ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:
Heart Failure in Adults

Eleventh Edition
December 2009

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

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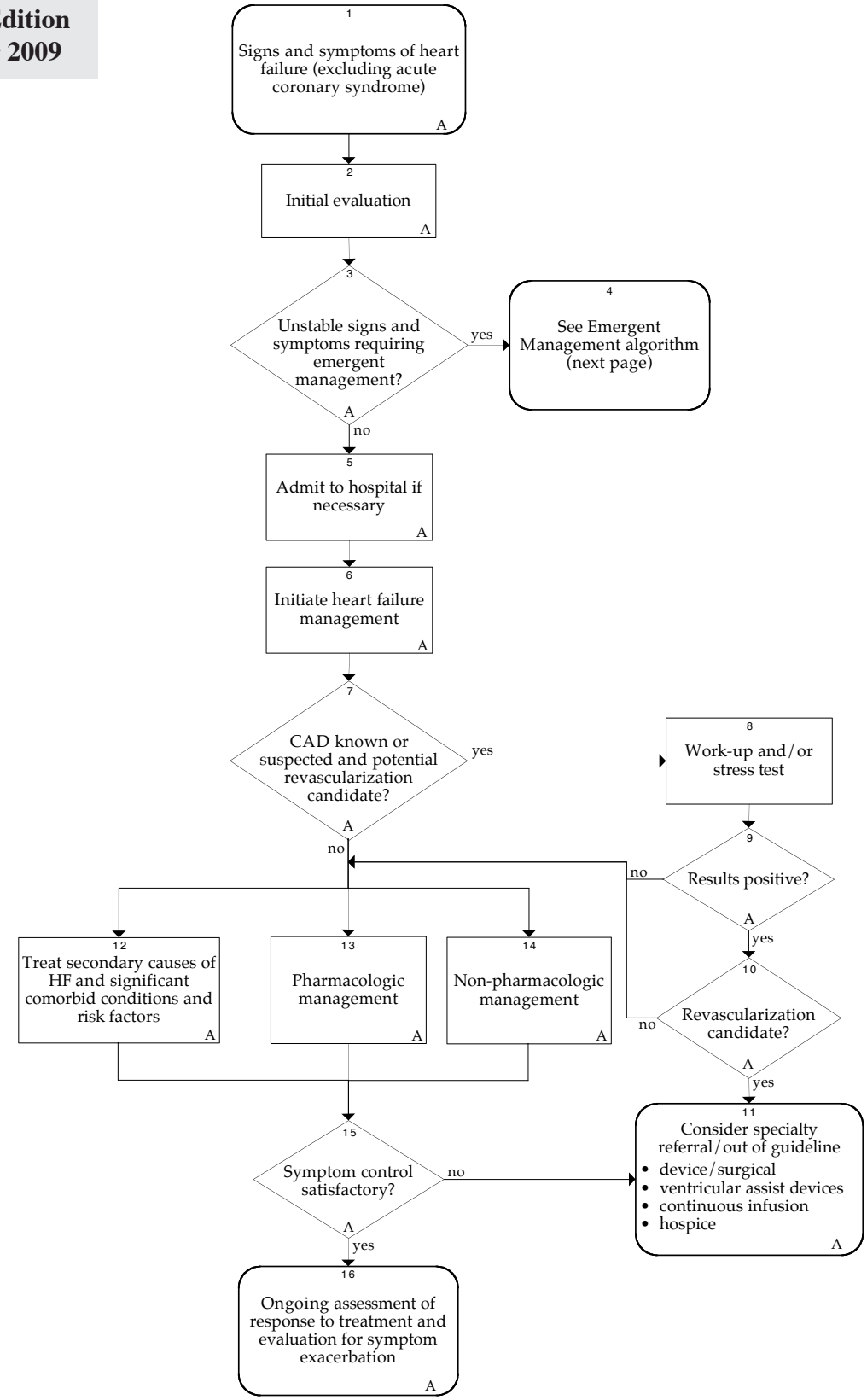
Main Algorithm

A = Annotation



Emergent Management Algorithm

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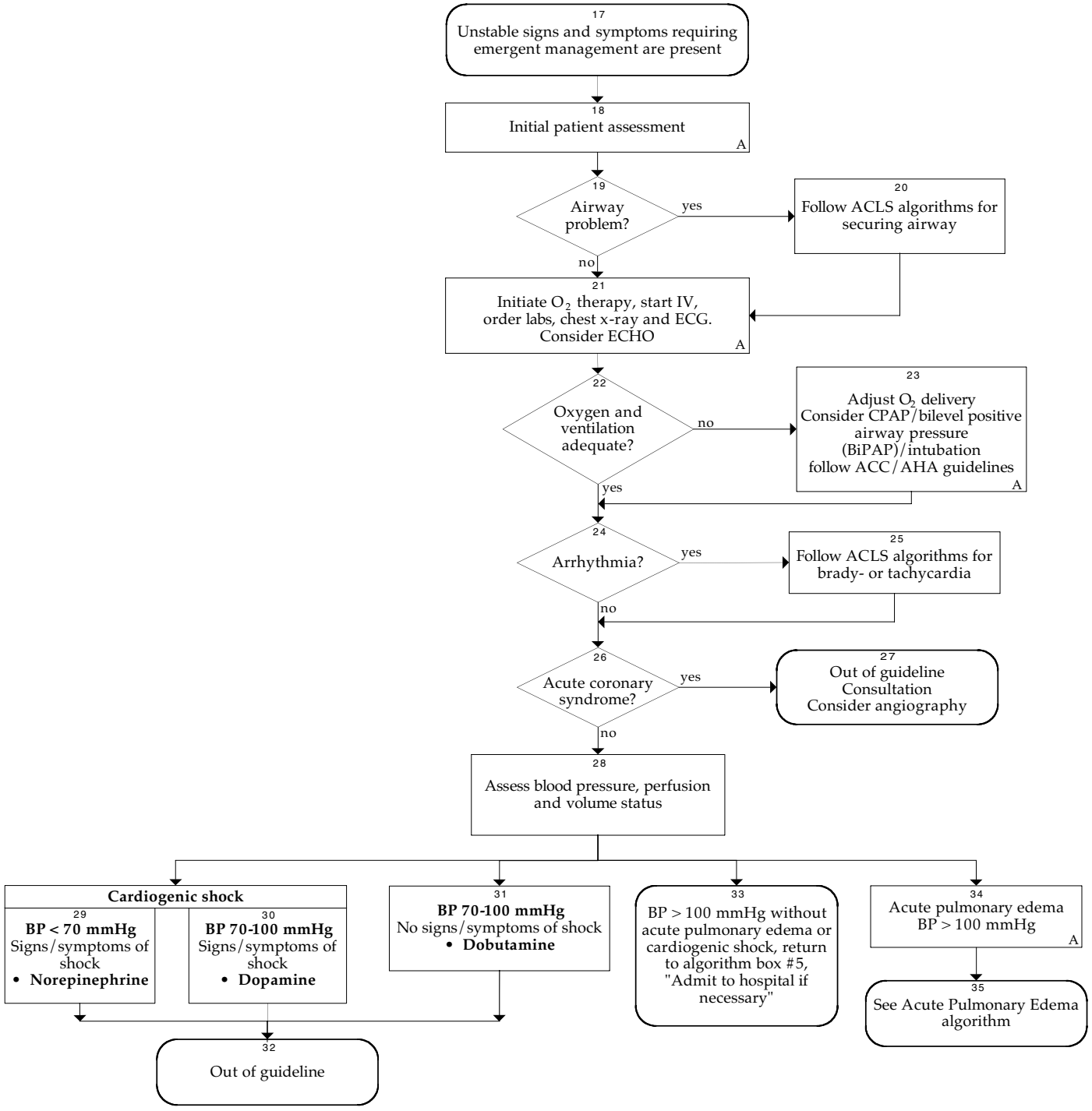
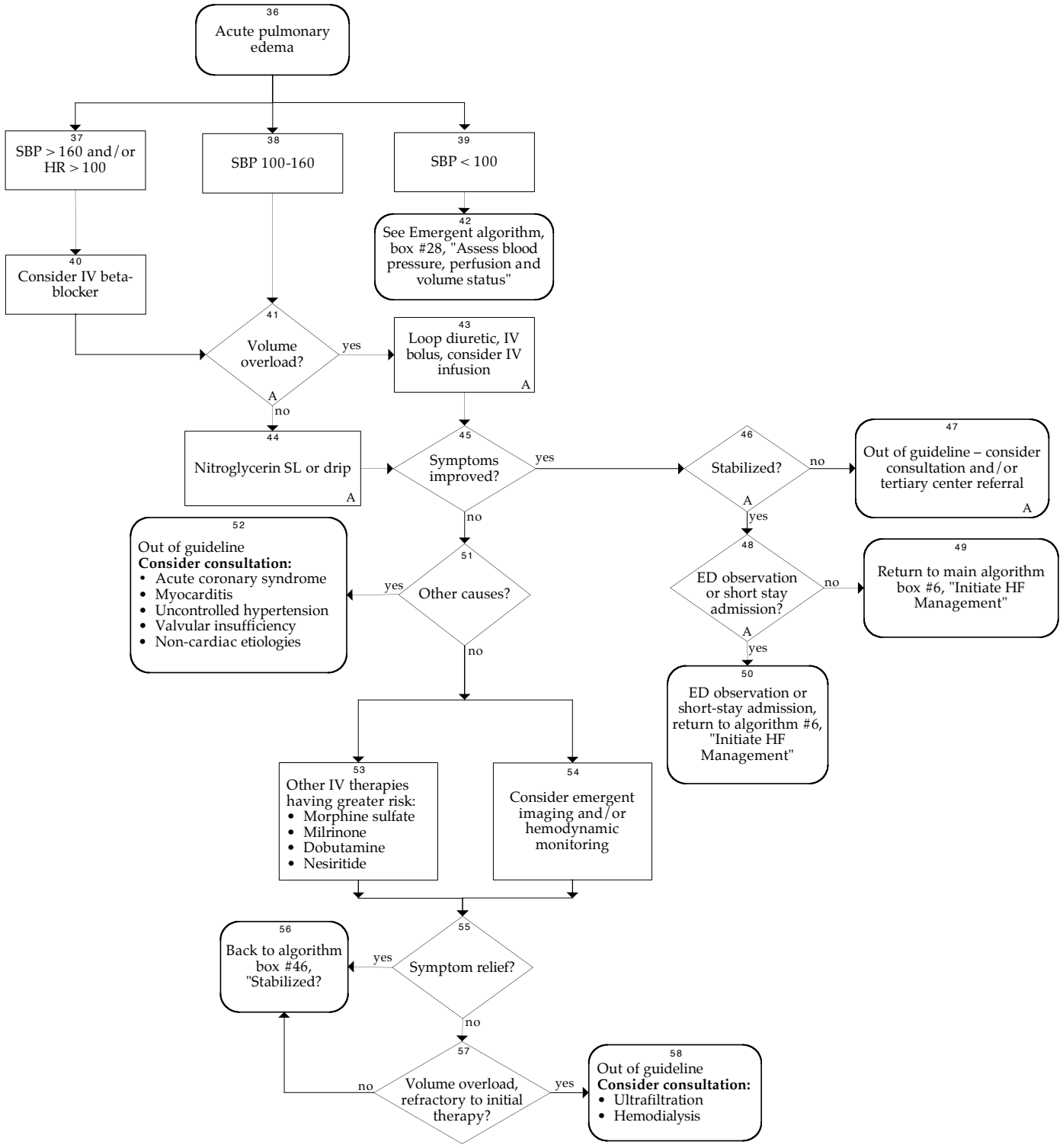


Acute Pulmonary Edema Algorithm

A = Annotation



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Foreword

Scope and Target Population

The management of adult patients age 18 and older with suspected heart failure and heart failure requiring hospitalization.

Clinical Highlights and Recommendations

- Evaluate patients presenting with heart failure for exacerbating and underlying causes, including coronary artery disease, hypertension, valvular disease and other cardiac and non-cardiac causes. *(Annotation #2)*
- Studies show that the distinction between systolic dysfunction and preserved systolic function is important, because the choice of therapy may be quite different and some therapies for systolic dysfunction may be detrimental if used to treat preserved systolic function. *(Annotation #2; Aim #3)*
- Daily weights are critical for managing heart failure and early detection of increases in fluid retention. Patients should call their provider about a two-pound or greater weight gain overnight or a five-pound or greater weight gain in a week. Patients can expect the provider to assess symptoms, adjust diuretics if appropriate, discuss dietary sodium compliance/restriction, review treatment plan, and recommend appropriate level of care (office visit, ER, etc.) *(Annotation #14; Aim #4)*
- Unless specific contraindications exist, treat all patients, including Class IV patients, with beta-blockers, starting with a low dose and titrating upward. *(Annotation #13; Aim #2)*
- Treat all patients with left ventricular systolic dysfunction with ACE inhibitors (or ARBs if intolerant) unless specific contraindications exist. *(Annotation #13; Aim #2)*
- Consider early specialty referral for patients with ischemia or those who are refractory despite optimal medical therapy. *(Annotation #11)*
- Brain natriuretic peptide (BNP) and NTproBNP are useful in the diagnosis and prognosis of heart failure in patients with dyspnea of unknown etiology. *(Annotation #2)*
- For patients self-described as African Americans, who have moderate-to-severe symptoms on optimal therapy with ACE inhibitors, beat-blockers and diuretics, the combination of hydralazine and nitrates is recommended because the combination has resulted in significant benefit to the group in randomized controlled trials. *(Annotation #13)*

Priority Aims

1. Decrease the readmission rate within 30 days of discharge following hospitalization for heart failure.
2. Optimize the pharmacologic treatment of adult patients with heart failure.
3. Improve the use of diagnostic testing in order to identify and then appropriately treat adult patients with heart failure.
4. Improve care of adult heart failure patients by assuring comprehensive patient education and follow-up care.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Develop a process that will allow primary care providers to identity patients who have been readmitted to the hospital with a diagnosis of heart failure.
2. Emphasize patient self-management strategies. These may include heart failure education and other actions designed to sustain engagement of patients with their heart failure care.
3. Develop a process to provide education to the patient and/or caregiver in the area of:
   - diet,
   - weight monitoring (to include: provider should be contacted about a two-pound or greater weight gain overnight or a five-pound or greater weight gain during the week),
   - activity level,
   - medications,
   - the importance of follow-up appointments, and
   - what to do if symptoms worsen.
4. Develop a process for timely, early specialty referral for patients with ischemia or those who are refractory despite optimal medical therapy.

Related ICSI Scientific Documents

Guidelines

- Antithrombotic Therapy Supplement
- Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS)
- Hypertension Diagnosis and Management
- Lipid Management in Adults
- Major Depression in Adults in Primary Care
- Palliative Care
- Stable Coronary Artery Disease
- Venous Thromboembolism Diagnosis and Treatment
- Venous Thromboembolism Prophylaxis

Order Sets

- Admission for Heart Failure Order Set
- Discharge for Heart Failure Order Set
- Emergent Orders for Heart Failure Order Set
- Venous Thromboembolism Prophylaxis for the Medically Ill Patient Order Set

Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

Robert Straka, PharmD has received honoraria from Pfizer Novartis and Schering-Plough in the amounts of $2,000; $1,500; and $2,000 respectively. The only engagement for which a marketed product was involved was Novartis Aliskiran. Mr. Straka served one time as a consultant to ARCA Pharmaceuticals for a product that is not currently on the market; he received honoraria in the amount of $1,500.

Stephen L. Kopecky, MD is a consultant for and has received honoraria in the amount of $1,500 from Glaxo Smith Kline. Dr. Kopecky is on the advisory board for Biophysical.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining input from and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A:	Randomized, controlled trial
Class B:	Cohort study
Class C:	Non-randomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study
Class D:	Cross-sectional study Case series Case report

B. Reports that Synthesize or Reflect Upon Collections of Primary Reports:

Class M:	Meta-analysis Systematic review Decision analysis Cost-effectiveness analysis
Class R:	Consensus statement Consensus report Narrative review
Class X:	Medical opinion

Citations are listed in the guideline utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Algorithm Annotations

Introduction

Heart failure is the term to describe the condition of the heart's failure to meet the body's metabolic demands with the symptomatic result of dyspnea, fatigue and cough. It is key to understand that the symptoms may be due to systolic dysfunction emanating from the right or left side of the heart, or may occur with preserved systolic function. This guideline delineates how to establish the etiology of heart failure and begin treatment. However, there is little data to guide us on which treatment is more beneficial in diastolic or systolic dysfunction. Until further studies are done, we will continue to use the term heart failure to apply to all of these symptomatic entities *(Persson, 2007 [A])*.

Heart failure is a major health problem in the United States, and the incidence of the disease is projected to increase. It was the most frequent diagnosis of Medicare patients discharged from the hospital in 2001. There are an estimated 5 million individuals currently diagnosed with heart failure, 550,000 new cases diagnosed annually, 1 million people hospitalized annually (including readmission rates of 30% to 60%), and over 260,000 annual deaths from heart failure. From 1979 to 2000, heart failure death rates increased 148% and hospital discharges increased 165%. Heart failure is a syndrome with many etiologies. Overall, 75% of patients have previously diagnosed hypertension. Of patients admitted with pulmonary edema, 85% have ischemic disease, 70% hypertension, 53% valvular lesions, and 52% with diabetes *(Edoute, 2000 [D])*. The prognosis of patients with a new diagnosis of heart failure is poor. Senni, et al. (1998) noted survival to be 86% at three months, 76% at one year, and only 35% at five years *(Senni, 1998 [B])*.

The outpatient treatment for heart failure has improved dramatically with the advent of neurohormonal and device approaches, patient education, and care or disease management strategies, in addition to traditional diuretic, digoxin and vasodilator therapy. Inpatient treatment has improved in many respects due to the aforementioned medications, improved imaging and physiologic monitoring, and early intervention for ischemic etiologies. However, decompensated heart failure remains problematic, in particular the treatment of acute pulmonary edema.

According to Felker et al., "the syndrome of decompensated heart failure remains poorly defined and vastly understudied *(Felker, 2003a [R])*. Few high-quality epidemiologic studies, randomized controlled trials, or published guidelines are available to guide the management of this complex disease. In addition, there is no consensus definition of the clinical problem that it presents, no agreed-upon nomenclature to describe its clinical features, and no recognized classification scheme for its patient population; all of which has contributed to the lack of therapeutic development in this critical arena of cardiovascular disease." The Adhere registry data is helpful in elucidating the heterogeneity of the population and treatments utilized currently.

Although heart failure is generally regarded as a hemodynamic disorder, there is a poor correlation between measures of cardiac performance and the symptoms produced by the disease. Patients with a very low ejection fraction (EF) may be asymptomatic, whereas patients with preserved left ventricular ejection fraction (LVEF) may have severe disability. The apparent discordance between EF and the degree of functional impairment is not well understood but may be explained in part by alterations in ventricular distensability, peripheral vascular resistance, valvular regurgitation, pericardial restraint, cardiac rhythm, conduction abnormalities and right ventricular function. As patients with reduced EF may have diastolic dysfunction in addition to systolic dysfunction, and patients with preserved EF may have both systolic and diastolic dysfunction, the ACC/AHA prefer the terminology heart failure (HF) with preserved ejection fraction (HFPEF) and heart failure with reduced ejection fraction (HFREF).

Mostly driven by clinical trial design, heart failure has nevertheless been dichotomized according to LVEF as heart failure with preserved ejection fraction (HFPEF) or heart failure with reduced ejection fraction (HFREF). Heart failure occurs at any level of left ventricular ejection fraction (LVEF). Most intervention

trials have shown significant benefits in trials with HFREF, but shown an unexplained resistance to therapy (especially to renin-angiotensin-aldosterone system inhibition) in HFPEF. Depending on the criteria used to delineate heart failure and the accepted threshold for defining preserved LVEF, it is estimated that as many as 20% to 60% of patients with heart failure have a relatively (or near) normal LVEF and, in the absence of valvular disease, are believed to have reduced ventricular compliance as a major contributor to the clinical syndrome.

In the Framingham Heart Study, patients presenting with heart failure were studied *(Lee, 2009 [C])*. They were divided into two groups with a cutoff LVEF of < 45%. The survival data did not differ between the two groups. Large registries have established that the distribution of LVEF in heart failure is unimodal. LVEF is a powerful prognostic parameter – when decreased – and useful in daily clinical practice to obtain a first impression of global ventricular pump performance during disease staging. Until further data is available, heart failure (HF) will continue to be separated into two groups - heart failure with preserved ejection fraction (HFPEF) or heart failure with reduced ejection fraction (HFREF). There is robust evidence to support current management recommendations for HFREF.

