



## Racial and Gender Trends in the Use of Implantable Cardioverter-Defibrillators Among Medicare Beneficiaries Between 1997 and 2003

Clinical indications for implantable cardioverter-defibrillators (ICDs) have expanded rapidly in the past decade. Randomized clinical trials have found that ICDs reduce mortality in patients with documented ventricular arrhythmias and in those with left ventricular dysfunction who are at high risk for sudden cardiac death.<sup>1-6</sup> In addition, ICDs have also demonstrated improvements in clinical outcomes in real-world populations,<sup>7,8</sup> suggesting favorable cost-effectiveness ratios when compared with standard medical therapy.<sup>9,10</sup> Despite these findings, there is some evidence that ICDs remain underutilized among eligible patients due to their high upfront costs and limited resources.<sup>11</sup>

Prior studies have documented racial and gender differences in the use of medical and surgical procedures, including ICDs.<sup>12-15</sup> Most of these reports suggest underuse and disparities in care for vulnerable populations, including blacks and women, when compared with whites and men.<sup>16-19</sup> What remains unclear, however, is the extent to which these differences have been exacerbated by expanding indications for procedures whose optimal roles in care are still evolving. If newer procedures disseminate more slowly among blacks and women, it would argue for the development of specific strategies for ensuring that emerging and innovative evidence is appropriately translated to vulnerable populations.

Accordingly, we examined changes in racial and gender differences in population-based rates of utilization for ICDs among Medicare beneficiaries between 1997 and 2003, a time frame that encompassed the publication of several

*Differences in the use of implantable cardioverter-defibrillators (ICDs) have been reported, but the extent to which they have widened after the publication of major clinical trials supporting their use is unclear. Using data on Medicare beneficiaries, the authors determined annual age-standardized population-based utilization rates of ICDs for white men, black men, white women, and black women from 1997 to 2003. During the study period, overall use of ICDs increased most for white men (81.7–254.7 procedures per 100,000 from 1997 to 2003) and black men (38.0–151.7 procedures per 100,000), with white women (28.9–98.4 procedures per 100,000) and black women (18.2–77.3 procedures per 100,000) showing smaller increases in comparison. After adjustment with multivariable regression models, differences in utilization rates between whites and men widened compared with blacks and women between 1997 and 2003, a period when indications for ICD therapy have expanded. Congest Heart Fail. 2009;15:51–57. ©2009 Wiley Periodicals, Inc.*

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landmark randomized clinical trials supporting their use. Examining the use of ICDs in Medicare beneficiaries over this time period represents an ideal opportunity to evaluate how expanding indications for newer procedures may affect racial and gender differences in utilization given that the majority of recipients of ICDs in the United States are 65 years or older, which allows for near complete capture of their utilization within this national data source.

### Methods

**Data Sources and Study Population.** For these analyses, Medicare Provider and Analysis Review (MEDPAR) Part A, Denominator, and Provider-of-Service (POS) files from 1997 through 2003 were obtained from the Centers for Medicare & Medicaid Services (CMS). Part A files include data on acute-care hospitalizations. Denominator files contain data on eligible Medicare beneficiaries for that year, including

demographic and enrollment information. POS files contain data on hospital providers, including facility characteristics and zip code locations. Data on all Medicare beneficiaries age 65 years or older enrolled in fee-for-service programs within the United States were included. To be consistent with prior literature on racial differences in the Medicare population, we excluded the non-black, non-white population (9.6% of the overall study population). After these exclusions, the average study cohort size annually was 26.6 million enrollees, of which 25.3 million (95%) had both Part A and Part B coverage. No substantial changes in the distribution of the population by race or gender were seen during this study period.

We used the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* procedural codes to identify patients undergoing ICD implantation with or without pacemaker capability (*ICD-9-CM* procedure codes 37.94–37.96) from 1997 to 2003. For the purposes of a secondary analysis, we also categorized ICD implantation as being performed for primary or secondary prevention. We considered an ICD to be placed for secondary prevention if a patient had an inpatient hospitalization for ventricular arrhythmia (*ICD-9* diagnosis codes 427.1 and 427.41) or cardiac arrest (*ICD-9* diagnosis code 427.5) within the prior year and did not have a concurrent myocardial infarction (*ICD-9* diagnosis code 410.x) during the index arrhythmic event. ICDs that did not meet criteria for secondary prevention were categorized as being performed for primary prevention.

