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Roy Robertson MD
Parkview Health, roy.robertson@parkview.com

Mindy Flanagan PhD
Parkview Mirro Center for Research and Innovation, mindy.flanagan@parkview.com

Kris Howard PharmD
Parkview Health, kris.howard@parkview.com

Elizabeth Meisberger PharmD
Parkview Health, elizabeth.meisberger@parkview.com

Emily Keltner BS, MA
Parkview Health, emily.keltner@parkview.com

See next page for additional authors

Authors

Roy Robertson MD; Mindy Flanagan PhD; Kris Howard PharmD; Elizabeth Meisberger PharmD; Emily Keltner BS, MA; Lovekirat Singh MS; Carly Daley PhD; Shauna Wagner BSN, RN; Tammy Toscos PhD; and Michael Mirro MD, FACC, FHRS, FAHA

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Roy Robertson MD[a], Mindy Flanagan PhD[b], Kris Howard PharmD[a], Elizabeth Meisberger PharmD[a], Emily Keltner MA[a], Lovekirat Singh MS[c], Carly Daley PhD[b], Shauna Wagner BSN RN[b], Tammy Toscos PhD[b], Michael Mirro MD, FACC, FHRS, FAHA[b,c]

[a]Parkview Heart Institute, 11108 Parkview Circle, Entrance 10, Fort Wayne, IN 46845

[b]Parkview Mirro Center for Research and Innovation, 10622 Parkview Plaza Drive, Fort Wayne IN 46845

[c]Indiana University Medical School, 340 West 10th Street, Indianapolis, IN 46202

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ABSTRACT

Background: Guideline directed medical therapy (GDMT) is the cornerstone of reducing mortality and morbidity in patients with heart failure with reduced ejection fraction (HFrEF); however, uniform prescribing remains low. There is potential for multidisciplinary care teams, including pharmacists, to improve GDMT use in outpatient care for patients with HFrEF. Investigation is needed to understand the impact of pharmacists in outpatient HFrEF care on GDMT prescribing.

Objectives: To examine the impact of integrating a pharmacist into an outpatient cardiology setting on GDMT prescription rates during HFrEF-related clinic visits.

Methods: This retrospective chart review study examined cardiology clinic visits (HF clinic, "general cardiology" clinic, and pharmacist-only visits) before and after integration of pharmacists in the clinic. Visits were included for HFrEF patients (EF < 40%) from January 1, 2018 to July 1, 2019.

Results: Pharmacist visits had a significantly higher rate of GDMT compliance and significantly lower rate of harmful medication prescriptions than general cardiology visits ($p<.05$). There was a significant difference in GDMT compliance between the HF clinic and the general cardiology clinic after the integration of pharmacists ($p<.05$), but no significant difference prior.

Conclusions: Integrating a pharmacist in the outpatient HFrEF care team can improve GDMT prescribing. Efforts should focus on workflow to optimize the role of the pharmacist in the clinic, and improving quality of data entry, such as standardized documentation of GDMT exceptions.

Key Words: heart failure, medication, ambulatory care, outpatient, chart review, medication, prescription

Abbreviations

GDMT	Guideline directed medical therapy
HFrEF	Heart failure with reduced ejection fraction
HF	Heart failure
EF	Ejection fraction
ACEI	Angiotensin-converting enzyme inhibitors
ARB	Angiotensin II receptor blockers

ARNI	Angiotensin receptor-neprilysin inhibitors
MRA	Mineralocorticoid receptor antagonist

