








BRIEF REPORT

A case study of inclusion of rural populations in research: Implications for science and health equity

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Abstract

Prior research highlights that rural populations have been historically under-represented/excluded from clinical research. The primary objective of this study was to describe the inclusion of rural populations within our research enterprise using Clinical Research Management System demographic information at a large academic medical center in the Southeast. This was a cross-sectional study using participant demographic information for all protocols entered into our Clinical Research Management System between May 2018 and March 2021. Descriptive statistics were used to analyze the representation of rural and non-rural participants and demographic breakdown by age, sex, race, and ethnicity for our entire enterprise and at the state level. We also compared Material Community Deprivation Index levels between urban and rural participants. Results indicated that 19% of the research population was classified as rural and 81% as non-rural for our entire sample, and 17.5% rural and 82.5% urban for our state-level sample. There were significant differences in race, sex, and age between rural and non-rural participants and Material Community Deprivation Indices between rural and non-rural participants. Lessons learned and recommendations for increasing the inclusion of rural populations in research are discussed.

Study highlights**WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?**

Rural populations have been historically excluded from research and there are many documented barriers to increasing inclusion of rural populations in research. These barriers include proximity to academic medical centers, limited infrastructure, including lack of research staff, electronic health records, and data collection capacity to support clinical trials. Further, research mistrust, lack of awareness of the potential benefits of research, and provider-level barriers including high turnover and lack of provider buy-in to participate in clinical trials. There is limited data to guide the inclusion of rural populations in research studies. There is no standardized definition of “rural” in the research community, no

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clear benchmarks to guide inclusion and limited guidance on how to consider rurality in analyses.

WHAT QUESTION DID THIS STUDY ADDRESS?

We used a case study approach to understand the state of inclusion of rural participants in research at a large academic medical center to serve as a starting point to monitor the inclusion of rural populations in research and to inform the development of strategies and recommendations to improve such inclusion.

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?

Our analysis describes the inclusion of rural participants in our research activities at rates that mirror state and US rural population estimates and highlights. We also found higher levels of area deprivation in rural research participants. We provide recommendations based on our experience monitoring inclusion that can be used by other CTSA's to think more comprehensively about the inclusion of rural research participants.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

Our findings and recommendations to the translational science community including defining rural in all studies and increasing accessibility at the study design level for inclusion of rural populations have the potential to increase the inclusion of rural participants in research and encourage further inquiry into this important area of science.

INTRODUCTION

Rural populations have been historically excluded from research.¹ Given there are documented chronic disease health disparities in rural populations,^{1,2} it is critical that research addressing these conditions is representative of rural populations. There are many documented barriers to increasing the inclusion of rural populations in research. Barriers are multilevel and include structural-level barriers including proximity to academic medical centers, limited infrastructure and research staff, internet capacity, electronic health records, and data collection capacity to support clinical trials; individual-level barriers including research mistrust and lack of awareness of the potential of benefits of research; and provider-level barriers including high turnover of health-care providers and lack of provider buy-in to participate in clinical trials.³⁻⁸ In the midst of these barriers, there are also strengths and opportunities in rural communities including community cohesion, resilience, and community-driven solutions to problems. These traits make rural communities ideal partners for research as community-informed solution have greater potential for impact and sustainability.³

Rurality is a complex term, as people living in rural areas represent a highly heterogeneous population. There is no standardized definition of “rural” in the research community; however, there are many federally recognized definitions of rural.⁴⁻⁶ Although many federal agencies have recognized rural populations as a priority research

population (e.g., National Institutes of Health), there are currently no formal reporting requirements from federal agencies on the inclusion of rural populations in research.

The Integrating Special Populations Core, within the Clinical and Translational Science Institute at a large Southeastern United States university, focuses on increasing the capacity of investigators to include historically excluded populations in research. In the state of North Carolina (NC), where our institution resides, it is estimated that ~19% of people live in rural areas.⁷ We developed a process to gather a snapshot of clinical research administrative data, detailed elsewhere.^{8,9} Our primary objective was to formulate a snapshot of the inclusion of rural populations within our research enterprise and in NC, where our institution is located. We compared the data to state-level population census data to benchmark our inclusion of rural populations and compared Material Community Deprivation Index (MCDI) scores¹⁰ across rural and urban demographics. These data provide contextual information that contributes to understanding barriers to inclusion in research.

