An Applied Framework in Support of Shared Decision Making about *BRCA* Genetic Testing

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Abstract

The United States Preventive Services Taskforce recommends that primary care providers screen patients for an increased risk of carrying a BRCA1 *or* BRCA2 *mutation and refer those who meet family history criteria to genetic counseling. Such screening requires detailed and accurate family history data, which often goes uncollected during a primary care visit due to time constraints, competing priorities, and lack of awareness on behalf of both patients and providers. In order to address these barriers and promote appropriate genetic counseling referral, we developed a user-centered framework that collects and communicates relevant data in order to prepare patients and their primary care providers for an informed discussion on genetic counseling referral. This paper describes this framework and the underlining data schema that makes it possible.*

Introduction

Hereditary breast and ovarian cancer syndrome (HBOC) is an inherited condition that is most often associated with mutations in the *BRCA1* and *BRCA2* genes.[1] Carriers of these pathogenic mutations face a lifetime breast cancer risk of 60-80%.[2] While the risk associated with these mutations is substantially higher than in the general population, preventative action can reduce a carrier's risk once she is identified. Such risk-reducing strategies include intensive breast cancer screening with mammography and breast MRI,[3-5] risk-reducing surgeries (prophylactic mastectomy, bilateral salpingo-oophorectomy [BSO]),[6-12] and chemoprevention.[13,14]

In order to promote detection of *BRCA1* and *BRCA2* mutations, the United States Preventive Services Task Force (USPSTF) recommends that primary care providers screen asymptomatic women with a family history of breast and ovarian cancer for an increased *BRCA* mutation risk.[15] Women who screen positive should receive genetic counseling and then *BRCA* testing if further indicated and desired.[15]

Despite the increasing availability and decreasing costs of multigene panel testing for hereditary cancer syndromes, many women at an increased risk of carrying *BRCA* mutations are never identified and are thus unable to receive genetic testing services.[16-19] In 2016, our research team screened 3,055 women who underwent mammographic screening at our large, urban institution.[20] Based on their family histories of breast and ovarian cancer, 369 (12%) of these women met USPSTF guidelines for *BRCA* genetic testing, yet only 17 (4.6%) of eligible women had received *BRCA* testing. Other sites have reported similar under-utilization of genetic testing services.[16] Although the prevalence of *BRCA* mutations is similar across non-Ashkenazi Jewish ethnic groups, Hispanic women, women of color, and women of lower education and income levels are less likely to be referred to genetic testing.[16,21,22]

Barriers to screening and referral in primary care include insufficient knowledge of HBOC and inability to intuit patient risk,[23-27] lack of time and competing priorities in the primary care encounter,[28,29] and inadequate reporting of family history in medical records.[20,30] In order to identify a patient who is eligible to benefit from genetic counseling, a primary care provider must obtain accurate family history data, and analyze it using valid hereditary risk models. This is demanding to fit into an already hurried primary care encounter. Both patients and providers at our institution report a significant lack of time and infrastructure needed to accomplish this task without disrupting workflow and patient care.[29]

We have developed an informatics-based framework to address these barriers and promote appropriate genetic counseling referrals in the primary care setting. This framework uses user-centered and interoperable tools to collect, analyze, and distribute family history data with the goal of promoting shared decision making by providing

personalized risk and decision support at the point of care. In this paper, we will describe these tools and the dataflow that enables them to efficiently communicate tailored and digestible information to the different stakeholders involved in a patient's decision to undergo *BRCA* genetic counseling.

Tools and Data Flow Framework

Step 1: Patient decision support through data collection, analysis, and personalized risk profile creation

Our framework uses a patient-centered decision aid (DA) named RealRisks to collect family history data, analyze it, and provide patient education and decision support.[31] RealRisks is designed to enable women to make shared and informed decisions about *BRCA* genetic testing. A shared and informed decision is one that is based on accurate and relevant knowledge, complies with the patient's values and desires, actively involves both the patient and provider, and is ultimately acted upon.[32,33] In order to accomplish these goals, RealRisks first educates the patient on breast cancer and the concept of risk. Patients have the ability to toggle between English and Spanish versions of the tool and can decide between "information-dense" (primarily presented through text) and "information-light" (primarily presented through comics) educational material. The educational material uses a narrative in which a fictitious character named Rose discusses breast cancer risk and prevention options with friends, family, and health care providers.

