

Strategies for Reducing Rehospitalization of Heart Failure Patients

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Activity Overview

Approximately 5 million individuals in the United States currently have heart failure (HF) and another 550,000 individuals acquire this disorder each year. Moreover, these numbers are only increasing with the aging of the population. Hospitalizations for HF have increased 157% between 1979 and 2002. These hospitalizations represent a major component of the total economic cost of this disorder, now estimated at \$27.9 billion annually, but have done little to improve mortality, which has increased 155% since 1979.

One factor that contributes to this morbidity, mortality, and economic burden is the inadequate utilization of evidence-based medicine. Despite the development of guidelines for treating HF and core performance measures for patients hospitalized with HF, estimates suggest that more than 50% of patients with HF are not prescribed therapy that would reduce mortality risk by 35%. These data provide a compelling rationale for the development of new educational initiatives to improve the care of HF patients.

The objective of this monograph is provide the latest information about proven strategies for reducing the frequency and duration of hospitalization in patients with HF.

Learning Objectives

After reading this monograph, participants will be able to

- Cite the morbidity, mortality, and economic burden of HF
- Explain the treatment gap between evidence-based therapies for HF and the typical medical management of patients with HF
- Identify specific roles for nurses and clinical pharmacists in the management of HF
- Discuss the impact of HF clinics, multidisciplinary disease management teams, telemonitoring, and emergency department/observation units on the management of patients with HF
- Describe therapeutic options for managing HF, including long-term therapy and intermittent outpatient IV therapy

Target Audience

This activity is intended for physicians, pharmacists, nurses, and other healthcare professionals interested in expanding their knowledge base in the treatment of HF.

CME Accreditation Statement



The University of Michigan Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. The University of Michigan Medical School

designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the educational activity.

Format

This activity is a self-study; completion of this activity involves reading the monograph, which includes charts/graphs and completing the post-test and evaluation form, which may take up to 1.5 hours. This self-study is available from April 1, 2005 to March 31, 2006.

CE Accreditation Statement



The University of Michigan College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

"Strategies for Reducing Rehospitalization of Heart Failure Patients" (ACPE Universal Program Number 029-999-05-025-H01) is approved for 1.0 hour (0.1 CEU) of continuing pharmacy education credit.

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There is no registration fee for this activity.

Disclosure Statement

Daniel E. Hilleman, PharmD, has participated in the Speakers' Bureau for AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Corporation, Pfizer Inc, and Scios Inc.

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Introduction

Heart failure (HF) causes considerable morbidity and mortality and ultimately results in a significant pharmacoeconomic burden. In the United States, approximately 5 million people are afflicted with this disease, and close to 550,000 new cases are reported each year.^{1,2} These numbers are increasing steadily despite effective treatments, and will continue to increase due to the aging of the US population.^{2,3} Currently, an estimated \$27.9 billion is spent annually in direct and indirect medical costs for the management of HF.²

Despite significant treatment advances during the past decade, patients still experience a high rate of early mortality that is directly attributable to complications of HF. Patients diagnosed with HF suffer a 6- to 9-fold increase in the risk of sudden cardiac death.² A retrospective study reported that approximately 11.6% of HF patients died within 30 days of their first hospital admission, while 33.1% died within 1 year.⁴ The long-term mortality due to HF is also significant: 50% of patients die within 5 years of diagnosis, and 70% to 80% of patients die within 8 years.^{2,5} Patients with New York Heart Association (NYHA) class IV HF in particular are at an increased risk of mortality within 60 days of hospitalization for an episode of acute decompensation.⁶ These numbers have not decreased despite the continuing advances in HF treatment; on the contrary, death from HF increased by 157% between 1979 and 2002.²

Overall, morbidity due to HF also persists despite recent therapeutic innovations. HF is the single greatest cause of hospital admissions and readmissions in patients over 65 years of age.⁷ The mean length of each hospital stay in this population is 5.5 days.⁷ These hospitalizations, along with skilled nursing care, account for 72% to 75% of the \$25.3 billion annual direct cost of managing HF.^{2,8} Approximately 75% of the costs associated with HF hospitalization accumulate within the first 48 hours,⁹ making cost containment difficult and the ultimate avoidance of hospitalization for HF a desirable pharmacoeconomic goal.

Approximately 995,000 hospital discharges due to HF are reported each year, and this number is not likely to decrease in the near future.⁷ In fact, HF hospitalizations increased by 157% between 1979 and 2002.² As the age of the US population increases, hospitalizations, morbidity, and mortality related to HF are also likely to increase.⁹ Many patients with HF suffer from episodes of acute decompensation requiring multiple hospitalizations, with 20% of hospitalized patients readmitted within 1 month of initial hospitalization, and 44% to 50% readmitted within 6 months.^{10,11} Improvements in patient care leading to reductions in these repeated

hospitalizations, as well as the estimated 3.8 million annual ambulatory care visits due to HF,¹² could directly impact the overall economic burden of this disease.

This monograph will offer an overview of the current state of inpatient and outpatient HF disease management, efforts to improve patient compliance with prescribed regimens, and the methods by which these services can be fully integrated for effective healthcare delivery.

Evidence-based HF Medicine and Quality-of-Care Measurements

One factor contributing significantly to the excessive morbidity, mortality, and economic burden of HF is the inadequate use of available evidence-based medicine. Evidence-based clinical practice guidelines have been developed for the management of HF patients,^{1,13-15} but despite the publication of these guidelines and the therapeutic innovations recommended, an unacceptable number of HF patients do not receive adequate pharmacologic regimens. In fact, it is estimated that more than 50% of HF patients do not receive beta-blocker therapy, a regimen that, if prescribed judiciously, could reduce the risk of early mortality by 35%.¹⁶

Current American College of Cardiology/American Heart Association (ACC/AHA) guidelines for HF management suggest a number of gold-standard treatment options based upon the severity of HF disease. In patients with stage A disease (at risk for HF without clinical or structural indications of disease), the ACC/AHA guidelines suggest proper control of hypertension and lipids; modification of behavior that contributes to disease risk (smoking cessation, exercise); and angiotensin-converting enzyme (ACE) inhibitor therapy in those with a history of atherosclerosis, diabetes, or hypertension. Stage B patients (evidence of asymptomatic left ventricular [LV] systolic dysfunction) with a history of reduced ejection fraction or myocardial infarction should also receive beta-blocker therapy, and those with a history of hemodynamically significant valvular disease should undergo valve replacement surgery. Diuretics and digitalis are also warranted in most stage B patients. All stage B patients should also receive regular evaluations for signs of worsening HF.¹

Patients with stage C and D disease suffer from symptomatic disease and require more aggressive therapy. Diuretics are suggested, especially in those with evidence of fluid retention. ACE inhibitors and beta-blockers should also be prescribed unless contraindicated. Intermittent intravenous therapy with inotropes has resulted in an increased risk of complications and mortality and is not recommended in these patients.¹ Patients with end-stage HF (stage D) should be referred for cardiac transplantation, if appropriate, and should be treated with the same recommended regimens as those with less aggressive disease.¹

Components of these current HF guidelines have been adapted to create core performance quality-of-care measures for patients hospitalized with HF.¹⁷⁻¹⁹ The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the nation’s predominant source for healthcare accreditation and has developed core performance measures based on existing HF care guidelines; these include adequate discharge instructions, LV function assessment, ACE inhibitor prescription for patients with LV dysfunction, and adult smoking cessation counseling (Table 1).^{18,19} Compliance with these JCAHO HF core performance measures was assessed recently using data from Medicare beneficiaries as well as data acquired by the Acute Decompensated Heart Failure National Registry (ADHERE®).^{20,21} Institutions participating in the ADHERE registry were representative of hospitals across the United States, and included community, tertiary, and academic care centers of varying sizes from all regions of the country. The ADHERE registry reported an inadequate level

Table 1. JCAHO Core Performance Measures for Heart Failure

Performance Measure	Criteria Met or Acceptable Alternative
<p>1. Heart failure patients discharged home with written instructions or educational materials given to patient or caregiver at discharge or during hospital stay that address all of the following:</p> <ul style="list-style-type: none"> • Activity level • Diet • Discharge medications • Follow-up appointment • Weight monitoring • What to do if symptoms worsen 	<p>Discharge instructions. For patients discharged home, with or without home health services, documentation of written instructions or educational materials given to the patient or caregiver must address all of the following:</p> <ul style="list-style-type: none"> • Activity level after discharge • Diet/fluid intake after discharge • Names of all discharge medications • Follow-up with a physician/nurse practitioner/physician assistant after discharge • Weight monitoring after discharge • What to do if heart failure symptoms worsen after discharge
<p>2. Heart failure patients with documentation in the hospital record that LVF was assessed before arrival, during hospitalization, or is planned for after discharge</p>	<p>LVF assessment. In cases where there is no reason documented by a physician, nurse practitioner, or physician assistant for not assessing LVF, there must be:</p> <ul style="list-style-type: none"> • Documentation that an echocardiogram, appropriate nuclear medicine test, or cardiac catheterization with a left ventriculogram was performed during this hospital stay OR • Documentation that one of the above diagnostic tests was performed anytime prior to arrival OR • Documentation of LVF, either as an ejection fraction or a narrative qualitative description (eg, “Pt. admitted with severe LV dysfunction”) OR • Documentation of a plan to assess LVF after discharge

ACE, angiotensin-converting enzyme; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; LVF, left ventricular function; LVSD, left ventricular systolic dysfunction.

