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Eliminating Medication Copayments Reduces Disparities In Cardiovascular Care

ABSTRACT Substantial racial and ethnic disparities in cardiovascular care persist in the United States. For example, African Americans and Hispanics with cardiovascular disease are 10–40 percent less likely than whites to receive secondary prevention therapies, such as aspirin and beta-blockers. Lowering copayments for these therapies improves outcomes among all patients who have had a myocardial infarction, but the impact of lower copayments on health disparities is unknown. Using self-reported race and ethnicity for participants in the Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) trial, we found that rates of medication adherence were significantly lower and rates of adverse clinical outcomes were significantly higher for nonwhite patients than for white patients. Providing full drug coverage increased medication adherence in both groups. Among nonwhite patients, it also reduced the rates of major vascular events or revascularization by 35 percent and reduced total health care spending by 70 percent. Providing full coverage had no effect on clinical outcomes and costs for white patients. We conclude that lowering copayments for medications after myocardial infarctions may reduce racial and ethnic disparities for cardiovascular disease.

Racial and ethnic disparities in cardiovascular care have been widely documented.[1] They have also been shown to persist in spite of overall improvements in cardiovascular mortality and risk factor control.[2,3] The disparities have been attributed, at least in part, to variations—not based on patient preference—in the receipt and long-term use of evidence-based therapies,[4–8] including preventive medications.[9,10] For example, adherence to statins is more than 50 percent lower for nonwhite patients, compared to their white counterparts.[11]

The Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) trial and a series of observational studies have demonstrated that reducing medication copayments is a cost-effective strategy for increasing adherence and improving cardiovascular outcomes.[12–19] This approach could also reduce disparities, since racial and ethnic minorities report higher rates of cost-related nonadherence than whites[20,21] and may thus be more likely to respond to interventions that address high out-of-pocket drug costs.

However, minority patients may have difficulty navigating the complexities of health insurance programs, including coverage expansions such as Medicare Part D.[22,23] Thus, insurance changes designed to improve access, such as copayment reductions, may inadvertently exacerbate disparities in care instead of ameliorating them, as has been observed with other quality improvement efforts.[24]

Using data from MI FREEE, we sought to evaluate whether providing full coverage without

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cost sharing for evidence-based secondary prevention medications—that is, drugs that have been proved to reduce adverse clinical events after a heart attack—had differential effects according to patients' self-identified race or ethnicity.

Study Data And Methods

PATIENT POPULATION AND STUDY DESIGN The design and primary results of the MI FREEE trial have been described elsewhere.[19,25] In brief, MI FREEE prospectively evaluated the impact of eliminating cost sharing (copayments, coinsurance, and contributions to deductibles) for secondary preventive medications in patients discharged from the hospital following myocardial infarction.

The study randomly assigned 5,855 patients to either full prescription coverage (2,845) or usual prescription coverage (3,010) for any brand-name or generic statin, beta-blocker, angiotensin-converting enzyme (ACE) inhibitor, or angiotensin receptor blocker.[25] Patients in the usual-coverage group paid out-of-pocket amounts for their prescribed medications that were set by their insurance plan design. We assigned patients to full or usual coverage by randomly assigning their plan sponsor to one of the two levels of insurance coverage. This ensured that all eligible employees of a given plan sponsor received the same coverage after randomization. Treatment choices were at the discretion of patients and their treating physician. Our cohort consisted of the 2,387 individuals (41 percent of the overall trial population) for whom self-reported race or ethnicity information was available.

MI FREEE demonstrated that eliminating copayments for secondary preventive therapies increased medication adherence by 4–6 percent ($p < 0.001$).[19] The primary outcome—a composite of the first readmission for a major vascular event (fatal or nonfatal myocardial infarction, unstable angina, stroke, or congestive heart failure) or coronary revascularization (coronary artery bypass surgery or percutaneous coronary intervention)—was not significantly reduced. However, the secondary clinical outcomes—readmission for a major vascular event (that is, excluding revascularization from the primary outcome) and rates of major vascular events or revascularization (that is, not only the first event)—were lower among patients who had full coverage with no cost sharing.

