Disparities in screening and diagnosis for triple negative breast cancer

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Foreword

The "Disparities in Screening and Diagnosis for Triple Negative Breast Cancer" paper, co-authored by CRA and Tigerlily Foundation, was made possible through funding provided by Gilead Sciences, Inc. As a leading biopharmaceutical company, Gilead recognizes the importance of supporting efforts that eliminate health care inequities and promote social justice. Since TNBC disproportionately affects minority communities and is diagnosed more frequently in younger women and women of color, Gilead believes it is critically important to understand and then work to address barriers to screening and diagnosis faced by women with TNBC.

Executive Summary

Charles River Associates (CRA) and Tigerlily Foundation (Tigerlily) examine the extent to which policies associated with triple negative breast cancer (TNBC) screening and diagnosis can exacerbate or ameliorate disparities in TNBC health outcomes among underserved populations in the United States (US).[1] In particular, the objective was to

- Describe evidence of the impact that social determinants of health and differences in access to screening and diagnosis have on TNBC patients' survival and
- Highlight how health policies in the US can support patient access to timely screening and diagnosis.

To do this, CRA conducted a comprehensive literature review of the TNBC policy landscape, which was enhanced by integrating insights from patient advocacy group, Tigerlily Foundation, to capture the real-world patient perspective and experience. Together, CRA and Tigerlily evaluated the extent to which screening and diagnosis policies and programs for TNBC patients support the needs of underserved populations and reduce health disparities and inequities (HDI). The report was conducted for and funded by Gilead Sciences (Gilead).

We focused on federal, state, and community-level policies and programs. The analysis covered six states—California (CA), Georgia (GA), Louisiana (LA), Massachusetts (MA), Michigan (MI), Pennsylvania (PA)—and included additional states with constructive policy examples. The states of focus were selected based on their high level of breast cancer incidence among Black women, whether they are considered a key leader in policy action, and to ensure regional representation across the US.

Our findings

Breast cancer is the most common cancer in the US and the most frequent cancer among women. Of these diagnoses, approximately 10%–20% of breast cancers are diagnosed as the triple negative subtype (TNBC).[2] The majority of TNBC cases occur in younger women under the age of 60. The relative incidence of the TNBC subtype is higher among racially diverse groups, and particularly Black women, and these groups are diagnosed at later stages of the disease more often than white women. The difference in the relative incidence of the TNBC subtype may be partly attributable to biological factors resulting from racial differences, such as tumor heterogeneity and gene expression. However, differences in socioeconomic status and social determinants of health can lead to differences in comorbidities such as obesity and diabetes, which, alone and in interaction with biological risk factors, may also affect the prevalence and trajectory of TNBC in Black, Hispanic, and low-income women.

[1] Terms commonly used in this paper are defined in the Appendix.

[2] Breastcancer.org. (2021, August). *Triple-negative breast cancer*. https://www.breastcancer.org/symptoms/types/triple-negative

Supporting access to screening and preventative measures

We find little recognition of the impact of HDI on TNBC patients. Policy debate and specific policies to mitigate this burden are limited. Based on the evidence gathered in this study, including the perspective of patients, we find that a lack of targeted mammography screening and genetic guidance can lead to missed opportunities to identify patients at high risk of TNBC. This disadvantages non-white patients, who are at higher risk of being diagnosed with TNBC but less likely to be invited to mammography or MRI screening or referred for genetic testing. Policies that rely on patient self-advocacy, such as breast density reporting, perpetuate disparities because factors such as institutional racism in the healthcare system and low educational attainment make patients less able to effectively advocate for themselves.[3]

We find evidence that several genetic testing referral tools are available for use by healthcare providers (HCPs) to assess patient risk for breast cancer. However, most tools focus on family background rather than patient demographics, and the lack of available data for certain minority populations makes even tools that do incorporate demographic factors less able to accurately assess their risk. Overall, we find inconsistency in targeted efforts and strategies to educate HCPs to eliminate bias and improve access to screening and genetic testing, and only one such effort in the states we assessed is specific to the TNBC subtype. Medical mistrust and low levels of patient efficacy exacerbate poor outcomes resulting from physician bias.

Finally, while progress has been made in creating screening programs for underinsured and uninsured women, significant gaps in access are caused by differences in coverage and affordability between private and public health plans. These differences are especially important for screening beyond general mammography, such as MRI or genetic testing, which are particularly important for detecting or preventing TNBC.

Ensuring timely TNBC diagnosis

Clear disparities in age of, time to, and stage of diagnosis exist between racial and ethnic groups in TNBC. Clinical guidelines to support TNBC diagnosis exist but contain little reference to high-risk populations such as racial and ethnic groups. The commitment of some state comprehensive cancer control (CCC) plans to reducing late-stage diagnosis of TNBC has the potential to target underserved populations.

We find that financial barriers to obtaining a TNBC diagnosis remain significant due to discrepancies in diagnostic coverage across states. The cost to patients of additional diagnostic imaging and biopsies varies greatly, depending on the type of imaging or procedure required. Policies that limit patient out-of-pocket costs for such procedures would help to lower barriers to patients investigating suspicious screening outcomes.

Access to breast cancer data by subtype to guide policy decisions and assess outcomes disparities is critical, especially given the difference in the relative incidence of subtypes across races. While federal law requires agencies such as the CDC to collect population-based cancer data, breast cancer subtypes, such as TNBC, are not reported. Further, cancer registries do not collect individual-level socioeconomic data, and academic studies have found evidence of racial misclassification. State-level CCC plan objectives, such as in Louisiana, encourage the analysis of cancer data to inform policy initiatives and reveal insights into racial differences. However, we find that many states have fallen behind in collecting the appropriate level of detailed data in their registries, which limits the extent to which policy action can be informed.

[3] American Academy of Family Physicians (AAFP). (2019, July). *Institutional Racism in the Health Care System*. https://www.aafp.org/about/policies/all/institutional-racism.html

Policy tools and implications

We find several opportunities for policy to close the disparities in TNBC outcomes and improve overall patient survival:

1. State CCC plans could foster more policy action targeting TNBC patient needs

State CCC plans provide a critical framework to develop policies and programs. However, a comparison of strategies set out in these plans (Executive Summary Table 1) reveals that states differ in how they prioritize access to screening measures to support TNBC diagnosis. Overall, states have clear strategies for general breast cancer screening, usually through mammography. However, policy objectives targeting young women, screening beyond general mammography (e.g., MRI), and TNBC-specific rates are limited.

Executive Summary Table 1: Summary of state CCC breast cancer strategies specific to screening and diagnosis

State CCC Breast cancer strategies	CA[4]	GA	LA	MA	PA	MI
	2011-15	2014-19	2017-21	2017-21	2019-23	2021-30
Targets for increased screening rates	✓	✓	✓	✓	✓	✓
Provision of screening programs	✗	✓	✓	✗	✓	✗
Improved screening of racially diverse[5] groups	✗	✓	✗	✓	✓	✓
Improved screening of young women (<40)	✗	✓	✗	✗	✗	✗
Additional screening imaging (e.g., MRI)	✗	✗	✗	✗	✗	✗
Targets specific to the TNBC subtype	✗	✗	✗	✗	✗	✓
Testing for genetic mutations/HBOC	✗	✓	✗	✗	✓	✓
Screening education for HCPs	✗	✓	✓	✓	✓	✓
Patient education or support	✗	✓	✓	✓	✓	✓
Provision of community patient navigation services early in patient journey	✓	✗	✓	✓	✓	✓
Targets for early diagnosis of racially diverse[6] groups	✗	✗	✓	✓	✗	✓
Lowering of coverage and cost barriers	✓	✓	✓	✗	✓	✓
Data collection to inform resource allocation	✗	✗	✓	✓	✗	✓

4 While the state CCC plan for California outlines cancer disparities among racially diverse groups in the state, the plan does not outline strategies or targets to specifically reduce these disparities.

5 *Racially diverse* indicates focus on Black, Hispanic, Native American, or Asian populations and is shorthand for ethnically diverse populations as well.

6 *Racially diverse* indicates focus on Black, Hispanic, Native American, or Asian populations and is shorthand for ethnically diverse populations as well.

Specifically, state CCCs should:

- Set screening objectives and targets specific to TNBC
- Set objectives to expand access to genomic testing
- Set objectives to target TNBC screening among diverse populations and younger women who are at greater risk for TNBC compared to other breast cancer subtypes
- Recommend the development of outcome measures and performance indicators for screening and diagnosis
- Recommend development of practice-policy communication loops to examine state and local policies that evaluate screening and follow-up with the aim of reducing the financial burden on community-based organizations and safety net hospitals[7]

2. Clinical guidelines and provider tools could support equitable access to genetic and genomic testing

Based on evidence and patient advocate insight regarding support areas that would most benefit patients' screening, genetic and genomic testing, the following areas are critical in improvement disparities in TNBC survival:

- The development of culturally and linguistically tailored patient education is necessary to support patient awareness of screening and genetic and genomic testing.
- Current screening guidelines (such as the United States Preventative Services Task Force (USPSTF)) do not reflect the existence of underserved populations or those at high risk for TNBC. Population-level screening efforts should be paired with tailored risk assessment tools and screening recommendations aligned to risk levels.
- Clinical guidelines should be updated to support evidence-based risk assessment and referral of patients for genetic counselling and testing. In addition, states should recommend genetic testing beyond BRCA 1 and BRCA 2 genes, since genomic testing can provide insights into the genetic underpinnings of TNBC.
- Centers for Medicare & Medicaid Services (CMS) could encourage the development of screening tools and offer improved HCP education opportunities to support the consideration of social determinants of health in screening referrals and follow-up care.
- Initiatives should be supported with opportunities for provider education on interpersonal bias.
- The affordability of screening for uninsured populations and the coverage of screening measures beyond mammograms (e.g., MRI) remain significant barriers to uptake. States that have not already expanded Medicaid access should do so.

[7] Henderson, V., Tossas-Milligan, K., Martinez, E., Williams, B., Torres, P., Mannan, N., Green, L., Thompson, B., Winn, R., & Watson, K.S. (2020). Implementation of an integrated framework for a breast cancer screening and navigation program for women from underresourced communities. *Cancer*, *126*, 2481-2493. https://doi.org/10.1002/cncr.32843

3. Federal legislation and clinical guidelines could be used to reduce late TNBC diagnosis

Evidence of disparities in the age and stage of diagnosis indicates there is scope for additional policy support for TNBC testing and diagnosis:

- Clinical guidelines, such as the USPTF, should be updated to recommend tailored and culturally relevant diagnostic approaches, especially in terms of follow-up after abnormal screening results.
- States should mandate plans to cover diagnostic services that may be required for high-risk patients and limit the out-of-pocket cost burden.
- Recent bills, such as the Triple-Negative Breast Cancer Research and Education Act of 2019, could be amended to require the National Institutes of Health to support the standardized collection of diagnosis data disaggregated by indicators of typically underserved populations. Data collected should be specific to breast cancer subtypes to ensure understanding of TNBC.

Despite significant progress in the policy environment for breast cancer, we find policy advances which target TNBC patients and underserved populations are lagging. Our assessment reveals a systematic lack of consideration of the key needs of underserved populations, despite significant evidence of the greater likelihood of TNBC diagnosis and disparities in survival. TNBC-targeted policies are skewed towards increasing uptake of screening, while initiatives which aim to close disparities in referral to genetic testing and improve diagnosis following initial screening are limited.

1. Introduction

In this study, Charles River Associates (CRA) and Tigerlily Foundation (Tigerlily) examine the extent to which policies associated with triple negative breast cancer (TNBC) screening and diagnosis can exacerbate or ameliorate disparities in TNBC health outcomes among underserved populations in the United States (US).[8] The report was conducted for and funded by Gilead Sciences (Gilead).

It is hoped that the findings from this review will aim to inform how targeted policy strategies can support access to care and improve TNBC patient outcomes.

