HARMONIZING EHR AND PATIENT GENERATED DATA FOR BREAST CANCER RISK ASSESSMENT AND PRECISION PREVENTION IN PRIMARY CARE

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OUTLINE

• Why breast cancer risk assessment and what are the benefits of precision prevention?
• Defining patient generated health data (PGHD) in the context of precision prevention.
• Examples and challenges based on ongoing clinical randomized controlled trials
• Summary and discussion
Breast cancer is the most common cancer among women with established risk factors and well-validated breast cancer risk assessment tools.

276,480 new cases
42,170 deaths
Breast cancer is preventable

It has been estimated that 50% to 60% of cancers could be prevented if known strategies were optimally used.

In order to maximize opportunities to both prevent and detect cancer early, there is a need to risk stratify populations, to identify those who will benefit from risk appropriate screening and prevention.

Validated risk assessment models are critical for risk-stratified breast cancer prevention and a “precision approach to cancer prevention.”
PRECISION PREVENTION

Population Approach
- Smoking bans, vaccinations
  - General population

High Risk Approach
- Low-dose lung CT screening in smokers
  - Individuals at high-risk
  - Carriers of high-risk mutations

Precision Prevention
- Risk reducing mastectomy, oophorectomy
  - Carriers of high-risk mutations

Precision Medicine
Precision Prevention

1. Risk Quantification
2. Efficacy $\Rightarrow$ Toxicity
3. Patient Preferences
Precision Prevention

The clinical utility of a risk model largely depends on its ability to stratify a population into categories with sufficiently distinct risks to substantially affect the risk–benefit balance of a prevention strategy.
THE POTENTIAL OF PATIENT GENERATED HEALTH DATA (PGHD) IN THE CONTEXT OF PRECISION PREVENTION
PATIENT GENERATED HEALTH DATA (PGHD) AND PRECISION PREVENTION

• Precision prevention calls for collecting and analyzing large amounts of data to capture an individual’s unique behavior, lifestyle, genetics, family history and environmental context.
• PGHD are defined by the Office of the National Coordinator for Health Information Technology (ONC) as “health-related data including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information-created, recorded, gathered or inferred by or from patients or their designees”
• This definition emphasizes that patients, not providers, are primarily responsible for capturing or recording these data and it is patients who direct the sharing or distributing of the data to stakeholders.
PGHD IN THE CONTEXT OF DECISION MAKING

How do we make this data actionable?

Self-management, biometric, and behavioral tracking

Patient preferences elicited for shared decision making, patient reported outcomes

Prediction models for precision prevention
PGHD INTO CLINICAL SETTINGS

- How can we integrate patient generated data into the electronic health record?
- What strategies can be pursued to effectively mine and analyze these data to support clinical decision-making?
- What are the barriers and challenges in the integration of patient generated data into health information systems?
- How can we facilitate patient engagement and empowerment while addressing ethical concerns associated with the use of pervasive and ubiquitous monitoring?
EXAMPLES AND CHALLENGES BASED ON ONGOING CLINICAL RANDOMIZED CONTROLLED TRIALS
OVERVIEW OF THE THREE CLINICAL TRIALS

• Use randomized clinical trial (RCT) design to implement decision support for breast cancer risk assessment and risk-stratified prevention.
  - *RealRisks Decision Aid* (Patients)
  - *Breast Cancer NAVigation Tool* (Providers)

• Focus on *RealRisks Decision Aid*
  - Steps using build upon the open SMART on FHIR (Fast Health Interoperability Resources) specification to implement across 26 sites.
GAPS ADDRESSED ACROSS RCTs

• Breast cancer is common with established risk factors and well-validated breast cancer risk assessment tools

• Effective interventions to reduce BC risk are known, but under-utilized in the primary care setting
  • Chemoprevention with SERMs and AIs have been shown in RCTs to reduce breast cancer incidence by 50-65% among high-risk women.
  • Estimated 1 Million Americans are at risk for early-onset cancer due to Lynch syndrome (LS) and Hereditary Breast and Ovarian Cancer (HBOC) syndrome.

