Evaluating Cardiovascular Health Disparities Using Estimated Race/Ethnicity

A Validation Study

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Background: Methods of estimating race/ethnicity using administrative data are increasingly used to examine and target disparities; however, there has been no validation of these methods using clinically relevant outcomes.

Objective: To evaluate the validity of the indirect method of race/ethnicity identification based on place of residence and surname for assessing clinically relevant outcomes.

Data Sources: A total of 2387 participants in the Post-MI Free Rx Event and Economic Evaluation (MI FREEE) trial who had both self-reported and Bayesian Improved Surname Geocoding method (BISG)-estimated race/ethnicity information available.

Study Design: We used tests of interaction to compare differences in the effect of providing full drug coverage for post-MI medications on adherence and rates of major vascular events or revascularization for white and nonwhite patients based upon self-reported and indirect racial/ethnic assignment.

Results: The impact of full coverage on clinical events differed substantially when based upon self-identified race (HR = 0.97 for whites, HR = 0.65 for nonwhites; interaction *P*-value = 0.05); however, it did not differ among race/ethnicity groups classified using indirect methods (HR = 0.87 for white and nonwhites; interaction *P*-value = 0.83). The impact on adherence was the same for self-reported and BISG-estimated race/ethnicity for 2 of the 3 medication classes studied.

Conclusions: Quantitatively and qualitatively different results were obtained when indirectly estimated race/ethnicity was used, suggesting that these techniques may not accurately describe aspects of race/ethnicity related to actual health behaviors.

Key Words: race and ethnicity, geocoding, measurement, health disparities

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Racial and ethnic disparities in care have persisted despite substantial efforts to reduce them.[1–3] Monitoring disparities and evaluating interventions require routinely collected data on race and ethnicity, but until recently, there have been no requirements for health insurance plans or health care providers in the United States to collect such information and, consequently, few have done so in a systematic way.[4,5] While recent initiatives, such as the requirements of "meaningful use," seek to improve the collection of self-reported race and ethnicity data,[6] it might take years for this to happen for the majority of patients, especially for those who are least likely to interact with the health care system. As a result, techniques that estimate race/ethnicity indirectly based upon an individual's surname and place of residence have been advocated as an interim step by the Institute of Medicine and others until direct measures are widely available.[7]

One such indirect method, the Bayesian Improved Surname and Geocoding Combination (BISG) method, estimates a patient's race/ethnicity probability distribution based on geocoding and the US Census Bureau surname list. The method has been validated in a study of almost 2 million Aetna enrollees and found to highly correlate with self-reported race/ethnicity.[8] Several studies have either implemented the BISG method to impute missing race/ethnicity or assessed the accuracy of racial/ethnic assignment in other populations[9–13]; however, there has been no validation of this method using clinically relevant outcomes. Accordingly, we used data from a recently conducted clinical trial[14] for which both self-identified and BISG-estimated information were available to compare whether the impact of the intervention on disparities as evaluated using estimated

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race/ethnicity was the same as that obtained using the "gold standard" self-identification technique.

METHODS

Patient Population and Study Design

The design and primary results of the Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) trial, as well as the impact of this trial in self-identified race/ethnicity subgroups, have been reported.[14–16] In brief, MI FREEE prospectively evaluated the impact of eliminating cost-sharing (copayments, coinsurance, or contribution to deductibles) for secondary preventive medications in patients discharged from hospital following MI. The study randomized 5855 post-MI patients to either full prescription coverage (N = 2845) or usual prescription coverage (N = 3010) for any brand name or generic statin, β-blocker, angiotensin-converting enzyme inhibitor, or angiotensin receptor blocker.[15] Patients were assigned to full or usual coverage by cluster randomizing their plan sponsor, ensuring that all eligible employees of a given plan sponsor received the same coverage after randomization. In the secondary analysis of the intervention's impact on the racial disparities, full drug coverage significantly reduced the rates of the trial's primary outcome (major vascular event or coronary revascularization) in patients who self-identified as being nonwhite (hazard ratio (HR) = 0.65; 95% confidence interval (CI), 0.44–0.97; $P = 0.04$), but had no effect for those of white race/ethnicity (HR = 0.97; 95% CI, 0.78–1.21; $P = 0.79$; P-value for interaction = 0.05).