1.1 Background on TNBC in the US

Breast cancer is the most common cancer in the United States (US) and among women, with approximately 281,550 cases expected to be diagnosed in 2021.[9] Of these diagnoses, approximately 10%–12% of breast cancers are diagnosed as triple negative (TNBC), although some sources suggest an estimated 20% of breast cancers may be triple negative.[10]

Table 1: Differences in TNBC outcomes by racial group in the US (2014-18; 2019)[11]

	TNBC incidence	Breast cancer mortality	% breast cancer diagnosed as TNBC subtype	TNBC diagnosis stage (per 100,000; % of all stages)		
	per 100,000			Localized	Regional	Distant
Non-Hispanic white women	12.2	20.3	10%	7.1 (64%)	3.3 (30%)	0.7 (6%%)
Black women (includes Hispanic)	22.8	28.4	21%	12.2 (56%)	7.9 (36%)	1.8 (8%)
Black-white gap	-10.6	-8.1	-11%	- 5.1 12%	-4.6 (-6%)	-1.1 (-2%)
Hispanic women	11.0	14.0	12%	6.0 (57%)	3.7 (35%)	0.8 (8%)
Hispanic-white gap	1.2	6.3	-2%	1.1 (7%)	0.4 (-5%)	-0.1 (-2%)

As Table 1 demonstrates, Black women are twice as likely to be diagnosed with TNBC as non-Hispanic white women (21% versus 10% of breast cancer diagnoses are the TNBC subtype), and Hispanic women are also diagnosed with the TNBC subtype more often than white women (12% vs. 10%).[12] Some of these differences in the relative incidence of the TNBC subtype may be attributed to biological factors resulting from racial differences, such as tumor heterogeneity and gene expression.[13] However, as Figure 1 demonstrates, socioeconomic disparities such as education, poverty, employment, neighborhoods that are unsafe can

8 Terms commonly used in this paper are defined in the Appendix.

9 National Cancer Institute Surveillance, Epidemiology, and End Results Program. (2021). *Cancer stat facts: Female breast cancer.* https://seer.cancer.gov/statfacts/html/breast.html

10 Breastcancer.org. (2021, August). *Triple-negative breast cancer.* https://www.breastcancer.org/symptoms/types/triple-negative

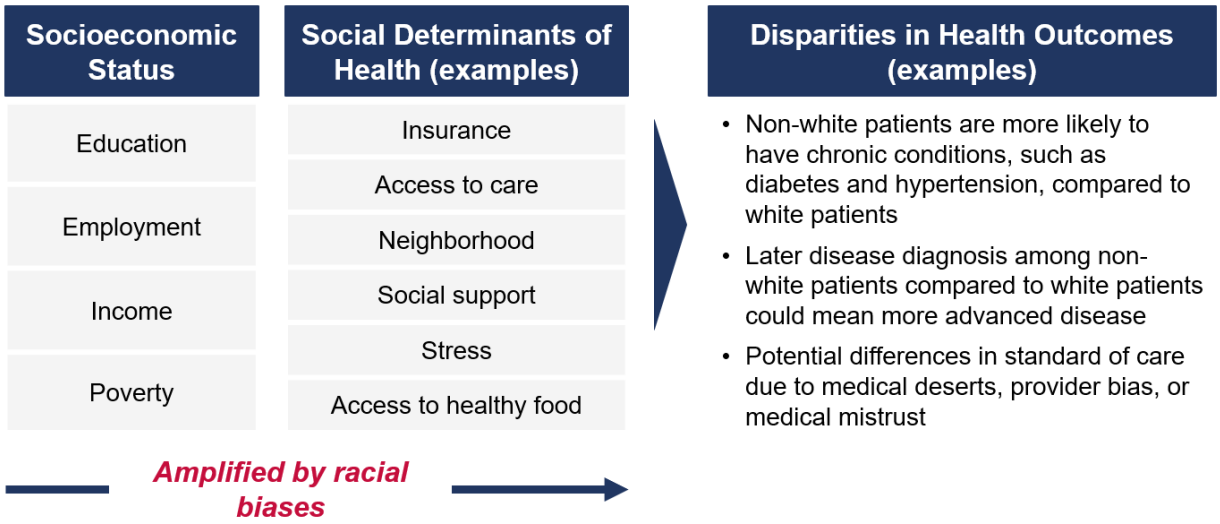
11 American Cancer Society. (2019). *Breast cancer facts & figures 2019-2020.* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf**;** NCI SEER 2014-2018. Retrieved October 21, 2021, from https://seer.cancer.gov/explorer/application.html?site=55&data_type=1&graph_type=2&compareBy=race&chk_race_5=5&chk_race_4=4&chk_race_3=3&chk_race_6=6&chk_race_2=2&rate_type=2&sex=3&age_range=1&stage=101&advopt_precision=1&advopt_show_ci=on&advopt_display=2

12 American Cancer Society. (2019). *Breast cancer facts & figures 2019–2020.* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf

13 Prakash, O., Hossain, F., Danos, D., Lassak, A., Scribner, R., & Miele, L. (2020). Racial disparities in triple negative breast cancer: A review of the role of biologic and non-biologic factors. *Frontiers in Public Health*, *8*, 576964. https://doi.org/10.3389/fpubh.2020.576964

contribute to the social determinants of health, such as healthy living support, access to care, social support, and insurance. In turn, the social determinants of health can lead to differences in comorbidities such as obesity and diabetes, which, alone and in interaction with biological risk factors, may also affect the prevalence and trajectory of TNBC in Black, Hispanic, and low-income women.[14,15]

Figure 1: Interaction of socioeconomic status, social determinants of health, and racial biases affecting health outcomes[16]



Outcomes for breast cancer patients have significantly improved due to medical research and access to innovative medicine, some of which has been driven by policy change and vocal patient advocacy groups. Nevertheless, TNBC, which is aggressive, is more likely to develop into more severe stages of disease and more likely to recur following treatment than other subtypes of breast cancer.[17] Early detection and diagnosis of TNBC are thus critical to patients' survival.

1.2 Diagnosis of TNBC in the US

Breast cancer is diagnosed as TNBC when there is an identified lack of receptors for estrogen, progesterone, and human epidermal growth factor (HER2), which are typically found in breast cancer.[18] TNBC is typically more aggressive, and, because it lacks these three receptors, fewer treatment options are available to target and kill the cancer cells.[19,20] TNBC is also more difficult to detect because it tends to lack features that are

[14] Prakash, O., Hossain, F., Danos, D., Lassak, A., Scribner, R., & Miele, L. (2020). Racial disparities in triple negative breast cancer: A review of the role of biologic and non-biologic factors. *Frontiers in Public Health*, *8*, 576964. https://doi.org/10.3389/fpubh.2020.576964

[15] Rey-Vargas, L., Sanabria-Salas, C. M., Fejerman, L., & Serrano-Gómez, S. J. (2019). Risk factors for triple-negative breast cancer among Latina women. *Cancer Epidemiology, Biomarkers & Prevention*, *28*(11) 1771–1783. https://cebp.aacrjournals.org/content/28/11/1771

[16] Norton, J.M., Moxey-Mims, M.M., Eggers, P.W., Narva, A.S., Star, R.A, Kimmel, P.L., Rodgers, G.P. (2016). Social determinants of racial disparities in CKD. *JASN*, 27 (9) 2576-2595. https://jasn.asnjournals.org/content/27/9/2576

[17] American Cancer Society. (2021, January). *Triple-negative breast cancer*. https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html

[18] Breastcancer.org. (2021, May). *Triple-negative breast cancer deadlier for Black women, partially due to lower surgery, chemotherapy rates*. https://www.breastcancer.org/research-news/triple-negative-breast-cancer-deadlier-for-black-women

[19] Centers for Disease Control and Prevention. (2021, September). *Triple-negative breast cancer*. https://www.cdc.gov/cancer/breast/triple-negative.htm

[20] Breastcancer.org. (2021, May). *Triple-negative breast cancer deadlier for Black women, partially due to lower surgery, chemotherapy rates*. https://www.breastcancer.org/research-news/triple-negative-breast-cancer-deadlier-for-black-women

detected through mammography, such as irregular mass shape, spiculated margins, and associated suspicious calcifications.[21] MRI screening has been found to consistently and more accurately detect abnormalities associated with the TNBC subtype.[22] After screening and diagnostic imaging, TNBC is confirmed through a biopsy analysis demonstrating that the tumor cells lack estrogen and progesterone receptors and produce little HER2 protein.[23]

There are several biological and nonbiological risk factors for TNBC. In contrast to other breast cancer subtypes, the majority of TNBC cases occur in younger women under the age of 60. Evidence suggests that women under the age of 40 are nearly twice as likely to be diagnosed with TNBC than women aged 50-64.[24] Testing positive for the BRCA1 or BRCA2 also increases the risk of TNBC; indeed, 60%–80% of TNBC tumors are associated with a BRCA1 mutation carrier.[25,26,27]

Research suggests that disparities in screening and diagnosis for breast cancer lead to worse outcomes in these at-risk population groups. As Table 1 demonstrates, Black and Hispanic women are not only at higher risk for TNBC compared to non-Hispanic white women, they also tend to be diagnosed more often at later regional and distant stages of the disease, when treatment is less likely to be effective. Black women have the lowest survival rate at each stage of diagnosis, and Hispanic women have a higher risk of mortality from TNBC compared to non-Hispanic white women.[28,29] While breast cancer mortality rates have been declining for older women aged 40–79 years, mortality rates for breast cancer in younger women below the age of 40 are rising, likely due to the rapid increase in late, distant-stage (the cancer has spread to "distant" parts of the body) diagnosis for this younger patient group.[30]

[21] Dogan, B. E. & Turnbull, L. W. (2012). Imaging of triple-negative breast cancer. *Annals of Oncology: Official Journal of the European Society for Medical Oncology*, *23* Suppl 6, vi23–vi29. https://doi.org/10.1093/annonc/mds191

[22] Dogan, B. E. & Turnbull, L. W. (2012). Imaging of triple-negative breast cancer. *Annals of Oncology: Official Journal of the European Society for Medical Oncology*, *23* Suppl 6, vi23–vi29. https://doi.org/10.1093/annonc/mds191

[23] American Cancer Society. (2021, January). *Triple-negative breast cancer*. https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html

[24] Scott, L.C., Mobley, L.R., Kuo, T.-M. and Il'yasova, D. (2019). Update on triple-negative breast cancer disparities for the United States: A population-based study from the United States Cancer Statistics database, 2010 through 2014. *Cancer*, 125: 3412-3417. https://doi.org/10.1002/cncr.32207

[25] Couch, F. J., Hart, S. N., Sharma, P., Toland, A. E., Wang, X., Miron, P., Olson, J. E., Godwin, A. K., Pankratz, V. S., Olswold, C., Slettedahl, S., Hallberg, E., Guidugli, L., Davila, J. I., Beckmann, M. W., Janni, W., Rack, B., Ekici, A. B., Slamon, D. J., Konstantopoulou, I., … Fasching, P. A. (2015). Inherited mutations in 17 breast cancer susceptibility genes among a large triple-negative breast cancer cohort unselected for family history of breast cancer. *Journal of Clinical Oncology*, *33*(4), 304–311. https://doi.org/10.1200/JCO.2014.57.1414

[26] Penn Medicine. *Triple-negative breast cancer risks and prevention*. Retrieved October 21, 2021, from https://www.pennmedicine.org/cancer/types-of-cancer/breast-cancer/types-of-breast-cancer/triplenegative-breast-cancer/triplenegative-breast-cancer-risk-prevention

[27] Penn Medicine. *Triple-negative breast cancer risks and prevention*. Retrieved October 21, 2021, from https://www.pennmedicine.org/cancer/types-of-cancer/breast-cancer/types-of-breast-cancer/triplenegative-breast-cancer/triplenegative-breast-cancer-risk-prevention

[28] Breastcancer.org. (2021, May). *Triple-negative breast cancer deadlier for Black women, partially due to lower surgery, chemotherapy rates.* https://www.breastcancer.org/research-news/triple-negative-breast-cancer-deadlier-for-black-women

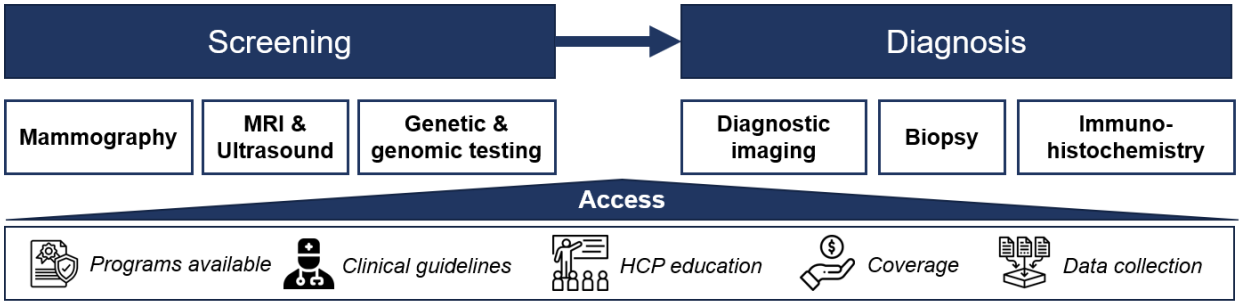
[29] Rey-Vargas, L., Sanabria-Salas, M. C., Fejerman, L., & Serrano-Gómez, S. J. (2019). Risk factors for triple-negative breast cancer among Latina women. *Cancer Epidemiology, Biomarkers & Prevention*, *28*(11), 1771-1783. https://cebp.aacrjournals.org/content/28/11/1771

[30] Hendrick, R. E., Helvie, M. A., & Monticciolo, D. L. (2021). Breast cancer mortality rates have stopped declining in US women younger than 40 years. *Radiology*. *299*(1), 143–149. https://doi.org/10.1148/radiol.2021203476

1.3 Our approach to addressing the question

For this policy analysis, we assessed the current policy landscape using official policy documents and academic research. Key policy components were identified and aligned to the TNBC patient journey. We focused on early phases of the TNBC patient journey—screening and diagnosis (Figure 2).