(Hogg, 2004 [R]; Hunt, 2000 [R]; Solomon, 2005 [A])

As the reader will see in this guideline's clinical algorithms, many of the recommendations for stable heart failure patients have a solid foundation in evidence-based medicine. In contrast, the acute pulmonary edema (APE) algorithm presents areas of weaker or absent evidence for some traditional therapies. The ICSI Heart Failure in Adults guideline will, it is hoped, serve to promote evidence-based dialogue and highlight the need for research in this extremely important disease *(American Heart Association, 2002 [R])*.

Other related guidelines for heart failure include the ACC/AHA Congestive Heart Failure guidelines, Pacemaker guidelines, and the Heart Failure Society of America guidelines.

Algorithm Annotations

Main Algorithm Annotations

1. Signs and Symptoms of Heart Failure (Excluding Acute Coronary Syndrome)

Signs and Symptoms of Congestion:

- Dyspnea
- Orthopnea
- Paroxysmal nocturnal dyspnea (PND)
- Cough (recumbent or exertional)
- Abdominal or epigastric discomfort
- Abdominal bloating (ascites)
- Early satiety
- Hemoptysis, frothy or pink-tinged sputum
- Pedal/leg swelling
- Weight gain (rapid)
- Sleep disturbances (anxiety or air hunger)
- Chest tightness or discomfort
- Unexplained confusion, altered mental status, or fatigue
- Nausea or anorexia
- Dependent edema

Signs and Symptoms of Poor Perfusion/Low Cardiac Output:

- Easy fatigability
- Poor energy level or endurance
- Decreased exercise tolerance
- Cachexia
- Muscle wasting or weakness
- Nausea or anorexia
- Early satiety
- Weight loss, unexplained
- Malaise
- Impaired concentration or memory
- Sleep disturbance
- Altered mentation (somnolence, confusion)
- Resting tachycardia
- Daytime oliguria with recumbent nocturia
- Cool or vasoconstricted extremities
- Cheyne-Stokes respiration (with or without apnea)

See Appendix A for the New York Heart Association Classification and ACC/AHA Staging System.

2. Initial Evaluation

Key Points:

- The diagnosis of heart failure should not be a single diagnosis. It is important to identify the etiology or precipitating factors as a cause of heart failure.
- It is important to determine whether ventricular dysfunction is systolic or diastolic, because therapies are quite different. Some therapies for systolic dysfunction may even be harmful if used to treat preserved systolic function.
- Ischemia is responsible for the majority of cases of heart failure. Two-thirds of systolic heart failure is due to ischemic heart disease. Identifying ischemia as a cause of heart failure is important, because a majority of these patients would benefit from revascularization.

The purpose of the initial evaluation, whether in the inpatient or outpatient setting, should be to confirm a diagnosis of heart failure and identify an etiology/precipitating factor(s).

Early triage should be performed to determine whether emergent or inpatient care is needed. Early identification of acute ischemia as the cause of heart failure is important, because prompt reversal of ischemia may impact outcome.

Consider consultation with cardiology during the initial evaluation and any time that it is felt appropriate in the ongoing management of heart failure patients.

Questions to Determine Severity:

A. History

Presenting symptoms

- Dyspnea/PND/orthopnea
- Recent weight gain
- Chest pain
- Palpitations
- Cough/sputum production
- Claudication
- Exercise tolerance
- Fatigue

- Blood loss/causes of anemia
- Recent fevers/viral infection
- Edema/ascites
- Color changes

Past medical history

- History of congestive heart failure (HF)
- History of myocardial infarction (MI)
- Cardiac risk factors
- Hypertension/smoking/diabetes/hyperlipidemia
- History/risk factors for thromboembolic disease
- History of thyroid dysfunction
- Recently postpartum
- History of snoring/sleep apnea
- Blunt chest injury
- Rheumatic fever
- HIV
- Bacterial endocarditis
- Claudication
- Screen for depression
- Foreign travel

Family history

- Screen for family history of ischemic heart disease, HF, congenital heart disease, risk factors for athero-sclerotic cardiovascular disease (ASCVD) and HF

Social history

- Smoking
- Alcohol use/abuse screen
- Drug abuse

Dietary history

- Salt and daily fluid intake
- Balanced diet

B. Physical Exam

- Vital signs, including weight and height
- Diaphoresis
- Diminished peripheral pulse or bruit
- Skin color: cyanosis, pallor, jaundice
- Lower extremity edema in the absence of venous insufficiency
- Elevated jugular venous pressure, positive hepato-jugular reflux
- Heart rate: tachycardia, bradycardia/arrhythmias
- Left lateral displacement of point of maximal impulse (PMI)
- Heart sounds: S3, S4 or murmur
- Lungs: labored breathing, rales above the lower 25% of the lung that do not clear with cough
- Abdomen: large, pulsatile, or tender liver or ascites

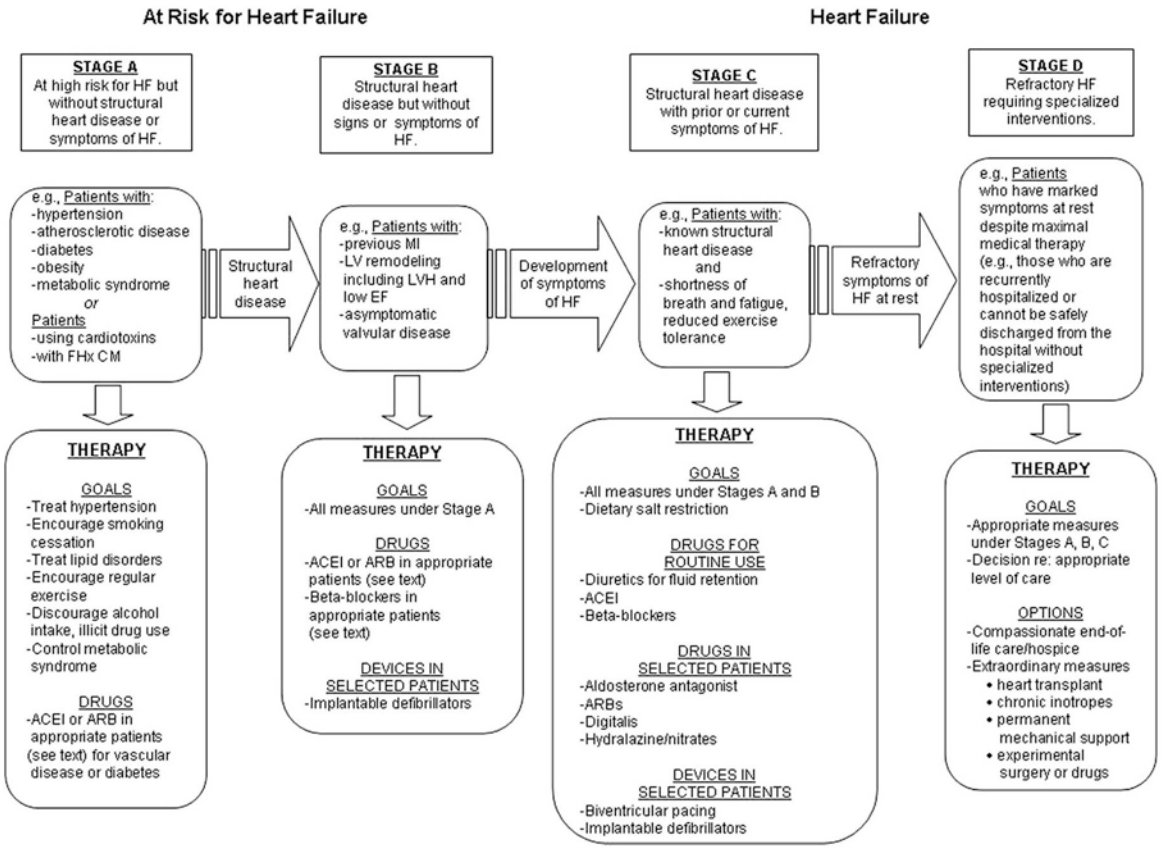
(Hunt, 2001 [R]; Jessup, 2009 [R])

C. Initial Laboratory Evaluation

- **Initial**
  - Complete blood count
  - Electrolytes (Na^+, K^+) and Cl^-, Bicarb, $Ca^{++,}$ MG^{++} (if on diuretics)
  - Renal function (BUN, Cr)
  - Liver function (AST, ALT, Alk phos, Bili, T Prot, Alb)
  - Urinalysis
  - Sensitive TSH (sTSH)
  - PT/INR
- **Inpatient/emergency department**
  - Arterial blood gases
  - Tests for myocardial injury: troponin, CK/CKMB
  - BNP
- **Other causes**
  - Ferritin/iron/TIBC/macrocytic anemias
  - Lipid profile
  - Blood culture if endocarditis suspected
  - Lymes serology (if suspect bradycardia/heart block)
  - Connective tissue disease work-up
  - HIV

(Hunt, 2001 [R]; Remme, 2001 [R])

Figure 1. ACC/AHA Heart Failure Grading



This figure was published in the Journal of the American College of Cardiology, Vol 53, Hunt SA, Abraham WT, Chin MH et al, 2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults, e1-90, Copyright Elsevier (2009).

Role of Brain Natriuretic Peptide (BNP)/NTproBNP in the Diagnosis and Management of Heart Failure

Brain natriuretic peptide (BNP) and NTproBNP assays have been found useful in the correct diagnosis of patients with dyspnea, especially when the patient has a history of pulmonary disease and/or cardiac disease. Since BNP and NTproBNP concentrations correlate positively with cardiac filling pressures, measurement of a low concentration make it unlikely that dyspnea is due to cardiac dysfunction.

The use of BNP/NTproBNP as a risk stratification technique has shown to reduce the length of hospitalization *(Mueller, 2004 [A])*. In patients with and without heart failure, BNP levels are inversely related to BMI *(McCord, 2004 [C])*. Also, the use of BNP or NTproBNP in conjunction with troponin has been shown to have significant incremental predictability on in-hospital mortality *(Fonarow, 2008 [B])*.

Persistent elevation of plasma BNP and NTproBNP despite optimum medical therapy also has prognostic significance. In hospitalized patients, persistent elevation of BNP/NTproBNP prior to discharge from the hospital is predictive of risk of death or readmission *(Hartmann, 2004 [C]; Logeart, 2004 [C])*.

The normal ranges of BNP and NTproBNP are age and sex dependent. In patients with chronic renal insufficiency, BNP levels may not be indicative of heart failure. In general a BNP less than 100 pg/mL helps

exclude a cardiac cause of dyspnea, BNP greater than 500 pg/mLwas highly specific and prognostic for short-term increased mortality risk. For those patients between 100 pg/mL and 500 pg/mL, which was about 26% of subjects in a BNP trial, two-thirds had heart failure and one-third did not. NTproBNP less than 125 pg/mL (for persons younger than 75 years) or less than 450 pg/mL (for persons older than 75 years) helps exclude a cardiac cause of dyspnea. BNP/NTproBNP is correlated with the severity of heart failure in patients with heart disease. However, there is currently insufficient evidence to support the use of BNP/NTproBNP to monitor outpatient therapy.

(Jourdain, 2007 [A]; Maisel, 2007 [R]; Redfield, 2002 [D]; Troughton, 2000 [A])

D. Diagnostic Tests

- Electrocardiogram
- Chest radiograph
- Assessment of ventricular function (echocardiogram, radionuclide ventriculography)
  - It is reasonable to reassess ejection fraction if patient is clinically decompensated or after patient has been titrated up to target doses of beta-blockers and ACE inhibitors.
- Ischemia evaluation in patients with CAD risk factors (stress test, angiography). Refer to ICSI Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS) guideline.

An electrocardiogram and a chest radiograph are fundamental parts of the initial evaluation for heart failure. In addition, the objective evaluation of ventricular performance is also a critical part for patients with suspected or known heart failure. Objective evaluation of left ventricular (LV) function is necessary because CXR, ECG and H&P often fail to distinguish normal from low EF in patients with heart failure *(Aguirre, 1989 [D]; Grossman, 1991 [R]; Soufer, 1985 [D]; Vasan, 1995 [M])*.

Specific etiologies of ventricular dysfunction

Studies show that the distinction between systolic dysfunction and diastolic dysfunction with preserved systolic function is important, because the choice of therapy may be quite different, and some therapies for systolic dysfunction may be detrimental if used to treat patients with primarily diastolic dysfunction. *(Owan, 2006 [C]; Topol, 1985 [C])*.

Diastolic dysfunction of mild degree is commonly associated with systolic dysfunction, but isolated diastolic dysfunction may be seen with left ventricular hypertrophy, myocardial ischemia, constrictive pericarditis or cardiac tamponade, or in the case of infiltrative diseases such as amyloidosis or in long-standing hypertension *(Persson, 2007 [A])*.

Interpretation of ventricular function testing

Congestive heart failure is a clinical syndrome that correlates poorly with ejection fraction. Some patients may have symptoms based on systolic dysfunction (heart failure with reduced ejection fraction [HFREF]), while others have heart failure with diastolic dysfunction and preserved systolic function (heart failure with preserved ejection fraction [HFPEF]). Measurement of LV function provides important prognostic information.

Objective assessment of left ventricular (LV) function is necessary because CXR, ECG and H&P often fail to distinguish normal from low EF in patients with heart failure.

Measurement techniques

Both echocardiography and radionuclide ventriculography may be used to measure left ventricular performance. Both methods are reasonably accurate and reproducible for the assessment of systolic

dysfunction, but may be influenced by operator technique and ventricular loading conditions. In general it is appropriate to think of the EF measurement in an individual patient at a particular point in time as being an estimate with a range of ± 5%. Reproducible and operator independent quantitative assessment of preserved systolic function is more difficult and may be influenced by changes in ventricular preload and afterload at the time of the test.

Measurements may vary with changes in the underlying disease process or with differences in systolic or diastolic ventricular loading conditions. Hence, they may change over time because of progression or regression of the underlying ventricular muscle dysfunction, and/or with changes in therapy as well as the level of hydration at the time of measurement. It is reasonable to reassess ventricular function after interventions or when symptoms have changed significantly. Changes in ventricular function may imply a change in prognosis and may require changes in therapy.

The quantitative assessment of systolic function does not imply an understanding of the underlying etiology of the ventricular dysfunction. Care must be taken to determine the cause of dysfunction so that specific therapy can be instituted, (e.g., treatment of ischemia, valve disease, hypertension, pericardial disease, hyperthyroidism).

The quantitative assessment of ventricular function is essential for the proper classification of the type of ventricular dysfunction and of the severity of dysfunction. Quantitative measurement is valuable for prognosis, as well as for the serial assessment of the response to therapy.

Table 1: Measurement Techniques of LV Function

Test	Advantage	Disadvantages
Echocardiogram	• Permits concomitant assessment of valvular disease, left ventricular hypertrophy, and left atrial size • Able to detect pericardial effusion and ventricular thrombus • More generally available • Can be done at time of stress testing • Can assess RV function	• Difficult to perform in patients with lung disease • Usually only semiquantitative estimate of ejection fraction provided • Technically inadequate in approximately 10% of patients under optimal circumstances
Radionuclide ventriculogram	• More precise and reliable measurement of ejection fraction • Can be done at time of stress testing	• Requires venipuncture and radiation exposure and regular R-R intervals • No assessment of valvular heart disease and left ventricular hypertrophy
Left ventriculogram	• Can be done at the time of coronary angiography • Can assess for mitral regurgitation and systolic function • Can measure pressure, particularly in diastolic filling pressure	• Invasive procedure that requires increased dye load with potential renal insufficiency and/or hypotension • Does not assess diastolic function or right ventricular function
MRI	• Most precise method for determining LV function, size and mass	• Requires patient to be in normal sinus rhythm and be able to suspend respiration for a short period of time • Can be difficult to perform in critically ill and unstable patients
Right heart catheterization (Swan-Ganz)	• Useful when bedside assessment of volume status is unclear	• Invasive procedure and does not assess coronary arteries or valvular heart disease • An indirect measure of LV function
Non-invasive Bioimpedence Hemodynamics	• Non-invasive measure of thoracic fluid	• Poor reliability • An indirect measure of LV function

In patients with CAD and angina, patients with suspected CAD as a cause of heart failure or patients with LV dysfunction but without angina, coronary angiography may be the investigation of choice to determine coronary anatomy and the need for revascularization. In patients in whom coronary artery disease has been excluded previously as the cause of left ventricular dysfunction, repeated invasive or non-invasive assessment for ischemia is generally not indicated.

Magnetic resonance imaging or computed tomography may be useful in evaluating ventricular mass, detecting right ventricular dysplasia or recognizing the presence of pericardial disease.

E. Assess for Causative and Precipitating Factors

Causes of heart failure can be classified as cardiac and non-cardiac. Refer to tables 2 (Cardiac-Related Causes of Heart Failure with Reduced Systolic Function) and 3 (Non-Cardiac Related Causes) for the salient features of the more common causes.

In patients with heart failure symptoms, it is important to determine if they have left or right ventricular systolic dysfunction or preserved systolic function. One-third of patients have predominantly preserved systolic function, one-third have both systolic and diastolic dysfunction and one-third have predominantly systolic dysfunction.

Diastolic dysfunction is difficult to measure. Doppler echocardiography is currently the method of choice to assess diastolic dysfunction. It is, however, technically difficult and requires expert interpretation. Furthermore, loading conditions affect mitral inflow pulsed-wave doppler parameters. Without tissue doppler imaging techniques, determining normal and pseudonormal diastolic filling pattern can be difficult. Pulmonary venous (PV) flow doppler and changes in mitral inflow parameters during valsalva maneuver can be used to distinguish pseudonormal and normal diastolic function. However, tissue doppler is now commonly used to differentiate these two patterns as well as estimate the left ventricular filling pressure. BNP and NTproBNP measurements may help in the diagnosis of heart failure (HF) in patients with preserved EF. Values are in general lower (though often abnormal) in these patients compared to those with systolic dysfunction. About two-thirds of patients with heart failure (HF) with preserved ejection fraction (EF) have moderate to severe diastolic dysfunction *(Bursi, 2006 [C]; Persson, 2006 [A])*.

The community prevalence of heart failure with preserved EF is high, and among these patients, most have preserved systolic function. Heart failure with preserved ejection fraction (HFPEF) has increased in prevalence over time. Patients with preserved ejection fraction (EF) are older, are more likely to be women, are less likely to be smokers or have a history of MI, and have a lower New York Heart Association class, but have similar comorbidities.

Patients with heart failure with preserved ejection fraction (HFPEF) have the same or only slightly better rates of survival than those with systolic heart failure *(Aurigemma, 2006 [R]; Bhatia, 2006 [B]; Owan, 2006 [C])*.

Table 2: Cardiac-Related Causes of Heart Failure with Reduced Systolic Function

Etiology	History and Physical	Main Treatment
*__Coronary artery disease__ • Most common cause of heart failure 1) Stable with or without ischemic cardiomyopathy 2) New ischemia	Hx: of stable CAD, or ischemic cardiomyopathy, chest pain, pulmonary edema, diabetes or other ischemic symptoms Px: Tachycardia, diaphoresis, hypoxia Labs: normal troponin, abnormal ECG or imaging (stress) test, Na^+, K^+	- ASA, beta-blocker, ACE inhibitor, statin, antiplatelets - Other treatment for ischemic cardiomyopathy - Evaluation for revascularization - Investigate for new ischemia and treat the new ischemia.
*__Hypertension__ • One of the most common causes of heart failure	Hx: family history of hypertension Px: elevated BP, S4 Labs: ECG, chest x-ray, urinalysis, lipid panel, electrolytes, renal function, studies for secondary hypertension and end organ damage	- For stable (and outpatient) patient, pharmacologic treatment needs individualization to fit heart failure patient. Heart failure medication will lower BP. - Non-pharmacologic treatment is also important (lifestyle management).
*__Valvular heart disease__	Hx: Dyspnea on exertion Px: Pulmonary edema, murmurs Labs: Echocardiogram and cardiac catheterization are essential	- Advanced valvular heart disease may need surgery. Systolic dysfunction from aortic stenosis usually improves after surgery. - Afterload reduction treatment is important in mitral regurgitation.
__Arrhythmia__ 1) Tachycardia-induced cardiomyopathy 2) Bradycardia/Heart block	Hx: tachycardia, palpitations, often A Fib Px: tachycardia Labs: ECG and rhythm monitor, electrolytes Hx: vertigo, syncope Px: sinus node dysfunction, AV block, bradycardia Labs: Lyme serology, electrolytes, ECG, rhythm monitor	- Control of the tachycardia should lead to improvement of ejection fraction. - Short-term treatment is atropine and temporary pacing. - Long-term treatment is pacemaker or biventricular pacing for patients with low LV ejection fraction.
__Myocarditis__	Hx: prior valvular disease, shortness of breath, fever Px: Exclude other specific cardiomyopathies, anemia, hematuria, murmur Labs: ECHO, ECG, MRI, Troponin, Chemistry Panel, blood cultures, specific viral or microorganism study, endomyocardial biopsy may be helpful but only to few types, i.e., Giant cell myocarditis	- Fulminating myocarditis will need urgent and aggressive treatment. - Steroid and immunosuppressive therapy may be helpful.
__Postpartum cardiomyopathy__	Hx: About 1 month before and 6 months after delivering, mostly early postpartum, shortness of breath, dyspnea on exertion Px: jugular venous distention, rales, S3, hepatomegaly, peripheral edema, murmurs Labs: ECG, chest x-ray, cardiac catheterization, myocardial biopsy, Iron/IBC, iron saturation test, TSH	- About 50% completely recover. - Subsequent pregnancy 1. Decrease LV function – deteriorate further 2. Normal LV function – better prognosis
*__Idiopathic cardiomyopathy__ __Viral or autoimmune__	Exclude other specific cardiomyopathies. Always consider alcohol intake as possible etiology.	- Acute or unstable - Stable condition
**__Acute, reversible, stress-induced cardiomyopathy/Takotsubo cardiomyopathy__	Hx: severe physical/emotional stress, chest pain Px: pulmonary edema, cardiac failure/collapse Labs: Troponins, BNP, other labs as for cardiogenic shock, ECG, echo, coronary angiogram, cardiac MRI	- As in acute coronary syndrome: negative inotropes, vasopressors, ASA, nitrates, heparin, IABC (Intra-aortic balloon counter pulsation) - There is rapid reversal of left ventricular function and survival without long term sequelae. IABC is not the only Rx modality to improve condition.

