

Final Consulting Report: Evaluating the Impact of Health Insurance
Coverage on Clinical Trial Participation Among Racial/Ethnic
Minorities and LGB Individuals

Prepared for Pyxis Partners

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Executive Summary

Overview

The overarching goal of our analysis is to elucidate the association between access to health insurance coverage and an individual's decision to participate in clinical trials, particularly for racial/ethnic and LGB minority populations. Our report is subdivided into four unique research questions, each varying in level of specificity and/or demographic of focus. To analyze these research questions, we adopt a series of qualitative and quantitative research methodologies. While the first research question is informed solely by qualitative analysis, the latter three are addressed through mixed methods approaches, with a strong focus on regression methods.

Methodology

To conduct the quantitative analysis for the latter three research questions, we use data from the publicly available National Cancer Institute's Health Information National Trends Survey (HINTS) 5-Cycle 4. In general, HINTS surveys are designed to monitor access and use to health information for a nationally representative sample of American adults (HINTS 5 – Cycle 4 Methodology Report, 2020). Importantly, data for this cycle was collected near the start of the COVID-19 pandemic, specifically from February to June of 2020, from 3,850 U.S. civilian, non-institutionalized adults. Although the specific focus of this HINTS survey on cancer-related trends presents some priming concerns, the dataset provided important demographic information on trends in invitation and participation rates in clinical trial research which makes it highly useful for our research purposes. Importantly, this dataset was distributed to a randomly selected population and, while some questions ask about cancer, the respondents are not limited to cancer patients or survivors and the questions associated with our variables of interest ask about clinical trials in general, not cancer-related clinical trials.

Although we did not have a variable that captured willingness to participate in clinical trials specifically, we operationalize this construct using two different variables in the HINTS dataset, *InvitedClinTrial* (a measure that indicates whether an individual has ever been invited to participate in a clinical trial) and *ParticipatedClinTrial* (a measure that indicates whether an individual has ever participated in a clinical trial). Importantly, the *ParticipatedClinTrial* variable represents a subset of the *InvitedClinTrial* variable, given that individuals would have to be invited to trials in order to participate. Importantly, neither variable captures the willingness to participate in clinical research for those who were not invited. Throughout our analyses, we conduct separate regressions to appropriately test associations that are potentially unique to both dependent variables.

Our primary independent variable of interest is *healthinsuranceb*, a derived variable to categorize the healthcare coverage variable, that conveys whether individuals in the database possess some type of public or private health insurance coverage. In addition to this, we attempt to observe the interaction effects of health insurance coverage with racial/ethnic minority status (**RQ3**) and LGB status (**RQ4**), to study the relationship between these variables as values change. We also employ a series of controls, which slightly vary depending on the research question being explored and whether we are evaluating trends in invitation and participation; these controls include but are not limited to age, birth gender, political affiliation, and pandemic effects. To account for any differences between survey participants and the larger populace, we used survey weights, provided by HINTS. This is to correct, for example, for phenomena like a

lower percentage of respondents reporting to be lesbian, gay, or bisexual in the data, than the real percentage (slightly upwards of 7%) actually represented in the population.

Lastly, our analyses required a substantial amount of variable recoding and generation, specifically to convert key dependent and independent variables into binary indicators that eliminated missing data. The processes for this and further details of variables created are elucidated in our report.

Analyses

Our first research question (**RQ1**) addresses the consequences of the lack of diversity in clinical trial research and actions undertaken to address the problem through qualitative research alone. The qualitative analysis we perform for our first research question highlights how homogeneity in clinical trials can lead to inaccurate or inappropriate generalization of study results to all demographics (Sirugo et al., 2019). A prime example of this issue is the anticoagulant Warfarin, which was approved for use in the 1950s after being tested only on those of European descent in clinical trials. Many decades later, it became evident that those of African descent require nearly two times the dose to achieve the same effect. There are also serious limitations in clinical devices that are designed to gauge health status. Pulse oximeters, for example, inaccurately ascertain the blood oxygen content of Black patients to be normal (i.e., false negative) at a higher rate than for their white counterparts (Sjoding, 2020). Though attempts have been made at the federal level to counteract the lack of diversity in clinical trials, they have been met with minimal success (Oh et al., 2015). Research entities have also taken steps towards greater participant diversification by training principal investigators on cultural competencies to combat historic mistrust of researchers among minorities or adjusting their recruitment strategies to include social media, but inequities still linger (FDA, 2020).

Our second research question (**RQ2**) addresses the role of insurance coverage on an individual's decision to participate in clinical research. The qualitative component of our analysis unearths slightly different effects stemming from type of coverage, with the passage of the ACA producing greater benefits for clinical trial enrollment for those covered by private plans compared to those enrolled in government entitlement programs (Mackay et al., 2016). With that said, legislation like the Clinical Treatment Act passed in 2020 have mandated Medicaid programs to cover routine patient costs associated with qualifying clinical trials and have therefore increased access. Despite some meaningful programmatic changes, immovable costs associated with trials and general concerns about insufficient reimbursement serve as major deterrents to participation (Lin et al., 2008). Importantly, oncologist and physician recommendations play a notable role in generating knowledge of trials among patients, but available literature suggests that these recommendations are not informed by patients' insurance status (Sullenger et al., 2022).

To study the association between insurance coverage and the decision to participate in clinical research (represented by both *InvitedClinTrial* and *ParticipatedClinTrial*) from a quantitative lens, we use a combination of chi-squared and multiple logistic regression models. In an effort to limit the influence of potentially confounding factors, the multiple logistic regression models use a series of demographic controls. Because the output of logistic regression models cannot be interpreted alone, we employed marginal effects, to convert log odds into interpretable output about the change in the probability of outcomes variables associated with explanatory variables. Of the models generated, only the chi-squared model cross-tabulating *healthinsurancecb* and *InvitedClinTrials* reveals coverage to be statistically significant. Following the use of marginal effects, the multiple logistic regression model demonstrating the relationship

between *healthinsuranceb* and *InvitedClinTrials* shows that *healthinsuranceb* is not statistically significant at the predetermined alpha level of 0.05, making it a non-useful predictor of being invited to participate. The coefficients for age and the binary indicator for Black racial identification are statistically significantly associated with invitation in this model, however. Specifically, those who identify as Black are found to be 8 percentage points more likely to be invited to a trial, which is a key finding of our report. In our participated model, having a ‘very conservative’ political viewpoint and identifying as Black are both statistically significantly associated with participation. Specifically, those who identify as Black are 26 percentage points less likely to participate, despite being 8 percentage points more likely to be invited, compared to their non-Hispanic white counterparts.

Our third research question (**RQ3**) addresses the effect of insurance coverage on racial/ethnic minorities’ willingness to participate. A review of available literature shows that observable discrepancies exist in levels of coverage across racial subgroups, with white Hispanics and Black individuals possessing significantly higher uninsured rates compared to their White Non-Hispanic counterparts (Buchmueller et al., 2016). Although the passage of the ACA has narrowed stark coverage gaps across racial groups, inequities in access linger and manifest in rampant discrepancies in quality of care across subgroups (Adams and Barns, 2004). There are also economic factors at play in determining coverage levels among racial subgroups, with stark differences in accumulated wealth and employment opportunities providing a partial explanation for differences in the ability to access private plans.

Similar to the approach in **RQ2**, we use chi-square analysis in addition to a series of logistic regression models to address associations for **RQ3**. Through chi-square analyses, we see that the associations between Black and being invited and Black and participating are statistically significant. Although we attempt to factor in interactive effects between racial subgroups and health insurance, the small sample size of many racial categories (i.e., Asian or American Indian/Alaska Native) results in insufficient variation (e.g., the non-existence of an individual who is American Indian with no health insurance who is invited to participate) and the subsequent inability for STATA to account for them within regressions, even following a consolidation of smaller racial categories into a single variable. Therefore, we were unable to test our null hypothesis of interaction effects between racial categories and insurance coverage, for either invitation or participation in clinical trials.

Our fourth research question (**RQ4**) addresses the role of insurance coverage on LGB minorities’ willingness to participate in clinical research. Overall, the qualitative analysis reveals notable progress in coverage levels for LGB+ minorities stemming from the passage of the Affordable Care Act and the legalization of same-sex marriage but a nonetheless persistent lack of equity. Prior to the passage of the ACA, many businesses denied coverage to same-sex couples on the basis of the Defense of Marriage Act, and it was commonplace for healthcare providers to charge clients at differential rates based on their sexual preferences or gender or for insurers to deny coverage altogether due to pre-existing conditions (i.e., HIV/AIDS) (Konrad, 2009). The ACA was instrumental in implementing anti-discriminatory safeguards and protecting individuals with pre-existing conditions, and therefore expanded the share of LGB+ minorities with coverage (Jones, 2022; McCarthy, 2021). With that said, the quality of care of providers is still mired with inadequacies, and this has manifested in (among many things) the denial of transition-related surgeries and hormonal treatments for transgender individuals as well as a general insensitivity from medical professionals towards an individual’s situation (Mahowald et al., 2020). Our chi-squared analyses show that the association between LGB+ and

being invited to participate in clinical trials is statistically significant. Although we attempted to run logit regressions with interactions for health insurance and LGB+ status, we were ultimately unable to observe any statistically significant results due to the low number of LGB+ individuals in our sample, especially when subdividing them by insurance status and participation in clinical trials.

Introduction

Clinical trials in the United States have historically underrepresented minority populations (Oh et al., 2015). The lack of racial/ethnic diversity in clinical trials has been documented since the 1990s and garnered national attention during the COVID-19 pandemic (Artiga et al., 2021). Individuals who identify with a minority sexual orientation status are also commonly left out of clinical trials (Oh et al., 2015). The resulting homogeneity in clinical trials threatens the generalizability of trial findings and adds to health disparities across demographics due to an improper standardization of medical interventions. (Sirugo et al., 2019). Prior research suggests that health insurance coverage is associated with an individual's willingness to participate in clinical trials, but this association has not been specifically studied among racial/ethnic and LGB individuals (Sullenger et al., 2022).

Pyxis Partners is interested in understanding the association between access to health insurance coverage and participating in clinical trials among racial/ethnic and sexual minority populations.¹ Pyxis works as a community engagement partner focused on helping organizations (such as the National Institutes of Health) reach communities that are underrepresented in biomedical research. Our project, which investigates the impact of racial/ethnic and LGB minorities' healthcare coverage status on their willingness to participate in clinical research, will contribute to Pyxis Partners' mission to improve health outcomes of people who live in the United States by helping them develop targeted engagement strategies for increasing participation in clinical research. Our research seeks to answer the following questions:

1. What are the consequences of the lack of diversity in clinical trials? What is currently being done to address the lack of diversity in clinical trials?
2. What is the role of insurance coverage on an individual's decision to participate in clinical research?
3. What is the impact of health insurance coverage on racial/ethnic minorities' willingness to participate in clinical trial research?
4. What is the impact of health insurance coverage on LGB minorities' willingness to participate in clinical trial research?

National Cancer Institute's Health Information National Trends Survey 5 Cycle 4

To conduct quantitative analyses for our research questions, we use data from the Health Information National Trends Survey (HINTS) 5- Cycle 4, which is publicly available and cross-sectional in kind. Data were collected from February to June of 2020 from approximately 3,900 U.S. civilian, non-institutionalized adults. Specifically, "HINTS provides [the National Cancer Institute] with a comprehensive assessment of the American public's access to and use of information about cancer across the cancer care continuum from cancer prevention, early

¹ Although the research question presented by Pyxis specifies the LGBTQI+ community, we define the scope here as 'sexual minority populations,' given most research does not provide clear specifications beyond this.

detection, diagnosis, treatment, and survivorship” (HINTS 5- Cycle 4 Methodology Report, 2020, p.1). In addition to unweighted sample size numerics, the dataset contains information on estimated weighted sample size. The codebook², methodology report³, and survey materials⁴ can all be downloaded at the specified links.

Although fairly comprehensive, this questionnaire asks specifically about cancer-related trends (as is its intended purpose). Thus, respondents may have been primed to answer clinical trial questions about cancer and our results may not be generalizable to individuals suffering from other illnesses and diseases or healthy subjects, individuals who are younger than 18, and/or individuals living outside the US.