For the present study we analyzed whether providing full coverage without cost sharing for medications after myocardial infarction had differential effects according to race and ethnicity. We restricted the MI FREEE cohort to patients for whom self-reported race or ethnicity information was available, as described in further detail below. This study was approved by the Institutional Review Board at Brigham and Women's Hospital.

DATA ON RACE AND ETHNICITY Aetna, one of the largest commercial insurers in the United States, collects voluntarily reported race and ethnicity information from its beneficiaries when they log on to a secure member portal at the time of plan enrollment and on an ongoing basis thereafter. Beneficiaries categorize themselves into one of six groups: white; black or African American; Hispanic; American Indian or Alaska Native; Asian, native Hawaiian, or other Pacific Islander; and two or more races. Aetna has this information for approximately 35 percent of its enrollees and 41 percent of the MI FREEE trial population.

Because the numbers in specific race and ethnicity categories were small, we classified patients as being white or nonwhite so that we would have enough statistical power to detect clinically meaningful effects. In a sensitivity analysis, we reran our models specifically comparing white and black patients.

OUTCOMES We evaluated the impact of race or ethnicity on the trial's prespecified and previously reported outcomes.[19] Medication adherence was evaluated using pharmacy refill data to calculate a medication possession ratio—that is, the number of days' supply a patient had of each medication class available, divided by the number of days of the patient's eligibility for that medication. For each of the three study medication classes and for all classes together, patients were categorized as being fully adherent if their medication possession ratio was at least 80 percent throughout the follow-up period.[26]

The trial's primary clinical outcome was assessed by applying validated algorithms with specificities of at least 95 percent to Aetna's health care utilization databases.[25] Health care spending was assessed using insurers' claims data and included patients' out-of-pocket costs and insurers' costs incurred for both pharmacy-related expenses (prescription drugs) and nonpharmacy-related expenses (office visits, emergency department and hospital admissions, and diagnostic testing and procedures).

STATISTICAL ANALYSIS Baseline characteristics by racial or ethnic group for patients randomly assigned to full or usual insurance coverage were compared using chi-square and *t* tests, as appropriate. To evaluate whether the impact of full coverage differed by race or ethnicity, we ran outcome models for white and nonwhite patients separately. Then we reran our models in-

The implications of copayment reductions on racial or ethnic disparities were unknown before this study.

cluding all patients and an interaction term between treatment assignment and racial or ethnic group.

Medication adherence and health care expenditures were compared using generalized estimating equations, with adjustment for the cluster-randomized design. A logit link function with binary distributed errors was used for full adherence. Health spending was evaluated with the use of a log-link function with variances proportional to the mean.

Clinical outcomes were evaluated as the time to the first event after randomization using Cox proportional hazards models. The exposure time was calculated as the time between the date when a patient was assigned to his or her randomized group and the date of an outcome event, loss of insurance eligibility, or the end of the study period. We adjusted for clustering using a robust sandwich estimator for the covariance matrix.[27]

All of the models also adjusted for the blocking factors used for sample stratification, age, and comorbidity score. To do this, we used a validated disease risk score that predicts mortality within one year of myocardial infarction.[28] Each patient's score was calculated based on published weights for sex and the characteristics observed in the index hospitalization: shock, diabetes with complications, congestive heart failure, malignancy, cerebrovascular disease, pulmonary edema, acute renal failure, chronic renal failure, and cardiac dysrhythmias.

Weights for age were not included in our calculations because none of the patients in the trial were sixty-five or older. However, we adjusted for this variable separately in our multivariable models. Consistent with the Institute of Medicine's definition of *racial and ethnic disparities*[29] and recommendations from Benjamin Le Cook and coauthors,[30] our primary models did not adjust for income. We then reran our models including income in quintiles, based on each patient's ZIP code of residence.

All statistical analyses were performed using the statistical software SAS, version 9.3.

LIMITATIONS This was a secondary analysis of a randomized controlled trial, and we did not randomly assign patients by race or ethnicity. Thus, it is possible that our results are subject to residual confounding. This is especially true since we relied on administrative claims data that did not contain detailed clinical information, such as blood pressure or cholesterol levels.

