Introducing a Comprehensive Informatics Framework to Promote Breast Cancer Risk Assessment and Chemoprevention in the Primary Care Setting

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Abstract

Breast cancer is the most commonly diagnosed cancer among women in the United States, and current routine screening prevention methods are costly and expose patients to unnecessary risks of overtreatment. The utilization of a risk-based stratification model, genetic testing, and chemoprevention could decrease the incidence of invasive breast cancer but uptake has been low among high-risk women. The goal of this project was to implement a comprehensive informatics framework to promote breast cancer risk assessment and chemoprevention in the primary care setting that was informed by potential user feedback. The framework provides evidence-based decision support to both providers and patients. For providers we developed a novel breast cancer risk navigation (BNAV) tool which incorporates an evidence-based breast cancer risk model into the electronic health record. For patients a decision aid was designed that allows participants to experience risk through an activity and to address patient-related barriers to chemoprevention. We conducted usability testing to determine barriers and facilitators affecting the toolbox use by providers. A total of seven subjects were recruited and completed the usability testing. Using think-aloud protocols, semi-structured interviews, and subject recordings, we identified recurring themes related to the usability of BNAV. Themes specifically aligned with the content, ease of use, and navigation of the application. This feedback was used to make interface changes to the application that more appropriately tailored BNAV to engage the target population of primary care providers and thus more effectively optimizing shared decision-making associated with breast cancer risk assessment and prevention in clinical practice. A comprehensive informatics framework to increase breast cancer risk assessment and chemoprevention in the primary care setting has been successfully introduced to address this challenge. Given the proven efficacy of breast cancer chemoprevention in high-risk populations, higher uptake may significantly reduce the public health burden of this disease.

Introduction

The U.S. Preventive Services Task Force recommends that clinicians engage in shared decision making with women at high-risk for breast cancer about medications to reduce their risk, also known as chemoprevention. However, uptake has been low (<5%) in the primary care setting. Breast cancer confers significant morbidity and mortality on women in the U.S. and the primary prevention of this disease is a major public health issue. Breast cancer risk assessment and available interventions for prevention, such as chemoprevention, are underutilized in the U.S. Selective estrogen receptor modulators (SERMs), tamoxifen and raloxifene, and the aromatase inhibitors, exemestane and anastrozole, have been shown to reduce breast cancer incidence by up to 50-65% among high-risk women [1-3, 19]. Based upon this evidence, the U.S. Preventive Services Task Force (USPSTF) and other professional organizations recommend that clinicians discuss chemoprevention with high-risk women [4-6]. An estimated 10 million women in the U.S. may be eligible for chemoprevention [7], but fewer than 5% of high-risk women offered a SERM agree to take it [8]. Compounding this underutilization is the fact that a large proportion of women may be unaware of their high-risk status due to our inability to adequately screen them in the primary care setting. Other reasons for lack of SERM uptake include concerns about side effects, inadequate time for counseling, and an insufficient level of knowledge about risk-reducing strategies on the part of primary care providers (PCPs) and patients [8-9]. Women from racial/ethnic minorities are less likely to seek breast cancer preventive care [10-11], contributing to higher rates of late stage diagnosis and poorer clinical outcomes in these populations compared to non-Hispanic whites [12-14]. Further research is needed to determine how knowledge about breast cancer, actual/perceived risk, and risks/benefits of chemoprevention are best communicated to women in order to promote breast cancer prevention strategies.

A recent update from the USPSTF recommends that clinicians engage in shared decision making with women who are at increased risk for breast cancer about medications to reduce their risk [4]. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. However, prescription behavior exhibited by the majority of PCPs is not sufficiently aligned with the recent USPSTF recommendations. New approaches aimed at changing PCP

prescription behavior towards women with increased risk for breast cancer are urgently needed. The goal of this project was to implement a comprehensive informatics framework to promote breast cancer risk assessment and chemoprevention in the primary care setting that was informed by potential user feedback.

Methods

Theoretical Underpinnings

Theory-based interventions demonstrated a better chance of achieving behavior change objectives in multiple studies. Theory of Planned Behavior (TPB) has been widely used for developing successful interventions to change health-related behaviors [15]. TPB as a psychological model of health decision making that posits an individual's intention to perform a particular behavior as the most immediate and important factor in determining that individual's behavior [16]. In turn, the major constructs that affect intention are attitude, subjective norms, and perceived behavioral control (PBC). TPB has been successfully used to affect physician behavior [16-18]. Thus, in this project the TPB-based persuasive messaging will be used to promote provider adherence with current chemoprevention guidelines.

