Hereditary Breast and Ovarian Cancer (HBOC) Screening Instrument

Final Project

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Section 1: Introduction

Background Information

Breast and ovarian cancer will touch the life of almost every person in the United States. According to the National Cancer Institute (NCI), one in eight women will have breast cancer at some time in her life (2010). The American Cancer Society has projected that there will be over 229,000 new cases of breast cancer diagnosed and nearly 40,000 deaths from breast cancer in 2012 alone (Siegel, Naishadham, & Jemal, 2012). Since up to 10% of all breast cancers are caused by single gene mutations that are inherited in family lines (Foulkes, 2008), the collection of family histories from populations of women, with attention to patterns of breast cancer heredity, offers the opportunity to identify candidates for timely and appropriate genetic counseling, genetic screening, and risk reduction interventions.

The vast majority of breast and ovarian cancers which show specific patterns of heredity are associated with mutations in the BRCA1 and BRCA2 genes (Blackwood & Weber, 1998; Foulkes, 2008). Women with harmful mutations in these genes have approximately a 60% lifetime risk of breast cancer compared to 12% in the general population and a 15-40% lifetime risk of ovarian cancer compared to 1.4% in the general population (NCI, 2009). In addition, approximately one person in 300 has inherited a deleterious mutation in one of these genes and the mode of inheritances is autosomal dominant (ACOG, 2009). This suggests that there are 1 million BRCA 1 and BRCA 2 mutation carriers with a markedly increased risk of developing breast and/or ovarian cancer in the U.S. population. In many cases across the U.S., providers do not have access to an accurate and sustainable method to identify women with BRCA1/BRCA2

gene mutations. This is evidenced by the fact that in the last 15 years of genetic screening, only 50,000 (approximately 5%) of these women have been identified (Hughes riskApps™, 2012).

Goals and Objectives

Based on these statistics, health care providers and patients would benefit from an evidenced-based, efficient, cost-effective population screening instrument that will enable women to:

1. Enter family medical history data into an online database, with special attention to any relatives who have had breast or ovarian cancer;
2. Calculate the risk of carrying a Hereditary Breast and Ovarian Cancer (HBOC) syndrome gene mutation;
3. Prompt providers to facilitate the referral of high risk patients to appropriate specialists who offer genetic counseling, DNA testing, and further optimal management of identified gene carriers and their families.

Since the target population of women at risk is large, the speed and efficiency of a computerized clinical support system will be needed to accomplish these goals. In addition, healthcare organizations will need to assess their ability to provide genetic counseling and testing resources in anticipation of a significantly increased volume with the use of this intervention. Table 1 describes the organizational strategies, goals, objectives, measures and targets for this initiative in more detail.

Stakeholders

Stakeholders from the healthcare organization, clinical leadership and community play an integral role in the successful accomplishment of the goals, objectives and measures for the HBOC screening instrument. These stakeholders will need to be engaged and collaborate on its

development, implementation and adoption. Table 2 identifies the key stakeholders and their roles and responsibilities.

First, senior administrators and clinical leadership will be required to provide strong support for this project's goals and objectives in accordance with the organization's mission and vision. The senior leadership group includes the Chief Executive Officer, Chief Medical Officer, Chief Nursing Officer, Chief Operations Officer, Chief Information Officer, Chief Financial Officer and Chief Patient Safety and Compliance Officer. These officers will appoint a steering committee and oversee the alignment of the genetic screening solution with the organization's strategic initiatives. They will also provide the financial, technical, and infrastructure resources.

Second, each clinic and mammography center staff member is responsible for the implementation, adoption and use of the instrument by patients. This group includes providers, nurses, interdisciplinary healthcare professionals, clinic and mammography center managers, clinic reception and administrative staff, and quality improvement and patient safety staff. These stakeholders will need to provide input into the instrument design and understand that their recommendations have been incorporated into the project plan.

Third, patients and community members are key stakeholders responsible for completing the screening instrument and completing the recommended referral and treatment processes. Patients will engage in their own care by entering detailed and accurate family history information into the system and collaborating with their providers to decrease their risks for breast and ovarian cancer. In order to achieve adoption, patients need to understand the value of the instrument and understand how it is an effective use of their time in the home or clinic setting. It is suggested that a community breast cancer or ovarian cancer patient advocacy group,

such as the local chapter of the Susan G. Komen for the Cure Foundation, provide a representative on the steering committee.

Information System Inventory

The HBOC screening instrument will require specific technical capabilities and system designs to ensure adoption by stakeholders. Figure 1 depicts the technology components needed for the HBOC screening instrument. The system implementation will be conducted in two parts:

1. Development and deployment of the screening instrument as a standalone system with web services;
2. Integration of the screening instrument with the healthcare provider's existing certified electronic health record (EHR) system.

Overview of Technical Requirements

The HBOC screening instrument will require the technical specifications necessary for it to become a web application with services. This will enable it to be used on standard desktop computers, tablet PCs, iPads, and other similar devices or to be incorporated as a module within certified EHR technology and within an online patient portal. The screening instrument will format patient input into a Health Level 7 (HL7) standard pedigree (HL7, 2012). It will also create reports in a portable document format (pdf) suitable for storage within the EHR. These will be used for explaining results to patients and to transmit results to other providers.

The HBOC instrument will utilize a three generation pedigree and analyze the data automatically in order to have minimal impact on the provider's workflow. It will also have the ability to automatically notify the patient's primary care physician (PCP) or the provider ordering the mammogram of positive screening results by secure messaging within the organization's

certified EHR technology. This alert will provide a link to supporting reports and information regarding interpretation of the screening results and recommendations for subsequent actions.

Development and Deployment Inventory

Table 3 lists the hardware, software, and personnel required for the initial development and deployment phase of the project. The standards used are those specified in the Department of Health and Human Services' (HHS) Notice of Proposed Rulemaking for the 2014 edition of standards and certification criteria for EHR technology (HHS, 2012a). The development and deployment of the HBOC Screening instrument will also include a formalized software development methodology in line with the Food and Drug Administration's (FDA) guidance for software contained in medical devices (Ricci, 2005).

Implementation and Integration Inventory

The implementation and integration of the HBOC instrument for a specific healthcare provider has an additional set of requirements listed in Table 4. The technical personnel will be highly dependent upon the scope of the technical integration with the certified ambulatory EHR technology. The HHS's proposed standards for the 2014 edition of certified EHR technology were consulted during the development of this inventory as well (HHS, 2012a).

Intervention Selection and Workflow Opportunities

The HBOC intervention consists of patient entry of family health history with special attention to relatives who have been diagnosed with breast and ovarian cancer. The synthesis of that information is put into an HL7 standard pedigree format. The pedigree is processed by the Hughes riskApps™ breast cancer genetic risk algorithm (Hughes riskApps™, 2012). This outputs the percentage risk that the patient carries an adverse mutation in BRCA1 or BRCA2. This includes a printable result report which can be used for discussion with the patient (Figures

18 and 19). This output is inserted at the appropriate point in the patient's EHR which displays a notification to the clinic nurse and to the provider that the breast cancer screening information is available.

In order to screen large populations at risk for gene mutations, the HBOC screening instrument will be implemented prior to or during primary care practitioner (PCP) visits and during appointments for routine imaging studies at mammography centers. PCPs would like to be involved in the process of identifying and caring for women with increased risk for breast and ovarian cancer (Escher & Sappino, 2000; Carroll et al., 1999). The workflow will incorporate the skills and expertise of the registration staff, clinic nurses, physicians, physician assistants, nurse practitioners, and information systems (IS) service staff. Table 5 defines details about these roles and responsibilities and the associated technology needed for each of these roles.

Opportunities to Use the HBOC Screening Instrument

The HBOC screening instrument can be used at home prior to or after the clinic or mammography center visit and during the clinic or mammography visit. Figures 2, 3, and 4 articulate the workflow and interchange between the various roles and responsibilities noted in Table 5. The design of the screening instrument will be optimized to avoid imposing significant time constraints or changes to the provider workflow. Electronic and oral instructions will be provided to the patient on the use of the HBOC screening instrument and its intent. An electronic consent form will need to be signed by the patient prior to any use of the instrument in order to mitigate risk of liability or misunderstanding of the screening instrument intent.

Registrars

The registrar will enter the patient into the clinic registration and scheduling system. This data will need to include the patient’s email address, so they can validate the use of the

HBOC screening instrument. Registration will provide the encounter link needed to track the HBOC screening tool. This will also create a Master Patient Index number, if the patient doesn't already have one. The registrar will provide the patient all the necessary information about the screening tool. During the appointment reminder call prior to the visit, the patient will be notified of the screening program and invited to collect information about any family history of breast and ovarian cancer.

Clinic Nurses

The clinic nurses will receive alerts when the patient completes the HBOC screening instrument and communicate this information to the providers. The clinic nurses need to understand the information needed and the data entry procedures in case a patient needs help with the instrument or instructions on how to complete it later in the home setting. They will need to understand how to contact the Information Systems (IS) service desk in the event of technology issues.

Providers

Providers play a fundamental role in discussing the results of the HBOC screening instrument. Providers will need to notify patients of screening results and convey with sensitivity the information about the meaning of a positive initial screening test and about the next steps in the screening process. The majority of patients who are positive for this type of screen will still be negative for DNA testing. The display of the screening result must be carefully designed to communicate this information. Providers must be prepared to calm any possible anxiety provoked by the initial positive screening result. Providers will refer patients with positive screening results to a genetic counselor as appropriate. Providers will also need to understand how to contact the IS service desk in the event of technology issues.

Patients

The patient will need to have a reasonable understanding of the HBOC application and how to complete it using a tablet. The patient will be required to sign the electronic consent prior to using the screening application. The patient will need to ensure that all of the information is entered accurately in order to achieve valid screening results. As a best practice, patients will be encouraged to complete the screening at home prior to their clinic visit. First, the home setting will provide more time and a better opportunity for the patient to gather all the required information in order to accurately answer the questions. This will allow the screening instrument to operate more accurately and effectively. Second, this will give the provider an opportunity to review the results and prepare for the discussion with the patient.

Information Systems (IS) Service Desk

The IS staff will need to ensure that they handle all technology issues in a timely and efficient manner. They will be responsible to know the screening application and understand how to troubleshoot it in the event of technical difficulty. The IS staff will also need training to provide technical assistance via phone, email, or live chat for patients who encounter problems while completing the screening instrument at home. Establishing IS service desk resources will lead to effective change management.

Change Management

Successful adoption begins with a change management plan that aligns with the mission, vision, and values of the healthcare organization. The change management plan has to include an analysis of the people, processes and technology that currently exist in the clinics, the mammography centers and in the home setting (Osheroff et al., 2012). This analysis is a key component to mitigate any risks as a result of the new screening process for breast and ovarian

cancer (Osheroff et. al., 2012). Some of the potential risks and unintended consequences of this implementation may include lack of adoption, wasted resources, frustrated clinicians or patients, and failure of the instrument to achieve its goal of improving genetic screening and appropriate genetic counseling referrals. A constructive change management plan includes the following tactical strategies to ensure that the behaviors of leadership, providers, staff and patients promote a team approach to adoption of the HBOC screening instrument.

Strategy 1: Lead by Example and Create a Culture that Embraces Change

The organizational leadership needs to establish a goal-oriented, step-by-step framework to influence others on the use of the HBOC screening instrument. The first part of this framework is creating the overall organizational culture and expectations of each employee to achieve the mission, vision and values through the use of the screening instrument. The change cannot be perceived by the employees as another initiative that will soon be forgotten (Mills, 2008). The organizational and clinical leadership can create a culture that demonstrates a can-do attitude, which can drive engagement and positive results in patient outcomes. The culture is often defined by the attitudes and priorities of the leadership team, which will ultimately influence others in their acceptance of the new screening workflow.

The use of the screening instrument needs to be a clear organizational priority. In order to demonstrate this, the leadership has to establish realistic goals and timeframes for implementation that align with other competing priorities. Leadership should also require that one of the yearly goals for each clinic and mammography center align with the organizational goal of using this screening instrument. The individual employee should also be held accountable for this work as part of the personal goal setting process. Personal goals should align with the yearly performance evaluations. Thus, the entire organization begins working

together as a partnership to adopt the screening instrument as a new strategy to improve community health. The organization should recognize achievement of these goals through rewards and incentives (Mills, 2008; Schroeder-Saulnier, 2009). Incentives may come in the form of special employee recognition, additional financial payments to the clinic or individual, gift certificates, or a celebration of this achievement. The leadership should solicit staff opinions about appropriate incentives for successfully implementing the HBOC screening instrument.

Clinical leadership should be required to pilot the use of the instrument first. The clinical leadership has to take an active role in using the instrument as part of their workflow and advocating for its use by provider colleagues and patients. This example of being an early adopter can influence other clinic and mammography center providers and employees. These leaders can also promote the use of the instrument by explaining the lessons they learned from the pilot and ensuring that the same mistakes do not occur at other sites.

Strategy 2: Phased Implementation Approach, Workload Evaluation, Pilot Studies

A phased implementation approach will be utilized as part of the change management plan (Figure 5). In phase 1, the workflow gaps, the technology and software, staffing in the clinics and mammography centers, staffing for implementation and IS support, and patient preferences about completing the screening will be thoroughly assessed. A patient survey will be sent out to determine whether patients prefer to take the screening at home or at the clinic or mammography center. The survey should also determine whether or not most patients have the ability to access the Internet, which may indicate whether the home setting is an option. In phase 2, the clinics will pilot the HBOC screening instrument, which will incorporate portions of the Hughes riskApps™ (http://www.hughesriskapps.net/), the National Cancer Institute Gail Model (http://www.cancer.gov/bcrisktool/), the HHS My Family Health Portrait

(https://familyhistory.hhs.gov/fhh-web/home.action), and Microsoft HealthVault (http://www.microsoft.com/en-us/healthvault/). After the pilots have been completed, phase 3 will include another assessment of the workflows, technologies and the personal health record (PHR)/EHR integration. Technology development will continue in an iterative process and take into account these assessment findings. In phase 4, the instrument will be integrated with the healthcare organizations' patient portal and the certified ambulatory EHR technology.

Since this new screening technology will alter the roles and responsibilities of the staff and providers, they will need to take accountability to ensure the screening instrument is embraced by patients and recognized as a valuable tool. This may be difficult because the screening instrument might cause undue burden on staffing resources depending on the number of patients that choose to utilize the instrument during the clinic or mammography center visit. A current analysis of clinic volumes will be needed to understand the impact of adding the consent process and patient education about the screening instrument. If too much strain is placed on the current resources, the HBOC instrument will not be adopted and the work to develop the technology may become wasted effort. To mitigate this, it is important to recognize that this screening instrument will inevitably add some time to the provider and employee roles and responsibilities during the increasingly busy workday.

The HBOC screening instrument needs to be integrated within existing workflows in careful and thoughtful ways. For example, the education materials should be placed in convenient locations at the registrar's desk, so that they are reminded to provide this information during the intake process. An electronic alert could help remind the registrar to provide this information and obtain consent. Employees and providers should have the opportunity to make suggestions on how the screening instrument could be streamlined to fit more effectively within

their current workflows. If the employee and provider suggestions are not utilized, this will give the impression that other priorities are more important and that they are not integral to the success of the project. This would discourage them from taking the time for education, explanation of the consent process, screening results review and discussion during the patient visit.

Some clinics and mammography centers may need to hire an additional temporary employee to assist with the implementation efforts depending on the analysis of clinic volumes. Depending on the healthcare organization, a centralized implementation team may be available to assist with adoption of new technologies. The requirement for additional staff will also depend on what percentage of patients choose to do the screening at home. In the first several months after implementation, the staffing workload analysis will need to account for the large number of established patients not previously screened by the HBOC instrument. Timing studies can be performed to ensure that this does not add a significant burden to patients or clinic staff. After this group completes the screening, it is anticipated the workload will be manageable with the same staffing levels.

Strategy 3: Technology Evaluation

If the screening instrument functions poorly due to technological difficulties, both clinicians and patients may become frustrated and decide not to use it. Thorough testing and validation of this technology prior to its use will help mitigate this risk. The clinical leadership may also consider investing in additional IS staffing resources depending on the call volumes. IS resource planning must account for help center calls about problems with the HBOC screening instrument. These calls must be answered promptly and courteously. Failure to resolve these problems in a timely manner will create the impression that the instrument is faulty and that

using it will be a waste of time. IS support staff for the patient portal will need training on the screening instrument. They need to be prepared to assist patients if problems arise with its use at home. In addition, if the screening results do not integrate smoothly into the ambulatory EHR, the providers may not see the benefit of this instrument despite patient adoption. Providers have to be able to access the results and counsel the patient during the visit. If this problem arises, IS staff resources can troubleshoot and make alterations. An online help system should also be accessible to assist with troubleshooting problems. In addition, some patients will be utilizing the HHS My Family Health Portrait and Microsoft HealthVault. Stakeholders in the healthcare organization need to periodically review these online resources to ensure that they remain viable technology options as part of the screening instrument.

Strategy 4: Effective Communication

Communication is a vital part of change management (Mills, 2008). Change can elicit emotions of fear and uncertainty (Mills, 2008). The leadership team needs to recognize these emotions are a normal part of human behavior and provide forums where staff can ask leadership why implementation of the screening instrument is important. Staff will need to be educated to understand the benefits of providing this type of screening and the improved outcomes that can be realized for women at high risk for breast and ovarian cancer. This communication may also come in the form of newsletters, discussion during staff meetings, or email. The organizational values will play a key role in driving engagement (Schroeder-Saulnier, 2009). These values can be communicated and leveraged to win the commitment of key stakeholders. If the organizational value is to support the communities it serves, the stakeholders can be engaged to provide breast and ovarian cancer risk assessments as a service to the community. Leadership can share success stories and experiences from other organizations that have implemented a

breast and ovarian cancer risk assessment in newsletters or other forums (Osheroff et. al, 2012). Providers will want to understand the current research associated with using an online breast and ovarian screening instrument. These stories can establish a powerful reason why the HBOC instrument is integral to the workflow and successful referral for genetic screening.