METHODS

Data collected

We obtained data from the University's Clinical Research Management System (CRMS), OnCore,[®] which captures

information about research participation in clinical trials and other prospective studies. The data included participant demographic information for all protocols entered into OnCore between May 2018 through March 25, 2021. Protocols could be of any status including open, closed to accrual, abandoned, or suspended. This study (Pro00107175) was deemed exempt by our IRB since the information requested is anonymous and reported only in the aggregate.

Measures

Rurality was determined by Rural–Urban Commuting Area (RUCA) codes designated as nonmetropolitan (RUCA codes of 4 or above). RUCA codes use population density, urbanization, and daily commuting to categorize census tracts.⁴ RUCA codes 1–10 represent metropolitan, micropolitan, small town, and rural commuting areas that are based on the size and direction of the primary commuting flows.¹¹ We used the ZIP Code approximation for RUCA codes.⁴ Primary RUCA codes 1, 2, or 3 were considered non-rural/metro and codes 4 through 10 as rural, with numbers 4–6 representing micropolitan (7–10) small town/rural.⁴

The age of a participant at the time of enrollment was reported in years. We grouped years of age into the following categories: 5 and under, 5–14, 15–24, 25–34, 35–59, 60–74, 75 and over.

Sex in OnCore is classified as male or female.

Race in OnCore is classified using six values: (1) American Indian or Alaska Native, (2) Asian, (3) Black or African American, (4) Native Hawaiian or Other Pacific Islander, (5) White, (6) 2 or more races. We created a grouped value “reported two or more” encompassing “2 or more races” and any combination of any two or more of the available six OnCore race selections.

Ethnicity in OnCore is classified as Hispanic (Latinx) or non-Hispanic (non-Latinx). Ethnicity is recorded independent of race.

MCDI uses six different census tract-level variables derived from the 2015 5-year American Community Survey for all the U.S. census tracts. The variables include (1) the fraction of households with income below poverty level in the last 12 months, (2) median household income in the past 12 months, (3) fraction of the population with low educational attainment, (4) fraction of population with no health insurance coverage, (5) fraction of households receiving public assistance income, food stamps or supplemental nutrition assistance program in the past 12 months, and (6) the fraction of houses that are vacant. Scores range from 0 to 1 and lower values denote lower “disadvantage.”¹⁰

Data analysis

Descriptive statistics were used to analyze the representation of participants that were rural and non-rural. The demographic breakdown by age, sex, race, and ethnicity is also presented. Unknown values including ZIP codes (8.6% of the entire sample of 285,209 records) representing coding errors or international locations, were excluded. Demographic characteristics were compared between rural and non-rural using Chi-square tests. Effect sizes were examined using the Cramer's V for race and age or Phi Coefficient for sex and ethnicity, with effect size based on Cohen's *d* criteria.¹¹ To provide a benchmark of rural inclusion we compared the NC CTSI CRMS sample to NC Census data on rurality defined by RUCA codes and characterized the demographic breakdown of rural and non-rural participants.¹² MCDI scores were compared between rural and non-rural participants in the full CRMS sample and those with NC zip codes (Table S1). Cohen's *d* criterion was used to compute effect sizes, and significance was set at ($p < 0.05$) for all statistical comparisons.

RESULTS

Of the total unique participants in OnCore ($N = 260,494$), 49,673 (19%) were classified as rural and 210,821 (81%) as non-rural. Of those residing in NC (214,778; 82% of the total sample), 37,568 (17.5%) were classified as rural and 177,210 (82.5%) non-rural. As a benchmark, the population in NC per the 2020 Census is 21.4% rural and 78.6% non-rural, using RUCA code to define rural. The frequencies (%) of demographic characteristics between rural and non-rural participants in the full CRMS sample and participants with NC zip codes, as well as the NC Census benchmark sample are reported in Table 1. Effect sizes for comparisons in rural and non-rural participants in the CRMS samples are also presented.

Statistical comparison of demographics between rural and non-rural participants in the CRMS sample found significant differences by age (0–5 years, $p < 0.0001$), sex (females, $p < 0.0001$), white race ($p < 0.0001$), and ethnicity (non-Latinx, $p < 0.0001$) for the full CRMS and NC-only subgroup. Visual inspection of NC Census benchmark comparisons indicates differences (5% or higher) in multiple age categories, race (in particular African American participants), ethnicity between our NC-only CRMS sample.

The mean (SD) and effect sizes for standardized differences of MCDI between rural and non-rural populations in the full CRMS sample and the NC subgroup are reported in Table 2. The means (SD) were higher for rural participants compared with non-rural participants

TABLE 1 Demographic characteristics of CTSI CRMS data and NC Census data.

