

An exploration of the disparities toward the LGBTQ+ population in oncology clinical trials

by

Kaley Jean

Bachelor of Science in Genetics and Classics: Ancient Mediterranean Civilizations, University of
New Hampshire, 2021

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This essay is submitted

by

Kaley Jean

on

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It was approved by

Sarah Krier, PhD, MPH, IDM Associate Professor

Jenna Carlson, PhD, Assistant Professor Human Genetics, Biostatistics

Essay Advisor: Wendy Hernandez, PhD, MS, Assistant Professor Human Genetics

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Kaley Jean, MPH

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Abstract

Oncology clinical trials serve as the foundation for advancing medical research into the development of new treatments, medications, and therapies. However, the severe underrepresentation of LGBTQ+ individuals in oncology clinical trials hampers the generalizability and effectiveness of the findings, ultimately leading to disparities in healthcare outcomes. While efforts to increase diversity in cohorts to properly represent the study populations, there is a persistent struggle to increase sexual and gender diversity due to discrimination towards the queer community. This manuscript analyzes the current methods to address underrepresentation and discrimination of the LGBTQ+ community in oncology clinical trials and determine the best methods to increase LGBTQ patient involvement in clinical trials. The goal is to highlight successful steps that will allow the scientific community to change with the psychosocial and political climates of the community to maintain a safe environment for participation for all communities.

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Preface

This study would not have been possible without the support of family, friends, and professors. Thank you to all who helped through every step of the process, whether it was the development of the idea, editing the paper, or providing mental and emotional support.

Thank you to my readers, Dr. Sarah Krier and Dr. Jenna Carlson for working through the idea and paper with me, as well as my essay advisor Dr. Wendy Hernandez for answering all of my questions and providing me with the missing pieces needed to put this together. Thank you to Diane Rose at Facing Our Risk of Cancer Empowered for giving me the idea for the study topic during my practicum over the summer. Thank you to my parents, family, and friends who pushed me to get to a position where I could perform this research, and for supporting my dreams no matter which road they lead me down. You all are the reason I was able start and finish this chapter of my life, and I know I can keep progressing with your support.

1.0 Background

1.1 Clinical Trials

When novel treatments and interventions are being introduced to healthcare and the scientific community, they can be entered into clinical trials, which are a method of observing how people are influenced or changed by new or different treatments, which is different from other forms of research study methods such as case-studies where researchers observe a cohort but do not influence any factors in the study¹. Unlike case-studies which are more likely to be used for finding cause and effect relationships, clinical trials are used to test the efficacy and safety of a treatment or intervention. Clinical trials are performed using cohorts, or groups, of people who represent the target population of the treatment or intervention to observe how the new intervention will affect the desired population¹. It is important that these cohorts accurately represent the target population of the study to accurately predict the effect of the new intervention on the population.

There are different variations of clinical trials that researchers can utilize when researching cancer treatments. If the researcher is testing a new treatment or a novel way to use an existing treatment, they will use a treatment trial, which is most common in oncology clinical trials. Prevention trials are used when researchers are testing ways to prevent a disease or outcome, either through an agent, such as a drug, or an action, like exercising. Screening trials are used to identify new methods of diagnosing cancer at earlier stages for easier treatment. A final clinical trial variety used in cancer research is palliative care trials, which seek to improve the quality of life of those with cancer, including improving side effects from their treatments, either through introducing a drug as a treatment or an activity, like attending support groups or exercising².

Previous literature shows that most research has been performed with cohorts consisting of primarily cis-gender white men. This is a problem, because research also shows that people of different sexes, races, and ethnicities experience and express diseases and conditions differently, and having cohorts that mostly consist of cis-gender white men does not accurately represent the American population³. A study performed by Roy et. al found that in 2020, 75% of the participants in trials testing new drugs were white when it is estimated that non-Hispanic white individuals only make up about 59.3% of the population⁴. A lack of diversity in clinical research trials means that the effects of novel treatments and interventions on certain populations is unknown. While there has been a large push for increasing the ethnic and racial diversity of clinical trial cohorts, there has been less enthusiasm about increasing gender and sexual diversity.