Strategy 5: Establish Clear Policies and Procedures

Clinical leadership need to establish and communicate policies and procedures that demonstrate how the instrument should be utilized, including the consent process and step-by-step instructions on accessing and completing the instrument. The consent process needs to be reviewed by the legal and compliance team to ensure that patients have a full understanding of what the screening instrument is intended to accomplish. This will mitigate any legal risk associated with the use of the screening instrument. Creating a ready-reference guide that includes these policies and procedures will assist employees in their interactions with patients.

Strategy 6: Prioritize Education and Follow-up

After policies and procedures are established, the leadership will need to invest time and financial resources in training and reference materials to help the clinic and mammography center employees understand how to use the instrument. Training can be accomplished through online computer-based training or group teaching during staff meetings. Selected end-users can be chosen to champion these efforts in each clinic and mammography center. They should be trained as experts to assist others. These champions should include people that may be skeptical of the instrument at first. They should be given a chance to provide input and be encouraged to become leaders in its adoption. Patients can also be asked to volunteer their time from the community to help other people understand the instrument and act as an example of how the screening instrument assisted them in their genetic screening for breast and ovarian cancer.

After the implementation occurs, leadership should not assume the work is complete. Scheduled follow-up communication and evaluations should occur at each clinic and mammography center (Schroeder-Saulnier, 2009). This will facilitate understanding of the successes, opportunities for improvement and potential need for modification of the workflow and screening instrument. Figure 6 articulates some of the top engagement drivers from an employee survey done by Right Management that will be reviewed by leadership (Schroeder-Saulnier, 2008). Through implementing these strategies, employees will take personal accountability for the adoption of the HBOC screening instrument.

Section 2: System Design

Model

Screening large populations to identify candidates for BRCA1 and BRCA2 genotyping requires the use of family history data to predict the probability of deleterious mutations. This has led to the development of more than a dozen statistical models to make such estimates. The models differ in their statistical methods, source populations, pedigree features and predicted outcomes (Parmigiani et al., 2007). In clinical practice, two different models applied to the same patient may give significantly different predicted probabilities. This has led to a number of studies of the performance of various models to determine whether one of them is definitively more accurate (Parmigiani et al., 2007).

Panchal, Ennis, Canon, & Bordelau (2008) studied seven of the statistical models developed to predict the probability of identifying BRCA mutations in an individual or family: BRCAPRO, Manchester, Penn II, Myriad II, FHAT and BOADICEA. Risk calculations using each model were performed for 200 non-BRCA carriers and 100 BRCA carriers. The areas under the receiver operating characteristic (ROC) curves were identified and sensitivities and

specificities for each were calculated using conventional methods. The researchers concluded that at conventional testing thresholds, the Penn II model most closely identified individuals for genetic testing (sensitivity = 0.93; specificity = 0.31). The BRCAPRO model came in second (sensitivity = 0.75; specificity = 0.62). After further review of the ROC plots published in this article, the ROC curves for BRCAPRO and Penn II are barely distinguishable. Furthermore, a similar study using larger testing populations was performed in 2007 and BRCAPRO was ahead overall (Parmigiani et al., 2007). The models varied in discrimination across different populations, however. Parmigiani et al. (2007) concluded: "All models identify women who probably carry a deleterious mutation of BRCA1 or BRCA2 with adequate discrimination to support individualized genetic counseling, although discrimination varies across models and populations" (p. 442). Switching the models to compare outcomes at different clinics will likely produce too many technical difficulties to be feasible. BRCAPRO is one of the earliest risk models developed and it has been validated across more patient data sets than almost any other (Parmagiani et al., 2007). The Hughes riskApps™ project selected this as the first model on their list for calculating the probability that a woman carries a BRCA mutation (Hughes riskApps™, 2012). There is no compelling data that any other model is better.

Design Document and Architecture

The HBOC requirements document will follow the IEEE 830:1998, IEEE Recommended Practice for Software Requirements Specifications (1998) and the ISO/IEC/IEEE 15289:2011, System and software engineering – Content of life-cycle information products (2011). These recommendations include a table of contents, introduction, purpose, scope, definitions/acronyms/abbreviations, references, overview, overall description, product perspective, product functions, user characteristics, constraints, assumptions and dependencies,

specific requirements, appendices and index. The design document will follow the IEEE 1016:2009, IEEE Standard for Information Technology—Systems Design—Software Design Document (2009). The design document will provide the conceptual mode, descriptions and views. The design document will use Unified Modeling Language (UML) (http://www.uml.org/). This design language will be a critical part of the prototyping process of the system. Figure 15 shows some of the use cases that will be incorporated into the design document. The design document will also incorporate iterative enhancements that will be required in each phase. Both technical and clinical stakeholders will be the owners of the design document. They will be accountable to ensure the document is updated during enhancements, bug fixes and modifications.

The proposed system architecture design is shown in Figure 13. Family history data will be formatted into an HL7 standard pedigree and transmitted to the Hughes riskApps™ BRCAPRO web service. This uses the family cancer patterns to calculate the probability of BRCA1/BRCA2 mutations. The system architecture will also contain an implementation of the open source NCI Gail Model Risk Calculator (NCI, 2011). These results will be incorporated with the Hughes riskApps™ BRCAPRO. At that point, the results will be returned in real time to the EHR as formatted reports structured in Clinical Document Architecture (CDA) (HL7, n.d.). CDA is the proposed standard for the 2014 edition of certified EHR technology (HHS, 2012a). Figure 14 shows some of the database tables from the Hughes riskApps™ model. Figure 16 shows the HBOC screening instrument package diagram across multiple models. Figure 17 shows the NCI's breast cancer risk assessment package class diagram.

Decision Logic and Intervention Content Specification

The HBOC screening instrument will employ a simple graphical user interface to collect a detailed three generation pedigree and determine the number of blood relatives who have or have had breast and/or ovarian cancer. The genetic risk algorithm requires information about parents, siblings, children, grandparents, aunts, uncles, nieces, nephews, and grandchildren. The patient will be asked to specify the following data about herself and family members in both maternal and paternal lines:

- Vital status (living or dead);
- Age if still living;
- Whether the individual has or has had breast and/or ovarian cancer;
- Whether individuals with breast cancer had one or both breasts involved;
- The age at diagnosis of each individual with breast and/or ovarian cancer;
- Any history of chemoprevention or risk reduction surgery;
- Family history of Ashkenazi Jewish descent.

In addition, the screening instrument will include the Gail Model algorithm, which combines the patient's family history with information from the patient's own medical history to predict a woman's risk of developing breast cancer in the next five and ten year time periods (Costantino, et al., 1999; NCI, 2011). The number of women with increased risk of breast cancer by the Gail Model calculation is larger than the number at risk for the hereditary syndromes. It is also pertinent to identify this group because treatment with chemoprevention using selective estrogen receptor modulators, such as Tamoxifen and Raloxifene, can reduce the risk of breast cancer by nearly 50% in these women (Smith & Good, 2003; Vogel, et al., 2006). The screening instrument will therefore also ask patients to input their age at menarche, age at first live birth,

race, number of breast biopsies (if any) and number of biopsies showing atypical hyperplasia (if any) (NCI, 2011).

The family history information will be synthesized into a Health Level 7 (HL7) Version 3 Standard Pedigree (HL7, 2012). The family history data will be processed by the BRCAPRO genetic risk algorithm (Berry et al., 2002). This is one of the best validated models for predicting BRCA1 and BRCA 2 mutations (Parmigiani et al., 2007). Several open source implementations of this model are available including a well-documented program from the Massachusetts General Hospital Avon Breast Clinic (Hughes riskApps™, 2012; Figure 1).

The initial clinic pilot implementation will follow the technology recommendations and requirements specified by the Hughes riskApps™ for the first phase of the project (Hughes riskApps™, 2012). The output is the percentage chance that the patient carries a deleterious mutation in the BRCA1 or BRCA2 gene. The data will also be processed by the Gail Model algorithm in the National Cancer Institute (NCI) Risk Assessment Tool (NCI, 2011; Figure 8). The output is the percentage chance that the patient will be diagnosed with breast cancer in the next five years. Genetic risk of 10% or greater and/or Gail Model risk of 1.7% or greater will be scored as "positive," since these threshold values indicate the need to refer the patient to a specialist for further evaluation. In those cases, the system will generate a graphical risk report in an easily understandable format for the clinician to use in subsequent discussions with the patient.

At the completion of the risk calculation, a notification will be sent to the clinic nurse and the risk percentages will be recorded in the patient's electronic record. Positive results will also trigger generation of an alert to the physician (or radiologist) to notify him/her of the positive

result. The alert will include links to concise summaries of the information needed for discussions with the patient. The summary will include:

1. Previously generated graphical reports;
2. Information about the biological basis and medical significance of the finding;
3. Information to put the screening result in a larger perspective (i.e. the majority of screen positive patients actually do not have a BRCA1 or BRCA2 mutation since the screening tool favors sensitivity over specificity);
4. Information about the reasons for referral to a genetic counselor due to increased genetic risk or a medical oncologist due to increased Gail Model risk. The provider will discuss options for procedures that provide further risk evaluation and possible outcomes and opportunities for intervention depending on the subsequent results.

If the patient elects to use the screening instrument at home via a web portal, similar information will be made available as a simple, concise electronic summary. This summary will also include online links to several evidence-based resources. These online sources provide detailed information on the topics of breast and ovarian cancer. Internet links will include the Susan G. Komen Foundation Breast Cancer Risk and Prevention page (Komen, 2012), the National Cancer Institute Understanding Risk page (NCI, n.d.) and the Cancer Risk and Genetic Testing Fact Sheet (NCI, 2009).

The screening instrument will also offer the patient a chance to utilize the HHS My Family Health Portrait application as shown in Figure 9 (HHS, 2012b). This can be used to create a more comprehensive pedigree with information that can be later used to calculate genetic risk for multiple diseases, both malignant and nonmalignant. This tool allows storage of the genetic risk data in the patient's personal health record, such as Microsoft HealthVault

(Figure 10). In addition, it has the functionality to report the data in the HL7 Version 3 Standard Pedigree format (2012). It also creates a printed version for discussion with the patient's healthcare provider(s). The HBOC screening instrument's expert content and technical requirements will lead to a widely accepted, robust, evidence-based tool that enables successful screening to identify women with a high risk for breast and ovarian cancer.

User Interface

System Input

The screening instrument will leverage lessons from consumer information technology to present a simple intuitive interface. The user interface will be worded at a sixth-grade reading level and optimized to require little or no assistance from staff at the clinics or mammography centers. This will also allow its completion in the home setting. The patient will enter the data in the questionnaire that collects the data needed for the Hughes riskApps™ and the NCI's Gail Model calculations (NCI, 2011; Figures 11 and 12). The patient will see each question visually and answer using the touch screen (tablet) or standard mouse click (desktop) technology. The patient will be able to electronically sign the consent form using her patient portal login credentials whether the HBOC screening instrument is accessed from home or at the clinic or mammography center. Typical user input screens are shown in Figure 8 from the NCI and Figure 21 from the Hughes riskApps™.

System Output

The patient will see a visual screen that will show a "positive" or "negative" result and instructions on next steps. Since the patient is seeking these results from the HBOC screening instrument, this is considered solicited output (Pusic & Ansermino, 2004). The HBOC screening instrument will then send unsolicited output to the provider and nurse in the form of an alert with

the results report. This is considered unsolicited because clinicians will automatically receive this output once the patient has completed the screen (Pusic & Ansermino, 2004). These reports will contain details about the logic behind the risk calculations and patient responses. Examples of the output interface are shown in Figures 18 and 19.

The output interface and screening results report need to be readily accessible within the provider's user interface in the ambulatory EHR, so it can be discussed easily with the patient. Figure 20 shows an example of the screening results being readily accessible to the clinician. The EHR messaging alert screen shows the message icon in the upper right of the screen. The message icon can also be displayed with a red lightning bolt icon to indicate a critical alert is waiting. The user interface may also incorporate visual pop-up screen alerts in the EHR once the screening is complete. The alert will require an acknowledgment from the provider that they have viewed the results because of the significance of reviewing the risk assessment data. The provider must provide a reason for overriding the alert.

Usability Testing

Ad hoc usability testing will be conducted for phase 1 of the project with the existing Hughes riskApps™, HHS My Family Health Portrait and the custom NCI Gail Model deployment. Formal usability testing and focus groups will be conducted on three groups of women ages 35-45, 45-65 and 65+. Usability testing will also be conducted for the providers and clinic nurses. Usability testing, including design considerations for novice, intermediate, and expert end-users, will be conducted as part of the system design process. The usability testing will also be conducted as ethnographic research in the subjects' home setting. All experiences and professional comments will be recorded digitally to share among all project stakeholders.

Knowledge Engineering

Knowledge Acquisition

The Hughes riskApps™ is a free cancer genetic risk assessment application available for download from http://www.hughesriskapps.net/ or for use as a web service. Installation, customization and training services can be purchased if desired. The Massachusetts General Hospital and the Newton Wellesley Hospital have developed this software to identify and manage women at high risk for hereditary cancer. It is currently in use at several breast and risk assessment clinics and is actively being implemented elsewhere. Clients include Massachusetts General Hospital, Newton Wellesley Hospital Breast Center, Brigham and Women's Hospital, Greater Baltimore Medical Center, and Texas Health Presbyterian Dallas. One of the main developers of the content is Kevin S. Hughes, M.D. He is co-director of the Avon Comprehensive Breast Evaluation Center, Surgical Director of the Breast Screening Program and Breast and Ovarian Cancer Genetics and Risk Assessment Program at Massachusetts General Hospital in Boston. He is also Associate Professor of Surgery at Harvard Medical School (Hughes riskApps™, n.d.a). The Hughes riskApps™ was chosen for the HBOC screening instrument for the following reasons:

- Credibility of the developers and extensive documentation of the model at the website and in the literature (Hughes riskApps™, n.d.a; Dominguez et al., 2005; Dominguez et al., 2007);
- Availability in multiple formats: desktop computer, tablet computer, clinician-assisted entry, and automated kiosk;
- Availability of a matched database component using standard software (Microsoft SQL 2005) optimized for use with the system;

- Implementation of recognized standards: HL7 v3 Pedigree Model and Genomic Profile (HL7, 2012);
- Ability to interface with widely available family health history resources: HHS My Family Health Portrait and Microsoft HealthVault;
- Quality and granularity of reports;
- Potential for a future upgrade to a more comprehensive cancer genetic risk screening including colorectal, endometrial, and pancreatic cancers as well as malignant melanoma.

The NCI Breast Cancer Risk Assessment instrument is based on the Gail Model named after Dr. Mitchell Gail, Senior Investigator in the Biostatistics Branch of NCI's Division of Cancer Epidemiology and Genetics. The Gail Model was chosen for inclusion in the HBOC screening instrument because of its ability to identify women who are at increased risk of breast cancer even though they do not carry BRCA1 or BRCA2 gene mutations. Appropriate use of chemoprevention can reduce the risk in these patients (Vogel, et al., 2006). The Gail Model is the archetype for breast cancer statistical risk models. For more than 15 years it has been validated through testing in large populations and has been shown to provide accurate estimates of breast cancer risk (NCI, 2011). This breast cancer risk assessment calculates the percentage risk of being diagnosed with invasive breast cancer risk over specified time periods in women ages 35 and older. The source code can be downloaded for free at http://www.cancer.gov/bcrisktool/.

Research scientists at NCI and the National Surgical Adjuvant Breast and Bowel Project worked on this model. They used data from the Breast Cancer Detection Demonstration Project completed by the NCI and American Cancer Society, which involved 280,000 women ages 35 to

74 years old. They also used data from the NCI's Surveillance, Epidemiology, and End Results (SEER) Program to develop the model. Although originally developed for white women, the model has also been updated for African American women based on the Contraceptive and Reproductive Experiences (CARE) Study and SEER data. It has also been updated for Asian and Pacific Islander women in the United States based on the Asian American Breast Cancer Study (AABCS) and SEER data. The CARE study had 1607 women with invasive breast cancer and 1637 without. The AABCS included 597 Asian and Pacific Islander women with invasive breast cancer and 966 women without (NCI, 2011).

One issue with this model is that it may underestimate risk in African American women with previous biopsies. Another issue is that it still needs validation for Hispanic women and other subgroups. Caution needs to be used in interpreting results for women with special risk factors, such as Hodgkin's disease with radiation to the chest and carriers of other gene mutations that increase risk of breast cancer. The tool should not be used in women who have already been given a diagnosis of breast cancer, including lobular carcinoma in situ or ductal carcinoma in situ (NCI, 2011). Women who have positive screens for both genetic and Gail Model risk will be managed by the protocols developed for genetic risk patients, since this confers a greater hazard.

The HHS My Family Health Portrait was chosen as one method to integrate pedigree data and share it with other family members and health care providers. Although dependent on the patient for profile creation and maintenance, this system provides a convenient mechanism for the patient to modify her family history as new health conditions are diagnosed in family members. If the screening results and other family history information are uploaded into

Microsoft HealthVault, the patient will have a seamless method to transfer this information due to relocation to a new geographical area.

Knowledge Representation

At the completion of data entry and calculation, the instrument will display a summary results screen indicating a "positive" or "negative" screening test. In the clinic or mammography center, the results screen will indicate that a discussion of the results with the physician will follow as part of the visit. In the home setting, the negative results screen will explain that the family history data indicates no significant increased risk of breast or ovarian cancer and no further action is necessary. Patients with a positive screen will receive instructions to make an appointment with their provider and a notification that the provider will also be receiving those results. These patients will also receive a brief explanation of the meaning of a positive screen and links to Internet resources where they can obtain more information. The provider will receive a more extensive report including the pedigree generated from the data entered and the numerical results of the risk calculation. The provider will also receive links to resources that can serve as a basis for the discussion with the patient.

Knowledge Inference

The logic flow for the questionnaires used to obtain the input data is shown in Figures 11 and 12. The questions provide all the data necessary for the Hughes riskApps^{TM} and Gail Model calculations.

