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Supplementary Material

A Randomized Trial to Maximize Identification and Genetic Counseling Referral of Women at Risk for Hereditary Breast and Ovarian Cancer

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ABSTRACT

Purpose: The Breast Cancer Genetics Referral Screening Tool (B-RST™) has been endorsed as one of several validated screening tools to identify women appropriate for cancer genetics referral. We conducted a randomized trial to determine the most effective means of follow-up for women who screened positive on B-RST™ 3.0.

Methods: Women undergoing screening mammography at one of four Emory clinics were approached to complete the B-RST™. Participants who screened positive were randomized to one of three follow-up groups: self-referral (Group 1), electronic health record (EHR) clinician messaging (Group 2), or direct contact (Group 3). We compared genetic counseling appointment scheduling and completion rates by group.

Results: Of 2,422 participants, 658 (27.2%) screened positive. Genetic counseling appointments were scheduled by 9.2%, 20.1% and 9.7% of Group 1, 2 and 3 participants respectively ($p=0.001$). Challenges to scheduling included lack of physician response to EHR messages and unsuccessful direct contact. Among those scheduled ($n=78$) 70.5% completed the appointment, with no difference between the three groups.

Conclusion: B-RST™ can be used effectively in mammography settings to identify high-risk women for cancer genetics referral. Follow-up via EHR appears an acceptable and efficient approach, but additional strategies are needed to facilitate completion of the genetic counseling process.

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Disclaimer

The handout format was changed by the journal Clinical Oncology and Research specifically for purposes of publication.

Supplementary Materials and Methods

I Item 1: Screen Positive Handout

i Breast Cancer Genetics Referral Screening Tool (B-RST™ 3.0)



B-RST™ is a screening tool designed to quickly identify who should be referred for cancer genetic counseling to formally evaluate family history and discuss the benefits and limitations of *BRCA* genetic testing for hereditary breast and ovarian cancer. B-RST™ is not a genetic test or a test for cancer.

Keep in mind that B-RST™ is a screening tool, not a test. It cannot say for sure if you do or do not have a genetic risk for cancer.

This result does not mean that you will get cancer. It only means that you have a higher chance to have a *BRCA* mutation and may be at increased risk for developing early onset breast cancer, or ovarian cancer.

Talk with your healthcare provider if you have questions about your B-RST™ result or need help scheduling an appointment with a cancer genetic counselor.

b Important Information

- i. Not everyone who screens positive on the B-RST™ is a good candidate for *BRCA* genetic testing. A genetic counselor will do a comprehensive cancer risk assessment to find out whether genetic testing is right for you.
- ii. It is often best for someone with a personal history of cancer to have genetic testing before his or her unaffected family members are tested.
- iii. Most insurance plans will cover the cost of genetic counseling for individuals at increased risk.
- iv. There is a federal law called the “Genetic Information Non-discrimination Act” (GINA) that prevents health insurance companies or employers from making decisions based on your genetic information.

B-RST™ Result = Positive Screen

a What Does This Result Mean?

- i. Based on the information you reported, you have a 5-10% or greater chance to have an inherited change (mutation) in the *BRCA* genes.
- ii. You are at increased risk for Hereditary Breast and Ovarian Cancer.
- iii. Your risks for breast and/or ovarian cancer may be greatly increased over the average population risk.
- iv. Cancer Genetic Counseling is recommended to:
 - a. Review your family history in more detail
 - b. Assess your risk for hereditary types of cancer
 - c. Discuss the benefits and limitations of *BRCA* genetic testing
 - d. Learn ways to lower your risk for cancer.

To schedule a cancer genetic counseling appointment at Emory Winship Cancer Institute or for more information:

Call 404-778-2577 to schedule an appointment with the Winship High Risk Breast Center. You will meet with a genetic counselor and learn about cancer screening and ways to reduce your risk.