The sample design had two stages. In the first, the researchers selected a randomized sample using a database of addresses (HINTS 5- Cycle 4 Methodology Report, 2020).⁵ In the second, they directed the households to randomize who completed the survey by birth date.⁶ Applying the weighted values prescribed by the researchers, we found respondents to reflect the following demographic characteristics: 66% non-Hispanic white (34% other racial identification), 95% heterosexual (5% non-heterosexual), and 49% assigned male at birth (51% assigned female at birth).

Our primary dependent variable of interest is whether an individual participated in a clinical trial after being invited to apply. We also use whether an individual is invited to participate as an additional dependent variable. Our independent variables are whether an individual has health insurance, the interaction of health insurance and racial/ethnic minority status and the interaction of health insurance and LGB status. We control for several relevant demographic variables to properly estimate the partial effect of health insurance on willingness to participate.

Research Question One (RQ1)

What are the consequences of a lack of diversity in clinical research? What is currently being done to address the lack of diversity in clinical trials?

Literature Review

In this section, we solely use previously published research to provide insight into consequences associated with the status quo and address wide-ranging actions and recommendations to engage wider subsets of the American populace in research. Homogeneity has limited clinical trial research in the United States, despite numerous initiatives taken to

² <https://hints.cancer.gov/data/download-data.aspx>

³ https://hints.cancer.gov/docs/methodologyreports/HINTS5_Cycle4_MethodologyReport.pdf

⁴ <https://hints.cancer.gov/data/survey-instruments.aspx#H5C4>

⁵ The Marketing Systems Group (MSG) was used to select a random sample of households within each distinct sampling group (HINTS 5- Cycle 4 Methodology Report, 2020). Addresses were grouped by neighborhoods with 34% or greater minority households, "high minority", and neighborhoods with less than 34% minority households, "low minority." Household demographics were determined using data from the Census Bureau's American Community Survey. The researchers oversampled the "high minority" group so that 72% of the sample came from high minority neighborhoods. All households present in the database, in the United States, that were not vacant were subject to sampling- including P.O. Boxes and seasonal homes. Surveys were collected from each of the four census regions (Northeast, Midwest, South, West).

⁶ Researchers used the Next Birthday Method to select participants (HINTS 5- Cycle 4 Methodology Report, 2020). Items were included to guide households in determining which individual should participate. For example, questions about whether there is more than one person over the age of 18 in the household, and, if so, how many. They were then instructed to have the person with the next upcoming birthday complete the survey. Finally, respondents were asked to indicate the "first name, nickname or initials" of the individual participating (HINTS 5- Cycle 4 Survey, 2020, p.1).

generate greater representation of historically marginalized subsets of the population. For example, federal legislation in the 1990s improved representation of women in clinical trials, but did not increase the participation rates of racial/ethnic or LGBT minorities (U.S. Department of Health and Human Services). In 2019, Congress passed legislation compelling the Government Accountability Office (GAO) to investigate and address barriers to clinical trial diversity (“Henrietta Lacks,” 2019). Principal investigators have also explored tactics such as building trust in underrepresented communities, increasing access through transportation and child care, and diversifying recruitment techniques (FDA, 2020). The success of these efforts has been mixed.

1. Consequences of homogenous samples

1.1 Lack of generalizability

Clinical trials are conducted to investigate the efficacy and safety of medical interventions; their results are intended to be generalizable to all demographics (Bothwell et al., 2016). However, the long-held notion that the findings of clinical trials are automatically generalizable to all populations has recently been challenged by evidence of differential outcomes (Sirugo et al., 2019). For example, studies have indicated that those born biologically male respond better to certain medications used to treat depression than those born biologically female, and vice versa (Bibbins-Domingo et al., 2022). Bibbins-Domingo et al. (2022) also report that ancestry has played a vital role in influencing decision-making on the dosage of a medication. For example, though the anticoagulant Warfarin has been approved for use since the 1950s, it only became clear in 2013 that those with African American ancestry may require almost twice the dose of those with European ancestry to achieve the same therapeutic effect. This is a consequence of Warfarin being tested only on those of European descent in clinical trials and the subsequent false assumption that the therapeutic dosage would apply to all demographics.

1.2 Limitations in technology

In recent years, evidence has shown that certain medical devices that use light to monitor health are less accurate on those with dark skin tones. For example, pulse oximeters – which measure the amount of oxygen in an individual's blood – show when a person has occult hypoxemia (<88%), and therefore requires oxygen therapy. A study which used data from 2014-2015 and 2020 demonstrated that, of those whose pulse oximeter levels were normal, Black individuals were almost 3 times as likely as white patients to actually have occult hypoxemia (Sjoding, 2020). This disparity had devastating consequences during the COVID-19 pandemic, when Black patients were not flagged as candidates for medical interventions that they required because their blood oxygen levels were inaccurately shown to be within a normal range (Fawzy et al., 2022).

Fitbits are wearable devices commonly used to monitor heart rate and steps and are also frequently used in clinical trials. Unfortunately, they only use green light to monitor movement and heart rate, and this color of light is absorbed more quickly by those with more melanin (darker skin) and are therefore less reliable when worn by people of color (Hailu, 2022). Hailu (2022) also found that other devices, such as the newer series of Apple Watches, use enhanced technology in addition to green light, and are more uniformly accurate across race. The consequences of wearable devices not working on darker skin transcend basic inconvenience. Approximately 21% of large companies that offer health insurance monitor their employees' activities through wearable devices, with some mandating the use of the device and tying

incentives like lower insurance premiums to wearing them. This means that those with darker skin may not receive the same benefits as those with lighter skin because the device improperly monitors their activities.

2. Actions and recommendations

2.1 Federal legislation

The Revitalization Act of 1993, which was passed by Congress and signed into law by President Clinton, required all government-funded research to adequately represent women and minorities and report the demographics. Since the implementation of the act, participation among women has greatly increased, but engagement among racial/ethnic and LGBTQI+ minorities has remained stagnant. In fact, less than 2% of the over 10,000 studies that have been conducted by the National Cancer Institute have met the National Institute of Health's requirements for diversity (Oh et al., 2015). To address this, the United States Congress passed the Henrietta Lacks Enhancing Cancer Research Act of 2019, which was later signed into law by President Trump ("Henrietta Lacks," 2019). Importantly, it requires the Government Accountability Office to investigate the barriers to diversity and address them.

2.2 Addressing mistrust

Racism and exploitation in research have generated widespread mistrust of researchers and medical professionals among minorities. Studies like the U.S. Public Health Service (USPHS) Syphilis Study at Tuskegee and the gynecological experiments conducted on enslaved Black women, among many others, have made minorities understandably hesitant to participate in research in the present day. To engage minorities, it is crucial that studies first engender trust in communities. The Food and Drug Administration made a couple recommendations to this end: (1) train principal investigators and research staff on cultural competency, and (2) create a community advisory board for members of minority groups to advise on study protocols (FDA, 2020). Additional recommendations include hiring individuals from minority communities to work on the studies, conducting focus groups to inform research protocol, and sharing the research findings with the community (Holzer et al., 2014).

2.3 Diversifying recruitment strategies

Common recruitment strategies that have been used historically, such as recruiting from hospitals and primary care settings, are insufficient to recruit minority groups nowadays. An alternate approach that has proven successful in diversifying recruitment is advertising through social media. This tool of engagement can be narrowed to reach specific racial, gender identity, and sexual orientation minorities either by their demographic or by ZIP Code (Pechmann et al., 2020).

2.4 Creating ease of access

Clinical trial staff and principal investigators can ease the burden of traveling to multiple visits for a trial by removing some of the financial barriers to participating (FDA, 2020). Researchers should offer transportation via rideshare, bus fares, or parking vouchers. Additionally, they could cover the cost of child care for parents during the duration of their research visit.

Methodology

Having summarized the key research findings into consequences of a lack of diversity in trials and corresponding actions taken to increase diversity, we now turn to **RQ2**, where we

begin to uncover the association between health insurance coverage and the decision to participate in clinical trial research.

Research Question Two (RQ2)

What is the effect of health insurance coverage on an individual's decision to participate in clinical trials?

Literature Review

In this section, we analyze whether an individual's access to health insurance affects their willingness to participate in clinical trials, with special attention placed on the type (public or private) or level of insurance coverage that an individual holds. Although the ACA played a role in expanding clinical trial coverage, our research demonstrates that (on balance) the impact was more positive for those with private plans as compared to public ones. Importantly, each state's unique policies surrounding insurance coverage (i.e., differences in Medicaid programs across states) played a large role in influencing levels of clinical trial participation. Additional limitations to clinical trial participation were protocol-related, patient-related, or physician-related.

1. Type of coverage: Public and private

1.1 Pre and Post Affordable Care Act General Coverage Trends

A publication in the *Journal of Clinical Oncology* gave insight into the state of coverage prior to the passage of the Patient Protection and Affordable Care Act (PPACA or ACA) (Kircher et al., 2012).⁷ Before the ACA passed in 2010,⁸ only eighteen states explicitly met the requirements made by the ACA for state mandates, while 33 did not. Within those 33 states, 15 did not have any pre-existing agreements regarding clinical trials. In particular, Phase 1 clinical trial coverage was the most frequent omission, with the second most being the coverage of therapeutic studies. The authors recommended next steps, including each state government creating and expanding agreements with insurance companies to provide better clinical trial coverage.

The ACA sets forth that insurers and health plans cannot limit or deny coverage of routine costs from approved clinical trials – a precaution that would, in theory, enable expansion. A group of researchers studied the ACA and focused on how it affected oncology clinical trial participation for Kansas residents aged 19 through 64 (Mackay et al., 2016). Through a cross-sectional design with data from the Census Bureau's 2012 ACS PUMS⁹ files and the 2014 Department of Health and Human Services Health Insurance Marketplace, the authors collected the number of people covered by insurance in 2012, and the number who were newly enrolled in 2014 following the implementation of the ACA. In 2012, 1,154,985 people were enrolled in private insurance in Kansas. After the ACA protection clause was passed, 4,618 of these individuals became newly covered for clinical trial participation and about 50,000 who were uninsured gained coverage. Even though the Affordable Care Act was beneficial in increasing

⁷ The Patient Protection and Affordable Care Act, also known as Obamacare, was first enacted and signed into law on March 23, 2010 by President Barack Obama (Healthcare.gov).

⁸ Obamacare was amended on March 30, 2010 by the Health Care and Education Reconciliation Act, resulting in the final version of the law - the Affordable Care Act (ACA) (Healthcare.gov).

⁹ "The American Community Survey (ACS) Public Use Microdata Sample (PUMS) files are records from individual people or housing units, with disclosure protection enabled" (Census.gov).

coverage for clinical trials, there are lingering exclusions in the law that continue to pose barriers for individuals, with Medicaid coverage limits and unregulated self-funded insurance plans in states being among them. As a result, there were no changes in coverage levels for those enrolled in public insurance.

1.2 General Insurance Approval Trends

A study completed with patients at Johns Hopkins explored the importance of insurance approval; there were 4,617 insurance requests submitted for clinical trial participation from July 2003 to July 2008, and 628 of those patients (13.6%) with health insurance were denied due to the lack of coverage for enrolling into a clinical trial (Klamerus et al., 2010). Pennsylvania is among the few states without a law mandating coverage of cancer clinical trial costs, and researchers observed that the highest number of patients who were denied coverage were from there. There was no statistically significant variance showing that this insurance denial was due to sex, race, or stage of disease.

