Clinical Practice Guideline

Physical Therapist Clinical Practice Guideline for the Management of Individuals With Heart Failure

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The American Physical Therapy Association (APTA), in conjunction with the Cardiovascular and Pulmonary Section of APTA, have commissioned the development of this clinical practice guideline to assist physical therapists in their clinical decision making when managing patients with heart failure. Physical therapists treat patients with varying degrees of impairments and limitations in activity and participation associated with heart failure pathology across the continuum of care. This document will guide physical therapist practice in the examination and treatment of patients with a known diagnosis of heart failure. The development of this clinical practice guideline followed a structured process and resulted in 9 key action statements to guide physical therapist practice. The level and quality of available evidence were graded based on specific criteria to determine the strength of each action statement. Clinical algorithms were developed to guide the physical therapist in appropriate clinical decision making. Physical therapists are encouraged to work collaboratively with other members of the health care team in implementing these action statements to improve the activity, participation, and quality of life in individuals with heart failure and reduce the incidence of heart failure-related re-admissions.

Physical therapists play a fundamental role in the examination, evaluation, and treatment of patients with heart failure (HF, formerly congestive heart failure and chronic heart failure, or CHF) throughout the continuum of care. Empirical evidence on the effectiveness of a variety of rehabilitation treatment interventions for patients with HF continues to evolve. Physical therapist interventions including education, resistance exercise, aerobic exercise, inspiratory muscle training, electrical stimulation, and behavior modification strategies can positively influence functional capacity, strength, and quality of life in patients with HF, and could contribute to decreased hospital readmissions.[1]

HF is a chronic and progressive condition in which the heart loses the ability to efficiently pump blood to the extremities, organs, and skin.[2] During episodes of acute decompensation, physiologic requirements for blood and oxygen delivery are unmet, resulting in a clinical syndrome with many signs and symptoms. The array of symptoms noted in patients with acute decompensated HF is due to a complex series of events involving pathophysiological and compensatory responses to cardiac muscle dysfunction.[3] These hemodynamic, neuroendocrine, inflammatory, and autonomic pathophysiological and compensatory responses negatively impact multiple organ systems, including the lungs, kidneys, liver, and skeletal muscles.[3,4] It is important to note that the deconditioning effects of HF on skeletal muscle function are compounded by these pathophysiological and compensatory changes, resulting in catabolic and histological changes.[4] In light of the complexity of HF, the challenges of achieving long-term physiological stability, the severity of signs and symptoms, and the involvement of multiple organs, patients with HF are likely to have substantial limitations to physical function, reduced health-related quality of life (HRQL), and require multiple hospital admissions and extensive medical care.[5]

Background and Need for a Clinical Practice Guideline in Heart Failure

According to the American Heart Association, the prevalence of HF for adults over 20 years of age is rapidly increasing. Recent statistics show that the prevalence of HF increased nearly 20% from 5.7 million (2009–2012) to 6.5 million (2011–2014).[2] One in 9 deaths in 2009 included HF as a contributing cause and half of people who develop HF die within 5 years of diagnosis.[6] Fifty-three percent of hospitalizations included patients with reduced ejection fraction and 47% with preserved ejection fraction, with black men comprising the highest proportion with reduced ejection fraction (70%) and white women comprising the highest proportion of preserved ejection fraction (59%).[2]

Hospital readmission in patients with HF is currently a focus of national interest due to its association with high health care expenditures.[7] Increasing attention is being placed on hospital readmissions for patients with HF due to the substantial burden it places on patients and payers.[7,8]

Readmission can operationally be defined as simply being admitted to the hospital within a specified period following an index (first, incident) admission. The costs associated with HF readmissions are nearly 31 billion dollars annually.[9] This total includes the cost of health care services, medications, and missed employment.[9] These costs have been rising at an alarming pace, prompting the Centers for Medicare and Medicaid Services (CMS) to implement the HF Readmissions Reduction Program in 2012.[10] According to the CMS final rule, readmission within 30 days of discharge from the hospital for patients with HF would result in an economic penalty to the reimbursement of that hospital system. The Readmission Reduction Program has prompted medical professionals and rehabilitation specialists to make changes in care delivery to reduce readmissions.

Considering the escalating readmissions and health care costs associated with HF, the American Physical Therapy Association (APTA) charged the Cardiovascular and Pulmonary Section with developing a clinical practice guideline for the management of patients with HF. Clinical practice guidelines (CPGs) utilize expert analysis of available data on the risks and benefits of procedures documented within the literature. CPGs provide clinicians with a set of ideal management strategies for use in individual patients. The present CPG provides physical therapists with recommendations based on the highest level of available evidence involving physical rehabilitation of the patient with HF. The aim is to provide physical therapists with evidence-based recommendations that assist in improving functional capacity and HRQL and reducing hospital readmissions for individuals with HF.

Physical therapists can utilize the key action statements in the present CPG in clinical decision making by reviewing the range of acceptable approaches to the examination and treatment of HF presented in this paper. However, they are cautioned that although these key action statements describe practices that meet the needs of many patients, they are unable to address each unique situation of an individual patient. Therefore, therapists may deviate from these guidelines as appropriate to meet the needs of the individual patient.

Pathophysiology of Heart Failure

HF is most commonly caused by cardiac muscle dysfunction. *Cardiac muscle dysfunction* is a general term describing altered systolic and/or diastolic activity of the myocardium that typically develops due to underlying abnormalities within the structure or function of the myocardium. Hypertension and coronary disease,

particularly myocardial infarction, were thought to be the primary causes of cardiac muscle dysfunction. However, a variety of other pathophysiologic causes have more recently become increasingly responsible for cardiomyopathy and subsequent HF, including diseases of the myocardium, pericardium, endocardium, heart valves, coronary vessels, as well as from toxins, poorly managed systemic hypertension, pulmonary and pulmonary and vascular diseases, and metabolic disorders.[11]

The subtypes of HF are categorized from both a structural and functional perspective. Structural HF may include left-sided, right-sided, or biventricular dysfunction. Left-sided HF occurs with left ventricular insult. Pathology of the left ventricle reduces cardiac output, leading to an accumulation of fluid within the left atrium with subsequent pulmonary congestion and pulmonary edema, which is augmented by renal-mediated fluid retention. Pulmonary edema produces the 2 hallmark pulmonary signs of dyspnea and cough.[12] Right-sided HF occurs following insult to the right ventricle. Pathology of the right ventricle is commonly caused by conditions that elevate pressures within the pulmonary arterial system.[13] With right-sided HF, reductions in right ventricular cardiac output results in venous congestion, producing the 2 hallmark peripheral signs of jugular venous distention and peripheral edema, as well as ascites and pleural effusion. Finally, biventricular failure occurs when both ventricles fail. Patients experiencing an acute exacerbation of heart failure typically present in biventricular HF, where left-sided heart failure results in pulmonary vascular congestion, right ventricular overload, and ultimately systemic venous congestion. These patients typically present with pulmonary and peripheral signs and symptoms of fluid overload including dyspnea, cough, jugular venous distention, and peripheral edema.

Functional HF may be due to either systolic or diastolic dysfunction of the left ventricle, and is referred to as HF with reduced ejection fraction (HFrEF) or HF with preserved ejection fraction (HFpEF), respectively. *Systolic dysfunction* in HFrEF refers to a decrease in myocardial contractility characterized by compromised contractile function of the ventricles resulting in reductions in ejection fraction, stroke volume, and cardiac output.[14] Patients with systolic dysfunction typically present with a compromised left ventricular ejection fraction (LVEF) less than 40%.[11] Randomized clinical trials have mainly enrolled patients with HFrEF and it is primarily in these patients that efficacious therapies have been demonstrated to date. *Diastolic dysfunction,* also known as HFpEF, is characterized by compromised diastolic function of the ventricles.[12] With this condition, the ventricles cannot fill adequately during the relaxation (diastolic) phase of the cardiac cycle. The impaired ventricular filling (reduced end diastolic volume [EDV]) decreases the volume of blood ejected with each contraction (stroke volume) and the overall volume of blood ejected per minute (cardiac output).[12] With HFpEF, LVEF is unaltered and remains between 55% and 75%.[12] To date, efficacious therapies for patients with HFpEF are less documented in the literature. Therefore, the reader will note that the key action statements in the present CPG are primarily directed towards patients with HFrEF, and limitations in evidence for those with HFpEF are discussed where appropriate.

Classification of Severity of Heart Failure

The American Heart Association/American College of Cardiology (AHA/ACC) and New York Heart Association (NYHA) have created 2 complementary HF classification systems of HF severity from both structural and functional perspectives.[2,15] From a structural perspective (Tab. 1), HF is staged based on the extent of structural damage to the myocardium and represents irreversible progression of disease severity. For example, if a patient moves from Stage A to B, then it is not expected that the patient would move back to Stage A.

The NYHA functional classification (Tab. 1) delineates four classes of HF based on symptoms with physical activity. NYHA classes represent variable patient symptoms that vary bi-directionally where there can be progression and regression depending on a patient's current state. NYHA classes I to IV gauge severity of symptoms in individuals with structural heart disease (AHA/ACC stages B, C, and D).

Recognition of Acutely Decompensated Heart Failure

In addition to the AHA/ACC stages and the NYHA functional classification system, the reader will find the term *stability* used throughout this document. In a patient with HF, stability first requires being compensated (AHA/ACC stages A–C and NYHA functional classifications I–III). Compensation also requires that the patient not currently be exhibiting the aforementioned pulmonary and venous congestion-associated signs and symptoms. *Stability* refers to the probability of staying compensated. A patient who is stable can participate, perform activities, exert with appropriate changes in vital signs without signs of exercise intolerance, and then return to baseline within a reasonable period of time.[16]

Felker and colleagues define acute decompensated HF as the presence of new or worsening signs/symptoms of dyspnea, fatigue, or edema that lead to hospitalization or unscheduled medical care (doctor visits or emergency department visits).[17] The hallmark signs of decompensation are related to increased congestion and increased ventricular filling pressures. Common signs and symptoms of HF exacerbation include fatigue, dyspnea, edema (pulmonary and peripheral), weight gain, and chest pain. It is important for clinicians to assess signs and symptoms of HF at every visit. Regular monitoring of

Table 1.
American Heart Association/American College of Cardiology (AHA/ACC) Stages and New York Heart Association (NYHA) Functional Classes of Heart Failure[a]

AHA/ACC Stage	Description	NYHA Class	Description
Stage A	At high risk for developing HF. No identified structural or functional abnormality, no signs or symptoms of HF.	N/A	
Stage B	Structural heart disease that is strongly associated with the development of HF but no signs and symptoms of HF.	I	No limitation in physical activity; ordinary physical activity does not cause fatigue, palpitations, or dyspnea.
Stage C	Symptomatic HF, associated with underlying structural heart disease.	I	No limitation in physical activity; ordinary physical activity does not cause fatigue, palpitations, or dyspnea.
		II	Slight limitation of physical activity; comfortable at rest but ordinary activity results in fatigue, palpitations, or dyspnea.
		III	Marked limitation of physical activity; comfortable at rest but less than ordinary activity results in fatigue, palpitations, or dyspnea.
		IV	Symptoms at rest; unable to do any physical activity without symptomology.
Stage D	Advanced structural disease with marked symptomology at rest despite maximal medical therapy.	IV	Symptoms at rest; unable to do any physical activity without symptomology.

[a]HF = heart failure; N/A = not applicable.

Table 2.
Definitions of Zone Colors Associated With Clinical Manifestations and Physical Therapist Recommendations[a]

Zone Color	Signs and Symptoms	Physical Therapist Recommendations
Green zone	• No shortness of breath • No swelling • No weight gain • No chest pain • No decrease in your ability to maintain your activity level	Continue activity and therapy as tolerated.
Yellow zone	• Weight gain of 2–3 lbs in 24 hrs • Increased cough • Peripheral edema: increased distal extremity swelling • Increase in shortness of breath with activity • Orthopnea: increase in the number of pillows needed	Symptoms may indicate an adjustment in medications and therefore warrants communication with the physician.
Red zone	• Shortness of breath at rest • Unrelieved chest pain • Wheezing or chest tightness at rest • Paroxysmal nocturnal dyspnea: requiring to sit in chair to sleep • Weight gain or loss of more than 5 lbs in 3 days • Confusion	Symptoms indicate overt decompensation and an immediate visit to the emergency department or physician office.