Adapted with permission from the Centers for Medicare and Medicaid Services and the Joint Commission on Accreditation of Healthcare Organizations.^{18,19}

Table 1. JCAHO Core Performance Measures for Heart Failure (continued)

Performance Measure	Criteria Met or Acceptable Alternative
3. Heart failure patients with LVSD and without ACE inhibitor contraindications who are prescribed an ACE inhibitor at hospital discharge	ACE inhibitor. Documentation that an ACE inhibitor was prescribed at discharge in patients with LVSD who are not participating in an ACE inhibitor-alternative clinical trial at the time of discharge and where there is no documentation of a potential contraindication/reason for not prescribing an ACE inhibitor at discharge (eg, ACE inhibitor allergy, moderate or severe aortic stenosis, or other reason documented by a physician, nurse practitioner, or physician assistant). LVSD is defined as documentation of a left ventricular ejection fraction less than 40% or a narrative description of LVEF consistent with moderate or severe systolic dysfunction. When there are two or more documented LVEFs, the LVEF closest to discharge is used.
4. Heart failure patients with a history of smoking cigarettes who are given smoking cessation advice or counseling during hospital stay	Adult smoking cessation advice/counseling. Documentation of smoking cessation advice or counseling in patients with a history of smoking cigarettes anytime during the year prior to hospital arrival. Smoking cessation advice/counseling includes prescription of a cessation aid.

ACE, angiotensin-converting enzyme; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; LVEF, left ventricular ejection fraction; LVSD, left ventricular systolic dysfunction.

Adapted with permission from the Centers for Medicare and Medicaid Services and the Joint Commission on Accreditation of Healthcare Organizations.^{18,19}

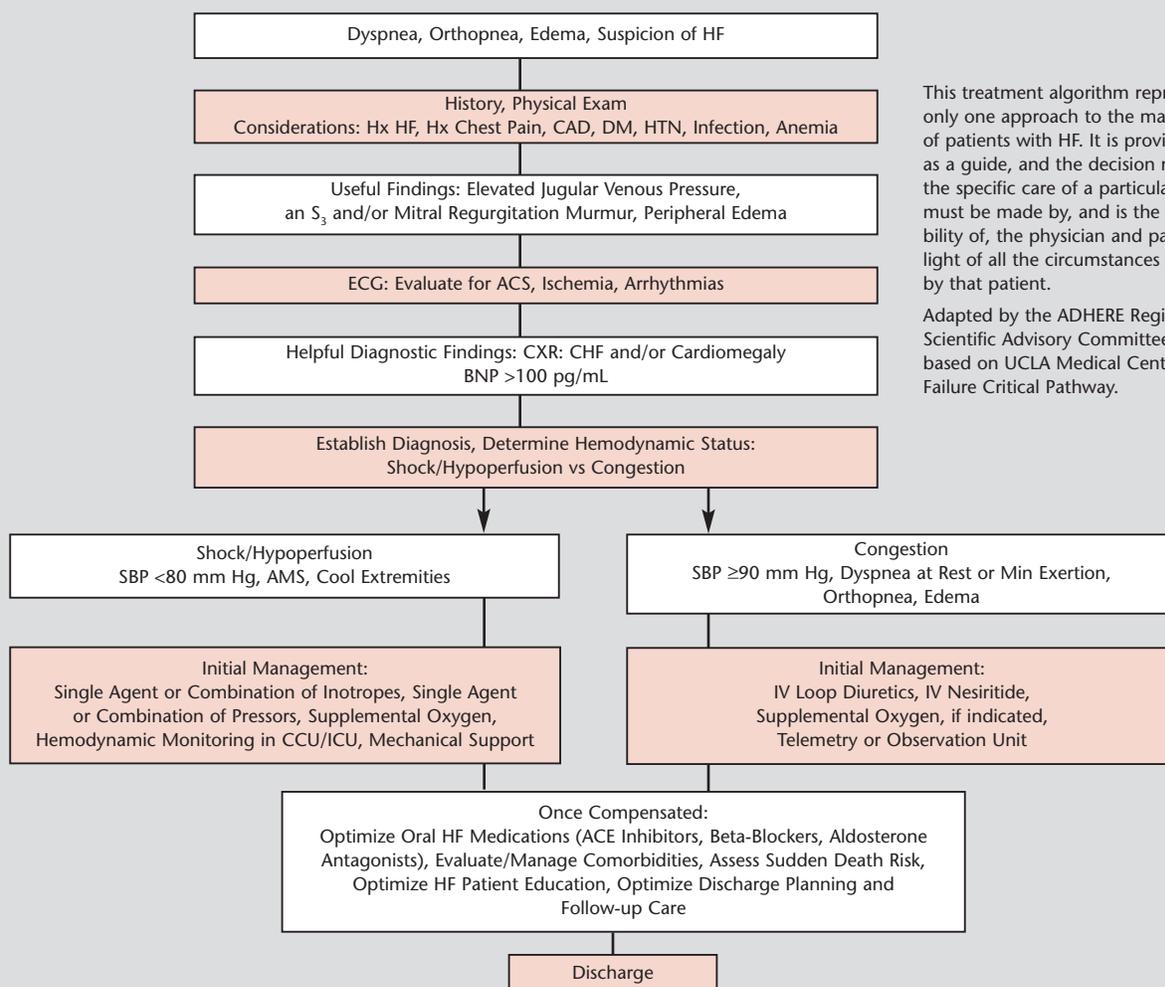
of compliance with JCAHO core performance measures. During hospitalization of patients with acute decompensated HF (ADHF), assessment of LV ejection fraction (LVEF) was documented or scheduled in 82% of patients; only 28% of patients received instructions on diet, weight monitoring, activity level, worsening symptoms, follow-up appointments, and medication management upon hospital discharge; only 31% of current smokers received counseling on smoking cessation; and ACE inhibitors were prescribed upon discharge to only 69% of eligible patients.²¹

A similar analysis of hospitalized Medicare patients reported unadjusted rates of LVEF documentation and ACE inhibitor prescription in 66.6% and 66.3% of patients, respectively.²² Predictors of increased LVEF documentation included being seen by an attending physician specializing in cardiology, being cared for at a teaching hospital, and being hospitalized at a healthcare facility in the Northeastern quadrant of the United States.²² Additional analyses have reported similar findings, including median rates of 76% and 81% for LVEF assessment and ACE inhibitor prescriptions, respectively, in one analysis.²³⁻²⁹ These analyses persuasively illustrate the continuing need to improve the quality of care for patients with HF.³⁰ Improvements in HF care may be most fully realized through an integration of inpatient and outpatient services to maintain patient stability and decrease the need for hospital admissions.³¹

Disease Management Implementation

Based on previous success with hospital-based disease management systems and findings from the ADHERE registry suggesting that opportunities exist for improvements in patient care, a hospital-specific ADHERE toolkit was developed. The toolkit provides a variety of resources to participating institutions in an electronic format (for facilitation of site-specific modifications), including treatment algorithms, critical pathways (Figure 1),³⁰ an admission checklist, preprinted order sets, a discharge checklist, patient education materials, patient medication fact sheets, and a patient compliance contract.³⁰ The ADHERE toolkit and other successful programs can be used as templates for creating effective, institution-specific resources for patients, family members, and providers.

Figure 1. ADHERE hospital toolkit: HF critical pathway.



This treatment algorithm represents only one approach to the management of patients with HF. It is provided solely as a guide, and the decision regarding the specific care of a particular patient must be made by, and is the responsibility of, the physician and patient in light of all the circumstances presented by that patient.

Adapted by the ADHERE Registry Scientific Advisory Committee and based on UCLA Medical Center's Heart Failure Critical Pathway.