1.3 Medicare FFS and Medicare Advantage (HMO)

The elderly are one of the fastest growing populations in the US, and the inclusion of all age groups in clinical research is crucial to improving its quality. Once again, we adopt a pre-and-post ACA lens of evaluation. In 2008, a group of authors affiliated with the University of Pittsburgh Medical Center (UPMC) Radiation Oncology Minorities Outreach Program studied the cost for clinical trials and the percentage of cancer patients with Medicare HMO (i.e., Medicare Advantage) and Medicare FFS (traditional Medicare) (Lin et al., 2008). Although participants with Medicare FFS¹⁰ had clinical trial costs fully reimbursed, those enrolled in Medicare Advantage¹¹ did not receive the same quality of benefits. Instead, they were forced to pay a rather hefty deductible in addition to one-fifth of the allowable costs.¹² The results show that the Medicare Advantage plans reimbursement policies caused significant restrictions to cancer clinical trial participation before the ACA was passed. Particularly, those enrolled in Medicare¹³ were especially concerned about financial hardships – with about 60% of patients declining to participate due to the fear of insufficient reimbursement.

The ACA benefits private insurance plans and facilitates reimbursements for clinical trial participation for enrollees. In part, this is accomplished through an amendment to the Public Health Services Act, which requires private insurers to cover routine costs for individuals participating in cancer or other life-threatening disease clinical trials (American Society of Clinical Oncology, 2014). Because Medicare Advantage is operated by private insurance networks, enrollees stand to gain from the ACA's provisions. Beneficiaries enrolled in traditional Medicare (the federally operated plan) had existing reimbursement for clinical trials prior to the ACA. Now, Medicare FFS and Medicare Advantage provide equivalent levels of coverage and address clinical trial costs associated with drugs and services that would normally be covered for

¹⁰ “The Medicare Fee-For-Service (FFS) program pays physicians, hospitals, and other health care facilities based on statutorily established payment systems, most of which are updated annually through regulations” (Congressional Research Service).

¹¹ Medicare Health Maintenance Organization (HMO) enrollees have a limited private-insured network of doctors, hospitals, and other providers for care. It does not include out-of-network costs.

¹² Both direct and indirect costs

¹³ Insurance that provides coverage for individuals over the age of 65.

care outside of a study (Medicare & Clinical Research Studies, 2019). Additionally, the prevention or management of side effects stemming from the clinical trial is also covered.

1.4 Medicaid

Passed in 2020 and enforced on January 1, 2022, the Clinical Treatment Act requires all Medicaid programs to cover costs associated with qualifying clinical trials in any phase of development (American Society of Clinical Oncology, 2008). Additionally, it requires coverage of qualifying clinical trials out-of-state and in circumstances where the doctor or hospital in conjunction with the clinical trial is outside the beneficiary's Medicaid care plan network. Even with the increased breadth in coverage, there is a persisting lack of adolescent and young adult representation in cancer clinical trial participation; the majority of this demographic group is insured through Medicaid. Per a publication in the *Journal of Adolescent and Young Adult Oncology*, sociodemographic factors are hypothesized to be the most likely reason for the low enrollment rate (Sullenger et al., 2022).

Using a regression analysis, the authors studied young adults aged 15 through 39 years old who were treated for cancer at the University of North Carolina between April 2014 and April 2019. They estimated adjusted risk ratios, hoping to examine the impact of insurance type against low enrollment in trials. Results showed that those with private health insurance or no insurance were more likely to enroll in a therapeutic clinical trial. Compared to non-Hispanic White patients, Hispanic young adults were less likely to enroll. Overall, the difference in rate of clinical trial enrollment suggests that health insurance type and race or ethnicity generate observable disparities in access. The authors proposed further research into resources, cultural, and language barriers to improve cancer survival rates among vulnerable, marginalized communities.

2. Additional factors limiting trial participation and steps forward

2.1 Physician and patient-related barriers

Oncologist or physician recommendations played an important role in determining patients' knowledge of trials. In a publication in the *Journal of Clinical Oncology*, a group of researchers outlined a cohort study consisting of patients with breast or ovarian cancer who received a therapeutic drug at the University of Alabama at Birmingham between January 2017 and February 2020 (Catson et al., 2022). The authors also included data from OnCore and ClinicalTrials.gov and ran a logistic regression model to estimate the number of trials offered versus enrollment, listing eligible patients, age, race and ethnicity, real-urban residence, Area Deprivation Index, cancer type, and cancer stage as variables. Two-thirds (65%) of patients were eligible for clinical trial enrollment, and 47% enrolled into a trial. Patients who were enrolled in private and public health insurance plans had similar odds of eligibility, of being offered to participate, and of actually enrolling (Catson et al., 2022). Their results showed that oncologists actually did not assess trial eligibility or offer trials on the basis of insurance status or insurance coverage. In a similar vein, patients did not decide to participate using insurance coverage as a factor (Catson et al., 2022).

In another study published in *Cancer Causes & Control: An International Journal of Studies of Cancer in Human Populations*, authors researched the number of physicians who conversed with and informed their patients about available clinical trials (Kaplan et al., 2013). Using data from the 46% of physicians that completed the survey, the authors found that medical oncologists were more likely than surgical and radiation oncologists to discuss clinical trial enrollments with breast cancer patients. Doctors who had a background in patient care were least

likely to discuss the trials. Additional barriers such as the distance from the patient's office to the specialized clinical trial office played a role in whether a patient received a referral. Albeit a thorough study, more research should be completed to assess the percentage of physicians that take private vs public health insurance; data from the American Medical Association Physician Masterfile practicing in those respective states would be useful to this end (Kaplan et al., 2013).

Methodology

To analyze the impact of health insurance coverage on an individual's decision to participate in clinical trial research, we use the HINTS dataset provided by the National Cancer Institute. Throughout our analyses, we use two dependent variables: *invitedclintrial* and *participatedclintrial*. *Invitedclintrial* measures whether an individual has ever been invited to participate in a clinical trial, while *participatedclintrial* measures whether an individual participated in the trial. Both variables are transformed into binary indicators. For *invitedclintrial*, if respondents have been invited to participate in a clinical trial, they are coded as 1. Conversely, if respondents have not been invited to participate in a clinical trial, they are coded as 0. For *participatedclintrial*, if respondents have participated in a clinical trial, they are coded as 1. Conversely, if respondents have not participated in a clinical trial, they are coded as 0.

For **RQ2** to **RQ4**, we use descriptive statistics, data visualizations, and regression analyses to formulate our results. Specifically, we use the former methods to get a sense of the data, its shape, appropriate measures of center, outliers, and general trends. We also examine the dataset for any possible errors. As necessary, variables are re-coded or transformed to best fit our regression analyses.

We use both chi-square tests and multivariate regression models for our analyses. Our regression models are run on several independent and control variables: *age, birth gender, income, occupational status, marital status, education level, race, sexual orientation, political viewpoint, and the effect of the COVID-19 pandemic*¹⁴. Control variables were selected based on thoughtful consideration of factors that might influence both models: 1) invitation to a clinical trial (age, birth gender, race/ethnicity, sexual orientation, and the effect of the COVID-19 pandemic); and 2) participation in a clinical trial (the aforementioned controls as well as marital status, political viewpoint, and education level). We intentionally chose not to include marital status, political viewpoint, and education level in our invitation models for two primary reasons. First, we could not discern a clear relationship between these factors and our dependent variable outside of the effect of the control variables already included in the model. Additionally, it is unlikely that researchers and/or individuals involved in determining eligibility have access to this type of demographic information as they decide who to invite to participate in a clinical trial. To make the model as realistic as possible, these three variables have ultimately been excluded.

Although we assess the impact of physician recommendations on clinical trial invitations in our qualitative analyses, we decided against controlling for this factor in our model given the limited quantity of data available. A full list of variables for this research question can be found in **Appendix A**.

Based on these variables and our RQ of interest, our primary null hypothesis is as follows:

¹⁴ On March 11, 2020, the World Health Organization announced the COVID-19 outbreak as a global pandemic, impacting the rest of the Cycle 4 field period.

$H_0: \beta_{Health\ Insurance} = 0$, which implies that having health insurance does not influence an individual's willingness to participate in a clinical trial, holding all other variables constant

If our results support the null hypothesis, the coefficient on whether an individual has health insurance will not be statistically significant, holding all other variables constant. Alternatively, if we find support for the alternative hypothesis, we would expect the coefficient on the term to be statistically significant, holding all other variables constant.

Results and Analysis

1. Variable Description

In order to conduct our chi-squared tests and regressions, our dependent variables required alteration. Namely, *invitedclintrial* and *participatedclintrial* were re-coded such that “I didn't know” and “I don't remember” responses are coded as missing data. *Healthinsuranceb*, *birthmale*, *lgb*, *occupation_employed*, and *pandemic* are recoded to make binaries and remove instances of missing values. Additionally, all race variables are recoded to make binaries and remove instances of missing values. In the original dataset, race and ethnicity were encoded separately. To better answer this research question, we cross-tabulated these two variables and created five new indicators as follows: white and Hispanic (*white_hisp*), white and non-Hispanic (*white_nohis*), Black (*black1*), American Indian or Alaska Native (*amindian1*), Asian (*asian1*) and multiple races (*multraces*). To circumvent collinearity problems that arose, we generated a new variable called *otherrace*, which included American Indian or Alaska Native (*amindian1*), Asian (*asian1*) and multiple races (*multraces*). To be clear, we used these newly encoded race variables for **RQ3** and **RQ4** as well, to ensure consistency of controls used across sections. Because it is the largest category, we used white and non-Hispanic as our reference.

Our key independent variable, *healthinsuranceb*, measures the amount of people who have healthcare coverage through a current employer or union, insurance purchased from an insurance company, Medicare, Medicaid, TRICARE or military healthcare, VA, Indian Health Services, and any other kind of healthcare coverage. Though our Literature Review delves into specifics of different private and public insurance plans, we do not include these distinctions in our quantitative analyses due to a lack of variability in the data related to the subgroups. In other words, there are too few individuals who are publicly insured in the HINTS dataset to conduct robust analyses.

2. Chi-Squared Analysis

To assess whether there is an association between health insurance coverage and invitation to a clinical trial, we first run a Chi-squared test. Chi-squared tests help us understand whether observed associations in the sample are due to chance alone. The result of a p-value of 0.001, depicted in **Table 1**, suggests that health insurance coverage is statistically significantly associated with the frequency with which a respondent is invited to partake in clinical trial research.

Then, we narrowed our analysis to only those respondents who were invited to participate in a clinical trial. The results of the chi-squared test in **Table 2** comparing healthcare coverage and actual participation in a clinical trial show that the p-value is greater than the 0.05 level of significance. Therefore, we fail to reject the null hypothesis that there is no statistically

significant relationship between healthcare coverage and participation in clinical trials within this sample.

Table 1. Association Between Healthcare Coverage and Invitation to Clinical Trials

Health insurance	Have you ever been invited to participate in a clinical trial?		Total
	Yes	No	
Not insured	9	185	194
Insured	427	3020	3447
Total	436	3205	3641

Pearson chi2(1) = 10.4610 Pr = 0.001

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 2. Association Between Healthcare Coverage and Participation in Clinical Trials

Health insurance	Did you participate in the clinical trial?		Total
	Yes	No	
Not insured	5	4	9
Insured	193	224	417
Total	198	228	426

Pearson chi2(1) = 0.3045 Pr = 0.581

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

3. Multiple Logistic Regression Models

3a. Invited

Table 3 (1) demonstrates the relationship between insurance status and being invited to a clinical trial when considering demographic controls. Our chosen controls for the model are: age, birth gender, sexual orientation, race, education, income, employment status, occupation, marital status, political viewpoint, and the effect of the pandemic. Because we are using logistic regression and the output is in log odds form, we cannot determine statistical significance from the regression output alone. Instead, we use average marginal effects.

Average marginal effects, the approach used in this Research Question and following ones, “sets the covariates to the values of the first observation in the sample and calculates the partial effect for that individual” (Jensen, 2022). STATA “then repeats this process for every other observation in the sample” and averages the partial effects (Jensen, 2022). The results of this process are outlined in **Table 4**.

Table 4 (1) demonstrates that the estimate for *healthinsuranceb* is not statistically significant, with a p-value of 0.052, meaning that health insurance is not a useful predictor of being invited to participate. The following two variables are statistically significant at the 0.05 alpha level with a positive marginal effect: age and an indicator for Black racial identification.