MI FREEE was a study of commercially insured people younger than sixty-five. Therefore, our results may be relevant for many nonelderly people who will receive coverage through insurance exchanges, but they may not be generalizable to Medicaid or Medicare beneficiaries.

Self-reported information about race or ethnicity was available for only 41 percent of the MI FREEE population. Aetna collects such information through its member portal for all commercially insured people from all segments of its business, including both fully and self-insured plan sponsors, and from all geographical regions. It is, of course, possible that this information is less complete for certain subgroups, which may limit the generalizability of our findings. However, it is reassuring that the members of our study sample were very similar to the overall trial population with regard to baseline characteristics and follow-up event rates.

As noted above, we grouped all nonwhite patients together so that we would have enough statistical power to detect clinically meaningful effects. We recognized that nonwhite patients are a heterogeneous group of people with very different attitudes about health and health care, abilities to access health services, levels of health literacy, and health-related behaviors. Our results were qualitatively similar when we compared white and black patients, although the slightly smaller effect size in these analyses could suggest that nonblack minority groups would benefit the most from reduced copayments for medications after myocardial infarction.

Study Results

BASELINE CHARACTERISTICS The baseline characteristics of the patients in our study sample were very similar to those in the overall trial population (for more details about how the trial participants with self-reported race or ethnicity data compared to the entire trial cohort, see online Appendix Exhibit A).[31] Of the study sample, 531 (22.2 percent) identified themselves as being of nonwhite race or ethnicity.

There were notable differences in baseline characteristics between white and nonwhite patients. Compared to white patients, nonwhite

patients had lower median incomes, were less likely to be on cardiovascular medications before their index myocardial infarction, had more comorbid conditions, and were less likely to receive invasive procedures during their index hospitalization (for more details about the characteristics of white and nonwhite patients, see Appendix Exhibit B).[31] During follow-up, nonwhite patients in the usual coverage cohort were less adherent to the study medications, were more likely to experience adverse clinical outcomes, and had higher rates of total health care spending, compared to white patients in the same cohort (for details about how outcomes compared for white and nonwhite patients, see Appendix Exhibit C).[31]

Among white patients, those who were randomly assigned to full prescription coverage without cost sharing were less likely to be male and more likely to be on a beta-blocker before their index myocardial infarction than those assigned to usual prescription coverage (Exhibit 1). Among nonwhite patients, those with full coverage were more likely to have chronic obstructive pulmonary disease than those with usual coverage. Otherwise, patient characteristics were well balanced between randomized groups.

IMPACT OF FULL COVERAGE BY SELF-IDENTIFIED RACE OR ETHNICITY For patients who identified themselves as white, full coverage without cost sharing significantly improved medication adherence to each and all three of the study med-

EXHIBIT 1

Baseline Characteristics For Full And Usual Prescription Coverage Cohorts, By Self-Reported Race Or Ethnicity

	Prescription coverage							
	White (*n*=1,856)				Nonwhite (*n*=531)			
	Full (*n*=946)		Usual (*n*=910)		Full (*n*=260)		Usual (*n*=271)	
Characteristic	**Median**	**SD**	**Median**	**SD**	**Median**	**SD**	**Median**	**SD**
Income ($)	51,665	19,905	52,340	18,871	45,307	19,113	46,402	17,445
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)	53.7	7.4	53.6	7.5	51.6	8.5	52.3	7.9
Comorbidity score	2.6	1.9	2.7	1.9	2.9	2.0	3.0	2.0
HEALTH CARE USE BEFORE INDEX HOSPITALIZATION								
Distinct drugs	9.1	6.5	8.7	6.5	8.2	5.9	8.3	6.2
Hospital admissions	0.4	1.9	0.5	1.5	0.5	1.6	0.4	0.9
Physician visits	5.7	6.5	5.5	6.5	5.6	7.8	5.5	7.7
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Male	702	74.2	724**	79.6	195	75.0	192	70.8
MEDICATION USE BEFORE INDEX HOSPITALIZATION								
ACE inhibitor or ARB	519	54.9	475	52.2	142	54.6	142	52.4
Beta-blocker	656	69.3	589**	64.7	166	63.8	172	63.5
Clopidogrel	534	56.4	492	54.1	133	51.2	147	54.2
COPD medication	112	11.8	108	11.9	24	9.2	28	10.3
Statin	608	64.3	561	61.6	143	55.0	153	56.5
Warfarin	55	5.8	62	6.8	13	5.0	9	3.3
COEXISTING ILLNESS								
CHF	238	25.2	244	26.8	82	31.5	90	33.2
COPD	158	16.7	154	16.9	44	16.9	26**	9.6
Diabetes	285	30.1	283	31.1	109	41.9	113	41.7
Hypertension	658	69.6	646	71.0	199	76.5	211	77.9
Previous MI	147	15.5	158	17.4	43	16.5	47	17.3
Stroke	43	4.5	39	4.3	15	5.8	22	8.1
PROCEDURE IN INDEX HOSPITALIZATION								
Angiography	904	95.6	863	94.8	240	92.3	248	91.5
CABG	179	18.9	182	20.0	47	18.1	47	17.3
PCI	653	69.0	604	66.4	163	62.7	180	66.4

