

Inadequacy and underreporting of study subjects' race and ethnicity in federally funded pelvic floor research



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BACKGROUND: The inclusion of participants who are Black, Indigenous people of color, and participants of various ethnicities is a priority of federally sponsored research.

OBJECTIVE: This study aimed to describe the reporting of race and ethnicity in federally funded research published by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development—funded Pelvic Floor Disorders Network.

STUDY DESIGN: Pelvic Floor Disorders Network publications were reviewed to determine whether race or ethnicity was reported. The number of participants included in each manuscript who were identified as White, Black, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and “other,” and the number of participants who identified as having Hispanic ethnicity were recorded. Data were analyzed by publication and by the pelvic floor disorder investigated, including urinary incontinence, pelvic organ prolapse, fecal incontinence, pregnancy-related pelvic floor disorders, and multiple pelvic floor disorders. Many publications reported on overlapping patient populations, which included primary trials and secondary analyses and studies. Data were analyzed both by counting participants every time they were reported in all papers and by counting the unique number of participants in only the original trials (primary paper published).

RESULTS: A total of 132 Pelvic Floor Disorders Network publications were published between 2003 and 2020. Of these, 21 were excluded because they were methods papers or described research without

participants. Of the 111 remaining articles, 90 (81%) included descriptions of race and 55 (50%) included descriptions of ethnicity. All 13 primary trials described race and 10 of 13 (76.9%) described ethnicity. Of those publications that described race, 50 of 90 (56%) included only the categories of “White,” “Black,” and “Other,” and 14 of 90 (16%) only described the percentage of White patients. Of the 49,218 subjects, there were 43,058 (87%) with reported race and 27,468 (56%) with reported ethnicity. Among subjects with race and ethnicity reported, 79% were reported as White, 9.9% as Black, 0.4% as Asian, 0.1% as American Indian or Alaska Native, and 4% as “other,” whereas 13% were reported to be of Hispanic ethnicity. The racial and ethnic diversity varied based on the pelvic floor disorder studied ($P<.01$), which was driven by pregnancy-related and fecal incontinence studies because these had lower proportions of White patients than studies of other pelvic floor disorders.

CONCLUSION: Federally funded Pelvic Floor Disorders Network research does not consistently report the race and ethnicity of participants. Even in the publications that report these characteristics, Black, Indigenous people of color, and people of Hispanic ethnicity are underrepresented. Consistent reporting and recruitment of a diverse population of women is necessary to address this systemic inequity.

Key words: ethnicity, gynecology, healthcare disparity, pelvic floor disorder research, race

Introduction

Racism and ethnic disparities in women's health are national crises.¹ Data on birth outcomes and female cancer screening and outcomes in Black, Indigenous, and people of color (BIPOC) lags behind the data available on White women.¹ In urogynecology, BIPOC women have a greater difficulty in accessing and utilizing care for pelvic organ prolapse (POP), urinary incontinence (UI), fecal incontinence (FI), and pregnancy-related pelvic floor injury.^{2–5}

Barriers to solving inequities stem from the lack of representation of BIPOC participants in large-scale, high-

quality research on women's health.⁶ The National Institutes of Health (NIH) prioritized the inclusion of racially and ethnically diverse women in NIH-funded research on women's health outcomes.⁷ Nonetheless, non-Hispanic White women are overrepresented in most of the women's health research.¹

The NIH-funded Pelvic Floor Disorder's Network (PFDN), a multicenter consortium of 9 federally funded centers, generates multicenter research focused on investigating pelvic floor disorders in women.⁸ We aimed to determine the racial and ethnic diversity in NIH-sponsored, peer-reviewed PFDN publications from its first publication in 2003 to August 2020 and to compare racial and ethnic disparities in pelvic floor disorders as the focus of the manuscript.

Materials and Methods

We reviewed all PFDN publications since inception of this NIH-funded research

network in 2001. The PFDN list of publications is publicly available and was accessed by our team on October 8, 2020 (<https://pfdnetwork.azurewebsites.net/ListofPublications/tabid/340/ctl/ViewPublications/mid/2023/Default.aspx>). The institutional review board (IRB) of the New York Medical College confirmed that this study did not need IRB approval because this study did not include human subject research. Three authors (C.L.G., K.V.M., and R.G.R.) each reviewed one-third of the papers and extracted and classified the data. Two authors (C.L.G. and K.V.M.) reviewed any questions or conflicts about the extracted data. Data that were extracted included the PubMed Identifier, title, publication date, total number of participants, whether race was reported (yes or no), number of participants identified in the paper as White, Black, Asian, American Indian or Alaska Native, and “other,” whether ethnicity

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AJOG at a Glance

Why was this study conducted?

