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ORIGINAL ARTICLE

Health Status Variation Across Practices in Outpatients With Heart Failure

Insights From the CHAMP-HF (Change the Management of Patients With Heart Failure) Registry

BACKGROUND: Although a key treatment goal for patients with heart failure with reduced ejection fraction is to optimize their health status (their symptoms, function, and quality of life), the variability across outpatient practices in achieving this goal is unknown.

METHODS AND RESULTS: In the CHAMP-HF (Change the Management of Patients With Heart Failure) registry, associations between baseline practice characteristics and Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary (OS) and Symptom Frequency (SF) scores were assessed in 3494 patients across 140 US practices using hierarchical regression after accounting for 23 patient and 11 treatment characteristics. We then calculated an adjusted median odds ratio to quantify the average difference in likelihood that a patient would have excellent (KCCQ-OS, ≥75) health status or minimal (monthly or fewer) symptoms (KCCQ-SF, ≥75) when treated at one practice versus another, at random. The mean (±SD) KCCQ-OS and KCCQ-SF were 64.2±24 and 68.9±25.6, with 40% (n=1380) and 50% (n=1760) having KCCQ scores ≥75, respectively. The adjusted median odds ratio across practices, for KCCQ-OS ≥75, was 1.70 (95% confidence interval, 1.54–1.99; *P*<0.001) indicating a median 70% higher odds of a patient having good-to-excellent health status when treated at one random practice versus another. In regard to KCCQ-SF, the adjusted median odds ratio for KCCQ-SF ≥75 was 1.54 (95% confidence interval, 1.41–1.76; *P*=0.001).

CONCLUSIONS: In a large, contemporary registry of outpatients with chronic heart failure with reduced ejection fraction, we observed significant practice-level variability in patients' health status. Quantifying patients' health status as a measure of quality should be explored as a foundation for improving care.

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WHAT IS KNOWN

- A primary goal of heart failure management is to optimize patients' health status—their symptoms, function, and quality of life.
- Prior studies have used heart failure morbidity and mortality as a means to describe variations between healthcare systems and providers.

WHAT THE STUDY ADDS

- This is the first study to examine outpatient practice variability in the health status and symptom control of patients with heart failure.
- We observed significant practice-level variability in patients' health status.
- Our findings emphasize the potential of a patient-reported outcome measures–based performance measure to incentivize practices to optimize the health status of their patients with heart failure in the outpatient setting.

A key goal of heart failure (HF) management is to optimize patients' health status[1]—their symptoms, function, and quality of life.[2–4] Although prior studies have used HF-related morbidity and mortality to describe variations between healthcare systems (ie, resource utilization[5,6] and patient volume[7]) and providers,[8,9] to date, there have been no studies describing health status differences across outpatient practices. Identifying practice-level differences in the successful management of patients' health status could provide novel insights into the current state of HF management across the United States and identify potential opportunities to improve care and patient-centered outcomes.

To address this gap in knowledge, we compared the health status of HF patients with reduced ejection fraction (HFrEF) across a heterogeneous sample of outpatient practice sites in the Change the Management of Patients With Heart Failure (CHAMP-HF) registry.[10] CHAMP-HF is a multicenter, prospective registry of outpatients with HFrEF that captures patients' health status using the short form of the disease-specific Kansas City Cardiomyopathy Questionnaire (KCCQ)-12.[11] Importantly, as payers and other stakeholders begin to explore the use of patient-reported outcome (PRO) measures to measure providers' care quality,[12] it is essential to define the extent of health status variability and identify opportunities to improve clinical outcomes for patients with HFrEF, if such performance measures are to have the potential to improve care.

