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Dear Dr. McClellan:

On behalf of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Cardiology (ACC), and the American Hospital Association, we are collectively responding to the Centers for Medicare & Medicaid Services (CMS) request for public comment on five specific questions raised by CMS regarding coverage of cardiac rehabilitation services. These questions cover clinical evidence for currently covered diagnoses, new indications for coverage, physician supervision and "incident to" issues, individual components of cardiac rehabilitation, and the appropriate number of sessions needed to achieve a net health benefit.

We appreciate CMS's timely consideration of these comments. We look forward to working with you as this issue continues to develop. Please feel free to contact the following individuals with any questions: Phillip Porte for the American Association of Cardiovascular & Pulmonary Rehabilitation (703-752-4353; Phil@GRQConsulting.com); Rebecca Kelly from the American College of Cardiology (301-493-2398 and RKelly@acc.org); and Roslyne Schulman from the American Hospital Association (202/626-2273 and rschulman@aha.org).

Question 1:

In persons age 65 years and older, what is the clinical evidence for a net health benefit from cardiac rehabilitation for the seven indications?

- **a. acute MI**
- **b. post CABG**
- **c. stable angina**
- **d. post heart valve replacement**
- **e. post angioplasty**
- **f. post heart or heart lung transplant**
- **g. congestive heart failure**

INTRODUCTION

The clinical evidence for a net health benefit from cardiac rehabilitation (CR) in patients with heart disease is conclusive, with meta-analyses of clinical trials consistently demonstrating a 25-30% reduction in total and cardiovascular mortality for CR participants compared to non-participants.[15,30] Participation in medically supervised CR programs has also been shown to reduce cardiovascular risk factors, including sedentary lifestyle and low physical fitness, obesity, dyslipidemia, endothelial dysfunction, hypercoagulability, abnormal sympathetic tone, and inflammation, in a variety of populations including men, women, and the elderly. Additionally, health-related Quality of Life (QOL) in patients participating in CR, including the elderly, is significantly improved. [1-2,5,9,12-13,15-23,25-27,30,34-35] Effectiveness analyses such as those by Witt et al. document that the benefits of CR extend beyond the clinical trial setting and that CR as practiced in the community results in substantial improvements in morbidity and mortality among CR participants in the current era of thrombolysis, revascularization and widespread use of pharmacological treatments known to improve prognosis among patients with coronary heart disease.[16]

Despite these well established benefits, CR remains underutilized, particularly by women, the elderly, and under-represented minority groups. It is estimated that only 20-30% of clinically appropriate patients are referred to CR programs following myocardial infarction (MI), coronary artery bypass grafting (CABG) or percutaneous intervention (PCI).[3,7,10,32]

Benefits appear to be independent of diagnosis at CR entry (post myocardial infarction versus other coronary artery disease diagnoses) and publication date (before 1995 versus after 1995).[31] The strength of these data is such that CR is considered standard of care for persons with coronary heart disease, as reflected by inclusion in practice guidelines by several national and international agencies.[4,6,11,14,17,24,28,29,34] This document reviews the literature specific to each of the listed diagnoses, providing the rationale for inclusion of CR in treatment plans to improve health outcomes for Medicare beneficiaries.

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A. Acute MI

Cardiac rehabilitation (CR) programs have long been recognized as integral to the comprehensive management of patients with cardiovascular disease, in particular, after a hospitalization for an acute coronary event.[2,17] The demonstration of a survival benefit after CR is well established for patients with acute myocardial infarction (MI).[9,12,13] Meta-analyses of randomized clinical trials of CR after MI were reported by Oldridge (1988) and O'Connor (1989) and documented a 24% and 20% decrease in total mortality, respectively, and a 25% and 22% decrease in cardiovascular mortality at 3 years of follow-up.[12,13] The review of Jolliffe et al. in 2001[9] using the Cochrane Database Systematic Review methodology, included more women, more older patients, and expanded the diagnostic categories to include not only MI, but also patients with coronary artery bypass grafting (CABG) surgery and patients after percutaneous coronary interventions. CR exercise programming was shown to reduce all cause mortality by 27% and cardiac mortality by 31%.[9] A similar analysis was reported by Taylor et al. in 2004[15] using a shorter follow-up period. Again, the CR program demonstrated significant reductions in all cause mortality by 20% and cardiac mortality by 26%.[15] Finally, in a contemporary U.S. population of 1,821 patients after MI in Olmstead County, Minnesota, Witt et al.[16] found that while women and persons over the age of 70 were less likely to participate in CR, an overall survival benefit was demonstrated, along with a decrease in recurrent MI.