[a]Adapted from https://innovations.ahrq.gov/qualitytools/red-yellow-green-congestive-heart-failure-chf-tool

signs and symptoms are necessary in evaluating a patient's response to exercise, signs of exercise intolerance, and stability over time. Worsening of symptoms places the patient at risk of urgent hospital admission and merits prompt medical attention.

Recommendations in the present CPG for the physical therapist in evaluating the symptomology of acute decompensation have been developed from four prior CPGs: the 2013 American College of Cardiology guidelines,[14] the 2006 Heart Failure Society of America guidelines,[18] the 2012 European Society of Cardiology guidelines,[19] and the 2011 Canadian Cardiovascular Society Heart Failure Management guidelines.[20] For this reason, recognition of decompensation is not a seperate action statement in this CPG, but rather a fundamental element of examination that should be performed when implementing any of the key action statements in the document below.

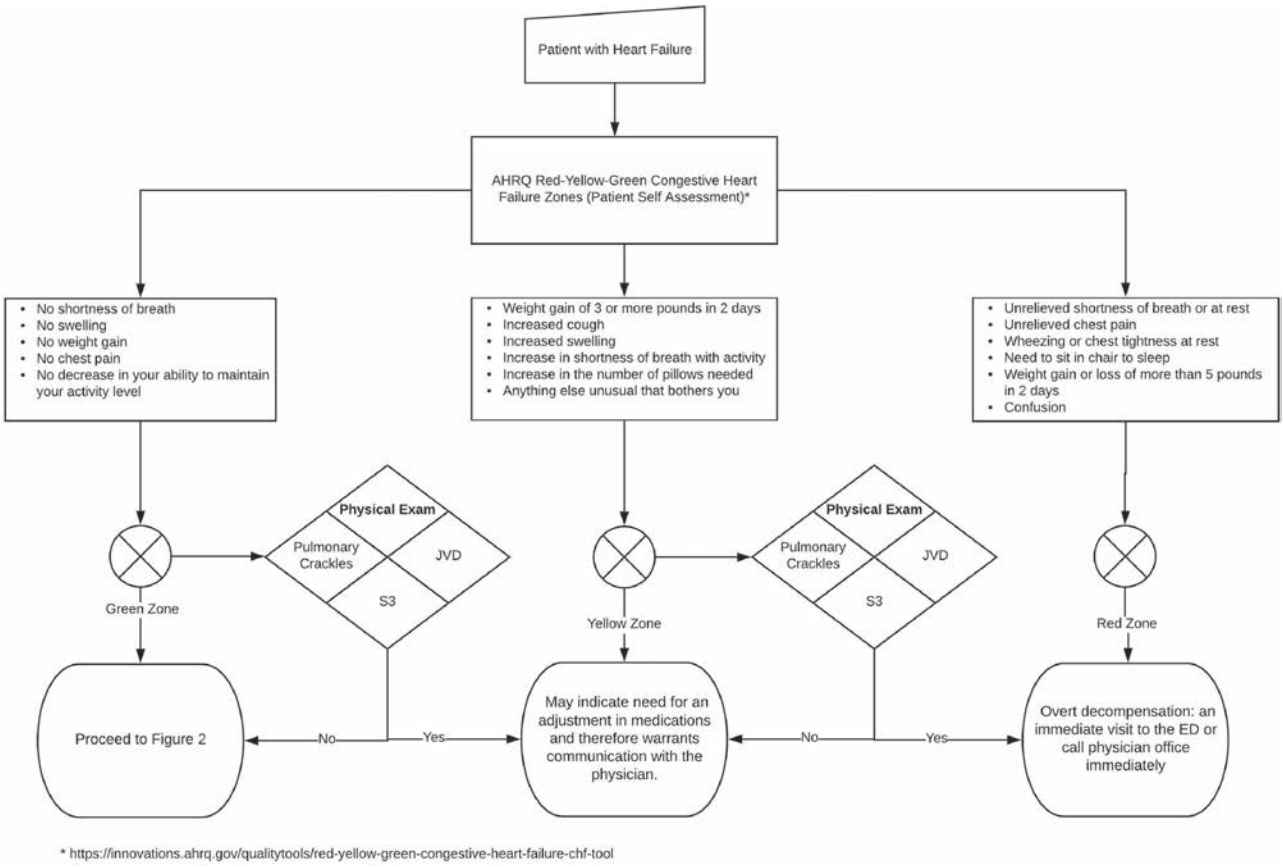

Figure 1.
Algorithm for patient with heart failure evaluated by a physical therapist. AHRQ = Agency for Healthcare Research and Quality; ED = emergency department; JVD = jugular venous distention; S3 = third heart sound.

To help physical therapists determine whether a patient is sufficiently stable to proceed with an intervention, we have provided an algorithm to determine whether a patient is compensated (Fig. 1), which is based in part on the Red-Yellow-Green CHF Tool developed by the Agency for Healthcare Research and Quality (Tab. 2). The Tool is divided into green ("all clear"), yellow ("caution"), and red ("medical alert") zones. Identification of specific signs and symptoms within each zone can help physical therapists recognize when it is appropriate to seek emergency medical assistance. A second algorithm was developed to help physical therapists determine which action statements are most appropriate for a particular patient based on participation, activity, endurance, and signs of exercise intolerance (Fig. 2). The algorithm in Figure 2 is based on expert opinion by the Guideline Development Group (GDG) and was reviewed by the external stakeholders. The available research reviewed, short of limiting itself through inclusion and exclusion criteria to patients with medically compensated HF, did not address specific examination-based criteria for when any of the interventions reviewed herein are appropriate. Based on this algorithm, physical therapy may not be indicated for individuals with HF that are not medically compensated or for those who are medically compensated and have no participation restrictions and are already physically active. Individuals with HF who have participation restrictions or are not physically active and do not have any activity limitations on exam should be encouraged to participate in some sort of physical activity. If an individual has an activity limitation, the physical therapist should determine whether that individual can perform the activity that is limited (eg, if the activity limitation is climbing stairs, whether the person can climb stairs at all must be examined). If the individual cannot perform the activity, then the appropriate intervention should be utilized, and several of the key action statements can be considered. If the activity can be performed, endurance for the activity is then considered, along with additional action statement considerations.

Physical therapists should recognize the presence of HF exacerbation and recommend prompt medical follow-up when the patient is presenting with signs and symptoms of acute decompensation. To reduce further clinical deterioration and subsequent hospital readmissions,

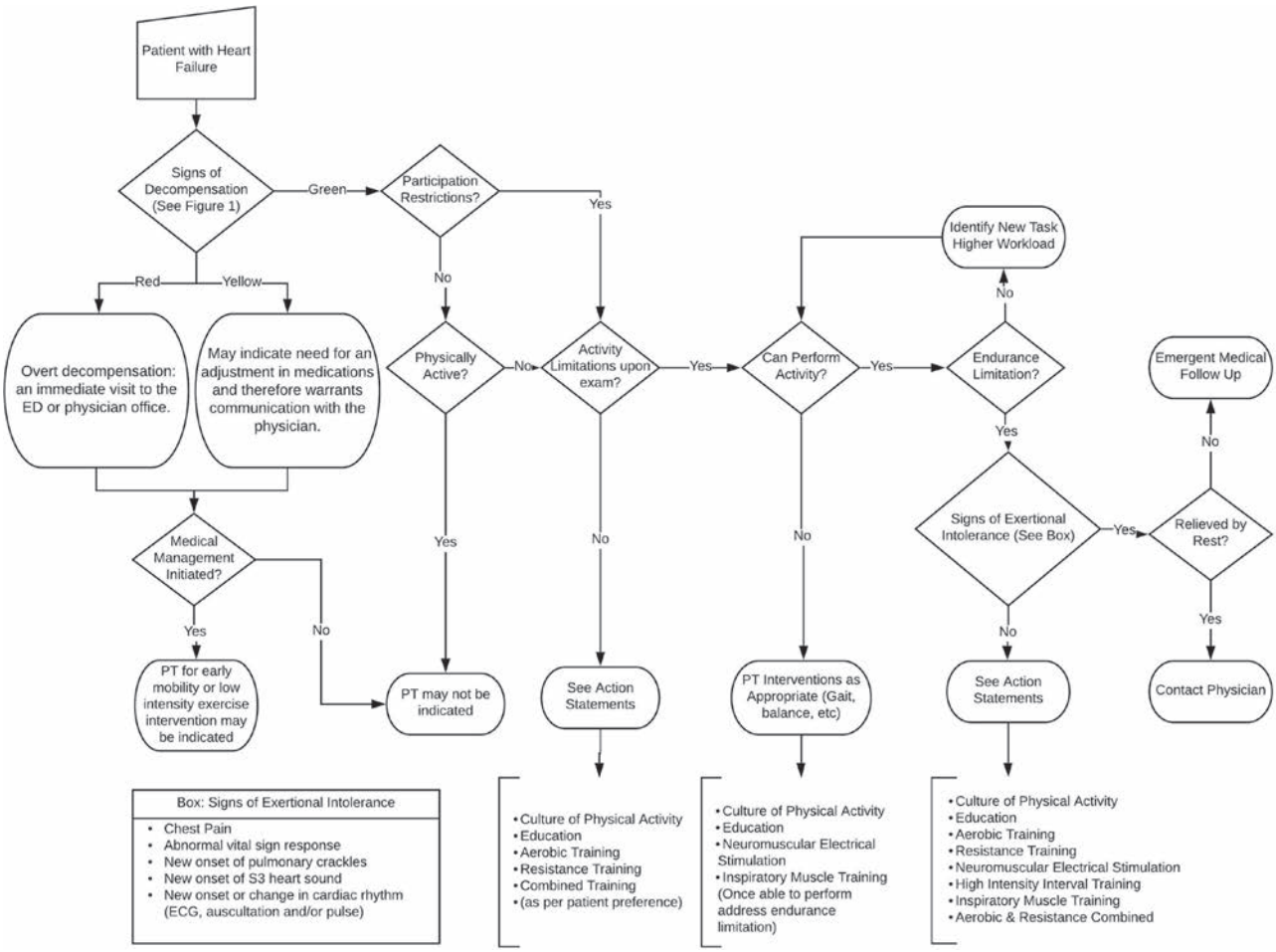

Figure 2.
Algorithm for patient with heart failure and signs of decompensation. ECG = electrocardiogram; ED = emergency department; PT = physical therapist; S3 = third heart sound.

physical therapists are integral members of the interprofessional team assisting with early detection of HF exacerbation and directing medical follow-up. Physical therapists should work within their health care systems to determine how these or similar algorithms for identification of HF exacerbation can be utilized within their specific contexts and patient care environments.

Adherence to Exercise-Based Interventions

Unlike research on exercise-based interventions in HF, the evidence for interventions to improve exercise adherence lacks a single meta-analysis due to a broad range of interventions and a broad range of measures, most of which are self-report. This broad range of qualitative measurement, lack of objective measurement, and lack of unifying conceptual framework precluded the present GDG from developing a key action statement on exercise adherence. However, a few observations about existing literature can be made to help guide clinicians when selecting exercise interventions and their associated training parameters in that consideration should be given to self-efficacy, readiness for behavior change, patient preferences, and individual constraints, which may improve long-term exercise adherence.[21–23] Approaches including motivational interviewing, transtheoretical model of behavior change, and Bandura's Social Cognitive Theory in isolation or in combination may be used.[22] Specific techniques and strategies based in these approaches include goal setting, positive feedback, facilitation of problem solving, learning by doing, role modeling, supportive visits and phone calls, and caregiver engagement.[22–24]

A construct related to exercise adherence is the translation of improved exercise capacity and performance into an increase in overall daily physical activity (ie, structured and incidental physical activity).[25] This is believed to be important in stopping the negative cycle of inactivity and deconditioning.[26] Similar to the literature on exercise

adherence, the research on interventions to improve overall daily physical activity lacks a consistent objective measurement that allows meta-analysis and precluded the present GDG from developing an individual key action statement. However, it appears that exercise-based interventions alone are insufficient for translating improved exercise capacity into increased overall daily physical activity and should therefore include the same psychosocial components to intervention delivery as previously outlined for interventions to improve exercise adherence.[26] Physical therapists should consider strategies for improving adherence when implementing the key action statements contained in the present CPG.

