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Survival Rates and Clinical Trial Participation Among Rural Cancer Patients

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This is to certify that the doctoral study by

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Walden University
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Abstract

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

The literature indicates that cancer patients in rural areas lack adequate access to clinical trials and may experience more harmful consequences than patients residing in urban areas. The purpose of the study was to compare cancer survival rates among patients living in rural and urban counties in a southeastern U.S. state with breast cancer and lung cancer. Analysis was conducted using secondary data from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program tumor registry, Comprehensive Cancer Center (CCC) tumor registry, and CCC OnCore Subject Accrual Data. A series of independent samples t-tests and factorial ANOVA were conducted to test urban-rural differences and differences in enrollments in clinical trials. A comparison of the 5-year survival rates of breast cancer and lung cancer patients from rural and urban counties showed roughly equivalent survival rates. Thus, findings did not support the hypothesis of higher lung or breast cancer survival rates among patients from urban areas. Clinical trial enrollment rates at CCC were significantly higher among breast cancer patients than among lung cancer patients. However, clinical trial enrollment rates did not differ significantly between rural and urban classification. Further research on the representation of rural patients with different cancer types is needed at the CCC and other cancer centers. Implications for positive social change include improving clinical trial participation and thus survival rates among rural and urban patients diagnosed with lung cancer or breast cancer.

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Dedication

I would like to dedicate this study to my mother, Lubov Revzina, who passed away from cancer. My mom was a beautiful woman, a kind and courageous person, a brilliant physician, an immigrant, a faithful wife, a devoted mother, and a loving grandmother. I know she would be proud of me for completing this important work in the field of oncology research.

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I would like to acknowledge my Emory University mentor Dr. Rebecca Pentz, and my family who have helped me reach this point in my academic career.

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Section 1: Foundation of the Study and Literature Review

Introduction

There have been recent developments in the medical industry for improving and managing cancer. Clinical trials are used to help develop therapeutic agents to increase the selection of high-efficacy agents for cancer treatment. These clinical trials are essential for the practice of evidence-based medicine; specific questions can be answered, leading to the development of novel cancer treatments or the improvement of existing interventions. However, participation in cancer clinical trials is generally low. According to Pathak et al. (2019), only approximately 3% of adult patients with cancer enroll in clinical trials. The authors further suggested that most cancer patients do not clearly understand the clinical importance or benefits of such trials; patients believe that current treatment methods are better than trials (Pathak et al., 2019).

Exploring the barriers of clinical trial participation in cancer research, Unger et al. (2016) found that fewer than 1 in 20 adult cancer patients participate in clinical trials associated with cancer. This finding is consistent with Pathak et al.'s (2019) indication that enrollment in cancer clinical trials is usually very low. Unger et al. further reported that although barriers to participation in clinical cancer trials have been the subject of extensive studies, participation rates in clinical cancer trials have not changed over time. These barriers are usually clinical, structural, and attitudinal and vary depending on demographics and socioeconomic factors (Unger et al., 2016). Furthermore, in a meta-analysis, Byrne et al. (2014) reported that as many as 25% of participants in clinical trials

do not understand their ethical and legal rights to voluntary participation and withdrawal from participation.

Previous interventions have been implemented to increase patients' knowledge of trials and facilitate informed decision making through patient decision aids (Flory & Emanuel, 2004; Gillies et al., 2015; Politi et al., 2016; Stacey et al., 2017). However, Goel et al. (2001) and Whelan et al. (2004) found that most cancer treatment decision aids are focused on helping patients decide between different approved interventions, such as lumpectomy versus mastectomy in breast cancer treatment or use of adjuvant chemotherapy for treatment of lymph-node negative breast cancer (Pathak et al., 2019).

In addition, few of these interventions have been applied to cancer patients residing in rural areas, and very limited interventions have been focused on clinical cancer trials. According to Hawley et al. (2016), patient decision aids play an important role in facilitating shared decision making between various stakeholders and can help support decisions associated with cancer clinical trials. This is consistent with previous research that has emphasized the role of patient decision aids in supporting cancer patients' decisions in minority populations to participate in clinical trials (Byrne et al., 2014; Politi et al., 2016).

Despite all these findings regarding low participation of cancer patients in clinical trials, a gap exists in clinical trial participation among rural cancer patients. Baquet et al. (2006) explored rural/urban participation in clinical trials and found that cancer patients residing in rural areas demonstrated lower participation rates than urban patients. Various studies have been conducted to recognize the care access differences among urban and

rural cancer populations. Differences include diagnosing, as urban populations are diagnosed early whereas rural populations receive diagnosis significantly later (Baquet et al., 2006; Virani et al., 2011). Researchers have also analyzed differences in cancer management in rural and urban areas (Coyne, Demian-Popescu, & Brown, 2004; Coyne, Demian-Popescu, & Friend, 2004; Flory & Emanuel, 2004).

The general conclusions in the literature indicate that cancer patients in rural areas lack adequate access to care and are thus likely to suffer the harmful consequences of the disease more than patients residing in urban areas. For instance, Unger et al. (2018) studied the "geographic distribution and survival outcomes for rural patients with cancer treated in clinical trials" and found that rural patients experience worse cancer outcomes. Bergin et al. (2018) identified that rural patients are more frequently diagnosed after an emergency and require more time to seek assistance.

Most past studies have been derived from the Surveillance, Epidemiology, and End Results registry U.S. Census data, focusing on cancer patients without considering location. Thus, this study was conducted to address significant problems for rural residents and cancer service providers. By considering the representation of rural cancer patients in comprehensive cancer center (CCC) clinical trials, the findings of the study may help to address major problems with cancer, such as costly treatments by several clinicians, depending on the location. In this research, I explored the representation of rural cancer patients in Georgia and in Georgia CCC clinical trials as well as the nature of barriers associated with cancer clinical trial barriers in rural areas and considered strategies for reducing barriers.

Problem Statement

Rural populations are more socioeconomically disadvantaged and less informed about new investigational drugs and novel treatment options through clinical trials than urban populations (Coughlin et al., 2019). Notably, the disease and its treatment can make it impossible for patients to drive or even go on foot, further increasing these problems. Dealing with such efforts as financial issues, transportation barriers, and limited access to clinical trials is necessary to access quality care (Parisi et al., 2020). Moreover, the Georgian Cancer Registry has determined there have been more deaths in rural counties because of late detection for cancer patients. To achieve the study objectives, I analyzed secondary data from the cancer registry data to represent rural cancer patients in the CCC clinical trials. My focus was to determine the difference in survival of individuals enrolled from rural areas and the correlation between poor outcomes and residency of patients in rural areas.

Past literature has indicated that, in the United States, cancer mortality rates are higher in rural areas compared to urban areas (Zahnd et al., 2018). Research also indicated that cancers with effective prevention, detection, and therapy account for higher mortality rates in rural areas relative to urban areas (Unger et al., 2018). Kosar et al. (2020) undertook a study to determine whether urban and rural patients with the same care experience similar health outcomes and found that the survival rate of rural patients was significantly lower in comparison to that of urban patients. Based on the findings, Kosar et al. (2020) concluded a disparity exists in treatment outcomes between rural and urban cancer patients. In a different study to determine perceptions rural cancer patients

on clinical trials, Ludmir et al. (2019) found a significant disparity in health outcomes between patients enrolled in clinical trials and patients not enrolled. Ludmir et al. (2019) recommended the need for further research focusing on specific aspects of cancer diagnosis and treatment outcomes, such as cancer stage detection and survival rates.

In past studies, researchers have established various social problems of potential underrepresentation of rural residents in clinical trials or other relevant treatment procedures (Davis et al., 2019). For instance, Forcina et al. (2019) undertook a study to determine the perceptions of cancer patients on their willingness to take part in clinical trials. Forcina et al.'s findings indicated that the majority of patients appreciated the role of clinical trials in helping them better manage the disease. However, some participants were concerned with the side effects of participating in clinical trials (Forcina et al., 2019). These findings are consistent with Echeverri et al.'s (2018) results in a study to determine the causes and effects of underrepresentation of rural residents in clinical trials. Underrepresentation was significantly and positively associated with low life expectancies, increased mortality rates, and higher rates of pain and suffering (Echeverri et al., 2018). Based on these findings, Echeverri et al. (2018) recommended further studies on cancer patient underrepresentation in clinical trials with a focus on cancer detection, treatment, and management.