Figure 2: Patient journey and access in TNBC screening and diagnosis



Source: CRA analysis

In order to evaluate the extent to which screening and diagnosis policies and programs for TNBC patients support the needs of underserved populations and reduce health disparities and inequities (HDI) we conducted a comprehensive search of academic literature, government reports, online newspaper articles, blogs, patient advocacy group websites, and medical association publications published. Our search terms included "triple negative breast cancer," "oncology," "legislation," "policy," and "program." To identify documents with details specific to each component of the screening and diagnosis patient journey, we used additional relevant terms, such as "screening," "genetic testing," "genetic counselling," "genomic testing," and "diagnosis." Finally, to identify the extent to which policies affect HDI, we combined the terms listed above with search terms such as "disparity," "inequity," "systemic racism," and terms relevant to our key populations such as "Black" and "Hispanic." The review focused on examining research published in the last 10 years covering both peer-reviewed journals and the grey literature. To ensure that the policy landscape assessment captured the real-world patient perspective, we integrated insights from Tigerlily, a patient advocacy organization with a mission to educate, advocate for, empower, and support young women before, during, and after breast cancer.

We focused on federal, state, and community-level policies and programs. The analysis covered six states—California (CA), Georgia (GA), Louisiana (LA), Massachusetts (MA), Michigan (MI), and Pennsylvania (PA)—and included additional states with informative policy examples. The states of focus were selected based on their high level of breast cancer incidence among Black women, whether they were considered a key leader in policy action, and to ensure regional representation across the US.

The next chapter in this report evaluates screening through mammography, MRI, ultrasound, and genetic and genomic testing. Next, chapter 3 on diagnosis includes a discussion of diagnostic imaging, biopsy, and immunohistochemistry. Within both chapters, policies are assessed in each relevant area of the patient journey as they relate to programs available, clinical guidelines, HCP education, coverage and affordability. Within chapter 3 we also consider the role of patient registries and data collection in improving TNBC diagnosis, especially for underserved populations. Chapter 4 concludes with policy recommendations resulting from our analysis in previous chapters, and we conclude the report in chapter 5.

2. Screening and preventative measures

In this chapter we first consider the policies associated to availability of screening and genetic testing, access and then issues associated with affordability.

2.1 Overview of screening and genetic testing programs for TNBC

Mammography screening

Breast screening mammography is correlated with improvements in breast cancer survival rates through early detection.[31] For that reason, the Breast and Cervical Cancer Mortality Prevention Act of 1990 directed the CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which, as of August 2021, funds seventy grantees in all jurisdictions, including all fifty states, the District of Columbia, six US territories, and thirteen American Indian and Alaska Native tribes and tribal organizations.[32]

To support screening for mammography, many providers follow national organization recommendations and guidelines. However, there is a lack of consensus in the screening guidelines, particularly as to the recommended age for screening and the definition of high-risk groups. For example, the United States Preventive Services Task Force (USPSTF), the American Academy of Family Practice,[33] and the American College of Physicians[34] all advise that women initiate mammography screening at age 50 and may begin screening between 40 and 49 years of age, depending on individual risk factors and personal choice (although the USPSTF recently published a framework to review its guidelines that considers screening age).[35] In 2015 the Protecting Access to Lifesaving Screenings (PALS) Act was passed to halt the implementation of the USPSTF recommendations that only selectively offer mammography to women aged 40 to 49. The PALS Act ensures women in this age group—more than 22 million Americans—receive insurance coverage without cost-sharing fees for mammograms.[36] The American Society of Clinical Oncology and the American Cancer Society have also lowered their age recommendation to initiate mammography screening at 45, with the option to start at age 40.[37] Currently, there is no national guideline for screening specific to women younger than 40.[38]

In 2021, the American College of Radiology (ACR) and Society of Breast Imaging (SBI) published breast cancer screening guidelines calling for heightened screening attention for Black women, transgender

[31] Mootz, A., Arjmandi, F., Dogan, B. E., & Evans, P. (2020). Health care disparities in breast cancer: The economics of access to screening, diagnosis, and treatment, *Journal of Breast Imaging*, *2*(6). https://doi.org/10.1093/jbi/wbaa093

[32] CDC. (2021, August). *National breast and cervical cancer early detection program*. https://www.cdc.gov/cancer/nbccedp/about.htm

[33] Khan, M., & Chollet, A. (2021). Breast cancer screening: Common questions and answers. *American Family Physician*, *103*(1), 33-41. https://www.aafp.org/afp/2021/0101/p33.html

[34] Qaseem, A., Lin, J. S., Mustafa, R. A., et al. (2019). Screening for breast cancer in average-risk women: A guidance statement from the American College of Physicians. *Annals of Internal Medine*, *170*, 547–560. https://www.acpjournals.org/doi/10.7326/m18-2147

[35] US Preventative Services Task Force. (2021, May). *Screening for breast cancer*. https://www.uspreventiveservicestaskforce.org/uspstf/document/final-research-plan/breast-cancer-screening1

[36] Bright Pink. (2015, December) *PALS Act*. https://www.brightpink.org/blog/tag/pals-act/; Tigerlily Foundation. (2015, January). *Breast Screening Advocacy Day*. https://www.tigerlilyfoundation.org/event/breast-screening-advocacy-day/; PALS Act, S.1936, 116th Congress (2019–2020). https://www.congress.gov/bill/116th-congress/senate-bill/1936?s=1&r=2

[37] American Cancer Society. (2021, August). *American Cancer Society guidelines for the early detection of cancer*. https://www.cancer.org/healthy/find-cancer-early/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html

[38] American Cancer Society. (2021, August). *American Cancer Society guidelines for the early detection of cancer*. https://www.cancer.org/healthy/find-cancer-early/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html

individuals, and other often overlooked or underserved populations.[39] Given twenty-three percent of breast cancer cases in Black women occur before the age of 50 (in white women, the figure is 16%), the failure to recommend screening before the age of 50, paired with an aggressive breast cancer subtype, may contribute to the higher rates of TNBC mortality seen in that population.[40] Recent estimates suggest that starting screening for Black women at age 40 could shrink Black-white mortality disparities by 57%.[41] The lack of consensus and guidelines for younger patients means that recommendations from primary care providers, among whom there are significant discrepancies, have a large impact on determining whether breast cancer screening occurs.[42]

MRI and ultrasound screening

TNBC is more challenging to detect mammographically than other breast cancer subtypes.[43] TNBC lacks the typical features observed mammographically to detect breast cancer, such as spiculated margins, irregular shape, and suspicious calcifications.[44] Ultrasound screening has been noted to be somewhat more sensitive to detection of TNBC; however, MRI is considered extremely sensitive for detecting TNBC and superior to both ultrasound and mammogram screening.[45] The American Cancer Society Guidelines for the Early Detection of Cancer note that "some women—because of their family history, a genetic tendency, or certain other factors—should be screened with MRIs along with mammograms." However they also report that a small number of women fall into this category.[46] Without setting out the women that this affects, this form of guidance appears confusing and can lead to inconsistencies in appropriate care based on factors such as variation in physician discretion and patient self-efficacy or advocacy.

Mammographic density is generally associated with more aggressive tumor types and ER-negative subtypes.[47] State-level policy efforts to improve screening access to MRIs are usually linked to breast density and other risk factors, such as Pennsylvania Senate Bill 595 enacted in July 2020.[48] The bill requires insurers to cover breast MRIs and ultrasounds for women with extremely dense breast tissue and other high-risk factors, such as a family or personal history of breast cancer or a genetic predisposition.[49] In Louisiana, Senate Bill 119 (June 2021) expands annual mammograms and access to supplemental MRI beginning at age 35 for

[39] Monticciolo, D. L., Malak, S. F., Friedewald, S. M., Eby, P. R., Newell, M. S., Moy, L., et. al. (2021). Breast cancer screening recommendations inclusive of all women at average risk: Update from the ACR and Society of Breast Imaging, *Journal of the American College of Radiology*, *18*(9). ISSN 1546–1440. https://doi.org/10.1016/j.jacr.2021.04.021

[40] Rebner, M., & Pai, V. R. (2020). Breast cancer screening recommendations: African American women are at a disadvantage, *Journal of Breast Imaging*, *2*(5), 416–421. https://doi.org/10.1093/jbi/wbaa067

[41] Chapman, C.H., Schechter, C.B., Cadham, C.J., et al. (2021). Identifying Equitable Screening Mammography Strategies for Black Women in the United States Using Simulation Modeling. *Ann Intern Med*, https://doi.org/10.7326/M20-6506

[42] Levy, D. E., Byfield, S. D., Comstock, C. B., Garber, J. E., Syngal, S., Crown, W. H., & Shields, A. E. (2011). Underutilization of BRCA1/2 testing to guide breast cancer treatment: black and Hispanic women particularly at risk. *Genetics in Medicine*, *13*(4), 349–355. https://doi.org/10.1097/GIM.0b013e3182091ba4

[43] Chen, Y., Susick, L., Davis, M. et al. (2020). Evaluation of triple-negative breast cancer early detection via mammography screening and outcomes in African American and white American patients. *JAMA Surg*ery. *155*(5), 440–442. https://jamanetwork.com/journals/jamasurgery/fullarticle/2761309

[44] McGarry, W. M., & Bhole, S. (2018). Triple-negative breast cancer: What crucial information can imaging add to the diagnosis, treatment and prognosis? *International Journal of Women's Health and Wellness, 5*(087). doi.org/10.23937/2474-1353/1510087

[45] McGarry, W. M., & Bhole, S. (2018). Triple-negative breast cancer: What crucial information can imaging add to the diagnosis, treatment and prognosis? *International Journal of Women's Health and Wellness*, *5*(087). doi.org/10.23937/2474-1353/1510087

[46] American Cancer Society. (2021, August). *American Cancer Society guidelines for the early detection of cancer*. https://www.cancer.org/healthy/find-cancer-early/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html

[47] Yaghjyan, L., Colditz, G. A., Collins, L. C., Schnitt, S. J., Rosner, B., Vachon, C., & Tamimi, R. M. (2011). Mammographic breast density and subsequent risk of breast cancer in postmenopausal women according to tumor characteristics. *Journal of the National Cancer Institute*, *103*(15), 1179–1189. https://doi.org/10.1093/jnci/djr225

[48] PA Breast Cancer Coalition. (2020, July). *Governor Wolf signs SB 595 for insurance coverage of breast MRI, ultrasound*. https://www.pabreastcancer.org/governorwolfsignssb595/

[49] PA Breast Cancer Coalition. (2020, July). *Governor Wolf signs SB 595 for insurance coverage of breast MRI, ultrasound*. https://www.pabreastcancer.org/governorwolfsignssb595/

high-risk women (defined as those with a predicted lifetime risk exceeding 20%). The bill also indicates that consideration will be given to supplemental imaging for women with high breast density, but this is dependent on physician recommendation.[50]

As of 2021, thirty-eight states and the District of Columbia have laws requiring some level of breast density notification after a mammogram; however, no standard across states outlines what or how patients are told about breast density.[51] To introduce a national standard, in March 2019, the FDA proposed an update to the Mammography Quality Standards Act to include a requirement for breast density reporting to both patients and health providers. This update has not yet been finalized or implemented. Furthermore, unlike the bills enacted in Pennsylvania and Louisiana, such reporting would not promote MRI screening but rather would notify the patient that breast density can influence the accuracy of mammography and advise them to talk to their healthcare provider about how density could relate to breast cancer risk.[52]

The lack of evidence-based guidelines for MRI may contribute to discrepancies in utilization, as studies have found that MRI for breast cancer screening is underutilized among high-risk women as compared to low-risk women. Low-risk (defined as <20% lifetime risk) white women are 62% more likely to receive MRI screening than non-white women with a low lifetime risk.[53] Furthermore, educational attainment can affect access to screening: research has found that high-risk women without education beyond high school are less likely to undergo MRI screening than high-risk women who graduated from college. The existing research suggests that the effect of education on screening may be mediated however by differences in patient-provided communication or patient income level.[54] However, even with high educational attainment, health literacy and disease awareness can be low, which remains a barrier to screening.[55]