Knowledge Maintenance

The HBOC screening instrument is derived from close integration of several shared publicly available resources on the Internet. The NCI (2011) specifically mentions that the Gail Model BRCA risk calculator may be updated if new research or data is made available and was

last updated in 2011. The Hughes riskApps™ (n.d.) also mentions that ongoing studies are being performed with this information and that the developers plan to keep the model up to date. Despite these efforts, the HBOC executive team will need to assign subject matter experts who will be accountable to perform a yearly review of the literature in this area. This review will confirm whether there is new or updated clinical research impacting patient screening for BRCA1/BRCA2. If the literature review determines new methods or models are more effective at screening women at risk for BRCA1/BRCA2, the HBOC executive team will need to allocate resources to modify the screening instrument as soon as possible with the updated criteria to ensure continued adoption and success.

Section 3: Evaluation

It is widely accepted that clinical decision support systems (CDSSs) can improve the quality, safety, and cost effectiveness of patient care. Unfortunately, high-quality evidence supporting these capabilities and evaluating the performance of CDSSs outside of experienced academic centers remains limited (Bright et al., 2012). Therefore, the HBOC screening instrument will benefit from a well-designed plan to accurately measure the effects and results of its CDS interventions throughout the development, implementation and use of this system (Osheroff et al., 2012). These measures will provide verification whether the HBOC system was built correctly and validate that the HBOC screening instrument was the right tool to build to achieve the target goals and outcomes.

The HBOC screening instrument will provide a combination of alerts/reminders and information retrieval/presentation type interventions to improve adoption and efficacy. These interventions will be evaluated by four classes of metrics: (1) system response measures, (2) structure measures, (3) process measures, and (4) outcome measures (Osheroff et al., 2012).

Some of this data will be provided in reports that will drill down by clinical setting (clinic or mammography center) and recipient role (provider, nurse or registrar). The HBOC executive team will review these metrics in a biweekly meeting while the instrument is being deployed to troubleshoot any identified issues. These metrics will need to be monitored closely in the initial phases of the application. The developers will be accountable to suggest modifications and enhancements to improve these metrics and achieve successful adoption.

System Response Measures

HBOC will log and track the following data and start and stop times for these events (Osheroff et al., 2012):

- The time to initiate the screening application;
- The screen refresh times after the patients complete each page of family history data and click "next" on the input device (PC or tablet);
- The time from submission of a completed pedigree to return of risk calculation results and integration into the appropriate area of the EHR;
- The time from clinician request for supporting information to the time of availability in a reply window.

When screenings are done at a provider clinic or mammography center, system response times will have a critical effect on workflow, usability and user satisfaction. In a home setting, delays of more than a few seconds between user input and system response will be perceived as frustrating and discourage its use. This data will be stored in a data warehouse for extraction and review. The executive leadership will need to be prepared to provide any required resources to facilitate the appropriate fixes to the system that will improve system response time.

Structure Measures

HBOC will log and track the following data (Osheroff et al., 2012):

- The number of times the screening instrument is used;
- The number of interruptive and non-interruptive alerts deployed;
- The number of times providers override or ignore alerts of positive screening test;
- The reasons the users override the alerts.

In order to ensure structure is successful, it is imperative that the delivery and design of the alerts are configurable depending on the provider's specialty and EHR. Radiologists in a mammography center typically do not interact with patients or review patient-specific data in the EHR. In this workflow, the positive screening alert will need to be designed in a colorful, visual display that is easily recognized by the radiologists' nurses. This will facilitate the nurses' ability to recognize when it is appropriate to provide patient-specific instructions if the result is positive. The HBOC executive leadership will need to be prepared to receive clinician feedback on overrides and respond to the enhancement requests especially during the pilot phases. Negative communication about these events may impede future deployment and successful adoption by other clinicians.

Process Measures

HBOC will log and track to following data:

- Whether registrars are receiving proper alerts that a patient is a candidate for screening at the time of check-in;
- Whether the system can properly recognize patients who have already been screened and suppress the alert to the registrar;

- The number and percentage of patients who are offered a chance to participate in the screening program;
- The number and percentage of patients who sign the consent and begin entering data;
- The time a patient takes to enter all the pedigree information;
- The number of times a patient has to save a family history questionnaire and return to it later to complete the data;
- The number of questionnaires saved but never completed and submitted for processing;
- The number of alerts deployed regarding positive screening results sorted by recipient role such as nurses, physicians and other clinic staff;
- The number and percentage of patients actually referred to specialists for genetic counseling and testing.

These process metrics will be mapped directly to the HBOC requirements and use cases. These metrics will also determine whether the HBOC screening instrument effectively enhances the identification of patients at increased risk for breast and ovarian cancer. It will also track their referral to specialists, while maintaining workflow productivity and effective, patient-centered clinical decision making.

Proper design of the application log system should allow most of this data to be acquired and reported electronically. On the other hand, specific data regarding user satisfaction and effect on workflow will have to be acquired by electronic or paper surveys and shadowing staff members during the actual care process. Survey data will be collected to answer the following questions about the effects of HBOC screening on the clinical workflows:

- Did the appropriate patients get offered the opportunity to use the screening instrument? How much time does education about the screening program and obtaining informed consent add to the check-in process? Does this slow the registrars down? Does this increase patient waiting time at the registration desk?
- Are the nurses receiving notification of completed screening instruments? Are these alerts causing negative disruptions in their workflow?
- Are providers properly receiving alerts about positive screening tests? Is the information needed to counsel a patient about a positive screening test easily and rapidly available and comprehensible?
- If the patient agrees to genetic counseling, are there easily accessible tools in the EHR to schedule the referral? Do the tools included with the screening instrument make it easy to provide additional education resources for patients who want them?
- Does the time required for patient discussion and consultation referral in case of a positive screen significantly slow patient care or obstruct clinic workflow?
- Are the providers satisfied with the usability of the screening instrument? Does it provide timely and useful information and help them feel that they have added a new skill that enhances the quality of the care they provide?

Patients are the primary users of the HBOC screening instrument. As key stakeholders, they will also be provided opportunities to give qualitative feedback and provide some quantitative data regarding the following questions:

- Did they have enough information to make an informed decision about whether to participate?

- Was the instrument easy and pleasant to use?
- Was there difficulty gathering the information necessary to answer the questions?
- For those using the instrument from home, was the system response fast enough for comfort and did the system provide enough information resources to answer their questions?
- Were they anxious about the possibility of receiving a positive screening result?
- What are their impressions of the notification of the positive or negative screening result? Did the information make sense and provide them an understanding of next steps?
- Did they have difficulty signing up and using the HHS My Family Health Portrait? How many patients signed up and used it?
- Did they have difficulty signing up and using the Microsoft HealthVault? How many patients signed up and used it?

Outcome Measures

The immediate purpose of the HBOC screening instrument is to identify women at increased risk of carrying harmful BRCA1/BRCA2 gene mutations and to refer them to appropriate genetic counseling services. The longer-range goal is to provide DNA testing to appropriate candidates, identify women who do carry such harmful mutations, and refer them to specialists who can provide treatments such as enhanced surveillance, chemoprevention, and risk reducing surgery. Ultimately, the desired result is two-fold: (1) a reduction in the number of cases of breast and ovarian cancer and (2) a reduction in the associated morbidity and mortality. These objectives provide a concise set of outcome measures:

- The number of high risk patients identified and referred for genetic counseling and screening;
- The number of patients who undergo DNA testing for BRCA1/BRCA2 gene mutations;
- The number of patients identified as having harmful mutations;
- The number patients treated with risk reduction strategies.

Study Design

In order to measure these outcomes accurately, the HBOC screening instrument would need to undergo a clinical trial. Two methodologies could be considered. First, researchers could use the gold standard of a randomized-controlled trial. The outcomes data of those using the instrument would be compared to those not using it. The disadvantage of this option would be the ethical implications of withholding screening from women at risk. Therefore, a preferable option would be to compare the HBOC screening instrument's outcome data to the historical averages observed in the same location prior to its implementation.

Section 4: Discussion

The HBOC screening instrument is designed to use population screening techniques to identify women at increased risk for breast and ovarian cancer. The major motivation for implementing the HBOC instrument is to identify women with family health history indicating an increased chance of carrying a BRCA1 and BRCA2 gene mutation. The screening instrument will leverage statistical models, technology, and decision support to facilitate identification of women whose risk of harboring such a mutation is 10% or greater. In the literature, this has been the conventional threshold which defines a "positive" screen where the patient's risk is high enough to justify referral for genetic counseling and DNA testing (Parmigiani et al., 2007;

Panchal et al., 2008). The ultimate goal is to mitigate the risk of confirmed gene carriers by appropriate treatment and intensified surveillance techniques.

Limitations, Scope and Future Enhancements

The HBOC screening instrument will need to be developed to accommodate women with various languages, cultures, ethnicities, and disabilities. This work will need to be done in phases. The initial development scope will only accommodate the English language, which will be a limitation in many communities. Each healthcare organization will need to evaluate language preference in their community on a case by case basis to determine the need for other languages. This may limit a nationwide implementation in the first phase. One possible workaround for this problem could be the use of paper screenings that could be translated into different languages until the electronic screenings could be developed (Bellcross et al., 2009; Ashton-Prolla et al., 2009).

Another limitation is difficulty accommodating patients with disabilities such as vision loss or colorblindness. The HBOC screening instrument will need to take into account these women through other methodologies such as a paper screening or one-on-one assistance entering the data or technical development enhancements that include voice-recognition capabilities. This would take more financial resources from each healthcare organization. The clinic staff could enter the answers to the questions that were provided on paper into the electronic instrument, although this would be too resource-intensive to accommodate on a large scale. An additional limitation may be the time it takes to complete the screening. Since the screening instrument incorporates the Hughes riskApps^{TM} and the Gail Model, timing studies will be required to evaluate whether the design needs modifications to improve adoption. The intent will be to create screening questions that are worded in a simple, straightforward manner so that women

can understand the instructions. If certain populations of women are unable to understand the information provided in the screening instrument, it will need to be modified.

In addition to enhanced language preferences, the goal will be to share the data with the National Health Information Exchange for population health improvement (ONC, 2011). This screening information could be used by other providers if the patient relocates to another geographical area or is followed by another group of providers due to a change in health insurance. One of the standards that the National Health Information Exchange will conform to is Direct (http://www.directproject.org). The HBOC screening instrument will need to be enhanced to conform to the Direct Project (Direct) specifications, which provide "a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet" (Direct Project, 2010, p. 4). Direct recipients include an extensive list of electronic health records (EHRs), health information organizations (HIOs) and health information exchanges (HIEs) participating in Direct (Direct Project, n.d.b). Core requirements for Direct are found in the Applicability Statement for Secure Health Transport document, which explains the Simple Mail Transfer Protocol (SMTP), Cryptographic Message Syntax (S/MIME) and X.509 certificates used for security purposes (Direct Project, 2010). The HBOC screening instrument design will consider developing to the Direct Project protocol using the .NET or Java Reference Implementations or leveraging existing Direct Project implementation, such as Microsoft HealthVault (Direct Project, n.d.a). The Direct standards are part of the proposed requirements for the 2014 edition of certified EHR technology (HHS, 2012a).

The HBOC risk assessment is limited to breast and ovarian cancer. A logical enhancement would be to broaden the scope of the screening and use family history data to

identify patients who are at risk of other hereditary cancer syndromes such as those involving colon cancer, endometrial cancer, pancreatic cancer, and malignant melanoma. These enhancements would require a more extensive family history questionnaire to derive a more detailed pedigree and would also require implementing several additional risk calculation algorithms. As a result, data entry may become so laborious that it deters patients from completing the screening instrument or even from participating at all. It is preferable to maintain the current scope and then make judgments about expansion when data is available about its current performance. The Hughes riskApps™ model does provide a pathway for such expansion if and when it is deemed appropriate.

Assumptions

One assumption is that the developers will continue to update the Hughes riskApps™ model and Gail Model algorithms used for this screening. These are well-established evidence-based risk calculation models. Providers will also continue to monitor the literature in this area for new developments and more accurate and effective models. This will confirm that the Internet resources continue to be based on the latest evidence. The development team will be prepared to modify the HBOC screening instrument if necessary.

A second assumption is that the HBOC screening instrument will be deployed where certified EHR technology is already implemented and adopted. This will also be important for the integration of the screening results with the EHR as part of the phased implementation approach. Providers will need to store these results electronically and be able to view these reports through an EHR. Providers who have adopted health information technology are also more likely to understand why HBOC screening would be valuable in the care of their patients.

A third assumption is that the leadership will provide the funding to purchase additional infrastructure such as tablet computers in order to make this instrument readily available without excessive waiting times. The leadership would have to provide this funding in order to accommodate the patients who are unable to complete the survey at home.

A fourth major assumption is that women will be willing to research their family health history. Some women may need extra education to understand the importance of researching their family health history and the value of using the screening instrument. They will also need education about what information is needed and about creative ways to obtain their family health history. Some women may not have available family members or other ready ways to find the necessary data. In those cases, there may not be a way to complete the instrument. Providers will need access to specific information about estimating the likelihood of carrying a BRCA1 or BRCA2 gene mutation when limited or no family history is available.

A fifth assumption is that there will be community support for cancer awareness and screening. Lack of knowledge about the biology and significance of BRCA1 and BRCA2 gene mutations may be a barrier to community support for the screening program. This could be addressed by a concise and targeted advertising program, possibly with the assistance of breast and ovarian cancer advocacy group(s) in the community. Each community will need to address the cultural barriers to adopting this screening instrument. Some women may not feel comfortable using this technology. One-on-one support may be needed in the clinic to address this issue. If patients are unwilling to use the technology, then clinic staff could provide a paper version of the instrument and enter the results into the screening instrument at a later date.

Lastly, it is assumed that the HBOC screening instrument will encounter both conceptual and technological problems during development, as is the case with most complicated

information technology projects. The initial implementation pilots will undoubtedly discover further opportunities for improvement and problems that will need to be addressed by modifications in the design. Therefore, changes will be made in an iterative manner to ensure that bugs are fixed, gaps are addressed and usability is optimized. Additional reports may need to be created to demonstrate the results in more meaningful ways.

Legal and Ethical Considerations

One vital consideration in the implementation of the HBOC screening instrument will be the liability issues involved in using such a tool. If a provider fails to review the screening instrument results and does not refer patients with a positive screen to the appropriate specialist, that provider may be at risk for malpractice litigation. Providers will need to understand the legal and ethical implications of disregarding the screening instrument alerts. They will also need to realize the importance of documenting the reason if they do not implement the recommended actions. The healthcare organization may want to keep an audit log that determines who has reviewed the results of the screening instrument as an additional confirmation that all results have been viewed by the appropriate provider. Healthcare organizations should consider creating a policy that this log will not be considered part of the legal medical record (Osheroff et. al., 2012). State and local laws will also need to be reviewed as to whether this metadata is considered part of the legal medical record (Osheroff et. al., 2012). In addition, the HBOC screening instrument will need to have thorough testing and validation in order to avoid errors in the results and reporting features. This will help mitigate the risk of litigation.

The HBOC screening instrument will need to maintain security of the data according to the Health Insurance Portability and Accountability Act (HIPAA) regulations. The healthcare

organization will be required to report any data breaches involving protected health information to the Office of Civil Rights (OCR) and potentially be audited for compliance to HIPAA (HHS, n.d.). Increased surveillance of genetic risk for breast and ovarian cancer could present an ethical dilemma. If data is breached, life or disability insurance premiums could increase or concealed employment discrimination could occur because of questions about increased risk of cancer or the possibility of Jewish ancestry.

Implementation Readiness in a Clinic Setting

The HBOC screening instrument can be ready for implementation as a real-world application in the clinics and mammography centers once teams are hired and assigned to complete the design and requirements. In order to achieve widespread adoption, the HBOC screening instrument will meet the technical requirements for a mobile web application. This is because one-third of American adults (35%) own a smartphone and 87% use it for Internet or email (Smith, 2011). HBOC screening will be designed for implementation on both the Apple and the Android operating systems. This initial scope was chosen because the Apple App Store and Google Android Market are the two largest in the U.S. (Koekkoek, 2011).

The implementation will be a phased approach as discussed in Figure 5. The implementation would be best piloted as a beta application in an oncology clinic where the providers have prior experience with HBOC screening, have well-established referral lines to genetic counselors and where the instrument may integrate more readily into workflow as shown in Figures 2, 3 and 4. This pilot workflow would not require referral to an oncologist as it would in a mammography center setting. The ideal candidate to test this application would be one of the physician champions assigned to the project.

Timetable

It is anticipated that it will take a total of 18 months to deliver the HBOC screening instrument as a final product. The first step will be to write a design requirements document to articulate the vision and details of HBOC screening instrument's functionality, technical aspects, and security provisions. These requirements will be expressed as use cases with corresponding diagrams that demonstrate the interactions between the users and the application. Details for use cases will come from the real-world clinic and mammography center workflows and other healthcare organizations' use of electronic risk assessments. A complete list of use cases will be delivered in two months. Afterwards, a prototype will be created over a three month timeframe to test and validate the use cases. This will include conceptual designs and mock-up screens of how the user will interact with HBOC. Next, a detailed plan and schedule will be written for coding, testing and validating the HBOC application functionality and technical components. It is estimated that this will take thirteen months because the process requires several iterative cycles of development incorporating feedback from users and stakeholders at each stage. After widespread implementation and adoption of the HBOC screening instrument, benefits should be realized rapidly by stakeholders.

Identifying individual carriers for the HBOC gene mutation provides the unique opportunity to discover entire families that are likely to have multiple relatives with this mutation. The HBOC screening instrument will facilitate genetic counseling and testing of first and second degree relatives of affected patients. This will rapidly accelerate the pattern of diagnosis and treatment of patients with BRCA1/BRCA2 mutations in affected family members. Families willing to share this information will provide unique long-term opportunities to study the effects of adding genealogy data to population screening.

Conclusion

Breast and ovarian cancer have devastating effects on the lives of women in the United States. The HBOC screening instrument will leverage evidence-based, cost-effective, online resources, including the Hughes riskApps™ and the National Cancer Institute's Gail Model, to facilitate effective and efficient screening for women at risk of BRCA1 and BRCA2 gene mutations and women ages 35 and older at increased risk of breast cancer by the Gail Model. Integrating the results of the HBOC screening with the certified electronic health record technology allows providers to facilitate the appropriate referral and optimal medical management of those at risk for breast and ovarian cancer. Encouraging patients to use online resources such as the HHS My Family Health Portrait and Microsoft HealthVault will empower them to take a more active role in diagnosing and managing their genetic risk for various types of cancer. The goals and objectives to implement the HBOC screening instrument will be realized through careful planning and insight by these stakeholder teams. Thus, the HBOC screening instrument has the potential to significantly reduce the morbidity and mortality caused by breast and ovarian cancer. It is anticipated that this research paper could eventually be submitted to the *Journal of the American Medical Informatics Association* or the *IEEE Transactions on Information Technology in Biomedicine* journal after actual development and implementation of this instrument.