This study aimed to describe the reporting of race and ethnicity in federally funded research published by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development—funded Pelvic Floor Disorders Network (PFDN).

Key findings

Federally funded PFDN research does not consistently report the race and ethnicity of participants, and in the studies that report these characteristics, Black, Indigenous people of color, and people of Hispanic ethnicity are underrepresented.

What does this add to what is known?

Although federal funding requires both diverse recruitment planning in applications for funding and reporting on the race and ethnicity of the women who were recruited, these characteristics have not been consistently included in PFDN publications. Only 81% of articles included information about race and half included a description of ethnicity.

was reported (yes or no), number of participants identified as Hispanic, whether other healthcare disparities were reported (yes or no), and the type of other healthcare disparities noted. These 3 authors then classified each publication according to which PFDN trial the paper reported on, whether the paper was the “primary paper” for the trial, and according to the pelvic floor disorder (PFD) investigated, including UI, POP, FI, pregnancy-related PFDs, or multiple PFDs. Many publications reported on overlapping patient populations. Therefore, we analyzed data both by counting participants every time they were reported in every study (participants reported [PRs]) and by counting unique participants in the original trials (primary paper published).

Data were analyzed by publication and by PFD condition. Numbers of publications and PRs were reported as counts. The number of participants included who were identified as White, Black, Asian, American Indian or Alaska Native, “other,” or of Hispanic ethnicity were reported as counts and percentages. Chi-squared tests were used to compare the proportion of papers that reported on race and ethnicity. Statistical significance was assessed at the $P < .05$ level. All analyses were carried out using Statistical Product and Service Solutions,

version 25.0 (International Business Machines Corporation, Chicago, IL).

Results

A total of 132 PFDN publications were published between 2003 and 2020. Of these, 21 papers were excluded because they were methods papers or papers that described research without participants. Of the 111 remaining articles, 90 (81%) included descriptions of the race and 55 (50%) included descriptions of the ethnicity of the included participants. All 13 primary trials papers described race and 10 of 13 (76.9%) described ethnicity. Of the publications that described race, 50 of 90 (56%) included only the racial descriptors White, Black, and “other,” and 14 of 90 (16%) only described the percentage of White patients.

Of the 49,218 PRs, there were 43,058 (87%) for whom race was reported and 27,468 (56%) for whom ethnicity was reported. Among the PRs with race and ethnicity reported, 79% were reported as White, 9.9% as Black, 0.4% as Asian, 0.1% as American Indian or Alaska Native, and 4% as “other,” whereas 13% were identified as being of Hispanic ethnicity.

Of the 3906 unique patients recruited to primary studies, all had a reported race and 3337 (85.4%) had a reported ethnicity. Ethnic distribution was similar

between PRs and unique patients (13.0% vs 13.1% Hispanic; $P = .09$), but racial distribution was significantly different (79.0% vs 82.5% White; $P < .01$). [Table 1](#) displays the racial and ethnic distribution by type of PFD studied for both PRs and unique participants in the original trials. The racial and ethnic diversity by analysis of PRs and of unique patients varied by PFD study topic ($P < .01$). Differences were driven by pregnancy-related and FI studies with lower proportions of White patients than studies of other PFDs ([Tables 1](#) and [2](#)).

Comment

Principal findings

Although federal funding requires both (1) an estimate of the number of women from various races and ethnicities to be recruited to studies in applications for funding and (2) later reporting of the number of women of various races and ethnicities that were recruited, these characteristics have not been consistently included in publications. We found that federally funded PFDN research does not consistently report the race and ethnicity of study participants. Only 81% of articles included information about the race of participants and half included a description of ethnicity. Even among the studies that reported these characteristics, BIPOC and people of Hispanic ethnicity were underrepresented.

Clinical implications

Reporting of race and ethnicity in research could lead to more awareness about recruitment of a diverse population and will inform future knowledge about racial differences in PFD prevalence, degree of bother, risk factors, access to medical treatment and surgery, and differences in outcomes.