Cancer diagnosis presents various challenges to patients. Nevertheless, having access to clinical trials and a supportive network are essential for patients to decide which treatments offer the best chances of survival and best potential quality of life (Ludmir et al., 2018). CCCs provide care by a multidisciplinary team of specialists in medical

oncology, surgery, and radiation therapy who discuss cases at specialty conferences such as tumor boards and offer a most suitable clinical trial for each patient to receive a new or experimental treatment (Schapira, 2020). The underrepresentation of rural cancer patients in clinical trials needs to be investigated to close the literature gap in this area and encourage more of these patients to participate in clinical trials.

By conducting secondary data analysis of cancer registry data and Oncore accrual data, I aimed to fill the gap of representation by determining if there is a difference in the ratio of cancer patients enrolled in clinical trials, with the inclusion criteria being patients with breast and lung cancers from rural counties (RUCC 4-9) versus urban counties at CCCs. Moreover, I compared and correlated the difference between cancer survival rates of Georgian patients with breast and lung cancer who live in rural counties and Georgian patients with breast and lung cancer who live in urban counties.

Purpose of the Study

With the latest state-of-the-art breakthrough cancer treatments, cancer patients can maintain a better quality of life and live longer (McDowell et al., 2019). Many of these treatments are available through clinical trials (National Cancer Institute [NCI], 2020). Therefore, cancer centers must enroll each eligible patient in the available clinical trials to increase their chance of survival. Clinical trials help scientists discover new ways to prevent and detect cancer and improve oncology patients' quality of life during and after treatment (NCI, 2020). According to the Georgia Cancer Registry, there are more deaths among rural cancer patients because of late detection. Thus, in this study, I sought to determine whether a difference exists in cancer survival rates among Georgian rural

cancer patients enrolled in CCC clinical trials and Georgian rural cancer patients not enrolled in CCC clinical trials.

The state of Georgia is located in the southeastern part of the United States and has a high population compared to other states. With such a high number of people living within the same locality, the assumption is that the prevalence of both communicable and chronic diseases is likely to be also high (CDC, 2012). In this study, I aimed to assess the hypothesis that rural patients are underrepresented at CCCs both as patients and on clinical trials in relation to the number of Georgians who live in rural counties. As Parisi et al. (2020) noted, with state-of-the-art breakthrough treatments, cancer patients can maintain a better quality of life and live longer. Many of these treatments are available through clinical trials (NCI, 2020). Therefore, the results of this study could benefit both oncologists and rural cancer patients in determining whether to enroll in CCC clinical trials and in earlier detection of cancer in patients.

Background

Despite continuous improvement in health outcomes, the United States continues to experience urban–rural health inequities, especially regarding cancer and other chronic diseases (Ludmir et al., 2018). Past literature has indicated that an underrepresentation of rural cancer patients in clinical trials is a possible predictor of health inequity (Yu et al., 2019). This underrepresentation and lack of participation in clinical trials have been linked to various factors. For instance, some rural patients lack awareness of disease symptoms and dangers, whereas other patients are discouraged by their oncologists (Guy et al., 2015). Based on Wickersham's (2014) survey, the control plan instituted in 2007

has only been useful for people living in Georgia's urban counties. This report aims to review the disparities in cancer representations, control measures, and clinical trials in Georgia's rural and urban areas in this plight.

Mortality rates from cancer are higher in rural areas than the urban centers in the United States (Fogleman et al., 2015). Specifically, according to the Georgia Cancer Registry, from 2004 to 2008, there were more cancer patients in rural counties in Georgia, and rural counties with a population of 35,000 have reported more deaths due to late screening. Wickersham (2014) noted that while there is progress in stabilizing or even minimizing deaths from different causes of cancer, data from the NCI (2014) show that more rural than urban counties have elevated mortality rates for all types of cancers. Of the highest cancer-death counties in Georgia, 24 of the 25 counties have populations fewer than 35,000 (NCI, 2014). In addition, 64% of the counties having the lowest rates of cancer are metropolitan (NCI, 2014). According to Lim and Drenkard (2020), several Georgians have been abandoned in health matters because of social determinants of health. These inequities have high social and economic costs both to individuals and societies.

A survey conducted by Yabroff et al. (2020) established there had been slower progress of intervention, prevention, and treatment of disease in Georgia's vulnerable counties. These areas are underdeveloped, and residents have lower education levels, making it hard for cancer campaign programs to reach these counties (Yabroff et al., 2020). The measures enacted have not been effectively implemented in the rural areas, resulting in imminent disparities of cancer cases in Georgia. Also, screening activities,

mainly found in Georgia's urban areas, have contributed to observed inequities (Fitzgerald & Deal, 2013). Moreover, Coughlin et al. (2020) affirmed that rural residents encounter long travel time to reach oncology care and face more barriers, including reduced income, illiteracy, and physical impairment. In this case, cancer services are located far from their vicinity, thereby jeopardizing access to awareness and treatment.

These determinants are an agglomeration of low education levels, joblessness, increased indices of poverty, and lack of health insurance (Mollica et al., 2018; Wickersham, 2014). Luque et al. (2015) observed that cultural practices have hindered some rural counties' services; most people believe that cancer is a punishment and, therefore, one must suffer the consequences. Georgia's leadership depends on communities receiving education and training about the dangers, detection, and prevention of cancer (Parikh & Wei, 2016). When patients realize they have cancer in a late stage, the disease can be hard to treat. According to Williams et al. (2016), urban counties have modern healthcare facilities that screen for cancer; conversely, rural patients must travel to urban centers to receive healthcare services to screen and treat cancer. Enrollment in clinical trials of individuals from rural areas is necessary to assist in developing screening and treatment appropriate for this patient population.

Many studies have shown that rural behaviors have led to surging cases of cancer in these counties. For instance, increased tobacco consumption and obesity increase cancer risk substantially. Moreover, these areas lack HPV vaccines due to the high numbers of people in rural areas (Fitzgerald & Deal, 2013). Therefore, it is essential to

investigate whether the enrollment in CCC clinical trials results in the early detection of cancer patients within the rural counties of Georgia.

Research Objectives

The main objectives of this study are (a) to compare the difference between the 5-year survival rate and living in rural areas versus urban areas for Georgia patients diagnosed with lung or breast cancer, (b) to determine if there is a difference in the ratio of cancer patients enrolled in clinical trials between patients with breast and lung cancers from rural counties (RUCC 4-9) versus urban counties at CCCs, and (3) to find out if there is a difference in the 5-year survival rate between Georgian cancer patients with lung or breast cancer who live in rural counties (RUCC 4-9), receive care at CCCs, and are enrolled in clinical trials at CCCs versus Georgian cancer patients with lung and breast cancer who live in urban counties, receive care at CCCs, and are not enrolled in clinical trials at CCC.

Research Questions and Hypotheses

RQ1a: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas?

$H_0$1a: There is no difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

H_A1a: There is a difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

RQ1b: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with breast cancer living in urban areas?

$H_0$1b: There is no difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

H_A1b: There is a difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

RQ2: Is there a difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs?

$H_0$2: There is no difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs.

H_A2: There is a difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs.

RQ3a: Is there a difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

$H_0$3a: There is no difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

H_A3a: There is a difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

RQ3b: Is there a difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

$H_0$3b: There is no difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive

care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

H_A3b: There is a difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

Framework

A variety of theories and models support health promotion and disease prevention practices. These theories and models are used to consider, describe, and direct health behavior and to define, create, and enforce interventions. The theory that grounds this study is part of community health education theory, specifically ecological theory (Whelan & Gatenby, 2020). The ecological point of view is a valuable framework to consider the spectrum of health and well-being factors. The actual application of the ecological theory is that, within this target population, a researcher accesses the connection between health of cancer patients and their general well-being, affect the quality of their lives both in the short-term and in the long-term. This theory grounds a study by allowing a researcher to understand and draw implications of disease and well-being of a populations as a whole.

As Hagger (2016) noted, many public health behavioral change theories focus on individual behavior based on rational and conscious choice. However, ecological theory

is a model that can help to provide a summary of the factors influencing such health behavior, including social determinants. The representation of such factors in the rural area surrounding work, age, and disease management systems is low. Such determinants are often influenced by a broader range of strengths, including economic, social, and political influences. This community health education theory focuses on how communities can be affected by an environment, political upheaval, poor sanitation, geographical location, chronic exposure to violence, and other factors. Also, community health education theory alleviates victim blaming (Raingruber, 2014). It is crucial to understand how political, economic, and social factors affect human health as individuals do not exist in a vacuum (Glanz et al., 2015).

