

openheart Heart failure management at home: a non-randomised prospective case-controlled trial (HeMan at Home)

Justin Helberg,¹ Daniel Bensimhon,² Vasili Katsadourous ,¹ Michelle Schmerge,^{3,3} Heather Smith,³ Kelly Peck,⁴ Kim Williams,³ William Winfrey,¹ Ankit Nanavati,² Jon Knapp,² Monica Schmidt,² Lisa Curran,² Megan McCarthy,² Mark Sawulski,² Lawrence Harbrecht,¹ Idalys Santos,¹ Ellie Masoudi,¹ Nischal Narendra¹

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ABSTRACT

Background/objectives Heart failure (HF) is a growing clinical and economic burden for patients and health systems. The COVID-19 pandemic has led to avoidance and delay in care, resulting in increased morbidity and mortality among many patients with HF. The increasing burden of HF during the COVID-19 pandemic led us to evaluate the quality and safety of the Hospital at Home (HAH) for patients presenting to their community providers or emergency department (ED) with symptoms of acute or chronic HF (CHF) requiring admission.

Design/outcomes A non-randomised prospective case-controlled of patients enrolled in the HAH versus admission to the hospital (usual care, UC). Primary outcomes included length of stay (LOS), adverse events, discharge disposition and patient satisfaction. Secondary outcomes included 30-day readmission rates, 30-day ED usage and ED dwell time.

Results Sixty patients met inclusion/exclusion criteria and were included in the study. Of the 60 patients, 40 were in the HAH and 20 were in the UC group. Primary outcomes demonstrated that HAH patients had slightly longer LOS (6.3 days vs 4.7 days); however, fewer adverse events (12.5% vs 35%) compared with the UC group. Those enrolled in the HAH programme were less likely to be discharged with postacute services (skilled nursing facility or home health). HAH was associated with increased patient satisfaction compared with Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) score in North Carolina. Secondary outcomes of 30-day readmission and ED usage were similar between HAH and UC.

Conclusions The HAH pilot programme was shown to be a safe and effective alternative to hospitalisation for the appropriately selected patient presenting with acute or CHF.

INTRODUCTION

Heart failure (HF) affects more than 64 million people worldwide¹ with a prevalence of 6.4 million people in the USA.² HF prevalence is expected to increase to 8.5 million people by 2030.³ HF is the most common reason for hospitalisation in the

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The Hospital at Home model (HAH) is a primary means for treating the acutely ill patients in many regions of the world including the UK and Australia. Multiple studies and systematic reviews have shown it to be safe and effective when compared with traditional care in the hospital. In fact, most studies have shown decreased adverse events, improved functional outcomes, improved patient satisfaction and decreased overall cost of care without an increased rate of mortality. The HAH model in the USA had not yet become mainstream, possibly owing to the lack of reimbursement for the care model. However, in November 2020, because of the COVID-19 pandemic, Medicare issued a temporary CMS waiver that allows hospital-level reimbursement for the HAH model. Since that time over 180 hospitals have applied for and obtained the CMS waiver. This model of care will likely become another standard of care for many communities and academic hospitals. It is important that internal medicine physicians understand the safety and quality of the programmes, along with the operations and how to deliver the care. It is for these reasons that we evaluated the safety of the HAH and are submitting this manuscript.

WHAT THIS STUDY ADDS

⇒ Our study is one of the first heart failure at home programmes in the USA and showed that this system would work well in our healthcare system and benefit patients.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study is an excellent first step in establishing more at home programmes for cardiac disease states.



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¹Internal Medicine Teaching Service, Cone Health, Greensboro, North Carolina, USA
²Cone Health, Greensboro, North Carolina, USA

³Remote Health Services, PLLC, Greensboro, North Carolina, USA

⁴Triad Healthcare Network, Greensboro, North Carolina, USA

Correspondence to

Dr Justin Helberg; Justin.t.helberg@gmail.com

HF is a significant economic burden for most health systems. Globally, the estimated cost of HF is \$108 billion dollars annually.⁶ In the USA, the total cost of HF was estimated at \$43.6 billion in 2020 and is projected to increase to \$69.7 billion by 2030.^{3,7} The annual median cost for HF was \$24383 per patient, with HF-specific hospitalisation accounting for the majority of the cost (median \$15879 per patient), indicating the most significant driver of annual cost is hospitalisation.⁸