After viewing the educational content, the patient reinforces what she has learned by playing risk games. During these games, she seeks to uncover a woman who will develop breast cancer within a pictograph of 100 clickable women. For example, in the game that conveys the 12% probability of an average woman developing breast cancer in her lifetime, 12 of the 100 women in the pictograph are pre-designated to develop breast cancer, and the patient continues to click women until she finds one of these 12. At this point, all 12 of the pre-disposed pictographic women are revealed in order to demonstrate what 12% visibly looks like. The educational material, narrative presentation, and risk games were developed with consistent feedback from members of our target patient populations and have been demonstrated to be usable, appropriate, and effective at improving risk perceptions.[34,35]

Next, the patient is instructed to gather information on the cancer history of her family members and enter it into a family tree. Specifically, the tool requests information on any *BRCA*-related cancer diagnoses in parents, grandparents, siblings, children, and aunts and uncles, along with age of diagnosis, presence of bilateral breast cancer, and known *BRCA* genetic test results. RealRisks enters this data into the BRCAPRO Model, which calculates the patient's five-year and lifetime breast cancer risks as well as the probability that she carries a mutation in the *BRCA1* or *BRCA2* genes.[36,37] This personalized risk information is then presented though another set of risk games, which allow the user to compare her risk with the average-risk among women of her same age.

RealRisks also inputs the information that is entered into the pedigree into the Six Point Scale in order to determine eligibility for genetic counseling. The Six Point Scale is a breast cancer risk assessment tool that has been demonstrated to effectively determine eligibility for genetic testing based on USPSTF guidelines in ethnically diverse, low-income women.[21] If a patient is deemed eligible, she will then be shown an educational module on genetic testing. After viewing the module, RealRisks will elicit the patient's intention to undergo genetic testing and the factors associated with this decision, such as potential benefits (*e.g.*, prevent getting or dying of cancer) and harms (*e.g.*, potential negative impact on family and employer discrimination). Facilitating the patient in documenting these factors is important because it can help her and her provider identify barriers and facilitators to undergoing genetic testing that cannot be solved by technology and education alone, such as fear of results. Hopefully this can lead to a discussion in which these anxieties or desires are appropriately addressed so that the patient is fully satisfied with her final decision.

RealRisks uses the patient-entered family history and preference data to generate an individualized Patient Action Plan. This action plan summarizes the patient's personalized breast cancer risk profile, detailed family history of cancer, preferences and values regarding *BRCA* genetic testing, and intention to undergo genetic testing (Figure 1). The patient is encouraged to print out the PDF of this action plan and bring it to her next health care appointment in order to facilitate the discussion of her risk status and decision to undergo genetic testing.

The tailored decision support offered by RealRisks not only coaches a patient through collecting her family history before her clinic visit, but also addresses other patient barriers to pursuing genetic counseling, such as inadequate knowledge, inaccurate risk perceptions, and low self-efficacy. This can help to ensure that the patient is informed, confident, and ready to discuss genetic counseling referral with her primary care provider.

