

# Hospital Variation and Characteristics of Implantable Cardioverter-Defibrillator Use in Patients With Heart Failure

## Data From the GWTG-HF (Get With The Guidelines–Heart Failure) Registry

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- Objectives** The aim of this study was to describe hospital variation and factors associated with adherence to guidelines for implantable cardioverter-defibrillator (ICD) therapy.
- Background** Studies have shown incomplete application of ICD therapy in eligible heart failure (HF) patients.
- Methods** New or discharge prescription rates for ICD therapy (ejection fraction  $\leq 30\%$  without documented ICD contraindications) for hospitals were calculated from participants in the GWTG-HF (Get With The Guidelines–Heart Failure) registry during January 2005 to June 2007. With hierarchical modeling, hospitals' patient case-mix adjusted ICD rate and hospital factors associated with ICD use were determined. The association of ICD rate and other quality of care indicators and procedure use was determined.
- Results** Overall use of ICD in-hospital or planned implantation rate was 20%. This rate ranged widely among hospitals, from 1% among the lowest tertile to 35% among the top tertile ( $p < 0.01$ ). After adjusting for patient case mix, independent hospital characteristics associated with higher ICD use were percutaneous coronary intervention, coronary artery bypass grafting, and heart transplant capability as well as larger hospital bed size ( $p < 0.01$ ). Hospital Centers for Medicare and Medicaid Services/Joint Commission on the Accreditation of Healthcare Organizations performance measures (discharge instructions, angiotensin-converting enzyme inhibitor/angiotensin II receptor blocker use, smoking cessation;  $p \geq 0.05$ ) were similar across ICD, whereas higher ICD-rate hospitals had higher adherence to GWTG-HF performance measures (beta-blocker use, evidence-based beta-blocker use, aldosterone-antagonist, hydralazine/nitrate;  $p < 0.05$ ) except warfarin in patients with atrial fibrillation ( $p = 0.18$ ).
- Conclusions** There is significant unexplained hospital variation in the use of ICD therapy among potentially eligible HF patients. However, hospitals that use ICD therapy more often also have more rapidly adopted other newer evidence-based HF therapies. (J Am Coll Cardiol 2009;53:416–22) © 2009 by the American College of Cardiology Foundation

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Several clinical trials have shown that implantable cardioverter-defibrillators (ICDs) reduce mortality in patients with a low left ventricular ejection fraction (LVEF) (1,2). Thus, the 2005 American College of

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Cardiology/American Heart Association (ACC/AHA) guidelines assign a Class I indication for ICD therapy in patients with an LVEF  $\leq 30\%$  and symptomatic heart failure (HF) receiving optimal medical therapy (3). Despite these guidelines, recent studies have highlighted the incomplete adoption of ICD therapy, including significant disparities by race and sex (4,5).

Reasons for the inconsistent and disparate use of guideline-recommended ICD therapy are unclear and might differ from medical pharmacotherapy. Barriers to medical therapy usually relate to knowledge, preferences, and biases among providers or patients (6). Although device therapy likely has similar barriers, other important limitations might exist. Hospitals require highly skilled professionals and technical facilities to deliver device therapies. To understand these issues, we examined hospital-level variation and characteristics associated with ICD therapy use in eligible HF patients in the GWTG-HF (Get With The Guidelines–Heart Failure) registry.

## Methods

**Data source.** The GWTG-HF registry is a voluntary quality improvement initiative started in 2005 to enhance adherence to practice guidelines in hospitalized HF patients. The design and validity of this program's methods have been published previously (7–11). Briefly, clinical data are abstracted for patients admitted with HF in compliance with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and Centers for Medicare and Medicaid Services (CMS) standards. With standardized definitions, variables collected include demographic and clinical characteristics, medical history, previous treatments, contraindications to evidence-based therapies, and in-hospital outcomes (8,9). Hospital data elements are collected for all enrolling hospitals from the American Hospital Association database (12). Data collection regarding ICD therapy includes prior implantation, new implantation, or planned implantation after hospital discharge. Reasons and contraindications for not placing an ICD are also collected: not receiving optimal medical therapy, recent onset HF, acute myocardial infarction within prior 40 days, economic, social, religious, compliance, a life-threatening illness that would compromise 1-year survival with good functional status, other contraindications, or other factors noted by the patient. Data quality is monitored via electronic data checks, and generated reports assure the completeness and accuracy of the submitted data. Only sites and variables with a high degree of completeness are used in analyses. All data were collected with an interactive case report form and patient management tool (Outcome Sciences, Inc., Cambridge, Massachusetts). The Duke Clinical Research Institute served as the data analysis center and analyzed the aggregate de-identified data for research purposes. All participating institutions were required to comply with local regulatory guidelines with their local institutional review board's approval of the GWTG-HF protocol. Because data are used primarily locally for quality improvement, sites were granted a waiver of informed consent under the common rule.