For the present study, we sought to assess the accuracy of estimated race/ethnicity based upon the BISG method by comparing the results obtained using this method with the results obtained through the gold-standard categorization based on self-reported race/ethnicity. Accordingly, we evaluated MI FREEE trial participants for whom both self-reported and BISG-estimated race and ethnicity data were available (N = 2387). Although relatively small in size, the MI FREEE trial provides a truly unique opportunity to not only evaluate the correlation between estimated and self-reported race/ethnicity identification methods, but to also evaluate the effect of the different classification methods on clinical outcomes. This study was approved by the Institutional Review Board at Brigham and Women's Hospital.

Race/Ethnicity Information, Categorization, and Assessment

Aetna, one of the largest commercial insurers in the United States, collects voluntarily reported race and ethnicity information for its beneficiaries when they log on to a secure member portal at the time of plan enrollment and on an ongoing basis thereafter during future interactions with health plan staff. For the purposes of this study, patients were categorized into the same 6 mutually exclusive groups that are used by the BISG method: white, black or African American, Hispanic, American Indian or Alaska Native, Asian or Pacific Islander, and 2+ races (multiracial). Aetna has self-reported race/ethnicity information available for approximately 30% of their enrollees and 41% (N = 2387) of the MI FREEE trial participants. As the majority of trial participants self-identified as white and the numbers in specific nonwhite categories were small, it was decided a priori to classify patients into 2 groups, white and nonwhite, to have enough power to detect clinically meaningful effects.[16]

Aetna also estimates race and ethnicity using the BISG method, which provides a patient's estimated probability of belonging to each of 6 racial/ethnical groups listed above based on geocoding at the block group level, US Census racial percentages, and US Census Bureau's 2000 surname list. To mirror our race/ethnicity categorization based on self-reported data, we classified patients as white or nonwhite. To do this, we assessed a range of cut points for the probability of belonging to the white group and chose 0.55 because it maximized the proportion of true positives and true negatives (0.88) with an acceptable trade-off between sensitivity and specificity (0.93 and 0.66, respectively). On the basis of this evaluation, a probability of belonging to a white race/ethnicity ≥ 0.55 was used to classify patients as being white. By way of comparison, a validation study from Kaiser Permanente Georgia found that a BISG cut point of 0.57 for white race maximized sensitivity and specificity of self-identified race/ethnicity among their members who self-identified as white.[11]

Correlation Between Self-identified and Predicted Race/Ethnicity

We assessed the accuracy of BISG method in our cohort by following the performance metric suggested by Elliott et al.[8,17] This approach defines the efficiency of prediction as the correlation between the estimated probability for each of the 6 racial or ethnic categories and the corresponding dichotomous indicator of self-reported race/ethnicity (eg, white/not white and black/not black).[8,17] The average correlation across all racial/ethnic groups was calculated by weighting the group correlations by group size.

Analyses of Adherence and Outcomes

We evaluated the impact of race/ethnicity on the trial's prespecified and previously reported outcomes.[14] Medication adherence was evaluated using pharmacy refill data to calculate a medication possession ratio (ie, the number of days a patient had a supply of each medication class available, divided by the number of days of eligibility for that medication). Patients were categorized as being fully adherent based upon a medication possession ratio $\geq 80\%$.[18] The trial's primary clinical outcome was a composite of the first readmission for a major vascular event (fatal or nonfatal MI, unstable angina, stroke, or congestive heart failure) or coronary revascularization (repeat CABG or percutaneous coronary intervention). This outcome was assessed by applying validated algorithms with specificities of at least 95% to Aetna's health care utilization databases.[15] All analyses were performed based on intention-to-treat principles.

Baseline characteristics by race/ethnicity subgroup for patients randomized to full and usual insurance coverage were compared based upon self-reported and estimated racial assignment. We then repeated previously reported analyses of study outcomes stratified by self-reported race/ethnicity[16] using the BISG classification. In all of these models the

parameter of interest was the interaction term between treatment assignment (ie, full vs. usual coverage) and race/ethnicity group (ie, white vs. nonwhite). Medication adherence was compared using generalized estimating equations, with adjustment for the cluster-randomized design and a logit-link function with binomial distributed errors. Clinical outcomes were evaluated using Cox proportional hazards models, adjusting for clustering using a robust sandwich estimator for the covariance matrix,[19] the blocking factors used for sample stratification, age, and comorbidity score.[20] Consistent with the Institute of Medicine's definition of racial/ethnic disparities and recommendations from Cook et al,[21] our primary models did not adjust for income. As a sensitivity analysis, we re-ran our models adjusting for income in quintiles based upon each patient's zip code of residence.