3b. Participated

Table 3 (2) demonstrates the relationship between insurance status and participation in a clinical trial, taking the same controls into account. Once again, we need to evaluate using marginal effects, which are depicted in **Table 4 (2)**. These results demonstrate that the estimate for *healthinsuranceb* is not statistically significant, with a p-value of 0.544, meaning that health insurance is not a useful predictor of deciding to participate.

The following two variables are statistically significant at the 0.05 alpha level with a negative marginal effect: Very Conservative and the indicator for Black racial identification. To conclude, we do not have evidence to support the hypothesis that healthcare coverage affects whether someone is invited to participate in a clinical trial or whether they end up participating, even upon controlling for variables that may influence invitation or participation levels.

Table 3. Logit Models for RQ2

VARIABLES	(1) Invitation	(2) Participation
healthinsuranceb = 1	0.536 (1.000)	-1.157 (3.260)
age	0.0176*** (0.00614)	0.00569 (0.0175)
birthmale = 1	0.0285 (0.201)	0.374 (0.461)
lgb = 1	0.815 (0.494)	-0.775 (1.546)
white_hisp = 1	0.0544 (0.507)	1.073 (0.992)
otherrace = 1	-0.185 (0.354)	-1.059 (1.170)
black1 = 1	0.764*** (0.273)	-1.425** (0.709)
educb_rec = 2, High School Graduate		1.116 (2.289)
educb_rec = 3, Some College		1.857 (2.354)
educb_rec = 4, Bachelor's Degree		2.440 (2.340)
educb_rec = 5, Post-Baccalaureate Degree		2.213 (2.312)
incomeranges_rec = 2, \$10,000 to \$14,999	0.194 (0.567)	0.583 (2.019)
incomeranges_rec = 3, \$15,000 to \$19,999	1.270* (0.666)	-0.0457 (2.023)

incomeranges_rec = 4, \$20,000 to \$34,999	0.362 (0.512)	-0.0139 (1.485)
incomeranges_rec = 5, \$35,000 to \$49,999	0.146 (0.537)	1.331 (1.564)
incomeranges_rec = 6, \$50,000 to \$74,999	0.372 (0.411)	0.559 (1.327)
incomeranges_rec = 7, \$75,000 to \$99,999	0.0496 (0.465)	0.705 (1.599)
incomeranges_rec = 8, \$100,000 to \$199,999	0.496 (0.443)	0.796 (1.434)
incomeranges_rec = 9, \$200,000 or more	0.298 (0.513)	0.677 (1.364)
occupation_employed_rec = 1, Selected	-0.0412 (0.251)	-0.806 (0.634)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.719 (1.184)
maritalstatus_rec = 3, Divorced		0.535 (0.857)
maritalstatus_rec = 4, Widowed		-0.438 (0.973)
maritalstatus_rec = 5, Separated		0.00836 (1.329)
maritalstatus_rec = 6, Single, never been married		-0.226 (0.761)
politicalviewpoint_rec = 1, Very Liberal		1.346 (0.935)
politicalviewpoint_rec = 2, Liberal		0.894 (0.782)
politicalviewpoint_rec = 3, Somewhat liberal		1.396 (0.866)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.709 (0.696)
politicalviewpoint_rec = 6, Conservative		-0.549 (0.673)
politicalviewpoint_rec = 7, Very Conservative		2.521 (1.716)
afterpandemic = 1	-0.300 (0.221)	-0.593 (0.547)
Constant	-4.019*** (0.880)	-1.312 (3.696)
Observations	2,865	321

Standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 4. Margins for RQ2

VARIABLES	(1) Margins for Invited	(2) Margins for Participation
healthinsuranceb = 1	0.035 (0.052)	-0.215 (0.554)
age	0.0013*** (0.000)	0.001 (0.003)
birthmale = 1	0.002 (0.015)	0.071 (0.087)
lgb = 1	0.084 (0.066)	-0.141 (0.266)
white_hisp = 1	0.004 (0.041)	0.203 (0.178)
black1 = 1	0.075** (0.033)	-0.260** (0.116)
otherrace = 1	-0.013 (0.024)	-0.194 (0.200)
educb_rec = 2, High School Graduate		0.159 (0.271)
educb_rec = 3, Some College		0.295 (0.274)
educb_rec = 4, Bachelor's Degree		0.407 (0.275)
educb_rec = 5, Post-Baccalaureate Degree		0.363 (0.278)
incomeranges_rec = 2, \$10,000 to \$14,999	0.012 (0.037)	0.112 (0.388)
incomeranges_rec = 3, \$15,000 to \$19,999	0.127 (0.083)	-0.008 (0.371)
incomeranges_rec = 4, \$20,000 to \$34,999	0.025 (0.035)	-0.002 (0.273)

incomeranges_rec = 5, \$35,000 to \$49,999	0.009	0.257
	(0.033)	(0.291)
incomeranges_rec = 6, \$50,000 to \$74,999	0.026	0.107
	(0.027)	(0.247)
incomeranges_rec = 7, \$75,000 to \$99,999	0.003	0.136
	(0.028)	(0.302)
incomeranges_rec = 8, \$100,000 to \$199,999	0.036	0.154
	(0.030)	(0.268)
incomeranges_rec = 9, \$200,000 or more	0.02	0.130
	(0.034)	(0.254)
occupation_employed_rec = 1, Selected	-0.003	-0.147
	(0.020)	(0.111)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.136
		(0.218)
maritalstatus_rec = 3, Divorced		0.102
		(0.159)
maritalstatus_rec = 4, Widowed		-0.083
		(0.183)
maritalstatus_rec = 5, Separated		0.0016
		(0.256)
maritalstatus_rec = 6, Single, never been married		-0.043
		(0.146)
politicalviewpoint_rec = 1, Very Liberal		0.265
		(0.172)
politicalviewpoint_rec = 2, Liberal		0.179
		(0.153)
politicalviewpoint_rec = 3, Somewhat liberal		0.274
		(0.150)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.1318
		(0.123)

politicalviewpoint_rec = 6, Conservative		-0.103
		(0.120)
politicalviewpoint_rec = 7, Very Conservative		0.438**
		(0.199)
afterpandemic = 1	-0.024	-0.113
	(0.018)	(0.103)
Observations	2,865	321

Standard errors in parentheses
 *** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Research Question Three (RQ3)

What is the impact of health insurance coverage on racial/ethnic minorities' willingness to participate in clinical trial research?

Literature Review

The U.S. healthcare system has long been characterized by significant racial and ethnic disparities in health insurance coverage and access to healthcare services. For our qualitative analysis, we summarize research on correlations between racial/ethnic minority status and the possession of healthcare, and use socioeconomic factors to further elucidate this relationship. Additionally, we discuss historical patterns of discrimination in the United States healthcare system.

1. Defining 'minority'

To contextualize minority health disparities, it is helpful to understand the definition of minority. The Agency for Healthcare Research and Quality includes Black individuals, Hispanics/Latinos, Asians and Pacific Islanders, and American Indians and Alaska Natives as racial or ethnic minorities, citing the ongoing lag in access to health care and health outcomes among these groups (AHRQ, n.d.). Mixed or multiracial categories should also be considered in analyzing racial and ethnic minority status and health insurance coverage (The Federal Register, n.d). Since racial/ethnic minority groups across the United States have higher rates of various health-threatening diseases, such as diabetes, hypertension, obesity, asthma and heart disease compared to white groups, it is crucial to study their levels of insurance coverage (CDC, 2021).

2. Disparities in coverage rates and health outcomes for minorities

2.1 Coverage levels pre-and-post-ACA

In 2013, the proportion of Hispanics and African Americans without insurance was 40.5% and 25.8% respectively, while only 14.8% of white individuals were uninsured (Buchmueller et al., 2016). Following the passage of the ACA, the uninsured rate of each ethnic group declined, with the decline among white individuals being the least. Compared with data recorded in 2013, the uninsured rate of Hispanics decreased by 7.1 percentage points, and that of African Americans decreased by 5.1 percentage points. As of 2015, after

the implementation of the ACA, it is estimated that more than 2 million African Americans, 3.5 million Hispanics and 6.7 million white individuals gained health insurance (Hayes et al., 2017).

While minorities and ethnic groups have made some improvements in insurance access under the ACA, African Americans have benefited the most among them (Ma, et al., 2022). African Americans now acquire health insurance through the health insurance market and via Medicaid at higher rates. The increase in the insured rate of Hispanics was relatively small, however, possibly because Hispanics were more likely to live in states that did not participate in Medicaid expansion or a community with poor publicity of ACA registration (Chen et al., 2016).

2.2. Health Outcomes and Health Care Delivery

Surely, the implementation of the ACA significantly increased public health insurance rates for African Americans and Hispanics, while also helping partially bridge the private insurance gap for African Americans. In many cases, minority groups received disrespectful treatment and faced barriers in accessing health care, resulting in vastly different medical experiences than their white counterparts (Adams and Barns, 2004). According to De-Chih Lee et al. (2021), African Americans may be more likely than Hispanic Whites to receive preventive services, such as blood pressure testing. However, this finding is at odds with other evidence that suggests racial and ethnic minorities continue to experience difficulty in accessing healthcare services and treatments. When compared to Hispanic whites, African Americans and Hispanics were 31% and 35% more likely to report that they did not have access to healthcare services, suggesting rampant discrepancies in care across racial lines (Shi et al., 2010). Additionally, Latin Americans are overrepresented in narrower plans and have fewer choices of providers under the insurance plans (Alcalá & Cook, 2018).

2.3 Unfair treatment

The existing research indicated that the discrimination rate of many different ethnic minorities in the healthcare field is higher than that of non-Hispanic white individuals (Stepanikova & Oates, 2017). Patients of racial/minority groups were more likely to encounter racial discrimination or unfair treatment in medical services than their white counterparts (Bailey et al., 2017). Research conducted by Leslie R.M Hausmann found that African Americans are more than three times as likely as white individuals to experience racial discrimination when seeking medical care (Hausmann et al., 2008). When patients had concerns about unfair treatment or discrimination, they were more likely to seek care from their own racial or ethnic providers (Chen et al., 2005). Minority patients' trust in providers has affected and continues to affect their quality of care and their choice of health insurance (Cooper & Powe, 2004). While the uninsured rate in the United States fell to historic lows after the implementation of the ACA, there remains a long way to go in terms of improving the quality of medical care for minorities.

3. The relationship between socioeconomic status, race, and insurance coverage

There are complex social and economic factors that contribute to differences in health care access among racial ethnic groups. Previous studies have indicated that economic status, cultural barriers, language ability, and health awareness can be used to explain differences in insurance coverage between minority/racial and white patients (Ma et al., 2022). According to Healthy People 2020, those who experience systemic barriers because of race/ethnic group, socioeconomic status, or historically related characteristics such as

discrimination or exclusion are more likely to face health disparities (Healthy People, 2020). Although the ACA expanded Medicaid coverage and reduced socioeconomic disparities to some extent, there are still wide discrepancies in levels of coverage (Mahal et al., 2020).

3.1 Income, Employment, and Wealth

Income was considered to be a major barrier to minority/ethnic access to health services (Chen et al, 2016). Referencing the previous study, income levels also expectedly played a sizable role in impacting insurance-related decision making, with lower-income individuals being more incentivized to purchase public insurance due to its lower cost, while those with higher incomes were more likely to be privately insured (Kao et al., 2010). A glance into wealth inequality in American households in 2016 revealed that the median net worth of white families was \$171,000, 10 times greater than Black families, whose median net worth was \$17,500 (Shapiro et al., 2013). Since the 1980s, the proportion of Black workers earning poverty wages has been 1.5 times that of white workers, and in 2017, the proportion of Black workers earning poverty wages was 0.3 percentage points higher than in 2006 (Cooper, 2018). Enterprises often employ a disproportionate number of low wage workers from ethnic minorities to do the dangerous jobs, many of whom were Hispanics (Thijssen et al., 2021). Nearly one-fifth of Hispanic workers can only earn the minimum wage, and one quarter of low wage workers were Hispanic immigrants (Cooper, 2018). These sharp divides partially explain why white individuals were more likely to have private insurance than Black and Hispanic individuals (Buchmueller and Levy, 2020). After the implementation of ACA, the coverage of medical insurance in all ethnic groups/races has expanded. Moreover, the elimination of certain economic barriers enabled Black and Asian patients to see doctors at nearly the same rate as White patients (Chen et al. 2016).

