Practice-Level Variation in Use of Recommended Medications Among Outpatients With Heart Failure
Insights From the NCDR PINNACLE Program

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Background—The objective of this study is to examine practice-level variation in rates of guideline-recommended treatment for outpatients with heart failure and reduced ejection fraction, and to examine the association between treatment variation and practice site, independent of patient factors.

Methods and Results—Cardiology practices participating in the National Cardiovascular Disease Registry Practice Innovation and Clinical Excellence registry from July 2008 to December 2010 were evaluated. Practice rates of treatment with angiotensin-converting enzyme inhibitors/angiotensin receptor blockers and β-blockers and an optimal combined treatment measure were determined for patients with heart failure and reduced ejection fraction and no documented contraindications. Multivariable hierarchical regression models were adjusted for demographics, insurance status, and comorbidities. A median rate ratio was calculated for each therapy, which describes the likelihood that the treatment of a patient with given comorbidities would differ at 2 randomly selected practices. We identified 12,556 patients from 45 practices. The unadjusted practice-level prescription rates ranged from 44% to 100% for angiotensin-converting enzyme inhibitors/angiotensin receptor blockers (median, 85%; interquartile range, 75%–89%), from 49% to 100% for β-blockers (median, 92%; interquartile range, 83%–95%), and from 37% to 100% for optimal combined treatment (median, 79%; interquartile range, 66%–85%). The adjusted median rate ratio was 1.11 (95% confidence interval, 1.08–1.18) for angiotensin-converting enzyme inhibitors/angiotensin receptor blockers therapy, 1.08 (95% confidence interval, 1.05–1.15) for β-blockers therapy, and 1.17 (1.13–1.26) for optimal combined treatment.

Conclusions—Variation in the use of guideline-recommended medications for patients with heart failure and reduced ejection fraction exists in the outpatient setting. Addressing practice-level differences may be an important component of improving quality of care for patients with heart failure and reduced ejection fraction.

Key Words: heart failure □ pharmaceutical preparations □ registries

Beta-blockers (BB) and angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) are guideline-recommended therapies for ambulatory patients with heart failure and reduced ejection fraction (HFREF). Among patients hospitalized for heart failure, the use of these therapies in routine practice has improved. In contrast, few quality improvement programs have focused on ambulatory care of HFREF despite national performance measures that encourage the use of these therapies in the outpatient setting. One program, The Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF), demonstrated improvements in use of guideline-recommended therapies among eligible patients with HFREF in outpatient cardiology practices.
contributing to unnecessary variation in use of recommended
therapies for HFREF is critical for developing effective inter-
ventions that could improve the quality of HF care.

The National Cardiovascular Disease Registry Practice
Innovation and Clinical Excellence (PINNACLE) registry
captures care provided in outpatient cardiology clinics and
provides an opportunity to understand variability in treatment
patterns among a national sample of ambulatory patients with
HFREF. The aims of this study were to determine the over-
all rates of ACEI/ARB and BB use, to examine the degree of
practice-level variation in the rates of treatment with ACEI/
ARB, BB, and an optimal combined treatment rate for eli-
gible patients with HFREF, and to determine the association
between practice site and variation in care, independent of
patient-level factors.

Methods

Data Source

Data from the National Cardiovascular Disease Registry PINNACLE
Registry were used for analyses. The PINNACLE program is a na-
tional office–based cardiovascular quality improvement registry with
voluntary participation. Participating practices collect data at the
point of care for each outpatient visit. Data are collected at the point
care using either PINNACLE paper–based chart abstraction forms or
a validated mapping algorithm from the electronic medical record
of each practice to capture requisite data elements comprehensively
for PINNACLE program participation. Data collected in the registry
include demographics, insurance information and longitudinal data
on symptoms, vital signs, medications, laboratory values, and com-
orbidities. In addition, medications are documented as prescribed or not
prescribed for a medical, patient, or system reason. If a medication
was documented as not prescribed for any reason, the patient was
considered ineligible for that medication. Data collection is standard-
ized through standard data definitions, uniform data entry and trans-
mision requirements, and data quality checks.