Sensitivity Analyses

To account for the uncertainty implicit in the estimated assessment of race/ethnicity, we re-ran our analyses using each patient's BISG-estimated probability of white race to create 100 imputed indicators of white race, instead of categorizing patients as white or nonwhite based on a cutpoint. In creating the imputations, we essentially considered race as missing data and the BISG probabilities as providing an imputation model for the missing data. For example, if the BISG method indicated that an individual had a 75% probability of being white, then that individual was classified as white in approximately 75% of the imputed race variables and as nonwhite for the rest of the 100 indicators. In analyzing the imputed data, the analyses described above were repeated 100 times using each of the 100 imputed indicators of white race to define race in the analysis, resulting in 100 sets of independent results. Model coefficients were then combined by averaging coefficients across imputations.[22]

In addition, as the direct use of predicted probabilities instead of categorical indicators is recommended by Elliott et al,[8] we repeated our analyses using the predicted probability of being white as a regressor in the final models and compared the *P*-values for the interaction term with the values obtained using the categorical indicators and the imputation method.

RESULTS

Our cohort consisted of 2387 patients, of whom 1856 (77.8%) self-identified as white, 183 (7.7%) as black, 147 (6.2%) as Hispanic, 135 (5.7%) as multiracial, 60 (2.5%) as Asian or Pacific Islander, and 6 (0.3%) as American Indian or Alaska Native. Table 1 displays baseline characteristics for patients randomized to full or usual coverage among racial/ethnic subgroups as categorized by self-reported and estimated race/ethnicity. Overall, the differences between treatment groups observed based on self-reported race/ethnicity assignment were also observed when the indirect method was used. For example, among patients of white race/ethnicity, patients assigned to full prescription coverage were less likely to be male and were more likely to have used a β-blocker before their index MI than patients assigned to usual prescription coverage, whereas among patients of nonwhite race/ethnicity, patients assigned to full coverage were more likely to have chronic obstructive pulmonary disease.

The racial/ethnic group assignment was reclassified for 298 patients (12.5%) when estimated, as opposed to self-reported, race/ethnicity information was used: 119 patients who self-identified as being white were assigned to nonwhite group using the BISG categorization method, and 179 self-identified nonwhite patients were assigned to the white BISG group (Table 2). Of the self-identified nonwhite patients who were assigned to the white BISG group, 45% self-identified as being multiracial, 37% as black, 10% as Hispanic, 6% as Asian, and the remaining as American Indian or Alaska Natives. Patients who changed their racial/ethnic group assignment were slightly younger than patients who did not (mean age 52 vs. 53 years; *P*-value = 0.002). White patients were more likely to be reclassified when they were from the South and areas with lower median incomes, whereas nonwhite patients were more likely to be reclassified when they were from the Northeast or Midwest and areas with higher median incomes than patients who were not reclassified (Table 2).

Correlation Between Self-reported and Predicted Race/Ethnicity

Table 3 presents the correlation of predicted race/ethnicity with self-reported one in our cohort as compared with the original validation study for BISG method.[8] As in the original evaluation, performance was the highest for Hispanics, followed by Asians, whites, and blacks, whereas the prediction of multiracial and American Indian or Alaska Natives groups was quite poor. Overall, BISG accuracy in predicting individual race/ethnicity was lower in our cohort than in the original validation study. Prediction of white race/ethnicity had a correlation of 0.66 with self-reported race/ethnicity in our cohort as compared with a correlation of 0.76 in the original validation study. The overall performance summarized through the weighted average correlation in our cohort was 0.62 as compared with 0.75 in original validation. All reported correlations are statistically significant at *P*-value <0.05.

Impact of Race/Ethnicity on Medication Adherence

The self-reported and BISG-based race/ethnicity identification method yielded similar results for adherence for 2 of the 3 medication classes studied. Table 4 shows the proportion of patients who were fully adherent (defined as medication possession of $\geq 80\%$) throughout follow-up to each and all 3 medication classes of interest. Overall, providing full coverage for post-MI secondary preventive therapies improved adherence to ACE inhibitor/ARBs and β-blockers in both racial groups. The amount of improvement that was observed in the different racial groups varied between the methods, although the overlapping CIs indicate no substantial difference (Table 4). In contrast, providing full coverage improved adherence to statins among patients who self-identified as nonwhite (OR = 1.82; 95% CI, 1.31–2.53) but no such effect was observed using the indirectly estimated race/ethnicity (OR = 1.03; 95% CI, 0.67–1.59).

