Title: Design and Rationale of a Randomized Trial: Using Short Stay Units Instead of Routine Admission to Improve Patient Centered Health Outcomes for Acute Heart Failure Patients (SSU-AHF)

Running Title: Short Stay Unit for Acute Heart Failure

Authors:

Hannah Fish-Trotter,[1] Sean Collins,[1] Shooshan Danagoulian,[2] Benton Hunter,[3] Xiaochun Li,[3] Phillip D. Levy,[2] Frank Messina, [3] Susan Pressler,[4] Peter S. Pang[3,5]

Affiliations

[1]Vanderbilt University School of Medicine, Nashville, TN

[2]Wayne State University School of Medicine, Detroit, MI

[3]Indiana University School of Medicine, Indianapolis, IN

[4]Indiana University School of Nursing, Indianapolis, IN

[5]Indianapolis EMS, Indianapolis, IN

Corresponding Author:

Peter S. Pang MD MS FACEP FACC

Director | Clinical Research

Chief Science Officer | CORE | Indianapolis EMS

Department of Emergency Medicine

Indiana University School of Medicine

ppang@iu.edu

317-880-3900

This is the author's manuscript of the article published in final edited form as:
Fish-Trotter, H., Collins, S. P., Danagoulian, S., Hunter, B., Li, X., Levy, P. D., ... & Pang, P. S. (2018). Design and rationale of a randomized trial: Using short stay units instead of routine admission to improve patient centered health outcomes for acute heart failure patients (SSU-AHF). Contemporary clinical trials, 72, 137-145. https://doi.org/10.1016/j.cct.2018.08.003

Disclosures:

Peter Pang is or has been in the past one year a **Consultant** for or received honoraria from: Baxter, BMS, Novartis, Trevena, Roche Diagnostics, **And has received research or other support from:** BMS, Roche, Novartis, PCORI, AHA, NHLBI, AHRQ

Phillip Levy is or has been in the last one year a consultant for and/or received honoria from: Novartis, Trevena, Roche Diagnostics, Astra Zeneca, Sciex, and Siemens. He has also received research support from: Pfizer, Roche Diagnostics, Novartis, Gilead, Edwards Lifesciences, Amgen, BCBSMF, GE/EMF, PCORI, NHLBI, and AHRQ.

Abstract

Nearly 85% of acute heart failure (AHF) patients who present to the emergency department (ED) with acute heart failure are hospitalized. Once hospitalized, within 30 days post-discharge, 27% of patients are re-hospitalized or die. Attempts to improve outcomes with novel therapies have all failed. The evidence for existing AHF therapies are poor: No currently used AHF treatment is known to improve long-term outcomes. ED treatment is largely the same today as 40 years ago. Admitting patients who could have avoided hospitalization may contribute to adverse outcomes. Hospitalization is not benign; patients enter a vulnerable phase post-discharge, at increased risk for morbidity and mortality. When hospitalization is able to be shortened or avoid completely, certain risks can be mitigated, including risk of medication errors, in-hospital falls, delirium, nosocomial infections, and other iatrogenic complications. Additionally, patients would prefer to be home, not hospitalized. Furthermore, hospitalization and re-hospitalization for AHF predominantly affects patients of lower socioeconomic status (SES). Avoiding hospitalization in patients who do not require admission may improve outcomes and quality of life, while reducing costs.

Short stay unit (SSU: less than 24 hours, also referred to as an 'observation unit') management of AHF may be effective for lower risk patients. However, to date there have only been small studies or retrospective analyses on the SSU management for AHF patients. In addition, SSU management has been considered 'cheating' for hospitals trying to avoid 30-day readmission penalties, as SSUs or observation units do not count as an admission. However, more recent analyses demonstrate differential use of observation status has not led to decreases in re-admission, suggesting this concern may be misplaced. Thus, we propose a robust clinical effectiveness trial to demonstrate the effectiveness of this patient-centered strategy.

Key Words: Acute heart failure, Short stay unit, quality of life, cost-effectiveness, emergency department

Background

Heart failure (HF) accounts for a large burden on the healthcare industry, both in terms of volume of emergency department (ED) visits and hospitalizations, as well as associated costs. Already, 6.5 million Americans are affected with HF. By 2030, prevalence is expected to increase by 25%.[1,2] Nearly $21 billion was spent on HF in 2012; by 2030 HF will cost over $53 billion per year.[1] For acute heart failure (AHF) patients, approximately 80-85% of patients presenting to the ED are hospitalized.[3] Hospitalization accounts for the vast majority of related expenditures.[1] Over time, the ED has evolved as the primary source of hospital admissions for AHF.[4] Thus, safely reducing admissions from the ED may be one pathway to reduce the cost burden of AHF. While improved primary care access and broader health insurance coverage are appealing solutions, early reports suggest enhanced insurance coverage may be associated with greater ED utilization by all patients, including those with AHF.[5,6] Therefore, differentiating patients with AHF who require admission versus direct ED discharge or a brief period of observation, may help improve outcomes while reducing costs.