Study Population

We identified patients with HFREF (left ventricular ejection frac-
tion, ≤40%) enrolled in the National Cardiovascular Disease Registry
PINNACLE registry between July 2008 and December 2010. BB and
ACEI/ARB therapy was considered indicated for all patients.
Patients with a documented reason for not prescribing any of the stud-
yed medication classes were considered ineligible and excluded from
analyses for that particular class. As we were interested in examining
practice-level rates of treatment in this study, we excluded practices
with <10 eligible patients with HFREF or with treatment rates of 0%
(n=3 practices).

Outcomes

Of primary interest was the extent of practice variation in rates of
treatment with each individual medication and a composite measure.
Therefore, the primary outcomes were practice-level rates of treat-
ment with ACEI/ARB, BB, and an optimal combined treatment mea-
 sure. The optimal combined treatment measure was calculated based
on a method used by the Joint Commission and was the percentage
of patients treated with all of the medications for which they were
eligible. Therefore, to meet the optimal combined treatment measure,
if a patient was only eligible for 1 medication, that 1 medication had
to be prescribed; if a patient was eligible for both medications, both
medications (ACEI/ARB and BB) had to be prescribed. Thus, the to-
tal number of patients eligible for the optimal combined treatment
measure was greater than the total number eligible for each individual
measure. Primary analyses were based on each patient’s first encoun-
ter in the registry. A sensitivity analysis was performed based on all
encounters within 1 year from the index visit.

Patient-Level Factors

Patient-level variables were chosen a priori based on previous litera-
ture and clinical importance. Variables selected as candidates for the
multivariable models included both demographics (age, sex, insur-
ance payer) and clinical factors (dyslipidemia, hypertension, diabetes
mellitus, current smoker, peripheral artery disease, atrial fibrillation
or flutter, history of stroke or transient ischemic attack, history of
myocardial infarction [MI], angina, coronary artery bypass grafting
within the previous year, and percutaneous coronary intervention
[PCI] within the previous year).

Statistical Analysis

Baseline characteristics between patients treated and not treated were
compared using t tests for continuous variables and χ² tests for cat-
egorical variables. Given that the primary unit of analysis for this
study was the practice, treatment rates were determined for ACEI/
ARB, BB, and the composite measure for each practice and examined
with descriptive plots.

Multivariable hierarchical modified Poisson regression models
then were constructed to determine (1) practice-level variation in
treatment rates and (2) the association between patient-level factors
and treatment rates. These were 2-level hierarchical models with the
practice modeled as a random effect and patient covariates as fixed
effects. To quantify practice-level variation, the median rate ratio
(MRR) was calculated. The MRR is determined from hierarchical
models with only patient-level factors included. The MRR estimates
the typical rate ratio between 2 randomly selected practices for a pa-
tient with given covariates. The MRR is always >1.0 (an MRR of
1.0 suggests no variation between practices). Because the MRR is
always >1.0, the confidence intervals will be >1.0 as well. The MRR
allows meaningful qualitative comparisons with the effect sizes of
patient factors included in hierarchical models, although a statistical
measure of significance for this comparison is not available. Thus,
the magnitude of the MRR was examined relative to the magnitude
of the demographic and clinical patient factors described above. No
variable selection procedures were performed.

Several secondary analyses were performed. First, hypothesizing
that practices with a greater number of patients with HFREF would
have higher treatment rates, we evaluated the impact of the number
of patients with HFREF at a practice in the multivariable models.
Second, we examined the impact of the length of participation time
in PINNACLE in the multivariable models. We hypothesized that
practices may have a learning curve and that those with longer par-
 ticipation time may have higher treatment rates. Third, to exclude the
possibility that higher treatment rates may represent better documen-
tation rather than better performance, we examined the correlation
between treatment rates and documentation of contraindications to
medications. If better performance is because of better documenta-
tion, a high correlation between treatment rates and documented con-
traindications would be expected. Finally, we evaluated treatment rates
by method of data collection (paper versus electronic health record)
by adding this to the multivariable models.

The rate of missing data was 13.2% for smoking status, 5.8% for
insurance status, 3.6% for PCI within 12 months, 3.4% for coronary
artery bypass grafting within 12 months, and 1.6% for history of MI.
To avoid casewise deletion of those cases with missing data points,
for each of these variables, a separate missing category was created
and included in the models.

