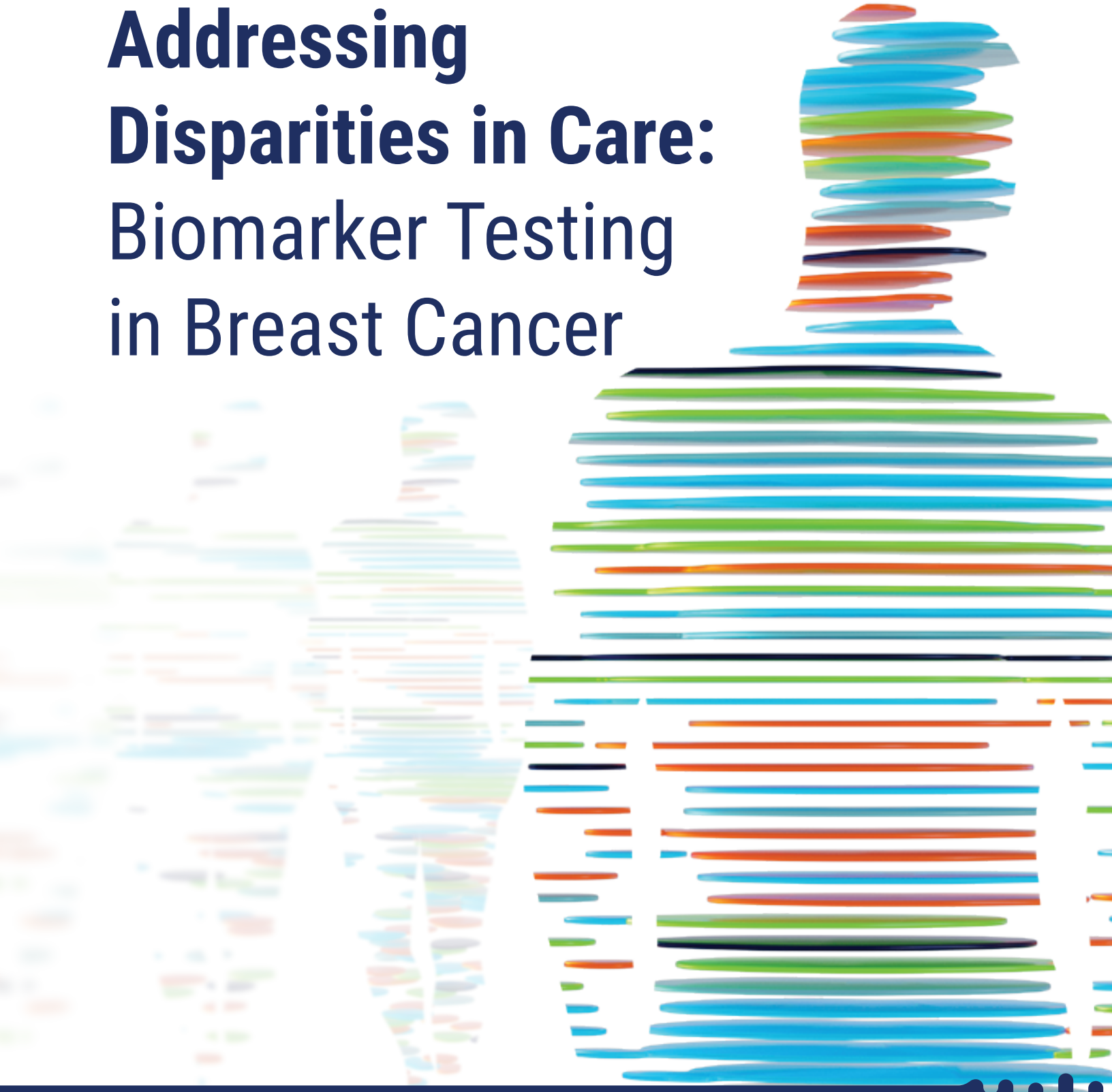
Addressing Disparities in Care: Biomarker Testing in Breast Cancer



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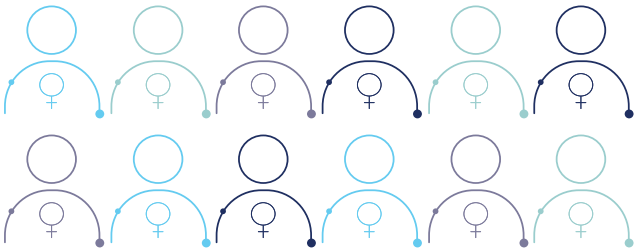
Disparities of Care