To contrast differences in utilization rates of ICDs with general trends in racial and gender differences in procedural utilization during this time period, we also analyzed data on patients undergoing pacemaker implantation (*ICD-9-CM* procedure codes 00.50, 00.53, 37.70–37.72, and 37.80–37.83) including single- and dual-chamber devices. These patients represent an ideal comparison group for several reasons. First, unlike with ICDs, no randomized clinical trials were published during this time

period that would have rapidly expanded indications for these devices. Moreover, pacemaker implantation is frequently performed by physicians also responsible for placing an ICD, thereby representing a reasonable proxy for temporal changes in access to these procedures. The Institutional Review Board of the University of Michigan and the CMS approved this protocol prior to its initiation.

**Statistical Analyses.** We calculated population-based rates of utilization for ICDs and pacemakers in white men, black men, white women, and black women between 1997 and 2003 in the United States. The numerator for these rates was the total number of patients in each racial and gender category that underwent the procedure in that calendar year. The denominator for these rates was the total number of eligible Medicare beneficiaries in each racial and gender category enrolled in the mid-point of that calendar year. All rates were adjusted for differences in age (65–69 years, 70–74 years, 75–79 years, 80–84 years, and 85 years and older) across years using direct standardization techniques with the total beneficiary population for the entire study period as the standard population.<sup>20</sup> Rates for ICDs used in secondary prevention were further adjusted for annual rates of qualifying ventricular arrhythmias and cardiac arrest, with rates among white men in each age stratum as the referent.

We visually examined trends in ICD use between 1997 and 2003, and qualitatively assessed whether racial and gender differences increased, decreased, or remained the same over time. To test for statistically significant changes in racial and gender differences over time, we constructed a series of linear regression models with white men as the primary reference group. Differences in population-based rates between white men and the other 3 racial and gender categories were the dependent variables in these separate models, with “year” (ie, independent variable) included as a continuous variable. As a result, the regression coefficient for the variable

“year” in the models represented mean annual increases or decreases from baseline differences in utilization. We also evaluated quadratic and cubic values of the variable year in our regression models but did not find that the inclusion of these exponential terms changed our results (results not reported). In addition, we separately compared rates for black men with black women and white women with black women.

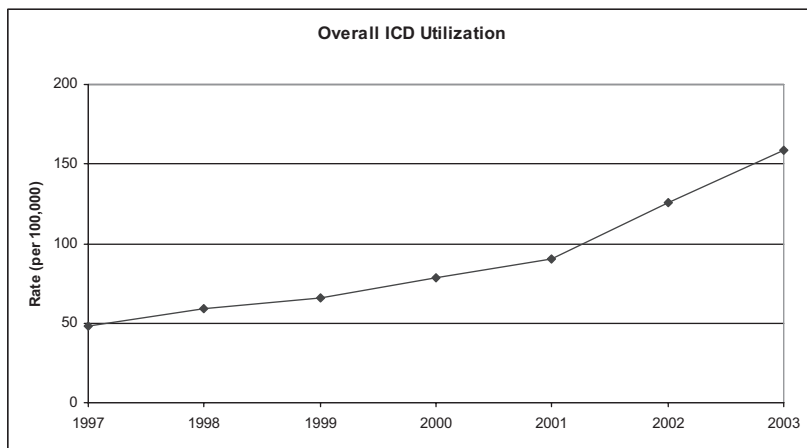
In a secondary analysis, we determined population-based rates of utilization for ICDs separately among patients identified as undergoing placement for primary and secondary prevention. We constructed similar linear regression models to those described above. For all analyses, the null hypothesis was evaluated at a 2-sided significance level of 0.05. All analyses were performed with SAS 9.1 (SAS Institute, Cary, NC).

## Results

From 1997 through 2003, age-standardized, population-based rates of ICD use in the Medicare population increased from 48.3 procedures per 100,000 to 158.9 procedures per 100,000. This increase did not occur linearly: rates increased by 10.5 procedures per 100,000 per year from 1997 to 2001 and then increased by 29.3 procedures per 100,000 per year from 2001 to 2003 (Figure 1). In contrast, age-standardized, population-based rates of utilization for pacemakers in the Medicare population showed a more gradual increase from 372.6 procedures per 100,000 in 1997 to 495.2 procedures per 100,000 in 2003, an average increase of 5% per year (Figure 2).

