Equitable Opportunities for Participation in Oncology Clinical Trials at the Cancer Treatment Centers of America in Chicago, IL: A Quantitative Study

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Researchers at the Cancer Treatment Centers of America (CTCA) in Chicago, Illinois[1] conduct oncology clinical trials with patients from Illinois' Cook and Lake Counties.[2] One challenge is obtaining sufficiently diverse populations to conduct trials. Clinical trials are essential for testing the safety and effectiveness of emerging treatments, but only 2% to 3% of all patients with cancer ever enroll in a clinical trial (Hamel et al. 2016). This challenge is even greater with racial and ethnic minorities, and the underrepresentation of minorities in oncology clinical trials reduces the generalizability of research findings. A great deal of research has been done on barriers to the enrollment of racial and ethnic minorities in clinical trials (Hamel et al. 2016; Brown et al. 2000; Murthy, Krumholz, and Gross 2004), but ultimately patient access to clinical trials is dependent upon physicians offering participation to their patients. It is our hypothesis that adult patients in underrepresented groups are less likely to be offered participation in clinical trials.

1.1 Survey Description

A systematic review of underrepresented minority participants in phase 3 cancer treatment and prevention clinical trials between 2001 and 2010 was conducted by researchers at the Wayne State University Karmos Cancer Institute and the H. Lee Moffitt Cancer Center in 2016. This study found that 83.9% of participants were White, 6.2% were Black/African American, 3.3% were Asian, 2.2% were Hispanic, and 0.1% were Native American (Hamel et al. 2016). Although the study found that minorities were more likely to be underinsured, to seek

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[1] According to CTCA's website, clinical trials are offered at its Chicago, Phoenix, and Atlanta locations. For the purposes of this study, we are using CTCA's Chicago location only as a sample population. As of November 14, 2021, CTCA-Chicago was offering 29 different clinical trials for various types/stages of cancer (Cancer Treatment Centers of America 2021).

[2] For the purposes of this study, we are assuming that patients for oncology clinical trials at CTCA-Chicago will be located within a commutable distance from CTCA's Chicago location, and will thus be drawn from Cook and Lake Counties. In an actual survey, we would determine how patients participating in trials at one of CTCA's locations are assigned to a particular location, and determine a sample size and corresponding demographic statistics based on that information. This level of detail is not publicly available so is not being used for this paper.

care at under-resourced hospitals, and to have concerns about the cost of participation, it also determined that the attitudes of health care professionals about trials and discussing such trials with patients and their families presented a major barrier to trial enrollment. The purpose of our study is to sample the adult patient population at CTCA to show that adult patients in underrepresented groups are less likely to be offered participation in clinical trials by their physicians. By comparing data on patients offered participation at CTCA with the proportion of racial and ethnic minorities in CTCA's coverage area, we hope to determine whether CTCA is offering oncology clinical trial participation in an equitable way.

2.1 Survey Design and Methodology

Our sample population is patients at CTCA, which provided care to 5,966 patients in 2020 (American Hospital Directory 2021). While the probability of patients participating will likely differ between different races and genders, we can use 19% as a baseline p-value for determining sample size. Previous research on the participation of Black female patients in oncology clinical trials showed that only 19% of the patients sampled were offered to participate in trials (Brown et al. 2000). Although this percentage is specific to that particular sample population, we are using this as a baseline due to a lack of more accurate or recent data. To calculate sample size with a 95% confidence interval and a 5% margin of error (Groves et al. 2009), a 19% p-value gives us a sample size of 237 patients, based on the following equation:

$$n = \frac{z^2 * p * q}{e^2} = \frac{1.96^2 * .19 * .81}{.05^2} = \frac{0.5912222}{.0025} = 236.48$$

If we aim for at least a 60% survey response rate, which should be the goal of researchers according to the American Journal of Pharmaceutical Education (Fincham 2008), we should increase our sample size by 158 and send surveys to 395 patients. If 60% of those who receive surveys respond, then we will achieve our desired sample size.

