Inequities in Patient Support, Well-being, and Treatment Access for Triple Negative Breast Cancer Patients

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Foreword

Inequities in Patient Support, Well-being, and Treatment Access for Triple Negative Breast Cancer Patients, co-authored by Charles River Associates and the Cancer Support Community, was made possible through funding provided by Gilead Sciences, Inc. (Gilead). As a leading biopharmaceutical company, Gilead recognizes the importance of supporting efforts that eliminate healthcare inequities and promote social justice. Since triple negative breast cancer (TNBC) disproportionately affects people from racial and ethnic minority groups 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 care and treatment faced by women with TNBC.

Executive summary

In this report, Charles River Associates (CRA) and Cancer Support Community (CSC) examine the extent to which policies associated with long-term support, well-being, and treatment innovation for triple negative breast cancer (TNBC) patients can exacerbate or ameliorate inequities in TNBC health outcomes among at-risk, under-resourced populations in the United States (US).[1] In particular, the objective was to

- Describe evidence of inequitable access to long-term patient support services, and the resulting disproportionate impact in the form of worse mental and physical health outcomes and financial burden, among typically underrepresented communities and
- Highlight how health policies in the US can address the drivers of inequitable resources and support patient access to long-term support services and innovative treatment.

To accomplish these objectives, CRA conducted a comprehensive review of the literature pertaining to the TNBC policy landscape, which was enhanced by integrating insights from the patient advocacy group CSC to capture the real-world patient perspective and experience. We included data insights from CSC's Cancer Experience Registry® (CER®) in this review to supplement our research.[2] The methods of the CER® have been previously described.[3,4] The CER® consists of responses from TNBC patients and survivors (N = 210) participating between January 2015 and August 2021.[5] Together, CRA and CSC evaluated potential policies and programs for long-term patient support and treatment innovation that could support the needs of at-risk, under-resourced populations and reduce health inequities that lead to disparities in outcomes. The report was conducted for, and funded by, Gilead Sciences, Inc. (Gilead).

We focused on federal, state, and community-level policies and programs. The analysis references six states: California (CA), Georgia (GA), Louisiana (LA), Massachusetts (MA), Michigan (MI), and Pennsylvania (PA) and includes additional states with constructive policy examples highlighted in the literature. The states of focus were selected based on their high level of breast cancer incidence among Black women and to ensure regional representation across the US.

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[1] Terminology commonly used in this paper are defined in the Appendix. Italicized words throughout the paper are defined in the glossary (Appendix Table 2).

[2] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[3] Zaleta, A. K., McManus, S., Fortune, E. E., DeRosa, B. W., Buzaglo, J. S., Olson, J. S., Goldberger, S., & Miller, M. F. (2021). CancerSupportSource®-15+: development and evaluation of a short form of a distress screening program for cancer patients and survivors. Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer, 29(8), 4413–4421. https://doi.org/10.1007/s00520-021-05988-2

[4] Zaleta, A. K., Miller, M. F., Olson, J. S., Yuen, E., LeBlanc, T. W., Cole, C. E., McManus, S., & Buzaglo, J. S. (2020). Symptom Burden, Perceived Control, and Quality of Life Among Patients Living With Multiple Myeloma. *Journal of the National Comprehensive Cancer Network : JNCCN*, *18*(8), 1087–1095. https://doi.org/10.6004/jnccn.2020.7561

[5] Certain analyses consist of a subset of the full sample size. These instances are noted throughout the report.

This paper is the final one in a series of three studies conducted by CRA for Gilead that identified evidence of inequities and disparities for TNBC patients throughout their sequence of care. In the first paper, our literature review identified barriers to screening and diagnosis for TNBC that worsen health outcomes in under-resourced populations in the US.[6] In the second paper, we described how TNBC is particularly challenging to treat because there are few treatment options compared to other types of breast cancer, and health outcomes are compounded by harmful coverage restrictions and treatment-associated costs that place a significant burden on under-resourced patients.[7]

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.[8] The majority of TNBC cases occur in younger women under the age of 60. The relative incidence of the TNBC subtype is higher among certain racial groups, particularly Black women. In addition, 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.[9, 10] However, CRA has previously found that inequitable distribution of resources and social determinants of health can lead to differences in health outcomes, such as a greater likelihood of chronic disease or comorbidities, 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.[11]

Ensuring equitable access to long-term patient support

From our literature review, we find evidence that TNBC patients who are non-white or who have lower income face several barriers accessing survivorship and palliative care, and as a result they also disproportionately experience burdensome physical and mental health side effects:

- Black breast cancer survivors or those who are uninsured or underinsured are less likely to receive sufficient care support (i.e., mammography surveillance) following initial cancer treatment, resulting in less effective post-treatment care.[12]
- Social determinants of health (SDoH) contribute to inequities in survivorship care. For example, providers' decision-making biases have been associated with gaps in survivorship care

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[6] Axelsen, K, Jayasuriya, R, Zacharko, C, Karmo, M. (2021, October 22). Disparities in screening and diagnosis for triple negative breast cancer. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2021/10/04132314/CRA-Gilead-Disparities-in-Screening-and-Diagnosis-TNBC.pdf. Accessed 11 April 2022.

[7] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[8] Breastcancer.org. (2021, August). Triple-negative breast cancer. https://www.breastcancer.org/symptoms/types/triple-negative. Accessed 11 April 2022.

[9] Dietze, E. C., Sistrunk, C., Miranda-Carboni, G., O'Regan, R., & Seewaldt, V. L. (2015, April). *Triple-negative breast cancer in African-American women: Disparities Versus Biology*. Nature reviews. Cancer. Retrieved July 12, 2022, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5470637/

[10] Beomyoung Cho, P. D. (2021, July 1). *Racial/ethnic differences in treatment and mortality among patients with triple-negative breast cancer*. JAMA Oncology. Retrieved July 12, 2022, from https://jamanetwork.com/journals/jamaoncology/fullarticle/2780032

[11] Axelsen, K, Jayasuriya, R, Zacharko, C, Karmo, M. (2021, October 22). Disparities in screening and diagnosis for triple negative breast cancer. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2021/10/04132314/CRA-Gilead-Disparities-in-Screening-and-Diagnosis-TNBC.pdf. Accessed 11 April 2022.

[12] Sabatino, S. A., Thompson, T. D., Richardson, L. C., Miller, J. Health Insurance and Other Factors Associated With Mammography Surveillance Among Breast Cancer Survivors, *Medical Care:* March 2012 - Volume 50 - Issue 3 - p 270-276. doi: 10.1097/MLR.0b013e318244d294

provision.[13] Patients in the CER® who received a useful survivorship care plan were over five times as likely to feel very prepared to manage symptoms, compared to those who did not receive such a plan. Despite this benefit, two-thirds of patients did not receive a plan.[14]

- Cancer patients living in rural areas tend to experience worse physical access barriers during their survivorship period.[15,16]
- Black breast cancer survivors lack access to culturally appropriate post-treatment services and are more likely to limit care due to financial hardship.[17,18]
- As there are no differences in guidelines for TNBC survivorship care compared to other breast cancers, guidelines may fail to address the needs of patients with TNBC who face a higher likelihood of cancer recurrence.[19,20] Guidelines for the receipt of palliative care among early-stage cancer patients are also lacking.[21]
- Breast cancer patients treated at minority-serving hospitals were less likely to have received palliative care services, and there are inequities in the provision of palliative care educational materials targeting under-resourced populations.[22,23]
- Physical side effects from breast cancer treatment with the greatest impact on overall quality of life are worse in minority women, which makes ongoing support even more important for these patients.[24] Factors such as younger age and lower income are correlated with feelings of distress and isolation in metastatic breast cancer (mBC) and TNBC patients.[25,26]

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[13] Rosa, W.E. et al. (2022) Palliative Care In The Face Of Racism: A Call To Transform Clinical Practice, Research, Policy, And Leadership. *Health Affairs Forefront.* Accessed May 25, 2022. Retrieved from: https://www.healthaffairs.org/do/10.1377/forefront.20220207.574426/

[14] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[15] Skolarus, T. A., Chan, S., Shelton, J. B., Antonio, A. L., Sales, A. E., Malin, J. L., & Saigal, C. S. (2013). Quality of prostate cancer care among rural men in the Veterans Health Administration. *Cancer,* 119(20), 3629–3635. https://doi.org/10.1002/cncr.28275

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[17] Haynes-Maslow, L., Allicock, M., & Johnson, L. S. (2016). Cancer Support Needs for African American Breast Cancer Survivors and Caregivers. *Journal of cancer education: the official journal of the American Association for Cancer Education,* 31(1), 166–171. https://doi.org/10.1007/s13187-015-0832-1

[18] Hastert, T. A., Banegas, M. P., Hamel, L. M., Reed, A. R., Baird, T., Beebe-Dimmer, J. L., & Schwartz, A. G. (2019). Race, financial hardship, and limiting care due to cost in a diverse cohort of cancer survivors. *Journal of cancer survivorship: research and practice,* 13(3), 429–437. https://doi.org/10.1007/s11764-019-00764-y

[19] Carey, L. A. (2021, June 22). *Follow-up care for TNBC*. Living Beyond Breast Cancer. Retrieved April 4, 2022, from https://www.lbbc.org/learn/types-breast-cancer/triple-negative-breast-cancer/treatments-and-research-triple-negative-5

[20] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[21] Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of palliative care into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline update. *Journal of Clinical Oncology*, *35*(1), 96–112. https://doi.org/10.1200/jco.2016.70.1474

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[23] Bazargan, M., & Bazargan-Hejazi, S. (2021). Disparities in Palliative and Hospice Care and Completion of Advance Care Planning and Directives Among Non-Hispanic Blacks: A Scoping Review of Recent Literature. *The American journal of hospice & palliative care*, *38*(6), 688–718. https://doi.org/10.1177/1049909120966585

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[25] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[26] Buzaglo, J. S., Miller, M., Harvey, A., & Golant, M. (2014, September). *Cancer-related Distress and Unmet Needs among Members of a Metastatic Breast Cancer Registry*. Cancer Support Community. Retrieved April 5, 2022, from https://www.cancersupportcommunity.org/sites/default/files/d7/document/2014_asco_breast_cer_mbc_distress_poster.pdf

To address the drivers of inequitable long-term patient care and support, we identified policy levers, which are summarized in Executive Summary Table 1.

Executive Summary Table 1: Potential policy levers to address barriers to equitable long-term patient support

Level	Expanding equitable access to survivorship and palliative care among TNBC patients
State	• States could use regulations, licensing requirements, and guidelines to expand access and tailor survivorship and palliative care services to under-resourced populations; they could also integrate TNBC-specific guidance into policy language. Promising examples are Vermont and Rhode Island.[27,28]
Federal	• American Society of Clinical Oncology (ASCO) palliative care and TNBC clinical practice guidelines could be revised to include clear guidance for referring early-stage cancer patients to palliative care and recognition of the need for greater survivorship and palliative care support.[29] • Provider education and training could increase awareness of the collaborative nature of palliative care. Education could support providers in assessing and identifying specific patient needs for palliative care services and coordination.
	Expand access to comprehensive survivorship and palliative care
State	• States could use value-based payment incentives to encourage equitable provision of survivorship and palliative care, following examples from Hawaii and California.[30,31] These incentives could be tied to electronic health record systems to systematically identify patients in need of tailored survivorship care.[32] • States could pass legislation to establish a council that makes palliative care a priority.[33,34] • Implementation of targeted licensing standards and reimbursement codes could incentivize equitable palliative care provision. California Medicaid managed care plans provide an example of this.[35]

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[27] Riley, T. and Purignton, K. (2019) States Chart A Policy Path To Improve Palliative Care Services Across The Care Continuum. *Health Affairs Forefront.* Accessed May 25, 2022. Retrieved from: https://www.healthaffairs.org/do/10.1377/forefront.20190807.984947/full/

[28] Palliative Care, State of Rhode Island Department of Health. Accessed May 25, 2022. Retrieved from https://health.ri.gov/healthcare/about/palliativecare/

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[30] National Academy for State Health Policy (NASHP). (2022, March 14). Strengthening Care for People with Serious Illness Seven Steps for Building a Community-Based Palliative Care Benefit Within Medicaid. Retrieved May 15, 2022, from https://www.nashp.org/seven-steps-for-building-a-community-based-palliative-care-benefit-within-medicaid/#toggle-id-5

[31] C-TAC. (2021, July 28). Hawai'i's New Managed Medicaid Benefit for Community-Based Palliative Care. Retrieved May 15, 2022, from https://www.thectac.org/2021/07/hawaiis-new-managed-medicaid-benefit-for-community-based-palliative-care/

[32] Klemp, J.R., Knight, C.J., Lowry, B. et al. (2022) Informing the delivery of cancer survivorship care in rural primary care practice. *J Cancer Surviv* 16, 4–12. https://doi.org/10.1007/s11764-021-01134-3

[33] TrackBill. (n.d.) Georgia HB509. Retrieved May 16, 2022, from https://trackbill.com/bill/georgia-house-bill-509-georgia-palliative-care-and-quality-of-life-advisory-council-create-provisions/1142222/

[34] *Palliative care and quality of Life Advisory Council*. Georgia Department of Community Health. (n.d.). Retrieved April 4, 2022, from https://dch.georgia.gov/palliative-care-and-quality-life-advisory-council/palliative-care-and-quality-life-advisory-council

[35] Palliative Care and SB 1004, DHCS Accessed May 26, 2022. Retrieved from: https://www.dhcs.ca.gov/provgovpart/Pages/Palliative-Care-and-SB-1004.aspx

Federal	• Congress could amend and pass the Metastatic Breast Cancer Access to Care Act to ensure that non-mBC patients (including TNBC patients) who are eligible for Social Security Disability Insurance (SSDI) and Medicare receive early access to support and care.[36] • Congress could pass the Palliative Care and Hospice Education and Training Act (PCHETA), which had already been passed by the House of Representatives as of March 2022, to promote education, awareness, and research of palliative care.[37, 38]
	Support provider adherence to care planning and access to culturally relevant patient navigation programs
State	• More states could encourage the implementation of quality improvement programs and incentives through alternative payment models (APMs) to ensure that under-resourced patients (including TNBC patients) are offered comprehensive survivorship care plans.[39,40]
Federal	• Survivorship care services at federally qualified health centers (FQHCs) or in rural locations could be expanded to better target care for under-resourced populations, including culturally relevant resources and services.[41,42] • The Centers for Medicare and Medicaid Services (CMS) could extend provisions of the Oncology Care Model (OCM) to survivorship and palliative care to help to improve the integration of patient navigators into TNBC care.[43]

Source: CRA analysis of multiple sources

Achieving equitable long-term patient financial well-being

TNBC patients may still suffer from post-treatment side effects, both physical and mental, as well as financial toxicity. Certain communities are disproportionately affected by these long-term impacts:

- The economic burden of care for metastatic TNBC (mTNBC) is found to be greater among non-white patients.[44]

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[36] S.1312 - 117th Congress (2021-2022): Metastatic Breast Cancer Access to Care Act. (2021, April 22). Accessed May 16, 2022, from https://www.congress.gov/bill/117th-congress/senate-bill/1312/all-info?r=6&s=1#:~:text=Official%20Titles%20as%20Introduced,cancer%20and%20for%20other%20purposes.

[37] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

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[39] US Government Accountability Office (GAO). (2021) Provider Performance and Experiences under the Merit-based Incentive Payment System. Retrieved February 23, 2022, from https://www.gao.gov/assets/gao-22-104667-highlights.pdf.

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[41] Halpern, M. T., Viswanathan, M., Evans, T. S., Birken, S. A., Basch, E., & Mayer, D. K. (2015). Models of Cancer Survivorship Care: Overview and Summary of Current Evidence. *Journal of oncology practice,* 11(1), e19–e27. https://doi.org/10.1200/JOP.2014.001403

[42] American Association for Cancer Research (AACR). (2022). Disparities in Cancer Survivorship. Accessed April 12, 2022, from https://cancerprogressreport.aacr.org/disparities/chd20-contents/chd20-disparities-in-cancer-survivorship/

[43] CMS. (2022, May 11). Oncology Care Model. Accessed May 16, 2022, from https://innovation.cms.gov/innovation-models/oncology-care

[44] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2020). Assessing direct costs of treating metastatic triple-negative breast cancer in the USA. *Journal of Comparative Effectiveness Research*, *10*(2), 109–118. https://doi.org/10.2217/cer-2020-0213

- CER® data demonstrate that TNBC patients who use a co-pay assistance program, face longer travel times, or participate in a clinical trial are also more likely to experience worse financial well-being compared to those who do not.[45]
- Younger cancer survivors are at higher risk of filing for bankruptcy due to their treatment costs.[46] Uninsured or underinsured breast cancer survivors disproportionately report worse financial outcomes.[47] CER® data indicate that TNBC patients covered through Medicaid experience higher levels of financial distress.[48]
- Even among insured breast cancer patients, financial toxicity is exacerbated by low household income.[49] CER® data show both mid-income and low-income TNBC patients experience higher levels of financial distress.[50]

To address the drivers of inequitable long-term patient financial well-being, we identified policy levers that are summarized in Executive Summary Table 2.