Table 1. Implementation of TPB-based constructs for tailored messaging

TPB construct	Implementation
Attitude	PCPs are given evidence-based information including a clinical summary, USPSTF guidelines and useful links (articles, sites). They are provided with step-by-step explanations, interactive quizzes, and case reports with self-assessment.
Subjective norms	PCPs are provided with access to video testimonials by local opinion leaders. Providers with best chemoprevention practices are acknowledged publically. PCPs may comment on chemoprevention in the blog.
Perceived behavioral control	Easy access to timely information, personalized statistics on guideline adherence, motivational feedback

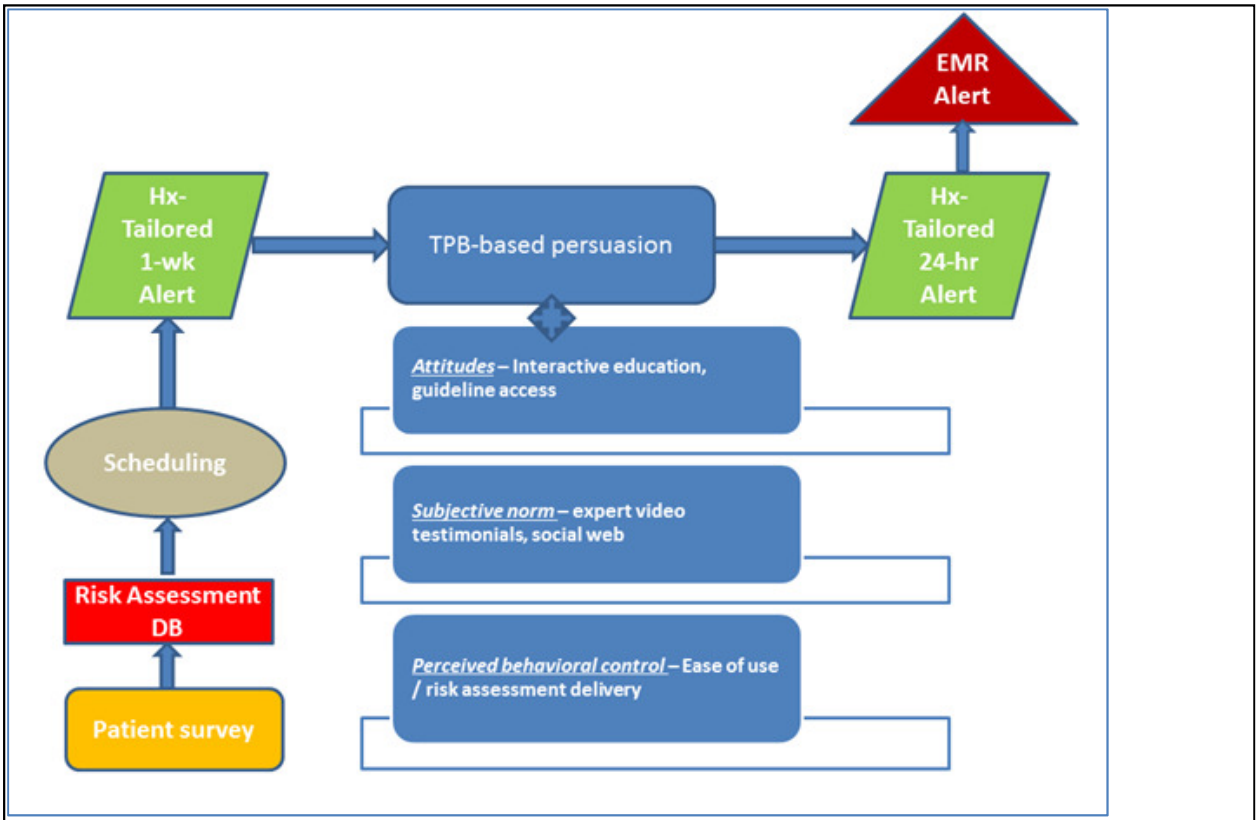

Figure 1. Information workflow for provider engagement in breast cancer prevention practices.

The comprehensive informatics framework to increase breast cancer risk assessment combines tools affecting both patients and providers and is implemented as Breast cancer risk NAVigation (BNAV) system. Approaches for implementing TPB-based constructs for tailored physician messaging are presented in Table 1. To support these approaches a web site has been built providing corresponding content (Breast Cancer Prevention Toolbox). Overall workflow for provider engagement in breast cancer prevention practices is depicted in Figure 1. High risk breast cancer patients are identified after completion of an online survey based on Gail model for breast cancer risk assessment [21]. Using clinic scheduling information, the BNAV system identifies high risk breast cancer patients who are scheduled for a PCP visit within a week. These PCPs receive then a short message informing them that a patient with high risk of breast cancer is scheduled for a visit. A link to the TPB-based Breast Cancer Prevention Toolbox is provided in the initial secure health messaging (SHM) notice to the primary care provider (PCP) one week prior to the clinic visit with the high-risk-of-breast-cancer woman. Based on each user access pattern, mid-week and 24-hr follow-up e-mails will be generated to ensure that content representing all TPB constructs has been accessed by each particular user. A notice within an existing Ambulatory Medicine preventive care dashboard indicating breast cancer risk is also posted in the electronic medical record (EMR) accessed by PCPs (called iNYP).