METHODS

Study Design

The data, methods used in the analysis, and materials used to conduct the research will not be made available to any researcher for purposes of reproducing the results or replicating the procedure. For this analysis, we used data from the CHAMP-HF registry: a prospective, observational study of outpatients with HFrEF at 149 US practice sites that has been described previously.[10] Patients eligible for enrollment met the following criteria: (1) age ≥18 years, (2) primary diagnosis of HFrEF (left ventricular ejection fraction ≤40% within 12 months of enrollment), (3) prescribed oral pharmacotherapy for HF at the time of enrollment, and (4) willingness to complete protocol requirements for study visits, procedures, and questionnaires. Patients were excluded if participating in any interventional clinical research study, receiving comfort care measures only or enrolled in a hospice program, had a life expectancy of <1 year, and had a history of, or planned, heart transplant, left ventricular assist device implantation, or dialysis. Data collected on enrollment included patient-level demographics and clinical characteristics, medical history, laboratory results, use of HF medications and devices, and patient-reported health status. Eligible sites were identified based on the completion of a feasibility survey, which provided investigators with the opportunity to ensure broad geographic and provider specialty representation. Study coordinators at each site were responsible for identification and enrollment of subjects during the course of a scheduled outpatient visit, with this analysis being limited to only those patients enrolled between December 2015 and March 2017. CHAMP-HF was sponsored by Novartis Pharmaceuticals Corporation, and all participating sites obtained local or central institutional review board approval before patient enrollment, as well as informed consent from each participant.

Data Collection

Site coordinators interviewed patients to collect their sociodemographic characteristics and health status while abstracting information from the medical record on medical history and medications at enrollment. Data collected from site feasibility surveys included practice specialty, annual patient volume, and availability of the following ancillary HF services: access to cardiac rehabilitation, dedicated HF clinic, multidisciplinary clinic, routine collection of PROs, and telemonitoring resources. The primary outcome for this cross-sectional analysis was the 12-item KCCQ Short Form (KCCQ-12) on enrollment—a reliable, sensitive, HF-specific PRO that measures patients' HF symptoms, physical and social limitations, and quality of life—that was completed by patients at each site through an electronic tablet.[11] The KCCQ-12 overall summary (OS) score and symptom frequency (SF) domain score were the primary outcomes for this study, to capture a summary of all clinically relevant HF domains (KCCQ-OS—the average of all 4 subscales) and symptoms alone (KCCQ-SF—the domain most likely to be optimized because of changes in diuretic and other cardiovascular therapies). Scores range from 0 to 100, where higher scores reflected better health status (fewer symptoms, fewer social or physical limitations, and better quality of life). A 5-point difference in KCCQ scores is considered to be clinically meaningful from both patients' and providers' perspectives.[13,14]

Statistical Analysis

The enrollment characteristics of the CHAMP-HF cohort were assessed with descriptive statistics, using proportions for categorical variables and means with SDs or medians with quartiles

for continuous variables. Differences in patient- and site-level characteristics across health status categories (poor [<25], fair [25–49], good [50–74], and excellent [≥75]) were assessed, with χ^2 tests for categorical variables and Kruskall–Wallis tests for continuous variables. To improve clinical interpretability for both the KCCQ-OS and KCCQ-SF scores, we categorized the scores. For the KCCQ-OS, patients were categorized as having poor to good (<75) and excellent (≥75) health status. For the KCCQ-SF, scores were dichotomized into daily to weekly (<75) versus monthly to no (≥75) symptoms.

We used hierarchical logistic regression, with site as a random effect to account for clustering within sites, to identify site variability in achieving excellent health status or monthly to no symptoms. As a secondary analysis, to describe site characteristics associated with better health status (and the magnitude of these mean differences by KCCQ score), we added site characteristics as fixed effects to the hierarchical model. To describe site-level variability in health status across participating sites, we plotted the site-specific proportion of patients exhibiting baseline KCCQ-OS or KCCQ-SF scores of ≥75 with 95% confidence interval (CI). To quantify the magnitude of these differences, we then calculated an adjusted median odds ratio (aMOR),[15] which estimates the median relative difference in 2 statistically identical patients having excellent health status or monthly to no symptoms when receiving treatment at 2 random sites within the CHAMP-HF registry. Finally, we used multivariable logistic regression to examine the proportional change in site-level variance after sequential adjustment for (1) patient, (2) patient and treatment, and (3) patient, treatment, and site characteristics for both KCCQ-OS and KCCQ-SF scores. For each sequential model, we obtained an estimate of the random site effect variance on the log-odds scale. The incremental proportional change in variance was calculated as proportional change in variance=(Va–Vb)/Va, where Va represents the variance of the prior model and Vb, the variance of the model with added covariates. To better quantify the differences across practices as a secondary analysis, we constructed adjusted linear regression analyses to more accurately describe the mean differences in KCCQ scores explained by site characteristics.

