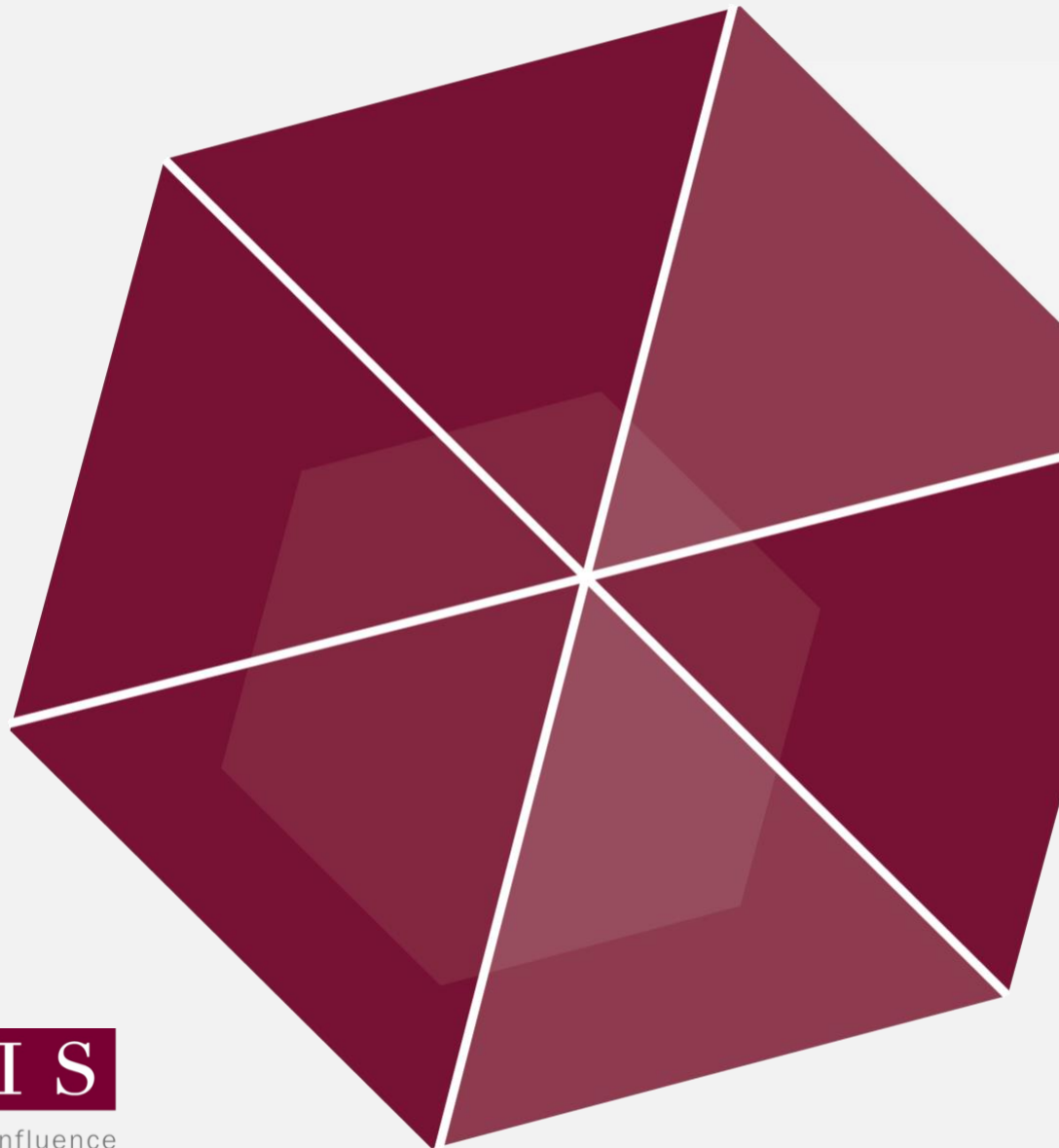


SHIFTING OUR FOCUS

How Canadian Health Systems
Can Better Care for Patients with
Rare Forms of Breast Cancer