Rationale for the Short Stay Unit (SSU) – AHF Trial

Accurate and effective tools to identify patients with high-risk features of AHF, namely those with renal dysfunction, unstable vital signs, and elevated biomarkers such as natriuretic peptide and troponin have been developed.[7-11] Such patients often require hospitalization. However, absence of higher risk features has yet to translate into low-risk characteristics identifying patients safe for direct ED discharge. Previous studies define low-risk as a low probability of re-admission within 30 days, or those having very low (< 1.0%) predicted mortality.[12,13] Thus far, the impact of such low-risk tools on ED provider decision making has been minimal. This is a result of limited implementation and evaluation of how these tools would impact real-time provider decision making and their association with patient outcomes. Furthermore, such studies are commonly retrospective, lack external validation, or are not well tested in a United

States patient cohort. Given these limitations, SSUs have emerged as an appealing alternative to direct ED discharge of patients, offering a measure of assurance for ED physicians who are uncomfortable with direct discharge. The SSU, also referred to as a clinical decision or observation unit, allows for additional evaluation and management of patients who do not meet high-risk criteria for inpatient admission. However, the lack of high-risk features does not necessarily indicate that the patient is of low-risk status. Prior studies defining low-risk markers have not been extensively test.[14,15,16] Thus, a lack of high-risk features suggests they may be good SSU candidates for a period of observation. The goals are: 1) achieve safe, on-going care for patients not-yet-ready for discharge 2) avoid added cost or family caregiver burden compared to inpatient admission.

While randomized, controlled trials of SSU care for AHF have yet to be conducted, several observational studies demonstrate the value of SSUs (Table 1). A retrospective study of 358 AHF patients demonstrated no increase in 30-day or 90-day readmission rates among patients who were cared for in an SSU compared to hospitalized patients, providing an important safety signal.[17] Other smaller studies suggest improved outcomes and reduced costs relative to inpatient admission.[18] However, absent sufficiently powered, prospective, randomized studies, the likelihood of widespread adoption is limited. To address this gap, we designed a randomized trial that seeks to better characterize SSU outcomes in patients with AHF, and simultaneously improve the evidence base for HF guidelines in this cohort. Our study has two principle aims: 1) the primary aim is to demonstrate the effectiveness of an SSU AHF management strategy, as compared to usual AHF care (i.e. inpatient admission) using days-alive-and-out-of-the-hospital (DAOOH); 2) secondary aims include evaluating differences in quality of life (QoL) scales as outcome measures; and adherence to HF guidelines at the time of discharge when compared to discharge from usual care (i.e. inpatient admission).

Methods

The SSU trial is a prospective, 1:1 randomized, controlled, comparative effectiveness study of a strategy of care (SSU care) vs. usual care (inpatient admission). Eligible subjects will be ED patients with AHF who would typically be admitted under usual care by the ED treatment team and who lack baseline high-risk features.

Study Population

A total of 526 patients at 4 sites will be enrolled over 4.5 years. As a contingency plan, if additional study sites are needed to meet our enrollment targets, we plan to convert our budget to a per-patient payment, allowing us to easily double our number of enrolling sites. All patients will provide written informed consent. Patients who present to the ED with signs or symptoms of AHF will be screened during times when research staff are available. Each site has distinct coverage ranging from 8 to 24 hours a day. Eligibility criteria (Table 2) are based on clinical stability, a prior HF history and no high-risk features or active comorbidities that would complicate their SSU stay. However, the initial ED management plan for patients must be intended inpatient admission. As a comparative effectiveness trial, the inclusion/exclusion criteria are relatively broad compared to other therapeutic clinical trials. Patients will be identified by dedicated, trained, experienced research personnel stationed in the participating EDs, utilizing electronic screening of 'tracking boards' in the ED, alert systems generated by the electronic health record, and direct interaction with members of the ED clinical care team. Patients with AHF are first pre-screened to determine if eligibility criteria are met; however, only after written informed consent will randomization occur. In accordance with prior observation unit guidelines, patients will not be excluded purely based on severely reduced ejection fraction.[13]

Study Treatment

Patients will be randomized 1:1 to either *Arm 1. SSU AHF Strategy* or *Arm 2. Usual Care (defined by routine inpatient admission),* but stratified by site to ensure equal site representation. A central computer-generated randomization scheme with random block sizes of two, four, and six will be created. The REDCap randomization module will be utilized to generate the randomization schema and patient allocation.

Those randomized to Arm 1 will receive AHF care in the SSU, with a recommended study treatment protocol based on guideline recommendations.[13] These patients will be assessed upon arrival to the SSU with quantification of urine output, systolic blood pressure, and signs and symptoms of volume overload. Importantly, there is significant latitude allowed for caregivers in the SSU to better reflect 'real-world' SSU practice. In the event that the SSU is at full bed capacity, the protocol can be initiated from the ED, until an SSU bed becomes available. Those patients with signs of total body volume overload and less pulmonary edema who warrant further treatment will be categorized as volume overload ('cardiac type'). Alternatively, patients will be categorized as 'vascular type' when hypertension predominates and symptoms occur over a shorter period of time, with less peripheral edema and weight gain, and more pulmonary congestion often due to vascular redistribution and not volume accumulation.[19] 'Cardiac type' patients will be treated primarily with IV loop diuretics. 'Vascular type' patients will be treated with an emphasis on vasodilators such as topical and sublingual nitroglycerin, as vascular redistribution is often a large contributor to symptoms, in addition to IV loop diuretics. Frequent reassessment aimed to aggressively, but safely, decongest patients will occur in the SSU arm.[20,21]

Once hemodynamic symptomatic improvement has been achieved, monitoring can be deescalated to every 6-8 hours with recommended scheduled doses of IV furosemide at 8-hour

intervals. Patients will be deemed stable for discharge per the recommended criteria listed in Table 3. These discharge criteria are based on the American College of Cardiology's Accreditation Services (formerly known as the Society of Cardiovascular Patient Care) short-stay AHF management recommendations.[13,22] Arm 2 (inpatient admission) subjects will continue on their originally planned care pathway of hospitalization, representing the 'usual care' comparator arm. Inpatient hospital admission is the most common approach to patients who present to the ED with signs of an AHF exacerbation.[3] Therefore, subjects randomized to Arm 2 will be treated according to management offered to AHF patients admitted to the hospital. Care in the inpatient arm will be at the discretion of the inpatient admitting team.