Our regression models accounted for 34 patient and treatment characteristics previously shown to be significant,[16] where patient characteristics included sociodemographics (age, sex, ethnicity, and race), socioeconomic status (employment status, insurance provider, highest level of education, and total annual household income), clinical comorbidities (body mass index, atrial fibrillation, chronic obstructive lung disease, chronic kidney disease, coronary disease, depression, diabetes mellitus, hypertension, hyperlipidemia, and smoking status), and HF severity (systolic blood pressure, pulse, left ventricular ejection fraction, history of ventricular arrhythmias, and number of hospitalizations in the prior 12 months). Additionally, 11 HFrEF treatment characteristics (cardiac resynchronization therapy, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, β-blocker, angiotensin–neprilysin inhibitor, mineralocorticoid receptor blocker, hydralazine, loop diuretic, digoxin, ivabradine, inotrope, and total number of HF therapies) were included. Nonlinear variables were handled by fitting piecewise linear splines. To examine the association between site characteristics and mean health status differences by KCCQ scores, we added 7 practice characteristics: annual HF patient volume, access to cardiac rehabilitation, access to telemonitoring services, dedicated HF clinic, physician specialty, routine use of PROs, and location (urban, suburban, or rural).

Rates of missing data for patient-level variables, overall, were small (<8%), except for household income (≈24% of patients). We applied multiple imputation to impute missing values of each variable. Five imputations were created using fully conditional specification method. The results across 5 imputed data sets were then combined by averaging, and SEs were adjusted to reflect both within-imputation variability and between-imputation variability. All estimates were reported using 95% CIs, and a P value ≤0.05 was considered statistically significant. All analyses were performed using SAS software (version 9.4; SAS Institute, Cary, NC). Analyses were performed independently by the Duke Clinical Research Institute, and the lead author takes responsibility for guiding data analysis and interpretation.

RESULTS

A total of 3552 patients were enrolled across 149 outpatient practice sites in the CHAMP-HF registry. After excluding patients who were ineligible per the study protocol (n=34) and those with missing KCCQ-12 (n=14) or sociodemographic (n=10) data, 3494 were included in the final analyses (Figure 1). Baseline patient characteristics are described in Table 1.

Site Characteristics and Patient Health Status Distributions

The characteristics of all enrolling practice sites are described in Table 2. Most sites were general cardiology practices (60.9%), followed by HF specialists (23.1%), internal medicine (7.8%), and family medicine (6.3%) practices. The majority of sites offered

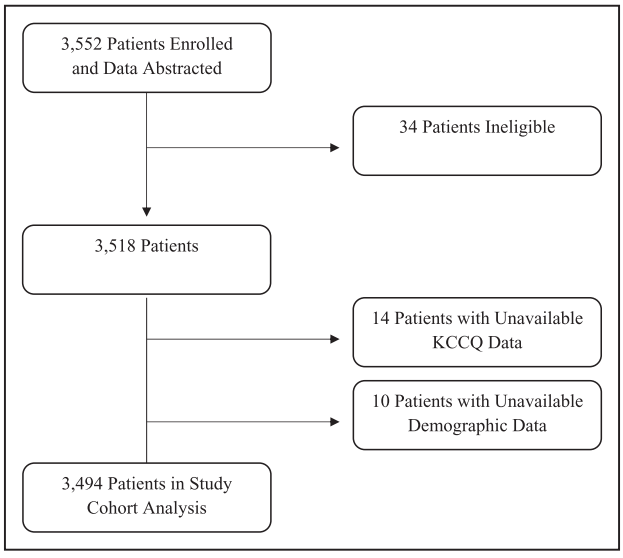

Figure 1. Patient exclusion flowchart.
KCCQ indicates Kansas City Cardiomyopathy Questionnaire.

Table 1. Distribution of Patient Characteristics (n=3494)

