Regional Variation in the Use of Implantable Cardioverter-Defibrillators for Primary Prevention
Results From the National Cardiovascular Data Registry

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Background—Although the use of implantable cardioverter-defibrillators (ICDs) for the primary prevention of sudden cardiac death varies by sex, race, and hospital, geographic variation in ICD use remains unexplored. Our objective was to quantify regional variations in the utilization of primary prevention ICDs in the United States, and to evaluate if an association exists between utilization and physician supply or the proportion of patients meeting the trial inclusion criteria.

Methods and Results—This is a cross-sectional analysis among the Medicare, fee-for-service population from the National Cardiovascular Data Registry. Using hospital referral regions, we calculated the age-, sex-, and race-adjusted rates of ICD placement for each region and assessed the correlation between these rates and (1) physician supply and (2) the proportion of patients meeting trial inclusion criteria. Substantial variation was found across quintiles of rate ratios of ICD implantation, ranging from 0.39 to 1.77 (compared with a national mean rate of 1.0). This ratio was not correlated with the supply of cardiologists ($R^2=0.01$), electrophysiologists ($R^2=0.01$), or with the proportion of patients meeting trial inclusion criteria ($R^2<0.01$). Over all, 13% of all patients receiving ICDs did not meet trial criteria.

Conclusions—Marked geographic variation in the use of primary prevention ICDs exists across the United States that is not correlated with physician supply. Although $>1$ in 10 patients received ICDs outside of trial criteria, this potential overuse did not explain the variation. Future studies should consider underuse or misuse of primary prevention ICDs as causes of geographic variation. (Circ Cardiovasc Qual Outcomes. 2011;4:00-00.)

Key Words: implantable cardioverter-defibrillators □ congestive heart failure □ regional variations

Implantable cardioverter-defibrillators (ICDs) have revolutionized the treatment of patients with left ventricular systolic dysfunction. ICDs reduce mortality in selected clinical trials among participants with heart failure and left ventricular systolic dysfunction (primary prevention).☆ 6 Because of the mortality benefit demonstrated in these trials, the Center for Medicare and Medicaid Services (CMS) announced in 2005 that coverage for primary prevention ICDs would be expanded.☆ Early estimates suggested that these expanded indications would increase the total number of beneficiaries eligible for an ICD to $>500$ 000.☆ Because of concerns about the scale of this expanded coverage, combined with the scarcity of evidence in an older Medicare population, CMS included a “coverage with evidence development” mandate for all primary prevention ICDs billed to Medicare.☆ This “coverage with evidence development” is operationalized through mandatory reporting in a registry for the purposes of “determination of reasonable and necessary and quality improvement.”☆

The use of many cardiovascular procedures in the United States varies substantially by geographic region. For example, in 1996, the rates of coronary angiography ranged from 10.2 to 65.7 per 1000 Medicare beneficiaries, and the rates of coronary artery bypass grafting ranged from 2.2 to 11.4 per 1000 Medicare beneficiaries between Grand Junction, Colorado, and Houma, Louisiana.☆ Research on the use of secondary prevention ICD in the 1990s showed that a substantial proportion of racial variations could be explained by regional variations.☆ Although it is known that the use of primary prevention ICDs varies by sex, race, and hospital,☆☆ the extent to which primary prevention ICD use varies by geographic region is unknown.
The purpose of this study is 3-fold: (1) to determine the extent of regional variation in ICD utilization across the United States using data in the National Cardiovascular Data Registry for ICDs (NCDR ICD Registry); (2) to examine if an association exists between utilization and physician supply in a given region; and (3) to examine if an association exists between utilization and the extent to which patients meet enrollment criteria of the major primary prevention trials.1–4

**WHAT IS KNOWN**

- It is known that there is sex and race variation in implantable cardioverter-defibrillator (ICD) use.
- It is known that there is hospital variation in ICD use.

**WHAT THE STUDY ADDS**

- This article adds evidence of marked regional variation in ICD use.
- Further, there is no association between the regional supply of cardiologists or electrophysiologists and the regional rate of ICD implantation.
- There is no association between the proportion of patients not meeting the criteria for ICD implantation and the regional rate of ICD implantation, suggesting that overuse of ICDs in ineligible patients is not the cause of this variation.