Methodology

To answer this question from a quantitative lens, we use various segments of the HINTS dataset. Control variables enlisted in the previous section are also incorporated to account for possible alternative explanations that could bias model estimates. A combination of descriptive statistics, data visualizations, and regression analyses of extant data are used to formulate results. As necessary, new variables are created and/or the data is transformed to best fit our regression analyses.

Once again, a logit regression is most appropriate given the type of data collected in the HINTS survey. Our dependent variables are as specified in **RQ2**: *invitedclintrial* and *participatedclintrial*. This model is run on several independent and control variables including: age, birth gender, income, occupational status, marital status, education level, race, sexual orientation, political viewpoint, and the effect of the COVID-19 pandemic on respondent answers. Several interaction terms between health insurance and racial/ethnic minority subgroups are also included in the model to identify whether health insurance status moderates the relationship between being racial/ethnic minority and willingness to participate in a clinical trial. A full list of variables for this research question can be found in **Appendix A**.

Based on these variables and our RQ of interest, our primary null hypothesis is as follows:

$H_0: \beta_{Health\ Insurance * Racial/Ethnic\ Minority\ Status} = 0$, which implies that the effect of having health insurance on willingness to participate in a clinical trial does not seem to be moderated by an individual's racial/ethnic group, holding all other variables constant

If our result supports the null hypothesis, then the coefficient on the interacted term will not be statistically significant, holding all other variables constant. Alternatively, if we find support for the alternative hypothesis, we would expect the coefficient on the interacted term to be statistically significant, holding all other variables constant.

Additionally, we plan to use tests of joint significance to understand whether health insurance influences both invitation and participation in clinical trials at either value of a given racial category that is found to be statistically significant. Using the same methodology, we uncover whether a given racial category that is statistically significant influences invitation and participation in clinical trials at either value of insurance coverage.

To better understanding our data and dive more deeply into our research questions, we decided to test four additional null hypotheses:

H0: An individual's health insurance status does not influence whether a person is invited to participate in a clinical trial regardless of racial/ethnic group, holding all other variables constant

H0: An individual's health insurance status does not influence whether a person participates in a clinical trial (after having been invited) regardless of racial/ethnic group, holding all other variables constant

H0: An individual's racial/ethnic belonging does not influence whether he/she/they are invited to participate in a clinical trial regardless of health insurance status, holding all other variables constant

H0: An individual's racial/ethnic belonging does not influence whether he/she/they participates in a clinical trial (after having been invited) regardless of health insurance status, holding all other variables constant

Results and Analysis

1. Recoding key variables

The variable recoding specifications replicate those specified in **RQ2**.

2. Chi-squared tests of association

To assess whether there is an association between an individual's racial/ethnic group and the likelihood of being invited to a clinical trial, we use white and Non-Hispanic (*white_nohisp*), white and Hispanic (*white_hisp*), Black (*black1*) and Other race (*otherrace*) variables to run Chi-squared tests separately. The results depicted in **Table 5** reveal a p-value of 0.000 for Black, 0.046 for White and Non-Hispanic, which suggests that the variable Black and White and Non-Hispanic are statistically significantly related to the frequency with which an individual is being invited to a clinical trial. Next, we use the same logic to assess whether there is an association between an individual's racial/ethnic group and having participated in a clinical trial after being invited. The results of Chi-squared test shown in **Table 6** also indicate that there is an

association between the variable Black and participation in a clinical trial, with a p-value of 0.010. Same association between the variable White and Non-Hispanic and participation in a clinical trial, with a p-value of 0.002.

Table 5. invitedclintrial Chi-Squared Tests of Association

Have you ever been invited to participate in a clinical trial?			
White and Non-Hispanic	Yes	No	Total
No	159	1008	1167
Yes	232	1831	2063
Total	391	2839	3230
Pearson chi2(1) = 3.9645 Pr = 0.046			
Have you ever been invited to participate in a clinical trial?			
Black	Yes	No	Total
No	297	2456	2753
Yes	94	383	477
Total	391	2839	3230
Pearson chi2(1) = 30.3911 Pr = 0.000			
Have you ever been invited to participate in a clinical trial?			
Other Race	Yes	No	Total
No	359	2539	2898
Yes	32	300	332
Total	391	2839	3230
Pearson chi2(1) = 2.1161 Pr = 0.146			
Have you ever been invited to participate in a clinical trial?			
White and Hispanic	Yes	No	Total

No	358	2514	2872
Yes	33	325	358
Total	391	2839	3230

Pearson chi2(1) = 3.1548 Pr = 0.076

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 6. participatedclintrial Chi-Squared Tests of Association

Did you participate in the clinical trial?			
White and Non-Hispanic	Yes	No	Total
No	57	97	154
Yes	123	107	230
Total	180	204	384

Pearson chi2(1) = 10.0419 Pr = 0.002

Did you participate in the clinical trial?			
Black	Yes	No	Total
No	148	145	293
Yes	32	59	91
Total	180	204	384

Pearson chi2(1) = 0.5674 Pr = 0.010

Did you participate in the clinical trial?			
Other Race	Yes	No	Total
No	170	184	354
Yes	10	20	30
Total	180	204	384

Pearson $\chi^2(1) = 2.3964$ Pr = 0.122

Did you participate in the clinical trial?

White and Hispanic	Yes	No	Total
No	165	186	351
Yes	15	18	33
Total	180	204	384

Pearson $\chi^2(1) = 0.0293$ Pr = 0.864

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

3. Multiple Regression Model

3a. Invited

3a.1 Interacted Model

Due to insufficient variation in many smaller racial categories (i.e., American Indian, Asian, Multiple Races), we were unable to run a multiple regression model that used *invitedclintrial* as the dependent variable.

3a.2 Non-Interacted Model

To determine whether there is an association between individuals' racial/ethnic group and being invited to participate in a clinical trial, we employed a logit regression model. Once again, we employed marginal effects, and the results replicate our findings in **RQ2**. Results depicted in **Table 7 (1)** demonstrated that the coefficient on the variable Black is statistically significant at the alpha level 0.05, possessing a p-value of 0.005. We also find the coefficient on age to have a statistically significant value.

To visualize the change in the probability of the outcome variable (*invitedclintrialb*) associated with a one-unit change in each predictor variable while all others are held constant, we adopted the margins command to the model generated in **Table 8 (1)**. As result displayed in **Table 8 (1)**, the coefficient on the variable Black is statistically significant at the threshold alpha level 0.018, possessing a p-value of 0.00. The coefficient of Black is 0.075, which indicates that compared to those who identify as white and non-Hispanic, Black respondents have a 7.5 percentage point greater probability of being invited to a clinical trial, holding all other variables constant. Also, *age* is a statistically significant value.

3b. Participated Model

3b.1 Interacted Model

Due to insufficient variation in many smaller racial categories (i.e., American Indian, Asian, Multiple Races), we were unable to run a multiple regression model that used *participatedclintrialb* as the dependent variable.

3b.2 Non-Interacted Model

Similarly, we ran another model with the same independent variables and controls. Now, the dependent variable is *participatedclintrialb*, which measures the act of having participated in a clinical trial after being invited. Results shown in **Table 7 (2)** demonstrate that the coefficients on the variables, Black has statistically significant values, holding all other variables constant. The average marginal effects of each variable are shown in **Table 8 (2)**. The coefficient on Black is -0.26. This indicates that, compared to those who identify as white and non-Hispanic, Black respondents have a 26 percentage point lower probability of participating in a clinical trial, holding all other variables constant. Besides, the indicator “Very Conservative” is statistically significant at the threshold alpha level 0.033, possessing a p-value of 0.00.

Table 7. Logit Models for RQ3

VARIABLES	(1) Invitation	(2) Participation
healthinsuranceb = 1	0.536 (1.000)	-1.157 (3.260)
age	0.0176*** (0.00614)	0.00569 (0.0175)
birthmale = 1	0.0285 (0.201)	0.374 (0.461)
lgb = 1	0.815 (0.494)	-0.775 (1.546)
white_hisp = 1	0.0544 (0.507)	1.073 (0.992)
otherrace = 1	-0.185 (0.354)	-1.059 (1.170)
black1 = 1	0.764*** (0.273)	-1.425** (0.709)
educb_rec = 2, High School Graduate		1.116 (2.289)
educb_rec = 3, Some College		1.857 (2.354)
educb_rec = 4, Bachelor's Degree		2.440 (2.340)
educb_rec = 5, Post-Baccalaureate Degree		2.213 (2.312)
incomeranges_rec = 2, \$10,000 to \$14,999	0.194 (0.567)	0.583 (2.019)
incomeranges_rec = 3, \$15,000 to \$19,999	1.270* (0.666)	-0.0457 (2.023)
incomeranges_rec = 4, \$20,000 to \$34,999	0.362 (0.512)	-0.0139 (1.485)
incomeranges_rec = 5, \$35,000 to \$49,999	0.146 (0.537)	1.331 (1.564)
incomeranges_rec = 6, \$50,000 to \$74,999	0.372	0.559

	(0.411)	(1.327)
incomeranges_rec = 7, \$75,000 to \$99,999	0.0496	0.705
	(0.465)	(1.599)
incomeranges_rec = 8, \$100,000 to \$199,999	0.496	0.796
	(0.443)	(1.434)
incomeranges_rec = 9, \$200,000 or more	0.298	0.677
	(0.513)	(1.364)
occupation_employed_rec = 1, Selected	-0.0412	-0.806
	(0.251)	(0.634)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.719
		(1.184)
maritalstatus_rec = 3, Divorced		0.535
		(0.857)
maritalstatus_rec = 4, Widowed		-0.438
		(0.973)
maritalstatus_rec = 5, Separated		0.00836
		(1.329)
maritalstatus_rec = 6, Single, never been married		-0.226
		(0.761)
politicalviewpoint_rec = 1, Very Liberal		1.346
		(0.935)
politicalviewpoint_rec = 2, Liberal		0.894
		(0.782)
politicalviewpoint_rec = 3, Somewhat liberal		1.396
		(0.866)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.709
		(0.696)
politicalviewpoint_rec = 6, Conservative		-0.549
		(0.673)
politicalviewpoint_rec = 7, Very Conservative		2.521
		(1.716)
afterpandemic = 1	-0.300	-0.593
	(0.221)	(0.547)
Constant	-4.019***	-1.312
	(0.880)	(3.696)
Observations	2,865	321

Standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 8. Margins for RQ3

(1)

(2)

VARIABLES	Margins for Invited	Margins for Participation
healthinsuranceb = 1	0.035 (0.052)	-0.215 (0.554)
age	0.0013*** (0.000)	0.001 (0.003)
birthmale = 1	0.002 (0.015)	0.071 (0.087)
lgb = 1	0.084 (0.066)	-0.141 (0.266)
white_hisp = 1	0.004 (0.041)	0.203 (0.178)
black1 = 1	0.075** (0.033)	-0.260** (0.116)
otherrace = 1	-0.013 (0.024)	-0.194 (0.200)
educb_rec = 2, High School Graduate		0.159 (0.271)
educb_rec = 3, Some College		0.295 (0.274)
educb_rec = 4, Bachelor's Degree		0.407 (0.275)
educb_rec = 5, Post-Baccalaureate Degree		0.363 (0.278)
incomeranges_rec = 2, \$10,000 to \$14,999	0.012 (0.037)	0.112 (0.388)
incomeranges_rec = 3, \$15,000 to \$19,999	0.127 (0.083)	-0.008 (0.371)
incomeranges_rec = 4, \$20,000 to \$34,999	0.025 (0.035)	-0.002 (0.273)
incomeranges_rec = 5, \$35,000 to \$49,999	0.009 (0.033)	0.257 (0.291)
incomeranges_rec = 6, \$50,000 to \$74,999	0.026 (0.027)	0.107 (0.247)

incomeranges_rec = 7, \$75,000 to \$99,999	0.003	0.136
	(0.028)	(0.302)
incomeranges_rec = 8, \$100,000 to \$199,999	0.036	0.154
	(0.030)	(0.268)
incomeranges_rec = 9, \$200,000 or more	0.02	0.130
	(0.034)	(0.254)
occupation_employed_rec = 1, Selected	-0.003	-0.147
	(0.020)	(0.111)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.136
		(0.218)
maritalstatus_rec = 3, Divorced		0.102
		(0.159)
maritalstatus_rec = 4, Widowed		-0.083
		(0.183)
maritalstatus_rec = 5, Separated		0.0016
		(0.256)
maritalstatus_rec = 6, Single, never been married		-0.043
		(0.146)
politicalviewpoint_rec = 1, Very Liberal		0.265
		(0.172)
politicalviewpoint_rec = 2, Liberal		0.179
		(0.153)
politicalviewpoint_rec = 3, Somewhat liberal		0.274
		(0.150)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.1318
		(0.123)
politicalviewpoint_rec = 6, Conservative		-0.103
		(0.120)
politicalviewpoint_rec = 7, Very Conservative		0.438**
		(0.199)

afterpandemic = 1	-0.024 (0.018)	-0.113 (0.103)
Observations	2,865	321

Standard errors in parentheses
 *** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Research Question Four (RQ4)

What is the impact of health insurance coverage on LGB minorities' willingness to participate in clinical trial research?

