Guideline Summary NGC-7987

Guideline Title

Disease management, advance directives, and end-of-life care in heart failure: HFSA 2010 comprehensive heart failure practice guideline.

Bibliographic Source(s)

Heart Failure Society of America, Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, Givertz MM, Katz SD, Klapholz M, Moser DK, Rogers JG, Starling RC, Stevenson WG, Tang WH, Teerlink JR, Walsh MN. Disease management, advance directives, and end-of-life care in heart failure: HFSA 2010 comprehensive heart failure practice guideline. J Card Fail 2010 Jun;16(6):e98-114. [210 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Disease management in heart failure. J Card Fail 2006 Feb;12(1):e58-69.

Scope

Disease/Condition(s)

Heart failure

Note: Heart failure is a syndrome caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by either left ventricular (LV) dilation or hypertrophy or both.

Guideline Category

Counseling

Management

Risk Assessment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Intended Users

Advanced Practice Nurses

Dietitians

Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

- To provide recommendations for the education and counseling of patients with heart failure and their caregivers
- To update and expand the previous 2006 clinical practice guidelines

Target Population

Patients with heart failure

Interventions and Practices Considered

1. Individualized education and counseling
2. Comprehensive disease management
3. End-of-life care

Major Outcomes Considered

- Adherence to treatment plan
- Participation in self care
- Quality of life
- Hospitalization rates

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search with relevant key words and phrases for each guideline section were provided to members of the subcommittees and the full Guideline Committee. Members of each subcommittee were asked to review the search and identify any additional relevant medical evidence for each assigned section.

The following databases were searched:

- Ovid Medline (1950 to the updated date when the search was conducted)
- Ovid Medline In-Process and other Non-Indexed Citations
- PubMed

The searches focused primarily on the period between the last guideline publication and current, although the authors went back to 2005 to account for publication lag between the completion of the guideline and its publication in 2006 (i.e., 2005–2010) in the event there was some information that should/could be added to the 2010 updated document. Generally only non-human studies and publications that were non-English were excluded.

The following search terms were used: Heart failure; disease management; terminal care; palliative care; hospices; advance directives; patient education as topic.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Hierarchy of Types of Evidence	
Level A	Randomized, Controlled, Clinical Trials May be assigned based on results of a single methodologically rigorous trial
Level B	Cohort and Case-Control Studies Post hoc, subgroup analysis, and meta-analysis Prospective observational studies or registries
Level C	Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Heart Failure Society of America (HFSA) Guideline Approach to Medical Evidence

Two considerations are critical in the development of practice guidelines: assessing strength of evidence and determining strength of recommendation. Strength of evidence is determined both by the type of evidence available and the assessment of validity, applicability, and certainty of a specific type of evidence. Following the lead of previous guidelines, strength of evidence in this guideline is heavily dependent on the source or type of evidence used. The HFSA guideline process has used three grades (A, B, or C) to characterize the type of evidence available to support specific recommendations (see Table 1.2 in the original guideline document).

HFSA Guideline Approach to Strength of Recommendation

Determining Strength. Although level of evidence is important, the strength given to specific recommendations is critical. The process used to determine the strength of individual recommendations is complex. The goal of guideline development is to achieve the best recommendations for evaluation and management, considering not only efficacy, but the cost, convenience, side effect profile, and safety of various therapeutic approaches. The HFSA guideline committee often determined the strength of a recommendation by the "totality of evidence," which is a synthesis of all types of available data, pro and con, about a particular therapeutic option. The HFSA guideline employs the categorization for strength of recommendation outlined in Table 1.3 in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Process of Guideline Development

Key steps in the development of this guideline are listed in Table 1.4 in the original guideline document. Having determined the broad scope of the current guideline, subcommittees of the guideline committee were formed for each section of the guideline. A literature search with relevant key words and phrases for each guideline section were provided to members of the subcommittees and the full Guideline Committee. Members of each subcommittee were asked to review the search and identify any additional relevant medical evidence for each assigned section. Changes in recommendation and background were carried out by each subcommittee with conference calls directed by the Guideline Committee chair. Each section was presented for comments and consensus approval to the Guideline Committee. Once subsections were complete, the Executive Council reviewed and commented on each section and these comments were returned to the Guideline Committee for changes and once complete, for final approval by the Executive Council.