Since many clinical trials predate aggressive revascularization and intensive pharmacological therapy, their applicability in the current era has been questioned. In an analysis of benefit versus year of CR enrollment, Witt et al.[16] convincingly demonstrate that the benefits of CR were more pronounced in recent years than in the past suggesting a greater, not lesser, need for CR services in contemporary coronary heart disease (CHD) care. Whether these benefits are due to physiological changes mediated by specific CR components such as exercise or are due to the comprehensive approach to secondary prevention in the CR setting is unknown. Improved endothelium-dependent vasodilation of coronary arteries resulting from exercise training may represent the most important physiologic mechanism to explain the marked reduction of myocardial ischemia and coronary events[7,8] although many other mechanisms have been proposed including favorable effects on blood lipids, blood pressure, and insulin sensitivity.[2,17]

CR improves prognosis after MI in a highly cost-effective manner by reducing recurrent hospitalization and health care expenditures, while prolonging life.[4,5,10] It compares favorably in terms of costs per year-life-saved with other well-established preventive and therapeutic interventions in the treatment of coronary heart disease such as cholesterol lowering, thrombolysis with tissue-plasminogen activator, and CABG surgery.[4]

Compared with younger patients, older coronary patients after MI have a diminished exercise capacity and higher rates of disability and mobility limitations.[11,14] Within the older age group, advancing age is a powerful predictor of higher rates of disability.[14] Coronary heart disease in the elderly is also characterized by a greater severity of angiographic disease, more severe left ventricular systolic dysfunction, a high prevalence of peripheral vascular disease, more medical co-morbidities, and greater rates of physical disability.[17] In that an improvement of exercise capacity is the single most predictable beneficial effect of CR,[17] CR effectively distances the older participant from physical disability, particularly with long-term participation.[3] For clinicians in the field, this is by far the most evident clinical benefit of CR in older patients after MI. It should be noted that CR exercise training includes both aerobic and resistance training. A randomized controlled trial of resistance training in disabled older women with coronary heart disease (post-MI and post-revascularization) documented improvements in directly measured physical functional performance which included both household activities and measures of endurance activities such as stair-climbing, grocery carrying, and 6-minute walk distance.[1,6]

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B. Post CABG

At entrance to CR, patients who have undergone coronary artery bypass graft (CABG) surgery have a significantly reduced exercise capacity compared to patients entering CR after myocardial infarction (MI) or after a percutaneous intervention, even after adjusting for age differences.[1] In that advanced age is also a predictor of diminished exercise capacity in patients with coronary heart disease, older patients after CABG surgery, particularly women, are a severely disabled group. Consequently, a primary role of CR in patients who have undergone CABG surgery is to provide an effective means for returning these patients to an appropriate level of functional independence. The ability of CR to improve functional capacity in patients $\geq$ 65 years of age, particularly women, has been frequently demonstrated over the past two decades.[2,3,6,11]

While the systematic review of Jolliffe et al.[5] and Taylor et al.[9] demonstrated an overall survival benefit of CR in pooled patients after MI, CABG surgery, and percutaneous coronary intervention, it is less clear whether CR confers a survival benefit in older subsets of patients after CABG surgery in that CABG surgery itself usually confers a survival benefit and in the elderly, returns patients to an actuarial survival curve similar to age-matched individuals without coronary heart disease.[7,8] However, a controlled trial of CR after CABG surgery with 10 year follow-up documented a decrease in total cardiovascular events and a reduction in hospital readmissions.[4] In addition, in a mixed population of 417 patients after CABG surgery and MI, improvements in peak exercise capacity after CR correlated with a decrease in long term mortality rates.[10] That is, cardiovascular mortality decreased more with greater increases in peak VO2 after training. Nonetheless, by far the most important clinical role of CR in older patients after CABG surgery is to prevent and treat coronary heart disease disability.[3]

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C. Stable angina

It has been known for more than 30 years that exercise training improves exercise tolerance in patients with chronic stable angina pectoris by increasing the anginal threshold and delaying the onset of electrocardiographic ischemia.[5] Furthermore, in many patients, angina can no longer be brought on by maximal exercise after exercise training.[1] Improved endothelium-dependent vasodilation of the coronary arteries resulting from exercise training may represent the most important mechanism to explain the marked reduction of myocardial ischemia.[3,4] A recent, randomized-controlled 12-month study in patients with stable angina compared outcomes of patients randomized to invasive percutaneous coronary interventions (PCI), primarily coronary stent placement, to patients receiving 12 months of exercise training.[2] At the end of 1-year, patients in the exercise group had an increased functional capacity compared to the PCI patients and had experienced fewer total coronary events requiring hospitalization. From a cost effectiveness point of view, CR improved functional capacity at half the cost of the interventional approach.

