

Supplementary Online Content

Rees CA, Stewart AM, Mehta S, et al. Reporting of participant race and ethnicity in published US pediatric clinical trials from 2011 to 2020. *JAMA Pediatr*. Published online March 21, 2022. doi:10.1001/jamapediatrics.2022.0142

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This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Comparison of proportion of participants enrolled in published clinical trials compared to United States Census at the county level by race and ethnicity

Race and Ethnicity¹	Participants enrolled, n (%)	Number of children 0-19 years old in counties where trials conducted, n (%)²	Odds Ratio (95% CI)³
American Indian/Alaska Native	2,815 (0.7)	236,790 (0.6)	1.16 (1.11-1.20)
Asian	11,869 (2.9)	2,930,878 (7.5)	0.38 (0.36-0.38)
Black/African American	93,988 (22.9)	6,614,102 (16.9)	1.50 (1.49-1.51)
Hispanic/Latino ⁴	105,770 (25.9)	13,104,152 (33.4)	0.71 (0.70-0.71)
Native Hawaiian/Pacific Islander	543 (0.1)	105,878 (0.3)	0.50 (0.46-0.54)
White	188,156 (46.0)	16,190,330 (41.3)	1.24 (1.23-1.25)

¹Comparison was done excluding participants whose race was not reported or whose race was reported as other as these are not available in the U.S. Census.

²U.S. Census racial groups included only non-Hispanic data (i.e., White, non-Hispanic) and was grouped in ages 0-19.

³Relative likelihood of being enrolled by race/ethnicity calculated with a 2x2 table with the two rows representing a given group (top row) and the sum of all other groups (bottom row), and columns representing trial enrollment counts (first column) and US census counts (second column) and using the cross-product ratio of the proportion of trial participants in each race or ethnicity group to expected proportion (i.e., children aged 0-18 in the U.S. Census in each race or ethnicity group).

⁴U.S. Census Hispanic included all children with ethnicity recorded as Hispanic, regardless of racial category

eTable 2. Comparison of proportion of participants enrolled in published clinical trials compared to United States Census by race and ethnicity stratified by trial size (n=612)

Race and Ethnicity¹	Participants enrolled, n (%)	United States Census, 0-18 years old, n (%)	Odds Ratio (95% CI)²
<i>Trials that Enrolled <100 Participants</i>			
American Indian/Alaska Native	36 (0.6)	651,733 (0.8)	0.66 (0.47-0.90)
Asian	287 (4.1)	3,911,472 (5.1)	0.80 (0.71-0.90)
Black/African American	1,551 (22.1)	10,600,476 (13.7)	1.78 (1.68-1.89)
Hispanic/Latino	1,384 (19.7)	19,693,433 (25.5)	0.72 (0.68-0.76)
Native Hawaiian/Pacific Islander	19 (0.3)	155,292 (0.2)	1.35 (0.81-2.11)
White	3,526 (50.2)	38,920,502 (50.4)	0.99 (0.95-1.04)
<i>Trials that Enrolled 100-499 Participants</i>			
American Indian/Alaska Native	615 (1.1)	651,733 (0.8)	1.26 (1.16-1.36)
Asian	1,027 (1.8)	3,911,472 (5.1)	0.34 (0.32-0.36)
Black/African American	18,605 (32.1)	10,600,476 (13.7)	2.97 (2.92-3.02)
Hispanic/Latino	12,933 (22.3)	19,693,433 (25.5)	0.84 (0.82-0.86)
Native Hawaiian/Pacific Islander	97 (0.2)	155,292 (0.2)	0.83 (0.67-1.02)
White	23,101 (39.8)	38,920,502 (50.4)	0.65 (0.64-0.66)
<i>Trials that Enrolled ≥500 Participants</i>			
American Indian/Alaska Native	2,161 (0.6)	651,733 (0.8)	0.74 (0.71-0.78)
Asian	10,555 (3.1)	3,911,472 (5.1)	0.59 (0.58-0.61)
Black/African American	73,832 (21.5)	10,600,476 (13.7)	1.72 (1.71-1.74)
Hispanic/Latino	91,453 (26.6)	19,693,433 (25.5)	1.06 (1.05-1.07)
Native Hawaiian/Pacific Islander	427 (0.1)	155,292 (0.2)	0.62 (0.56-0.68)
White	161,529 (47.0)	38,920,502 (50.4)	0.87 (0.87-0.88)

¹ Comparison was done excluding participants whose race was not reported or whose race was reported as other as these are not available in the U.S. Census.