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Table of Contents

Breast Cancer in Canada: A Tale of Two Diseases	1
“I Feel Forgotten”: Four Key Themes from Our Research	3
Closing the Gaps and Filling the Cracks	10
Why Canadian Health Systems Need a Sharper Focus on Rare Breast Cancers	14

Breast Cancer in Canada: A Tale of Two Diseases

Despite enormous advances in diagnosis and treatment, breast cancer remains the most common cancer among Canadian women¹ – and their second-leading cause of death from cancer. According to epidemiological modelling from the Canadian Cancer Society (CCS) this year, approximately 28,600 Canadian women will be diagnosed with breast cancer – representing 25% of all new cancer cases in women this year.² 5,500 Canadian women will die from the disease, roughly 15 every single day.²

Each Canadian diagnosed with breast cancer will follow a treatment pathway filled with some moments of progress and hope, and others of regress and fear. From diagnosis to treatment and beyond, most breast cancer patients face a wide range of physical, emotional, psychological and practical challenges that can be tremendously overwhelming and burdensome. This disease not only requires extensive medical interventions, but can also cause significant emotional and psychological trauma to patients and their families.

However, for a particular subset of breast cancer patients diagnosed with relatively aggressive subtypes of the disease, their journey will include notably unique obstacles, hurdles and setbacks. What was once historically thought of as a single disease, emerging evidence portrays breast cancer as a complex and heterogenous disease that requires a distinct treatment and care approach.

Triple-Negative Breast Cancer (TNBC) is a specific subtype that is classified by the lack of expression of estrogen, progesterone and HER2 receptors on the tumour cells. Accounting for approximately 15% to 20% of all diagnosed breast carcinomas,³ TNBC is recognized as being notoriously aggressive and extremely challenging to treat, since neither traditional hormonal therapies nor HER2 targeted therapies have proven effective on TNBC.⁴

1*Excluding non-melanoma skin cancers <https://cancer.ca/en/cancer-information/cancer-types/breast/statistics> (accessed November 29, 2022)

2 <https://cancer.ca/en/cancer-information/cancer-types/breast/statistics> (accessed December 8, 2022)

3 Garrido-Castro AC, Lin NU, Polyak K. Insights into molecular classifications of triple-negative breast cancer: improving patient selection for treatment. *Cancer Discov.* 2019;9(2):176–198.

4 Dent R, et al. Triple-negative breast cancer: clinical features and patterns of recurrence. *Clin Cancer Res* 2007;13:4429–34.

Although there have been transformative advances in treatments for other breast cancer subtypes, patients with TNBC face greater challenges due to limited therapeutic options resulting in the poorest survival rates. It is concerning that despite accounting for less than one-fifth of all breast cancer cases, TNBC is responsible for a disproportionately high percentage of deaths. These factors make TNBC a significant clinical and public health concern, emphasizing the urgent need for better understanding of its biology, development, and access to new therapies for this patient group.

When compared to other subtypes such as HR-positive breast cancer, TNBC patients are also at a high risk of recurrence and developing distant metastases.⁴ Studies show that around one-third of TNBC patients will present with tumours that have spread beyond its initial site to other parts of the body⁴ further contributing to this clinically aggressive and difficult-to-treat characteristics of the disease. And importantly, TNBC has a disproportionate impact on a select set of patients – in particular, women under 40⁵ and Black women.⁶

Looking to better understand the perspectives of patients with TNBC, the physicians who treat them and the organizations who advocate on their behalf, Santis Health conducted a total of 8 interviews with members of the Canadian breast cancer community, including 3 patients with lived experience, 3 representatives of patient advocacy organizations and 2 medical oncologists. Of the group interviewed, 6 of the 8 people we spoke with had lived experience with breast cancer.