**Population-Based Utilization by Race and Gender.** During the study period, overall rates of ICD use increased most for white men (81.7 procedures per 100,000 in 1997 to 254.7 procedures per 100,000 in 2003) and black men (38.0–151.7 procedures per 100,000), with white women (28.9–98.4 procedures per 100,000) and black women (18.2–7.3 procedures per 100,000) showing smaller increases in comparison (Table I; Figure 1). Compared with white men, a

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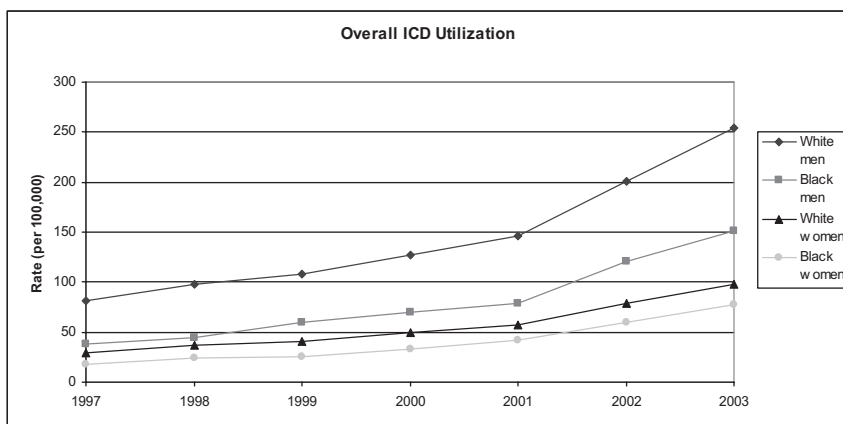


Figure 1. Age-adjusted national rates of overall implantable cardioverter-defibrillator (ICD) implantation (A) and by race and gender groups (B) among Medicare enrollees, 1997 through 2003.

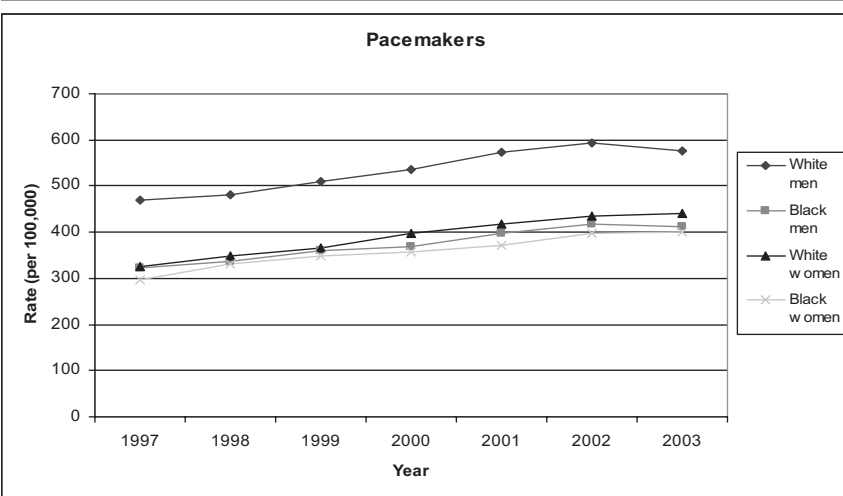


Figure 2. Age-adjusted national rates of pacemaker implantation among Medicare enrollees, 1997 through 2003.

**Table I.** Rates of Implantable Cardioverter-Defibrillator Procedures in Medicare Enrollees, 1997 and 2003<sup>a</sup>

	1997	2003	CHANGE
Overall			
White men	81.7	254.7	173.0
Black men	38.0	151.7	113.7
White women	28.9	98.4	69.5
Black women	18.2	77.3	59.1
Primary prevention			
White men	10.4	56.9	46.5
Black men	5.5	34.3	28.8
White women	1.9	12.4	10.5
Black women	1.2	13.7	12.5
Secondary prevention			
White men	71.3	197.8	126.5
Black men	32.5	117.4	84.9
White women	27.0	86.0	59.0
Black women	17.0	63.6	46.6

<sup>a</sup>Rates are per 100,000 enrollees.

significant widening of existing differences in utilization rates were seen from 1997 to 2003 across the other 3 racial and gender categories (Table II). The difference in utilization rates for white men as compared with black men widened on average by +9.0 procedures per 100,000 per year over the study period or a relative increase of 21% annually ( $P=.002$ ).