Significance

The results of this study can provide much-needed insights into the underrepresentation of the rural Georgia cancer population in clinical trials, which will form the basis for interventions to improve clinical trial participation. Clinical trials allow the actual use of interventions to determine their effectiveness on the targeted health outcomes (Charlton et al., 2015). Specifically, the results of this study can be used by providers of cancer care, including oncologists, social workers, providers of mental wellbeing, and palliative services, to identify barriers to enrollment into clinical trials, which provides a better avenue for enhanced care.

As demand for cancer treatment is expected to rise because of the aging U.S. population, and as the Affordable Care Act increases the number of Americans with insurance, it is essential to broaden these initiatives and develop new methods to ensure

that both rural and urban cancer patients receive quality care services (Galewitz et al., 2021). While no single solution solves the challenges of the underrepresentation of rural cancer patients' treatment entirely, there has been a range of promising solutions (Charlton et al., 2015). These include clinics of outreach projects and services for practitioners and patient education. The study is also beneficial to technology experts on oncology and other applications of telemedicine. Clinical trials are necessary to test the effectiveness of initiatives and new methods. Clinical trials will help determine whether initiatives can increase or decrease the desired health outcome.

Nature of the Study

A quantitative, non-experimental, comparative design was used to compare Georgia rural cancer patients enrolled in CCC clinical trials and Georgia rural cancer patients not enrolled in CCC clinical trials. The independent variables in this study include Georgians in rural counties and rural patients. The dependent variables in this study are rural patients at CCC, Georgian rural CCC patients on clinical trials, Georgian rural CCC patients, and Georgian rural cancer patients not enrolled in CCC clinical trials and not patients of CCC. The population under study was defined by various characteristics. First, the population lives in rural areas in Georgia. Second, the population is composed of both men and women between ages 45 and 65. Lastly, the population has been diagnosed with cancer.

I used a quantitative, as opposed to a qualitative, approach in the study because the focus was on a comparison of ratios of cancer patients enrolled in clinical trials for patients with breast and lung cancers from rural counties versus from urban counties at

CCC. A quantitative approach provides an objective measure of potential differences in the ratio of the two identified groups of Georgia cancer patients. Secondary data were collected from the Georgia Cancer Registry, CCC tumor registry, and Oncore database. A comparative design was deemed appropriate because the purpose of the study was to compare the numeric measures of the variables for the two groups considered in the study. A complex and thorough understanding of cancer clinical trials is important in a quantitative study. The analysis would offer insight into patient representation by collecting data using secondary sources in periodical journals and books. The research could provide improved understanding of how to use questionable problems and priorities.

Limitations, Challenges, and Barriers

A limitation to this study was not having the most recent rural–urban continuum codes (RUCC). The only available RUCC was for 2013. However, this data set was still relevant for this study because it was last updated on December 10, 2020 (USDA ERS Rural–Urban Continuum Codes, 2021). This study was limited to available data from secondary sources. This study was limited to rural cancer patients within Georgia. Specifically, this study was limited to CCC clinical trials.

Literature Review

Barriers to Cancer Clinical Trials

Engaging the community has the potential of enhancing patients' accessibility to cancer clinical trials. As a result, the move could be significant in alleviating cancer clinical trial barriers. Ellis et al. (2019) suggested that physicians should be engaged in

referring potential cancer patients to clinical trials to reduce such barriers. Furthermore, Ellis et al. asserted that advances realized in cancer treatment can be attributed to successful completions of clinical trials. However, Ellis et al.'s (2019) research reveals that despite the contributions and recommendations of clinical trials, 99% of adult cancer patients still face barriers to cancer clinical trials.

Unger et al. (2016) suggested that understanding barriers to clinical trial participation is vital because patients' decisions regarding what cancer treatment they prefer are complex and deeply personal. However, Unger et al. caution that incorporating clinical trial treatment adds another level of complexity to patient care. Patients may face numerous barriers to participation in trials because of multiple environmental and other factors (Unger et al., 2016).

Felder et al. (2019) argued there is significant underrepresentation of certain populations in clinical trials, which leads to the disparity that only yields favor to specific participant groups. The removal of such barriers would lead to diverse representation (Felder et al., 2019), and diverse representation could ensure safety across various genetic and biological characteristics. According to Unger et al. (2016), eliminating barriers to clinical trials requires the availability of assessment trials. Assessment trials are essential because they involve discussions with patients, so they become eligible for the clinical trial. Patients who experience assessment trials are in a position to decide whether to participate in the clinical trial. Unger et al. acknowledged that allowing patients to make their own decision on whether to participate in trials is significant toward evaluating their eligibility and influencing a positive attitude toward clinical trial decision making. Felder

et al. (2019) asserted that most clinical trials do not reflect the populations affected by the respective diagnosis. Attaining representative participation from entire groups of potential cancer patients should be the goal in addressing issues that arise from clinical disparities (Felder et al., 2019).

Researchers have identified and documented some of the barriers that participants experience in relation to cancer clinical trials, including lack of awareness, eligibility criteria, cultural barriers, fear, lack of being recruited or invited, and mistrust between the medical community and scientific groups (Felder et al., 2016). Robbins et al. (2009) identified various factors that could be deterring physicians' recommendations for trial participation. First, physicians develop a significant inclination toward certain treatments prescribed to patients when guiding patients to care (Robbins et al., 2009). Moreover, physicians frequently develop concerns that clinical trials can interfere with their relationships with patients (Robbins et al., 2009). Such concerns act as significant barriers to clinical cancer testing. According to physicians, the introduction of uncertainty could subvert patients' confidence in their physicians' expertise (Talarico et al., 2005).

PubMed Central (2019) recognizes that despite the evolution in radiation therapy in the United States, many treatments follow protocols and new technologies employed with potentially riskier radiation dose schedules compared to standard radiation therapy. Such concerns coupled with the burden of traveling long distances to seek medical attention and treatment regimens that involve multiple modalities act as barriers to cancer clinical trials (Stewart et al., 2007). Stewart et al. suggested that potential cancer patients who live in remote and resource-challenged populations might not have exposure to

cancer clinical trials. As a result, such populations not only grapple with challenges and barriers to cancer clinical trials but also miss the benefits associated with radiation therapy delivery (Langford et al., 2014).

Faulk et al. (2020) studied factors that contribute to improvement in pediatric cancer and acknowledged the role of cooperative clinical trials in enhancing cancer survival cases. Nonetheless, Clisant et al. (2012) maintained that unique barriers, such as infrastructural limitations, contribute immensely to participation barriers for cancer clinical trials. Clisant et al. emphasized that inaccessibility for certain populations make it difficult to understand the challenges patients in rural settings experience. Ellis et al. identified urological cancer trials as one area in which patients are accrued more slowly compared to other cancer trials.

Lara et al. (2001) classified barriers to cancer clinical trial participation into categories: (a) attitudinal, (b) clinical, (c) demographic, (d) socioeconomic, and (e) structural. Structural barriers are those that relate to the absence or unavailability of trials. Clinical barriers refer to instances in which patients do not meet eligibility requirements; attitudinal barriers are those that pertain to both physicians and patients. According to Green et al. (2003), structural barriers refer to factors that make it difficult for patients to access clinical facilities, especially CCC. Many factors, such as the cost of transport, availability of childcare, and access to insurance, could be associated with structural barriers to cancer clinical trials. Particularly, uninsured patients experience worse cancer outcomes at later stages of cancer (Langford et al., 2014). In addition, such patients usually experience greater comorbid burden during their cancer diagnosis. As a

result, their potential or ability to participate in cancer trials is reduced significantly. Somkin et al. (2005) suggested that patients who have access to cancer care face cancer clinical barriers related to histology of the patient and stage of diagnosis.

Melisko et al. (2005) identified another barrier to cancer clinical trials as clinical barriers. Some populations have access to trials, but patients are rendered ineligible (Melisko et al., 2005). The most common reason patients are ineligible is because eligibility protocols and criteria are narrow (Kim et al., 2017). However, Melisko et al. maintained that the narrowness of eligibility protocols is necessary to realize a treatment effect that has approximate consistency with all cohorts. Siminoff et al. (2000), however, maintained that eligibility should be inclusive enough to enable trials to target a significant patient population to which new treatment can be applied. According to Ford et al. (2008), eligibility criteria may also eliminate patients from cancer clinical trials based on safety issues that could sacrifice generalizability in a narrow perspective. Exclusion of patients based on safety concerns and eligibility reasons makes trial accessibility limited (Coyne et al., 2003).