The COVID-19 pandemic has vastly affected patient care. Many have avoided needed care, with 55% of adults living with multiple chronic conditions and 67% of providers reported increased difficulties managing their patients' chronic conditions due to delays or avoidance of medical care.^{9,10} This is supported by national data illustrating a decline in emergency department (ED) visits for heart attacks, stroke and hyperglycaemic crisis in the 10 weeks after the national emergency declaration in March 2020.¹¹ The avoidance and delay in care have led to increased morbidity and mortality among many patients, especially those with HF.¹² The increasing clinical and economic burden of HF during the COVID-19 pandemic led to the evaluation of alternative options to provide safe, quality care that is financially beneficial to patients presenting with acute on chronic HF (CHF).

The Hospital at Home model (HAH) is a primary means for treating the acutely ill patient in many regions of the world including the UK and Australia.¹³ Multiple studies and systematic reviews have shown it to be safe and effective when compared with traditional care in the hospital. In fact, most studies have shown decreased adverse events, improved functional outcomes, improved patient satisfaction and decreased overall cost of care without an increased rate of mortality.^{14–24}

This pilot study aimed to evaluate the quality and safety of the HAH for patients presenting to their community providers or ED with signs and symptoms of acute on CHF requiring admission for intravenous diuretic therapy. The study was a collaborative effort between the Internal Medicine Teaching Service at Cone Health, Heart Failure Clinic and Remote Health Services, PLLC, funded and supported by Triad Health Network, an Accountable Care Organization, a subsidiary of Cone Health in Greensboro, North Carolina.

METHODS

An evaluation of the HAH model for patients presenting with acute on CHF to the Moses Cone Health System was conducted. The design was a non-randomised prospective case–controlled comparison of patients enrolled in the HAH versus admission to the hospital (usual care, UC). Patients were enrolled between 28 January 2021 and 27 May 2021. A total of 40 patients were needed for detailed financial analysis. The protocol was submitted to the Cone Health Institutional Review Board and deemed a quality improvement project.

Table 1 Inclusion/exclusion

Inclusion	Exclusion
Age >18 years	New HF
Community dwelling	HR >100 or >120 on ambulation
Previous diagnosis of HF (systolic or diastolic)	Resting SaO ₂ <90% after triage and initial treatment in ED
Lives with 25 miles of ED	SBP <100 mm Hg or >160 mm Hg after triage and initial treatment in ED
Appropriate home support	New ischaemic changes on ECG or new arrhythmia
Telephone access	Creatinine >2×baseline, CKD stage V or ESRD on HD
Informed consent	Delirium or dementia without appropriate home support
Need for intravenous diuretics	Lack of social support/unstable living situation

Acute decompensation of HF defined as a worsening of both specific chronic heart failure signs (peripheral oedema, pulmonary rales) and symptoms (dyspnoea, fatigue) caused by abnormal cardiac function and supported by appropriate investigations (electrocardiography, chest X-ray, laboratory tests, echocardiogram).
CKD, chronic kidney disease; ED, emergency department; ESRD, end-stage renal disease; HD, haemodialysis; HF, heart failure; HR, heart rate; SBP, systolic blood pressure.

Participant selection

Patients aged 18 years or older with known HF (systolic or diastolic) were prospectively enrolled. They presented to their community providers or ED with acute decompensated HF requiring inpatient admission. Acute decompensated HF was defined as worsening of both specific HF signs (peripheral oedema, pulmonary rales, increased abdominal girth) and symptoms (dyspnoea, fatigue) caused by abnormal cardiac function and supported by appropriate investigation (electrocardiography, chest X-ray, laboratory tests, echocardiography). To be eligible for the HAH programme, patients had to reside within a 25-mile catchment area. Specific inclusion/exclusion criteria were developed after a detailed literature review and retrospective analysis against previous admissions at Moses Cone.^{21,25–43} No patients who were admitted to the HF at home programme required inotropes or oxygen at the time of admission. The exclusion criteria were in place to ensure the sickest patients were admitted to the hospital since they required close monitoring. The criteria can be seen in [table 1](#). Patients who declined enrolment into the HAH programme served as the control group (UC).