This paper focuses on gender and sexual minority groups, also commonly referred to as the LGBTQ+ community. Many identities fall into this category, though an overarching label that is sometimes used is “queer”, though not all individuals in this community will use the label, or any label at all. “Gender minority” refers to individuals who do not fit the traditional binary spectrum of gender, such as individuals identifying as transgender, non-binary, or gender-fluid, however not even sex is completely binary, as various factors during development may affect an individual’s chromosomes and hormones, leading to individuals born with extra chromosomes such as XXY individuals, or people born intersex. This requires a distinction between the terms “sex” and “gender”. Sex is the biological factors determining male and female identities, such as chromosomes and reproductive organs, while gender is the social construct of man and woman including gender expression. An individual who expresses their gender matching their sex assigned at birth are cisgender, while individuals who do not match their expressed gender with their sex assigned at birth are transgender or gender non-conforming. “Sexual minority” refers to

individuals who do not fit the traditional sexual ideas of only being attracted to others of the opposite gender, including behavior and preferences, such as individuals who identify as gay, lesbian, bisexual, pansexual, or asexual. In 2021, following the inclusion of questions involving gender and sexual identity questions, the US Census found that 11.7% of Americans self-identified as a sexuality other than straight, 0.6% of adults identified as transgender, and 1.7% of adults identified as something other than male, female, or transgender⁵ (Figure 1). Other results from the 2021 US Census showed that of individuals born female at birth, only 97.4% identify as a woman while the other nearly 3% identify as a man, transgender, or none (Table 1). Similarly, of those individuals who were born male, only 97.3% identify as a man while the rest identified as either a woman, transgender, or none (Table 1).

1.2 Importance of Diversity in Clinical Trials

The lack of diversity in clinical trial cohorts and testing perpetuates a lack of cultural competency in healthcare which has important and dire consequences. For instance, regarding cancer treatments, using predominantly cis-gendered cohorts could lead to researchers missing the effects of gender affirming treatment and hormone therapy on cancer treatments, or the potential for cancer treatments, such as mastectomies, to have negative effects of body dysmorphia in patients. It also avoids the implications of gender affirming care on the likelihood of an individual being diagnosed with cancer, or how transitioning may affect cancer care. Additionally, previous research has shown that there is a higher rate of various cancers including anal, breast, prostate, and lung cancer in LGBTQ+ individuals than their heterosexual and cisgender counterparts⁵. Another important reason to have diverse cohorts is because people will experience and express

conditions and their symptoms in different ways, so even if there is no specific population to study, diverse populations are necessary to fully understand how treatments will affect each population.

One of the problems affecting minority groups that can be perpetuated by low diversity in study cohorts is a lack of trust in the scientific and healthcare communities. This mistrust is largely due to prior mistreatment from past misuse of minority groups in clinical trials and scientific studies, such as the Tuskegee Syphilis Study. Studies like these show a long history of the scientific and medical communities stigmatizing minority populations, like underrepresented gender and sexual groups, through methods such as refusing access to proper medical care and withholding information. Outside of these studies, current healthcare providers continue to manifest this mistrust by ignoring what pain or ailments minority patients may be expressing, and not being properly trained in or acknowledging nuances of caring for underrepresented groups, leading to further subpar care⁴.

While the lack of diversity in research cohorts is a dilemma for all minority groups, the recent push for increasing diversity has largely been focused on ethnic and racial diversity. Although this is a large and necessary improvement, there is still a lack of representation for gender and sexual minority groups, as well as a lack of acknowledgement for intersectionality. Intersectionality is an important topic both in and out of the medical field and is defined as the method for analyzing how the multiple identities an individual holds interact with each other and systems of oppression⁶.