Physician attitudes also have significant contributions to cancer clinical trials. Somkin et al. (2005) observed that physicians have an obvious and vital role to play in linking patients with CCCs for clinical trial participation. A growing body of evidence is now demonstrating that cancer clinical trials have helped in achieving high-quality care. However, Melisko et al. (2005) recognized that physicians also face barriers against enrollment to trials. Physicians have a likelihood of treating, off protocol, eligible patients with only a single arm of the trials (Melisko et al., 2005). Consequently,

physicians may fail patients on trials for personal bias or attitude toward clinical trials related reasons (Melisko et al., 2005). Several previous studies have revealed the primary reason or barrier for nonparticipation among eligible protocol patients was physician preference or barrier (Blevins Primeau, 2019).

The Institute of Medicine (2010) acknowledged that some physicians develop a strong inclination toward particular treatments for specific patients. These physicians may fail to discuss a trial with a patient despite the patient's eligibility. Physicians have also been identified as responsible for interference of patient–physician relationships in cancer clinical trial participation. Physicians have a misconception that introducing uncertainty would subvert their patients' confidence in the physician's expertise (Ford et al., 2008). A physician's willingness to take part in trials could also be influenced by practical considerations, such as lack of or inadequate incentives. According to Ford et al. (2008), some physicians do not like to spend time attending to clinical trial enrollment details or explaining clinical trials to potential cancer clinical trial patients. Furthermore, physicians may also fail to refer patients for trials when they are aware the process could consume much of their time. For instance, oncologists have indicated believing that clinical trials and related paperwork are time consuming (Rivers et al., 2013). As a result, such experts may not refer patients for clinical trials (Rivers et al., 2013).

Another barrier to cancer clinical trial participation is the attitude of patients about clinical trials. Efforts should be enhanced to reduce physician, clinical, and structural barriers to cancer clinical trial participation. Nevertheless, patients have the ultimate decision in whether to participate in the trials (Javid et al., 2012). A patient's personal

preference dictates their choice regarding participating in the trials, and their decision may be influenced by family and friends.

According to Ward et al. (2008), patients have always displayed fear when confronted with the prospect of participating in clinical trials. Residual mistrust of medical science could be attributed to such fear, and patients may be uneasy because of past experiences with abuse (Ferrari & Bleyer, 2007). Patients have expressed fear or dislike of randomization in clinical trials, which has been identified as the most popular reason for patients declining to participate in trials (Ferrari & Bleyer, 2007). Kohler et al. (2012) suggested physicians should limit the use of the word *randomization* to help patients with fear and unease; instead, physicians should rely on an analogy to describe the process of randomization. However, patients could misinterpret the analogy (Bleyer et al., 2006). Ferrari and Bleyer (2007) also identified the potential effects of chemotherapy as a cause of fear among patients. Patients may dictate the type of treatment they receive because of attitude and perception related to certain types of medical prescriptions (Ferrari & Bleyer, 2007).

Hunger et al. (2012) classifies barriers to cancer clinical trial participation into attitudinal, clinical, demographic, socioeconomic, and structural. Structural barriers are those that relate to the absence or unavailability of trials. Clinical barriers refer to instances in which patients do not meet the eligibility, while attitudinal barriers are those that pertain to both physicians and patients. According to Bond and Pritchard (2006), structural barriers refer to factors that make it difficult for patients to access clinical facilities, especially the cancer clinic. Many factors such as the cost of transport,

availability of childcare, and access to insurance could be associated with structural barriers to cancer clinical trials. Particularly, uninsured patients usually reveal worse cancer outcomes at later stages of cancer (Howlader, 2012). In addition, such patients usually greater comorbid burden during their cancer diagnosis. As a result, their potential or ability to participate in the cancer trial usually reduce significantly.

As stipulated by Coyne et al. (2003), patients who have access to cancer care face cancer clinical barriers related to histology of the patient and stage. Felder et al. add that there is significant underrepresentation in clinical trials, which leads to the disparity that only yields favor to specific participants who yield favor from the clinical trials. The authors maintain that removal of such barriers in the scientific perspective necessitates diverse representations to arrive at testing of variations in outcomes. In addition, diverse representations would also ensure the therapies' safety across a variety of genetic and biological characteristics. According to Unger et al. (2016), eliminating barriers to clinical trials requires the availability of assessment trials. The assessment trials are essential because if discussed with the patient, the clinical trial becomes eligible. As a result, the patient would be in a position to make a decision on whether he or she can participate in the trial or not. At this point, Unger et al. acknowledge that allowing patients to make their own decisions on whether to participate in the trials is significant towards evaluating their eligibility and influencing positive attitudes towards clinical trials.

National Cancer Institute (2016) identifies another barrier to cancer clinical trials as clinical barriers. Ineligibility to take part in clinical trials is one of the main problems

that faces research processes, even though there are a large number of willing participants. This is a problem that affects the number of patients that take part in a study, which might be relatively low in number based on the incorporated eligibility protocols and criteria are narrow. However, Comis et al. (2003) maintain that the narrowness of the eligibility protocols cannot be mitigated because it is a condition necessary to realize a treatment effect that has approximate consistency with all cohorts. However, there is also an opposing view by Murthy, Krumholz & Gross (2004). which maintains that eligibility should be inclusive enough to enable the trials to target a significant patient's population to which a new treatment would be applied. The authors maintain that removal of such barriers in the scientific perspective necessitates diverse representations to arrive at testing of variations in outcomes. In addition, diverse representations would also ensure the therapies' safety across a variety of genetic and biological characteristics. According to Murthy et al. (2004), eligibility criteria may also eliminate patients from cancer clinical trials based on safety issues that could sacrifice generalizability in a narrow perspective. Besides, exclusion of patients based on safety concerns and eligibility reasons makes the accessibility of the trials limited Lewis et al. (2003). This is important to increase the reliability and validity.

According to Lewis et al., patients have always displayed fear when confronted with the prospect of participating in clinical trials. Residual mistrust and medical science could be attributed to such fear and being uneasy with experiences in past abuses. Patients who express fear demonstrate dislike of randomization, which has been identified through studies as the most popular reason for the declines in participating in

trials. Unger et al. (2016) suggest that to control such fears and uneasy behaviors among patients, physicians should always limit the use of the word randomization.

According to Unger et al. (2016), eliminating barriers to clinical trials requires the availability of assessment trials. The assessment trials are essential because if discussed with the patient, the patient might become eligible to clinical trial. The justification for this is that clinical trials, before they can be fully approved and started, must be thoroughly assessed by the ethics committee to consider diverse population and its chances to be eligible. Information collected from the studies are used in the decision-making processes of other medical conditions that arise in the future. As a result, the patient would be in a position to make a decision on whether he or she can participate in the trial or not. At this point, Unger et al. acknowledge that allowing patients to make their own decision on whether to participate in the trials is significant towards evaluating their eligibility and influencing a positive attitude towards clinical trials. Felder et al. also maintain that attaining representative participation from the entire groups of potential patients of cancer should not be the only goal towards addressing issues that arise from clinical disparities. Kohler et al. (2012) add that to control fears and mistrust behaviors among patients, physicians should always limit the use of the word randomization. Instead, they should rely on the analogy that describes the process of randomization. However, caution must be taken to avoid patients who could misinterpret the analogy upon the realization that they have been randomized (Bleyer, Budd, Montello, 2006). Ferrari & Bleyer (2007) also identify the potential effects of chemotherapy as the cause of fear among patients. As a result, patients sometimes dictate the type of treatment they

would wish to receive because of the attitude and perception they have against certain types of medical prescriptions. Research provisions by Talarico, Chen & Pazdur (2004) points out that factors including stereotyping or bias of participants from minority groups may also have a role in limiting minority participation in the cancer clinical trials. Besides, Kemeny et al. (2003) also identified constraints faced during language translation when recruiting non-English speaking groups also has a significant contribution as a barrier to participation in cancer clinical trials offered to patients. The communication component hinders web-based training that is offered to sharpen the decision-making skills of the physician in general (Kornblith et al., 2002). Furthermore, where discussion of trials with the patient is involved, language barriers tend to be prohibitive hence hindering their possible consent to the process. Talarico, Chen & Pazdur (2004) also lament about the establishment of cancer trial centers in the urban centers that may not be distributed and accessible uniformly, becoming a potential barrier to clinical trials of cancer.

