

# Racial and Ethnic Representation in Nephrolithiasis Guidelines: Are They Generalizable?

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<b>OBJECTIVE</b>	To assess whether clinical trials guiding kidney stone care adequately describe the race, ethnicity, and other key demographic variables of their study populations. Guidelines such as those from the American Urological Association represent the highest level of evidence informing clinical practice. We aim to investigate if studies on which they are based include sufficiently diverse patient populations for generalizable results.
<b>METHODS</b>	We reviewed American Urological Association/Endourological Society Guidelines for the Medical and Surgical Management of kidney stones for all referenced clinical trials reporting human subjects. Study populations were reviewed for reported sex/gender, race, ethnicity, and study country of origin.
<b>RESULTS</b>	Of the 381 studies referenced, 287 met inclusion criteria. Only 18 (6.3%) reported the race or ethnicity of their subjects, and 254 (87%) reported sex/gender. Among studies reporting any race or ethnicity data, there were 468,281 participants, of which 48.5% were White, 1.0% Black, 0.6% Hispanic/Latino, 0.2% Asian, 0.3% other, 0.04% American Indian/Alaska Native, and 0.001% Native Hawaiian/other Pacific Islander. The remaining 49.4% of subjects had insufficient information to categorize into a race or ethnicity category. Factors associated with decreased likelihood of reporting race or ethnicity included cross-sectional studies (OR 0.14, $P = .027$ ) and international studies (OR 0.93, $P = .012$ ).
<b>CONCLUSION</b>	A small proportion of studies cited in the kidney stone guidelines report patient race or ethnicity. Among studies reporting these data, minority patients are underrepresented. Future research should include subject racial composition and strive to enroll underrepresented patients to ensure broadly generalizable kidney stone care recommendations. UROLOGY xx: xxx–xxx, xxxx. © 2024 Elsevier Inc. All rights are reserved, including those for text and data mining, AI training, and similar technologies.

Diversity within clinical research is critical to ensuring that findings are generalizable across different racial and ethnic groups. Despite increasing awareness of this need, disparities in racial and ethnic representation in clinical research continue to be a prominent issue.<sup>1,2</sup> Only 43% of United States-based clinical trials include any information regarding the race or ethnicity of their subjects.<sup>2</sup>

In an effort to provide a framework for how race and ethnicity should be recorded and presented for clinical investigations, the National Institutes of Health (NIH) published guidelines for reporting race and ethnicity in

medical literature.<sup>3</sup> The guidelines encourage specific verbiage to describe race and ethnicity in published literature. Additionally, several groups have attempted to put forward guidelines for the methodologies of disclosing and collecting sociodemographic information, including race and ethnicity. The International Committee of Medical Journal Editors recommend reporting, at a minimum, descriptive data for demographic information, regardless of known relevance.<sup>4</sup> Authors are recommended to define several parameters regarding demographic considerations, including race, and justify why those parameters are used in studies. A disclosure should be made regarding who classified subjects' race and ethnicity and why the chosen classification system was used.

Within the field of urology, diversity in research has become particularly salient for clinical practice guidelines, which have been shown to include studies with patient populations that are not broadly representative.<sup>5–7</sup> The

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American Urological Association (AUA) guidelines for the medical and surgical treatment of kidney stones are widely recognized and followed by practicing urologists.<sup>8</sup> We aimed to evaluate the racial, ethnic, and gender reporting and composition of the studies cited within these guidelines. We hypothesized that the majority of studies referenced in the guidelines fail to report the racial and ethnic composition of their study populations. AUA guidelines for the medical and surgical treatment of kidney stones were identified as an appropriate and relevant body of literature for this review due to their significant influence on the treatment of kidney stones across the United States (US).<sup>8–10</sup> The guidelines for medical management of nephrolithiasis are reported based on systematic reviews published in *Recurrent Nephrolithiasis in Adults: Comparative Effectiveness of Preventative Medical Strategies* (2012), which was composed by the Agency for Healthcare Research and Quality.<sup>9</sup> The guideline authors also included 46 studies outside of this systematic review from studies published between 1948 and 2011 to supplement the Agency for Healthcare Research and Quality's work.