ACE, angiotensin-converting enzyme; ACS, acute coronary syndromes; AMS, altered mental status; BNP, B-type natriuretic peptide; CAD, coronary artery disease; CCU, coronary care unit; CHF, congestive heart failure; CXR, chest x-ray; DM, diabetes mellitus; ECG, electrocardiogram; HF, heart failure; HTN, hypertension; Hx, history; ICU, intensive care unit; IV, intravenous; SBP, systolic blood pressure. Adapted with permission from Fonarow.³⁰

Inpatient HF Disease Management

An effective inpatient disease management program incorporates a multidisciplinary approach that involves active participation and communication among all parties concerned with the care of the patient.^{32,33} Disease management programs identify a target patient population, adhere to evidence-based practice guidelines, and institute a system for process and outcomes measurement. Communication among

Table 2. Components of a Disease Management Program

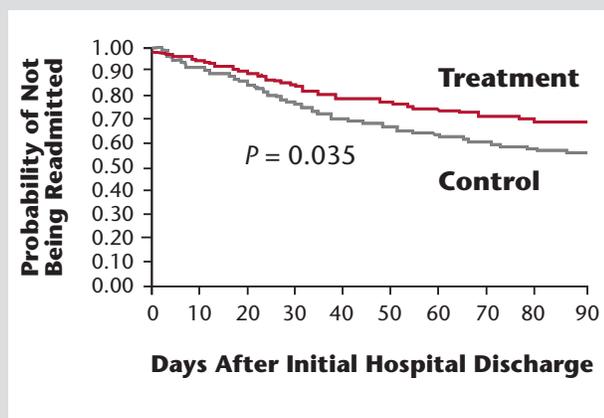
Disease Management Components

- Population identification
- Evidence-based practice guidelines
- Collaborative practice models to include healthcare and support-service providers
- Patient self-management education
- Process and outcomes measurement, evaluation and management
- Routine reporting/feedback loop

healthcare providers, patients, family members, and support services facilitates collaborative practice models as well as patient and family caregiver self-management education. A feedback and monitoring system is also designed to identify problems and opportunities for continuing improvement (Table 2).^{32,33}

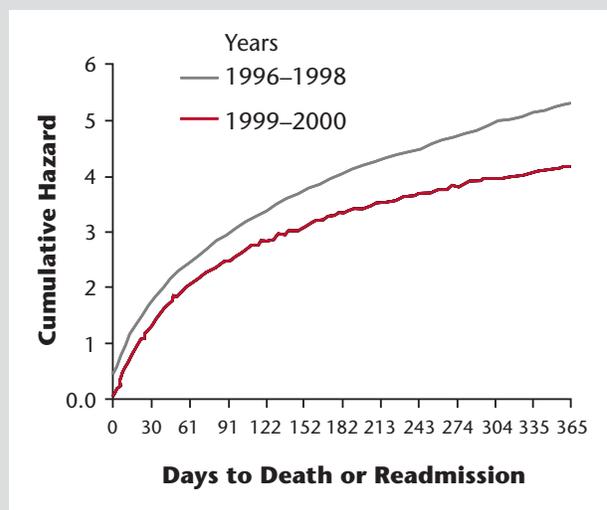
These disease management tools have resulted in measurable clinical benefits. Rich et al described participation in an HF management program that included comprehensive patient and family education, dietary assessment and instruction, social services consultation for discharge planning, a clinical medication review, and intensive follow-up care.³⁴ Patients randomized to receive intensive HF management services benefited from a significant reduction in hospital readmissions; the number of readmissions for HF was reduced by 56.2% in this group compared with controls (Figure 2).³⁴ Multiple readmissions occurred in 6.3% of the treatment group compared with 16.4% of the control group, resulting in an overall readmission reduction of 44.4%.³⁴ Avoidance of hospitalization in the disease management group resulted in an overall total cost savings of \$460 per patient.³⁴ The implementation of a similar disease management program based on HF treatment guidelines resulted in a 45% reduction in the rate of repeated hospitalizations.³⁵

Figure 2. Kaplan-Meier curves for the probability of not being readmitted to the hospital at 90 days following participation in a nurse-directed, multidisciplinary heart failure program.



Adapted with permission from Rich et al.³⁴

Figure 3. Analysis of 19,083 heart failure patients following participation in an institutional heart failure discharge medication program.



Adapted with permission from Pearson et al.³⁶

Another disease management program reported an increase in ACE inhibitor use from 65% to 95%, as well as reductions in hospital readmission rates and mortality after 1 year of program implementation (Figure 3).³⁶ Increases in LVEF documentation and ACE inhibitor use, as well as significant reductions in length of hospital stay, have been reported.³⁷

Outpatient Disease Management

Disease management programs, through an outpatient HF clinic or observation unit within the emergency department or inpatient setting, possess the same basic components as those of inpatient programs. An outpatient disease management program depends on a multidisciplinary approach and the availability of social services designed to enhance follow-up surveillance, improve and reinforce patient education and family caregiver involvement, and improve clinical guideline compliance. Successful outpatient disease management programs can also result in improved long-term patient outcomes

Table 3. Outpatient Disease Management Options

Outpatient Disease Management

- Patient home visits
- Disease telemanagement
- Patient telemonitoring
- Specialized outpatient heart failure clinic

and reductions in unnecessary hospitalizations, resulting in significant pharmacoeconomic benefits. Outpatient disease management can be accomplished through a variety of means, including patient home visits, disease telemanagement, patient telemonitoring, care through a specialized outpatient HF clinic, or a combination of these strategies (Table 3).

Clinical data are available that demonstrate the benefits of outpatient disease management programs, including significant decreases in rehospitalizations and hospital days and reductions in total medical costs. A retrospective chart review by Cintron et al reported a 60% reduction in rehospitalizations and an 85% reduction in the number of hospital days, as well as a 75% net reduction in total medical costs, after the addition of a nurse practitioner offering disease management services.³⁸ Another nurse-managed clinic reported a 4% decrease in readmissions and a length of stay decrease of 1.6 days within 6 months of the implementation of an intensive HF patient follow-up program.³⁹

A more intensive disease management program implemented in HF patients referred for cardiac transplantation provided an initial inpatient evaluation coupled with routine follow-up care. Services included weight and vital sign monitoring, compensatory changes in diuretics and other medication dosing regimens, dietary and exercise counseling, and comprehensive disease management education, through a specialized outpatient HF center.³¹ Participants reported significant improvements in the subjective and objective measurements of functional status, reflected by an 85% reduction in hospital admissions compared with the 6 months immediately preceding the study period.³¹ This reduction in hospital admissions ultimately resulted in an estimated cost savings of more than \$9,000 per patient.³¹

Telemonitoring HF disease management programs have demonstrated similar results. A multicenter program implemented telemonitoring services (weekly telephone conversations between a nurse and the patient), post-hospitalization follow-up including a nurse home visit, and healthcare provider education to increase awareness of the disease management program and existing treatment guidelines.⁴⁰ An assessment performed 12 months after implementation of the program indicated a significant reduction in hospitalizations of 63% compared with the same period during the year prior to implementation.⁴⁰ The 30- and 90-day readmission rates decreased by 75% and 74%, respectively. In addition to this reduction in hospitalizations, the average length of stay, total hospital days, and emergency department use for patients with diagnoses related to HF were also reduced.⁴⁰ Recent outpatient disease management programs have similarly reported reductions in emergency department visits and rehospitalizations,^{29,41-49} a longer length of time before hospital readmission,⁴³ reductions in healthcare costs,^{43,44} improvements in patient self-care,^{42,49} and improved prescribing of effective long-term regimens.^{29,41}

Home-based healthcare and assessment

The most important component to successful home healthcare for patients with HF is the effective communication of instructions to patients prior to hospital discharge. Patient education is critical to long-term HF care because patient behaviors regarding medication management, diet, weight control, smoking cessation, exercise, and follow-up care can have a major impact on the course of HF.^{1,21,31} Comprehensive discharge planning, including postdischarge support, has also been shown to reduce readmission and improve outcomes in older patients with HF.⁵⁰ Despite the importance of patient education and adequate follow-up care for patients with HF, multiple studies have reported that many patients do not receive adequate education about medication, diet, and self-monitoring.^{17,21,51} In fact, up to 50% of HF hospital readmissions are due to medication or dietary noncompliance.⁵¹

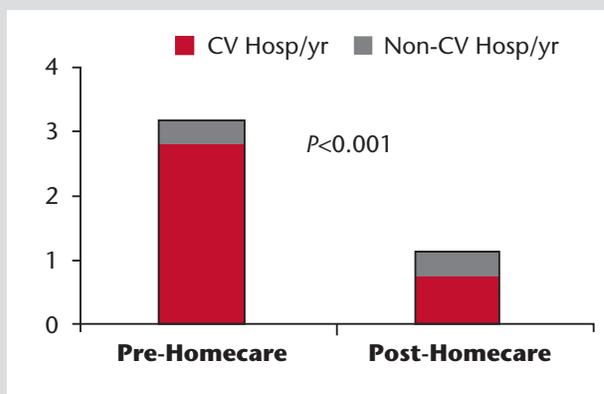
Indeed, adequate home healthcare has the ability to improve HF symptoms and reduce hospital admissions.^{52,53} The factors most significantly associated with readmission in one study included the adequacy of home healthcare, medication compliance, and patients' self-assessment of health status.⁵³ These findings highlight the importance of effective home care in reducing the high risk of HF readmission, especially among elderly patients.

