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RESEARCH ARTICLE
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The Systemic Exclusion of Native Americans from Cancer Clinical Trials.

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Abstract

Introduction: A major source of health care disparities derives from the underrepresentation of ethnic minorities in clinical trials. The inclusion of ethnic minorities is necessary to generalize the results in terms of efficacy and toxicology of medications in cancer treatment. **Methodology:** In this retrospective study, 80 cancer clinical trials with an aggregate of 278,470 participants performed within the last ten years were selected at random. The number of ethnic minorities participating and inclusion of them in the results were evaluated. **Results:** Only, 42.5% of cancer clinical trials reported the ethnic background of participants in their trials while even less 5% reported the efficacy or toxicology of the therapeutic intervention for ethnic minorities. Whites, Hispanics, African Americans, and Native Americans make up 60.1%, 18.5%, 13.4% and 1.5% of the population they made up 85.3%, 2.54%, 7.6% and 0.12% of the participants that reported ethnicity, respectively. Out of 278,470 participants in cancer clinicals trials only 133 (0.048%) could be identified as Native American . **Conclusion**: Native Americans were nearly completely excluded from cancer clinical trials. African Americans and Hispanics were greatly underrepresented. Cancer Clinical trials may not be generalizable and have been inherently racist in the United States. This has led to the unnecessary death and suffering of Native Americans from cancer.

Keywords: Cancer, Clinical Trials, Native Americans, Health Care Disparities, Racism, Pharmacogenetics, Pharmacology, Therapeutics

1 | INTRODUCTION

Each year in the United States there are 1.8 million new cancer cases diagnosed and 606,520

cancer deaths. [1] Native Americans and other ethnic groups face higher death rates following the development of cancer due to delays in early detection, early intervention which in turn are caused by poverty, lack of access to health care, poor dis-semination medical knowledge, and delays in treat-ment due to racism and indifference by health care providers. [2] It is often thought that the efficacy and toxicity of therapeutic interventions to treat cancer should be the same, as these interventions have to go through rigorous phase I, phase II and phase III clinical trials followed by approval by the FDA. However, this assumes that the clinical trials are generalizable, that is, that the results of the clin-ical trial in terms of efficacy and toxicity can be applied to others with the similar condition. This, however, may be blatantly false. The efficacy of a drug (Pharmacodynamics) depends on the interac-tion of a drug with not only the target receptor but the often multiple signal transduction pathways once the receptor has been bound by the drug. Not only can the receptor target vary by ethnic group but the signal transduction pathways. This is shown by increased death rates due to asthma by African Americans. The common rescue inhalers such as albuterol often fail African Americans as they may have a mutation of their target β-receptor. [3] Additionally, how the drug is metabolized by the human body (pharma-cokinetics) may greatly influence the toxicity of a drug. Again, in the case of African Americans, an-thracyclines which are very useful in treating cancer for the majority population may unnecessarily kill African Americans. [4] Thus, the inclusion of ethnic minorities in cancer clinical trials is necessary to understand if a therapeutic intervention will be safe and effective for a particular ethnic group. Without including ethnic minorities, the results of clinical trials may not be generalizable. In this retrospec-tive analysis, the authors investigate the inclusion or exclusion of Native Americans from cancer clinical trials.

2 | METHODOLOGY

In this study, cancer clinical trials that were performed within the United States within the past ten years were selected by searching PubMed and using the term cancer and clinical trial. One hundred and one papers were then screened to ensure that 1) they were clinical trials, 2) they were performed in the United States and 3) that the number or participants was clearly defined. Of these 80 papers were selected.[5-84] 5These papers were then evaluated for the inclusion
of ethnic minorities in the methods and reporting of results.

3 | RESULTS

In this study, 80 cancer clinical trials from the United States with an accrued aggregate of 278,470 participants were evaluated for the inclusion of ethnic minorities. Of these studies, less than half, 42% reported the participants by ethnic group. Even less 5% reported the results of the intervention in ethnic groups. Participation by Whites, Hispanics, African Americans, Hispanics, and Native Americans among the trials that reported participants by ethnic groups the participation rate was White 85.3%, Hispanic 2.54%, African Americans 7.6%, Asians 6.2%, and Native Americans 0.12%. This is compared to the general population of Whites 60.1%, 18.5% Hispanics, African Americans 13.4%, Asians 6.2%, and Native Americans 1.5%. **See Fig 1.**

The actual participation rate among African Americans, Hispanics and Native Americans in cancer clinical trials may be lower than reported as 58% of cancer clinical trials did not report participation by ethnic group hence, hinting at a homogenous white population for the most part in these trials that did not report ethnic group. The actual rate of participation by African Americans, Hispanics and Native American may be as low as 2.0%, 0.61%, and 0.48% respectively. In terms of reporting the results by ethnic group only 4 out of the clinical trials did so, or 5%. Of these, only 1 trial had useful data in terms of the cancer therapeutic intervention for Native Americans or 1% of the trials.

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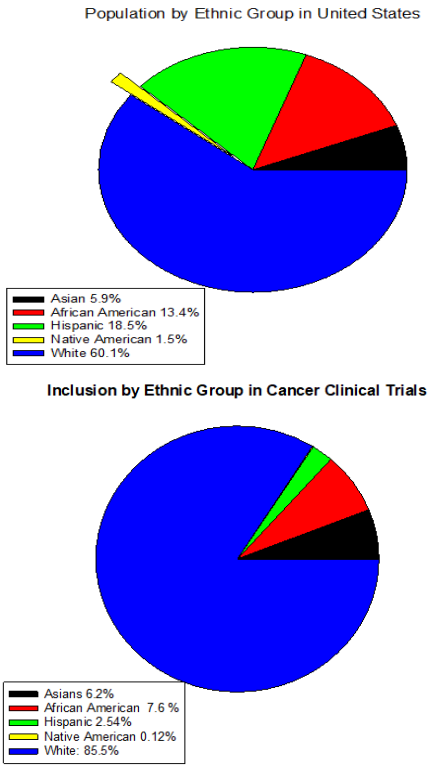

FIGURE 1: Relative Participation of Ethnic Groups in Cancer Clinical Trials

4 | DISCUSSION

Native Americans and other minority populations have been marginalized in health care and cancer treatment by social economic barriers to preventive care, early detection, and optimal treatment. Some of the known causes are include inadequate health insurance; personal obstacles to health care; low health literacy rates; and delays in the dissemination of advances to minority communities, and cultural incompetence and discrimination by health care providers.[85-87] Yet, as this study shows, the problem may be even more fundamental in that the very medications used may be less ef-fective and more dangerous to Native American and other ethnic minority groups aggravating the known ongoing,

systemic racism, as marginalized racial/ethnic groups also receive lower-quality health care. The generalizability of cancer clinical trials to Native American is in question. This exclusion of Native Americans could not have occurred without the collusion or indifference of the National Institutes of Health, Food & Drug Administration, Pharmaceutical company's and our major academic centers and hospitals. Research has dispelled the often cited cause that minotiries are less willing to enroll in clinical trials (Wendler et al. 2006:0 Structural racism that systematically excludes Native Americans from clinical trials is not only unethical but in violation of the spirit of The U.S. National Institutes of Health (NIH) Revitilization Act of 1993.

5 | CONCLUSION

Native Americans have been excluded from cancer clinical trials. African Americans and Hispanics were greatly underrepresented. Cancer Clinical trials may not be generalizable and have been inherently racist in the United States. This has most likely led to the unnecessary death and suffering of Native Americans and others from cancer.

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