**Study population.** We confined the analysis to patients who met Class I recommendations for ICD therapy on the basis of the 2005 ACC/AHA HF guidelines, including an LVEF  $\leq 30\%$ , at the time of data collection (3). Patients

were excluded if they had documented reasons for not placing or contraindications to ICD therapy as described in the preceding text. Patients were excluded from the primary analysis if they had a prior ICD in place or were transferred in from another hospital. Hospitals enrolling  $<10$  ICD-eligible patients or hospitals without any reported procedures (i.e., coronary angiography, percutaneous coronary intervention [PCI], coronary artery bypass grafting [CABG], or cardiac transplant) were excluded.

**Statistical analysis.** The primary outcome measure was the placement of ICD during hospital stay or documented plans for ICD implantation after discharge among eligible patients with LVEF  $\leq 30\%$  without a prior ICD. For univariate analyses, hospitals were divided into tertiles, on the basis of rates of ICD use in eligible patients. We examined characteristics of hospitals capable of ICD therapy defined as at least 1 ICD procedure compared with hospitals without any implantations. At the patient level, we compared between the 2 hospital types the use of medical therapy, other cardiac procedures, the CMS/JCAHO (13) performance measures, and GWTG-HF Clinical Performance Measures (14) according to ACC/AHA HF guidelines. Cochran-Mantel-Haenszel row-mean scores tests were used to compare the trend of the adherence rates and categorical baseline characteristics variables, and Cochran-Mantel-Haenszel nonzero correlation tests were used for comparing the continuous variables among the tertiles. Wilcoxon rank-sum test and chi-square tests were used to compare the continuous and categorical variables in hospitals with versus without ICD implantations, respectively.

Multivariable analysis with hierarchical model with hospital random effects was performed to model ICD use variation among and between hospitals, adjusted for the hospital's patient case-mix, and calculate the adjusted hospital-specific ICD rate. In ICD-eligible patients, the degree of missing data was  $<6\%$  for all the covariates, except 7.5% for systolic blood pressure. Factors for which  $p \geq 0.05$  were removed from the model. The reduced model included age, sex, race (white, black, and other races), insurance status (Medicare, Medicaid, other [e.g., health maintenance organization, Veteran's Administration, and no insurance]), systolic blood pressure, and comorbid conditions, including chronic renal failure, anemia, atrial fibrillation, cerebrovascular accident or transient ischemic attack, chronic obstructive pulmonary disease, ischemic

## Abbreviations and Acronyms

**ACC** = American College of Cardiology

**AHA** = American Heart Association

**CABG** = coronary artery bypass grafting

**CMS** = Centers for Medicare and Medicaid Services

**GWTG-HF** = Get With The Guidelines–Heart Failure

**HF** = heart failure

**ICD** = implantable cardioverter-defibrillator

**JCAHO** = Joint Commission on the Accreditation of Healthcare Organizations

**LV** = left ventricular

**LVEF** = left ventricular ejection fraction

**PCI** = percutaneous coronary intervention

heart disease, depression, diabetes mellitus, hyperlipidemia, and renal insufficiency.

The hospital's case-mix adjusted ICD rate was calculated from the reduced model with observed ICD rate in each hospital divided by the hospital's estimated expected ICD rate and then multiplied by the overall observed ICD rate. The estimated expected rate was calculated as the hospital-specific mean of the predicted probabilities of ICD use, adjusted for the aforementioned covariates but without the site random effect. Then the hospitals' adjusted ICD rates were compared in each subgroup of hospitals according to teaching status; capability of PCI, CABG, or transplant; bed size; and geographic location. Wilcoxon rank-sum and Kruskal-Wallis tests were used for comparison of adjusted ICD rates in 2 samples and regions, respectively. The Cochran-Mantel-Haenszel nonzero correlation test was used to compare the trend of adjusted ICD rates with bed size.