Variable	CTSI CRMS data			CTSI CRMS data for NC			Census data for NC 2020		
	Rural (N = 49,673)	Non-rural (N = 210,821)	Effect size	Rural (N = 37,568)	Non-rural (N = 177,210)	p-value	Rural (N = 2,229,746)	Non-rural (N = 8,209,667)	Effect size
Age									
0–5	2467 (5.0%)	15,443 (7.3%)	0.12	2088 (5.6%)	12,995 (7.3%)	<0.0001*	113,629 (5.1%)	460,844 (5.6%)	0.1
5–14	1704 (3.4%)	11,138 (5.3%)		1372 (3.7%)	8963 (5.1%)		260,339 (11.7%)	1,044,713 (12.7%)	
15–24	2479 (5.0%)	15,942 (7.6%)		2067 (5.5%)	14,032 (7.9%)		273,971 (12.3%)	1,127,438 (13.7%)	
25–34	3661 (7.4%)	27,670 (13.1%)		3037 (8.1%)	24,718 (13.9%)		244,653 (11%)	1,117,447 (13.6%)	
35–59	16,568 (33.4%)	69,425 (32.9%)		12,316 (32.8%)	56,686 (32.0%)		688,151 (30.9%)	2,652,396 (32.3%)	
60–74	17,671 (35.6%)	55,851 (26.5%)		12,926 (34.4%)	46,203 (26.1%)		454,914 (20.4%)	1,293,048 (15.8%)	
75 and over	5112 (10.3%)	15,236 (7.2%)		3752 (10.0%)	13,510 (7.6%)		194,089 (8.7%)	513,781 (6.3%)	
Missing	11 (0.0%)	116 (0.1%)		10 (0.0%)	103 (0.1%)		—	—	
Gender									
Female	27,506 (55.4%)	124,715 (59.2%)	0.03	21,239 (56.5%)	109,129 (61.6%)	<0.0001*	1,140,167 (51.1%)	4,231,882 (51.6%)	0.1
Male	22,167 (44.6%)	86,102 (40.8%)		16,329 (43.5%)	68,078 (38.4%)		1,089,579 (48.9%)	3,977,785 (48.5%)	
Missing	0 (0%)	4 (0.0%)		0 (0%)	3 (0.0%)		—	—	
Race									
White	34,952 (70.4%)	138,744 (65.8%)	0.09	25,311 (67.4%)	110,837 (62.5%)	<0.0001*	1,474,772 (66.1%)	5,013,710 (61.1%)	0.04
Black	11,452 (23.1%)	48,748 (23.1%)		9539 (25.4%)	46,292 (26.1%)		438,824 (19.7%)	1,701,394 (20.7%)	
Asian	132 (0.3%)	5085 (2.4%)		103 (0.3%)	4284 (2.4%)		17,361 (0.8%)	325,690 (4%)	
American Indian	729 (1.5%)	743 (0.4%)		700 (1.9%)	681 (0.4%)		51,924 (2.3%)	78,108 (1%)	
Native Hawaiian	49 (0.1%)	207 (0.1%)		43 (0.1%)	153 (0.1%)		1010 (0.1%)	7508 (0.1%)	
2 or more races	484 (1.0%)	4688 (2.2%)		436 (1.2%)	4413 (2.5%)		120,417 (5.4%)	496,973 (6.1%)	
Other	—	—		—	—		125,438 (5.6%)	586,284 (7.1%)	
Missing	1875 (3.8%)	12,606 (6.0%)		1436 (3.8%)	10,550 (6.0%)		—	—	
Ethnicity									
Non-Hispanic	40,689 (81.9%)	171,713 (81.4%)	0.06	31,118 (82.8%)	147,014 (83.0%)	<0.0001*	2,023,745 (90.8%)	7,297,071 (88.9%)	0.05
Hispanic or Latino	825 (1.7%)	9213 (4.4%)		771 (2.1%)	8444 (4.8%)		206,001 (9.2%)	912,596 (11.1%)	
Missing	8159 (16.4%)	29,895 (14.2%)		5679 (15.1%)	21,752 (12.3%)		—	—	

*Denotes statistical significance (p -value < 0.05) for Chi-square test of independence for categorical variables.

in all demographic categories. Additionally, moderate ($0.5 \leq$ and < 0.8) to large (≥ 0.8) effect sizes were observed for most demographic categories, except for the “Hispanic or Latino” category (effect size = 0.43 entire CMRS sample and effect size = 0.40 for NC sample), indicating substantial mean differences in the MCDI between rural and non-rural participants. This further underscores that the means of the deprivation indices in the majority of demographic categories differ by more than 0.5 standard deviations between rural and non-rural participants.