A physician-supervised, nurse-mediated home healthcare program for HF patients confirmed the utility of home-based follow-up in HF disease management. Nursing contact through an initial home visit and subsequent telephone contact focused on patient education, dietary instructions, medication review, and the suggestion of strategies to improve medication and dietary compliance.⁵⁴ This home-care strategy resulted in a significant reduction in general medical and cardiology office visits, as well as emergency department visits for HF and for all causes, compared with the year prior to enrollment.⁵⁴ Daily dietary sodium intake fell by 38%, and average daily medication doses increased substantially, suggesting improvements in patient compliance. Participants also reported significant improvements in functional status and exercise capacity.⁵⁴

Home-based patient assessment can be another important component of a successful HF disease management program, as clinical instability can be better treated if identified earlier, possibly avoiding an episode of ADHF requiring hospitalization.⁵⁵ Early clinical instability was independently correlated with advanced age and the presence of comorbidities, including diabetes,⁵⁵ and patients exhibiting signs of clinical instability at the first visit were more likely to self-report noncompliance with fluid restriction and medication regimens.⁵⁵ Home-based patient assessments also

offer an independent opportunity to improve outcomes. An intensive program of home-based patient surveillance reported a significant improvement in functional status as measured by the ability to perform daily activities, graded on a 4-point scale. The mean rate of all hospitalizations and those due to cardiovascular complications decreased significantly with home-based surveillance (Figure 4).⁵⁶

Figure 4. Hospitalization rate between the year before and the year after initiation of a home-care surveillance program.



CV, cardiovascular. Adapted with permission from Kornowski et al.⁵⁶

Skilled home visits by nurses are often critical to the success of an outpatient disease management program. A randomized trial of discharged HF patients compared patients receiving standard follow-up care through a primary care physician with patients receiving specialized home-based intervention through a nurse and pharmacist.⁵⁷ Patients randomized to receive home-based intervention had fewer unplanned readmissions and fewer days of hospitalization, with a trend toward a reduction in both out-of-hospital deaths and total mortality.^{57,58} Nurse specialists in another study conducted a home visit following discharge and returned as needed. Home visits included an assessment of clinical signs and weight as well as blood collection for appropriate laboratory analyses. Medications were also reviewed with patients and family members.⁵⁹ Patients surviving the study period demonstrated a reduction in total hospital readmission days and outpatient clinic visits.⁵⁹ A similar program run by nurse specialists through a combination of home visits and telephone contact reported a 35% decrease in HF hospitalizations in the 9 months following program initiation, and a resulting estimated cost savings of \$165,000.³³ A more intensive program of patient surveillance and education through frequent nurse specialist home visits and telephone contact resulted in a significant decrease in cardiovascular-related hospitalizations and a significant improvement in quality of life as measured by the Minnesota Living With Heart Failure Questionnaire.⁶⁰

Another randomized, controlled trial comparing patients receiving specialized home-based nursing care with patients receiving standard outpatient follow-up care services was conducted to assess the efficacy of this strategy. The intervention program followed a formal nursing protocol, a patient self-care guide, and interactive training to enhance patient teaching and support skills.⁶¹ Patients receiving this intervention required fewer skilled nursing visits without a significant increase in outpatient physician visits or emergency department admissions.⁶¹ Another randomized trial comparing standard follow-up care with a 3-month program of detailed discharge planning and home follow-up directed by advanced practice nurses reported a greater length of time before hospital readmission or mortality, fewer total readmissions, and significant reductions in mean utilization costs after 52 weeks.⁶² The weight of evidence from these multiple studies demonstrates the consistent value of intensive follow-up care by skilled specialist nurses.

Patient telemonitoring and telemanagement

Home-based patient telemonitoring through specialized care devices connected by telephone lines, cable networks, or broad-band technology allows clinicians to monitor physiologic variables on a daily or continuous basis.⁶³ This monitoring can assist physicians in making decisions regarding therapeutic adjustments while reducing the frequency of office visits. Multiple randomized studies have evaluated this strategy and report variable success.⁶⁴⁻⁷⁰

A telemedicine system, through which nurses reviewed daily patient data and contacted physicians for follow-up when symptoms or weight changes suggested a worsening of HF, reported decreases in hospitalizations and emergency department visits in the telemonitoring group compared with similar patients who had chosen to not participate.⁶⁴ The nonrandomized implementation of another multidisciplinary HF management program, including compliance monitoring through a computerized telephone system, reported a high rate of patient compliance (89.5%) after the program had been running for 18 months.⁶⁵ Hospitalizations due to HF were also reduced to 0.6 per patient per year, compared with the national benchmark of 1.7 per patient per year.⁶⁵ A similar study of follow-up telemedicine through telephone consultations and single-lead remote electrocardiographic monitoring reported a reduction in HF hospitalizations compared with the year prior to program initiation.⁶⁶ A randomized study comparing home nursing visits with nurse-based telemedicine using trans-telephonic home monitoring devices to remotely measure weight, blood pressure, heart rate, and oxygen saturation reported significant benefits, including fewer HF readmissions at 3 and 6 months.⁶⁷

Meanwhile, a randomized evaluation by Johnston et al reported no effect of real-time telemonitoring through a remote video system on quality indicators or resource utilization when added to an established disease management program that provided home care visits and telephone contact.⁶⁸ A crossover study comparing real-time with two-way video nursing evaluations reported few differences in the assessment strategies; real-time nursing was more likely to identify pedal or ankle edema whereas telemonitored nursing was more likely to identify changes in nail color.⁶⁹ Additional studies of telemonitoring failed to demonstrate significant sustained effects compared with live nursing follow-up.⁷⁰

Programs comparing telemonitoring strategies with standard primary care follow-up have reported more favorable results. A randomized, three-arm trial comparing home telecare delivered via a two-way videoconference device with an integrated electronic stethoscope, nurse telephone calls, and standard outpatient follow-up care reported reductions in mean HF-related readmission charges of 86% and 84% in the telecare and telephone groups, respectively, compared with the standard care group.⁷¹ Both intervention groups reported significantly fewer HF-related emergency department visits and costs than the standard care group.⁷¹ A similar trial compared standard follow-up care with a telemedicine program consisting of telephone intervention to assess symptoms, determine compliance with drug therapy, and offer dietary and physical activity recommendations. The study reported a significant decrease in the primary end point of all-cause mortality and/or HF-related hospitalization in patients receiving telecare-based follow-up, which was due primarily to a reduction in hospital admissions.⁷²

The largest multicenter trial to date evaluating telemedicine randomized 280 patients to receive standard care or standard care plus home-based weight and symptom monitoring through the AlereNet™ system (Alere Medical Incorporated, Reno, NV). The investigators reported a significant reduction in mortality ($P < 0.0003$) among patients whose weight and symptoms were monitored daily, especially in females and patients less than 65 years of age.⁷³ The HF component of a large integrated telehealth network estimated that telemonitoring interventions could reduce HF hospitalization costs from \$8 billion to \$4.2 billion each year.⁷⁴

A nurse-run program that focused on an intensive diuretic treatment algorithm based on telemonitoring reported a 30-day readmission rate of 0.7%, compared with the national average of 17%; a 50% reduction in hospitalization rates; and a 52% reduction in hospital costs due to HF.⁷⁵ A summary of this telemonitoring program is presented in Figure 5; other diuretic management programs have used different approaches to patient management.