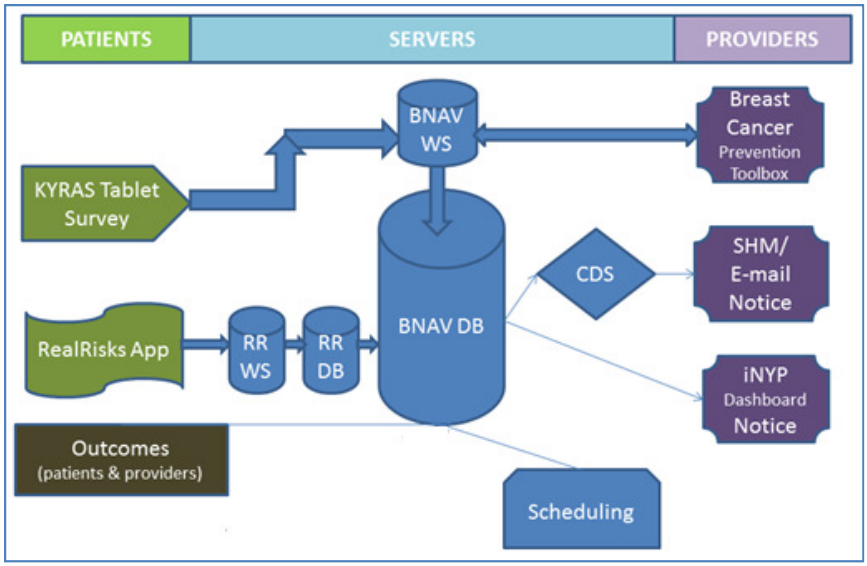

Figure 2. Overall BNAV architecture.

Technical Design

In order to facilitate PCP engagement in breast cancer prevention practices, we designed a tablet-based survey for collecting patient data and generating risk letters (Know Your Risk: Assessment at Screening (KYRAS) for breast cancer survey), a web application for patient risk assessment and decision support (RealRisks), a decision support server, a physician engagement website (Breast Cancer Prevention Toolbox), and a notice in the iNYP EMR dashboard. The overall architecture of the BNAV system can be seen in Figure 2.

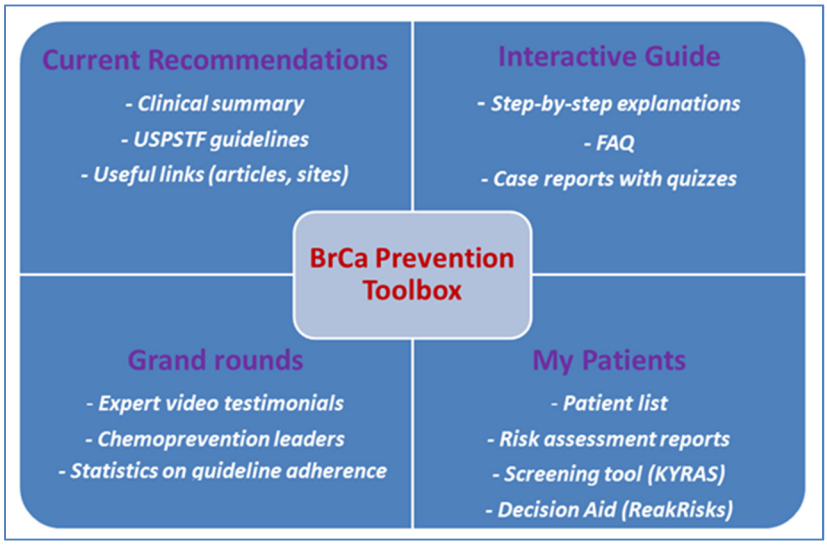

Figure 3. Breast Cancer Prevention Toolbox design.

Data are collected from patients using the KYRAS tablet survey and the RealRisks app where it is then sent to the BNAV database. The BNAV database then is used to provide data for the Breast Cancer Prevention Toolbox, generate SHM and email notices to the patient's PCP, and populate the iNYP dashboard notice in the patient's EMR.

E-mail and SHM notices are sent at the beginning of the week to the patient's PCP notifying them of an upcoming clinic visit with a patient at high risk for breast cancer. The notices include a link to the Breast Cancer Prevention Toolbox where the provider can log in using their Columbia University login. The toolbox provides information about

breast cancer chemoprevention and genetic testing in addition to relevant information for the provider's individual patients at high risk for breast cancer (Figure 3).