Anchored by the stories of these 8 individuals, this report attempts to capture the unique challenges faced by Canadian TNBC patients and present a core set of recommendations that would address the massive unmet need that rare breast cancers represent.

An important note on the independence of this work: Although support for this project came from Gilead Sciences Canada, Inc., the insights and recommendations contained in this paper are Santis' own and based on the perspectives, advice and recommendations we received through both our stakeholder interviews and secondary research.

⁵ Keegan TH, et al. Occurrence of breast cancer subtypes in adolescent and young adult women. *Breast Cancer Res.* 2012;14(2):R55.

⁶ Sorlie T, et al. Gene expression patterns of breast carcinomas distinguish tumor subclasses with clinical implications. *Proc Natl Acad Sci USA.* 2001;98:10869–10874.

“I Feel Forgotten”: Four Key Themes from Our Research

Four key themes clearly emerged from our interviews:

1. Patients with aggressive subtypes too often **felt ignored and marginalized** along their breast cancer journey
2. Multiple **access gaps** leave too many patients with TNBC underserved
3. Beyond better access to innovative and effective diagnostics, treatments and therapies, patients need a broad range of **additional care resources**
4. For younger patients with breast cancer dealing with aggressive subtypes, **dedicated support for caregivers and families** is imperative

1. Patients with Aggressive Subtypes Too Often Felt Ignored and Marginalized Along Their Breast Cancer Journey

Virtually every patient we spoke to talked about the importance of self-advocacy in their cancer journey, from pre-diagnosis to receiving their first treatment. Several interviewees spoke of feeling brushed off by the health care system due to their young age. One patient experienced a significant delay in her diagnosis despite the rapidly growing size of the lump and her persistent effort to get the lump screened and biopsied. This was a common theme throughout multiple stories where patients were left to advocate for themselves, leaving them with more anxiety and fear.

Although most breast cancers are found in women over the age of 50, the aggressive, triple negative breast cancer subtype typically affects pre-menopausal women, Black women, and women with a family

history of breast cancer. As a result, many strongly expressed the need to lower the age bracket for breast cancer screening as well as including racial and cultural considerations given the high prevalence of disease in Black women.

While late stage and triple-negative breast cancers are substantially different (in terms of prognosis, treatment and outcome) from the most common perceptions of early-stage breast cancer, they are deeply misunderstood and often confused by the public. Due to this misconception, TNBC patients we interviewed expressed deep feelings of isolation, as they grappled with uncertainty, loneliness and hopelessness even within the broader breast cancer community.

"There was no support for Black women. If there was support, it wasn't for people who looked like me. This was the hardest thing for me going through my journey with breast cancer."

Breast Cancer Patient

"A lot of young women are dying and are being brushed off by the system because they are too young."

Breast Cancer Patient

"Our TNBC community was built on this united feeling of isolation."

Patient Advocacy Organization

"Early TNBC patients can feel that their breast cancer doesn't have the same transformative targeted treatments as those who benefit from, say, Herceptin. This can leave them feeling isolated from the broader breast cancer community, compounding the cancer-related anxiety they already feel."

Patient Advocacy Organization

2. Multiple Access Gaps Leave Too Many Patients with TNBC Underserved

The women we spoke to identified three distinct access gaps – each of which prevented too many TNBC patients from getting the care they needed. The first gap was overall access to clinical treatment. Although most of our interviewees lived in a major urban centre with proximate access to exceptional cancer treatment centres, every patient we spoke to mentioned other women living in more rural and remote communities who faced substantial diagnosis and treatment delays. Our physician interviewees also

acknowledged that the geography would have a major impact on the timeliness of diagnosis and treatment. In addition, one oncologist noted that there are significant disparities in access to treatment between provinces, which further exacerbates the widespread inequities of TNBC care across Canada. With the aggressive nature of TNBC, it is vitally important for these patients to receive the appropriate care they need immediately following their diagnosis.

“During the pandemic, a lot of Canadian women reached out to our organization, desperate - absolutely desperate to get across the border for access to treatments and clinical trials.”