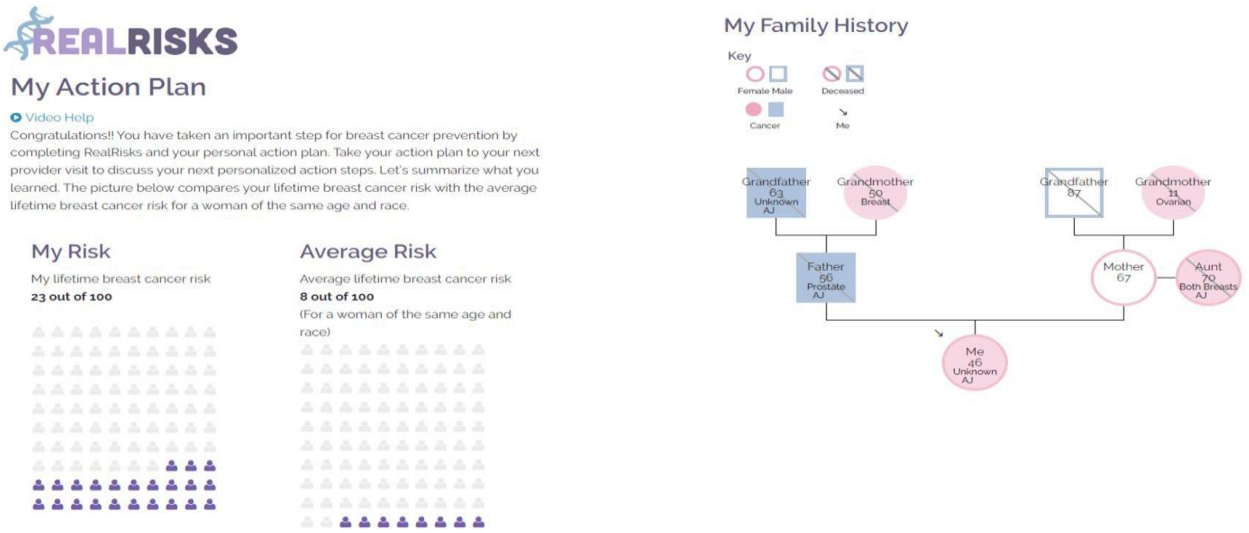

Figure 1 Example summaries provided by the Patient Action Plan

A graphical representation of how data is transferred, analyzed, stored, and distributed in order to provide patient decision support is shown in Figure 2. Read from the top, the patient enters data into RealRisks, which uses the Six Point Scale and BRCAPRO Model to determine eligibility for *BRCA* testing and calculate the patient's personalized breast cancer risk scores, respectively. RealRisks then combines these risk scores with educational material in order to provide tailored education and decision support.

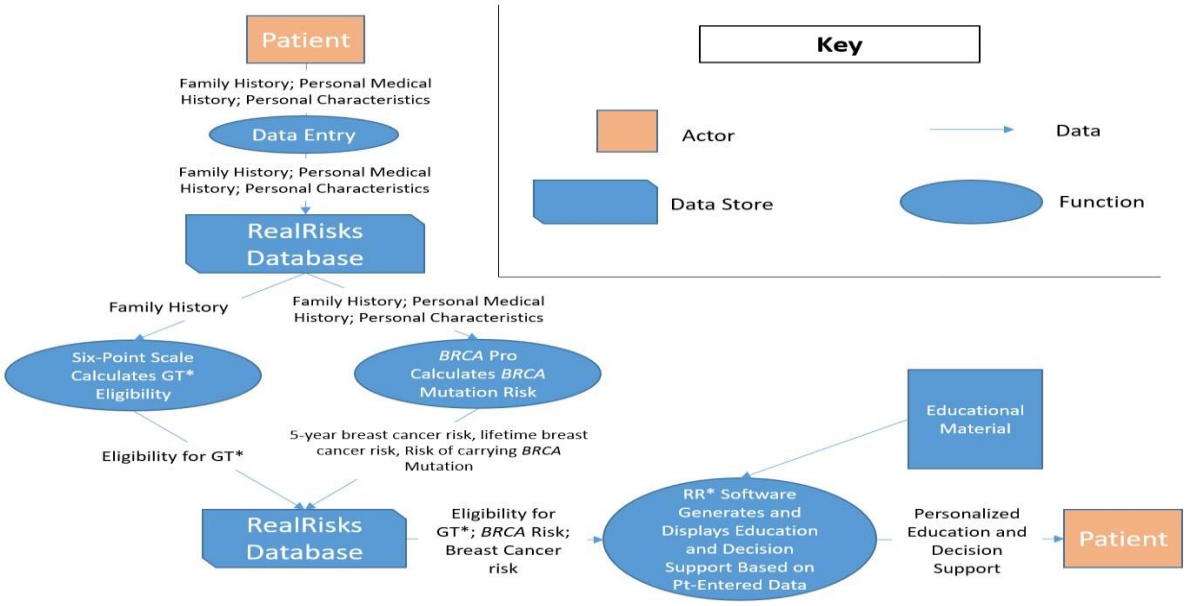

Figure 2 Dataflow enabling patient decision support *GT=genetic testing; RR=RealRisks; Pt=Patient.