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Table 1: *Goals and Objectives*

(Osheroff et.al., 2012)

Organizational Goal	**Clinical Goal**	**Clinical Objective**	**Measure**	**Target**
Develop disease management and condition specific initiatives to improve patient outcomes	Facilitate early detection of patients with high HBOC risk	The number of BRCA1 and BRCA2 gene carriers identified	50% above historical average	Supports national and state initiatives to improve cancer screening
Improve care coordination	Increase referrals to appropriate specialty clinics, genetic counseling, and DNA testing for patients who merit these interventions	The number of high risk patients referred for genetic screening compared to historical averages	10% above the historical average	Fulfills mission to improve care coordination and patient outcomes
Optimize cost-effective patient care	Facilitate therapeutic interventions that decrease case incidence of breast and ovarian cancers caused by HBOC genetic syndromes	The number of high risk patients started in surveillance and treatment programs compared to historical averages	10% above the historical average	Fulfills mission to provide quality care at low-cost to support local communities
Enhance patient education and engagement in the care and decision making process	Empower patients to understand and take action to mitigate their individual genetic risk for breast and ovarian cancer	Improve the average amount of time required to complete the screening instrument	Target a 10 minute time to complete screening instrument (Patients may take as much time as needed)	Fulfills national, state and organizational initiatives to improve patient engagement
Improve patient satisfaction scores	Facilitate communication and education to patients regarding breast and ovarian cancer risk	Improve patient satisfaction score with the screening instrument	Improve by 10% compared to historical average	Supports clinic patient satisfaction scores

Organizational Goal	**Clinical Goal**	**Clinical Objective**	**Measure**	**Target**
Enhance clinician knowledge regarding evidence-based interventions	Improve clinician knowledge of breast and ovarian cancer	Improve scores on survey of clinician knowledge for evidence-based interventions for breast and ovarian cancer	Improve scores by at least 5% compared to historical results	Supports national and state initiatives to keep clinical competencies current
Enhance clinician engagement in diagnosis and treatment	Improve provider engagement in the diagnosis and management of patients at increased risk for breast and ovarian cancer	Provider satisfaction with the timeliness and usefulness of the information provided by the instrument and its ability to support workflow	Measure by improvement in survey results	Supports job satisfaction scores

Table 2: *Stakeholder Roles and Responsibilities*

(Osheroff et. al., 2012)

Stakeholder	**Primary Function**	**Role and Responsibility**	**Strategic Outcome**
Ambulatory Clinics Chief of Staff	Governance and Executive Sponsor	Champion project engagement with clinic executives and providers	Use family history data and genetic screening referrals to improve patient outcomes
Radiology Center Chief of Staff	Governance and Executive Sponsor	Champion project engagement with radiology physicians and mammography center staff	Use family history data and genetic screening referrals to improve patient outcomes
Chief Executive Officer	Governance and Executive Sponsor	Champion project engagement with other executives and approve financial capital resources in collaboration with the Chief Financial Officer	Ensure executive oversight and support for the HBOC screening instrument implementation and adoption by clinicians and patients
Chief Operations Officer	Governance and Executive Sponsor	Champion project engagement with other executives and ensure process changes are safe, effective and efficient with the HBOC screening tool	Ensure executive oversight and support from a process perspective for the HBOC screening instrument implementation and adoption by clinicians and patients
Chief Financial Officer	Governance and Executive Sponsor	Fiscal management and support of the HBOC screening tool project for the clinics	Ensure financial accountability and viability of the healthcare organization
Chief Medical Officer	Governance and Participation on Project Steering Committee	Champion physicians to participate and ensure adoption of genetic screening workflow	Use family history data and genetic screening referrals to improve patient outcomes
Chief Nursing Officer	Participation on Project Steering Committee	Champion providers and nurses to participate and ensure adoption of genetic screening workflow	Use family history data and genetic screening referrals to improve patient outcomes

Stakeholder	Primary Function	Role and Responsibility	Strategic Outcome
Chief Information Officer	Governance and Participation on Project Steering Committee	Champion project with the prioritization and allocation of appropriate departmental IT and vendor resources	Use family history data and genetic screening referrals to improve patient outcomes; Accountable for information technology systems, infrastructure and privacy/security concerns
Chief Privacy and Security Compliance Officer	Participation in Advisory Committee; Participation in taskforce as needed	Ensures HIPAA compliance with special genetic and family history privacy regulations	Privacy and security of all patient information
Director of Clinical Informatics	Governance and Participation on Project Steering Committee	Ensures successful systems implementation; Seeks new technology to improve workflow; Champions project with physicians	Use family history data and genetic screening referrals to improve patient outcomes; Accountable for information technology systems
Clinic and Imaging Service Managers	Participation on Project Steering Committee	Ensures clinic workflows meet patient needs; Seek new technology to improve workflow; Responsible for registration and medical assistant workflow	Use family history data and genetic screening referrals to improve patient outcomes; Accountable to meet quality metrics
Medical Oncology Division Chief	Participation on Project Steering Committee	Care and referral for patients identified as high risk for hereditary cancer syndromes; Champion the new screening tool	Use family history data and genetic screening referrals to improve patient outcomes; Accountable to meet quality metrics
Genetic Counseling Staff Representative	Participation in Project Steering Committee	Advise patients on genetic risks and receive alerts from genetic screening tool	Use family history data and genetic screening information to advise patients of risks and treatment options

Stakeholder	Primary Function	Role and Responsibility	Strategic Outcome
Outpatient Quality and Patient Safety Consultant	Participation on Project Steering Committee	Determine quality metrics required to meet regulatory requirements and improve patient outcomes	Achieve quality regulations; Responsible to gather and analyze accurate measure data
Cancer Nurse Navigator/Case Manager	Participation on Project Steering Committee	Advise patients through cancer diagnostic and treatment process	Use family history data and genetic screening referrals to improve patient outcomes; Patient advocate; Accountable to meet quality metrics
Physician Champions	Participation in Advisory Committee	Champion physicians to participate and ensure adoption of genetic screening CDS workflow	Use family history data and genetic screening referrals to improve patient outcomes
Community Patient Advocacy Group Representative	Participation in Advisory Committee	Advocate for patient engagement; Feedback on project outputs (e.g. patient training materials and communications)	Patient advocate for safe medication practices; Accountable for community engagement in health care and providing accurate information to their provider (e.g. family history and risks)

Table 3: *Development and Deployment Inventory*

(Osheroff et. al., 2012)

Hardware	
	Production Web/HTTP Servers (clustered, with shared session scope) (2)
	RDBMS/SQL Server (no redundancy, but daily backups) (1)
	Firewall Routers to establish a DMZ (2)
	Development/Staging Web/HTTP RDBMS/SQL combined Server (1)
	Source Control Repository
	Apple iPads (First, Second, Third Generation)
	Android Tablets (Samsung, Acer, Asus)
	Onsite/Offsite Backup with Disaster Recovery Plan
Software and Standards	
	Surgeon General's Family Health History Tool (HL7 v3, SNOMED CT)
	Microsoft HealthVault for HL7 Pedigree Storage (HL7 v3, SNOMED CT)
	SOAP Web Services (Application Services--these will also be duplicated as HTTP REST Services for Internet User Interface integration.)
	-Submit HL7 CDA XML Pedigree
	-Retrieve Gail Modified Model Questions
	-Submit Gail Modified Model Answers
	-Retrieve Gail Modified Model Analysis
	-Retrieve HBOC Screening Report Generation
	User Interface will be created on HTML/CSS/Javascript standards to be operated within a web browser.
Personnel	
	Project Manager (1)
	UI Designer/Developer (2)
	Service/Backend Developer (2)
	Software/DB/Security Architect (1)
	Business Analyst/User Acceptance Tester (1)
	Clinical Decision Rule and Alert Designer (2)

Table 4: *Implementation and Integration Inventory*

(Osheroff, et. al., 2012)

Hardware	
	1 Tablet for every 3 Physicians in Ambulatory Clinic that can be used for HBOC Screening
	Desktop PC used as Kiosk that can be used for HBOC Screening in Clinic
	Secure, Reliable, and Robust (bandwidth) Wireless Internet availability and connectivity
Software and Standards	
	Ambulatory EHR System for alert to provider
	Registration System (ADT) System (Demographic Data Entry and Master Patient Index Storage)
	Clinic Patient Portal
	HL7 Pedigree Standard
Personnel	
	Project Manager (1)
	Clinic Software Trainers (3)
	EHR Front End Developers (2)
	EHR Integration Developer (2)

Table 5: *Roles and Responsibilities for HBOC Screening Instrument Workflow*

Role	**Responsibilities**	**Technology Needed**
Registrars	• Schedules patient for follow-up visit into the registration and scheduling systems; • Provides information about the availability of the HBOC screening instrument and the resources needed to complete the screening according to a predefined written script; • Answers questions about the HBOC screening tool; • Offers patient registration for organization's patient portal, Microsoft HealthVault patient portal and Department of Health and Human Services Patient Portal • Discusses patient consent process with the HBOC screening tool • Refers to clinic nurse or provider as needed for additional questions and concerns	• Desktop computers • Registration and Scheduling Systems • Internet connectivity • Tablets for screening instrument application • Network printer
Clinic Nurses	• May receive alerts for results of HBOC screening instrument if the provider is too busy and may not have received and acknowledged the alert; • May print out the results of HBOC screening for the provider upon request; • Reviews screening results and communicates with provider as needed in preparation for clinic visit	• Desktop computers • Ambulatory certified electronic health record (EHR) technology • Internet connectivity • Tablets for screening instrument application • Network printer

Role	Responsibilities	Technology Needed
	• Provides patient education as needed depending on the guidance of the provider and patient needs	
Providers (Physicians, Physician Assistants, Nurse Practitioners)	• Reviews the results of the HBOC screening instrument from the EHR • Prepares for discussion with the patient about the result • Provides additional education materials about the result • Provides referral information to the genetic counselor as appropriate • Provides education on what information is needed for the HBOC screening instrument if the patient was unable to complete the screening prior to the clinic visit	• Desktop computers • Ambulatory certified EHR technology • Internet connectivity • HBOC screening instrument application • Network printer
Patients	• Completes HBOC screening instrument on tablet in clinic or mammography center	• Tablets • HBOC screening instrument application • Desktop computer in waiting room • Internet connectivity • Network printer
IS Service Desk	• Provides assistance with HBOC screening instrument technology, Internet connectivity, and other technical issues	• Desktop computers • Internet connectivity • HBOC screening instrument application • Network printer