INTRODUCTION

Millions of people worldwide are affected by heart disease, and it is the leading cause of death in the United States.[1] Heart failure (HF) affects over 6 million people in the United States age 20 and older, and this number is expected to increase to over 8 million people age 18 and older by 2030.[2] Evidence demonstrates that guideline directed medical therapy (GDMT) is the cornerstone of reducing mortality and morbidity in patients with HFrEF.[3] However, gaps in physicians' use and appropriate titration of medications exist.[4] Prescribing GDMT for patients with HFrEF is a complex decision-making process that includes multiple providers, communication with patients, and assessment and adjustment of treatment and therapy for the duration of the patients' lives. Patient safety is a key concern, as patients have contraindications and intolerances to medications (herein referred to as exceptions to GDMT) that must be evaluated before adjusting doses. Optimization of GDMT significantly improves health outcomes and quality of life for people with HFrEF, and the process is highly personalized due to complexity of the therapy and the need to navigate exceptions.[5]

Multidisciplinary interventions and approaches to the treatment of heart failure have the potential to improve patient outcomes.[6] Due to the complexity of GDMT, pharmacists are particularly helpful in guiding decision making for titrating medication as well as patient education.[7] Findings from a small pilot study following 36 patients in an outpatient setting suggested that there is potential for a pharmacist-managed medication titration clinic to enhance titration, improve left ventricular EF, and enhance clinical and economic outcomes.[8] In order to examine the overall impact of integrating pharmacists in a HF clinic on adherence to GDMT prescription, we conducted a retrospective chart review to compare the number of patients who were on GDMT medications before and after the integration of the pharmacists into the clinic. GDMT classes of medications include: (angiotensin-converting enzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), or angiotensin receptor-neprilysin inhibitors (ARNI), beta-blockers, and mineralocorticoid receptor antagonist (MRA). We evaluated the impact of a pharmacist position integrated in an outpatient HF clinic on GDMT adherence rates for patients

with HFrEF by comparing 1) percentage of patients on GDMT across a cardiology outpatient setting and 2) percentage of patients on harmful medications across a cardiology outpatient setting, before and after integration of pharmacists into the HF clinic.

METHODS

A retrospective observational study was conducted across 14 cardiology outpatient locations in one healthcare system. A HF clinic operates at two of the 14 locations, and at one of these locations, pharmacist visits were integrated into patient care. At all other locations, outpatient cardiology visits were considered "general cardiology" clinic visits. Visits were included for patients who met the following criteria: 18 years or older, Medicare or Medicare replacement as primary insurance, low ejection fraction (EF < 40%), and one or more clinic visits in a target cardiology clinic during January 1, 2018 to July 1, 2019. Visits were excluded for patients who did not meet inclusion criteria or were receiving hospice or palliative care. Approval for this study was obtained from the hospital's Institutional Review Board prior to data collection.

Integration of Pharmacists

The HF clinic integrated pharmacists in October 2018 and beginning in November 2018. A pharmacist was included as part of the HF clinic infrastructure, dedicating 16 hours per week in the clinic. The pharmacist had individual appointments with patients, and by nature of being in the HF clinic, were also available for consults with other providers. Pharmacist visits were focused on patient education about medications and could occur prior or subsequent to visits with a nurse practitioner (NP) in the HF clinic. Pharmacists would consult with NPs regarding medication changes, however there was no standardized documentation of these interactions. The pharmacist visits were documented and billed separately in the medical record. Outpatient visits in the HF clinic were typically scheduled for 30 minutes with the NP or pharmacist. General cardiology outpatient visits were typically scheduled for 15 minutes with the physicians and 20 minutes with NPs. The primary outcome of interest was GDMT compliance which included prescriptions for the following three medication categories: 1) ACEI, ARB, or ARNI, 2) beta-blocker, and 3) mineralocorticoid receptor antagonist (MRA).