In summary, given the high incidence of HF readmissions within the first 30 days following hospital discharge, physical therapists can play an important role in routinely assessing for signs and symptoms of decompensation and offer patients appropriate advice based on their symptomology. The results of their assessment should be communicated with the rest of the health care team. The early detection of HF exacerbation by the physical therapist with prompt medical follow-up can prevent further clinical deterioration and subsequent hospital readmissions, and is also required for safe and appropriate implementation of the key action statements in the present CPG.

Methods

The GDG was comprised of physical therapy educators with extensive clinical and research experience in cardiovascular and pulmonary practice. The GDG referred to previous work from the CVP section as well as other APTA-supported CPGs and international CPG-development processes. In July 2014, the GDG initiated the process to develop a list of topic areas to be covered by the CPG after polling the CVP section. Topic areas were brought forward by CVP section members that were included by the GDG as considerations that molded our decision making of inclusion or exclusion. A list was developed to determine the focus of the CPG by input by CVP members and the GDG formulated the scope of the CPG.

Literature Review

A search strategy was developed and performed under advisement of 2 librarians and by the GDG members to identify literature published prior to January 2018 addressing HF. Searches were performed in the following databases: PubMed, CINAHL, and Cochrane Database of Systematic Reviews. MeSH headings were used when possible for key words. Results were limited to articles written in English. The search strategy by key words, MeSH terms, and databases is shown in Appendix 1. Using this search strategy, 32,862 non-duplicate publications were identified. To narrow this search, the focus was placed on meta-analyses, systematic reviews, and clinical practice guidelines, which resulted in 356 publications. Abstracts and full text (as necessary) were reviewed by at least 2 members of the GDG, with a third available should disagreement arise (no instances of disagreement occurred). Meta-analyses, systematic reviews, and clinical practice guidelines were reviewed for whether they specifically addressed the patients, interventions, comparisons, and outcomes of interest for this CPG. Specifically, whether they: included adult patients with HF during adulthood (acquired not congenital) and only such patients, whether interventions tested are interventions utilized by physical therapists, whether reviews were of randomized controlled studies, and whether outcomes tested were relevant for physical therapy. Due to the extensive amount of systematic reviews, most of which had substantial overlap of included randomized controlled trials (RCTs), the GDG decided to only review individual RCTs if significant gaps in systematic review coverage were noted. Based on these criteria, 127 systematic reviews, meta-analyses or CPGs were determined to be relevant for the development of the present CPG. A flow chart of article selection is provided in Appendix 2.

Clinical practice guidelines published from 2008 to 2014 were searched including the same key words and MeSH terms using the National Guideline Clearinghouse (NGC, www.guideline.gov/) database. The NGC database identified 277 guidelines using the key word of "heart failure," of which 16 were deemed as appropriate to be reviewed by the GDG.

Evidence Summary Tables

Evidence summary tables with data extracted from the included articles (demographics of subjects, total number of subjects, total number of RCTs, inclusion/exclusion criteria, intervention parameters, measures of effect size, key conclusions and observations, overlap of RCTs between systematic reviews/meta-analyses, etc) for each intervention were developed by 3 members of the GDG and then each was reviewed by 2 other members for accuracy. These tables were reviewed by all members of the GDG prior to meeting for key action statement development and were the basis for the development of each key action statement.

Appraisal of Evidence

The appraisal team consisted of CVP section members who were interested in HF and represent both clinicians and educators. One of the GDG investigators oversaw the appraisal team and sent the articles to the appraisers using a random approach. Prior to sending the appraisal team articles that were included in this CPG for review, the reliability of the appraisers was established. Each appraiser was paired with another appraiser and asked to appraise an article individually. After the article was appraised by each appraiser, the pair of appraisers then compared their appraisals of the article. The pair of appraisers had

Table 3.
Grades of Recommendation for Action Statements

Grade	Recommendation	Quality
A	Strong	A preponderance of level I studies
B	Moderate	A preponderance of level II studies
C	Weak	Single level II study or a preponderance of level III and IV studies, including consensus statements
D	Theory	A preponderance of evidence from animal or cadaver studies, from conceptual/theoretical models/principles, or from basic science/bench research, or published expert opinion.
P	Best practice	Recommended practice based on current clinical practice norms.
R	Research	An absence of research on the topic, or conclusions from higher-quality studies on the topic are in disagreement.

to be within 1 point on the appraisal tool. If there was disagreement greater than 1 point, the pair of appraisers discussed their reasoning to determine why the score was different. Discrepancies that were not able to be resolved were graded using the mean of the 2 appraiser scores.

The use of specific appraisal tools was decided upon by the GDG after attending the APTA Guideline Education session. The Appraisal of Guidelines, Research and Evaluation, or AGREE II was utilized for CPG critical appraisal. The Assessment of Multiple Systematic Review (AMSTAR) tool was used for appraisal of systematic reviews. The University of Oxford Centre for Evidence-Based Medicine critical appraisal tool was used for randomized controlled trials.[27]

The GDG decided on using the level of evidence classification that was utilized by previously published physical therapy CPGs (Tab. 3). Table 3 shows the criteria for the grades/strength of recommendation for the key action statements. The grade represents the strength of recommendation that reflects the quality of evidence that the GDG feels supports a given key action statement.

External Review Process by Stakeholders

Fourteen of 18 stakeholders responded to the call for review. Four reviewers declined the invitation to review and provide feedback. The reviewers constituted stakeholders from inside and outside of the physical therapy profession: members of the Cardiovascular and Pulmonary Section, previous CPG authors, present or past journal editorial directors, a health care provider who also has HF (patient representative), and selected members of the American Association of Cardiovascular and Pulmonary Rehabilitation and American College of Sports Medicine were provided with the opportunity to review and give feedback on the written document. All stakeholder comments were reviewed by the GDG and changes were made where the GDG felt the feedback was warranted.

Role of the Funding Source

The Cardiovascular & Pulmonary Section of APTA and APTA provided funds to support the development and preparation of this document but had no influence on the content or the key action statements of this clinical practice guideline. The guideline is editorially independent from the funding source.

Document Structure and Scope of the CPG

The key action statements are organized in Table 4 with their assigned recommendation grade, followed by a standardized content outline that was generated by BRIDGE-Wiz software (http://gem.med.yale.edu/BRIDGE-Wiz/). The key action statements are organized with a content title that addresses the specifics of the statement, a recommendation of an observable action, the evidence quality for the key action statement, and strength of the recommendation. Each action statement describes the: (1) benefits, harms, and potential costs associated with the recommendation, (2) delineation of the assumptions or judgments in formatting the recommendation, (3) potential reasons for intentional vagueness within the recommendation, (4) role of patient preferences, and (5) exclusions. Each key action statement is then followed by a summary of evidence to highlight the interpretation of evidence, justify the strength of recommendation, and assist clinicians with implementation of the key action statement. The GDG regularly met for extensive discussion based on data extracted in the evidence summary tables to reach consensus regarding each key action statement. Much of the variability in considering the strength of evidence for a guideline was eliminated for the GDG with the inclusion of only systematic reviews and meta-analyses of RCTs. When discussions about evidence did occur, they were based on easily identified criteria within the evidence summary tables, such as the number of subjects, number of trials, study criteria, and patient characteristic, and were therefore easily resolved. In deliberating the strength of the recommendation, the GDG utilized the Clinical Practice Guidelines We Can

Table 4.
Key Action Statements[a]

Number	Statement	Key Phrase
1	Physical therapists and other health care practitioners should advocate for increased total daily physical activity as an essential component of care in patients with stable heart failure. (Evidence Quality I; Recommendation Strength: A—Strong)	Advocate for increased total daily physical activity as an essential component of care
2	Physical therapists must educate on and facilitate components of chronic disease management behaviors to reduce the risk of hospital readmission. These measures include education on daily weight assessment, signs and symptoms of an exacerbation, nutrition, and medication management/medication reconciliation. (Evidence Quality I; Recommendation Strength: A—Strong)	Educate on and facilitate chronic disease management behaviors
3	Physical therapists must prescribe aerobic exercise training for patients with stable, NYHA Class II-III HFrEF using the following parameters: Time: 20–60 min; Intensity: 50%–90% of peak VO_2 or peak work; Frequency: 3–5/wk; Duration: at least 8–12 wks; Mode: treadmill or cycle ergometer or dancing (Evidence Quality I; Recommendation Strength: A—Strong)	Prescribe aerobic exercise training
4	Physical therapists should prescribe high-intensity interval exercise training in selected patients for patients with stable, NYHA Class II-III HFrEF using the following parameters: Time: >35 min; Intensity: >90%–95% of peak VO_2 or peak work; Frequency: 2–3/wk; Duration: at least 8–12 wks; Mode: treadmill or cycle ergometer. HIIT total weekly exercise doses should be at least 460 kcal, 114 mins, or 5.4 MET-hrs. (Evidence Quality I; Recommendation Strength: A—Strong)	Prescribe high intensity interval training
5	Physical therapists should prescribe resistance training exercise for upper and lower body major muscle groups for patients with stable, NYHA Class II-III HFrEF using the following parameters: 2–3 sets per muscle group, 60%–80% 1RM, 45–60 mins per session, 3 times per week for at least 8–12 wks (Evidence Quality I; Recommendation Strength: A- Strong)	Prescribe upper and lower body resistance training
6	Physical therapists may prescribe combined resistance and aerobic training for patients with stable, NYHA Class II-III HFrEF using the following parameters: Combine 20–30 minutes of aerobic training with 20–30 mins of resistive training, 2–3 sets per major muscle group, 60%–80% 1RM, 3 times per week for at least 8–12 wks. (Evidence Quality II; Recommendation Strength: B- Moderate)	Prescribe combined aerobic exercise and resistance training
7	Physical therapists should prescribe inspiratory muscle training with a threshold* (or similar) devices (ie, device where resistance is not flow-dependent) for outpatients in the home and clinic setting with stable, Class II and III HFrEF with or without baseline inspiratory muscle weakness using the following parameters: 30 min/day at >30% maximal inspiratory pressure (PI_{Max} or MIP), 5–7 days/wk, for at least 8–12 wks. (Evidence Quality I; Recommendation Strength: A—Strong)	Prescribe inspiratory muscle training
8	Physical therapists may prescribe combined inspiratory muscle training and aerobic exercise training with a threshold (or similar) device (ie, device where resistance is not flow-dependent) for outpatients in the home and clinic setting with stable, Class II and III HFrEF with or without baseline inspiratory muscle weakness using the following parameters: 30 min/day at >30% maximal inspiratory pressure (PI_{Max} or MIP), 5–7 days/wk, for at least 8–12 wks. (Evidence Quality: II, Recommendation Strength: B –Moderate)	Prescribe combined inspiratory muscle training and aerobic exercise training
9	Physical therapists should prescribe NMES in patients with stable, NYHA Class II-III HFrEF using the following parameters: biphasic symmetrical pulses at 15 to 50 hertz, on/off time 2/5 seconds, pulse width for larger muscles of the lower extremity should be 200 to 700 us and for small lower extremity muscles 0.5 to 0.7 ms, 20%–30% of MVIC, intensity to muscle contraction, 5–7 days/week for at least 5–10 wks to the quadriceps, gluteals, hamstrings, and gastrocnemius (Evidence Quality I; Recommendation Strength: A—Strong)	Prescribe neuromuscular electrical stimulation

[a]HFrEF = heart failure with reduced ejection fraction; HIIT = high intensity, interval training; MET = metabolic equivalent; MIP/PImax = maximal inspiratory pressure; NMES = neuromuscular electrical stimulation; NYHA = New York Heart Association; VO_2 = oxygen uptake; 1RM = 1 repetition maximum.