**Methods**

**Study Design**

This is a cross-sectional study of regional variation in the use of ICDs, using the NCDR for ICDs. Use of the NCDR database was approved by the NCDR ICD Registry Research and Publications Committee, and analysis was approved by the Yale University School of Medicine Human Investigation Committee.

**Data Sources**

**National Cardiovascular Data Registry for ICDs**

The NCDR-ICD registry was used to identify the occurrence and geographic location of primary prevention ICD implants.2–4 Participation in this registry is mandated by CMS for reimbursement for all Medicare primary prevention ICDs, although many hospitals are registering all the ICDs they implant regardless of insurance status. It contains information on patient characteristics, including demographics and cardiac history; procedural characteristics, including device details, diagnostic studies, and complications; and hospitalization, including other cardiac procedures and discharge medications. This analysis used data from 2006 and 2007, the first 2 full calendar years in which data collection for the NCDR-ICD was performed. Data are submitted by participating hospitals using NCDR-certified software and data quality is examined with the Data Quality Reporting process.3,4 Implanting centers are mandated to enter complete and accurate data to receive Medicare reimbursement.

**Hospital Referral Regions**

Hospital referral regions (HRRs) are regions within which patients receive care. A total of 306 different HRRs have been defined by the Dartmouth Atlas project, and are based on referral patterns for tertiary care using major cardiovascular and neurological procedures from the Medicare claims data.4–6 Crosswalk files between zip codes, hospitals, and HRRs are available to the public at the Dartmouth Atlas website.7 We excluded six regions for which there were no hospitals reporting data to the NCDR ICD registry.

**Medicare Denominator File**

The Medicare Denominator file was used to calculate the number of Medicare beneficiaries in each HRR. This file contains the beneficiary unique identifier, state and county codes, zip code, date of birth, date of death, sex, race, age, as well as eligibility information for each Medicare beneficiary enrolled in Medicare during a calendar year. For this analysis, the population recorded in December of 2005 was as representative of the population for whom referrals for primary prevention ICD implantation would be made at the beginning of the study.

**American Medical Association Masterfile**

The American Medical Association Masterfile was used to determine the supply of cardiologists and electrophysiologists in each HRR. It is a record of all US physicians maintained and continually updated from multiple sources by the American Medical Association.8–10 For this analysis, the population of physicians in December 2007 was used.

**Study Population**

Although many hospitals are registering all the ICDs they implant into the NCDR-ICD, this analysis included only older (>65 years), Medicare, fee-for-service beneficiaries, because this is the only population for which the mandated participation in the NCDR-ICD is enforceable. Patients with other types of insurance (eg, Medicare-managed care or other private coverage) were excluded, because these may not be reported completely in all hospitals. The study population was restricted to patients identified in the NCDR-ICD as receiving an ICD for primary prevention. Thus, patients receiving an ICD for secondary prevention, including those with a history of syncope, cardiac arrest, or sustained ventricular tachycardia were also excluded (Figure 1).
between regions were valid, we adjusted for patients’ demographics, received primary prevention ICDs. To ensure that the comparisons in inclusion criteria in each HRR, we examined only patients who had basis of the rate ratio, we grouped the HRRs into quintiles of ICD use. Dividing the adjusted rate per HRR by the national average rate. On the statistical analysis

**Table 1. Criteria Used to Determine If an ICD Was Implanted Appropriately**

| Inclusion A (SCD-HeFT): | i. NYHA class II or III AND
|                        | ii. LVEF <35% AND
|                        | iii. Prior heart failure OR
|                        | iv. If patient meets criteria ii and iii above and is in NYHA class IV, consider patient as fitting criteria if intraventricular conduction is abnormal and if device is biventricular pacemaker (COMPANION)*
| Inclusion B (MADIT II): | i. Myocardial infarction >40 days prior AND
|                        | ii. LVEF <30% AND
|                        | iii. Prior myocardial infarction AND
|                        | iv. NYHA class I or II or III OR
|                        | v. If patient meets criteria i, ii, and iii above and is in NYHA class IV, consider patient as fitting criteria if intraventricular conduction is abnormal and if device is biventricular pacemaker (COMPANION)*
| Inclusion C (MUSTT): | i. Ischemic heart disease AND
|                        | ii. LVEF <40% AND
|                        | iii. Nonsustained ventricular tachycardia
|                        | iv. EPS finding: Ventricular tachycardia induced, sustained monomorphic/polymorphic, ventricular flutter/fibrillation

NYHA indicates New York Heart Association; LVEF, left ventricular ejection fraction; and EPS, electrophysiological study finding.