Consensus

The Heart Failure Society of America (HFSA) Guideline Committee sought resolution of difficult cases through consensus building. An open, dynamic discussion meant that no single voice was allowed to dominate. Written documents were essential to this process, because they provided the opportunity for feedback from all members of the group. On occasion, consensus of opinion was sufficient to override positive or negative results of almost any form of evidence. The HFSA process had a strong commitment to recommendations based on objective evidence rigorously reviewed by a panel of experts. Issues that caused difficulty for the HFSA guideline process were some of the more important ones faced by the committee, because they mirrored those that are often most challenging to clinicians in day-to-day practice. The foundation of the HFSA guideline process was the belief that the careful judgment of recognized opinion leaders in these controversial areas is more likely to be correct than ad hoc decisions made "on the spot" by physicians in practice.

Rating Scheme for the Strength of the Recommendations

Classifying the Strength of the Recommendations

"Is recommended"	Part of routine care Exceptions to therapy should be minimized.
"Should be considered"	Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.
"May be considered"	Individualization of therapy is indicated.
"Is not recommended"	Therapeutic intervention should not be used

Cost Analysis

In a meta-analysis of 29 randomized trials of multidisciplinary heart failure (HF) disease management programs involving 5039 patients, disease management programs were associated with significantly lower mortality and hospitalization rates. The majority of the trials included in this meta-analysis that analyzed cost-effectiveness (15 of 18) demonstrated that the strategies were cost saving.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Each section was presented for comments and consensus approval to the Guideline Committee. Once subsections were complete, the Executive Council reviewed and commented on each section and these comments were returned to the Guideline Committee for changes and once complete, for final approval by the Executive Council.

Recommendations

Major Recommendations

The strength of evidence (A, B, C) and strength of recommendations are defined at the end of the "Major Recommendations" field.

Education and Counseling

1. It is recommended that patients with heart failure (HF) and their family members or caregivers receive individualized education and counseling that emphasizes self-care. This education and counseling should be

delivered by providers using a team approach in which nurses with expertise in HF management provide the majority of education and counseling, supplemented by physician input and, when available and needed, input from dieticians, pharmacists, and other health care providers. (Strength of Evidence = B).

Teaching is not sufficient without skill building and specification of critical target behaviors. It is recommended that essential elements of patient education (with associated skills) are utilized to promote self-care as shown in the Table below. (Strength of Evidence = B).

Table. Essential Elements of Patient Education With Associated Skills and Target Behaviors

Elements of Education	Skill Building and Critical Target Behaviors
Definition of heart failure (HF) (linking disease, symptoms, and treatment) and cause of patient's HF	• Discuss basic HF information, cause of the patient's HF, and how symptoms relate to HF status
Recognition of escalating symptoms and concrete plan for response to particular symptoms	• Identify specific signs and symptoms (e.g., increasing fatigue or shortness of breath with usual activities, dyspnea at rest, nocturnal dyspnea or orthopnea, edema) • Perform daily weights and know how to respond to evidence of volume overload • Develop action plan for how and when to notify the provider, changes to make in diet, fluid and diuretics
Indications for use of each medication	• Reiterate medication dosing schedule, basic reason for specific medications, and what to do if a dose is missed
Modify risks for HF progression	• Smoking cessation • Maintain blood pressure in target range • Maintain normal HgA1c, if diabetic • Maintain specific body weight
Specific diet recommendations: individualized low-sodium diet; recommendation for alcohol intake	• Understand and comply with sodium restriction • Demonstrate how to read a food label to check sodium amount per serving and sort foods into high- and low-sodium groups • Reiterate limits for alcohol consumption or need for abstinence if history of alcohol abuse
Specific activity/exercise recommendations	• Comply with prescribed exercise
Importance of treatment adherence and behavioral strategies to promote	• Plan and use a medication system that promotes routine adherence • Plan for refills