	Overall (%) or Median (Q1–Q3)
Demographics	
Age, y	68.0 (59.0–75.0)
<40	111 (3.2%)
40–64	1307 (37.4%)
65–80	1638 (46.9%)
>80	438 (12.5%)
Men	2473 (70.8%)
White	2616 (74.9%)
Black	572 (16.4%)
Hispanic	589 (16.9%)
BMI	29.2 (25.5–33.8)
Insurance status	
Managed care	574 (16.4%)
Private insurance	330 (9.4%)
Medicare	2038 (58.3%)
Medicaid	317 (9.1%)
Highest level of education	
Less than high school	425 (12.2%)
High school	1187 (34.0%)
Some college	1094 (31.3%)
4-y college	440 (12.6%)
Graduate or other professional degree	348 (10.0%)
Total household income	
<$25 000	1076 (30.8%)
$25 000–$49 999	685 (19.6%)
$50 000–$74 999	417 (11.9%)
$75 000–$99 999	212 (6.1%)
$100 000–$149 999	184 (5.3%)
≥$150 000	95 (2.7%)
Employee status	
Full time	496 (14.2%)
Part time	252 (7.2%)
Disability for medical reasons	877 (25.1%)
Not employed for other reasons	1869 (53.5%)
Medical history	
COPD	1054 (30.2%)
CKD	693 (19.8%)
Depression	874 (25.0%)
Diabetes mellitus	1426 (40.8%)
Tobacco use/smoking	689 (19.7%)
Atrial fibrillation	1258 (36.0%)
Coronary artery disease	2177 (62.3%)
Hyperlipidemia	2643 (75.6%)
Hypertension	2872 (82.2%)
VT/VF	661 (18.9%)
CRT therapy	234 (6.7%)
New York Heart Association classification	
I	344 (9.8%)
II	1914 (54.8%)
III	1004 (28.7%)
IV	87 (2.5%)
Unknown	145 (4.1%)
No. of prior hospitalizations within 12 mo of screening	
0	2173 (62.2%)
1	886 (25.4%)
≥2	435 (12.4%)
Vital signs on enrollment	
Systolic, mm Hg	120 (110–131)
Diastolic, mm Hg	72 (64–80)
Heart rate, bpm	72 (66–81)
Clinical measures and laboratory results	
LVEF, %	30 (23–35)
N-Terminal pro-B-type natriuretic peptide, pg/mL	2013 (794–5490)
HbA1c %	6.4 (5.8–7.6)
Hemoglobin, g/dL	13.2 (11.8–14.4)
Serum creatinine, mg/dL	1.1 (0.9–1.4)
BUN, mg/dL	20.0 (16.0–28.0)
Sodium, mmoL	139 (137–141)
eGFR, mL/min per m^2	
<30	122 (3.5%)
30–45	304 (8.7%)
45–60	491 (14.1%)
>60	1200 (34.3%)
Missing	1377 (39.4%)
Medication on enrollment	
ACEi/ARB	2102 (60.2%)
β-Blocker	2894 (82.8%)
MRA	1161 (33.2%)
ARNI	451 (12.9%)
Loop diuretic	2139 (61.2%)
Hydralazine	193 (5.5%)
Digoxin	475 (13.6%)
Ivabradine	42 (1.2%)
Inotrope	14 (0.4%)
No. of medications	3.0 (2.0–4.0)
Site characteristics	
Patients enrolled per site	22.5 (8.0–37.0)
Physician specialty	
Family practice	219 (6.3%)

(*Continued*)

Table 1. Continued

	Overall (%) or Median (Q1–Q3)
Internal medicine	273 (7.8%)
HF specialist	807 (23.1%)
Other cardiologist	2128 (60.9%)
Others*	67 (1.9%)
No. of patients with HF managed annually	1200 (480–3000)

ACEi indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor–neprilysin inhibitor; BMI, body mass index; BUN, blood urea nitrogen; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; eGFR, estimated glomerular filtration rate; HF, heart failure; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid antagonist; VF, ventricular fibrillation; and VT, ventricular tachycardia.

*Emergency medicine/urgent care.

cardiac rehabilitation (62.1%) and telemonitoring (65.4%) services, with less than half routinely collecting PRO measures (30.2%) or possessing a dedicated HF clinic (39.7%). Finally, more patients were treated at a suburban (40.5%), rather than urban (32.9%), or rural (26.6%) location.

The overall mean (±SD) KCCQ-OS was 64.2 (±24), with the following distributions of patient health status observed: poor (<25; n=228, 6.5%), fair (25–49; n=785, 22.5%), good (50–74; n=1101, 31.5%), and excellent (≥75; n=1380, 39.5%). The overall mean KCCQ-12-SF score was 68.9 (±25.6), with the following distributions of SF: daily (<40; n=548, 15.7%), weekly (40–74; n=1186, 33.9%), monthly (75–99; n=1219, 34.9%), and no symptoms (100; n=541, 15.5%).