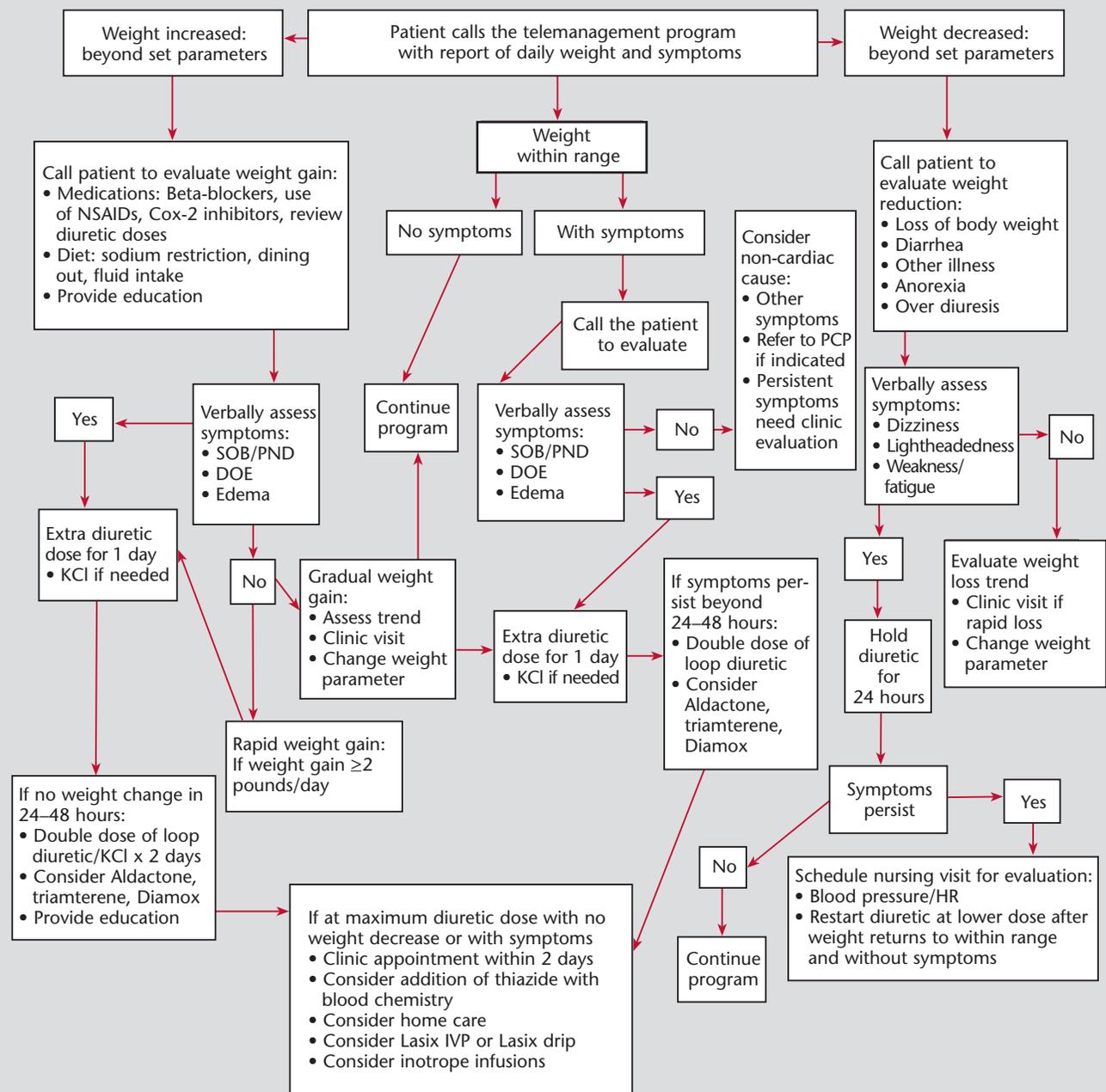
Other supportive technologies for follow-up care have also been investigated, including interactive decision-support software. One study randomized patients to receive either standard follow-up care or telephone-based case management guided by interactive decision-support software. Supportive care through the telemanagement service resulted in significant decreases in HF-related hospitalizations, hospital days, and treatment costs.⁷⁶

The data currently reported from telemanagement studies for HF patients suggest that telemonitoring is most effective when compared with the lack of any specialized follow-up care; telemonitoring might be most useful as an adjunct to specialized home-based disease management in an effort to quickly identify troubling symptoms requiring intervention. In fact, one recent study of 1069 patients reported that long-term exposure to a disease management program resulted in greater life expectancy, without improvement in functional capacity or reduction in healthcare costs.⁷⁷ Patients participating in these programs generally report satisfaction with the care received through telemanagement,⁶⁸⁻⁷⁰ suggesting that future technologic advances might lead to improved care as well as patient well-being and compliance.

Role of the emergency department/HF observation unit

Early, effective treatment for HF in the emergency department or a specialized HF observation unit has been proven to improve clinical outcomes and reduce utilization costs.⁷⁸⁻⁸⁰ Early treatment strategies may also reduce the need for hospitalizations.⁷⁸⁻⁸⁰ Compared with placebo, initiation of intravenous (IV) vasoactive therapy in the emergency department reduced median overall hospital length

Figure 5. Diuretic treatment algorithm for use with an HF telemanagement program.



DOE, dyspnea on exertion; HR, heart rate; IVP, intravenous push; KCl, potassium chloride; NSAIDs, nonsteroidal anti-inflammatory drugs; PCP, primary care physician; PND, post-nocturnal dyspnea; SOB, shortness of breath. Adapted with permission from Mueller et al.⁷⁵

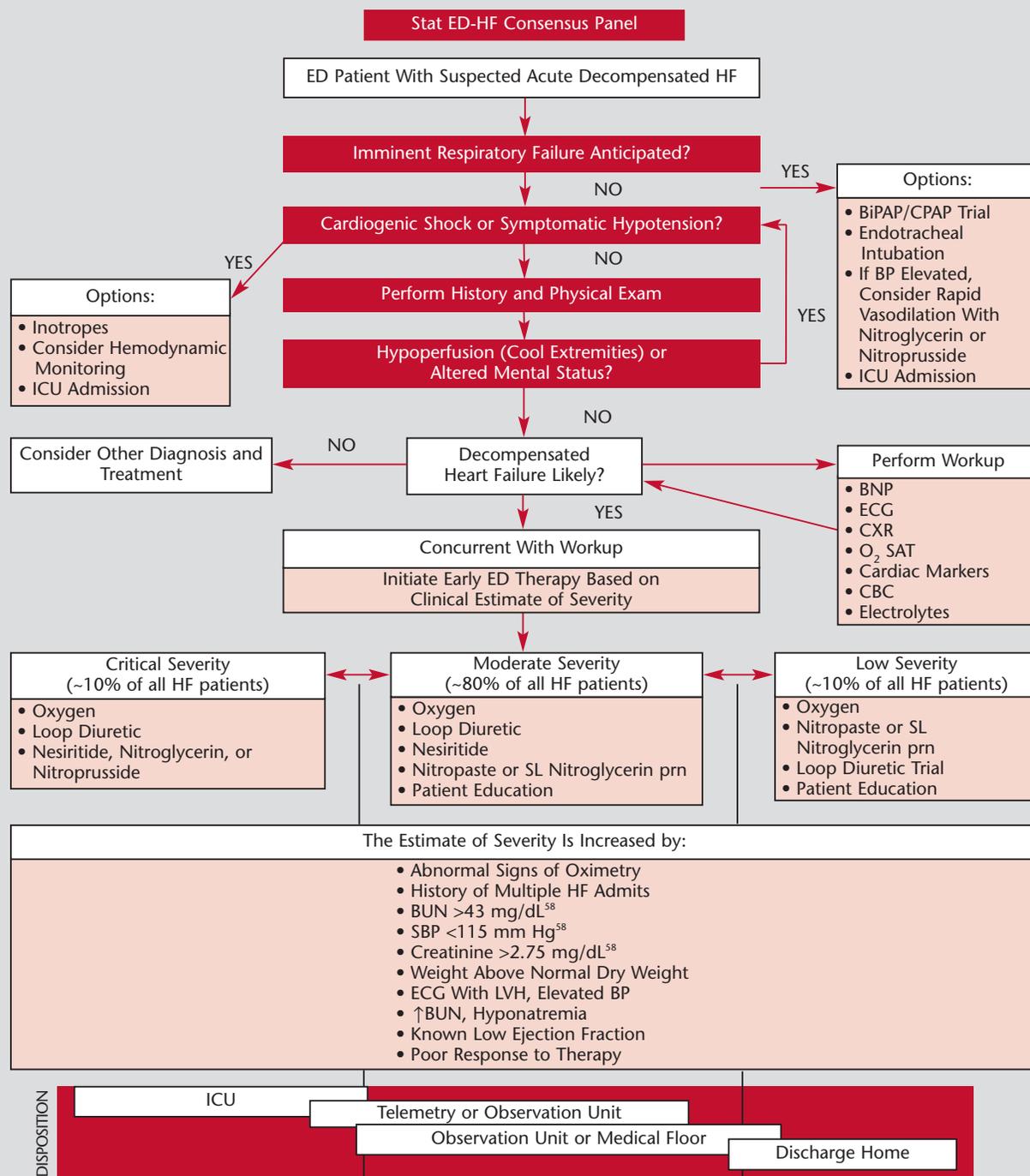
of stay (3.0 days vs 7.0 days) and median length of stay in intensive and critical care units (2.1 days vs 4.5 days, $P < 0.001$).⁷⁹ Furthermore, compared with initiation of vasoactive therapy with nesiritide following hospital admission, initiation of nesiritide in the emergency department resulted in significantly reduced hospital length of stay (4.1 days vs 5.7 days, $P > 0.0001$).⁸⁰

