Heart Failure Postdischarge Clinic: A Pharmacist-led Approach to Reduce Readmissions

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Introduction

Heart failure (HF) is a major cardiovascular syndrome that affects approximately 5.7 million adults in the United States.[1] Although the survival rate after HF diagnosis has improved over time, the death rate from this disease remains high. It is estimated that 50% of those diagnosed with HF will die within 5 years after the first diagnosis.[1] The cost of HF is also staggering with total estimated expenditure exceeding $30 billion in the United States in 2012.[2] These costs are mostly due to exacerbations of the disease that require expensive emergency room visits, hospitalizations, and rehospitalizations.[2,3] The high rate of rehospitalizations for HF have stimulated medical centers to find innovative pathways to reduce them, particularly in light of the Centers for Medicare and Medicaid (CMS) rule of readmission penalties under the Affordable Care Act.[4] The American Heart Association's Get with The Guidelines registry has presented data supporting early postdischarge visits to reduce readmission rates, usually between 7 and 10 days.[5] However, although the American College of Cardiology (ACC)/American Heart Association Guidelines also recommend an early visit, there is no prescription of the processes that should occur during that early visit nor who should be the principal provider of the encounter.

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Although clinical trials have proven that optimal medical therapy can reduce morbidity, mortality, and hospitalizations in patients with HF, gaps still exist between evidence and actual practice.[5-10] While the Affordable Care Act expanded Medicaid coverage for more individuals, neither quality measures for HF nor in-hospital mortality improve as reported by the Get with The Guidelines registry.[11] Unfortunately, about 50% of patients with chronic diseases do not take their medications as directed and nonadherence to medications could lead to cardiac decompensation and subsequent hospitalization for these patients.[12,13] Therefore, issues leading to medication nonadherence, such as lack of patient knowledge and lack of follow-up appointments must be addressed to improve medication adherence and subsequent clinical outcomes.

Due to their expertise in drug therapy, pharmacists are particularly well-suited to provide patients the necessary medication interventions to optimize medication regimen and improve medication adherence. Results from recent studies have supported the positive impact that pharmacists can have on various cardiac patients such as those with HF, coronary heart disease, or cardiovascular disease risk factors.[14-17]

Particularly complex is a large hospital-outpatient environment where both academic and nonacademic cardiologists practice in an inner-city setting and who care for patients with a mix of age, sex, race, and ethnicity. Montefiore Medical Center had already embarked on a program to improve quality care in HF using expansive education of nurses, physician assistants, and other cardiology team members in an attempt to deal with the unacceptable readmission rates for HF. However, no coordinated approach in the outpatient setting existed. In search of a process that would include both an early postdischarge visit and a collaborative care intervention with pharmacists, we established an early postdischarge HF clinic and named it "Brown Bag." Patients were given a note stating that they should bring all their medicines from home, new or old, in a "brown bag." Thus, the name of the clinic. The clinic was modeled to the successful pharmacist-led clinic at the Louis Stokes Cleveland VA Medical Center where not only does medication reconciliation occur, but where pharmacists can initiate/uptitrate HF medical therapy according to Guidelines.[18] The clinic also served as a training site for Cardiology Fellows, Pharmacy Interns, and Internal Medicine Residents rotating on Cardiology. The primary purpose of this study was to determine if attendance to the "Brown Bag" clinic would reduce the large 30-day readmission rate of 28% at the 3 Montefiore hospitals in the Bronx. Additionally, the patient's health status early postdischarge was also obtained with an accepted instrument for HF to determine if that instrument was also

informative to predict readmissions and to assess the quality of life of this multiracial/ethnic population.[19,20] Our objective was to compare the group that attended Brown Bag Clinic (BBC) to the group that failed to attend clinic, although scheduled (Control) in respect to HF readmissions and mortality.