²Relative likelihood of being enrolled by race calculated with a 2x2 table with the two rows representing a given group (top row) and the sum of all other groups (bottom row), and columns representing trial enrollment counts (first column) and US census counts (second column) and using the cross-product ratio of the proportion of trial participants in each race or ethnicity group to expected proportion (i.e., children aged 0-18 in the U.S. Census in each race or ethnicity group).

eTable 3. Comparison of proportion of participants enrolled in published clinical trials compared to United States Census by race and ethnicity excluding trials that were race- or ethnicity-specific by design

Race and Ethnicity¹	Participants enrolled, n (%)	United States Census, 0-18 years old, n (%)²	Odds Ratio (95% CI)³
American Indian/Alaska Native	2,402 (0.6)	651,733 (0.8)	0.72 (0.69-0.75)
Asian	11,764 (3.0)	3,911,472 (5.1)	0.57 (0.56-0.58)
Black/African American	84,447 (21.3)	10,600,476 (13.7)	1.70 (1.69-1.72)
Hispanic/Latino ⁴	103,668 (26.2)	19,693,433 (25.5)	1.04 (1.03-1.04)
Native Hawaiian/Pacific Islander	540 (0.1)	155,292 (0.2)	0.68 (0.62-0.74)
White	188,143 (47.5)	38,920,502 (50.4)	0.89 (0.89-0.90)

¹Comparison was done excluding participants whose race was not reported or whose race was reported as other as these are not available in the U.S. Census.

²U.S. Census racial groups included only non-Hispanic data, i.e., White, non-Hispanic

³Relative likelihood of being enrolled by race or ethnicity calculated with a 2x2 table with the two rows representing a given group (top row) and the sum of all other groups (bottom row), and columns representing trial enrollment counts (first column) and US census counts (second column) and using the cross-product ratio of the proportion of trial participants in each race or ethnicity group to expected proportion (i.e., children aged 0-18 in the U.S. Census in each race or ethnicity group).

⁴U.S. Census Hispanic included all children with ethnicity recorded as Hispanic, regardless of racial category

eTable 4. Comparison of proportion of participants enrolled in published clinical trials compared to United States Census by race and ethnicity by trial type

Race and Ethnicity ¹	Participants enrolled, n (%)	Odds Ratio (95% CI) ³
Behavioral (Trials n=244)		
American Indian/Alaska Native	2,128	1.08 (1.03-1.12)
Asian	9,452	0.79 (0.77-0.80)
Black/African American	54,671	1.91 (1.89-1.92)
Hispanic/Latino ⁴	74,989	1.37 (1.36-1.38)
Native Hawaiian/Pacific Islander	451	0.96 (0.86-1.94)
White	89,657	0.61 (0.60-0.62)
Drug/Biologic (Trials n=195)		
American Indian/Alaska Native	365	0.47 (0.42-0.52)
Asian	1,313	0.27 (0.26-0.29)
Black/African American	14,366	1.16 (1.13-1.18)
Hispanic/Latino ⁴	17,619	0.69 (0.68-0.70)
Native Hawaiian/Pacific Islander	35	0.19 (0.13-0.26)
White	57,606	1.63 (1.61-1.65)
Device/Procedure (Trials n=75)		
American Indian/Alaska Native	27	0.09 (0.06-0.13)
Asian	382	0.21 (0.18-0.23)
Black/African American	10,404	2.71 (2.65-2.77)
Hispanic/Latino ⁴	3,971	0.38 (0.37-0.39)
Native Hawaiian/Pacific Islander	20	0.29 (0.18-0.44)
White	19,377	1.26 (1.23-1.29)
Dietary Supplement (Trials n=44)		
American Indian/Alaska Native	23	0.56 (0.35-0.83)
Asian	171	0.68 (0.58-0.79)
Black/African American	1,713	3.39 (3.19-3.60)
Hispanic/Latino ⁴	632	0.43 (0.39-0.47)
Native Hawaiian/Pacific Islander	13	1.32 (0.70-2.26)
White	2,189	0.80 (0.75-0.84)
Health Services (Trials n=21)		
American Indian/Alaska Native	0	0 (0.00-0.02)
Asian	174	0.20 (0.17-0.23)
Black/African American	1,859	0.80 (0.76-0.84)
Hispanic/Latino ⁴	3,185	0.70 (0.67-0.72)
Native Hawaiian/Pacific Islander	17	0.51 (0.30-0.82)
White	11,156	2.04 (1.98-2.11)
Screening/Referral (Trials n=26)		
American Indian/Alaska Native	258	1.50 (1.32-1.69)
Asian	273	0.25 (0.22-0.28)
Black/African American	7,842	3.88 (3.78-3.40)
Hispanic/Latino ⁴	4,134	0.74 (0.71-0.76)
Native Hawaiian/Pacific Islander	7	0.17 (0.07-0.35)
White	7,641	0.58 (0.57-0.60)

¹Comparison was done excluding participants whose race was not reported or whose race was reported as other as these are not available in the U.S. Census.