Usability Testing

The most effective user centered design methods should be incorporated to promote optimal provider engagement and uptake of the tool in clinical practice. This usability testing intended to qualitatively measure users' engagement with the BNAV tool and provide the developers with tangible opportunities for tool improvement. Prior to each usability study, the provider participants were presented with a brief description of the Breast Cancer Navigation toolbox and its objectives. Participants were provided with a paper copy of the potential BNAV email notification, a notification sample from a breast oncologist regarding the patient, and a notification sample from a genetic counselor regarding the patient. After the subjects viewed the materials and presented their initial reactions, the facilitator loaded the web-based BNAV toolbox dashboard for the participant and began the audiovisual and consented live stream recordings.

Each study was conducted over the course of about one hour's duration in a conference room with an individual provider, a study facilitator, and an observer present. Pairs of researchers conducted the usability studies by fulfilling the roles of moderator (or facilitator) and observer. The moderator received consent from the participants, oriented the subject to the toolbox program, and provided guidance and assistance as the participant completed the study. The observer used Morae Observer software to view a slightly delayed stream of the subject's facial expressions and interactions. The observer coded the usability study in real time on a laptop. The observer documented and noted comments, reactions, and quotes while the facilitator explained the study and interacted with the participants. The stream captured the audio and visual image of each subject. The study facilitator was positioned across from the subject, while the observer remained as silent and unobtrusive as possible, in a corner of the room. Participants provided consent to be audio and visual recorded.

During each study, the facilitator instructed participants to think aloud and conducted the semi structured interview process. Each participant tested the toolbox prototype on the same laptop computer and browser type. Each participant utilized the toolbox prototype in a usability testing session, which lasted, on average, for 60-70 minutes. Participants were asked to freely navigate and complete the BNAV modules in any order they desired or to which came naturally, and to follow a think-aloud protocol while navigating through the decision support tool. Participants voiced intentions and reactions regarding the education modules on genetic testing and/or chemoprevention, the design of the toolbox, and their comprehension of the information presented. If a participant ceased thinking aloud, the moderator prompted the individual with questions relating to the application. Commonly used prompts included "how are you feeling about the information on this page", "what are you currently thinking about", and "why did you decide to move to that section". This interaction was not necessary for the majority of participants. The study subjects were given opportunities to ask questions throughout the study and discuss the relative merits of BNAV and express their concerns on potential implementation issues, specifically considering clinical practice. The facilitator refrained from interacting with the participant beyond prompting and answering questions about the toolbox applications.

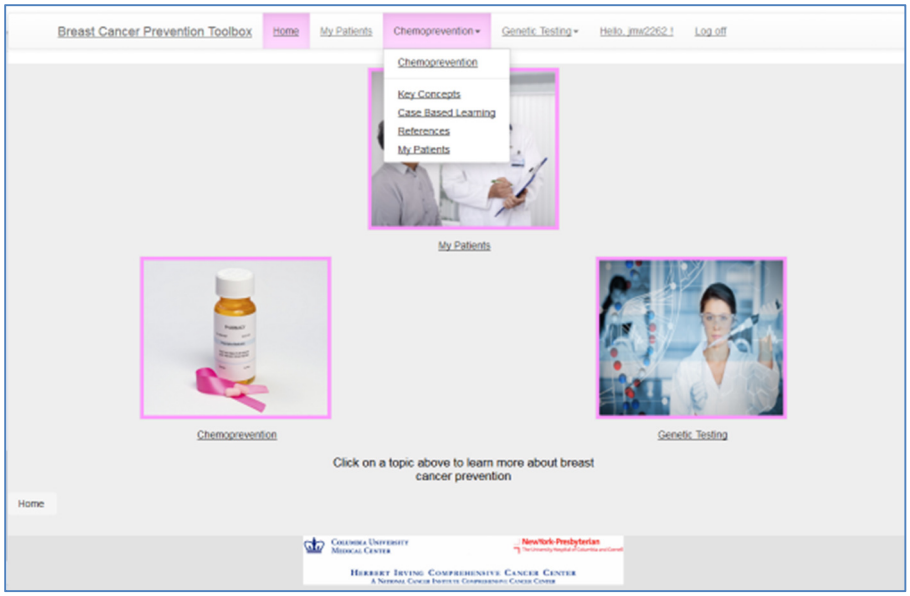

Figure 4. Breast Cancer Prevention Toolbox Home Page.

All of the usability testing recordings and analysis used the Morae Recorder, Observer, and Manager software version 3.3.4 (Techsmith Corporation, Okemos, MI). This software allows for users to create templates for the observer to

quickly and easily denote markers related to "error", "participant prompted", "quote", or "observation". This software further simplifies the coding process. Tasks were noted in the Morae software by the recorder to identify when subjects had completed specific modules or activities in the BNAV toolbox, such as "viewed action plan" or "reviewed chemoprevention". The participant recordings were coded by two researchers – the observer and the moderator / facilitator. The study protocol was approved by Institutional Review Board at Columbia University Medical Center.

