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# Non-adherence to guidelines for genetic testing in families with ovarian cancer shows racial bias

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**Abstract** 

Purpose: The National Comprehensive Cancer Network (NCCN) recommends germline genetic

testing for individuals at risk for hereditary ovarian cancer. We sought to determine the

proportion and characteristics of individuals meeting testing criteria in a multicenter biobank who

were appropriately offered testing.

Methods: In this retrospective cohort study, we identified Mass General Brigham Biobank

participants meeting genetic testing criteria per NCCN guidelines. Logistic regression was used

to analyze sociodemographic factors associated with which participants were offered testing.

completed testing, and had a family history that matched their self-report documented in the

electronic medical record (EMR).

Results: Most eligible participants (909/1441, 63.1%) were not offered genetic testing.

Participants who were Black or Hispanic had a lower likelihood of being offered testing.

Compared with self-report, 988 (68.6%) participants had a family history of ovarian cancer

documented in their EMR. Older age, Hispanic ethnicity, and public insurance use were

associated with decreased likelihoods of accurate family history documentation. Correct

documentation was associated with an increased likelihood of being offered testing.

**Conclusions:** The majority of participants in this study did not receive NCCN-compliant care.

Germline genetic testing for hereditary ovarian cancer screening is underutilized and access to

this testing is currently inequitable.

**Keywords:** ovarian cancer, health disparities, hereditary cancer predisposition

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## Introduction

Ovarian cancer, the deadliest gynecological cancer, is projected to affect 20,000 people and cause 13,000 deaths in the United States in 2024.<sup>1,2</sup> Approximately 23% of cases are thought to occur in people with an inherited predisposition to cancer, primarily due to pathogenic variants in *BRCA1* (HGNC: 1100) and *BRCA2* (HGNC: 1101).<sup>3</sup>

The National Comprehensive Cancer Network (NCCN) guidelines for the detection and risk reduction of hereditary ovarian cancer recommend germline multigene testing of unaffected individuals with a first- or second-degree relative diagnosed with epithelial ovarian cancer, regardless of age.<sup>4</sup> The proportion of individuals meeting these criteria who undergo genetic testing, however, is unknown. Previous studies have examined genetic testing rates among affected patients, but to our knowledge, there has been no investigation into testing rates among individuals without a personal history of ovarian cancer meeting these criteria.<sup>5-7</sup> Additionally, prior research suggests that access to hereditary cancer predisposition testing may be inequitable among individuals from minoritized populations.<sup>1,8-10</sup>

In this retrospective cohort study, we analyzed data from a multicenter biobank to determine the proportion and characteristics of individuals who were appropriately offered germline genetic testing according to NCCN guidelines. To further investigate underlying causes of non-adherence with these guidelines, we also evaluated whether participants' self-reported family histories of ovarian cancer were accurately documented in their electronic medical records (EMR).

# **Methods**

# **Study Population**

The Mass General Brigham Biobank (MGBB) is a research biorepository that included 139,664 participants at the time of our query in January 2023. Approximately 65,000 participants completed health surveys, which included questions related to personal and family medical history. Surveys were completed as an electronic form sent via email or as a paper form sent via mail with a pre-paid return envelope. Surveys were completed independently unless help from a research coordinator was requested. The majority of questions focused on the participant's sociodemographic characteristics, medical history, and lifestyle. Participants were also asked to list all known medical diagnoses for each family member (mother, father, siblings, children, maternal grandparents, paternal grandparents) from a pre-defined list, with the option of "other" to account for diagnoses not listed. Cancer is a listed diagnosis and, if selected, participants are then given the opportunity to select the cancer type(s), including: breast, colon, endometrial, lung, melanoma, ovarian or prostate, blood, and other. Of the participants who completed health surveys, we identified 1,441 who were living, assigned female at birth, had no personal history of ovarian cancer reported in their health survey and confirmed during EMR review, indicated a family history of ovarian cancer in a first- or second-degree relative in their health survey, and had primary care and/or cancer care clinical notes available for review in the Mass General Brigham EMR (Supplemental Figure 1).