- A **disparity of care** is a difference between population groups in the way they access, experience, and receive health care[1]



Can be linked to social, economic, and environmental disadvantage[2]

Primarily impacts groups of people who have systematically experienced greater obstacles to health, based on racial or ethnic background, or other characteristics linked to discrimination or exclusion[2]

- For patients with **breast cancer (BC)**, disparities in care exist between patient populations in any stage of the disease (ie, eBC, mBC)[3]
  - Disparities in BC care may markedly affect testing rates and therapeutic decisions for patients at the same stage of disease, which can potentially contribute to differences in overall patient outcomes[3,4]
  - Variation in BC outcomes results not only from specific tumor biology differences, but also from modifiable and nonmodifiable external factors that create disparities of care[3,5]

External Factors Causing BC Disparities of Care[5-8]

Race and ethnicity	Aging rate	Socioeconomic position	Environmental and chemical exposure	Psychosocial stressors	Comorbidities and lifestyle	Poverty	Rurality	Organizational and health care systems

Overall Patient Outcomes in eBC and mBC

Despite marked advances in BC survival, **disparities** persist and affect large populations **with respect to timeliness of diagnosis, receipt of treatment,** and **long-term health outcomes**.[3]

Based on **2024** BC statistics,[9]

313,510 estimated new cases*

42,780 estimated deaths* **in the United States**

BC represents a significant global health challenge.

Global estimates indicate 2.3 million new cases of **female** BC in 2022, contributing to nearly 12% of all new cancer cases.[10]

BC mortality has decreased due to improved screening and treatment options.

Nevertheless, 25% to 30% of patients experience disease **recurrence** and mortality due to metastatic disease.[11]

eBC, early breast cancer; mBC, metastatic breast cancer.
*For both male and female patients.

Disparities of Patient Outcomes in eBC and mBC

Disparities in BC care can influence distribution of **health outcomes** across different population groups (ie, categorized by race and ethnicity, geography, and socioeconomic status [SES]).

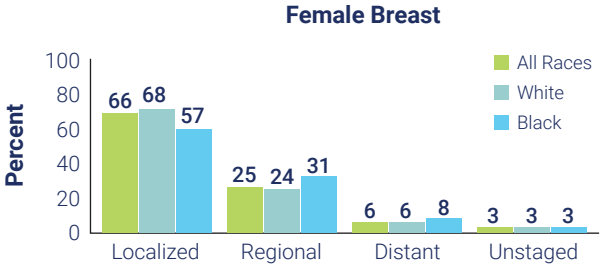
Breast Cancer Survival Disparities by Race, United States[3,9]

Racial disparities in BC mortality have been widely documented for several decades and persist despite advances in receipt of mammography across racial groups. This persistence leads to questions about the roles of biological, social, and health system determinants in poor outcomes.[3,9]

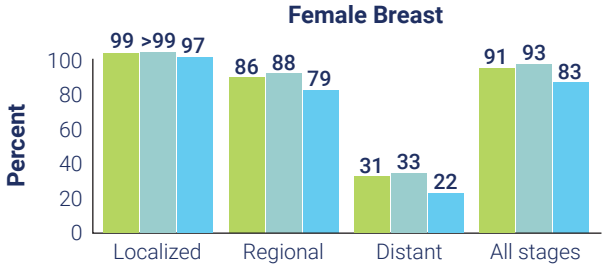
Different **ethnic populations** are characterized by various susceptibilities to BC, such as diversity in organ structure and development of disease in conjunction with diet.[5]

Generally, **Black** individuals are known to possess a significantly greater BC burden, with the poorest likelihood of survival leading to the worst incidence of death of any race.[5]

Stage distribution for BC by race, 2016-2020



5-year survival by race at stage of BC diagnosis, 2013-2019[9]