*2005 ACC/AHA Practice Guidelines
** *(Sharkey, 2005; Kurisu, 2002; Desmet, 2003)*

Table 3: Non-Cardiac Related Causes

Etiology	History and physical	Work-up
Alcoholic cardiomyopathy	Moderate intake of alcohol (alcohol-related social or medical problems need not be present)	Labs: elevated MCV, gamma glutamyl transferase (GGT), serum uric acid, triglycerides
Sarcoidosis	Hx: fever, weight loss, anorexia, fatigue, isolated neurological complaints Px: Chest X ray positive for bilateral hilar adenopathy, skin lesions	Chest x-ray, ECG (heart block), pulmonary function tests Labs: calcium, liver function tests
Amyloidosis	Hx: diarrhea, gastrointestinal upset, DOE, check for associations (carpal tunnel, rheumatic diseases) Px: skin lesions	ECG (heart block, decreased forces) fat aspirate or rectal biopsy Labs: BNP/NTproBNP, CTN
Hemochromatosis	Hx: new-onset diabetes, weight loss, lassitude, weakness, abdominal pain Px: hepatomegaly, splenomegaly, skin pigmentation	Labs: serum ferritin, iron binding and saturation, serum calcium Liver biopsy, CT or MRI of liver
Low oxygen-carrying capacity (anemia)	Hx of blood loss/anticoagulation Px: pallor	Labs: CBC Subsequent work-up based on type of anemia
Fluid overload (dietary, lifestyle, medication, etc.)	Hx: missed medication, dietary indiscretion, over-the-counter meds, renal failure Px: edema, weight increase	Labs: creatinine, BUN, serum albumin
Renal failure/Nephrotic syndrome/Glomerulonephritis		Labs: urinalysis (proteinuria) Urinalysis (red blood cells or cellular casts)
Thyroid disorders	Px: myxedema – pale, cool skin	Labs: thyroid function tests, thyroid antibodies. Sensitive TSH with further testing as needed
Systemic infection	Hx: Fever, cough, dysuria	CXR, CT scan Labs: Culture, hematology, serology

(continued on next page)

Table 3: Non-Cardiac Related Causes (cont.)

Etiology	History and physical	Work-up
Pulmonary causes • Cor pulmonale • Pulmonary hypertension • Pulmonary embolism	Hx: SOB, prolonged immobilization Px: Tachycardia, hypoxia, RV overload and/or failure	CXR, CT, ABGs, ECHO
Cardiac toxins • Alcohol • Chemotherapy • Stimulants (methamphetamine, ephedra, cocaine) • Tricyclic antidepressants, vascular (renal) toxins • COX-1 and COX-2 inhibitors • Licorice • Glitazones • Glucocorticoids, androgens, estrogens	Hx: cardiotoxic agent exposure	• ECHO • Discontinue or seek alternatives to exacerbating drugs
Sleep apnea	Hx: snoring, nocturnal awakening, A Fib, sudden cardiac arrest	Overnight polysomnography

3. Unstable Signs and Symptoms Requiring Emergent Management?

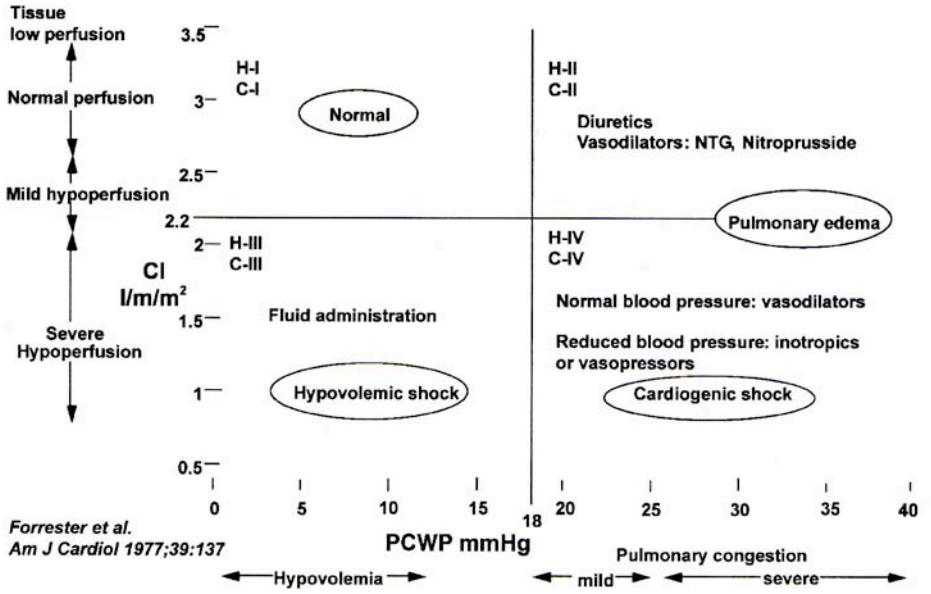
Unstable symptoms may include:

- Dyspnea: at rest/orthopnea (change from baseline), sudden onset of shortness of breath (SOB), worsening SOB, exertional dyspnea, gasping
- SaO_2 less than 90%
- Coughing up pink/frothy sputum
- Dizziness or syncope
- Chest pain
- Systolic BP less than 80-90 mmHg and symptomatic
- Evidence of hypoperfusion (cyanosis, decreased level of consciousness, etc.)

Assess Blood Pressure, Perfusion and Volume Status

The following figure provides a guide to the challenge of bedside hemodynamic assessment.

Figure 2. Clinical and Hemodynamic Subsets



Adapted from: Forrester JS, Diamond GA, Swan HJC. Correlative classification of clinical and hemodynamic function after acute myocardial infarction. *Am J Cardiol* 1977;39:137-45.

5. Admit to Hospital if Necessary

Consider hospitalization in the presence or suspicion of heart failure with any of the following findings:

- Clinical, laboratory or electrocardiographic evidence of acute myocardial ischemia or infarction
- Severe symptoms of heart failure refractory to outpatient therapy
- Pulmonary edema or severe respiratory distress
- Thromboembolic complications requiring interventions
- Severe complicating medical illness (e.g., pneumonia, renal failure)
- Management of clinically significant arrhythmias (hemodynamic effects)
- Anasarca (generalized edema)
- Inadequate social support for safe outpatient management
- Symptomatic hypotension or syncope
- Hyperkalemia

By definition, these patients are Stage C and D, NYHA Class III or IV. (See Appendix A for the New York Heart Association Classification and ACC/AHA Staging System.) Heart failure should not be the final, stand-alone diagnosis. There should always be an associated etiology and/or contributing factor. The etiology of heart failure and the presence of exacerbating factors or other diseases that may have an important influence on management should be carefully considered in all cases.

6. Initiate Heart Failure Management

Pharmacologic Management of Heart Failure:

Medication	Beneficial Subsets	Initial Daily Dose	Optimal (Target) Daily Dose(s)
ACE Inhibitors	NYHA Class I-IV	Captopril: 6.25 mg 3 times Enalapril 2.5 mg twice Fosinopril 5 to 10 mg once Lisinopril: 2.5 to 5 mg once Perindopril: 2 mg once Quinapril 5 mg twice Ramipril 1.25 to 2.5 mg once Trandolapril 1 mg once	Captopril: 50 mg 3 times Enalapril 10 to 20 mg twice Fosinopril 40 mg once Lisinopril 20 to 40 mg once Perindopril: 8 to 16 mg once Quinapril 20 mg twice Ramipril 10 mg once Trandolapril 4 mg once
Angiotensin II Receptor Antagonists	NYHA Class I-IV Reduce afterload and improve cardiac output. Can be used for patient with ACE inhibitor cough.	Candesartan 4 to 8 mg once Losartan 25 to 50 mg once Valsartan 20 to 40 mg twice	Candesartan 32 mg once Losartan 50 to 100 mg once Valsartan 160 mg twice
Hydralazine and Long-Acting Nitrates	Patients intolerant to ACE inhibitors African-Americans with moderate-severe symptoms on optimal therapy	Hydralazine 25 mg four times daily Isosorbide dinitrate 20 mg three times daily Isosorbide mononitrate	Hydralazine 50 mg four times daily Isosorbide dinitrate 40 mg three times daily
Diuretics	Fluid overload (edema, ascites, dyspnea, weight gain)	Furosemide 40 mg Bumetanide 1.0 mg Torsemide 10 mg Chlorthiazide 500 mg Hydrochlorthiazide 25 mg	Furosemide 160 to 200 mg Bumetanide 4 to 8 mg Torsemide 100 to 200 mg Chlorthiazide 1,000 mg Hydrochlorthiazide 50 mg
Aldosterone Antagonists	NYHA Class III-IV	Spironolactone 12.5 mg once Eplerenone 50 mg once	Spironolactone 25 mg once Eplerenone 50 mg once
Beta-Blockers	Stable NYHA Class I-IV	Bisoprolol: 1.25 once Carvedilol 3.125 mg twice Metoprolol succinate extended release (metoprolol CR/XL): 12.5 to 25 mg once	Bisoprolol: 10 once Carvedilol 25 mg twice (50 mg twice for patients over 85 kg) Metoprolol succinate extended release (metoprolol CR/XL): 200 mg once

Treatment of systolic dysfunction

The cornerstone of treatment is the use of beta-blockers and ACE inhibitors. Certain beta-blocking medications have been shown to improve clinical symptoms and ventricular function in patients with systolic dysfunction.

Studies are underway to determine which patient subgroups (e.g., ischemic disease or dilated cardiomyopathy) are most likely to respond to specific beta-blocking agents *(Packer, 1996a [A]; Packer, 2001 [A]; Waagstein, 1993 [A])*.

Beta-blockers decrease hospitalizations and mortality, and have objective beneficial effect on measures of exercise duration. The MERIT HF study of metoprolol succinate compared to placebo showed a mortality reduction at one year in patients with NYHA Class II-IV heart failure and, recently, the COMET trial has shown carvedilol to produce an additional 17% risk reduction in mortality versus metoprolol tartrate *(Ander-*

sson, 1994 [A]; Bristow, 1996 [A]; CIBIS-II Investigators and Committees, 1999 [A]; MERIT-HF Study Group, 1999 [A]; Packer, 1996a [A]; Packer, 2001 [A]; Packer, 2002 [A]; Poole-Wilson, 2003 [A]).

ACE inhibitors prolong life in patients with heart failure symptoms and EF less than 35% and reduce symptom development in asymptomatic patients with EF less than 35% *(The SOLVD Investigators, 1991 [A]; The SOLVD Investigators, 1992 [A])*.

There is also a mortality benefit in the use of ACE inhibitors in patients with recent myocardial infarction and asymptomatic EF less than 40% *(Pfeffer, 1992 [A])*.

ACE inhibitors slow disease progression, improve exercise capacity and decrease hospitalizations and mortality *(Captopril-Digoxin Multicenter Research Group, 1988 [A]; CONSENSUS Trial Study Group, 1987 [A]; Packer, 1999 [A])*.

Patients who are intolerant of ACE inhibitors may benefit from the combination of hydralazine and nitrates. This treatment has been shown to improve survival compared to placebo but is less effective than ACE inhibition *(Cohn, 1986 [A]; Cohn, 1991 [A])*. ARB's are recommended for patients intolerant of ACE inhibitors *(Hunt, 2009 [R])*.

For patients self-described as African Americans, who have moderate-to-severe symptoms on optimal therapy with ACE inhibitors, beta-blockers and diuretics, the combination of hydralazine and nitrates is recommended because the combination has resulted in significant benefit to the group in randomized controlled trials *(Jessup, 2009 [R])*.

Digoxin improves symptoms for patients in sinus rhythm with ventricular dilatation, elevated filling pressures and a third heart sound *(Arnold, 1980 [D]; Lee, 1982 [A]; Packer, 1993 [A])*.

Digitalis improves symptoms, exercise tolerance and quality of life, but neither increases nor decreases mortality *(Digitalis Investigation Group, 1997 [A])*. Digoxin significantly increased ventricular ejection fraction compared to both placebo and captopril. It also decreased hospitalizations and treatment failure compared to placebo *(Captopril Digoxin Research Group, 1988 [A])*. The ACC/AHA 2009 Guideline Focused Update lists Digitalis as beneficial in heart failure patients with reduced LVEF to decrease hospitalizations for HF-Class IIa Level B *(Hunt, 2009 [R])*.

Finally, diuretics should be used, in the smallest doses necessary, to control fluid retention. Care should be taken to avoid hypokalemia, hypomagnesemia, prerenal azotemia, or orthostatic hypotension. Diuretic doses may need to be reduced in order to introduce or optimize treatment with ACE inhibitors and beat-blockers. Aldosterone antagonists have been shown to reduce mortality. Addition of an aldosterone antagonist is recommended in selected patients with moderately severe to severe symptoms of HF and reduced LVEF who can be carefully monitored for preserved renal function and normal potassium concentration. Creatinine should be 2.5 mg per dL or less in men or 2.0 mg per dL or less in women and potassium should be less than 5.0 mEq per liter. Under circumstances where monitoring for hyperkalemia or renal dysfunction is not anticipated to be feasible, the risks may outweigh the benefits of aldosterone antagonists. An ARB or isosorbide/hydralazine combination can be considered in patients intolerant to ACE inhibitors *(Hunt, 2009 [R])*.

Treatment of heart failure with preserved ejection fraction (HFPEF)

Recent cross-sectional, population-based echocardiographic studies show that about half of all patients with heart failure have preserved left ventricular ejection fraction . Cohort studies of hospitalized patients show a smaller proportion of heart failure with preserved ejection fraction (HFPEF). Compared to those with reduced systolic function, patients with HFPEF are more often female, older, less likely to have coronary artery disease, and more likely to have hypertension. Patients with HFPEF are less symptomatic and receive different pharmacologic therapy than patients with reduced ejection fraction. Morbidity and mortality rates

in patients with HFPEF are high but not quite as high as in patients with reduced systolic function *(Hogg, 2004 [R])*.

Depending on which study is considered, the morbidity/mortality rates may be the same as heart failure with reduced ejection fraction. Myocardial infarction or other evidence of atherosclerotic disease appears to be less common in heart failure with normal LVEF. The morbidity and mortality associated with HFPEF is comparable to HFREF and is characterized by frequent and repeated hospitalizations *(Hogg, 2004 [R])*.

In the Framingham Heart Study, heart failure was attributed to coronary artery disease in 52%, valvular heart disease in 8%, hypertension in 26% and other causes in 14%. Multivariable predictors of HFPEF versus heart failure with reduced ejection fraction (HFREF) included elevated systolic blood pressure, atrial fibrillation and female sex. Conversely, prior myocardial infarction and left bundle-branch block QRS morphology reduced the odds of HFPEF. Long-term prognosis was grim, with a median survival of 2.1 years (5-year mortality rate, 74%), and was equally poor in men and women with HFREF or HFPEF *(Lee, 2009 [C])*.

In contrast to the treatment of heart failure due to reduced LVEF, few clinical trials are available to guide the management of patients with heart failure and relatively preserved LVEF. For the management of patients with heart failure with preserved ejection fraction (HFPEF), it is particularly important to address the underlying etiology. Ischemia and hypertension must be optimally controlled. Pericardial disease must be specifically treated if present. Control of atrial tachyarrhythmias may be of particular importance since these patients need adequate time for diastolic filling, and they poorly tolerate tachycardia. Beta-blockers may be of value to slow the heart rate and allow a longer time interval for diastolic filling.

In general, drugs used to treat systolic dysfunction (ACE, ARBs, diuretics, beta-blockers) are generally used in patients with heart failure with preserved systolic function but indicated to manage co-morbidities *(Yusuf, 2003 [A])*.

Diuretics may be helpful to control volume overload and edema. They should be used in the lowest dose needed since excessive diuresis may cause orthostatic hypotension or prerenal azotemia. Arteriolar vasodilators or venodilators should be used with caution because they may cause serious hypotension *(Topol,1985 [C])*.

Patients with hypertrophic cardiomyopathy should be identified and may benefit from genetic counseling. Patients with hypertrophic cardiomyopathy may benefit from beta-blockers to slow heart rate. Some may benefit from verapamil or disopyramide if beta-blockers are not effective. In cases of significant intracavitary pressure gradients, dual chamber pacing or septal myectomy surgery may be indicated. Particular attention must be given to the control of atrial tachyarrhythmias. Care should be taken to avoid venodilators and arterial vasodilators.

See Annotation #13, "Pharmacologic Management," for inpatient medications.

For patients with predominant heart failure with preserved ejection fraction (HFPEF):

Treat specific contributing causes:

- Hypertension (goal is blood pressure of less than 130/80 mmHg) *(Hunt, 2009 [R])*.
- Ischemic heart disease
- Hypertrophic cardiomyopathy – consider referral to subspecialist (for verapamil, disopyramide, surgical myectomy, pacemaker)
- Constrictive pericarditis

Pharmacologic Management for Preserved Systolic Function:

Medication	Beneficial Subsets	Dosing Comments
ACE Inhibitors	NYHA Class I-IV Use with caution because they may cause serious hypotension.	Start low and titrate to maximum tolerated dose based on BP, creatinine, etc.
Angiotensin II Receptor Antagonists	NYHA Class I-IV Reduce afterload and improve cardiac output. Can be used for patient with ACE inhibitor cough.	Candesartan or valsartan dose usually increased every 2 weeks until goal of 32 mg/day.
Diuretics	Use with caution to manage fluid retention but not at doses that cause significant orthostatic hypotension or prerenal azotemia.	Furosemide increase as needed, or other loop diuretic such as torsemide or Bumetanide.
Beta-Blockers	Patients with atrial fibrillation	Start low. Use a higher dose than in systolic dysfunction. Dose usually increased every two weeks as tolerated.

(See also Annotation #13 for further description of pharmacology in management.)

7. Coronary Artery Disease Known or Suspected and Potential Revascularization Candidate?

Refer to the ICSI Stable Coronary Artery Disease guideline.

9. Results Positive?

Refer to the ICSI Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS) guideline, and its Clinic Evaluation algorithm.

10. Revascularization Candidate?

Refer to the ICSI Diagnosis and Treatment of Chest Pain and Acute Coronary Syndrome (ACS) guideline.

11. Consider Specialty Referral/Out of Guideline

Key Points:

- Primary care providers should continue to be involved in the decision-making process when subspecialty consultation and management are necessary.
- Communication between the primary caregiver and the cardiologist is key and should be encouraged even before the need for a referral in order to integrate seamless diagnostic and therapeutic care.

Once it has been determined that the patient is a candidate for revascularization, the next step is angiography performed by a cardiologist. Subspecialty consultation will generally involve not only performance of the procedure, but also recommendations for further management. Primary care providers should continue to be involved in the decision-making process. Primary care providers should also be familiar with risks

associated with various patterns of disease distribution seen on angiogram. The decision to proceed with revascularization must be determined on an individual basis. Consultation should take place among the patient, primary care provider, cardiologist and cardiovascular surgeon to determine the most appropriate course of action.

If the results of the angiogram do not show significant CAD or if the decision is made not to proceed with revascularization, pharmacological management should be continued (see Annotation #13, "Pharmacologic Management").

Patients with advanced structural heart disease and marked symptoms of heart failure at rest despite maximum medical therapy and who require specialized interventions are outside of this guideline. These are primarily Stage D classed patients.