Data Collection and End Points

The primary endpoint of this study is the number of DAOOH at 30 days following discharge, accounting for both frequency and duration of hospitalizations (Tables 4 and 5). This data will be collected by hospital electronic medical record chart review, as well as telephone calls to patients at 30- and 90- days. Those patients who experience death during hospitalization will be counted as zero DAOOH. Secondary endpoints include QOL and a cost-effectiveness analysis between the two arms at 30 days. QOL will be measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ), a patient-reported survey designed to measure QOL in HF patients, where lower scores indicate lower QOL. To ensure feasibility we previously piloted the KCCQ in ED patients with AHF.[23] Exploratory endpoints include: 1) caregiver burden, as measured by two separate caregiver burden instruments (Bakas Caregiving Outcomes Scale and the Oberst Caregiving Burden Scale) [See Appendix] ; 2) cost-effectiveness of the SSU AHF strategy of care at 90 days; 3) resource utilization measured by the Modified Resource Utilization Questionnaire for Heart Failure (mRUQ-HF) at 90 days; 4) all-cause mortality at 30 and 90 days; 5) all-cause re-hospitalization at 30 and 90 days; 6) DAOOH at 90 days; and 7) HF

Guideline medication adherence at 30 days. The primary and secondary endpoints will be collected by study team members who are blinded to study arm.

Cost Effectiveness Analysis (CEA)

Cost will be defined as broadly as possible, to capture not only monetary costs as part of the SSU treatment, but also costs associated with follow up care, as captured by all sources of payment. In addition to the KCCQ, we will also measure quality of life using the SF-12. The SF-12 will be converted into the SF-6D, allowing direct assessment of Quality Adjusted Life Years (QALYs) necessary for the CEA. The SF-6D allow for the generation preference weights and probabilities necessary to conduct the cost-utility analysis. Since the participant will be completing the SF-12 survey at the beginning and end of the episode, all models estimating the effectiveness will include the baseline score in the vector of participant characteristics. Multinomial regression analysis will be conducted to assess the impact of the SSU stay on these outcomes of interest, adjusting for patient characteristics which might predispose treatment intensity and, thus, costs.

We have requested from each participating hospital information about the reimbursement and payment received for each episode of treatment. Combined with the patient insurance information, this will allow us to estimate per episode patient, private insurance, and public insurance cost of delivery of care. Because the duration of SSU and usual treatment are not comparable, we will, instead, compare total per patient cost, combining all admissions and readmissions for each study arm.

Furthermore, the mRUQ-HF questionnaire will include information about out of hospital healthcare utilization, allowing us to estimate the additional costs of non-hospital care using a Medicare cost dictionary for an approximate outpatient care associated with each study arm.

Statistical Analysis and Power Calculations

Assuming a 10% attrition rate, we will randomize 534 patients 1:1, which will provide 80% power (alpha 0.05, two-sided) to demonstrate a one-day difference in the primary outcome at 30 days post-randomization. The primary analyses will be performed in accordance with the intent-to-treat principle. Patients will be analyzed according to the group to which they were randomized. A per-protocol analysis will also be performed as a secondary analysis, for which patients will be analyzed by the treatment group where they ultimately were managed. In the per-protocol analysis, those patients who crossed over to the inpatient arm after randomization would be analyzed in the inpatient arm. Analysis of the primary endpoint will entail description of continuous data using means (standard deviations) or medians (interquartile range), while categorical data will be described using frequency and percentages. Group comparisons of continuous variables will be drawn from either two-sample t-tests, or Wilcoxon's Rank Sum test for variables that do not appear normally distributed. Categorical data comparisons will be presented based on the Chi-square, or Fisher's exact test if any cell counts are below 5. The analysis of our secondary endpoints will involve review of the KCCQ data, as well cost-effectiveness analysis. The KCCQ scores will be compared amongst the two arms using three different methods. First, we will exclude subjects who die without KCCQ in the analysis. Second, we will set KCCQ=0 for those who die without the 30-day KCCQ and include these people in the analysis. Third, we will create a composite binary endpoint of KCCQ<c or death, where c is a threshold. The chi-square test and logistic regression will be used to compare this outcome. We will select several relevant values for the threshold c and tabulate the results. The three analysis schemes allow us to understand how robust the comparison of KCCQ is with respect to different treatments of death. Exploratory endpoints analysis will also be performed. The analysis of caregiver burden will be similar to the KCCQ analysis described above, using both caregiver survey instruments. Resource utilization will be measured by the mRUQ-HF, a

14-item self-questionnaire related to healthcare utilization. The mRUQ measures costs from a societal perspective, involving an assessment of resources consumed.