Method

Using the previously established model at the Cleveland VA Hospital, the BBC was introduced at Montefiore Medical Center due to the high readmission rate in all 3 hospitals in the Bronx in year 2012 (28%) leading to application of CMS penalties. The clinic was to take place 7-10 days post HF hospitalization with appointments given prior to discharge and noted in the electronic health record. Managed by a PharmD trained in HF therapy by the National Heart Failure Training Program,[21] the focus was on medication, with the option to perform medication reconciliation and uptitration according to the SERIOUS model of Guideline-directed Medical Therapy (GDMT) with physician guidance in a collaborative fashion.[18,22] The process is unique in that not only does traditional medication reconciliation occur, but also initiation and/or uptitration of GDMT, as well as removal of contraindicated or unnecessary medications. During the BBC visit, a HF cardiologist was available for consultation on site. In addition, General Cardiology Fellows who were on a HF rotation were expected to attend clinic as part of their educational experience. During the BBC, patients received a 1-hour education session using a proprietary education booklet.[23] The educational content included information on their disease states, rationale for the medical therapy, and discussions on the importance of dietary and medication compliance. Patients were instructed on how to respond to escalating signs/symptoms (such as increased shortness of breath or peripheral edema) and be provided with a tangible plan (detailed in the education booklet) on how to respond to particular symptoms (eg, instructions given by the pharmacist on use of diuretics). If the patient's clinical status appeared to be worsening since discharge, the patient was examined by the HF Cardiologist/Cardiology Fellow.

In order to evaluate patients' health status, the Kansas City Cardiomyopathy Questionnaire (KCCQ) was administered at the beginning of the 1-hour clinic visit. The KCCQs were distributed to patients by the clinic staff prior to meeting the HF PharmD and collected during the clinic visit. The responses were then scored and recorded to determine each patient's

baseline Health-Related Quality of Life. The KCCQ has been validated in the HF population.[19,20]

Patients were then scheduled to be followed by their primary cardiologist or a HF specialist who would resume the care and continue to pursue GDMT optimization. Thus, the next appointment was made at the end of the BBC encounter.

Data were collected using the electronic health record at the time of hospitalization and at the time of the BBC and subsequently. Medications were noted at beginning of the clinic encounter and at the end of the clinic with a final list of medications. Patients who failed to attend BBC clinic were labeled as Controls and were followed through medical records for readmissions, if readmitted to Montefiore Medical System. The primary outcome was readmission within 30 and 90 days. Secondary outcomes were readmissions after 90 days and up to 1 year, as well as 30-day, 90-day, and 1-year mortality. If data were not available, calls were made to confirm patients' status. The data were analyzed on patients during March 2012-December 2014.

Statistical Analysis

Means and standard deviations or numbers and proportions of baseline covariates were calculated among controls and participants of the BBC. *P* values were calculated testing for the difference between BBC participants and controls with Student's *t* test. Chi-square test was performed for categorical variables to test equivalence between different groups.

Readmission rate and death rate were reported in 30 days, 90 days, and 1 year within BBC participants and controls. Chi-square test was performed for comparing the equivalence between groups. Fisher's exact test was performed for the comparison if small cell numbers (<=5) appears.

A Cox model was performed to evaluate the association between time to readmissions and BBC visit, within 30 days, 90 days, or 1 year. The raw model was initially analyzed. A subsequent model was adjusted for age, sex, and Body mass index (BMI). The final model additionally adjusted for ejection fraction (EF), systolic blood pressure, diastolic blood pressure, and NTpro-BNP at admission. NTpro-BNP at admission was shown as raw and as log-transformed in 2 separate models considering the skewed shape of its distribution.

The association of BBC visit status and 1-year mortality or time to mortality within 1 year were evaluated with the same models in Cox regressions.

Regarding the variety of medication, conversions were made for angiotensin-converting-enzyme inhibitors (ACEI) into enalapril equivalents, angiotensin II receptor blockers into valsartan equivalents, beta blockers into carvedilol equivalents, and mineralocorticoid receptor antagonists into spironolactone equivalents.[24] The usage and dosage of enalapril equivalents, valsartan equivalents, carvedilol equivalents, and spironolactone equivalents were reported before and after BBC visits for BBC participants. Changes of medications before and after BBC visits were divided into 3 categories: no change, increasing dose only, and adding new medication(s) with possible dose increase. Associations between time to readmission and converted medication dose change or medication change categories were evaluated with Cox regressions. Subgroup analysis was performed among the subgroup of BBC participants.

Summary of KCCQ scores are reported among BBC participants. Relative risk regressions and Cox regressions were performed to evaluate the association of 90-day readmission and KCCQ-Overall Summary Score and KCCQ-Clinical Summary Score. The same covariates were adjusted for the models as with the regression of readmission and BBC visit status.

A P value of 0.05 was considered statistically significant for all analyses. All analyses were completed using R version 3.4.1.