SOURCE Authors' analysis of baseline characteristics of MI FREEE trial participants with self-reported race or ethnicity information (see Note 19 in text). **NOTES** $N = 2,387$. Medication use before the index hospitalization and coexisting illnesses were assessed on the basis of all filled prescriptions and available diagnoses during the twelve-month period preceding the hospitalization. *Medication use* was defined as the filling of at least one prescription during that period. ACE is angiotensin-converting enzyme. ARB is angiotensin receptor blocker. COPD is chronic obstructive pulmonary disease. CHF is congestive heart failure. MI is myocardial infarction. CABG is coronary artery bypass graft. PCI is percutaneous coronary intervention. **$p < 0.05$

EXHIBIT 2

Full Adherence To Medications After Myocardial Infarction, By Prescription Coverage Cohorts And Self-Reported Race Or Ethnicity

	White (*n*=1,856)				Nonwhite (*n*=531)				
	Coverage, % adherent				Coverage, % adherent				
Medication class	Full (*n*=946)	Usual (*n*=910)	OR[a]	95% CI	Full (*n*=260)	Usual (*n*=271)	OR[a]	95% CI	Interaction *p* value
ACE inhibitor or ARB	29.7	24.3	1.31	1.06,1.62	27.7	19.6	1.20	0.88,1.64	0.42
Beta-blockers	33.2	26.3	1.41	1.14,1.75	28.8	20.7	1.53	1.01,2.32	0.63
Statins	43.2	34.7	1.44	1.17,1.77	36.2	26.2	1.82	1.31,2.53	0.59
All medication classes	12.9	9.7	1.35	1.04,1.77	12.3	5.5	2.26	1.41,3.61	0.10

SOURCE Authors' analysis of whether the effect of providing full coverage on medication adherence in MI FREEE differed by race or ethnicity (see Note 19 in text). **NOTES** *Full adherence* was defined as having a supply of medications available on at least 80 percent of days during follow-up. Patients who did not fill a particular prescription after randomization were considered to be nonadherent. OR is odds ratio. CI is confidence interval. [a]*p* values for tests of odds ratios significantly different from 1 were all 0.01 or lower except for all medication classes for whites ($p = 0.03$) and angiotensin-converting enzyme inhibitors or angiotensin receptor blockers ($p = 0.25$) and beta-blockers ($p = 0.04$) for nonwhites.

ication classes (Exhibit 2). For nonwhite patients, full coverage significantly increased adherence to beta-blockers, statins, and all three of the study medications, but not adherence to ACE inhibitors or angiotensin receptor blockers.

There was no significant interaction between which coverage group patients were assigned to and their race or ethnicity (Exhibit 2). However, there was a trend toward a greater impact of full coverage without cost sharing on adherence to all three of the study medications among nonwhite patients compared to white patients.

Providing full drug coverage without cost sharing significantly reduced rates of the primary clinical outcome—the first readmission for a major vascular event or coronary revascularization—among nonwhite patients (Exhibit 3). However, it had no effect on those who identified themselves as white (Exhibit 4).