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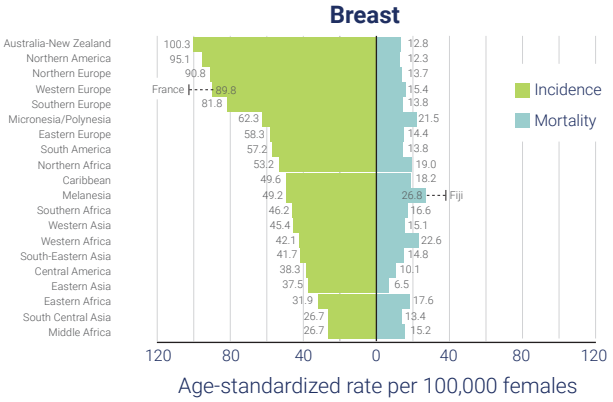
Incidence and Mortality of Breast Cancer by Geography, Global Cancer Statistics[10]



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Geographic variation reflects population demographic characteristics, differences in the prevalence of cancer risk factors, early detection practices, as well as access to care.[9]

In the United States, different states have a large influence on the health of residents by controlling **accessibility** and **affordability** of health insurance through the marketplace and Medicaid.[9]

Studies indicate that certain **environmental exposures** and **lifestyle** variables contribute 70% to 95% of the different risk factors that influence the **incidence of BC**.[5]

Mortality of De Novo Female mBC by Socioeconomic Status, US Cancer Statistics[8]

Subdistribution hazard ratio (SHR) for overall BC survival

SES quintile	Crude SHR (95% CI)	Adjusted SHR (95% CI)[a]
1st	1.35 (1.30-1.39)	1.22 (1.17-1.26)
2nd	1.27 (1.22-1.31)	1.20 (1.15-1.24)
3rd	1.18 (1.14-1.22)	1.13 (1.10-1.18)
4th	1.10 (1.06-1.13)	1.08 (1.04-1.11)
5th	ref	ref

ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.
[a]Adjusted for race/ethnicity, SES quintile, rurality, age, year of diagnosis, ER/PR status, HER2 status, radiation, chemotherapy, surgery, marital status, and insurance status.

SES is a critical measure that can impact care outcomes, with individuals of lower SES often experiencing disparities in outcomes of care and increased mortality, compared with patients with higher SES.

It is important to note that the disparities discussed here can be interrelated and include additional factors. Patients may experience multiple disparities of care simultaneously that need to be addressed.

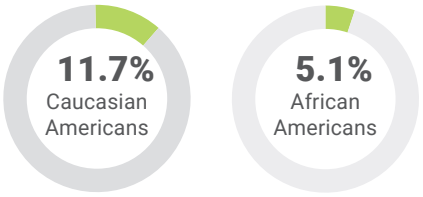
Disparities in Biomarker Testing in eBC and mBC

Similar to disparities in BC outcomes, disparities between populations have been observed in the ability to receive optimal BC screening and optimal biomarker testing for patients with BC.

- Despite advances in BC testing criteria and knowledge about detection strategies for mutation carriers, studies suggest that few women at high risk of hereditary BC are offered genetic testing[12]
- High-risk Black women are less likely to be counseled or tested than high-risk White women, mirroring racial disparities found in other aspects of cancer care and outcomes[12]

Racial Disparities in BC Genomic Testing, United States[14]

In a recent study of all patients with BC in Virginia…

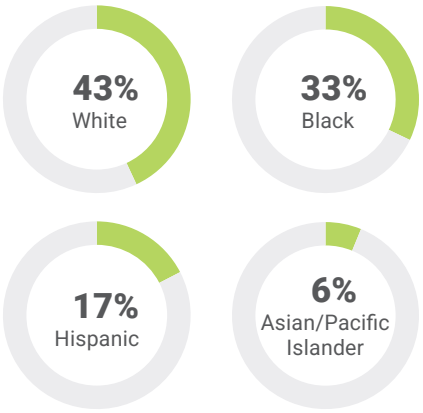


…received **genomic testing** for BC.

- Although regular screening via **mammography** has been relatively stable for the past two decades, disparities in BC testing still exist[9]
  - Black women are less likely to receive a provider referral for mammography and timely follow-up after an abnormal screening test[9]
  - Mammography screening and other routine health care that were suspended early in the pandemic have been slower to rebound among people of color[9]

Racial Disparities in Mammography Screening, United States[15]

In a meta-analysis between 1946 and 2015…

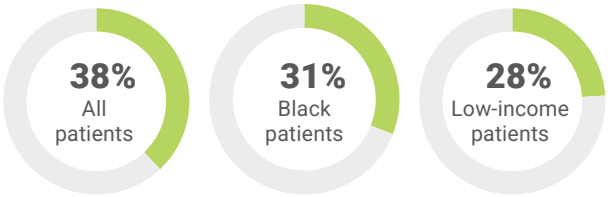


…underwent **mammography** testing.