Solutions to Barriers to Clinical Trials

According to Behring et al. (2019), healthcare providers have vital roles to play in the recruitment of the patients who are underrepresented to be successful in cancer clinical trials. The providers are essential because they are the ones who introduce the clinical trial opportunity to the patients. The biasness of the providers may occur because they are the deciders of which patients to refer for participation trials. Therefore, further research is needed to put into consideration the knowledge, attitude, beliefs held by the provider, as well as the eligibility of patients to enroll in the trials. The two factors have

the potential of influencing the ability and willingness to disseminate the required information with regard to the trials and need to be researched further. Furthermore, Behring et al. point out the importance and significance of exploring financial barriers to enrollment in clinical trials. Studies suggest that only a small minority of 5% of adults get enrolment in clinical trials. Studies reveal that there are trial disparities and gaps existing along sociodemographic, ethnic, and age lines. This reveals nonwhite, poor, and younger patients who possess private insurance. This category of potential cancer patients faces the barrier of financial toxicity to cancer clinical trials making them less likely to take part in the trials. Chino and Zafar (2019) add that insurance and cost concerns remain the largest obstacles that bar populations from taking part in clinical trials. It is therefore paramount that there should be a change clinical paradigm towards addressing clinical and structural barriers that limit trial enrolments. Changing the clinical paradigm should help in expanding the clinical access trials to the populations of the community as well as advocating for health policy changes. The health policy changes should include procedures that guarantee coverage of insurance for clinical trials (Chino & Zafar, 2019). Besides, barriers to clinical trials can be limited through consideration of non-coercive financial assistance to include participants. Financial policies should also focus on factoring in educational costs to participants to enable them to understand and appreciate the role of clinical trials in improving medical advancements. Moreover, Ellis et al. (2020) maintains that cost transparency with regard to clinical trials is vital. Besides, the authors also outline that there should be an expansion to foundation assistance towards enhancing equitable access to clinical trials for everyone. According to Felder, Pena &

Chapital (2009), urologists should be cognizant of the fact that they have a significant role to play in initiating conversations with the patient with regard to clinical trials. However, this conversation should not come in the context of sampling but as a treatment counseling. When conversing about the trials, patients should be offered an opportunity to weigh their options by explaining to them all the available options.

To influence the participant's attitude and perception, they should realize that the role of staff is only to help them recognize trials that are both available and relevant to them. In the process, Guadagnolo et al. (2010) emphasize the need for the physicians to allow a discussion on the emerging questions from the participants. Besides, staff who may view participation in trials as an additional workload, according to Niranjan et al. (2021), should be assisted to delegate trial tasks to external resources. For instance, Niranjan et al. (2021) suggest that such extra workload could be delegated to cancer center trial staff. In addition, urology staff should also play the role of reinforcing trial recommendations by doctors, providing reminders to urologists with regard to available trials, fielding questions from participants, and educating patients with regard to options of clinical trials. Behring et al. acknowledge that urologists have a vital role to play in maintaining a positive relationship between doctors and patients. In the process, the patients taking part in the clinical trials should feel that trial discussion is not targeted at interference. In addition, urologists should also play the role of referring patients to urologists who specialize in cancer or oncologists for options of treatment that they may not be in a position to offer. Therefore, Howerton et al. (2007) suggest that clinical trial navigators should be employed both within the community and clinical settings.

Furthermore, there is also a need to increase awareness of clinical research using community outreach approaches as well as making trials available in rural and remote areas. Moreover, Ellis et al. (2020) also adds that there should be effective partnerships and strategies that encompass institutional level investments, community partners, and providers to facilitate the participation of greater minority in cancer clinical trials. Broad-based education is evidently needed both on institutional and community levels to help in orienting minorities who dwell in the community and minority patients to enable them to appreciate clinical research roles to advance scientific discovery.

Studies suggest that only a small minority of 5% of adults are enrolled in clinical trials (Howerton et al., 2007). Such studies also reveal that there are trial disparities and gaps existing along sociodemographic, ethnic, and age lines. This reveals nonwhite, poor, and younger patients who possess private insurance. This category of potential cancer patients faces the barrier of financial toxicity to cancer clinical trials making them less likely to take part in the trials. Ownsley et al. (2005) add that insurance and cost concerns remain the largest obstacles that bar populations from taking part in clinical trials. It is therefore paramount that there should be a change in clinical paradigm towards addressing clinical and structural barriers that limit trial enrolments. Broad-based education is evidently needed both on institutional and community levels to help in orienting minorities who dwell in the community and minority patients to enable them to appreciate clinical research roles to advance scientific discovery. Changing the clinical paradigm should help in expanding the clinical access trials to the populations of the community as well as advocating for health policy changes. The health policy changes

should include procedures that guarantee coverage of insurance towards clinical trial (Cook et al., 2005). The more rapid trial completion would be, the quicker it would allow for the development of new treatment (Unger et al., 2017). Engaging the community in participating in cancer clinical trials has the potential of enhancing the accessibility of cancer clinical trials. As a result, the move could be significant in alleviating cancer clinical trial barriers.

Section 2: Research Design and Data Collection

Introduction

The overarching objective of the current study was to compare the survival rates and participation in clinical trials of breast and lung cancer patients from rural counties in Georgia to the corresponding statistics of patients from Georgia's metropolitan areas. I posited that rural patients' lower access to health services would have a negative impact on their survival outcomes. Data were collected and analyzed to answer three research questions and associated hypotheses. First, I asked whether the 5-year survival rate of rural lung cancer patients differs from the survival rate of urban lung cancer patients at the county level. Second, I sought to determine whether the 5-year survival rate of rural breast cancer patients differs from that of urban breast cancer patients at the county level. The third research question related to whether enrollment in clinical trials of patients treated at CCC in Georgia differed significantly by cancer type (breast/lung) and residence (urban/rural). I then used the data collected from CCC to determine whether the 5-year survival rates of rural lung cancer patients differed significantly from the survival rates of urban lung cancer patients at the individual level. Lastly, the CCC data were used to determine whether the 5-year survival rates of rural breast cancer patients differed significantly from the survival rates of urban breast cancer patients at the individual level.

Research Design and Rationale

In this study, I used a quasi-experimental research design to test causal relationships (Miller et al., 2020). This research design was focused on understanding whether a relationship exists between the survival rates of lung and breast cancer patients

and their locations, rural or urban. This study was conducted in participants' natural environment, which is Georgia, and in different locations, urban and rural (see Maciejewski, 2020; Rogers & Revesz, 2019). This increases the probability of a clear and informed picture of the trends and relationships as well as connections that exist between the various elements in the study.

Methodology

A methodology is the actual technique a researcher uses to analyze collected data. A researcher justifies selecting one particular methodology as opposed to another and the effect the methodology has on the validity and reliability of results (Churruca et al., 2021). This study describes the representation of the rural Georgian population with breast and lung cancer as patients in CCC and clinical trial participants. I also investigated whether the 5-year survival rates of lung and breast cancer patients differed based on whether they lived in rural or urban residences. A quantitative, non-experimental, comparative design was used to compare Georgia rural cancer patients enrolled in CCC clinical trials and Georgia rural cancer patients not enrolled in CCC clinical trials.

This study was a secondary data analysis of cancer-related data from the SEER Tumor Registry, CCC Tumor Registry, and CCC OnCore. The cumulative county level data of lung and breast cancer patients from the last 60 months was used to determine whether the 5-year survival rates of lung and breast cancer patients differed based on rural/urban residence. The total number of cancer patients were aggregated based on the National Center for Health Statistics (NCHS) rural–urban classification scheme for

counties (RUCCs). The NCHS (2017) classification system has nine categories; the first three correspond to metropolitan areas of varying population sizes while the remaining six correspond to nonmetropolitan areas that vary based on population size and adjacency to a metropolitan area. The data set is comprised of nine breast-cancer and nine lung-cancer survival rates for each of the rural–urban classifications.

The data used in this study were deidentified, except for the data from the CCC, which had ZIP codes associated with the study participants. Quality Committee, Independent Ethics Committee, and Institutional Review Board approvals were obtained before any data collection and initiation of statistical analysis. Therefore, the data and results cannot be linked back to the study participants.

Research Question and Hypotheses

RQ1a: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas?

$H_0$1a: There is no difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

H_A1a: There is a difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

DV: Five-year survival rate for Georgia patients diagnosed with lung cancer (County level data)

Groups: Rural counties vs. Urban counties

Test statistic: Independent Samples t-Test

RQ1b: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with breast cancer living in urban areas?

$H_0$1b: There is no difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

H_A1b: There is a difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas.

DV: Five-year survival rate for Georgia patients diagnosed with breast cancer (County level data)

Groups: Rural counties vs. Urban counties

Test statistic: Independent Samples t-Test

RQ2: Is there a difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs?

$H_0$2: There is no difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs.

H_A2: There is a difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs.