Call 404-778-1900 or 1-888-946-7887 and ask to speak with a genetic counselor E-mail a genetic counselor at WinshipGeneticCounseling@emoryhealthcare.org

Visit (Link 1)

- v. This screening tool only looks at familial risk factors for breast and ovarian cancer. Information about other cancer risk factors can be found at:
 - a. Centers for Disease Control and Prevention - (Link 2)
 - b. National Cancer Institute - (Link 3)

c Other Resources

- i. (Link 4) - excellent resource for individuals at potential hereditary risk for breast/ovarian cancer.
- ii. (Link 5) - resource for young women at high risk for breast/ovarian cancer.
- iii. (Link 6) - Centers for Disease Control, Office of Public Health Genomics: Breast and Ovarian Cancer and Family Health History.

- iv. (Link 7) - National Cancer Institute Fact Sheet. *BRCA1* and *BRCA2*: Cancer Risk and Genetic Testing.

II Item 2: EHR Messaging to Clinician

i Screen Positive (EeMR Clinical Messaging)

a High Risk - Cancer Genetics Referral Needed

Your patient completed the B-RST (Breast Cancer Genetics Referral Screening Tool) during her recent mammography appointment. Her result was screen positive, indicating that she is at increased risk for hereditary breast and ovarian cancer due to her (personal and) family history. As such, she would benefit from genetic counseling and consideration of genetic testing. While your patient was previously seen for genetic counseling (X) years ago, there have been significant changes in the field which would make consideration of a follow-up appointment appropriate. Please refer your patient to genetic counseling as below (This language may not apply). Please note your patient was given written information regarding her result, implications, and resources at the time of her appointment. To refer Ms. XXXX for genetic counseling please forward this clinical message to the GENETICS WINSHIP pool. Genetic counselors are currently available to see patients at the Winship Main Campus location, Emory Midtown, and Emory/Saint Joseph’s Hospital. For further information or questions about the Winship Genetic Counseling Program: Please contact Christine Stanislaw, MS, CGC (404) 778-8525 Or visit (Link 1). For further information or questions about the breast cancer genetics referral screening tool (B- RST): Please visit: (Link 8). This message was sent on behalf of Christine Stanislaw, MS, CGC, Director of Genetic Counseling at Winship Cancer Institute of Emory.

III Item 3: Call Protocol and Scripts

i B-RST Call Protocol

a Call Log

The Call Log serves as a record of all call attempts for participants randomized to Group 3. EACH ATTEMPT to reach a participant must be entered as a separate line in the Call Log, even if calls are made in the same day or made to the same number. Please fill out every column for each call attempt. Use the wording for call results in this document as you enter information in the Call Log (see table below).

b Instructions for Each Column

- i. MRN: Enter the MRN of the participant.
- ii. Date: Date (MM/DD/YY) of the call attempt
- iii. Call Start Time: __ : __ AM/PM – Enter exact time and indicate if a.m. or p.m.
- iv. Call End Time: __ : __ AM/PM – Enter exact time and indicate if a.m. or p.m.
- v. Number Used: If known, indicate whether the number you dialed is a home, cell, or other number.
- vi. If “Other”, please specify type in the notes column.

- vii. Call Status: Indicate status of call, whether you spoke with participant, spoke with other, did not receive an answer, left a voicemail, or if the status is best described as “other”.
- viii. If “Other”, please specify type in the notes column.

c Potential Call Attempt Results

Interview attempts
1. Spoke with Participant
2. Spoke with Other
3. No Answer
4. Left Voicemail
5. Other: _____ - If “Other”, please specify.
• Invalid/Disconnected #
• Busy Signal
• No Answer
• Wrong # per person/voicemail/fax/other
• Left Message with Other (explain _____)
• Started interview but didn’t finish (explain _____)

- i. Call Outcome: Indicate if spoke to participant or need to call back.
- ii. Notes: Include anything that requires follow-up, specific reasons the participant does or does not want to receive genetic counseling, etc. Always record why the interview was not completed (per call attempt). Use the listed call results below for wording. If “Other”, please provide details. Feel free to use the “Notes” box to include information about who you spoke with, what the conversation entailed, and what you think the next step should be (if you have suggestions).
- iii. Notes: Include helpful info such as specific day/time to call back, person you spoke to if not participant (wife, child, etc.), etc.
 - a. Best day to call: Weekdays (M-F), Weekend, or a specific day of the week.
 - b. Best time to call: Daytime, Morning, Afternoon, Evening, other - If “Other”, please specify. Please include information about from where or from whom this information was obtained.
 - c. Best # to call: H/C/W/O - If O (Other), please specify.