Figure 1: *HBOC Screening Instrument Technology Components*

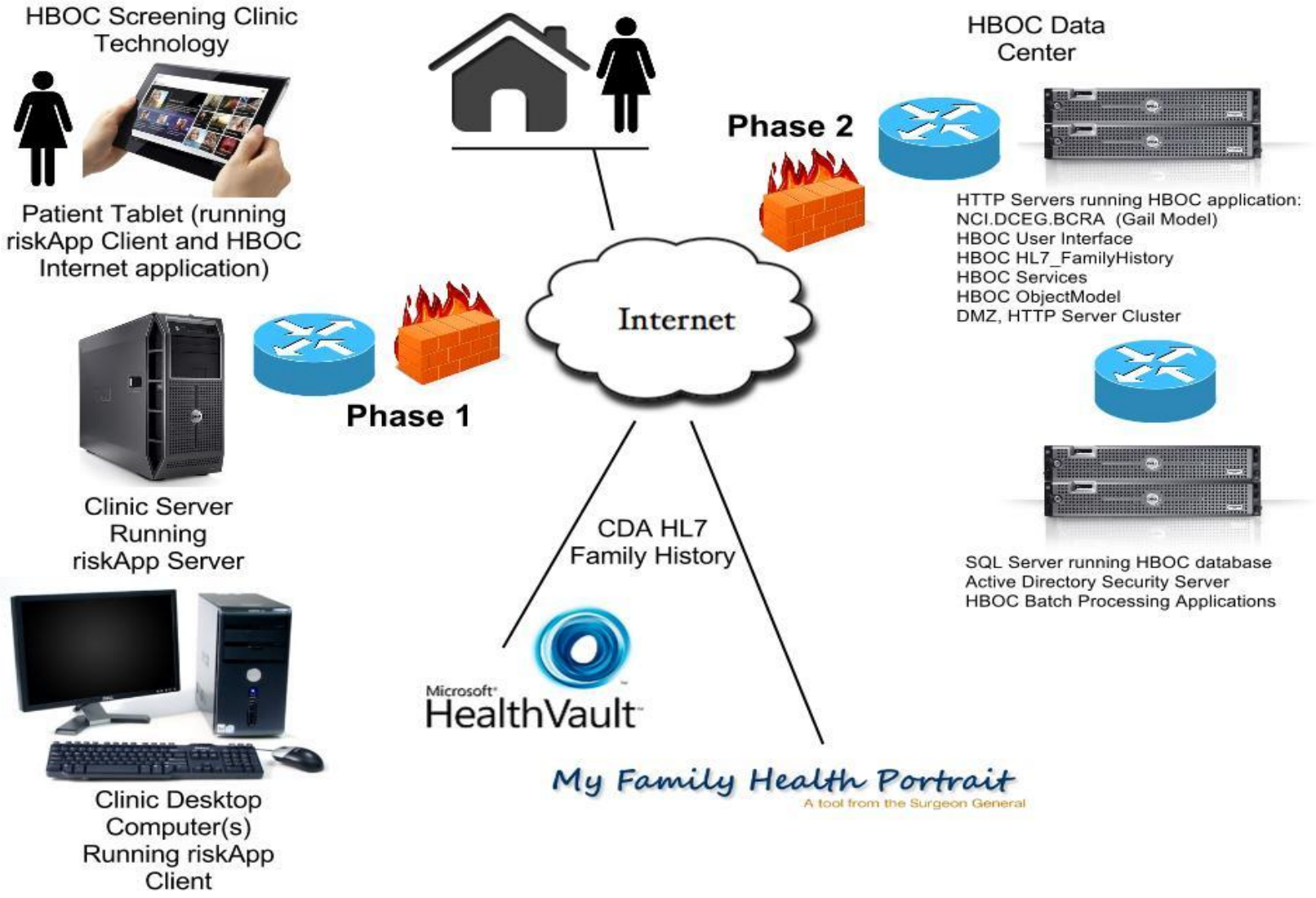


Figure 2: *Clinic Workflow*

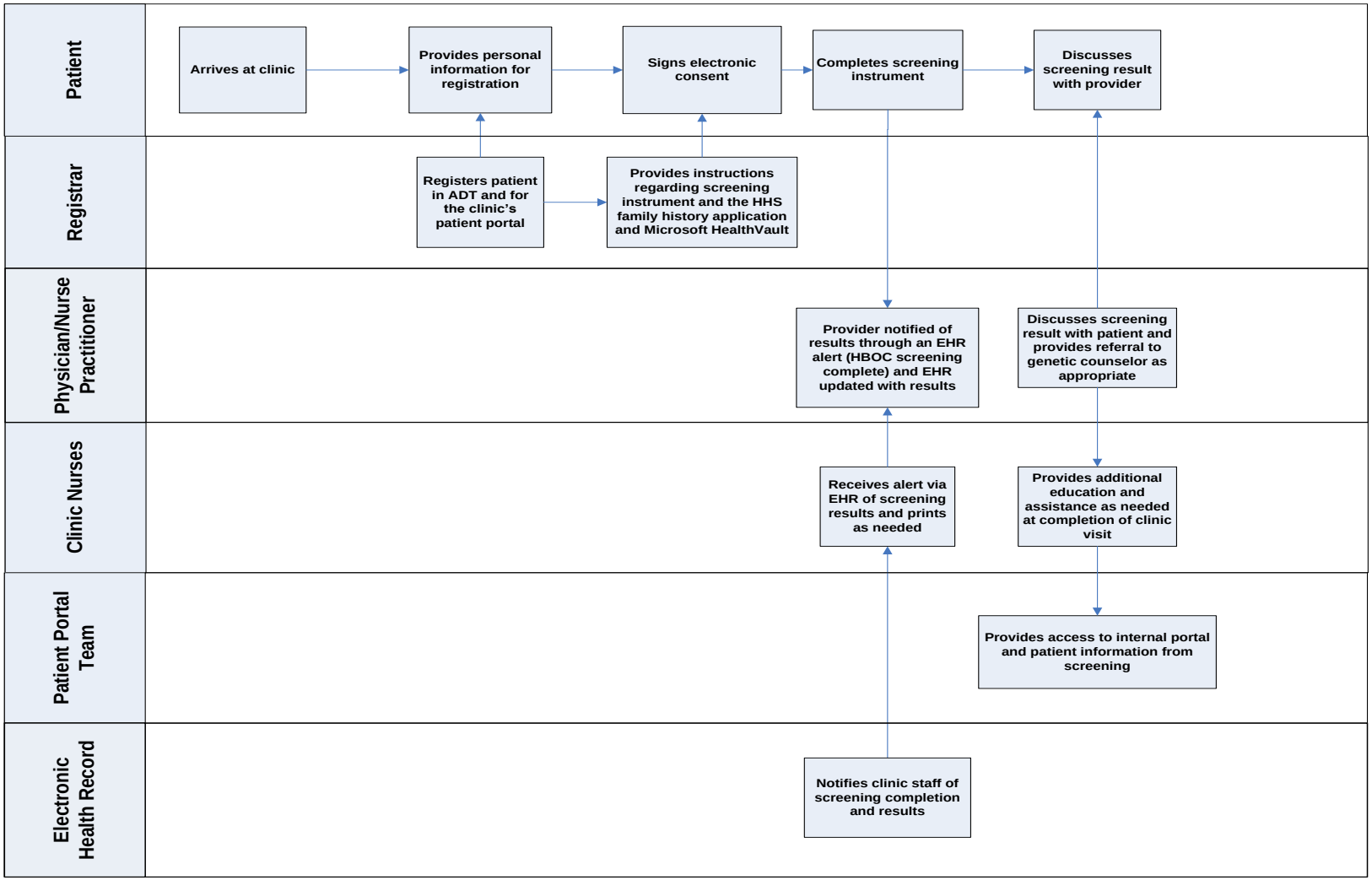


Figure 3: *Mammography Center Workflow*

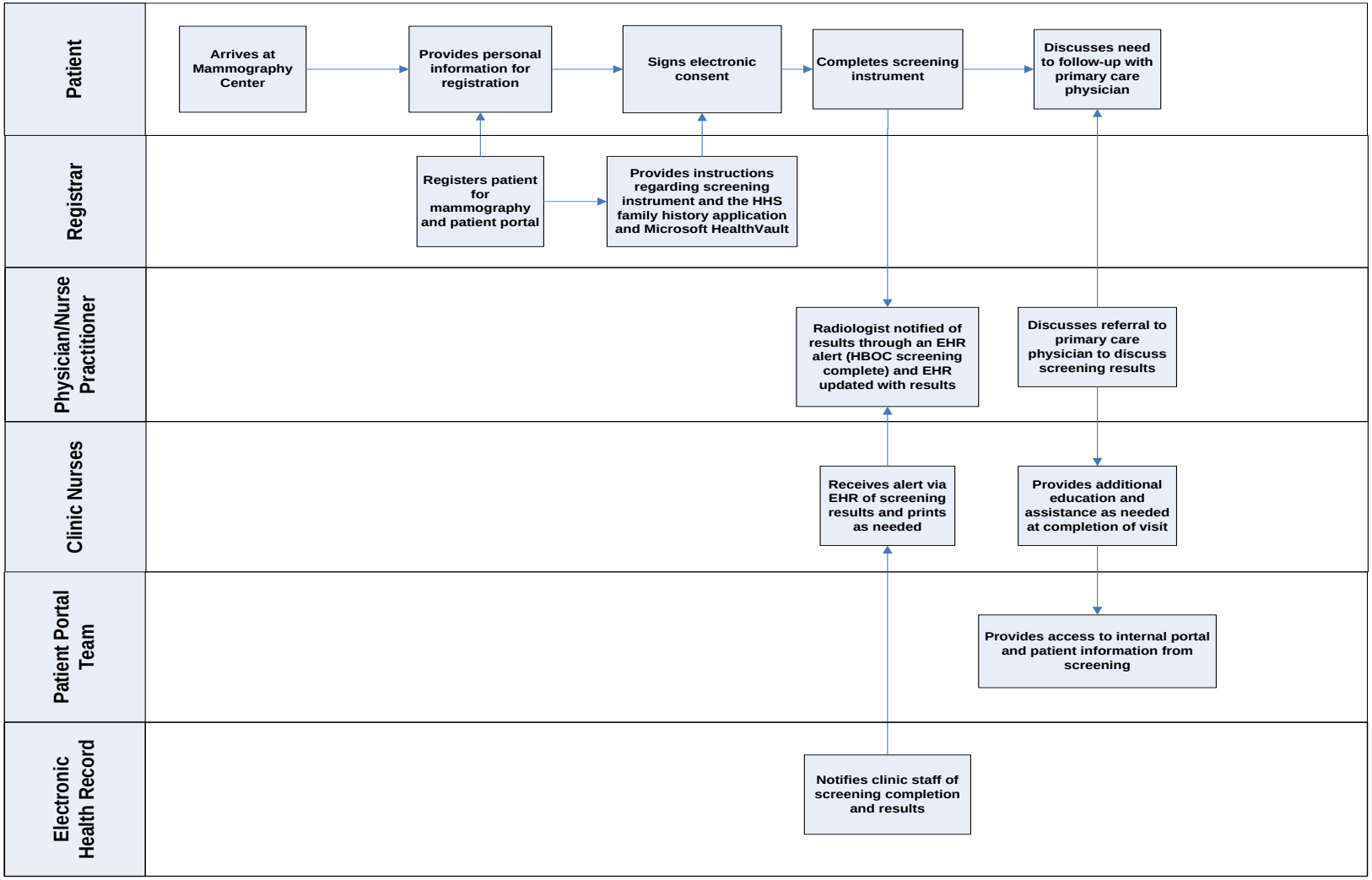


Figure 4: *Preregistration Workflow*

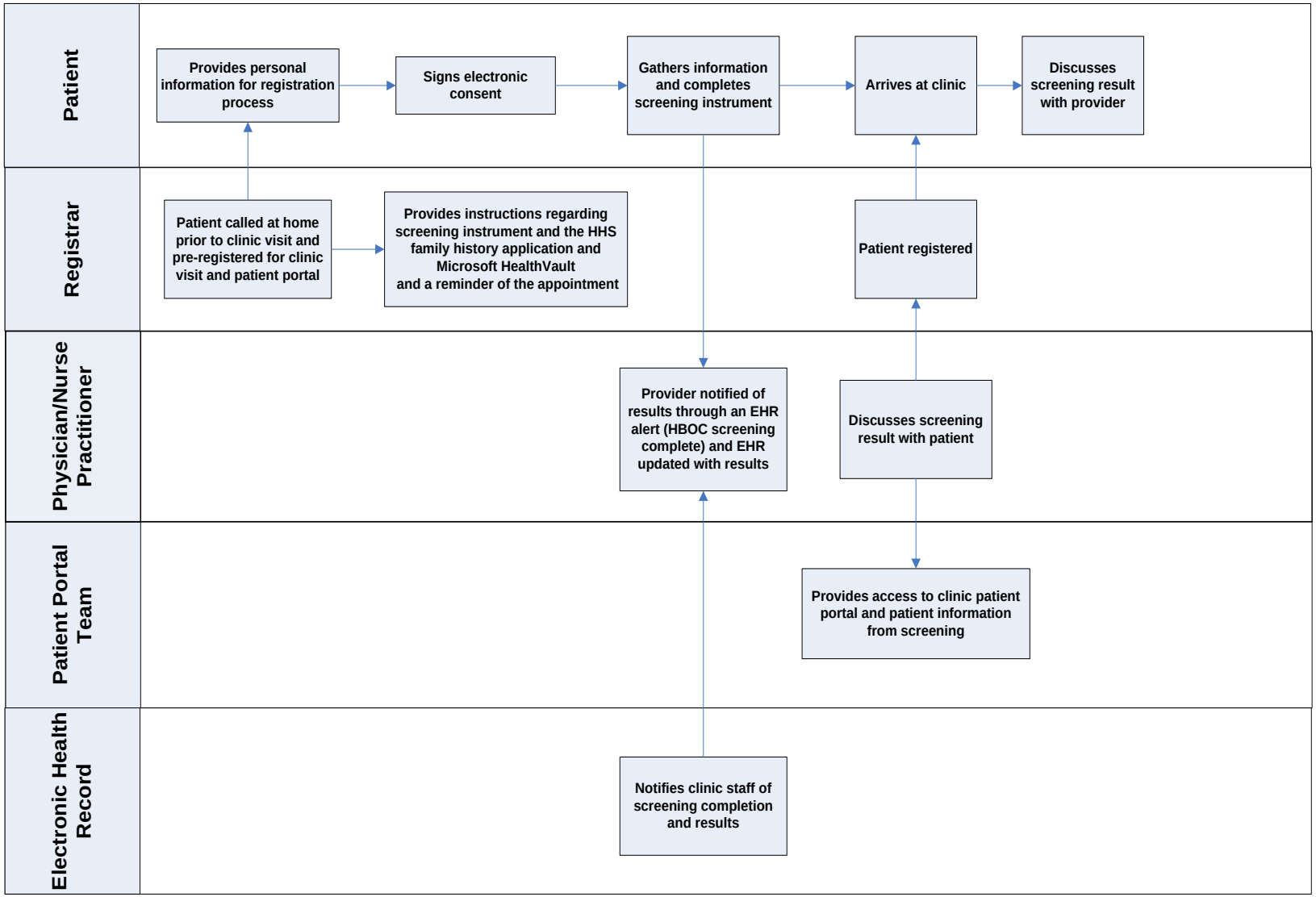


Figure 5: *Implementation Phases*

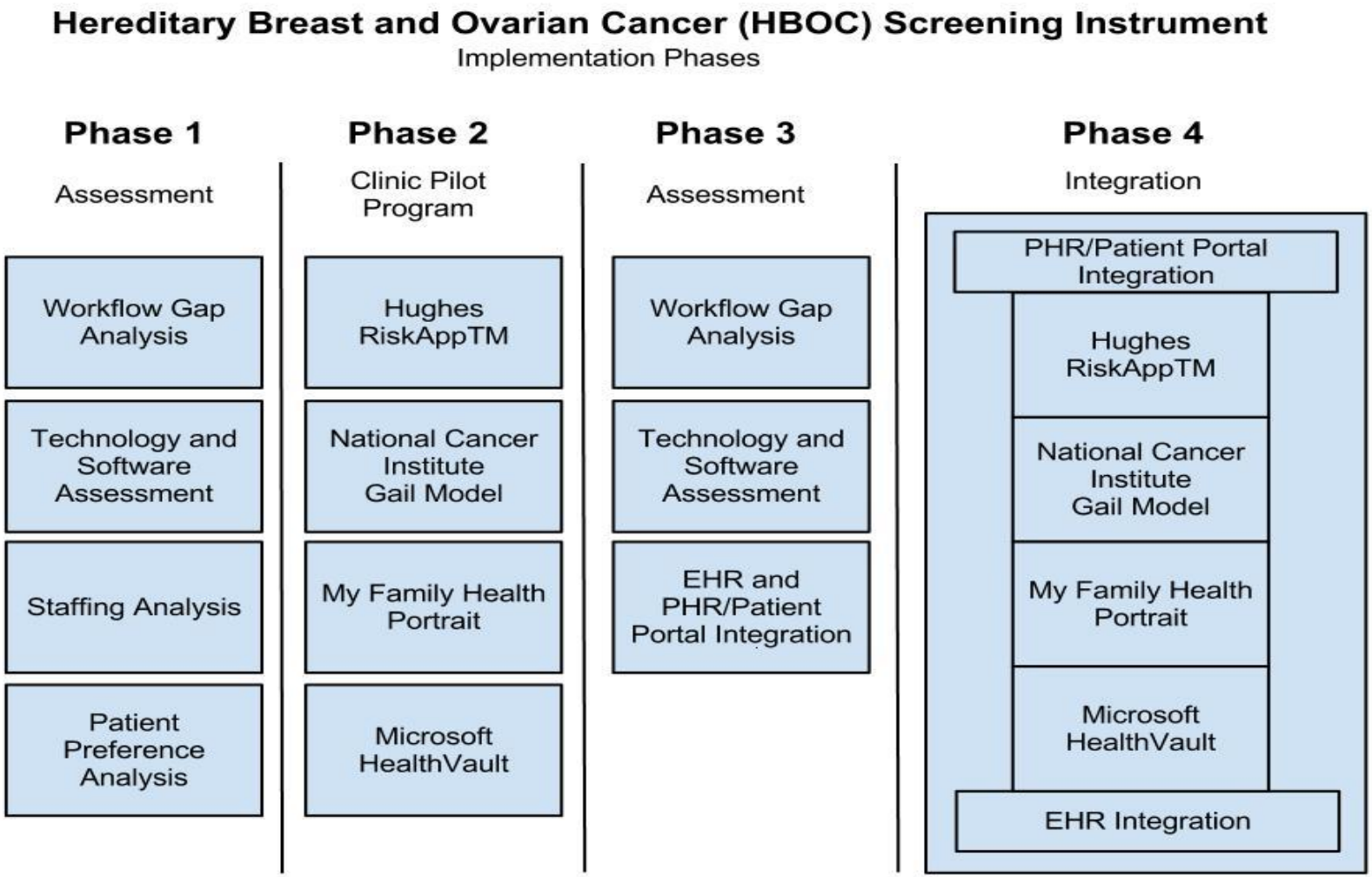


Figure 6: *Top Global Engagement Drivers*

From the Right Management Global Benchmarking Employee Engagement Study, December 2008 (Schroeder-Saulnier, 2008)

1. I am committed to my organization's core values
2. Our customers think highly of our products and services
3. My opinions count
4. I have a clear understanding of what is expected of me at work
5. I understand how I can contribute to meeting the needs of our customers
6. I have been fairly rewarded
7. Senior leaders value employees
8. Everyone is treated with respect at work, regardless of who they are
9. I can concentrate on my job when I am at my work area
10. My personal work objectives are linked to my work area's business plan
11. I clearly understand my organization's mission
12. Senior leaders have the capability to make my organization successful
13. I am encouraged to take ownership of my work
14. My organization is involved in supporting the community
15. There are career opportunities for me at my organization
16. You can balance work and personal interests at my organization and still progress
17. My organization allows me to maintain a reasonable balance between my family and work life
18. The amount of pressure I experience in my role is reasonable
19. There is sufficient incentive to perform well at my organization
20. My pay is competitive compared to similar jobs in my organization
21. My immediate manager gives me the support I need to do my job well
22. People in my organization have the capability to do their jobs effectively
23. My organization is effective at attracting and retaining talent
24. I have the authority that I need to do my job well
25. My organization actively promotes health and well-being
26. My organization invests in its people's learning and development

Figure 7: *Hughes riskApps WorkFlow-260*

(Hughes riskApps™, 2012)

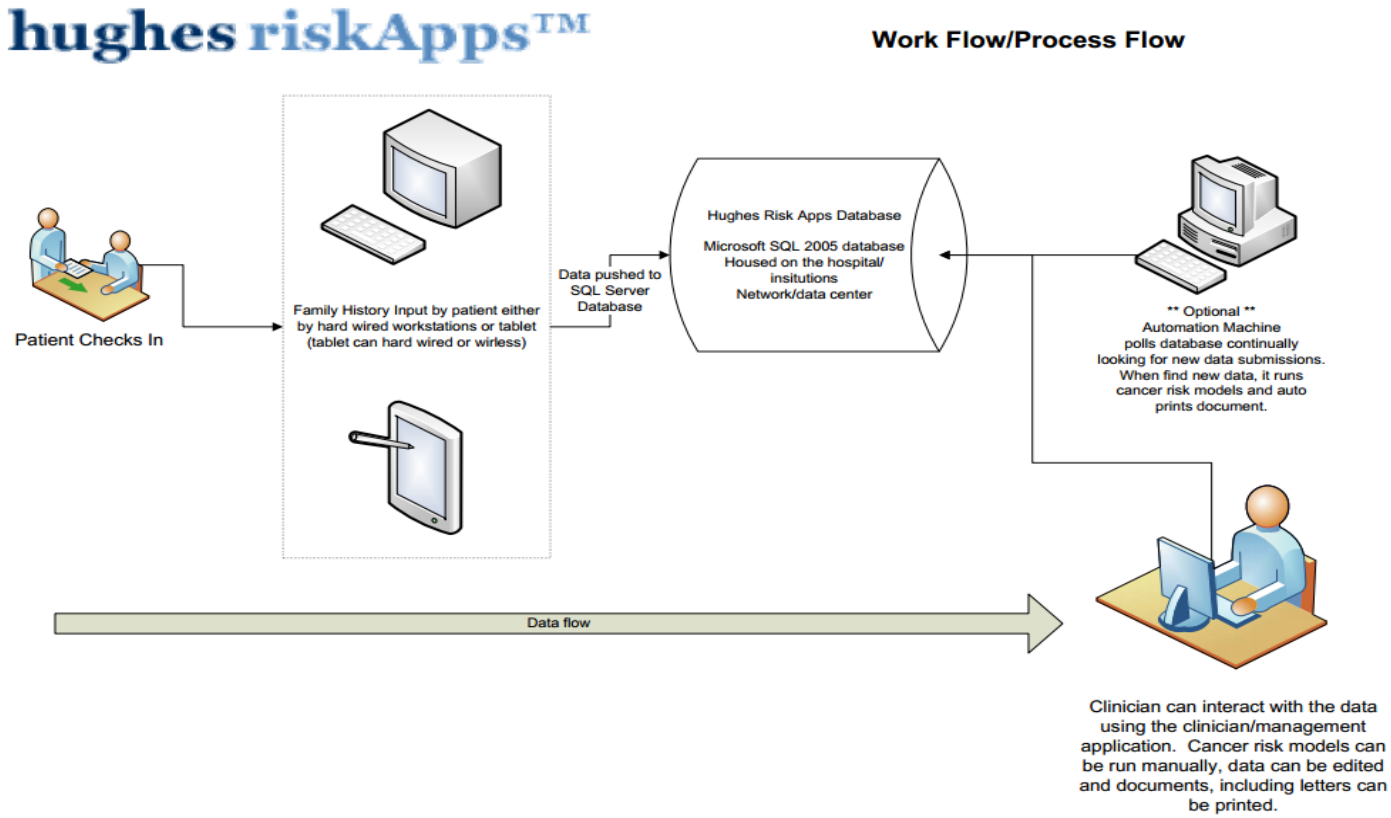


Figure 8: *Breast Cancer Risk Assessment Tool*

(NCI, 2011)