Literature Review

Literature on LGBTQ+ health insurance spans several decades. To get a clear picture of how LGB access to health coverage has changed over time, this section of the literature review is divided into two parts: pre-ACA and post-ACA. Such a time-sensitive analysis provides insight into how insurance providers and the federal government have both expanded and limited access to coverage for these individuals over time. The United States' historical adherence to traditional values has manifested in, among many things, a failure to acknowledge sexual minorities as equals in society. Not only have these value systems been passed down through generations, but biases against the LGB community have crept into governmental policies as well.

Homosexuality dates back to ancient times but same-sex marriage was only legalized in the United States in 2015 – a step forward that was staunchly opposed by many (Burnett, 2015). Even though the country has become more socially progressive, LGB individuals continue to face discrimination across various sectors and institutions, with the healthcare industry being prominent among them.

Despite efforts to expand access to health insurance, LGB+ individuals remain less likely to have coverage compared to their heterosexual counterparts (Bosworth et al., 2021). Previous literature has put forth several explanations for this phenomenon. They include the following: stigma associated with being in a 'non-traditional' partnership, financial disincentives to acquiring dependent benefits, and lack of accessible insurance programs (Ash and Badgett, 2008; Dawson et al., 2018). The Affordable Care Act (ACA) and legalization of same-sex marriage helped diminish the coverage gap, but inequities still linger (Nguyen et al., 2018). In a brief released by the Assistant Secretary of Planning and Evaluation Office of Health Policy, Bosworth et al. noted that uninsured rates for LGB+ individuals were 1.3 percentage points higher than rates for non-LGB+ individuals in 2019 (Bosworth et al., 2021).

1. Pre-Affordable Care Act

1.1 Disparities in coverage

In the mid-2000s, even as states were beginning to legalize same-sex marriage, only a fraction of medium-sized businesses offered domestic partner benefits (Konrad, 2009). The percentage fell significantly when small companies were included in the calculation (Konrad, 2009). Some firms were able to deny coverage using the Defense of Marriage Act, a law that prevented sexual minority couples from receiving federal benefits even if their union or marriage was recognized by their state (Konrad, 2009; Cornell Law School Legal Information Institute, n.d.). Of the firms that provided domestic partner benefits, administrative burdens made the process of obtaining them particularly onerous. Employees in same-sex relationships

were often required to provide documented proof of their relationship, pay more in federal and state taxes, and offer proof of legal custodianship if children were involved (Konrad, 2009). These represented barriers to entry that heterosexual couples, for the most part, did not encounter.

Analyzing disparities in health insurance coverage, Buchmueller and Carpenter compared various health-related outcomes between individuals in same- and different-sex relationships (Buchmueller and Carpenter, 2010). Using a series of logistic regressions, the researchers found that, compared to heterosexual respondents, gay men and lesbian women had significantly higher uninsured rates (Buchmueller and Carpenter, 2010). Several factors informed these statistics. Before the implementation of the Affordable Care Act, health care providers could legally deny coverage to individuals based on pre-existing conditions, such as HIV status – a virus that disproportionately affects gay and bisexual men (Minority HIV/AIDS Fund, n.d; Dawson et al., 2018). Even if an LGBT individual was able to obtain coverage, health care providers could restrict the types of services they were able to receive (Dawson et al., 2018). Transgender individuals, for instance, were often denied treatments associated with gender transition (Dawson et al., 2018). Insurance companies could also charge clients at differential rates based on their sexual preferences or gender, leading many LGBT individuals to pay more for coverage (Dawson et al., 2018). LGBTQ+ individuals had to weigh the benefits of having health coverage against the financial and emotional costs associated with procuring it, leading many to be uninsured.

1.2 Disparities in access to care and health outcomes

In conjunction with having lower insurance rates, individuals in same-sex relationships also had comparatively worse health outcomes and access to care than people in different-sex relationships (Ash and Badgett, 2008; Buchmueller and Carpenter, 2010). Specifically, lesbian women were more likely than heterosexual women to delay care because of cost-related concerns and less likely to have received preventative cancer screenings (e.g., Pap smear or mammogram). They were also less likely to have interacted with certain medical professionals or to have had a recent check-up (Buchmueller and Carpenter, 2010). These statistics were similar for straight and gay men, with the exception that gay men were more likely to have had annual checkups (Buchmueller and Carpenter, 2010). This is generally consistent with subsequent findings that individuals in same-sex relationships tend to be in worse health than their heterosexual peers (Ash and Badgett, 2008).

While research on health insurance gaps between same- and different-sex couples before 2010 is insightful, it has several limitations. Most notably, data on an individual's sexual orientation were not directly collected by most surveys in the turn of the century. Instead, researchers either had to assume a participant's sexual orientation based on their self-reported relationship type, or had to leave out important subgroups due to scarce information (Buchmueller and Carpenter, 2010; Ponce et al., 2010). Buchmueller and Carpenter's identification of sexual minorities, for example, left out bisexual individuals, married same-sex couples, and couples with non-traditional living arrangements (Buchmueller and Carpenter, 2010). As a result of the sparsity of specific data, researchers were unable to decipher between subgroups within the LGBTQ+ community, having to focus on the distinction between same- and different sex relationships instead.

2. Post-Affordable Care Act

2.1 Transformations in public attitude and legislation

Today, both the percentage of Americans who identify with the LGBTQ+ community and the public's overall acceptance of same-sex relationships are higher than in previous years (Jones, 2022; McCarthy, 2021). This is not to discount the continued discrimination LGBTQ+ individuals face, especially when it comes to equitable access to medical services and health insurance (Mahowald et al., 2020). Rather, it emphasizes the profound impact that both the Affordable Care Act and legalization of same-sex marriage have had on advancing LGBTQ+ rights and liberties.

The ACA, also known as Obamacare, has generated noteworthy transformations in health care coverage for LGBTQ+ people. In addition to expanding Medicaid, it protects individuals with pre-existing conditions and establishes nondiscriminatory safeguards that have improved coverage levels for minority groups broadly (Medina and Mahowald, 2020). Consequently, health insurance has become more affordable for sexual minorities (Medina and Mahowald, 2020). Before the ACA took effect in 2013, 17.4 percent of LGB+ individuals were uninsured compared to just 8.3 percent in 2016 (Bosworth et al., 2021). Repeated attempts to repeal the ACA during the Trump administration, however, have led an uptick in this number – 12.7 percent as of 2019 (Bosworth et al., 2021).

2.2 Persisting barriers to individualized care

Despite gains in coverage, unique challenges persist within the healthcare community. Some healthcare professionals, for example, have not received proper training on how to provide 'culturally competent care' to members of the LGBTQ+ community (Bosworth et al., 2021). Therefore, the quality of care medical staff provides has been affected by a general insensitivity towards an individual's specific situation and a lack of understanding of their required services. For example, medical professionals and insurance companies may question a woman's request for testosterone treatment. In a survey conducted by Mahowald et al. at the Center for American Progress, nearly half of transgender participants recalled being denied transition-related surgeries and/or hormonal treatments (Mahowald et al., 2020). Insurance companies often refused or failed to update client records following name and/or gender changes, with roughly a third of transgender Americans having been affected by this negligence (Mahowald et al., 2020). As a result of these discriminatory practices, gaps in health outcomes and access to services remain between the LGBTQ+ community and heterosexual individuals.

Recent studies have increasingly differentiated between health-related measures within segments of the LGBTQ+ community. Macapagal et al. addressed this gap in the literature by analyzing health access, use, and experiences within a sample of 206 LGBTQ adults between 18 and 27 years old (Macapagal et al., 2016). They found that more than half of respondents had some type of health insurance, whether it was private or public (Macapagal et al., 2016). Individuals who were both a sexual and racial minority, however, had lower coverage rates, as did HIV positive participants (Macapagal et al., 2016). On the other hand, bisexual individuals were more likely than their LGQ peers to be insured, which meant that gay men and lesbian women were less likely to have had an annual checkup (Macapagal et al., 2016). In terms of access to services and overall healthcare experiences, transgender individuals were generally worse off than cisgender participants; many transgender emerging adults reported postponing care as a consequence of inherent discrimination in the healthcare system (Macapagal, 2016).

2.3 Data limitations and generalizability

Although researchers are making concerted efforts to refine and update their

methodology, several limitations restrict the generalizability of their findings. Because some LGBTQ+ individuals may not be comfortable sharing their sexual orientation on surveys or in experiments, researchers may have a distorted view of the data. Therefore, it is possible that the health insurance gap between LGBTQ+ and heterosexual individuals is larger than reported in modern studies. Additionally, when researchers obtained information on a participant's sexual orientation, their sample sizes were often too small, unrepresentative, or otherwise biased, which made the process of arriving at well-defined conclusions difficult (Nguyen et al., 2018; Gonzales, 2021; Ramsey et al., 2022).

Methodology

To answer this research question, we examine three main segments of the HINTS data: respondents' previous invitation to and participation in clinical research trials, various facets of their demographic information, and the effect of the COVID-19 pandemic. Control variables from each section will be incorporated to account for possible alternative explanations that could bias model estimates.

In this case, a logit regression is most appropriate given the type of data collected in the HINTS survey dataset. Our dependent variables are as specified under **RQ2**. This model is run on several independent and control variables including: age, birth gender, income, occupational status, marital status, education level, race, sexual orientation, political viewpoint and the effect of the COVID pandemic on respondent answers. An interaction term is also included in the model to examine whether an individual's health insurance status plays a moderating role in the relationship between sexual orientation and willingness to participate in clinical trials. A full list of variables for this research question can be found in **Appendix A**.

Based on these variables and our RQ of interest, our primary null hypothesis is as follows:

$H_0: \beta_{Health\ Insurance * Sexual\ Orientation} = 0$, which implies the effect of having health insurance on willingness to participate in a clinical trial does not seem to be moderated by an individual's sexual orientation), holding all other variables constant

If our results support the null hypothesis, then the coefficient on the interacted term (above) will not be statistically significant, holding all other variables constant. Alternatively, if we find support for the alternative hypothesis, we would expect the coefficient on the interacted term to be statistically significant, holding all other variables constant.

To create a more comprehensive picture of the data, we also decided to test four additional null hypotheses:

H_0 : An individual's health insurance status does not influence whether he/she/they are invited to participate in a clinical trial regardless of sexual orientation, holding all other variables constant

H_0 : An individual's health insurance status does not influence whether he/she/they participates in a clinical trial (after having been invited) regardless of sexual orientation, holding all other variables constant

H_0 : An individual's sexual orientation does not influence whether he/she/they are invited to participate in a clinical trial regardless of health insurance status, holding all other variables constant

H_0 : An individual's sexual orientation does not influence whether he/she/they participates in a clinical trial (after having been invited) regardless of health insurance status, holding all other variables constant

Results to this effect will help us explore the relationship between health insurance status, sexual orientation and clinical trial participation/invitation on a more granular level. For example, we will be able to answer important questions, such as whether the marginal effect of having health insurance on an individual's likelihood to participate in a clinical trial is statistically significantly different for members of the LGB community and their heterosexual counterparts. In addition to our primary null hypothesis, these findings will help us determine whether sexual orientation moderates the relationship between health insurance and being invited to participate and/or choosing to participate in a clinical trial.