## METHODS

All studies cited by the AUA medical and surgical kidney stone management guidelines were reviewed. Studies cited within the guidelines were included if they reported the result of human subjects research. Systematic reviews, meta-analyses, commentaries, and basic science research were excluded. This study was exempt from review by the Institutional Review Board.

All studies were reviewed by two of three reviewers. Full text articles were obtained for the studies included in the review. Studies were assessed for any mention of the race, ethnicity, and gender/sex composition of the study

population, whether in the abstract, body of the manuscript, or tables/figures. Data were extracted from the individual publications using a standardized survey form completed by the reviewer for each study. Variables of interest included publication year, study aim, study type, intervention, measured outcome, random allocation, study phase, trial type, total number of participants, reporting of gender or sex, and reporting of race or ethnicity (Table 1).

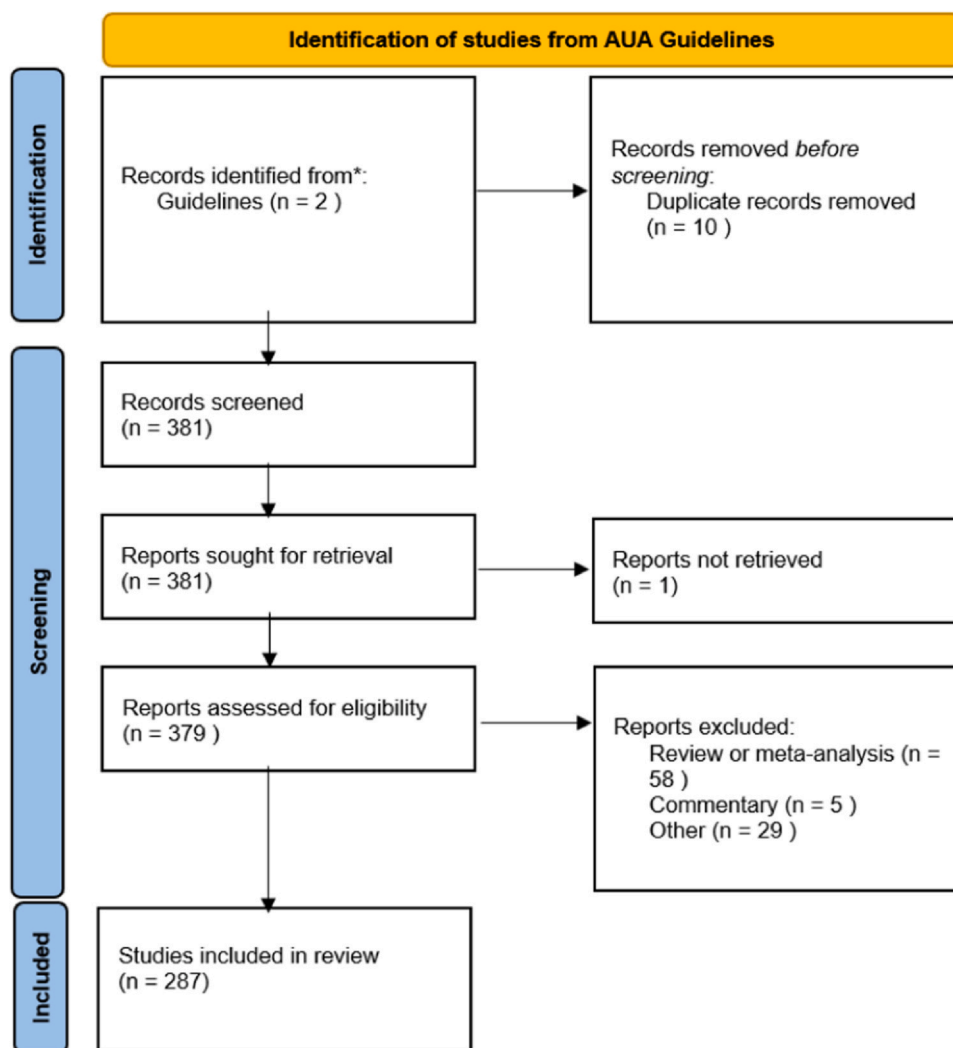
Descriptive statistics were used to summarize the general characteristics of the studies included in the review. This included the calculation of frequencies, percentages, means, and standard deviations to represent the distribution of study types, interventions, publication years, participant numbers, gender representation, racial and ethnic composition, and other relevant parameters. Univariate analyses were conducted to examine the associations between specific study characteristics and the reporting of race, ethnicity, or gender. Odds ratios with 95% confidence intervals were computed to identify significant factors associated with the likelihood of reporting these demographic details. Univariate logistic regression models were applied to examine the relationship between studies conducted in the US and the reporting of race or ethnicity, as well as other factors such as study type (eg, cross-sectional study, prospective study) and the reporting of gender. Those studies which reported the race or ethnicity of their study populations were further assessed for compliance with the NIH guidance on reporting race and national origin.<sup>3</sup>