Executive Summary Table 2: Potential policies to ensure equitable long-term patient financial well-being

Level	Alleviate the financial burden of TNBC on under-resourced patients
State	• States could implement Medicaid waivers to help pay for nonclinical services that are related to a disease or treatment (e.g., case management, housing supports).[51] • Medicaid pilot programs, such as programs that provide financial support for co-pay assistance programs, could specifically target under-resourced TNBC patients.[52] • State governments could implement programs that pay for medical services for qualified low-income patients at community health centers or acute care hospitals.[53] • States that have not done so already could expand the Affordable Care Act (ACA) and Medicaid access to address disparities in access to palliative care and the financial burden of TNBC.[54]

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[45] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[46] Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., Newcomb, P., Hollingworth, W., & Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health affairs (Project Hope)*, *32*(6), 1143–1152. https://doi.org/10.1377/hlthaff.2012.1263

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[48] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[49] Landier, W., Dai, C., Sparks, J., Anthony, K. R., Barrett, J. S., Hageman, L., Francisco, L., Rocque, G. B., Stringer-Reasor, E. M., Nabell, L., & Bhatia, S. (2020). Financial toxicity among breast cancer survivors with health insurance. *Journal of Clinical Oncology*, *38*(15_suppl), 12073–12073. https://doi.org/10.1200/jco.2020.38.15_suppl.12073

[50] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[51] Elizabeth Hinton and Lina Stolyar Published: Aug 05, 2021. (2022, March 16). *Medicaid authorities and options to address social determinants of Health (SDOH) - issue brief*. KFF. Retrieved April 11, 2022, from https://www.kff.org/report-section/medicaid-authorities-and-options-to-address-social-determinants-of-health-sdoh-issue-brief/

[52] These are patient-specific factors that CER® data demonstrates to be associated with greater levels of financial toxicity.

[53] *Health Safety Net*. Mass.gov. (n.d.). Retrieved April 5, 2022, from https://www.mass.gov/orgs/health-safety-net

[54] Cole, A. P., Lipsitz, S. R., Kibel, A. S., Mahal, B. A., Melnitchouk, N., Cooper, Z., & Trinh, Q. D. (2021). Is Medicaid expansion associated with increases in palliative treatments for metastatic cancer? Journal of comparative effectiveness research, 10(9), 733–741. https://doi.org/10.2217/cer-2020-0178

Federal	Congress could introduce legislation to: • Reduce high-cost share for cancer patients receiving coverage through the ACA;[55,56] • Provide financial support to breast cancer patients who face indirect costs of care, such as loss of income;[57] and • Support coverage of medically necessary treatment for patients with mental and physical side effects from cancer treatment, aligning with the goals of the Cancer Moonshot.[58]

Source: CRA analysis of multiple sources

Supporting equitable access to innovative TNBC care and treatment in the long term

The Biden administration has committed to reducing the prevalence and burden of cancer.[59] Our literature review identified policy gaps that may inhibit the development of, and patient access to, TNBC treatment in the long term, impeding achievement of the administration's goals:

- Coverage of innovative diagnosis and testing is relatively nascent and, where implemented, uptake has been inequitable.[60,61] Incentives to launch innovative diagnosis and testing approaches may be limited by lack of affordable coverage or gaps in coverage.
- Policy proposals that encourage investments in novel TNBC treatments could help to reduce long-standing inequities that exacerbate negative outcomes for TNBC patients, especially those in under-resourced communities.[62,63]

To address the drivers of equitable long-term patient access to innovative TNBC treatment, we identified policy levers that are summarized in Executive Summary Table 3.

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[55] Segel, J. E., & Jung, J. (2019). Coverage, financial burden, and the Patient Protection and Affordable Care Act for patients with cancer. Journal of Oncology Practice, 15(12). https://doi.org/10.1200/jop.19.00138

[56] Rosenzweig, M., West, M., Matthews, J., Stokan, M., Yoojin Kook, Y. K., Gallups, S., & Diergaarde, B. (2019). Financial Toxicity Among Women With Metastatic Breast Cancer. Oncology nursing forum, 46(1), 83–91. https://doi.org/10.1188/19.ONF.83-91

[57] Palmer, N. R., Weaver, K. E., Hauser, S. P., Lawrence, J. A., Talton, J., Case, L. D., & Geiger, A. M. (2015). Disparities in barriers to follow-up care between African American and White breast cancer survivors. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer*, *23*(11), 3201–3209. https://doi.org/10.1007/s00520-015-2706-9

[58] See for example, existing legislation such as the Access to Breast cancer Diagnosis Act (which eliminates patient cost-sharing for medically necessary diagnostic impact) and the Lymphedema Treatment Act (ensures Medicare coverage for the medically necessary compression treatments).

[59] *Cancer Moonshot℠*. National Cancer Institute. (n.d.). Retrieved April 5, 2022, from https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

[60] *H.R.2428 - Access to Breast Cancer Diagnosis Act of 2019*. Congress.gov. (n.d.). Retrieved April 5, 2022, from https://www.congress.gov/bill/116th-congress/house-bill/2428/amendments

[61] Sheinson, D. M., Wong, W. B., Meyer, C. S., Stergiopoulos, S., Lofgren, K. T., Flores, C., Adams, D. V., & Fleury, M. E. (2021). Trends in Use of Next-Generation Sequencing in Patients With Solid Tumors by Race and Ethnicity After Implementation of the Medicare National Coverage Determination. JAMA network open, 4(12), e2138219. https://doi.org/10.1001/jamanetworkopen.2021.38219

[62] National Council on Disability (2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. Retrieved from https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

[63] National Minority Quality Forum, Traditional Value Assessment Methods Fail Communities of Color and Exacerbate Health Inequities. Retrieved from: https://static1.squarespace.com/static/5be307ae5b409bfaa68b1724/t/5f58fbb6eaffbe1bb7c24416/1599667126706/Disparities+and+Value+Assesssment+White+Paper.pdf.

Executive Summary Table 3: Potential policies to ensure equitable patient access to innovative TNBC treatment in the long term

Level	Enhance coverage and encourage development of innovative, patient-centered healthcare delivery
State	• States could apply for projects authorized under Section 1115 waivers to promote innovative cancer care delivery and payment models that support patient coverage.[64] • State health plans could develop APMs and other payment reforms with providers, community-based organizations, and FQHCs to incentivize innovative care delivery.
Federal	• CMS could integrate learnings from the OCM into a successor model to encourage development of value-based, patient-centered cancer care models.
	Maintain incentives for research and development of TNBC medicine
Federal	• CMS could ensure that approved Medicaid waivers advance health equity and Section 1115 demonstrations uphold the federal open-formulary requirement, supporting access for low-income cancer patients without any alternative treatment.[65] • Congress could ensure protection of policies that have demonstrated successful innovation in oncology. Policy reforms could also incentivize the development of cancer drugs for earlier lines of therapy and for historically underrepresented populations.[66]

Source: CRA analysis of multiple sources

We recognize that our recommendations above are far-reaching, and any implementation will require further assessment of the benefits and unintended trade-offs. This study should be taken as a starting point for detailed examination of policies to address health inequity for TNBC patients.

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[64] Cancer Action Network (January 2020). Medicaid Section 1115 Research and Demonstration Waivers. Retrieved from (https://www.fightcancer.org/sites/default/files/FINAL-Medicaid%201115%20Waivers%2001.09.20.pdf).

[65] The Commonwealth Fund (April 5, 2022) Oregon Seeks to Limit Medicaid Coverage of Accelerated-Approval Drugs. Retrieved from: https://www.commonwealthfund.org/blog/2022/oregon-seeks-limit-medicaid-coverage-accelerated-approval-drugs

[66] Fierece Biotech, April 6, 2022. FDA oncology chief aims to open up accelerated approval for earlier cancer treatment under 'Project FrontRunner'. Retrieved from: https://www.fiercebiotech.com/biotech/fda-oncology-chief-eyes-accelerated-approval-earlier-cancer-treatment-under-planned-project

1. Introduction

In this study, Charles River Associates (CRA) and Cancer Support Community (CSC) examine the extent to which policies associated with patient support, well-being, and treatment for triple negative breast cancer (TNBC) patients can exacerbate or ameliorate disparities in TNBC health outcomes among under-resourced populations in the United States (US).

It is intended that the findings from this review will inform how health and public policy strategies can ensure more equitable access to support and care to improve TNBC patient health outcomes. Specifically, we focus on population groups that face barriers and are at risk of developing TNBC, namely women who are Black, Hispanic, or young (less than 40 years old) and/or who have lower income or reside in areas that are rural, remote geographically, or *medical deserts*.[67]

The report was conducted for and funded by Gilead Sciences (Gilead).

1.1. Overview of triple negative breast cancer in the US in under-resourced populations

Breast cancer is the most common cancer in the US and among women, with approximately 287,850 expected new cases in 2022.[68] Of these diagnoses, approximately 10%–12% of breast cancers are diagnosed as TNBC, with some sources suggesting that 20% of breast cancers may be triple negative.[69] Black and Hispanic women have a higher relative incidence (21% and 12%, respectively) of the TNBC subtype compared with non-Hispanic white women (10%).[70] Furthermore, Black women are usually diagnosed at younger ages compared to white women (56.3 versus 59.7 years of age). TNBC diagnosis in Black women tends to occur at later stages of the disease, with larger and more aggressive tumors, positive lymph node tissue, and poor *differentiation* compared to white women.[71] Furthermore, non-Hispanic Black women have been found to have lower three-year survival rates than non-Hispanic white women (79.4% vs. 83.1%).[72]

In previous reports, CRA found that barriers to screening for, and diagnosis of, TNBC can exacerbate these worse health outcomes in under-resourced populations in the US.[73] It is important to implement policies that will support early detection in these populations, especially because TNBC is more challenging to detect through traditional mammography screening compared to other breast cancers and many under-resourced populations already face a poor prognosis due to a greater, and increasing, likelihood of late, distant-stage (the cancer has spread to “distant” parts of the body, away from where it originated)

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[67] Terminology commonly used in this paper are defined in the Appendix. Italicized words throughout the paper are defined in the glossary (Appendix Table 2)

[68] National Cancer Institute Surveillance, Epidemiology, and End Results Program. (2022). Cancer stat facts: Female breast cancer. https://seer.cancer.gov/statfacts/html/breast.html. Accessed 12 July 2022.

[69] Breastcancer.org. (2021, August). Triple-negative breast cancer. https://www.breastcancer.org/symptoms/types/triple-negative. Accessed 11 April 2022.

[70] American Cancer Society. (2019). Breast cancer facts & figures 2019–2020. https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf. Accessed 11 April 2022.

[71] Sternberg, A. (2021, May 21). *Outcome data for black women with early TNBC suggest research needed to combat disparities*. Cancer Network. Retrieved April 4, 2022, from https://www.cancernetwork.com/view/outcome-data-for-black-women-with-early-tnbc-suggest-research-needed-to-combat-disparities. Accessed 11 April 2022.

[72] Fei Wang, Wei Zheng, Christina E. Bailey, Ingrid A. Mayer, Jennifer A. Pietenpol and Xiao-Ou Shu. (2021, February 15). Racial/Ethnic Disparities in All-Cause Mortality among Patients Diagnosed with Triple-Negative Breast Cancer. Cancer Res. (81) (4) 1163-1170; DOI: 10.1158/0008-5472.CAN-20-3094

[73] Axelsen, K, Jayasuriya, R, Zacharko, C, Karmo, M. (2021, October 22). Disparities in screening and diagnosis for triple negative breast cancer. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2021/10/04132314/CRA-Gilead-Disparities-in-Screening-and-Diagnosis-TNBC.pdf. Accessed 11 April 2022.

diagnosis.[74,75] Furthermore, few treatment options are available for TNBC compared to other types of breast cancer, and TNBC is particularly challenging to treat when it is diagnosed at later stages, as there are few biomarkers for effective targeted therapy.[76]

The social determinants of inequitable TNBC care

There are reports that set out the evidence of disparities in TNBC patient outcomes, but few investigate the link to healthcare inequities. Specifically, the inequitable distribution of resources that underpin social determinants of health (healthy living support, access to care, social support, and insurance) can lead to disparities in health outcomes. Furthermore, people of color are more likely to have a greater likelihood of chronic disease or comorbidities, such as obesity and diabetes.[77] These factors, in combination with biological risk factors, may also affect the prevalence and trajectory of TNBC in Black, Hispanic, and low-income women.[78,79]

- Under-resourced communities face a poor TNBC prognosis due to greater, and increasing likelihood of, late, distant-stage (the cancer has spread to “distant” parts of the body) diagnosis.
- Later-stage and metastatic TNBC (mTNBC), which is more common in Black women compared to white women, has a poor prognosis. The clinical goal of curing the patient diagnosed at an early stage shifts to extending survival.[80]
- Black women are less likely to receive (as noted in the cited study) surgery and systemic treatments available for TNBC and often face treatment-initiation delays and prolonged treatment duration, leading to worse survival outcomes.[81,82]
- Policies that target under-resourced communities with limited access to early-detection resources – such as MRI screening for those at high risk – and to appropriate follow-up diagnostic care are critical to ensure timely diagnosis once an abnormality has been detected through initial screening.[83]

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[74] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[75] Axelsen, K, Jayasuriya, R, Zacharko, C, Karmo, M. (2021, October 22). Disparities in screening and diagnosis for triple negative breast cancer. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2021/10/04132314/CRA-Gilead-Disparities-in-Screening-and-Diagnosis-TNBC.pdf. Accessed 11 April 2022.

[76] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2021). Real-world effectiveness outcomes in patients diagnosed with metastatic triple-negative breast cancer. Future oncology (London, England), 17(8), 931–941. https://doi.org/10.2217/fon-2020-1021

[77] Thorpe, K.E., Chin, K.K., Cruz, Y., Innocent, M.A., Singh, L. (2017, August 17). "The United States Can Reduce Socioeconomic Disparities By Focusing On Chronic Diseases", Health Affairs Blog. Retrieved from https://www.healthaffairs.org/do/10.1377/forefront.20170817.061561/full/. Accessed 28 February, 2022.

[78] 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.

[79] 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.

[80] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2021). Real-world effectiveness outcomes in patients diagnosed with metastatic triple-negative breast cancer. Future oncology (London, England), 17(8), 931–941. https://doi.org/10.2217/fon-2020-1021;

[81] Cho B, Han Y, Lian M, et al. Evaluation of Racial/Ethnic Differences in Treatment and Mortality Among Women With Triple-Negative Breast Cancer. JAMA Oncol. 2021;7(7):1016–1023. doi:10.1001/jamaoncol.2021.1254

[82] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[83] Axelsen, K., Jayasuriya, R., Zacharko, C., Karmo, M. (2021, October). Disparities in screening and diagnosis for triple negative breast cancer. Charles River Associates. Retrieved from https://media.crai.com/wpcontent/uploads/2021/10/04132314/CRA-Gilead-Disparities-in-Screening-and-Diagnosis-TNBC.pdf. Accessed 28 February 2022.

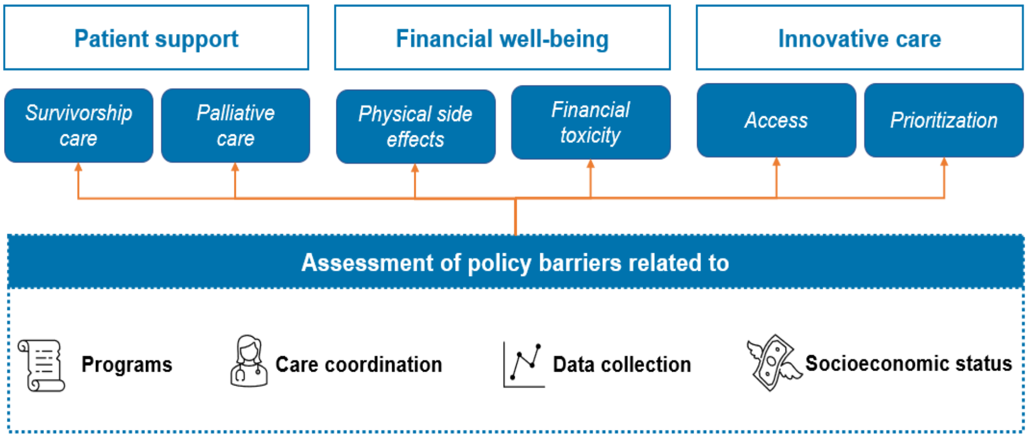
- Policies that support timely access to optimal care and appropriate treatments – such as policies that would limit excessive *utilization management* practices for TNBC treatments (such as step therapy or fail first, meaning that a patient must “fail” on one or more lower-cost medications before gaining access to the treatment prescribed by their physician) or that would encourage investment into patient navigation programs that support clinical trial enrollment in under-resourced communities – were found to be critical to reducing these inequities.[84]

This report considers inequities in the ongoing patient support phase of the TNBC patient journey.

1.2. Our approach

For this policy analysis, we assessed the current policy landscape using government policy documents and academic research. Key policy components were identified and aligned to the TNBC patient journey. We focused on the phases of the TNBC patient journey following patient diagnosis, care, and treatment (Figure 1).

Figure 1: Patient journey within TNBC post-treatment care



Source: CRA Analysis

To evaluate the extent to which care and treatment 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. Our search terms included “triple negative breast cancer,” “oncology,” “legislation,” “policy,” and “program.” To identify documents with details specific to ongoing patient support , we used additional relevant terms, such as “care coordination,” “navigation,” “education,” “survivorship,” “palliative care,” follow-up,” “post-treatment,” “outcomes,” “real world evidence,” “quality of life,” “financial toxicity,” “socioeconomic support,” “mental health,” “employment,” “cost,” “innovative treatment,” “innovative diagnostics,” “optimal cancer care models,” and “R&D investment.” Finally, to identify the extent to which policies affect *HDI*, we combined the terms listed above with the search terms “disparity,” “inequity,” “systemic racism,” and terms relevant to our *key populations*, “Black” and “Hispanic.”