Results and Analysis

1. Discussion of key variables

In order to conduct our chi-squared tests and logit regressions, several key variables required alteration. Most notably, *sexualorientation* was originally coded to reflect the following subgroups: missing data, multiple responses selected in error, something else, heterosexual, homosexual, or bisexual. For simplification, the lattermost categories were combined into a single measure of LGB status. The newly generated variable, *lgb*, equals one when an individual identifies as either 'gay or lesbian' or 'bisexual' and zero if they selected 'heterosexual.' The remaining observations, which include missing data, error responses and individuals who specified a different sexual orientation, were all excluded from the analysis. This decision was made following careful examination of the 'other' sexual orientation category. For those who chose to elaborate, many responded with inappropriate or inapplicable answers, such as 'Christian,' 'Human,' and 'Too Old.'

2. Chi-squared tests of association

To assess whether there is an association between individuals' sexual orientation and likelihood of being invited to participate in a clinical trial, we first run a Chi-squared test. The results, indicated in **Table 9**, suggest that membership (or lack thereof) in the LGB community is statistically significantly related to the frequency with which a respondent is invited to partake in clinical trial research. This finding is consistent with the literature on clinical trial diversity, noted in our review of **RQ1**, in which historically marginalized communities are often underrepresented in sample groups. Perhaps it is the case, as our research suggests, that sexual minorities are simply not invited to participate in clinical trials in the first place. Hence, there is a lower probability that they will take part in clinical research. However, it may also be the case that, once invited, LGB individuals decide not to participate in the clinical trial at higher rates. The possibility for discrimination or identification, for example, may influence their willingness to participate. This is the question we turn to next.

Based on the previous model, we narrowed our analysis to examine the decision individual's made regarding whether to participate in a clinical trial after having been invited. A

subsequent Chi-squared test was run using this subgroup of 403 individuals. The resulting output, demonstrated in **Table 10**, yields a p-value greater than our predetermined threshold of 0.05. Thus, there does not appear to be a statistically significant relationship between sexual orientation and participation in a clinical trial. This indicates that, once an individual receives an invitation, there is no discernable difference in participation rates between members of the LGB community and their heterosexual counterparts.

Table 9. invitedclintrial Chi-Squared Test of Association

LGB	Have you ever been invited to participate in a clinical trial?		Total
	Yes	No	
No	380	2891	3271
Yes	31	124	155
Total	411	3015	3426

Pearson chi2(1) = 9.8502 Pr = 0.002

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 10. participatedclintrial Chi-Squared Test of Association

LGB	Did you participate in the clinical trial?		Total
	Yes	No	
No	178	195	373
Yes	13	17	30
Total	191	212	403

Pearson chi2(1) = 0.2144 Pr = 0.643

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

3. Logit Regressions

3a. Invited

3a.1 Interacted Model

Although we modeled the relationship between being invited to participate in a clinical trial and health insurance using post-estimation, the output did not reveal any interesting or unique results to those already identified in the previous sections; neither *lgb* nor *healthinsuranceb* were useful predictors of our first dependent variable. Furthermore, using a differencing approach to see how the average marginal effect of sexual orientation and health insurance status change over values of the other, we found additional insignificant results:

- The marginal effect of being a member of the LGB community is not statistically significant at a p-value less than 0.05 regardless of whether they have health insurance.
- The marginal effect of identifying with the LGB community is not statistically significantly different for people who have insurance and people who don't.
- The marginal effect of having health insurance is not statistically significant at a p-value less than 0.05 regardless of whether the individual identifies with the LGB community.
- The marginal effect of having health insurance is not statistically significantly different for individuals who identify with the LGB community or as heterosexual.

The following two variables were statistically significant at the 0.05 level: (1) age and (2) an indicator for Black racial identification.

3a.2 Without Interaction

In addition to modeling the relationship between our key variables of interest and clinical trial invitation rates with our interacted variable of interest, (*lgb*healthinsuranceb*), we also chose to run a regression without this term. The results of this test are included in **Table 11 (1)**, and are supplemented by corresponding average marginal effects in **Table 12 (1)**.

Compared to the interaction-inclusive model, this model specification yields similar average marginal effects for nearly all variables. In the non-interacted regression, for example, the effect of being a member of the LGB community on an individual's likelihood of being invited to participate in a clinical trial is 0.08, all else equal. This is roughly the same estimate outputted by the interacted model. A similar conclusion can be drawn when comparing the effects of having health insurance on an individual's likelihood of being invited to a clinical trial between the interacted and non-interacted regression models.

Per our definition of statistical significance established previously, there are two estimates that have a p-value less than 0.05. Interestingly, they are the same variables that were statistically significant in the interacted model: (1) age and (2) an indicator for Black racial identification.

3b. Participated

3b.1 Interacted Model

The impact of having health insurance on an individual's decision to participate in a clinical trial, whilst considering control demographic variables and our key interaction is modeled almost identically as described above. Where appropriate, *invitedclintrialb* has been replaced with *participatedclintrialb* to elicit the appropriate estimates. Upon further investigation, we found that there is limited variation between the four subgroups (lgb, no health insurance; lgb, health insurance; not lgb, no health insurance; not lgb, health insurance) when *participatedclintrialb* = 1. For example, there are no sample respondents who participated in the clinical trial, identify with the LGB community but don't have health insurance. Similarly, there are only 5 non-LGB individuals who do not have health insurance and chose to participate in the clinical trial. For these reasons, we decided to also run the logistic regression without the interaction between sexual orientation and health insurance coverage. This ultimately eased our interpretation of average marginal effects on an individual's likelihood of participating in a clinical trial after having been invited.

3b.2 Without Interaction

To better explore the effect of health insurance coverage and sexual orientation on participation rates in clinical trials, we ran a logit regression model without the interaction term of interest (*healthinsuranceb*lgb*). These results are modeled in **Table 11 (2)**. As mentioned previously, statistical significance cannot be determined based on these estimates. Thus, an examination of the average marginal effects of each variable on *participatedclintrialb* have been calculated and are included in **Table 12 (2)**.

Per the regression output, the effect of identifying with the LGB community on an individual’s likelihood of participating in a clinical trial can be interpreted in the following way: being a member of the LGB community is expected to *decrease* an individual’s likelihood of participating in a clinical trial. It should be noted, however, that this estimate is not statistically significant and should therefore be interpreted with caution.

Compared to the *invitedclintrialb* regression without the interaction term between sexual orientation and health coverage, the same number of estimates are statistically significant. Yet, a point of divergence is in the number of observations used to calculate average marginal effects. There are far more individuals who recalled having previously been invited to participate in a clinical trial than those who actually chose to participate: 2,865 vs. 321, respectively.

The marginal effect of being a member of the LGB community on participation rates in clinical trials is not statistically significant regardless of whether he/she/they have health insurance. We also cannot say that the marginal effect of identifying with the LGB community is statistically significantly different for people who have insurance and people who don’t. Conversely, when the average marginal effects of having health insurance on participation rates in clinical trials are considered, regardless of LGB identification, an almost identical conclusion can be reached, as shown in **Table 12 (2)**.

Looking at the average marginal effects of each variable, only two are statistically significant: (1) an indicator for Black racial identification and (2) having a ‘very conservative’ political viewpoint. The last finding in particular is contrary to what one might expect in the age of COVID. Conservative-identifying or conservative-leaning individuals have generally been more hesitant to adhere to COVID-19 protocols and receive recommended vaccinations; it is interesting that this group is more likely than others to participate in clinical trials (given they are previously invited). Even after the impact of the pandemic has been controlled for, this result remains statistically significant at the 0.05 level.

Table 11. Logit Models for RQ4

VARIABLES	(1) Invitation	(2) Participation
lgb = 1	0.815 (0.494)	-0.775 (1.546)
healthinsuranceb = 1	0.536 (1.000)	-1.157 (3.260)
age	0.0176*** (0.00614)	0.00569 (0.0175)
birthmale = 1	0.0285	0.374

	(0.201)	(0.461)
white_hisp = 1	0.0544	1.073
	(0.507)	(0.992)
black1 = 1	0.764***	-1.425**
	(0.273)	(0.709)
otherrace = 1	-0.185	-1.059
	(0.354)	(1.170)
educb_rec = 2, High School Graduate		1.116
		(2.289)
educb_rec = 3, Some College		1.857
		(2.354)
educb_rec = 4, Bachelor's Degree		2.440
		(2.340)
educb_rec = 5, Post-Baccalaureate Degree		2.213
		(2.312)
incomeranges_rec = 2, \$10,000 to \$14,999	0.194	0.583
	(0.567)	(2.019)
incomeranges_rec = 3, \$15,000 to \$19,999	1.270*	-0.0457
	(0.666)	(2.023)
incomeranges_rec = 4, \$20,000 to \$34,999	0.362	-0.0139
	(0.512)	(1.485)
incomeranges_rec = 5, \$35,000 to \$49,999	0.146	1.331
	(0.537)	(1.564)
incomeranges_rec = 6, \$50,000 to \$74,999	0.372	0.559
	(0.411)	(1.327)
incomeranges_rec = 7, \$75,000 to \$99,999	0.0496	0.705
	(0.465)	(1.599)
incomeranges_rec = 8, \$100,000 to \$199,999	0.496	0.796
	(0.443)	(1.434)
incomeranges_rec = 9, \$200,000 or more	0.298	0.677
	(0.513)	(1.364)
occupation_employed_rec = 1, Selected	-0.0412	-0.806
	(0.251)	(0.634)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.719
		(1.184)
maritalstatus_rec = 3, Divorced		0.535
		(0.857)
maritalstatus_rec = 4, Widowed		-0.438
		(0.973)
maritalstatus_rec = 5, Separated		0.00836
		(1.329)
maritalstatus_rec = 6, Single, never been married		-0.226

		(0.761)
politicalviewpoint_rec = 1, Very Liberal		1.346
		(0.935)
politicalviewpoint_rec = 2, Liberal		0.894
		(0.782)
politicalviewpoint_rec = 3, Somewhat liberal		1.396
		(0.866)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.709
		(0.696)
politicalviewpoint_rec = 6, Conservative		-0.549
		(0.673)
politicalviewpoint_rec = 7, Very Conservative		2.521
		(1.716)
afterpandemic = 1	-0.300	-0.593
	(0.221)	(0.547)
0b.healthinsuranceb#0b.lgb		
0b.healthinsuranceb#1o.lgb		
1o.healthinsuranceb#0b.lgb		
1.healthinsuranceb#1.lgb		
0b.lgb#0b.healthinsuranceb		
0b.lgb#1o.healthinsuranceb		
1o.lgb#0b.healthinsuranceb		
1o.lgb#1o.healthinsuranceb		
Constant	-4.019***	-1.312
	(0.880)	(3.696)
Observations	2,865	321

Standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Table 12. Margins for RQ4

(1)

(2)