## RESULTS

The guidelines for the medical and surgical treatment of kidney stones together cited a total of 391 publications.

**Table 1.** Characteristics of AUA guideline studies meeting inclusion criteria for the medical and surgical treatment of nephrolithiasis ( $n = 287$ )

	Number of studies (N)	% of total studies meeting inclusion criteria
Total studies reviewed	287	100
Studies reporting any race or ethnicity	18	6.3
Reporting white race	18	6.3
Reporting black race	11	3.8
Reporting hispanic/latino race	8	2.8
Reporting Asian race	6	2.1
Reporting American Indian/Alaska native race	3	1.0
Reporting other race	3	1.0
Reporting Native Hawaiian/ Other Pacific Islander Race	1	0.3
<i>Origin</i>		
United States Studies	141	49.1
International Studies	146	50.9
<i>Study characteristics</i>		
Randomized controlled trial	77	26.8
Non-randomized controlled trial	40	13.9
Prospective cohort study	96	33.4
Cross sectional cohort study	8	2.8
Retrospective cohort study	66	23.0



**Figure 1.** Prisma figure.

There were ten duplicate citations between the two guidelines, yielding a total of 381 unique publications. Fifty-eight of these publications were excluded because they were reviews or meta-analyses, five were excluded as commentary, 29 were excluded due to other exclusion criteria, and two were excluded as book chapters. In total, 287 studies were included in our review (Fig. 1).