Similar but more pronounced effects were seen when white men were compared with white women (difference, +16.3 procedures per 100,000 per year or a relative increase of 31% annually;  $P=.002$ ) and black women (difference, +17.8 procedures per 100,000 per year or a relative increase of 28% annually;  $P=.001$ ). Moreover, the existing difference in utilization rates for black men as compared with black women widened on average by +8.8 procedures per 100,000 per year or a relative increase of 44% annually ( $P=.001$ ), whereas the difference for white women as compared with black women widened by +1.6 procedures per 100,000 per year or a relative increase of 15% annually ( $P=.001$ ).

No significant widening or narrowing in differences for pacemaker utilization were noted among the 4 race and gender categories throughout the study period, with each group achieving similar absolute utilization rate gains over time (Figure 2).

**Table II.** Widening of Baseline Differences in Implantable Cardioverter-Defibrillator (ICD) Utilization Between Racial and Gender Subgroups

	BASELINE UTILIZATION DIFFERENCE <sup>a</sup>	ANNUAL CHANGE FROM BASELINE GAP <sup>b</sup>
Overall ICDs		
White men	Reference	Reference
Black men	43.7	9.0 (21%) <sup>c</sup>
White women	52.8	16.3 (31%) <sup>c</sup>
Black women	63.5	17.8 (28%) <sup>c</sup>
White women	Reference	Reference
Black women	10.7	1.6 (15%) <sup>c</sup>
Black men	Reference	Reference
Black women	19.8	8.8 (44%) <sup>c</sup>
Primary prevention		
White men	Reference	Reference
Black men	4.9	2.2 (45%) <sup>c</sup>
White women	8.5	4.7 (55%) <sup>c</sup>
Black women	9.2	4.5 (49%) <sup>c</sup>
White women	Reference	Reference
Black women	0.7	-0.3 (-43%) <sup>c</sup>
Black men	Reference	Reference
Black women	4.3	2.2 (51%) <sup>c</sup>
Secondary prevention		
White men	Reference	Reference
Black men	38.8	6.8 (18%) <sup>c</sup>
White women	44.3	11.5 (26%) <sup>c</sup>
Black women	54.3	13.4 (25%) <sup>c</sup>
White women	Reference	Reference
Black women	10.0	1.8 (18%) <sup>c</sup>
Black men	Reference	Reference
Black women	15.5	6.6 (43%) <sup>c</sup>

<sup>a</sup>Rates are per 100,000. <sup>b</sup>Rates represent the annual absolute (and relative, in %) change per 100,000 from the baseline difference in ICD utilization between the compared groups. <sup>c</sup>P for trend <.05 in linear regression models.

**Population-Based Utilization by Indication.** For ICDs implanted for primary prevention, rates of utilization over time increased most for white men (10.4 procedures per 100,000 in 1997 to 56.9 procedures per 100,000 in 2003) and black men (5.5–34.3 procedures per 100,000), with women showing smaller increases (Table I; Figure 3). In addition, the rate of increase was linear from 1997 to 2001 for all 4 groups but then rose sharply in 2002, coincident with the publication of the Second Multicenter Automated Defibrillator Implantation Trial (MADIT-II). Existing differences in rates of ICD use widened between white men and the other 3 racial and gender categories during the study period (Table II).

Similar trends were generally noted for ICDs implanted for secondary prevention. Rates of utilization over time increased most for white men (71.3–197.8 procedures per 100,000) and black men (32.5–117.4 procedures per 100,000), with women showing smaller

increases (Table I; Figure 3). In contrast to rates associated with primary prevention, changes over time were, in large part, linear for all 4 groups. Still, a significant widening in the existing differences in ICD utilization rates was seen across each race and gender category when compared with white men during this time period (Table II).

## Discussion

We found that rates of ICD use not only differed by race and gender, but that such differences widened from 1997 to 2003, a time period that was characterized by the publication of several landmark randomized clinical trials related to their use. The widening was most notable for ICDs implanted for primary prevention and grew most markedly after publication of the MADIT-II trial in 2002 when indications and reimbursement for primary prevention were expanded. In contrast, we found no increases in the existing differences of

pacemaker use during this time period. Our findings highlight that there is a potential for disparities in the utilization of newer procedures like ICDs to widen among vulnerable populations as indications for their use expand.