VARIABLES	Margins for Invited	Margins for Participation
healthinsuranceb = 1	0.035 (0.052)	-0.215 (0.554)
age	0.0013*** (0.000)	0.001 (0.003)
birthmale = 1	0.002 (0.015)	0.071 (0.087)
lgb = 1	0.084 (0.066)	-0.141 (0.266)
white_hisp = 1	0.004 (0.041)	0.203 (0.178)
black1 = 1	0.075** (0.033)	-0.260** (0.116)
otherrace = 1	-0.013 (0.024)	-0.194 (0.200)
educb_rec = 2, High School Graduate		0.159 (0.271)
educb_rec = 3, Some College		0.295 (0.274)
educb_rec = 4, Bachelor's Degree		0.407 (0.275)
educb_rec = 5, Post-Baccalaureate Degree		0.363 (0.278)
incomeranges_rec = 2, \$10,000 to \$14,999	0.012 (0.037)	0.112 (0.388)
incomeranges_rec = 3, \$15,000 to \$19,999	0.127 (0.083)	-0.008 (0.371)
incomeranges_rec = 4, \$20,000 to \$34,999	0.025 (0.035)	-0.002 (0.273)
incomeranges_rec = 5, \$35,000 to \$49,999	0.009 (0.033)	0.257 (0.291)
incomeranges_rec = 6, \$50,000 to \$74,999	0.026 (0.027)	0.107 (0.247)

incomeranges_rec = 7, \$75,000 to \$99,999	0.003	0.136
	(0.028)	(0.302)
incomeranges_rec = 8, \$100,000 to \$199,999	0.036	0.154
	(0.030)	(0.268)
incomeranges_rec = 9, \$200,000 or more	0.02	0.130
	(0.034)	(0.254)
occupation_employed_rec = 1, Selected	-0.003	-0.147
	(0.020)	(0.111)
maritalstatus_rec = 2, Living as married or living with a romantic partner		0.136
		(0.218)
maritalstatus_rec = 3, Divorced		0.102
		(0.159)
maritalstatus_rec = 4, Widowed		-0.083
		(0.183)
maritalstatus_rec = 5, Separated		0.0016
		(0.256)
maritalstatus_rec = 6, Single, never been married		-0.043
		(0.146)
politicalviewpoint_rec = 1, Very Liberal		0.265
		(0.172)
politicalviewpoint_rec = 2, Liberal		0.179
		(0.153)
politicalviewpoint_rec = 3, Somewhat liberal		0.274
		(0.150)
politicalviewpoint_rec = 5, Somewhat Conservative		-0.1318
		(0.123)
politicalviewpoint_rec = 6, Conservative		-0.103
		(0.120)
politicalviewpoint_rec = 7, Very Conservative		0.438**
		(0.199)

afterpandemic = 1	-0.024 (0.018)	-0.113 (0.103)
Observations	2,865	321

Standard errors in parentheses
 *** p<0.01, ** p<0.05, * p<0.1

Source: National Cancer Institute. (2020). Health Information National Trends Survey 5 (Cycle 4) [Data set]. Retrieved April 18, 2023, from <https://hints.cancer.gov/data/download-data.aspx#H5C4>

Limitations

The dataset we analyzed, HINTS 4 Cycle 5, is novel in that it provides preliminary insight into the characteristics of individuals who were invited to participate in clinical trials and those who participated in clinical trials. Clinical trial related datasets typically only capture demographic information of those who did participate in trials. Nevertheless, our analyses were often constricted by the reduced power of the regressions due to the small sample size of those who participated.

Recommendations

Based on the findings of our analyses, we propose the following recommendations:

1. In response to these findings, focus groups can be conducted with Black individuals to understand barriers to participation (i.e., transportation or a lack of childcare) and general potential for policy interventions. Following focus groups, inform physicians and research organizations that our analyses suggest that Black individuals are less likely than white non-Hispanics to participate in clinical trials (despite being more likely to be invited) and themes gathered from focus groups.
2. Leverage community partnerships to identify data sources (which may not be publicly available) and are similar to HINTS but do not prime participants to respond about cancer-related clinical trials. These datasets would be most beneficial if they ask directly about willingness to participate, insurance coverage, and demographic factors such as age, sex at birth, race, ethnicity, gender identity, sexual orientation, income, education, and political affiliation.
3. Collect survey data with a sample that is representative of the U.S. population. This survey could increase response rates by explicitly asking “Suppose you were invited to participate in a clinical trial; would you participate?” This would capture willingness to participate rather than narrowing the sample to those who have participated. Additionally, the survey could ask a variety of demographic questions including sex at birth, gender identity, sexual orientation, race, ethnicity, income, education, and political viewpoint to capture potential demographic differences in those who are and are not willing to participate in clinical research. For further specification, questions could probe more narrowly on the phase of clinical trials that individuals are willing to participate in (phase 1 investigates safety and dosing of the intervention, phase 2 focuses on effectiveness and side effects, and phase 3 compares the novel treatment to an existing treatment) or the type of trial (surgical, behavioral, pharmaceutical).

Conclusion

The goal of our analyses was to examine the association between access to health insurance coverage and an individual's decision to participate in clinical trials, and how this association might differ among racial/ethnic and LGB minority populations. We divided our research into four sections to analyze associations on a more granular level.

Analysis for **RQ1** examined the present lack of diversity in clinical trials, the consequences of homogenous clinical trials, and what is currently being done to address the homogeneity through a literature review. Through this analysis, it was clear that the lack of diversity has led to medical interventions, wearable devices, and medications that are more effective for some racial groups than others, exacerbating health disparities.

RQ2 examined the relationship between health insurance and an individual's decision to participate in clinical trials. Our literature review suggests that health insurance may be associated with participation in clinical trials. Legislation such as the Clinical Treatment Act of 2020 mandated that Medicaid cover some routine costs associated with qualifying for clinical trials. However, concern over the lack of reimbursement continues to deter some individuals from participating. To analyze this research question, we used chi-square and logistic regression analyses. The bivariate analyses revealed a statistically significant relationship between having insurance and being invited to participate in a clinical trial. However, bivariate tests do not elucidate the direction of the association. The bivariate test for the relationship between having insurance and participating in clinical trials was not statistically significant. Logistic regression analyses did not yield a significant association between insurance status and invitation or participation in clinical trials, holding all other variables constant. However, age was positively and statistically significantly associated with both invitation to and participation in clinical trials. Most notably, our regression analyses show that Black individuals are 8 percentage points more likely to be invited to participate in clinical trial research and 26 percentage points less likely to participate; these associations are statistically significant at conventional levels.

RQ3 examined the relationship between health insurance status and willingness to participate in clinical trials among racial/ethnic minorities. Our literature review revealed that there are discrepancies in access to health insurance coverage across races with white Hispanic and Black individuals being uninsured at significantly higher rates compared to White Non-Hispanic. Similar to the second research question, the coefficient for age was positively and statistically significantly associated with being invited. Our logistic regressions lacked sufficient variability for the interaction terms of race/ethnicity and insurance for the participation dependent variable; we therefore could not analyze interacted regressions. Non-interacted regressions yielded the same finding as previously reported: Black individuals are 8 percentage points less likely to be invited to participate in clinical trials and 26 percentage points less likely to participate.

Our final research question, **RQ4**, analyzed the relationship between insurance coverage and willingness to participate among LGB+ minorities. Our literature review indicates that, while there has been significant progress in increasing insurance coverage among LGB+ individuals because of the Affordable Care Act and the legalization of same-sex marriage, LGB+ individuals still lag behind heterosexual individuals in access to health insurance coverage. Our quantitative analysis consisted of chi-square and logistic regressions. Chi-square analyses reveal that LGB+ minority status is statistically significantly associated with being invited to participate in a clinical trial; there was not a statistically significant association between being an LGB+ minority and participating in clinical trials. Interacted models between health insurance and

LGB+ minority status lacked sufficient variation to yield statistically significant results. Non-interacted regressions yielded the same finding as previously reported: Black individuals are 8 percentage points less likely to be invited to participate in clinical trials and 26 percentage points less likely to participate.

To our knowledge, our project is the first to directly analyze willingness to participate in clinical trials and whether insurance status impacts willingness. While we found some statistically significant and interesting associations between demographic characteristics and whether or not someone was invited to participate or participate, our findings were limited by the small sample of individuals who were invited and even smaller sample of individuals that participated.

We propose several suggestions to continue this research further. First, we suggest that focus groups are conducted to further understand why Black individuals are more likely to be invited to participate and less likely to participate in clinical trials, compared to non-Hispanic white individuals. Second, we propose that Pyxis Partners leverages existing relationships to identify data that we may not have had access to that would elucidate the relationship between insurance status and willingness to participate more clearly. Third, we propose that Pyxis Partners or a partner organization collects data from a large sample that asks about willingness to participate in clinical trials as well as demographic characteristics.

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Appendix A - Logit Model Variables (including IVs, DVs and controls) for RQ2 to RQ4

Survey Question	Code
<p>C6. Are you <u>currently</u> covered by any of the following types of health insurance or health coverage plans?</p> <ol style="list-style-type: none"> Insurance through a current or former employer or union Insurance purchased directly from an insurance company Medicare, for people 65 or older, or people with certain disabilities Medicaid, Medical Assistance, or any kind of government-assistance plan for those with low incomes or a disability TRICARE or other military health care VA (including those who have ever used or enrolled for VA health care) Indian Health Service Any other type of health insurance or health coverage plan (Specify) 	<i>healthinsurance*</i>
G6. Have you ever been invited to participate in a clinical trial?	<i>InvitedClinTrial</i>
G7. Did you participate in the clinical trial?	<i>ParticipatedClinTrial</i>
P1. What is your age?	<i>Age</i>
P2. On your original birth certificate, were you listed as male or female?	<i>BirthGender</i>
<p>P5. Which of the following best describe your current occupational status?</p> <ul style="list-style-type: none"> Employed Unemployed for 1 year or more Unemployed for less than 1 year Homemaker Student Retired Disabled Other-Specify 	<i>Occupation_Employed</i> <i>Occupation_1YUnEmployed</i> <i>Occupation_Less1YUnEmployed</i> <i>Occupation_Homemaker</i> <i>Occupation_Student</i> <i>Occupation_Retired</i> <i>Occupation_Disabled</i> <i>Occupation_Other_OS</i>
<p>P6. What is your marital status?</p> <ol style="list-style-type: none"> Married Living as married or living with a romantic partner Divorced Widowed 	<i>MaritalStatus</i>

<p>5. Separated 6. Single, never been married</p>	
<p>P7. What is the highest grade or level of schooling you completed?</p> <ol style="list-style-type: none"> 1. Less than 8 years 2. 8 through 11 years 3. 12 years or completed high school 4. Post high school training other than college (vocational or technical) 5. Some college 6. College graduate 7. Postgraduate 	<p><i>Education</i></p>
<p>P8. Are you of Hispanic, Latino/a, or Spanish origin? One or more categories may be selected. Mark all that apply.</p> <p>No, not of Hispanic, Latino/a, or Spanish origin Yes, Mexican, Mexican American, Chicano/a Yes, Puerto Rican Yes, Cuban Yes, another Hispanic, Latino/a, or Spanish origin</p>	<p><i>Hisp_Cat</i></p>
<p>P9. What is your race? One or more categories may be selected. Mark all that apply.</p> <p>White Black or African American American Indian or Alaska Native Asian Indian Chinese Filipino Japanese Korean Vietnamese Other Asian Native Hawaiian Guamanian or Chamorro Samoan Other Pacific Islander</p>	<p><i>Race_Cat2</i></p>
<p>P11. Do you think of yourself as...</p> <ol style="list-style-type: none"> 1. Heterosexual, or straight 2. Homosexual, or gay or lesbian 3. Bisexual 91. Something else - Specify 	<p><i>SexualOrientation</i> <i>SexualOrientation_OS</i></p>

<p>P15. Thinking about politics these days, how would you describe your own political viewpoint?</p> <ol style="list-style-type: none"> 1. Very Liberal 2. Liberal 3. Somewhat Liberal 4. Moderate 5. Somewhat Conservative 6. Conservative 7. Very Conservative 	<p><i>PoliticalViewpoint</i></p>
<p>P16. Thinking about members of your family living in this household, what is your combined annual income, meaning the total pre-tax income from all sources earned in the past year?</p> <ol style="list-style-type: none"> 1. \$0 to \$9,999 2. \$10,000 to \$14,999 3. \$15,000 to \$19,999 4. \$20,000 to \$34,999 5. \$35,000 to \$49,999 6. \$50,000 to \$74,999 7. \$75,000 to \$99,999 8. \$100,000 to \$199,999 9. \$200,000 or more 	<p><i>IncomeRanges</i></p>
<p>Additional, non-survey variable that indicates whether survey responses were collected after the 2020 Pandemic was declared a public health emergency</p>	<p><i>pandemic</i></p>

* Derived variable to categorize the health care coverage variables (C6a-h)