²U.S. Census racial groups included only non-Hispanic data, i.e., White, non-Hispanic

³Relative likelihood of being enrolled by race or ethnicity calculated with a 2x2 table with the two rows representing a given group (top row) and the sum of all other groups (bottom row), and columns representing trial enrollment counts (first column) and US census counts (second column) and using the cross-product ratio of the proportion of trial participants in each race or ethnicity group to expected proportion (i.e., children aged 0-18 in the U.S. Census in each race or ethnicity group).

⁴U.S. Census Hispanic included all children with ethnicity recorded as Hispanic, regardless of racial category

eTable 5. Factors associated with pediatric clinical trial enrollment with a diversity index at least that of the state in which the trial was conducted

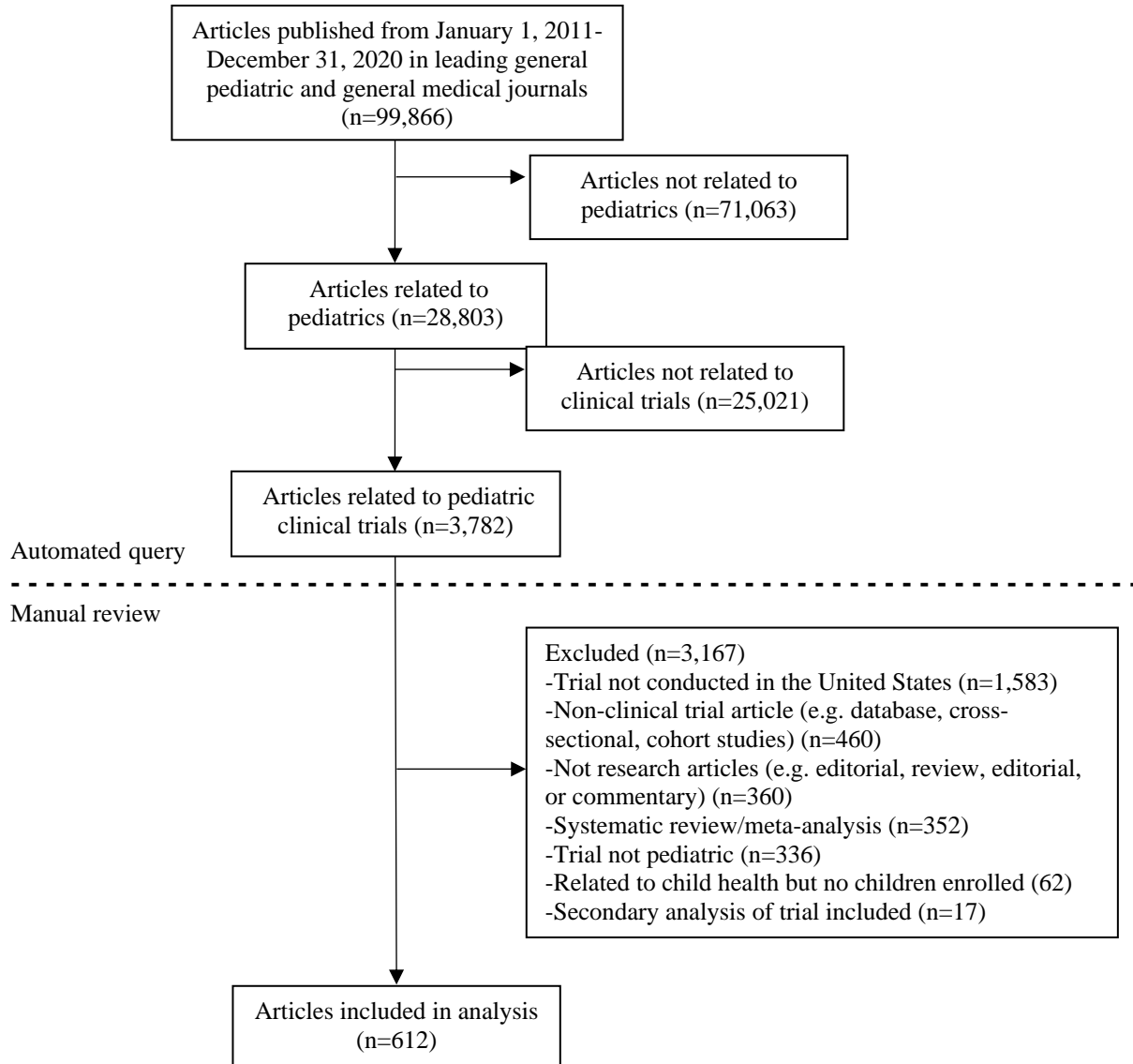
	Odds Ratio (95% CI)	Adjusted Odds Ratio ¹ (95% CI)
Trial allocation		
Not randomized	<i>Referent</i>	-
Randomized	0.65 (0.16-2.68)	-
Trial masking		
Open label/Non-blinded	<i>Referent</i>	-
Single blind	0.64 (0.29-1.44)	-
Double blind	0.98 (0.42-2.25)	-
Other	0.63 (0.12-3.22)	-
Not specified	0.50 (0.15-1.65)	-
Trial enrollment		
<100	<i>Referent</i>	<i>Referent</i>
100-499	1.26 (0.64-2.47)	1.2 (0.60-2.30)
>500	2.30 (1.11-4.70)	2.00 (0.90-4.30)
Trial intervention		
Drug/biologic	<i>Referent</i>	-
Behavioral	1.07 (0.51-2.23)	-
Device/procedure	1.03 (0.31-3.37)	-
Dietary supplement	1.75 (0.58-4.31)	-
Screening/Referral	2.45 (0.77-7.81)	-
Health services	0.32 (0.04-2.72)	-
Other	10.5 (0.99-110.36)	-
Funding source		
Public and Private	<i>Referent</i>	-
Private	0.66 (0.28-1.54)	-
Public	0.97 (0.49-1.89)	-
None Reported	0.60 (0.12-3.10)	-
Trial recruitment involved community stakeholders		
Yes	0.39 (0.16-0.97)	0.40 (0.10-0.90)
No	<i>Referent</i>	<i>Referent</i>
In journal with race/ethnicity reporting statement²		
Yes	1.87 (0.92-3.80)	1.70 (0.80-3.60)
No	<i>Referent</i>	<i>Referent</i>
Participant age group in article		
All pediatric age groups enrolled	0.43 (0.16-1.14)	-
Neonate (0-30 days)	0.67 (0.29-1.56)	-
Infant (31-365 days)	1.15 (0.45-2.94)	-
Toddler (1-3 years)	1.52 (0.46-4.95)	-
Pre-school age (4-5 years)	0.42 (0.09-1.99)	-
School age (6-12 years)	1.37 (0.69-2.81)	-
Adolescent (13-18 years)	<i>Referent</i>	-
Participant language reported in article		
Yes	0.70 (0.40-1.21)	-
No	<i>Referent</i>	-
Socioeconomic data reported in article³		
Yes	0.95 (0.56-1.63)	-
No	<i>Referent</i>	-