Data Collection

Data extracted from the electronic health record included demographics, co-morbidities, provider, race, date of encounter, encounter type, medications, clinic, and medical diagnoses. Patient encounters subsequent to EF measured by echocardiogram with results greater than or equal to 40% were omitted. Additionally, patients with angioedema were excluded from the sample. Four exceptions to GDMT prescribing were considered, patients with: 1) heart rates below 60 bpm, 2) systolic blood pressure below 90 mmHg, 3) 2 or more potassium values above 5mmol/L, and 4) 2 or more creatinine values above 2.5 mg/dL. When any of these conditions were present in the 30 days prior to the patient encounter, the visit was excluded from analyses. After these exclusions, the sample contained 2013 visits for 754 unique patients. Medication lists on each visit were screened for GDMT medication classes, and the following were considered on GDMT: patients who were on each of the three classes of medications, and patients who were African-American and not on ACEI, ARB, ARNI, but were on hydralazine and nitrate. If these conditions were not met, patients were considered not on GDMT at those visits. Additionally, rates of harmful medication (i.e., ibuprofen) prescriptions were calculated as well as the number of clinic visits for each type, before and after pharmacist integration. SEE APPENDIX FOR GDMT MEDS CRITERIA.

Data Analysis

As indirect effects on GDMT compliance could occur in the HF clinic with pharmacists available for provider consults, visits were coded into the following three categories: 1) general cardiology clinic visit; 2) HF clinic visit (where pharmacist installed); 3) pharmacist visit (in HF clinic).

The number of patients with GDMT compliant prescriptions were estimated (as best linear unbiased predictions) separately for the general cardiology clinic, HF clinic, and HF clinic with a pharmacist. This same approach was used to estimate rates for harmful medication prescriptions and compliance for three medications comprising GDMT. Calculations were conducted separately for pre-integration and post-integration periods. Pairwise comparisons between estimates by visit type were conducted (general cardiology vs HF clinic, general cardiology vs HF clinic with pharmacist, HF clinic vs HF clinic with pharmacist).

Due to the nested structure of the clinic visits within patient, a multilevel model was tested. These models permit predictors to vary at more than one level (patient, clinic visit) and account for non-independent (or correlated) observations. GDMT compliance was a dichotomous variable; hence, parameters were estimated using a logistic generalized linear mixed models (GLMM). Predictors entered in the model included: integration phase (pre/post), study group (general cardiology visits, HF clinic visits, and pharmacist visits).

The number of general cardiology clinic visits, HF clinic visits, and pharmacist visits were counted for pre-integration and post-integration time periods. Paired t-tests were used to compare number of clinic visits between pre- and post-integration for general cardiology clinic visits and HF clinic visits, separately. Patients that had at least one visit in the general cardiology clinic were included in analysis comparing number of general cardiology visits between pre- and post-integration. Similarly, patients had to have one HF clinic visit to be in included for comparison of number of HF clinic visits. As a supplementary analysis, a test of independence between GDMT compliance and provider type (NPs and physicians) was calculated (in general cardiology clinics only).

RESULTS

The sample contained 754 unique patients that were about 65% male and 92.0% White. Sample demographics and comorbidities are shown in Table 1.

GDMT compliance

The average number of clinic visits per patient was 2.67 (SD=1.86, median=2, range=1, 11). Of the total clinic visits during the study timeframe, 52.76% (1062/2013) occurred prior to the pharmacist integration and 47.24% (951/2013) occurred after the pharmacist intervention.

Table 1. Characteristics of the sample based on the *first* encounter that appeared for each unique patient in the data set

Characteristics of unique patients who had encounter(s) included in the study (N=754)	
Age mean (SD), range	73.8 (11.3), 34-89+
Gender n (%)	
Male	488 (64.7)
Female	266 (35.3)
Ethnicity n (%)	
Not Hispanic or Latino	738 (97.9)
Hispanic or Latino	5 (0.7)
No information	11 (1.4)
Race n (%)	
White or Caucasian	694 (92.0)
Black or African American	45 (6.0)
Asian	2 (0.3)
Burmese	1 (0.1)
Native Hawaiian or Pacific Islander	1 (0.1)
No information	11 (1.4)
Comorbidities n (%)*	
Hypertension	548 (72.7)
Diabetes	323 (42.8)
Coronary artery disease	448 (59.4)
Atrial Fibrillation	277 (36.7)
EF value mean (SD), range	29 (7.1), 5-39
*percent total equals more than 100 because people are counted in more than one group	