- Assumes that all recommendations for Stages A, B, C have been maximized, including utilization of neurohormonal inhibitors
- Management of fluid status has been aggressively pursued
- Accuracy of Stage D diagnosis is confirmed
- Any contributing conditions have been identified and treated

Device/surgical

- Cardiac transplantation is the only established surgical approach to treatment of refractory heart failure. Additional interventional and surgical treatments of refractory heart failure are experimental.
- Cardiac resynchronization therapy (CRT)

  CRT or biventricular pacing can be used to treat individuals who remain symptomatic despite optimal medical therapy. By treating ventricular dyssynchrony (as evidenced by wide QRS greater than or equal to 0.12 sec), CRT has resulted in significant improvements in measurements of quality of life, functional class, exercise capacity, degree of mitral regurgitation, and left ventricular ejection fraction (LVEF). Meta-analyses of several CRT trials have shown reduced heart failure hospitalizations and a reduction of mortality with or without implantable cardioversion defibrillator (ICD) therapy.

  Indications for CRT are outlined in the ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm abnormalities. CRT with or without ICD is indicated for patients with NYHA functional class III or IV symptoms of heart failure despite optimal medical therapy, LVEF less than or equal to 35%, a QRS duration of greater than or equal to 0.12 seconds, and sinus rhythm *(Epstein, 2008 [R])*.

  For patients who meet the criteria for CRT with or without ICD, but who are in atrial fibrillation or who have frequent dependence on right ventricular pacing, CRT is a reasonable therapy.

  Patients with dyssynchrony but only New York Heart Associations Class I or II symptoms of heart failure do not currently have indications for CRT therapy. However, a recent study by Moss et al (MADIT-CRT) evaluated the benefits of CRT-ICD vs ICD alone in patients with LVEF less than or equal to 30%, LV dyssynchrony with QRS duration of 130 msec or more and NYHA class I or II symptoms if ischemic cardiomyopathy or NYHA Class II symptoms if non-ischemic etiology. CRT combined with ICD was associated with a 34% reduction in the primary endpoint of death or heart failure event compared to ICD alone. The benefit was primarily due to a 41% reduction in risk of heart failure events, most evident in patients with a QRS duration of 150 msec or greater *(Moss, 2009 [A])*.

CRT studies have largely included patients with LBBB. Clinical benefit has been greatest in patients with a QRS duration of greater than 150 msec. Intraventricular mechanical delay has been identified by echocardiographic evaluation in some patients with normal QRS duration. However, no large randomized clinical trial has demonstrated clinical benefit from CRT in patients with normal QRS duration (less than 120 msec).

CRT is not recommended for patients whose functional status or life expectancy is limited by chronic non-cardiac conditions.

- Implantable cardioverter defibrillator (ICD)

  ICD therapy is indicated for both primary and secondary prevention of sudden cardiac death in qualifying heart failure patients.

- Secondary prevention

  Patients with prior cardiac arrest or documented sustained ventricular arrhythmias (ventricular fibrillation [VF] or hemodynamically unstable sustained ventricular tachycardia [VT]) have a high risk of recurrence. If completely reversible causes are excluded, an ICD placement is indicated for secondary prevention to reduce mortality in this patient population.

- Primary prevention

  Patients with low LVEF, from either ischemic or non-ischemic etiology are at increased risk of sudden cardiac death. Primary prevention refers to placement of an ICD for those individuals at risk but who have not yet had an episode of sustained VT, VF or cardiac arrest.

  ICD therapy is indicated for primary prevention in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III.

  For similar patients in NYHA functional Class I, the LVEF requirement for ICD placement for primary prevention is less than 30%.

  For similar patients with LVEF less than 40% and non-sustained VT, ICD placement is indicated if inducibile VF or sustained VT can be demonstrated at electrophysiology study.

  For patients with non-ischemic dilated cardiomyopathy, in NYHA functional Class II or III, ICD therapy is indicated for LVEF less than or equal to 35% and may be considered for those in NYHA functional Class I (Class IIb indication).

  Patients with reduced left ventricular systolic function, heart failure and syncope of unclear origin have an increased rate of subsequent death. These patients should be considered for referral for ICD evaluation.

  ICD placement should not be considered for patients who do not have a life expectancy of at least one year with acceptable functional status.

- Radiofrequency catheter ablation may be indicated in patients with heart failure and reciprocating tachycardias or selected patients with atrial fibrillation. However, there is insufficient data on the role of ablation on sustained ventricular tachycardias in patients with heart failure.

- Revascularization should be considered in patients with significant coronary artery disease defined as left main disease, three-vessel disease, or two-vessel disease with proximal LAD involvement, with evidence of ischemia.

- Valve surgery is indicated in patients with severe left ventricular dysfunction, and severe mitral valve insufficiency or aortic stenosis surgery may lead to symptomatic improvement in selected heart failure patients.

Left ventricular assist devices

- The devices provide hemodynamic support as a bridge to cardiac transplantation and for the treatment of severe myocarditis.
- Left ventricular assist devices as destination therapy are reasonable in selected patients with refractory end stage heart failure who are not candidates for heart transplant, and who have an estimated one year mortality over 50% with medical therapy (Class IIa indication) *(Epstein, 2008 [R])*.

Continuous (not intermittent) infusions of positive inotropic agents such as dobutamine, dopamine, or milrinone

- Patients who cannot be weaned from IV to oral therapy on multiple attempts may require placement of a central line to allow for continuous infusion of above agents.
- This therapy may reduce symptoms at end of life, though it does not prolong life.

Palliative Care and Hospice

- After medical and nonmedical therapy have been optimized and patients still have severe symptoms, referral to palliative care and hospice services will provide patients and families with access to resources.
- Services have only recently been extended to patients dying of heart failure.
- Palliative use of continuous or intermittent inotropic agents may be helpful in alleviating symptoms.

Please see the ICSI Palliative Care guideline for more information.

(Abraham, 2002 [A]; Agency for Health Care Policy and Research, 1994a [R]; Agency for Health Care Policy and Research, 1994b [R]; ACC/AHA Practice Guidelines, 2005 [R]; Cazeau, 2001 [A]; Hunt, 2001 [R]; Moss, 2002 [A]; Remme, 2001 [R])

If patients continue to have symptoms refractory to care, they should be considered for a referral. Consider referral to subspecialist for/when:

- Patient has progressive or persistent symptoms of heart failure despite optimal medical therapy.
- Patient has severe valvular disease associated with heart failure.
- Patient is intolerant of medical therapy.
- Patient has significant or symptomatic atrial or ventricular arrhythmias.
- Patient has angina refractory to medical therapy or evidence of signficant ischemia on stress testing.
- Patient is likely to need invasive testing such as angiography and subsequent coronary intervention or surgery.
- Patient has LVEF of less than or equal to 40% despite optimal medical therapy.
- Referral to a specialist should be considered if patient is a candidate for CRT therapy (see Device/Surgical earlier in this section).
- Referral to a specialist should be considered if patient is a candidate for ICD therapy (see Device/Surgical earlier in this section).

- NYHA Class III or IV symptoms are refractory to medical management, including those patients exhibiting signs of diuretic resistance.
- Symptoms are rapidly progressive in spite of maximal medical management.
- Patients with syncope of unknown cause or those who have undergone cardioversion for ventricular tachycardia or fibrillation should be referred to a cardiologist.
- Patients in whom moderate doses of vasodilating drugs cannot be tolerated for whatever reason.
- Young people (i.e., less than 60) with NYHA Class I-II heart failure with either severe left ventricular dysfunction, severe left ventricular dilatation, or significant valvular regurgitation. Many of these patients may be candidates for cardiac transplantation or other cardiac surgical procedures. Consultation with a cardiologist should be strongly considered, as well as a diagnostic work-up, even in patients with minimal symptoms.
- Consider referral for biventricular pacing of NYHA Class III-IV patients who are already on optimized medical therapy, and have an LVEF less than or equal to 35% with intraventricular conduction delay (as defined by QRS greater than or equal to 0.12 seconds).
- Patients with NYHA Class I and II symptoms, but EF less than 30% and dyssynchrony, manifested by QRS interval greater than 130 msec, benefited from CRT with or without ICD. CRT did not impact mortality over ICD alone *(Moss, 2009 [A])*.
- Consider referral for ICD placement in patients with both ischemic and non-ischemic cardiomyopathy that meet guideline recommendations, for the primary prevention of sudden cardiac death.

(Epstein, 2008 [R])

12. Treat Secondary Causes of Heart Failure and Significant Comorbid Conditions and Risk Factors

Treat as indicated by the particular disease state. Specific treatment modalities for secondary causes of HF are considered outside of the scope of this guideline. See also Table 2: Cardiac-Related Causes of HF with Reduced Systolic Function, and Table 3: Non-Cardiac Related Causes. See also ICSI Hypertension Diagnosis and Treatment guideline.

Atrial Fibrillation in Heart Failure

Several studies have been done in patients with heart failure and atrial fibrillation that will influence management of this arrhythmia *(Kober, 2008 [A]; Roy, 2008 [A])*. Patients with heart failure are at increased risk for atrial fibrillation and constitute an important subgroup of all patients with this arrhythmia. Atrial fibrillation affects 10%-30% of patients with chronic heart failure. Atrial fibrillation may be a marker of poor prognosis, in which the primary problem is poor ventricular function, neurohormonal activation, or inflammation, with no independent effect of atrial fibrillation on outcome.

In the multi-center AF-CHF trial on patients with heart failure who had LVEF less than 35% and atrial fibrillation, a strategy of "rhythm control" with drugs and cardioversion was not superior to a strategy of "rate control" *(Roy, 2008 [A])*. There was no significant difference between the two groups in primary outcome of time to cardiovascular death. Secondary outcomes were similar in the two groups, including death from any cause, stroke, worsening heart failure, and the composite of death from cardiovascular causes, stroke or worsening heart failure.

The control of ventricular rate and the prevention of thromboembolic events are essential elements of treatment of heart failure in patients with an underlying supraventricular arrhythmia. Beat-blockers and digoxin

used either alone or in combination are the drugs of choice for achieving rate control. Digoxin is effective in controlling ventricular rate at rest, but may not achieve satisfactory rate control with exertion. Amiodarone may be added to beat-blockers and/or digoxin if adequate rate control is not achieved. Of anti-arrhythmics used in patients with heart failure with reduced ejection fraction and AF, only amiodarone and dofetilide do not effect survival adversely *(Roy, 2008 [A])*.

In a similar patient -population, that was resistant to drug treatment for both rhythm and rate control, electrophysiological interventions such as pulmonary vein isolation and atrio-ventricular node ablation combined with bi-ventricular pacing have shown promising results *(Khan, 2008 [A])*. The work group awaits results of ongoing trials.

13. Pharmacologic Management

Key Points:

- Carvedilol, metoprolol succinate (extended release) and bisoprolol have demonstrated reductions in mortality over other generic beta-blockers for patients with all classes of heart failure.
- ACE inhibitors should be prescribed for all patients with left ventricular systolic dysfunction unless specific contraindications exist. An elevated baseline creatinine is not a specific contraindication.
- In non-African Americans, ACE inhibitors are more effective in decreasing heart failure mortality than the isosorbide dinitrate/hydralazine combination. In contrast, combining hydralazine and nitrates is recommended for patients self-described as African Americans, with moderate-severe symptoms on optimal therapy with ACE inhibitors, beat-blockers and diuretics.
- Angiotensin receptor blockers should be considered primarily for patients who are intolerant of ACE inhibitors or those receiving standard drug therapy (including ACE inhibitors) who continue to show clinical deterioration.
- Routine use of angiotensin receptor blockers with ACE inhibitors and aldosterone antagonists cannot be recommended.
- Diuretics should not be the sole therapy for patients with signs of volume overload, and vasoactive drugs should be considered.
- Loop diuretics are more effective in severe heart failure than thiazide diuretics and combination therapy with thiazide (or thiazide-like medication), and loop diuretics are effective in refractory cases of volume overload.
- Aldosterone blocking agents (spironolactone, eplerenone) reduce mortality in patients with NYHA Class III-IV heart failure for patients on stable doses of digoxin and ACE inhibitors.
- Currently, the work group recommends that nesiritide be reserved for patients with acutely decompensated heart failure who remain volume overloaded despite aggressive treatment with diuretics/vasodilators display tolerance and/or resistance to vasodilators or diuretics, or demonstrate significant side effects to other vasodilators.

- When considering the use of calcium channel blockers (CCB) in heart failure patients, only dihydropyrine CCBs such as amlodipine and felodipine have been shown to be safe. Nondihydropyridine calcium channel blockers such as diltiazem and verapamil, should be avoided in heart failure due to their negative effects on inotropicity.

The following is an overview of the pharmacological approach to drug selection for patients with heart failure. The optimal management of patients with heart failure is complex. Numerous drugs from various classes are needed for each patient, and frequent titration and dosage adjustments may be needed on an ongoing basis. The following section summarizes major conclusions regarding the optimal use of agents prioritized by beta-blockers, vasodilators, diuretics, aldosterone blocking agents, inotropes, calcium channel blockers, antiarrhythmic agents, and anticoagulants. Some classes of agents are clearly most beneficial to manage symptomatology (diuretics, for example), while others, such as neurohormonal antagonists (ACE inhibitors and beta-blockers), are clearly morbidity and mortality-reducing agents. Although these classifications are arbitrary, they hopefully serve to organize the information presented in this section.

For detailed information about medication comparisons, interactions and dosing, the work group recommends the following sources:

Epocrates: www.epocrates.com
Micromedex: www.micromedex.com
Lexi-Comp: www.lexi.com
UpToDate: www.uptodate.com
PDR.net: www.pdr.net

Beta-Blockers

- When only one drug can be initiated for heart failure, beta-blockers are preferred *(Fonarow, 2007 [M]; Sliwa, 2004 [A])*.
- Studies strongly support use of certain beta-blockers that have demonstrated reductions in mortality and hospitalizations (e.g., carvedilol, metoprolol succinate [extended release], bisoprolol) in patients with NYHA Class I-IV HF. Recent data from COMET demonstrated carvedilol to have a 17% risk reduction in mortality over metoprolol tartrate (immediate release) *(Beta-Blocker Evaluation of Survival Trial Investigators, The, 2001 [A]; CAPRICORN Investigators, The, 2001 [A]; Freemantle, 1999 [M])*.
- Beta-blockers should be started as soon as the patient is stable (without fluid overload or hypotension).
- Start cautiously in acute heart failure or during an exacerbation. After appropriate stabilization, they may be safely started in the inpatient setting.
- Should start at low initial doses and gradually titrate up at rates consistent with those from key studies *(Sliwa, 2004 [A])*.
- Beta-blockers should not be unnecessarily reduced or discontinued. Sudden cessation may cause a reflexive increase in sympathetic output and worsen heart failure.
- If significant bradycardia/AV block occurs with use of beta-blockers, the dose may need to be decreased. If hypotension or fluid retention occurs, either the dose of beta-blocker, ACE inhibitor or diuretics should be adjusted as clinically appropriate.
- Patients should be informed that positive effects of beta-blockers may not be seen until several months after titration to target dose.

- Beta-blockers have been shown to have an objective beneficial effect on measures of exercise duration *(Bristow, 1996 [A]; CIBIS-II Investigators and Committees, 1999 [A]; MERIT-HF Study Group, 1999 [A])*.
- To decrease mortality and reinfarction among patients with compensated heart failure following acute myocardial infarction.
- To improve hemodynamics in patients with idiopathic dilated cardiomyopathy *(Australia/New Zealand Heart Failure Research Collaborative Group, 1997 [A]; Packer, 1996b [A])*.
- For rate control in tachycardia-induced heart failure, the work group prefers beta-blockers over other agents.

Carvedilol

- The COMET trial demonstrated carvedilol to have a 17% risk reduction in mortality over metoprolol tartrate *(Poole-Wilson, 2003 [A])*. In type 2 diabetic patients, carvedilol did not adversely affect HgbA1C as compared to metoprolol tartrate. Carvedilol has demonstrated the ability to reduce insulin resistance and microalbuminemia while metoprolol tartrate did not show the same benefits *(Bakris, 2004 [A])*.
- Recommended starting dose for carvedilol is 3.125 mg twice daily for two weeks. Dosage can be doubled every two weeks to highest level tolerated by patient to maximum 25 mg twice daily (less than 85 kg) or 50 mg twice daily (greater than 85 kg). It is suggested that after initiation of each new dose, patients should be observed for signs of dizziness or lightheadedness. Also consider instructing patients to take carvedilol two hours before ACE inhibitors to decrease potentiating effects. Carvedilol should be taken with food to slow the rate of absorption and reduce the risk of postural hypotension.
- Carvedilol has been shown to reduce heart failure related hospitalizations and death *(Australia/New Zealand Heart Failure Research Collaborative Group, 1997 [A]; Packer, 1996b [A]; Packer, 2002 [A]; Poole-Wilson, 2003 [A])*.

Metoprolol Succinate

- In the MERIT HF study of metoprolol succinate compared to placebo, a mortality reduction was shown at one year in patients with NYHA Class II-IV heart failure *(MERIT-HF Study Group, 1999 [A])*.
- There are no head-to-head trials comparing carvedilol and metoprolol succinate (extended release) *(Beta-Blocker Evaluation of Survival Trial Investigators, The, 2001 [A]; CAPRICORN Investigators, The, 2001 [A]; Freemantle, 1999 [M])*.
- Recommended starting dose of metoprolol succinate is 25 mg/once daily. In patients with more severe heart failure (NYHA Class III or IV), recommended starting dose is 12.5 mg/once daily. The dose may then be doubled every two weeks up to the highest tolerated dose or up to 200 mg/once daily.

Vasodilators

Angiotensin converting enzyme (ACE) inhibitors

- For patients with asymptomatic or mildly symptomatic decreases in LV systolic performance, use of ACE inhibitors has been shown to decrease mortality, progression of heart failure and need for hospitalization *(Captopril-Digoxin Multicenter Research Group, The, 1988 [A]; CONSENSUS Trial Study Group, 1987 [A]; Cohn, 1991 [A]; Packer, 1991 [A]; Pfeffer, 1992 [A]; SOLVD Investigators, The, 1992 [A]; SOLVD Investigators, The, 1991 [A])*.
- ACE inhibitors should be prescribed for all patients with left ventricular systolic dysfunction unless specific contraindications exist *(Masoudi, 2004 [C])*.

- Contraindications include:

  history of intolerance or adverse reactions to these agents including angioedema, persistant cough and/or rash,

  serum potassium greater than 5.5 mEq/L,

  symptomatic hypotension (unless due to excessive diuresis),

  severe renal artery stenosis,

  pregnancy, and

  cough and rash side effects.

- In patients who are intolerant to ACE inhibitors, an angiotensin receptor blocker (ARB) should be initiated.
- Approach to initiating ACE inhibitor therapy:

  Start at a low dose and titrate upward over several weeks to targeted moderate to high doses and maximum tolerated dose.

  Consider holding one dose of diuretic before giving the first dose of ACE inhibitors, particularly in patients with low baseline blood pressure.

  Where possible, heart failure patients should have their ACE inhibitor dose gradually increased to achieve target doses based on the individual's tolerance and side effects with other heart failure medications *(Packer, 1999 [A])*.

- **Hypotension:** Patients should be well hydrated before initiation or increase of ACE inhibitors. If the patient develops hypotension in the absence of hypovolemia, splitting the dose or switching from a.m. to at-bedtime dosing (in long-acting agents) may be helpful. If this is ineffective, the dose should be reduced to the highest dose tolerated.
- Periodically monitor for changes in renal function and potassium, as well as other electrolytes with these agents, especially when titrating doses and when concomitantly administered with other agents known to affect electrolytes (diuretics, ACE inhibitors, angiotensin blocking agents, aldosterone antagonists).
- **Renal insufficiency:** Creatinine should be monitored regularly in patients on ACE inhibitors, and more frequently during active titration. An increase in serum creatinine of 0.5 mg/dL or more is an indication for reassessment of volume status. There is no absolute level of creatinine to preclude the use of ACE inhibitors.
- All ACE inhibitors that have been studied to date in treatment of heart failure have shown benefit. Therefore, simpler dosing regimens may be equally effective and less expensive.
- For patients with asymptomatic or mildly symptomatic decreases in LV systolic performance, use of ACE inhibitors has been shown to decrease mortality, progression of HF and need for hospitalization *(Captopril-Digoxin Multicenter Research Group, The, 1988; CONSENSUS Trial Study Group, 1987; Cohn, 1991; Packer, 1991; Pfeffer, 1992; SOLVD Investigators, The, 1992; SOLVD Investigators, The, 1991)*.
- In non-African Americans, ACE inhibitors are more effective in decreasing heart failure mortality than the isosorbide dinitrate/hydralazine combination *(Cohn, 1991 [A])*.
- In studies demonstrating decreased mortality in heart failure, relatively high doses of ACE inhibitors were used.
- Enalapril 20 mg daily (twice daily dosing)

- Lisinopril 20-40 mg daily. Lower dose therapy has been shown to be less effective in reducing mortality *(Packer, 1999 [A])*.
- Captopril 100-150 mg daily (three times daily dosing).