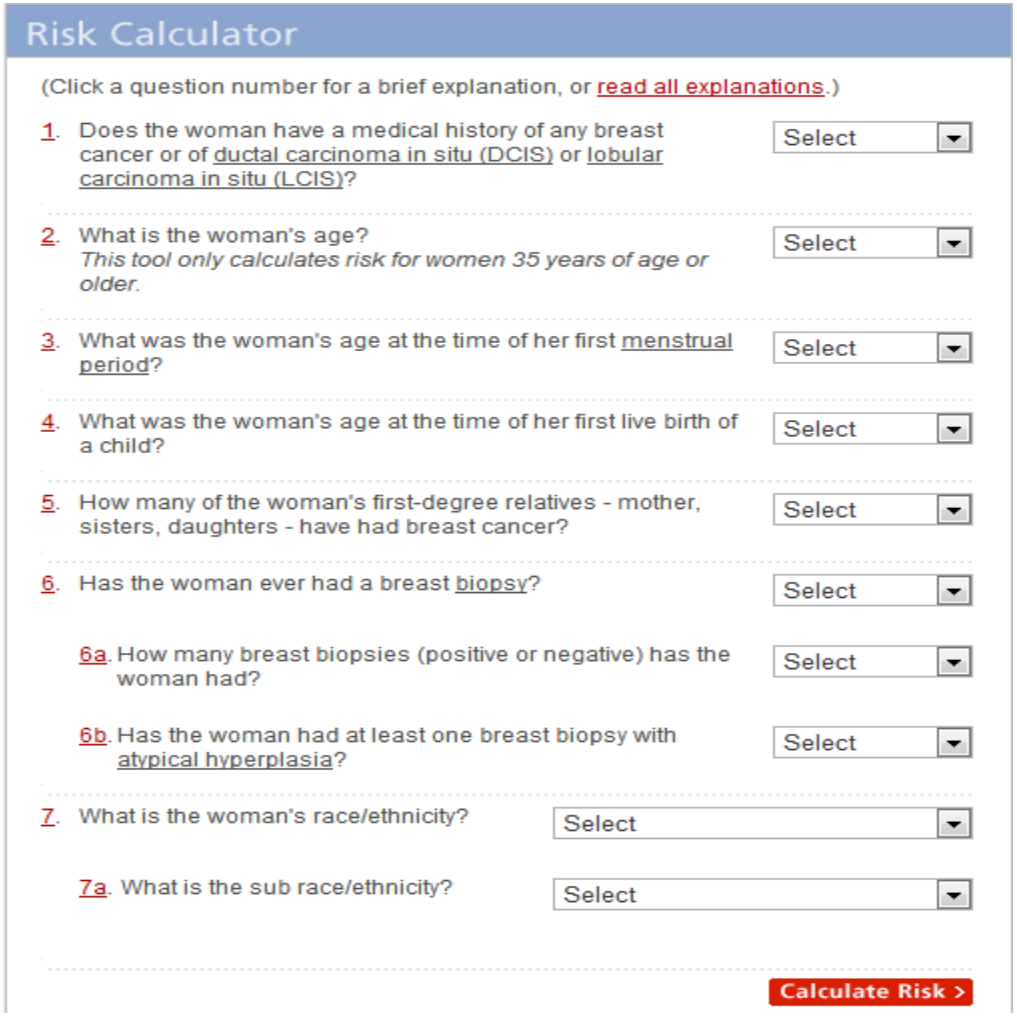


Figure 9: *My Family Health Portrait*

(HHS, 2012b)

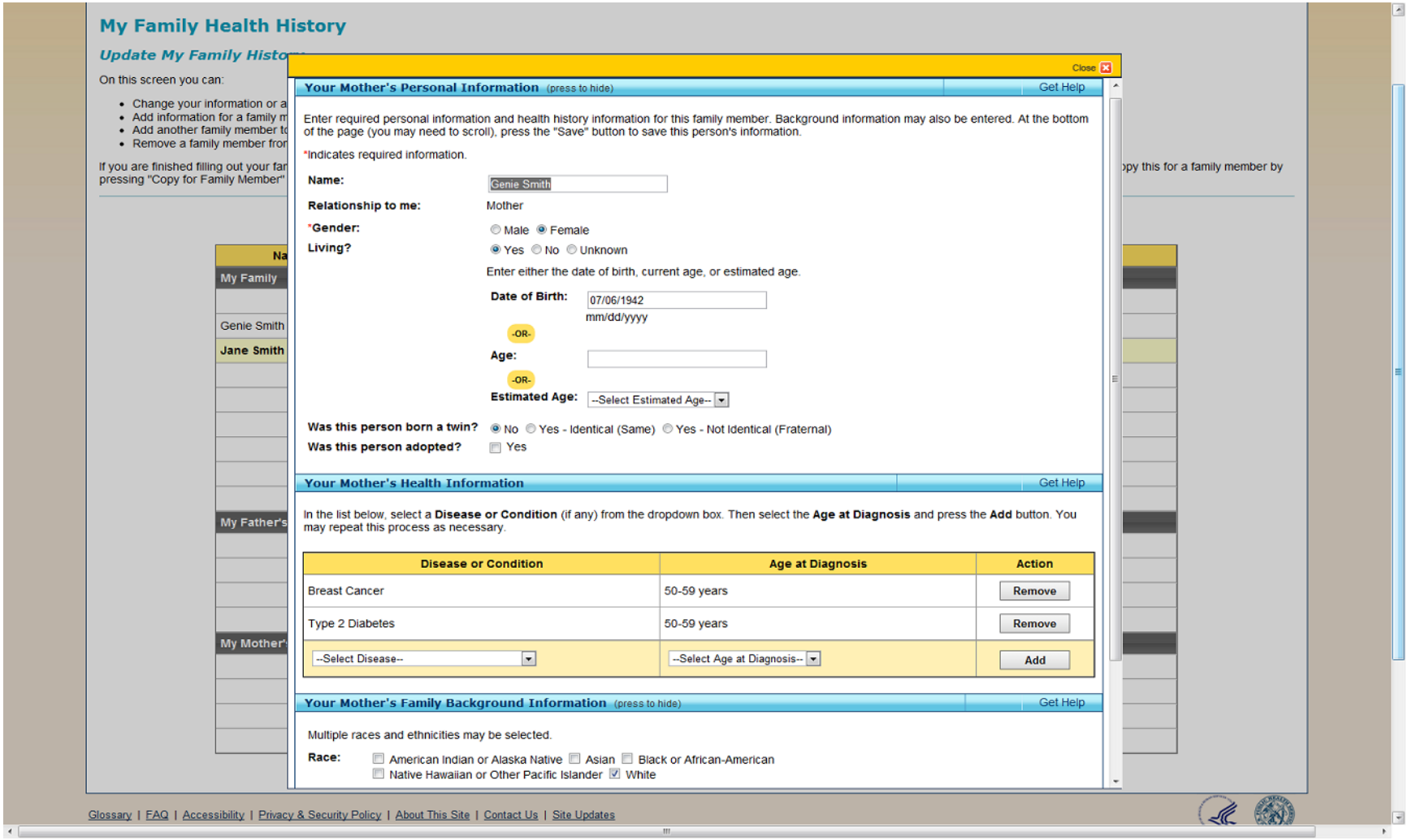


Figure 10: *Microsoft HealthVault Family History*

(Microsoft, 2012)

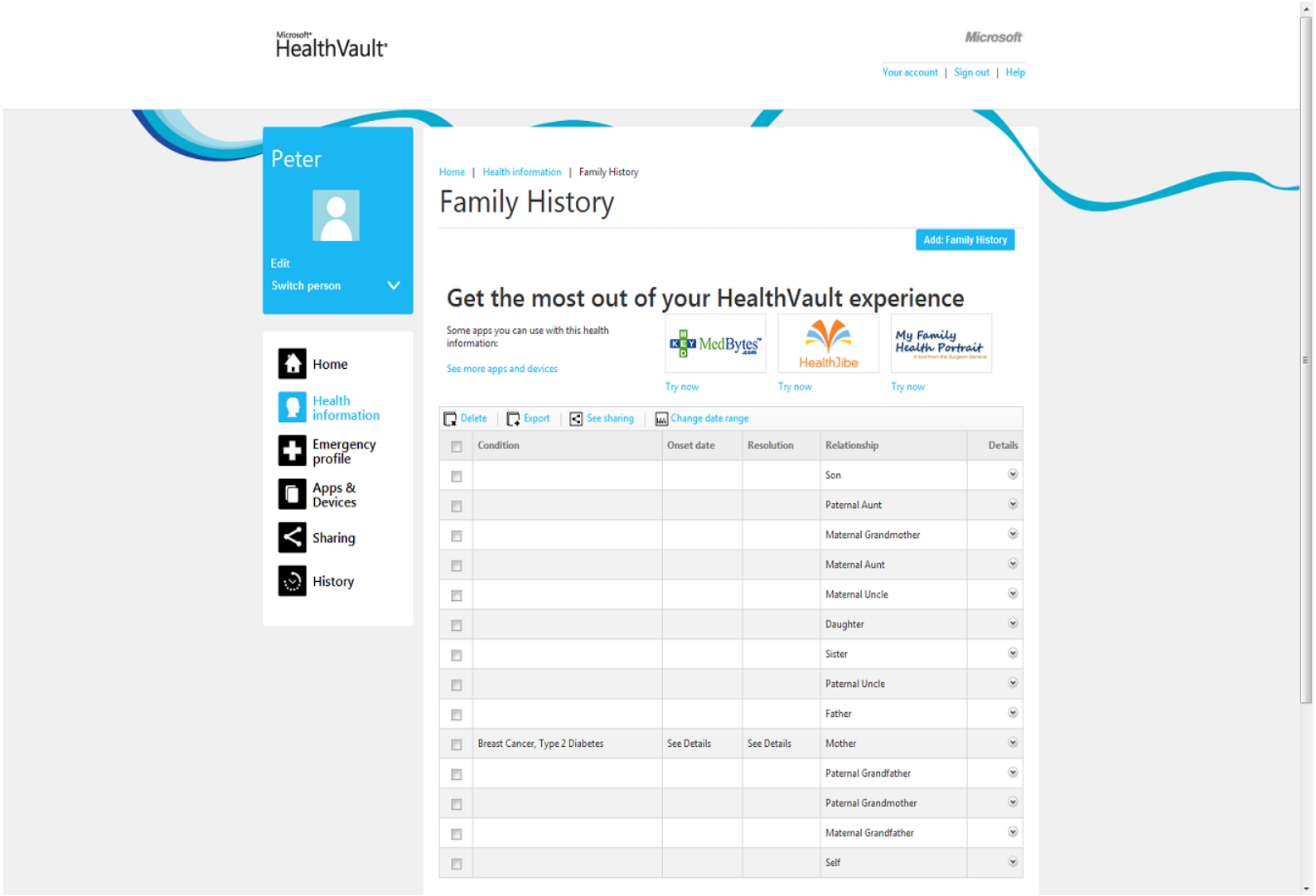


Figure 11: *HBOC Screening Instrument Questionnaire*

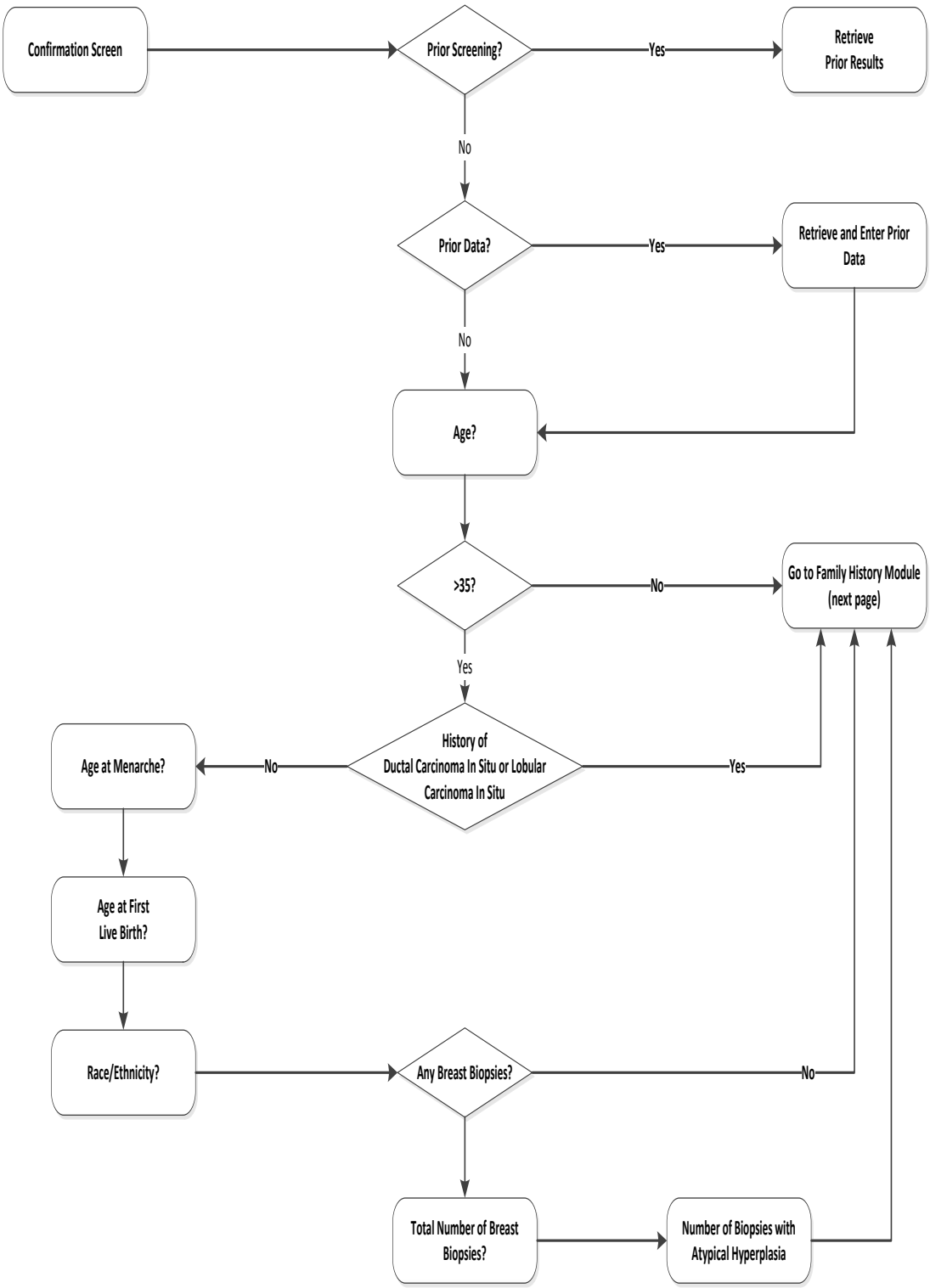
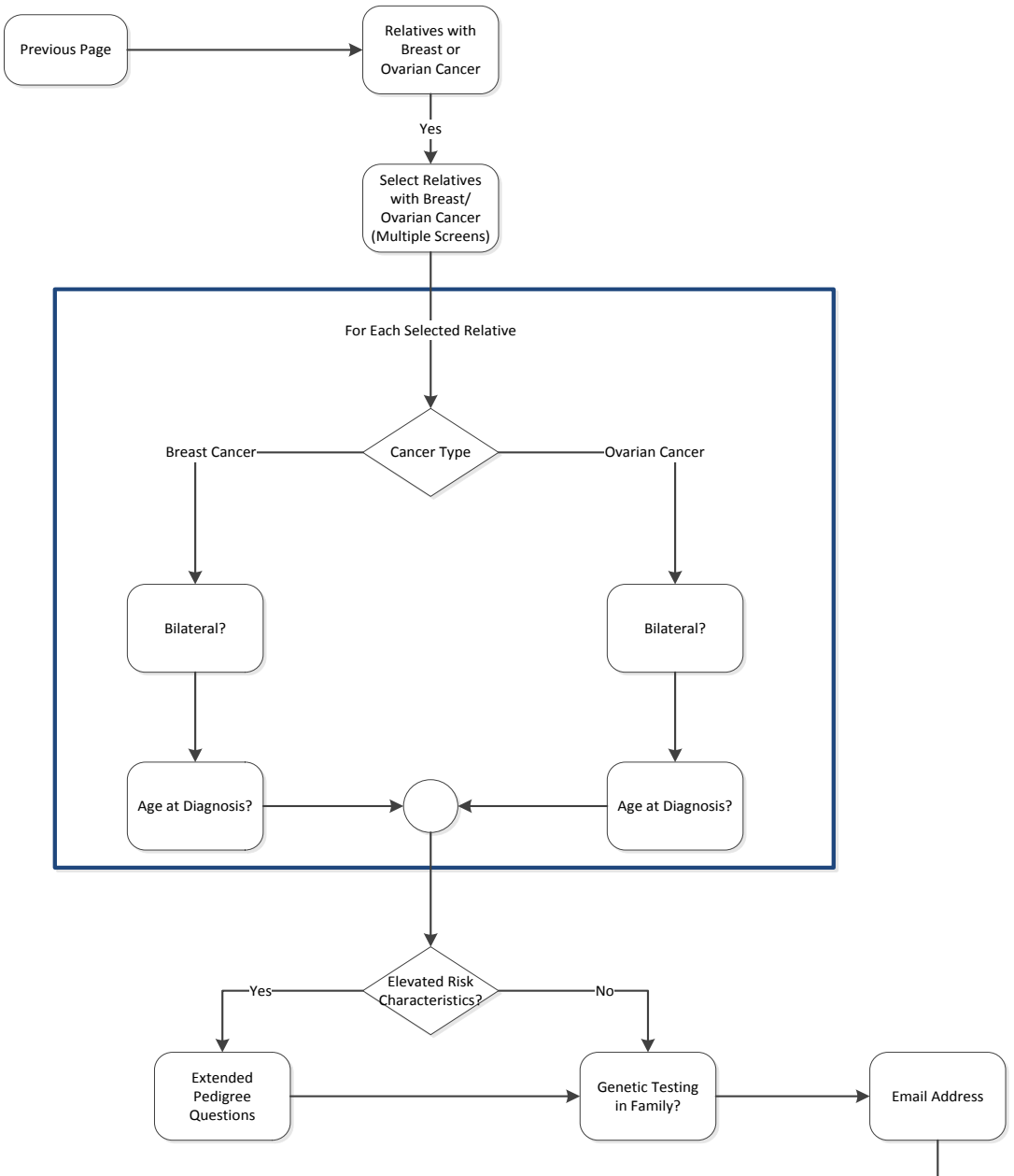


Figure 12: *HBOC Screening Instrument Questionnaire Continued*



Elevated Risk Characteristics
Jewish and at least one breast cancer in family
Not Jewish and at least two breast cancers in family
At least one ovarian cancer in family
At least one male breast cancer in the family
At least one bilateral breast cancer in family
At least one breast cancer under age 50