Trust developed by the IOM Committee on Standards for Developing Trustworthy Clinical Practice Guidelines.[28] The reader will note the use of the word "should," "may," and "must" as action words in each of the key action statements. Lomotan et al (2010) suggest that "must" conveys the strongest level of obligation and that guideline developers rarely use the term, except in cases of a clear legal standard or potential for imminent patient harm.[29] "Should" is the most common deontic verb, and it conveys an intermediate level of obligation between "must" and "may."[29] The use of these action words was deliberated by the GDG and is discussed under each key action statement under the Value Judgements and Summary of the Evidence subheadings.

This CPG uses literature available prior to January 2018 to create the key action statements. The CPG addresses HF via 9 action statements. Algorithms were created to make this CPG clinically useful and are based on the key action statements and other CPGs (see Figs. 1 and 2).

Action Statement 1: Advocate for increased total daily physical activity as an essential component of care

Physical therapists and other health care practitioners should advocate for a culture of physical activity as an essential component of care in patients with stable heart failure. (Evidence Quality I; Recommendation Strength: A—Strong).

Action Statement Profile

Aggregate evidence quality. Level I.

Risks, harm, cost. Injuries from participation in activity or falls.

Benefit–harm assessment. Preponderance of benefit.

Value judgments. Across the continuum of care, the evidence supports the benefits of physical activity and several associated risks associated with bed rest and inactivity.

Intentional vagueness. None

Role of patient preferences. Evidence indicates several peripheral muscle disturbances in addition to central cardiovascular pathology in patients with stable HF. Therefore, patients should be encouraged to increase activity as much as possible to offset the adverse sequelae noted with inactivity.

Exclusions. Patients with decompensated HF.

Summary of Evidence

The vision statement of the American Physical Therapy Association defines the need for therapists to transform society by optimizing movement to improve the human experience. In patients with HF, low levels of physical activity are associated with poor prognosis, greater mortality, and lower 11-month event-free survival.[30–33] Decades of research have demonstrated numerous physiologic, musculoskeletal, and psychosocial benefits of physical activity, both total daily energy expenditure and exercise-related energy expenditure.[34] These benefits may translate into improved exercise capacity, quality of life, and prognosis in patients with HF.

A hallmark characteristic of HF is reduced exercise capacity. The severity of exercise limitation in patients with HF is not correlated to the extent of cardiac dysfunction alone. Several peripheral disturbances in patients with HF have been documented, including impaired vasoreactivity, reduced skeletal muscle oxidative capacity, functional iron deficiency, and decreased bone mineral density.[35,36] Physical activity addresses both central and peripheral alterations and therefore serves as a useful therapy for patients with HF.

For the purposes of this paper, we utilize operational definitions for physical activity and exercise provided by Thompson and colleagues. Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure beyond resting expenditure.[37] Exercise as described by Thompson, is a subset of physical activity involving structured, repetitive, and purposeful movements in an effort to improve overall physical fitness.[38]

In the past, exercise was restricted in patients with HF until the late 1970s and 1980s. In 1988, Sullivan and colleagues took a bold step forward and published a landmark study on changes in exercise capacity with unmonitored exercise training in ambulatory patients with HF using invasive hemodynamic monitoring, radionuclide angiography and lactate analysis.[39] The researchers recognized improvements in exercise capacity in 12 patients with left ventricular HF (LVEF 24 $\pm$ 10%) following exercise training largely through training-induced changes in peripheral function.[40] This study was the impetus to subsequent research trials that have consistently demonstrated overall improvements in exercise capacity and quality of life in patients with stable HF.[41] Despite extensive literature delineating positive effects of exercise, prescriptive exercise training often has several challenges to implement. These include poor adherence, reduced access to care, and limited translation of improved exercise capacity into increased total daily physical activity. In these situations, encouraging physical activity through participation in activities that individuals enjoy, in addition to the aforementioned psychosocial intervention strategies for improving adherence to exercise-based interventions, may be necessary for overcoming these challenges.

Guidelines for physical activity have been disseminated through the American College of Sports Medicine's Exercise is Medicine (EIM) campaign, the American Heart Association (AHA), and the U.S. Department of Health and Human Services. In general, for patients with cardiovascular diseases, these groups recommend 150 minutes per week of moderate-intensity physical activity (eg, brisk walking) or 75 minutes per week of vigorous-intensity physical activity (eg, running or jogging), or an equivalent combination.[42] Physical therapists and other health care practitioners can advocate for a culture of physical activity by disseminating this dosage of physical activity to patients and caregivers.

In summary, participation in physical activity, both exercise and total daily physical activity, should be encouraged in patients with HF across the continuum of care. As movement experts, physical therapists have a vital

role in recommending activity and exercise to improve exercise capacity, quality of life and potentially improving prognosis and event-free survival.

Action Statement 2: Educate on and facilitate components of chronic disease management behaviors

Physical therapists must make appropriate nutrition referrals, perform medication reconciliation, and provide appropriate education on preventative self-care behaviors to reduce the risk of hospital readmissions. These behaviors include:

- Daily weight measurement to identify increases greater than 2 to 3 lbs in 24 hours or 5 lbs over 3 days
- Recognition of signs and symptoms of an exacerbation
- Action planning using the Red-Green-Yellow CHF Tool
- Following a nutrition plan
- Medication management/medication reconciliation

(Evidence Quality I; Recommendation Strength: A—Strong)

Action Statement Profile

Aggregate evidence quality. Level I.

Benefits:

- Significant reduction in all-cause hospital readmissions (RR = 0.59, CI = 0.44–0.80 $P < .001$[43]; RR = 0.73, CI = 0.57–0.93[44]; RR = 0.87, CI = 0.79–0.95[45])
- Significant reduction in heart failure readmissions (RR = 0.44, CI = 0.27–0.71, $P < .001$[43]; RR = 0.70, CI = 0.61–0.81[45]; RR = 0.66, CI = 0.52–0.83[44])

Risks, harm, cost. None.

Benefit–harm assessment. Preponderance of benefit.

Value judgments. The GDG utilized "must" in the key action statement based on the overwhelming preponderance of evidence indicating the benefits of patient education on reducing hospital readmissions. The extent to which a physical therapist performs components of medication reconciliation is expected to depend on practice setting and level of clinical experience.

Intentional vagueness. Although existing research has not studied use of chronic disease self-management interventions in patients with HF when performed exclusively by physical therapists, the GDG believed that such interventions were appropriate to be performed by physical therapists, especially in the context of the interprofessional team.

Role of patient preferences. The role of shared decision making is essential to understanding the patient's priorities and maximize the utilization of the education provided.

Exclusions. None.

Summary of Evidence

The need for effective education on preventive self-care measures is increasingly important given escalating hospital admissions and readmissions and high mortality in patients with HF. The complexity of HF requires patients to recognize signs and symptoms of decompensation, have an established action plan, comply with medications, and adhere to diet and exercise recommendations. The array of self-care tasks pose challenges for patients, especially the elderly, and therefore needs to be reiterated by several members of the team, including physical therapists.

Readmission rates have been reported to be as high as 20% within 30 days and up to 50% by 6 months for patients with a diagnosis of HF.[46] Reports from a cross-sectional chart-review investigation on 435 patients admitted to an urban university hospital with complaints of shortness of breath or fatigue and evidence of HF indicated non-compliance with medications and diet as the most common identifiable abnormalities associated with clinical deterioration prior to admission.[47] Education on self-management of HF has been found to not only decrease hospital readmission for patients with heart failure, but also all-cause readmissions and possibly decreased mortality in this population.[43,48–50] However, there are important caveats to this body of evidence, including definition of and lack of consistency in patient education interventions, variability in the delivery of interventions (in isolation vs. as part of a specialized team approach) and the effect on mortality.[44,51] Furthermore, it appears that patient education on self-monitoring alone (and not other chronic disease self-management techniques) for acute decompensation is ineffective for reducing hospitalization compared with implantable wireless pulmonary artery pressure monitors.[52]

Several systematic reviews have focused exclusively on self-care strategies and disease management programs and have documented positive outcomes in patients with HF. Jovicic et al[43] completed a systematic review of 6 randomized controlled trials involving self-management interventions for 857 patients, 18 years of age or older and diagnosed with HF. The authors reported that self-management significantly decreased all-cause hospital readmissions by 41% (RR = 0.59, CI = 0.44–0.80; $P < .001$), decreased HF readmissions by 66% (RR = 0.44, CI = 0.27–0.71; $P < .001$) with no change in HF-related mortality with cost savings of $1300–$7515 per patient per year.[43]

Holland published a systematic review of 30 randomized controlled trials involving patients 56 to 86 years of age and NYHA Classification II to IV.[53] Common elements within the education included one-to-one education concerning HF, medications, diet, exercise advice, symptom monitoring, and self-management across a number of visits. Patients also received phone calls at a rate of 1.4 calls per month on average and had access to remote monitoring. The results indicate a reduction in all-cause hospital readmissions by 13% (RR = 0.87, CI = 0.79–0.95), and reduced all-cause mortality by 20% (RR = 0.79, CI = 0.69–0.92). Additionally, HF admission decreased by 30% (RR = 0.70, CI = 0.61–0.81).[45]

McAlister et al provide the results of 29 randomized controlled trials involving 5039 patients that primarily focused on the outcomes with the use of a multidisciplinary team approach in the management of patients with HF.[54] The investigators divided the trials into 2 homogeneous groups of studies. The multidisciplinary team approach demonstrated reduced all-cause mortality by 25% (RR = 0.75, CI = 0.59–0.96), HF hospitalizations by 26% (RR = 0.74, CI = 0.63–0.87), and all-cause hospitalizations by 19% (RR = 0.81, CI = 0.71–0.92). Trials that involved programs for enhancing self-care activities reduced HF hospitalizations by 44% (RR = 0.66, CI = 0.52–0.83), and all-cause hospitalizations by 27% (RR = 0.73, CI = 0.57–0.93) with no effect on mortality (RR = 1.14, CI = 0.67–1.29).[55] Further, in 5 out of 6 trials that assessed compliance, higher adherence rates to medications occurred in those treated with the multidisciplinary team approach, and 15 out of 18 studies evaluated cost observed improvements in cost savings. None of the studies included in this systematic review specifically involved physical therapy services.

Education on self-care strategies involves teaching the patient a variety of behaviors, including daily weight assessment, recognition of signs and symptoms of exacerbation, nutrition, and medication management. In 2009, Boren provided a systematic review of 35 randomized controlled trials involving 7413 patients with HF.[48] The investigators identified 20 different educational topics (average of 6.6 topics covered per study), which were categorized into 4 major categories, including knowledge and disease management, social interaction and support, fluid management, and diet and activity.[48] Physical therapists can address these during their examination and intervention with patients to optimize patient outcomes.

The importance of nutrition in mitigating the progression of HF has been repeatedly emphasized in several CPGs published by the American College of Cardiology and European Society of Cardiology.[11,56] The utilization of the Dietary Approaches to Stop Hypertension (DASH) Diet is highly recommended as a useful dietary approach for individuals with HF and hypertension, both of which commonly coexist in patients. The DASH diet is high in fresh vegetables, fruits, low-fat dairy products, whole grains, poultry, fish, and nuts and is low in sweets, sugar-sweetened beverages, and red meats. Further, this diet reduces consumption of saturated fat, total fat, and cholesterol while increasing dietary potassium, magnesium, calcium, protein, and fiber. Adopting a dietary plan based on DASH guidelines has been shown to reduce systolic BP readings by 8 to 14 mmHg.[56] Dietary guidelines with an adherence to sodium restrictions is also useful in preventing HF exacerbations. A Cochrane Database systematic review in 2013 indicates a 2- to 8-mmHg drop in systolic BP with the utilization of this dietary sodium restriction of no more than 100 meq/day.[57] In light of the known association between sodium intake and hypertension, LV hypertrophy, and cardiovascular disease, the AHA recommends restriction of sodium to 1.5 g/d to be appropriate for most patients with Stage A and B HF.[11] For patients with Stage C and D HF, the AHA recommends sodium restriction to less than 3 g/day.[11] The authors noted that there was insufficient evidence to support a more significant sodium restriction for those with stage C and D HF. Therefore, physical therapists should inquire with the interdisciplinary team as to any specific dietary recommendations provided to the patient and regularly inquire about and encourage the patient to be adherent with those recommendations.