TABLE 1. Baseline Characteristics of the Study Population

	Categorization Based on Self-reported Values				Categorization Based on Indirectly Estimated Probabilities*			
	White		Nonwhite		White		Nonwhite	
Characteristics	Full Prescription Coverage (N = 946)	Usual Prescription Coverage (N = 910)	Full Prescription Coverage (N = 260)	Usual Prescription Coverage (N = 271)	Full Prescription Coverage (N = 979)	Usual Prescription Coverage (N = 937)	Full Prescription Coverage (N = 227)	Usual Prescription Coverage (N = 224)
Age [mean (SD)] (y)	53.7 (7.4)	53.6 (7.5)	51.6 (8.5)	52.3 (7.9)	53.4 (7.6)	53.6 (7.6)	52.6 (8.0)	52.3 (7.8)
Male [n (%)]	702 (74.2)	724 (79.6)†	195 (75.0)	192 (70.8)	731 (74.7)	745 (79.5)†	166 (73.1)	171 (70.1)
Income [median (SD)] ($)	51,665 (19,905)	52,340 (18,871)	45,307 (19,113)	46,402 (17,445)	52,067 (19,798)	52,447 (18,591)	42,676 (18,543)	45,350 (18,152)
Medication use before hospitalization [n (%)]								
ACE inhibitor or ARB	519 (54.9)	475 (52.2)	142 (54.6)	142 (52.4)	538 (55.0)	491 (52.4)	123 (54.2)	126 (51.6)
β-blocker	656 (69.3)	589 (64.7)†	166 (63.8)	172 (63.5)	683 (69.8)	608 (64.9)†	139 (61.2)	153 (62.7)
Clopidogrel	534 (56.4)	492 (54.1)	133 (51.2)	147 (54.2)	547 (55.9)	502 (53.6)	120 (52.9)	137 (56.1)
COPD medications	112 (11.8)	108 (11.9)	24 (9.2)	28 (10.3)	112 (11.4)	111 (11.8)	24 (10.6)	25 (10.2)
Statin	608 (64.3)	561 (61.6)	143 (55.0)	153 (56.5)	631 (64.5)	579 (61.8)	120 (52.9)	135 (55.3)
Warfarin	55 (5.8)	62 (6.8)	13 (5.0)	9 (3.3)	57 (5.8)	63 (6.7)	11 (4.8)	8 (3.3)
Coexisting illness [n (%)]								
Congestive heart failure	238 (25.2)	244 (26.8)	82 (31.5)	90 (33.2)	245 (25.0)	253 (27.0)	75 (33.0)	81 (33.2)
COPD	158 (16.7)	154 (16.9)	44 (16.9)	26 (9.6)†	158 (16.1)	157 (16.8)	44 (19.4)	23 (9.4)†
Diabetes	285 (30.1)	283 (31.1)	109 (41.9)	113 (41.7)	297 (30.3)	298 (31.8)	97 (42.7)	98 (40.2)
Hypertension	658 (69.6)	646 (71.0)	199 (76.5)	211 (77.9)	671 (68.5)	674 (71.9)	186 (81.9)	183 (75.0)
Previous MI	147 (15.5)	158 (17.4)	43 (16.5)	47 (17.3)	150 (15.3)	164 (17.5)	40 (17.6)	41 (16.8)
Stroke	43 (4.5)	39 (4.3)	15 (5.8)	22 (8.1)	48 (4.9)	43 (4.6)	10 (4.4)	18 (7.4)
Comorbidity score [mean (SD)]	2.6 (1.9)	2.7 (1.9)	2.9 (2.0)	3.0 (2.0)	2.6 (1.9)	2.7 (1.9)	3.03 (2.0)	3.0 (2.0)
Procedure on index hospitalization [n (%)]								
Angiography	904 (95.6)	863 (94.8)	240 (92.3)	248 (91.5)	934 (95.4)	885 (94.5)	210 (92.5)	226 (92.6)
CABG	179 (18.9)	182 (20.0)	47 (18.1)	47 (17.3)	188 (19.2)	190 (20.3)	38 (16.7)	39 (16.0)
PCI	653 (69.0)	604 (66.4)	163 (62.7)	180 (66.4)	663 (67.7)	615 (65.6)	153 (67.4)	169 (69.3)
Health care utilization [mean (SD)]								
No. distinct drugs	9.1 (6.5)	8.7 (6.5)	8.2 (5.9)	8.3 (6.2)	9.0 (6.4)	8.8 (6.6)	8.8 (6.2)	7.9 (5.8)
Hospital admission	0.4 (1.9)	0.5 (1.5)	0.5 (1.6)	0.4 (0.9)	0.4 (1.8)	0.5 (1.5)	0.6 (1.7)	0.4 (0.7)
No. physician visits	5.7 (6.5)	5.5 (6.5)	5.6 (7.8)	5.5 (7.7)	5.5 (6.5)	5.6 (6.6)	6.1 (8.0)	5.1 (7.5)