DISCUSSION

We sought to determine the inclusion of participants that were rural in research at a large academic medical center. Consistent with our overall CTSI sample (19% rural), approximately, 20% of the entire US population lives in rural areas.¹³ Our NC sample had a slightly lower representation of the rural population (17.5%) than census data. It is also important to note when we compare NC Census-level data and our participants in NC, we see differences in the inclusion of rural subpopulations suggesting that for some subpopulations, we need more targeted rural recruitment.

Further, we found statistically significant differences in race, ethnicity, sex, and age in rural participants compared with non-rural participants, although the associations were small to negligible. It is well documented that many minoritized groups, regardless of their rurality, are historically excluded from research,^{14,15} and our data suggest perhaps for some groups, even more so when rurality is considered. We saw the largest differences in the inclusion of Latinx populations, in both the full CRMS sample and those within NC showing that Latinx rural populations are underrepresented compared with urban populations. We did observe relatively higher rates of inclusion of rural adults 65 and older compared with urban adults. These numbers are likely driven by the larger number of older adults residing in rural areas¹⁶ and potentially by protocols focused specifically on older rural populations. This suggests the need for even more granular analysis of our data down to the protocol level and continued engagement of rural communities in research. Finally, we note that the COVID-19 pandemic could have affected shifts in rural population participation in research. The increased contact with health systems and the need to reimagine research, leading to many more remote research opportunities may have removed some barriers to participation.¹⁷ MCDI levels were higher in all demographic comparisons between urban and rural, suggesting that rural participants live in areas that are more deprived compared with

urban participants. Other studies have supported the relationship between higher community deprivation using the Area Deprivation Index and rurality.¹⁸ The level of deprivation observed may contribute to structural barriers that prevent participation in research and limit the effectiveness of intervention programs and policies being tested.¹⁹ For example, in those who identify as Asian and African American or Black we saw slightly lower rates of inclusion compared with population-level data and higher MCDI levels, suggesting that higher levels of deprivation may in part explain barriers to research participation. In contrast, rural 60–75 year olds were over-represented in our CRMS sample compared with the rural population-level data of the same age, even with higher deprivation indices, suggesting that we maybe implementing recruitment strategies in this population that help to overcome structural impediments to research participation. This should be explored in future work as this is based on our observation of the data presented. Meaningful, long-term research partnerships with rural communities are needed that center rural people and voices in the development of research agendas and include rural communities throughout the research process. In turn, the new knowledge and programs created will be meaningful for whom they are designed. Further, prioritization of research funding focusing on rural populations and building local research infrastructure in rural communities is needed.¹⁵

There are limitations of this analysis, including our inability to determine how many study protocols were included that focused specifically on recruiting only rural populations, which could bias the overall institutional inclusion rates reported. Even with such limitations, the rural snapshot provides a starting point for understanding the overall inclusion of rural populations at an institutional level. Future steps for our group involve looking at this data at the individual protocol level to determine differences based on clinical research units and looking at changes over time to evaluate how recommendations are affecting inclusion.

Recommendations

Based on our experience and guided by the literature, we propose the following recommendations when considering the inclusion of rural populations in research at the enterprise level:

Provide benchmark inclusion guidance

There are few relevant benchmarks for rural inclusion. Adequacy of inclusion depends largely on where

TABLE 2 Material community deprivation index was reported as mean (SD) for rural and non-rural research participants.