#### Characteristics of Racial Representation

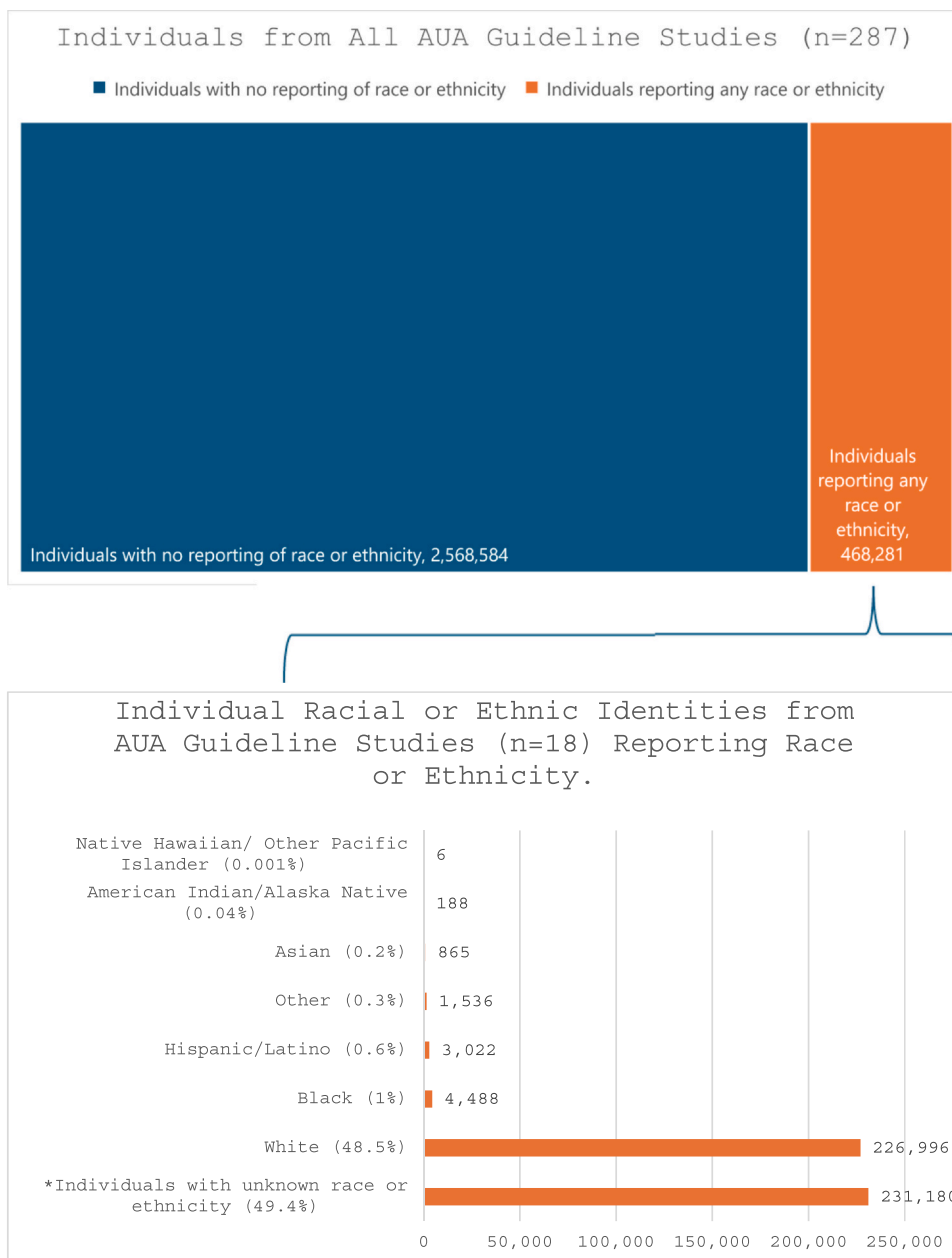
Of 287 studies, 18 (6.3%) reported any race or any ethnicity of their study populations. All 18 studies reported White race. Eleven of these studies (3.8%) reported Black race, eight studies (2.8%) reported Hispanic or Latino race or ethnicity, six studies (2.1%) reported Asian race, three studies (1.0%) reported American Indian/Alaska Native race, three studies (1.0%) reported any other race or other ethnicity, and one study (0.3%) reported Native Hawaiian/other Pacific Islander race (Table 1).

Among the 18 studies that reported any racial or ethnic demographic data, the total number of participants was 468,281. The racial composition of

participants in these studies was 48.5% White race, 1.0% Black race, 0.6% Hispanic or Latino race or ethnicity, 0.3% other, 0.2% Asian race, 0.04% American Indian/Alaska Native race, and 0.001% Native Hawaiian/other Pacific Islander race. Approximately half of the study participants (49.4%) from the 18 studies that mentioned any race or ethnicity could not be categorized into discrete racial or ethnic categories. This large subset includes studies whose methods mentioned race or ethnicity but included insufficient information to appropriately categorize their participants (for example, reporting nationality as a surrogate for race or ethnicity or reporting collective categories such as “non-white”). Such participants were categorized in our study as unknown race or ethnicity (Fig. 2). The remaining 269 studies that did not report any racial or ethnic demographic data included 2568,584 participants.

#### Non-Racial Study Characteristics

The year of publication ranged from 1949 to 2021, with the median publication year 2006 (IQR 1999-2011). The



**Figure 2.** Racial or ethnic identities of individual participants from AUA Guideline studies ( $n = 18$ ) reporting race or ethnicity. \*Individuals with unknown race or ethnicity had insufficient data for NIH best practices recommended categories for race or ethnicity. As an example, individuals may be represented in a study that categorized participants as “white” or “non-white” with insufficient information to categorize the latter individuals.

mean number of participants for each study was 10,581 participants (median 75, IQR 191). Overall, 254 of the studies reported gender. Of the studies that did report gender for experimental and/or control groups, 55.8% of the participants were male. These studies were conducted in 40 countries, including 144 studies in the US.