If you spoke to the participant, please indicate the time when the call ended on the space provided.

d Frequency of Call Attempts

Do not call a participant more than once per telephone number per day. You may call a participant more than once per day only if:

- i. You get a busy signal
- ii. You are disconnected during the phone call
- iii. The participant or someone who lives in the household asks you to call back later.

Do not call a participant more than 3 times, and only use email and text options one time each. This only includes valid call attempts to any available phone number. In general, a valid attempt means the phone rang to the right number. Invalid attempts are defined as: busy,

disconnected, participant unavailable (no ring), or wrong number. Follow the order below, and wait at least two days before the next attempt:

Call → Text → Call → Email → Call

Example: 1st call on Monday, text on Wednesday, 2nd call Friday, email Saturday, 3rd call Tuesday

e Prior to Calling a Participant

- i. Review the call history for the participant you are about to call.
- ii. Make sure that you know who you are calling (names) and the B-RST risk factors of the participant before you make the call.

f During the Call

- i. Some participants may not want to use their cell phone minutes for the interview. If this is the case, make sure you offer to call them on a landline phone. Make a note of this number in the notes section of the call log.
- ii. You may reach the participant at an inconvenient time (e.g., at work, driving, running errands). Only proceed with the call if the participant says that this is a convenient time to complete the call.
- iii. If any of the telephone numbers we obtain become disconnected, make a note of it in the call log.
- iv. If at any time the participant asks you to call them back, always confirm the phone number, day, and time before you end the call.
- v. If someone hangs up on you, you do not need to call them back unless you have good reason to believe it was accidental. You can place another call 2 days after the hang up occurred.
- vi. If a call is disconnected during an interview, immediately call them back. If you do not reach the participant to finish the interview, try calling the participant the next day.

ii Call Management

a Organizing and Prioritizing Calls

Your highest priority should be requested call backs - review the spreadsheet and look for requested call backs before making any other calls!

b Updating the Spreadsheet

c Complete a Call Log Entry

Update the Excel Call Log sheet with any relevant information. The Call Log captures key information and allows us to review and summarize study progress and outcomes. You will enter information into the Call Log at the time of each call attempt to a participant. The B-RST Referral Study Database spreadsheet is saved to the BRST Study folder on Box.

iii Email Script

Dear Ms. _____,

My name is Chelsea, and I am a research assistant for the genetics research study at Emory University. I am following up on a phone call I made to you on XX/XX/XX. At your recent screening mammogram appointment at Winship, you participated in a research study where you answered a series of questions about your personal and family history of breast and ovarian cancer.

As a part of this study, you were randomly assigned to receive a phone call regarding options for genetic counseling. If you are interested in learning more about genetic counseling at Emory or have questions, please call me back at (404) 895-7877. Alternatively, please feel free to reply to this email with times or days when you are available for me to call you back.

I look forward to hearing from you!

Best,
Chelsea Leonard

iv Text Scripts

Ms. _____,

This is Chelsea from the genetics research study at Emory. When you have a chance, please give me a call about the survey you completed at your recent mammogram appointment at Winship. My telephone number is (404) 895-7877. Thanks, Chelsea Leonard.

Ms. _____,

This is Chelsea from the genetics research study at Emory. When we last spoke, you asked I give you a call back in about a week so you could read more on the information you received after taking our study questionnaire. Have you had a chance to do this yet? Please let me know when it would be convenient for me to call for a quick follow up. My telephone number is (404) 895-7877. Thanks, Chelsea Leonard.

v Voicemail Script

Dear Ms. _____,

My name is Chelsea Leonard, and I am a research assistant for the genetics research study at Emory University. At your recent screening mammogram appointment at Winship, you participated in a research study where you answered a series of questions about your personal and family history of breast and ovarian cancer.