All analyses were performed using the SAS statistical package ver-
sion 9.1 (SAS Institute, Cary, NC). The authors had full access to the
data and take full responsibility for the integrity of the data. All authors
have read and agreed to the article as written. The American College
of Cardiology PINNACLE registry approved the analysis and the Mid
America Heart Institute human investigation committee determined that
informed consent was not applicable to the data collected by the registry.

Results

A total of 12,556 patients with HFREF from 43 practices
were identified. Practices had a median of 13 physicians
practice-level variation in the treatment rates for ACEI/ARB, BB, or optimal combined treatment persisted. The adjusted MRR for practice effect was 1.11 (95% confidence interval, 1.08–1.18) for ACEI/ARB therapy, 1.05 (95% confidence interval, 1.05–1.15) for BB therapy, and 1.17 (95% confidence interval, 1.13–1.26) for optimal combined treatment. For each therapy as well as the optimal combined therapy measure, the effect size of the MRR was larger than the adjusted odds ratio of any patient-level factor (Table 2), suggesting that the association between practice site and treatment was stronger than that of any individual patient factor.

In secondary analyses, the number of patients with HFREF at a practice was not associated with treatment and did not change the MRR for treatment for ACEI/ARB, BB, or the optimal combined treatment measure. Similarly, length of time participating in PINNACLE was not associated with treatment and did not change the MRR for treatment with ACEI/ARB, BB, or the optimal combined treatment measure. Paper data reporting was associated with higher treatment rates for all measures but did not change the MRR for any of the measures. The rate of documented exclusions for ACEI/ARB was not correlated with treatment with ACEI/ARB (Spearman weighted correlation, 0.13; P=0.40). However, a modest correlation was observed between the rate of documented exclusions for BB and treatment rates (Spearman weighted correlation, 0.5; P=0.001), although the absolute rate of documented exclusions for BB was low and varied little between practices (ranging from 1% to 5%).

Discussion

The PINNACLE Registry provides contemporary information on the real-world use of guideline-recommended medications for HFREF in the outpatient setting from >40 cardiology practices across the United States. Although rates of ACEI/ARB and BB use among patients with HFREF treated in outpatient cardiology clinics are relatively high, variations in care exist. We observed variation by practice for individual and combined measures of therapy. In all cases, fully adjusted models suggested that practice was a stronger predictor of treatment than any individual patient characteristic. These findings suggest that efforts to improve the use of evidence-based therapies in the outpatient setting should focus on practice site, in addition to patient factors.

Our findings are consistent with a previous study, IMPROVE HF, which reported similar rates of use of guideline-recommended therapies in eligible patients across a sample of cardiology or multispecialty practices between 2005 and 2007.8 When these data are compared with more contemporary data from PINNACLE, the rate of ACEI/ARB use is not different (80% in IMPROVE HF versus 79% in PINNACLE), and the rate of BB use is slightly higher (86% in IMPROVE HF versus 89% in PINNACLE). At the practice level, similar mean practice rates of treatment were observed for ACEI/ARB (80% in IMPROVE HF versus 81% in PINNACLE) and BB (88% in IMPROVE versus 87% in PINNACLE). Although average rates of medication prescription are relatively high
and may suggest a ceiling effect of these performance measures, observed practice variation indicates that these remain important targets for quality improvement efforts. A number of practice-level factors may contribute to variation in care. However, IMPROVE HF did not find a significant association between improvement in care and a number of practice-level factors.
The focus of quality improvement for HFREF has largely been at the hospital level, with several national performance improvement programs designed to assess and improve care in the hospital setting.¹⁴-¹⁶ Policies such as 30-day readmission penalties, while implemented at the hospital level, have brought attention to care provided outside of the hospital. Such policies may stimulate change in the ambulatory setting, particularly among integrated healthcare systems and accountable care organizations. Although much of the care for heart failure occurs in the ambulatory setting, few quality improvement programs have focused on ambulatory care of HFREF. IMPROVE HF demonstrated that a practice-based performance improvement program consisting of clinician education, clinical decision support tools, data collection, and benchmark quality reports resulted in improvement in the overall adherence to performance metrics for heart failure in the ambulatory setting.⁵ However, we found that in contemporary practice, practice site continues to be an important contributor to variability in treatment. Thus, addressing practice-level factors remains an important opportunity to improve the use of evidence-based heart failure therapies in the outpatient setting.