Step 2: Dissemination of personalized risk profiles and patient preferences to providers

It is not enough, however, to simply provide decision support to patients; informed and shared decisions regarding *BRCA* genetic counseling referral require the well-timed communication of risk information to the patients' health care providers. Our framework addresses this need with two tools, the Breast Cancer Risk Navigation Toolbox (BNAV) and an EHR-embedded notice, that provide decision support to providers prior to and during the patient's clinical encounter.

Breast Cancer Risk Navigation Toolbox (BNAV)

In order to be useful to providers, decision support tools need to generate and present evidence-based resources in a way that addresses information needs without obstructing clinical workflow.[29,38] To meet this need, we developed the Breast Cancer Risk Navigation Toolbox (BNAV). BNAV is an online toolbox modeled on the theory of planned behavior.[39] It provides health care providers with a personalized table that outlines each of their high-risk patients' risk profiles and preferences for genetic testing. The tool also provides educational modules and supporting evidence on hereditary cancer and genetic testing, breast cancer screening, patient-centered care, and chemoprevention in order to provide sufficient knowledge to inform decisions about genetic counseling.

Populating BNAV with these risk profiles—which are created using data the patient entered into RealRisks—involves further data flow. First, all of the discrete patient-entered data and the risk numbers calculated from this data are synchronized from the RealRisks database (PostgreSQL) into the BNAV database (Microsoft SQL server) each night. While all patient-entered data remains in the RealRisks database, the BNAV database serves as a central repository for all of the project's data. Once the synchronization is completed, we link a patient to her provider using patient-reported and scheduling data so that each provider's toolbox is customized and includes only that provider's patient data.

When a provider logs in to the BNAV tool using our institution's authentication system, she will see a table containing each of her participating patients' five-year and lifetime risk estimates, eligibility for genetic testing, and Patient Action Plan PDF. An example table is provided in Figure 3.