Medication use before hospitalization and coexisting illnesses were assessed on the basis of all filled prescriptions and available diagnoses during the 12-month period preceding the index hospitalization. Medication use was defined as the filling of at least 1 prescription during this period.

*White = probability of being white ≥ 0.55.

†*P*-value < 0.05.

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation.

Impact of Race/Ethnicity on Clinical Outcomes

The results for clinical outcomes are presented in Table 5. When categorizing patients based on self-reported race/ethnicity, providing full drug coverage for secondary preventive therapies following an MI significantly reduced the rates of the trial's primary outcome (first major vascular event or revascularization) among patients who self-identified as nonwhite (HR = 0.65; 95% CI, 0.44–0.97; *P* = 0.04) but had no effect for those of white race/ethnicity (HR = 0.97; 95% CI, 0.78–1.21; *P* = 0.79, *P*-value for interaction = 0.05).

In contrast, when race/ethnicity was classified based upon the indirect method, full coverage did not reduce the rate of clinical events for any of the patient groups. Specifically, full insurance coverage resulted in a nonsignificant reduction in first major vascular event or revascularization from full coverage for both white (HR = 0.87; 95% CI, 0.69–1.09) and nonwhite individuals (HR = 0.87; 95% CI, 0.58–1.30; interaction *P*-value 0.83).

Repeating our analyses adjusting for income did not change the findings for either of the race/ethnicity identification methods.

Sensitivity Analyses

Using imputation instead of dichotomizing race/ethnicity based upon a threshold value achieved qualitatively similar although quantitatively smaller racial/ethnic differences in adherence (Table 4). As with our primary results, in

TABLE 2. Characteristics of Patients Who Did and Did Not Have Their Race/Ethnicity Assignment Reclassified When Using Indirectly Estimated Instead of Self-reported Data

	Self-identified White		Self-identified Nonwhite	
Characteristics	**Reclassified (N = 119)**	**Not Reclassified (N = 1737)**	**Reclassified (N = 179)**	**Not Reclassified (N = 352)**
Age [mean (SD)] (y)	53.0 (8.44)	53.7 (7.39)	51.4 (9.03)	52.3 (7.73)
Male [n (%)]	87 (73.1)	1339 (77.1)	137 (76.5)	250 (71.0)
Income [median (SD)] ($)	43,514 (19,112)	52,581 (19,291)†	49,054 (18,176)	44,241 (18,135)†
Midwest [n (%)]	8 (6.7)	231 (13.3)†	15 (8.4)	17 (4.8)†
Northeast [n (%)]	20 (16.8)	546 (31.4)†	51 (28.5)	75 (21.3)†
South [n (%)]	75 (63.0)	745 (42.9)†	82 (45.8)	199 (56.5)†
West [n (%)]	16 (13.4)	214 (12.3)	30 (16.8)	60 (17.0)
Medication use before hospitalization [n (%)]*				
ACE inhibitor or ARB	66 (55.5)	928 (53.4)	101 (56.4)	183 (52.0)
β-blocker	78 (65.5)	1167 (67.2)	124 (69.3)	214 (60.8)
Clopidogrel	73 (61.3)	953 (54.9)	96 (53.6)	184 (52.3)
COPD meds	16 (13.4)	204 (11.7)	19 (10.6)	33 (9.4)
Statin	67 (56.3)	1102 (63.4)	108 (60.3)	188 (53.4)
Warfarin	4 (3.4)	113 (6.5)	7 (3.9)	15 (4.3)
Coexisting illness [n (%)]*				
Congestive heart failure	39 (32.8)	443 (25.5)	55 (30.7)	117 (33.2)
COPD	22 (18.5)	290 (16.7)	25 (14.0)	45 (12.8)
Diabetes	31 (26.1)	537 (30.9)	58 (32.4)	164 (46.6)
Hypertension	90 (75.6)	1214 (69.9)	131 (73.2)	279 (79.3)
Previous MI	20 (16.8)	285 (16.4)	29 (16.2)	61 (17.3)
Stroke	2 (1.7)	80 (4.6)	11 (6.1)	26 (7.4)
Comorbidity score [mean (SD)]	2.8 (2.1)	2.7 (1.9)	2.8 (2.0)	3.1 (2.0)
Procedure on index hospitalization [n (%)]				
Angiography	113 (95.0)	1654 (95.2)	165 (92.2)	323 (91.8)
CABG	13 (10.9)	348 (20.0)†	30 (16.8)	64 (18.2)†
PCI	84 (70.6)	1173 (67.5)	105 (58.7)	238 (67.6)
Health care utilization [mean (SD)]				
No. distinct drugs	8.88 (6.02)	8.92 (6.50)	8.46 (6.15)	8.13 (5.99)
Hospital admission	0.31 (0.61)	0.42 (1.71)	0.37 (0.92)	0.51 (1.43)
No. physician visits	5.5 (5.69)	5.58 (6.53)	5.49 (6.59)	5.59 (8.30)