Several limitations should be considered in the interpretation of this study. First, PINNACLE practices may be highly motivated for quality improvement. Therefore, observed treatment rates may be higher than in practices not participating in PINNACLE. In particular, care provided in internal medicine and family practice clinics is unknown and may differ substantially from that of the PINNACLE sites. Furthermore, practices participating in PINNACLE were predominantly urban, which

### Table 2. Patient Characteristics Associated With Prescription Rates

<table>
<thead>
<tr>
<th></th>
<th>ACEI/ARB Rate Ratio (95% CI)</th>
<th>β-Blockers Rate Ratio (95% CI)</th>
<th>Composite of ACEI/ARB and BB Rate Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 to &lt;75</td>
<td>0.98 (0.96–1.00)</td>
<td>0.98 (0.97–0.99)</td>
<td>0.96 (0.95–0.98)</td>
</tr>
<tr>
<td>≥75</td>
<td>0.93 (0.90–0.95)</td>
<td>0.97 (0.95–0.99)</td>
<td>0.91 (0.88–0.94)</td>
</tr>
<tr>
<td>Women</td>
<td>0.97 (0.95–1.00)</td>
<td>1.01 (0.99–1.02)</td>
<td>0.99 (0.96–1.01)</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>0.97 (0.93–1.02)</td>
<td>0.97 (0.94–1.01)</td>
<td>0.97 (0.92–1.03)</td>
</tr>
<tr>
<td>Public</td>
<td>0.97 (0.93–1.02)</td>
<td>0.99 (0.95–1.03)</td>
<td>0.97 (0.92–1.03)</td>
</tr>
<tr>
<td>A-fib</td>
<td>0.99 (0.97–1.02)</td>
<td>1.00 (0.98–1.03)</td>
<td>1.00 (0.97–1.03)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>1.03 (1.01–1.06)*</td>
<td>1.02 (0.99–1.05)</td>
<td>1.04 (1.00–1.08)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.01 (0.98–1.03)</td>
<td>1.01 (1.00–1.02)</td>
<td>1.01 (0.98–1.04)</td>
</tr>
<tr>
<td>PAD</td>
<td>1.00 (0.97–1.04)</td>
<td>0.99 (0.97–1.02)</td>
<td>1.00 (0.97–1.04)</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>1.01 (0.98–1.04)</td>
<td>0.98 (0.94–1.03)</td>
<td>0.99 (0.95–1.04)</td>
</tr>
<tr>
<td>Angina</td>
<td>0.99 (0.96–1.03)</td>
<td>0.99 (0.97–1.02)</td>
<td>0.98 (0.95–1.02)</td>
</tr>
<tr>
<td>Ml history</td>
<td>1.01 (0.98–1.04)</td>
<td>1.03 (1.01–1.04)*</td>
<td>1.03 (0.99–1.06)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.99 (0.97–1.01)</td>
<td>0.99 (0.97–1.01)</td>
<td>0.98 (0.95–1.01)</td>
</tr>
<tr>
<td>CAGB within 12 mo</td>
<td>0.96 (0.87–1.06)</td>
<td>1.01 (0.98–1.05)</td>
<td>0.95 (0.84–1.06)</td>
</tr>
<tr>
<td>PCI within 12 mo</td>
<td>1.06 (1.03–1.09)*</td>
<td>1.04 (1.01–1.06)*</td>
<td>1.08 (1.04–1.13)*</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.00 (0.97–1.03)</td>
<td>1.02 (1.00–1.03)</td>
<td>1.02 (0.98–1.05)</td>
</tr>
<tr>
<td>Practice median rate ratio</td>
<td>1.11 (1.08–1.18)</td>
<td>1.08 (1.05–1.15)</td>
<td>1.17 (1.13–1.26)</td>
</tr>
</tbody>
</table>

A-fib indicates atrial fibrillation; ACEI/ARB, angiotensin-converting enzyme inhibitors/angiotensin receptor blockers; BB, β-blockers; CAGB, coronary artery bypass grafting; CI, confidence interval; MI, myocardial infarction; PAD, peripheral arterial disease; and PCI, percutaneous coronary intervention.