Results

Between March 2012 and December 2014, 196 patients were given appointments to the BBC, of which 42 were HF with EF >45% (HFpEF) and were excluded from this analysis in order to assess GDMT as per Guidelines specific to heart failure with reduced ejection fraction (HFrEF). Of the remaining 154, 109 (84%) patients attended the BBC and 45 (30%) patients failed to show up to clinic and are referred to as the "Control" group, reflecting the general HF discharge population. The reasons for not attending the clinic were variable, and included wanting to be rescheduled (n = 7), not wanting to be scheduled (n = 3), confusion with another clinic, transportation difficulties (n = 2), changing provider (n = 2), incorrect date (n = 2), conflict with other appointments (n = 6), and due to feeling ill (n = 1). The baseline characteristics of the 2 groups were similar as shown in Table 1. Both the BBC participants and the control groups had elevated NT-ProBNP at admission demonstrating similar prognostic levels. The KCCQ scores were only available in the BBC participant group and had low values for physical and social limitation and overall summary.

The outcomes of readmission and mortality are shown in Table 2. Thirty and 90-day readmission rates were lower in patients who attended

TABLE 1. Baseline characteristics.

Mean ± SD or n (%)	BBC participants (N = 109)	Control (N = 45)	*P* value
Age	64 ± 12	63 ± 15	0.558
Female, n (%)	49 (45.0%)	22 (48.9%)	0.656
BMI	28.7 ± 7.0	30.4 ± 13.9	0.457
Ejection fraction	28 ± 8	26 ± 8	0.230
Systolic BP	124 ± 21	119 ± 21	0.213
Diastolic BP	72 ± 15	70 ± 12	0.298
HR	81 ± 15	78 ± 12	0.128
Creatinine*	1.3 (1.0-1.6)	1.4 (1.0-1.9)	0.628
Pro-BNP at admission*	4972 (1507-9663)	6645 (3414-15211)	0.156
Physical limitation*	54.2 (39.6-77.1)		
Symptom stability*	75.0 (50.0-100.0)		
Symptom frequency*	66.7 (44.8-88.2)		
Symptom burden*	75.0 (50.0-91.7)		
Total symptom score*	70.8 (50.0-89.6)		
Self-efficacy*	75.0 (62.5-100.0)		
Quality of life*	58.3 (33.3-75.0)		
Social limitation*	50.0 (29.7-68.8)		
Overall summary*	57.6 (48.3-70.2)		
Clinical summary*	61.5 (49.3-79.7)		

* Median (IQR).

the BBC, compared to the Controls (9.2% vs 20%, $P = 0.063$ and 24.8% vs 48.9%, $P = 0.003$, respectively). All readmissions in the Control group and 60% of BBC group were related to HF exacerbation. Time to first readmission was similar between the 2 groups with 14 days in the BBC participants and 18 days in the control.

There were no deaths in either group at 30 days and none in the BBC group at 90 days. However, there were 3 deaths in the Control group between 31 and 90 days postdischarge (62, 74, and 83 days postdischarge, $P = 0.290$ [Fisher]).

Table 3 presents the Cox model association between time to readmissions and BBC status. The adjusted models controlling for age, sex, BMI,

TABLE 2. Outcomes: readmission and mortality

	BBC participants (N = 109)	Control (N = 45)	*P* value
Readmission in 30 d	10 (9.2%)	9 (20.0%)	0.063
Readmission in 90 d	27 (24.8%)	22 (48.9%)	0.003
Readmission in 1 y	65 (59.6%)	25 (55.6%)	0.641
Mortality in 30 d	0 (0.0%)	0 (0.0%)	NA
Mortality in 90 d	0 (0.0%)	3 (6.7%)	NA
Mortality in 1 y	5 (5.2%)	5 (11.1%)	0.290 (Fisher)

TABLE 3. Association between time to readmissions and BBC status using Cox models.

	30-d readmission			90-d readmission		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
Model 1	0.45	0.18, 1.10	0.078	0.41	0.23, 0.71	0.002
Model 2	0.11	0.01, 0.87	0.037	0.19	0.08, 0.45	0.0002
Model 3	0.02	0.0006, 0.63	0.026	0.17	0.07, 0.43	0.0002
Model 4	0.009	0.0001, 0.63	0.030	0.16	0.06, 0.43	0.0003
	1-y readmission			**1-y mortality**		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
Model 1	0.83	0.52, 1.32	0.436	0.44	0.13, 1.53	0.198
Model 2	0.59	0.34, 1.02	0.060	0.43	0.10, 1.79	0.244
Model 3	0.53	0.30, 0.96	0.037	0.40	0.09, 1.74	0.219
Model 4	0.55	0.31, 0.99	0.047	0.48	0.11, 2.14	0.333

