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Case Study: Uptake of Risk Appropriate Behaviors Following Breast Cancer Risk Stratification in the Mammography Screening Population

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Description of the Problem

Women at elevated risk for breast cancer should be informed about supplemental screening with breast magnetic resonance imaging (MRI), risk-reducing medication, and genetic risk assessment.¹ Risk stratification uses statistical models (e.g., modified Gail,² Tyrer-Cuzick (TC),³ and BRCAPRO⁴) to estimate a woman's risk of developing breast cancer and/or a carrying an undiagnosed deleterious germline genetic mutation. Women at 20% lifetime risk of breast cancer are eligible for supplemental screening breast MRI.¹ Women at 1.7% 5-year risk of breast cancer are also eligible for risk-reducing medications.¹ Women at >5%

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risk of carrying a *BRCA1/2* pathogenic variant may benefit from genetic risk assessment.⁵ Ideally, women meeting these criteria would be identified and informed about risk management strategies. Despite national guidelines suggesting routine breast cancer risk stratification, it is profoundly underutilized.⁶

Screening mammography represents one opportunity to evaluate patients and communicate information to patients and providers. The minority (0.4%–6%) of screening mammography patients are estimated to have a ~20% lifetime risk of breast cancer and would therefore be eligible for supplemental screening.⁷

Several previous studies examining the link between risk stratification and risk management behaviors have calculated estimated risk *after* the completion of a risk management behavior (e.g., screening breast MRI). Thus, the vast majority of patients and providers were unaware of their level of risk prior to decision-making about risk appropriate behaviors.^{7,8}

To address this gap, we prospectively assessed risk management behaviors in a sample of women at ~20% lifetime risk (N=72) who underwent risk stratification at the time of screening mammography. Six months post-mammography, participants reported recall of risk level and subsequent uptake of risk-appropriate behaviors (e.g., high risk clinic visit, supplemental screening breast MRI, risk-reducing medication, and genetic counseling and testing).

What Was Done

Risk Stratification and Notification Procedures

In 2017, breast cancer risk stratification was implemented at our institution as part of routine screening mammography. Each patient enters her own history electronically at the time of check in for her appointment. Patients can elect to not complete any portion of the questionnaire or opt-out of risk stratification entirely. MagView® mammography information management software (Burtonsville, MD) estimates lifetime risks using the modified Gail, TC7, and BRCAPRO models and automatically inserts the three estimates into the mammogram report. These estimates are included in the reports that are sent to the referring provider electronically or by fax, and to patients via a mailed lay letter. All patients, regardless of breast cancer risk status, receive risk stratification results.

Materials

Patient Letters.—Initially, letters were reviewed by our institutional Patient and Family Advisory Committee and revised based on their feedback. Subsequently, 10 patients undergoing a screening mammogram and 10 providers that frequently order mammograms (e.g., obstetricians/gynecologists, family medicine) gave feedback on the letters via a 30-minute semi-structured interview. The final version includes the risk stratification results (“average” or “elevated”), American Cancer Society (ACS) recommendations for supplemental screening MRI, and contact information for the high risk clinic at our institution.

Provider reports.—Risk communication within the mammography reports was refined using feedback from interviews with 10 providers described above. The final version of the mammography report includes the mammogram result, risk stratification result (numerical estimates from all three models are provided), and ACS recommendations for supplemental screening MRI.

Participants

Eligible participants were women: (1) with estimated lifetime breast cancer risk ≥20% based on an estimate from any of the modified Gail, TC7, and/or BRCAPRO models; (2) ≥18 years old; (3) capable of speaking and reading English and/or Spanish; and (4) able to provide a mailing address and working telephone number. Women with a personal history of breast cancer were excluded.

Study Procedures

A longitudinal, observational design was used. This HIPAA compliant study was approved by our institutional review board. Participants completed study questionnaires 6-months post-screening mammogram. The 6-month follow-up period was based on the commonly performed screening regimen for high risk women at our institution, with screening mammograms and breast MRI staggered at 6-month intervals. Approximately 6 months following their screening mammogram, eligible participants were mailed an introductory letter and the survey. Written informed consent was documented via paper forms mailed and returned with the survey materials. Participants received a \$30 gift card following completion of the survey.

Measures

Demographic characteristics.—Participants self-reported demographic characteristics (Table 1).

Risk recall.—Participants self-reported breast cancer risk (“high”, “average”, or “low”). Risk recall was coded as accurate if participants reported risk stratification results as “high”.

Risk management behaviors.—Engagement in breast cancer risk management behaviors was categorized as yes (1) or no (0): attending an appointment with a high risk specialist, undergoing screening breast MRI, initiating risk-reducing medication, attending genetic counseling, or completion of genetic testing.

Statistical Analysis

Descriptive statistics characterized the frequency of breast cancer risk management behaviors at the 6-month follow-up. Non-responders were considered lost to follow-up; all percentages were calculated with respondents as the denominator. Fisher’s exact test was used to examine differences in risk management behaviors by accuracy of risk recall. Logistic regression was used to examine the relationship between estimated lifetime risk and engagement in breast cancer risk management behaviors. Significance was specified at $p < 0.05$. All analyses were conducted in SPSS (version 25, IBM).