Discussion

Significant resources have been allocated to establish methodologies for identifying patients who are high-risk for readmission, as well as risk factors for poor outcomes.[14,16,24] This is a particularly common challenge among the HF patient population, as HF is the leading cause of readmissions among Medicare beneficiaries.[25] In an effort to reduce readmission rates to the hospital, penalties have been implemented and directed at hospitals with higher than expected HF readmission rates. Despite the assumption that higher quality of care will reduce readmission rates, little to no correlation exists between readmission rates and quality of care.[26] In fact, readmission rates appear to correlate with regional readmission trends rather than quality of care provided.[27] This suggests care provided in short stay units and readmission rates may be independent of one another.

Hospitals have developed strategies to minimize readmissions as a direct response to the Hospital Readmission Reduction Program. It has been suggested that some hospitals or health care systems may be 'gaming the system' to avoid readmission penalties by placing patients in observation status.[28] However, an analysis of Medicare beneficiaries demonstrates no association between decreased readmissions and increased utilization of observation status.[28] We designed our study to ensure quality care is delivered with the goal of not necessarily reducing 30-day readmissions, but rather providing care in a more timely and cost-effective manner, with 30-day outcomes similar to an inpatient admission. In other words, the SSU facilitates continued high-quality patient care, while minimizing the financial and resource burdens associated with inpatient management. Ultimately, if patients require a longer treatment course, they should and will be hospitalized, demonstrating the versatility and inherent safety of

an observation unit-based protocol. However, the potentially high observation to inpatient ratio may lead some health systems to hesitate to implement an observation unit HF pathway. This study will help address this concern.

Historical and objective exam, laboratory and imaging findings will be used to identify AHF patients prior to SSU entry.[29] The ability to further monitor patients in a SSU may provide a safe alternative for those who have no high-risk features but for whom it is unclear if they are truly low-risk.[13,22,29] We have based our entry criteria on prior studies and consensus recommendations for identifying candidates suitable for entry to an SSU. The American College of Cardiology's Accreditation Services has offered guidance for these criteria, focusing on data both at time of presentation to the ED, as well as after initial therapy has been administered.[13] Specifically, this committee recommended patients with renal dysfunction, hyponatremia, hypotension, ischemic changes on ECG, or elevated cardiac troponin should be admitted to the hospital for monitoring and treatment in an inpatient bed (Category B recommendation).[13] Thus, we have excluded these higher-risk patients. These patients have been identified by the following criteria, outlined in Table 6.

Conclusions

Hospitalization for AHF results in a significant financial healthcare burden. Safely reducing costs while maintaining quality is essential. Reducing admission from the ED is one potential strategy. Prior studies suggest SSU management of AHF is both cost-effective and equivalent in the degree of quality of care provided when compared to those admitted to the hospital. However, those studies were limited by non-experimental designs and small samples. Thus, we have designed the SSU-AHF to fill this knowledge gap. Patients with AHF will be readily identified during the initial phase of ED evaluation based on bedside assessment and results of ED testing. We will then utilize a randomized controlled trial design to further evaluate the efficacy

of SSU management in terms of 30- and 90- day outcomes, with particular interest in the quantity of time patients remain outside of the hospital following SSU discharge and how this impacts resource utilization and QOL. If this proposal confirms our hypothesis, further evidence will be available in support of SSU as an alternative to inpatient admission for low-risk patients with AHF who meet specific criteria. This would allow for further development of formal guidelines for such patients presenting to the ED with AHF.

Table 2: Eligibility Criteria

Inclusion	Exclusion
1) ED physician clinical diagnosis of AHF; 2) Planned admission for AHF by the treating ED team 3) Systolic blood pressure > 115mmHg*, heart rate < 115bpm, Oxygen saturation > 93% on room air^; 4) Previous history of HF	1) Patients hospitalized within the last 30 days ONLY if the institution mandates these patients are observed. Otherwise, these patients remain eligible. 2) Transplanted organ of any kind or ventricular assist device patient; 3) End stage renal disease, on dialysis, or eGFR < 30 mL/min; 4) Acute coronary syndrome (e.g. EKG changes consistent with ischemia or troponin elevation secondary to ACS as per the treating ED clinician); 5) Other acute co-morbid conditions (e.g. sepsis, altered mental status); 6) Hemoglobin < 9, sodium < 135, BUN > 40, eGFR < 30; 7) Patients who require ventilatory support of any kind or intravenous vasodilators/vasopressor/inotropic support at the time of ED disposition 8) Pregnant patients or any patient who has been pregnant in the last 3 months

	9) ≤ 18 years of age 10) Any patient who in the opinion of the clinician or investigator should not be in an SSU or requires ICU level care or will require inpatient rehabilitation or skilled nursing facility after discharge from the ED or hospital 11) Planned discharge from the emergency department 12) De novo (new onset) AHF