Patient Advocacy Organization

“I fight tooth and nail to get the necessary treatments for my patients. For drugs that are not approved yet, I go straight to the pharmaceutical company and ask them myself.”

Physician Oncologist

“One of the biggest challenges that these patients face is the delayed time between diagnosis and the start of therapy. And often, getting the appropriate treatment is another challenge.”

Physician Oncologist

“In our organization, where many of the patients are diagnosed under 40, we see some heartbreaking goals when it comes to making milestones. Goals like living long enough to see their toddler off to their first day of school or long enough that a child “will be able to remember me” or that “I can just get them through high school.”

Patient Advocacy Organization

The second gap was access to new medicines. While the rise of genetic testing and precision medicine have helped to improve the management of common types of breast cancer that has allowed many women to lead cancer-free lives, the progress has only begun in TNBC and metastatic, (m)TNBC. With many promising medicines emerging in other countries, multiple interviewees mentioned how difficult it is to comprehend why these therapeutics remain inaccessible in Canada. Physicians also highlighted their frustration in the difficulty of securing access for their patients to the necessary drugs that are approved for use but not funded. Collectively, patients, patient advocacy groups, and oncologists all feel a sense of desperation for patients with TNBC and mTNBC as they anxiously await approval for drugs that can lead to progression-free and overall survival and ultimately improve patients' quality of life. Numerous recent studies have highlighted the extended time gap between the regulatory approval of new cancer medicines and patient access to these transformative therapies⁷ – and that gap is acutely felt by patients with TNBC.

The final gap we unpacked relates to delayed access to biomarker testing – both finding a proximate testing centre and receiving timely results. Patients can often undergo their first treatment without knowing the specific biology of their tumour – which can lead to potentially unnecessary or ineffective procedures, which in turn can even disqualify them from clinical trials participation. Identifying the genetic and molecular characteristics of the tumour is a critical step in deciding on the best course of treatment. As a result, delayed tumour-specific diagnoses are especially problematic for TNBC since these tumours have rapid growth rate, and because these patients are already faced with limited therapeutic options.

⁷ For example, *Improving Access to Innovative Cancer Therapies in Canada* (Lymphoma Canada et al.; 2018) and *Tomorrow Can't Wait: The Value of Breakthrough Cancer Treatments for Canadians* (Conference Board of Canada; 2022).

3. Beyond Better Access to Innovative and Effective Diagnostics, Treatments and Therapies, Patients Need a Broad Range of Additional Care Resources

As multiple interviewees emphasized, the supports that cater to the patients' mental, physical, and emotional wellbeing as they undergo cancer care are equally important but often overlooked. These types of care include physiotherapy, palliative care, and psychological and sexual health counselling.

While the focus is on prolonging life and overall survival, patients emphasized how insufficient they found the support and education they received about living with

the aftermath of cancer treatment. A number of women told powerful stories about how the side effects of their treatment had led to early menopause, cognitive impairments, and significant changes to their reproductive and sexual health – all taking place without sufficient educational resources and other peer and expert supports. And with TNBC patients often undergoing more aggressive treatment plans, their side effects were often commensurately intense.

"You can't go back to your normal life. You are never the same, it's a continuing isolation."

Breast Cancer Patient

"These women carry a lot of burden that come with this disease. Today is here but tomorrow may not be."

Patient Advocacy Organization

"I was a young woman in my 30s with children, in the middle of my career and I went into full menopause. It was great that I finished all my treatments but now I had other problems, and there was no support for any of these."

Breast Cancer Patient

"When it comes to a diagnosis of mTNBC, it commonly affects the bones, lungs, liver and brain with significant symptoms, having a devastating impact on the day-to-day life and quality of life of patients and their families."