• Precision prevention (customized preventive and therapeutic options that take individual genetic, environment, and lifestyle variability into account) replaces the “one-size-fits all”.
IMPLEMENTATION TRIALS OF REALRISKS AND BNAV

Eligibility:
- Women, age 35-75
- 5-yr Gail risk score >1.66%
- No prior use of SERM or AI
- English or Spanish-speaking

Stratification factors:
- Menopausal status
- Hispanic ethnicity

(N = 300 patients
N = 50 providers)

Primary Endpoint: Chemoprevention 6 mo.
Funding: NIH/NCI (MPI Kukafka, Crew)
TC: $3,471,467

Primary Endpoint: Genetic Counseling 6 mo.
Funding: Research Scholar ACS (PI Kukafka)
TC: $1,042,500

Providers:
- ACN provider with high-risk patient
  (N = 76)
- High-risk patients:
  - Women, age 21 or older
  - Meets family history criteria for BRCA genetic counseling
  (N = 190)

RealRisks and BNAV + standard educational materials
Standard educational materials alone
Primary Endpoint: Chemoprevention Informed Choice
Funding: NIH/NCI (MPIs Kukafka, Crew)
TC: ~$3,450,000
INTEGRATION INTO CLINIC WORKFLOW

PROVIDERS: BNAV tool

Identification of eligible patients

Risk quantification

Facilitate shared decision making with patient

Primary Care Encounter

Reinforce health behaviors made by specialist

Genetics Clinic:
Pre/post-test genetic counseling

Breast Clinic:
Screening, Risk-reducing surgeries, Chemoprevention, Lifestyle modification

Facilitate shared decision making with specialist

Risk quantification

Facilitate shared decision making with PCP

Facilitate shared decision making with specialist

PATIENTS: RealRisks decision aid
Take Charge of Your Breast Cancer Risk

- Learn what risk really means
- Identify what you can do to reduce your breast cancer risk
- Develop an action plan to share with your doctor

Log in  Sign up

Notice in iNYP

Patient Provider Encounter
PGHD and EHR Data flow in the context of risk-stratified Breast Cancer Prevention

Data Generation

Data Collection
- Data Verification

Data Sharing
- Data Communication

Data Utilization

Electronic Patient-Generated

Electronic Patient Modified

EHR Data

Decision Aid's Risk algorithm
- Healthcare provider

Patient-Provider Interaction/Patient-Technology Interaction

Risk-stratified BC Prevention Services-Generic Testing, Chemoprevention, Screening

Patient
REALRISKS DECISION AID

Risk Perceptions

Risk Communication

Risk Game: Lifetime Risk of Breast Cancer

If you found someone with breast cancer, how much would you be surprised?

Click the people until you find too many!

Lifetime Risk

You found someone with breast cancer. For an average 40 year old woman, her lifetime risk of breast cancer is 1 in 31.

In this previous game, you saw that her 5 year risk of breast cancer is 1 in 31.

Preference Elicitation

Pros and Cons of Genetic Testing

Your Risk

Based on your cancer risk profile and family history, you have a great chance that you may test positive for BRCA1 or BRCA2.

Drag the slider to reflect how you feel about each item.

This is very important to me

This is somewhat important to me

This is not important to me

Preferences for risk-stratified services after deliberation

COLUMBIA
Columbia University Irving Medical Center
Enforces an individual right of access to a “computable” version of one’s medical record.
IDENTIFYING WOMEN AT HIGH RISK FOR BREAST CANCER USING EHR DATA

Women undergoing screening mammography, 2014-2016 (N=15,836)

Excluded from analysis:
1) Age<35 or >74 (N=1444)
2) Missing race/ethnicity (N=4250)
3) Prior breast cancer (N=373)
4) Breast implants/mastectomy (N=282)

Included in analysis (N=9514)

High Risk (N=1443, 15.2%)

Low-Average Risk (N=8071, 84.8%)

Both EHR and self-report data (N=1495)

Breast Cancer Surveillance Consortium (BCSC) Model

<table>
<thead>
<tr>
<th>Age</th>
<th>Race/ethnicity</th>
</tr>
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<tbody>
<tr>
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</table>

First-degree family history
Benign breast disease
Mammographic density

JCO Clin Cancer Inform 2019
Take Charge of Your Breast Cancer Risk

- Learn what risk really means
- Find out what you can do to reduce your breast cancer risk
- Develop an action plan to share with your health care provider

Log in

Understand Risk

Learn about what goes into breast cancer risk. Take a survey to find out your risk and play an interactive game to find out how lifestyle choices can reduce your risk.

Your lifestyle
Welcome to RealRisks, Erica!