- For patients with eBC, use of gene expression profiles can be important predictive and prognostic assays to help guide the need for adjuvant therapy[13]
- Black and lower-income women with HR+, HER2- stage I-II tumors are less likely to receive Oncotype DX® testing relative to non-Black and higher-income women[13]

Disparities in Genomic Expression Profile Testing, United States[13]

In a recent analysis of patients with eBC in the Carolina Breast Cancer Study…



…received **Oncotype DX®** testing.

PULSE CHECK ☐ Have all the required testing information/appropriate education materials been provided to the patient?

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Oncotype DX is a registered trademark of Exact Sciences Corporation.
HER2-, human epidermal growth factor receptor 2–negative; HR+, hormone receptor–positive.

Barriers to Testing

Underserved population groups may have encountered multilevel **barriers to testing** that resulted in a decline in the utilization of BC biomarker testing and potentially in disparities of care.[16,17]

Society/Health Care System

- Insurance coverage and cost transparency[16]
- HMO patients are less likely to be tested[16]
  - Suggests administrative barriers such as prior authorization requirements or the use of restricted provider lists may also play a role in low utilization[16]

Health Care Leaders/Clinic

- The short supply of genetic counselors has also been a concern[16]
  - It is not known whether patients are seeking and failing to find genetic counselors[16]
- Tailoring to patient population (resource distribution and access)[16]

Provider

- Limited physician knowledge of and compliance with practice guidelines may result in too few recommendations for testing[16]
- Inconsistent identification of high-risk patients[16]
- Inadequate communication with genetic professionals[16]
- Implicit or explicit bias leads to a lack of endorsement of testing to patients even when the provider knows about testing and its benefits[17]

Patient

- Beyond barriers affecting access to testing, some patients may have refused genetic testing when it was offered due to[16]
  - Limited knowledge of hereditary cancer testing
  - Lack of awareness of testing implications in BC diagnosis
  - Perceived costs
- Testing utilization depends on patients' personal preferences or beliefs[16]
- Patients may refuse testing based on historical injustices in health care and medical research[16]
- Patients fear that genetic risk information may be used by an insurer or employer to discriminate against them[16]
- Genetic counseling is a strongly recommended component of the genetic testing process[16]
  - Genetic testing typically requires an additional appointment for the patient — an opportunity to be lost to follow-up[16]

HMO, health maintenance organization.

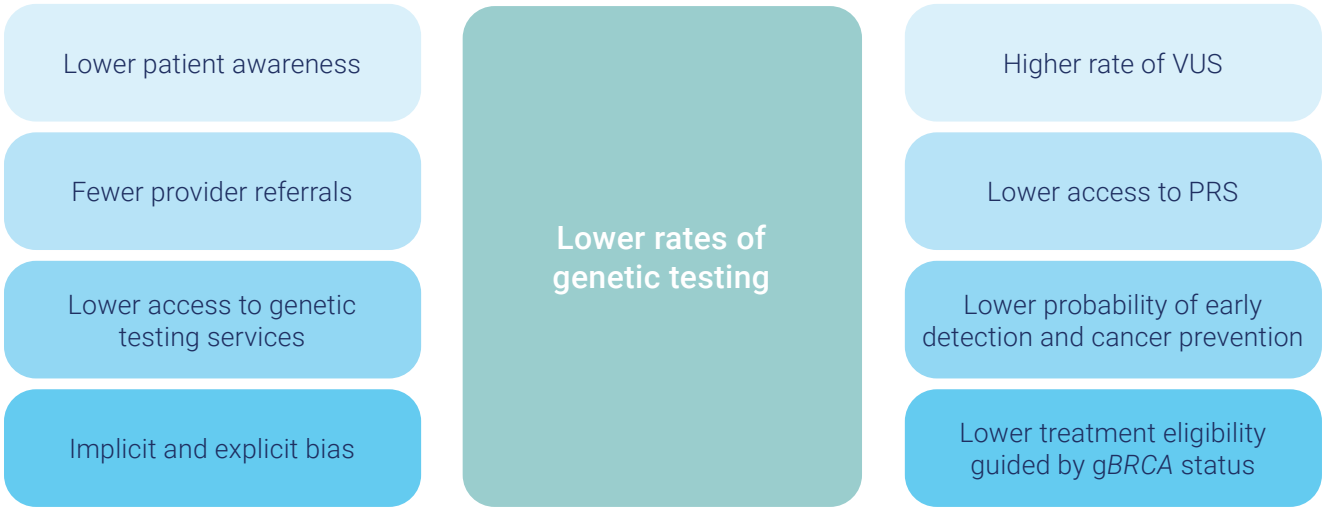
Testing Disparities Observed by Specific Groups