Estimated posterior modes of GDMT compliance for post-integration period by visit type are shown in Table 2. Pharmacist visits had a significantly higher rate of GDMT compliance and significantly lower rate of harmful medication prescriptions than general cardiology visits ($p<.05$). There was a significant difference in GDMT compliance between the HF clinic and the general cardiology clinic after the integration of pharmacists ($p<.05$), but no significant difference prior. There were no significant differences between pharmacist visits and HF clinic visits in prescriptions for ARB, ACE, ARNI; MRA; and beta blockers. As shown in Table 3, rates of GDMT compliance did not change in the general cardiology clinic or HF clinic from pre- to post-integration period.

Table 2. Posterior modes of GDMT compliance and harmful medication prescriptions for pre-intervention and post-intervention by visit type

Time period	General Cardiology clinic	HF clinic	Pharmacist visits
Pre-intervention (n=1062)			
GDMT compliance	.25[a]	.31[a]	-
ACEI, ARB, or ARNI	.64[a]	.58[a]	-
MRA	.45[a]	.58[b]	-
Betablocker	.93[a]	.94[a]	-
Harmful Medication	.16[a]	.09[b]	-
Post-intervention (n=951)			
GDMT compliance	.24[a]	.35[b]	.41[b]
ARB, ACE, or ARNI	.67[a]	.70[a]	.71[a]
MRA	.40[a]	.56[b]	.63[b]
Betablocker	.92[a]	.95[a]	.97[a]
Harmful Medication	.18[a]	.07[b]	.04[b]

Note: ARB=Angiotensin receptor blockers, ACE=angiotensin converting enzyme inhibitors. Superscripts indicate results from pairwise comparisons between posterior modes: the same superscript indicates no difference; different superscripts indicate a significant difference ($p<.05$) between modes.

Table 3. Summary of results from logistic random effects model predicting GDMT compliance from visit type and integration period (pre/post) (n=2013 visits)

Predictor	Estimate	Standard Error	p-value
Intercept	-0.53	0.32	.10
Integration period (pre vs post)	0.15	0.15	.30
Visit type (general vs pharmacist)	-0.80	0.34	.02
Visit type (heart failure vs pharmacist)	-0.38	0.34	.27

During the pre-integration period, 741 general cardiology clinic visits and 321 HF clinic visits occurred. During the post-integration period, 630 general cardiology clinic visits and 240 HF clinic visits occurred. As shown in Table 4, about 20% of patients had visits in the HF clinic in the pre-integration and post-integration period; in contrast, nearly 60% had visits in general cardiology clinics for the same time periods. During the post-integration period, pharmacists had

81 visits with 71 patients. About 82% (58/71) of patients with a pharmacist visit had other HF clinic visits during the post-integration period as well. For both general cardiology clinic and HF clinic the number of visits per patient declined significantly from pre- to post-integration period ($t(661)= 2.69$, $p=.007$ and $t(247)=2.56$, $p=.01$, respectively).

Table 4. Healthcare utilization frequencies by visit type and intervention period (n=754 patients)

Time period	General Cardiology clinic	HF clinic	Pharmacist visits	Total visits
Pre-integration, n(%)			--	
0	312 (41.38)	595 (78.91)		251 (33.29)
1	251 (33.29)	73 (9.68)		226 (29.97)
2	122 (16.18)	42 (5.57)		133 (17.64)
3+	69 (9.15)	44 (5.84)		144 (19.10)
Post-integration, n(%)				
0	326 (43.24)	606 (80.37)	683 (90.58)	240 (31.83)
1	289 (38.33)	90 (11.94)	65 (8.62)	281 (37.27)
2	87 (11.54)	35 (4.64)	4 (0.53)	109 (14.46)
3+	52 (6.90)	23 (3.05)	2 (0.27)	124 (16.45)

Note: IQR=interquartile range

In a comparison of GDMT compliance between provider type, nurse practitioners (29%) and physicians (27%) in general cardiology clinics had equivalent rates of GDMT compliance.