*Indicates patient characteristics significantly associated with prescription rates.
may also limit the generalizability of our findings. Second, documentation of contraindications may not be complete or accurate and does not include information on specific adverse reactions or contraindications. However, PINNACLE has data completeness and quality requirements for participation in the registry. Furthermore, to the extent that participating practices depend on the PINNACLE program to report for their pay-for-performance measures, it is in the best interest of the practices to submit complete data. Third, we were unable to explore the role of specific practice-level factors because limited data were available on practice characteristics. Finally, we were unable to assess other important aspects of heart failure care (eg, use of aldosterone antagonists, implantable cardioverter-defibrillators). Although these other aspects of care are class I guideline indications, they are not established consensus performance measures for heart failure care.4

In conclusion, we found significant variation among outpatient practices in prescription of evidence-based therapies for patients with HFREF. This variation was independent of differences in case mix and was greatly influenced by the practice at which patients received care. Thus, efforts to improve the use of evidence-based HFREF therapies in the outpatient setting should target practice-level factors.

Acknowledgments
The views in this article are those of the authors and do not necessarily reflect the views of the Department of Veterans Affairs.

Sources of Funding
Dr Allen is supported by a Career Development Grant Award from the National Heart, Lung, and Blood Institute (NHLBI; 5K23HL05896). Dr Chan is supported by a Career Development Grant Award (K23HL102224) from the NHLBI. Dr Maddox is supported by a Veterans Affairs Health Services Research and Development Career Development Award. Dr Peterson is supported by a K08 award (1K08HS019814-01) from Agency for Healthcare Research & Quality. Dr Spertus has a research contract with the American College of Cardiology Foundation to support analyses of the PINNACLE Registry.
Disclosures
Dr Allen serves as a consultant for Amgen, Janssen Scientific Affairs, and for the Robert Wood Johnson Foundation. Dr Masoudi has a contract with the American College of Cardiology Foundation. Dr Masoudi has research support from the National Heart, Lung, and Blood Institute, Agency for Healthcare Research & Quality, and the American College of Cardiology Foundation. Dr Spertus has grant support from the National Institutes of Health, the American Heart Association, and Genentech, Lilly, and EvaHeart. Dr Spertus serves as a consultant to United Healthcare, St Jude Medical, Genentech, and Amgen. The other authors report no conflicts.

References

CLINICAL PERSPECTIVE
Because most heart failure care occurs in the ambulatory setting, outpatient practices are a natural focus for investigating the quality of heart failure care. Little is known about the contribution of practice site to practice-level variation in treatment of outpatients with heart failure and reduced ejection fraction. Previous studies have not found an association between a number of practice characteristics and improvement in use of guideline recommended therapies. Using the National Cardiovascular Disease Registry (NCDR) Practice Innovation and Clinical Excellence (PINNACLE) registry, we examined practice-level variation in rates of guideline-recommended treatment for outpatients with heart failure and reduced ejection fraction and examined the association between treatment variation and practice site, independent of patient factors. We found significant variation among outpatient practices in prescription of evidence-based therapies. This variation was independent of differences in case mix and was greatly influenced by the practice at which patients received care. This suggests that previously unstudied practice-level factors may be involved, such as differences in guideline familiarity, culture of practice, or implementation of tools and systems to ensure that recommended care is provided. Efforts to improve the use of evidence-based therapies in the outpatient setting should focus on practice site in addition to patient factors, and further work is needed to understand the characteristics and processes of high-performing practices and to disseminate those processes to all practices to improve the use of guideline-based therapies for heart failure and reduced ejection fraction in the outpatient setting.
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Circ Heart Fail. 2013;6:1132-1138; originally published online October 15, 2013; doi: 10.1161/CIRCHEARTFAILURE.113.000163

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