## **Data Collection**

Each participant's EMR was reviewed and their sociodemographic characteristics were recorded from pre-defined structured fields, including: date of birth, race, ethnicity, primary language, insurance type, and zip code. Using date of birth, we computed age for each participant as of January 1, 2024. When available, each participant was assigned an area

deprivation index (ADI), normalized to state, based on zip code. The ADI is a composite measure of neighbourhood socioeconomic conditions, considering income, education, employment, and housing quality, used to assess health disparities, previously defined by Singh et al.<sup>11</sup> We also queried each participant's EMR using the following search terms: *BRCA*, *cancer*, *genetic*, *mutation*, *ovarian*, *panel*, and *pathogenic*, in addition to review of primary care and/or cancer care clinical notes. As all participants reported a family history of ovarian cancer, we recorded whether this information was documented in their EMR. We noted whether germline genetic testing was discussed, offered, accepted, and the results of testing, if completed. If testing was declined, the reason for refusal was recorded.

#### Statistical Analysis

Analyses were completed using RStudio (version 2023.09.1+494) and SAS/SAT software (version 9.4). Sociodemographic characteristics were summarized with medians for continuous variables and percentages for categorical variables. Logistic regression was used to assess which factors were associated with a participant's likelihood of receiving appropriate genetic care, completing testing when offered, and their likelihood of correct family history documentation in the EMR with their sociodemographic characteristics.

Based on prior literature and after assessing collinearity between variables, we tested the following factors as independent variables in the models: age, race, ethnicity, primary language, insurance type, ADI. Age was scaled so that each unit corresponded to 10 years. ADI was classified into three groups: very low + low, medium, high + very high. We converted multi-level categorical variables into binary indicator variables. For ordinal categories, we set the lowest level as the reference, and for other categories, we chose the reference based on clinical interpretability. For all analyses, races were limited to white, Black, and Asian, and insurance

types were limited to private and public as these were the only defined groups with sufficient sample sizes to allow for meaningful conclusions.

We fit two types of models: (1) bivariate logistic regression and (2) multivariate logistic regression that included all variables. Due to high collinearity between race, ethnicity, and primary language, we chose one of these three variables to include in each multivariate model based on the strength of bivariate associations and number of individuals in each category.

Odds ratios (OR) and adjusted OR (aOR) with 95% confidence intervals (CI) were reported. *p* <0.05 was considered statistically significant.

## Results

Of 139,664 participants in the MGBB, 1,441 with a median age of 60.0 years met inclusion criteria. The majority identified as white (89.0%) and non-Hispanic (90.2%), spoke English as their primary language (99.0%), used private insurance (66.9%), and lived in very low deprivation areas (37.7%) (Table 1).

Of 1,441 participants, 532 (36.9%) received appropriate genetic care and 909 (63.1%) did not. Among participants whose care followed NCCN guidelines, 428 (80.5%) were offered and accepted genetic testing, 50 (9.4%) were offered genetic testing but declined, and 54 (10.2%) discussed genetic testing with a clinician and determined it was not indicated, either because the proband or a closer relative had already received negative genetic testing results.

Bivariate logistic regression analyses revealed Black race was significantly associated with a lower likelihood of appropriately being offered genetic testing (OR, 0.27; 95% CI, 0.11-0.65; p=0.0032), as was Hispanic ethnicity (OR, 0.35; 95% CI, 0.14-0.90; p=0.029) (Figure 1). In a

multivariate logistic regression model including age, race, insurance type, and ADI, only Black race was significantly associated with a lower likelihood of being offered genetic testing (aOR, 0.34; 95% CI, 0.14-0.84; p=0.019) (Figure 1).

Family history of ovarian cancer in a first- or second-degree relative was correctly documented in the EMR of 988/1441 participants (68.6%). Bivariate logistic regression analyses showed Hispanic ethnicity (OR, 0.43; 95% CI, 0.21-0.90; p=0.024) and public insurance use (OR, 0.78; 95% CI, 0.61-0.99; p=0.045) were significantly associated with a lower likelihood of correct family history documentation. In a multivariate logistic regression model including age, ethnicity, insurance type, and ADI, older age (aOR, 0.92; 95% CI, 0.85-0.99; p=0.021) and Hispanic ethnicity (aOR, 0.40; 95% CI, 0.19-0.83; p=0.014) were significantly associated with a lower likelihood of correct family history documentation. Correct documentation in the EMR was significantly associated with an increased likelihood of being offered testing (p<0.001).