The goal of our survey is to compare the experience of underrepresented adult oncology patients with the experience of the majority (White) patients. To do this, we will use a stratified sample to ensure it is representative of the overall patient population of 5,966 patients mentioned above. Since our predictive question is concerned with underrepresented groups being offered participation in clinical trials, the sample should reflect the demographic makeup of the CTCA service area. CTCA serves both Cook County and Lake County in Illinois, encompassing the Chicago metro area. The racial demographics of both counties are shown in Table 1.1 below.

Table 1.1: Racial Demographics of Cook and Lake Counties, IL

	Cook County	**Lake County**	**Combined Percentage**	**Number of Patients to Sample**	**Number of Patients to Send Surveys**
White	43.49%	61.00%	45.31%	103	179
Hispanic/Latino	23.65%	21.33%	23.38%	53	93
Black/African - American	22.18%	6.49%	20.37%	46	81
Asian	8.04%	8.07%	8.05%	18	32
Two or More Races	2.51%	2.51%	2.18%	N/A[3]	N/A
Total Population Over 18	4,172,402	544,037	4,716,439		

(U.S. Census Bureau 2020)

[3] For the purposes of this study, we are only looking at patients of one race.

3.1 Data Preparation & Analysis

The majority of the survey questions will be categorical, with the exception of age and household income. After the survey has been conducted, data capture would use either a Microsoft Excel or Google Sheets spreadsheet (Groves et al. 2009). Data collection would be delegated within our research group. The data preparation phase includes enumeration of our categorical questions through coding to ensure proper groupings. With regard to race, we anticipate Whites constituting our majority group, and will perform comparisons between this group and minority groups. We can compare data from the White (majority) group with a figure combining minority groups as well. We can further analyze data by creating groups that combine race and gender to gain further insights, such as understanding the differences in clinical participation between Black women and Black men.

Exploratory analysis can reveal percentages of each ethnic group included in our survey, enabling us to determine any correlation between ethnic demographics and rate of invitation to participate in oncology clinical trials. We can use the Pearson correlation coefficient to measure the linear relationship between different ethnic groups, using a score from -1 to 1. This methodology can be applied in this type of survey, since groups can be stratified into various sub-demographics for further insight and analysis (Murthy et al. 2004). With the responses we can perform logistic regression using chi-squared tests and mutual information feature selection to help determine which of our survey questions are most effective in understanding patient care in regards to clinical trials (Brownlee 2019). Survey metadata will be generated throughout the analytical process for documentation purposes (Groves et al. 2009).

3.1.1 Possible Sources of Bias

Our purpose is to identify racial disparities in participation in clinical oncology trials. It is important to address any potential sources of bias so our findings can be utilized for further analysis. Previous studies found that the largest source of bias in patient surveys comes from different demographic attributes between survey respondents and non-respondents (Compton, Glass, and Fowler 2019). In particular, Compton, Glass, and Fowler found that patient survey respondents are more likely to be older, female, and White compared to non-respondents (2019). Bias with survey respondents is the most significant concern for our study. To most effectively prevent potential disparities in survey respondents, we will utilize a relatively long collection period, make repeated callbacks, and keep our survey questions as short and simple as possible to prevent misinterpretation (Groves et al. 2009, 2011). These measures will likely increase the time and costs involved with our survey, but will significantly increase the accuracy of our results.

4.1 Survey Significance and Applications

Under-enrollment of racial and ethnic minorities in oncology clinical trials reduces the generalizability of research findings, significantly limiting the medical community's progress with developing effective and broadly applicable cancer treatments. Although many factors contribute to minorities' proportionally low participation in oncology clinical trials, our survey focuses on a key institutional element limiting minority participation: offers to participate from cancer treatment providers. Whether minorities ultimately participate or not, the first barrier to participation is being offered this opportunity by physicians. By identifying demographic disparities in offers to participate in oncology clinical trials at CTCA, the results of our survey can be used to focus attention on this issue and institute measures to improve the processes for

offering trial participation. Our survey results can also be used to focus on particular minorities; for instance, if a disparity exists with a particular ethnic group, such as Hispanics, efforts can be focused on that particular demographic. These efforts are an integral first step in improving minority participation and the generalizability of CTCA's research results.