*Medication use before hospitalization and coexisting illnesses were assessed on the basis of all filled prescriptions and available diagnoses during the 12-month period preceding the index hospitalization. Medication use was defined as the filling of at least 1 prescription during this period.

†*P*-value < 0.05.

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation.

this analysis, providing full coverage appeared to have no effect on the adherence to statins among patients of nonwhite race/ethnicity (OR = 1.26; 95% CI, 0.99–1.61) but also have no effect on adherence to β-blockers in either racial/ethnic group.

The imputation method's results for clinical end points were similar to those obtained when patients were dichotomized based on indirect estimation, with no differences in the effect of full coverage based on race/ethnicity (HR = 0.87; 95% CI, 0.69–1.11 for white individuals; HR = 0.83; 95% CI, 0.53–1.30 for nonwhite; interaction *P*-value 0.80).

Using BISG probabilities directly as regressors in models produced results similar to those obtained with categorical indicators or the imputation method (Appendix Table 1A, Supplemental Digital Content 1, http://links.lww.com/MLR/B41).

DISCUSSION

In our evaluation of methods to classify race and ethnicity, we found quantitatively and qualitatively important differences in results when we performed analyses using predicted race/ethnicity based upon place of residence and surname, and self-reported information. While the 2 methods were moderately correlated and achieved similar results when evaluating the impact of an intervention on a surrogate

TABLE 3. Correlation of Individual Predicted Race/Ethnicity With Self-reported Race/Ethnicity in the Current Study as Compared With the Original Validation Study[8]

Cohort	White	Black	Hispanic	Asian	AI/AN	Multiracial	Weighted Average	Nonwhite
Current study	0.66	0.58	0.76	0.71	0.04	0.01	0.62	0.66
Original validation cohort[8]	0.76	0.70	0.82	0.77	0.11	0.02	0.75	–

Correlation for nonwhite group was not calculated in the original validation cohort.

AI/AN indicates American Indian or Alaska Native.

TABLE 4. Full Adherence to Post-MI Medications* for Full and Usual Coverage Cohorts Stratified by Race/Ethnicity Based Upon Different Methods of Race/Ethnicity Identification