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[84] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

The review included over 170 academic studies, cancer organization white papers, state and federal government documents, and media articles, and it focused on examining research published in the last ten years. To ensure that the policy landscape captured the real-world patient perspective, we integrated insights from Cancer Support Community (CSC), a patient advocacy organization with a mission to ensure “all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community.”[85] We included data insights from CSC’s Cancer Experience Registry® (CER®) to supplement the research in this review.[86] In 2013, CSC launched the CER®, an online research initiative examining the physical, emotional, practical, and financial impact of cancer. Individuals diagnosed with cancer are invited to answer core registry questions asked of all participants, regardless of their diagnosis. To date, the CER® also includes questions specific to living with fourteen distinct cancer diagnoses. CER® methods have been previously reported.[87,88]

An overview of the Cancer Experience Registry

Participants were recruited through CSC’s community-based network partners and online communities, CSC’s toll-free support helpline, other advocacy organizations, partnering hospitals, and social media. Participants were invited to complete the survey online. Surveys were typically completed at home, but some were completed in a clinic on a computer or tablet. Ethical and Independent Review Services (E&I) served as the study institutional review board of record. All procedures performed involving human participants were in accordance with the ethical standards of the 1964 Helsinki Declaration and its amendments or comparable ethical standards. Participants provided advance electronic informed consent.

From January 2015 to August 2021, 210 US residents with a history of TNBC took part in the CER®; they constitute the current analytic data set.[89] The sample size varies across survey items as a result of participants skipping items and different survey versions over the seven-year span, so the relevant sample size is reported when the CER® is referenced.[90] There are several cases with small sample sizes, which highlights the need for greater research.

While the CER® makes an important contribution to the understanding of met and unmet needs of people living with TNBC, there is a growing need for research that represents diverse patient voices among historically underserved and underrepresented groups. Increasing the diversity of participants in the CER® is a top priority for CSC, and ongoing initiatives continue to explore and expand strategies to recruit historically

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[85] Cancer Support Community (CSC). (n.d.) About Us. https://www.cancersupportcommunity.org/about-us. Retrieved April 11, 2022.

[86] Cancer Support Community (CSC). (n.d.) Cancer Experience Registry® (CER®). https://www.cancersupportcommunity.org/registry. Retrieved April 11, 2022.

[87] Zaleta, A. K., McManus, S., Fortune, E. E., DeRosa, B. W., Buzaglo, J. S., Olson, J. S., Goldberger, S., & Miller, M. F. (2021). CancerSupportSource®-15+: development and evaluation of a short form of a distress screening program for cancer patients and survivors. Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer, 29(8), 4413–4421. https://doi.org/10.1007/s00520-021-05988-2

[88] Zaleta, A. K., Miller, M. F., Olson, J. S., Yuen, E., LeBlanc, T. W., Cole, C. E., McManus, S., & Buzaglo, J. S. (2020). Symptom Burden, Perceived Control, and Quality of Life Among Patients Living With Multiple Myeloma. *Journal of the National Comprehensive Cancer Network : JNCCN*, *18*(8), 1087–1095. https://doi.org/10.6004/jnccn.2020.7561

[89] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[90] The sample was 81% Non-Hispanic White (*n* =170), 7% Non-Hispanic Black (*n* = 15), 5% Hispanic (*n* = 11), and 7% Non-Hispanic other or multiple race categories identified (*n* = 14). A total of 33 (16%) participants reported they lived in a rural location; 35 (17%) earned an annual household income <$40K. Mean (SD) age was 53 (10) years; 22 (10%) were <40 years of age. The median time since diagnosis was 2 years with 13% of TNBC participants within 1 year of their cancer diagnosis, 27% 1 to <2 years, 33% 2 to <5 years, and 26% 5 or more years. Only 2 participants (1%) indicated they were uninsured.

underrepresented cancer patients and caregivers to the CER®, including those impacted by TNBC.

1.3. Structure of the report

This report is structured as follows:

- Chapter 2 examines the drivers of inequitable coordination for long-term patient support and care
- Chapter 3 evaluates inequities in patient’s financial burdens
- Chapter 4 reviews the policy environment for TNBC treatment
- Chapter 5 presents conclusions and our policy recommendations

2. Inequitable access to long-term patient support

TNBC patients have a higher risk of disease metastasis and recurrence, a worse prognosis, and worse side effects compared to those with other breast cancer types.[91,92] Support services, such as post-treatment care coordination and palliative care services, have been found to positively affect future patient health and quality of life for patients and their families.[93,94] Palliative care is an important component of survivorship care and entails a patient- and family-centered approach that identifies and treats pain and other physical, psychosocial, and spiritual problems resulting from cancer.[95] While palliative care is historically viewed as end-of-life care, in 2017 the American Society of Clinical Oncology (ASCO) updated its guidelines on palliative care to recommend dedicated palliative services beginning early in the disease course.[96] However, under-resourced communities have less access to post-treatment surveillance and palliative care services.[97,98] In this section, we first explore the importance of post-treatment survivorship care among TNBC patients and then consider palliative care specifically, examining areas of inequity for under-resourced communities.

2.1. Addressing barriers to survivorship and palliative care for TNBC patients

Breast cancer patients who have entered the post-treatment phase, also known as survivors, are supported through healthcare services known as survivorship care.[99]

Inequities in access to survivorship (follow-up) care

Survivorship, or follow-up, care consists of routine medical check-ups to screen for potential cancer recurrence and any side effects that manifest after completion of initial treatment.[100] Follow-up care is particularly important for TNBC survivors, because the

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[91] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[92] Sun, B. (n.d.) Triple-Negative Breast Cancer. *Johns Hopkins Medicine.* Retrieved May 13, 2022, from https://www.hopkinsmedicine.org/health/conditions-and-diseases/breast-cancer/triple-negative-breast-cancer

[93] Dührsen, U., Deppermann, K. M., Pox, C., & Holstege, A. (2019). Evidence-Based Follow-up for Adults With Cancer. *Deutsches Arzteblatt international*, *116*(40), 663–669. https://doi.org/10.3238/arztebl.2019.0663

[94] World Health Organization. (n.d.). *Palliative care*. World Health Organization. Retrieved April 4, 2022, from https://www.who.int/health-topics/palliative-care

[95] Fred Hutchinson Cancer Center. (n.d.). *Palliative Care for Metastatic Breast Cancer*. Fred Hutch. Retrieved April 4, 2022, from https://www.fredhutch.org/content/dam/www/research/divisions/public-health-sciences/epidemiology/bci-25/KSPDF/KS%20Palliative%20Care%20Metastatic%20030617.pdf

[96] Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of Palliative Care Into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of clinical oncology : official journal of the American Society of Clinical Oncology, 35(1), 96–112. https://doi.org/10.1200/JCO.2016.70.1474

[97] Lee Smith, J., & Hall, I. J. (2015). Advancing Health Equity in Cancer Survivorship: Opportunities for Public Health. *American journal of preventive medicine,* 49(6 Suppl 5), S477–S482. https://doi.org/10.1016/j.amepre.2015.08.008

[98] Bazargan, M., & Bazargan-Hejazi, S. (2021). Disparities in Palliative and Hospice Care and Completion of Advance Care Planning and Directives Among Non-Hispanic Blacks: A Scoping Review of Recent Literature. *The American journal of hospice & palliative care*, *38*(6), 688–718. https://doi.org/10.1177/1049909120966585

[99] Fred Hutch. Survivorship Care after Curative Treatment for Breast Cancer. https://www.fredhutch.org/content/dam/www/research/divisions/public-health-sciences/epidemiology/bci-25/KSPDF/KS%20Survivorship%20After%20030617.pdf

[100] The American Cancer Society medical and editorial content team. *Follow-up Care After Breast Cancer Treatment*, American Cancer Society, 5 Jan. 2022, https://www.cancer.org/cancer/breast-cancer/living-as-a-breast-cancer-survivor/follow-up-care-after-breast-cancer-treatment.html.

recurrence rate is higher for TNBC than for other breast cancers.[101] According to CER® data, one-half (50%) of TNBC patients surveyed (*n* = 167) had not received a survivorship care plan from their provider.[102] Of those who had, 84% found it to be useful. Patients who found the survivorship care plan useful were over five times as likely to feel very prepared to manage symptoms, compared to those who did not receive a plan. In addition, patients who had a member of their healthcare team offer help coordinating distress-related care were over three times more likely to feel quite a bit or very prepared to manage their symptoms compared to patients who did not receive this support.[103]

There is academic evidence of inequities in the receipt of follow-up care for patients living in rural areas, women of color, and those with inadequate health insurance. Patients living in rural areas tend to have worse access to care and oncology resources during the survivorship period.[104] In addition, Black and uninsured or underinsured cancer survivors are more likely to receive insufficient support or surveillance following their initial cancer treatment.[105] For example, 25% of breast cancer survivors did not receive appropriate mammography surveillance, and uninsured or publicly insured women are at greater risk for not receiving mammography surveillance.[106] Furthermore, it has been noted that TNBC can appear *benign* on mammography and that MRI is the most sensitive imaging test for detecting this subtype of breast cancer.[107] However, ASCO clinical guidelines do not recommend routine MRI surveillance, except for patients who have been identified as high-risk.[108] There remains a need for greater understanding of the comparative effectiveness of multimodality surveillance regimens, particularly for TNBC patients.[109]

Research on cancer survivors suggests that social determinants of health, such as low education attainment or being uninsured, are associated with lower likelihood of cancer survivorship care plan provision; potential explanations of this disparity include insufficient time during clinical encounters, inadequate staff, and minimal funding resources.[110] This affects the quality of care these patients receive as they transition to the post-treatment phase. Patients treated through a multidisciplinary combination of an oncologist and a primary care physician were significantly more likely to receive a survivorship care plan: 63% of survivors treated by a team of care providers received a care plan, while only around 43% of survivors treated by an oncologist *or* a primary care physician received

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[101] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[102] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[103] Analyses were adjusted for income, age, currently receiving treatment, time since diagnosis, receiving part or all of care at an academic cancer center, geographic region, type of insurance, and advanced cancer status.

[104] Skolarus, T. A., Chan, S., Shelton, J. B., Antonio, A. L., Sales, A. E., Malin, J. L., & Saigal, C. S. (2013). Quality of prostate cancer care among rural men in the Veterans Health Administration. *Cancer,* 119(20), 3629–3635. https://doi.org/10.1002/cncr.28275

[105] Lee Smith, J., & Hall, I. J. (2015). Advancing Health Equity in Cancer Survivorship: Opportunities for Public Health. *American journal of preventive medicine,* 49(6 Suppl 5), S477–S482. https://doi.org/10.1016/j.amepre.2015.08.008

[106] Sabatino, S. A., Thompson, T. D., Richardson, L. C., Miller, J. Health Insurance and Other Factors Associated With Mammography Surveillance Among Breast Cancer Survivors, *Medical Care:* March 2012 - Volume 50 - Issue 3 - p 270-276. doi: 10.1097/MLR.0b013e318244d294

[107] McGarry W.M., Bhole S. (2018). Triple-Negative Breast Cancer: What Crucial Information can Imaging Add to the Diagnosis, Treatment and Prognosis? *Int J Womens Health Wellness* 5:087. doi. org/10.23937/2474-1353/1510087

[108] Runowicz CD, Leach CR, Henry NL, et al. (2016). American Cancer Society/American Society of Clinical Oncology breast cancer survivorship care guideline. *J Clin Oncol*; 34:611–635

[109] Lam, D. L., Houssami, N., & Lee, J. M. (2017). Imaging Surveillance After Primary Breast Cancer Treatment. *AJR. American journal of roentgenology,* 208(3), 676–686. https://doi.org/10.2214/AJR.16.16300

[110] Timsina, L. R., Zarzaur, B., Haggstrom, D. A., Jenkins, P. C., Lustberg, M., & Obeng-Gyasi, S. (2021). Dissemination of cancer survivorship care plans: who is being left out?. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer,* 29(8), 4295–4302. https://doi.org/10.1007/s00520-020-05915-x

one.[111] Therefore, policies and programs that aim to improve care coordination for under-resourced populations are important for advancing health equity among TNBC patients.

Existing literature highlights several factors related to SDoH that explain why inequities exist. For example, rural patients live far from medical centers that provide survivorship care. Interventions, such as telemedicine provision, to connect rural cancer survivors to care have failed to improve inequities in access because of poor access to fixed broadband or a satellite clinic.[112] Black breast cancer survivors report that they have poor access to post-treatment support services that are culturally appropriate.[113] In other cancers, survivors have reported being uninformed about the appropriate follow-up protocol for post-treatment surveillance.[114] Financial hardship differs by race, with Black breast cancer survivors being more likely to report cancer-related debt and, as a result, more likely to limit care due to cost.[115] Furthermore, there are few differences in guidelines for survivorship care for TNBC and those for other forms of breast cancer.[116] As a result, breast cancer survivorship guidelines may fail to address the needs of patients with TNBC, who face a higher likelihood of cancer recurrence.[117]

Academic studies point to provider decision-making bias as a driver of inequitable provision of survivorship care. For example, one study identified the association between unmet supportive needs among Hispanic/Latinx breast cancer patients and limited provider communication.[118] Gaps in provision can occur in the absence of systems or guidelines that account for underserved patients. A 2016 survey of US health providers responsible for survivorship care implementation identified that 44% of respondents lacked a system for identifying survivors as eligible for plans.[119] Notably, 73% of respondents to the same survey reported identifying patients eligible for survivorship plans on a case-by-case basis, revealing the potential for provider bias.

To address these inequities in access to survivorship care, policies need to be implemented to appropriately provide them to under-resourced populations and tailor the

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[119] Benci, J. L., Vachani, C. C., Hampshire, M. K., Bach, C., Arnold-Korzeniowski, K., Metz, J. M., & Hill-Kayser, C. E. (2020). Factors Influencing Delivery of Cancer Survivorship Care Plans: A National Patterns of Care Study. Frontiers in oncology, 9, 1577. https://doi.org/10.3389/fonc.2019.015775

provision of survivorship care to meet their specific needs. For example, increasing survivorship care services at federally qualified health centers (FQHC) or in rural locations can better target care for under-resourced populations and help providers begin to understand how to meet the needs of these patients.[120] Culturally relevant resources and services also need to be provided to improve access to survivorship care by non-white patients.[121] Further, implementation of data to identify underrepresented patients and eliminate the potential for bias and updated clinical guidelines could enable the systematic, equitable provision of survivorship care. Education materials for oncologists, primary care physicians, nurses, and nurse navigators can ensure that survivorship care is provided in a culturally appropriate and patient-empowering manner.

Inequities in access to palliative care

Palliative care is an element of survivorship care that seeks to improve the quality of life of patients and their families by relieving serious health-related suffering – physical, psychological, social, and/or spiritual – during survivorship.[122] Increased access to palliative care is vital to improving health equity for TNBC patients because the incorporation of palliative care in cancer treatment results in better patient outcomes, such as higher quality of life, lower rates of depression, and prolonged survival.[123] Furthermore, TNBC has fewer targeted treatment options compared to other receptor-positive breast cancer subtypes, and the aggressive chemotherapy treatments typically used for TNBC can cause significant side effects.[124,125]

Data from the CER® revealed that almost that half (47%) of TNBC patients surveyed were at least a little interested in seeing a palliative or supportive care provider for the management of symptoms or side effects.[126] Despite this finding, Figure 2 illustrates that TNBC patients typically never or rarely accessed palliative care support during the year before they completed the survey.[127] Specifically, the CER® survey shows that one-third (31%) of TNBC patients surveyed never or rarely accessed an oncology provider (doctor or nurse) for support with symptoms and side effects (no variation by income, insurance, or region was observed). The survey results also indicate that almost three-fifths (56%) of respondents reported that they never or rarely accessed a primary care provider (doctor or nurse) for palliative care support in the prior year. A very small proportion (9%) utilized a palliative care provider in the prior year.

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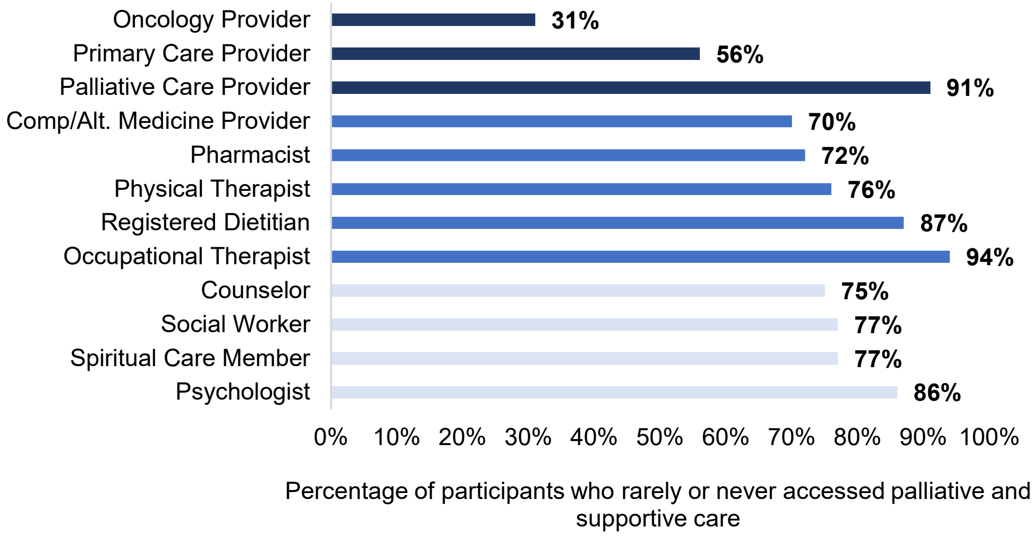
[125] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[126] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[127] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

Figure 2: Lack of palliative and supportive care provider utilization for symptom and side effect support in the prior year



Source: n = 66 TNBC patients from the Cancer Experience Registry

Palliative care services are less likely to be provided to typically underrepresented populations. In a 2019 retrospective study, researchers found significantly lower odds of receiving palliative care among metastatic prostate, lung, breast, and colon cancer patients treated at minority serving hospitals (MSHs) compared to non-MSHs.[128] Another factor that contributes to disparate access to palliative care is a difference in the provision of educational materials targeting underserved populations and physician communication that these services are available. A study conducted in 2011 found that knowledge of hospice and palliative care was significantly lower among both non-Hispanic Black cancer patients compared to their white counterparts and among persons with limited education.[129] Medicare patients may also face palliative care access issues, as palliative care services administered by a Medicare-certified hospice have strict qualifying criteria, including attending and hospice physician certification and short recertification time frames requiring documentation of patient life-expectancy.[130] Such qualifying criteria, which include a medical prognosis of a life expectancy of six months or less, are outdated and based on the historic view of palliative care as end-of-life care. This is misaligned with the recent definitions and clinical guidelines provided by ASCO and NCCN discussed previously, which recommend that palliative care services be accessible to patients at all cancer stages.