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Appendix A

Patient Survey

The Cancer Treatment Centers of America in Chicago wants to increase the participation of underrepresented groups in oncology clinical trials. By participating in this survey, your responses will help us understand whether participation in oncology clinical trials is being offered in an equitable way, and will contribute to future improvements in the accessibility of clinical trials.

1. Have you ever been asked to participate in an oncology clinical trial at CTCA-Chicago?
    a. Yes
    b. No
2. If you were asked to participate, did you participate?
    a. Yes
    b. No
    c. I have never been asked
3. If you were not asked to participate at CTCA-Chicago, were you asked to participate in a trial at another cancer treatment center? If yes, which center?
    a. Yes
        1. Please list center name
    b. No
4. Would you be open to participating in an oncology clinical trial in the future?
    a. Yes
    b. No
    c. Maybe
5. What is your biggest concern about participating in an oncology clinical trial?
    a. Safety of an untested treatment
    b. Financial difficulties
    c. Distance from treatment center
    d. Other
    e. No concerns
6. What is your race?
    a. White
    b. Black/African-American
    c. Hispanic/Latino
    d. Asian
    e. Two or more races
7. What is your sex?
    a. Male

   b. Female
   c. Other
   d. Prefer not to answer
8. What is your age?
   a. 18 - 30 years old
   b. 31 - 50 years old
   c. 51- 65 years old
   d. Over 65 years old
9. Do you feel CTCA-Chicago has sufficient resources to conduct effective clinical trials?
   a. Yes
   b. No
   c. I don't know
10. Are you aware of clinical trials offered at CTCA-Chicago?
   a. Yes
   b. No
   c. I don't know
11. How often do you visit CTCA-Chicago for treatment?
   a. Few times a week
   b. Weekly
   c. Bi-weekly
   d. Monthly
   e. Quarterly
   f. 1 - 2 times a year
12. How far is your commute to CTCA-Chicago?
   a. Less than 10 miles
   b. 10 - 30 miles
   c. 30 - 50 miles
   d. More than 50 miles
13. Are you willing to travel to other oncology treatment centers in the Chicago area to participate in a clinical trial?
   a. Yes
   b. No
   c. I don't know
14. Do you have health insurance?
   a. Yes
   b. No
15. If yes, do you feel your health insurance can sufficiently cover the costs of your clinical trial?
   a. Yes
   b. No

16. Please rate your overall relationship with your oncology care provider on a scale of 1 (poor relationship) to 5 (great relationship).
    a. 1
    b. 2
    c. 3
    d. 4
    e. 5
17. Please rate your communication with your oncology care provider on a scale of 1 (poor communication) to 5 (great communication).
    a. 1
    b. 2
    c. 3
    d. 4
    e. 5
18. What is your estimated household income?
    a. Less than 20,000/year
    b. $20,001 - 40,000/year
    c. $40,001 - 60,000/year
    d. $60,001 - 80,000/year
    e. More than $80,000/year
    f. Prefer not to say
19. If you have participated in a clinical trial, did you do so with the support of your family and friends? If you did not participate, do you think your family and friends would support you if you did participate?
    a. Yes
    b. No
    c. I don't know
20. Do you feel that a clinical trial would be beneficial for your oncology treatment?
    a. Yes
    b. No
    c. I don't know
21. Did you receive information about ongoing clinical trials from a source outside of your oncology center?
    a. Internet
    b. Word of mouth
    c. Family/friends
    d. Local church or community outreach
    e. Have not received outside information
22. Which of the following best represents your understanding of the purpose of informed consent?

a. I do not know what informed consent is.
b. Informed consent primarily focuses on patient safety.
c. Informed consent primarily focuses on provider protection.
d. None of the above.

Thank you for participating in this survey.Your response will help CTCA-Chicago establish strategies to be inclusive and representative of the general population in oncology clinical trials.