A suggested algorithm for the early emergency department management of HF patients is presented in Figure 6.⁷⁹ Observation unit treatment strategies for HF are generally provided in an effort to stabilize the patient and optimize existing long-term HF regimens and can be a critical tool in the avoidance of repeated emergency department visits and hospitalizations.⁸¹ Therapy with diuretics, ACE inhibitors, and other long-term medications is optimized during the observation unit stay, and patients receive appropriate diagnostic analyses. Cardiology and dietary consultations can be helpful in identifying suboptimal regimens. Patient education materials can also be effectively disseminated in the observation unit setting.⁸² HF observation unit care in appropriate patients has been proven to be safe and effective, with outcomes similar to those found in HF patients admitted as inpatients.⁸³

Careful patient selection is required for any outpatient treatment strategy, as some patients do require hospital admission due to significant comorbidities or complex clinical presentation. HF patients presenting with unstable vital signs, evidence of acute myocardial ischemia, cardiac arrhythmia requiring continuous IV therapy, or evidence of inadequate systemic perfusion are generally admitted as inpatients and are inappropriate candidates for observation unit care.^{82,84} A low threshold for hospital admission is also recommended in patients who are frail, elderly, or suffering from severe comorbidities.⁸²

In the Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in Outpatients with Natrecor® (PROACTION) study, patients presenting to the emergency department with ADHF were randomized to receive standard care plus at least 12 hours of IV therapy with either nesiritide (Natrecor®, Scios Inc, Fremont, CA) or placebo in the emergency department or specialized HF observation unit.⁸⁵ A total of 237 emergency department patients with ADHF were enrolled. The addition of nesiritide, a recombinant analog of human brain-type natriuretic peptide (hBNP), to standard care reduced overall admission rates and readmission rates within 30 days of the emergency department visit.⁸⁵ No significant differences in drug termination, symptomatic hypotension, ventricular arrhythmias, or death were observed between treatment groups.⁸⁵ The reduced length of stay and readmission rate with nesiritide administration resulted in a lower overall cost of care in patients receiving nesiritide in addition to standard therapy when compared with costs in patients receiving standard care alone.⁸⁵

Figure 6. Guidelines for the early stabilization and disposition of ADHF in the ED.



This treatment algorithm represents only one approach to the management of patients with HF. It is provided solely as a guide, and the decision regarding the specific care of a particular patient must be made by, and is the responsibility of, the physician and patient in light of all the circumstances presented by that patient.

BiPAP, bilevel positive airway pressure; BNP, B-type natriuretic peptide; BP, blood pressure; BUN, blood urea nitrogen; CBC, complete blood cell count; CPAP, continuous positive airway pressure; CXR, chest x-ray; ECG, electrocardiogram; ED, emergency department; HF, heart failure; ICU, intensive care unit; LVH, left ventricular hypertrophy; prn, as needed; SBP, systolic blood pressure; SL, sublingual. Adapted with permission from Emerman.⁷⁹

Role of the Clinical Pharmacist in HF Care

The clinical pharmacist has a unique opportunity to impact the long-term management and outcomes of HF patients through the appropriate and judicious use of available pharmacologic regimens. The ADHERE registry reported that proper patient education occurred in only 28% of evaluated cases upon discharge — this education included instructions on diet, weight monitoring, activity level, worsening symptoms, follow-up appointments, and medication management. In addition, only 31% of current smokers received counseling on smoking cessation, and ACE inhibitors were prescribed upon discharge to only 69% of eligible patients.²¹

Recent clinical data suggest that the addition of a clinical pharmacist to a multidisciplinary HF management team can result in significant improvements in care. A randomized study compared HF patients receiving routine primary care and those receiving specialized care with medication evaluations, therapeutic recommendations to the attending physician, patient education, and follow-up telemonitoring provided by a clinical pharmacist.⁸⁶ A 6-month follow-up evaluation reported a significant reduction in all-cause mortality and HF events and a higher rate of achieving the target ACE inhibitor dosage in the patients receiving intervention through a clinical pharmacist,⁸⁶ suggesting that medication consultations may be an important component of HF management. Other multidisciplinary HF teams have reported similar promising outcomes for patients, including a lower rate of hospital readmission.³⁴ Pharmacists play a multifaceted role in HF management due to the amount of medications often required for HF and comorbid conditions, and they should therefore play a role in any multidisciplinary HF team.^{86,87}

Clinical pharmacists can have a significant influence on the implementation of proper discharge education by championing the adoption of and adherence to these aspects of JCAHO core performance measures. As compliance with prescribed medications is a common cause of rehospitalization in HF patients, proper discharge planning and patient education can significantly affect long-term outcomes and future resource utilization.

Therapeutic Options for HF Management

Long-term HF management

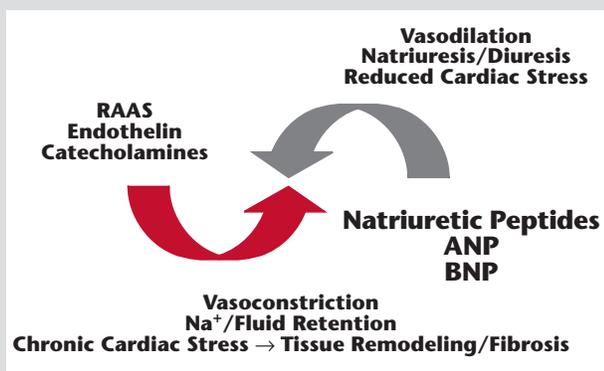
Diuretics are routinely prescribed to patients with LV dysfunction and symptoms of HF because of their ability to prevent fluid retention and volume overload.¹ Although diuretics are useful in providing symptomatic relief associated with fluid retention, scant data are available on their ability to improve long-term HF outcomes.⁸⁸ Oral diuretic therapy is sometimes insufficient to achieve and maintain the necessary hemodynamic response for symptomatic control in advanced HF.¹ Neurohormonal antagonists, including ACE inhibitors, beta-blockers, angiotensin II receptor blockers, and aldosterone antagonists, have also been identified as critical to successful long-term HF management. These agents all counteract the deleterious neurohormonal release of angiotensin II, norepinephrine, aldosterone, and other products in response to HF.^{86,87} Therapy with beta-blockers has resulted in protection from worsening symptoms, hospital readmissions, early mortality, and sudden death.⁸⁹⁻⁹³ Similar effects on hospital admissions, morbidity, and mortality have been observed with the use of angiotensin II receptor blockers and aldosterone antagonists.⁹⁴⁻⁹⁷ ACE inhibitor therapy has also been proven to consistently reduce hospitalizations and early mortality due to HF,^{98,99} and the optimization of ACE inhibitor dosing has been shown to reduce hospitalizations and utilization costs.¹⁰⁰

Despite the proven benefits of ACE inhibitors, beta-blockers, and other neurohormonal antagonists in HF, the use of these agents is still limited by several factors. Advanced HF patients are particularly vulnerable to hypotension and renal insufficiency with the administration of ACE inhibitors, and susceptible to a worsening of HF after beta-blocker therapy.¹ Moreover, the combination of ACE inhibitor and aldosterone antagonist therapy has been associated, in one population-based time-series study, with a significant increase in hyperkalemia and associated morbidity and mortality, potentially negating the beneficial effects of these therapies in some patients.¹⁰¹ Finally, ACE inhibitors and beta-blockers do not always yield and maintain the necessary hemodynamic response for symptom control in advanced HF,¹ suggesting that additional supportive therapies are necessary. Despite the potential for complications, however, it is important to initiate and maintain these important therapies in all HF patients who do not present with signs of adverse effects.