	Full Adherence*								
	White				Nonwhite				
Medication	Full Rx Coverage (%)	Usual Rx Coverage (%)	Odds Ratio (95% CI)	*P*	Full Rx Coverage (%)	Usual Rx Coverage (%)	Odds Ratio (95% CI)	*P*	Interaction (*P*)
Self-reported race/ethnicity									
ACE inhibitor or ARB	29.7	24.3	1.31 (1.06–1.62)	0.01	27.7	19.6	1.20 (0.88–1.64)	0.25	0.42
β-blockers	33.2	26.3	1.41 (1.14–1.75)	0.001	28.8	20.7	1.53 (1.01–2.32)	0.04	0.63
Statins	43.2	34.7	1.44 (1.17–1.77)	<0.001	36.2	26.2	1.82 (1.31–2.53)	<0.001	0.59
All 3 medication classes†	12.9	9.7	1.35 (1.04–1.77)	0.03	12.3	5.5	2.26 (1.41–3.61)	<0.001	0.10
Indirectly estimated race/ethnicity: binary categorization									
ACE inhibitor or ARB	30.0	23.8	1.36 (1.10–1.68)	0.004	26.0	20.9	1.41 (0.88–2.25)	0.16	0.92
β-blockers	33.4	25.9	1.44 (1.17–1.76)	<0.001	27.3	21.3	1.46 (1.01–2.12)	0.05	0.89
Statins	44.1	33.3	1.59 (1.30–1.95)	<0.001	31.3	30.7	1.03 (0.67–1.59)	0.88	0.08
All 3 medication classes†	13.0	9.3	1.45 (1.10–1.90)	0.009	11.9	6.6	1.90 (1.12–3.22)	0.01	0.46
Indirectly estimated race/ethnicity: imputation method									
ACE inhibitor or ARB	29.6	23.3	1.39 (1.08–1.78)	0.01	28.0	22.9	1.41 (1.08–1.83)	0.01	0.67
β-blockers	33.1	25.5	1.26 (0.98–1.61)	0.07	29.4	23.5	1.26 (0.98–1.63)	0.07	0.23
Statins	43.4	32.9	1.58 (1.24–2.01)	<0.001	36.2	32.5	1.26 (0.99–1.61)	0.06	0.66
All 3 medication classes†	12.9	8.9	1.58 (1.12–2.22)	0.009	12.5	8.3	1.53 (1.05–2.21)	0.03	0.73

*Full adherence was defined as having a supply of medications available on at least 80% of days during follow-up. Patients who did not fill a particular prescription after randomization were considered to be nonadherent; Full Rx coverage and Usual Rx coverage % represent the percentage of patients who were fully adherent to their medication throughout follow-up.

†Full adherence to all 3 medication classes.

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CI, confidence interval; Rx, prescription.

measure (ie, providing full drug coverage for post-MI medications on adherence to 2 of the 3 medication classes evaluated), analyses based on self-reported information demonstrated that patients of nonwhite race/ethnicity were significantly more adherent to their prescribed statins and experienced a lower rate of vascular events when their post-MI medications were fully covered, whereas the analysis based on BISG showed no such effects.

Indirect methods of race/ethnicity assignment have intuitive appeal for monitoring disparities across broad populations as no primary data collection is required, and these methods have been encouraged as an alternative to direct measures when self-reported data are not available.[5] The specific instrument we evaluated, RAND's BISG, has been shown to be highly correlated with self-reported race/ethnicity in a study of almost 2 million Aetna enrollees.[8]

The correlation between BISG and self-reported race/ethnicity in our study was lower than previously reported. This may be a result of the increasing complexity of the demographics of the US population since the 2000 Census. Examining patients whose racial classification changed when predicted as opposed to self-reported information was used may also provide insight into the lower correlation between the two and different results obtained using these methods. For example, patients of self-reported nonwhite race were more likely to be misclassified as white if they lived in the Northeast and in areas with higher median income, whereas patients who self-identified as white were more likely to be reclassified as nonwhites if they lived in the South and in areas with lower median income. This is not surprising as the BISG method is based on geocoding and therefore its accuracy depends on the degree of racial/ethnic segregation in a patient's census block group. Other studies have also found a higher rate of misclassification and smaller disparities for enrollees of commercial plans, particularly for members of black or Asian race/ethnicity, when indirect race/ethnicity information based on geocoding was used.[23,24] In addition, differences in the distribution of racial/ethnic groups between our study cohort and those of other investigators may have also contributed to the lower correlation we observed. In particular, 5.7% of our cohort self-identified as multiracial, whereas only 0.2% of subjects in the original validation study belonged to this group. Identifying multiracial individuals from surname and residence remains challenging if not impossible.[8] With the US population becoming more diverse and increasingly multiracial and multiethnic, we can only expect more misclassification with the current methods of race/ethnicity estimation.