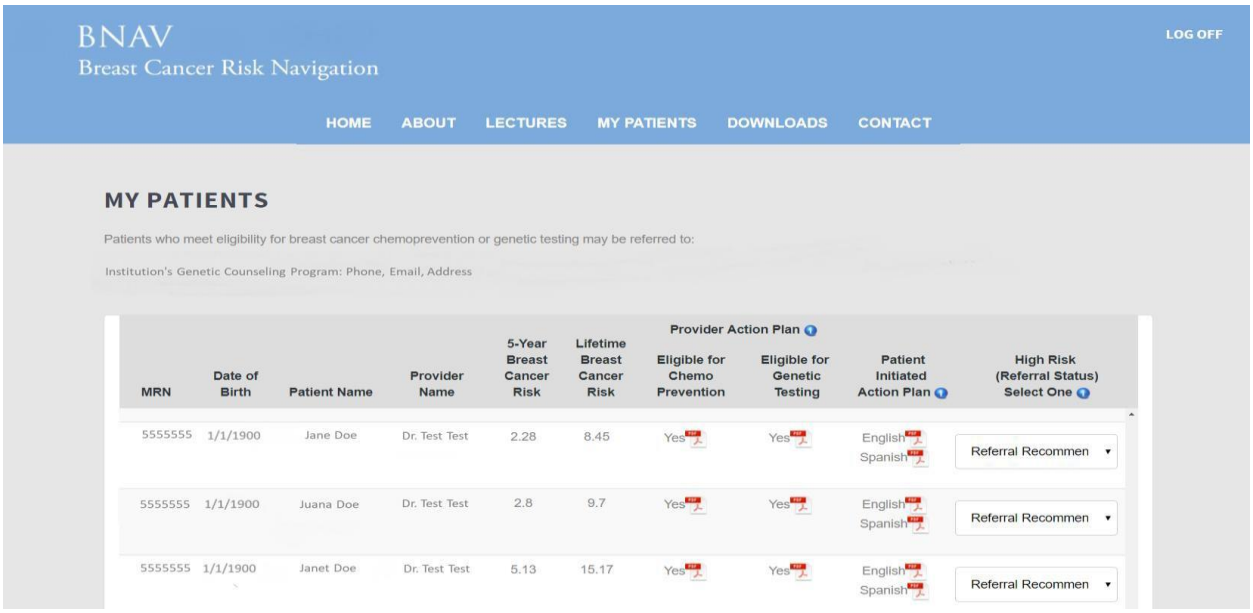

Figure 3 An example of the personalized patient table included in the BNAV Toolbox

BNAV also uses the discrete data points pulled from the RealRisks Database to create a "Provider Action Plan" (Figure 4). Compared with the Patient Action Plan, the Provider Action Plan more succinctly summarizes key risk information and patient preferences. These Provider Action Plans appear in BNAV and are also sent to providers via email and secure health message a few days before a patient's appointment in order to prepare the provider for discussing genetic counseling referral with the patient.

	YOUR PATIENT	GENERAL POPULATION
LIKLYHOOD OF TESTING POSITIVE FOR A *BRCA1* OR *BRCA2* MUTATION [2]	48.9%	0.25% (1:400)
ABSOLUTE BREAST CANCER RISK[2]	5-year = 4.5% Lifetime (to age 90) = 23.19%	5-year = 2.23% Lifetime = 6.03%
INTENTION TO UNDERGO *BRCA* GENETIC TESTING[3]	Will probably get tested	*Options Presented to Patient* Definitely will not get tested / Probably will not get tested / Probably will get tested / definitely will get tested / I was already tested
FAMILY HISTORY	Mother, ovarian cancer diagnosed at age 70 Sister 1, breast cancer diagnosed at age 47 Sister 2, breast cancer diagnosed at age 45, *BRCA1* positive	*Family History Red Flags*[1] • breast cancer diagnosed before age 50 years • bilateral breast cancer • breast cancer in a male family member • two or more family members with *brca*-related cancers including breast, ovary, pancreas, prostate, or melanoma • ashkenazi jewish ancestry • having a blood relative with a known *brca* mutation
FACTORS THAT INFLUENCE DECISION ABOUT UNDERGOING GENETIC TESTING	• Potential relief if test is negative • Help prevent getting cancer • Cost of testing • "Just need to know"	Discussing perceived barriers to genetic testing may favorably influence uptake of genetic counseling/testing.

Figure 4 An example of the Provider Action Plan

EHR Notice

To further integrate the personalized risk information into clinical care, the patient's risk scores and eligibility are also synchronized from the BNAV Database into an Electronic Health Record (EHR)-embedded dashboard that displays this information in an alert (Figure 5). This dashboard is frequently used by our institution's providers during the clinic visit. The combination of high-risk flags in the EHR dashboard along with Provider Action Plans sent prior to a patient's visit offers the provider multiple cues to action for discussing referral to genetic counseling during the clinical encounter.