1.3 Specific Aims and Methods

The goal of this study is to highlight and analyze the disparities faced by the LGBTQ+ community in oncology clinical trials. We conducted an extensive review of the literature in order to assess the current state of disparities towards gender and sexual minority groups by reading current literature on the topic, including barriers for the minority groups to get involved in clinical trial research, then we analyzed the literature to describe current strategies being utilized to address the issues. Finally, we addressed the merits and drawbacks of each strategy and proposed a strategy that could be used moving forward to better address the issue of discrimination towards gender and sexual minority individuals in oncology clinical trials, as well as the low participation rate in oncology clinical trials by these individuals.

2.0 Methods

Data for this research comes from current literature surrounding the issue of discrimination towards the population in oncology clinical trials. The literature was found during the month of October in 2023 through searches on PubMed including terms “LGBT in clinical trials”, “LGBT cancer”, and “LGBT cancer clinical trials”. Results were limited, with the earliest publications being in 2005 and the largest quantities of publications for a search term totaling 243. These publications were further narrowed down to exclude publications that were not focused on cancer or clinical trials, as many of the publications involved HIV/AIDS and mental health in the LGBTQ+ community. Following these exclusions, the literature was further narrowed down to only include publications where the full version was available and the gender and sexual minority population were the focus of the article, as many clinical trial research publications place a high emphasis on racial and ethnic minorities. From this search, six pieces of literature were included in the analysis of the issue.

Following identification of the included publications, they were read to identify common themes involving barriers to clinical trials, negative experiences, as well as plans to address the issue for the future.

3.0 Literature Review

As shown through the search methods, literature pertaining to sexual and gender minorities in oncology clinical trials is limited. A large majority of research involving the community began with studies of HIV, or human immunodeficiency virus, and research involving mental health was also common. Overall, research involving the queer community in clinical trials is very limited, but there is more research involving discrimination towards racial and ethnic minorities in clinical trials. This highlights the need of increasing queer presence in clinical trial cohorts to address the needs and nuances of the population.

3.1 Minority Stress

When involving minority groups in research, it is important to be familiar with and understand the minority stress model. The minority stress model is a framework used to examine the impact of discrimination and stigma on the mental health of minority groups and is often used to identify and create interventions to address mental health in these groups as well^{7,8} (Figure 2).

One study by Bauermeister et al. utilized the minority stress model to examine a novel online method to address mental health in LGBTQ youth⁹. The study utilizes the minority stress model to highlight areas of importance in youth stress, such as hostile homophobic culture, fear of rejection, and stigma from outside sources. They also utilize the map of minority stress to identify key points to provide their novel intervention at to best address the mental health of the

population. Another topic they discuss is the impact of treating minority stress as an individual endeavor, instead of as an issue that can be addressed systemically⁹.

Another study written by Fish and Williamson looks specifically at the influence that the minority stress model has on cancer care and outcomes for gender and sexual minority individuals in the United Kingdom⁷. They cited that though there are fewer national surveys requesting gender and sexual identities compared to the United States, the United Kingdom still shows that individuals who identify as a member of the LGBTQ community are more likely to report being diagnosed with cancer. Using the minority stress theory, they hypothesize that contributors such as prior prejudice events, internalized homophobia, and fear of rejection will influence the individual's relationship with healthcare and result in negative outcomes with cancer care⁷. Results from the study found that participants felt pressured to "remain or be pushed back into the closet", and those that identified themselves as members of the LGBTQ community received subpar care, including an uncomfortable treatment environment and lowered access to the usual psychological care offered to cancer patients. While they cited many negative outcomes from the minority stress model, they also found some positive aspects of the model providing beneficial outcomes of care. The final findings of the study suggested that positive and negative aspects of the minority stress model affected whether the outcomes of patient care will have a positive or negative outcome⁷.