Figure 13: *System Design and Data Flow of HBOC Screening Instrument Model*

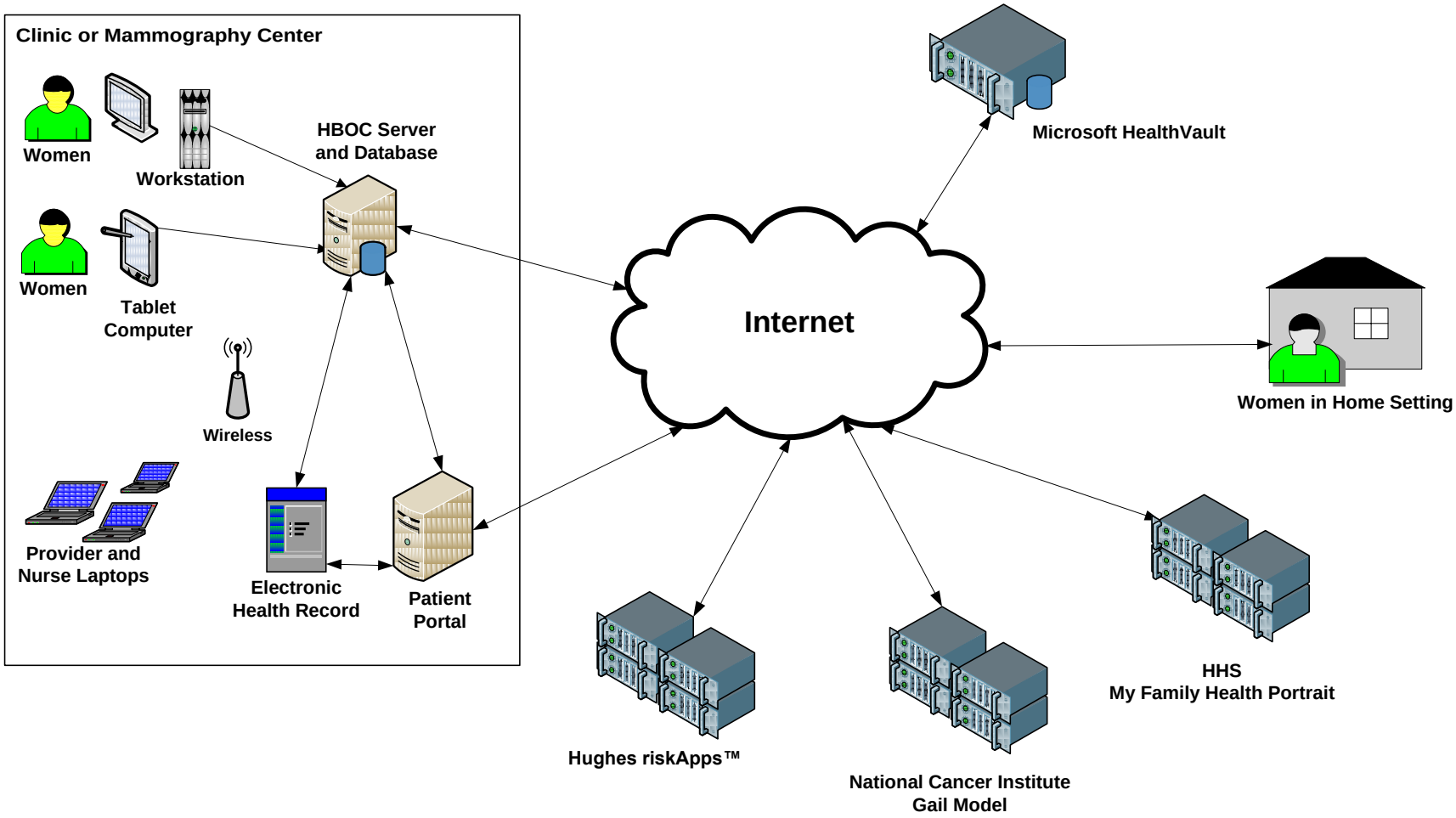
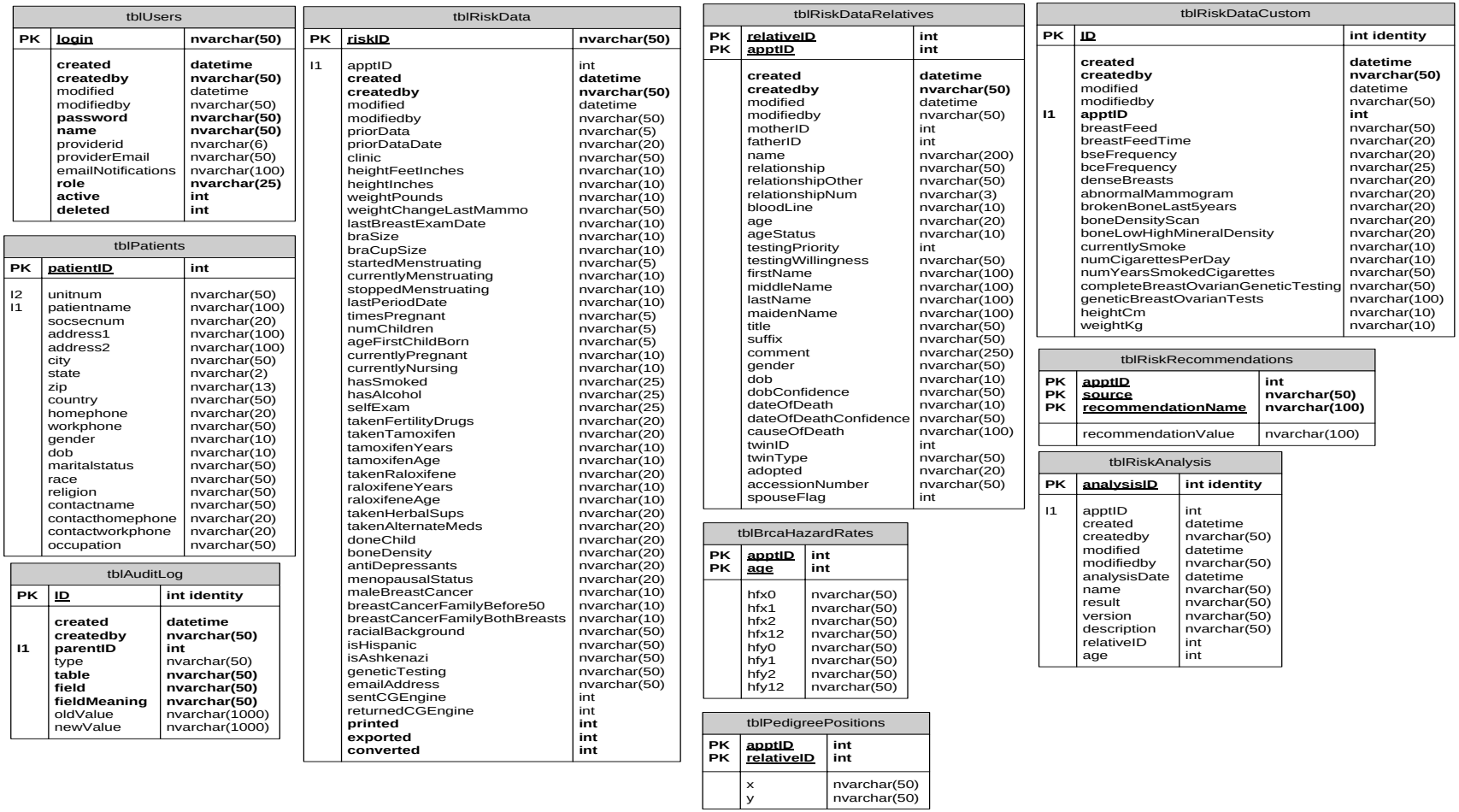


Figure 14: *Sampling of Database Tables for Hughes riskApps™ Model*

(Hughes riskApps™, n.d.b)



tblUsers

PK	login	nvarchar(50)
	created	**datetime**
	createdby	**nvarchar(50)**
	modified	datetime
	modifiedby	nvarchar(50)
	password	**nvarchar(50)**
	name	**nvarchar(50)**
	providerid	nvarchar(6)
	providerEmail	nvarchar(50)
	emailNotifications	nvarchar(100)
	role	**nvarchar(25)**
	active	**int**
	deleted	**int**

tblPatients

PK	patientID	int
I2	unitnum	nvarchar(50)
I1	patientname	nvarchar(100)
	socsecnum	nvarchar(20)
	address1	nvarchar(100)
	address2	nvarchar(100)
	city	nvarchar(50)
	state	nvarchar(2)
	zip	nvarchar(13)
	country	nvarchar(50)
	homephone	nvarchar(20)
	workphone	nvarchar(50)
	gender	nvarchar(10)
	dob	nvarchar(10)
	maritalstatus	nvarchar(50)
	race	nvarchar(50)
	religion	nvarchar(50)
	contactname	nvarchar(50)
	contacthomephone	nvarchar(20)
	contactworkphone	nvarchar(20)
	occupation	nvarchar(50)

tblAuditLog

PK	ID	int identity
	created	**datetime**
	createdby	**nvarchar(50)**
I1	**parentID**	**int**
	type	nvarchar(50)
	table	**nvarchar(50)**
	field	**nvarchar(50)**
	fieldMeaning	**nvarchar(50)**
	oldValue	nvarchar(1000)
	newValue	nvarchar(1000)

tblRiskData

PK	riskID	nvarchar(50)
I1	apptID	int
	created	**datetime**
	createdby	**nvarchar(50)**
	modified	datetime
	modifiedby	nvarchar(50)
	priorData	nvarchar(5)
	priorDataDate	nvarchar(20)
	clinic	nvarchar(50)
	heightFeetInches	nvarchar(10)
	heightInches	nvarchar(10)
	weightPounds	nvarchar(10)
	weightChangeLastMammo	nvarchar(50)
	lastBreastExamDate	nvarchar(10)
	braSize	nvarchar(10)
	braCupSize	nvarchar(10)
	startedMenstruating	nvarchar(5)
	currentlyMenstruating	nvarchar(10)
	stoppedMenstruating	nvarchar(10)
	lastPeriodDate	nvarchar(10)
	timesPregnant	nvarchar(5)
	numChildren	nvarchar(5)
	ageFirstChildBorn	nvarchar(5)
	currentlyPregnant	nvarchar(10)
	currentlyNursing	nvarchar(10)
	hasSmoked	nvarchar(25)
	hasAlcohol	nvarchar(25)
	selfExam	nvarchar(25)
	takenFertilityDrugs	nvarchar(20)
	takenTamoxifen	nvarchar(20)
	tamoxifenYears	nvarchar(10)
	tamoxifenAge	nvarchar(10)
	takenRaloxifene	nvarchar(20)
	raloxifeneYears	nvarchar(10)
	raloxifeneAge	nvarchar(10)
	takenHerbalSups	nvarchar(20)
	takenAlternateMeds	nvarchar(20)
	doneChild	nvarchar(20)
	boneDensity	nvarchar(20)
	antiDepressants	nvarchar(20)
	menopausalStatus	nvarchar(20)
	maleBreastCancer	nvarchar(10)
	breastCancerFamilyBefore50	nvarchar(10)
	breastCancerFamilyBothBreasts	nvarchar(10)
	racialBackground	nvarchar(50)
	isHispanic	nvarchar(50)
	isAshkenazi	nvarchar(50)
	geneticTesting	nvarchar(50)
	emailAddress	nvarchar(50)
	sentCGEngine	int
	returnedCGEngine	int
	printed	**int**
	exported	**int**
	converted	**int**

tblRiskDataRelatives

PK	relativeID	int
PK	apptID	int
	created	**datetime**
	createdby	**nvarchar(50)**
	modified	datetime
	modifiedby	nvarchar(50)
	motherID	int
	fatherID	int
	name	nvarchar(200)
	relationship	nvarchar(50)
	relationshipOther	nvarchar(50)
	relationshipNum	nvarchar(3)
	bloodLine	nvarchar(10)
	age	nvarchar(20)
	ageStatus	nvarchar(10)
	testingPriority	int
	testingWillingness	nvarchar(50)
	firstName	nvarchar(100)
	middleName	nvarchar(100)
	lastName	nvarchar(100)
	maidenName	nvarchar(100)
	title	nvarchar(50)
	suffix	nvarchar(50)
	comment	nvarchar(250)
	gender	nvarchar(50)
	dob	nvarchar(10)
	dobConfidence	nvarchar(50)
	dateOfDeath	nvarchar(10)
	dateOfDeathConfidence	nvarchar(50)
	causeOfDeath	nvarchar(100)
	twinID	int
	twinType	nvarchar(50)
	adopted	nvarchar(20)
	accessionNumber	nvarchar(50)
	spouseFlag	int

tblBrcaHazardRates

PK	apptID	int
PK	age	int
	hfx0	nvarchar(50)
	hfx1	nvarchar(50)
	hfx2	nvarchar(50)
	hfx12	nvarchar(50)
	hfy0	nvarchar(50)
	hfy1	nvarchar(50)
	hfy2	nvarchar(50)
	hfy12	nvarchar(50)

tblPedigreePositions

PK	apptID	int
PK	relativeID	int
	x	nvarchar(50)
	y	nvarchar(50)

tblRiskDataCustom

PK	ID	int identity
	created	**datetime**
	createdby	**nvarchar(50)**
	modified	datetime
	modifiedby	nvarchar(50)
I1	**apptID**	**int**
	breastFeed	nvarchar(50)
	breastFeedTime	nvarchar(20)
	bseFrequency	nvarchar(20)
	bceFrequency	nvarchar(25)
	denseBreasts	nvarchar(20)
	abnormalMammogram	nvarchar(20)
	brokenBoneLast5years	nvarchar(20)
	boneDensityScan	nvarchar(20)
	boneLowHighMineralDensity	nvarchar(20)
	currentlySmoke	nvarchar(10)
	numCigarettesPerDay	nvarchar(10)
	numYearsSmokedCigarettes	nvarchar(50)
	completeBreastOvarianGeneticTesting	nvarchar(50)
	geneticBreastOvarianTests	nvarchar(100)
	heightCm	nvarchar(10)
	weightKg	nvarchar(10)

tblRiskRecommendations

PK	apptID	int
PK	source	nvarchar(50)
PK	recommendationName	nvarchar(100)
	recommendationValue	nvarchar(100)

tblRiskAnalysis

PK	analysisID	int identity
I1	apptID	int
	created	datetime
	createdby	nvarchar(50)
	modified	datetime
	modifiedby	nvarchar(50)
	analysisDate	datetime
	name	nvarchar(50)
	result	nvarchar(50)
	version	nvarchar(50)
	description	nvarchar(50)
	relativeID	int
	age	int