¹Adjusted for variables with overall *P* value <0.2 in the bivariable model.

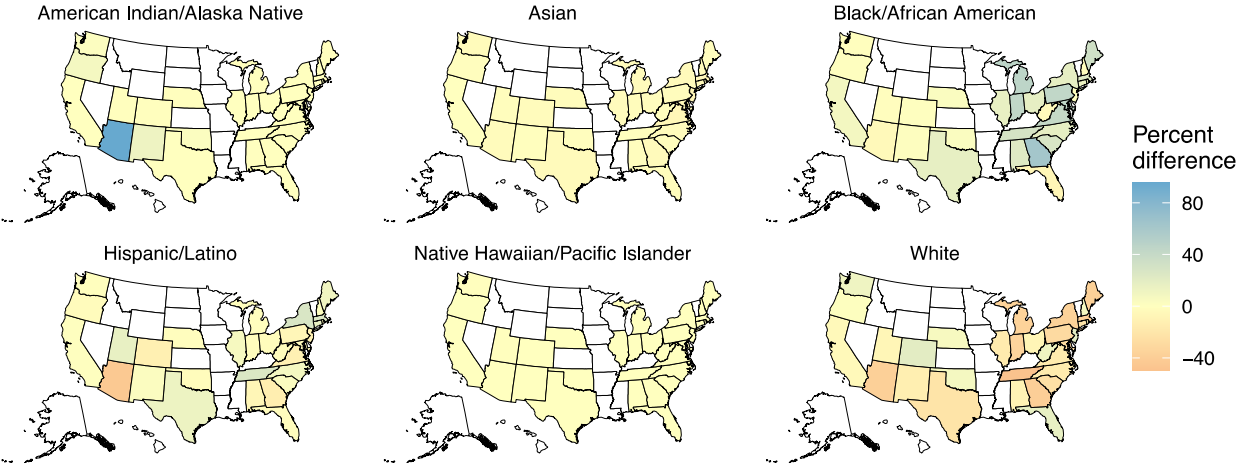
²*JAMA Pediatrics, Lancet Child & Adolescent Health, Pediatrics, Journal of Adolescent Health, Lancet, Journal of the American Medical Association (JAMA), and PLoS Medicine* include race/ethnicity reporting statements.