#### Univariate Analysis

Study design associated with being less likely to report any race or ethnicity included cross-sectional studies (OR 0.14, 95% CI 0.03-0.66,  $P = .027$ ). Studies conducted outside of the US were less likely to report any

race or ethnicity (OR 0.93, 95% CI 0.87-0.99,  $P = .012$ ). When studies that reported any race or ethnicity were compared to those that did not, the percentage of women was significantly higher (54% versus 43%,  $P = .022$ ). Studies reporting race or ethnicity had a more recent median year of publication (2007 versus 2006,  $P = .593$ ). None of these variables remained statistically significant on multivariate regression analysis.

#### Adherence to NIH Guidelines

Of the 18 studies that reported race or ethnicity, 15 were conducted in the US and were thus examined for their

adherence to NIH racial and reporting guidelines. Six of these studies (40%) satisfied all NIH guidelines for the reporting of race and ethnicity. Five studies (28%) did not capitalize all races and ethnicities. All but one study (94%) adhered to the guideline of not using race or ethnicity as a standalone noun. Five studies (28%) used collective terms such as “non-white,” rather than indicating specific groups. All studies avoided using race/ethnicity as interchangeable terms.

## DISCUSSION

The correlation between race or ethnicity and specific health disparities persists independent of environmental influences, rendering demographic data pertinent to clinical investigations. These data potentially function as proxies for unquantified factors integral to the social determinants of health, encompassing aspects such as privilege, wealth, and resource accessibility.<sup>11</sup> This study demonstrates that clinical research cited by the AUA medical and surgical guidelines for the treatment of kidney stones rarely describes the racial or ethnic compositions of their study populations. Of the 287 studies analyzed, only 18 studies (6.3%) reported any race or ethnicity data. Fifteen of these were US studies, of which 6 (40%) reported race and ethnicity in accordance with NIH best practices.<sup>12</sup> These findings indicate a significant under-reporting of racial and ethnic data, as well as a large disparity in racial and ethnic representation among the studies. Interestingly, of the participants in the few studies that did report on race or ethnicity, almost half had insufficient or inappropriately described demographic information, which prevented these patients from being categorized into the racial or ethnic groups outlined in our study. This discrepancy can be attributed to a failure of most studies to adhere to NIH best practices, such as the use of collective terms rather than specific race or ethnicity categories.

Variations in metabolic risk factors across demographics have been historically shown to be minimal, with the highest prevalence seen among White patients.<sup>13</sup> However, the incidence of nephrolithiasis has been increasing overall, impacting more racial and ethnic minorities than previously understood.<sup>14</sup> Furthermore, publications regarding quality of care, such as time to intervention and analgesic use, show disparities across racial and ethnic groups,<sup>15,16</sup> highlighting how differences in care are delivered across diverse populations can be nuanced, yet impactful. For these reasons, appropriate racial and ethnic data reporting is particularly relevant for stone disease research.

This is the first investigation into the racial and ethnic representation and reporting in studies that inform guidelines for the management of nephrolithiasis. However, a handful of previous studies addressing the lack of racial and ethnic transparency in urological guidelines have been conducting with results echoing our