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D. Post heart valve replacement

The net health benefit from CR following heart valve surgery is related to the reversal of post operative deconditioning and abnormal cardiovascular dynamics with exercise training, to assessment for post operative depression and for unhealthy behaviors, and to enhanced monitoring for arrhythmias and fluid overload resulting from valvular heart disease. The data available for patients who have undergone heart valve surgery support the fact that medically prescribed CR results in improvement in exercise tolerance, cardiovascular hemodynamics, symptomatology, functional capacity, and quality of life. In addition, CR provides the opportunity to educate patients regarding the safety of increasing the level of physical activity and to monitor signs or symptoms that may occur in these patients after surgery, thus facilitating return to a productive, independent lifestyle.[11]

In 1991, the Agency for Health Care Policy and Research stated that CR programs are beneficial to patients who have undergone cardiac valve surgery.[4] These programs are particularly beneficial because this patient population is often highly deconditioned and very symptomatic prior to surgery. The majority of patients, prior to undergoing aortic valve or mitral valve replacement or repair, are identified as NYHA class III-IV[6,8,9] and peak functional capacity is 4 to 5 METS.[7] This level of exercise capacity is 30% of that of age-matched control patients.[2] In addition, the cardiovascular hemodynamics and symptomatology in these patients are similar to those of chronic heart failure patients with elevated pulmonary capillary wedge pressures, depressed cardiac indices, and pronounced dyspnea with minimal exertion.[7] Although valve replacement or repair in these patients improves NYHA Classification on the average by one class, only small improvements in peak oxygen uptake occur[2,6-9] and exercise capacity for the majority of valve patients six months after surgery is still only 55% compared to normal control patients.[2] Abnormal rest and exercise cardiovascular hemodynamics persist six months to a year after surgery.[2] During the post-surgical period, most patients exhibit abnormal rest to exercise changes in left ventricular ejection fraction (LVEF).[5]

Supervised exercise training post-surgery is beneficial in this deconditioned and symptomatic patient population. One study revealed that exercise training after aortic valve replacement increased peak physical working capacity, while improving cardiovascular response and patient perception of effort at a given workload.[10] Moderate exercise training has also been shown to improve peak oxygen uptake by 25% after aortic/mitral valve surgery.[5] Single aortic or mitral valve replacement patients, who undergo treatment in a comprehensive CR program post-operatively, have significant improvements in their ability to perform activities of daily living and in their jobs.[3] Reemployment after valve surgery corresponds to a patient's physical working capacity, with greater physical work capacity associated with higher return to work.[10] In a non-randomized study of patients who had undergone heart valve replacement, there was a significant improvement in quality of life following 6 months of exercise training compared to the non-exercise group and this improvement was correlated to increases in VO_{2peak} as a result of the training.[14]

Improvement in functional capacity as a result of CR has also been documented in women following mitral valve replacement. After eight weeks of exercise training, peak oxygen uptake (VO_{2peak}) and peak physical work capacity were significantly increased compared to a control group.[12] Improvements of this magnitude are clinically important because an increase in VO_{2peak} of 1 $mL \cdot kg^{-1} \cdot min^{-1}$ results in a 10% reduction in subsequent cardiac mortality in women.[13]

CR is an important therapeutic intervention after valve surgery for monitoring medical management and providing a medically supervised program to improve functional capacity while reducing symptoms associated with daily activities and improving self-confidence, particularly in older patients. Older patients who undergo valve surgery have longer hospital stays, more complications and require more follow-up care after discharge from the hospital. Resumption of physical activity in a medically monitored CR program post-surgery contributes to better outcomes for these elderly patients.[1]

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E. Post angioplasty

Between 1987 and 2002, the number of percutaneous coronary intervention (PCI) procedures performed to treat acute coronary ischemic syndromes increased by 324%.[4] Fifty percent of these procedures were done in patients over 65 years of age. Unlike their younger counterparts with commercial insurance, Medicare beneficiaries with coronary artery disease (CAD) who have been treated with PCI, rather than coronary artery bypass graft (CABG) surgery, do not have coverage for CR. Both risk factor modification and exercise therapy favorably impact factors involved in progression of disease and restenosis of a PCI, thus CR for this population is as important as it is for other populations who are currently covered by CMS for CR.[1,2,11,14,15,18,27,29,31,32,34,35]