In regards to medication management, the APTA position statement adopted by the House of Delegates advocates that physical therapists assist patients in medication management in an effort to promote patient safety and reduce hospital readmissions. Further, medication reconciliation is the third goal of the 2011 National Patient Safety Goals delineated by the Joint Commission on Accreditation for Health Care Organizations. The goal discusses improving the safety of using medications and calls on organizations to accurately and completely reconcile medications across the continuum of care.

In clinical practice, patients often receive new medications or have changes made to their existing medications at various times in transitions of care. These changes place patients at risk for adverse drug events if all medications are not routinely reconciled at various points during the continuum of care from acute care to rehabilitation and home care. *Medication reconciliation* is a process of comprehensively reviewing all medications that the patient is taking, in an effort to create the most accurate list of medications that can be compared against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications and maximizing patient safety. When conducting a medication reconciliation intervention, the therapist must consider identifying all the medications that the patient is in fact taking, comparing that to what the physician prescribed, checking for interactions, duplications, and omissions, contacting the physician to collaborate as needed, and educating the patient regarding the same. The rehabilitation professional

can have a role in this process, and is currently a required standard of practice in home health settings.

Several systematic reviews and CPGs support the use of educational interventions in HF. Although physical therapist services have not been explicitly included in prior research, physical therapists, as members of the interprofessional team, must include education on self-care behaviors as part of the overall care in an effort to reduce hospitalizations and maximize outcomes in patients with HF.

Action Statement 3: Prescribe aerobic exercise training

Physical therapists must prescribe aerobic exercise training for patients with stable, NYHA Class II to III HF using the following parameters:

Time: 20 to 60 minutes.

Intensity: 50% to 90% of peak VO_2 or peak work.

Frequency: 3 to 5 times per week.

Duration: at least 8 to 12 weeks.

Mode: treadmill or cycle ergometer or dancing.

(Evidence Quality I; Recommendation Strength: A—Strong)

Action Statement Profile

Aggregate evidence quality. Level I.

Benefits:

- Improved peak VO_2 (weighted mean difference [WMD] 1.04–4.9 mL/kg/min) proportional to training intensity where higher training intensities yield greater changes in peak VO_2[41,58–78]
- Improved QoL (WMD 5.83–9.7 points on the Minnesota Living with Heart Failure Questionnaire [MLHFQ])[41,62,63,73,77–79]
- Reduced all-cause and HF-related hospital admissions and hospital days (RR = 0.61–0.64 and 0.92, respectively)[63,66,73,78]

Aggregate evidence quality. Level II.

Benefits:

- Potential improvement in LVEF (2%–3%), EDV, ESV[41,60,64,75]
- Potential improvement in survival[63,80]

Risk, harm, cost. No additional adverse events beyond usual care.

Benefit-harm assessment. Preponderance of benefit.

Value judgments. The guideline developers have utilized "must" in the key action statement based on the overwhelming preponderance of evidence, but clinicians should recognize that "must" is applicable only for patients who are consistent with the populations studied.

Intentional vagueness. Only aerobic exercise training parameter ranges are provided in the present guideline as there has been a lack of standard parameters used across studies. Setting of exercise training is not specified though home-based training programs are significantly less studied. The only modes of exercise that have been extensively studied have been cycle ergometry, treadmill walking, or dancing. However, other modes of aerobic training would be appropriate, especially when adapting the exercise prescription to individual patient preferences.

Role of patient preferences. Given that intervention durations in included studies frequently exceeded 3 months, and that continued adherence is required to maintain training effects, selection of training parameters should consider self-efficacy, readiness for behavior change, patient preferences, and individual constraints.

Exclusions. The use of aerobic exercise training has not been studied in patients who are unstable/acutely decompensated, who have significant musculoskeletal or pulmonary comorbidities, or who are in an inpatient setting or who have significant comorbidity. Therefore, clinical judgment must be used in the decision to include aerobic exercise training in these populations.

Summary of Evidence

Of all rehabilitation interventions for individuals with HF, aerobic exercise training is by far the most studied. The recommendations in the present key action statement are based on 26 meta-analyses of over 50 randomized trials of exercise training that include aerobic exercise training.[41,58–79,81–83] The strength of language used in the present key action statement (ie, "the clinician must") reflects this overwhelming preponderance of evidence and makes clear that in appropriately selected individuals, aerobic exercise training confers clear benefits across a variety of important health-related outcomes.

The characteristics of individuals studied and upon whom the present guideline is based are relatively narrow. Although a significantly greater proportion of subjects studied were men, younger in age (ie, late 50s to early 60s), NYHA Class II to III, and had HFrEF, those who are older, female, and/or have HFpEF may still benefit,[62,63,67,84] though the effects may be attenuated.[63] In an analysis of trials that included individuals 70 to 81 years old,[67] significant improvements compared to the control were noted for 6MWT and generic HRQL, but not for hospitalization, mortality, or peak VO_2. Those with NYHA Class IV are substantially under-represented, but may still benefit with an attenuated effect.[63] However, patients with

Class IV HF who meet the criteria for clinical stability may not be found in routine clinical practice. Specifically with regard to HFpEF, 4 separate meta-analyses with significant overlap of the same 8 studies concluded that the benefits of exercise training were similar to that of those with HFrEF, though only 5 of the 8 studies included aerobic exercise training alone (the others included NMES, IMT, or combined aerobic and resistance training).[67,81–83] One study identified an improved E/e' ratio (a measure of atrial pressure associated with diastolic dysfunction) following aerobic training as a possible mechanism for the improvements in exercise tolerance and cardiac function.[85] No study reported any adverse events, regardless of the exercise training mode.

With regard to comorbidities, clinical trials of aerobic exercise training largely exclude individuals with musculoskeletal or pulmonary diseases that affect the individual's ability to exercise, so generalization of the present key action statement to those with significant comorbidity is limited. A sub-group analysis from the HF-ACTION trial found that in patients with cancer and HF, there was no benefit in peak VO_2 or HRQL outcomes compared to the usual care group, and there was an increased risk of cardiovascular mortality and hospitalization in the exercise training group among those who were not able to adhere to the training protocol.[86]

Although a wide range of training parameters were studied, and all but 2[69,76] subgroup analyses failed to identify a substantial effect of training parameters on measured outcomes,[62–65,78,87] there appears to be a benefit to providing aerobic exercise training using a relatively higher intensity, interval-based format compared to similar training volumes using a lower intensity, continuous training format.[58,64,76,88,89] It should be noted that the use of high-intensity interval training (ie, > 90%–95% of peak work or peak VO_2 is covered in a separate key action statement in the present guideline), where outcomes associated with this method of high-intensity interval training are superior to those found in interval and continuous training intensities of <90% of peak work/peak VO_2.[63,69,75–77,90] However, when confining the discussion about training parameters to continuous aerobic exercise training at training intensities less than 80%, Vromen et al[69] found that total energy expenditure during the program was the most important determinant of improvement in peak VO_2.

The modes of aerobic exercise training that have been studied include treadmills, cycle ergometers, dancing, and aquatic exercise. With regard to dancing, a meta-analysis of 2 trials (total of 181 subjects) by Gomes-Neto et al demonstrated improvements in peak VO_2 and HRQL compared to controls but not aerobic exercise.[74] With regard to aquatic exercise, 4 of 5 low-quality studies reviewed by Graetz et al found small improvements in peak VO_2.[91] Unfortunately, no meta-analysis has accounted for this potentially important variable with regard to specificity of training and whether walking-based training modes result in better functional or HRQL outcomes given that walking is a component of many functional activities.

With regard to combined aerobic and resistance exercise training, the research that directly examines the addition of resistance/strength training is limited, and does not appear to offer additional benefit to peak VO_2. This is discussed in greater detail in the combined aerobic and resistance exercise training key action statement.

The setting of exercise training is not specified in the present key action statement, though home-based training programs are somewhat less studied compared with outpatient, clinic-based settings. However, the 2010 and 2016 reviews by Dalal et al[92] and Zwisler et al,[68] respectively, found no difference in exercise capacity and HRQL outcomes based on setting. In comparing home-based aerobic exercise to usual activity, Chin et al[47] found significant improvements in peak VO_2 and 6MWT of a magnitude comparable to those reported in other analyses, but found no difference in HRQL.

With regard to patient safety, a meta-analysis by Smart et al[61] noted that there were no deaths in 60,000 patient exercise hours and that there was a lower adverse event rate in exercising subjects compared to control. Similarly, Ismail et al found no reported deaths in 123,479 patient exercise hours.[59] In addition, the HF-ACTION trial, which included 1159 subjects completing 36 exercise sessions (total of 41,724 patient sessions), found no difference in the number of subjects having an adverse event within 3 hours of an exercise training session, and there was no difference in all-cause death or hospitalization in the 30-month follow-up period.[93] Finally, a recent randomized trial in patients with hypertrophic cardiomyopathy demonstrated that moderate intensity aerobic exercise improved aerobic capacity without any difference in adverse events.[94] As to whether cardiopulmonary exercise testing (CPET) is required prior to initiating an aerobic exercise training program for ensuring safety and determining exercise training intensity, no patients were reported as having withdrawn due to safety issues during CPET when they met the inclusion and exclusion criteria. This suggests that CPET is not needed with proper patient selection according to the criteria identified in the present key action statement. Clinical judgment, in consultation with other pre-exercise screening guidelines, is needed for those patients not well-studied.[95] Without a baseline CPET, exercise intensity would need to be guided by use of predicted maximum HR (in those not using beta blockers) and RPE, recognizing the potential issues of under-dosing exercise with RPE.[93] Therefore, practical application of the present key action statement to patients typically seen in clinical practice across the continuum of care should consider clinical stability, current status of coronary artery disease, and history of and risk for arrhythmia, etc, and

should consider appropriate clinical measures for measuring exercise intensity.

Given that intervention durations in included studies frequently exceeded 3 months, and that continued adherence is required to maintain training effect,[96] strategies to enhance adherence to exercise should be considered. In the HF-ACTION trial,[97] exercise adherence, measured by number of minutes per exercise per week, decreased from a median of 95 minutes per week by the 4- to 6-month follow-up to 74 minutes per week at 10- to 12-month follow-up (full adherence was defined as >120 minutes per week). A subgroup analysis by Cooper et al[98] revealed that, although perceived social support was not associated with clinical outcomes, it was associated with exercise adherence. Characteristics of patients with low adherence (<90 minutes per week) included those who were female, younger, black, NYHA Class III to IV, and had lower baseline exercise capacity and HRQL.

Action Statement 4: Prescribe high-intensity interval exercise training in selected patients

Physical therapists should prescribe high-intensity, interval-based exercise (HIIT) for patients with stable, NYHA Class II to III HFrEF using the following parameters:

Time: >35 total minutes of 1 to 5 minutes of high intensity (>90%) alternating with 1 to 5 minutes at 40% to 70% active rest intervals, with rest intervals shorter than the work intervals.

Intensity: >90 of peak VO_2 or peak work.

Frequency: 2 to 3 times per week.

Duration: at least 8 to 12 weeks.

Mode: treadmill or cycle ergometer.

(Evidence Quality: II, Recommendation Strength: B—Moderate)

Action Statement Profile

Aggregate evidence quality. Level II.

Benefits:

- Improved peak VO_2 of 1.0 to 2.14 mL/kg/min above that achieved with moderate-to-vigorous intensity continuous exercise training.[58,59,75,76,90]
- Reduced mortality rate as well as all-cause and HF-related hospital admissions and hospital days, but not better than other intensities of exercise training.[59,76]

Risk, harm, cost. Deaths and other adverse events were not different compared to controls and other exercise training intensities.

Benefit-harm assessment. Preponderance of benefit.

Value judgments. None.

Intentional vagueness. There is no consensus for screening of patients for eligibility to participate in high-intensity training, including the need for baseline CPET.

Role of patient preferences. Adherence is thought to be higher with shorter, higher intensity, interval-based sessions.[59,76]

Exclusions. Patients for whom high intensity and high heart rates might be contraindicated (eg, some types/settings of ICDs, history of exercise-related adverse events, suboptimally treated coronary artery disease).