Genetic testing

Genetic testing has been growing in importance since the identification of the BRCA1 and BRCA2 genes and the determination of how they can be used to identify patients who are at increased risk for TNBC.[56] State CCC plans have identified the importance of expanding access to genetic testing among underserved populations. For example, Michigan and Alabama CCC plans include objectives to increase awareness and utilization of genetic testing among Black women.[57,58]

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50 American College of Radiology. (2021, July). *Louisiana governor signs breast cancer screening bill into law.* https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-June-12-2021-Issue/Louisiana-Governor-Signs-Breast-Cancer-Screening-Bill-Into-Law

51 Dense Breast Info. (2021). *State Legislation Map*. https://densebreast-info.org/legislative-information/state-legislation-map/

52 FDA. (2019, March). *FDA advances landmark policy changes to modernize mammography services and improve their quality*. https://www.fda.gov/news-events/press-announcements/fda-advances-landmark-policy-changes-modernize-mammography-services-and-improve-their-quality

53 Haas, J. S., Hill, D. A., Wellman, R. D., Hubbard, R. A., Lee, C. I., Wernli, K. J., Stout, N. K., Tosteson, A. N., Henderson, L. M., Alford-Teaster, J. A., & Onega, T. L. (2016). Disparities in the use of screening magnetic resonance imaging of the breast in community practice by race, ethnicity, and socioeconomic status. *Cancer*, *122*(4), 611–617. https://doi.org/10.1002/cncr.29805

54 Haas, J. S., Hill, D. A., Wellman, R. D., Hubbard, R. A., Lee, C. I., Wernli, K. J., Stout, N. K., Tosteson, A. N., Henderson, L. M., Alford-Teaster, J. A., & Onega, T. L. (2016). Disparities in the use of screening magnetic resonance imaging of the breast in community practice by race, ethnicity, and socioeconomic status. *Cancer*, *122*(4), 611–617. https://doi.org/10.1002/cncr.29805

55 Oldach, B. R., & Katz, M. L. (2014). Health literacy and cancer screening: a systematic review. *Patient Education and Counseling*, *94*(2), 149–157. https://doi.org/10.1016/j.pec.2013.10.001

56 American Cancer Society. (2018, October). *Study: New genes linked with triple-negative breast cancer.* https://www.cancer.org/latest-news/study-newly-identified-genes-risk-triple-negative-breast-cancer.html

57 Michigan Department of Health & Human Services. (2021). *Cancer prevention and control section*. https://www.michigancancer.org/PDFs/CancerPlan/CancerPlan2021-2030/2020CancerPlan.pdf

58 Alabama Public Health. *Alabama cancer control plan 2016–2021*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/alabama_ccc_plan-508.pdf

Despite evidence that other genetic mutations are linked to TNBC, screening guidelines for genetic testing, including the USPSTF and National Comprehensive Cancer Network (NCCN) only recommend genetic counselling within a narrow patient population.[59] The National Comprehensive Cancer Network (NCCN) recommends genetic testing for people with a TNBC diagnosis at age 60 years or younger or those who meet criteria based on a personal or family history of cancer.[60] Both the USPSTF and the American Cancer Society (ACS) recommend genetic testing for women who are high risk and recommend that these women should first be referred to a genetic counsellor to further evaluate risk and weight the pros and cons of testing.[61]

In addition to BRCA1 and BRCA2, other genes have been specifically linked to an increased risk for TNBC: BARD1, PALB2, and RAD51D. Research has found that a woman with an inherited mutation in any one of these genes has more than a 20% lifetime risk for breast cancer—more than 8% higher than the general population.[62] However, BRCA1 and BRCA2 are the only gene mutations that clinical guidelines consider appropriate for a woman to qualify for additional MRI screening.[63]

The lack of consensus in policy supporting access to genetic testing may be a contributing factor to worse outcomes.[64] Studies indicate that Black and Hispanic women—including those with strong family histories of cancer—are much less likely than white women to receive genetic counselling or genetic testing for breast cancer.[65] For example, in a study of 100 Black women at increased risk for carrying the BRCA 1 or BRCA 2 mutation only 28% received genetic counselling and testing.[66] This is especially problematic given new research suggesting that Black women may also have a higher rate of BRCA1 or BRCA2 mutations than previously thought.[67] Furthermore, in the absence of a cancer diagnosis, compared to white women, Black women have been found to have one fifth the odds of accessing genetic counselling.[68] There are low rates for Hispanic women as well: in a sample of 1,474 commercially insured patients aged 20-40 with newly diagnosed, early-onset breast cancer cases only 30% of women received BRCA1 or BRCA2 testing.[69] Lack

[59] American Cancer Society. (2018, October). *Study: new genes linked with triple-negative breast cancer.* https://www.cancer.org/latest-news/study-newly-identified-genes-risk-triple-negative-breast-cancer.html

[60] National Comprehensive Cancer Network (NCCN). *Genetic/familial high-risk assessment: breast and ovarian.* (2019, January). https://www2.tri-kobe.org/nccn/guideline/gynecological/english/genetic_familial.pdf

[61] CDC. *Bring Your Brace Campaign - Assessing Risk in Young Patients.* (2021, September). https://www.cdc.gov/cancer/breast/young_women/bringyourbrave/health_care_provider_education/risk-assessment-management-strategies/risk-assessment.htm

[62] American Cancer Society. (2018, October). *Study: new genes linked with triple-negative breast cancer.* https://www.cancer.org/latest-news/study-newly-identified-genes-risk-triple-negative-breast-cancer.html

[63] American Cancer Society. (2018, October). *Study: new genes linked with triple-negative breast cancer.* https://www.cancer.org/latest-news/study-newly-identified-genes-risk-triple-negative-breast-cancer.html

[64] Levy, D. E., Byfield, S. D., Comstock, C. B., Garber, J. E., Syngal, S., Crown, W. H., & Shields, A. E. (2011). Underutilization of BRCA1/2 testing to guide breast cancer treatment: black and Hispanic women particularly at risk. *Genetics in Medicine*, *13*(4), 349–355. https://doi.org/10.1097/GIM.0b013e3182091ba4

[65] Armstrong, K., Micco, E., Carney, A., Stopfer, J., & Putt, M. (2005). Racial differences in the use of BRCA1/2 testing among women with a family history of breast or ovarian cancer. *JAMA*, *293*(14), 1729–1736. https://doi.org/10.1001/jama.293.14.1729

[66] Sheppard, V. B., Mays, D., LaVeist, T., & Tercyak, K. P. (2013). Medical mistrust influences Black women's level of engagement in BRCA 1/2 genetic counseling and testing. *Journal of the National Medical Association*, *105*(1), 17–22. https://doi.org/10.1016/s0027-9684(15)30081-x

[67] Fletcher, J. Medical News Today. (2021, March). *Genetic testing and treatment outcomes for women of color with breast cancer.* Medical News Today. https://www.medicalnewstoday.com/articles/genetic-testing-and-treatment-outcomes-for-women-of-color-with-mbc#Genetic-mutations-and-breast-cancer-risk-for-women-of-color

[68] Levy, D. E., Byfield, S. D., Comstock, C. B., Garber, J. E., Syngal, S., Crown, W. H., & Shields, A. E. (2011). Underutilization of BRCA1/2 testing to guide breast cancer treatment: Black and Hispanic women particularly at risk. *Genetics in Medicine*, *13*(4), 349–355. https://doi.org/10.1097/GIM.0b013e3182091ba4

[69] The same study also found lower rates of genetic testing among Black women. Levy, D. E., Byfield, S. D., Comstock, C. B., Garber, J. E., Syngal, S., Crown, W. H., & Shields, A. E. (2011). Underutilization of BRCA1/2 testing to guide breast cancer treatment: Black and Hispanic women particularly at risk. *Genetics in Medicine*, *13*(4), 349–355. https://doi.org/10.1097/GIM.0b013e3182091ba4

of guidance can lead to inconsistent genetic testing for women at high-risk of factors associated with TNBC and may contribute to worse outcomes among non-white patients.

Patients undergoing genetic testing are more likely to undergo risk-reducing surgery.[70] Addressing genetic testing disparities will become increasingly important as treatment moved towards precision medicine. Lack of guidance can lead to inconsistent genetic testing for women at high-risk of risk factors associated with TNBC may contribute to worse outcomes among non-white patients.

Differences in health literacy and educational attainment have also been found to create barriers to important screening activities and the extent to which patients consider genetic testing and information.[71] Furthermore, as these genes are inherited, disparities in access to genetic counselling and testing prevents women belonging to these groups who may also carry the gene mutation from being aware of broader risk within their family.

The issue has been identified by some states. Georgia has implemented the project, "Georgia Breast Cancer Genomics ESP: Enhancing Breast Cancer Genomics through Education Surveillance and Policy." This project addresses key populations, especially focusing on reducing the burden of breast cancer among at-risk young (between ages 18-49) and Black women. While the goal of the project is to maximize understanding and utilization of appropriate genetic assessment, the focus of this program on is only on testing for BRCA 1 and BRCA 2 mutations (rather than BARD1, PALB2, and RAD51D for example).[72]

The importance of genetic testing in early detection will only increase. Today, patients undergoing genetic testing are more likely to undergo risk-reducing surgery.[73] But understanding genetic testing disparities will become increasingly important as treatment moves towards precision medicine

Genomic testing

While genetic tests are designed to detect a single gene mutation (such as the BRCA1 and BRCA 2 mutations), genomic tests consider all of a person's genes.[74] Cancer tumor genomic assays (or tests) analyze a sample of a tumor to see how active certain genes are and how they influence each other and the person's environment. Genomic testing is especially relevant in the study of TNBC and the implications of social determinants of health, given cancers are typically caused by a combination of genetic and environmental factors. Consequently, genomic testing can offer insights into how a patients' genome might indicate TNBC risk, progression and likelihood of recurrence. Further, genomic testing can indicate relevant diagnostic methods and if chemotherapy should be a part of the treatment regimen.[75]

[70] Bayard,S., Chen, Y., Fasano, G.A., Davis, M., Walker, E.M., Bensenhaver, J.M., et al. (2021). Racial disparities in genetic testing of breast cancer patients. *Journal of Clinical Oncology*, *39*:15_Suppl, 10591-10591. https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.10591

[71] Kaphingst, K. A., Khan, E., White, K. M., Sussman, A., Guest, D., Schofield, E., et al. (2021). Effects of health literacy skills, educational attainment, and level of melanoma risk on responses to personalized genomic testing. *Patient Education and Counseling*, *104*(1). https://doi.org/10.1016/j.pec.2020.07.019

[72] Georgia Department of Public Health. *Enhancing cancer genomics practice through education, surveillance and policy.* Retrieved October 21, 2021, from http://geneticalliance.org/sites/default/files/tier1statetools/GA_breast_cancer_gen_consortium.pdf

[73] Bayard,S., Chen, Y., Fasano, G.A., Davis, M., Walker, E.M., Bensenhaver, J.M., et al. (2021). Racial disparities in genetic testing of breast cancer patients. *Journal of Clinical Oncology*, *39*:15_Suppl, 10591-10591. https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.10591

[74] National Human Genome Research Institute. (2018, September). *Genetics vs. Genomics Fact Sheet*. https://www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics

[75] Virginia Breast Cancer Foundation. (2021). *Genetic and genomic testing*. https://www.vbcf.org/genetic-and-genomic-testing/

This affects our understanding of the root causes of the disease. Several markers from genomic databases have been identified as having the potential to explain the racial and ethnic disparities.[76] In particular, genomic markers can be informative about population groups that are exposed to sociodemographic factors such as medical deserts, low income, stress, and pollution. However, the limited samples of tumors from underserved populations, insufficient details about patient and tumor characteristics in the data, and limited follow-up information on underserved populations continue to inhibit the translation of genetic knowledge into clinical benefits for all individuals.

Genomic testing for hereditary breast and ovarian cancer (HBOC) screening may be cost effective in younger women and result in a reduction of cancer cases compared to testing on the basis of family history.[77] However, USPSTF guidelines do not explicitly mention or recommend genomic testing to be considered for screening in women.[78]

Implications

The lack of targeted mammography screening and genetic guidance can lead to missed opportunities to identify patients at high risk of TNBC. This inadvertently disadvantages non-white patients who are at higher risk of being diagnosed with TNBC but are less likely to be invited to mammography or MRI screening or referred for genetic testing. Genetic testing guidelines are limited to BRCA1 and BRCA2 for TNBC. The USPSTF does not currently recommend genomic testing, despite its benefits to younger women. Furthermore, access to imaging that is better able to detect TNBC is impeded by policies that require an initial mammography demonstrating abnormalities or physician discretion. While some efforts have been made to target high-risk women, such as increased reporting of breast density, the reliance on patient self-advocacy further perpetuates disparities, as factors such as institutional racism and low educational attainment reduce the ability of patients to effectively advocate for themselves.[79, 80] These factors may contribute to the survival disparities between white and non-white TNBC patients.