Results

A total of 7 participants took part in the usability testing for BNAV. All 7 of the subjects were physicians practicing in primary care clinics. The usability themes for the BNAV toolbox were placed into categories of Content, Ease of Use, and Navigation. The identified issues in each of the themes relates to an item that could be addressed by improving the design, layout, or dashboard features / navigation of the BNAV tool. Based on the provider's location of toolbox navigation towards which specific comments were targeted, themes were further categorized as concerned with the BNAV Notification, Education / Training Modules on Chemoprevention and/or Genetic Testing, or the My Patients dashboard. Tables 2 and 3 display the topics and resulting problem descriptions or issues. Table **4** displays a set of the resulting changes to the BNAV toolbox that were implemented based on the feedback from usability studies. Utilizing this provider feedback to allowed improvements **f**or the decision support tool's focus in user engagement to be optimized. Accordingly, several perceived barriers to clinical uptake of the clinical decision support and shared decision-making tool were tailored to future users' needs, preferences and values promoting user-centered design.

Table 2. Themes identified during the usability studies specific to provider notifications.

Theme	Notification	Comment / Problem Description
Ease of Use	BNAV Provider Notification	- Secure health message (SHM) preferred over email notification; providers receive too many emails; both SHM and email wouldn't hurt for a secondary alert / reminder - Appropriate to receive BNAV patient notification one week prior to patient visit for ample review time - The BNAV patient notification primes the provider to have breast cancer on the mind for discussion when patient arrives to have that conversation
	Breast Clinic / Genetic Counselor Notifications	- Too much information presented without adequate summary - Too time consuming to process
Content	BNAV Provider Notification	-Would be helpful to have mammogram or screening results present
	Breast Clinic / Genetic Counselor Notifications	-The presence of a clinical recommendation would be helpful, specifically concerning the Genetic Testing patient information
Navigation	Breast Clinic / Genetic Counselor Notifications	-Information is not well summarized -Difficult to locate specific actionable patient information

After addressing suggestions generated during usability testing, we successfully designed and implemented the BNAV system. The KYRAS patient survey was developed in Adobe Flash and stores the survey data in a Microsoft SQL Server database. The survey is hosted on our Windows Server 2008 BNAV server and accessed through a wireless connection on a Windows RT touch-screen tablet. The patient decision aid RealRisks was developed as a mobile web app using Ruby on Rails and is hosted on a Linux server running Nginx. The data is stored in a PostgreSQL database before being transferred to the BNAV server. The provider-facing Breast Cancer Prevention Toolbox (Figure 4) was developed in Microsoft .NET and is hosted on the BNAV server. Data is stored using SQL Server and is updated from the KYRAS and RealRisks databases.

The toolbox contains learning sections on chemoprevention and genetic testing. Each section consists of sections about key concepts, references to articles and guidelines, and case-based learning. The Key Concepts section for both chemoprevention and genetic testing contains a clinical summary document and multimedia information about each breast cancer prevention topic. The multimedia learning information is presented as series of slideshows for different learning objectives (Figure 5) and videos of Columbia University breast cancer experts discussing specific topics related to breast cancer prevention (Figure 6).

Case Based learning for genetic testing and chemoprevention consists of several hypothetical case reports which are outlined for the PCP. Once they have read the case reports they can choose to either learn more and review the learning

objectives relevant to that particular case or proceed to a quiz where they are asked multiple choice questions pertaining to that specific case (Figure 7).

After they have taken the quiz they are shown which answers are correct and detailed explanations are available for each question. They can then take a survey asking them "What Would You Do?" which asks them which option they would take for the patient in the case report. These answers are collected in the database and then the app displays what percentage of providers chose those options.

Table 3. Themes identified during the usability studies specific to the BNAV Toolbox.

Theme	Location	Comment / Problem Description
Ease of Use	BNAV Dashboard	-BNAV home page should be more transparent with about what can be found by accessing each link
	My Patients Dashboard	-Ability to take patient notes would be helpful -Links for 5 year risk and patient action plan often overlooked / not obvious -Patient preference driven action plan helpful but difficult to understand and time consuming to review -Patient color coating should be more transparent; both in visualization and also understanding why certain patients IDs are colored as they are -Providers pleased with ability to sort patient list by risk value or action plan
	Training / Education Modules	-Participants pleased that training materials are broken out by subtopic so users do not spend unnecessary time / energy reviewing information to which they may previously been exposed
Content	My Patients Dashboard	-Average risk score should be displayed so providers can be reminded / aware of the relative patient risk values to general population -Would prefer more detail regarding patient referral status
	Training / Education Modules	-Training slideshow information more informative than the clinical summary, but also more time consuming to review
Navigation	BNAV Dashboard	-Would be helpful to have intuitive "Back" or "Next" buttons to facilitate navigation -Lack of consistency in browser navigation: some of the embedded links open new tabs in the web browser, others stay in same browser tab, others open new window -Users varied in dashboard navigation once the BNAV tool had been opened. However, most commented that the My Patients dashboard link should be more prominent on the homepage since it would be the first module the user engages after receiving the patient notification
	Training / Education Modules	-Training videos should include a text transcript so users can quickly scroll through the materials

Table 4. Changes addressing issues identified during the usability studies specific to the toolbox.