Participation in CR post-PCI is associated with marked improvement in functional capacity, lipid profile, exercise tolerance and maximal oxygen consumption, morbidity (decreased clinical events), decreased readmission rate, improved sympathovagal balance, improved quality of life (QOL), and decreased inflammation (C-reactive protein, CRP).[1,2,5,9,10,19-21,29] In a randomized trial of patients who underwent PCI, those participating in CR not only improved lifestyle significantly, but these changes were also more persistent over the course of the five year follow-up, compared to the group that did not participate in CR.[19] Patients who have undergone PCI in the presence of a myocardial infarction have been shown to have improved endothelial function as a result of six months of exercise training.[10] Post-PCI patients respond favorably to CR and exercise training and respond similarly to other patient populations, as evidence above indicates.[1,2,27,29]

Belardinelli et al.[5] in a randomized trial, demonstrated that PCI patients who participate in CR experience a significant increase in maximal oxygen uptake and QOL compared to a control group which experienced no change in those variables. After participation, the CR group had significantly less residual stenosis and significantly improved thallium scores (reflecting myocardial perfusion). In addition, clinical events were significantly lower in the CR group than in the control group (11.9% vs. 32.2%). Readmission rate in the CR group was 18.6% vs. 46% in the control group. It has also been demonstrated that lack of progression in functional capacity in a CR program may be an early indicator of restenosis in this population.[12]

Thrombosis, inflammation, and endothelial dysfunction contribute to acute coronary syndromes, as well as to restenosis following PCI.[17,18,24,32,33] Though acute exercise may lead to a state of increased coagulability and unbalanced hemostasis, this appears to be temporary. Elderly patients with CAD often exhibit disturbances in the balance between procoagulatory and fibrinolytic parameters.[27] Physical conditioning favorably affects fibrinolytic variables and fibrinogen in younger and older patients.[28] Exercise training reduces fibrinogen and plasminogen activator and modulates platelet activation following acute exercise, thereby reducing the risk of restenosis.[27,29] Inflammation is moderated, as shown by reduced CRP in patients undergoing CR post-PCI and endothelial function is improved.[10,22]

Endothelial dysfunction and inflammation play a role in the evolution and progression of CAD and restenosis following PCI.[16-18,24,32] The inflammatory response and alterations in endothelial function subsequent to the trauma of PCI, as well as those caused by oxidative or hemodynamic stressors, may lead to intimal proliferation and restenosis.[17,18,24,32] Conditions resulting in endothelial dysfunction include advanced age, cardiovascular disease risk factors, and CAD.[7,14,16,25,32] Exercise training prevents and restores age-related declines in endothelium-dependent vasodilatation in athletic, healthy, and hypertensive men, as well as in cardiac patients with a variety of diagnoses including post-PCI patients.[5,7,10,18,27,32] This may also help to explain the improvement in hyperemic myocardial blood flow (flow reserve) seen in patients following a CR program of exercise and low-fat diet.[6,8] Endothelial dysfunction has also been shown to be involved in restenosis after PCI.[14,17] Thus, CR and exercise training have the potential to improve restenosis post-PCI.[14,17]

Improvements in autonomic function may partially explain the increased survival demonstrated in a meta-analyses of exercise rehabilitation studies following MI.[8,11,23] Autonomic dysfunction is associated with an increased risk of sudden death and exercise may be cardioprotective in patients with CAD.[8] Gielen, et al.[7] showed that exercise training accompanied by multifactor risk reduction, similar to that provided in medically supervised CR programs, slows CAD progression. In sum, this body of literature shows that CR and exercise training positively affects the basic pathophysiology of CAD and the underlying disease process.

