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COUNCIL PERSPECTIVES

# Heart Failure as a Newly Approved Diagnosis for Cardiac Rehabilitation

## Challenges and Opportunities

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**ABSTRACT**

Many see the broadened eligibility of cardiac rehabilitation (CR) to include heart failure with reduced ejection fraction (HFrEF) as a likely catalyst to high CR enrollment and improved care. However, such expectation contrasts with the reality that CR enrollment of eligible coronary heart disease patients has remained low for decades. In this review, entrenched obstacles impeding utilization of CR are considered, particularly in relation to potential HFrEF management. The strengths and limitations of the HF-ACTION (Heart Failure-A Controlled Trial Investigating Outcomes of Exercise Training) trial to advance precepts of CR are considered, as well as gaps that this trial failed to address, such as the utility of CR for patients with heart failure with preserved ejection fraction and the conundrum of poor patient adherence. (J Am Coll Cardiol 2015;65:2652–9) © 2015 by the American College of Cardiology Foundation.

The recent decision by the U.S. Center for Medicare Services (CMS) to extend cardiac rehabilitation (CR) coverage to patients with heart failure with reduced ejection fraction (HFrEF) (1) caps years of cumulative research showing the benefits of exercise training, lifestyle modifications, medication adherence, education, and other CR elements to moderate HFrEF pathophysiology and improve clinical outcomes (2–4). Many healthcare experts anticipate that the new CMS eligibility will translate rapidly into CR enrollment by HFrEF patients (5). However, CMS coverage of CR for coronary heart disease (CHD) is longstanding and has been reinforced over time by data demonstrating improved outcomes among CHD patients who attended CR (i.e., consistently beyond the evolving standards of contemporary care), yet underenrollment has persisted (6). Therefore, irrespective of CMS eligibility, CR implementation for HFrEF patients may constitute more of a challenge than many presume.

## HISTORICAL PERSPECTIVE: CR FOR CHD

CR was formulated as a safe, effective program to guide exercise progression for myocardial infarction (MI) patients as part of a shift from standards of

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prolonged bed rest to standards of earlier activity and greater emphasis on self-care (6). Subsequently, evolving insights regarding atherosclerosis initiation, progression, and regression indicated that CR not only had potential to reduce morbidity and mortality by moderating the sequelae of sedentary behaviors (e.g., pulmonary emboli, deconditioning), but that it also could more fundamentally moderate the pathophysiology of atherosclerosis (6). Overall, the rationale for CR for acute coronary syndromes, revascularization, and/or chronic CHD has progressed over time, but utilization has persistently lagged (6).

The inherent weakness of CR research has contributed to poor CR utilization for CHD. CR benefits were originally based predominantly on small single-site investigations (7) that tended to enroll mostly middle-aged, ethnically homogeneous males who were also usually better educated and motivated than patients who did not attend CR. Given the limited statistical power of such studies, assessments of CR mortality benefits relied on meta-analyses (8), and were subject to the inherent limitations of such secondary analyses.

Nonetheless, recent analyses of large contemporary databases corroborate CR benefits for patients across spectra of different ages, sexes, and therapies (including both revascularization and adjunctive treatments). The Rochester Epidemiologic Project (9) showed that CR benefits on mortality and recurrent MI were greater as cardiac care advanced over time. Suaya et al. (10) used propensity-based matching, regression modeling, and instrumental variables to show mortality reductions in all demographic and clinical subgroups, including patients with acute MI and revascularization procedures.

## IS CR FOR HFrEF DIFFERENT?

Evolving over 20 years, multiple smaller HFrEF exercise training trials demonstrated wide-ranging physiological and clinical benefits, including improved exercise capacity, favorable cardiac remodeling, and improved autonomic balance (11). However, most of the formative trials were completed at single centers with implicit selection bias akin to the CR for CHD literature. Moreover, skepticism regarding the utility of exercise therapy for HFrEF was magnified by safety concerns. In comparison to patients with CHD, HFrEF patients tend to be more prone to arrhythmia, hemodynamic instability, and fluid overload, and are often older and frailer, and have more comorbidities. Concerns were particularly intensified when 1 exercise trial reported adverse remodeling in patients who had sustained recent anterior Q-wave MIs (12). Remarkably, that study engendered widespread apprehension regarding exercise training for heart failure (HF), despite its small size (only 13 patients) and that only 3 patients had HF. Proponents of exercise training for HFrEF countered with assertions regarding the predominant safety of exercise training in multiple other studies (13).

Amid such contention, the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) trial was designed to definitively assess the safety and efficacy of exercise training for HF, and to potentially justify changes in practice standards (4). The National Heart, Lung, and Blood Institute made a forward-thinking decision to invest appreciably in the promise of therapeutic exercise. The HF-ACTION trial was large (targeting 3,000 patients), resource-intensive, and expensive (approximately $40 million) (personal communication, C. M. O'Connor, January 2015).

### ABBREVIATIONS AND ACRONYMS

**CHD** = coronary heart disease
**CMS** = Center for Medicare Services
**CPX** = cardiopulmonary exercise testing
**CR** = cardiac rehabilitation
**HF** = heart failure
**HFpEF** = heart failure with preserved ejection fraction
**HFrEF** = heart failure with reduced ejection fraction
**LVAD** = left ventricular assist devices
**MI** = myocardial infarction
**$VO_2$** = oxygen uptake

## WHAT THE HF-ACTION TRIAL ACCOMPLISHED

The HF-ACTION trial assessed the safety and efficacy of exercise training for medically stable patients with HFrEF (left ventricular ejection fraction ≤35%, New York Heart Association functional class II to IV). Notable features included the large and diverse study population, the randomized controlled trial design, and the requirement for optimal medical management, including pharmacologic therapy with an angiotensin-converting enzyme inhibitor and beta-blockers. Approximately 40% of patients (exercise group and controls) had implanted cardiac defibrillators, and 18% had biventricular pacing. Given such comprehensive baseline care, the trial's capacity to assess additive benefits of a CR-like intervention were intended to be unambiguous.

The HF-ACTION exercise group began with 36 supervised training sessions for 30 min of exercise 3 times per week, with an individualized exercise prescription on the basis of cardiopulmonary exercise testing (CPX). Halfway through this training period, patients received, at no cost, a home treadmill or stationary bicycle and a heart-rate monitor for personal use. They were instructed to exercise 5 times per week at moderate intensity for 40 min. In contrast, the usual-care group was only given instructions regarding the benefits of exercise training at moderate intensity for 30 min per day, as recommended by the existing American College of Cardiology/American Heart Association guidelines (14).