Repeating our analyses after we adjusted for income did not change our findings (hazard ratio for nonwhite patients: 0.66; 95% CI: identical to that in Exhibit 3; hazard ratio and 95% CI for white patients were identical to those in Exhibit 4; p value for interaction $= 0.05$). When we restricted the analysis to the 183 patients who identified themselves as black, we had results that were qualitatively similar to those for all nonwhite patients (hazard ratio: 0.76; 95% CI: 0.40, 1.45). However, our study was statistically underpowered to demonstrate significant effects (for detailed results of the comparison of white and black patients, see Appendix Exhibit D).[31]

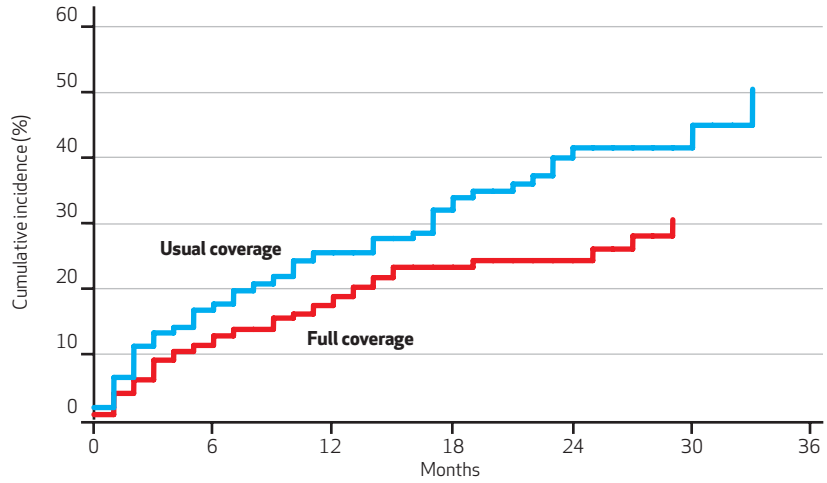
Providing full prescription medication coverage without cost sharing reduced total health care spending by 70 percent among patients who identified themselves as nonwhite (relative spending: 0.30; 95% CI: 0.16, 0.56; $p < 0.05$) (Exhibit 5). However, it did not reduce spending among white subjects (relative spending: 1.29; 95% CI: 0.60, 2.74; $p = 0.52$; p value for interaction < 0.001)

Discussion

In our secondary analysis of the MI FREEE trial, we found that providing full coverage without cost sharing for cardiovascular medications improved adherence for all patients. But full coverage was significantly more effective in reducing both rates of major vascular events or revascularization and total health care spending for people who identified themselves as nonwhite, compared to those who identified themselves as white.

EXHIBIT 3

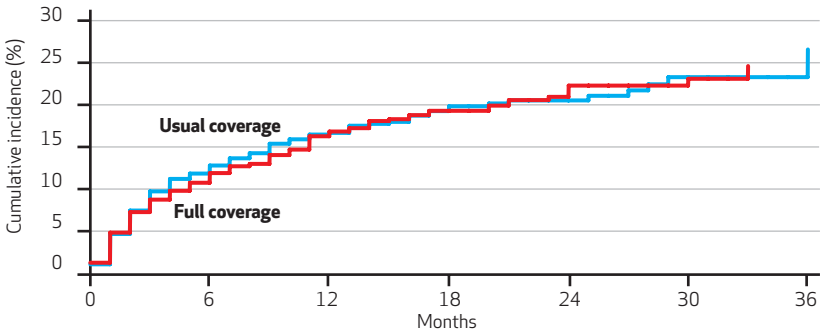
Cumulative Incidence Of First Major Vascular Event Or Revascularization Among Nonwhite Patients, By Prescription Coverage Cohorts



SOURCE Authors' analysis of clinical outcome data for MI FREEE trial participants who self-identified as being of nonwhite race or ethnicity (see Note 19 in text). **NOTE** Hazard ratio is 0.65 (05% CI: 0.44, 0.97; $p = 0.04$).

EXHIBIT 4

Cumulative Incidence Of First Major Vascular Event Or Revascularization Among White Patients, By Prescription Coverage Cohorts



SOURCE Authors' analysis of clinical outcome data for MI FREEE trial participants who self-identified as being of white race or ethnicity (see Note 19 in text). **NOTE** Hazard ratio is 0.97 (95% CI: 0.78, 1.21; $p = 0.79$).