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Studies have noted that one reason for inequities in palliative care provision is providers' implicit bias and structural racism.[131] In a 2021 survey of oncologists, one-third (31%) of respondents recognized implicit bias in palliative and hospice care provision (often, very often, and almost always).[132] There is a growing body of evidence demonstrating that Black patients are less likely to be believed when they report pain and symptoms and are three times more likely than white patients to say that their preferences were not taken into account in healthcare decision-making.[133, 134, 135] These trends reflect the effect of physicians' implicit biases.

Overall, there is significant evidence of inequitable provision of palliative care to under-resourced and underrepresented cancer patients.[136] However, we find there is still a general shortage of studies examining the extent of the disparity in palliative care provision for breast cancer patients in underserved communities; such studies would help researchers and clinicians better understand the barriers that prevent certain communities from receiving appropriate care.[137] Furthermore, there is an even larger gap in studies that focus specifically on palliative care in TNBC patients. Disparities in access to palliative care become critical when considering the inequities TNBC patients face in physical and mental health side effects of treatment, which palliative care services seek to address.

2.2. Reducing disparity in physical and mental health treatment effects for TNBC patients

Even after breast cancer treatment has been completed, survivors can suffer from both physical and mental health deterioration that can become chronic and negatively affect a survivor's quality of life.[138] Studies show that cancer patients suffer from a variety of treatment side effects, such as fatigue, general pain, and nerve damage caused by chemotherapy.[139] As treatment for TNBC and other breast cancers is largely the same, physical side effects for TNBC specifically are similar.[140] In addition to physical effects of treatment, research has found that breast cancer survivors are more likely to experience anxiety, depression, sleep disturbance, and other mental health problems compared to

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[131] Rosa, W.E. et al. (2022) Palliative Care In The Face Of Racism: A Call To Transform Clinical Practice, Research, Policy, And Leadership. *Health Affairs Forefront.* Accessed May 25, 2022. Retrieved from: https://www.healthaffairs.org/do/10.1377/forefront.20220207.574426/

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[139] *Patient Insights - 2020 CANCER EXPERIENCE REGISTRY REPORT*. Cancer Support Community. (2020, June). Retrieved April 11, 2022, from https://www.cancersupportcommunity.org/sites/default/files/file/2020-07/CSC_Registry_Report_June_2020.pdf

[140] *Treatment of triple-negative breast cancer: Treatment of TNBC*. American Cancer Society. (n.d.). Retrieved April 11, 2022, from https://www.cancer.org/cancer/breast-cancer/treatment/treatment-of-triple-negative.html

women with no prior cancer.[141] Mental health effects are particularly relevant to TNBC survivors – studies have shown that a TNBC diagnosis results in extra emotional effects compared to a diagnosis of other forms of breast cancer due to heightened anxiety about recurrence and feelings that no targeted therapies will be beneficial.[142]

Evidence from the literature aligns with findings from the CER®'s CancerSupportSource™ (CSS), a validated set of distress-screening questions that examines concepts related to 25 psychosocial, practical, and physical needs of cancer patients and survivors, plus four additional items (totaling 29 items). The top-ranked items reveal that the most prominent concerns among TNBC respondents answering the CSS questions (sample size ranges from 105 to 195) were primarily physical, cognitive, or future-oriented in nature:

- Regarding concerns about the future, more than one-half of respondents reported being moderately to very seriously concerned about cancer progressing or coming back (57%) and worrying about the future and what lies ahead (54%).
- Consistently, close to one-half rated items of physical well-being a moderate to very serious concern: eating and nutrition (55%), exercising and being physically active (55%), feeling too tired to do the things you need or want to do (49%), sleep problems (42%), moving around (40%), and body image concern (52%).

Data from the CER® provide insights into numerous patient-reported symptoms and functional domains, including physical and mental health among TNBC patients (sample size ranges from 205 to 208), using the Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29 v2.0). Five domains assess symptoms, with higher scores corresponding to worse symptomology (pain interference, fatigue, sleep disturbance, anxiety, and depression), and two domains assess function, with lower scores corresponding to worse functioning (physical and social function). Participants rate each symptom item with reference to the past seven days; function scales have no time frame specified. These scores can be used to identify elevated symptom burden and functional impairments relative to the general population and other cancer populations. A difference of three points in PROMIS T-scores from the population norm can be considered clinically meaningful.[143]

Overall, as shown in Table 1, CER® participants with TNBC were more likely to report higher scores relating to symptoms and deficits (relative to the general US population normal score of 50) in the majority of daily functions included in the PROMIS-29 domains. Fatigue and anxiety scores were the highest among TNBC patients, exceeding the established PROMIS threshold for mild severity.[144] Specifically, TNBC patients within two years of diagnosis (*n* = 84), compared to patients with recently diagnosed breast cancer (MY-Health study), reported elevated levels of fatigue, anxiety, and depression.

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[144] *Home*. PROMIS. (n.d.). Retrieved June 8, 2022, from https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis

Table 1: PROMIS symptom and functional status reference values for TNBC patients in the CER® by time since diagnosis (*n* = 210)*

		Pain interference		Fatigue		Sleep disturbance		Anxiety		Depression		Physical function		Social function	
Group	n	M	SE	M	SE	M	SE	M	SE	M	SE	M	SE	M	SE
Cancer Experience Registry: TNBC															
Total	210	54.2	0.7	55.3	0.8	53.5	0.6	56.2	0.8	51.9	0.7	45.3	0.6	48.8	0.7
MY-Health Cohort (cancer reference group)															
Breast, <2 years diagnosis	*1,588*	*52.8*	*0.3*	*52.5*	*0.3*	*51.7*	*0.3*	*49.6*	*0.3*	*48.5*	*0.3*	*44.9*	*0.3*	*50.7*	*0.3*
Cancer Experience Registry: TNBC by time since diagnosis															
<2 years	*84*	*55.0*	*1.2*	*56.5*	*1.1*	*54.1*	*1.0*	*58.7*	*1.1*	*53.8*	*1.1*	*43.6*	*0.9*	*46.8*	*1.2*

*Higher scores indicate greater symptom burden (pain interference, fatigue, sleep disturbance, anxiety, depression)/higher function (physical and social)

Source: Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

Evidence of inequities in physical side effects

There is evidence of inequitable physical side effects from treatment, particularly for Black breast cancer survivors.[145,146] A 2015 research study on breast cancer disparities found that among the physical side effects of treatment that had a great impact on overall quality of life were fatigue and sleep disturbance, which were found to be worse in minority women. Research also shows that Black women are less likely to meet the recommended levels of post-treatment physical activity, which results in lower physical functioning.[147] However, other studies have noted that disparities in frequency of complications are complex to measure, since women of color are generally less likely to have prophylactic mastectomy or reconstruction, which increase complication rates.[148] Aside from race, the literature also shows that early-stage breast cancer patients with markers of lower socioeconomic status, such as living in socioeconomically disadvantaged neighborhoods, are more likely to report higher levels of pain as a treatment side effect, possibly due to being undertreated for pain.[149] The same study

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[145] DeSantis, C. E., Ma, J., Goding Sauer, A., Newman, L. A., & Jemal, A. (2017). Breast cancer statistics, 2017, racial disparity in mortality by state. CA: a cancer journal for clinicians, 67(6), 439–448. https://doi.org/10.3322/caac.21412

[146] Husain, M., Nolan, T. S., Foy, K., Reinbolt, R., Grenade, C., & Lustberg, M. (2019). An overview of the unique challenges facing African American breast cancer survivors. Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer, 27(3), 729–743. https://doi.org/10.1007/s00520-018-4545-y

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[148] Lovelace, D. L., McDaniel, L. R., & Golden, D. (2019). Long-term effects of breast cancer surgery, treatment, and survivor care. *Journal of Midwifery & Women's Health*, *64*(6), 713–724. https://doi.org/10.1111/jmwh.13012

[149] Choi, H. Y., Graetz, I., Shaban-Nejad, A., Schwartzberg, L., Vidal, G., Davis, R. L., & Shin, E. K. (2022). Social disparities of pain and pain intensity among women diagnosed with early-stage breast cancer. *Frontiers in Oncology*, *12*. https://doi.org/10.3389/fonc.2022.759272

shows strong associations between pain severity and employment status or insurance type.[150] This could be because women living in such neighborhoods are undertreated for pain. Inequities in physical outcomes are critical when examining TNBC patients, since TNBC incidence is disproportionately higher in Black women than in their white counterparts.[151] As discussed in an earlier paper from this series, present-day experiences of discrimination in healthcare settings that Black patients face, including being undertreated for pain, not only result in such inequities but also contribute to medical mistrust, perpetuating a cycle of poor care and treatment outcomes.[152]

While reporting PROMIS values generated in groups with fewer than fifty people is not recommended, results from the CER® demonstrated noteworthy differences in PROMIS scores by race and ethnicity for physical symptoms.[153] As seen in Table 2 , sample sizes in Hispanic and non-Hispanic Black groups are small; clearly, there is a need for more research that seeks to understand the patient experience for all persons with TNBC.

Notably, CER® PROMIS scores by race and ethnicity suggest that Hispanic TNBC patients report high symptom burden and poor functioning with fatigue, pain interference, and physical function exceeding, on average, the established PROMIS thresholds (≥60.0 for symptom scales; ≤40.0 for function scales) for moderate symptoms and deficits in functioning.

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[150] Choi, H. Y., Graetz, I., Shaban-Nejad, A., Schwartzberg, L., Vidal, G., Davis, R. L., & Shin, E. K. (2022). Social disparities of pain and pain intensity among women diagnosed with early-stage breast cancer. *Frontiers in Oncology*, *12*. https://doi.org/10.3389/fonc.2022.759272

[151] Siddharth, S., & Sharma, D. (2018). Racial disparity and triple-negative breast cancer in African American women: A multifaceted affair between obesity, biology, and socioeconomic determinants. *Cancers*, *10*(12), 514. https://doi.org/10.3390/cancers10120514

[152] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. Charles River Associates. Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[153] Jensen, R. E., Potosky, A. L., Moinpour, C. M., Lobo, T., Cella, D., Hahn, E. A., Thissen, D., Smith, A. W., Ahn, J., Luta, G., & Reeve, B. B. (2017). United States Population-Based Estimates of Patient-Reported Outcomes Measurement Information System Symptom and Functional Status Reference Values for Individuals With Cancer. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *35*(17), 1913–1920. https://doi.org/10.1200/JCO.2016.71.4410

Table 2: PROMIS physical symptoms and functional status reference values for TNBC, by race/ethnicity*

		Fatigue		Pain interference		Physical function		Social function	
Group	n	M	SE	M	SE	M	SE	M	SE
Cancer Experience Registry: TNBC by race/ethnicity									
Non-Hispanic White	*170*	*55.2*	*0.9*	*53.4*	*0.8*	*45.5*	*0.7*	*49.2*	*0.8*
Non-Hispanic Black	*15*	*53.2*	*3.2*	*58.7*	*2.4*	*44.1*	*2.0*	*49.6*	*2.5*
Hispanic	*11*	*61.2*	*3.2*	*62.1*	*2.8*	*39.2*	*2.8*	*40.6*	*2.0*

*Higher scores indicate greater symptom burden (fatigue, pain interference)/higher function (physical and social). *Source: Cancer Support Community, Cancer Experience Registry, January 2015–August 2021*

Source: Cancer Support Community, Cancer Experience Registry, January 2015–August 2021

Multiple studies evaluating the impact of exercise among survivors in Black communities have been conducted.[154] For example, a research team at the University of Massachusetts Boston and Dana-Farber Cancer Institute has shown how exercise helps Black and Hispanic patients recover from chemotherapy.[155] However, there is a lack of programs in place implementing exercise for these groups.

Socioeconomic factors are also often drivers of disparities in post-treatment side effects. While there are few programs specifically addressing inequity in side effects, there are policies or programs that aim to increase access to healthcare in socially disadvantaged neighborhoods. For example, the federal government's Health Resources and Services Administration provides funding and assistance to federally qualified health centers (FQHCs) that provide care to populations of lower socioeconomic status.[156] While the Affordable Care Act (ACA) increased access to FQHCs for under-resourced populations, access challenges remain, especially for rural populations.[157] Despite the existence of some programs or policies that may help decrease inequity in post-treatment effects of breast cancer, there is a lack of policies that specifically address these issues and a lack of services for TNBC patients specifically.

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[154] Nock, N. L. (2015). A community-based exercise and Support Group Program improves quality of life in African American breast cancer survivors: A quantitative and qualitative analysis. *International Journal of Sports and Exercise Medicine*, *1*(4). https://doi.org/10.23937/2469-5718/1510020

[155] *Thriving and surviving: UMass Boston, Dana Farber Team Studies how exercise helps black and Hispanic patients recover from chemo*. University of Massachusetts Boston. (n.d.). Retrieved April 11, 2022, from https://www.umb.edu/news/detail/thriveing_and_surviving_umass_boston_and_dana_farber_team_studying_how_exercise_helps_black_and_hispanic_patients_recover_from_chemo

[156] *State and federal efforts to enhance access to basic healthcare*. Commonwealth Fund. (n.d.). Retrieved April 11, 2022, from https://www.commonwealthfund.org/publications/newsletter-article/state-and-federal-efforts-enhance-access-basic-health-care

[157] Behr, C. L., Hull, P., Hsu, J., Newhouse, J. P., & Fung, V. (2022). Geographic access to federally qualified health centers before and after the affordable care act. BMC health services research, 22(1), 385. https://doi.org/10.1186/s12913-022-07685-0

Evidence of inequities in mental health outcomes

A systematic review of sixty studies of adverse mental health outcomes for breast cancer survivors found that these women experienced anxiety from fear of recurrence, depression, neurocognitive dysfunction, sexual dysfunction, and suicide more commonly than a comparison group of women with no prior cancer.[158] In findings among metastatic breast cancer (mBC) patients previously reported from the CER® (n = 599), younger age and lower income were found to contribute to feelings of distress, and these results were consistent among CER® TNBC patients (n = 189).[159,160] Additionally, lower income was found to have a significant association with feelings of isolation for both mBC and TNBC patients. Furthermore, studies have shown a link between fear of cancer recurrence and heightened anxiety in survivors.[161] With a higher likelihood of recurrence of TNBC compared to other forms of breast cancer (approximately 40% for TNBC compared to 7%-11% for early breast cancer), anxiety levels are also likely higher for TNBC patients.[162,163]

Similar to CER® data for physical symptoms and functional status, noteworthy differences were also observed in PROMIS scores by race and ethnicity for mental health symptoms, as shown in Table 3. However, this data also comes from sample groups with fewer than 50 people, underscoring the need for more research to better understand these disparities in TNBC.[164]

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[159] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[160] Buzaglo, J. S., Miller, M., Harvey, A., & Golant, M. (2014, September). *Cancer-related Distress and Unmet Needs among Members of a Metastatic Breast Cancer Registry*. Cancer Support Community. Retrieved April 5, 2022, from https://www.cancersupportcommunity.org/sites/default/files/d7/document/2014_asco_breast_cer_mbc_distress_poster.pdf

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[162] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[163] COH HoldCo Inc. (2022, March 2). *Recurrent breast cancer*. Cancer Treatment Centers of America. Retrieved April 5, 2022, from https://www.cancercenter.com/cancer-types/breast-cancer/types/rare-breast-cancer-types/recurrent-breast-cancer#:~:text=Komen%C2%AE%20organization%2C%20women%20with,local%20recurrence%20during%20this%20time.

[164] Jensen, R. E., Potosky, A. L., Moinpour, C. M., Lobo, T., Cella, D., Hahn, E. A., Thissen, D., Smith, A. W., Ahn, J., Luta, G., & Reeve, B. B. (2017). United States Population-Based Estimates of Patient-Reported Outcomes Measurement Information System Symptom and Functional Status Reference Values for Individuals With Cancer. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *35*(17), 1913–1920. https://doi.org/10.1200/JCO.2016.71.4410

Table 3: PROMIS mental health symptoms and functional status reference values for TNBC by race/ethnicity*

		Sleep disturbance		Anxiety		Depression	
Group	n	M	SE	M	SE	M	SE
Non-Hispanic White	*170*	*53.3*	*0.7*	*55.9*	*0.8*	*51.7*	*0.8*
Non-Hispanic Black	*15*	*55.8*	*2.7*	*56.7*	*2.2*	*51.7*	*1.9*
Hispanic	*11*	*56.0*	*3.2*	*57.9*	*4.1*	*55.6*	*3.8*

*Higher scores indicate greater symptom burden (sleep disturbance, anxiety, depression)/higher function (physical and social). *Source: Cancer Support Community, Cancer Experience Registry, January 2015–August 2021*

To minimize health disparities in cancer, mental health programs that are specific to communities at increased risk of TNBC are critical. A 2015 study that examined Black cancer focus groups found a lack of survivor support services and a lack of a strong social support network with other survivors and caregivers to be two common needs of survivors and caregivers.[165] Despite this research, information on the extent of disparities in the post-treatment mental health of breast cancer survivors is still limited, and it is more limited yet with regard to TNBC survivors specifically.