3.2 Discrimination in Oncology Clinical Trials

Regarding publications focused on oncology clinical trials and gender and sexual minorities, there are few papers focused on clinical trials specifically and more so on how to further involve the individuals from the target population. A publication written by Roy et al. was an

overview of discrimination towards minority groups in oncology clinical trials, including topics involving the LGBTQ population⁴. The overview identifies the minority groups that are underrepresented in oncology clinical trials and their increased risk for diagnosis before focusing on radiation clinical trials. They also highlighted barriers to cancer screening, such as mistrust in the scientific community from homophobic stigma and abuse, lower socioeconomic status, and a lack of diversity in the research team that discourages diversity in participants⁴. The overview suggests increasing diversity in research teams and creating relationships with local communities of minority individuals, however the researchers found that there was little research surrounding the topic of recruitment and participation in oncology clinical trials for members of the LGBTQ community.

A second paper focuses on targeting campaigns to increase cancer screening and prevention methods for sexual and gender minorities. The study finds that there are lower rates of screening in these individuals, which leads to later diagnoses of cancers as well as a higher prevalence of cancers¹¹. The study also discusses ways that sexual and gender minority identities are being neglected in current research, such as excluding transgender men from cervical cancer research although they should be eligible. When listing methods for addressing the lack of screening and prevention services, some options included getting the underrepresented community involved with strategy-making and making the clinical trials and interventions with diversity as an explicit priority. The researchers also emphasized how psychosocial aspects of being a member of the gender and sexual minority have changed, such as the achievement of marriage equality, the availability of PrEP for HIV prevention, and the general increase in advocacy for transgender individuals, and that these changes should be considered in the establishment of prevention methods¹¹.

Another paper utilized sexual and gender minority cancer survivors, care providers, and advocates to determine the state of discrimination in cancer research, as well as determine possible methods for addressing the discrimination. This publication, written by Waters et al., involved identifying LGBTQ+ cancer survivors and those who either provided them with care or advocacy during their treatment and conducting interviews to identify common themes through coding methods¹². The three main themes that the study found to be involved in research disparities were cisheteronormativity - which is the cultural belief that cisgender, gender binary, and heterosexual identities should be treated as the societal norm - study design, and study recruitment and data collection. These themes surmised that inclusivity in the study should be thought of during conception of the study, including using sexual and gender minority friendly images and language, including members of the community in designing the study, and involving a way to include minority identities in the data collection of studies. The study and its participants also acknowledged that while some of these suggestions were easy to implement, other changes may take time to disseminate, but it should be an effort moving forward¹².

4.0 Results

4.1 Literature Review

The studies investigated above suggest multiple options for addressing discrimination towards the LGBTQ population. A common theme is including the minoritized community in the structure of the research, both through receiving their opinion on the study design and having members of the community participate in running the study. This would help to address the lack of trust that the community has in the scientific and healthcare communities by making the study more inclusive and having representation in the study as a sign of a safe space. There was also a broad need for increased cultural competence in researchers, including training on inclusive language and nuances that come with working with gender and sexual minority individuals, which would aim to address not only the lack of trust held by the community, but also to address biases held by caregivers and researchers to make a more inclusive and safer environment.

4.2 Addressing Changes

A method to increase participation in clinical trials is to utilize respondent-driven sampling, which would also address a lack of trust from the LGBTQ+ community. Respondent-driven sampling is similar to snowball sampling in that the sampling method utilizes current participants to recruit a limited number of new participants¹³. This method is beneficial for use with minoritized communities because it utilizes networks within a community that aren't easy to access by

someone who is not already involved, increasing the reach of study recruitment. Another study investigating the use of respondent-driven sampling found that the method may benefit from being modified for different target populations, such as incorporating social media when recruiting sexual and gender minority youth¹⁴. Methods of participant retention cited in another paper found that it was important to change accessibility and communication in clinical trials¹⁴. Making clinical trials accessible for individuals may include transportation reimbursement, gender-inclusive bathrooms for site visits, and keeping site visits at a minimum for those with busy schedules, such as those in the process of transitioning¹⁵. Increasing communication would benefit both the participants and those running the clinical trials, as it would build trust between those involved and allow for feedback. This same paper also highlighted the importance of cultural competency training placing emphasis on inclusive language in the informed consent process and demographics to accurately describe the study participants and create a welcoming environment¹⁵. Specifics from the paper include accurately defining and acknowledging the differences between sex and gender, and ensuring there is a diverse staff to ensure accurate information is included and staff are held accountable.