DV: Ratio of cancer patients enrolled in clinical trials between patients with breast and lung cancers

Groups: Lung cancer patients from Rural counties, Breast cancer patients from Rural counties, Lung cancer patients from Urban counties, and Breast cancer patients from Urban counties (four groups)

Test statistic: ANOVA

RQ3a: Is there a difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

$H_0$3a: There is no difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

H_A3a: There is a difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for

Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

DV: Five-year survival rate between the Georgian cancer patients with lung cancer, receive care at CCC and enrolled in clinical trials at CCC (County level data)

Groups: Rural counties vs. Urban counties

Test statistic: Independent Samples t-Test

RQ3b: Is there a difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

$H_0$3b: There is no difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

H_A3b: There is a difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC.

DV: Five-year survival rate between the Georgian cancer patients with breast cancer, receive care at CCC and enrolled in clinical trials at CCC (County level data)

Groups: Rural counties vs. Urban counties.

Test statistic: Independent Samples t-Test

Threats to Validity

The number of participants being either too small or too great may have a significant effect on the validity of results and findings. A researcher must ensure that the representative sample is standard and that the characteristics they possess capture that of the entire population (FitzPatrick, 2019). Additionally, personal bias, which mainly emanates from the participants or the researcher, may also affect the presentation of findings. For instance, when a researcher does not use random sampling in selecting a sample, there are risks of bias (Laraway et al., 2019). Clinical testing may also affect the validity of results and findings, especially if a researcher manipulates the process (Sürücü & Maslakçi, 2020). This means results presented do not capture a true and fair value of the respondents.

Ethical Considerations

The main goal of the study is to evaluate the rural Georgian cancer population's representation in clinical trials at the CCC and, if this population is underrepresented, enhance the clinical trial participation for lung and breast cancer patients for rural population both in the short-term and in the long-term. The data that were used in this study is deidentified except for the data from the CCC (it had zip codes associated with the study participants). The Quality Committee, Independent Ethics Committee and

Institutional Review Boards Committee's approvals were obtained before any data collection and initiation of the statistical analysis. Therefore, the data and results cannot be linked back to the study participants. The researcher does not have any financial gain from conducting this study.

Testing the hypotheses developed by the researcher proves whether they are true or void. The research questions are also expected to act as a guide and influence the direction the study takes. The main focus of the study is patients with cancer, in rural and urban areas, with a bias on those affected on their lungs and breasts. With the use of different statistical tests, the researcher is able to capture different dimensions, while remaining within the stipulated framework as guided by the research questions.

Data

The cumulative county level data of lung and breast cancer patients from the last 60 months were used to determine whether the 5-year survival rates of lung and breast cancer patients differed based on rural/urban residence (RQs 1 &2). The total number of cancer patients were aggregated based on the National Center for Health Statistics (NCHS) rural-urban classification scheme for counties (RUCCs). The NCHS's classification system has nine categories, the first three corresponding to metropolitan areas of varying population sizes while the remaining six correspond to non-metropolitan areas that vary based on population size and adjacency to a metropolitan area (NCHS, 2017). The data set comprises of nine breast-cancer and nine lung-cancer survival rates for each of the rural-urban classifications.

The participation of rural and urban patients in clinical trials (RQ 3) and survival rate of were analyzed using data collected from a CCC. The data set comprises of all lung and breast cancer patients who received treatment at the center between 2010 and 2016. The original lung cancer data set had 1,367 cases. However, survival rate values were missing for 17 of the cases. Cases with missing information were deleted resulting in a final sample of 1,350 patients. The original breast cancer data set had 2,264 observations. 36 of the cases were missing survival rate values and were eliminated from the study resulting in a final sample of 2,228.

Secondary Data Types and Sources of Information

A 5-year relative cancer-related data were collected from the Georgia Cancer Registry, specifically from the Georgia Center for Cancer Statistics (GCCS). Only data acquired from 2010 to 2016 is considered for this study since it is the only available recent information on the GCCS website. The Georgia Center for Cancer Statistics (GCCS), a division of the Department of Epidemiology in the Rollins School of Public Health at Emory University, was founded in 1976 to provide population-based incidence data for a five-county region in the southeastern United States, as part of the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program. The GCCS also operates the Rural Georgia SEER Registry (since 1978), covering an additional ten counties to the southeast of Metropolitan Atlanta. (GCCS, 2020). The researcher linked the numbers in the spreadsheet "rural G.A." to the RUCC codes in the spreadsheet "G.A. County RUCC Codes" corresponding to each county and calculated the proportion of cancer cases in each rural Georgia county. RUCC was developed by the

United States Department of Agriculture (USDA). RUCC form a classification scheme that distinguishes metropolitan (metro) counties by the population size of their metro area and nonmetropolitan (nonmetro) counties by the degree of urbanization and adjacency to a metro area or areas (NCI, 2014).

A 5-year relative cancer-related data were collected from the SEER Tumor Registry, CCC Tumor Registry (CCC) and OnCore subject accrual data (CCC). The Surveillance, Epidemiology and End Results (SEER) Program of the National Cancer Institute (NCI) is an authoritative source of information on cancer incidence and survival in the United States. SEER currently collects and publishes cancer incidence and survival data from population-based cancer registries covering approximately 35% of the U.S. population (NCI, 2020). Since this registry contains data from 1975 to 2017, the information utilized will be from 2010 to 2016 (5 years). The OnCore Enterprise Research system, or OnCore, is a vendor-supported Clinical Trials Management System (CTMS). OnCore allows research teams to track subject details as needed for their specific trials (Uhlmansiek, 2020).

Section 3: Presentation of the Results and Findings

Introduction

Capturing results and findings in an analytical manner directly contributes to the achievement of the goals and objectives identified. By conducting secondary data analysis of a 5-year relative cancer-related data from the SEER Tumor Registry, CCC Tumor Registry, and CCC OnCore subject accrual data, this study aimed to fill a gap in the representation of Georgian cancer patients from rural counties (RUCC 4-9) as patients in CCC and as clinical trials participants. Moreover, the differences were compared and correlated between the cancer survival rate of Georgian patients with breast and lung cancer who live in rural counties and Georgian patients with breast and lung cancer who live in urban counties. A series of independent samples t-tests and a factorial ANOVA were conducted, and the results are presented in this section.

Results

A comparison of the 5-year survival rates of breast/lung cancer patients from rural and urban counties showed roughly equivalent survival rates at an alpha level of 0.05. The findings did not support the hypothesis of higher lung or breast cancer survival rates among patients from urban areas. The conclusion was drawn that 5-year breast and lung cancer survival rates do not differ by rural–urban classification. To the effect of rural–urban classification and cancer type on participation in clinical trials, the findings showed that the clinical trial enrollment rate at CCC was significantly higher among breast cancer patients than lung cancer patients. However, the clinical trial enrollment rate did not differ significantly based on rural–urban classification.

Rural Versus Urban Area Georgian Patients' Cancer Survival Rates

The average breast cancer and lung cancer 5-year survival rates in Georgia's rural counties were compared to the corresponding statistics in urban counties using independent samples t-tests. The findings are presented in Table 1 and Table 2. Prior to the t-test analysis, the normality and homogeneity of variance assumptions were tested. Levene's test of homogeneity of variance was non-significant for the breast cancer (F = 4.91, p = .06) and lung cancer tests (F = 2.44, p = .16); thus, the homogeneity of variance assumption holds. Shapiro-Wilk's normality tests were non-significant both for the breast (W = 0.88, p = .16) and lung cancer (W = 0.92, p = .42) tests demonstrating approximate normality of the survival rates distributions. The independent samples t-tests were performed after confirmation of the normality and homogeneity of variance assumptions.

On average, the 5-year breast cancer survival rate in urban counties was 89.13% (SD = 0.31). The average 5-year breast cancer survival rate was lower in rural counties (M = 85.40, SD = 2.79). From the t-test results, shown in Table 2, the difference in breast cancer survival rates was not significant ($t(7)$ = 2.23, p = .06). The null hypothesis of equal breast cancer survival rates in urban and rural areas is retained. Lung cancer survival rates were substantially lower than breast cancer survival rates for both rural and urban counties. On average, the lung cancer survival rate in urban counties was 23.60% (SD = 2.46), slightly higher than the survival rate in rural counties (M = 22.25, SD = 1.07). The mean difference was non-significant at a 5% significance level ($t(7)$ = 1.20, p = .27). There is not sufficient data at the county level to support the hypothesis of lower lung cancer survival rates in rural counties.