(Cohn, 1986 [A]; Cohn, 1991 [A]; Pfeffer, 1992 [A])

Angiotensin Receptor Blockers (ARBs)

- ARBs are to be used if ACE inhibitors are not tolerated.
- Based on the findings of the series of CHARM studies, recommendations to consider adding an angiotensin receptor blocker to standard optimized drug therapy for those with systolic dysfunction may be supported *(Granger, 2003 [A]; McMurray, 2003 [A]; Pfeffer, 2003 [A]; Yusuf, 2003 [A])*. An ARB is the preferred alternative to hydralazine/isosorbide dinitrate in most patients because of ease of use except in renal dysfunction, hyperkalemia and possibly in African-Americans *(Taylor, 2004 [A])*.
- Specifically, acccording to the CHARM-Added trial, *(McMurray, 2003 [A])*, there is a benefit in terms of composite cardiovascular endpoints when adding ARB to a regimen of an ACE inhibitor and beta-blockers (triple therapy) *(Cohn, 2001 [A]; Granger, 2003 [A]; McMurray, 2003 [A]; Pfeffer, 2003 [A]; Yusuf, 2003 [A])*. This observation is consistent overall, with the results of the Val-HeFT study *(Cohn, 2001 [A])*. In spite of subgroup analysis from Val-HeFT suggesting that the addition of an ARB to the ACE inhibitor and beta-blocker may have resulted in a negative effect on both mortality and morbidity, the group feels that based on the findings from the CHARM-Added study *(McMurray, 2003 [A])*, the combination of ARBs to and ACE and beta-blocker regimen is more favored than disfavored at this time.
- Only Valsartan and Candesartan are approved for use in patients with heart failure.
- Direct comparison with regards to mortality in patients with heart failure showed no difference between the ARB Losartan and the ACE inhibitor Captopril *(Pitt, 2000 [A])*.
- According to the VALIANT trial, 2003, there is no benefit when adding ARB to ACE inhibitors in early post-MI patients.
- Contraindications to ARBs include history of intolerance or adverse reactions to serum potassium greater than 5.5 mEq/L, symptomatic hypotension (unless due to excessive diuresis), severe renal artery stenosis and pregnancy.
- The addition of aliskiren to standard therapy for heart failure that includes an ACE inhibitor or ARB, beta-blocker, and an aldosterone antagonist, appears to lower BNP levels. Compared to placebo in this population, aliskiren showed significant improvements in measures of mitral regurgitation (p=0.0006) and left ventricular filling pressure *(McMurray, 2008 [A])*.

Diuretics

- Patients with signs of volume overload should be started on a thiazide or loop diuretic; however, this should not be sole therapy.
- Loop diuretics are preferred over thiazides in patients experiencing severe volume overload, severe renal insufficiency (creatinine clearance less than 30 mL/min) or persistent edema while on thiazide diuretics.
- If the patient remains fluid overloaded on a loop diuretic alone, adding a thiazide or metolazone in combination with the loop diuretic can be beneficial *(Funke Küpper, 1986 [A]; Sigurd, 1975 [C]; Whight, 1974 [D])*. When used together, the thiazide diuretic should be given 30-60 minutes before the loop diuretic to increase overall diuretic effectiveness.

- Studies of bumetanide and furosemide in treating edematous states indicate that continuous infusions of loop diuretics may be more efficacious and induce fewer side effects than bolus intravenous injections *(Dormans, 1996 [A]; Rudy, 1991 [A])*. These studies revealed that for patients with severe heart failure (Class III or IV) and/or chronic renal insufficiency, continuous low-dose infusions of loop diuretics produced greater natiuresis than the same amount of diuretic administered as intermittent bolus injections. These infusions resulted in lower peak serum drug concentrations and are theorized to be associated with fewer extrarenal toxicities (e.g., ototoxicity) as a consequence.
- Periodically monitor for changes in renal function and potassium as well as other electrolytes with these agents, especially when titrating doses and when concomitantly administered electrolytes (diuretics, ACE inhibitors, angiotensin blocking agents, and aldosterone antagonists).
- Excessive diuresis may result in:
    - prerenal azotemia,
    - orthostatic hypotension, which may indicate overdiuresis in the absence of congestive symptoms, and may be accompanied by an increased BUN to creatinine ratio. If volume depletion is not present, intolerance of the ACE inhibitor is likely (see "ACE inhibitors" earlier in this annotation).
    - hypokalemia, which may indicate overdiuresis in the absence of congestive symptoms, and may be accompanied by an increased BUN to creatinine ratio. If volume depletion is not present, intolerance of the ACE inhibitor is likely (see "ACE inhibitors" earlier in this annotation).
    - hypomagnesemia, which often accompanies hypokalemia. If high doses of diuretic are used, serum magnesium levels should be checked regularly and oral supplementation given as indicated. Hypomagnesemia may prevent correction of hypokalemia.
    - inability to achieve optimal dose of ACE inhibitor, and
    - activation of the RAAS system.
- Diuretic effectiveness may be increased by one to two hours of bed rest (supine position) after taking diuretics.
- Hyponatremia is an indication for fluid restriction in a volume-overloaded patient and a decrease in diuretic in a volume-depleted patient.
- A few studies have raised questions about whether torsemide may be the preferred diuretic when treating heart failure. Although not designed as a mortality study, the TORIC study suggested a lower mortality among congestive heart failure patients treated with torsemide compared to furosemide/other diuretics *(Cosin, 2002 [C])*. Another small, open-label study comparing furosemide with torsemide confirmed that torsemide-treated patients were less likely to be readmitted for heart failure and all cardiovascular causes, and appeared to be less fatigued *(Murray, 2001 [A])*. Until more rigorous studies are completed, no recommendations can be made regarding the ideal choice of diuretic in this patient population, other than to use the lowest possible dose.

Aldosterone Blocking Agents

Spironolactone

- A multicenter, randomized clinical trial showed a reduction in mortality among patients with NYHA Class III-IV HF who were treated with spironolactone 25-50 mg per day. These patients were already on stable doses of digoxin and ACE inhibitors. In the RALES study, 25 mg per day of spironolactone was found to decrease morbidity and mortality. The mechanism is felt to be due to inhibition of aldosterone

effects on myocardial cell death. Hyperkalemia is a side effect of spironolactone, and potassium levels should be checked three to seven days after starting the drug *(Pitt, 1999 [A])*.

Eplerenone

- Eplerenone, a selective aldosterone antagonist with fewer endocrine side effects than spironolactone, was evaluated in the EPHESUS trial. It was used in study subjects who had a myocardial infarction 3 to 14 days prior and had an LVEF less than 40% with evidence of heart failure (in 90%) and/or diabetes mellitus. Patients with a plasma creatinine greater than 2.5 mg/dL or potassium over 5 mEq/L were excluded. The starting dose was 25 mg/day, increased to 50 mg/day after four weeks. There was a significant lower rate of all-cause mortality (14.4%) due to reduction in cardiovascular mortality, reduction in sudden cardiac death, decreased mortality and hospitalizations for heart failure. Most patients in this trial (unlike RALES) were on an ACE inhibitor, α2-adrenoceptor blocking agent and a beta-blocker *(Pitt, 2003 [A])*.
- The mean LVEF in EPHESUS was 33% (compared to 25% in RALES), suggesting that patients with less severe heart failure than seen in the RALES trial might benefit from aldosterone antagonism. The NYHA class in the EPHESUS trial could not be established, because most patients had an MI two weeks prior to enrollment.
- The current recommendation would be to use spironolactone for patients who fulfill the RALES criteria (current or recent NYHA class IV HF, class III HF with patient being in class IV heart failure in the past six months, preserved renal function, or reduced potassium concentration). Eplerenone could be used for patients who have had a recent MI, LVEF less than 40%, and symptomatic HF and/or diabetes as a pharmacologic alternative to spironolactone with less risk of gynecomastia. However, the cost and lack of outcome studies in the heart failure area would be limiting factors.

Inotropes

The inotropes – dobutamine, dopamine and milrinone – have failed to demonstrate the ability to improve mortality in the treatment of severe decompensated heart failure. A review of the literature has, in fact, shown an increase in mortality with the use of these agents. The use of inotropes in heart failure should therefore be restricted to those patients needing symptomatic relief who are no longer responding to other therapies. As palliative treatment in select patients, the available data supports continuous infusion over repetitive intermittent infusion.

Digoxin

In subjects in normal sinus rhythm with preserved systolic function (PSF) and mild to moderate heart failure symptoms on optimal therapy, digoxin had no effect on the endpoints of all-cause or cardiovascular mortality or hospitalization *(Ahmed, 2006 [A])*.

Serum levels of less than 1.0 ng/mL are considered therapeutic. Levels greater than 1.2 have been associated with greater side effects. Serum levels do not always correlate to symptoms of digoxin toxicity.

Digoxin has been found useful:

- In heart failure patients with atrial fibrillation with a rapid ventricular response.
- In combination with ACE inhibitors in reducing hospitalizations in heart failure patients *(Packer, 1993 [A])*.

Digoxin should not:

- Be initiated in asymptomatic heart failure patients as it remains unsupported by clinical trials.
- Be "loaded" either orally or intravenously. Loading doses are generally not needed and steady state generally takes one week to reach (longer in patients with renal impairment).

Digoxin cautions:

- Monitor for symptoms of toxicity (nausea, confusion, visual disturbance, anorexia), reduction of renal function or conduction abnormality.
- To avoid digitalis toxicity, care should be used to use lower doses in the elderly and those with renal impairment, check digitalis level in one to two weeks after start of therapy in elderly or renal-impaired patients, and beware of drug interactions with new medications.
- Post hoc retrospective analysis of mortality statistics regarding the use of digoxin in heart failure indicate that the drug may actually increase mortality in women when compared to placebo. There are no randomized, prospective studies to confirm gender-based differences, but practitioners may want to consider this information when prescribing digoxin to women. If digoxin therapy is to be continued in women, it may be reasonable to recommend that lower dosing (0.125 mg per day) should be used and lower serum levels (1.0 or less) should be maintained *(Digitalis Investigation Group, The, 1997 [A]; Rathore, 2002 [A])*.

Other Vasodilators

- Alpha-adrenergic blockers (prazosin, terazosin) have not demonstrated survival or functional benefit in the treatment of heart failure *(Cohn, 1986 [A])*.

Nitroglycerin (intravenous)

- Intravenous nitroglycerin is indicated for the treatment of heart failure in patients with concomitant acute myocardial infarction.
- Nitroglycerin can be used to treat pulmonary edema.
- Following acute MI, early parenteral nitrate therapy has been documented to result in a lower incidence of new heart failure *(Flaherty, 1983b [A]; Yusef, 1988 [M])*.
    - Intravenous nitroglycerin is the only dosage form approved in the U.S. for use in heart failure associated with acute myocardial infarction, although sublingual, transmucosal and transdermal dosage forms have been used for both acute and chronic symptomatic control.
- Nitroglycerin is normally reserved for patients with adequate cardiac index and an elevated pulmonary wedge pressure (greater than 18 mmHg). A combination of diuretics and nitroglycerin or nitrates is effective in lowering pulmonary capillary wedge pressure.
- In one study of nitroglycerin versus nitroprusside, results supported a preference for nitroglycerin for the treatment of heart failure and/or acute hypertension complicating acute myocardial infarction *(Flaherty, 1983a [R])*.

Nitroglycerin (intravenous) cautions

- Severe hypotension, particularly with upright posture, may occur even with small doses of nitroglycerin. The drug, therefore, should be used with caution in subjects who may have volume depletion from diuretic therapy or in patients who have low systolic blood pressure (e.g., below 90 mmHg).

- Paradoxical bradycardia and increased angina pectoris may accompany nitroglycerin-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.
- Tolerance to this drug and cross-tolerance to continuous use of other nitrates may occur within days.

Nitroprusside (intravenous)

- Nitroprusside is FDA indicated for the treatment of acute congestive heart failure.
- Nitroprusside has been shown to cause significant and sustained symptomatic improvement in severe, refractory heart failure due to a variety of causes *(Cohn, 1982 [A]; Guiha, 1974 [D]; Shah, 1977 [D])*. However, in acute MI patients with subsequent left ventricular failure, the use of nitroprusside has been associated with an increase in mortality *(Cohn, 1982 [A])*. Due to this study and the well-known propensity for nitroprusside to induce a "coronary steal syndrome," it is recommended to avoid use of nitroprusside in patients experiencing ischemia.
- Nitroglycerin is preferred over nitroprusside due to the following issues:
  - many hospitals require an arterial line for monitoring of blood pressure during a nitroprusside infusion. This often requires the patient to remain in an intensive care setting during the infusion.
  - Nitroprusside is well known for causing cyanide and thiocyanate toxicity. This necessitates frequent monitoring and the use of sodium thiosulfate to prevent toxicity.

Nesiritide

- Nesiritide is FDA approved for the intravenous treatment of patients with acutely decompensated heart failure who have dyspnea at rest or with minimal activity.
- Most studies looking at the use of nesiritide in heart failure have shown a reduction in heart failure symptoms while having a neutral effect on mortality. However, when compared to inotropes, nesiritide has shown a comparative benefit in mortality.
- In patients hospitalized with decompensated heart failure, nesiritide was shown to improve hemodynamic function and clinical status *(Colucci, 2000 [A])*. When added to standard care in patients hospitalized with acutely decompensated heart failure, one study confirmed that nesiritide significantly reduced pulmonary capillary wedge pressure more than nitroglycerin or placebo. These effects were sustained for at least 24 hours *(Publication Committee for the VMAC Investigators, 2002 [A])*.
- In comparison with dobutamine, nesiritide causes significantly fewer heart rate variances, tachycardia, premature ventricular beats, repetitive beats and neurohormonal activation *(Burger, 2001 [A]; Burger, 2002 [A])*. In comparison to dobutamine, nesiritide is associated with a shorter treatment course, the use of fewer additional parenteral agents, a lower hospitalization rate and a significantly lower mortality rate at six months *(Burger, 2002 [A]; Silver, 2002 [A])*.
  - while the studies above have shown benefit, a meta-analysis in 2005 demonstrated that when Compared with non-inotrope based control therapy, nesiritide was associated with an increased risk of death after treatment for acutely decompensated heart failure *(Sackner-Bernstein, 2005 [M])*.
- Currently, the work group recommends that nesiritide be reserved for patients with acutely decompensated heart failure who remain volume overloaded despite aggressive treatment with diuretics/vasodilators, displaying tolerance and/or resistance to vasodilators or diuretics, or demonstrating significant side effects to other vasodilators.

If nesiritide is used, take into consideration the following:

- In patients with severe heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with nesiritide may be associated with azotemia.
- The best candidates for nesiritide therapy are patients with decompensated heart failure who have clinical evidence of fluid overload and/or raised central venous pressure *(Hobbs, 2001 [R])*.
- There is little experience with infusions of nesiritide for more than 48 hours.
- Until further studies can be done, it is the opinion of this work group that other vasodilators and/or diuretics be attempted prior to a trial of nesiritide.

Hydralazine/Long Acting Nitrates

- Hydralazine combined with isosorbide dinitrate has been shown to reduce mortality and increase exercise tolerance in patients with symptomatic heart failure *(Cohn, 1991 [A]; Cohn, 1986 [A])*.
- Combining hydralazine and nitrates is recommended for patients self-described as African Americans, with moderate-severe symptoms on optimal therapy with ACE inhibitors, beat-blockers, and diuretics *(Jessup, 2009 [R]; Taylor, 2004 [A])*.
- In non-African Americans, ACE Inhibitors are more effective in decreasing heart failure mortality than hydralazine/long acting nitrate combinations *(Cohn, 1991 [A])*.
  - Hydralazine/long acting nitrates (usually isosorbide dinitrate) may be considered as a therapeutic option in those patients experiencing intolerance to ACE inhibitor and ARB usage.
- If higher doses of ACE inhibitors or ARBs are not tolerated despite euvolemia, a lower dose should be continued and/or a trial of hydralazine/isosorbide dinitrate instituted.

Calcium Channel Blockers

- Diltiazem, nifedipine and verapamil have been associated with adverse outcomes in patient with diminished LV function and should be avoided.
- Among the dihydroopyridine calcium antagonists, only two have shown safety in the heart failure patient population: amlodipine and felodipine.
  - The PRAISE study demonstrated no adverse effects on survival or cardiac morbidity when amlodipine was added to patients with NYHA Class II or III heart failure with EF less than 30% and in whom an ACE inhibitor, digoxin and diuretics were already being used *(Packer, 1996 [A])*.
- The V-HeFT-III trial studied felodipine vs placebo when added to heart failure patients already taking a diuretic and enalapril. No difference was reported between felodipine and the placebo in overall mortality or for mortality in subgroups with or without coronary disease. Felodipine had no effect on peak exercise capacity, quality of life, or need for hospitalization, but did reduce plasma atrial natriuretic peptide (ANP). During long-term follow-up, the favorable effects on ejection traction and ANP did not persist, but felodipine prevented worsening of exercise tolerance and quality of life *(Cohn, 1997 [A])*.

Testosterone

- Long-acting testosterone therapy, given in addition to standard therapy, improved exercise capacity, muscle strength, glucose metabolism, and baroreflex sensitivity in elderly men with moderately severe heart failure.
- Testosterone replacement therapy improves functional capacity and symptoms in men with moderately severe heart failure.

(Malkin, 2005 [A]; Caminiti, 2009 [A])

Antiarrythmics

- The routine use of prophylactic antiarrythmic drug therapy to prevent sudden cardiac death in patients with cardiomyopathy, heart failure and asymptomatic ventricular ectopic activity (ventricular premature beats [VPBs] or nonsustained ventricular tachycardia [NSVT]) is not recommended. These drugs are less likely to suppress ventricular arrhythmias in patients with heart failure and may be associated with proarrhythmia, which is more likely in heart failure, and worsening of left ventricular function *(Bardy, 2005 [A]; Gottlieb, 1990 [A]; Hallstrom, 1995 [A])*.
- Nearly all antiarrhythmic agents can exert clinically significant negative inotropic effects, which may limit the utility and safety of these drugs in patients with left ventricular dysfunction.
- Only amiodarone and dofetilide have been shown to be mortality neutral when treating arrythmias in patients with heart failure.
- The recent publication of the results of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) demonstrated that in patients with NYHA Class II or Class III HF and LVEF of 35 percent or less, amiodarone had no favorable effect on survival, despite the use of appropriate dosage and reasonable compliance rates over longer periods than in other placebo controlled trials. Whereas single-lead, shock-only ICD therapy reduces overall mortality and the relative risk of death by 23 percent, resulting in an absolute reduction of 7.2 percentage points at five years among patients with HF who received state-of-the-art background medical therapy, and the benefit did not vary according to the cause of HF *(Bardy, 2005 [A])*.
- In the Multicenter Automatic Defibrillator Implantation Trial 2 (MADIT 2), a study of patients who had had a myocardial infarction, and in the Antiarrhythmics versus Implantable Defibrillators (AVID) study, a secondary prevention trial, the worse the ejection fraction, the greater the benefit of ICD therapy. In the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial, patients in NYHA Class III derived the largest survival benefit from ICD therapy *(The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators, 1997 [A]; Kadish, 2004 [A]; Moss, 2002 [A])*.

Anticoagulants

- Anticoagulation with warfarin is indicated in heart failure patients with atrial fibrillation, mechanical heart valves, or in patients with impaired systolic function (i.e., EF less than 20%), prior thromboemboli and left ventricular mural thrombi. No studies to date have shown a significant difference in major outcomes with patients taking warfarin *(Cleland, 2004 [A])*.
- Emboli due to ventricular thrombi in patients with chronic congestive failure are uncommon and occur most frequently in patients with very low ejection fractions (less than 20%) *(Dunkman, 1993 [A])*.
- Patients with atrial fibrillation and heart failure are at high risk for thromboemboli *(Stroke Prevention in Atrial Fibrillation Investigators, The, 1992 [B])*. In atrial fibrillation patients, the CHADS2 score is a widely used clinical model for stratifying those at risk for emboli and to assist with decision making regarding the initiation of warfarin *(Gage, 2001 [C]; Go, 2003 [C])*.

Refer to the ICSI Antithrombotic Therapy Supplement.

14. Non-Pharmacologic Management

Key Points:

- Dietary indiscretion is the most common cause of exacerbation of heart failure. Therefore, all patients with heart failure should receive dietary instruction regarding sodium intake.