Theme	Location	Problem Description	Resulting Change
Ease of Use	BNAV Dashboard	Unclear about what can be found by accessing each link	Hover over a link and a drop down menu appears with site subsections
	My Patients	Links for patient risk and action plan often overlooked / not obvious	PDF icon in place for each patient risk and action plan link
Content	My Patients	Unfamiliar with the average risk score relative to general population and recommended steps in referral process	The average patient risk score and referral recommendations added to My Patients module
Navigation	BNAV Dashboard	My Patients module link should be distinguished from education links	My Patients link and icon placed prominently in homepage, distinct from education modules

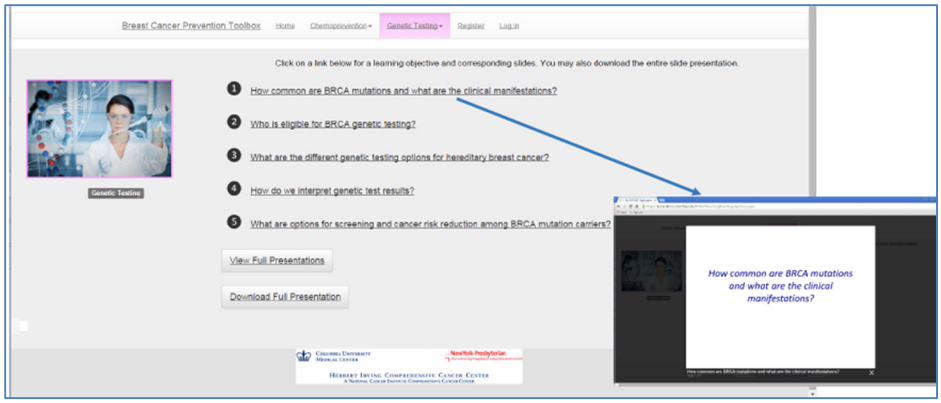

Figure 5. Breast Cancer Prevention Toolbox Learning Objectives.

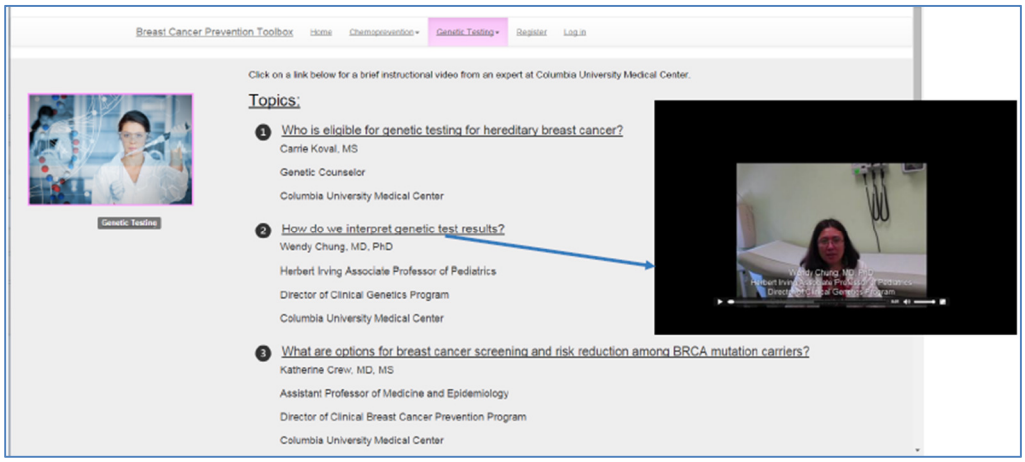

Figure 6. Breast Cancer Prevention Toolbox Expert Videos.