Summary of Evidence

The evidence surrounding the safety and efficacy of HIIT training for patients with HF is mounting, and the developers expect that future revisions to the present guideline will include a recommendation for this mode of exercise with the strongest (ie, "must") language. However, there still are relatively few studies using small sample sizes, and it should be noted that there is a paucity of evidence surrounding patient selection and predictors of those who respond best to this type of training.[76] As with other key action statements in the present guideline, extrapolation to those patient characteristics not well-studied or not yet studied (eg, HFpEF, Class I and IV, older adults, women) is challenging. Additionally, Haykowsky et al[75] recommend that before performing HIIT, all patients with HFrEF should undergo CPET and all training sessions should be performed in a supervised setting after careful assessment and with monitoring. In contrast, Ismail et al[76] suggest that verification of tolerance to lower intensity exercise may be sufficient to progress toward increasingly higher intensities. Therefore, the present CPG is unable to make a specific recommendation about the need for baseline CPET.

With regard to on/off training parameters, most studies ranged from 1 to 5 minutes of high intensity (>90%) alternating with 1 to 5 minutes at 40% to 70%, with the most common paradigm being 4 bouts of 4 minutes at high intensity with 3 minutes of low intensity active rest intervals (total > 28 minutes). The majority of studies used active rest intervals rather than non-active rest intervals, and those that used non-active rest intervals used shorter work intervals of 30 to 60 seconds.

Some variation existed with regard to total training time per session, with most between 28 to 40 minutes of total training time. The analysis by Ismail et al[76] found slightly better improvements in peak VO_2 with sessions lasting greater than 35 minutes and that total weekly exercise

doses should be at least 460 kcal, 114 minutes, or 5.4 MET•hours to produce the greatest changes in peak VO_2.[76]

As noted in other key action statements within the present guideline, adherence should be a primary consideration for intervention selection for any given patient. With regard to HIIT, greater adherence/reduced study withdrawal was found in those studies using interval training and session durations <35 minutes and were able to attain similar outcomes as those protocols with longer session durations.[76,77] Taken together, shorter HIIT sessions may allow for the greatest long-term adherence, although this has not been verified, and Ismail et al[76] suggest that maintenance of benefit (after 3 months) might be accomplished by reducing session frequency.

With regard to clinical setting for the performance of HIIT, it has only been studied in supervised, outpatient settings. Thus, extrapolation of safety and efficacy to independent, home-based exercise may not be appropriate.

Action Statement 5: Prescribe resistance training

Physical therapists should prescribe resistance training for the upper and lower body major muscle groups for patients with stable, NYHA Class I to III HFrEF using the following parameters:

Time: 45 to 60 minutes per session.

Intensity: 60% to 80% 1RM, 2 to 3 sets per muscle group.

Frequency: 3 times per week.

Duration: at least 8 to 12 weeks.

(Evidence Quality I; Recommendation Strength: A—Strong)

Action Statement Profile

Aggregate evidence quality. Level I.

Benefits:

- Improved aerobic capacity (WMD 0.52–3.99 mL/kg/min)[99–102] and 6-minute walk test distance (WMD 41.77–59.26 m)[99–101]
- Improved quality of life (WMD 5.71 points on the MLHFQ)[99–101]
- Improved strength using 1 RM (but not high velocity movement using isokinetic testing) (standardized change score 0.43–0.77)[100]

Risk, harm, cost. No documented risks or harms other than transient musculoskeletal pain that may require adjustment of the exercises performed. Valsalva maneuver should be avoided (evidence grade V).

Benefit–harm assessment. Preponderance of benefit.

Value judgments. The GDG was unable to recommend this key action statement at the highest level (eg, "must") due to issues related to limited sample size and narrow patient selection criteria.

Intentional vagueness. Although a significantly greater proportion of subjects studied were middle-aged men, sex should not be used to exclude women, given that Pu et al included only women with effect sizes equal to or better than those of the younger male cohorts.[103]

Role of patient preferences. Effect sizes on all main outcomes in RT are similar to that of aerobic training, and therefore patient preference for mode of exercise to improve long-term adherence should factor significantly into treatment planning.

Exclusions. Patients with NYHA Class IV were excluded from all trials. Giuliano et al[100] note that, "Resistance exercise has an effect on skeletal muscle, but elicits less strain on the cardio-respiratory system compared to aerobic exercises. It may therefore be a suitable alternative for patients with CHF." However, they also note that the absence of data does pose a problem for issuing guidelines for the use of RT in the elderly and those with severe disease. Inclusion of resistance training in addition to an aerobic exercise program is considered under a separate key action statement.

Summary of Evidence

The evidence utilized to create the above recommendations were based on 5 systematic reviews on resistance training in patients with HF.[99–102,104] Each systematic review evaluated the impact of resistance training alone or in combination with aerobic training on the outcome variables measured. These systematic reviews utilized for this key action statement encompassed evaluation of over 2000 patients and, in 1 systematic review alone, over 31,263 patient hours of resistance training.[99]

The patient populations examined as part of these systematic reviews were Class I, II, and III HF. In the included studies, the participants were mostly men greater than 50 years of age and HFrEF. Patients with HFpEF were excluded in all studies of resistance training in HF. Variables measured included HRQL, functional capacity such as 6-minute walk test (6MWT) and VO_2 max, strength and cardiac function. All 4 systematic reviews acknowledge no issues with safety related to resistance training in HF.[99–102]

The intensity of the resistance training interventions in studies included in 3 out of 4 of the systematic reviews used a resistance training intensity of exercise set at 60% to 80% of the 1 repetition maximum (1RM). The one other systematic review showed a majority of studies using 40% to 60% of 1RM. A majority of study participants exercised

2 to 3 days per week. The studies examined in the systematic reviews also tended to be longer in duration, with some studies lasting up to 6 months in duration. The mode of exercise varied widely from study to study within the separate systematic reviews. Modes included anything from traditional to wrist and ankle weights to hydraulic and pneumatic resistance. However, studies often just referred to progressive resistive exercise (PRE) and did not define a mode of exercise. In addition, bouts of exercise alternated between high intensity intervals and continuous bouts of 8 to 10 reps of a single exercise.

With regard to selection of interventions, resistance training provides an alternate mode of exercise with expected clinical outcomes comparable to that of other interventions considered in the present CPG, although it should be noted that there are no meta-analyses and only a few individual trials of resistance versus aerobic exercise training.[105–107] Clinical trials have only focused on the addition of resistance training to aerobic exercise, and is thus a separate key action statement. Resistance training can be especially effective in patients that do not tolerate continuous or interval aerobic training or other therapeutic modalities. Accommodating patient preference for mode of exercise may increase patient adherence, and thus resistance training should be offered as an option.

No study included measures of functional status (other than HRQL measures) to offer insight as to the ways in which improved muscular strength and endurance translate into improvements in daily function, especially in individuals with focal muscle weakness directly contributing to movement dysfunction, such as gluteal or gastrocnemius-soleus weakness contributing to abnormal gait patterns and/or mechanical inefficiencies with gait. It is important for physical therapists to determine whether strength deficits that relate to function and utilize these as a primary form of intervention. It is also equally important for physical therapists to determine the patient's 1RM at baseline to ensure that underdosing of resistance exercise does not occur. However, testing 1RM may not be clinically feasible in many patients, and therefore estimation of %1RM can be made using the formulas outlined in Supplementary Table 1 (available at https://academic.oup.com/ptj). In clinical situations wherein the therapist is unable to determine 1RM due to weakness, the Omni Res scale is a preferred method of increasing strength as the patient improves. Patients are asked to perform a strength-specific exercise initiated with body weight only and using the Omni Res scale, the patient is asked to rate intensity level. This would be the patient's baseline Omni Res score. As an example of patient progression, the patient is asked to perform the exercise with 3 sets of 6 repetitions and rate their intensity level. When the Omni Res score of intensity falls below a level of 5, the amount of resistance increases by 1 lb. The Omni Res scale can be used to document strength gains and the GDG suggests that initially the physical therapist is conservative in addressing the progression of strength in patients with HF.

Although Valsalva can occur with higher weight loads, evidence towards the negative effect of the Valsalva is weak and conscious cuing on the part of the physical therapist to avoid the Valsalva maneuver can increase the patient's safety during the task. The increase in core stability using the Valsalva maneuver when lifting can also be accomplished, without increased atrial pressure, using forced exhalation during lifting.[108] The clinician should also consider repetition to failure. If a patient is easily able to complete 10 reps of an exercise, reassessment of 1RM may be warranted.[104]

With regard to safety, no systematic review reported an increase in adverse events associated with resistance training. However, it is important to note that the patients studied met relatively strict inclusion criteria. Transient musculoskeletal pain was the most commonly reported complication among studies that was able to be resolved through adjustment of the exercises performed with few subsequent drop-outs.

Action Statement 6: Prescribe combined resistance and aerobic training

Physical therapists may prescribe combined aerobic and resistance training for patients with stable, NYHA Class II to III HFrEF using the following parameters:

Time: 20 to 30 minutes of resistance training added to aerobic exercise training.

Intensity: 2 to 3 sets per major muscle group, 60% to 80% 1RM.

Frequency: 3 times per week.

Duration: at least 8 to 12 weeks.

(Evidence Quality: II, Recommendation Strength: B—Moderate)

Action Statement Profile

Aggregate evidence quality. Level II.

Benefits (beyond those of aerobic exercise training alone):

- Improved muscular strength and endurance[109,110]
- Improved HRQL (WMD 8.3 to 10.9 points on the MLHFQ)[64,99]

Risk, harm, cost. No documented risks or harms other than transient musculoskeletal pain that may require adjustment of the exercises performed. Valsalva maneuver should be avoided (evidence grade V).

Benefit–harm assessment. Preponderance of benefit.

Value judgments. Because only a few studies, using small samples sizes, have empirically compared combined resistance and aerobic training to aerobic training alone, the developers were unable to recommend this action statement at a higher level.

Intentional vagueness. Presence of baseline muscular strength impairment.

Role of patient preferences. Total exercise training time should be considered.

Exclusions. None.

Summary of Evidence

Given that: (1) the strongest recommendation level has been assigned to aerobic exercise training, (2) the benefits of an added resistance training program have been relatively less well studied, and (3) the additional effects of an added resistance training program on peak VO_2 are limited, physical therapists should be intentional in their decisions to add resistance training. Although a combined exercise training program appears to result in modestly greater improvements in muscular strength and endurance,[109,110] LVEF and left ventricular end-diastolic diameter,[110] and quality of life,[64,99] the added effect on peak VO_2 is much less clear.[64] The addition of resistance training is hypothesized to result in greater improvements in flow-mediated vasodilation[105,111] and skeletal muscle mass area resulting in reduced neurohumoral activation, improved LV function, and subsequent improvement in aerobic capacity.[110,112] The 2013 meta-analysis by Smart et al unequivocally concluded, on the basis of 4 studies, that combined exercise training was superior to intermittent aerobic exercise alone for improving peak VO_2.[58] However, a 2016 meta-analysis by Cornelis et al[64] with 1 additional study did not find any additional improvement in peak VO_2 with the addition of resistance training, and concluded that there were errors in the 2013 Smart et al analysis and conclusion.[58]

Although mild to moderate strength impairments were noted at baseline in studied subjects, no studies included subjects with normal strength, and therefore the developers were unable to comment on the use of combined resistance and aerobic training in individuals with minimal strength impairment. Additionally, no study included other measures of functional status (other than quality-of-life measures) to offer insight as to the ways in which improved muscular strength and endurance translate into improvements in daily function, especially in individuals with focal muscle weakness directly contributing to movement dysfunction such as gluteal or gastrocnemius-soleus weakness contributing to abnormal gait patterns and/or mechanical inefficiencies with gait.

Specifically with regard to HFpEF, 4 separate meta-analyses of the same 8 studies concluded that the benefits of exercise training were similar to that of those with HFrEF, though only 2 of the 8 studies included combined aerobic and resistance exercise training (the others included only aerobic exercise, neuromuscular electric stimulation, or inspiratory muscle training).[67,81–83,113] No study reported any adverse events, regardless of the exercise training mode.