- Sodium restriction alone may provide substantial benefits for heart failure patients. Dietary counseling is important for patients to learn the need for fluid balance management, avoiding excess sodium and/or water intake. Referral to a dietitian should be considered for patients with comorbid conditions or repeat episodes of edema.
- Daily weights are important for managing heart failure and early detection of increases in fluid retention. Patients should call their provider about a two-pound or greater weight gain overnight or a five-pound or greater weight gain in a week.
- Simplifying medication regimes as much as possible should be explored. All medications, including over-the-counter (OTC) medications, should be reviewed at each visit.
- Major depression is common in patients hospitalized with heart failure and is independently associated with a poor prognosis. Additionally, depression is independently associated with a substantial increased risk of heart failure in older patients with isolated systolic hypertension.
- Consider utilizing a heart failure clinic or case management for patients with medical problems or at high risk for rehospitalization.

Patient education for early symptom recognition and counseling about the disease process should be initiated at this time. See the Resources Available section for Web sites and tools to assist the provider and patient with non-pharmacologic management of heart failure.

Dietary Recommendations

Dietary indiscretion remains a common cause of exacerbation of heart failure and reinforcement of the importance of dietary compliance should occur at each interaction *(Dracup, 1994 [M])*.

Assess usual diet, plan dietary modifications in accordance with checking for commonly used foods, ethnic foods or special dietary restrictions and practices. Avoid overly restrictive diet regimens unless medically necessary.

Sodium restriction

A reduction in dietary sodium intake of 2,000-3,000 mg per day alone may provide substantial hemodynamic and clinical benefits for heart failure patients. Unfortunately patients (and physicians) frequently rely solely on diuretics to control symptoms. Stress the importance of reading labels, and a no-salt-added diet. If patient has repeat episodes of edema or failure, a daily sodium intake of 2,000 mg or less is recommended. Patients should be referred to a registered dietitian if there are repeat episodes of edema or for comorbid conditions such as diabetes, dyslipidemia and renal failure. It is important to help patients prioritize dietary modifications. For example, low-fat, low-saturated fat diets would be appropriate for patients with hypercholesterolemia. Dietary modifications may need to be liberalized to increase compliance with dietary restrictions required for management of heart failure.

There are specific recommendations for sodium restrictions, these are the generally accepted and utilized guidelines. A goal of 2-3 grams of sodium daily is reasonable for many patients and is achieved by following a no-added-salt (NAS) diet and the judicious use of processed foods. A stricter recommendation of 2,000 mg sodium/day or less and not more than 700 mg/meal may be considered for patients with moderate to severe heart failure. Education on alternatives for flavoring and label reading should be conducted by a registered dietitian. Caution patients about the use of potassium-containing salt substitutes and potassium intake in general, which could contribute to the development of significant hyperkalemia.

(Adams, 2006 [R]; Dracup, 1994 [M])

When appropriate, patients should have dietary counseling to teach them about the need for management of fluid balance, and the importance of avoiding excess sodium and/or water intake.

Fluid management

Patients should be advised to avoid excessive fluid intake. Not all patients require a fluid restriction, however, if patient is edematous or hyponatremic (serum sodium less than 130 mEq/L), a 1,500 or 2,000 cc/day fluid restriction should be recommended.

Alcohol intake

Since even moderate usage may be associated with decreasing ventricular systolic function, alcohol use should be discouraged, or at the least, saved for special occasions. One drink is considered 10 oz. of beer, 5 oz. of wine or 1.5 oz. of hard liquor. In severe heart failure or those with alcoholic cardiomyopathy, complete abstinence is recommended.

Dietary Supplements and Vitamins

Formerly called herbals, any over-the-counter dietary supplement or vitamin product should be discussed with a health care provider to make sure there is not an interaction with the disease condition or other medications.

Multiple vitamin-mineral supplementation should be considered for those on diuretic therapy and restricted diets to ensure an adequate intake of the recommended daily equivalent of essential nutrients *(Adams, 2006 [R])*.

Daily Weights

Daily weights should be taken upon rising in the morning (before eating and after urinating), on the same scale, wearing the same amount of clothing. Patients should report significant gains or losses to their care provider, along with any new or worsening symptoms. Patients should be instructed to keep an ongoing record of these weights and bring these values to all medical appointments. Patients should call about a greater than or equal to two-pound weight gain overnight or a five pound or greater weight gain in a week. To avoid dehydration, patients should additionally call their health care provider if they have decreased oral intake of fluids and are experiencing unanticipated weight loss of greater than three to five pounds. Daily weights are critical for managing heart failure and early detection of fluid retention. Increases in body weight are associated with hospitalization for heart failure and begin at least one week before admission. Daily information about the patient's body weight identifies a high-risk period during which interventions to avert decompensated heart failure and subsequent hospitalization may be beneficial.

(Agency for Health Care Policy and Research, 1994a [R]; Chaudhry, 2007 [C]; Dracup, 1994 [M]; Heart Failure Society of America, 1999 [R])

Medications

Because of the advanced age of this population and the complexity of medication regimes, every effort should be made to simplify and clarify a patient's medications.

- Group medications so they are taken together (i.e., not more than four times per day).
- Cut down on the frequency of each medication taken per day (i.e., twice daily versus three times daily if bioequivalent).
- Emphasize taking medications at the appropriate time to maximize symptom control (i.e., take nitrates on an empty stomach; however, caution regarding the increased risk of syncope with elderly patients).

- NSAIDs and COX-2 inhibitors are not recommended in patients with chronic heart failure.

All medication instructions, including over-the-counter medications, should be reviewed at each interaction, written clearly and reinforced verbally. The indications and possible side effects of each medication should be explained and patients should be reminded not to stop or change their medications without talking to their provider or nurse.

Vaccinations

Pneumococcal vaccine and annual influenza vaccination are recommended in all patients with heart failure in the absence of contraindications *(Adams, 2006 [R])*.

Exercise and Activity Guidelines

Bed rest may be prescribed for patients with decompensated heart failure, because it encourages diuresis and reduced myocardial oxygen consumption. However, investigators have now shown that regular exercise in heart failure patients produces positive effects and represents minimal risks. Regular physical activity increases functional status and decreases symptoms of heart failure, except in patients with acute myocarditis or recent MI for whom exercise restrictions are appropriate.

Exercise instruction should be included as a part of a comprehensive heart failure program. Referral to a cardiac rehabilitation program is recommended for exercise prescription and modeling and will contribute to patients' compliance with exercise, functional improvement and quality of life. Participation in a formal program may also contain education and compliance monitoring of lifestyle management components for heart failure.

Patients should be counseled about the benefits of a low-intensity aerobic exercise and light weight conditioning programs. Abnormal responses to exercise, such as lightheadedness, chest pain, marked dyspnea, or unusual fatigue should also be discussed with the patient. Increased workload on the heart, either too heavy or too sustained, may result in decompensation of heart failure. Modifications to a patient's daily work schedule and duties may become necessary to accommodate the need for more frequent rest breaks and decreased functional abilities.

Patients should be advised that if they are overly tired the day following an exercise session, modifications are in order. Patients should incorporate an appropriate warm-up and cool-down period.

Note: It is not uncommon for patients who have been exercising for approximately six weeks to need an increase in diuretic dosage. Care should be taken that this does not discourage the patient from continuing exercise training.

(Belardinelli, 1995 [C]; Coats, 1992 [A]; Dracup, 1994 [M]; Fletcher, 2001 [R]; Flynn, 2009 [A]; Piña, 2003 [R]; Sullivan, 1996 [R])

Make sure to arrange home care services or home care physical therapy to aid the patient with activities of daily living.

Recommendations should be made to make exercise a pleasurable and convenient activity for patients with heart failure. These recommendations should be blended with activities of daily living and potentially free of cost. The following can be adapted for patients with heart failure, because many patients have other comorbid conditions:

> In patients with stable heart failure, a low-intensity home walking exercise (HWE) program is effective in improvement of functional status and symptoms. HWE programs involving home visits will have more compliance from the patients compared to hospital-based cardiac rehabilitation programs *(Corvera-Tindel, 2004 [A])*. Comprehensive outpatient rehabilitation programs for patients with NYHA

class II and III heart failure for even 12 weeks improve exercise capacity and quality of life *(Meyer, 2003 [D])*.

Phase 3 Cardiac Rehabilitation

Phase 3 programs are outpatient nonmonitored. At hospital discharge, patients should receive an exercise prescription based on tolerance to in-hospital activity, risk factors and stress testing (if done). Unless there is a long-term effort of encouragement, most patients will revert back to previous sedentary activities *(Holmback, 1994 [A])*.

Phase 3 cardiac rehabilitation emphasizes exercise training and activity prescription, risk factor modification, and psychosocial evaluation and counseling in an attempt to lower morbidity and mortality. The following should be considered when writing an exercise prescription:

- **Exercise treatment.** Education about the signs and symptoms of overexertion, angina and cardiopulmonary distress is important.
- **Type of exercise.** Aerobic exercise is emphasized. It includes any activity that preferentially uses large muscle groups and can be maintained for a prolonged period (e.g., walking). Pure isometric exercise should be minimized because it may result in LV decompensation in patients with poor LV function.
- **Intensity of exercise.** This should be based on an exercise tolerance test or the MET level at discharge from phase 2 rehabilitation. In patients with an angina threshold of 2-3 METs, exercise training may not be appropriate. In general, moderate intensity (to 40%-60% of functional capacity) is advisable during the first weeks of conditioning, with a goal to reach 40%-85%, or that of the functional capacity of the population at large *(Lavie, 2009 [R])*.
- **Target heart rate.** This should be determined from an exercise test or a monitored exercise session. If this is not feasible, target heart rate can be calculated as follows:

  220 – age = maximum heart rate

  65% x maximum heart rate = target heart rate

  This applies to patients who are not taking a beta-blocker and who have been shown to tolerate the heart rate without ischemia.
- **Monitoring rate of perceived exertion (RPE).** The Borg scale of perceived exertion is a useful tool in guiding exercise programs. It is used in conjunction with the target heart rate when instructing patients on exercise tolerance. Target rates are usually between 11 (fairly light) and 14 (somewhat hard to hard). RPE is advantageous for many reasons: it is unaffected by negative chronotropic medications, unlike heart rate monitoring; it is quite reproducible across age, gender and cultural origin; and lastly, it requires only patient attunement to symptoms *(Squires, 1990 [R])*.
- **Duration of exercise.** Initially, multiple 10-minute bouts distributed throughout the day may be optimal for some patients. During the first two to six weeks of participation, exercise duration should be gradually increased from 30 minutes to 45 minutes or more. (This does not include the warm-up, cool-down or stretching periods crucial to any workout.) Duration should be increased to 20-30 minutes before intensity is increased. A steady rate of perceived exertion should be maintained by increasing frequency as tolerated. Patients should exercise for 200 minutes per week in four to five divided sessions.
- **Frequency of exercise.** From the onset, exercise frequency should be three to five times per week.

Smoking Cessation

Cigarette smoking increases the incidence of congestive heart failure (HF) *(American Heart Association, 2005 [C])*. In fact, using the NHANES I epidemiologic data, cigarette smoking is clearly an independent risk factor for heart failure *(He, 2001 [B])*. As heart failure continues to increase in prevalence in the U.S., we will need to look at how to prevent decompensation of previously stable heart failure patients. Several precipitating factors have been suggested in the relapse of heart failure, and one of them includes cigarette smoking *(He, 2001 [B])*. Cigarette smoking activates the sympathetic nervous system, which causes an elevation in blood pressure and heart rate, which in turn increases myocardial oxygen consumption *(Narkiewicz, 1998 [C]; Winniford 1986 [C])*. Smoking also decreases myocardial oxygen supply, due to reduced diastolic filling time and increased carboxyhemoglobin level *(Nicolozakes, 1988 [C])*. Both increases in myocardial oxygen consumption and decreased myocardial oxygen supply have adverse effects on the heart. Research on the participants in the Study of Left Ventricular Dysfunction (SOLVD) showed that current cigarette smoking increased mortality and hospitalization compared to ex-smokers and those who never smoked *(Suskin, 2001 [B])*. Quitting smoking is associated with a significant decrease in risk of all-cause mortality among patients with coronary heart disease *(Critchley, 2003 [M])*. In fact, in patients with left ventricular dysfunction, research on the SOLVD participants showed that quitting smoking substantially decreases morbidity and mortality within two years *(Suskin, 2001 [B])*.

For more information, see the ICSI Preventive Services for Adults guideline.

Coping with Chronic Disease

Education and counseling

Comprehensive education and counseling are essential for patients and caregivers to gain an understanding of disease process and recommendations for disease management. The goals should focus on giving patients, family and caregivers the knowledge and self-care tools to effectively participate in treatment plans. Emphasis should be placed on understanding the definition and cause of the patient's heart failure, symptom recognition, medication usage and indications, risk factor modification, diet, activity and lifestyle recommendations, and the importance of treatment adherence.

Hospital discharge

Comprehensive discharge planning with detailed written instructions for the patient and caregivers should be implemented to promote compliance and understanding of treatment and educational goals. Discharge instructions should address medication regimes, dietary instructions for sodium and fluid restriction recommendations, activity level, weight monitoring and what to do if symptoms return or worsen. A discharge follow-up appointment should be scheduled within one to two weeks to assess the patient's status, titrate medications toward recommended target doses and to reinforce and supplement education initiated in the hospital.

(Adams, 2006 [R]; Arnold, 2008 [R]; Arnold, 2006 [R]; Jessup, 2009 [R]; Koelling, 2005 [A])

Transitional care

Transitional, or transition of care, is an important aspect of patient management that promotes continuity of care and facilitates safe and timely transfer of patient from one level of care to another. Transitional care particularly targets patients at high risk for heart failure readmission; for example, those with previous hospitalizations, multiple comorbidities or medications, cognitive or functional impairment, depression, or limited social support. Patients with new-onset heart failure should be assessed and treated with some urgency, because their mortality is high within the first few weeks after diagnosis. Referral to a comprehensive heart failure disease management program should be considered for these high risk patients. Many models of chronic disease management programs in primary care are being developed across the country and offer great opportunities for innovative care delivery to heart failure patients and their families. This

heart failure care, however, should complement but not replace the other comprehensive care delivered by the PCP *(Arnold, 2008 [R])*.

Heart failure management programs

Referral to a heart failure clinic or care management program should be considered if the patient has complex medical problems or is at high risk for rehospitalization (criteria for high-risk readmission is BNP greater than 350 pg/mL). Heart failure disease management programs have been shown to improve patient outcomes. Studies have been done looking at the management of heart failure using both clinic and home-based care models. These have shown convincing evidence that the rate of rehospitalization and costs can be significantly reduced as well as improving quality of life *(Adams, 2006 [R]; Gregory, 2006 [C]; Hartmann, 2004 [C]; Logeart, 2004 [C]; Redfield, 2002 [D]; Sisk, 2006 [C]; Whellan, 2007 [M])*.

A heart failure care management or disease management program may include the following components:

- Assessment and Care Planning – nurse determines health education needs and monitoring priorities for each patient.
- Routine monitoring – nurse determines the frequency based on the patient's care plan.
- Patient Self Monitoring – nurse teaches patient better self-management skills by instructing and encouraging them to monitor their health.
- Patient Education – nurse teaches patient how to recognize signs and symptoms of their disease; how to monitor vital signs and daily weights; the cause of diseases; how to better adhere to diet, exercise, and medication regimens; and strategies to cope with chronic illness.
- Care Coordination – nurse teaches patients how to better communicate with their health care provider.
- Service Arrangement – nurse identifies patients who need additional services such as transportation, meal delivery, home health services, and spiritual care.
- Depression – nurse takes ongoing assessments of depression status, medication adherence and makes mental health treatment/referrals as needed *(Lichtman, 2008 [R])*.

(Esposito, 2008 [A])

Stress reduction

Stress reduction and relaxation techniques may be of benefit to some patients and should be encouraged.

(Beary, 1974 [C]; Mandle, 1996 [M])

Depression, adjustment disorder with depression

Major depression is common in patients hospitalized with heart failure and is independently associated with a poor prognosis *(Jiang, 2001 [B])*. It is independently associated with a substantial increase in the risk of heart failure among older persons with isolated systolic hypertension. This association does not appear to be mediated by myocardial infarction *(Abramson, 2001 [B])*. An increasing number of depressive symptoms is a negative prognostic factor for patients with heart failure, just as it is for patients with CHD *(Vaccarino, 2001 [B])*. It is an independent risk factor for functional decline and death in heart failure patients *(Guck, 2003 [R])*.

Frequently, depression is not assessed, or not treated adequately or at all. As yet there are no data to support the hypothesis that antidepressant treatment improves cardiac morbidity and mortality *(Jiang, 2005 [R])*. **Nevertheless, consensus opinion is to treat depressed cardiac patients with a safe drug rather than**

watchful waiting since they would benefit from symptomatic relief of their depressive symptoms, and there is a potential improvement in their cardiovascular risk profile *(Ballenger, 2001 [R])*.

Although tricyclic antidepressants are affective against depression, they are associated with cardiovascular side effects including orthostatic hypotension, slowed cardiac conduction, antiarrythmic activity, and increased heart rate. SSRIs, by contrast, are well tolerated and have a more benign cardiovascular profile and would be preferred initial agents for treatment of depression in individuals with cardiovascular disease *(Jiang, 2005 [R])*.

The current advisory from the American Heart Association indicates clinicians should screen for depression by administering one of several self-report instruments. Cognitive behavioral therapy (CBT) is the most effective, skill-based psychological treatment for depression. Though well designed studies are still needed, it would appear that the newer agents, particularly the SSRIs, are preferred over the TCAs, which should be avoided when treating depression in patients with heart failure *(Guck, 2003 [R]; Jessup, 2009 [R])*.

Screening for depression can include asking the following questions from the PHQ-2.

Over the past two weeks, have you been bothered by:

1. Little interest or pleasure in doing things?
2. Feeling down, depressed or hopeless?

If the patient answers "yes" to either of the above questions, consider using a questionnaire to further assess whether the patient has sufficient symptoms to warrant a full clinical interview and a diagnosis of clinical major depression. An example of such a questionnaire is the PHQ-9 (Patient Health Questionnaire).

(Lichtman, 2008 [R])

This should not be considered a comprehensive screening for depression, which is beyond the scope of this guideline. See the ICSI Major Depression in Adults in Primary Care guideline for more information.

Advanced Directives

The Minnesota Health Care Directive established by the Minnesota Legislature in 1998, is a written document that satisfies State of Minnesota requirements for advance directives. This document combines the functions of a Living Will and Durable Power of Attorney for Health Care into a single legal declaration; i.e., it informs others of the individual's wishes about health care and allows naming a person ("agent") to decide if the individual is unable to decide or if the individual wants someone else to decide. An attorney is not required for document completion, and the document can be amended or revoked at any time by the author.

See the ICSI Preventive Services for Adults guideline for more information.

End-of-Life Considerations

Ongoing patient and family education regarding prognosis for functional capacity and survival is recommended for patients with heart failure as part of disease management. A patient's status should be medically and psychologically optimized before discussing end of life care.

Discussion regarding end of life care should be considered for those with advanced heart failure with symptoms at rest despite repeated attempts to optimize medical treatments. Whenever possible, the patient should be involved in the decision making process. Discussion is recommended regarding the option of inactivating ICDs for patients with heart failure at the end of life. Aggressive procedures performed within the final days of life are not appropriate. See the ICSI Palliative Care guideline for more information.

(ACC/AHA Practice Guidelines, 2005 [R])

15. Symptom Control Satisfactory?

- Consider reassessment of ventricular function (echocardiography or radionuclide ventriculography) if the symptoms persist despite changes in pharmacologic management, or if symptoms markedly change.

16. Ongoing Assessment of Response to Treatment and Evaluation for Symptom Exacerbation

- After initial evaluation and diagnosis, follow-up of heart failure patients in the ambulatory setting should focus on optimizing pharmacologic therapy and prevention of heart failure exacerbations.
- Patient education should be ongoing and consistently reinforced, and family members should be a part of this process whenever possible. Symptoms of worsening heart failure should be explained, and patients should be advised to contact their provider or nurse if these symptoms develop.
- Patients should be advised to call their provider about a greater or equal to two pounds/day weight gain or five or more pounds/week. They can expect the provider to assess symptoms, adjust diuretics if appropriate, discuss dietary sodium compliance/restriction, review treatment plan, and recommend appropriate level of care (office visit, ER, etc.).
- Also refer to Appendix B, "Strategies to Address Adherence to Treatment Plan."

Accessibility

Intimidation by or frustration with large health care systems and social isolation are factors that distance patients from their health care providers. A patient's failure to maintain this contact, as well as inadequate patient education, contribute to poor patient compliance and high hospital admission and readmission rates in this population *(Moser, 1996 [R]; Rich, 1995 [A])*.