[76] Smith, C. E., Fullerton, S. M., Dookeran K. A., Hampel, H. Tin, A., et al. (2016). Using genetic technologies to reduce, rather than widen health disparities. *Health Affairs*, *35*(8), 1367–1373. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1476

[77] Guzauskas, G. F., Garbett, S., Zhou, A., et al. (2020). Cost-effectiveness of population-wide genomic screening for hereditary breast and ovarian cancer in the United States. *JAMA Network Open*, *3*(10), e2022874. doi:10.1001/jamanetworkopen.2020.22874 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772341

[78] U.S. Preventive Services Task Force. (2016, January). *Breast cancer: Screening*. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#fullrecommendationstart

[79] American Academy of Family Physicians (AAFP). (2019, July). *Institutional racism in the health care system.* https://www.aafp.org/about/policies/all/institutional-racism.html

[80] Haas, J. S., Hill, D. A., Wellman, R. D., Hubbard, R. A., Lee, C. I., Wernli, K. J., Stout, N. K., Tosteson, A. N., Henderson, L. M., Alford-Teaster, J. A., & Onega, T. L. (2016). Disparities in the use of screening magnetic resonance imaging of the breast in community practice by race, ethnicity, and socioeconomic status. *Cancer*, 122(4), 611–617. https://doi.org/10.1002/cncr.29805

2.2 Programs and tools to increase access to screening and genetic testing

Healthcare providers play an important role in evaluating patient risk for breast cancer and recommending appropriate screening and testing. The CDC has risk assessment tools available on their website from several different organizations in the US that HCPs can use to assess hereditary risk for breast cancer.[81] These tools include the Breast Cancer Genetics Referral Screening Tool (B-RST), the NIH Families SHARE, and the NCI Breast Cancer Risk Assessment Tool, as well as the USPSTF's recommended tools such as the Pedigree Assessment tools.[82] Each tool is intended to support care providers in completing a risk assessment and becoming more familiar with the factors that can put their patients at risk for breast cancer. There are seven main factors considered when assessing risk for breast cancer: age, age at first period, age at the birth of a first child (or has not given birth), family history, number of past breast biopsies, number of breast biopsies showing atypical hyperplasia, and race or ethnicity.[83]

There are concerns about the degree to which these screening tools are tailored to different population groups. Screening tools for healthcare providers primarily focus on family history, although some tools, such as NCI's Breast Cancer Risk Assessment tool, include questions around patient demographics, incorporating race within an individual's risk assessment.[84] While the tool is validated for several population groups – white, Black, Hispanic, Asian, and Pacific Islander women – the NCI notes that the tool may underestimate risk in Black women with previous biopsies and Hispanic women that were not born in the US, and it lacks data on American Indian / Alaska Native women to accurately calculate their risk.[85]

Despite the many tools available for healthcare providers, evidence demonstrates an inconsistency and potential bias in physician behavior across population groups. In a study of Black women with a high risk of BRCA mutations, one third were not referred for genetic counselling and testing.[86] Physicians serving a disproportionate share of minority populations or Medicaid patients were significantly less likely to order a test for BRCA mutations or refer their patients to genetic counselling.[87] Black women also report higher levels of medical mistrust than white women and patients with higher medical mistrust are found to have lower engagement with genetic counselling and testing, even after sociodemographic factors and self-efficacy are accounted for. [88, 89] It is therefore important to educate patients, policies that focus on improving interactions

[81] CDC. (2021, September). *Assessing risk in young patients.* https://tinyurl.com/n5u2ufsy

[82] CDC. (2021, September). *Assessing risk in young patients.* https://tinyurl.com/n5u2ufsy

[83] Susan G. Komen. (2021, February). *Estimating breast cancer risk*. https://www.komen.org/breast-cancer/risk-factor/understanding-risks/gail-method/

[84] NIH National Cancer Institute. *Breast cancer risk assessment tool*. Retrieved October 21, 2021, from https://bcrisktool.cancer.gov/calculator.html

[85] NIH National Cancer Institute. *Breast cancer risk assessment tool.* Retrieved October 21, 2021, from https://bcrisktool.cancer.gov/#eq

[86] Thompson, H. S., Sussner, K., Schwartz, M. D., Edwards, T., Forman, A., Jandorf, L., Brown, K., Bovbjerg, D. H., & Valdimarsdottir, H. B. (2012). Receipt of genetic counseling recommendations among Black women at high risk for BRCA mutations. *Genetic Testing and Molecular Biomarkers*, *16*(11), 1257–1262. https://doi.org/10.1089/gtmb.2012.0114

[87] Shields, A. E., Burke, W., & Levy, D. E. (2008). Differential use of available genetic tests among primary care physicians in the United States: Results of a national survey. *Genetics in Medicine*, *10*(6), 404–414. https://doi.org/10.1097/GIM.0b013e3181770184

[88] Cuevas, A. G., O'Brien, K. & Saha, S. (2016). African American experiences in healthcare: "I always feel like I'm getting skipped over." *Health Psychology*, *35*(9), 987–995. https://doi.org/10.1037/hea0000368; Bickell, N. A., Weidmann, J., Fei, K., Lin, J. J., & Leventhal, H. (2009). Underuse of breast cancer adjuvant treatment: Patient knowledge, beliefs, and medical mistrust. *Journal of Clinical Oncology*, *27*(31), 5160–5167. https://doi.org/10.1200/JCO.2009.22.9773

[89] Sheppard, V. B., Mays, D., LaVeist, T., & Tercyak, K. P. (2013). Medical mistrust influences Black women's level of engagement in BRCA 1/2 genetic counseling and testing. *Journal of the National Medical Association*, *105*(1), 17–22. https://doi.org/10.1016/s0027-9684(15)30081-x; Sutton, A. L., He, J., Tanner, E., Edmonds, M. C., Henderson, A., Hurtado de Mendoza, A., & Sheppard, V. B. (2019). Understanding medical mistrust in Black women at risk of BRCA 1/2 mutations. *Journal of Health Disparities Research and Practice*, *12*(3), 35–47.

between patients and providers and addressing structural barriers within the healthcare system are key to reduce obstacles to screening and genetic testing for breast cancer.

Several state (CCC) plans, published under the mandate of the National CCC Program, include patient and provider education as a strategy.[90] Massachusetts's objectives include increasing the proportion shared decision-making conversations that women aged 40-49 have had with their provider around breast cancer screening. The state is also exploring statewide data collection or surveys on the occurrence of such conversations.[91] Louisiana states a strategy to "educate the public and providers on Louisiana Breast & Cervical Health program (LBCHP) eligibility policies, and services" and Georgia's strategic initiatives include carrying out "educational campaigns targeting physicians and patients regarding screening for breast and cervical cancer and HBOC (hereditary breast and ovarian cancer)." However, of the states assessed, many – including California, Pennsylvania, Georgia – have not published updates for 2021.[92] M, in a recently published update, is the only one of the six state CCC plans that explicitly refer to breast cancer subtypes, specifically TNBC in Black women.

Implications

There are several screening tools available for HCP use to assess patient risk for breast cancer. However, most tools focus on family background and less so on patient demographics; even for tools that do incorporate demographic factors, the lack of data available for certain minority populations reduces the ability for these tools to accurately assess their risk. Furthermore, while these tools are intended to educate HCPs on patient risk, the evidence suggests that they are ineffective at addressing physician bias towards screening referrals for low-income and minority groups. Medical mistrust and low levels of patient self-efficacy exacerbate poor outcomes resulting from physician bias. Across states, there is a lack of consistency in targeted efforts and strategies to educate HCPs to eliminate bias and improve access to screening and genetic testing, and of the efforts that exist only one is specific to the TNBC subtype.

2.3 Affordable access to screening measures

Uninsured women are much less likely to get mammograms than women with health insurance.[93] For example, in 2018 among women ages 50-74, only 38% of uninsured women had a mammogram in the last two years, compared with 75% of insured women.[94] Women who are under or uninsured, between the ages of 40 to 64, and at or below 250% of the Federal Poverty Level are eligible to receive coverage for breast cancer screenings through the National Breast Cancer and Cervical Early Detection Program (NBCCEDP). This program does not reach most women for whom it is intended to serve: while 10% of American women are eligible for this service, only 11% of eligible women accessed NBCCEDP funded screening.[95] While 55% of the women receiving mammograms through the program between 2003-2014 were non-white, only 16.4%, were Black, the group most at risk for TNBC. This suggests that, despite programs designed to reach low-income women such as the NBCCEDP, there are still gaps remaining in the effectiveness of such programs

[90] American Childhood Cancer Organization. (2021). *State CCC plan*. https://www.acco.org/state-comprehensive-cancer-control-plan/

[91] Massachusetts Comprehensive Cancer Prevention and Control Network. (2017, January). *Massachusetts statewide 2017–2021 cancer plan*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/massachusetts_ccc_plan-508.pdf

[92] CDC. (2021, July). *National comprehensive cancer control program*. cdc.gov/cancer/ncccp/ccc_plans.htm

[93] Susan G. Komen. (2021, October). *Comparing breast cancer screening rates among different groups in the U.S.* https://www.komen.org/breast-cancer/screening/screening-disparities/?ecid=social%3A285

[94] American Cancer Society. (2019). *Breast cancer facts and figures 2019–2020.* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf

[95] Kaiser Family Foundation. (2019, September). *Coverage of breast cancer screening and prevention services*. https://www.kff.org/womens-health-policy/fact-sheet/coverage-of-breast-cancer-screening-and-prevention-services/

to reach the at-risk and underserved population groups.[96] One reason for the poor outcomes of the NBCCEDP program is lack of funding. Cited as an already underfunded program, the US House of Representatives did not allocate any budget increases to the program in the most recent budget vote in July, 2021.[97] Without appropriate funding for these programs, wait lists are implemented and outreach to vulnerable populations living in hard-to reach areas is not possible.[98] The programs also focus primarily on screening coverage for mammography.

Access to screening programs is also differentiated by geography, as women in Black communities and rural areas tend to reside in medical deserts, which are regions with insufficient supply of healthcare, such as screening, mammography, and diagnostic imaging facilities.[99] The increased travel burden, including time and financial costs, placed on women living in such areas reduces their likelihood of engagement in screening and increases the likelihood of a later-stage diagnosis.[100] Furthermore, women living in underserved areas tend to lack insurance coverage (or even have existing medical debt), be lower-income, and have reduced knowledge of health issues.[101] Studies show that mobile mammography programs can help to support women overcome these barriers; however due to the way such services are delivered, these programs tend to have poorer patient retention and follow-up.[102, 103]

At the state level, funds from the NBCCEDP provide public coverage for mammography screening. In Louisiana, the LBCHP provides free mammograms to women aged 40 to 64 with a household income at or below 250% of the Federal Poverty who are uninsured, not covered, or unable to afford their co-pay/deductible. The LBCHP offers services in 13 centers across the state with no more than approximately 100 miles between sites of services. However, access is limited for younger women (below the age of 40), who must have breast cancer symptoms or other noticeable breast changes to be eligible. Furthermore, the program outlines that it does not pay Medicare co-pays and that women under Medicare Part B and or Medicaid are only eligible for navigation services.[104] Similarly, in Pennsylvania, the Breast and Cervical Cancer Ealy Detection Program (BCCEDP) provides screening services to low income, uninsured, or underinsured patients, covering the costs of mammogram screening at over 100 centers to patients who qualify in the state.[105] These programs do not outline service coverage for additional imaging, such as MRI, that is often better able to detect TNBC and, when covered, has high co-insurance rate to patients, compared to mammograms. Therefore even with these programs the existence of an out-of-pocket cost to patients for

[96] CDC. (2019). *Summarizing the second decade of progress towards breast and cervical cancer control. 2003–2014*. https://www.cdc.gov/cancer/nbccedp/pdf/nbccedp-national-report-2003-2014-508.pdf

[97] ACS Cancer Action Network. (2021, October). *In a time when early cancer detection is needed, the House passes a bill that does not prioritize lifesaving programs.* https://www.fightcancer.org/news/time-when-early-cancer-detection-needed-house-passes-bill-does-not-prioritize-lifesaving

[98] Women's Congressional Policy Institute. *Breast and cervical cancer program subject of house of committee hearing.* Retrieved October 21, 2021, from https://www.wcpinst.org/source/breast-and-cervical-cancer-program-subject-of-house-committee-hearing/

[99] Tung E.L., Hampton D.A., Kolak M., Rogers S.O., Yang J.P., Peek M.E. (2019) Race/ethnicity and geographic access to urban trauma care. *JAMA Netw Open*;2(3):e190138. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2727264

[100] Miles, R. C. (2020, September 25). Closing the gap: Disparities in breast cancer mortality among African American women. *Radiology: Imaging Cancer*. https://pubs.rsna.org/doi/full/10.1148/rycan.2020200124

[101] Amey, C. H., Miller, M. K., & Albrecht, S. L. (1997). The role of race and residence in determining stage at diagnosis of breast cancer. *The Journal of Rural Health*, *13*(2), 99–108. https://doi.org/10.1111/j.1748-0361.1997.tb00939.x

[102] Vang, S., Margolies, L. R., & Jandorf, L. (2018). Mobile mammography participation among medically underserved women: A systematic review. *Preventing Chronic Disease*, *15*,180291. DOI:http://dx.doi.org/10.5888/pcd15.180291external icon

[103] Depke, J. L., Boreen, A., & Onitilo, A. A. (2015). Navigating the needs of rural women with breast cancer: A breast care program. *Clinical Medicine & Research*, *13*(3–4), 149–155. https://doi.org/10.3121/cmr.2015.1260

[104] Louisiana Breast & Cervical Health Program. *Program eligibility*. Retrieved October 21, 2021, from https://lbchp.org/eligibility/

[105] Pennsylvania Cancer Control, Prevention and Research Advisory Board. (2019, June). *Pennsylvania cancer control plan.* https://ftp.cdc.gov/pub/Publications/Cancer/ccc/pennsylvania_ccc_plan-508.pdf

imaging such as an MRI can act as a deterrent to patients, even if it was the more appropriate screening option for them.