Therefore, the amount of time a patient is willing to dedicate to exercise training must be considered when determining the duration of the aerobic and resistance training components of a combined intervention. Additional muscular strength and endurance benefits, without compromise to improvement in peak VO_2, were demonstrated when resistance training was added to the same aerobic exercise program performed by the control group,[114] as well as when total exercise time was held constant (eg, 20 minutes of aerobic training and 20 minutes of resistance training compared to 40 minutes of aerobic training only).[109–111,115] Thus, the developers suggest that, when selecting a combined aerobic and resistive exercise training program, the total exercise time not be extended beyond what would be spent on aerobic exercise training alone due to a risk of decreasing adherence to a program with a greater time commitment.[116]

Action Statement 7: Prescribe inspiratory muscle training

Physical therapists should prescribe inspiratory muscle training with a threshold (or similar) device (ie, device where resistance is not flow dependent) for patients with stable, Class II and III HFrEF with or without baseline inspiratory muscle weakness using the following parameters:

Time: 30 min/day or less if using higher training intensity (>60% maximal inspiratory pressure [MIP also known as PI_{Max}]).

Intensity: >30% MIP.

Frequency: 5 to 7 days/wk.

Duration: at least 8 to 12 weeks.

(Evidence Quality: I, Recommendation Strength: A—Strong)

Aggregate evidence quality. Level I.

Benefits:

- Improved maximum inspiratory pressure (MIP) (WMD 14.56–31.87 cmH2O)[117–120]
- Improved sustained maximum inspiratory pressure (SMIP) (WMD 144.74 pressure time units)[118]
- Improved exercise tolerance (peak VO_2 WMD 1.67–4.0 mL/kg/min; 6MWT WMD 23.66–80.0 m)[117–120]
- Improved quality of life (MLHFQ WMD 12.25 points)[117]

Risk, harm, cost. No documented risks or harms, though consideration should be given to those individuals at risk for vocal fold dysfunction and pneumothorax, as well as those with markedly elevated left ventricular end diastolic volumes. Device cost can vary. Patient time to complete an intervention, especially with lower training intensities and longer durations or when combined with other interventions, should be considered.

Benefit–harm assessment. Preponderance of benefit.

Action Statement Profile

Inspiratory muscle training at >60% MIP with sets/repetitions and/or intervals to fatigue.

Aggregate evidence quality. Level I

Benefits. Potentially greater, more rapid gains with less overall training time.

Risk, harm, cost. Potentially greater negative intrapleural and intrathoracic pressures than lower training intensities.

Benefit–harm assessment. Preponderance of benefit.

Value judgments. Despite a Level I aggregate evidence quality, the GDG was unable to recommend this action statement at the highest level (ie, "should" vs. "must") due to relatively small sample sizes and strict patient selection criteria.

The GDG included 2 action statements for inspiratory muscle training (IMT) (IMT alone and IMT combined with aerobic exercise training) because some patients may not be able to participate in an aerobic exercise program.

Intentional vagueness. Only IMT parameter ranges are provided in the present guideline as there has been a lack of standard parameters used across studies. The term "inspiratory muscle training" was used in the guideline without specifying training for endurance (low intensity/high repetitions vs. or strength [high intensity/low repetitions]).

Role of patient preferences. Amount of time the patient is willing to spend on a single intervention, especially if other interventions are being utilized.

Amount of time a patient is willing to spend on 1 intervention (ie, 30 minutes of low intensity IMT) versus higher intensity shorter treatment sessions.

Exclusions. None.

Summary of Evidence

In patients with HF, IMT is an intervention targeted at the underlying structural and metabolic muscle fiber changes that contribute to impaired inspiratory muscle strength and endurance that are known to be associated with dyspnea, poor quality of life, and poor prognosis.[121–124] As summarized below, the effects of IMT on a number of important clinical outcomes has prompted some to propose IMT as an alternative intervention for those who are unable or unwilling to participate in a more traditional rehabilitation program.[117,125]

With regard to effect of IMT alone on clinical outcomes based on reported weighted mean differences, meaningful improvements in SMIP exercise tolerance and HRQL[117] have consistently been demonstrated.

It is interesting to note that these benefits have been observed across a wide range of training intensities, with higher training intensities appearing to result in greater improvements with overall less training time per session, which might be appealing to patients unable or unwilling to perform IMT for 30 minutes continuously at lower workloads. However, this is somewhat confounded by the presence of impairment in baseline MIP. Most high intensity training studies except for Weiner et al[126] and Marco et al[127] included patients with normal baseline MIP,[128–130] which limits generalization to patients with impaired baseline MIP. However, the subgroup meta-analysis by Montemezzo et al[118] found that weighted mean differences for patients with baseline weakness were greater than those without (31.87 vs. 14.72 cmH20), but that difference was nonsignificant.

The synthesis of effects of IMT training intensity is also somewhat confounded by a lack of matching training intensity to the appropriate measurement, where the effect of low intensity/high repetitions (ie, training for muscular endurance) has mostly been assessed with tests of muscular strength (ie, MIP). Although this issue was identified over 20 years ago,[8] little data has since been gathered regarding the importance of inspiratory muscle strength versus endurance to inform decision making about IMT training intensity. Although their sample size was very small (n = 11 in the intervention group), Marco et al[127] demonstrated substantial changes in both inspiratory strength and endurance using 5 sets of 10 repetitions at 100% of the 10 RM in patients with baseline weakness. So it may be that loading of any intensity induces improvements in strength and endurance in such patients, but this has yet to be elucidated across multiple studies and larger samples.

It is important to note that IMT has not been studied or is understudied in many individuals with HF, including HFpEF, clinical settings other than outpatients, patients with clinical instability, NYHA Class IV symptoms, and significant comorbid COPD or other chronic pulmonary disease. Palau 2014 studied HFpEF in a small sample of patients with Class II to IV HF who had mildly impaired MIP with findings similar to those already outlined.[131] Additionally, IMT in patients with HF and comorbid conditions might preclude the ability to demonstrate

improvement, such as those with severe COPD with hyperinflation or neuromuscular conditions that result in irreversible inspiratory muscle weakness. With regard to clinical setting, only outpatient and home-based programs have been studied, so the evidence is unable to inform decisions regarding the use of IMT in other settings and the timing of initiating IMT as a patient progresses through the continuum of care. Thus extrapolation to patients with understudied characteristics and settings, although not inappropriate, should be performed with caution.

With regard to safety, no adverse events related IMT have been reported in the carefully selected patients included in randomized trials. However, Level V evidence suggests that IMT might be contraindicated in those at risk for vocal fold dysfunction and pneumothorax and those with unstable asthma and emphysematous bullae near the pleura due to the large negative airway, intrathoracic, and intrapleural pressures.[132] Additional Level V evidence raises concern for those with markedly elevated left ventricular end diastolic volumes due to enhanced venous return that occurs with large negative intrathoracic pressures which may result in worsening HF symptoms.[8] For these patients, and although not well studied, expiratory muscle training could be considered as this would not be associated with large negative intrathoracic pressures, and improvements in expiratory muscle strength may be associated with improved symptoms and functional performance.[133]

Finally, despite a Level I aggregate evidence quality, the GDG was unable to recommend this action statement at the highest level (ie, "should" vs. "must") due to relatively small sample sizes and strict patient selection criteria. Additionally, the GDG included 2 action statements for IMT (IMT alone and IMT combined with aerobic exercise training) because some patients may not be able to participate in an aerobic exercise program, and as previously discussed, use of IMT alone in lieu of other interventions is one of the theoretical underpinnings of IMT.

Regarding practical application of the present CPG to clinical practice in patients typically seen in clinical practice across the continuum of care, the MIP is typically not known or measured. However, Cahalin et al provide an excellent outline of procedures that can be used by clinicians to measure the MIP and develop an IMT prescription.[133]

Action Statement 8: Prescribe combined inspiratory muscle training and aerobic exercise training

Physical therapists may prescribe inspiratory muscle training with a Threshold (or similar) device (ie, device where resistance is not flow dependent) for patients with stable, Class II, and III HFrEF with or without baseline inspiratory muscle weakness as an adjunct to aerobic exercise training using the following parameters:

Time: 30 min/day.

Intensity: >30% maximal inspiratory pressure (PI_{Max} or MIP).

Frequency: 5 to 7 days/wk.

Duration: at least 8 to 12 weeks.

(Evidence Quality: II, Recommendation Strength: B–Moderate)

Action Statement Profile

Aggregate evidence quality. Level II.

Benefits (beyond those achieved with aerobic exercise training alone):

- Improved MIP (WMD 20.89 cmH2O)[134]
- Improved HRQL (WMD 4.43 points on the MLHFQ)[134]

Risk, harm, cost. No documented risks or harms, though consideration should be given to those individuals at risk for vocal fold dysfunction and pneumothorax, as well as those with markedly elevated left ventricular end diastolic volumes. Device cost can vary. Patient time to complete an intervention especially with lower training intensities and longer durations or when combined with other interventions, should be considered.

Benefit–harm assessment. Preponderance of benefit.

Value judgments. Despite a Level I aggregate evidence quality according to the evidence grading criteria, the GDG was unable to recommend this action statement at the highest level (ie, "should" or "must") due to relatively small sample sizes, too few studies, and strict patient selection criteria.

Intentional vagueness. Only IMT parameter ranges are provided in the present guideline as there has been a lack of standard parameters used across studies. The term "inspiratory muscle training" was used in the guideline without specifying training for endurance (low intensity/high repetitions vs. or strength [high intensity/low repetitions]).

Role of patient preferences. Amount of time the patient is willing to spend on combined interventions, especially if low intensity/longer session duration IMT is added to an aerobic exercise program.

Exclusions. None.

Summary of Evidence

In patients with HF, IMT is an intervention targeted at the underlying structural and metabolic muscle fiber changes that contribute to impaired inspiratory muscle strength and endurance that is known to be associated with

dyspnea, poor quality of life, and poor prognosis. As summarized in the preceding key action statement, IMT as a single intervention results in meaningful improvements in MIP, exercise tolerance, and quality of life have consistently been demonstrated. However, it is also important to address the use of IMT combined with aerobic exercise training.

Based on the 3 studies[135–137] included in the meta-analysis by Neto et al, the addition of IMT to an aerobic exercise program resulted in additional improvements in MIP (12.9–23.5 cmH2O, pooled effect of 20.89 cmH2O), and HRQL by 3.3 to 12 points on the MLHFQ (pooled effect of 4.43 points). However, there was no additional benefit in peak VO_2 (0–1.9 mL/kg/min, non-significant pooled effect of 0.89 mL/kg/min).[134]

Interpretation of these findings is confounded by Winkelmann et al[135] including only patients with inspiratory muscle weakness and using low intensity IMT, compared to Adamopoulos et al[136] and Laoutaris et al,[137] who used high intensity IMT in patients with normal inspiratory muscle strength. For example, although the improvement in MIP, peak VO_2, and HRQL was significantly greater in the IMT group, Winkelmann et al[135] observed substantial improvements across all measures in both groups, supporting the idea that aerobic exercise alone improves ventilatory muscle function in those with baseline weakness. In contrast, Adamopoulos et al[136] found no additional increase in peak VO_2, despite an improvement in MIP using high intensity IMT.

Regarding feasibility for application to clinical practice, 2 of the 3 studies[135,138] had drop-out rates of 21.4% and 36.8%. Only Winkelmann et al[135] reported the reason for drop-outs, which was primarily due to "logistical" reasons. Given the challenges of exercise adherence in patients with HF, the present guideline developers believe that selection of intervention combinations should incorporate individual preferences to ensure adherence.[21,24]

The reader is referred to the inspiratory muscle training key action statement for relevant discussion regarding IMT safety, patient selection, and clinical application considerations, which are also applicable to the present key action statement.

Action Statement 9: Prescribe neuromuscular electrical stimulation

Physical therapists should prescribe neuromuscular electrical stimulation (NMES) in patients with stable NYHA Class II to III HFrEF using the following parameters:

- Time: 30 to 60 minutes per session.
- Waveform: Biphasic symmetrical pulses at 15 to 50 Hz.
- Intensity: On/off time 2/5 seconds, pulse width for larger muscles of the lower extremity should be 200 to 700 ms and for small lower extremity muscles 0.5 to 0.7 ms, 20–30% of MVIC, intensity to muscle contraction.
- Frequency: 5 to 7 days/week.
- Duration: at least 5 to 10 weeks.