- To prevent heart failure exacerbation, efforts and resources should be directed toward early intervention in the form of increased accessibility to care and education aimed at symptom recognition and treatment plan adherence.
- Frequently, patients wait until they are in crisis before seeking medical assistance, bypassing the provider's office and going straight to the emergency department (ED). Limited hours and limited/untrained staff at providers' offices have been cited as reasons patients seek acute care with worsening symptoms of heart failure.
- Case managers and heart failure clinics have been shown to be effective strategies to avert ED visits and hospitalizations by providing patients with a contact person who is familiar with their care in order to expedite treatment alternatives. This contact person, usually a nurse, is available to answer questions and clarify instructions, potentially increasing treatment plan compliance. The nurse should have adequate ancillary support services available, e.g., social workers, dietary.
  - A mid-level provider can provide an appropriate level of care adjusting medications and dosages.
  - NTproBNP has been shown to be useful in determining the long-term prognosis of patients with congestive heart failure. After hospital admission the euvolemic/dry BNP value at discharge can be used as a meaningful and valuable baseline level for subsequent monitoring and management of patients with heart failure.
- Time between visits is important for the patient to formulate questions and assimilate the previously presented information. Family members and caregivers should also be involved in education to support the patient's efforts.

(Hafferkamp, 1996 [R]; Kasper, 2002 [A]; Moser, 1996 [R]; Rich 1995 [A])

Emergent Management Algorithm Annotations

Introduction

There are no evidence-based, generally accepted, comprehensive treatment guidelines for decompensated heart failure in the literature. Some of the medications are well researched, others are not. There are no therapeutic trials defining the optimal sequence of drug interventions (e.g., diuretics, inotropes, vasodilators, or neurohormonal) for this condition. Further, there are few "head-to-head" trials of drugs between drug classes.

Some treatments in current practice (e.g., IV ACE inhibitors, long-term IV dobutamine) are not included because the published reports involved very small numbers of patients. Milrinone and dobutamine, although well known to change hemodynamic measures, are not associated with improved clinical outcomes and may, in fact, increase mortality.

Morphine is considered to be a first-line drug of choice in many previous recommendations. Again, hemodynamic and antianxiety effects are substantiated, but improved clinical outcomes are not. Studies are lacking in the evaluation of potential adverse effects, such as respiratory depression. The negative effects may be overshadowed by the positive effects of other drugs being administered. Interestingly, many recent studies are not including morphine in the first-line therapeutic regimen.

Clinical Focus

The following approach to the acutely symptomatic, decompensating heart failure patient begins with the basic "ABCs" of resuscitation, then proceeds with an assessment of volume status. This guideline focuses on the decompensated patient with adequate blood pressure who is not in shock.

18. Initial Patient Assessment

- History
- Physical

Notes:

- Patients with decompensated aortic stenosis should not receive vasodilator agents (vs. mitral regurgitation patients, who benefit greatly).
- Patients with jugular venous distension from right ventricular infarct may require a fluid challenge.
- Patients with low cardiac output and peripheral vasoconstriction have unreliable non-invasive blood pressure measures.
- Digoxin, as an inotrope, is not useful in the acute management of decompensated heart failure (it may be used to control atrial fibrillation).

Differential Diagnosis:

- Chronic obstructive lung disease
- Asthma exacerbation
- Volume overload (iatrogenic)
- Chordae rupture
- Acute coronary syndrome
- Pulmonary embolism
- Sepsis
- Severe pneumonia
- Anaphylaxis
- Takotsubo cardiomyopathy

21. Initiate O_2 Therapy, Start IV, Order Labs, Chest X-Ray and ECG. Consider ECHO

A. Initial Laboratory Assessment:

- CBC
- Electrolytes (Na+, K+)
- Renal function (BUN, creatinine)
- Magnesium (if on diuretics)
- Calcium
- Urinalysis
- Digoxin level (if on digoxin)
- PT/INR if on coumadin
- Cardiac markers (CKMB, troponin)
- Glucose
- BNP (if the diagnosis is uncertain)
- Blood gases (may be indicated if the patient is hypoxic, has underlying lung disease or has persistent respiratory distress)

B. ECG and Continuous Rhythm Monitoring: Recommended in All Cases

C. Imaging: A Chest X-ray is Recommended in All Cases

- An emergent echocardiogram is indicated for the patient who is not improving with initial interventions.

23. Adjust O_2 Delivery/Consider CPAP/Bilevel Positive Airway Pressure (BiPAP)/Intubation/Follow ACC/AHA Guidelines

Non-invasive ventilory support has been proven effective and may reduce the need for intubation. Continuous positive airway pressures (CPAP) and bilevel positive airway pressure are both effective airway supports. Bilevel use is controversial in patients with acute MI *(Kosowsky, 2000 [R])*.

34. Acute Pulmonary Edema BP Greater than 100 mmHg

Patients with edema, jugular venous distension, positive hepatojugular reflux and/or rales are likely to be volume overloaded.

Causes of Acute Pulmonary Edema:

- Acute myocardial infarction/ischemic heart disease
- Pericardial tamponade
- Obstructive or severe valvular disease
- Cardiomyopathy (e.g., infectious, toxic, hypothyroidism, peripartum, hypertrophic)
- Acute renal failure
- Hyper/hypothyroidsm
- Arrhythmias
- Malignant hypertension

- Hypermetabolic conditions (thyrotoxicosis, pheochromocytoma, heat stroke)
- Pulmonary embolus

Acute Pulmonary Edema Algorithm

41. Volume Overload?

Patients with persistent volume overload may be candidates for continuous IV diuretics, ultrafiltration or hemodialysis (all out of guideline).

43. Loop Diuretic, IV Bolus, Consider IV Infusion

- Furosemide is the most commonly used loop diuretic, with the dose adjusted upward if the patient is currently on oral doses. Diuretic effect occurs in 30 minutes, with peak effect in one to two hours.
- The absorption of oral loop diuretics is considerably reduced when edema has spread to the lining of the gastrointestinal tract. In this setting, loop diuretics with higher absorption rates, such as torsemide and bumetanide, may be more effective.

(Internet sites last accessed December 8, 2009: www.cardiosmart.org, www.tripdatabase.com, www.chfpatients.com)

The pharmacologic characteristics of all loop diuretics are similar. Therefore, a lack of response to adequate doses of one loop diuretic mitigates against the administration of another loop diuretic; instead, combinations of diuretics with different mechanisms of action should be given *(Brater, 1998 [R])*.

In patients who have poor responses to intermittent doses of a loop diuretic, a continuous intravenous infusion can be tried. If an effective amount of the diuretic is maintained at the site of action at all times, a small but clinically important increase in the response may occur *(Dormans, 1996 [A]; Rudy, 1991 [A])*. There are other reasons to consider giving a continuous infusion of a loop diuretic. It may be easier for nursing staff to give a continuous infusion than intermittent bolus intravenous doses. In addition, with a continuous infusion, decisions about the timing of doses of an additional diuretic are simplified. Finally, by closely monitoring urinary output, one can unambiguously determine whether the added drug was beneficial.

Another strategy to enhance the response to a loop diuretic is to add an oral or IV thiazide diuretic *(Ellison, 1991 [R]; Epstein, 1977 [D]; Olesen, 1971 [A]; Sica, 1996 [D])*. Metolazone is frequently given in the United States, whereas other thiazides are given elsewhere. The pharmacologic characteristics of metolazone are similar to those of other thiazides. Some formulations of the drug are absorbed poorly and slowly, and it has a long elimination half-life (about two days). Thus, metolazone accumulates over a period of about 10 days. Other thiazides have the same synergistic effects when combined with a loop diuretic. Since the absorption of other thiazides, such as hydrochlorothiazide, is more rapid and predictable, they may be preferable to metolazone.

44. Nitroglycerin Sublingual or Drip

Concurrent with diuretic therapy is the initiation of vasodilators:

- Nitroglycerin, 0.4 mg sublingual or paste

Many patients will improve symptomatically with the "first-line therapy" and may be transferred to an observation unit or inpatient bed.

(Jain, 2003 [R]; Marx, 2002 [R])

Patients who are not improving will need more aggressive treatment:

- Begin nitroglycerin infusion at 10-20 mcg/min and increase by 10-20 mcg/min every 3-5 minutes to achieve desired effect. The maximum dose is 300 mcg/min.
- We recommend the upward titration of nitroglycerin before converting to nesiritide.

Alternative dosing protocols exist; they may provide a greater safety margin, such as:

Polyethylene lined tubing should be used with nitroglycerin drips, 5 mcg/min, initial titration should be in 5 mcg/min increments at intervals of 3-5 minutes guided by patient response; if no response is seen at 20 mcg/min, incremental increases of 10 and 20 mcg/min may be used; polyethylene lined tubing, initial dose 25 mcg/min IV.

Additional note: some ICUs and EDs are now titrating in mcg/kg/min.

(Jain, 2003 [R]; Marx, 2002 [R])

A patient who continues to exhibit signs and symptoms of volume overload despite aggressive loop diuretics and IV nitroglycerin may be a candidate for nesiritide.

Nesiritide reduces pulmonary capillary wedge pressure and improves dyspnea in patients with acute decompensated heart failure. Compared with dobutamine, ventricular arrhythmias and cardiac arrest occurred less frequently with nesiritide. Nesiritide can cause symptomatic hypotension comparable to nitroglycerin; however, the duration of symptomatic hypotension with nesiritide is longer (2.2 hours versus 0.7 hours) *(Burger, 2001 [A]; Burger, 2002 [A]; Colucci, 2000 [A])*.

- Nesiritide 2 mcg IV bolus, then 0.01 mcg/kg/min IV infusion.
- Nesiritide, a natriuretic peptide, has been tested in combination with diuretics but not with IV nitroglycerin. The safety profile is favorable in comparison with the phosphodiesterase inhibitors (e.g., milrinone) or the adrenergic inotropes (e.g., dobutamine).

The experience with nesiritide to date has been limited, in comparison with the other two drugs.

46. Stabilized?

Patients who stabilize may be admitted to an observation unit or monitored hospital bed.

Unstable criteria include:

- Unstable vital signs
- ECG or serum markers of myocardial ischemia
- Decompensation (concomitant end-organ hypoperfusion, volume overload and systemic vasoconstriction)
- Requiring continuous vasoactive medication (e.g., nitroglycerin, nitroprusside, dobutamine or milrinone) to stabilize hemodynamics
- Non-sustained ventricular tachycardia not caused by electrolyte imbalance
- Acute mental status abnormality
- Severe electrolyte imbalances, in particular potassium or K+; these should be rechecked/monitored with the aggressive use of loop diuretics and/or aldosterone antagonists.

47. Out of Guideline – Consider Consultation and/or Tertiary Center Referral

Patients who remain unstable are candidates for ICU admission or tertiary care center referral. Consider consultation for emergent imaging and physiologic assessment, either non-invasive or invasive (e.g., pulmonary artery catheterization). This evaluation will allow more precise medical management and will determine candidates for mechanical devices, continuous inotropic therapy, biopsy, surgical interventions or hospice.

48. Emergency Department Observation or Short-Stay Admission?

Some heart failure patients may be managed in a short-stay or observation unit. A short stay for diagnosis, intensive therapy and education has demonstrated advantages. Institutions that utilize observation units will need to have selection criteria and observation protocols to achieve optimal results.

Peacock and Albert provide a framework for the use of observation units in the management of heart failure patients. Observation units provide a cost-effective alternative to hospitalization for select patients *(Peacock, 2006 [R])*.

Appendix A – Heart Failure Classification Comparison

ACC/AHA 2001 Staging Compared to NYHA Functional Classification

ACC/AHA, 2001		NYHA	
A	At high risk of developing HF, but without structural heart disease or symptoms of HF	**None**	
B	Structural heart disease, but without symptoms of HF	**I**	Asymptomatic
C	Structural heart disease with prior or current symptoms of HF	**II**	Symptomatic with moderate exertion
		III	Symptomatic with minimal exertion
		IV	Symptomatic at rest
D	Refractory HF requiring specialized interventions	**IV**	

ACC = American College of Cardiology, AHA = American Heart Association,
NYHA = New York Heart Association, HF = Heart Failure

The New York Heart Association (NYHA) classification is a four-level scheme for grading the functional incapacity of patients with cardiac disease. Although criticized for lack of reliability, this system is still widely used.

The ACC/AHA heart failure grading scheme takes into consideration the natural history and progressive nature of heart failure.

For each of these classes, recommendations for prevention, ongoing surveillance for disease progression and specific medical therapy are outlined. This new classification scheme is often used in conjunction with the NYHA classification described above.

Appendix B – Strategies to Address Adherence to Treatment Plan

The provider-patient relationship plays an essential role in improving compliance. A member of the health care team should assess for medication and dietary adherence at every visit. The preferred approach is to ask nonthreatening, open-ended questions. Include probes for factors that contribute to nonadherence, including adverse reactions, misunderstanding of treatment plan, depression, cognitive impairment, complex dosing regimens and financial constraints.

1. **Assess knowledge of heart failure**
   - When you hear the words heart failure, what does that mean to you?
   - What do you know about your heart and the type of heart failure you have, and what may have caused it to develop?
2. **Assess adherence to daily weights**
   - Can you tell me why it is important to weigh yourself every day?
   - Are you willing and able to weigh yourself at home every day to monitor for fluid weight gain?
   - Is there anything that might keep you from being able to weigh yourself at home on a regular basis?
3. **Assess adherence to medication regimen**
   - Can you tell me why you are taking this medicine?
   - Do you have a reminder system for taking your medications?
   - In general, how often do you miss or skip doses of any of your prescribed medications for any reason?
   - What is the most common reason(s) you might miss or skip a dose?
   - What do you do when you miss a dose?
   - Is the cost of medication interfering with your treatment?
   - Are you experiencing any unusual symptoms that you think may be due to your medications?
4. **Assess adherence to low sodium diet**
   - Has your doctor (provider) ever talked with you about limiting the amount of salt, or sodium you eat?
   - Did your doctor (provider) tell you how much sodium you can have in a day?
   - Why is it so important for you to follow a low sodium diet?
   - Who prepares your meals? Is he/she aware of your sodium restriction?
   - What steps do you take to limit the sodium in your diet?
   - What things do you/might you find (most) difficult about following a low sodium diet?
5. **Assess Adherence to Treatment Plan**
   - Are you comfortable with your ability to follow the treatment plan we have designed for you?
   - What is the most difficult task you have in following your treatment plan?

Source: Marshfield Clinic

Appendix C – Measurement Tool – Optional Medical Record Review Format for ACE Inhibitor Use

Name of Patient _____ Reviewer's Initials _____

Medical Record # _____ Date of Review: _____

Three month period reviewed: _____ to _____

Month being reviewed: _____

Date of visit with any diagnosis of heart failure according to the medical group's billing system or appointment list:

Review the most recent visit of this patient with heart failure in the review period.

1. Documentation of diagnosis of heart failure at this visit or within the last six months:

   yes _____ no _____ NYHA classification _____

Synonyms for heart failure:

heart failure	decreased LV function	low ejection fraction
decreased ejection fraction	dilated cardiomyopathy	low EF
decreased EF	left ventricular dysfunction	ischemic cardiomyopathy

2. a. Documentation of patient on ACE inhibitor at this visit or within the last six months: (Drug should be documented on that visit day OR within the past six months OR on last recorded medication list.)

   yes _____ no _____ ACE inhibitor dose _____

Generic Name	**Trade Name**
captopril ± HCTZ	Capoten, Capozide
enalapril ± HCTZ	Vasotec, Vaseretic
lisinopril ± HCTZ	Prinivil, Zestril, Zestoretic
benazepril	Lotensin
fosinopril	Monopril
quinapril	Accupril
moexipril	Univasc
ramipril	Altace
trandolapril	Mavik
amlodipine + benazepril	Lotrel

New ACE inhibitors can be added as they are released.

b. Contraindication:

   yes _____ no _____ reason _____

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Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

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This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Decrease the readmission rate within 30 days of discharge following hospitalization for heart failure.

   Possible measure for accomplishing this aim:

   a. Percentage of adult patients with a primary discharge diagnosis of heart failure who are readmitted for heart failure within 30 days of discharge.

2. Optimize the pharmacologic treatment of patients with heart failure.

   Possible measures for accomplishing this aim:

   a. (inpatient): Percentage of adult patients with a primary discharge diagnosis of heart failure who have left ventricular systolic dysfunction (LVSD) and who do not have contraindications to taking both angiotensin-converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARBs), who are prescribed an ACE inhibitor or an ARB at hospital discharge. (CMS/The Joint Commission quality measure)

   b. (outpatient): Percentage of adult heart failure patients who have ever had LVSD and were prescribed or were taking an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blockers (ARB) within the last 12 months of the clinic visit, or who have contraindications to taking both ACEI or an ARB (primary care and outpatient cardiology).

   c. (inpatient): Percentage of adult patients with a primary discharge diagnosis of heart failure who have LVSD and who do not have a contraindication to taking beta-blockers, who are prescribed beta-blocker therapy at hospital discharge.

   d. (outpatient): Percentage of adult heart failure patients who have ever had LVSD and were prescribed or were on beta-blocker therapy within the last 12 months of the clinic visit or who have a contraindication to taking beta-blockers (primary care and outpatient cardiology).

   e. (outpatient): Percentage of adult heart failure patients who have ever had LVSD and met the following (for which they are eligible) at their last clinic visit: prescribed or were taking ACEI/ARB, prescribed or were on beta-blocker therapy, nonsmoker (primary care and outpatient cardiology).

3. Improve the use of diagnostic testing in order to identify and then appropriately treat adult patients with heart failure.

   Possible measures for accomplishing this aim:

   a. (inpatient): Percentage of adult patients with a primary discharge diagnosis of heart failure with documentation in the hospital record that left ventricular systolic function (LVS) was evaluated before arrival, during hospitalization, or is planned for after discharge. (CMS/The Joint Commission quality measure)

   b. (outpatient): Percentage of adult heart failure patients with documentation that LVS function was evaluated or will be evaluated (primary care and outpatient cardiology).

4. Improve care of adult heart failure patients by assuring comprehensive patient education and follow-up care.

   Possible measures for accomplishing this aim:

   a. (inpatient): Percentage of adult patients with a primary discharge diagnosis of heart failure discharged home with written instructions or educational material given to the patient or his or her caregiver at discharge or during the hospital stay, addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen. (CMS/The Joint Commission quality measure)

   b. (outpatient): Percentage of adult heart failure patients to whom (or to their caregivers) written or verbal instructions or educational material are given during the clinic visit, addressing one or more of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen (primary care and outpatient cardiology).

   c. (inpatient): Percentage of adult patients with a primary discharge diagnosis of heart failure who have used tobacco anytime during the year prior to hospital arrival and who are given smoking cessation advice or counseling during the hospital stay or at discharge. (CMS/The Joint Commission quality measure)

   d. (outpatient): Percentage of adult heart failure patients who are current tobacco users and who are given smoking cessation advice or counseling at the last clinic visit (primary care and outpatient cardiology).

   e. (outpatient): Percentage of patients treated for heart failure who have an improved score on a Quality of Life survey.

Measurement Specifications – Inpatient Heart Failure

Possible Success Measure #1a

Percentage of adult patients with a primary diagnosis of heart failure who are readmitted for heart failure within 30 days of discharge.

Population Definition

Adult patients with a primary diagnosis of heart failure who were discharged alive.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure who were readmitted for heart failure within 30 days of discharge.

Denominator: Number of adult patients with a primary diagnosis of heart failure who were discharged 30 days from the measurement period.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age
- Patients who died prior to discharge
- Patients who were transferred to another hospital
- Patients who left against medical advice
- Patients discharged to hospice

Readmission rate = Number of patients readmitted within 30 days of discharge

Number of patients discharged 30 days from measurement period

Measurement Period

There are two possible periods of evaluations: measuring admission that occurs 30 days prior to a discharge and measuring readmission that occurs 30 days following discharge. For the first option, a hospital would start with the discharges for March and then look at the previous 30 days to see whether any of these discharges were readmissions from a previous hospital stay for heart failure. For the second option, a hospital would start with the discharges for February and track for the next 30 days whether any of these patients are readmitted to the hospital.

Monthly data will be submitted quarterly.

Suggested Sample Size

The suggested sample size is 20 patients per month.

Possible Success Measure #2a

Percentage of adult patients with a primary diagnosis of heart failure who have left ventricular systolic dysfunction (LVSD) and who do not have contraindications to taking both angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARBs), who are prescribed an ACEI or an ARB at hospital discharge.

Population Definition

Adults patients with a primary diagnosis of heart failure and who have left ventricular systolic dysfunction (LVSD)*.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure with LVSD who are prescribed an ACEI or ARB at hospital discharge.

Denominator: Number of adult patients with a primary diagnosis of heart failure with LVSD and without contraindications to both ACEI and ARB.