findings. A study by Brown et al evaluated racial representation among studies informing the AUA and Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction guidelines for the diagnosis and treatment of overactive bladder. Among 387 studies analyzed, Black, Hispanic, and American Indians/Alaska Native groups were underrepresented based on US population estimates from the US Census. The analysis revealed highly variable representation of Asian, Hispanic, and Black participants and found that no meaningful increase in participation of these underrepresented groups over the 30-year publishing period.<sup>5</sup> Another investigation by Brandon et al examined the studies within the American College of Obstetricians and Gynecologists and the American Urogynecologic Society Practice Bulletin on pelvic organ prolapse. In their analysis of 53 studies, only 57% reported race or ethnicity. The authors found that non-white participants were also underrepresented, which remained consistent across all regions of the US (with the exception of the western US, where no single-centered studies were represented).<sup>6</sup> Similarly, Gonzalez et al examining the AUA/Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction guidelines for stress urinary incontinence, found that only nine out of 52 studies reported racial or ethnic demographic data. Interestingly, the authors found that geographic location of studies did not correlate with enrollment of non-white participants and that regions with higher proportions of Black, Hispanic, and Asian populations were associated with lower representation of those groups.<sup>7</sup>

The Journal of the American Medical Association updated guidelines for reporting race and ethnicity in medical and science journals in 2021.<sup>17</sup> Similar to the International Committee of Medical Journal Editors, the Journal of the American Medical Association guidelines recommend that authors specify the methods for identifying a subject's race or ethnicity, such as through an open-ended response or a survey with predefined options. Methodologies should be specified, and justification for collection or omission of race. In 2016, the NIH implemented requirements of reporting sex/gender and race/ethnicity for registered Phase III clinical trials in the 21st Century Cures Act.<sup>17</sup> However, more widespread enforcement of guidelines outside of government-registered clinical trials is not strictly enforced. Some authors have suggested mandatory sociodemographic data collection and reporting for all clinical studies.<sup>18</sup> Brandon et al proposed the use of a “diversity index score,” an objective measure demonstrating how representative a research cohort is to the study's larger population of interest. This calculated index could be useful in interpreting the generalizability of study findings. In fact, Brandon et al even suggested that studies should aim to over-represent the racial and ethnic minorities in a given cohort relative to the locoregional population or the US population overall. Gonzalez et al specifically cites strategies for affirming inclusivity in research methodologies,



such as offering research material in multiple languages, enforcing racial recruitment thresholds, and partnering research institutions with organizations serving marginalized communities. Indeed, none of the studies in their review reported using non-English language questionnaires, even though 75% of the questionnaires that were used had validated translations in other languages.<sup>7</sup> Encouragingly, the broader scope of ongoing urologic research is trending towards more inclusivity in the literature; PubMed queries such as “racial disparities in urology” and “diversity inclusivity in urology” show publication results by year increasing over the last 10 years and peaking after 2020, demonstrating efforts trending towards more inclusivity of diverse populations.

Our findings should be interpreted within the context of the study’s limitations and should be taken alongside acknowledgment that the current guidelines still represent the best evidence we have for stone disease management. First, only 6.3% of the clinical studies cited by the AUA stone management guidelines describe the racial and ethnic composition of their study populations, limiting conclusions about the racial and ethnic makeup of the entire cohort. It is possible that those studies which fail to report demographic data are in fact more diverse than those which do, though we suspect that this is unlikely. Furthermore, the finding that 93.7% of cited studies failed to provide this basic demographic data highlights the major gap in reporting, regardless of the composition of those trials. Finally, it is difficult to infer if any lapse in reporting of a specific race or ethnicity category (eg, studies with no data for Native Hawaiian/Other Pacific Islander Race reported) is due to true underrepresentation in a given study or due to small sample size. We believe it is more likely that our findings underestimate the true severity of racial and ethnic minorities’ underrepresentation among the research that informs AUA guidelines.

## CONCLUSION

AUA guidelines for the medical and surgical management of nephrolithiasis are based on clinical studies that often fail to report the race and ethnicity of their study populations. Among studies that did report race and ethnicity, minority groups are underrepresented, potentially limiting studies’ generalizability. This research underscores the need to address racial and ethnic disparities in urological research, particularly in clinical trials acting as pillars of guideline-based management for nephrolithiasis. As the field of urology strives to deliver evidence-based practice, it is crucial that the evidence we rely upon be inclusive, robust, and reflective of our diverse patient populations.

## Ethical Declarations

This study was exempted by the Institutional Review Board.

## Disclosures

None.

## Declaration of Competing Interest

The authors have no conflict of interest to declare.

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