(Evidence Quality I; Recommendation Strength: A—Strong)

Action Statement Profile

Aggregate evidence quality. Level I.

Benefits:

- Improved muscle strength and endurance (WMD 25.0–30.74 Nm)[139–142]
- Improved VO_2 max (WMD 0.76–4.98 mL/kg/min)[139,141,143]
- Improved distance in 6MWT (WMD 34.78–85.66 m)[139–143]
- Improved QOL (WMD 2.21–6.77 points on MLHFQ)[141,143]

Risks, harm, cost. There were no adverse events attributable to the NMES intervention throughout the available evidence. Patients did experience mild self-limited cramps or muscle soreness. NMES units and electrodes can vary in cost but handheld devices can be just as powerful as larger NMES devices.

Benefit–harm assessment. Preponderance of benefit.

Value judgments. Despite a Level I aggregate evidence quality, the GDG was unable to recommend this action statement at the highest level (ie, "should" vs. "must") due to relatively small sample sizes and strict patient selection criteria.

Intentional vagueness. Although most studies investigating NMES included a significantly greater proportion of men, the GDG feels that the use of NMES on women who have similar clinical characteristics should not be precluded. The GDG provided a range of NMES parameters within this action statement because there has been a lack of standard parameters used across studies. Insufficient data exist regarding the use of NMES in those with and without baseline strength impairment.

Role of patient preferences. Patient tolerance to electric stimulation varies, and intensity to at least visible muscle contraction is required to be effective for NMES. Additionally, the duration of treatment investigated in the literature is up to 2 total hours, which may affect patient adherence due to patient discomfort.

Exclusions. Patients with implanted ICDs/pacemakers were excluded from all randomized trials. However, several case series studies on patients (total of 11 patients with bipolar sensing pacemakers and 6 patients with ICDs) demonstrated that there were not any adverse effects from NMES.[144–146] The GDG did not find literature regarding the use of NMES in HF patients with a high risk of venous thromboembolism and/or thrombophlebitis.

Summary of Evidence

When considering options for the patient with HF, NMES should be considered as an option for patients with NYHA Class II/III HF to improve muscle weakness. Muscle weakness negatively impacts functional status and quality of life.[147–149] NMES has been demonstrated to result in substantial improvements in peak VO_2[139,141,143,150] and 6MWT[139–143,150] compared to controls with effect sizes similar to those found with other exercise-based interventions.

NMES has also been shown to improve muscle strength and endurance, and improve oxidative capacity and capillarization of type 2 muscle fibers. Ranges of muscle strength improvement were noted to be between 22% and 35% increase in isometric and isokinetic peak torque.[151,152]

The literature includes patients with NYHA Class IV HF; however, more literature is needed to support this treatment option for this class of underrepresented patients. NMES is able to serve as an evidence-based option for patients with HF who may be unwilling or unable to participate in exercise-based interventions such as aerobic exercise, inspiratory muscle training, or resistance training. Physical therapists commonly encounter patients unwilling or unable to participate in physical therapy for numerous reasons. Large variations in clinical presentation may occur and fluctuate based on time of day impacting activity and participation levels. This variability may result in a low adherence to specific modes of exercise or limit exercise capacity. NMES is an option for patients with HF with noted improvements in muscle strength and endurance in the literature. Although many patients may not tolerate NMES or have barriers to obtaining the necessary equipment, this was not a factor the GDG believed should influence the strength of the recommendation for NMES (ie, that NMES should be a lower priority than exercise-based interventions) due to the strength of existing evidence.

Baseline weakness was not a criterion used to include or exclude patients. Although 1 study observed a greater percent improvement in those patients with greater baseline impairment, clinically meaningful improvements can be expected in those patients with NYHA Class II to IV HF. Although patients with NYHA Class IV HF were included from the studies considered by the GDG, they are generally underrepresented in this literature. However, the GDG feels that NMES may be a feasible alternative to whole body exercise for those patients with Class IV HF.

Few studies clearly stated the instructions provided to patients as to what, if any, activity should be performed during NMES treatment. One study specifically instructed patients to be ambulatory while receiving NMES. Fall risk, baseline level of inactivity, and exercise tolerance should be considered when providing patient instructions for patients who receive NMES during gait. The GDG recommends that patients avoid mobility during stimulation to avoid the risk of falls and to perform isometric or isotonic exercises during the contraction phase for a given muscle group.

The literature varies regarding application of NMES and specific muscle groups targeted. The GDG therefore selected muscles that were believed to be the most appropriate: quadriceps, hamstrings, gastrocnemius, and gluteals. These muscles of the lower extremity were chosen because these muscles are used for functional activities and participation. In addition, these larger muscles of the lower extremity are more tolerant to increasing the intensity of the NMES. In order to deliver optimal electrical stimulation to the muscle fibers, space should be adequate between NMES electrodes. Consideration for appropriate sized electrodes must be taken in order to achieve proper distribution of electrical stimulation across all muscle fibers targeted. This will increase muscular recruitment and improve patient tolerance.

With regard to electric stimulation dosing, the majority of studies used 60 minutes per session, with some using 30 minutes, and 1 using 240 minutes. Although no prior studies commented on dose-response relationship, there may be an effect of dose on peak VO_2 but not on other outcomes.[153]

Most studies were completed in the outpatient setting, with some using a home-based setting. Given that NMES units are small and portable, use of NMES could be considered throughout the continuum of care.

Conclusion

The evidence-based resources provided in this CPG should empower clinicians to utilize a multitude of options to optimize patient care across the continuum of care. Although a patient may not be able to perform all of the suggestions mentioned in this guideline, this CPG intends to provide the physical therapist with a toolbox of options to consider to maximize patient outcomes. While maintaining patient safety, these options can improve functional mobility within the context of the movement system and optimize quality of care to those with a

diagnosis of stable HF. The GDG was unable to establish a prioritization of interventions included in the present CPG as the available research does not provide the necessary comparative data between interventions, nor does it provide insight as to which is the most effective intervention in particular subgroups of patients with HF in decreasing readmissions, increasing function, and increasing quality of life.

Implementation

In order to implement and disseminate the recommendations of this CPG, the GDG has taken or is in the process of taking the following steps:

- Preliminary sharing of CPG recommendations at APTA's Combined Sections Meeting 2018;
- Open access to the CPG;
- Production of podcasts about the CPG aimed at physical therapists;
- Presentations on the CPG by the GDG at local, state, regional, and national seminars; and
- Organization of a team in 2023 to revise the present CPG by 2025.

Research Needs

Specific research needs related to each intervention are addressed within each Action Statement. Here we attempt to provide overarching needs related to the following questions:

- What are the variations in response or outcomes between patients with HFrEF and HFpEF?
- Of all of the exercise-related options, which are the most effective in particular subgroups of patients with HF in decreasing readmissions, increasing function and increasing quality of life?
- What are appropriate interventions and exercise dosing/parameters for:
  - Patients soon after (within days) of acute exacerbation?
  - Patients in acute care, inpatient rehab, subacute rehab, or home health early post-acute care?
  - Patients undergoing upward titration of cardiac remodeling agents and not yet on a stable, optimal pharmacologic regimen?
- Are there variations in response or outcomes associated with common comorbidities?
- What is the influence of combining or staging interventions (such as starting with E-Stim and progressing to aerobic training)?
- What is the influence of resistance training in specific instances of muscle weakness (eg, targeted therapeutic exercise)?
- What particular presentations of movement dysfunction in patients with HF may warrant particular combinations of interventions?
- What is the efficacy and role of exercise-based interventions for those with NYHA Class I and IV HF?

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Dr Collins and Dr Heick provided concept/idea/research design. All authors provided writing, data collection, data analysis, and input into Key Action Statements. Dr Shoemaker, Dr Lefevbre, Dr Dias, and Dr Heick each led the development and summary of Key Action Statements. Dr Collins and Dr Shoemaker developed the algorithms. Dr Collins and Dr Heick provided project management, fund procurement, and consultation. Dr Heick managed the article review process. Dr Lefevbre managed the external guideline review process.

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Disclosures and Presentations

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

This guideline is scheduled to be updated 5 years from date of publication.

This CPG is not intended as the sole source of guidance in managing patients at risk for or diagnosed with heart failure. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision making strategies. This CPG is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to managing the problem. This CPG may be used to develop policy or suggest policy changes, or it may provide discussion about current policy. However, it is up to individual facilities to determine whether they want to adopt these CPG key action statement recommendations in place of their existing policies or protocols.

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Appendix 1.
Key Words for Literature Search

Search Strategy Using PICO Format

The populations, interventions, comparisons, and outcomes included to select evidence are included below. This is a comprehensive and inclusive list.

Populations

Adults with heart failure

- Excluding congenital causes in congruence with the ACCF/AHA 2013 guidelines (Committee et al, 2013)
- Including both heart failure with reduced ejection fraction and with preserved ejection fraction and delineate when able

Interventions

Coordination, communication, and documentation

- Addressing required functions
- Admission and discharge planning
- Case management
- Collaboration and coordination with agencies
- Communication & Documentation across settings
- Cost-effective resource utilization
- Data collection, analysis, and reporting
- Interdisciplinary teamwork
- Referrals to other professionals or resources

Instruction, education and training of patients/clients and caregivers regarding

- Current condition
- Enhancement of performance
- Health, wellness, and fitness programs
- Plan of care
- Risk factors for pathophysiology
- Transitions across settings
- Transitions to new roles

Procedural interventions

Therapeutic exercise (particularly for Body Structures/Functions: aerobic capacity/endurance, circulation, muscle performance, motor function, posture, range of motion, ventilation, and respiration; Activities: self-care, ambulation, stair climbing; Participation: home management, work, community leisure).

- Aerobic capacity/endurance conditioning
  - Balance, coordination, and agility training
  - Body mechanics and postural stabilization
  - Flexibility exercises
  - Gait and locomotion training
  - Neuromotor developmental training
  - Relaxation
- Strength, power, and endurance training of skeletal (including ventilatory) muscles
- Functional training in self-care, home management, work, community, and leisure
  - ADL training
  - Barrier accommodations or modifications
  - Device and equipment use and training
  - Functional training programs IADL training
  - Injury prevention or reduction
- Leisure and play activities and training (relate to sustaining an active lifestyle)

Manual therapy

- Massage
- Mobilization
- Passive range of motion

Prescription, application, and, as appropriate, fabrication of devices and equipment

- Adaptive devices
- Assistive devices
- Orthotic devices
- Protective devices
- Supportive devices

Airway clearance techniques

- Breathing strategies
- Manual/mechanical techniques
- Positioning

Electrotherapeutic modalities

- Biofeedback
- Electrical stimulation

Physical agents and mechanical modalities

- Compression therapies

Comparisons

We included groups with all possible comparisons, such as standard care, different interventions, and baseline comparisons in longitudinal observational studies without a control group.

Outcomes

Functional measures; ADLs; aerobic capacity; strength; endurance; LOS; number of visits; discharge destination; quality of life; readmission rates, adverse events.

- Impact on pathology/pathophysiology (Health Condition)
  - Morbidity
  - Disease progression
  - Exacerbations
- Impact on impairments (Body Structures/Functions)
  - Aerobic capacity/endurance
- Impact on functional limitations (activities)
  - Ambulation, ADLs
- Impact on disabilities (participation)
- Impact on health, wellness, and fitness (vague)
- Impact on societal resources
- Patient/client satisfaction

Additional evidence selection criteria will include:
Health care settings: Across the spectrum from critical care to outpatient (including home care).
Timeframe: No limit.
Study design: We included practice guidelines, systematic reviews with or without meta-analysis; RCTs, prospective comparison studies, prospective non comparison studies, retrospective studies, case series/case reports; and excluded any cross sectional design studies.
Publication status: Only published full papers were included (Not unpublished manuscripts or abstracts of conference proceedings).
Language: Our search and inclusion included English language publications

Appendix 2.

Flow Chart of Article Selection