Intermittent outpatient IV therapy

Inotropic agents have traditionally been used during episodes of ADHF when oral medications are inadequate to sufficiently control symptoms of fluid overload and decompensation. Despite a variety of specific mechanisms, including beta-adrenergic stimulation and phosphodiesterase inhibition, all positive inotropes ultimately increase contractility by increasing intracellular levels of cyclic adenosine monophosphate, leading to an increased release of calcium by the sarcoplasmic reticulum and an ultimate increase in cellular contractile force.¹⁰² These agents have the clinical effect of improving short-term hemodynamics at the expense of a documented increase in adverse events and mortality.^{88,103,104} For example, the inotrope dobutamine is a catecholamine and may exert a deleterious effect in patients with HF due to the exacerbation of underlying ischemia or malignant ventricular arrhythmias; the mechanism by which it increases cardiac contractility might also increase myocardial oxygen demand, resulting in excessive cardiac strain. Recent data also suggest that dobutamine might have a direct toxic effect on myocardial cells due to long-term adrenergic stimulation.¹⁰² Clinical data support the fact that dobutamine and other inotropes result in negative effects on HF in the long term, including the risk of arrhythmia, tachycardia, ischemia, resuscitated cardiac arrest, and early mortality.^{102,103,105-110} More recent data suggest that positive inotropes might indeed result in a deleterious neurohormonal activation that may partially account for the poor outcomes associated with these therapies.¹¹¹ Based on the risk profile and lack of efficacy demonstrated with inotropic agents, the current ACC/AHA guidelines state that not only is intermittent inotropic therapy not useful, but it may cause deleterious effects.¹ Inpatient inotropic support for HF patients with end-stage disease has been less controversial, but should still be used with caution on a primarily palliative basis.¹

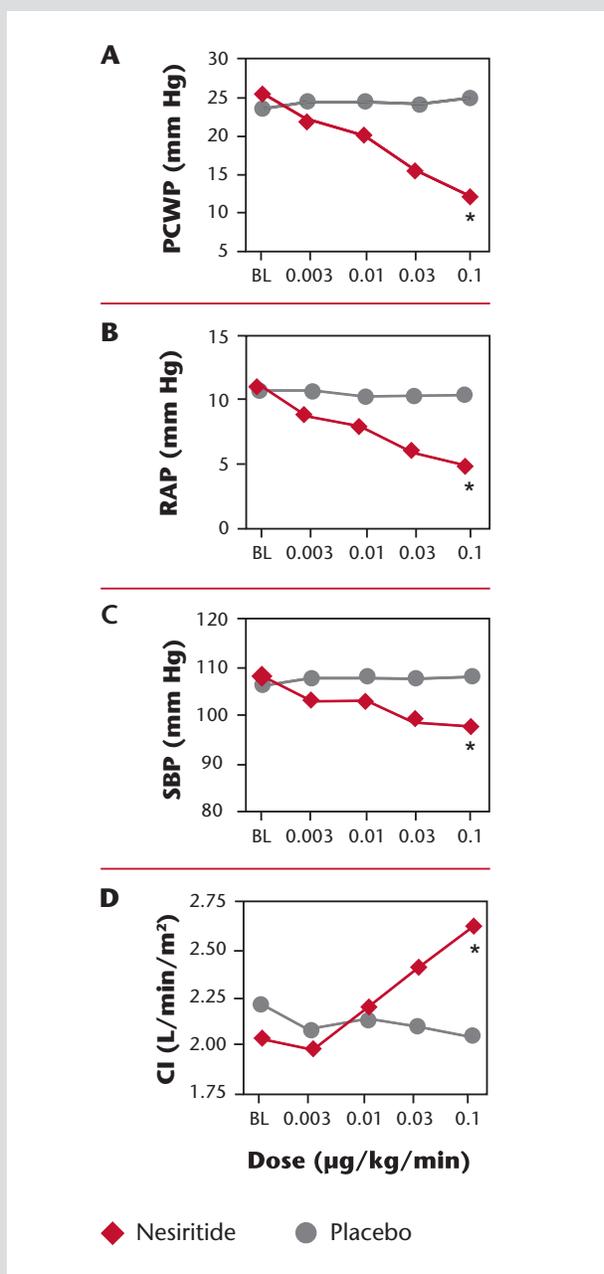
Figure 7. Opposition of neurohormonal forces in HF.



ANP, atrial natriuretic peptide; BNP, brain natriuretic peptide; RAAS, renin-angiotensin-aldosterone system.

Nesiritide is another IV therapy that might offer an improved efficacy and safety profile in patients suffering from ADHF. Nesiritide is a recombinant analog of hBNP, a counter-regulatory hormone produced by ventricles in response to pressure and volume overload.¹¹² The administration of nesiritide increases the circulating levels of BNP and overcomes the neurohormonal response initiated by HF (Figure 7).¹¹³ Similar to ACE inhibitors and beta-blockers, nesiritide independently counteracts this neurohormonal response observed in HF patients.¹¹⁴⁻¹¹⁹

Figure 8. Dose-related hemodynamic effects of nesiritide and placebo in heart failure patients.



(A) Pulmonary capillary wedge pressure (PCWP); (B) right atrial pressure (RAP); (C) systolic blood pressure (SBP); and (D) cardiac index (CI). BL, baseline. Adapted with permission from Marcus et al.¹²⁰

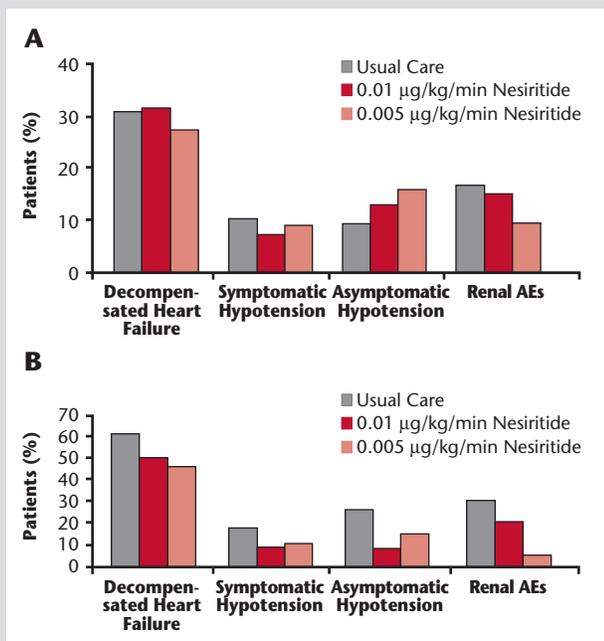
* $P < 0.01$ for nesiritide infusion vs placebo.

The increases in natriuresis and diuresis with nesiritide therapy produce dose-dependent reductions in pulmonary capillary wedge pressure, pulmonary artery pressure, and systolic blood pressure (Figure 8).^{117,118,120-122} Nesiritide has also demonstrated the ability to increase cardiac index without a subsequent increase in heart rate.^{117,120,122} Unlike positive inotropic therapy, nesiritide does not demonstrate inotropic or chronotropic effects,^{108,117,121,123} and is not proarrhythmic.^{108,110,124} When administered at recommended dosages, nesiritide results in predictable and sustained clinical effects that do not require invasive hemodynamic monitoring.⁸⁸ Although the pharmacologic properties of nesiritide have been associated with diuretic and renal benefits, recent data suggest that these benefits are not conferred in some patients. One study of 15 patients with chronic HF and worsening serum creatinine reported a lack of renal improvement after nesiritide therapy.¹²⁵ Controversy continues to exist as to whether nesiritide therapy confers additional benefits in all HF patients, and clinicians should understand the limitations of any planned regimen.

Recent trials have reported the efficacy of intermittent infusion therapy with nesiritide in the outpatient setting for appropriate patients. Bhaskaran et al described a weekly IV nesiritide regimen in 14 NYHA class III and IV patients who had persistent fluid overload despite maximum levels of standard therapy.¹²⁶ This 12-week regimen with nesiritide resulted in significant improvements in NYHA class, mitral valve regurgitation, pulmonary artery pressure, diastolic dysfunction, mean LVEF, and diuretic use.¹²⁶ Another study of IV nesiritide versus dobutamine in patients hospitalized with ADHF resulted in a 40% reduction ($P < 0.05$)

in hospitalizations within 20 days of initial discharge in nesiritide-treated patients.¹²⁷ Six-month mortality was also reduced in patients receiving nesiritide therapy.¹²⁷ Although these data suggest a benefit with nesiritide therapy, they should be interpreted with caution due to the open-label design and nonrandomized selection of therapies used in the study population. Finally, these data were further complicated by the fact that the doses of nesiritide used in this population were up to 3 times higher than the current recommended 2- $\mu\text{g}/\text{kg}$ bolus followed by an infusion of 0.010 $\mu\text{g}/\text{kg}/\text{min}$.¹²³

Figure 9. Selected adverse events (AEs) for (A) all and (B) high-risk patients through week 12 in the FUSION-I study. Renal AEs included increased blood urea nitrogen, increased serum creatinine, abnormal kidney function, acute kidney failure, and oliguria.



Note: The frequency of AEs was similar across treatment groups for each parameter measured.