Although prior studies have shown that blacks are less likely to receive an ICD for secondary prevention, no prior reports have examined whether differences in use have widened or narrowed over time. In addition, earlier studies focused on relative differences in the use of ICDs.<sup>11,17,21,22</sup> In contrast, we examined absolute differences in rates of utilization. Absolute differences provide a better measure of the total number of at-risk Medicare beneficiaries who may benefit from the narrowing or elimination of racial or gender differences in procedural utilization. This is because trends in absolute differences have a consistent interpretation, regardless of whether the primary outcome is receipt or nonreceipt of therapy.<sup>15</sup> For instance, if adherence to an effective medication increases from 2% to 80% among whites but only from 1% to 60% among blacks, this would represent a significant 19% absolute increase in the difference in adherence but a paradoxical relative decrease (from 2.0 to 1.3). Conversely, if nonadherence was the outcome measured instead of adherence, the absolute difference (in this case, decrease in nonadherence) would remain at 19% and there would instead be a relative decrease in nonadherence from 1.0 to 0.5. Therefore, from a policy perspective, absolute differences provide a more informative and consistent assessment of disparities in resource utilization across populations. In this study, we found that although rates of utilization for ICDs increased over time for blacks and women, these increases did not reduce baseline racial and gender gaps because the corresponding rates for whites and men increased even faster. Prior research evaluating absolute differences in the use of medical therapies has similarly argued that this approach may provide a more useful benchmark for policy-makers interested in addressing racial and gender disparities<sup>15</sup> and therefore highlights the need to examine both relative

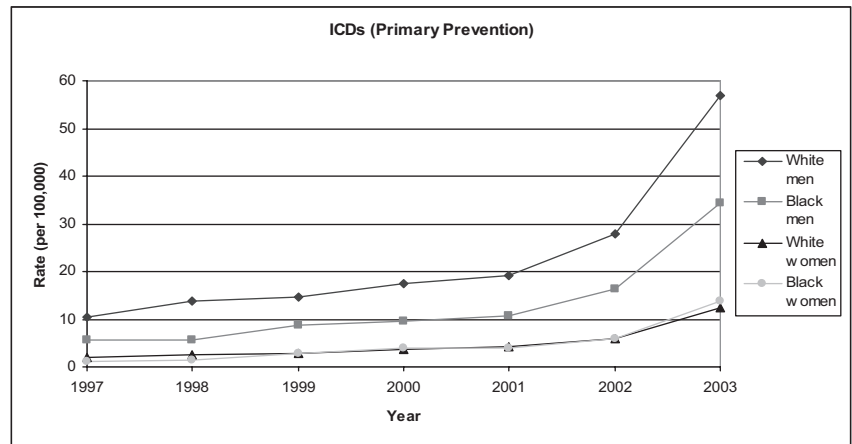
and absolute differences in the utilization of effective therapies.

The reasons for observed racial and gender differences in observed racial and gender differences in utilization rates of effective therapies likely reflect complex interactions between patients, providers, healthcare markets, and geographic factors. It is possible that differences may be attributable to the “overuse” of ICDs in whites and men. It may also be that “underuse” in blacks and women is largely responsible for these differences.<sup>16,18,19</sup>

Our analysis is unfortunately unable to differentiate between these 2 possibilities. Prior evidence does suggest that patient preferences and cultural norms for particular therapies can be a significant determinant for procedural utilization and may be partly responsible for these differences across various racial and ethnic groups.<sup>23</sup> There may also be differences in the intensity and frequency with which physicians engage patients in the decision-making process, which may influence patient acceptance of ICD therapy. Although a patient’s ability to pay may affect whether therapy is offered by a physician, this is unlikely to be an explanation for our observed racial differences, as our study population was an insured Medicare population where the vast majority (95%) had both Part A and Part B coverage. Lastly, geographic variation in access to care may affect which patient subgroups will likely receive state-of-the-art therapies, although one would not expect geography to have a significant impact on gender differences in utilization. The fact that we also demonstrated no significant change in differences in utilization rates for pacemakers during the study period suggests that access to care may be less likely to explain our results.