³Included insurance type or status, household income, community-level income, caregiver education, caregiver employment status, receipt of social benefits.

eFigure 1. Selection of articles included in analysis of pediatric clinical trial enrollment by race and ethnicity



eFigure 2. Difference in percentages of trial participants and state population by race among single-state clinical trials



eAppendix. Supplement Query. PubMed query to identify pediatric clinical trials published in leading pediatric and general medical journals.

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((((((((((("JAMA pediatrics"[Journal]) OR ("The Lancet. Child & adolescent health"[Journal])) OR ("Pediatrics"[Journal])) OR ("The Journal of adolescent health : official publication of the Society for Adolescent Medicine"[Journal])) OR ("The Journal of pediatrics"[Journal])) OR ("The New England journal of medicine"[Journal])) OR ("Lancet (London, England)"[Journal])) OR ("JAMA"[Journal])) OR ("BMJ (Clinical research ed.)"[Journal])) OR ("PLoS medicine"[Journal])) AND ("pediatrics"[MeSH Terms] OR "pediatric"[Title/Abstract] OR "child"[MeSH Terms] OR "child"[Title/Abstract] OR "children"[Title/Abstract] OR "adolescent"[MeSH Terms] OR "adolescent"[Title/Abstract] OR "adolescents"[Title/Abstract] OR "adolescence"[Title/Abstract] OR "teen"[Title/Abstract] OR "teens"[Title/Abstract] OR "teenagers"[Title/Abstract] OR "teenager"[Title/Abstract] OR "youth"[Title/Abstract] OR "youths"[Title/Abstract] OR "infant"[MeSH Terms] OR "infants"[Title/Abstract] OR "infant"[Title/Abstract] OR "baby"[Title/Abstract] OR "babies"[Title/Abstract] OR "infant, newborn"[MeSH Terms] OR "neonate"[Title/Abstract] OR "neonates"[Title/Abstract])) AND (((("clinical trial"[Publication Type] OR "Adaptive Clinical Trial"[Publication Type] OR "Clinical Trial, Phase I"[Publication Type] OR "Clinical Trial, Phase II"[Publication Type] OR "Clinical Trial, Phase III"[Publication Type] OR "Clinical Trial, Phase IV"[Publication Type] OR "Controlled Clinical Trial"[Publication Type]) OR ("Clinical Trials as Topic"[mesh] OR "Adaptive Clinical Trials as Topic"[mesh] OR "Clinical Trials, Phase I as Topic"[mesh] OR "Clinical Trials, Phase II as Topic"[mesh] OR "Clinical Trials, Phase III as Topic"[mesh] OR "Clinical Trials, Phase IV as Topic"[mesh] OR "Controlled Clinical Trials as Topic"[mesh] OR "Non-Randomized Controlled Trials as Topic"[mesh] OR "Randomized Controlled Trials as Topic"[mesh] OR "Single-Case Studies as Topic"[mesh] OR "multicenter studies as topic"[mesh] OR "double blind method"[mesh])) OR ("clinical trial" OR "clinical trials" OR "randomized trial" OR "randomized trials" OR "randomised trial" OR "randomised trials" OR "randomized controlled trial" OR "randomized controlled trials" OR "randomised controlled trial" OR "randomised controlled trials" OR "single blind" OR "single blinded" OR "double blind" OR "double blinded" OR "triple blind" OR "triple blinded" OR ((randomised OR randomized) AND (trial OR trials)) OR ((single OR double OR doubled OR triple OR tripled OR treble OR treble) AND (blind* OR mask*)) OR ("4 arm" OR "four arm")))) AND (("2011/01/01"[Date - Publication] : "2020/12/31"[Date - Publication]))
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