There is some positive progress. Recently, these states have begun to enact legislation supporting screening in younger women and for other forms of imaging. For example, the LA Senate Bill 119, enacted in June, 2021 expands coverage to women to receive annual MRIs at age 25 and annual mammograms at age 30 with a hereditary susceptibility to breast cancer. Furthermore, the bill expands coverage to annual mammography for any woman older than 40 years old.[106] The PA Senate Bill 595, passed in 2020 requires insurers to cover breast MRIs and ultrasounds for women with very dense breasts or other high-risk factors.[107] It has also been found that most private plans will cover (but often with patient out-of-pocket costs) MRI screening services for patients that meet eligibility criteria largely aligned with NCCN guidelines, while public plans often have no policies in place specific to MRI screening.[108]

Turning to genetic testing, despite clinical guidelines establishing standards for BRCA genetic testing, there are differences in coverage policies, particularly between private and public payers. Medicare only covers preventative services for individuals with signs and symptoms, therefore, there must be a personal history with cancer to qualify for BRCA genetic testing.[109] In one study, states that were analyzed had no policies for genetic counselling for Medicaid programs (no policies: California, New York, Arizona; service is covered but no eligibility criteria: Illinois), while all four public payers in the study (UHC, Humana, Aetna, and Cigna) covered genetic counselling.[110]

Implications

While some progress has been made to create screening programs for under or uninsured women, significant gaps remain in coverage and affordability between private and public health plans. These differences are especially important for screening MRI or genetic testing which are particularly important for detecting or preventing TNBC. Unlike public plans, private plans tend to provide coverage to these types of screening in line with clinical guidelines.

There are also issues with access to healthcare. While mobile mammography programs can help reach underserved rural populations, the tendency for poor patient retention and follow-up creates challenges in detecting TNBC which often requires supplemental imaging after mammography.

While younger women are disproportionately impacted by the TNBC subtype, their coverage for screening measures are limited to require demonstrated hereditary risk and family history for all types of insurance. For these younger women there also needs to be education amongst providers to ask the necessary questions and assess patient risk.

[106] American College of Radiology. (2021, June). *Louisiana governor signs breast cancer screening bill into law*. https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-June-12-2021-Issue/Louisiana-Governor-Signs-Breast-Cancer-Screening-Bill-Into-Law

[107] PA Breast Cancer Coalition. (2020, July). *Governor Wolf signs SB 595 for insurance coverage of breast MRI, ultrasound*. https://www.pabreastcancer.org/governorwolfsignssb595/

[108] Wang, G., Beattie, M., Ponce, N. et al. (2011). Eligibility criteria in private and public coverage policies for BRCA genetic testing and genetic counseling. Genet Med 13, 1045–1050. https://doi.org/10.1097/GIM.0b013e31822a8113

[109] American Society of Clinical Oncology. *Genetic testing coverage & reimbursement*. Retrieved October 21, 2021, from https://www.asco.org/news-initiatives/current-initiatives/genetics-toolkit/genetic-testing-coverage-reimbursement

[110] Wang, G., Beattie, M., Ponce, N., et al. (2011). Eligibility criteria in private and public coverage policies for BRCA genetic testing and genetic counseling. *Genetic Medicine*, *13*, 1045–1050. https://doi.org/10.1097/GIM.0b013e31822a8113

3. Testing and diagnosis programs

After providing an overview of testing and diagnosis programs, we consider issues associated to affordability and then how this links to registries and data collection and improving diagnosis in the future.

3.1 Overview of testing and diagnosis programs

Diagnosis of TNBC is typically made using imaging tests and biopsy. If diagnostic imaging suggests there is a risk of breast cancer, a biopsy will be required before breast cancer is confirmed and diagnosed. Breast biopsy involves removing cells or tissue from the breast area of suspicion and the procedure also permits for classification of the breast cancer subtype via immunohistochemistry (IHC).[111, 112] The cancer cells are checked for certain features and TNBC is confirmed if the cells do not have estrogen or progesterone receptors, and do not make too much of the HER2 protein (i.e. the cells test "negative" on all three tests).[113]

Accurate detection of TNBC detection requires expertise and experience with clinicians to evolving radiographical technologies and new cancer tumor modalities.[114] The role of immunohistochemistry (IHC) and onco-pathologist is crucial in the clinical identification of TNBC.[115] Nevertheless, there is a lack of research and evidence on the availability of specialists who support the diagnosis of TNBC and whether this contributes to diagnosis disparities.

State CCC plans' focus primarily on screening with less emphasis on improving diagnosis. Plans generally mention the need to "promote adherence to national guidelines for cancer diagnosis" and to set targets for reducing late diagnosis of TNBC.[116,117] Some states, such as Massachusetts, are specific in setting targets for reductions in late-stage breast cancer diagnosis for Black, non-Hispanic women.[118] By contrast, NCCN guidance on diagnosing TNBC do not consider racial and ethnic differences in populations.[119] This may contribute to diagnosis disparities.

Research studies reveal disparities in the diagnosis of TNBC. Women under the age of 40 are more likely to be diagnosed with TNBC than any other breast cancer subtype.[120] A larger proportion of women diagnosed with TNBC receive their diagnosis at a later stage of the disease compared to women diagnosed with other

[111] Susan G. Komen. (2020, December). *Biopsies*. https://www.komen.org/breast-cancer/diagnosis/biopsies/

[112] Dass, S. A., Tan, K. L., Selva Rajan, R., Mokhtar, N. F., Mohd Adzmi, E. R., Wan Abdul Rahman, W. F., Tengku Din, T., & Balakrishnan, V. (2021). Triple negative breast cancer: A review of present and future diagnostic modalities. *Medicina* (Kaunas, Lithuania), *57*(1), 62. https://doi.org/10.3390/medicina57010062

[113] American Cancer Society. (2021, January). *Triple-negative breast cancer.* https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html

[114] Fabienne, A., Milner, D. A. & Brock, J. E. (2020). Can pathology diagnostic services for cancer be stratified and serve global health? *Cancer*, *126*, S10. https://doi.org/10.1002/cncr.32872

[115] Thakur, V., & Kutty, R. V. (2019). Recent advances in nanotheranostics for triple negative breast cancer treatment. *Journal of Experimental & Clinical Cancer Research*, *38*, 430. https://doi.org/10.1186/s13046-019-1443-1

[116] *Michigan cancer plan. 2021–2030*. https://www.michigan.gov/documents/mdhhs/CancerPlanFinal_726417_7.pdf

[117] The Massachusetts Comprehensive Cancer Prevention and Control Network. (2017, January). *Massachusetts statewide 2017–2021 cancer plan*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/massachusetts_ccc_plan-508.pdf

[118] Example from North Carolina plan. *North Carolina cancer control action plan 2020–2025*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/north-carolina-ccc-plan-508.pdf

[119] National Comprehensive Cancer Network Guidelines. *Breast cancer*. Retrieved October 21, 2021, from https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1419

[120] Scott, L. C., Mobley, L. R., Kuo, T. M., & Il'yasova, D. (2019). Update on triple-negative breast cancer disparities for the United States: A population-based study from the United States Cancer Statistics database, 2010 through 2014. *Cancer*, *125*(19), 3412–3417. https://doi.org/10.1002/cncr.32207

types of breast cancer.[121] Non-white patients are more likely to be diagnosed with breast cancer at a later stage of breast cancer compared to white patients: white (66%) and Asian Pacific American (64%) patients are more frequently diagnosed with breast cancer at an early, localized stage of the disease than Black (56%), Hispanic (58%), and American Indian/Alaska Native (60%) patients.[122] TNBC tumors tend to be larger, to include more lymph node tissue, and to be diagnosed late in Black patients.[123] Black women have been found to have a significantly longer time delay from diagnosis to treatment compared with white women (sixty-one versus forty-three days, respectively). [124]

One reason for diagnosis disparities could be gaps in follow-up care for underserved populations. For example, studies have identified longer delays in follow-up after an abnormal mammogram among Black women compared with white women.[125,126,127] Delays in follow-up care are associated with lower survival rates.[128,129] Additionally, lacking are holistic, community-based wraparound support services that could help eliminate barriers to care throughout the patient journey.

Implications

Clear disparities between racial and ethnic groups in TNBC exist with respect to age of patients diagnosed, time to diagnosis, and stage of cancer diagnosed. Clinical guidelines to support TNBC diagnosis exist but contain little reference to high-risk populations such as racial and ethnic groups. The commitment of some, but not all, state CCC plans to reduce late-stage diagnosis of TNBC has the potential to target underserved populations.

3.2 Affordable access to testing and diagnosis

Diagnostic imaging

If mammography screening or a clinical exam reveals a lump or other symptom of breast cancer, diagnostic imaging (e.g., MRI, ultrasound, or diagnostic mammography) is used to confirm the presence of the disease or the need for a biopsy. Screening mammograms are usually covered by private plans and other public plans and programs, but the high costs associated with diagnostic imaging usually result in a high cost-share burden

[121] Scott, L. C., Mobley, L. R., Kuo, T. M., & Il'yasova, D. (2019). Update on triple-negative breast cancer disparities for the United States: A population-based study from the United States Cancer Statistics database, 2010 through 2014. *Cancer*, *125*(19), 3412–3417. https://doi.org/10.1002/cncr.32207

[122] American Cancer Society. (2019). *Breast cancer facts & figures 2019–2020.* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf

[123] Cho, B., Han, Y., Lian, M., Colditz, G. A., Weber, J. D., Ma, C., & Liu, Y. (2021). Evaluation of racial/ethnic differences in treatment and mortality among women with triple-negative breast cancer. *JAMA Oncology*, *7*(7), 1016–1023. https://doi.org/10.1001/jamaoncol.2021.1254

[124] Thomas, K., Shiao, J., Rao, R., Minhajuddin, A., et al. (2017). Constructing a clinicopathologic prognostic model for triple-negative breast cancer. *American Journal of Hematology/Oncology*, *13*(1):11–21. https://www.gotoper.com/publications/ajho/2017/2017jan/constructing-a-clinicopathologic-prognostic-model-for-triple-negative-breast-cancer

[125] Battaglia, T. A., Santana, M. C., Bak, S., et al. (2010). Predictors of timely follow-up after abnormal cancer screening among women seeking care at urban community health centers. *Cancer*, *116*(4), 913–21. https://doi.org/10.1002/cncr.24851

[126] DeSantis, C. E., Miller, K. D., Sauer, A. G., Jemal, A., & Siegel, R. L. (2019). Cancer statistics for African Americans. *CA: A Cancer Journal for Clinicians*, *69*(3), 211–233.

[127] Warner, E. T., Tamimi, R. M., Hughes, M. E., et al. (2012). Time to diagnosis and breast cancer stage by race/ethnicity. *Breast Cancer Research and Treatment*, *136*(3), 813–821.

[128] Curtis, E., Quale, C., Haggstrom, D., & Smith-Bindman, R. (2008). Racial and ethnic differences in breast cancer survival: How much is explained by screening, tumor severity, biology, treatment, comorbidities, and demographics? *Cancer*, *112*(1), 171–180.