Racial descriptions were limited to reporting the number of Black and White women and rarely included women of other races. In 1993, the NIH Revitalization Act directed the NIH to establish guidelines for the inclusion of women and marginalized populations in clinical research.⁹ This law stated that “. . . women and minorities must be included in all NIH-funded research,

TABLE 1
Numbers for participants reported

Characteristics	Urinary incontinence	Pelvic organ prolapse	Fecal incontinence	Pregnancy-related pelvic floor disorders	Multiple pelvic floor disorders	Total	P value
Number of publications	29	45	11	17	9	111	—
Number of PRs	13,780	16,996	6094	7126	5222	49,218	
Number of PRs with race reported (%)	12,610 (91.5)	13,243 (77.9)	5872 (96.4)	6188 (86.8)	5145 (98.5)	43,058 (87)	—
Number of White PRs (%)	11,124 (88.2)	11,487 (86.7)	3416 (58.2)	4340 (70.1)	3642 (70.8)	34,009 (79.0)	<.01
Number of Black PRs (%)	721 (5.7)	642 (4.8)	1171 (19.9)	1030 (16.6)	703 (13.7)	4267 (9.9)	
Number of Asian PRs (%)	26 (0.2)	15 (0.1)	5 (0.1)	129 (2.1)	0	175 (0.4)	
Number of Native American PRs (%)	25 (0.2)	14 (0.1)	9 (0.2)	0	0	48 (0.1)	
Number of "other" PRs (%)	384 (0.3)	491 (3.7)	216 (3.7)	375 (6.1)	257 (5.0)	1723 (4.0)	
Number of PRs with ethnicity reported (%)	5433 (39.4%)	9365	5789	2782	4099	27,468 (56%)	—
Number of Hispanic ethnicity PRs (%)	692 (12.7)	959 (10.2)	1113 (19.2)	240 (8.6)	616 (15.0)	3620 (13.0%)	<.01

Data are expressed as number or number (percentage).

PRs, participants reported.

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unless a clear and compelling rational and justification establishes . . . that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.” The NIH policy further outlines that cost cannot be a consideration for inclusion and that if considerable differences in disease processes are anticipated, trial design should take this into account. The NIH strongly encourages the inclusion of race and ethnicity and analyses that investigate differences in disease states and outcomes for these subpopulations. The PFDN was established in 2001 to establish collaborative research on PFDs and improve patient care⁸ after the NIH mandate to include minoritized populations and to specify the race and ethnicity of participants. Furthermore, the International Committee of Medical Journal Editors guidelines for reporting race and ethnicity state that authors should define how they measured race and ethnicity and justify the relevance of reporting (<http://www.icmje.org/recommendations/browse/manuscript-preparation/preparing-for-submission.html>). Our work suggests that research could more closely adhere to these guidelines.

In addition, for PFDN publications, BIPOC and women of Hispanic ethnicity are underrepresented with only 10.4% of participants identified as Black, Asian or American Indian or Alaska Native and only 13% identified as being of Hispanic ethnicity. US census data indicate that 76.3% of the population is White, 13.4% Black, 5.9% Asian, 1.3% American Indian or Alaska Native, and 18.5% of the population is Hispanic.¹⁰ In our study, the distribution of races reported was 79% White, 9.9% Black, 0.4% Asian, and 0.1% American Indian or Alaska Native. The population in federally funded PFDN research had fewer participants in every other racial and ethnicity group except for White race. These statistics fall short of the proportion of BIPOC in the US population and indicate that there exists systemic racism in research on PFD.

Some PFDN studies describe differences in PFD prevalence,^{11,12} degree of bother,^{13,14} and risk factors^{15,16} by racial

TABLE 2
Numbers for primary trials (unique participants)

Characteristics	Urinary incontinence	Pelvic organ prolapse	Fecal incontinence	Pregnancy-related pelvic floor disorders	Multiple pelvic floor disorders	Total	P value
	5	3	2	1	2	13	—
Number of primary publications	1553 (100)	871 (100)	430 (100)	921 (100)	131 (100)	3906	—
Number of unique participants with race reported ^a	1371 (88.2)	764 (87.7)	348 (80.9)	656 (71.2)	82 (62.6)	3221 (82.5)	<.01
White (%)	150 (9.6)	50 (5.7)	61 (14.1)	175 (19.0)	0	476 (11.2)	
Black (%)	8 (0.5)	7 (0.8)	2 (0.5)	35 (3.8)	0	52 (1.3)	
Asian (%)	10 (0.6)	6 (0.7)	0	0	0	16 (0.4)	
Native American (%)	110 (7.1)	38 (4.7)	18 (4.2)	55 (6.0)	25 (19.1)	246 (6.3)	
“other” (%)	181 (5.4)	100 (3.0)	36 (1.1)	921 (27.6)	50 (1.5)	3337	—
Number of unique participants with ethnicity reported	181 (17.0)	100 (11.5)	36 (8.4)	70 (7.6)	50 (100)	437 (13.1)	.01
Hispanic (%)							

Data are expressed as number or number (percentage).