Health Status Variability Across Sites—aMOR

The proportion of CHAMP-HF patients at each site that had KCCQ-OS or KCCQ-SF scores ≥75 are shown in Figures 2 and 3, respectively. There was a wide range in the proportion of patients with excellent health status (0%–77%) and monthly or fewer symptoms (8%–82%). The aMOR across sites was large, after adjusting for 24 patient and treatment characteristics, suggesting substantial variability across sites. For overall health status (KCCQ-OS), the aMOR was 1.70 (95% CI, 1.54–1.99; $P<0.001$) indicating an average 70% (95% CI, 54%–99%) higher odds of having excellent health status if the same patient was treated at 1 random site versus another ($P<0.0001$). For good-to-excellent symptom control, the aMOR was 1.54 (95% CI, 1.41–1.76) indicating that for any 2 randomly selected practices, the median odds that a patient would have minimal symptoms was 54% (95% CI, 41%–76%) higher at 1 site versus another ($P=0.001$). Site variability was substantially reduced after adjusting for patient characteristics (proportional change in variance, 38.9%). However, subsequent adjustments were not associated with further reductions (proportional change in variance of −2.9% with the addition of medical therapies and −0.2% with added site characteristics). A different pattern was seen for KCCQ-SF, where adjustment for patient characteristics reduced observed variability by 21%; no further reduction was observed after adjusting for medical

Table 2. Distribution of Site Characteristics, Overall and by KCCQ-OS Categories (n=3494)

Site Characteristics	Overall (n=3494)	Poor (<25), n=228 (6.5%)	Fair (25–49), n=785 (22.5%)	Good (50–74), n=1101 (31.5%)	Excellent (≥75), n=1380 (39.5%)	*P* Value
Physician specialty						<0.001
Family practice	219 (6.3%)	16 (7.0%)	85 (10.8%)	68 (6.2%)	50 (3.6%)	
Internal medicine	273 (7.8%)	19 (8.3%)	75 (9.6%)	124 (11.3%)	55 (4.0%)	
HF specialist	807 (23.1%)	59 (25.9%)	179 (22.8%)	231 (21.0%)	338 (24.5%)	
Other cardiologist	2128 (60.9%)	133 (58.3%)	433 (55.2%)	653 (59.3%)	909 (65.9%)	
Others*	67 (1.9%)	1 (0.4%)	13 (1.7%)	25 (2.3%)	28 (2.0%)	
No. of patients with HF managed annually, median (Q1–Q3)	1200 (480–3000)	1000 (350–2000)	1000 (350–2000)	1057 (310–2500)	1500 (500–3000)	<0.001
Access to cardiac rehabilitation	2169 (62.1%)	151 (66.2%)	442 (56.3%)	680 (61.8%)	896 (64.9%)	<0.001
Routine site collection of PROs	1055 (30.2%)	77 (33.8%)	223 (28.4%)	362 (32.9%)	393 (28.5%)	0.041
Dedicated for patients with HF	1388 (39.7%)	106 (46.5%)	309 (39.4%)	412 (37.4%)	561 (40.7%)	0.062
Patient population						<0.001
Urban	1148 (32.9%)	74 (32.5%)	292 (37.2%)	388 (35.2%)	394 (28.6%)	
Suburban	1416 (40.5%)	88 (38.6%)	276 (35.2%)	399 (36.2%)	653 (47.3%)	
Rural	930 (26.6%)	66 (28.9%)	217 (27.6%)	314 (28.5%)	333 (24.1%)	
Patient telemonitoring resources	2284 (65.4%)	134 (58.8%)	524 (66.8%)	710 (64.5%)	916 (66.4%)	0.120

HF indicates heart failure; and PRO, patient-reported outcome measure.

*Emergency medicine/urgent care.

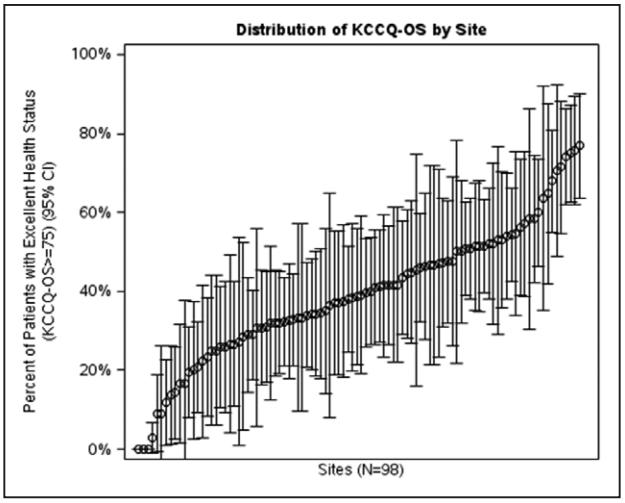

Figure 2. Unadjusted Kansas City Cardiomyopathy Questionnaire Overall Summary (KCCQ-OS) site variability (site, n=98).
Each circle represents the percentage of patients with KCCQ-OS ≥75 for each site, with 95% confidence intervals (CIs).

therapies, and an incremental 23.5% reduction was observed with the addition of site characteristics.