A  $p$  value  $<0.05$  was considered statistically significant for all tests. All analyses were performed with SAS software version 8.2 (SAS Institute, Cary, North Carolina).

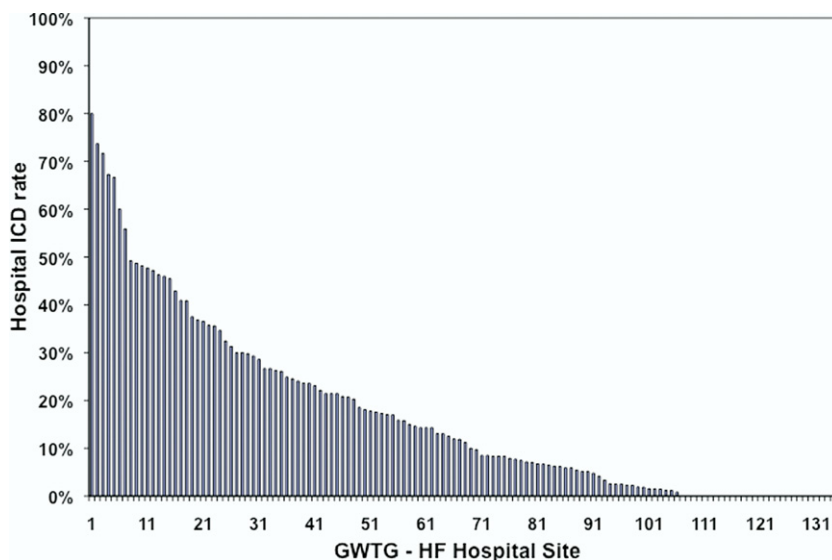
## Results

**Analysis cohort.** From January 1, 2005, through June 26, 2007, 54,750 HF patients were discharged from 234 GWTG-HF hospitals. Six procedure-capable hospitals without any procedures recorded and 94 hospitals with  $<10$  ICD-eligible patients were excluded. We also excluded 2,545 of 12,693 patients with an ICD in place at the time of the index HF hospital stay. The final analysis cohort consisted of 134 hospitals with 10,148 ICD-eligible patients.

**Hospital ICD rates.** The overall use of ICD therapy (new or planned) at discharge was 20.0%. **Figure 1** shows the hospital-level variation in new or planned ICD therapy in eligible patients without a prior ICD ranging from 0% to 80%, with a mean rate of 17.2%. The median rate was 11.6% with 25th and 75th interquartile ranges of 1.5% and 26.3%, respectively. Discharge of ICD therapy by hospital tertiles of use was 35%, 12%, and 1% ( $p < 0.001$ ).

The highest ICD-rate hospitals were more likely to treat whites and patients with hyperlipidemia and prior myocardial infarction but were similar in their treatment of women and patients with other cardiac risk factors and comorbidities compared with low or medium ICD-rate hospitals (**Table 1**). High ICD-rate hospitals were also more likely to provide cardiac procedures (i.e., coronary angiography, PCI, CABG, or transplant), have more beds, and have an academic affiliation than low or medium ICD-rate hospitals (**Table 2**). Hospital processes resulted in similar discharge performance measures across all 3 hospital volume categories, but high ICD-rate hospitals were more likely to meet GWTG-HF performance measures with the exception of warfarin use in HF patients with atrial fibrillation than low or medium ICD-rate hospitals (**Table 3**).

**ICD-capable versus non-ICD-capable hospitals.** Analysis of hospitals with at least 1 implant versus none showed differences in patient and hospital characteristics between these hospitals. There were 28 hospitals with 874 patients without any ICD implants, and 106 hospitals with 9,274 patients with at least 1 implant. Eligible patients presenting to ICD-capable hospitals were more likely to be younger (age 66 years vs. 69 years,  $p < 0.001$ ) and to be black (28% vs. 23%,  $p < 0.001$ ),



**Figure 1. Rates of New or Planned ICD Therapy at GWTG-HF Hospitals for Eligible HF Patients Without an ICD**

Hospital implantable cardioverter-defibrillator (ICD) rate = new or planned ICD use/eligible heart failure (HF) patients. GWTG-HF = Get With The Guidelines–Heart Failure registry.