Intervention

Once an appropriate patient was identified in the ED or community clinic, a programme physician would present to the bedside or electronically evaluate the patient. If the primary reason for admission was acute decompensated HF,

Box 1 Heart failure at home kit

Blood pressure cuff.
 Pulse oximeter.
 Digital scale.
 Urinal.
 Flexible measurement tape.
 Heart failure education material.
 Vitals logs.
 Emergency contact information for Remote Health Services.

the HAH programme was discussed with the patient. If in the ED, the patient was then given intravenous furosemide equivalent to 2.5× their home diuretic dose to ensure an appropriate response. Depending on the patient's clinical comorbidities and a functionality screen, pharmacy and physical therapy were consulted. Pharmacy would obtain a medication reconciliation and ensure the patient had all needed chronic medications at home. Physical therapy performed a standard evaluation and social determinants of health screen to ensure patients had a home environment appropriate for care. Case management then evaluated the patient for intake and coordination of care. On discharge from the hospital, the patient would be given an 'HF at Home Kit', the contents of which can be seen in [box 1](#). Depending on the time of enrolment, the patient would receive an in-person versus telephonic visit once arriving home. Patients were then seen anywhere from three to five times per day by a member of Remote Health Services' HAH team. Initially, at least two of the visits would be conducted by an RN/paramedic in conjunction with a nurse practitioner supervised by a physician for optimisation of their HF regimen, intravenous diuretic therapy and lab work. The majority of patients received two times a day intravenous diuretic therapy during their acute phase and daily or every other day basic metabolic panel depending on underlying renal function. If any issues occurred with medical management, the HF clinic physician was available for further care recommendations. Additionally, patients were evaluated by the mobility team for exercise tolerance, they were educated about the importance of mobility, acute diuresis and side effects on mobility, and they began cardiopulmonary rehabilitation. During times when there were no members of the healthcare team in the home, patients were monitored using intermittent remote patient monitoring, which included blood pressure, pulse oximetry, heart rate and respiratory rate. The patient also had access to a Remote Health Services 24/7 call centre and rapid mobile urgent care if needed. After treatment in the acute phase, patients entered a 30-day transitional phase where they were periodically assessed by the HAH team. All patients were scheduled in the Cone Health Heart Failure Transitions of Care clinic, and a discharge summary that included admission date, dry weight, medication changes and recent lab work was provided for the visit. During the 30-day period, any patient that had been engaged in the model could re-engage if they noticed an increase in their

weight or acute worsening of their symptoms. ED and at home treatment workflows can be found in online supplemental files 1 and 2.

Data collection

Patients were followed during the acute phase of the HAH programme and for a transitional 30-day period. Primary outcomes included length of stay (LOS), adverse events, discharge disposition and patient satisfaction. Secondary outcomes included 30-day readmission rates, 30-day ED usage and ED dwell time. Data were collected during the course of enrolment to monitor safety outcomes and ensure patients were receiving appropriate care.

RESULTS

Of the 60 patients, 40 were in the HAH and 20 were in the UC group. HAH patients were more likely to be >80 years old and female. Patients in the UC group did have slightly higher Elixhauser Comorbidity Index and more patients had diabetes, chronic obstructive pulmonary disease (COPD) and cardiac arrhythmias. [Table 2](#) summarises the patient characteristics for each group.

Comparison of primary and secondary outcomes ([table 3](#)) during the acute phase of treatment and 30 days after admission demonstrated that HAH patients had slightly longer LOS (6.3 days vs 4.7 days); however, fewer adverse events (12.5% vs 35%) compared with the UC group. Those enrolled in the HAH programme were less likely to be discharged to a skilled nursing facility (SNF) (2.5% vs 15%) or be discharged with home health services (2.5% vs 45%). HAH was associated with increased patient satisfaction compared with Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) score in North Carolina. All 40 patients would recommend the programme to others or re-enrol in the programme if needed. Overall experience was 9.41 out of 10 and overall care was 9.77 out of 10.

Secondary outcomes were similar between HAH and UC groups with 30-day readmission rates (12.5% vs 10%) and ED usage (10% vs 10%). ED dwell time for those seen in the ED was decreased for those in the HAH even with the addition of the HAH team evaluations (7.1 hours vs 9.3 hours).