We believe that this differential effect of copayment reductions across racial and ethnic groups is the result of nonwhite patients' significantly lower baseline rate of adherence and higher baseline risk of recurrent cardiovascular events, compared to white patients. In this context, a similar magnitude of adherence improvement for white and nonwhite patients appears to have translated into clinically and economically meaningful effects for nonwhite patients because of their comparatively worse baseline status.

Substantial racial and ethnic disparities in cardiovascular care persist in the United States.[2,3,32] For example, African Americans and Hispanics with cardiovascular disease are 10–40 percent less likely than whites to receive secondary prevention therapies, such as aspirin and beta-blockers.[33,34] Compared to white patients, after a stroke nonwhite patients are 15 percent less likely to receive smoking cessation counseling, 16 percent less likely to be discharged on an antithrombotic medication, and almost 10 percent less likely to be on a lipid therapy.[35] Even in an integrated health care system like the Veterans Health Administration, disparities of 10 percentage points in cholesterol control measures and 6 percentage points in blood pressure control measures have been observed when comparing black and white patients.[36]

Strikingly, we found that providing full coverage without cost sharing for evidence-based medications after myocardial infarction essentially eliminated the large disparities in rates of adverse coronary events that were evident between white and nonwhite patients in the control group of this study. As a result, our findings support increasing the frequency with which efforts to address cardiovascular disparities are accompanied by a relatively simple policy change: reducing or eliminating copayments for medications.[37]

Programs that reduce copayments for evidence-based medications, a strategy often called value-based insurance design,[38] are now widely used in the United States by all of the largest health insurers and many of the largest employers.[39] The peer-reviewed literature evaluating this benefit design supports its ability to increase the use of essential medication and improve clinical outcomes without increasing overall health care spending.[12,14,15,17–19] The implications of copayment reductions on racial or ethnic disparities were unknown before this study.

Earlier lessons from other policy changes suggest that there may have been reason to be concerned that such an intervention would do little to address disparities. For example, racial and ethnic minority groups report having greater difficulty accessing information about and receiving services provided by Medicare Part D, a program that substantially improved access to essential medications.[22] It is therefore imperative to establish an empirical basis from which to predict the impact of commonly used benefit design changes on health disparities.

Under the Affordable Care Act, there will be a substantial expansion of coverage for the most vulnerable patients, among whom racial and ethnic minorities are overrepresented.[40,41] As these populations gain coverage, eliminating economic barriers to highly effective cardiovascular medications should be considered as one way to improve the health of these patients while also reducing their total cost of care. In fact, the Affordable Care Act calls for the creation of guidelines to facilitate the broader use of insurance benefits that reduce or eliminate copayments for evidence-based medications.

EXHIBIT 5

Total Health Care Spending, By Prescription Coverage Cohorts And Self-Reported Race Or Ethnicity

	Spending	
Cohort	**White (n=1,856)**	**Nonwhite (n=531)**
Mean total spending		
Full coverage	$73,755	$ 37,198
Usual coverage	56,163	119,887
Relative spending	1.29	0.30
p value	0.52	< 0.001

SOURCE Authors' analysis of health spending data for MI FREEE trial participants based upon self-reported race or ethnicity (see Note 19 in text). **NOTES** p values are for relative spending significantly different from 1. For interaction between treatment assignment and racial or ethnic group, $p < 0.001$.

Much of the infrastructure necessary to implement this benefit design change already exists. As movement toward a more value-based reimbursement system progresses, providers—who will increasingly assume financial risk for the total cost of care for the populations they serve in accountable care models—should encourage payers to reduce financial barriers to highly effective medications as a way to improve the quality of care for those who need it most.

Of course, it would not be feasible to implement a value-based insurance design plan differentially according to race or ethnicity. However, our results suggest that, at a minimum, eliminating copayments could improve cardiovascular outcomes and reduce disparities for racial and ethnic minorities without adversely affecting nonminority beneficiaries. This suggests that the policy would, on average, benefit patients with cardiovascular disease and would not have any detrimental effects.