Racial Disparities in BC Testing

Patient-level factors, as well as provider-/system-level factors, contribute to low level of testing among minority patients.[12]

- Despite improved access to genetic services, racial disparities in genetic testing rates persist[12]
- Perceptions that racial discrimination is top of mind can be particularly concerning for Black patients, as that perception may generate a negative attitude toward genetic testing resulting in an underutilization of testing services[12]
- In addition to patient-level factors, provider-level and system-level factors contribute to lower genetic testing rates among Black people[12]
- Minority populations may have a higher probability of being impacted by multiple factors leading to disparities in testing, including socioeconomic indicators and disparities in access to testing, among others[9]

Summary of contributing factors and impact of lower genetic testing rates among Black women[12,17]



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Advances in BC diagnosis and treatment may further widen existing BC survival disparities across racial/ethnic groups.[12]

Consequently, it remains imperative to broaden genetic testing opportunities across the entire population, to ensure that all populations have an equal opportunity to benefit from the tremendous diagnostic and therapeutic advances.[12]

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BRCA, breast cancer gene; g*BRCA*, genomic *BRCA1/2* test; PRS, polygenic risk score; VUS, variant of uncertain significance.

Socioeconomic Inequities in BC Testing

Several socioeconomic factors, such as family income, food insecurity, neighborhood-level poverty, and proximity to clinics/hospitals, contribute to inequities in BC testing.

Socioeconomic indicators at the individual and neighborhood levels are related to low BC screening. Renting a home, food insecurity, and overcrowding were significantly associated with lower BC screening rates.[18]

- Renting versus owning a home was examined as a marker of financial insecurity, which is often associated with lower income levels, food insecurity, overcrowding, and poorer health outcomes

For many individuals and families, after basic needs have been paid for, there are insufficient funds remaining for non-urgent health expenses, such as preventive cancer screenings, which has the pernicious effect of later staging or higher acuity of illness at diagnosis.[19]

Family income variables may also reflect education-related differences in understanding of genetics and/or willingness to undergo genetic testing.[16]

Neighborhood-level median household income and neighborhood-level poverty were significantly associated with barriers to BC screening, which may be due to limited access to care and resources supporting good health and preventive services.[18]

Geographical proximity to clinics/hospitals offering testing and access to specialists.[20,21]

Patients living in rural areas often experience negative impacts of poor socioeconomic determinants of health.[22]

The fundamental aim in both high- and low-SES groups is to downstage cancer diagnosis to improve mortality rates and the cost of treatment.[16,23]

Increasing health insurance coverage is associated with statistically significant and clinically relevant improvements for low-income adults, including access to care, use of preventive services, and self-reported health.[1]

Utilization of a mobile BC screening unit to bring BC screening to low-SES, underserved communities and housing developments, while also partnering with food bank services to address food insecurity can help to mitigate disparities.[18]

PULSE CHECK

- [ ] Have I ensured that the patient understands the information I've shared?
- [ ] Have I considered any socioeconomic factors that may impair the patient's ability to understand or follow through with testing requirements?

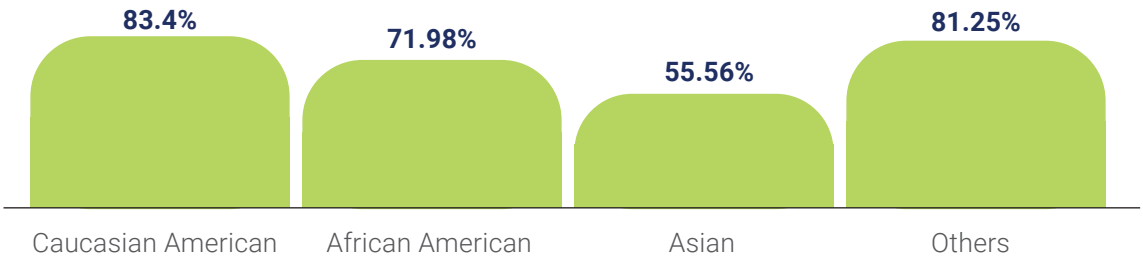
Disparities Observed by Specific Test Type

Disparities should be considered when utilizing **specific types of BC tests** at certain stages during a patient's disease progression.