**Table 1** Baseline Characteristics of ICD-Eligible HF Patients Among High-, Medium-, and Low-Volume ICD Hospitals

	High ICD Use (n = 4,500) 48 Hospitals	Medium ICD Use (n = 3,548) 42 Hospitals	Low ICD Use (n = 2,100) 44 Hospitals	p Value
<b>Patient characteristics</b>				
Age (yrs)*	68 (56, 78)	69 (56, 79)	68 (55, 79)	0.44
Female	34	38	36	0.03
Race				<0.001
Black	22	33	32	
White	67	56	55	
Insurance				<0.001
Medicare	49	45	51	
Medicaid	6	9	7	
Other	34	36	27	
Atrial fibrillation	20	22	21	0.32
Diabetes mellitus	36	38	37	0.09
Hyperlipidemia	38	32	30	<0.001
Hypertension	63	66	64	0.004
History of myocardial infarction	15	9	11	<0.001
Peripheral vascular disease	10	9	9	0.25
History of stroke	11	11	10	0.83
Renal insufficiency†	15	14	14	0.66
Cigarette smoking	25	23	28	0.03
<b>Procedures performed</b>				
Coronary angiography	16	12	6	<0.001
Coronary artery bypass grafting	1.0	0.4	0	<0.001
Percutaneous coronary intervention	1.2	1.2	0.14	0.001
Right heart catheterization	6.5	3.7	1.1	<0.001
Heart transplant	0.02	0.08	0	0.93

Reported as percentages. \*Expressed as median (25th, 75th percentile). †Serum creatinine >2.0 mg/dl. HF = heart failure; ICD = implantable cardioverter-defibrillator.

but these hospitals had similar frequencies in the treatment of women (36% for both,  $p = 0.77$ ) and patients with cardiac risk factors and comorbid illnesses. The ICD-capable hospitals were larger (mean beds 416 vs. 210,  $p < 0.001$ ) and were more likely to have an academic affiliation (62% vs. 53%,  $p < 0.001$ ) as well as were more likely to be capable of PCI (86% vs. 63%,  $p < 0.001$ ), CABG (75% vs. 38%,  $p < 0.001$ ), and cardiac transplants (15% vs. 0%,  $p < 0.001$ ). The hospitals were similar in meeting performance measures for HF patients, with the exception of ICD-capable hospitals more likely providing aldosterone antagonists, warfarin in patients with atrial fibril-

lation, evidence-based beta-blocker drugs, and lipid-lowering agents at discharge ( $p < 0.001$ ) than non-ICD-capable hospitals.

**Adjusted hospital ICD rates.** When adjusting ICD rates for patient case mix, hospital characteristics associated with higher ICD use in eligible patients were heart transplant, PCI, and CABG capabilities as well as larger hospital bed size and academic status (Fig. 2). Additional unadjusted exploratory analysis at the hospital level showed no statistical association of ICD use with private payer mix or percentage of blacks treated but a weak

**Table 2** Comparison of Hospital Characteristics Among High-, Medium-, and Low-Volume ICD Hospitals

	High ICD Use (n = 4,500) 48 Hospitals	Medium ICD Use (n = 3,548) 42 Hospitals	Low ICD Use (n = 2,100) 44 Hospitals	p Value
Hospital size (beds)*	449 (334, 590)	353 (274, 527)	216 (128, 330)	<0.001
Academic	68	59	52	<0.001
Region				<0.001
Northeast	16	26	26	
Midwest	38	20	13	
South	33	31	45	
West	13	20	11	
PCI capable	91	88	61	<0.001
CABG capable	89	79	23	<0.001
Heart transplant capable	23	10	2.6	<0.001

Reported as percentages. \*Expressed as median (25th, 75th percentile).

CABG = coronary artery bypass grafting; ICD = implantable cardioverter-defibrillator; PCI = percutaneous coronary intervention.