DISCUSSION

After the integration of pharmacists, the rate of GDMT compliance for HF clinic visits became significantly higher than general cardiology clinic visits. Encounters where all three classes of medications were prescribed for eligible patients among the general cardiology visits was low. Low rates of MRA prescriptions may be a primary factor impacting overall GDMT compliance. These findings align with research examining prescription of ACE/ARB/ARNI, beta-blocker, and MRA therapy, where 27%, 33%, and 67% of eligible patients were not prescribed these medications, respectively.[4]

During this study time period, the HF clinic workflow was undergoing adjustments, such as when patients see the nurse practitioner and when they see the pharmacist, and for how long, in an effort to make the best use of pharmacist input for improving GDMT compliance.

Undocumented interactions, known as “curbside consultations” [9] that occurred between the nurse practitioners and pharmacists in the HF clinic may have influenced GDMT prescription rates for the HF clinic visits, particularly as compared to the cardiology clinic in the post-integration phase.

One important finding that emerged during the data collection process was that exceptions to GDMT prescription were not uniformly or consistently documented. The ability to document GDMT exceptions, such as inability to prescribe appropriate therapy due to abnormal lab values or abnormal vital signs, is an important consideration in assessing the overall GDMT compliance of providers. In an electronic health record that does not allow for the documentation of exceptions to GDMT in a discrete fashion, the provider who attempts to place their patient on appropriate GDMT but is unable to prescribe all recommended therapies due to contraindications appears noncompliant even though they may be prescribing appropriately for the patient situation. Allowing prescribers to document discretely their prescribing decisions will more accurately reflect the true story of provider GDMT compliance. EMR systems require enhanced data governance to ensure standardization of documentation with prescribing medication. Efforts to create templates or workflow changes should focus on systematically documenting and recording decisions about medications at point of care.[10]

The ability to document and track GDMT is especially important as GDMT is continually evolving with evidence research to determine optimal therapy. For example, at the time of this study, guidelines did not include SGLT2s, a class of medications that has been added to the guidelines since 2017.[11] While the parameters for GDMT for this study included patients who were African-American and on hydralazine and isosorbide and not ACEI, ARB, or ARNI, updated guidelines emphasize that ARNIs are preferred if possible. The combination of hydralazine and isosorbide has been shown to be effective and is considered a key therapy among African Americans. However, clinical trials for ARNIs and newer medications have included very few African Americans, and newer, effective medications that show efficacy in these clinical trials should still be prescribed for African Americans so as not to broaden the disparity in treatment [11]. Black adults, among whom heart failure prevalence, hospitalization, and mortality rates are proportionally higher than for other races.[12] Additionally, research suggests that GDMT requires attention to the individual patients’ needs [5] and proper guideline

and tracking of GDMT would help with monitoring status and GDMT-related decision making at both the patient and population levels.

Study Limitations

The pharmacists were integrated in a busy cardiology practice, and the study lacks standardized documentation of implementation procedures and changes in the workflow and communication. Thus, we are unable to account for the potential impacts of these factors during the transition to integration of pharmacists that may have influenced the results. This study was a retrospective analysis of a large cardiology group within a Health System. The results of this effort may not translate to other practice models. Also, the appropriateness of GDMT prescription may not be accurately reflected due to lack of standardized documentation of exceptions to GDMT or other EMR data quality issues; moreover, the rate of these exceptions could vary between HF visits and general cardiology visits. Beta-blockers were included for GDMT that are not GDMT beta-blockers (see APPENDIX).