Table 3

SCPC Discharge OBS Criteria
- 7-point Dyspnea Likert
- Assessment of ambulatory status. Walk to the bathroom and back or up and down hall or other equivalent.
○ "How short of breath do you feel when walk around?"
▪ Not short of breath at all
▪ My usual or baseline SOB
▪ Mildly Worse than my usual or baseline SOB
▪ Moderately Worse than my usual or baseline SOB
▪ Severely Worse than my usual or baseline SOB
- Record of physical exam for rales, JVD, and peripheral edema.
- Record of body weight at beginning and end of SSU/OBS stay
- Record of ED labs and SSU/OBS unit labs
- Question for practitioner: "was the cause of the patients decompensation identified?" [YES/NO]
- Question for practitioner: "To the extent possible, was the precipitant treated or reversed?" [YES/ NO / Not able to be reversed or treated]
- "Was patient transitioned from IV to oral diuretics?" [YES/NO]
- "Was education performed?" [YES/NO]
- "Did medicine reconciliation occur?" [YES/NO]
- "Was follow up visit arranged? [Appt made for patient / Patient has to make their own appointment / No follow up arranged]
It is recommended at the time of discharge that change in symptoms of congestion, as measured by improvement in dyspnea, is documented. Level of Evidence: B
- 7 point Likert Scale
It is recommended at the time of discharge that the patient be able to ambulate without an exacerbation or recurrence of symptoms including significant dyspnea above baseline and orthostasis. Level of Evidence: B
- assessment of ambulatory status. Walk to the bathroom and back or up and down hall or other equivalent.
- "How short of breath do you feel when walk around?"
○ Not short of breath at all
○ My usual or baseline SOB
○ Mildly Worse than my usual or baseline SOB
○ Moderately Worse than my usual or baseline SOB
○ Severely Worse than my usual or baseline SOB
At the time of discharge improvement in other signs such as decreased rales, edema, and jugular venous pressure, and a decrease in body weight should be considered as parameters of decreased congestion. Level of Evidence: B

- By discharge physical exam in notes/medical record
It is recommended at the time of discharge that no significant alterations in serum electrolytes, with an emphasis on serum sodium and creatinine, are present. Level of Evidence: A
- By discharge lab values
It is recommended that prior to discharge several goals must be met including:
- Question for practitioner: "was the cause of the patients decompensation identified?" [YES/NO]
- "To the extent possible, was the precipitant treated or reversed?" [Yes/ No / Not able to be reversed or treated]
- "Was patient transitioned from IV to oral diuretics?" [YES/NO]
- "Was education performed?" [YES/NO]
- "Did medicine reconciliation occur?" [YES/NO]
- "Was follow up visit arranged? [Appt made for patient / Patient has to make their own appointment / No follow up arranged]
the reasons for acute decompensation have been identified and (partially) reversed; transition from intravenous to oral diuretic has been completed; patient and family education has been addressed; the initial outpatient pharmacologic regimen has been established; compliance with Joint Commission core measures for heart failure has occurred; and a follow-up clinic visit is arranged for between 7 and 10 days after discharge. Level of Evidence: C

Table 4. Primary, secondary and exploratory endpoints

Primary Endpoint	Secondary Endpoints	Exploratory Endpoints
Number of days alive and out of hospital at 30 days post-discharge	• Quality of life[1] • Cost-effectiveness between two arms at 30 days	• Caregiver burden[2] • Cost-effectiveness of the SSU AHF strategy of care at 90 days • Resource utilization[3] • All-cause mortality at 30 & 90 days • All-cause re-hospitalization at 30 & 90 days • Days alive and out of hospital at 90 days • HF Guideline adherence at time of discharge

[1] as measured by Kansas City Cardiomyopathy Questionnaire

[2] as measured by Bakas Caregiving Outcomes Scale and the Oberst Caregiving Burden Scale

[3] as measured by the Modified Resource Utilization Questionnaire for Heart Failure (mRUQ-HF)

Table 5. Data collection time points through 90-day follow-up

Schedule of Events Timepoint/Visit	Screen	Baseline	ARM 1 – Pre-Discharge from SSU	ARM 2 – Pre-Discharge from Hospital Floor	30 & 90 Day Follow up
Informed Consent	X				
Medical History		X			
Physical Exam		X	X	X	
Clinical lab tests*		X	X~	X~	
ECG*		X			
CXR*		X			
KCCQ (QoL) & SF-12			X	X	X
Oberst Caregiving Burden Scale and Bakas Caregiving Outcomes Scale		X	X	X	X[1]
HF Guideline Assessment			X	X	
Collect concomitant meds		X	X	X	X
mRUQ-HF (resource utilization)					X^
Cost Effectiveness Measures (i.e. DRG)					X
Guideline adherence assessment		X	X	X	X[1]
SCPC Discharge Criteria Adherence			X	X	
Assessment of AE/SAE's through 5			X	X	

days					
Vital Status, ED visits, Hospital days, Re-admission status			X	X	X
*per standard of care. Typical labs include: Na, K, renal function, HgB, troponin, Natriuretic Peptide levels. ~only if performed per usual care					

SOC = standard of care, ED = Emergency Department, QoL = quality of life, HF = heart failure, mRUQ = modified resource utilization questionnaire, EMR = electronic medical record, DRG = diagnosis related group

[1]Only through 30 days

^only at 90 days

Table 6: High-Risk Features[13,15,27]

- New-onset HF
- Vital signs:
  - Systolic blood pressure <85 mmHg or >175 mmHg
  - Heart rate >135 beats/min
  - Resp rate >32 breaths per minutes
  - Oxygen saturation <90%
- Airway instability (need for >4L/min supplemental oxygen
- Ischemic changes on ECG
- Need for titratable IV infusions
- Need for noninvasive ventilation
- Signs of poor perfusion
- Signs of altered mental status
- Poor response to initial therapy
- Renal dysfunction
- Hyponatremia
- Troponin >0.1 µg/L in the setting of normal renal function