**Results**

Regional Variations

Regional variation in the use of primary prevention ICDs across the United States is shown in Figure 2. Adjusted rates vary from 75 per 100 000 beneficiaries (rate ratio, 0.39 compared with the national average) in the lowest quintile of utilization to 338 per 100 000 beneficiaries (rate ratio, 1.77 compared with the national average in the highest quintile of utilization). By HRR, the rates ranged from 22 to 736 per 100 000 Medicare beneficiaries (Figure 3).

Supply of Cardiologists and Electrophysiologists

No correlation was found between the supply of cardiologists and electrophysiologists and the rate of implantation of primary prevention ICDs ($R^2=0.01$ for both, Figure 4). We also assessed whether there was an association between rate of implantation and the ratio of electrophysiologists to cardiologists in an HRR, but no association was found. ($R^2<0.01$, data not shown).

Clinical Trial Inclusion Criteria

Overall, 13% of the registered recipients of primary prevention ICDs did not meet clinical trial criteria. No association was found between the rate of utilization and the proportion of patients meeting clinical trial criteria per HRR. However, marked variation in the proportion meeting clinical trial

**Sensitivity Analysis**

Because our numerator uses the hospital zip code and the denominator uses the patient’s zip code of residence, we examined the extent to which patients received their ICDs outside of their HRR of residence to examine the extent to which this may have contributed to the variability seen in our data. Using the 2006 Medicare Part B claims data, we determined the proportion of patients who received an ICD (CPT code 33249) in the region in which they live. According to this analysis, 80% of patients have their ICD (primary or secondary prevention) implanted in the HRR in which they live.

**Role of the Sponsors**

The NCDR had no role in the design or conduct of the study, the management, analysis, or interpretation of the data. The manuscript was approved with only minor editorial changes by the NCDR Research and Publications Committee before manuscript submission.

**Study Population**

A total of 64,220 primary prevention ICDs in the >65 years, fee-for-service, Medicare population were identified from a total of 230,326 ICDs registered in the NCDR-ICD in 2006 and 2007 (Figure 1). The average age of Medicare ICD recipients in our sample was 76 years, 73% were male, 88% were in New York Heart Association class II or III, and 72% had ischemic cardiomyopathy (Table 2).
<table>
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<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q5</th>
<th>P</th>
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<td>3616</td>
<td>7992</td>
<td>14 939</td>
<td>20 413</td>
<td>17 260</td>
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<td>35.5</td>
<td>36.3</td>
<td>36.3</td>
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<td>27.8</td>
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<td>72.4</td>
<td>73.5</td>
<td>71.2</td>
<td>73.0</td>
<td>74.0</td>
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<tr>
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<td>59.4</td>
<td>59.1</td>
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<td>58.7</td>
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<td>43.1</td>
<td>43.1</td>
<td>40.3</td>
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<td>14.7</td>
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<td>132.7</td>
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<td>1.41</td>
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<td>3.3</td>
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<td>Electrophysiology study done, %</td>
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<tr>
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<td>25.3</td>
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<td>48.9</td>
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<tr>
<td>Length of stay, d</td>
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<td>3.1</td>
<td>3.3</td>
<td>3.9</td>
<td>3.6</td>
<td>4.1</td>
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<td>Private/community, %</td>
<td>86.7</td>
<td>93.0</td>
<td>86.8</td>
<td>81.3</td>
<td>85.6</td>
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<td>39.8</td>
<td>42.4</td>
<td>52.4</td>
<td>46.6</td>
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<tr>
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<td>60.2</td>
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<td>50.0</td>
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<tr>
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<td>23.8</td>
<td>29.4</td>
<td>38.9</td>
<td>47.7</td>
<td>50.4</td>
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CHF indicates congestive heart failure; NYHA New York Heart Association; MI, myocardial infarction; and CABG, coronary artery bypass graft.
criteria was present across HRRs, ranging from a low of 47.8% to a high of 95.9%.