Click to watch an overview of RealRisks
Understand Your Breast Cancer Risk!
You can get started by first working through the Understanding Risk module. You can also view the introduction again.

1. Understanding Risk

2. Breast Cancer Risk Factors
   In this module, you will learn about specific breast cancer risk factors.
   - 📚 Chapter 2: At the Doctor’s Office
   - 📚 Learn More About Breast Cancer Risk Factors
   - 🤔 Find Out Your Breast Cancer Risk

3. Family History

4. Genetic Testing

Accomplishments

11/11
Work through each section to create an action plan!

Video Help

Meet Rose and Mia
Connect to Your Medical Record

To better estimate your breast cancer risk, we recommend allowing RealRisks to connect with your medical record. Under current United States law, it is your right to connect and use your medical record data.

You may click "Skip" if you do not want to do this or if you cannot login to your Patient Portal.

Your medical site: University of Michigan Health System

We may use information from your medical record to better understand your breast cancer risk.

Connect  Skip
If you are experiencing a life threatening emergency, please call 911.
Allow Access to Your Account

RealRisks wants you to share your health data with them by linking your MyChart account. Note that this app might have been created by a developer who is not affiliated with your healthcare organization.

What you need to know about RealRisks
Before allowing RealRisks to access your account, please be aware of the following important details. This information is provided by the creators of RealRisks.
All mentions of the term “data” hereafter refers to the data from your electronic health record.

Who is offering the app?
This app is provided by your healthcare provider, who must follow HIPAA federal health privacy laws.

How is this app funded?
This app is funded by grants from NIH, ACS.

Where does this app save your data?
This app can save your data on servers, outside of your device.

Who has access to your data when you provide it to this app?
Other than you, the following people and groups may have access to the data that you provide this app, consistent with the privacy policy and
How does the app developer use your data?
The app developer may use data about you to improve its services in the future.
The app developer may use data about you for research.
Columbia University’s privacy policy and statements may have more details on how and when the app uses your data.

Want to dive deeper? Read more from the app developers of RealRisks.

Allow or Deny Access

RealRisks wants your permission to access the following information:

- Care Team
- Demographics
- Health History
- Lab Results
- Medications
- Problems
- Procedures
- Vitals

This app will have access to your information until Tuesday, June 11, 2019, 4:19 PM

If you have concerns with any one of the points listed above, please deny RealRisks from accessing your account.

If you want to grant access, please proceed by confirming you have read the statements above. You can find further information within the app’s privacy policy and statements.

[Back] [Deny Access] [Allow Access]
Verify Your Medical Record Data

This is the information pulled from your Electronic Medical Record. This information will be used to estimate your breast cancer risk.

Please change the information on the left if it is incorrect or missing.

If you believe the answers in the right column are incorrect, please contact us at: swog1904@cumc.columbia.edu

<table>
<thead>
<tr>
<th>Age</th>
<th>History of breast cancer or of ductal carcinoma in situ (DCIS), breast augmentation, or mastectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>64</td>
<td>No</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Prior breast biopsies (positive or negative)</th>
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<tbody>
<tr>
<td>White</td>
<td>Proliferative changes with atypia</td>
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<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>BI-RADS® breast density (radiologic assessment of the density of breast tissue by radiologists who interpret mammograms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Hispanic or Latino</td>
<td>Heterogeneously dense</td>
</tr>
</tbody>
</table>

Have any of your first-degree relatives (mother, sister or daughter) been diagnosed with breast cancer?

| Yes | Heterogeneously dense |

Save
Risk Game: Your 5 Year Risk of Breast Cancer

Now you can play the risk game with your own risk numbers for the next 5 years. Click on the women until you find one with breast cancer, this will show your breast cancer risk for the next five years.

*These risk scores are based upon known breast cancer risk factors, such as family history. However, getting genetic testing for breast cancer genes may further clarify your risk.*

Your Five Year Risk

This game showed your 5-year Breast Cancer Risk.

Start a new game with **10 Year Breast Cancer Risk**

Start 10 Year Game
Summary

• Provided some background on precision prevention for breast cancer.
• Steps we are taking in ongoing clinical trials to help harmonize patient generated data and EHR data in clinical care for risk-stratified prevention.
• While the best types of data for EHR integration are unknown at this point in time, our hope is use our ongoing trials to illustrate that when the data are integrated into workflow, become highly actionable and lead to improved health outcomes, feasibility and acceptance are high for both patients and providers.