TABLE 5. Impact of Full Coverage on Rates of Major Vascular Events or Revascularization* Stratified by Race/Ethnicity Based Upon different Methods of Race/Ethnicity Identification

	White				Nonwhite				
Classification Method	Full Rx Coverage Rate/ 100 Person-Year	Usual Rx Coverage Rate/ 100 Person-Year	Hazard Ratio† (95% CI)	*P*	Full Rx Coverage Rate/ 100 Person-Year	Usual Rx Coverage Rate/ 100 Person-Year	Hazard Ratio† (95% CI)	*P*	Interaction (*P*)
Self-reported race/ethnicity									
Not adjusting for income	15.3	16.0	0.97 (0.78–1.21)	0.79	18.6	30.1	0.65 (0.44–0.97)	0.04	0.05
Adjusting for income			0.97 (0.78–1.21)	0.79			0.65 (0.44–0.97)	0.04	0.05
Indirectly estimated race/ethnicity: binary categorization									
Not adjusting for income	14.6	17.1	0.87 (0.69–1.09)	0.23	22.4	26.6	0.87 (0.58–1.30)	0.49	0.83
Adjusting for income			0.87 (0.69–1.09)	0.23			0.87 (0.58–1.30)	0.49	0.84
Indirectly estimated race/ethnicity: imputation method									
Not adjusting for income	14.7	17.2	0.87 (0.69–1.11)	0.28	20.7	25.2	0.83 (0.53–1.30)	0.42	0.80
Adjusting for income			0.87 (0.69–1.11)	0.28			0.83 (0.53–1.30)	0.43	0.81

*Events are based on the first occurrence of any of the composite outcome events (fatal or nonfatal myocardial infarction, unstable angina, stroke, congestive heart failure, or coronary revascularization).

†Hazard ratios have been adjusted for the cluster, block randomized design, age, and comorbidity score.

CI indicates confidence interval; Rx, prescription.

To our knowledge, no prior research has compared the ability of self-reported and indirect measures to distinguish the effects of an intervention on clinically relevant outcomes. From a methodological perspective, we are also unaware of prior studies that have used imputation with race/ethnicity-predicted probabilities to properly account for uncertainty. It is certainly conceivable that self-identified race/ethnicity may be more strongly related to actual health behaviors than an estimated probability based on a person's last name and area of residence.[25] As a result, even a small degree of misclassification, as our study demonstrates, may lead to qualitatively different results compared with evaluations based on self-reported information and to failure to detect the clinical benefits of an intervention in the patients of nonwhite race/ethnicity. Therefore, while more research is clearly needed to evaluate the performance of these methods, our findings support proposals to collect race/ethnicity information directly from patients, as has been mandated in legislation, such as the Affordable Care Act, and accreditation standards, such as those from The Joint Commission.[26] Although indirect methods might be appealing in the current state of race/ethnicity data collection, relying on them to identify disparities or to evaluate interventions, particularly with respect to clinical indicators, might lead to wrong conclusions, inappropriate allocation of resources, and misguided policies.

Our study has several limitations. We evaluated clinical outcomes in 2387 commercially insured patients who were participants of MI FREEE trial and had self-reported and indirectly estimated race/ethnicity recorded, which may limit the generalizability of our findings. The results may differ for individuals who did not report their race/ethnicity, do not have health insurance, or those with Medicare coverage. Self-reported race/ethnicity information was available for only 41% of the MI FREEE trial population. Aetna collects this information on an ongoing basis from all segments of its business and across all geographic regions. While it is possible that this information might be less complete for certain groups, which could have led to selection bias, it is reassuring that the subgroup of the trial that had self-reported race/ethnicity information available did not differ from those who did not have it with regards to baseline characteristics (Appendix Table 2A, Supplemental Digital Content 1, http://links.lww.com/MLR/B41).

Indirect methods of race/ethnicity assignment require larger sample sizes to estimate disparities than self-reported data.[8] As a result, we might have been underpowered to detect the disparities with the indirect methods. As noted earlier, to have enough statistical power, we grouped all "nonwhite" patients together even though this group may not be homogenous with regard to medication adherence, attitudes about health, and other health-related behaviors. Classifying individuals into groups instead of directly using the probabilities might have led to a loss of efficiency and produced biased results as the BISG method was not developed to have racial/ethnic groupings collapsed in this manner. That said, any misclassification introduced by our choice to collapse racial groups should apply equally to both the direct and indirect methods we evaluated. Further, the results we obtained from the imputation analyses, which account for the uncertainty implicit in the indirect estimation of race/ethnicity, and from the analyses that incorporated the direct probabilities instead of categorical indicators were very similar to results obtained when patients were categorized.

In conclusion, using indirectly estimated race/ethnicity in place of self-reported information may lead to qualitatively and quantitatively different results when outcomes are assessed, suggesting that indirect methods may not accurately

capture aspects of race/ethnicity related to actual health behaviors. Efforts to detect, track, and improve disparities should be based on self-reported rather than indirectly identified race/ethnicity.

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