It should be noted that even white patients in our study had very low levels of adherence and a very high risk of major adverse coronary events. Thus, their complete lack of benefit from reductions in medication copayments was somewhat surprising. This result underscores calls to develop and evaluate other strategies to promote the long-term use of evidence-based therapies for patients with cardiovascular disease.[42]

Conclusion

Our results demonstrate that a simple, low-risk benefit design change can improve clinical outcomes and reduce costs in nonwhite populations with cardiovascular disease while reducing disparities in care. It has been difficult to identify such interventions as the health care system undergoes transformation. The broader implementation of this change should be considered. ■

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Errata

MUENNIG ET AL., JUNE 2013, P. 1072

Peter Muennig and colleagues presented research on the mortality effects of the Florida Family Transition Program, a welfare reform experiment initiated in the 1990s that put time limits on welfare benefits and required enrollees to participate in employment-related services. The authors found that enrollees in this program experienced a 16 percent higher mortality rate compared to enrollees in a control group who received regular benefits and had no additional employment requirements or job counseling. This finding was reported by the authors to be significant at the 0.01 level (hazard ratio: 1.16; 95 percent confidence interval: 1.14, 1.19; $p < 0.01$). A reader subsequently raised concerns about the magnitude of the standard errors reported in the article, noting that they seemed implausibly small. This, in turn, raised concerns about the validity of the finding of a significant difference in mortality between the experimental and control groups. *Health Affairs* followed up on this concern by assigning the published article to three independent reviewers and asking them to comment on the appropriateness of the methods and the validity of the finding. Reviewers found that the authors' use of a cluster-robust variance estimator was inappropriate in light of the small number of clusters (two) used in this analysis, because variances estimated by this method are biased downward toward zero as the number of clusters diminishes—a problem that had not been detected in the initial reviews of the paper. As a consequence, the standard errors reported in the article are understated, and the reported finding of a significant difference in mortality between the experimental and control groups is not supported by evidence presented in the article. Below the authors present the results of additional analysis they conducted to avoid the problems noted above for cluster-robust variance estimators with a small number of clusters. In the new analysis, the authors did not find a significant difference in mortality between the experimental and control groups. *Health Affairs* regrets the error and is grateful to David C. Norris for bringing this to our attention. We also acknowledge with gratitude the assistance of three anonymous reviewers who reviewed and commented on the published work for us.

The Authors Respond: In this erratum we revisit our analyses in our June 2013 article. In the article we present the point estimate and confidence interval for the impact of participating in the Florida Family Transition Program in Escambia County on mortality while controlling for year of birth, year of assignment, and site location and clustering the standard errors on location (1.16; 95 percent CI: 1.14, 1.19). (Note that the point estimates are hazard ratios.) We present here the results for the comparable analysis without clustering, while including location fixed effects as well as the other covariates above (1.16; 95 percent CI: 0.83, 1.64). The location fixed effects approach helps account for common characteristics within site but, unlike clustering, does not rely on having a large number of clusters. In the article we also presented combined results including participants in both Escambia and Alachua Counties, again controlling for year of birth, year of assignment, and site location and clustering the standard errors on location. The point estimate for that analysis is 1.26 (95 percent CI: 1.10, 1.45). Without clustering the standard errors around location, while controlling for location fixed effects as well as the other covariates, the new point estimate is 1.26 (95 percent CI: 0.96, 1.66). In both analyses the new results are no longer statistically significantly different from zero.

In reviewing our results, we identified two instances where results were incorrectly reported. First, the reported confidence interval for the combined sample, 1.09, 1.46, should have been stated as 1.10, 1.45. Second, there were 140 (not 142) deaths in Escambia, 74 (not 75) within the experimental group, and 66 (not 67) within the controls. [*Peter Muennig, Zohn Rosen, and Elizabeth Ty Wilde*]

BAZZOLI ET AL., MAY 2014, P. 745

Note 1 contained an error in the source's page numbers. The correct page numbers are 208–19. The article has been corrected online.

CHOUDHRY ET AL., MAY 2014, P. 868

In Exhibit 4, the 95% confidence interval in the note was incorrect. The correct 95% CI is 0.78, 1.21. The article has been corrected online.