2. It is recommended that patients' literacy, cognitive status, psychologic state, culture, and access to social and financial resources be taken into account for optimal education and counseling. Because cognitive impairment and depression are common in HF and can seriously interfere with learning, patients should be screened for these. Patients found to be cognitively impaired need additional support to manage their HF. (Strength of Evidence = B)

3. It is recommended that educational sessions begin with an assessment of current HF knowledge, issues about which the patient wants to learn, and the patient's perceived barriers to change. Education sessions should address specific issues (e.g., medication nonadherence) and their causes (e.g., lack of knowledge vs. cost vs. forgetting) and employ strategies that promote behavior change, including motivational approaches. (Strength of Evidence = B)

4. It is recommended that the frequency and intensity of patient education and counseling vary according to the stage of illness. Patients in advanced HF or with persistent difficulty adhering to the recommended regimen require the most education and counseling. Patients should be offered a variety of options for learning about HF according to their individual preferences:

- Videotape
- One-on-one or group discussion
- Reading materials, translators, telephone calls, mailed information
- Internet
- Visits

Repeated exposure to material is recommended because a single session is never sufficient. (Strength of Evidence = B)

5. It is recommended that during the care process patients be asked to:

- Demonstrate knowledge of the name, dose, and purpose of each medication
- Sort foods into high- and low-sodium categories
- Demonstrate their preferred method for tracking medication dosing
- Show provider daily weight log
- Reiterate symptoms of worsening HF
- Reiterate when to call the provider because of specific symptoms or weight changes (Strength of Evidence = B)

6. During acute care hospitalization, only essential education is recommended, with the goal of assisting patients to understand HF, the goals of its treatment, and the post-hospitalization medication and follow-up regimen.

Education begun during hospitalization should be supplemented and reinforced within 1-2 weeks after discharge, continued for 3-6 months, and reassessed periodically. (Strength of Evidence = B)

Disease Management Programs

7. Patients recently hospitalized for HF and other patients at high risk for HF decompensation should be considered for comprehensive HF disease management. High-risk patients include those with renal insufficiency, low output state, diabetes, chronic obstructive pulmonary disease, persistent New York Heart Association (NYHA) class III or IV symptoms, frequent hospitalization for any cause, multiple active comorbidities, or a history of depression, cognitive impairment, inadequate social support, poor health literacy, or persistent nonadherence to therapeutic regimens. (Strength of Evidence = A)

8. It is recommended that HF disease management programs include the components shown in the Table below, based on patient characteristics and needs. (Strength of Evidence = B)

Table. Recommended Components of a HF Disease Management Program

- Comprehensive education and counseling individualized to patient needs
- Promotion of self care, including self-adjustment of diuretic therapy in appropriate patients (or with family member/caregiver assistance)
- Emphasis on behavioral strategies to increase adherence
- Vigilant follow-up after hospital discharge or after periods of instability
- Optimization of medical therapy
- Increased access to providers
- Early attention to signs and symptoms of fluid overload
- Assistance with social and financial concerns

9. It is recommended that HF disease management include integration and coordination of care between the primary care physician and HF care specialists and with other agencies, such as home health and cardiac rehabilitation. (Strength of Evidence = C).

10. It is recommended that patients in a HF disease management program be followed until they or their family/caregiver demonstrate independence in following the prescribed treatment plan, adequate or improved adherence to treatment guidelines, improved functional capacity, and symptom stability. Higher risk patients with more advanced HF may need to be followed permanently. Patients who experience increasing episodes of exacerbation or who demonstrate instability after discharge from a program should be referred again to the service. (Strength of Evidence = B)

Advance Directives and End-of-life Care

11. It is recommended that patient and family or caregiver decisions about quality of life and prognosis be included in the disease management of HF. (Strength of Evidence = C)

12. It is recommended that:

a. Seriously ill patients with HF and their families be educated to understand that patients with HF are at high risk of death, even while aggressive efforts are made to prolong life.