^a All primary trials reported race.

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and ethnic differences. In a study evaluating women in an equal-access health-care system, prolapse prevalence was high and did not vary between racial groups, however, comparisons were limited to White and Black women only because of low numbers of other races.³ Prevalence of urgency and stress incontinence did vary by race in this population and prevalence was high in all groups.³ During 2005 through 2006, the National Health and Nutrition Examination Survey (NHANES) oversampled some groups, including Black populations and Mexican Americans, to provide better prevalence estimates. A cross-sectional study that utilized this 2005 through 2006 NHANES data for symptoms of pelvic floor disorders demonstrated no difference in the weighted prevalence of UI or prolapse by race or ethnicity.¹⁷ Ultimately, these data indicate the high prevalence of pelvic floor disorders across racial and ethnic groups and underscore the importance of more equal representation in PFD research. Functional disorders are likely to be influenced not only by ancestry, but also by other social determinants of health such as socioeconomic status, level of education, or insurance status. In a specialty in which care is largely driven by the level of symptom bother, it may be important to understand how these differences impact patient’s perception of disease. We know relatively little about how PFDs differentially affect Black and Hispanic women, but the existing research indicates that PFDs affect BIPOC. For example, a large study from a multicenter network indicated that race and ethnicity were not associated with the severity or bother for women before anti-incontinence surgery.¹⁸

Evidence suggests that BIPOC persons may have decreased access to surgical care and higher risks for poorer outcomes following treatment for PFDs. BIPOC persons are underrepresented in the population that received surgery for stress UI⁴ and POP.⁵ A review of 48,005 women in the 2005 to 2015 American College of Surgeons National Surgical Quality Improvement Program database demonstrated that far greater White women underwent prolapse surgery and

that Black women had higher complication rates. Furthermore, Hispanic and other underrepresented minoritized populations more likely underwent a less appropriate surgery (no apical suspension).¹⁹

Strengths and limitations

Study strengths include the consideration of all PFDN publications and the exclusion of only those papers that did not have study participants. We have used the NIH definitions for race and ethnicity reporting and applied those standards to the publications reviewed. Limitations include that we did not have access to data that may have been collected but were not included in publication. The race and ethnicity data entered and utilized in these studies may not reflect self-reported information. The limitations of electronic medical record documentation on race and ethnicity data have been demonstrated previously and significant discordance between documented and self-reported race and ethnicity has been reported.^{20,21} We chose to analyze our data based on patient representation in publications and the number of distinct individuals included in all research. This may overrepresent underreporting. We chose this as the unit of comparison because some ancillary studies recruited and included women who did not participate in the primary trial and it was impossible to determine the race and ethnicity of these additional participants. Multiple publications on the same skewed population of women compounds the problem of underrepresentation. Nonetheless, when we analyzed our data based on unique participants included in primary trials, our results were similar.

Conclusion

Over a nearly 20-year period, the PFDN has not reported on or included a representative fraction of BIPOC individuals or those of varied ethnicities. In addition, despite the data that suggest that functional disorders are influenced by a variety of other social determinants of health, few of these are included in pelvic floor research. Unfortunately, this

systemic racism limits our understanding of PFD and how to treat it among BIPOC women. Better reporting of these characteristics should be included in future research and more BIPOC individuals and women of Hispanic ethnicity must be included in clinical trials. In addition to including a more diverse patient population in pelvic floor research and investigating social determinants of health that impact outcomes, attention must also be paid to increasing the diversity among those conducting the research. Over the last year, the NIH has reprioritized the promotion of diversity, equity, and inclusion in biomedical research with the NIH UNITE initiative that plans to address structural racism in research by focusing on many facets including personnel inclusiveness, equity, and diversity (<https://www.acd.od.nih.gov/documents/presentations/02262021BiomedicalResearch.pdf>). The future of pelvic floor research will be greatly improved with a commitment to diversity in patient and investigator recruitment and support. ■

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