hope to conduct many additional analyses using data that have been gathered from this evaluation. For example, we will examine if there are differences in use of the tool or outcomes by study site. We also will examine differences in provider outcomes by demographic characteristics, by experience with and attitudes toward CDS tools, and by experience using the tool (e.g., providers who did and did not have patients identified at increased risk of having a mutation). We could develop a knowledge index for both patients and providers using existing items on the survey. We also will assess if background or demographic variables such as experience with cancer (e.g., family member had cancer, age) influenced outcomes or use of the tool. Also, additional data from the tool itself could be examined (e.g., length of time on each page of the tool) to help understand how patients and providers use the tool. Finally, some survey

items ask both patients and providers about the clinical encounter. As we are able to link patient records to provider checklists, we will be able to compare a patient's account of the clinical encounter and patient–provider communication to the clinician's. Although sample sizes are small, data are rich and there is great potential to learn more about the influence and use of the *Cancer in the Family* tool.

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