Patient Advocacy Organization

4. For Young Breast Cancer Patients Dealing with Aggressive Subtypes, Dedicated Support for Caregivers and Families is Imperative

While the Canadian health care system intends to be patient-centered, caregivers and families are often undervalued and overlooked. Acting as a support system for their loved ones, caregivers play an essential role in a patient's cancer care journey. However, many interviewees expressed concerns around the lack of support and resources extended to their families.

Moreover, as aggressive breast cancer subtypes disproportionately affect younger women with young families, these women are often burdened with an additional layer of challenges related to being the primary caretaker of their children while managing their own symptoms. Several women faced considerable hardships due to the lack of care extending to their children who developed depression and eating disorders following their mother's diagnosis.

"I was shocked to find that support was NOT given to my husband and children."

Breast Cancer Patient

"Just as much we provide support for the women, we need to provide support for the men to help them support the women in their lives."

Patient Advocacy Organization

"There is almost no support given to caregivers - but it is equally important to support families and caregivers to make sure that the patients are adequately supported."

Patient Advocacy Organization

"In order for the patient to get the BEST care possible, we need to make sure that the people around them also get the care that they need such as psychological counselling and social services."

Physician Oncologist

As a part of our research, Santis had extensive discussions with multiple breast cancer advocacy organizations. To provide deeper and more personal insights into the significant treatment and care gaps faced by so many TNBC patients, we are including below verbatim remarks from one of the patient group leaders we spoke with:



When living with breast cancer – in particular metastatic or with a high-risk of recurrence – additional time waiting for treatments can have fatal consequences. When it takes too much time for people to get new cancer treatments, how can they be effective? New treatments for many breast cancer subtypes have brought so much hope to the community, especially those with high-risk breast cancer or those with metastatic breast cancer. But it's taking longer and longer to get these new treatments to the people who need them. The treatment breakthroughs are somewhat bittersweet against the reality of the current delays in reviews, negotiations, and provincial listings.

One of the gut-wrenching parts of my job is taking a call from someone who is truly desperate to access a new treatment that I know would make such a difference in their outcome but it's currently going through one of the stages of our approval and evaluation system, and I know they do not have months to wait. These types of calls been happening more than ever over the past two years as so many game-changing new treatments have been making their way to our Canadian system. It's been very exciting to see the data coming out of major oncology conferences and know these treatments will transform lives soon, but my heart breaks for those who needed the treatments yesterday.

Industry and government bodies need to urgently work out creative, innovative solutions to tackle the key issues causing delays in patient access to new cancer treatments. Rethink is open to being part of the solution, but we need a commitment from the groups that hold the power. And that commitment needs to be to new thinking and new implementation. Because the status quo isn't working and it's getting worse."

Closing the Gaps and Filling the Cracks

As we reflected on the diverse but consistent experiences faced by patients with TNBC, clinicians and advocates, three complementary areas of system reform came into sharp relief:

1. Investing in **expedited access** to promising new therapies
2. Expanding research and **accelerating diagnostic testing** for high-risk populations
3. **Improving and increasing supports** for not only patients, but also caregivers and families

1. Investing in Expedited Access to Promising New Therapies

In the powerful words of the Canadian Agency for Drugs and Technologies in Health last February, *“There are no effective treatments available for patients with triple-negative breast cancer. Many patients do not respond to available treatment options. Even for patients who do respond, the cancer may still return and spread in the breast or to another part of the body.”*⁸

Factor in the intense disease burden and aggressive nature of TNBC, and provincial payers would be well-served to prioritize the negotiation and reimbursement of new therapies that specifically target those rare forms of breast cancer that collectively comprise a “disease within a disease”. The recent development of new treatments for TNBC has sparked tremendous hope and excitement among patients and physicians. Breast cancer advocacy organizations have also praised the promising nature of these therapies, which have the potential to fundamentally shift the treatment paradigm for TNBC.⁸ However, multiple studies showed how far behind Canada is to its global peers when it comes to access to new medicines.⁹ Thus, an intensified focus on addressing the unmet needs of patients with rare and aggressive forms of breast cancer is long overdue, as this would result in slower disease progression, longer survival times and ultimately more lives saved.