ICD-9 codes: 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients less than 18 years of age
- Patients with potential contraindications or other reasons for the provider to not prescribe an ACEI at discharge
- Patients with potential contraindications or other reasons for the provider to not prescribe an ARB at discharge
- Patients transferred to another hospital
- Patients who died
- Patients who left against medical advice
- Patients discharged to hospice

Potential contraindication or other reason for not prescribing an ACEI and a potential reason or other reason for not prescribing an ARB at discharge include:

- ACEI and ARB allergy
- Moderate or severe aortic stenosis
- Physician, nurse practitioner or physician assistant documentation of reasons for not prescribing both an ACEI and ARB at discharge
- ACEI allergy and physician, nurse practitioner or physician assistant documentation for not prescribing an ARB at discharge
- ARB allergy and physician, nurse practitioner or physician assistant documentation for not prescribing an ACEI at discharge
- Patient had a left ventricular assistive device (LVAD) or heart transplant procedure during hospitalization

- Patient reasons (refusal, financial hardship, side effects, etc.)
- Pregnancy
- Hyperkalemia (ARB)
- Renal insufficiency (ACEI) or renal dysfunction (ARB)

Measurement Period

The time of evaluation is at hospital discharge. Monthly data will be submitted quarterly.

Definition of Terms

* Left ventricular systolic dysfunction is defined quantitatively as left ventricular ejection fraction less than 40%, and qualitatively as moderately or severely depressed left ventricular systolic function.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #2c

Percentage of adult patients with a primary diagnosis of heart failure who have LVSD and who do not have a contraindication to taking beta-blockers, who are prescribed beta-blocker therapy at hospital discharge.

Population Definition

Adult patients with a primary diagnosis of heart failure and who have left ventricular systolic dysfunction (LVSD)*.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure with LVSD who are prescribed beta-blocker therapy at hospital discharge.

Denominator: Number of adult patients with a primary diagnosis of heart failure with LVSD and without contraindications to beta-blockers.

ICD-9 codes: 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients less than 18 years of age
- Patients with contraindications or other reasons for the provider to not prescribe beta-blocker therapy at discharge
- Patients transferred to another hospital
- Patients who died
- Patients who left against medical advice
- Patients discharged to hospice

Potential contraindication or other reason for not prescribing a beta-blocker include:

- Allergy to beta-blocker
- Bradycardia less than 50 bpm without beta-blocker therapy
- Advanced heart block (greater than one first-degree AV block) unless treated by pacemaker
- Severe bronchospasms/COPD/asthma/reactive airway disease
- Patient reasons (refusal, financial hardship, side effects, etc.)

Measurement Period

The time of assessment is at hospital discharge. Monthly data will be submitted quarterly.

Definition of Terms

* Left ventricular systolic dysfunction is defined quantitatively as left ventricular ejection fraction less than 40%, and qualitatively as moderately or severely depressed left ventricular systolic function.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #3a

Percentage of adult patients with a primary diagnosis of heart failure with documentation in the hospital record that left ventricular systolic function (LVS) was evaluated before arrival, during hospitalization or is planned for after discharge.

Population Definition

Adult patients with a primary diagnosis of heart failure.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure with documentation in the hospital record that left ventricular systolic function (LVS)* was evaluated before arrival, during hospitalization or is planned for after discharge.

Denominator: Number of adult patients with a primary diagnosis of heart failure.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age
- Patients who died prior to discharge
- Patients who were transferred to another hospital
- Patients who left against medical advice
- Patients discharged to hospice
- Patients with reason(s) documented by a physician, nurse practitioner or physician assistant for no LVS function evaluation

Measurement Period

The period for assessment is during the hospital stay and at discharge. Monthly data will be submitted quarterly.

Definition of Terms

* The most useful evaluation of left ventricular systolic is the comprehensive two-dimensional echocardiogram coupled with Doppler flow studies. Radionuclide ventriculography can also be performed to evaluate left ventricular ejection fraction and volume. Description of left ventricular systolic function may be quantitative (i.e., ejection fraction) or qualitative (e.g., "moderately depressed" or visually estimated ejection fraction).

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #4a

Percentage of adult patients with a primary diagnosis of heart failure discharged home with written instructions or educational material given to the patient or his or her caregiver at discharge or during the hospital stay, addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen.

Population Definition

Adult patients with a primary diagnosis of heart failure who are discharged home or to home care.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis for which there is documentation that they or their caregivers were given written instructions or educational material addressing all* of the following:

1. Activity level
2. Diet
3. Discharge medications
4. Follow-up appointment
5. Weight monitoring
6. What to do if symptoms worsen

Denominator: Number of adult patients with a primary diagnosis who are discharged home or to home care.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age

Measurement Period

The time of assessment is at hospital discharge. Monthly data will be submitted quarterly.

Comments

* Completion of all six categories is required for this measure.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #4c

Percentage of adult patients with a primary diagnosis of heart failure who have used tobacco anytime during the year prior to hospital arrival and who are given smoking cessation advice or counseling during the hospital stay or at discharge.

Population Definition

Adult patients with a primary diagnosis of heart failure who have used tobacco anytime during the year prior to hospital arrival and who are discharged alive.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure who have used tobacco anytime during the year prior to the hospital arrival are given smoking cessation advice or counseling during the hospital stay.

Denominator: Number of adult patients with a primary diagnosis of heart failure who have used tobacco anytime during the year prior to hospital arrival.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age
- Patients who died prior to discharge
- Patients who were transferred to another hospital
- Patients who left against medical advice
- Patients discharged to hospice

Measurement Period

The time of assessment is at hospital discharge. Monthly data will be submitted quarterly.

Definition of Terms

* Tobacco user is defined as someone who has smoked tobacco anytime during the year prior to hospitalization.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Measurement Specifications – Outpatient Heart Failure

Possible Success Measure #1a

Percentage of adult patients with a primary diagnosis of heart failure who are readmitted for heart failure within 30 days of discharge.

Population Definition

Adult patients with a primary diagnosis of heart failure who were discharged alive.

Data of Interest

Numerator: Number of adult patients with a primary diagnosis of heart failure who were readmitted for heart failure within 30 days of discharge.

Denominator: Number of adult patients with a primary diagnosis of heart failure who were discharged 30 days from the measurement period.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age
- Patients who died prior to discharge
- Patients who were transferred to another hospital
- Patients who left against medical advice
- Patients discharged to hospice

Readmission rate (%) = Number of patients readmitted within 30 days of discharge.

Number of patients discharged 30 days from measurement period.

Measurement Period

There are two possible periods of assessments: measuring admission that occurs 30 days prior to a discharge and measuring readmission that occurs 30 days following discharge. For the first option, a hospital would start with the discharges for March and then look at the previous 30 days to see whether any of these discharges were readmissions from a previous hospital stay for heart failure. For the second option, a hospital would start with the discharges for February and track for the next 30 days whether any of these patients are readmitted to the hospital.

Monthly data will be submitted quarterly.

Suggested Sample Size

The suggested sample size is 20 patients per month.

Notes

While hospitals have traditionally tracked the readmission rate within 30 days of discharge, care provided in the outpatient setting plays a major role in reducing the readmission rate.

Possible Success Measure #2b

Percentage of adult heart failure patients who have ever had LVSD and were prescribed or were taking an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blockers (ARB) within the last 12 months of the clinic visit, or who have contraindications to taking both ACEI or an ARB (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who have ever had left ventricular systolic dysfunction (LVSD)* and who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients who have ever had LVSD who were prescribed or were taking an ACEI or ARB within the last 12 months of the clinic visit, and those patients with potential contraindications or other reasons for provider to not prescribe ACEI or ARB.

Exclusions:

- Patients less than 18 years of age
- Hospice patients

Potential contraindication or other reason for not prescribing an ACEI and a potential contraindication or other reason for not prescribing an ARB include:

- ACEI and ARB allergy
- Moderate or severe aortic stenosis
- Physician, nurse practitioner or physician assistant documentation of both a reason for not prescribing an ACEI and a reason for not prescribing an ARB
- ACEI allergy and physician, nurse practitioner or physician assistant documentation for not prescribing an ARB
- ARB allergy and physician, nurse practitioner or physician assistant documentation for not prescribing an ACEI
- Patient had a left ventricular assistive device (LVAD) or heart transplant procedure during hospitalization
- Patient reasons (refusal, financial hardship, side effects, patient intolerance of both an ACEI and an ARB through previous attempts with both, etc.)
- Pregnancy
- Hyperkalemia (ARB)
- Renal insufficiency (ACEI) or renal dysfunction (ARB)

Denominator: Number of adult heart failure patients who have ever had LVSD and had a clinic visit in the month in question.

ICD-9 codes: 428.0, 428.1,428.20, 428.21, 428.22, 428.23, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

Data for the month in question cover the prior 12 months. Monthly data will be submitted quarterly.

Definition of Terms

* Left ventricular systolic dysfunction is defined quantitatively as left ventricular ejection fraction less than 40%, and qualitatively as moderately or severely depressed left ventricular systolic function.

The clinic visit is defined as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Examples

A patient who has ever had LVSD and has contraindications to both ACEIs and ARBs would be included in the numerator.

A patient who has ever had LVSD, has contraindications to ACEIs and is on an ARB would be included in the numerator.

A patient who has ever had LVSD, has contraindications to ARBs and is on an ACEI would be included in the numerator.

A patient who has ever had LVSD, has contraindications to ACEIs but is not on an ARB would NOT be included in the numerator.

A patient who has ever had LVSD, has contraindications to ARBs but is not on an ACEI would NOT be included in the numerator.

A patient who has ever had LVSD and refuses to take either an ACEI or an ARB would be included in the numerator.

Possible Success Measure #2d

Percentage of adult heart failure patients who have ever had LVSD and were prescribed or were on beta-blocker therapy within the last 12 months of the clinic visit or who have a contraindication to taking beta-blockers (primary care and outpatient cardiology).

Population Definition

Adults heart failure patients who have ever had left ventricular systolic dysfunction (LVSD)* and who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients who have ever had LVSD and who were prescribed or were on beta-blocker therapy within the last 12 months of the clinic visit, and those patients with potential contraindications or other reasons for provider to not prescribe beta-blocker therapy.

Exclusions:

- Patients less than 18 years of age
- Hospice patients

Potential contraindication or other reason for not prescribing a beta-blocker include:

- Allergy to beta-blocker
- Bradycardia less than 50 bpm without beta-blocker therapy
- Advanced heart block (greater than one first-degree AV block) unless treated by pacemaker
- Severe bronchospasms/COPD/asthma/reactive airway disease
- Patient reasons (refusal, financial hardship, side effects, etc.)

Denominator: Number of adult heart failure patient who have ever had LVSD and had a clinic visit during the month in question.

ICD-9 codes: 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

Data for the month in question cover the prior 12 months. Monthly data will be submitted quarterly.

Definition of Terms

* Left ventricular systolic dysfunction is defined quantitatively as left ventricular ejection fraction less than 40%, and qualitatively as moderately or severely depressed left ventricular systolic function.

The clinic visit is defined as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Examples

A patient who has ever had LVSD and has contraindications to beta-blockers would be included in the numerator.

A patient who has ever had LVSD and refuses to take beta-blockers would be included in the numerator.

A patient who has ever had LVSD, is not on beta-blockers and does not have contraindications would NOT be included in the numerator.

Possible Success Meaure #2e

Percentage of adult heart failure patients who have ever had LVSD and met the following (for which they are eligible) at their last clinic visit: prescribed or were taking ACEI/ARB, prescribed or were on beta-blocker therapy, non-smoker (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who have ever had left ventricular systolic dysfunction (LVSD)* and who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients who have ever had LVSD and met the following at their last clinic visit:

1. Prescribed or were taking ACEI/ARB within the last 12 months of the clinic visit or have contra-indications to both
2. Prescribed or were on beta-blocker therapy within the last 12 months of the clinic visit or who have contraindications to taking beta-blockers
3. Non-smoker

Exclusions:

- Patients who are less than 18 years of age
- Hospice patients

Denominator: Number of adult heart failure patients who have ever had LVSD and had a clinic visit during the month in question.

ICD-9 codes: 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

The measurement period is monthly. Monthly data will be submitted quarterly.

Definition of Terms

* It must be documented that the patient has ever had LVSD (e.g., ejection fraction less than 40% during patient's medical history).

The clinic visit is described as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Examples

- A patient who has ever had LVSD, has contraindications to both ACEI/ARB and meets the other two components of the measure would be included in the numerator.
- A patient who has ever had LVSD, has contraindications to both ACEI/ARB and to beta-blockers and is a nonsmoker would be included in the numerator.
- A patient who has ever had LVSD who has contraindications to only an ACEI and is not on an ARB would NOT be included in the numerator.
- A patient who has ever had LVSD, was prescribed or taking ACEI/ARB and a beta-blocker but is a smoker would NOT be included in the numerator.

Possible Success Measure #3b

Percentage of adult heart failure patients with documentation that LVS function was evaluated or will be evaluated (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients with documentation that left ventricular systolic (LVS) function* was evaluated or will be evaluated.

Exclusions:

- Patients who are less than 18 years of age
- Patients with reason(s) documented by a physician, nurse practitioner or physician assistant for no LVS function evaluation

Denominator: Number of adult heart failure patients with a clinic visit during the month in question

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

The measurement period is monthly. Monthly data will be submitted quarterly. For the patients who are in the monthly sample, the data cover the entire span of the patients' primary care and outpatient cardiology histories.

Definition of Terms

*The most useful evaluation of left ventricular function is the comprehensive two-dimensional echocardiogram coupled with Doppler flow studies. Radionuclide ventriculography can also be performed to evaluate left ventricular ejection fraction and volume. Description of left ventricular systolic function may be quantitative (i.e., ejection fraction) or qualitative (e.g., "moderately depressed" or visually estimated ejection fraction)

The clinic visit is defined as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #4b

Percentage of adult heart failure patients to whom (or to their caregivers) written or verbal instructions or educational material are given during the clinic visit, addressing one or more of the following: activity level, diet, medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients for whom there is documentation that they or their caregivers were given written instructions or educational material addressing one or more of the following:

1. Activity level
2. Diet
3. Medications
4. Follow-up appointment
5. Weight monitoring
6. What to do if symptoms worsen

Denominator: Number of adult heart failure patients who had a clinic visit during the month in question.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Exclusions:

- Patients who are less than 18 years of age

Measurement Period

The measurement period is monthly. Monthly data will be submitted quarterly.

Definition of Terms

- The clinic visit is described as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with multiple disciplines (e.g., nurse, dietician, social worker, exercise physiologist, etc.). Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Measure of Success #4d

Percentage of adult heart failure patients who have used tobacco anytime during the previous year and who were given smoking cessation advice or counseling at the last clinic visit (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who have used tobacco anytime during the previous year who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients who have used tobacco anytime during the previous year and who were given smoking cessation advice or counseling at their last clinic visit.

Exclusions:

- Patients who are less than 18 years of age

Denominator: Number of adult heart failure patients who have used tobacco anytime during the previous year who had a clinic visit during the month in question.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

The measurement period is monthly. Monthly data will be submitted quarterly.

Definition of Terms

* Tobacco user is defined as someone who have used tobacco anytime during the previous year.

The clinic visit is described as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Possible Success Measure #4e

Percentage of adult heart failure patients who have not used tobacco anytime during the previous year (primary care and outpatient cardiology).

Population Definition

Adult heart failure patients who had a clinic visit during the month in question.

Data of Interest

Numerator: Number of adult heart failure patients who have not used tobacco anytime during the previous yearat the time of the clinic visit.

Exclusions:

- Patients who are less than 18 years of age

Denominator: Number of adult heart failure patients who had a clinic visit during the month in question.

ICD-9 codes: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.20, 428.21, 428.22, 428.23, 428.30, 428.31, 428.32, 428.33, 428.40, 428.41, 428.42, 428.43, 428.9. (See ICD-9 Code Descriptions table at the end of this measurement section.)

Measurement Period

The measurement period is monthly. Monthly data will be submitted quarterly.

Definition of Terms

The clinic visit is described as an office visit with a physician, nurse practitioner or physician assistant. Education office visits may include a visit with a nurse. Exclude visits for the purpose of testing or device checks only.

Suggested Sample Size

The minimum sample size is 20 patients per month.

Descriptions of ICD-9 Codes

ICD-9-CM Code	Description
402.01	Malignant, hypertensive heart disease with heart failure
402.11	Benign, hypertensive heart disease with heart failure
402.91	Unspecified, hypertensive heart disease with heart failure
404.01	Malignant, hypertensive heart and renal disease with heart failure
404.03	Malignant, hypertensive heart and renal disease with heart failure and renal failure
404.11	Benign, hypertensive heart and renal disease with heart failure
404.13	Benign, hypertensive heart and renal disease with heart failure and renal failure
404.91	Unspecified, hypertensive heart and renal disease with heart failure
404.93	Unspecified, hypertensive heart and renal disease with heart failure and renal failure
428.0	Unspecified congestive heart failure
428.1	Left heart failure
428.20	Unspecified, systolic heart failure
428.21	Acute systolic heart failure
428.22	Chronic systolic heart failure
428.23	Acute or chronic systolic heart failure
428.30	Unspecified, diastolic heart failure
428.31	Acute diastolic heart failure
428.32	Chronic diastolic heart failure
428.33	Acute or chronic diastolic heart failure
428.40	Unspecified, combined systolic and diastolic heart failure
428.41	Acute combined systolic and diastolic heart failure
428.42	Chronic combined systolic and diastolic heart failure
428.43	Acute or chronic combined systolic and diastolic heart failure
428.9	Unspecified, heart failure

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Develop a process that will allow primary care providers to identify patients who have been readmitted to the hospital with a diagnosis of heart failure.
2. Emphasize patient self-management strategies. These may include heart failure education and other actions designed to sustain engagement of patients with their heart failure care.
3. Develop a process to provide education to the patient and/or caregiver in the area of:
   - diet,
   - weight monitoring (to include: provider should be contacted about a two-pound or greater weight gain overnight or a five-pound or greater weight gain during the week),
   - activity level,
   - medications,
   - the importance of follow-up appointments, and
   - what to do if symptoms worsen.
4. Develop a process for timely, early specialty referral for patients with ischemia or those who are refractory despite optimal medical therapy.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Heart Failure in Adults guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Association of Heart Failure Nurses	Specialty organization dedicated to advancing nursing education, clinical practice and research, to improve heart failure patient outcomes.	Health Care Professionals	http:// www.AAHFN.org
	American College of Cardiology	Offers clinical statements and guidelines to help address contemporary practice issues within the field of cardiology.	Health Care Professionals	http://www.acc.org
	American Heart Association	"Go Red for Women" – Physician Tool Kit	Health Care Professionals	http:// www.americanheart.org
	Channing L. Bete, Co.	Learning to Live with Heart Failure; 31-pg handbook	Patients and Families	800-628-7733 item # 92403 E
	Heart Failure Matters	Offers information to understand heart failure.	Patients and Families	http://www.heartfailurematters.org
	Heart Failure Society of America	The Heart Failure Society of America, Inc. (HFSA) represents the first organized effort by heart failure experts from the Americas to provide a forum for all those interested in heart function, heart failure and congestive heart failure research and patient care. Go to the Web site for more information.	Health Care Professionals	http://www.hfsa.org http://www.hfsa.org/journal.asp
	Krames Communications	Krames: Cardiac Resynchronization Therapy; 16-pg booklet	Patients and Families	800-333-3032 #11468
	Mayo Clinic	Heart failure, also known as congestive heart failure (CHF) means your heart can't pump enough blood to meet your body's needs. Any number of underlying heart conditions can lead to heart failure. Over time, conditions such as coronary artery disease or high blood pressure gradually sap your heart of its strength, leaving it too weak or too stiff to fill and pump efficiently. Information at this site include: signs and symptoms, causes, risk factors, when to seek medical advice, screening and diagnosis, complications, treatment, prevention, self-care, coping skills.	Health Care Professionals; Patients and Families	http://www.mayoclinic.com/health/heart-failure/DS00061
	Minnesota Health Care Directive	MN Department of Health/MN Board of Aging's Senior Linkage	Patients and Families	http://www.health.state.mn.us/ 1-800-333-2433

* Available to ICSI members only.

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	NIH – Medline Plus	Interactive patient tutorial. Also for print.	Patients and Families	http://www.nlm.nih.gov/medlineplus/tutorials/congestiveheartfailure.html
*	North Clinic	Tobacco Cessation Program	Health Care Professionals	Call ICSI to order: 952-814-7060
	Park Nicollet	Hypertension, Understanding	Health Care Professionals; Patients and Families	Download from ICSI Web site: http://www.icsi.org
	Park Nicollet	Lipids, Understanding	Health Care Professionals; Patients and Families	Download from ICSI Web site: http://www.icsi.org
	Park Nicollet	Triglycerides, Facts About	Health Care Professionals; Patients and Families	Download from ICSI Web site: http://www.icsi.org
*	Prichett and Hull Associates, Inc.	Pamphlet: A Stronger Pump	Health Care Professionals	http:// www.p-h.com
	Study Group on Heart Failure Awareness and Perception in Europe (SHAP)	Web site providing information on heart failure prevention and treatment.	Patients and Families	http:// www.heartfailure-europe.com

* Available to ICSI members only.