Although racial differences in utilization of invasive treatments have been documented widely throughout the cardiovascular literature, gender differences in their use have been less well studied. Because we did not have patient-level data on rates of ischemic heart disease and left ventricular dysfunction in the population, and because men have higher rates of ischemic heart disease than age-matched women, differences in disease severity and clinical indica-

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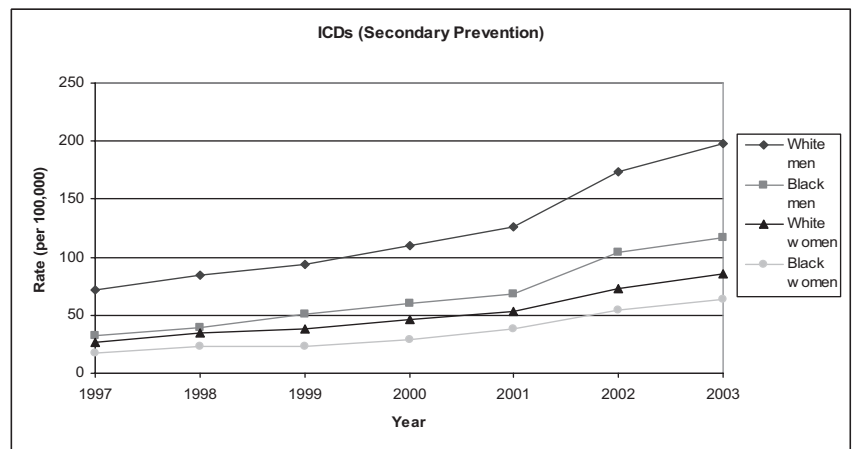


Figure 3. Age-adjusted national rates of implantable cardioverter-defibrillator (ICD) implantation for primary prevention (A) and secondary prevention (B) among Medicare enrollees, 1997 through 2003.

tions certainly explain a portion of the gender differences observed in the use of ICDs for primary prevention. However, significant gender differences and widening of such differences were similarly observed in the utilization of ICDs for secondary prevention, even after controlling for population-based rates of incident-qualifying ventricular arrhythmias for an ICD. Therefore, further studies are needed to determine factors related to underuse of ICDs in women.

An important aspect of our study was the separation of patients into those undergoing ICD placement for primary and secondary prevention. At the beginning of our study period, clinical trials

such as the Amiodarone vs Implantable Defibrillator (AVID) trial established the mortality benefit of ICDs in secondary prevention for patients with documented ventricular arrhythmias.<sup>5</sup> Rates of ICD use for secondary prevention therefore increased for each racial and gender group annually during our study period, although disproportionately so for whites and men. This accounted for the widening of existing differences noted over time in this population. In contrast, the use of ICDs for primary prevention was limited until 2002 and overall population-based rates of utilization remained low. After the publication of the MADIT-II trial, however, use of

ICDs rose in this population also with a similar widening in existing differences across racial and gender categories.

As the Institute of Medicine and healthcare policy-makers focus on eliminating or narrowing racial and gender disparities in healthcare outcomes, it is important to recognize that appropriately translating findings from emerging and innovative therapies to vulnerable populations remains a real challenge. Our study supports the hypothesis that the benefits of expanding indications for evolving technologies, like ICDs, are not equitably distributed among blacks and women. Although there has been a concerted effort to improve recruitment of these patients in contemporary clinical trials, future studies may be needed to identify strategies for ensuring that this evidence is evenly disseminated.

Our study should be interpreted in the context of the following limitations. We did not assess ICD utilization in patients under 65 years of age. Because the majority of ICD recipients are Medicare eligible, it is unlikely that inclusion of these patients would have significantly affected our results. We also did not have clinical information on left ventricular ejection fraction or the precise indication for receiving an ICD. As a result, our estimates of utilization rates

for primary and secondary prevention, which were secondary analyses in this study, may contain misclassification bias and should be interpreted with these considerations in mind. Moreover, differential indications may explain some of the observed differences in our study, although it is unlikely that the prevalence of the underlying indications for ICDs in different racial and gender groups would have changed over our period of observation. Therefore, widening differences in the rates of procedure use over time suggest there is differential penetration of new knowledge or differential intensity of recommendation of ICD therapy to disadvantaged populations, including black patients and women. As mentioned previously, our study is unable to establish what the "right" utilization rate for ICDs should be. Therefore, we are unable to know whether observed differences were due to overuse, underuse, or both. Regardless, differences in utilization rates across race and gender are important considerations for policy-makers.

## Conclusions

We found that baseline rates of ICD utilization differed by race and gender, and that these differences widened from 1997 to 2003 as the indications for these

procedures expanded. Our study raises questions about the potential for disparities in newer procedures to worsen as the benefits of landmark randomized clinical trials are translated into routine clinical practice. Accordingly, more research into the dissemination of new knowledge into practice is needed if the Institute of Medicine's goal for a more equitable healthcare system is to be realized.

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