Variable	Community deprivation index			Community deprivation index for NC		
	Rural (N = 48,986)	Non-rural (N = 208,645)	Effect size for mean difference using Cohen's <i>d</i>	Rural (N = 37,042)	Non-rural (N = 175,474)	Effect size for mean difference using Cohen's <i>d</i>
Age						
0–5	0.453 (0.0642)	0.369 (0.0959)	0.91	0.458 (0.0642)	0.381 (0.0919)	0.88
5–14	0.448 (0.0632)	0.359 (0.0985)	0.94	0.452 (0.0654)	0.373 (0.0938)	0.87
15–24	0.452 (0.0621)	0.382 (0.0936)	0.77	0.455 (0.0639)	0.390 (0.0900)	0.74
25–34	0.444 (0.0645)	0.369 (0.0946)	0.82	0.447 (0.0666)	0.374 (0.0940)	0.80
35–59	0.451 (0.0613)	0.359 (0.0919)	1.06	0.455 (0.0646)	0.365 (0.0917)	1.03
60–74	0.451 (0.0606)	0.359 (0.0872)	1.12	0.453 (0.0654)	0.362 (0.0872)	1.10
75 and over	0.447 (0.0645)	0.357 (0.0874)	1.09	0.447 (0.0718)	0.359 (0.0873)	1.05
Missing	0.456 (0.0500)	0.398 (0.102)	0.58	0.458 (0.0521)	0.406 (0.101)	0.53
Gender						
Female	0.451 (0.0622)	0.366 (0.0923)	0.97	0.453 (0.0664)	0.370 (0.0917)	0.94
Male	0.449 (0.0615)	0.359 (0.0910)	1.05	0.453 (0.0650)	0.366 (0.0897)	1.02
Missing	—	0.324 (0.138)	—	—	0.369 (0.129)	—
Race						
White	0.443 (0.0603)	0.348 (0.0866)	1.16	0.445 (0.0643)	0.352 (0.0858)	1.13
Black	0.469 (0.0591)	0.405 (0.0880)	0.77	0.472 (0.0627)	0.406 (0.0874)	0.78
Asian	0.428 (0.0855)	0.312 (0.0987)	1.18	0.427 (0.0892)	0.319 (0.0979)	1.10
American Indian	0.527 (0.0396)	0.432 (0.126)	1.00	0.529 (0.0354)	0.442 (0.123)	0.97
Native Hawaiian	0.435 (0.0794)	0.355 (0.101)	0.82	0.437 (0.0837)	0.373 (0.0943)	0.70
2 or more races	0.435 (0.0695)	0.387 (0.0933)	0.53	0.437 (0.0712)	0.391 (0.0914)	0.51
Missing	0.448 (0.0662)	0.376 (0.0961)	0.78	0.450 (0.0701)	0.385 (0.0932)	0.72
Ethnicity						
Non-Hispanic	0.451 (0.0618)	0.362 (0.0918)	1.02	0.453 (0.0658)	0.367 (0.0912)	0.99
Hispanic or Latino	0.441 (0.0738)	0.403 (0.0906)	0.43	0.442 (0.0745)	0.408 (0.0873)	0.40
Missing	0.448 (0.0611)	0.357 (0.0892)	1.09	0.453 (0.0645)	0.365 (0.0875)	1.05

Note: The percentages are calculated out of number of patients in each row; **Moderate (0.5 \geq and <0.8) to large (\geq 0.8) effect sizes were observed for most demographic categories, except for the “Hispanic or Latino” category (effect size = 0.43 entire sample and 0.40 for NC sample), indicating substantial mean differences in the MCDI between rural and non-rural participants.

geographically the research is conducted, the degree to which individuals can participate (e.g. physical infrastructure vs. remote), and the focus of the research with respect to disease and intervention type. The Rural Health Information Hub, supported by the Health Resources and Service Administration provides researchers a starting point with collated rural resources to inform inclusion.²⁰

Define and measure rurality in all research studies

Rurality is heterogeneous, there are many ways to measure rurality, and recent research suggests that some definitions may be better than others depending on the

purpose of analysis.²¹ Research organizations should encourage and support investigators as they measure rurality as part of their research using methods and definitions that are most appropriate to the issue being studied.

Consider the inclusion of rural populations at the study design level

Investigators need to consider how they are designing studies to be inclusive of rural populations. Travel distances, the digital divide, and the research infrastructure available at clinics, all need to be considered.^{17,22,23} Decentralized clinical trials that include remote research methods have the potential to increase access. However,

a digital divide exists in many rural areas.²⁴ Therefore, we must ensure we do not further inequities by relying only on remote research, and we must continue to advocate for physical infrastructure that can increase capacity for clinical research at the local level.

Involve rural communities as partners throughout the research lifecycle

Community-engaged approaches are key to engaging rural populations in research. Engagement is needed throughout the research lifecycle, and engagement is key to enhancing inclusion.²⁵ There are many unique characteristics and strengths of rural communities and research must be tailored accordingly for maximum community benefit.⁹ Providing resources and infrastructure to community partners and community clinics is also key to sustaining research in rural communities including adequate payment and resources given to community partners.

CONCLUSIONS

We offer recommendations to the translational science community to increase the inclusion of rural participants in research based on our experience and literature. Future research should consider augmenting these recommendations with qualitative data from investigators who have been able to employ strategies to increase the inclusion of rural populations in their research. This should be integrated with rural community perspectives on how to increase inclusion in research.

AUTHOR CONTRIBUTIONS

D.N. wrote the manuscript; D.N., K.L., S.S., D.K., J.G and K.E. designed the research, A.P. analyzed the data; F.M., contributed to critical editing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declared no competing interests for this work.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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