b. Patients with HF be made aware that HF is potentially life-limiting, but that pharmacologic and device therapies and self-management can prolong life. In most cases, chronic HF pharmacologic and device therapies should be optimized as indicated before identifying that patients are near end-of-life.

c. Identification of end-of-life in a patient should be made in collaboration with clinicians experienced in the care of patients with HF when possible.

d. End-of-life management should be coordinated with the patient's primary care physician.

e. As often as possible, discussions regarding end-of-life care should be initiated while the patient is still capable of participating in decision-making. (Strength of Evidence = C)

13. End-of-life care should be considered in patients who have advanced, persistent HF with symptoms at rest despite repeated attempts to optimize pharmacologic, cardiac device, and other therapies, as evidenced by 1 or more of the following:

- HF hospitalization (Setoguchi, Stevenson, & Schneeweiss, 2007; Solomon et al., 2007) (Strength of Evidence = B)
- Chronic poor quality of life with minimal or no ability to accomplish activities of daily living (Strength of Evidence = C)
- Need for continuous intravenous inotropic therapy support (Elkayam et al., 2007; Stevenson et al., 2004) (Strength of Evidence = B)

14. It is recommended that end-of-life care strategies be individualized and include core HF pharmacologic therapies, effective symptom management and comfort measures, while avoiding unnecessary testing. New life-prolonging interventions should be discussed with patients and caregivers with careful discussion of whether they are likely to improve symptoms. (Strength of Evidence = C)

15. It is recommended that a specific discussion about resuscitation be held in the context of planning for overall care and for emergencies with all patients with HF. The possibility of sudden cardiac death (SCD) for patients with HF should be acknowledged. Specific plans to reduce SCD (for example with an implantable cardioverter defibrillator [ICD]) or to allow natural death should be based on the individual patient's risks and preferences for an attempt at resuscitation with specific discussion of risks and benefits of inactivating the ICD. Preferences for attempts at resuscitation and plans for approach to care should be readdressed at turning points in the patient's course or if potentially life-prolonging interventions are considered. (Strength of Evidence = C)

16. It is recommended that, as part of end-of-life care, patients and their families/caregivers have a plan to manage a sudden decompensation, death, or progressive decline. Inactivation of an implantable defibrillation device should

be discussed in the context of allowing natural death at end of life. A process for deactivating defibrillators should be clarified in all settings in which patients with HF receive care. (Strength of Evidence = C)

17. Patients with HF receiving end-of-life care should be considered for enrollment in hospice that can be delivered in the home, a nursing home, or a special hospice unit. (Strength of Evidence = C)

Definitions:

Strength of Evidence

Hierarchy of Types of Evidence	
Level A	Randomized, Controlled, Clinical Trials May be assigned based on results of a single methodologically rigorous trial
Level B	Cohort and Case-Control Studies Post hoc, subgroup analysis, and meta-analysis Prospective observational studies or registries
Level C	Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

Strength of Recommendations

"Is recommended"	Part of routine care Exceptions to therapy should be minimized.
"Should be considered"	Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.
"May be considered"	Individualization of therapy is indicated.
"Is not recommended"	Therapeutic intervention should not be used

Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

References Supporting the Recommendations

Elkayam U, Tasissa G, Binanay C, Stevenson LW, Gheorghiade M, Warnica JW, Young JB, Rayburn BK, Rogers JG, DeMarco T, Leier CV. Use and impact of inotropes and vasodilator therapy in hospitalized patients with severe heart failure. Am Heart J 2007 Jan;153(1):98-104. PubMed

Setoguchi S, Stevenson LW, Schneeweiss S. Repeated hospitalizations predict mortality in the community population with heart failure. Am Heart J 2007 Aug;154(2):260-6. PubMed

Solomon SD, Dobson J, Pocock S, Skali H, McMurray JJ, Granger CB, Yusuf S, Swedberg K, Young JB, Michelson EL, Pfeffer MA, Candesartan in Heart failure: Assessment of Reduction in Mortality and morbidity (CHARM) [trunc]. Influence of nonfatal hospitalization for heart failure on subsequent mortality in patients with chronic heart failure. Circulation 2007 Sep 25;116(13):1482-7. PubMed