“Breakthrough treatments—and timely access for the patients to benefit from them—are the key to changing these dire outcomes. Access to innovative treatment matters.”

Patient Advocacy Organization

⁸ <https://canjhealthtechnol.ca/index.php/cjht/article/view/pc0254/pc0254>

⁹ Lussier Hoskyn, Explaining Public Reimbursement Delays for New Medicines for Canadian Patients

2. Expanding Research and Accelerating Diagnostic Testing for High-Risk Populations

More and more studies highlight the complexity of TNBC as higher numbers of Black women are disproportionately impacted by this disease. As the underlying health disparities in TNBC prognosis and outcome are multifactorial and complex, there is a dire need for increased population-based research to further understand the prominent racial differences in the incidence and mortality rates of TNBC. The high prevalence of TNBC in younger women is also evident and has been clearly shown. Almost all the TNBC patients we interviewed were diagnosed with their illness in their 20s and 30s – far below the current age bracket for breast cancer screening programs.

For these reasons, Canadian health care systems should introduce explicit ethnocultural and demographic lenses to their screening criteria in order to increase the likelihood that more cases of TNBC will be caught earlier and treated more effectively.

“From my own personal experience and from what I’ve seen joining the TNBC community, I believe that the age for screening should be lowered to 40.”

Breast Cancer Patient

3. Improving and Increasing Supports for Not Only Patients, but Also Caregivers and Families

Almost all the women we spoke to expressed deep concerns around the lack of the support and resources extended to their families. As TNBC typically afflicts younger women, these patients are often burdened with an additional challenge of managing their own cancer treatment journey while caring for young children and aging parents.

As they talked about the hardships faced by their own children – including depression and eating disorders following their diagnoses – and the psychological and emotional damage TNBC inflicts on relationships and marriages, it is clear that health system leaders need to develop and deploy a new suite of supports that extend beyond patients themselves and include their families and loved ones. This should include extensive educational resources geared towards caregivers and families, as well as more children-friendly resources about what cancer means. Considering the needs of cancer patients through the design of more robust programs for short- and long-term medical leave would also be an important step.

“Many caregivers and families don’t feel comfortable acknowledging their needs and seeking support. They often say: “I don’t deserve it because I don’t have cancer” – and we need to change this.”

Patient Advocacy Organization



Why Canadian Health Systems Need a Sharper Focus on Rare Breast Cancers

Breast cancer patients with aggressive disease subtypes face unique and multifaceted burdens across their cancer care journey, including marginalization within the breast cancer community, limited access to supportive resources, and insufficient support for caregivers and families. However, perhaps the most pressing issue of all is the lack of access to promising new therapies. Without timely access to these innovative treatments, which have the potential to extend survival and enhance quality of life, patients with TNBC will face even greater difficulties throughout their cancer care, exacerbating other existing challenges highlighted in this paper. The insights gained from our interviews highlight how much work needs to be done to close the treatment and care gap facing so many TNBC patients.

It is abundantly clear that these patients are in dire need of new treatments that will extend their lives and reduce the burden of disease on themselves as well as their families. Having “more time” and finding “more hope” in new treatments was a consistent theme we heard across multiple conversations. There is an urgent need for industry and government organizations to collaborate and come up with innovative solutions to address the major issues causing delays in patient access to new cancer treatments. This commitment must involve adopting new approaches and implementing them effectively, as the current system is ineffective, and patients are bearing these consequences.

Although the progress made in the prevention, diagnosis and treatment of breast cancer more broadly is worthy of celebration, too many patients with TNBC and other forms of rare and aggressive breast cancer face enormous and growing unmet needs. Our outreach and analysis clearly show that it will take a concerted and coordinated effort by a wide range of stakeholders to deliver the supports these patients need – from patient groups and clinicians, to researchers and politicians, to the innovators who discover new drugs and the civil servants who reimburse them.