Differences in Health Status by Site Characteristics—Fully Adjusted Linear Regression Models

Marked site-level differences were observed, by KCCQ-OS score, in fully adjusted linear regression analyses. Compared with patients enrolled at family practices, those at HF (+6.5 points; 95% CI, 0.5–12.4; *P*=0.033) and general cardiology (+6.5 points; 95% CI, 1.4–11.7; *P*=0.012) practices had significantly higher scores, whereas those enrolled at internal medicine (+3.7; 95% CI, −2.3 to 9.7; *P*=0.228) clinics had similar scores. Patients enrolled at a suburban setting, also, had higher health status compared with those at an urban setting (+3.2; 95% CI, 0.2–6.1; *P*=0.034). There were no other practice characteristics associated with patients' health status (Table 3).

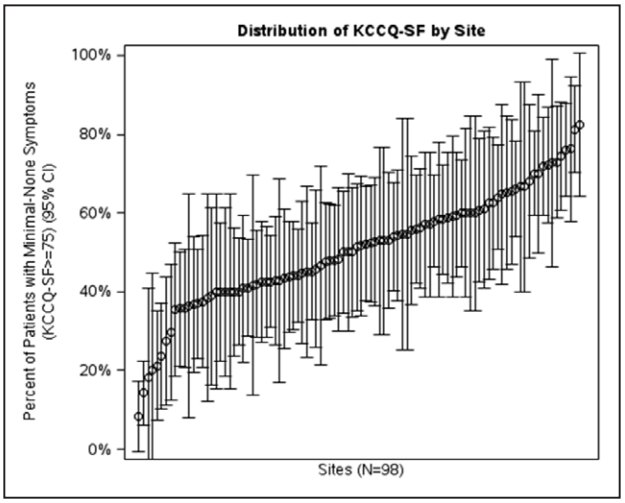

Figure 3. Unadjusted Kansas City Cardiomyopathy Questionnaire Symptom Frequency (KCCQ-SF) site variability (site, n=98).
Each circle represents the percentage of patients with KCCQ-SF ≥75 for each site, with 95% confidence intervals (CIs).

Similar findings were observed for KCCQ-SF assessments where, compared with patients treated by family practices, those treated at HF (+5.4 points; 95% CI, −1.0 to +11.9; *P*=0.10), general cardiology (+5.0 points; 95% CI, −0.5 to +10.6; *P*=0.074), and internal medicine (+5.4 points; 95% CI, −1.0 to +11.9; *P*=0.10) practices had a nonstatistically significant trend for fewer symptoms. Those enrolled at a suburban setting had significantly better symptom control than those treated in an urban setting (+3.3; 95% CI, +0.1 to +6.4; *P*=0.043).

DISCUSSION

Examining health status variability across practices is an important next step to establishing the suitability of PROs for quality assessment, as currently being developed by the Centers for Medicare and Medicaid Services and for defining the potential to improve patient-centered outcomes. This is the first study, of which we are aware, to ever examine the outpatient practice variability in health status and symptom control. Substantial practice-level differences highlighted a potential opportunity for improvement, which persisted after adjustment for numerous patient and treatment characteristics—and where patient characteristics were the most important in explaining the unadjusted variation in practices' mean KCCQ scores. We found that, after full adjustment, there was a 70% median odds of a statistically identical patient having excellent health status at 1 random practice versus another and a 54% difference in average likelihood of having minimal symptoms. Identifying and disseminating the management styles of high-performing practices has the potential to reduce practice variability and improve the symptoms, function, and quality of life of outpatients with HFrEF. Moreover, our study results emphasize the potential of a PRO-based performance measure to incentivize practices to optimize the health status of their patients with HFrEF in the outpatient setting,[17] which can complement current efforts focusing on inpatient and early postdischarge outcomes.