2.3. Supporting coordination of survivorship and palliative care

Survivorship care plans to improve care coordination

In addition to follow-up visits, the ASCO Guidelines and the Commission on Cancer recommend that breast cancer survivors work with their healthcare providers to create a survivorship care plan.[166,167,168] These plans help to support care coordination and typically consist of a summary of the diagnosis and treatment, follow-up exam schedule, potential treatment side effects, and emotional and financial support resources.[169] Care planning is also important for coordinating healthcare provider responsibility for managing patients and resolving any issues as they transition from receiving care from an

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[165] Haynes-Maslow, L., Allicock, M., & Johnson, L.-S. (2015). Cancer support needs for African American breast cancer survivors and Caregivers. *Journal of Cancer Education*, *31*(1), 166-171. https://doi.org/10.1007/s13187-015-0832-1

[166] Carey, L. A. (2021, June 22). *Follow-up care for TNBC*. Living Beyond Breast Cancer. Retrieved April 4, 2022, from https://www.lbbc.org/learn/types-breast-cancer/triple-negative-breast-cancer/treatments-and-research-triple-negative-5

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[168] American College of Surgeons, Accreditation Committee Clarifications for Standard 3.3 Survivorship Care Plan. www.facs.org/publications/newsletters/coc-source/special-source/standard33. Accessed May 20, 2015.

[169] Carey, L. A. (2021, June 22). *Follow-up care for TNBC*. Living Beyond Breast Cancer. Retrieved April 4, 2022, from https://www.lbbc.org/learn/types-breast-cancer/triple-negative-breast-cancer/treatments-and-research-triple-negative-5

oncologist to receiving care from their general practitioner.[170] Among TNBC patients in the CER® who had received a survivorship plan, 84% found it to be useful. Those who found the survivorship care plan useful were over five times as likely to feel very prepared to manage symptoms, compared to those who did not receive a plan.[171] These data highlight the need for providers to offer survivorship care plans more frequently and consistently to their breast cancer patients.

Patient navigation services to support patients throughout the post-treatment period

Patient navigators play an important role in treatment and care (as discussed in an earlier paper co-authored by CRA and Komen, *Inequities in Care and Treatment for Triple Negative Breast Cancer Patients*) and are also developing an important role in care coordination during the post-treatment period. In a previous report, it was noted that patient navigation programs lack standardized guidelines, reimbursement, and integration into the health delivery system to effectively support all patients, particularly those from under-resourced communities.[172,173] Patient navigators can help meet informational needs of patients by providing guidance on issues such as the potential impact of treatment side effects on a survivor's life, from their career to their relationships.[174,175] The benefit of patient navigators has been shown through studies on breast cancer survivorship, which demonstrate greater adherence to post-treatment surveillance recommendations by patients who have patient navigators compared to those without navigators.[176] This is particularly important as, according to CER® data, patients who had a member of their healthcare team offer help coordinating distress-related care were over three times more likely to feel quite a bit or very prepared to manage their symptoms compared to patients who did not receive this support . [177]

Under-resourced patients can be better supported through cancer survivor and caregiver care plans by making these actions priorities: routinely assessing their needs, providing personalized care information and referrals to appropriate care, and implementing new interventions and methods of survivorship care.[178]

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[170] Cavallo, J. (2013, December 1). Living With Cancer: The Role of Palliative Care in Long-Term Survivorship Care. A Conversation With Mary McCabe, RN, MA. *The ASCO Post.* Retrieved May 13, 2022 from https://ascopost.com/issues/december-1-2013/living-with-cancer-the-role-of-palliative-care-in-long-term-survivorship-care/

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[177] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

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Guidelines and programs to support access to palliative care

To support access to palliative care services, best-practice-setting organizations such as the National Comprehensive Cancer Network (NCCN) and ASCO have published guidelines on how to incorporate palliative care early in the continuum of cancer treatment; evidence shows that doing so results in better patient outcomes, such as improved quality of life and patient satisfaction and a decrease in caregiver burden.[179,180] ASCO recommends that advanced cancer patients receive dedicated palliative care services within eight weeks of diagnosis alongside active treatment. While the guidelines state early that cancer patients may also be referred to palliative care services, there is minimal guidance for this group of patients.[181] The 2021 updates to the NCCN palliative care guidelines acknowledge that the goal of palliative care is the same for all stages of the disease and that patients should undergo a comprehensive assessment by their oncology team to determine their palliative care needs.[182] Specific to mBC patients, the *Journal of Oncology Practice* released updated guidelines in April 2021 that classify cancer progression and palliative care into different categories to better inform physicians on the best approaches for groups of mBC patients.[183]

In addition, in recent years, there has been action across multiple states to provide funding for palliative care programs and education. These efforts can help to address inequities in access to palliative care services by improving patient awareness and understanding. For example, in Georgia, a bill was approved in 2016 that created the Georgia Palliative Care and Quality of Life Advisory Council as part of the state's Office of Health Strategy and Coordination; the Council will advise the Department of Community Health on matters related to palliative care initiatives in the state.[184,185] West Virginia passed a bill in 2020 that requires the State Advisory Coalition on Palliative Care to work with the Bureau of Public Health to develop educational resources to increase awareness of palliative care programs.[186] The American Cancer Society supports both federal and state policy change to increase patient access to palliative care, including improving insurance coverage of palliative care and creating more public awareness around it. [187] At

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[179] Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of palliative care into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline update. *Journal of Clinical Oncology*, *35*(1), 96–112. https://doi.org/10.1200/jco.2016.70.1474

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[181] Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of palliative care into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline update. *Journal of Clinical Oncology*, *35*(1), 96–112. https://doi.org/10.1200/jco.2016.70.1474

[182] Dans, M., Kutner, J. S., Agarwal, R., Baker, J. N., Bauman, J. R., Beck, A. C., Campbell, T. C., Carey, E. C., Case, A. A., Dalal, S., Doberman, D. J., Epstein, A. S., Fecher, L., Jones, J., Kapo, J., Lee, R. T., Loggers, E. T., McCammon, S., Mitchell, W., Ogunseitan, A. B., … Campbell, M. (2021). NCCN Guidelines® Insights: Palliative Care, Version 2.2021. Journal of the National Comprehensive Cancer Network: JNCCN, 19(7), 780–788. https://doi.org/10.6004/jnccn.2021.0033

[183] Kida, K., Olver, I., Yennu, S., Tripathy, D., & Ueno, N. T. (2021). Optimal supportive care for patients with metastatic breast cancer according to their disease progression phase. *JCO Oncology Practice*. https://doi.org/10.1200/op.20.00622

[184] TrackBill. (n.d.) Georgia HB509. Retrieved May 16, 2022, from https://trackbill.com/bill/georgia-house-bill-509-georgia-palliative-care-and-quality-of-life-advisory-council-create-provisions/1142222/

[185] *Palliative care and quality of Life Advisory Council*. Georgia Department of Community Health. (n.d.). Retrieved April 4, 2022, from https://dch.georgia.gov/palliative-care-and-quality-life-advisory-council/palliative-care-and-quality-life-advisory-council

[186] *Senate Bill 748*. West Virginia Legislature. (n.d.). Retrieved April 4, 2022, from https://www.wvlegislature.gov/Bill_Text_HTML/2020_SESSIONS/RS/signed_bills/senate/SB657%20SUB1%20ENR_signed.pdf

[187] *Disparities in palliative care*. American Cancer Society. (n.d.). Retrieved April 4, 2022, from https://www.fightcancer.org/policy-resources/disparities-palliative-care

the federal level, the Palliative Care and Hospice Education and Training Act (PCHETA) was passed by the House of Representatives (as of March 2022); it promotes education, awareness, and research regarding palliative care.[188] Further, in an effort to improve quality of healthcare delivery and create meaningful measures for palliative care, the CMS-funded Palliative Care Measures Project was completed in 2021; it developed patient-reported quality measures for community-based palliative care, including alternative payment models (APMs).[189] As of July 2021, the state of Hawaii is pursuing a state-wide Medicaid benefit for community-based palliative care (CBPC), which would extend comprehensive, high-quality palliative care to patients with a serious illness enrolled in Medicaid, include state-wide coverage for advanced care planning, care coordination, expert pain and symptom management, and mental health services.[190] A similar program for state-wide CBPC has also been implemented in California. These measures are intended to address gaps currently seen in palliative care by encouraging physicians to provide patient-centered care with effective symptom management and communication.[191]

In 2021, a bill called the Metastatic Breast Cancer Access to Care Act was introduced; it would allow mBC patients who are eligible for Medicare to access support and care sooner, which could help to mitigate the effects of low income on mBC patients and their quality of life.[192] At the state level, the Michigan Department of Health and Human Services has a breast cancer survivor program for those under the age of 45, which offers support and education for young women who have had breast cancer and includes specific resources on mental health.[193] Despite evidence of community-level organizations offering programs to help address the psychosocial impacts of cancer or extend palliative care services to under-resourced populations, there is a lack of federal and state legislative and programmatic leadership to formalize and improve access to such initiatives.

2.4. Summary and implications

Research findings highlight the importance of post-treatment support, including care coordination and access to palliative care services, for improved patient outcomes and

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[188] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[189] American Academy of Hospice and Palliative Medicine. (2021, December 7). *New patient-reported experience measures available for palliative care and other providers*. New Patient-Reported Experience Measures Available for Palliative Care and Other Providers. Retrieved April 4, 2022, from https://www.prnewswire.com/news-releases/new-patient-reported-experience-measures-available-for-palliative-care-and-other-providers-301439274.html

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[191] American Academy of Hospice and Palliative Medicine. (2021, December 7). *New patient-reported experience measures available for palliative care and other providers*. New Patient-Reported Experience Measures Available for Palliative Care and Other Providers. Retrieved April 4, 2022, from https://www.prnewswire.com/news-releases/new-patient-reported-experience-measures-available-for-palliative-care-and-other-providers-301439274.html

[192] Alec Stone MA. (2022, March 18). *US senators introduce Metastatic Breast Cancer Access to Care Act*. ONS Voice. Retrieved April 5, 2022, from https://voice.ons.org/advocacy/us-senators-introduce-metastatic-breast-cancer-access-to-care-act

[193] *Young breast cancer survivor program*. SOM - State of Michigan. (n.d.). Retrieved June 28, 2022, from https://www.michigan.gov/mdhhs/keep-mi-healthy/chronicdiseases/cancer/young-breast-cancer-survivor-program

quality of life. Despite this, disparity in access exists for TNBC patients, as summarized in Table 4.

Table 4: Summary of inequities in post-treatment and palliative care for TNBC patients and implications

Key takeaways
1. Black cancer survivors and those who are uninsured or underinsured are more likely to receive insufficient care support (i.e., mammography surveillance) following initial cancer treatment, resulting in less effective post-treatment care.[194,195] Social determinants of health contribute to inequities in survivorship care. For example, low education attainment and being uninsured are each associated with a lower likelihood of receiving a cancer survivorship care plan, which negatively impacts quality of care as patients transition to the post-treatment period.[196]
2. Inequities in access to survivorship care are multifaceted; survivors living in rural areas experience physical access barriers, while Black breast cancer survivors lack access to culturally appropriate post-treatment services and are more likely to limit care due to financial hardship.[197,198,199] Providers' decision-making bias has been associated with gaps in survivorship care provision.[200]

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[194] Lee Smith, J., & Hall, I. J. (2015). Advancing Health Equity in Cancer Survivorship: Opportunities for Public Health. *American journal of preventive medicine,* 49(6 Suppl 5), S477–S482. https://doi.org/10.1016/j.amepre.2015.08.008

[195] Sabatino, S. A., Thompson, T. D., Richardson, L. C., Miller, J. Health Insurance and Other Factors Associated With Mammography Surveillance Among Breast Cancer Survivors, *Medical Care:* March 2012 - Volume 50 - Issue 3 - p 270-276. doi: 10.1097/MLR.0b013e318244d294

[196] Timsina, L. R., Zarzaur, B., Haggstrom, D. A., Jenkins, P. C., Lustberg, M., & Obeng-Gyasi, S. (2021). Dissemination of cancer survivorship care plans: who is being left out? *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer,* 29(8), 4295–4302. https://doi.org/10.1007/s00520-020-05915-x

[197] Haynes-Maslow, L., Allicock, M., & Johnson, L. S. (2016). Cancer Support Needs for African American Breast Cancer Survivors and Caregivers. *Journal of cancer education: the official journal of the American Association for Cancer Education,* 31(1), 166–171. https://doi.org/10.1007/s13187-015-0832-1

[198] Behr, C. L., Hull, P., Hsu, J., Newhouse, J. P., & Fung, V. (2022). Geographic access to federally qualified health centers before and after the affordable care act. BMC health services research, 22(1), 385. https://doi.org/10.1186/s12913-022-07685-0

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[200] See, for example: Rosa, W.E. et al. (2022) Palliative Care In The Face Of Racism: A Call To Transform Clinical Practice, Research, Policy, And Leadership. *Health Affairs Forefront.* Accessed May 25, 2022. Retrieved from: https://www.healthaffairs.org/do/10.1377/forefront.20220207.574426/

3. **Provision of materials targeting awareness of palliative care services among non-white mBC patients is lower. Patients treated at minority-serving hospitals were less likely to received palliative care services.[201] Guidelines for the receipt of palliative care among early-stage cancer patients are lacking. [202]**

4. **Physical side effects from breast cancer treatment with the greatest impact on overall quality of life are found to be worse in minority women. Certain factors, such as younger age and lower income, are correlated with feelings of distress and isolation in mBC patients, which can exacerbate late-term mental health problems associated with cancer diagnosis and treatment. [203,204]**

5. **Patients from the CER® who received a useful survivorship care plan were over five times as likely to feel very prepared to manage symptoms, compared to those who did not receive such a plan. Despite this benefit, two-thirds of patients did not receive a plan.[205]**

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[201] Cole, A. P., Nguyen, D.-D., Meirkhanov, A., Golshan, M., Melnitchouk, N., Lipsitz, S. R., Kilbridge, K. L., Kibel, A. S., Cooper, Z., Weissman, J., & Trinh, Q.-D. (2019). Association of care at minority-serving vs non–minority-serving hospitals with use of palliative care among racial/ethnic minorities with metastatic cancer in the United States. *JAMA Network Open*, *2*(2). https://doi.org/10.1001/jamanetworkopen.2018.7633

[202] See, for example: Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of palliative care into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline update. *Journal of Clinical Oncology*, *35*(1), 96–112. https://doi.org/10.1200/jco.2016.70.1474

[203] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[204] Buzaglo, J. S., Miller, M., Harvey, A., & Golant, M. (2014, September). *Cancer-related Distress and Unmet Needs among Members of a Metastatic Breast Cancer Registry*. Cancer Support Community. Retrieved April 5, 2022, from https://www.cancersupportcommunity.org/sites/default/files/d7/document/2014_asco_breast_cer_mbc_distress_poster.pdf

[205] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

3. Inequities in long-term patient financial well-being

A TNBC diagnosis and treatment can affect survivors even after initial treatment has been completed. Survivors can experience long-term physical and mental health effects (as discussed in the previous section), as well as financial toxicity.[206,207] Certain socioeconomic factors, such as being non-white, younger in age, and low income are correlated with worse post-TNBC treatment outcomes.[208] For underrepresented populations, this is relevant since younger Black women are disproportionately impacted by TNBC.[209] Furthermore, non-white TNBC patients experience a heavier financial burden, which is exacerbated by recurrence, which is more likely for TNBC than for other forms of breast cancer.[210,211] In this section, we explore inequities in post-TNBC-treatment long-term effects leading to disparities in the impacts of financial toxicity.

3.1. Financial support and toxicity for TNBC patients

The economic burden of medical costs associated with TNBC is substantial, and it increases with disease severity.[212] Nearly half of all cancer survivors suffer from financial toxicity, the economic burden that results from medical treatment.[213] In addition to costs during treatment, many survivors will need to pay for other care once treatment has been completed, as there can be residual symptoms and side effects related to treatment.

Data from the CER® provide insights into financial toxicity experienced by TNBC patients, including actions taken by TNBC patients because of medical costs[214]:

- More than half (53%) of TNBC patients reported more than $250 per month in out-of-pocket costs related to cancer; 28% spent more than $500; 12%, more than $1000.
- One-third (32%) wished they had received more help with getting financial advice and assistance.
- Nearly two-in-five (38%) were moderately to very seriously concerned about health insurance or money.

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[206] DeSantis, C. E., Ma, J., Goding Sauer, A., Newman, L. A., & Jemal, A. (2017). Breast cancer statistics, 2017, racial disparity in mortality by state. CA: a cancer journal for clinicians, 67(6), 439–448. https://doi.org/10.3322/caac.21412

[207] Husain, M., Nolan, T. S., Foy, K., Reinbolt, R., Grenade, C., & Lustberg, M. (2019). An overview of the unique challenges facing African American breast cancer survivors. Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer, 27(3), 729–743. https://doi.org/10.1007/s00520-018-4545-y

[208] Vadaparampil, S. T., Christie, J., Donovan, K. A., Kim, J., Augusto, B., Kasting, M. L., Holt, C. L., Ashing, K., Halbert, C. H., & Pal, T. (2017). Health-related quality of life in Black breast cancer survivors with and without triple-negative breast cancer (TNBC). *Breast cancer research and treatment,* 163(2), 331–342. https://doi.org/10.1007/s10549-017-4173-0

[209] 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

[210] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2020). Assessing direct costs of treating metastatic triple-negative breast cancer in the USA. *Journal of Comparative Effectiveness Research*, *10*(2), 109–118. https://doi.org/10.2217/cer-2020-0213

[211] Sieluk, J., Song, Y., Freimark, J., Huang, M., Haiderali, A., Berman, R., Wang, T., Signorovitch, J., & Hirshfield, K. M. (2021). The economic burden of recurrence in triple-negative breast cancer among working age patients in the United States. *Advances in Therapy*, *39*(2), 943–958. https://doi.org/10.1007/s12325-021-01913-5

[212] Huang, M., Haiderali, A., Fox, G. E., Frederickson, A., Cortes, J., Fasching, P. A., & O'Shaughnessy, J. (2022). Economic and humanistic burden of triple-negative breast cancer: A systematic literature review. *PharmacoEconomics*. https://doi.org/10.1007/s40273-021-01121-7

[213] Dean, L. T., Moss, S. L., Ransome, Y., Frasso-Jaramillo, L., Zhang, Y., Visvanathan, K., Nicholas, L. H., & Schmitz, K. H. (2019). "It still affects our economic situation": long-term economic burden of breast cancer and lymphedema. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer*, *27*(5), 1697–1708. https://doi.org/10.1007/s00520-018-4418-4

[214] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

- Three-fifths (61%) reported that no one from their healthcare team talked to them about the cost of their care.