Gene Expression Profiling (GEP) Testing

- In **eBC**, molecular prognostic indicator tests — GEP tests (such as 21-gene assay) — have been introduced to provide additional predictive and prognostic information beyond that provided by histopathologic variables, so that chemotherapy might be avoided without increasing the risk of recurrent disease[24,25]
- The National Comprehensive Cancer Network® (NCCN®) and ASCO recommend GEP for certain patients with HR+, HER2- eBC[25,26]
- Despite established clinical utility, there are lower GEP testing rates in certain patient populations, specifically[13,27]:
  - Black, Asian American, and Hispanic women
  - Patients with lower SES
  - Patients in rural areas

Percentages of Patients Who Receive GEP Testing[14]



- Studies have shown GEP assay uptake can vary by patients' SES[24]
  - A 6% lower prevalence of Oncotype DX® use among patients residing in low-SES areas than among those residing in higher-status areas[24]
  - Among patients with low and median Oncotype DX® assay recurrence scores, those who underwent testing in high-SES areas were 28% less likely to receive adjuvant chemotherapy compared with 21% for those in low-SES areas, suggesting that, even among those receiving testing, there were additional barriers to appropriate care[24]

Barriers to GEP Testing

Resources for Providers[13]	Insurance Coverage[13,24]	Patient Preferences[28]	Patient-Provider Communication[29]
Hospitals without multidisciplinary services (including multidisciplinary tumor boards [MTBs]) may be less likely to offer GEP testing	Out-of-pocket testing costs may be prohibitive for some patients Patients with Medicaid are less likely to receive testing	Patients may refuse testing, which may be related to concerns about chemotherapy	Providers may not have sufficient time to explain the importance of testing

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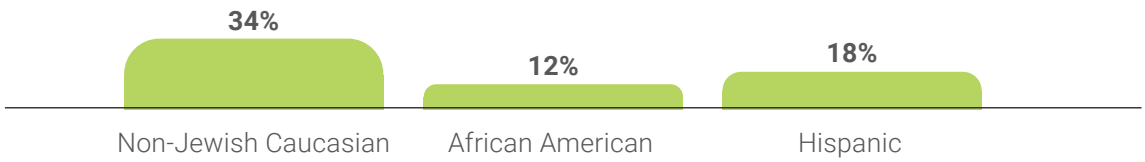
ASCO, American Society of Clinical Oncology.

Germline Testing

- In **mBC**, germline testing supports more accurate risk evaluation to inform screening and risk-reducing medical and surgical strategies[30]
- NCCN recommends germline testing for *BRCA1/2* for any BC subtype[25]
- Despite established clinical utility, there are lower *BRCA1/2* testing rates in certain patient populations, specifically[16]:
  - Black and Hispanic women
  - Patients enrolled in HMOs
  - Low-income families
  - Patients not receiving therapy (ie, chemotherapy, radiotherapy, hormone replacement therapy)

Percentages of Patients Who Receive *BRCA1/2* Genetic Testing[16]



- In adjusted analyses, women of Jewish ethnicity were significantly more likely to be tested, whereas Black women and Hispanic women were significantly less likely to be tested than non-Jewish White women[16]
  - This may indicate differences in barriers and motivators between populations that impact the testing rates
- The role of genetic counseling in the *BRCA1/2* testing process may prove a greater burden to low-income women, who are more likely to hold less flexible jobs and rely on public transportation, and thus may have more difficulty getting to medical appointments[16]
  - Even modest cost-sharing requirements for testing may prove sufficiently burdensome to deter testing among low-income women

Barriers to Germline Testing[16]