A paper written by Whitton et al. highlights cultural competency as the most important method of addressing structural change in clinical trials. The authors cite that this starts before recruitment for the study begins during the planning for the study¹⁶. This would include using inclusive language in creating informed consent materials, survey questions, and training for the staff participating in the study. The cultural competence preparation should also be used in advertisement to ensure that those looking to join the study can be sure that the environment they are entering is inclusive and friendly to different identities. This should include a website

highlighting the inclusivity of the study, as well as ensuring that the internet presence of those running the clinical trials is inclusive and show cultural competence¹⁶.

5.0 Conclusions

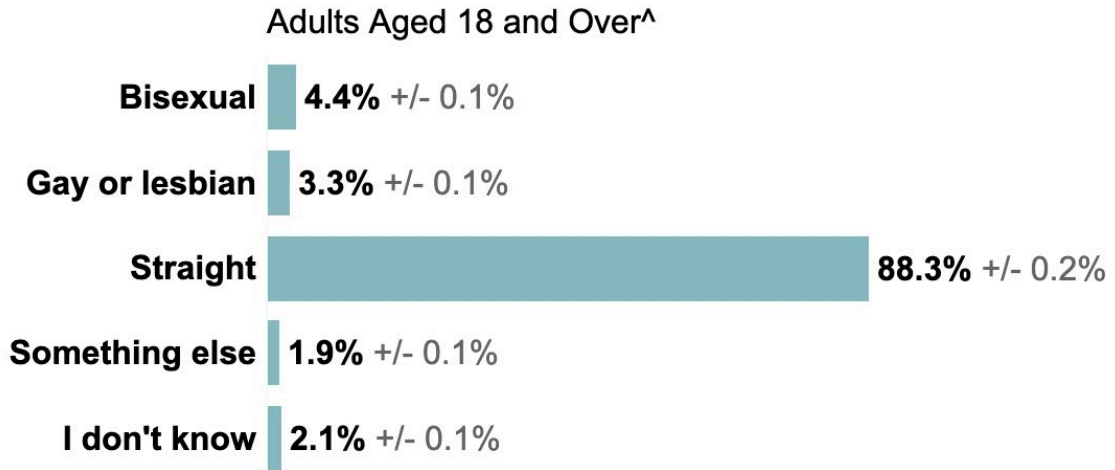
There is a large need to decrease discrimination towards gender and sexual minority individuals in oncology clinical trials. These individuals are at higher risk of a multitude of cancers compared to their cisgender and heterosexual counterparts but are less likely to receive preventative medicine or be involved in clinical trials. This lack of participation is a detriment because researchers are missing multiple factors of interest for cancer patients. Proposed methods to address the discrimination towards gender and sexual minorities include increasing diversity in the research team, increasing the prevalence of cultural competency training, and changing study designs and data collection to not only address factors of the minority stress model for underrepresented individuals, but also to acknowledge the ever changing psychosocial and political climate affecting the queer community.

As previously stated, some of these changes can be made easily, such as using more inclusive language like “partner” instead of “husband” or “wife” and providing opportunities for participants to self-identify to create a more inclusive space. Some of the changes that may take more time, such as hiring and incorporating a diverse team, reaching out to minoritized communities to receive feedback about study design, and creating training based on cultural competency and inclusion, will be valuable changes for the future and for mending the bridge between the sexual and gender minority groups and the scientific community.