Among 478 participants who were offered genetic testing, there were no statistically significant associations between their sociodemographic characteristics and likelihood of completing testing. Of 428 participants (89.5%) who completed testing when offered, 103 (24%) had a positive result, 56 (13%) had a variant of uncertain significance, 258 (60%) had a negative result, and 11 (3%) had testing pending at the time of analysis. Of 50 participants (10.5%) who were offered testing and declined, the majority (41/50, 82%) were reportedly not interested, 5/50 (10%) had testing denied by insurance, 2/50 (4%) hoped to convince the proband in their family to complete testing first, and 1/50 (2%) were either concerned about potential insurance denial or had previously undergone prophylactic bilateral salpingo-oophorectomy and so did not feel germline testing was needed.

# **Discussion**

In this retrospective cohort study from a multicenter biobank, 63.1% of participants who met NCCN criteria for hereditary ovarian cancer screening were not offered the recommended genetic testing and substantial healthcare disparities were identified. Like other types of preventive care, access to germline genetic risk assessment is inequitable. This finding could be related to a range of underlying factors, such as communication barriers, the presence of other more acute healthcare needs, systemic discrimination, or perceived differences in insurance coverage. Similar to a study that investigated methods to identify patients at high risk for breast cancer, we also found that correct documentation of a positive family history of ovarian cancer in the EMR was inconsistent but strongly associated with an increased likelihood of NCCN-compliant care. This finding suggests a path forward, in which patient self-report of family history may be critical to identifying at-risk individuals who are eligible for preventive genetic testing.

Among participants in this study who were offered genetic testing, the majority completed it, regardless of their sociodemographic characteristics. Despite prior research studies that have suggested that Black and Hispanic individuals may have more concerns about genetic testing, <sup>15,16</sup> our findings from this cohort suggest that individuals of all backgrounds were interested and perceived personal value in preventive genetic testing. Notably, however, we do acknowledge the limited diversity in this cohort and the relatively small number of minoritized participants studied compared to white non-Hispanic participants. Additionally, approximately one in four participants received a positive test result, indicating an increased personal risk of cancer. These individuals were afforded opportunities to undergo risk-reducing procedures, initiate chemoprevention, participate in high-risk surveillance programs, and enable more informed familial cascade testing.<sup>4</sup> Inequities in preventive cancer predisposition testing can

therefore contribute to more major downstream disparities in cancer incidence and long-term health.

This study has several limitations. In addition to the homogeneity of the cohort, this cohort is representative of one health system and is derived from a research biobank. Consequently, individuals less willing to participate in research are underrepresented. Additionally, since family history is self-reported, inaccuracies in reporting may arise and family history may be incompletely known.

In conclusion, we found that the majority of participants in a multicenter health system did not receive NCCN-compliant care. Hereditary ovarian cancer screening via germline genetic testing is significantly underutilized and access to this testing is inequitable. Using electronic self-report instruments to gather family history could improve the identification of patients with a familial risk for cancer, though we acknowledge the limitations of this method, as noted above. 17 To ensure that eligible patients are identified, decision support tools that alert clinicians to patients meeting NCCN criteria could be implemented. Importantly, however, for success, this would require clinicians respond to the alert in already-busy clinical settings. 18 To meet the needs of at-risk patients, more robust mechanisms for genetic testing in the primary care setting will also be needed. Genetic counselors have been successfully integrated into primary care practices in some settings, and this model could be expanded in the future. This would require education regarding genetic testing and the role of genetic counselors for providers in these practices, increased availability of genetic counselors amidst a workforce shortage, and overcoming logistical barriers such as space and time constraints. 19 Providing informed consent by video may be another feasible approach, which has been trialed in research studies related to prenatal cell-free DNA screening tests.<sup>20</sup>

Notably, our findings suggest that patients from diverse backgrounds are interested in pursuing preventive genetic testing when it is offered to them. Most participants in this study who were offered testing completed it, demonstrating that the barriers to NCCN-compliant care may now lie primarily in the health care system. Given that approximately one in four of these individuals were found to have genetic variants associated with a cancer predisposition syndrome, we have a tremendous opportunity to improve the surveillance and health of individuals with a familial risk for cancer. Patient self-report of family history data, decision support tools, adjustments in the workforce, and virtual consents may be useful tools for reaching patients at risk for hereditary cancer predisposition syndromes.

# **Data Availability**

Deidentified data is available upon request from the corresponding author pending the appropriate institutional data user agreement.