References

1. Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. *Circulation Heart failure.* 2013;6(3):606-619.
2. Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. *Circulation.* 2017;135(10):e146-e603.
3. Storrow AB, Jenkins CA, Self WH, et al. The burden of acute heart failure on U.S. emergency departments. *JACC Heart failure.* 2014;2(3):269-277.
4. Schuur JD, Venkatesh AK. The growing role of emergency departments in hospital admissions. *The New England journal of medicine.* 2012;367(5):391-393.
5. Dresden SM, Powell ES, Kang R, McHugh M, Cooper AJ, Feinglass J. Increased Emergency Department Use in Illinois After Implementation of the Patient Protection and Affordable Care Act. *Annals of emergency medicine.* 2017;69(2):172-180.
6. Taubman SL, Allen HL, Wright BJ, Baicker K, Finkelstein AN. Medicaid increases emergency-department use: evidence from Oregon's Health Insurance Experiment. *Science.* 2014;343(6168):263-268.
7. Weintraub NL, Collins SP, Pang PS, et al. Acute heart failure syndromes: emergency department presentation, treatment, and disposition: current approaches and future aims: a scientific statement from the American Heart Association. *Circulation.* 2010;122(19):1975-1996.
8. Pang PS, Jesse R, Collins SP, Maisel A. Patients with acute heart failure in the emergency department: do they all need to be admitted? *J Card Fail.* 2012;18(12):900-903.
9. Lassus J, Gayat E, Mueller C, et al. Incremental value of biomarkers to clinical variables for mortality prediction in acutely decompensated heart failure: the Multinational Observational Cohort on Acute Heart Failure (MOCA) study. *International journal of cardiology.* 2013;168(3):2186-2194.
10. Stiell IG, Clement CM, Brison RJ, et al. A risk scoring system to identify emergency department patients with heart failure at high risk for serious adverse events. *Acad Emerg Med.* 2013;20(1):17-26.
11. Fonarow GC, Adams KF, Jr., Abraham WT, Yancy CW, Boscardin WJ. Risk stratification for in-hospital mortality in acutely decompensated heart failure: classification and regression tree analysis. *Jama.* 2005;293(5):572-580.
12. Diercks DB, Peacock WF, Kirk JD, Weber JE. ED patients with heart failure: identification of an observational unit-appropriate cohort. *Am J Emerg Med.* 2006;24(3):319-324.
13. Peacock WF, Fonarow GC, Ander DS, et al. Society of Chest Pain Centers recommendations for the evaluation and management of the observation stay acute heart failure patient-parts 1-6. *Acute cardiac care.* 2009;11(1):3-42.
14. Collins SP, Jenkins CA, Harrell FE, Jr., et al. Identification of Emergency Department Patients With Acute Heart Failure at Low Risk for 30-Day Adverse Events: The STRATIFY Decision Tool. *JACC Heart failure.* 2015;3(10):737-747.
15. Stiell IG, Perry JJ, Clement CM, et al. Prospective and Explicit Clinical Validation of the Ottawa Heart Failure Risk Scale, With and Without Use of Quantitative NT-proBNP.

Academic emergency medicine : official journal of the Society for Academic Emergency Medicine. 2017;24(3):316-327.

16. Hsieh M, Auble TE, Yealy DM. Validation of the Acute Heart Failure Index. *Annals of emergency medicine.* 2008;51(1):37-44.
17. Schrager J, Wheatley M, Georgiopoulou V, et al. Favorable bed utilization and readmission rates for emergency department observation unit heart failure patients. *Acad Emerg Med.* 2013;20(6):554-561.
18. Peacock WFt, Remer EE, Aponte J, Moffa DA, Emerman CE, Albert NM. Effective observation unit treatment of decompensated heart failure. *Congestive heart failure.* 2002;8(2):68-73.
19. Fallick C, Sobotka PA, Dunlap ME. Sympathetically mediated changes in capacitance: redistribution of the venous reservoir as a cause of decompensation. *Circulation Heart failure.* 2011;4(5):669-675.
20. Collins SP, Levy PD, Martindale JL, et al. Clinical and Research Considerations for Patients With Hypertensive Acute Heart Failure: A Consensus Statement from the Society for Academic Emergency Medicine and the Heart Failure Society of America Acute Heart Failure Working Group. *Acad Emerg Med.* 2016;23(8):922-931.
21. Collins S, Martindale J. Optimizing Hypertensive Acute Heart Failure Management with Afterload Reduction. *Current hypertension reports.* 2018;20(1):9.
22. Collins SP, Lindsell CJ, Naftilan AJ, et al. Low-risk acute heart failure patients: external validation of the Society of Chest Pain Center's recommendations. *Critical pathways in cardiology.* 2009;8(3):99-103.
23. Sauser K, Spertus JA, Pierchala L, Davis E, Pang PS. Quality of life assessment for acute heart failure patients from emergency department presentation through 30 days after discharge: a pilot study with the Kansas City Cardiomyopathy Questionnaire. *J Card Fail.* 2014;20(1):18-22.
24. Auble TE, Hsieh M, Gardner W, et al. A prediction rule to identify low-risk patients with heart failure. *Acad Emerg Med.* 2005;12(6):514-521.
25. Gupta A, Allen LA, Bhatt DL, et al. Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure. *JAMA Cardiol.* 2018;3(1):44-53.
26. Pandey A, Golwala H, Xu H, et al. Association of 30-Day Readmission Metric for Heart Failure Under the Hospital Readmissions Reduction Program With Quality of Care and Outcomes. *JACC Heart failure.* 2016;4(12):935-946.
27. Epstein AM, Jha AK, Orav EJ. The relationship between hospital admission rates and rehospitalizations. *The New England journal of medicine.* 2011;365(24):2287-2295.
28. Zuckerman RB, Sheingold SH, Orav EJ, Ruhter J, Epstein AM. Readmissions, Observation, and the Hospital Readmissions Reduction Program. *The New England journal of medicine.* 2016;374(16):1543-1551.
29. Peacock WFt, Young J, Collins S, Diercks D, Emerman C. Heart failure observation units: optimizing care. *Annals of emergency medicine.* 2006;47(1):22-33.