[129] George, P., Chandwani, S., & Gabel, M., et al. (2015). Diagnosis and surgical delays in African American and white women with early-stage breast cancer. *Journal of Women's Health* (Larchmt), *24*(3), 209–217.

being imposed on patients.[130] Patient costs vary significantly depending on the diagnostic test. One study found that patient costs for diagnostic breast MRIs, which are better able to detect the TNBC subtype, were much higher ($1,021) than for mammograms ($234).[131] Large variations in cost confuse and frustrate patients and have been found to exacerbate an already stressful situation and experience.[132]

There is evidence that some women decide to cancel or delay physician-recommended diagnostic tests and wait to save money or for better coverage once they learn the cost.[133] A nationwide research study using hospital data from the National Cancer Data Base pertaining to over 550,000 non-elderly women (ages 18 to 64) with breast cancer found that differences in health insurance explained 35% of the excess risk of death from breast cancer in Black women compared to white women. Indeed, this study found insurance coverage to be the most significant factor contributing to risk of death from breast cancer compared to four other factors studied (patient demographics, comorbidities, tumor characteristics, and form of treatment).[134] The study also found that 22.7% of Black women—a rate three times higher than for white women (8.4%)—were uninsured or covered through Medicaid.[135] Other studies have found similar disparities, showing that Black women are twice as likely to be uninsured or reliant on public insurance compared to white women.[136] This is especially relevant to the aggressive TNBC subtype, which not only disproportionately affects Black women but also is more commonly diagnosed at an advanced stage in Black women. Uninsured patients, who are more often Black, also receive diagnosis at more advanced states of the disease than insured patients, and women often report financial strain and lack of insurance as a reason for not adhering to screening protocols.[137]

In 2019, Congress proposed the Access to Breast Cancer Diagnosis (ABCD) Act, which "prohibits private health insurance plans from imposing higher cost-sharing requirements on breast cancer diagnostic examinations than initial breast cancer screening examinations." The bill also notes that "[d]iagnostic examinations are generally required after an initial screening detects an abnormality and typically require additional mammogram images."[138] Passing this legislation would be an important step in reducing financial barriers to diagnostic tests, which can impose on patients hundreds to thousands of dollars in out-of-pocket costs.[139]

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130 Susan G. Komen. *Understanding cost & coverage issues with diagnostic breast imaging*. (2019, January). https://www.komen.org/uploadedFiles/_Komen/Content/What_We_Do/Advocacy/komen-understanding-cost-coverage-with-dbi-final-report.pdf

131 Susan G. Komen. (2021, February). *Susan G. Komen® commends introduction of diagnostic imaging legislation in Arkansas*. https://blog.komen.org/news/arkansas-diagnostic-bill/

132 Susan G. Komen. (2019, January). *Understanding cost & coverage issues with diagnostic breast imaging.* https://www.komen.org/uploadedFiles/_Komen/Content/What_We_Do/Advocacy/komen-understanding-cost-coverage-with-dbi-final-report.pdf

133 Susan G. Komen. (2019, January). *Understanding cost & coverage issues with diagnostic breast imaging*. https://www.komen.org/uploadedFiles/_Komen/Content/What_We_Do/Advocacy/komen-understanding-cost-coverage-with-dbi-final-report.pdf

134 American Cancer Society. (2017, October). *Study: Lack of insurance linked to higher breast cancer death rates in Black women*. https://www.cancer.org/latest-news/study-lack-of-insurance-linked-to-higher-breast-cancer-death-rates-in-black-women.html

135 American Cancer Society. (2017, October). *Study: Lack of insurance linked to higher breast cancer death rates in Black women*. https://www.cancer.org/latest-news/study-lack-of-insurance-linked-to-higher-breast-cancer-death-rates-in-black-women.html

136 Thomasson, M. (2006). Racial differences in health insurance coverage and medical expenditures in the United States: A historical perspective. *Social Science History*, *30*(4), 529–550. doi:10.1017/S0145553200013572

137 Khan, R., Abuali, I., Vick, E. J., Smart, L., Xie, C., & Charif, M. (2020, May). Effect of race and insurance status on stage at diagnosis and overall survival of triple-negative breast cancer (TNBC): Analysis of the National Cancer Data Base (NCDB). *Journal of Clinical Oncology*, *38*(15), Suppl, e19086-e19086. https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.e19086

138 Access to Breast Cancer Diagnosis Act of 2019, H.R.2428. 116th Congress (2019–2020). https://www.congress.gov/bill/116th-congress/house-bill/2428?s=1&r=4

139 Susan G. Komen. (2021, April). *Susan G. Komen® commends introduction of legislation in U.S. Senate to remove cost barriers to diagnostic imaging*. https://blog.komen.org/news/abcd-act/. Details and actions related to the bill can be found at Access to Breast Cancer Diagnosis Act of 2021, S.1067, 117th Congress (2021–2022). https://www.congress.gov/bill/117th-congress/senate-bill/1067?r=2&s=1

At the state level, legislation has been enacted requiring health insurers to cover diagnostic breast imaging, including follow-up testing after abnormal findings, in Arkansas, Colorado, Illinois, and Texas.[140] Notably, in Illinois, while additional screening using MRI imaging is included if it is deemed medically necessary, coverage for diagnostic imaging is specified to be for mammography, and some high-deductible insurance plans for which mandatory coverage would cause disqualification from participation in health savings accounts are excluded. Other states, including New York, are considering implementation of similar policies.[141]

Diagnostic biopsy

Even for patients with coverage for a medically necessary breast biopsy, out-of-pocket contributions are high, with one study finding costs average $1,940 for commercial patients and $1,901 for Medicare patients.[142] Paid amounts for patients also vary greatly depending on the type of biopsy performed, with the most expensive biopsy being MRI and ultrasound image–guided surgical biopsy procedures ($1,909) and the least expensive being ultrasound-guided fine needle aspiration biopsies ($249).[143] Another study found that the average total patient out-of-pocket costs for core-needle biopsy, the most commonly used biopsy procedure, was $669. Furthermore, ancillary costs of biopsy procedures, such as follow-up physician visits, anesthesia, and pathology, often require additional patient payments that can range anywhere from hundreds to thousands of dollars.[144]

Implications

Implementation of the Access to Breast Cancer Diagnosis Act would be an important step in removing financial barriers to diagnosis and reducing discrepancies in diagnostic coverage across states. The cost to patients of additional diagnostic imaging and biopsies vary greatly depending on the type of imaging or procedure required. Policies that limit patient out-of-pocket costs for such procedures would help to reduce barriers patients face for investigating suspicious screening outcomes.

3.3 Registries and data collection and its role in improving diagnosis

In this section we consider how an established and population-representative cancer registry that captures data, including patient demographics, tumor type, and disease outcomes, can be a powerful resource for policy making. Specifically, registry data can be used to track disparities in cancer care, treatment, and linkage

[140] *An act concerning coverage of diagnostic examinations for breast cancer under certain health benefit plans*. State of Arkansas. Senate Bill 290. 93rd General Assembly, 2-21. https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/SB-290-081921.pdf; *An act concerning health insurance coverage for breast imaging*. (2019). House Bill 191301. https://leg.colorado.gov/sites/default/files/documents/2019A/bills/2019a_1301_enr.pdf, Illinois General Assembly. *Illinois compiled statutes*. https://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=021500050K356g; Stockler, A. (2019, December 28). Illinois will require insurers to cover diagnostic mammogram follow-ups to initial screenings in 2020. *Newsweek*. https://www.newsweek.com/diagnostic-mammogram-illinois-insurance-healthcare-1479473

[141] Stockler, A. (2019, December 28). Illinois will require insurers to cover diagnostic mammogram follow-ups to initial screenings in 2020. *Newsweek*. https://www.newsweek.com/diagnostic-mammogram-illinois-insurance-healthcare-1479473

[142] Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research*, *10*, 157–167. https://doi.org/10.2147/CEOR.S150260

[143] Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research*, *10*, 157–167. https://doi.org/10.2147/CEOR.S150260

[144] Vlahiotis, A., Griffin, B., Stavros, A. T., & Margolis, J. (2018). Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research*, *10*, 157–167. https://doi.org/10.2147/CEOR.S150260

to care. Registries can also support scientists and researchers as they work to understand and address the biological factors and social determinants that limit access to care among racial and ethnic groups.[145]

In 1992, the Cancer Registries Amendment Act authorized the CDC to make grants through the National Program of Cancer Registries (NPCR) to states to support population-based, statewide cancer registries. The objective was to enable state and local health departments to understand local cancer trends and patterns and to direct cancer control programs, including those focused on prevention and early detection. Before the NPCR was established, most states with registries lacked the resources and legislative support they needed to gather complete data, and some states had no cancer registry at all.[146] However, the CDC admits that although state registries use standardized data codes for both race and ethnicity, the collection of this information by health care facilities and the procedures for assigning and verifying codes for race and ethnicity are not well standardized.[147] Studies have found that racial misclassification contributes to underestimates of cancer incidence and death rates among racial groups, especially American Indian and Alaska Native populations. Poor data-collecting abilities have led to an effort to improve the quality of data collection in federal programs. This recent initiative, "Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government," would improve the ability of organizations to assess health policies, ensure that such policies advance health equity, and produce better insight into current disparities in health barriers and burdens.[148,149]

In addition, based on registry data, the CDC reports rates or numbers of new cancers or cancer deaths by race/ethnicity, sex, and age group for all cancers combined or for common types of cancer.[150] The CDC aggregates breast cancer rates but does not report rates of breast cancer subtypes such as TNBC. Further, cancer registries do not collect individual-level socioeconomic data. Insufficient non-discriminatory data collection and lack of dissemination of outcomes indicators for priority populations could propagate the inequitable distribution of federal and state resources.

United States Cancer Statistics are the official federal cancer statistics; they draw from combined cancer registry data collected by the CDC and National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program.[151] At the state level, many CCC plans are committed to integrating data to identify areas of unmet need. Massachusetts and Michigan have as an objective analyzing Cancer Registry data to identify racial and ethnic disparities in treatment (not specific to breast cancer).[152,153] In Michigan, they have recognized that it is important to improve data collection on race and ethnicity in patient registries to better track, identify, and address health inequities. Currently, there is a concern that Michigan data is not available in many categories, hindering determination of whether disparities exist by race and ethnicity, education,

[145] The research aspect of registries and data collection will be discussed in a follow-up to this study.

[146] Pollack, L. A., Jones, S. F., Blumenthal, W., et al. (2020). Population health informatics can advance interoperability: National Program of Cancer Registries electronic pathology reporting project. *JCO Clinical Cancer Informatics*, *4*, 985-992. https://ascopubs.org/doi/10.1200/CCI.20.00098

[147] CDC. (2021, June). *Interpreting race and ethnicity in cancer data*. https://www.cdc.gov/cancer/uscs/technical_notes/interpreting/race.htm#

[148] National Health Council. (2021, July). *OMB Equity RFI—comments*. https://nationalhealthcouncil.org/wp-content/uploads/2021/07/OMB-Equity-Comments-Final.pdf

[149] Pharmaceutical Research and Manufacturers of America. (2021, July). *Re: Methods and leading practices for advancing equity and support for underserved communities through government*. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/FINAL-070621_PhRMA-Response_OMB-RFI1.pdf

[150] CDC. (2021, June). *Cancer data and statistics*. https://www.cdc.gov/cancer/dcpc/data/index.htm

[151] CDC. (2021, June). *Cancer data and statistics*. https://www.cdc.gov/cancer/dcpc/data/index.htm

[152] Massachusetts Comprehensive Cancer Prevention and Control Network. (2017, January). *Massachusetts statewide 2017–2021 cancer plan*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/massachusetts_ccc_plan-508.pdf

[153] *Michigan cancer plan. 2021–2030*. https://www.michigan.gov/documents/mdhhs/CancerPlanFinal_726417_7.pdf

income, insurance type, sexual or gender identity, or geography.[154] Louisiana also has a stated strategy to map data from the state's tumor registry (LTR) using data visualization software and identify areas in the state that have high mortality rates and would benefit from early detection interventions. However, due to small numbers of other minority groups in the state, data in the LTR are stratified only by Black and white patients.[155]

Implications

The Cancer Registries Amendment Act was an important first step in establishing cancer registries and data collection across states. It is important, however, to implement policy to guide a standardized and verifiable form of segregated data collection, such as by race and breast cancer subtype. Access to breast cancer data by subtype is critical in guiding policy decisions and assessing disparities, especially given the difference in the relative incidence of subtypes across races. While some states, such as Louisiana, are taking action to use data to inform policy initiatives and produce insights into differences by some races, many states have fallen behind in collecting the appropriate level of detailed data within their registries. This will be important for reducing disparities in areas like TNBC in the future.