5.1 Limitations

This review of literature is limited in the number of publications available for analysis. There were a limited number of publications found that fit the research question, and in general there is a lack of research surrounding the queer community. A search through PubMed with the lone term “LGBT” resulted with the earliest publication being from the year 2000, and the results that came from the search were not entirely surrounding the LGBTQ community, but instead were only mentioned. This lack of content is important, and points to much needed future research that can be addressed, such as ways to lower the incidence of cancer risk behavior like smoking in minority populations, and how intersectionality can influence these individuals’ chances of being diagnosed with cancer. This study was also possibly limited by the search criteria used to identify papers to be used in the literature review, however the narrow search criteria was used to keep the research specific and avoid broadening findings to discrimination in the general healthcare field. Our study was also limited by the lack of sampling strength in the publications analyzed, as those publications that performed research had low sample sizes due to a low number of individuals feeling comfortable participating or willing to disclose their identities due to fear of discrimination or stigma, as seen in the minority stress model. Nonetheless, this study addressed barriers to participation in oncology clinical trials among the LGBTQ+ community and discussed changes that promote inclusivity and diversity in clinical research. The inclusion of LGBTQ+ individuals in oncology clinical trials is essential for advancing health equity and improving healthcare outcomes.

Appendix A Tables and Figures



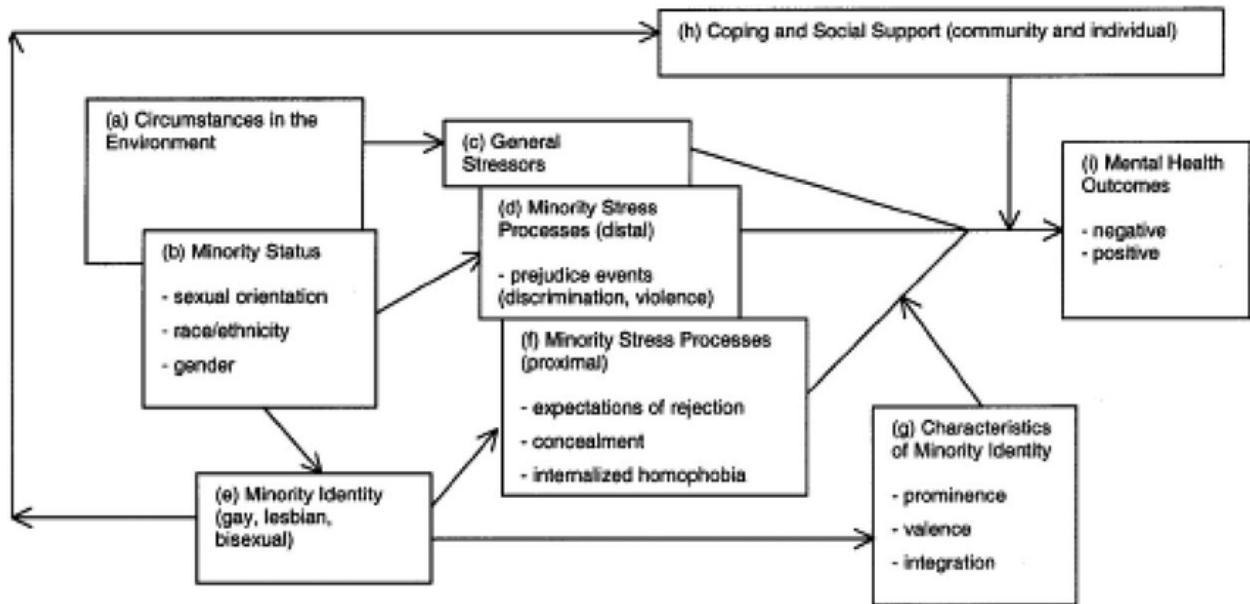
Appendix Figure 1 Sexual Identities in the 2021 US Census

A figure from the US Census Bureau showing the distribution of sexual identity for adults 18 years or older in the United States.

Appendix Table 1 Gender Identities in the 2021 US Census

Sex	Gender	% Identifying
Female	Woman	97.4
	Man	0.3
	Transgender	0.6
	None	1.7
Male	Woman	0.4
	Man	97.3
	Transgender	0.6
	None	1.7

Results from the US Census Bureau showing the distribution of gender identities of adults 18 years or older in the United States, describing sex and gender identity.



Appendix Figure 2 The Minority Stress Model

A map of the minority stress model demonstrating the relationships between different aspects of minority experiences, such as minority identity and social support, and their influence on the individual's mental health.

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