CONCLUSION

Integrating a pharmacist into the clinic can help increase prescription of GDMT in the HF clinic. Improved GDMT compliance was observed within both pharmacist-only visits and within visits with other clinicians at the HF clinic wherein the pharmacist was embedded. Future studies should focus on understanding what aspects of integration of pharmacists (individual patient visits, location and placement of the pharmacist in the clinic, adjacence of pharmacist visits to NP visits, and curbside consultations with NPs) helped improve GDMT compliance in the HF clinic. Additionally, efforts should focus on improving documentation and tracking of GDMT to reflect the methods, decision-making, and clinician engagement when prescribing GDMT.

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APPENDIX

Medications used for determining GDMT eligibility in the chart review:

ACE	**ARB**	**Hydralazine**	**Nitrate**	**Entresto (ARB/Angiotensin II)**
benazepril (Lotensin)	candesartan (Atacand)	apresoline (Hydralazine)	isosorbide dinitrate (Isordil)	sacubitrol/valsartan (Entresto)
capozide (Captopril/HCTZ)	irbesartan (Avapro)	hydra-zide (Hydralazine/HCTZ)	isosorbine mononitrate (Imdur)	
captopril (Capoten)	olmesartan medoxomil (Benicar)			
enalapril (Vasotec)	losartan (Cozaar)			
fosinopril (Monopril)	valsartan (Diovan)			
lisinopril (Zestoretic)	azilsartan medoxomil (Edarbi)			
lotensin (Benazepril)	telmisartan (Micardis)			
moexipril (Univasc)	valsartan (prexxartan)			
monopril (Fosinopril)	eprosartan mesylate (Teveten)			
perindopril (Aceon)				
prinzide (Lisinopril/HCTZ)				
quinapril (Accupril)				
ramipril (Altace)				
trandolapril (Mavik)				
uniretic (Moexipril/HCTZ)				
vaseretic (Enalapril/HCTZ)				

MRA	Beta Blocker*	Digoxin (harmful)*	Calcium channel blockers (harmful)	Nonsteroidal anti-inflammatory NSAIDs (harmful)
eplerenone (Inspra)	acebutolol (Sectral)	digoxin	amlodipine (Norvasc)	diclofenac (Voltaren)
spironolactone (Aldactone)	atenolol (Tenormin)	cardoxin	diltiazem (Cardizem, Tiazac, Dilacor)	etodolac (Lodine, Lodine XL)
	bisoprolol fumarate (Zebeta)	digox	felodipine (Plendil)	fenoprofen (Nalfon)
	metoprolol tartrate (Lopressor)	digitek	isradipine (Dynacirc)	flurbiprofen (Ansaid)
	metoprolol succinate (Toprol XL)	lanoxin	nifedipine (Adalat, Procardia)	ibuprofen (Advil, Motrin)
	carvedilol (Coreg or Coreg CR)	lanoxicaps	nicardipine (Cardene)	indomethacin (Indocin)
	esmolol (Brevibloc)		nimodipine (Nimotop)	ketoprofen (Orudis)
	labetalol (Trandate)		nisoldipine (Sular)	ketorolac (Toradol)
	nadolol (Corgard)		verapamil (Calan, Verelan, Isoptin)	meclofenamate (Meclomen)
	nebivolol (Bystolic)			mefenamic acid (Ponstel)
	penbutolol (Levatol)			meloxicam (Mobic)
	pindolol (Visken)			nabumetone (Relafen)
	propranolol (Inderal)			naproxen (Aleve)
	sotalol (Betapace)			oxaprozin (Daypro)
				piroxicam (Feldene)
				salsalate (Disalcid)
				sulindac (Clinoril)
				tolmetin (Tolectin)

*The beta blockers highlighted in yellow are not considered GDMT per current guidelines. Amlodipine is the only non-harmful calcium channel blocker, and Digoxin is not currently considered harmful and should not have been included. (https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.11.025?_ga=2.184910889.1400773485.1531464937-823548432.1529040707)