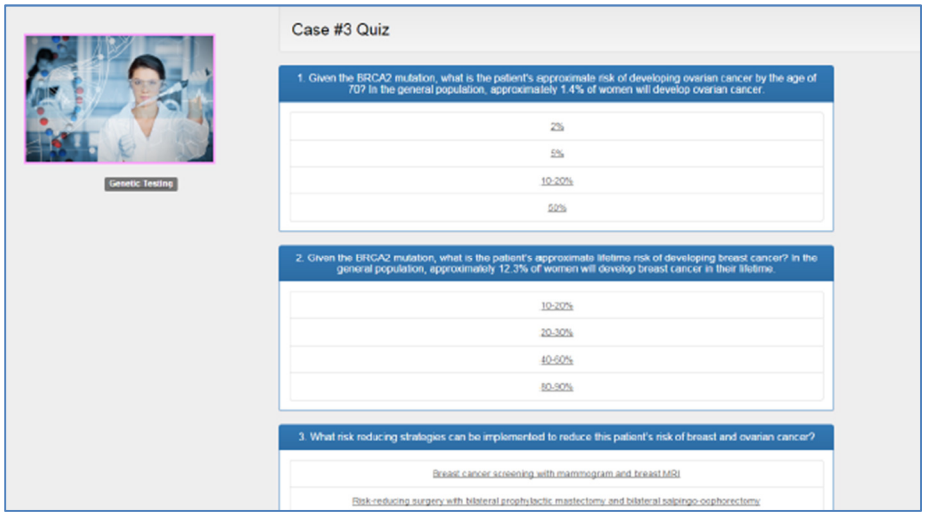

Figure 7. Breast Cancer Prevention Toolbox Case Based Learning Quiz.

The "My Patients" section of the toolbox (Figure 8) displays relevant patient information for patients with a high risk of breast cancer from multiple BNAV sources to the provider. The patient's 5-year risk of invasive breast cancer according to the Gail model is shown with a link to a PDF action plan with detailed information relating to that patient's risks, preferences, attitudes, and action items related to chemoprevention. The page also lists whether the patient is eligible for genetic testing and has a link to a more detailed action plan with family history, patient identified

pros and cons of genetic testing, and action items. There is also a link to the patient action plan generated by the RealRisks site and the referral status of the patient can be tracked by the provider for each patient.

The iNYP dashboard notice has been designed using secure web services and is implemented on NYP server using risk and referral information from the BNAV database (Figure 9). The notice indicates the patient's 5-year and lifetime risk of invasive breast cancer compared to the general population, high-risk criteria for breast cancer, and referral status. It also indicates whether the patient meets the guidelines for being eligible for genetic testing and provides contact information to refer patients for genetic counseling or a high-risk consultation in the breast clinic.

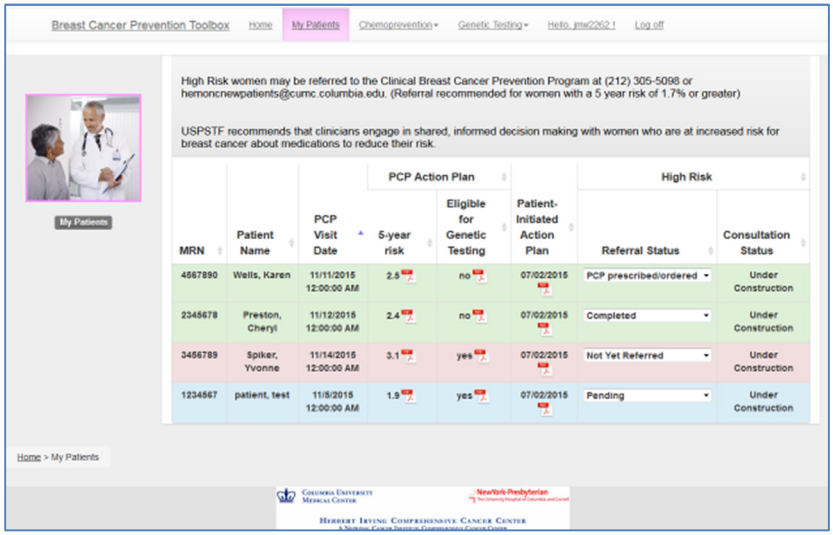

Figure 8. Breast Cancer Prevention Toolbox "My Patients."

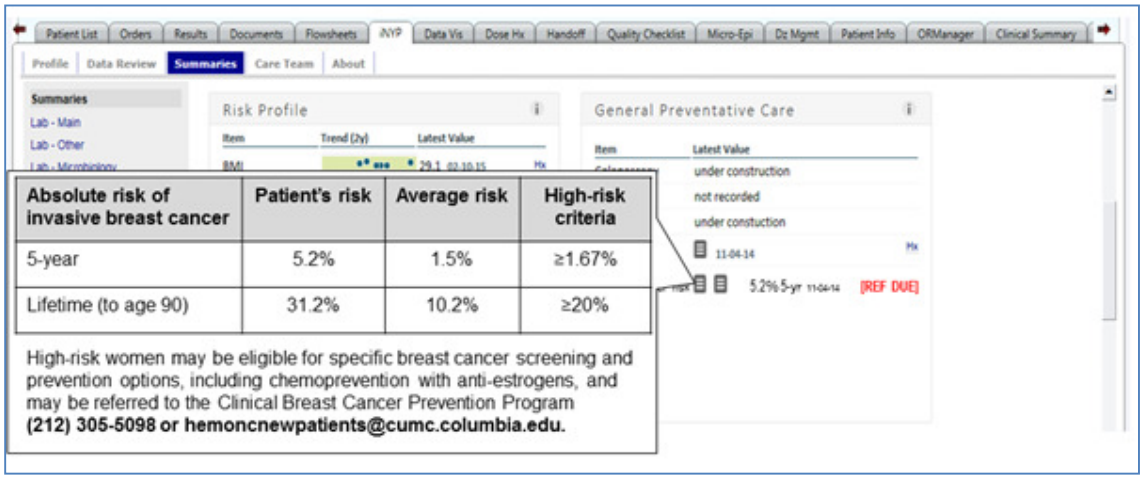

Figure 9. BNAV notice in electronic health record (iNYP Preventive Care Dashboard).