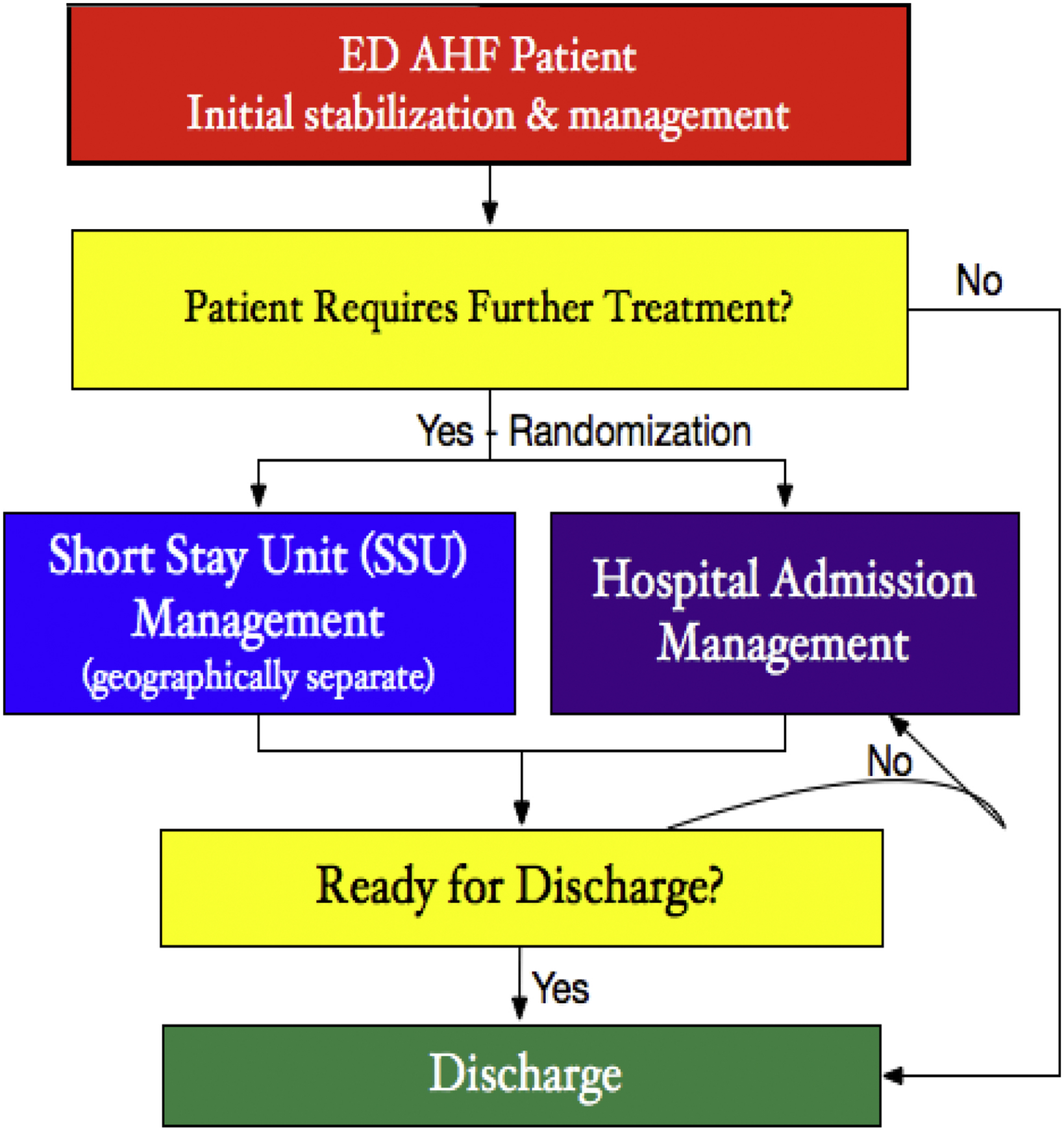
ED AHF Patient
Initial stabilization & management
Patient Requires Further Treatment?
No
Yes - Randomization
Short Stay Unit (SSU) Management
(geographically separate)
Hospital Admission Management
No
Ready for Discharge?
Yes
Discharge