Table 1

Mean and SD of 5-Year Breast and Lung Cancer Survival Rates in Urban and Rural Counties

Variables	N	M	SD
5-year breast cancer survival rates (%)			
Urban	3	89.13	0.31
Rural	6	85.40	2.79
5-year lung cancer survival rates (%)			
Urban	3	23.60	2.46
Rural	6	22.25	1.07

Table 2

Independent Sample T-Test Results for Difference in Breast and Lung Cancer Survival Rates in Urban and Rural Counties

	MD	t	df	p	95% CI
Breast cancer survival rate (%)	3.73	2.234	7	0.061	–0.22 to 7.678
Lung cancer survival rate (%)	1.35	1.196	7	0.271	–1.32 to 4.02

CCC Clinical Trial Enrollment Rate Across Rural and Urban Groups

I hypothesized that enrollment in clinical trials would be lower among cancer patients in rural areas compared to cancer patients in urban areas. The hypothesis was tested using data on the entire population of lung and breast cancer patients who received treatment from a CCC in Georgia between 2010 and 2016. To calculate the proportion of patients enrolled in rural areas, the data were divided in the nine rural–urban categories. I anticipated that clinical enrollment would differ not only across the urban–rural dimension but also by cancer type. A 2 x 2 factorial ANOVA with proportion of population involved in a clinical trial as the dependent variable and urban/rural and breast cancer/lung cancer as the factors was conducted. The descriptive statistics and ANOVA

results are presented in Table 3 and Table 4. Enrollment in clinical trials among lung cancer patients was higher in urban areas (M = 11.46%, SD = 5.64%) compared to rural areas (M = 5.78%, SD = 3.02%). Conversely, enrollment in clinical trials among breast cancer patients was higher in rural areas (M = 90%, SD = 22.36%) than in urban areas (M = 59.42%, SD = 52.38%). However, the findings are skewed by the few numbers of breast cancer patients from rural areas receiving treatment at CCC.

Table 3

Mean and SD of Percentage of Patients Enrolled in Clinical Trials by Type of Cancer and Urbanization

Cancer	Rural	M (%)	SD (%)	N
Lung cancer	Urban	11.46	5.64	3
	Rural	5.78	3.02	6
Breast cancer	Urban	59.42	52.38	3
	Rural	90.00	22.36	5
Total	Urban	35.44	42.43	6
	Rural	44.06	46.25	11
	Total	41.02	43.79	17

Levene's test of homogeneity of variance was significant, indicating violation of the homogeneity assumption ($F(3, 13) = 8.46$, $p = .002$). Similarly, the assumption of normality of the dependent variable—proportion of patients enrolled in clinical trial—was violated, as indicated by the Shapiro-Wilk test ($W = 0.74$, $p < .001$). The validity of the ANOVA findings is limited by the violation of the homogeneity and normality assumptions, especially when considering the small sample size. From the ANOVA findings presented in Table 4, the cancer main effect was significant ($F(1, 13) = 28.94$, $p < .001$) while the urban–rural main effect ($F(1, 13 = 1.03$, $p = .33$) and the cancer x

rural/urban interaction effect ($F(1, 13) = 2.18$, $p = .16$) were non-significant. Enrollment in clinical trials differed significantly across the types of cancer. Looking at the mean profile plot in Figure 1, the average enrollment in clinical trials was significantly higher among breast cancer patients than among lung cancer patients. In contrast, the average enrollment in clinical trials did not differ significantly based on rural–urban categorization.

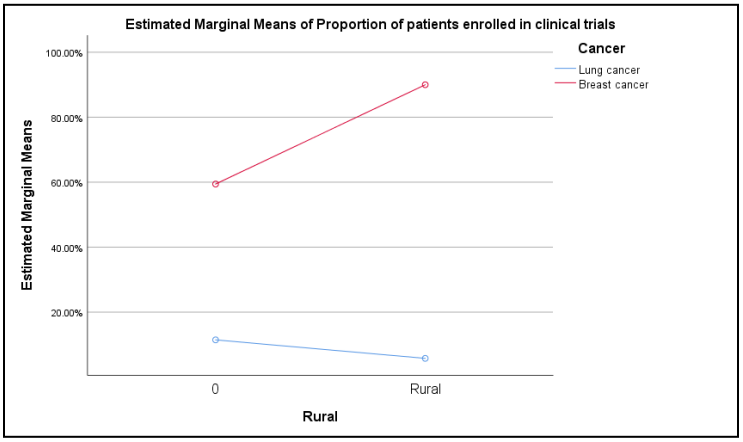
Table 4

2 x 2 Factorial ANOVA with Percentage Enrolled in Clinical Trials as DV and Cancer Type and Rural/Urban as IVs

Source	Type III sum of squares	df	Mean square	F	Sig.
Corrected model	23085.86	3	7695.29	13.17	0.00
Intercept	26878.77	1	26878.77	46.00	0.00
Cancer	16910.22	1	16910.22	28.94	0.00
Rural	599.70	1	599.70	1.03	0.33
Cancer * Rural	1272.38	1	1272.38	2.18	0.16
Error	7595.80	13	584.29		

Figure 1

Mean Profile Plot for the Proportion of Patients Enrolled in Clinical Trial by Cancer and Rural/Urban Status



Comparison of 5-Year Survival Rates by the Type of Cancer and Urbanization for Georgian CCC Patients

The 5-year survival rates of rural and urban patients from Georgia over the past 5 years did not differ significantly as was indicated by the t-test analysis of county level data. Individual-level data from a CCC in metropolitan Georgia were used to determine whether the 5-year survival rates of rural and urban patients receiving treatment at the CCC differed significantly. The findings are presented in Table 5 and Table 6.

The average 5-year breast cancer survival rate of cancer patients from rural areas (M = 8.81, SD 3.69) was slightly higher than the survival rate of patients from urban areas (M = 7.49, SD = 3.83). The difference in survival rate means was, however, non-significant ($t(2226) = 0.84$, $p = .40$). Overall, the survival rates of lung cancer patients were lower than that of breast cancer patients in the state-level data. The 5-year lung cancer survival rate of urban patients was slightly higher (M = 3.50, SD = 3.39) than the survival rate of rural patients (M = 3.39, SD = 3.16). The mean difference was ($t(1348) = 9.46$, p = .64). The findings demonstrate roughly equivalent breast cancer and lung cancer survival rates for rural and urban patients enrolled at a cancer center in Georgia.

Table 5

Mean and SD of 5-Year Rural and Urban Breast and Lung Cancer Patients from a CCC

Variables	N	M	SD
Breast cancer survival rates			
Urban	2,222	7.49	3.83
Rural	6	8.81	3.69
Lung cancer survival rates			
Urban	1,135	3.50	3.39
Rural	215	3.39	3.16

Table 6

Independent Sample T-Test Results for Difference in Breast and Lung Cancer Survival Rates in Urban and Rural Counties From a CCC

Variable	t	df	p	95% CI
Breast cancer survival rate	–0.84	2226	0.40	–4.39 to 1.75
Lung cancer survival rate	0.46	1348	0.64	–0.35 to 0.58

Sample Characteristics

For county-level data sets, 83% of breast cancer patients were from urban areas and 17% were from rural areas. In contrast, 74% of lung cancer patients were from urban areas and 26% were from rural areas. The breast and lung cancer data sets were comprised of all patients diagnosed with breast/lung cancer over the last 5 years in Georgia. Therefore, the samples are highly representative of the population of lung cancer and breast cancer patients.

For the CCC data set, 19% of the lung cancer patients were from rural counties with the other 81% from metropolitan areas while 0.3% of the breast cancer patients were from rural areas while 99.7% were from metropolitan areas. Rural patients are heavily underrepresented in the lung CCC's sample as indicated by the significantly lower percentage of lung/breast cancer patients from rural areas when compared to the overall proportions from the state level data set. This was as expected given that the proportion of urban/rural patients represented in the sample is dependent on whether the center is in a metropolitan or non-metropolitan county.

Statistical Data Analysis and Findings

RQ1a, RQ1b, RQ3a, RQ3b

The Independent Samples t-test is used to test whether there is a difference between the five-year survival rate and living in rural areas versus urban areas for Georgia patients diagnosed with lung cancer; and whether there a difference between the five-year survival rate and living in rural counties versus urban counties for Georgia patients diagnosed with breast cancer, this study will take into consideration two major groups namely, the rural counties and urban counties. It will compare and contrast the survival rates between the two regions and conclusions will be drawn at the end based on the collected data.

It is also used to test whether there a difference between the five-year survival rate between the Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC and enrolled in clinical trials at CCC and those in Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC and not enrolled in clinical trials at CCC; and whether there a difference between the ten-year survival rate between the Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC and enrolled in clinical trials at CCC versus the Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC and not enrolled in clinical trials at CCC. Groups: Two [Rural counties vs. Urban counties.