As shown in Table 5, participants also reported delaying treatment and taking extra financial measures to accommodate the costs of cancer.

Table 5: CER® Insights: TNBC patients delaying treatment and taking extra financial measures to accommodate the cost of cancer (n = 104–193)

Respondents (%) who sometimes, often, or always . . .	
Postpone seeking psychological counseling or support	25
Delay follow-up on recommendations for complementary treatment (e.g., physical therapy, occupational therapy, nutrition counseling)	18
Postpone doctor appointments	8
Postpone follow-up screening and/or blood work	8

Data from the CER® include an index measure of financial well-being (the FACIT-COST score, "Functional Assessment of Chronic Illness Therapy-Comprehensive Score for financial Toxicity"), which has been shown to be a reliable and valid measure of financial toxicity.[215] To determine a patient's score, the respondents are asked to rate eleven questions pertaining to financial well-being.[216] Lower scores in the FACIT-COST measure indicate worse financial well-being, i.e., higher levels of financial toxicity, such that a score of zero indicates severe financial toxicity and a score of 26 or more indicates no financial toxicity.

The data demonstrate that worse financial well-being is associated with longer travel time to treatment and use of a co-pay assistance program among TNBC patients (*n* = 94).[217] However, when adjusted for covariates that were significantly associated with the financial toxicity score (currently receiving treatment, low-income status, type of insurance, employment status, age, and monthly out-of-pocket costs), this finding was not statistically significant, suggesting some of these other factors may be at play in this correlation. The same survey also found that taking part in a clinical trial is associated with worse financial well-being among TNBC patients (*n* = 94).[218,219] Since metastatic breast cancer patients are often *refractory* and have fewer treatment options, they may participate in clinical trials to access additional investigational treatment options.[220]

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[215] de Souza, J. A., Yap, B. J., Wroblewski, K., Blinder, V., Araújo, F. S., Hlubocky, F. J., Nicholas, L. H., O'Connor, J. M., Brockstein, B., Ratain, M. J., Daugherty, C. K., & Cella, D. (2016). Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the comprehensive score for financial toxicity (cost). *Cancer*, *123*(3), 476–484. https://doi.org/10.1002/cncr.30369

[216] Patients are asked questions about: having sufficient savings, having higher than expected out-of-pocket expenses, worry about financial problems as a result of their illness or treatment, feeling like they have no choice about the amount of money spent on care, frustration with not being able to work or contribute as much as usual, satisfaction with current financial situation, ability to meet monthly expenses, feeling financially stressed, concern about keeping job and income, impact of cancer or treatment on satisfaction with financial situation, feeling in control of their financial situation.

[217] Increasing travel time to 45 minutes, compared to travel time under half an hour is associated with a decrease in the FACIT-COST measure by 9.7 points. The FACIT-COST score decreased by 14 points for patients who said they used a form of co-pay assistance compared to those who said they did not.

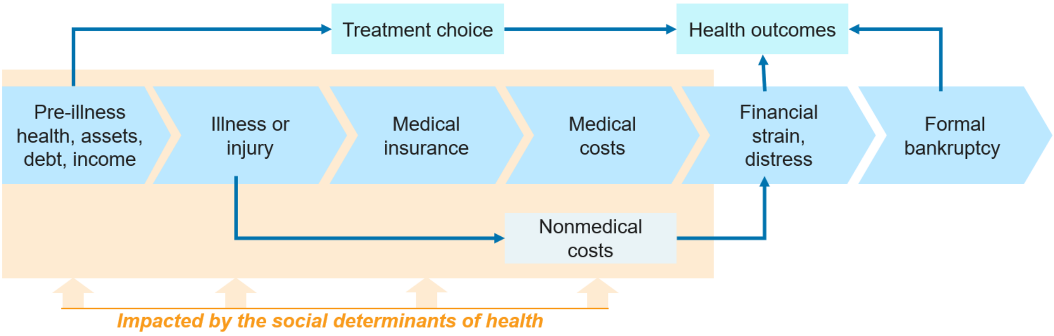
[218] The FACIT-COST measure decreased on average by 9 points for patients who participated in a clinical trial compared to those who did not.

[219] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[220] Komen. (2021, March 30). Clinical Trials for People with Metastatic Breast Cancer. Retrieved May 3, 2022 from https://www.komen.org/breast-cancer/metastatic/clinical-trials/

Metastatic cancer patients in general are particularly susceptible to financial toxicity, as treatment involves expensive chemotherapy or immunotherapy that can last for years. This may be one reason why an association was found between clinical trial participation and financial toxicity. A 2019 cross-sectional analysis of mBC patients found that most of them experienced financial toxicity, which correlated with a lower quality of life and overall cancer-related distress.[221] Additionally, given the high risk of recurrence in TNBC patients, studies have been conducted that show substantially higher incremental direct and indirect economic burden associated with recurrence compared to non-recurrent patients.[222]

Figure 3: Interaction of severe illness and the social determinants of health with treatment choice and health and financial outcomes



Source: CRA analysis of Ramsey (n.d.)

Evidence of the disproportionate impact of financial toxicity on under-resourced communities

There is significant evidence of disproportionate effects of financial toxicity on cancer patients, specifically those with TNBC. In 2018, the National Cancer Institute published a conceptual framework that relates numerous sociodemographic factors to financial toxicity, such as age, income, race, employment status, and insurance status (Figure 3).[223] In a 2014 longitudinal study of women with breast cancer, Black women and English-speaking Latina women were found to report more economically motivated nonadherence to treatment and hardships related to medical expenses, such as having to move out of a house due to medical expenses or having utilities turned off from unpaid bills, compared to their white counterparts.[224] Furthermore, the economic burden of mTNBC care, measured by out-of-pocket costs and medical debt, is greater among non-white patients.[225] Younger cancer patients are also more vulnerable to financial toxicity. A study conducted on bankruptcy rates found that the relative risk of filing for bankruptcy of

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[221] Financial toxicity among women with metastatic breast cancer. (2018). *Oncology Nursing Forum*, 83–91. https://doi.org/10.1188/19.onf.83-91

[222] Sieluk, J., Song, Y., Freimark, J., Huang, M., Haiderali, A., Berman, R., Wang, T., Signorovitch, J., & Hirshfield, K. M. (2021). The economic burden of recurrence in triple-negative breast cancer among working age patients in the United States. *Advances in Therapy*, *39*(2), 943–958. https://doi.org/10.1007/s12325-021-01913-5

[223] NIH. (2022, March 4). *Financial toxicity and cancer treatment (PDQ®)–health professional version*. National Cancer Institute. Retrieved April 5, 2022, from https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-hp-pdq

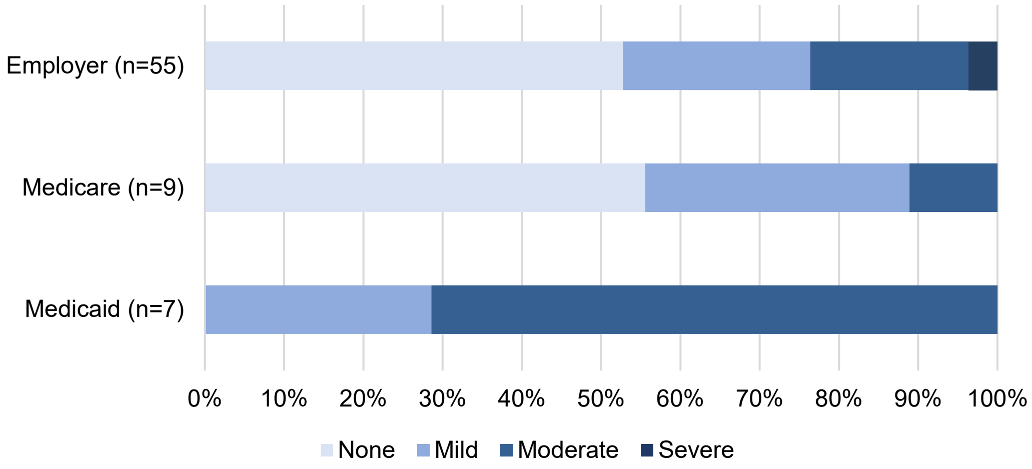
[224] Jagsi, R., Pottow, J. A., Griffith, K. A., Bradley, C., Hamilton, A. S., Graff, J., Katz, S. J., & Hawley, S. T. (2014). Long-term financial burden of breast cancer: experiences of a diverse cohort of survivors identified through population-based registries. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, *32*(12), 1269–1276. https://doi.org/10.1200/JCO.2013.53.0956

[225] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2020). Assessing direct costs of treating metastatic triple-negative breast cancer in the USA. *Journal of Comparative Effectiveness Research*, *10*(2), 109–118. https://doi.org/10.2217/cer-2020-0213

cancer survivors versus noncancer controls increased in the younger-age cohort.[226] With younger Black women being at higher risk for TNBC, inequities in financial burden are of particular concern.[227] Furthermore, younger women with TNBC will likely face long-term impacts of financial toxicity because the diagnosis will interrupt or limit their ability to start a family, pursue higher education, and advance in their career.[228]

Lower income and lack of insurance are also correlated with higher levels of financial toxicity. Those who are not covered by insurance are at elevated risk of financial hardship, especially with the cost of cancer case increasing with new therapies. For example, a study of young breast cancer survivors found that those with a self-funded insurance policy disproportionately reported worse financial outcomes.[229] And data from the CER® found that TNBC patients who have Medicaid have higher levels of financial distress, highlighting how the effects of financial toxicity vary by health insurance type (Figure 4).[230]

Figure 3: Level of financial toxicity measured by FACIT COST segmented by insurance type among TNBC patients participating in the Cancer Experience Registry (*n* = 71)[231]



Source: Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

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[226] Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., Newcomb, P., Hollingworth, W., & Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health affairs (Project Hope)*, *32*(6), 1143–1152. https://doi.org/10.1377/hlthaff.2012.1263

[227] 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

[228] Komen. (2022, January 28). Unique Issues for Young Women with Breast Cancer. Retrieved May 15, 2022, from https://www.komen.org/breast-cancer/treatment/by-diagnosis/young-women-and-breast-cancer/

[229] Tangka, F. K. L., Subramanian, S., Jones, M., Edwards, P., Flanigan, T., Kaganova, Y., Smith, K. W., Thomas, C. C., Hawkins, N. A., Rodriguez, J., Fairley, T., & Guy, G. P. (2020). Insurance coverage, employment status, and financial well-being of young women diagnosed with breast cancer. *Cancer Epidemiology Biomarkers & Prevention*, *29*(3), 616–624. https://doi.org/10.1158/1055-9965.epi-19-0352

[230] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[231] de Souza JA, Yap BJ, Hlubocky FJ. The development of a financial toxicity patient-reported outcome in cancer: the COST measure. *Cancer.* 2014;120(20):3245–3253.

Furthermore, even among insured breast cancer patients, financial toxicity is exacerbated by low household income.[232] For example, a 2019 study found, despite the study participants largely being insured, that financial toxicity is more common among low-income women with mBC.[233] Additionally, data from the CER® show that financial distress varies significantly by annual household income; approximately three-in-five (57%) of TNBC patients with an annual household income less than $39,999 were categorized as having moderate to severe financial distress compared to 21% of those with higher income. Furthermore, 56% of TNBC patients with an annual household income less than $39,999 reported wanting to receive more financial advice, as opposed to 24% of those who had an annual household income over $40,000 (although results were not statistically significant).[234] As the federal poverty threshold in 2022 for a family of four is an annual income of approximately $28,000, these data highlight the need to address financial toxicity for both mid-income and low-income patients.[235]

Based on our literature review, we find that, arguably, the federal policy with the biggest impact on the financial burden of healthcare has been the 2010 Patient Protection and Affordable Care Act (ACA), which has significantly improved insurance coverage for cancer patients since its implementation.[236] However, this wider coverage has also proliferated insurance benefits that have high cost sharing, which has significant implications for those with progressive, chronic diseases such as metastatic breast cancer.[237] Furthermore, the ACA does little to mitigate the financial burden of indirect costs of care, such as loss of income.[238] More specifically to breast cancer, the federal Breast and Cervical Cancer Prevention and Treatment Program was created in 2001 to provide treatment to low-income persons with Medicare diagnosed with breast or cervical cancer.[239]

While there is a lack of state or local programs that offer financial support specifically for cancer patients, there is government support to address social determinants of health in general. For example, states can choose to implement Medicaid waivers to help pay for nonclinical services that are related to a disease or treatment, including case management, housing supports, and employment supports.[240] Additionally, cancer patients can apply for general hospital financial assistance programs to help alleviate the impacts of financial toxicity. Oncology social workers, financial navigators (at hospitals that have them), and patient navigators are usually the ones to directly help patients apply for financial assistance programs.[241] One example of an assistance program is the Health

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[232] Landier, W., Dai, C., Sparks, J., Anthony, K. R., Barrett, J. S., Hageman, L., Francisco, L., Rocque, G. B., Stringer-Reasor, E. M., Nabell, L., & Bhatia, S. (2020). Financial toxicity among breast cancer survivors with health insurance. *Journal of Clinical Oncology*, *38*(15_suppl), 12073–12073. https://doi.org/10.1200/jco.2020.38.15_suppl.12073

[233] Financial toxicity among women with metastatic breast cancer. (2018). *Oncology Nursing Forum*, 83–91. https://doi.org/10.1188/19.onf.83-91

[234] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[235] *Federal Poverty Level (FPL) - healthcare.gov glossary*. HealthCare.gov. (n.d.). Retrieved May 4, 2022, from https://www.healthcare.gov/glossary/federal-poverty-level-fpl/

[236] Segel, J. E., & Jung, J. (2019). Coverage, financial burden, and the Patient Protection and Affordable Care Act for patients with cancer. *Journal of Oncology Practice*, *15*(12). https://doi.org/10.1200/jop.19.00138

[237] Financial toxicity among women with metastatic breast cancer. (2018). *Oncology Nursing Forum*, 83–91. https://doi.org/10.1188/19.onf.83-91

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[239] Services, D. of H. C. (n.d.). *Welcome to the breast and Cervical Cancer treatment program*. Breast and Cervical Cancer Treatment Program. Retrieved April 5, 2022, from https://www.dhcs.ca.gov/services/medi-cal/Pages/BCCTP.aspx

[240] Elizabeth Hinton and Lina Stolyar Published: Aug 05, 2021. (2022, March 16). *Medicaid authorities and options to address social determinants of Health (SDOH) - issue brief*. KFF. Retrieved April 11, 2022, from https://www.kff.org/report-section/medicaid-authorities-and-options-to-address-social-determinants-of-health-sdoh-issue-brief/

[241] Cancer Support Community

Safety Net Fund, a Massachusetts government program that pays for medical services for qualified low-income patients at community health centers and acute care hospitals.[242] Additionally, Boston Medical Center has partnered with its licensed community health centers to offer medical treatment to low-income patients either without cost or at a reduced cost.[243] Although there are few programs created specifically for TNBC survivors, these financial support programs may benefit them.

3.2. Summary and implications

TNBC patients may suffer from post-treatment side effects, both physical and mental, as well as financial toxicity. Certain communities are disproportionately affected by these long-term impacts, as summarized in Table 6.

Table 6: Summary of inequities in long-term impact and financial toxicity associated with TNBC

Key takeaways
1. The economic burden of mTNBC care is greater among non-white patients, highlighting the need for TNBC-specific financial support programs for survivors.[244]
2. Breast cancer patients who use a co-pay assistance program, face longer travel times, or participate in a clinical trial are more likely to experience worse financial well-being compared to those who do not. [245]
3. Younger cancer survivors are at higher risk of filing for bankruptcy due to their treatment costs, demonstrating that financial toxicity is higher among younger people. [246]
4. Uninsured or underinsured breast cancer survivors disproportionately report worse financial outcomes. Furthermore, even among insured breast cancer patients, financial toxicity is exacerbated by low household income.[247] Patients with low and middle income report being unable to meet their monthly expenses, and they have an unmet need for financial advice.[248]

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[242] *Health Safety Net*. Mass.gov. (n.d.). Retrieved April 5, 2022, from https://www.mass.gov/orgs/health-safety-net

[243] *Patient financial assistance*. Boston Medical Center. (n.d.). Retrieved April 5, 2022, from https://www.bmc.org/services/patient-financial-assistance

[244] Skinner, K. E., Haiderali, A., Huang, M., & Schwartzberg, L. S. (2020). Assessing direct costs of treating metastatic triple-negative breast cancer in the USA. *Journal of Comparative Effectiveness Research*, *10*(2), 109–118. https://doi.org/10.2217/cer-2020-0213

[245] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[246] Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., Newcomb, P., Hollingworth, W., & Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health affairs (Project Hope)*, *32*(6), 1143–1152. https://doi.org/10.1377/hlthaff.2012.1263

[247] Landier, W., Dai, C., Sparks, J., Anthony, K. R., Barrett, J. S., Hageman, L., Francisco, L., Rocque, G. B., Stringer-Reasor, E. M., Nabell, L., & Bhatia, S. (2020). Financial toxicity among breast cancer survivors with health insurance. *Journal of Clinical Oncology*, *38*(15_suppl), 12073–12073. https://doi.org/10.1200/jco.2020.38.15_suppl.12073

[248] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

4. Ensuring equitable access to innovative TNBC treatment in the long term

In 2016, Joe Biden launched the Cancer Moonshot to improve progress in the fight against cancer. Five years later in 2022, the Biden administration revitalized this program with Cancer Moonshot Reignited (Moonshot), which highlights goals to reduce the death rate from cancer by at least 50% over the next twenty-five years and improve the experience of people and their families living with and surviving cancer, ultimately aiming to end how cancer is currently experienced.[249] In previous research, CRA has found that innovative forms of screening, diagnosis, treatment, and care have demonstrated benefits for high-risk and under-resourced TNBC patients because they allow for earlier detection, improved survival rates, and better quality of life.[250] However, to meet the administration's goals, innovation in many forms, such as personalized treatment, care delivery, and support, is required. Policies to better support development of, and access to, these forms of innovation are required.