Our findings extend prior studies' descriptions of specialty-level differences in cardiovascular outcomes in patients with HFrEF. However, although those analyses focused on traditional end points, including guideline-

Table 3. Linear Regression: Adjusted Mean KCCQ-OS and KCCQ-SF Score Differences by Provider Specialty, Developed Settlement, and Heart Failure Services*

	Point Estimate (95% CI)	*P* Value
KCCQ-OS		
Physician specialty (ref: family practice)		
Internal medicine	3.7 (−2.3 to 9.7)	0.228
HF specialist	6.5 (0.5 to 12.4)	0.033†
Other cardiologist	6.5 (1.4 to 11.7)	0.012†
Others†	12.3 (4.0 to 20.6)	0.004†
Patients with HF managed annually, n	0.6 (−0.7 to 2.0)	0.372
Access to cardiac rehabilitation	2.0 (−1.0 to 5.0)	0.184
Dedicated for patients with HF	−0.4 (−3.3 to 2.5)	0.790
Routine site collection of PROs	0.0 (−2.6 to 2.6)	0.992
Patient population (ref: urban settlement)		
Suburban	3.2 (0.2 to 6.1)	0.034†
Rural	0.6 (−2.7 to 4.0)	0.705
Patient telemonitoring resources	0.2 (−2.6 to 2.6)	0.912
KCCQ-SF		
Physician specialty (ref: family practice)		
Internal medicine	5.4 (−1.0 to 11.9)	0.100
HF specialist	5.4 (−1.0 to 11.9)	0.100
Other cardiologist	5.0 (−0.5 to 10.6)	0.074
Others†	12.6 (2.7 to 22.4)	0.013†
Patients with HF managed annually, n	0.5 (−1.0 to 1.9)	0.527
Access to cardiac rehabilitation	0.8 (−2.4 to 4.0)	0.643
Dedicated for patients with HF	−0.8 (−4.0 to 2.3)	0.613
Routine site collection of PROs	−0.4 (−3.2 to 2.4)	0.759
Patient population (ref: urban settlement)		
Suburban	3.3 (0.1 to 6.4)	0.043†
Rural	1.4 (−2.2 to 5.0)	0.457
Patient telemonitoring resources	−0.5 (−3.6 to 2.5)	0.722

ACEi indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin-receptor neprilysin inhibitor; CI, confidence interval; HF, heart failure; PRO, patient-reported outcome measures; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary; and KCCQ-SF, Kansas City Cardiomyopathy Questionnaire Symptom Frequency.

*Model variables: age, sex, race, ethnicity, body mass index, total annual household income, employment status, chronic obstructive lung disease, chronic kidney disease, depression, atrial fibrillation, number of prior heart failure hospitalizations within prior 12 mo, pulse, left ventricular ejection fraction, ACEi/ARB, ARNI, loop diuretic, physician specialty, number of patients with heart failure managed annually, access to cardiac rehabilitation, dedicated heart failure clinic, routine collection of PROs, availability of telemonitoring resources, and patient population.

†Emergency medicine/urgent care.

directed medical therapy,[18] hospitalization,[19] and mortality,[20,21] we found substantial variations in patient-reported health status—an evolving benchmark of patient care. Nonetheless, although our findings suggest that patients treated by cardiovascular providers were more likely to experience better health status as compared with those treated by primary practitioners, future studies are needed to better understand the subtleties of clinical practice, regardless of specialty, associated with optimizing patients' health status.[22]

The discovery that patients enrolled and treated at suburban, as opposed to urban or rural, settings exhibit improved health status is not novel. However, our work extends prior studies' reporting on patient access to healthcare and hospitalization rates across developed settings[23] to that of health status. The finding that patients receiving care at suburban practices demonstrated better quality of life is logical given our current understanding of the positive relationship between socioeconomic status and HF-related quality of life.[24–27] Importantly, these health status differences remained after adjusting for multiple indicators of patient socioeconomic status.