Stevenson LW, Miller LW, Desvigne-Nickens P, Ascheim DD, Parides MK, Renlund DG, Oren RM, Krueger SK, Costanzo MR, Wann LS, Levitan RG, Mancini D, REMATCH Investigators. Left ventricular assist device as destination for patients undergoing intravenous inotropic therapy: a subset analysis from REMATCH (Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure). Circulation 2004 Aug 24;110(8):975-81. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Education and counseling may help patients, their families, and caregivers acquire the knowledge, skills, strategies, problem solving abilities, and motivation necessary for adherence to the treatment plan and effective participation in self-care.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

It must be recognized that the evidence supporting recommendations is based largely on population responses that may not always apply to individuals within the population. Therefore, data may support overall benefit of one treatment over another but cannot exclude that some individuals within the population may respond better to the other treatment. Thus, guidelines can best serve as evidence-based recommendations for management, not as mandates for management in every patient. Furthermore, it must be recognized that trial data on which recommendations are based have often been carried out with background therapy not comparable to therapy in current use. Therefore, physician decisions regarding the management of individual patients may not always precisely match the recommendations. A knowledgeable physician who integrates the guidelines with pharmacologic and physiologic insight and knowledge of the individual being treated should provide the best patient management.

Implementation of the Guideline

Description of Implementation Strategy

The value of a practice guideline is significantly influenced by the scope of its dissemination. The first and second Heart Failure Society of America guidelines were available on the Internet, and thousands of copies were downloaded. The current document will be implemented on the Internet both for file transfer and as a hypertext source of detailed knowledge concerning heart failure (HF).

Implementation Tools

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

End of Life Care

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Heart Failure Society of America, Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, Givertz MM, Katz SD, Klapholz M, Moser DK, Rogers JG, Starling RC, Stevenson WG, Tang WH, Teerlink JR, Walsh MN. Disease management, advance directives, and end-of-life care in heart failure: HFSA 2010 comprehensive heart failure practice guideline. J Card Fail 2010 Jun;16(6):e98-114. [210 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 (revised 2010 Jun)

Guideline Developer(s)

Heart Failure Society of America, Inc - Disease Specific Society

Source(s) of Funding

Heart Failure Society of America, Inc

Guideline Committee

Heart Failure Society of America Guideline Committee

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Financial Disclosures/Conflicts of Interest

Committee members and reviewers from the Executive Council received no direct financial support from the Heart Failure Society of America (HFSA) or any other source for the development of the guideline. Support was provided by the HFSA administrative staff, but the writing of the document was performed on a volunteer basis primarily by the Committee. Financial relationships that might represent conflicts of interest were collected annually from all members of the Guideline Committee and the Executive Council. Current relationships are shown in Appendix C of the "2010 HFSA Guideline Executive Summary" companion document (see the "Availability of Companion Documents" field).

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Disease management in heart failure. J Card Fail 2006 Feb;12(1):e58-69.

Guideline Availability

Electronic copies: Available from the Heart Failure Society of America, Inc. Web site.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 S, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

Availability of Companion Documents

The following are available:

- Heart Failure Society of America. Executive summary: The 2010 HFSA comprehensive heart failure practice guideline. J Card Fail 2010 Jun. Electronic copies: Available from the Journal of Cardiac Failure Web site.
- Heart Failure Society of America. Development and implementation of a comprehensive heart failure practice guideline. J Card Fail 2010 Jun;16(6):e3-6. Electronic copies: Available from the Journal of Cardiac Failure Web site.
- Heart Failure Society of America. Conceptualization and working definition of heart failure. J Card Fail 2010 Jun;16(6):e34-7. Electronic copies: Available from the Journal of Cardiac Failure Web site.
- PowerPoint slides. HFSA 2010 comprehensive heart failure guideline. Electronic copies: Available from the Heart Failure Society of America, Inc. Web site.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 South, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 31, 2006. The information was verified by the guideline developer on August 10, 2006. This NGC summary was updated by ECRI Institute on October 14, 2010. The updated information was verified by the guideline developer on November 23, 2010.

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