4.1. Supporting innovation in TNBC diagnosis and care

A growing body of evidence suggests that enhanced screening methods are critical, as they can help with identification of TNBC at earlier stages, which can facilitate timely access to treatment and improve patient outcomes.[251] In addition, newer forms of breast imaging tests, such as 3D mammography and contrast-enhanced mammography, are currently being explored as alternatives that allow for shorter waiting times and greater accuracy.[252] Further, genetic profiling of tumor cells has facilitated the development of personalized treatment, which can improve TNBC outcomes and advance health equity.

Our literature review identified strategies that aim to support the development of an environment that promotes access to innovative TNBC treatment. For example, some states, including Arkansas, Colorado, Illinois, and Texas, have enacted legislation to require insurance plans to cover diagnostic breast imaging, which could support under-resourced TNBC patients.[253,254,255,256] We also find evidence of gaps in policy support of improved access among under-resourced populations:

- **Policy gaps in coverage of innovative diagnosis and testing**: At the federal level, the Access to Breast Cancer Diagnosis Act was introduced in Congress in 2019 to help reduce financial barriers for diagnostic tests; however there has been little movement on it in Congress since then.[257] CMS issued a national coverage determination for the coverage of next-generation sequencing, but academic studies

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[249] *Cancer Moonshot℠.* National Cancer Institute. (n.d.). Retrieved April 5, 2022, from https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

[250] Axelsen, K., Jayasuriya, R., Zacharko, C., Smith, K., Guthrie, M., Gordon-Rose, O., Brown, S., Kuhn, E. (2022, March 15). Inequities in Care and Treatment for Triple Negative Breast Cancer Patients. *Charles River Associates.* Retrieved from https://media.crai.com/wp-content/uploads/2022/03/15101341/Gilead-CRA-Report-Treatment-and-Care-for-TNBC.pdf. Accessed 11 April 2022.

[251] Centers for Disease Control and Prevention. (2021, July 30). *Promoting early detection and treatment of cancer*. Centers for Disease Control and Prevention. Retrieved May 13, 2022, from https://www.cdc.gov/cancer/ncccp/priorities/early-detection-treatment.htm

[252] *Newer and experimental breast imaging tests*. American Cancer Society. (n.d.). Retrieved April 5, 2022, from https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/experimental-breast-imaging.html

[253] *State of Arkansas 93rd General Assembly a bill ... - acr.org*. (n.d.). Retrieved April 5, 2022, from https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/SB-290-081921.pdf

[254] House Bill 19-1301. (n.d.). Retrieved April 5, 2022, from https://leg.colorado.gov/sites/default/files/documents/2019A/bills/2019a_1301_enr.pdf

[255] *Illinois Compiled Statutes. Illinois General Assembly*. (n.d.). Retrieved April 5, 2022, from https://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=021500050K356g

[256] Stockler, A. (2019, December 28). Illinois will require insurers to cover diagnostic mammogram follow-ups to initial screenings in 2020. Newsweek. Retrieved April 5, 2022, from https://www.newsweek.com/diagnostic-mammogram-illinois-insurance-healthcare-1479473

[257] *H.R.2428 - Access to Breast Cancer Diagnosis Act of 2019*. Congress.gov. (n.d.). Retrieved April 5, 2022, from https://www.congress.gov/bill/116th-congress/house-bill/2428/amendments

have found that it has not supported equitable access to testing.[258] Michigan and Alabama have included objectives to increase awareness and utilization of genetic testing among Black women in their comprehensive cancer control plans.[259,260] However, many states do not refer to under-resourced populations in their policy or plans.

- **Gaps in value-based payment incentives for innovative, equitable healthcare provision**: CMS Innovation Center has developed and tested new healthcare payment and service delivery models. An example of value-based care in cancer is the Oncology Care Model (OCM), developed by CMS in 2016, which encourages value-based treatment costs through high-performance-based payment arrangements. However, the model made little direct reference to addressing health equity and is due to end in 2022, with no follow-on model announced.[261] More recently, CMS has published a refreshed innovation strategy that commits to advancing value-based care.[262] The strategy indicates that CMS aims for alternative payment and care delivery models to advance health equity.
- Separately, at the state level, Section 1115 waivers can be used to implement value-based payment models that target care for under-resourced patients eligible for Medicaid.[263,264] However, while Section 1115 waivers can provide opportunities to reduce inequities, some states can also use them to implement eligibility and access restrictions that disproportionately affect under-resourced populations.[265]

Our review suggests that while the policy environment for TNBC has progressed, challenges remain. Further legislative changes and a realignment of incentives may be required to ensure equitable access to innovative TNBC diagnostics and treatments.

4.2. Supporting treatment innovation to address HDI in TNBC

Supporting the development of and access to innovative treatment is vital to address TNBC outcome inequities.[266,267] For example, recent FDA approval of targeted therapies for small subgroups of TNBC patients that include immune checkpoint inhibitors has shown promise and encourages the development of more personalized treatment in

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[258] Sheinson, D. M., Wong, W. B., Meyer, C. S., Stergiopoulos, S., Lofgren, K. T., Flores, C., Adams, D. V., & Fleury, M. E. (2021). Trends in Use of Next-Generation Sequencing in Patients With Solid Tumors by Race and Ethnicity After Implementation of the Medicare National Coverage Determination. JAMA network open, 4(12), e2138219. https://doi.org/10.1001/jamanetworkopen.2021.38219

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

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

[261] Kline, R. M. (2021). Bundled payment models in oncology: Learning to think in new ways. *JCO Oncology Practice*. https://doi.org/10.1200/op.20.00735

[262] CMS Innovation Center Strategy Refresh. Retrieved from https://innovation.cms.gov/strategic-direction-whitepaper

[263] Hinton, E and Stolyar, L. (2021) Medicaid Authorities and Options to Address Social Determinants of Health (SDOH). Retrieved from https://www.kff.org/medicaid/issue-brief/medicaid-authorities-and-options-to-address-social-determinants-of-health-sdoh/

[264] Gerlach, L. and Shah, M.N (2021) As States Continue To Experiment In Medicaid, Look To Section 1115 Waiver Evaluations To Understand What Works. *Health Affairs Forefront.* Accessed 3 June 2022. Retrieved from https://www.healthaffairs.org/do/10.1377/forefront.20210505.113960/full/

[265] Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State, (May 3, 2022) *KFF.* Accessed 3 June 2022. Retrieved from https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/

[266] McArthur, H.L. (2021, August 10). A New Era of Hope for Patients With Triple-Negative Breast Cancer. *The ASCO Post.* https://ascopost.com/issues/august-10-2021/a-new-era-of-hope-for-patients-with-triple-negative-breast-cancer/

[267] Tarantino, P., Corti, C., Schmid, P., Cortes, J., Mittendorf, E. A., Rugo, H., Tolaney, S. M., Bianchini, G., Andrè, F., & Curigliano, G. (2022). Immunotherapy for early triple negative breast cancer: research agenda for the next decade. *NPJ breast cancer*, 8(1), 23. https://doi.org/10.1038/s41523-022-00386-1

TNBC to help improve treatment outcomes.[268] Still a high priority is developing a wider variety of immunotherapy and chemotherapy combination treatments and identifying more biomarkers to select high responders to this type of therapy.[269]

At the federal level, the reignition of the Cancer Moonshot program shows federal support for cancer treatment innovation and improvement of survival outcomes.[270] Grants and funds from this program can also be used to target inequities in cancer. For example, researchers at the Washington University School of Medicine in St. Louis are using their Cancer Moonshot program grant to study disparities seen in rare and under-studied cancers that affect underrepresented groups.[271]

However, we also find evidence of several policies and initiatives that threaten the development of and access to innovative TNBC cancer treatment:

- The FDA's accelerated approval process has enabled patients to access new drugs 3.4-4.7 years earlier, which represents a meaningful difference to cancer patients' lives and health outcomes.[272] Legislation to address the FDA's accelerated approval pathway could be updated to promote transparency and communication between all stakeholders, including patient advocacy organizations and the patients they represent.
- Several states have applied for Section 1115 waivers that will likely result in reduced access to innovative treatment.[273] One example is Oregon, which as of May 2022 had applied for a waiver that would allow it to deny Medicaid coverage of accelerated approval drugs. Notably, this would reduce access to newer and more costly drugs by lower-income patients in the state.[274]
- A Section 1115 waiver request for Tennessee that allows its state Medicaid program to be excluded from a federal mandate for open formularies was approved in 2021; this allows Tennessee to cover a limited number of drugs per therapeutic class, which limits patients' access to a wider variety of drugs.[275]
- Traditional value-assessment methods, such as those used by the Institute for Clinical and Economic Review, are increasingly utilized across insurance plans and state government bodies to help inform drug price negotiations and coverage

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[268] Hossain, F., Majumder, S., David, J., & Miele, L. (2021). Precision Medicine and Triple-Negative Breast Cancer: Current Landscape and Future Directions. *Cancers*, *13*(15), 3739. https://doi.org/10.3390/cancers13153739

[269] Emens L. A. (2021). Immunotherapy in Triple-Negative Breast Cancer. *Cancer journal (Sudbury, Mass.)*, *27*(1), 59–66. https://doi.org/10.1097/PPO.0000000000000497

[270] *Cancer Moonshot℠*. National Cancer Institute. (n.d.). Retrieved April 5, 2022, from https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

[271] Strait, J. E. (2021, November 5). *Cancer Moonshot Grant funds research into reducing health disparities*. Washington University School of Medicine in St. Louis. Retrieved April 12, 2022, from https://medicine.wustl.edu/news/cancer-moonshot-grant-funds-research-into-reducing-health-disparities/

[272] Julia A. Beaver et al., A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review, 4 JAMA Oncology 849, 851

[273] *Section 1115 research and demonstration waivers*. MACPAC. (2019, June 24). Retrieved May 12, 2022, from https://www.macpac.gov/subtopic/section-1115-research-and-demonstration-waivers/

[274] *Oregon seeks to limit Medicaid coverage of accelerated-approval drugs*. Commonwealth Fund. (2022, April 5). Retrieved May 12, 2022, from https://www.commonwealthfund.org/blog/2022/oregon-seeks-limit-medicaid-coverage-accelerated-approval-drugs

[275] Guth, M., Musumeci, M. B., & Rudowitz, R. (2021, November 12). *Tennessee & other Medicaid 1115 Waiver Activity: Implications for the Biden administration*. KFF. Retrieved May 12, 2022, from https://www.kff.org/medicaid/issue-brief/tennessee-other-medicaid-1115-waiver-activity-implications-for-the-biden-administration/

decisions[276] – despite significant evidence of the negative implications for patient access and health equity of ICER's methods.[277,278]

Careful consideration and analysis of appropriateness of use and implications for patient access and health equity must remain front and center during all drug price negotiations and coverage decisions. The findings of this paper and our prior research suggest that if the policies that threaten innovation are implemented, research and development of cancer drugs, especially those that meet complex unmet patient needs, will be at risk, and they indicate the need for policies that incentivize research and development (R&D) investment in transformational medicines and investment that moves beyond more predictable investments.[279] Policies that fail to include these considerations may negatively and disproportionately affect the development and availability of treatments, especially for under-resourced TNBC patients.

4.3. Summary and implications

Our literature review identified policy gaps that may inhibit the development of, and patient access, to TNBC treatment in the long term, as summarized in Table 7.

Table 7: Summary of policy barriers to equitable access to TNBC treatment and care in the long term

Key takeaways
1. The Biden administration has committed to reducing the prevalence and burden of cancer.[280]
2. Coverage of innovative diagnosis and testing is relatively nascent and, where implemented, uptake has been inequitable. [281,282] Incentives to launch innovative diagnosis and testing approaches may be limited by lack of affordable insurance and/or gaps in coverage.
3. Policy proposals that encourage investments in novel TNBC treatments could help to reduce long-standing inequities that exacerbate negative outcomes for TNBC patients, especially those in under-resourced communities.

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[276] ICER. (2020, December 10). How independent assessment of drug value can help states. Retrieved May 12, 2022, from https://icer.org/news-insights/commentaries/how-independent-assessment-of-drug-value-can-help-states/

[277] National Council on Disability (2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. Retrieved from https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

[278] National Minority Quality Forum, Traditional Value Assessment Methods Fail Communities of Color and Exacerbate Health Inequities. Retrieved from: https://static1.squarespace.com/static/5be307ae5b409bfaa68b1724/t/5f58fbb6eaffbe1bb7c24416/1599667126706/Disparities+and+Value+Assesssment+White+Paper.pdf.

[279] Axelsen, K. et al. (2021) An Analysis of the Effect of Drug Pricing Provisions in the Build Back Better Act on Pharmaceutical Innovation. Retrieved from: https://media.crai.com/wp-content/uploads/2022/01/11163314/CRA_LS_An-Analysis-of-the-Effect-of-Drug-Pricing-Provisions-in-BBB-on-Pharmaceutical-Innovation.pdf

[280] *Cancer Moonshot℠*. National Cancer Institute. (n.d.). Retrieved April 5, 2022, from https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

[281] *H.R.2428 - Access to Breast Cancer Diagnosis Act of 2019*. Congress.gov. (n.d.). Retrieved April 5, 2022, from https://www.congress.gov/bill/116th-congress/house-bill/2428/amendments

[282] Sheinson, D. M., Wong, W. B., Meyer, C. S., Stergiopoulos, S., Lofgren, K. T., Flores, C., Adams, D. V., & Fleury, M. E. (2021). Trends in Use of Next-Generation Sequencing in Patients With Solid Tumors by Race and Ethnicity After Implementation of the Medicare National Coverage Determination. JAMA network open, 4(12), e2138219. https://doi.org/10.1001/jamanetworkopen.2021.38219

5. Conclusions and potential policy options

In this section, we draw on the evidence presented in this study, including insights from a cancer advocacy group, CSC, to identify potential policies that improve outcomes for TNBC patients. Our literature review provides a starting point for policy changes that advance equitable access to TNBC patient care, including treatment and support.

5.1. Addressing inequitable access to long-term patient support

Our analysis suggests that overcoming inequitable access to survivorship and palliative care is critical to improving long-term support for under-resourced TNBC patients and reducing physical and psychosocial disparities.

Update guidelines and standards to address implicit bias and expand equitable access to survivorship and palliative care among TNBC patients

At the state level:

- States could use regulations, licensing requirements, and guidelines to expand access and tailor survivorship and palliative care services to underserved patient groups. Lessons from states with promising practices could be leveraged and integrated into policy language applied to TNBC and other cancer patients:
    - Vermont requires providers to complete continuing medical education to demonstrate competency in identifying and engaging patients who could benefit from palliative care.[283] Rhode Island requires physicians to complete at least four hours of continuing medical education every two years on priority topics that include end-of-life and palliative care.[284] Mandated topics could include recognition of physician implicit bias and structural racism.

At the federal level:

- ASCO palliative-care guidelines recommend that advanced cancer patients receive dedicated palliative care services early in their disease. Similar to the 2021 update to NCCN palliative care guidelines, the ASCO guidelines could be expanded to encourage the referral of early-stage cancer patients to palliative care services.[285] Passage of PCHETA could be an important mechanism to achieve this goal. Similarly, TNBC clinical practice guidelines could be updated to recognize the need for greater survivorship and palliative care support.
- Education and training of providers could emphasize the collaborative, or “interprofessional,” nature of palliative care, as emphasized in the 2021 update to the NCCN guidelines. Oncologists who treat TNBC could receive targeted training on how to assess and identify specific patient needs for palliative care services and coordination.
- Increased federal funding to FQHCs could support survivorship care services that recruit and are tailored to the needs of under-resourced populations. Such funding could be targeted at rurally located FQHCs and include resources for review and revision of survivorship care standards to ensure that necessary elements for under-resourced populations are incorporated.

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[283] Riley, T. and Purignton, K. (2019) States Chart A Policy Path To Improve Palliative Care Services Across The Care Continuum. *Health Affairs Forefront.* Accessed May 25, 2022. Retrieved from: https://www.healthaffairs.org/do/10.1377/forefront.20190807.984947/full/

[284] Palliative Care, State of Rhode Island Department of Health. Accessed May 25, 2022. Retrieved from https://health.ri.gov/healthcare/about/palliativecare/

[285] Ferrell, B. R., Temel, J. S., Temin, S., Alesi, E. R., Balboni, T. A., Basch, E. M., Firn, J. I., Paice, J. A., Peppercorn, J. M., Phillips, T., Stovall, E. L., Zimmermann, C., & Smith, T. J. (2017). Integration of palliative care into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline update. *Journal of Clinical Oncology*, *35*(1), 96–112. https://doi.org/10.1200/jco.2016.70.1474

Implement incentives and pass legislation to expand access to comprehensive survivorship and palliative care

At the state level:

- States could use value-based payment incentives to encourage equitable provision of survivorship and palliative care. Section 1115 Waivers could be structured such that providers are encouraged to provide CBPC services for typically under-represented TNBC patients. Payment incentives could be tied to use of electronic health record-driven systems that aim to systematically identify patients in need of tailored survivorship care.[286]
    - States such as California have taken action to implement statewide community-based palliative care (CBPC) services through a Section 1115 Waiver and could serve as a model for other states.[287] Hawaii is pursuing a Section 1115 Waiver that would provide coverage of comprehensive palliative care services for all Medicaid beneficiaries across the state.[288]
    - States could follow Georgia's example by passing legislation similar to H.B. 509 (2016), which established the Palliative Care and Quality of Life Advisory Council, to prioritize palliative care within the Department of Health.[289,290] Similar legislation could mandate the council to engage in activities evaluating the unmet palliative care needs of under-resourced populations.
    - Licensing standards and reimbursement codes could also be used to incentivize provision of equitable palliative and care. California has established palliative care standards for its Medicaid managed care health plans that ensure access for all age groups and include cancer disease-specific criteria.[291]

At a federal level:

- Congress could pass legislation to support early access to palliative care services. For example, the Metastatic Breast Cancer Access to Care Act that was introduced into Congress in 2021 waives the waiting period for Social Security Disability Insurance (SSDI) benefits, allowing mBC patients who are eligible for Medicare to access care and support, including reimbursable palliative care services, sooner.[292] The Act may help to mitigate the effects of low income on mBC patients and their quality of life.[293] Congress could amend the Act to capture TNBC patients and ensure passage.