**Table 3** Adherence to CMS/JCAHO Performance Measures and GWTG-HF Performance Measure Based on ACC/AHA HF Guidelines Among High-, Medium-, and Low-Volume ICD Hospitals

	High ICD Use (n = 4,500) 48 Hospitals	Medium ICD Use (n = 3,548) 42 Hospitals	Low ICD Use (n = 2,100) 44 Hospitals	p Value
<b>CMS/JCAHO performance measures</b>				
Patients discharged with 6 instructions*	83	82	81	0.05
Discharged with ACEI/ARB in patients with LV dysfunction	86	89	86	0.91
Patients with smoking history discharged with smoking cessation	92	86	91	0.09
<b>Composite performance measures</b>				
Composite performance measure (successes/total eligible)†	90 (18)	90 (17)	88 (19)	0.006
Composite performance measure for 100% compliance	69	69	65	0.01
<b>GWTG-HF performance improvement measures</b>				
Discharged with beta-blocker in patients with LV dysfunction	89	90	87	0.02
HF patients with atrial fibrillation discharged on warfarin	66	68	61	0.18
HF patients with LV dysfunction discharged on aldosterone antagonist	31	29	20	<0.001
HF patients with LV dysfunction discharged on evidenced-based beta-blocker (bisoprolol, carvedilol, metoprolol succinate)	73	70	68	<0.001
Black HF patients discharged on hydralazine and isorbide dinitrate combination	7	6	3	<0.001
HF patients discharged on lipid-lowering medication	61	56	51	<0.001
HF patients with systolic BP <140 mm Hg and diastolic BP <90 mm Hg	83	82	79	0.005
HF patients with EF ≤30% with new ICD or discharged with ICD	35	12	1	<0.001

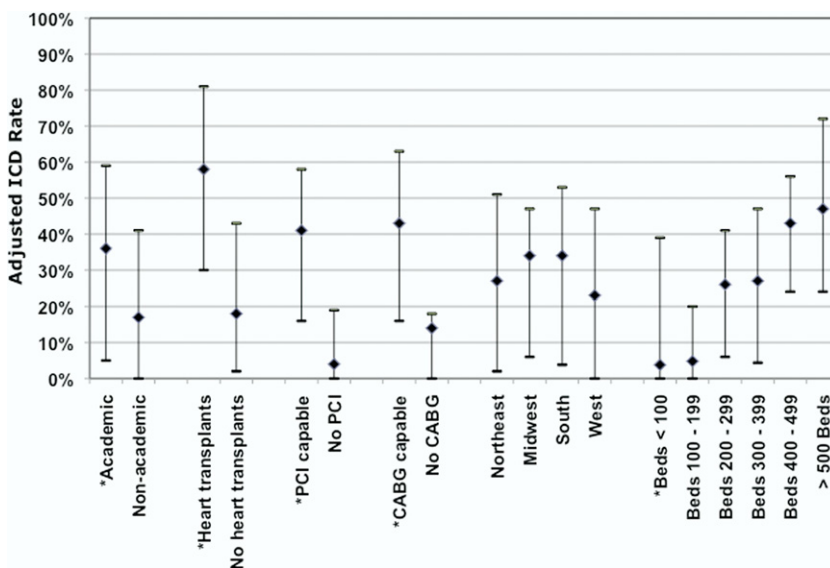
Reported as percentages. \*Instructions at discharge for: activity level, diet, discharge medications, follow-up appointments, weight monitoring, and if symptoms are to worsen. †Expressed as mean (SD). ACC = American College of Cardiology; ACEI = angiotensin-converting enzyme inhibitor; AHA = American Heart Association; ARB = angiotensin II receptor blocker; BP = blood pressure; CMS/JCAHO = Centers for Medicare and Medicaid Services/Joint Commission on the Accreditation of Healthcare Organizations; EF = ejection fraction; GWTG-HF = Get With The Guidelines-Heart Failure registry; HF = heart failure; ICD = implantable cardioverter-defibrillator; LV = left ventricular.

association of higher ICD use as the percentage of uninsured patients decreased (p = 0.05).

**Discussion**

To our knowledge, this study is the first to describe hospital variation and hospital factors associated with ICD use in

eligible patients. Four important observations were noted in our study. First, overall ICD therapy remains low in eligible patients with only one-fifth of potentially eligible patients receiving new implantations or prescription for implantation at discharge. Second, there is wide (35-fold) variation of ICD therapy use in eligible patients in GWTG-HF



**Figure 2** Association of Case-Mix Adjusted Hospital ICD Use With Hospital Characteristics

Represented by median rates and interquartile ranges. \*p < 0.05. CABG = coronary artery bypass grafting; ICD = implantable cardioverter-defibrillator; PCI = percutaneous coronary intervention.



hospitals. Third, important structural characteristics, such as hospital size and procedural capabilities, are associated with ICD therapy use. Finally, the wide variation in ICD therapy versus narrower variation in performance measures of care suggests that hospitals approach ICD guideline recommendations differently from medical therapy, but higher ICD-use hospitals are more likely to adopt newer HF therapies.