[154] *Michigan cancer plan. 2021–2030*. https://www.michigan.gov/documents/mdhhs/CancerPlanFinal_726417_7.pdf

[155] *Louisiana comprehensive cancer control plan 2017–2021*. https://ftp.cdc.gov/pub/Publications/Cancer/ccc/louisiana_ccc_plan.pdf

4. Policy tools and implications

Across the US, despite the development of policies to support breast cancer patients, recognition of specific effects of HDI on TNBC patients and actions to mitigate them is limited. Based on evidence gathered in this study, including insights from a TNBC patient advocacy group, we identify a need for policy change in a number of areas to improve the lives of patients with TNBC. This section outlines recommendations for resource prioritization to address needs within the patient journey for screening and diagnosis. Specifically, we recommend actions to improve availability of programs, clinical guidelines, education and tools for HCPs, coverage and affordability, and data collection.

4.1 Overall prioritization

State CCC plans provide a critical framework to incentivize other policies and programs. However, comparing strategies across state CCC plans (Table 2), it becomes clear that there are many discrepancies in how states are prioritizing access to screening measures to support TNBC diagnosis across jurisdictions. Overall, states have clear strategies for general breast cancer screening, usually through mammography. However, gaps in policy objectives targeting young women, screening beyond general mammography (e.g., MRI), and TNBC-specific rates are limited. Improving the screening and diagnosis of underserved TNBC patients in states could be achieved in several ways:

- **Screening objectives and targets specific to TNBC**—for example, by referencing the need to expand access to supplemental imaging better able to detect TNBC and to genetic testing.
- **Specific reference to objectives to expand access to genomic testing**, which can better identify diagnostic and treatment methods for racial and ethnic groups of TNBC patients, should be specifically referenced.
- **Include objectives to target TNBC screening among diverse populations or younger women** who are at greater risk for TNBC compared to other breast cancer subtypes.
- **Recommend the development of outcome measures and performance indicators and screening and diagnosis metrics** to support the continuous evaluation and improvement of TNBC screening and diagnosis measures within state CCC plans.
- **Recommend development of practice–policy communication loops to examine state and local policies that evaluate screening and follow-up** with the aim of reducing the financial burden on community-based organizations and safety net hospitals should be recommended.[156]

[156] Henderson, V., Tossas-Milligan, K., Martinez, E., Williams, B., Torres, P., Mannan, N., Green, L., Thompson, B., Winn, R., & Watson, K. S. (2020). Implementation of an integrated framework for a breast cancer screening and navigation program for women from underresourced communities. *Cancer*, *126*, 2481–2493. https://doi.org/10.1002/cncr.32843

Table 2: Summary of state CCC breast cancer strategies specific to screening and diagnosis[157]

State CCC Breast cancer strategies	CA[158]	GA	LA	MA	PA	MI
	2011-15	2014-19	2017-21	2017-21	2019-23	2021-30
Targets for increased screening rates	✓	✓	✓	✓	✓	✓
Provision of screening programs	✗	✓	✓	✗	✓	✗
Improved screening of racially diverse[159] groups	✗	✓	✗	✓	✓	✓
Improved screening of young women (<40)	✗	✓	✗	✗	✗	✗
Additional screening imaging (e.g., MRI)	✗	✗	✗	✗	✗	✗
Targets specific to the TNBC subtype	✗	✗	✗	✗	✗	✓
Testing for genetic mutations/HBOC	✗	✓	✗	✗	✓	✓
Screening education for HCPs	✗	✓	✓	✓	✓	✓
Patient education or support	✗	✓	✓	✓	✓	✓
Provision of community patient navigation services early in patient journey	✓	✗	✓	✓	✓	✓
Targets for early diagnosis of racially diverse[160] groups	✗	✗	✓	✓	✗	✓
Lowering of coverage and cost barriers	✓	✓	✓	✗	✓	✓
Data collection to inform resource allocation	✗	✗	✓	✓	✗	✓

4.2 Support for screening and preventative measures

Based on evidence and patient advocate insight regarding support areas that would most benefit patients screening and genetic and genomic testing, the following areas are critical in reducing disparities in TNBC survival:

- **Develop culturally and linguistically tailored patient education necessary to support patient awareness of screening and genetic and genomic testing**. This is particularly important for TNBC given its aggressive nature. Materials should be culturally and linguistically tailored to address awareness gaps and any cultural or faith-based believes that may prevent uptake among underserved populations. The development of education programs and materials could be mandated

[157] CDC. *Comprehensive cancer control plans*. Retrieved October 21, 2021, from https://www.cdc.gov/cancer/ncccp/ccc_plans.htm.

[158] While the state CCC plan for California outlines cancer disparities among racially diverse groups in the state, the plan does not outline strategies or targets to specifically reduce these disparities.

[159] *Racially diverse* indicates focus on Black, Hispanic, Native American, or Asian populations and is shorthand for ethnically diverse populations as well.

[160] *Racially diverse* indicates focus on Black, Hispanic, Native American, or Asian populations and is shorthand for ethnically diverse populations as well.

by federal legislation. For example, in 2009, the EARLY Act authorized the CDC to develop initiatives to increase knowledge of breast health and breast cancer among women, especially young and high-risk women.[161] Similar legislation could empower the CDC and HHS to develop TNBC education materials targeting key population groups

- **Include TNBC high-risk underserved populations in screening guidelines (such as the USPSTF)**. Population-level screening efforts should be paired with tailored risk assessment tools and screening recommendations aligned to the level of risk. Clinical guidelines could support patient referral to screening beyond mammography, such as MRI, which is particularly relevant to TNBC patients and young women.
    - Guidelines from other organizations discussed in this paper (the AAFP, ACP, ASCO, ACS) should also be updated. The ACR guidelines provide a model for these updates: addressing the higher risk for Black women and recommending screening begin at 40, with a risk-assessment competed by all women at 30 to determine if screening should start sooner.
- **Update clinical guidelines to support evidence-based risk assessment and referral of patients for genetic counselling and testing.** In addition, states should recommend genetic testing beyond the BRCA 1 and BRCA 2 genes, since genomic testing can provide insights into the genetic underpinnings of TNBC. Some states, including Georgia, have model policy language recommending genetic testing for high-risk women (young, Black) that could be leveraged. Guidelines should also consider the most appropriate genomic tests for non-white patients, given emerging evidence that not all genomic tests are accurate across racial population groups.[162] Innovative approaches to close the disparity in genetic counselling referral could include the following:[163]
    - Greater access to genetic counsellors from diverse backgrounds
    - Cascade testing (genetic counselling and testing of blood relatives of individuals with specific genetic mutations, allowing them to pursue appropriate cancer screening and risk-reduction strategies)
    - Intergenerational genetic counselling programs for young mothers
    - Peers and Cancer Empowerment (PeACE) sessions, which are peer-led support groups for genetic testing among young adults, delivered over the phone and/or online
- Support these initiatives with opportunities for provider education on an interpersonal bias.
- **Encourage the development of screening tools and offer improved HCP education opportunities, through CMS, to support the consideration of social determinants of health in screening referrals and follow-up care.** Innovative education materials and tools to increase access to screening and genetic and genomic referral and counselling among underserved

[161] CDC. (2021, September). *Advisory committee on breast cancer in young women*. https://www.cdc.gov/cancer/breast/what_cdc_is_doing/young_women.htm

[162] NIH National Cancer Institute. (2021, February). *Oncotype DX breast cancer test may be less accurate for Black patients*. https://www.cancer.gov/news-events/cancer-currents-blog/2021/oncotype-dx-breast-cancer-less-accurate-black-women

[163] O'Neill, S. C., Hamilton, J. G., Conley, C. C., et al. Improving our model of cascade testing for hereditary cancer risk by leveraging patient peer support: a concept report. *Hereditary Cancer Clinical Practice*, *19*, 40. https://doi.org/10.1186/s13053-021-00198-7

populations could be developed in partnership with community-based organizations, using non-oncology clinical settings and maximizing telehealth.[164]

- **Improve affordability of screening for uninsured populations and coverage of screening measures beyond mammograms (e.g., MRI), which currently remain a significant barrier to uptake.** States that have not done so already should provide expanded Medicaid access. State legislation should also mandate plans to cover screening beyond general mammography and genetic and genomic testing. Coverage should be paired with educational materials that are understandable and accessible and that contain appropriate language to empower patient access.

4.3 Support for testing and diagnosis programs

Evidence of disparities in the age and stage of diagnosis indicate there is scope for additional policy support for TNBC testing and diagnosis:

- **Update clinical guidelines such as the USPTF and NCCN to recommend tailored and culturally relevant diagnosis approaches, especially in terms of follow-up after abnormal screening results**. This could include the recommendation to use telehealth (electronic health records, electronic reminders) and the use of diverse patient navigation programs and community health workers.
- **Introduce state mandates for plans that cover diagnostic services that may be required for high-risk patients and limit the out-of-pocket cost burden.** Providers could foster copay assistance and vouchers for diagnostic services for underinsured or uninsured groups.
- **Amend recent bills, such as the Triple-Negative Breast Cancer Research and Education Act of 2019, to require the NIH to support the standardized collection of diagnosis data**, disaggregated by indicators of typically underserved populations. Data collected should be specific to breast cancer subtypes to ensure understanding of TNBC. State CCC plans could leverage data and promote data analysis from genetic databases such the Molecular Taxonomy of Breast Cancer International Consortium (METABRIC) to inform policy change.

[164] Cohen, S. A. et al. (2019). Genetic counseling and testing in a community setting: Quality, access, and efficiency, *American Society of Clinical Oncology Educational Book*, *39*, e34-e44

5. Conclusion

This paper aimed to assess the screening and diagnosis policy environment for underserved TNBC patients. We analyzed legislation and associated policies and regulations in the US and key states and integrated the perspective of the key needs of TNBC patients.

As recognized in academic and policy research, we find significant progress in the policy environment for breast cancer. However, we find that policy advances targeting TNBC patients and underserved populations are lagging. Our assessment reveals a systematic lack of consideration of the key needs of underserved populations despite significant evidence of those populations' greater likelihood of TNBC diagnosis and disparities in survival. In addition, we find that TNBC-targeted policies are skewed toward increasing uptake of screening, while initiatives that aim to close disparities in referral to genetic testing and improve diagnosis following initial screening are limited. Based on the analysis, we find that policy action is needed. Advocacy groups and community-based organizations can play an important role in further shaping the policy environment with the objective of effectively addressing HDI faced by TNBC patients.

Additional research could address limitations in our understanding of how specific policies and programs link to support the needs of underserved patients. We hope the information and recommendations in this paper provide a strategic framework to inform dialogue, establish collaborations, and define best practices in TNBC management to address HDI and inform patient care.

Appendix: Definitions

- **Healthcare disparities and inequities (HDI):** Obstacles to health for groups of people who have systematically experienced greater social or economic obstacles to health leading to an avoidable difference in health outcomes that are systematic and unjust.[165]
- **Hereditary breast and ovarian cancer syndrome (HBOC):** a genetic condition that increases the risk of getting breast, ovarian, and other cancers. HBOC is hereditary and usually caused by a genetic mutation.[166]
- **Key populations**: Underserved populations at risk of developing TNBC, namely women who are Black, Hispanic, young (<40 years old), low-income or who live in areas that are rural or remote geographically or medical deserts
- **Medical deserts:** Regions with inadequate access to healthcare services, which may exist in urban or rural areas and contribute to health disparities.
- **Racially diverse:** Indicates focus on Black, Hispanic, Native American, or Asian populations and is shorthand for ethnically diverse populations as well.
- **State Comprehensive Cancer Control (CCC) Plans:** State plans to address the burden of cancer within the region, based on the data collected about the people living within the state geography. State CCC plans are usually updated every 5 years.[167]
- **TNBC diagnosis stage:**[168]
    - **Localized:** Cancer is limited to the place where it started, with no sign that it has spread
    - **Regional:** Cancer has spread to nearby lymph nodes, tissues, or organs
    - **Distant:** Cancer has spread to distant parts of the body

[165] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., & Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. *Journal of public health management and practice*: *JPHMP*, 22 Suppl 1(Suppl 1), S33–S42. https://doi.org/10.1097/PHH.0000000000000373

[166] NIH National Cancer Institute. *HBOC syndrome*. Retrieved October 21, 2021, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hboc-syndrome

[167] National Comprehensive Cancer Control Program (NCCCP). (2021, July) *Comprehensive Cancer Control Plans.* https://www.cdc.gov/cancer/ncccp/ccc_plans.htm

[168] NIH National Cancer Institute. (2015, March). *Cancer staging*. https://www.cancer.gov/about-cancer/diagnosis-staging/staging#:~:text=Distant%E2%80%94Cancer%20has%20spread%20to,to%20figure%20out%20the%20stage