Independent samples *t*-test involves the assumption of normality. Thus, a Shapiro-Wilk test will be conducted to determine whether the data follows a normal distribution.

If the data is non-normally distributed, the non-parametric counterpart called the Mann-Whitney U test would be utilized. A significance level of .05 will be used for the analyses.

ANOVA (RQ2)

ANOVA test is used to determine if there is a difference in the ratio of cancer patients enrolled in clinical trials between patients with breast and lung cancers from rural counties (RUCC 4-9) versus urban counties at CCC? Groups: Lung cancer patients from rural counties, Breast cancer patients from Rural counties, Lung cancer patients from Urban counties, and Breast cancer patients from Urban counties (four groups).

Analysis of Variance or ANOVA aids in determining whether or not there are significant differences between the means of the independent variables. (Qualtrics, 2022). ANOVA helps to determine whether the differences between data groups are statistically significant and functions by analyzing the levels of variance within the groups through samples taken from each. (Qualtrics, 2022).

RQ1a: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with lung cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with lung cancer living in urban areas?

Finding: The five-year survival rates of lung cancer patients from rural Georgian counties and urban Georgian counties were roughly equivalent at an alpha level of 0.05. The findings do not provide support for the hypothesis of higher lung cancer survival rates among patients from urban areas.

RQ1b: Is there a difference between the 5-year survival rate for Georgia patients diagnosed with breast cancer living in rural areas and the 5-year survival rate for Georgia patients diagnosed with breast cancer living in urban areas?

Finding: The five-year survival rates of breast cancer patients from rural Georgian counties and urban Georgian counties did not differ significantly at an alpha level of 0.05. The findings do not provide support for the hypothesis of higher breast cancer survival rates among urban area patients from urban areas.

RQ2: Is there a difference in the ratio of cancer patients with breast and lung cancers enrolled in clinical trials from rural counties (RUCC 4-9) versus urban counties at CCCs?

Finding: Factorial ANOVA findings showed that the clinical trial enrollment rate among rural counties patients did not differ significantly from the rate observed among patients from urban counties. However, the clinical trial enrollment rate was significantly higher among breast cancer patients than lung cancer patients treated at the CCC.

RQ3a: Is there a difference between the 5-year survival rates for Georgian cancer patients with lung cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with lung cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

Finding: The five-year survival rates of lung cancer Georgian patients from rural areas receiving care at a Cancer center in Georgia between 2010 and 2016 did not differ significantly from the survival rates of the urban Georgian counterparts. Furthermore,

there was no interaction between urban/rural status and enrollment in clinical trials at the CCC and the survival rates of rural patients enrolled in clinical trials did not differ from the survival rates of urban patients not enrolled in clinical trials.

RQ3b: Is there a difference between the 5-year survival rates for Georgian cancer patients with breast cancer who live in rural counties (RUCC 4-9), receive care at CCC, and are enrolled in clinical trials at CCC and the 5-year survival rates for Georgian cancer patients with breast cancer who live in urban counties, receive care at CCC, and are not enrolled in clinical trials at CCC?

Finding: The findings were similar to 3a) above: The five-year survival rates of Georgian breast cancer patients from rural areas receiving care at a CCC in between 2010 and 2016 did not differ significantly from the survival rates of the breast cancer patients from urban areas in the same treatment cohort. As with 3a), there was no interaction between urban/rural status and enrollment in clinical trials; hence, the survival rates of rural breast cancer patients enrolled in clinical trials did not differ from the survival rates of urban patients not enrolled in clinical trials.

Summary

A series of independent samples t-tests and factorial ANOVA were conducted with the objective of comparing the survival outcomes and clinical trial participation rates of rural and urban lung cancer patients. Comparison of the five-year survival rates of breast/lung cancer patients from rural counties and urban counties showed roughly equivalent survival rates at an alpha level of 0.05. The findings did not provide support for the hypothesis of higher lung cancer survival rates among patients from urban areas.

When the comparison was repeated using individual-level data from a cancer center in Georgia, similar findings were reported.

The conclusion was, therefore, drawn that the five-year breast and lung cancer survival rates do not differ by rural-urban classification. With respect to the effect of rural-urban classification and cancer type on the participation in clinical trials, the findings showed that the clinical trial enrollment rate was significantly higher among breast cancer patients than lung cancer patients. However, the clinical trial enrollment rate did not differ significantly based on rural-urban classification. Overall, the findings of the current study are indicative of equitable provision of cancer treatment and care for patients in rural and urban Georgia.

Overall, the findings of the current study are indicative of equitable provision of cancer treatment and care for patients in rural and urban Georgia areas at the CCC.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

This study provided a meaningful analysis of Georgian rural population patients with lung and breast cancers in clinical trials for this CCC. The findings of this study can help the CCC with decision making, patient education interventions, networking and outreach programs, grant acquisition, and further development. With a bias on lung and breast cancer, the results and findings depict the prevalence and survival rates in the urban and rural areas.

Summary of Key Findings

Overall, the findings indicate that cancer treatment and care at the CCC for patients in rural and urban Georgia areas are equitable. Both rural and urban areas have similar rates. Enrollment of breast cancer patients compared to lung cancer patients could be closely attributed to the early detection rate. Perhaps there is more awareness among breast-related cancers compared to lung cancer, and the former is related to an external part of the body while the latter is internally located. The insignificant differences between patients who live in rural and urban areas could be assumed to be a development and improvement in the CCC.

Interpretation of Findings

Lung and breast cancer patients receive almost similar attention and care, when subjected to the healthcare system. This could be connected to the fact that patients with either lung or breast cancer seek medical assistance when needed. Equitable provision of treatment encourages patients, after initial diagnosis, to initiate treatment processes. This

may have a direct effect on the survival rate after a 5-year period. The almost equal survival rate among patients in both urban and rural areas indicates the quality of treatment patients face in both locations.

Limitation of the Study

A limitation of this study is not having more recent RUCC. The only available RUCC was for 2013. However, this data set is still relevant for this study because it was last updated on December 10, 2020 (USDA ERS - Rural-Urban Continuum Codes, 2021).

This study was limited to available data from secondary sources and the researcher could not explore all factors that influence rural populations. In addition, the study was limited to a 5-year period, which might not adequately capture changes over time or allow for trends or patterns in rural cancer populations to be observed.

This study was limited to the rural cancer patients with lung and breast cancer within the state of Georgia, which might differ from rural cancer population with lung and breast cancer in other states. Specifically, this study was limited to Georgian CCC clinical trials. The racial and socioeconomic status of the urban and rural Georgian populations was not included in this analysis.

In conclusion, this study had several limitations, such as not having contemporary RUCC, secondary data sources, the limited period of five years, restriction to only lung and breast types of cancer, lack of comparison with other states' rural populations, and inability to explore all factors influencing rural populations.

Recommendations

This study showed equitable provision of cancer treatment for patients with lung cancer and breast cancer in both rural and urban Georgia at the CCC and significantly lower clinical trial enrollment among lung patients than breast patients. Further research is needed to evaluate the representation of rural patients with different cancer types (not only lung and breast) as patients and as clinical trial participants at the CCC, at different cancer centers, and in different states. Such research could help CCCs, and other cancer centers have more profound knowledge of their patient portfolio that could inform their efforts to diversify the patient population.

Furthermore, educating cancer patients is critical to ensure patients understand the importance or benefits of clinical trials and their ethical and legal rights to voluntary participation and withdrawal from participation. Through clinical trials, unique questions can be answered, targeting particular cancer variations for each patient, enhancing existing interventions, and improving patients' quality of life or prognosis. Hence, ensuring the vast and equal participation of rural and urban cancer patients in clinical trials is essential. Further research is needed to identify barriers preventing cancer patients from participating in clinical trials, whether clinical, structural, attitudinal, demographical, or socioeconomic.

Overcoming identified obstacles, whether through educational campaigns or financial assistance, should be a part of rural patient outreach programs. Rural patient outreach programs are a necessary initiative for each cancer practice to ensure adequate

access to cutting-edge treatment, proper care, and the best possible outcome for all cancer patients regardless of their location and distance to the CCC.

Future researchers should reconsider undertaking their clinical experiments by collecting data over a longer period. This directly contributes to the validity and reliability of results. Ethical considerations should be strictly followed when undertaking clinical experiments. because the process involves directly interacting with actual medical-related information. A researcher must assure that data and results cannot be traced back to specific study participants.

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