DISCUSSION

A total of 60 patients were evaluated for enrolment into the HAH programme, 20 patients in the Internal Medicine Residency Clinic and Heart Failure clinic, and 40 patients presenting to the Moses Cone ED. All 20 patients from the clinic setting accepted enrolment into the programme, and 20 of the 40 patients approached in the ED elected to enrol in the programme. Of the 20 patients who declined admission to the HAH, the most common reasons for declining admission were lack of comfort with the model and not wanting providers visiting their homes. Our acceptance rate of 66% is consistent with prior US studies evaluating the HAH model.⁴⁴ Selecting

Table 2 Patient demographics

	Overall (%)	Enrolled to HAH (N=40)	Control (N=20)	P value
Age				0.12
18–40	1.7	2.5	0.0	
41–60	11.7	10.0	15.0	
61–80	41.7	32.5	60.0	
>80	45.0	55.0	25.0	
Sex				0.58
Male	55.0	42.5	50.0	
Female	45.0	57.5	50.0	
Common comorbidity				
COPD	46.4	33.3	70.0	0.008
CKD	58.9	52.8	70.0	0.21
Cardiac arrhythmias	42.9	30.6	65.0	0.01
DM	50.0	33.3	80.0	<0.001
HTN	94.6	91.7	100.0	0.18
Metastatic cancer	1.8	2.8	0.0	0.45
Pulmonary HTN	12.5	13.9	10.0	0.67
Hypothyroidism	16.1	16.7	15.0	0.87
Cirrhosis	3.6	5.6	0.0	0.28

CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HAH, Hospital at Home; HTN, hypertension.

appropriate patients for the HAH model is essential for providing safe care. Inherent to the HAH model is selection bias. Programmes such as this are a reasonable alternative for some but not for all patients who present to the hospital with acute or acute on chronic illnesses. Our selection criteria were developed through a detailed literature review then retrospectively compared with prior HF admissions to ensure selected patients had a low mortality risk. During the retrospective analysis, the selection criteria correlated with a 1.8% inpatient mortality rate. Multiple safety nets were implemented, including two separate physician assessments, a pharmacy assessment, and a physical therapy assessment to ensure the appropriateness of patient selection. As illustrated in the results, these additional assessments did not increase ED dwell time (7.1 hours HAH vs 9.3 hours UC). Of those enrolled in the programme, four patients did require escalation back to the hospital for a step up in care; one for acute kidney injury (AKI), one for hepatic encephalopathy, one for cardiac chest pain and one for pancreatitis. There were no deaths during the acute treatment phase in the HAH or UC group. [Table 2](#) illustrates a statistically significant difference in comorbidities between the HAH and UC groups. However, it is important to recognise that the

Table 3 Primary and secondary outcomes

		Enrolled to HAH (N=40)	Control (N=20)	P value
Primary outcomes	LOS	6.3 days	4.7 days	–
	Adverse events	5	7	–
	Falls	0	0	–
	Delirium	2	0	–
	AKI	3	1	–
	Hyperglycaemia	0	1	–
	Hypoglycaemia	0	2	–
	Medication errors	0	2	–
	Other	0	1	–
	Discharge disposition/services			<0.001
	Home	38	8	–
Home with HH	1	9	–	
SNF	1	3	–	
Overall experience	9.41	–	–	
Overall care	9.77	–	–	
Recommend	Yes (all)	–	–	
Secondary outcomes	ED dwell time	7.1 hours	9.3 hours	–
	30-day readmission rate	12.50%	10%	0.78
	ED usage	10.00%	10%	–

AKI, acute kidney injury; ED, emergency department; HAH, Hospital at Home; LOS, length of stay; SNF, skilled nursing facility.

patients in the UC group would have been enrolled in the HAH if they agreed.

A concern with the HAH model is that health systems will admit patients to the programme that do not truly require inpatient admission. We attempted to mitigate this by including a requirement for intravenous diuretic therapy in the inclusion criteria and having a programme physician evaluate potential patients. We subsequently evaluated the ED acuity of patients presenting to the ED and the admission status of the UC group. Of the 40 patients evaluated in the ED, 18 patients were triaged as ‘Emergent’ and 21 as ‘Urgent’. One patient did not have their acuity listed. Of the 20 patients in the UC, only 1 patient was admitted to observation. The remaining 19 patients were admitted to inpatient status, with the most common levels of care being Telemetry,¹¹ Progressive⁴ and Med-Surg.⁴ Based on this information, we feel confident that the patients enrolled in the study would have otherwise been admitted to the brick-and-mortar hospital. One way health systems may be able to ensure they are enrolling appropriate patients is through independent or third-party chart reviews, similar to how hospitals evaluate patients for inpatient versus observation status.