Model 1: Raw model.
Model 2: Adjust for age, sex, BMI.
Model 3: Adjust for age, sex, BMI, EF, SBP, DBP, NT-proBNP at admission.
Model 4: Adjust for age, sex, BMI, EF, SBP, DBP, log(NT-proBNP) at admission.
HR=hazard ratio; CI=confidence intervals; SBP systolic BP; DBP diastolic BP; ACC, American College of Cardiology; CMS Centers for Medicare and Medicaid; HFrEF heart failure with reduced ejection fraction; BMI- Body mass index

EF, blood pressures, NTPro-BNP, and BBC participation, were significant for 30-day, 90-day, and 1-year readmission.

For 1-year mortality, when controlled for age, gender, BMI, EF, NTpro-BNP, and BBC participation, the hazard ratio remained <1 but did not reach statistical significance (Table 3). Kaplan-Meier time to readmission was analyzed up to 365 days post HF discharge and is depicted in Figure 1.

For BBC participants, the medications at the time of hospital discharge and at the end of the BBC encounter are illustrated in Table 4. The majority of patients were on beta blockers. Less patients were discharged on ACEI than recommended in Guidelines and an additional 12 patients had ACEI initiated during the clinic. Less patients were on angiotensin II receptor blockers medications at the end of the clinic but the dosage was higher and more compatible with recommendations in Guidelines. Spironolactone use was similar pre-BBC and post-BBC and lower by percent for HFrEF than recommended in Guidelines.

Several exploratory analyses were conducted. Since a focus of the BBC clinic is medication reconciliation and uptitration, Tables 5.1 and 5.2 explore medication changes and divides them into "no change," "dose

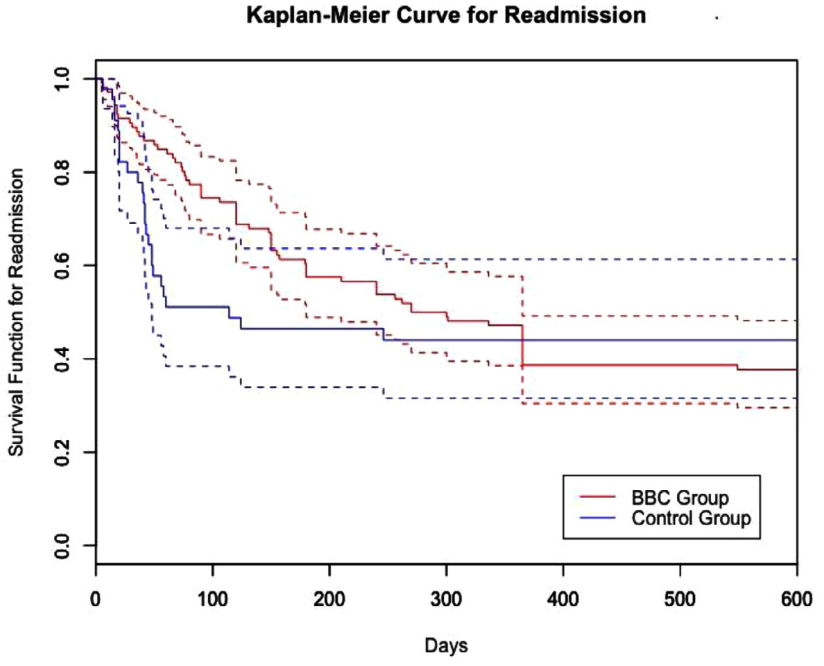

FIG 1. Kaplan-Meier survival estimates for readmission: presented for nonparticipants (n = 45) and participants (n = 109) of the BBC with confidence intervals. The red curve are the clinic patients while the blue curve represents the control group. Follow-up was censored at 365 days. Confidence Intervals as shown in dotted lines. BBC, Brown Bag Clinic (Color version available online).

up," and "new medication or both." Using a Cox model, the association between 30 days readmissions and medication changes was not significant. However, at 90 days, dose increase was statistically significant for the raw model (Model 1) and all the subsequent adjusted models, (For Models 2, 3, and 4, see Table 3).

TABLE 4. Summary of medications before and after BBC.