Our findings must be interpreted in context of the following limitations. First, although CHAMP-HF represents one of the largest registries capturing disease-specific health status of patients with HFrEF in routine clinical care, it was conducted in voluntary participating sites committed to clinical research and might, therefore, not be fully generalizable to the entire country. Second, although patients were enrolled at a singular designated clinic, it was not recorded whether they received care from other providers in regard to their HF management. However, the fact that our findings were comparable to other specialty-level differences in HFrEF outcomes supports our findings. Third, our analysis was cross-sectional, and further work to address patients' health status trajectories over time, and whether site-level variability in titration of medical therapies contributes to health status differences, is needed. Moreover, we were unable to collect the duration or frequency by which a patient had been seen by a provider and whether there was a difference in the duration of care across clinics that might have influenced our findings. Fourth, the associations we observed might have been influenced by residual measured or unmeasured confounders. Some may think that we should not have adjusted for treatment because that is one of the key mediators of health status benefit, but including these adjustments underscored the magnitude of variability and the need to better understand such variations (including whether the doses and tailoring of treatments are optimal). Finally, this analysis was not able to formally test mediators of observed difference in health status across vulnerable groups or define practice patterns to reduce these disparities. This is particularly relevant in that we know that, overall, the routine collection of PROs was 30.2% but do not know what PROs were routinely used in the practices or whether the patients with the greatest potential to benefit from telemonitoring or cardiac rehabilitation services were receiving these therapies.

CONCLUSIONS

In leveraging data from a unique, observational registry of stable outpatients with HFrEF, we found substantial site-level variability in patients having excellent health status or monthly to no symptoms. These findings support the use of PROs as a measure of healthcare quality in HFrEF and inform the need to develop novel strategies to improve patient outcomes, thereby reducing differences in outpatient care quality.

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Health Status Variation Across Practices in Outpatients With Heart Failure: Insights From the CHAMP-HF (Change the Management of Patients With Heart Failure) Registry

Yevgeniy Khariton, Adrian F. Hernandez, Gregg C. Fonarow, Puza P. Sharma, Carol I. Duffy, Laine Thomas, Xiaojuan Mi, Nancy M. Albert, Javed Butler, Kevin McCague, Michael E. Nassif, Fredonia B. Williams, Adam DeVore, J. Herbert Patterson and John A. Spertus

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The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1, Lines 1-2 Page 3	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5, Lines 3-10, Lines 16-19		
Objectives	3	State specific objectives, including any pre-specified hypotheses	Page 5, Lines 16-19		
Methods					
Study Design	4	Present key elements of study design early in the paper	Page 5, Lines 22-24 Page 6, Line 1		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, Lines 22-24 Page 6, Lines 7-14 Page 6, Lines 20-22		
Participants	6	*(a) Cohort study* - Give the eligibility criteria, and the	Page 6, Lines 1-7 Page 6, Lines 10-14	RECORD 6.1: The methods of study population selection (such as codes or	

		sources and methods of selection of participants. Describe methods of follow-up *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed *Case-control study* - For matched studies, give matching criteria and the number of controls per case		algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	Page 6, Lines 20-23 Page 7, Lines 1-13 Page 8, Lines 22-23 Page 9, Lines 1-15	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 7, Lines 6-13 Page 7, Lines 18-22 Page 8, Lines 1-2		
Bias	9	Describe any efforts to address potential sources of bias	See Reference 10		
Study size	10	Explain how the study size was	See Reference 10		

		arrived at			
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Page 7, Lines 18-23		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed *Case-control study* - If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Page 7, Lines 18-23 Page 8, Lines 1-22 Page 9, Lines 1-23 Page 10, Lines 1-4		
Data access and cleaning methods		..	--	RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	
Linkage		..	--	RECORD 12.3: State whether the study included person-level, institutional-	

				level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram	Provided number of patients enrolled/site (IQR) in Table 1.	RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.*, study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	
Descriptive data	14	(a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount)	Table 1 and Table 2. Page 9, Lines 18-23 Reference 10		
Outcome data	15	*Cohort study* - Report numbers of outcome events or summary measures over time *Case-control study* - Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study* - Report numbers of outcome events or summary measures	Page 10, Lines 18-23		
Main results	16	(a) Give unadjusted estimates			

		and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Page 11 Page 12, Lines 1-10		
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	--		
Discussion					
Key results	18	Summarise key results with reference to study objectives	Page 12, Lines 13-23 Page 13, Lines 1-5		
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 14, Lines 1-23	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	-- See Conclusion.		
Generalisability	21	Discuss the generalisability (external validity) of the study	Page 14, Lines 1-5		

		results			
Other Information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 16, Line 2		
Accessibility of protocol, raw data, and programming code		..	See Reference 10 Page 5, Lines 23-24	RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	

*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.