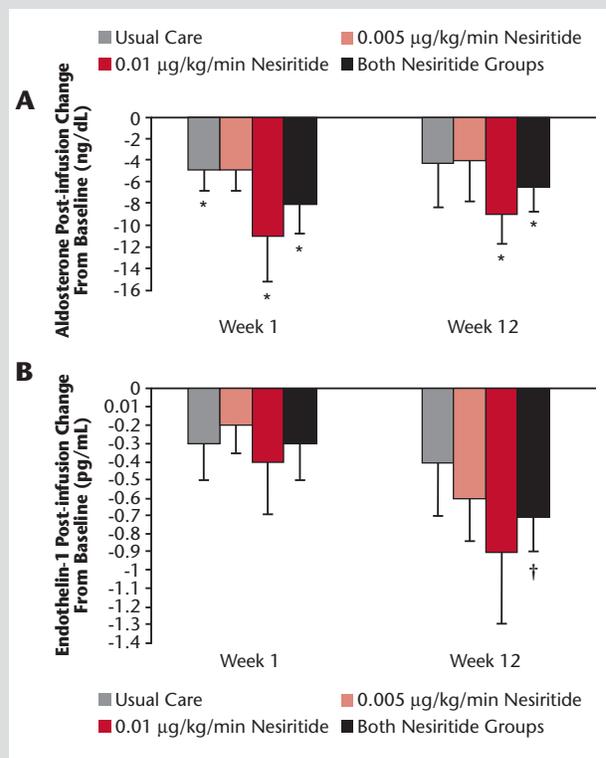
Adapted with permission from Yancy et al.¹³⁰

A study of intermittent nesiritide infusions in the outpatient setting has also reported promising results. Patients given maximum standard care for chronic decompensated HF received outpatient infusion therapy one to three times per week. Nesiritide infusions resulted in a 94% reduction in HF hospitalizations compared with the previous year, improvements in NYHA functional class in 89% of patients, and a reduction in diuretic dependence in 45% of patients.^{128,129}

A larger, multicenter, open-label evaluation reported similar positive findings. All enrollees were receiving the maximum tolerated doses of long-term oral therapy due to persistent episodes of ADHF. Patients were assigned to receive one of three treatment regimens over a 12-week period: standard care as determined by the investigator (including the possibility of inotropes) or nesiritide administered as a 2- $\mu\text{g}/\text{kg}$ bolus followed by a 4- to 6-hour 0.01- $\mu\text{g}/\text{kg}/\text{min}$ infusion or a 1- $\mu\text{g}/\text{kg}$ bolus followed by a 4- to 6-hour 0.005- $\mu\text{g}/\text{kg}/\text{min}$ infusion.¹³⁰ Compared with standard care, nesiritide, at both doses, significantly decreased the risk of death and rehospitalization in a sub-

group of high-risk patients.¹³⁰ All treatment groups reported improved quality of life over the course of the treatment period, and the rate of adverse events was similar between treatment groups (Figure 9).¹³⁰ Nesiritide administration in these patients also resulted in reductions in endogenous levels of aldosterone and endothelin-1 (Figure 10),¹³⁰ neurohormones that are implicated in deleterious HF symptoms and long-term remodeling.

Figure 10. Neurohormonal concentrations from the FUSION-I study. Changes (mean \pm SE) from baseline in (A) aldosterone and (B) endothelin-1 concentrations after infusion.



* $P < 0.02$ compared with baseline, † $P = 0.008$ compared with baseline. Adapted with permission from Yancy et al.¹³⁰

Clinicians who use nesiritide to manage patients with ADHF need to be aware that the administration of this agent can be associated with dose-related hypotension, which is the most common treatment-emergent adverse effect. The hypotension associated with nesiritide is usually mild or asymptomatic and often responds to a temporary discontinuation of infusion, followed by reinitiation at a lower dose upon resolution of the hypotension.^{120,121,124} Clinicians should keep in mind, however, that hypotension could persist due to nesiritide's relatively long pharmacodynamic half-life. The cost of nesiritide as compared with other therapies should also be considered when choosing appropriate therapeutic interventions, although the use of nesiritide in an outpatient setting to avoid hospitalization can result in significant pharmacoeconomic savings.

Although preliminary findings suggest that nesiritide might offer an efficacious and safe alternative to outpatient inotropic support in patients suffering from chronic ADHF, further studies will be needed to fully characterize the regular use of nesiritide in these patients.

Conclusion

HF is responsible for substantial rates of morbidity, mortality, and healthcare utilization, especially in the elderly population of patients eligible for Medicare. A substantial source of this burden is due to a significant treatment gap between current disease management practices and evidence-based clinical guidelines. Inpatient and outpatient disease management programs, HF clinics, home visitations, and telemedicine have all proven effective in enhancing adherence to evidence-based clinical guidelines, leading to reductions not only in morbidity and mortality but, ultimately, in the cost of treating patients who have HF. The early initiation of effective HF therapies in the emergency department and HF observation unit especially leads to decreases in both the frequency and duration of hospitalizations. Medical practitioners should be willing to champion the implementation and utilization of programs proven to enhance adherence to evidence-based HF regimens.

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(References continued on page 31)

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Post-Test

Please choose the single correct answer for each question.

1. Which of the following is *not* a JCAHO core performance measure?
 - a. Smoking cessation counseling
 - b. Weight management counseling
 - c. ACE inhibitor prescription to patients with documented LVEF
 - d. LVEF documentation
2. Which of the following features is (are) cited as critical to a successful disease management program?
 - a. Targeted patient population
 - b. Adherence to evidence-based practice guidelines
 - c. Process for outcomes measurement
 - d. All of the above
3. Which follow-up strategy has been most successful and cost-effective following hospital discharge due to HF?
 - a. Skilled nursing home visit follow-up
 - b. Primary care office follow-up
 - c. Cardiologist office follow-up
 - d. None of the above
4. Which of the following therapies has *not* demonstrated consistent efficacy and is *not* considered a component of standard care for the long-term management of HF?
 - a. ACE inhibitor therapy
 - b. Beta-blocker therapy
 - c. Diuretic therapy
 - d. Positive inotropic therapy
5. Which of the following statements is *true*?
 - a. The majority of costs of HF hospitalization accrue within the first 48 hours following admission.
 - b. Outpatient HF treatment strategies have not demonstrated significant cost savings.
 - c. Disease management using telemonitoring strategies has not been effective for HF.
 - d. All of the above
6. Despite advances in treatment options, HF has been responsible for steady or increasing rates in _____ over the past 30 years.
 - a. mortality
 - b. multiple hospitalizations
 - c. significant pharmacoeconomic burden
 - d. all of the above
7. Nesiritide has demonstrated the ability to decrease all of the following measurements in patients with ADHF *except*:
 - a. pulmonary capillary wedge pressure
 - b. pulmonary arterial pressure
 - c. cardiac index
 - d. systemic blood pressure
8. What is the most common adverse effect associated with nesiritide use?
 - a. Arrhythmia
 - b. Tachycardia
 - c. Ischemia
 - d. Hypotension
9. Patients presenting with ADHF should *not* be managed in the emergency department or HF observation unit setting if they demonstrate:
 - a. ongoing ischemic chest pain
 - b. mild hypotension
 - c. systolic blood pressure <85 mm Hg
 - d. a and c
10. Innovative disease management systems have made use of all of the following *except*:
 - a. physician home visits
 - b. remote diagnostic devices
 - c. nurse home visits
 - d. interactive decision-support software



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Answer Form				
Please circle the letter that represents your answer for each question.				
1.	a	b	c	d
2.	a	b	c	d
3.	a	b	c	d
4.	a	b	c	d
5.	a	b	c	d
6.	a	b	c	d
7.	a	b	c	d
8.	a	b	c	d
9.	a	b	c	d
10.	a	b	c	d

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Activity Evaluation

Please rate this activity on the following elements (circle your responses).

5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor

1. Activity topic and content

5 4 3 2 1

2. How well activity met your expectations

5 4 3 2 1

3. Level of difficulty of material

5 4 3 2 1

4. Applicability of activity examination questions

5 4 3 2 1

5. Activity was objective, fair balanced, and free of commercial influences

5 4 3 2 1

6. Usefulness of information to your practice

5 4 3 2 1

7. How well activity met each of its stated goals and objectives:

- Cite the morbidity, mortality, and economic burden of HF

5 4 3 2 1

- Explain the treatment gap between evidence-based therapies for HF and the typical medical management of patients with HF

5 4 3 2 1

- Identify specific roles for nurses and clinical pharmacists in the management of HF

5 4 3 2 1

- Discuss the impact of HF clinics, multidisciplinary disease management teams, telemonitoring, and emergency department/observation units on the management of patients with HF

5 4 3 2 1

- Describe therapeutic options for managing HF, including long-term therapy and intermittent outpatient IV therapy

5 4 3 2 1

8. Overall opinion of the activity

5 4 3 2 1

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