Outcomes and Limitations

Sample

Of the 299 screening mammography patients with an estimated lifetime risk 20% using any of the 3 models (Figure 1), we approached 153 ($153/299 = 51\%$) and consented 72 ($72/153 = 47\%$). Estimated lifetime breast cancer risk for these women ranged from 0%–39.7% for the modified Gail model, 4.2%–27.2% for BRCAPRO, and 12.5%–77.3% for the TC7. The average participant age was 52 years (range 32–71), most were non-Hispanic White, college educated, and privately insured (Table 1). Sixty six women ($66/72 = 92\%$) completed the 6-month follow-up assessment. Completers did not significantly differ from non-completers in self-reported demographic characteristics (all p 's > 0.12).

Risk Recall

At the 6-month follow-up, 20 respondents ($20/66 = 30\%$) did not recall receiving the letter with their risk stratification results. A further 19 ($19/66 = 29\%$) recalled receiving the letter but incorrectly recalled their risk as average ($3/66 = 5\%$), low ($5/66 = 8\%$), or did not know ($11/66 = 17\%$) (Table 2). Less than half ($26/66 = 39\%$) correctly identified themselves as high risk.

Risk Management Behaviors

Since screening mammography, 10 women ($10/66 = 15\%$) had engaged in any breast cancer risk management behavior (Table 2). Women who correctly recalled their high risk status were 2.4 times more likely to report uptake of any risk management strategy compared to women who did not accurately recall their high risk (RR=2.4, 95% confidence interval=1.5–4.0, $p=0.01$). Estimated lifetime breast cancer risk was not related to uptake of risk management strategies (all p 's > 0.15).

Of the 10 women who engaged in any risk management behavior, 4 ($4/66 = 6\%$) attended a high risk clinic appointment, 6 ($6/66 = 9\%$) underwent a breast MRI, 1 ($1/66 = 2\%$) started risk-reducing medication, 3 ($3/66 = 5\%$) attended genetic counseling, and 3 ($3/66 = 5\%$) completed genetic testing. Half ($n=5$) engaged in more than 1 risk management behavior and the remaining 5 in only 1 (Table 2).

Limitations

First, patients were primarily non-Hispanic, White, and college graduates. Women of other races/ethnicities and/or education levels may respond differently to the risk stratification information presented in these letters. Tailoring of risk communication materials based on cultural characteristics and/or educational attainment may be necessary to ensure understanding among these groups. Second, results may be subject to selection bias as we were only able to approach 51% of the women identified as high risk, and only 47% of those approached consented to participate. Third, breast cancer risk management behaviors were collected via self-report. Future studies should also include obtaining consent for electronic medical record data verification as these patients are referred from outside medical facilities. Fourth, the 6 month follow-up time point may have limited our understanding of patients' risk-management decisions. Future studies with longer follow-up are necessary to fully

capture patients' utilization of risk-management strategies. Finally, risk stratification occurred between October 2017 and September 2018, prior to availability of the TC model version 8. The TC8 incorporates breast density and may provide a more accurate assessment of breast cancer risk. Thus, additional efforts to evaluate the impact of risk stratification on breast cancer risk management behaviors are warranted.

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Figure 1 –.
Study Flow.

Table 1 –

Demographic characteristics for participants (N=72).

Sociodemographic Characteristic	n(%)
Race (White)	65 (90)
Ethnicity (non-Hispanic)	64 (89)
Relationship status (partnered)	57(79)
Education	
12 th grade/GED	1(1)
Vocational or some college	13(18)
Graduated college or higher	58(81)
Employment status (currently working) *	51(71)
Household income	
<\$50,000	10(14)
\$50,000	57 (79)
Insurance status (private)	53 (74)

* One patient missing data

Table 2 –

Recall of risk stratification results and uptake of breast cancer risk management behaviors at 6-months post-risk stratification in women with 20% lifetime risk (N=66).

Risk Recall	N (%)
Do you recall receiving a letter with the results of your preliminary estimate of your lifetime risk of breast cancer?	
Yes	46 (69.7)
No	20 (30.3)
What was the preliminary estimate of your lifetime risk of developing breast cancer?	
High	26 (39.4)
Average	3 (4.5)
Low	5 (7.6)
Don't Know	11 (16.7)
N/A – did not recall letter	20 (30.3)
Missing	1 (1.5)
Risk-Reducing Behavior	
Appointment with high risk specialist	
Yes, attended.	4 (6.1)
No, but I have scheduled an appointment.	5 (7.6)
No, and I will not schedule an appointment.	56 (84.8)
Don't know	1 (1.5)
Received breast MRI	
Yes	6 (9.1)
No	60 (90.9)
Taken tamoxifen or raloxifene	
Yes	1 (1.5)
No	64 (97.0)
Missing	1 (1.5)
Genetic counseling appointment	
Yes, attended.	3 (4.5)
No, but I intend to.	4 (6.1)
No, and I do not intend to.	58 (87.9)
Missing	1 (1.5)
Completed genetic testing	
Yes	3 (4.5)
No	62 (93.9)
Missing	1 (1.5)
Engaged in 3 risk-reducing behaviors	
High risk clinic appointment, breast MRI, and genetic testing	1 (1.5)
Breast MRI, genetic counseling, and genetic testing	1 (1.5)
Engaged in 2 risk-reducing behaviors	
High risk clinic appointment and genetic counseling	1 (1.5)
High risk clinic appointment and breast MRI	1 (1.5)

Risk Recall	N (%)
High risk clinic appointment and risk-reducing medication	1 (1.5)

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