Figure 1

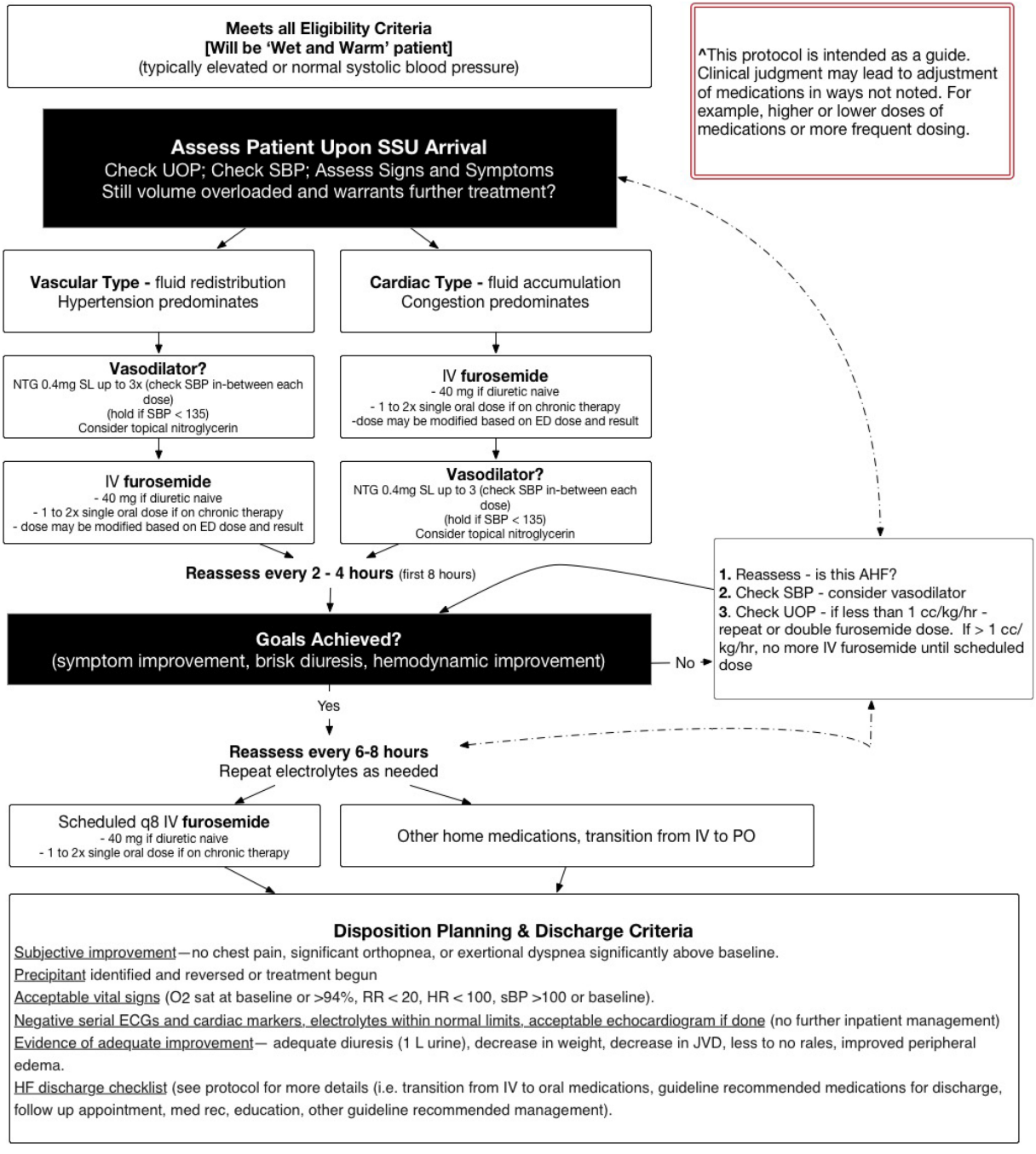
Meets all Eligibility Criteria
[Will be 'Wet and Warm' patient]
(typically elevated or normal systolic blood pressure)
^This protocol is intended as a guide. Clinical judgment may lead to adjustment of medications in ways not noted. For example, higher or lower doses of medications or more frequent dosing.
Assess Patient Upon SSU Arrival
Check UOP; Check SBP; Assess Signs and Symptoms
Still volume overloaded and warrants further treatment?
Vascular Type - fluid redistribution
Hypertension predominates
Cardiac Type - fluid accumulation
Congestion predominates
Vasodilator?
NTG 0.4mg SL up to 3x (check SBP in-between each dose)
(hold if SBP < 135)
Consider topical nitroglycerin
IV furosemide
- 40 mg if diuretic naive
- 1 to 2x single oral dose if on chronic therapy
-dose may be modified based on ED dose and result
IV furosemide
- 40 mg if diuretic naive
- 1 to 2x single oral dose if on chronic therapy
- dose may be modified based on ED dose and result
Vasodilator?
NTG 0.4mg SL up to 3 (check SBP in-between each dose)
(hold if SBP < 135)
Consider topical nitroglycerin
Reassess every 2 - 4 hours (first 8 hours)
1. Reassess - is this AHF?
2. Check SBP - consider vasodilator
3. Check UOP - if less than 1 cc/kg/hr - repeat or double furosemide dose. If > 1 cc/kg/hr, no more IV furosemide until scheduled dose
Goals Achieved?
(symptom improvement, brisk diuresis, hemodynamic improvement)
No
Yes
Reassess every 6-8 hours
Repeat electrolytes as needed
Scheduled q8 IV furosemide
- 40 mg if diuretic naive
- 1 to 2x single oral dose if on chronic therapy
Other home medications, transition from IV to PO
Disposition Planning & Discharge Criteria
Subjective improvement—no chest pain, significant orthopnea, or exertional dyspnea significantly above baseline.
Precipitant identified and reversed or treatment begun
Acceptable vital signs (O2 sat at baseline or >94%, RR < 20, HR < 100, sBP >100 or baseline).
Negative serial ECGs and cardiac markers, electrolytes within normal limits, acceptable echocardiogram if done (no further inpatient management)
Evidence of adequate improvement— adequate diuresis (1 L urine), decrease in weight, decrease in JVD, less to no rales, improved peripheral edema.
HF discharge checklist (see protocol for more details (i.e. transition from IV to oral medications, guideline recommended medications for discharge, follow up appointment, med rec, education, other guideline recommended management).

Figure 2