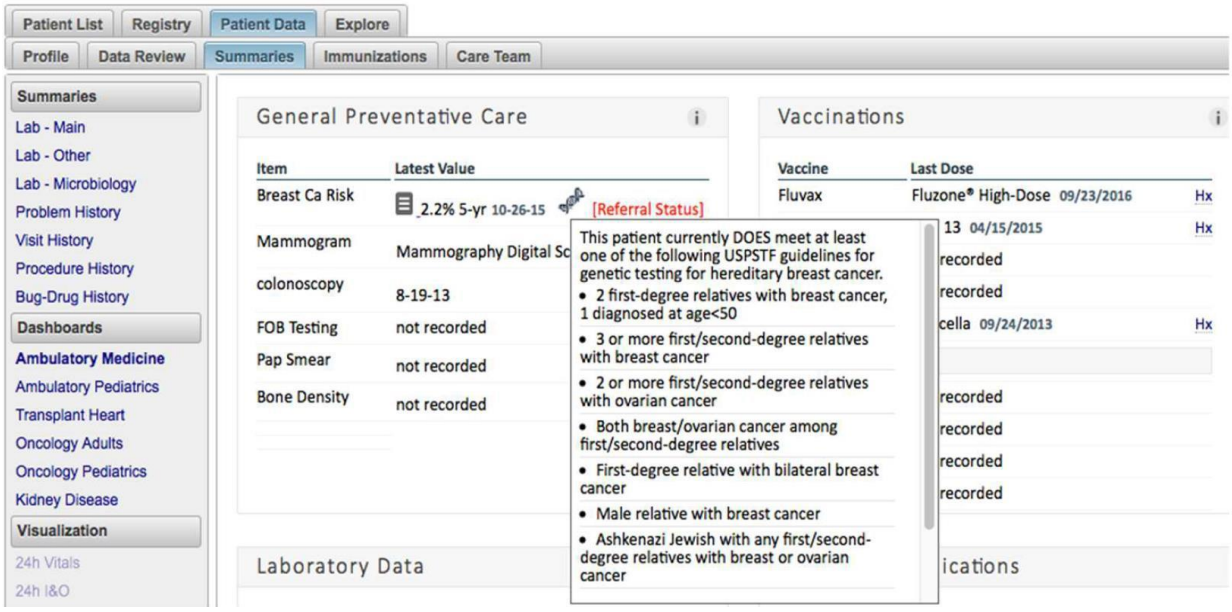

Figure 5. An example of the BNAV notice in electronic health record (iNYP Preventive Care Dashboard).

Figure 6 provides a graphical representation of how data is transferred in order to present key information to patients and their health care providers before and during the point of care. Read from the top left, the patient first receives tailored education and decision support from RealRisks. She then enters her intention to undergo *BRCA* genetic counseling into RealRisks. RealRisks combines this information with the patient's personalized risk profile to provide her with her Patient Action Plan. The patient's data is then synchronized with the BNAV database, which produces the Provider Action Plan. The BNAV Patient Table and the EHR-Embedded Dashboard also pull data from the BNAV database in order to display the patient's personalized risk profile. By the time of the clinic encounter, the patient's risk status and preferences are communicated to the provider by the action plan, EHR-embedded dashboard, BNAV Patient Table, and the patient herself.