Provider Expertise	Enrollment in HMO	Patient Preferences	Patient Awareness and Education
Clinicians must be aware of and understand the latest evidence-based guidelines for diagnosis and care, collect and interpret family and clinical history information from the patient, and discuss possible testing with the patient and/or refer the patient for genetic counseling	HMO patients are less likely to be tested than those with POS insurance plans, which suggests that administrative barriers, such as prior authorization requirements or the use of restricted provider lists, may also play a role in low utilization	Patients' personal preferences or beliefs or fears that genetic risk information may be used by an insurer or employer to discriminate against them	Patients may have refused *BRCA1/2* testing when it was offered due to limited knowledge of hereditary cancer testing

POS, point of service.

mBC testing

- In **mBC**, predictive biomarker testing is essential for determining patient eligibility for targeted therapeutics[30]
- NCCN recommends assessment of specific biomarkers on metastatic tumor subtypes, including HR status, HER2 expression, and g*BRCA1/2* mutation status for all newly mBC subtypes; PD-L1 expression for metastatic triple-negative carcinomas; and *PIK3CA* mutation status for estrogen receptor-positive, HER2- carcinomas[25]
- In a retrospective study of patients newly diagnosed with invasive BC, a comprehensive multidisciplinary care (cMDC) program was implemented to assess the rate of genetic referrals[31]
  - The overall rate of genetic referrals was higher after implementation of cMDC
  - African American patients were less likely to comply with attending the genetics appointment than Caucasian American patients
    - When patients attended the genetics appointment, genetic testing was recommended at similar rates for African American and Caucasian American patients
    - For those for whom testing was recommended, rates of actual testing were similar for both races
  - Significantly more cMDC patients attended their appointment at the suburban location vs the urban location
    - Genetic testing was recommended at similar rates at both locations
    - For those for whom testing was recommended, rates of actual testing were similar across locations
  - The number of inappropriate referrals also increased with the implementation of cMDC, which indicates providers may require reminders or education about guideline criteria, especially as an inappropriate referral may be associated with unnecessary health care costs

Barriers to mBC Testing[31]

Inadequate Referrals	Insurance Coverage	Patient Adherence	Patient Education and Income
Lack of referral for eligible patients as seen in the non-cMDC group may have been the limiting factor for receipt of the service, as genetic services were provided once referred	Genetic referrals were more likely to be offered to patients with private than public insurance	There was no difference in the rates of genetic testing recommended or completed, suggesting that the barrier to testing most likely lies in the adherence of patients to genetic appointments	Several factors have been associated with offering genetic referral, including college education, age below 45 years, and household income >$35,000 in the year prior to diagnosis

PD-L1, programmed cell-death ligand 1; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

Additional Specific BC Testing Situations

Adoption of Ki-67 biomarker testing remains low due to variability in results, with the test also being underutilized in patients without health insurance.

Assessment of Ki-67

- Ki-67 is a biomarker associated with cellular proliferation that can be evaluated by IHC[32]
- The reliability and reproducibility of Ki-67 remain controversial, although some researchers have shown it to be valuable as a marker for prognosis and outcome[32]
- The Ki-67 biomarker has been proposed as an inexpensive alternative for making chemotherapy decisions, but its adoption among US physicians remains low due to variability in testing results[32,33]
- Disparity between Ki-67 measurements and tumor gene expression tests in patients with hormone-sensitive eBC was evaluated[33]
  - Agreement between Ki-67 and tumor gene expression tests is limited. Ki-67 values cannot accurately be used to reflect any of the molecular scores assessed[33]
  - The use of Ki-67 to determine suitability for adjuvant chemotherapy requires validation before it can replace the existing tests[33]
  - Tumor gene expression tests may prove superior to Ki-67 for the identification of patients likely to benefit from adjuvant chemotherapy[33]
- Retrospective analyses of the utilization of Ki-67 testing in a multisite study from one hospital indicated that the primary variable indicating low use of Ki-67 testing was lack of insurance. Grade 2/3 tumors at diagnosis were predictive of receiving a Ki-67 test[34]
  - Within this study overall utilization rates were low, at 22.9%

Retesting for Hormone Receptor Status Conversion

HR status may change in metastatic tissue and should be reassessed upon recurrence to inform treatment.[31]

- HR status is one of the key factors in determining the treatment of BC[35]
  - Black women with HR+ cancer have a 50% risk of death[36]
- Previous studies suggested that HR status may change in metastatic tissue[35]
- NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) suggest that tumor tissue be tested for HR and HER2 status both for de novo mBC and for cancers that have progressed from localized to mBC[25,35]
- Re-biopsy upon recurrence or progression may provide important insight into disease progression with the potential to inform subsequent treatment decisions[35]

To minimize disparities in testing in these specific situations, it is important to consider the barriers that your patients may face and address their ability and willingness to be tested. Addressing the ability of your patients to be tested up front will help provide additional information that can help guide therapeutic choices

IHC, immunohistochemistry.