N (%)/median (IQR); daily dose	Before BBC	After BBC
Carvedilol	90 (94.7%)	93 (97.9%)
Dosage	25.0 (12.5-35.9)	25.0 (12.5-50.0)
Enalapril	57 (60.0%)	69 (72.6%)
Dosage	20.0 (5.0-30.0)	20.0 (10.0-40.0)
Valsartan	17 (17.9%)	12 (12.6%)
Dosage	80.0 (40.0-160.0)	160.0 (80.0-160.0)
Spironolactone	45 (47.4%)	45 (47.4%)
Dosage	25.0 (25.0-25.0)	25.0 (25.0-25.0)

TABLE 5.1. Association between time to 30 readmissions and medication changes (Cox).

	Model 1			Model 2		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
No change	Ref			Ref		
Dose up	0.54	0.18 1.64	0.275	0.48	0.15, 1.54	0.215
New med or both	0.47	0.06, 3.60	0.470	0.43	0.06, 3.35	0.424
	Model 3			**Model 4**		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
No change	Ref					
Dose up	0.41	0.11, 1.58	0.196	0.41	0.11, 1.57	0.192
New med or both	0.61	0.08, 4.95	0.643	0.52	0.06, 4.24	0.543

TABLE 5.2. Association between time to 90 readmissions and medication changes (Cox).

	Model 1			Model 2		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
No change	Ref			Ref		
Dose up	0.48	0.24, 0.97	0.041	0.42	0.20, 0.89	0.023
New med or both	0.72	0.26, 2.03	0.534	0.65	0.23, 1.85	0.417
	Model 3			**Model 4**		
	HR	**95% CI**	***P* value**	**HR**	**95% CI**	***P* value**
No change	Ref					
Dose up	0.35	0.14, 0.85	0.021	0.30	0.12, 0.74	0.009
New med or both	0.64	0.19, 2.19	0.480	0.50	0.14, 1.73	0.272

Model 1: Raw model.
Model 2: Adjust for age, sex, BMI.
Model 3: Adjust for age, sex, BMI, EF, SBP, DBP, NT-proBNP at admission.
Model 4: Adjust for age, sex, BMI, EF, SBP, DBP, log(NT-proBNP) at admission.

As illustrated in Table 1. KCCQ mean scores were low, Quality of Life = 58.3, Overall Summary = 57.6, and Clinical Summary = 61.5. None of the average scores calculated from the KCCQs exceeded 70.0. Table 6 details the association between time to 90-day readmissions and KCCQ Clinical and Overall Summary scores using the same models as presented above. The Clinical Summary Score was significant in the raw model but became less so using Model 2. The Overall Summary was non-significant for all the models and may reflect the small numbers.

TABLE 6. Association between time to readmissions and KCCQ-overall summary (Cox).

	90-d readmission vs Overall Summary			90-d readmission vs Clinical Summary		
	HR	95% CI	*P* value	HR	95% CI	*P* value
Model 1	0.97	0.94, 1.01	0.094	0.97	0.94, 1.00	0.039
Model 2	0.98	0.94, 1.01	0.158	0.97	0.94, 1.00	0.054
Model 4	0.67	0.42, 1.05	0.081	–	–	–

HR=hazard ratio; CI=confidence intervals; SBP systolic BP; DBP diastolic BP; ACC, American College of Cardiology; CMS Centers for Medicare and Medicaid; HFrEF heart failure with reduced ejection fraction; BMI- Body mass index

Discussion

This analysis of a nonrandomized cohort of patients who have been discharged from a HF admission and attend a pharmacist-led postdischarge clinic, demonstrated both a lower 30-day and 90-day readmission rate compared to a scheduled but "noshow" Control group. The BBC and Control group were nearly identical in demographics and severity of HF dispelling the myth that only those who are doing well will attend a 7-10-day postdischarge appointment. The Control readmission rate is consistent with the high readmission rate at this Institution during the same time, thus giving credence to the findings reported here. In addition, although the numbers are small, the mortality of the BBC group was also lower at 90 days compared to Controls, in contrast to current discussion about increasing mortality in the environment of readmission reductions.[25] The population reported here had demographics compatible with poor prognosis including markedly elevated Pro-BNP levels on admission, and a poor health status as measured by the KCCQ. This study is also unique in that we measured the Health status in a group that has not been well described by the KCCQ, ie, 7-10 days post discharge in a PharmD clinic.