Discussion

A comprehensive informatics framework to increase breast cancer risk assessment and chemoprevention in the primary care setting has been successfully implemented using TPB-based approach. Affecting simultaneously patients and providers may potentially result in better adherence to chemoprevention guidelines. Introduction of an interactive application may facilitate patient acceptance of optimal breast cancer prevention strategies and improve patient-provider communication. Clinical decision support for high risk breast cancer patients embedded into EMR coupled with a theory-based interactive online tool promulgating guideline-concordant practices may further engage providers into shared informed decision making with women who are at increased risk for breast cancer as recommended by USPSTF. However, the impact of the proposed informatics framework as a whole and its particular components is

currently unknown. To address this gap in our knowledge a definitive randomized controlled trial testing the patient and provider decision support tools is being conducted.

In our breast clinic, the chemoprevention uptake rate among high-risk women is 37%, compared to less than 5% reported for other high-risk populations [20]. Our goal is to expand our success in the breast clinic by offering specialized risk counseling to a broader population of racially/ethnically diverse women screened in the primary care setting. A novel breast cancer risk navigation (BNAV) tool, which incorporates the Gail breast cancer risk model into the EMR, has been implemented to address this goal. In order to alleviate patient-related barriers to chemoprevention, a decision aid, RealRisks that allows participants to experience risk through an activity has been introduced. The development of above mentioned tools was informed by iterative input from patient and providers. As a result of this input, BNAV system integration into clinic workflow was introduced as it is depicted in Figure 10. Addressing future users' concerns and suggestions during the formative stage of development greatly facilitated successful introduction of the final product into every-day clinical practice.

Successful implementation of information technologies in routine clinical practice requires careful evaluation in target user populations [22]. Usability issues may be a major barrier towards acceptance of new technologies both in patient [23] and provider populations [24]. Ongoing input from patients [25] and providers [24] throughout entire development and implementation cycle is a crucial ingredient of successful translation of research findings into clinical practice. As inadequately tested information systems may become source of errors [26], implementation of bioinformatics solutions such as decision support tools for genetic testing will require careful and comprehensive evaluation including usability issues, system acceptance and overall impact on clinical performance.

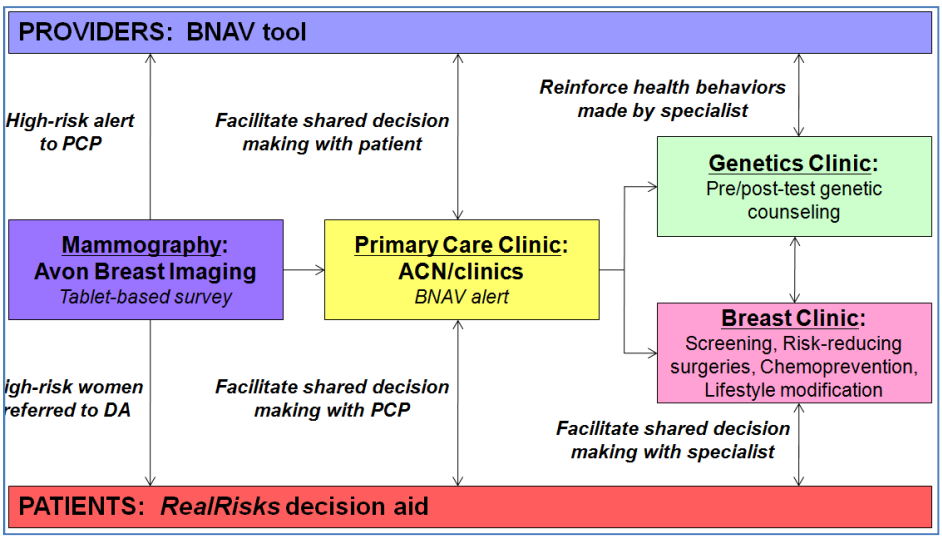

Figure 10. BNAV system integration into clinic workflow

Conclusion

This project seeks to overcome important patient and physician-related barriers to chemoprevention uptake in the primary care setting. A comprehensive informatics framework to increase breast cancer risk assessment and chemoprevention in the primary care setting has been successfully introduced to promote preventive care and genetic testing based on personalized risk assessment. Given the proven efficacy of breast cancer chemoprevention in high-risk populations, higher uptake may significantly reduce the public health burden of this disease.

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