Figure 15: *HBOC Screening Instrument Use Case Diagram*

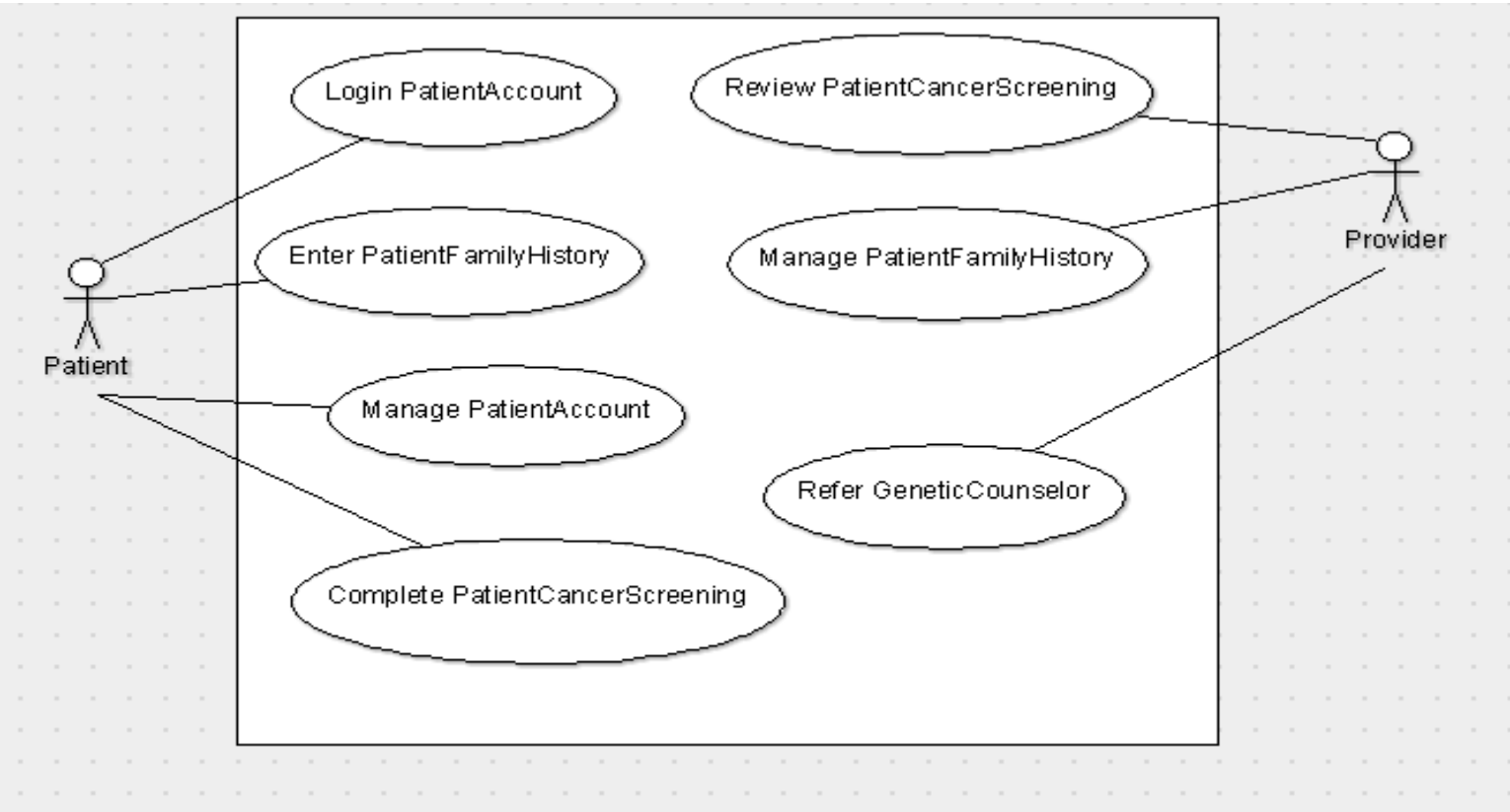


Figure 16: *HBOC Screening Instrument Package Diagram Across Multiple Models*

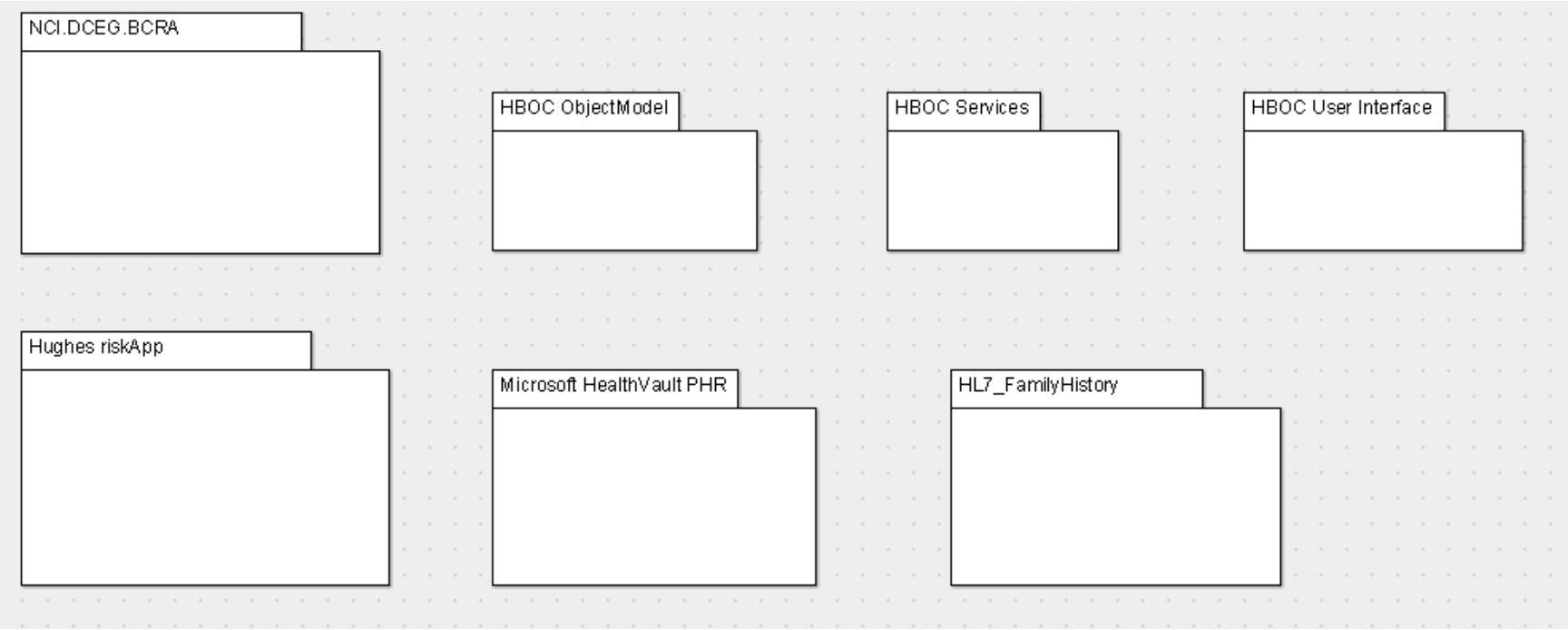


Figure 17: *NCI Breast Cancer Risk Assessment Package Class Diagram*

(NCI, 2011)

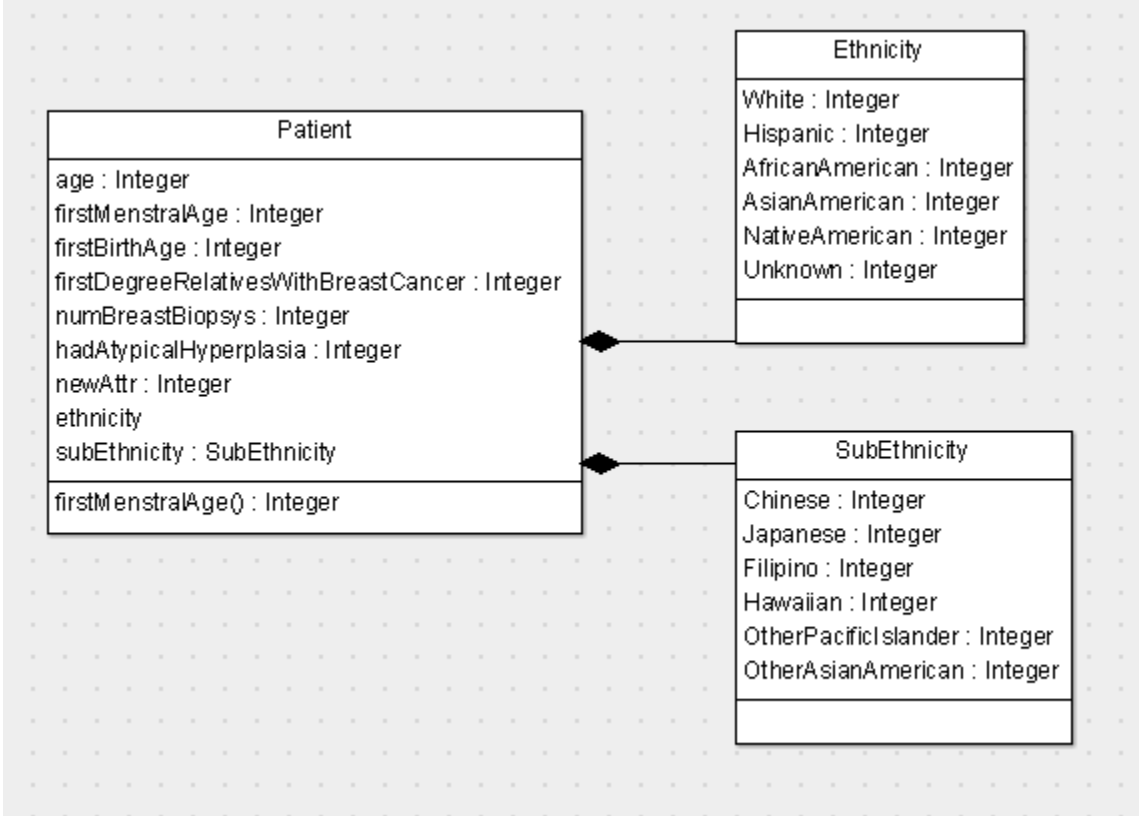


Figure 18: *BRCAPRO Lifetime Risk Sample Report*

(Hughes, n.d.)

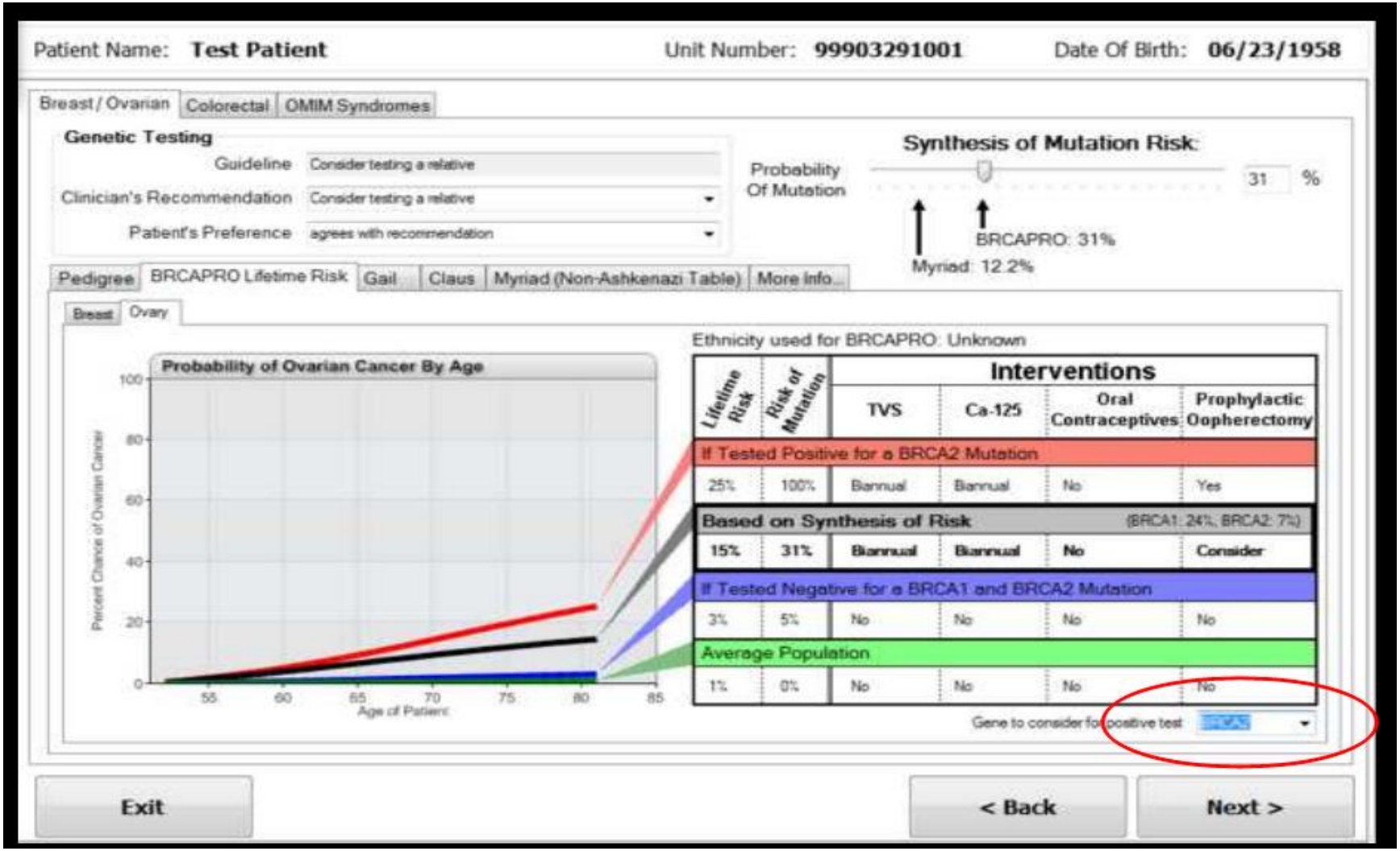


Figure 19: *Gail Model Risk Sample Report*

(Hughes, n.d.)

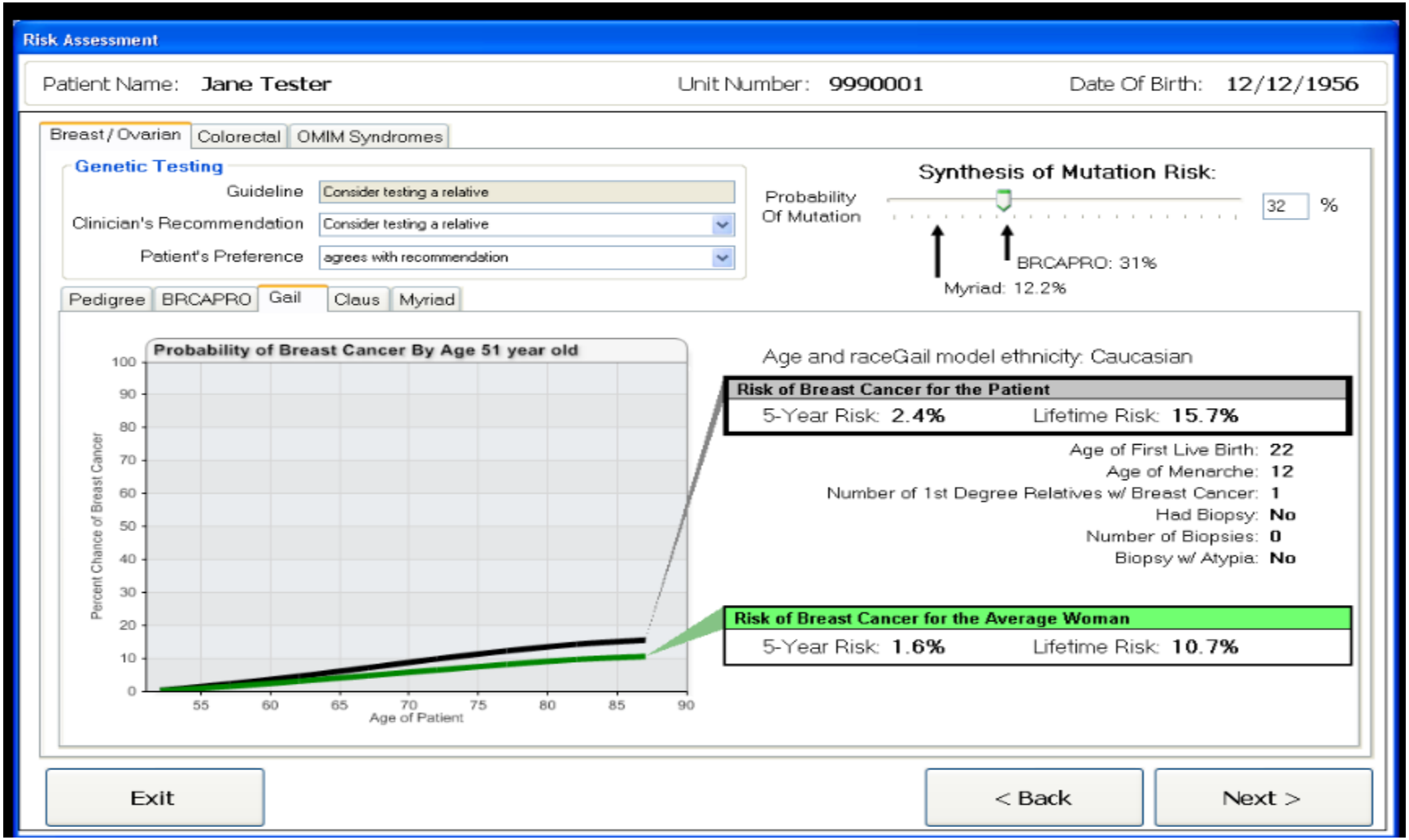


Figure 20: *EHR Sample Screen*

(Showing messaging icon in the top right of the screen) IKnowMed EHR © McKesson Specialty Health

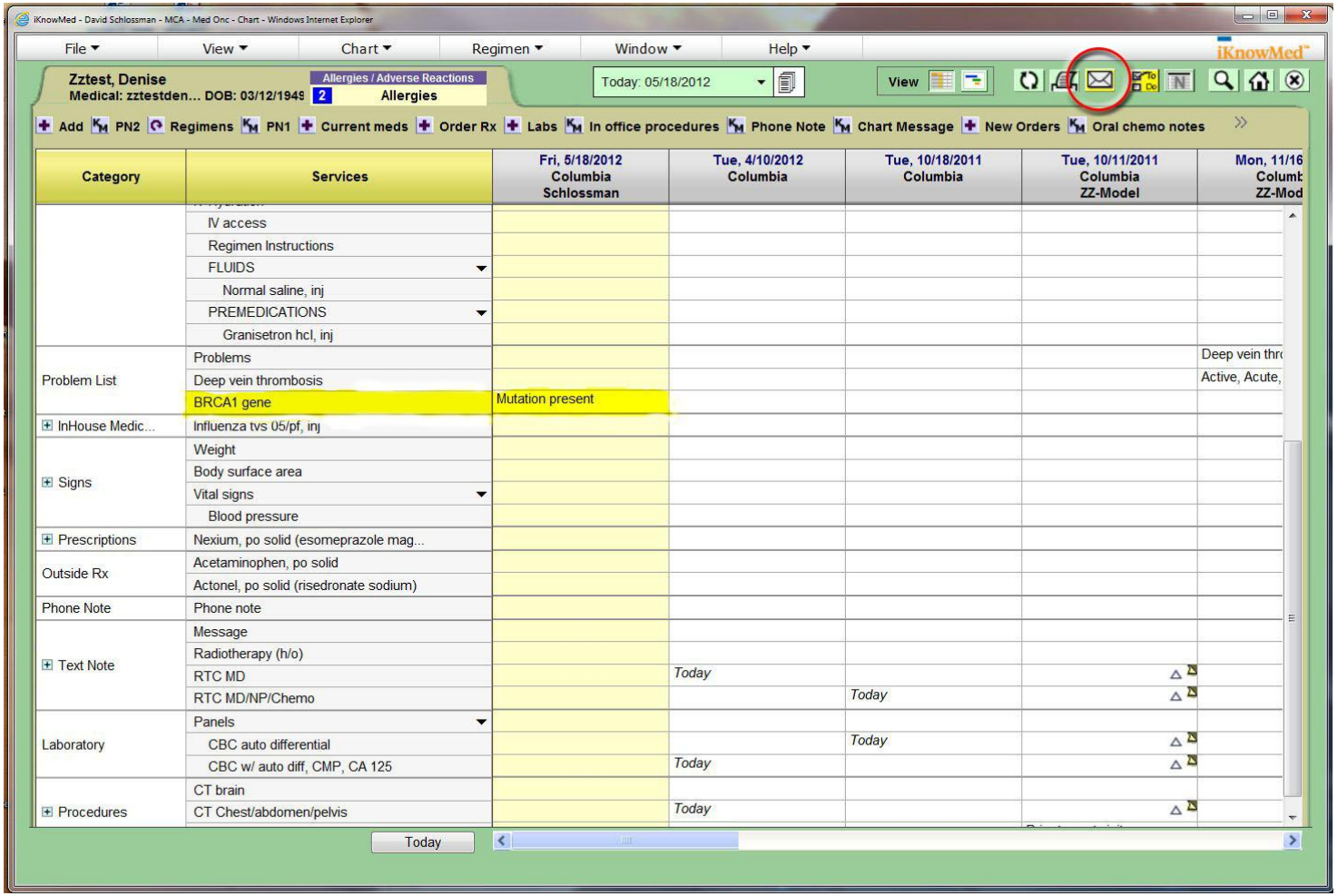


Figure 21: *Hughes riskApps™ User Interface Examples*

(Hughes, n.d.)