Primary outcomes did not illustrate a statistically significant difference in LOS, adverse events or functional

outcomes. While not statistically significant the HAH group did have increased LOS compared with UC. This is contradictory to other studies that have mainly illustrated a reduction in LOS. Part of this discrepancy may be explained by lack of oversight in patient's diet and fluid intake while at home. This may initially be viewed as a limitation of HF at home; however, it will allow one to adjust medications based on the patient's lifestyle and prevent readmissions. The majority of studies reported in the USA have focused on multiple diagnoses, including CHF, COPD, pneumonia and cellulitis. To the best of our knowledge, this is the first study strictly enrolling CHF patients in the USA and only the second study reported between Europe and the USA.²²

The HAH group did have a trend towards less adverse events with a relative risk reduction of 64%. Both the HAH and UC groups had patients with diuretic-induced AKI (three vs one), and the HAH group had two patients experience episodes of delirium/encephalopathy. The total number of adverse events was 5 (12.5%) in the HAH group and 7 (35%) in the UC group. There may have been more adverse events in the UC group that were not identified as adverse events were pulled based on the patient's problem list and documentation. Patients enrolled in the HAH group were less likely to use postacute services, 2 HAH versus 12 UC. This alone led to significant cost savings for the ACO who sponsored the programme. The HAH group reported increased patient satisfaction compared with HCAHPS score in North Carolina. All 40 patients would recommend the programme to others or re-enrol in the programme if needed. Overall experience was 9.41 out of 10, and overall care was 9.77 out of 10. According to CMS, this compares to 72% of patients that rated their overall care between 9 and 10 and 69% of patients that would recommend the treatment hospital. Unfortunately, we were unable to obtain patient satisfaction scores from the UC group for comparison.

Secondary outcomes, including ED dwell time, 30-day readmission rates and 30-day ED usage, were not statistically significant. ED dwell times were reduced in the HAH group compared with the UC group by an average of 2.2 hours. The 30-day readmission rate was similar between the HAH and UC groups; however, both groups had lower readmission rates than the national average for patients with HF. The lower readmission rate is likely related to selecting lower 'risk' patients as outlined above. Mendoza *et al* published a study evaluating the HAH model for acute decompensated HF in Europe finding similar readmission rates between the HAH and UC groups.²²

Cost is an important consideration when evaluating alternative care models. When the possibility of a programme was evaluated in February 2020, the HAH model in the USA had not yet become mainstream, possibly owing to the lack of reimbursement for the care model. However, in November 2020, because of the COVID-19 pandemic, Medicare issued a temporary CMS waiver that allows hospital-level reimbursement for the

HAH model. Several studies have looked at the financial feasibility of the HAH model. Thirty-two have shown an average reduction in total cost by 18%–30% and a decrease in direct variable cost by 50%–60%.^{17 45–47} Given this significant reduction, implementing an HAH model may result in higher contribution margins and net income while freeing up beds for diagnoses/procedures with higher contribution margins for hospital operators. Furthermore, there is also significant cost saving when looking at discharge venues. The HAH group had one patient discharged to an SNF and another discharged with home health services compared with the UC group that had three patients discharged to an SNF and nine patients discharged with home health services. Had we enrolled 40 patients in the UC group this cost savings would likely have been significantly larger. Future studies should conduct detailed financial analysis to help health systems better understand the business case for implementing and maintaining the hospital-at-home model.

Multiple studies and systematic reviews have shown the HAH model to be safe and effective when compared with traditional care in the hospital. This pilot study is consistent with prior studies of the US HAH programmes showing a trend towards decreased adverse events, improved functional outcomes and improved patient satisfaction without an increased rate of mortality.^{14–24} Because this is a pilot study, it is not generalisable of the study but is an excellent first step. Future studies should focus on increasing sample size and considering a randomised controlled trial design. Additionally, the HAH model is an excellent time for providers to initiate and aggressively titrate goal directed therapy and is another area to focus on moving forward. The HAH programme was shown to be a safe and effective alternative to hospitalisation for appropriately the selected patient presenting with acute on CHF.

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ORCID iD

Vasili Katsadourous <http://orcid.org/0009-0004-5401-5731>

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