**Discussion**

Variable use of a life-saving, guideline-recommended therapy (such as ICDs) would be significant; understanding the factors behind this variation would have policy implications. Using the CMS-mandated ICD registry, we found marked variation in rates of implantation of primary prevention ICDs, which was not associated with the regional supply of either cardiologists or electrophysiologists. Although 13% of Medicare beneficiaries receiving primary prevention ICDs did not meet strict clinical trial criteria for ICD implantation, there was no association between the proportion meeting evidence-based criteria and rate of utilization.

The finding of greater than 4-fold variation in use of primary prevention ICDs between the lowest and highest quintiles of utilization is important. The Institute of Medicine recognizes that variations in practice often represent variations in quality of care. The variation observed in our study is of particular concern, given the substantial expansion of indications for this therapy. Research on other cardiovascular interventions at the HRR level has demonstrated broad variation in the rates of cardiac catheterization, percutaneous intervention, carotid stents, carotid endarterectomy, coronary artery bypass graft surgery, and valvular surgery. Our findings are consistent with a study demonstrating that implantation rates of ICDs vary markedly among the select hospitals participating in the Get With the Guidelines registry, with some hospitals implanting ICDs in >80% of eligible patients, whereas other hospitals did not implant any ICDs in eligible patients. Our study expands on this finding by including all registered ICDs in the Medicare fee-for-service population and all regions in the United States.

This striking variation in rates of ICD implantation raises the question of whether patient variation is driving the
variation in use. We know from the 2008 Behavioral Risk Factor Surveillance System that rates of Coronary Artery Disease and Myocardial Infarction vary >2-fold by regions, with rates being highest in the southeast United States. However, our analysis shows high utilization regions immediately adjacent to low utilization regions in the southeast and throughout the United States (Figure 2), which would not be expected if underlying disease was driving the variation. Further, the 2-fold variation in disease prevalence would not explain the >4-fold variation we see in our analysis. Another consideration is that, perhaps, patients in rural regions are being referred to urban regions to have their ICD procedure. Again, the variation seen in our analysis does not demonstrate this, with many of the high utilization regions being rural regions (Figure 2). However, distance and access issues have not been ruled out as a contributor to the variation seen in this analysis. A third explanation is that, perhaps, these variations represent age, sex, and racial differences across regions. This is not possible, however, given that these rates are adjusted for age, sex, and race.

If patients are not driving this variation, then are physicians the driving factor? A particularly important finding from this study is the lack of correlation between the rate of ICD use and the regional supply of cardiologists or electrophysiologists. We believe this finding to be robust, given recent evidence that >92% of ICDs are implanted by either cardiologists or electrophysiologists. This is counter to results of prior research that demonstrate that for many health care interventions, use is strongly correlated with the availability or supply of that intervention. Other studies have found a strong correlation between the number of cardiologists per 100,000 residents and the number of visits to cardiologists. Given that some believe that ICDs are being underutilized, and others believe that the supply of cardiologists is diminishing, we expected to see a relationship between supply and utilization. Perhaps this lack of association is a function of varied physician knowledge or attitudes related to ICDs.

A finding of substantial geographic variation in procedural rates could reflect inappropriate patient selection and overuse in high-utilization regions. Inappropriate patient selection could represent 1 of 2 things: “technically” inappropriate procedures, or those discordant with the guidelines or “clinically” inappropriate procedures, or those discordant with a patient’s well-informed preferences. In this report, we found no association between regional implantation rate and adherence to clinical inclusion criteria (ie, “technically” appropriate patient selection). This is consistent with early retrospective studies that have demonstrated that regional variations in utilization of coronary artery bypass graft, percutaneous transluminal coronary angioplasty, and coronary angiography were not associated with regional variations in “technically” appropriate care. However, these studies have been criticized because of biases introduced in retrospective classification of procedure outcomes. More recent work has demonstrated an association between appropriateness and utilization for caesarean sections. The data available in the NCDR-ICD offer a unique opportunity to examine the association between technically appropriate care and utilization as it is a national, mandated registry with an extensive amount of clinical information.