As a part of this study, you were randomly assigned to receive a phone call regarding options for genetic counseling. If you are interested in learning more about genetic counseling at Emory or have questions, please call me back at (404) 895-7877. I look forward to hearing from you! All the best.

vi Participant Reached Call Script

Hello, Ms., my name is Chelsea Leonard and I am a research assistant with the Emory Winship Cancer Institute. I am calling to follow-up on

the breast cancer genetics referral screening tool (or B-RST) that you completed during your recent mammogram appointment at Emory.

Unaffected: As you may recall, your B-RST result indicated you are at increased risk for Hereditary Breast and Ovarian Cancer based on your family history.

Affected: As you may recall, your B-RST result indicated that your breast (ovarian) cancer (and your family history of cancer) might have a hereditary cause.

You were given some materials that explained this result and the importance of seeing a cancer genetic counselor to further discuss what it means for you and your family. Does this sound familiar to you? Do you have questions about any of the information you received? (I can hold on for a minute if you have access to the materials and want to get them right now. (Address questions as appropriate). If patient does not have access to materials anymore, offer to mail another brochure. Confirm patient's address.)

When you completed the B-RST, you agreed to participate in a study about the best way to follow up with people who screen at increased risk. As part of this study, you were randomly selected to receive a phone call about your B-RST results and to assist you in scheduling a cancer genetics counseling appointment. Is now a good time to talk for about 5-10 minutes? - if NO, arrange a time to call back.

If YES

The genetic counseling appointment will involve reviewing your family history in more detail; assessing your specific risks for hereditary cancer; discussing the availability, benefits and limitations of genetic testing; talking about what this means for you and your family members and learning ways to lower your risk for cancer. Please be aware that whether or not you undergo genetic testing for hereditary cancer is completely your decision. The genetic counseling appointment itself and any genetic testing pursued are not part of the study and would be billed to your insurance. Most insurance providers cover genetic counseling and testing for people at risk for hereditary breast and ovarian cancer. The Cancer Genetic Counseling Clinic will help you to determine if these services are covered by your insurance policy.

Do you have any questions about what we've reviewed so far? (if yes, answer as needed). Would you be interested in scheduling a cancer

genetic counseling appointment at this time? If Yes - Great - I will give you your contact information to scheduling office and someone will call you to make the appointment. You can also call 404-778-1900 and ask to speak to a cancer genetic counselor or email one with your questions by going to WinshipGeneticCounseling@emoryhealthcare.org. This contact information is also included on the handouts that you received at the time of your mammogram.

To prepare for your appointment, I would like to spend a few minutes learning a bit more about your family history. Is that OK?

1. Summarize patient's B-RST results for her and ask if accurate? Ask for age of diagnosis of each family member described in B-RST results.
2. Ask patient if any additional family members have had cancer?
 - i. For each family member with current cancer or history of cancer, obtain:
 - a. Relationship to patient?
 - b. On mom or dad's side?
 - c. Type of cancer?
 - d. Age of diagnosis?
3. If unsure... Ask for general decade (e.g., 30s?, 40s?). If still unsure, ask over 50? Under 50? If still unsure, move to next family member
4. Ask patient if any family member has previously undergone genetic testing. If so, what were findings?

Closing: Thank you so much for your time. You should be hearing from the scheduler shortly. Remember, you can always ask to speak to a genetic counselor prior to your appointment by calling (404) 778-1900.

If No - OK. You can always schedule an appointment yourself by calling (404) 778-1900. You can also call this number and request to speak to a cancer genetic counselor, or email one with your questions by going to WinshipGeneticCounseling@emoryhealthcare.org. This contact information is also included on the handouts that you received at the time of your mammogram. Thank you for your time.

If *NOT RIGHT NOW*

Ok, Ms. _____, no problem. Is there a time I could call you back that would work better for your schedule?