# **Funding Statement**

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## **Author Contributions**

Conceptualization: J.O.O., P.N., N.B.G.; Data Curation: J.O.O., S.K., E.P.; Formal analysis: J.O.O., A.N., S.L., N.B.G.; Investigation: J.O.O.; Visualization: J.O.O., S.L.; Writing-original draft: J.O.O.; Writing-review & editing: J.O.O., A.N., S.L., S.K., E.P., R.C.G., P.N., N.B.G.

## **Ethics Declaration**

This study was reviewed by the Mass General Brigham Institutional Review Board and determined to be exempt.

# **Conflict of Interest**

Ms. Perez is a paid consultant for Allelica.

Dr. Green receives compensation for advising the following companies: Allelica, Atria, Fabric, Genomic Life and Juniper Genomics; and is co-founder of Genome Medical and Nurture Genomics.

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Dr. Natarajan reports personal fees from Allelica, Apple, AstraZeneca, Blackstone Life Sciences, Creative Education Concepts, CRISPR Therapeutics, Eli Lilly & Co, Esperion Therapeutics, Foresite Labs, Genentech/Roche, GV, HeartFlow, Magnet Biomedicine, Merck, Novartis, TenSixteen Bio, and Tourmaline Bio; equity in MyOme, Preciseli, and TenSixteen Bio; and spousal employment at Vertex Pharmaceuticals.

Dr. Gold reports personal fees from RCG Consulting and Ambry Genetics.

Dr. Omorodion, Dr. Nathan, Dr. Lipsitz, and Dr. Koyama do not report any conflict of interest.

# **Supplemental File Listing**

Supplemental Figure 1. Process diagram for identification of study cohort.

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# **Figure Legends**

Figure 1. Forest plot demonstrating the association between a participant's likelihood of receiving appropriate genetic care and their sociodemographic characteristics.

	Overall	White	Black	Asian/Pacific Islander	Native American/ Alaskan Native	Other	Multiracial
Total	1441	1283 (89.0%)	42 (2.9%)	35 (2.4%)	2 (0.1%)	61 (4.2%)	18 (1.2%)
Age (median in years)	60.0	60.7	55.3	46.3	39.7	53.3	56.1
Ethnicity				8			
Hispanic	69 (4.8%)	21 (1.6%)	9 (21.4%)	0	1 (50%)	36 (59.0%)	2 (11.1%)
Non-Hispanic	1299 (90.2%)	1200 (93.5%)	30 (71.4%)	30 (85.7%)	1 (50%)	22 (36.1%)	16 (88.9%)
Other	73 (5.1%)	62 (4.8%)	3 (7.1%)	5 (14.3%)	0	3 (4.9%)	0
Primary Language							
English	1427 (99.0%)	1279 (99.7%)	42 (100%)	34 (97.1%)	2 (100%)	53 (86.9%)	17 (94.4%)
Spanish	4 (0.3%)	2 (0.2%)	0	1 (2.9%)	0	0	1 (5.6%)
Other	10 (0.7%)	2 (0.2%)	0	0	0	8 (13.1%)	0
Insurance Type							
Private	964 (66.9%)	853 (66.5%)	30 (71.4%)	28 (80.0%)	2 (100%)	39 (63.9%)	12 (66.7%)
Public	446 (31.0%)	403 (31.4%)	12 (28.6%)	6 (17.1%)	0	19 (31.2%)	6 (33.3%)
International	2 (0.1%)	2 (0.2%)	0	0	0	0	0
Unknown	29 (2.0%)	25 (2.0%)	0	1 (2.9%)	0	3 (4.9%)	0
Area Deprivation Index <sup>a</sup>							
Very Low Deprivation	509 (37.7%)	470 (38.9%)	6 (17.1%)	19 (59.4%)	1 (50%)	7 (12.1%)	6 (35.3%)
Low Deprivation	334 (24.7%)	304 (25.2%)	7 (20%)	4 (12.5%)	0	14 (24.1%)	5 (29.4%)
Moderate Deprivation	248 (18.4%)	214 (17.7%)	11 (31.4%)	5 (15.6%)	0	17 (29.3%)	1 (5.9%)
High Deprivation	180 (13.3%)	151 (12.5%)	6 (17.1%)	3 (9.4%)	1 (50%)	18 (31.0%)	1 (5.9%)
Very High Deprivation	80 (5.9%)	68 (5.6%)	5 (14.3%)	1 (3.1%)	0	2 (3.5%)	4 (23.59

a. Area Deprivation Index included for 1351/1441 participants that it was available for.