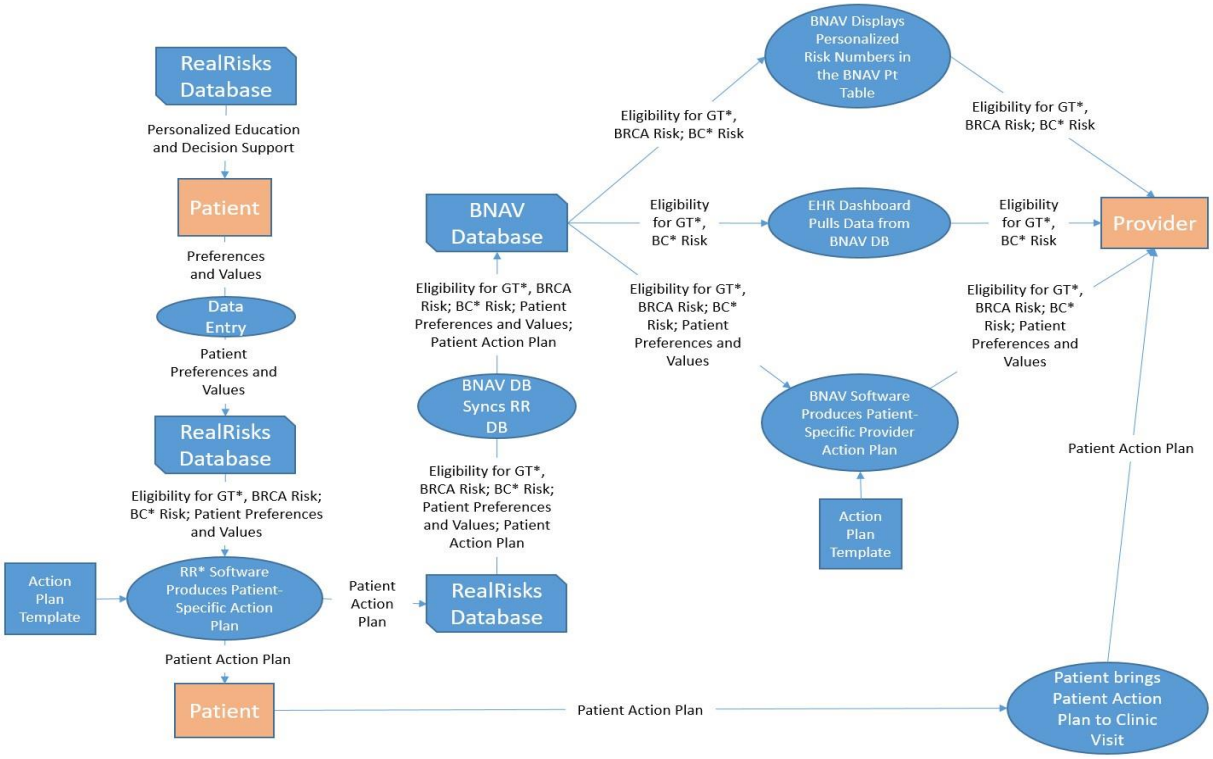

Figure 6 Dataflow for distributing personalized risk information to patients and providers *GT=genetic testing; RR=RealRisks; DB=Database; BC=Breast Cancer.

Conclusion

In this paper, we have described our framework's tools and how the data they use is stored, transferred, and disseminated in order to provide necessary information at the opportune time. Personalized prevention requires the analysis of patient risk factors and the well-timed communication of relevant data to both the patient and those involved in her medical care. To help realize this goal, this framework provides an infrastructure that delivers the timely and personalized data needed to promote appropriate referral for genetic counseling in the primary care setting. Patients enter otherwise arduously-collected family history directly into RealRisks, which applies validated risk assessment tools to analyze this data and risk stratify the patient. By the time the clinical encounter takes place, both the provider and the patient are prepared: they have been informed of the patient's unique breast cancer and mutation risk, they have been given decision support to help them understand this information, and they have made a preliminary decision on how best to proceed.

Decision aids have not been widely incorporated into routine clinical practice.[40,41] Many DAs, including the RealRisks DA developed by our team, have components that summarize the best scientific evidence to support decision-making, communicate risk, and clarify patients' values and preferences. However, while DAs may be necessary, they are insufficient in and of themselves to routinize decision-making about genetic testing in the clinic.[40] A systematic review found that interventions to help meet the complex decision making needs of patients when considering genetic testing are lagging behind the expanding knowledge of genetics and the increasing availability of genetic tests.[42] In particular, there is a lack of studies targeting both patients and providers, which are needed to foster optimal clinical practices. Findings in other clinical areas reveal that targeting both the patient and the provider appears more effective than targeting either the patient or the provider alone.[43] Interventions that address the complex decision making needs of both patients and their providers' are needed, and the framework we developed for distributing personalized risk and patient preference information begins to fill an important gap and may potentially result in better adherence to *BRCA* genetic testing guidelines.

In 2014, the USPSTF updated their guidelines for *BRCA* testing, and a Healthy People 2020 objective was established to increase the proportion of women with a family history consistent with HBOC who receive genetic counseling.[15] Efficiently screening high-risk women in the primary care setting, presenting pertinent risk information to patients and providers at the right time, and engaging women in making informed decisions will help meet this objective and may result in significant health impact. We are currently conducting a randomized controlled trial funded by the American Cancer Society (RSG-17-103-01) to evaluate this framework's effectiveness in promoting appropriate genetic counseling referral in a diverse primary care setting. Patient-oriented outcomes include decreasing decisional conflict and increasing shared and informed decision-making. Our goal is to improve cancer risk assessment and enhance uptake of risk-appropriate screening and prevention strategies by overcoming important patient, provider, and organization-level barriers.

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