Although we found no overall association between rate of ICD implantation and technical appropriateness of patient selection, 13% of Medicare beneficiaries received ICDs outside of clinical trial criteria and in some regions this rose to >50%. This suggests that, whereas technically inappropriate care does not explain this variation, it probably exists. The question of whether a procedure is “clinically” appropriate would require an exploration of patients’ preferences. Although data on patient preferences for ICDs does not exist, research in other interventions suggests that patient preferences are stable across regions, and are not a contributor to the regional variations in utilization.

Other causes must be contributing to the substantial variation we observed. A particular challenge in understanding the causes of this variation is that we do not know what the right rate is. It is possible that ICDs are underutilized and the...
rates are too low. Although strong data demonstrate that primary prevention ICDs reduce mortality,1-5 other studies have found that only 20% of eligible patients are even being offered this potentially life-saving therapy, with wide variations between hospitals. This suggests that underuse may also be contributing to this variation.11

Another explanation is that perhaps ICDs are being misused in a pattern discordant from patients’ preferences. Although patient preferences for medical care have never been shown to vary, perhaps ICDs are an exception.36,37 ICDs are different from most other therapies for heart failure that have been shown to reduce mortality in that they involve significant trade-offs. Along with the mortality reduction associated with ICDs come a host of potential risks. Some studies suggest that, compared with similar patients without ICDs, patients with ICDs have more heart failure admissions,38 a lower quality of life, particularly if shocked,39,40 and an increased incidence of anxiety, depression, and post-traumatic stress disorder.41 Further, ICDs can fail,42 fire inappropriately,43 and, if not properly deactivated, cause significant suffering through unnecessary shocks at the end of life.44 Although we have no data demonstrating variations in physician opinions or patient preferences for ICDs, other studies suggest that patient preferences are poorly incorporated into clinical decision-making,45 and there are serious concerns about whether cardiologists are adequately informing their patients.46,47 Perhaps the reason that earlier work on “technical” appropriateness did not explain regional variations was because the definition of technically appropriate care did not incorporate variations in patients’ preferences and was thus not clinically appropriate. However, how potential misuse relates to utilization of ICDs remains unknown.

Several factors should be considered in the interpretation of this study. First, data on ICD implantations is entered by the physicians and practices. Although CMS mandates that hospitals register their ICDs for the Medicare population, currently CMS does not conduct an official audit or enforcement process to ensure the quality or completeness of this data. However, because physicians are required to register their ICDs accurately to receive payment, we have no reason to believe that there is systematic underreporting. Second, the denominator used the patient zip code of residence to assign the HRR, whereas the numerator used the hospital zip code as the patient zip codes are not available for analysis with the NCDR because of privacy concerns. However, HRRs are specifically defined as referral areas where patients receive tertiary cardiovascular care such as ICD placement. Further, in a secondary analysis of the claims data alone, we found that 80% of the patients received their ICD in the HRR in which they lived, which would only explain a small proportion of our variation. Third, we used the denominator of all Medicare beneficiaries because of the impossibility in using the claims data to identify a cohort of potentially eligible patients as well as regional variations in disease coding practices.48,49 Indeed, to determine who is eligible for an ICD for primary prevention, we would need to know both the ejection fraction and the New York Heart Association symptom class for all Medicare beneficiaries in each HRR. This clinical information is not available. This approach to the determination of the denominator, however, is a well-accepted approach to defining geographic variation in procedure use.24,25

Conclusions
Marked variation exists in the use of primary prevention ICDs across the United States. This variation is not associated with the regional supply of either cardiologists or electrophysiologists, nor is it associated with adherence to evidence based patient selection criteria. The lack of association raises the question of how much physician opinion and local practice patterns drive this variation. Research into physicians’ attitudes and patients’ preferences regarding ICD implantation is needed to further understand this observed regional variation. Findings such as these are indeed the reasons that CMS mandated an ICD registry for the purposes of “evidence development and quality improvement.” This study is an example of the developing evidence; realizing the quality improvement that should naturally follow will offer many challenges.

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