We found that the use of ICD therapy is associated with key hospital characteristics—the presence of cardiovascular procedure capabilities, academic affiliation, and a larger size. Furthermore, ICD implantation rates are associated with higher rates of other cardiac procedures, mirroring the findings of prior studies examining the diffusion and variation of the use of other cardiac procedures, specifically PCI and CABG (15–17). Other factors influencing ICD use might include the availability of electrophysiologists and dedicated facilities. However, capacity limitations should not affect discharge prescription of ICD therapy, but long wait times or difficulty getting timely follow-up in the appropriate clinic might deter referring physicians or patients.

Individual physician preferences and opinions regarding ICD therapy for chronic HF could also explain the wide variation in ICD rates in GWTG-HF hospitals. The lack of diagnostic criteria beyond LVEF to stratify patients who might receive maximal benefit from ICD therapy might contribute to limited adoption of this technology. Cost considerations might also play a role in the broader adoption of ICD therapy. Furthermore, ICD use could be influenced by recent public and physician concerns over the safety of the devices (18,19). Additionally, the lag in dissemination of clinical trial data and guideline recommendation updates into broader clinical practice, particularly in the non-cardiologist community, might explain the low rates of ICD use in our cohort (6,20).

**Clinical implications.** Physicians' reluctance to recommend ICD therapy underscores the difficulty to characterize "on chronic optimal medical therapy" as well as assessment of symptomatic HF in the hospitalized setting (3). However, hospital systems with the infrastructure to perform other cardiac procedures might be overzealous in defining a reasonable functional class or optimal medical therapy. Regardless of the source of variation, these qualitative issues highlight the difficulty in establishing ICD therapy as a quality metric for patients with chronic HF and should be considered before tying device therapy metrics to reimbursement.

Although there was no significant variation in adherence to CMS/JCAHO metrics, adherence to GWTG-HF performance measures—which includes HF therapies with more recent clinical evidence—was higher at ICD implanting and high ICD-rate hospitals versus their counterparts. This observation suggests that GWTG-HF hospitals with higher rates of ICD use are overall more rapid adopters of evidence-based therapies. Furthermore, early hospital adopters of newer HF therapies seem to incorporate this evidence more rapidly than their counterparts regardless of financial incentives. Future studies should investigate the

processes of these hospitals to understand how they more rapidly assimilate evidence-based therapies into routine clinical practice compared with their peers.

**Study limitations.** First, the GWTG-HF initiative is a registry of patients hospitalized with decompensated HF, which could overestimate the number of patients eligible for ICD therapy. However, we confined the analysis to patients who would have qualified for ICD therapy before hospital stay (i.e., patients with a history of chronic HF and no documented contraindication to ICD therapy). Second, GWTG-HF might include hospitals with a higher likelihood of following evidence-based recommendations, thus likely conveying a best-case scenario. Third, standardized reporting might have led to underreporting of contraindications to ICD therapy, and chart review might not have identified patients with anticipated survival of <1 year, unless explicitly stated by the charting physician. The variation observed might represent variation in documentation of patient ineligibility for ICD placement or variation in documentation of post-discharge ICD placement referral. Fourth, although we controlled for insurance status, out-of-pocket expenses could affect patient decisions for ICD therapy. Finally, because we have limited information about the hospital characteristics, specialties of the caring physician, and the availability of electrophysiologists implanting these devices, we can only make limited judgments on the resources and capabilities at each site for ICD implantation.

## Conclusions

In spite of ACC/AHA Class I guideline recommendations for ICD use in patients with an LVEF  $\leq 30\%$  and symptomatic HF on optimal medical therapy, the variation in ICD use by GWTG-HF hospitals is wide, 0% to 80%, with an overall ICD use of <20% in potentially eligible patients. We identified hospital factors that could limit ICD use in HF patients among participating hospitals. Even though other challenges exist in the guideline-based use of this therapy, further studies are needed to determine constraints in the broader adoption of device therapies in HF patients.

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**Key Words:** heart failure ■ hospital ■ ICD ■ registry.