HF is a major healthcare burden and one of the main contributor to that burden is repeated hospitalizations.[26,27] Indeed, with the prevalence of HF continues to grow along with its healthcare and economic effect on the US population, making it crucial to find ways to limit its effects on the population. There are different models designed to limit readmissions with the use of a team based, nonphysician healthcare providers. Several studies have suggested the importance of pharmacists-based programs to help in medication reconciliation and medication education at the time of discharge.[28,29] Multiple reports have been published in the past 5 years demonstrating various models of pharmacist-run clinics but not all include uptitration[30] but have concentrated on education and review of

discharge medications rather than a true medication intervention.[31,32] Others have initiated the Pharmacists involvement during the hospitalization and prior to discharge.[32] Thus, to date, there is not overall accepted model of PharmD care and may depend on the internal "culture" of the system it is deployed in.

Laramee et al randomized patients before discharge to close monitoring by case managers that started while patients are still in the hospital and included a 12 weeks telephone follow-up to ensure compliance.[33] The 90-day readmission was similar. One can argue that most admissions are within 30 days and an earlier follow-up could have made a difference.

Our BBC is an example of a successful model, a 1-time clinic after a HF admission, which has been shown to reduce readmissions. The focus on this clinic is to initiate or uptitrate GDMT while emphasizing the importance of medication adherence and ensuring a smooth transition from the hospital to the next clinic appointment with the patient's cardiologist or the HF program. Although the goal of the clinic was mainly medication management, preventing earlier HF readmissions could not be explained by the changes of GDMT alone. Even though there was a trend towards higher doses or more patients on HF medications, it was not reflected in all medications and patients. This illustrates the importance of other factors contributing to lower or delayed admissions including patient education on adherence, and a patient-centered approach with a team or cardiologist that will "own" the patient, and continue frequent visits and uptitration along with biomarker measures for effective lowering of elevated pro-BNP.

We found interesting that the reasons for nonattending the BBC were primarily socioeconomic, such as transportation and not related to the HF syndrome in itself. This observation suggests that virtual visits using technology could replace the personal visit for patients with difficulty in transportation. Whether that approach would result in the same findings is still unknown and a randomized trial would be strongly suggested.

An additional benefit of the BBC clinic was to educate Cardiology Fellows and Internal Medicine residents in a type of team-based encounter that is unique and that they may not face until in practice and being asked to reduce readmissions. Certainly, in the coming era of bundled payments these skills may become necessary.

There are limitations to this analysis given that there may have been patients missed for discharge appointments and could drive the Institution's high readmission rates even higher than our Control group. Patients who were admitted to general or family medicine and cared for by hospitalists may not have the advantage of the reduction in

readmissions program. Furthermore, our small numbers limited the analysis whereas the benefits could have been greater with a longer period of follow-up and a larger population. We also did not measure medication adherence in any detailed manner. Nonetheless, given the demographics, these patients had marked disease with poor prognosis and poor health status as measured by the KCCQ.[20]

In summary, reduction in HF readmissions is possible even in a complex multiracial/ethnically diverse population with a high Medicaid coverage. Team approach to care and the involvement of HF trained PharmD's in collaboration with an HF Cardiologist can positively affect patient outcomes. Whether the model illustrated here will be effective across all care settings is unknown but worth exploring.

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The reduction of hospital readmission after hospitalizations for heart failure is very important in order to avoid penalties from CMS. The authors from Montefiore-Einstein Medical Center demonstrate the effectiveness in reducing hospital readmissions of a PharmD led post discharge clinic, named “Brown Bag” clinic, in collaboration with a HF that is uniquely focused on initiation and uptitration of medical therapy as per Guidelines by the PharmD.

Several perspectives can be drawn from this interesting manuscript.

First, the cohort of patients who have been discharged from a HF admission and attend a pharmacist led post discharge clinic, had both a lower 30-day and 90-day readmission rate compared to a scheduled but ‘no-show’ Control group.

Second, patients include in the study had marker of poor prognosis such as elevated poor prognosis including markedly elevated Pro-BNP levels on admission, and a poor health status as measured by the KCCQ.

Third, the reduction in HF readmissions is possible even in a complex multi-racial/ethnically diverse population with a high Medicaid coverage.

Finally, a team approach to care for patients with heart failure and the involvement of HF trained PharmD’s in collaboration with an HF Cardiologist can positively affect patient outcomes.

I want to thank the authors for a very interesting and clinically meaningful manuscript.