Information on Inaccuracies in BC Testing in Some Subgroups

Because BC biomarker testing rates may vary in different populations, risk assessment scores of predictive or prognostic value would need to account for these disparities for a more accurate, individualized approach.

- Racial disparities in gene expression analysis score results can lead to substantial overestimation, particularly in Black patients, but there are likely to be overestimations even in Jewish women for whom the polygenic risk score is currently used[37]
  - Current evidence suggests that an agnostic application of a White European *BRCA* expression baseline to those outside this population is likely to erroneously exaggerate the risks[37]
- Tumor genomic testing is important in informing treatment decisions to reduce racial survival disparities among Black women with BC[38-40]
  - Genomic tests such as 21-gene recurrence score (RS) assay have been shown to underestimate risk in Black women with BC
    - Despite similar RS results, Black women had worse clinical outcomes compared with White women
  - More recent genomic tests (MammaPrint®, BluePrint®) and classification highlight racial disparities in the distribution of distinct high-risk molecular subtypes among HR+, HER2- eBC

Impact of Testing Disparities[29,41]

Understanding disparities of care in BC testing is essential to identify barriers that decrease biomarker testing utilization in different populations.

Individual-, provider-, clinic-, and societal-level barriers have been shown to undermine the potential impact of genetic testing on BC care.

Barriers to biomarker testing not only affect individual health care choices but also can have broader system impact. Patients who are not evaluated for biomarkers may never contribute to clinical trials and thereby limit understanding of new therapies and perpetuate biases through unrepresentative clinical trial populations.

There is a need to address barriers across multiple levels (patient, provider, clinic, system) and at multiple stages in the testing process (identification, referral, counseling, and testing).

Approaches and Actions to Reduce Testing and Care Disparities

A multilevel approach is needed to address the numerous disparities in BC care.[24]

Approaches Addressing Barriers to BC Testing

Health Care System[24,29]

Genetic testing opportunities should be enhanced across the entire population to ensure that all benefit from them.

A comprehensive, population-based, and standardized model that considers and balances challenges at each level and can be adapted to unique health care systems is critical to overcoming this problem on a large scale.

Health insurance coverage should be expanded to reduce racial/ethnic disparities and SES inequities.

Clinical Research[24]

Understanding disparities of care in different populations is important to identify possible reasons for reduced enrollment opportunities in clinical trials.

Ensure inclusion of underrepresented populations in clinical research so that results more clearly represent the population at large.

Diversity, Equity, and Inclusion[24,28]

Recognize the effects of barriers to testing and optimal care for historically underserved patient populations.

Additionally, reevaluate and validate BC biomarker tests within minority populations to ensure that test discrepancies do not lead to inappropriate therapy.

Provider Knowledge and Expertise[16]

Clinicians must be aware of and understand the latest evidence-based guidelines for diagnosis and care.

Clinicians should collect and interpret family and clinical history information from the patient and be able to discuss possible testing approaches while fully addressing any concerns the patient may have.

Patient Education and Awareness[29,42,43]

Enhance patient-provider communication and discuss both testing and therapeutic strategies with your patients so they are willing and able to both undergo biomarker testing and follow the optimal therapeutic strategy on which you agree.

For BC screening strategies, work with primary care providers to encourage screening and consider inclusion of a genetic counselor or health navigator in the genetic testing process.

The overall aim in addressing the disparities in BC care is to increase appropriate utilization of BC biomarker testing and improve overall patient outcomes.

Notes

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Summary

Disparities in BC care may markedly affect testing rates and therapeutic decisions for patients with BC with the same stage of disease.

- This results in disparities in BC health outcomes, as reported across different population groups (ie, race and ethnicity, SES, geography)

Disparities in biomarker testing between populations have been observed that may contribute to disparities in care and outcomes.

Underserved population groups may have encountered multilevel barriers to biomarker testing that result in a decline in test utilization.

A multilevel approach is needed to address the numerous disparities of care related to BC, with an aim to increase appropriate utilization of BC biomarker testing and improve overall patient outcomes.

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