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[286] Klemp, J.R., Knight, C.J., Lowry, B. et al. (2022) Informing the delivery of cancer survivorship care in rural primary care practice. *J Cancer Surviv* 16, 4–12. https://doi.org/10.1007/s11764-021-01134-3

[287] National Academy for State Health Policy (NASHP). (2022, March 14). Strengthening Care for People with Serious Illness Seven Steps for Building a Community-Based Palliative Care Benefit Within Medicaid. Retrieved May 15, 2022, from https://www.nashp.org/seven-steps-for-building-a-community-based-palliative-care-benefit-within-medicaid/#toggle-id-5

[288] C-TAC. (2021, July 28). Hawai'i's New Managed Medicaid Benefit for Community-Based Palliative Care. Retrieved May 15, 2022, from https://www.thectac.org/2021/07/hawaiis-new-managed-medicaid-benefit-for-community-based-palliative-care/

[289] TrackBill. (n.d.) Georgia HB509. Retrieved May 16, 2022, from https://trackbill.com/bill/georgia-house-bill-509-georgia-palliative-care-and-quality-of-life-advisory-council-create-provisions/1142222/

[290] *Palliative care and quality of Life Advisory Council*. Georgia Department of Community Health. (n.d.). Retrieved April 4, 2022, from https://dch.georgia.gov/palliative-care-and-quality-life-advisory-council/palliative-care-and-quality-life-advisory-council

[291] Palliative Care and SB 1004, DHCS Accessed May 26, 2022. Retrieved from: https://www.dhcs.ca.gov/provgovpart/Pages/Palliative-Care-and-SB-1004.aspx

[292] S.1312 - 117th Congress (2021-2022): Metastatic Breast Cancer Access to Care Act. (2021, April 22). Accessed May 16, 2022, from https://www.congress.gov/bill/117th-congress/senate-bill/1312/all-info?r=6&s=1#:~:text=Official%20Titles%20as%20Introduced,cancer%20and%20for%20other%20purposes.

[293] Alec Stone MA. (2022, March 18). *US senators introduce Metastatic Breast Cancer Access to Care Act*. ONS Voice. Retrieved April 5, 2022, from https://voice.ons.org/advocacy/us-senators-introduce-metastatic-breast-cancer-access-to-care-act

- Congress could pass PCHETA to promote education, awareness, and research of palliative care.[294]

Implement incentives to support provider adherence to care planning and expand federal funding to support access to culturally relevant patient navigation programs

- APMs have been found to incentivize provider performance. More states could encourage the use of quality improvement programs and incentive through APMs to ensure that patients are offered comprehensive survivorship care plans, in line with current clinical guidelines.[295] APMs could target underserved TNBC patient groups (defined by clinical risk factors or geographic location).

At the federal level:

- Through increased federal investment, survivorship care services at FQHCs or in rural locations could be expanded to better target care for under-resourced populations.[296] Culturally relevant resources and services targeting TNBC patients could also be provided to improve access to survivorship care among non-white patients.[297]
- CMS could extend the lessons from the Oncology Care Model (OCM) to help to improve the integration of community-based patient navigators into TNBC care. This could be expanded to include survivorship and palliative care.

5.2. Reducing inequities in long-term patient financial well-being

Our analysis finds that under-resourced TNBC patient populations – namely those who are non-white, young, uninsured, insured through Medicaid, or middle income or low income or who have a metastatic TNBC diagnosis – face a disproportionately negative financial impact following their cancer diagnosis and treatment. Improved policy support targeting these groups could reduce disparities in outcomes. The analysis suggests several policy options:

Implement programs and legislation to alleviate the financial burden of TNBC on under-resourced patients

At the state level:

- States could implement Medicaid waivers to help pay for nonclinical services that are related to TNBC treatment, including case management, housing supports, and employment supports.[298] Pilot programs could specifically target under-resourced TNBC patients and provide full coverage for services such as travel to care centers and enhanced financial support to patients accessing co-pay assistance programs or

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[294] Stewart, R. L., Updike, K. L., Factor, R. E., Henry, N. L., Boucher, K. M., Bernard, P. S., & Varley, K. E. (2019). A multigene assay determines risk of recurrence in patients with triple-negative breast cancer. *Cancer Research*, *79*(13), 3466–3478. https://doi.org/10.1158/0008-5472.can-18-3014

[295] US Government Accountability Office (GAO). (2021) Provider Performance and Experiences under the Merit-based Incentive Payment System. Retrieved February 23, 2022, from https://www.gao.gov/assets/gao-22-104667-highlights.pdf.

[296] Halpern, M. T., Viswanathan, M., Evans, T. S., Birken, S. A., Basch, E., & Mayer, D. K. (2015). Models of Cancer Survivorship Care: Overview and Summary of Current Evidence. *Journal of oncology practice,* 11(1), e19–e27. https://doi.org/10.1200/JOP.2014.001403

[297] American Association for Cancer Research (AACR). (2022). Disparities in Cancer Survivorship. Accessed April 12, 2022, from https://cancerprogressreport.aacr.org/disparities/chd20-contents/chd20-disparities-in-cancer-survivorship/

[298] Elizabeth Hinton and Lina Stolyar Published: Aug 05, 2021. (2022, March 16). *Medicaid authorities and options to address social determinants of Health (SDOH) - issue brief*. KFF. Retrieved April 11, 2022, from https://www.kff.org/report-section/medicaid-authorities-and-options-to-address-social-determinants-of-health-sdoh-issue-brief/

participating in clinical trials. These are patient-specific factors that CER® data demonstrate are associated with greater levels of financial toxicity.[299]

- States governments can implement programs, such as the Health Safety Net Fund in Massachusetts, that pay for medical services for qualified low-income patients at community health centers or acute care hospitals.[300] Qualification criteria for these patients could be expanded to include both mid-income and low-income patients at risk of declaring bankruptcy, as CER® data highlight the need to address financial toxicity for both middle-income and low-income breast cancer patients.
- Recent research concludes that the ACA and Medicaid expansion are associated with a significantly greater increase in the use of palliative treatments.[301] This is particularly important to address disparities in the financial burden of TNBC, as non-white patients are more likely to reside in states that have not adopted Medicaid Expansion and are at greater risk of falling into the Medicaid "coverage gap."[302] Based on this evidence, states that have not done so could expand Medicaid access.

At the federal level:

- While the ACA has been found to have had a significant impact on improving insurance coverage for cancer patients, there is a high-cost share for patients enrolled in this program.[303,304] The federal government could introduce legislation to reduce cost share for cancer patients receiving coverage through the ACA.
  - Furthermore, federal legislation supporting breast cancer patients could be introduced that provides financial support to patients who face indirect costs of care, such as loss of income.[305]
  - Bills similar to existing legislation such as the Access to Breast Cancer Diagnosis Act (which eliminates patient cost-sharing for medically necessary diagnostic impact) and Lymphedema Treatment Act (which ensures Medicare coverage for medically necessary compression treatments) could be implemented for medically necessary treatments for patients experiencing mental health and physical side effects of cancer treatment. This would be aligned with the goals of the Moonshot.

5.3. Ensuring equitable access to innovative TNBC care in the long term

Our assessment suggests that policies to better support TNBC patient access to innovative treatment should be consistent and equitable. Policies could incentivize the research and development of treatment that specifically addresses unmet TNBC patient

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[299] Cancer Support Community, Cancer Experience Registry, January 2015-August 2021

[300] *Health Safety Net*. Mass.gov. (n.d.). Retrieved April 5, 2022, from https://www.mass.gov/orgs/health-safety-net

[301] Cole, A. P., Lipsitz, S. R., Kibel, A. S., Mahal, B. A., Melnitchouk, N., Cooper, Z., & Trinh, Q. D. (2021). Is Medicaid expansion associated with increases in palliative treatments for metastatic cancer?. Journal of comparative effectiveness research, 10(9), 733–741. https://doi.org/10.2217/cer-2020-0178

[302] Artiga, S., Hill, L., Orgera, K., Damico, A. (2021, July 16). Health Coverage by Race and Ethnicity, 2010-2019. *Kaiser Family Foundation (KFF).* Retrieved May 16, 2022, from https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/

[303] Segel, J. E., & Jung, J. (2019). Coverage, financial burden, and the Patient Protection and Affordable Care Act for patients with cancer. Journal of Oncology Practice, 15(12). https://doi.org/10.1200/jop.19.00138

[304] Rosenzweig, M., West, M., Matthews, J., Stokan, M., Yoojin Kook, Y. K., Gallups, S., & Diergaarde, B. (2019). Financial Toxicity Among Women With Metastatic Breast Cancer. Oncology nursing forum, 46(1), 83–91. https://doi.org/10.1188/19.ONF.83-91

[305] Palmer, N. R., Weaver, K. E., Hauser, S. P., Lawrence, J. A., Talton, J., Case, L. D., & Geiger, A. M. (2015). Disparities in barriers to follow-up care between African American and White breast cancer survivors. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer*, *23*(11), 3201–3209. https://doi.org/10.1007/s00520-015-2706-9

needs that are disproportionately experienced by under-resourced patients. Our assessment suggests several policy options:

Enhance coverage and use incentives to encourage development of innovative, patient-centered healthcare delivery

At the state level:

- States could apply for demonstration or pilot projects authorized under Section 1115 waivers to promote the development of innovative cancer care delivery and payment models that support patient eligibility and coverage.[306]
- Through waivers, demonstration projects or state plan amendments, state health plans could develop APMs and other payment reforms with providers, community-based organizations, and federally qualified health centers to reward and incentivize innovative care delivery.

At the federal level:

- The OCM is set to expire in Summer 2022 with no announced replacement. CMS could integrate learnings from the OCM into a successor model to encourage the development and delivery of value-based, patient-centered cancer care models.

Congress should implement legislation and regulatory guidance to maintain incentives for R&D of TNBC medicine

- Medicaid supports historically under-resourced populations, and any Section 1115 waivers should do no harm to patient outcomes. CMS could enforce the Innovation Centers' 2030 objectives by ensuring that approved Medicaid waivers advance health equity. CMS could also ensure that Section 1115 demonstrations uphold the federal open-formulary requirement, thereby supporting access for some low-income beneficiaries with cancer and without any alternative treatment.[307]
- As of 2020, over 100 breast cancer treatments are currently in development and will require legislative and regulatory support to ensure equitable access.[308] Congress has previously recognized the importance of ensuring rapid access to drugs, for example, through the timely reauthorization of the Prescription Drug User Fee Program Act (PDUFA) and the development of the FDA's Accelerated Approval program. Congress could ensure the protection of policies that have demonstrated successful innovation in oncology. Reforms of federal and state policies could incentivize the development of cancer drugs for earlier lines of therapy and for historically under-represented populations.[309]

We recognize that our recommendations are far-reaching, and any implementation will require further assessment of the benefits and unintended trade-offs. As mentioned above, this study should be taken as a starting point for detailed examination of the policies to address health inequity for TNBC patients.

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[306] Cancer Action Network (January 2020). Medicaid Section 1115 Research and Demonstration Waivers. Retrieved from (https://www.fightcancer.org/sites/default/files/FINAL-Medicaid%201115%20Waivers%2001.09.20.pdf).

[307] The Commonwealth Fund (April 5, 2022) Oregon Seeks to Limit Medicaid Coverage of Accelerated-Approval Drugs. Retrieved from: https://www.commonwealthfund.org/blog/2022/oregon-seeks-limit-medicaid-coverage-accelerated-approval-drugs

[308] PhRMA. (2020). Medicines in development 2020 Report. Retrieved July 12, 2022, from https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/MID-Reports/MID_Cancer_2020_FINAL.pdf

[309] Fierce Biotech, April 6, 2022. FDA oncology chief aims to open up accelerated approval for earlier cancer treatment under 'Project FrontRunner'. Retrieved from: https://www.fiercebiotech.com/biotech/fda-oncology-chief-eyes-accelerated-approval-earlier-cancer-treatment-under-planned-project

6. Appendix

Appendix Table 1: Sample characteristics from the CSC Cancer Experience Registry (CER)

Sociodemographic and Clinical Characteristics among Triple Negative Breast Cancer Patients and Survivors Participating in the Cancer Experience Registry from January 2015 through August 2021.

	Full Sample N = 210		Sample for Preparedness to Manage Side Effects Analysis *n* = 175		Sample for FACIT-COST Analysis [310] *n* = 94	
	M/n	*SD/%*^{a}	*M/n*	*SD/%*^{a}	*M/n*	*SD/%*^{a}
Age	53.0	10.3	53.5	10.4	52.3	11.3
Race/Ethnicity						
Non-Hispanic White	170	81%	142	81%	76	81%
Non-Hispanic Black	15	7%	13	7%	6	6%
Hispanic or Latino/a	11	5%	9	5%	6	6%
Non-Hispanic Other Races	14	7%	11	6%	6	6%
Geographic Location						
Urban	135	64%	110	63%	58	62%
Suburban	39	19%	35	20%	21	22%
Rural	33	16%	28	16%	15	16%
Employment Status						
Full-time	93	44%	77	44%	41	44%
Part-time	27	13%	20	11%	13	14%
Retired	36	17%	34	19%	16	17%
Unemployed	51	24%	42	24%	23	24%
Income Status						
<$40K	35	17%	29	17%	14	15%
$40K+	134	64%	112	64%	63	67%
Prefer not to share/missing	41	20%	34	19%	17	18%
Insurance Status						
Employer	131	62%	109	62%	55	59%
Government	46	22%	40	23%	26	28%

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[310] FACIT-COST is a measure of financial toxicity

	Full Sample N = 210		Sample for Preparedness to Manage Side Effects Analysis *n* = 175		Sample for FACIT-COST Analysis [310] *n* = 94	
	M/n	*SD/%*[a]	*M/n*	*SD/%*[a]	*M/n*	*SD/%*[a]
Multiple Insurance	22	10%	18	10%	8	9%
Other	8	4%	6	3%	4	4%
Uninsured	2	1%	2	1%	1	1%
Years Since Diagnosis	3.9	5.5	3.7	4.7	3.5	4.6
Ever Metastatic, or Stage IV at Diagnosis, or Metastatic Breast Cancer Diagnosis	54	26%	43	25%	18	19%
Currently Receiving Treatment	86	41%	70	40%	34	36%
Received All or Part of Care at Academic Comprehensive Cancer Center	63	30%	52	30%	36	38%

Appendix Table 2: Glossary of terms

Term	Definition
Benign	Abnormal collection of cells that is noncancerous. It does not invade nearby tissue or spread to other parts of the body.[311,312]
Differentiation	Differentiation describes how the tumor tissue looks compared to the normal tissue it developed from. Cancer cells that are well-differentiated appear to be more like normal cells, growing and spreading slower compared to differentiated or undifferentiated cancer cells.[313]
Health disparity and inequity (HDI)	A particular type of health difference that is closely linked with social, economic, and/or environmental disadvantages. These disparities adversely affect groups of people who have systematically experienced greater obstacles to health (i.e., based on their racial/ethnic group, religion, socioeconomic status, or gender).[314]
Key populations	Underserved populations who are at risk for developing TNBC, namely women who are Black, Hispanic, young (<40 years old), or low-income or who live in areas that are rural, remote geographic areas, or medical deserts
Medical deserts	Medical deserts are regions with inadequate access to healthcare services, which may exist in urban or rural areas, and which contribute to health disparities.
Refractory cancer	Cancer that does not respond to treatment. The cancer may be resistant at the beginning of treatment, or it may become resistant during treatment. Also called resistant cancer.[315]
Utilization management	A set of techniques used by or on behalf of purchasers of healthcare benefits to manage healthcare costs by influencing patient care decision-making through case-by-case assessments of the appropriateness of care before its provision.[316]

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[311] *NCI Dictionary of Cancer terms*. National Cancer Institute. (n.d.). Retrieved July 12, 2022, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/benign-tumor

[312] *Benign tumor: Definition, types, Causes & Management*. Cleveland Clinic. (n.d.). Retrieved July 12, 2022, from https://my.clevelandclinic.org/health/diseases/22121-benign-tumor

[313] *NCI Dictionary of Cancer terms.* National Cancer Institute

[314] Ndugga, N., & Artiga, S. (2021, May 12). *Disparities in health and healthcare: 5 key questions and answers*. KFF. Retrieved May 24, 2022, from https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/#:~:text=Healthy%20People%202020%20defines%20a,health%20based%20on%20their%20racial

[315] *NCI Dictionary of Cancer terms*. National Cancer Institute. (n.d.). Retrieved May 24, 2022, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/refractory-cancer

[316] Gray, B. H. (1989). *Controlling costs and Changing Patient Care? the role of Utilization Management*. National Academy Press.