Atherosclerosis, endothelial dysfunction, and low levels of bone marrow-derived endothelial or cardiac progenitor cells seem to be associated with a poor prognosis and recurrent events in patients with CHD.[30] Cardiac progenitor cells are able to differentiate into various mature cell types including endothelial cells and may play a role in promoting repair of a damaged or dysfunctional endothelium and assist in maintenance of normal vascular function.[30] It has been reported that exercise training as part of a CR program results in increased integration of these cells into the endothelium of patients with atherosclerosis and CAD.[13,26]

Another benefit of CR participation for persons with PCI is the early identification of restenosis as manifested by new onset signs and symptoms of myocardial ischemia, leading to prompt medical attention that minimizes myocardial damage and complications. This is facilitated by the increased surveillance provided by physician supervised CR programs designed to improve patient safety.[3] Close monitoring for signs and symptoms of ischemia and left ventricular dysfunction is an essential and critical benefit of CR for Medicare beneficiaries and the immediate availability of a physician allows for rapid decision-making to minimize progressive complications. In addition, patients in CR programs are provided with intensive education and medical interventions known to reduce the risk of future coronary events. Besides supervised exercise training, programs for smoking cessation, management of lipid disorders, diabetes, hypertension, and overweight, and stress management are also available in most facilities.[3,34]

Since the AHCPR[31] guidelines were published 10 years ago, clinical practice has shifted from revascularization through CABG to revascularization by multiple percutaneous interventions, but the underlying disease process remains the same. Medicare patients undergoing percutaneous intervention thus have the same needs for improvement in exercise capacity, reduction in coronary risk factors, and education and derive the same benefits from CR participation as patients undergoing surgical revascularization.

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F. Post heart or heart-lung transplant

While human-to-human (homologous) heart transplantation was first attempted in 1967, the frequency and success of this procedure did not increase substantially until the mid-1980s, largely due to the discovery of improved immuno-suppressant medications. The frequency of heart transplantation has leveled off and has remained stable over the past decade with 2,500 operations performed annually in the United States.[5] This plateau is purely due to a lack of available donors, since the prevalence of those requiring heart transplantation, primarily due to heart failure, continues to rise. The one, five and ten year survival rates after heart transplantation are reasonably high (80%, 68%, and 48%, respectively),[4] particularly when compared to the average annual mortality of 30-50% commonly reported for class IV heart failure patients. Nevertheless, patients who undergo heart transplantation face a myriad of medical problems associated with persistent heart failure pathophysiology, deconditioning due to convalescence before and after surgery, side effects of immunosuppressive medications (muscle and bone loss, fat gain, infections, etc.), and risk of organ rejection.

Several studies have examined the acute exercise response of patients following heart transplant and found that endurance exercise capacity, i.e., peak MET level or peak oxygen uptake, is reduced by 40-50% compared to age-matched, healthy control subjects.[2,6,7,9,10] The hemodynamic responses (heart rate, blood pressure, cardiac output) to exercise are also impaired due cardiac denervation and medications.[2,6,7,9,10] Furthermore, the ventilatory response to exercise is excessive and inefficient compared to normal individuals and appears to be due to persistent heart failure pathophysiology and diaphragm muscle fatigue.[3] Bone mass and density are significantly reduced as well, compared to healthy subjects.[8]

Since the early 1980s, a number of well-designed studies[3,6-10] have demonstrated that exercise training has the potential to reverse or diminish many of the physiologic abnormalities observed in heart transplant patients. Most exercise training studies have been modeled after supervised CR programs where exercise is conducted 3-4 times per week for 12-16 weeks at "moderate" intensity levels. In these programs, endurance capacity (peak MET level or peak oxygen uptake) improves by approximately 20-50 % due to improved peripheral adaptations (muscle and vascular changes leading to increased oxygen extraction) and central hemodynamics including an increase in heart rate and cardiac output.[6-10] Ventilatory responses to exercise improve, i.e., more efficient ventilation.[6,7] Lean body mass increases (increased bone mineral density and muscle mass) while fat mass decreases.[1,6]

Two studies warrant closer attention as they clearly demonstrate the importance of a structured exercise program (both endurance and resistance type) in heart transplant patients. Kobashigawa et al.[8] completed the first randomized trial of 27 heart transplant patients to either a medically supervised CR program or an unstructured home exercise program. The length of the trial was six months and included endurance exercise and musculoskeletal strengthening for both groups. The group that participated in medically supervised CR increased peak oxygen uptake by 49% versus 18 % for the home exercise group. The CR group also had a significantly greater increase in peak exercise workload and reduction in ventilatory response. Furthermore, the mean dose of prednisone, number of patients taking hypertensive medications, the average number of rejection or infection episodes, and weight gain, did not differ between the groups.

Second, the report of Braith[1] is also very relevant since this investigation utilized strength training as the primary modality of training. Transplant patients that completed six months of resistance exercise training were able to return their bone mineral density level toward pre-transplant levels, while non-exercising patients had a decrease of 6%. This study eloquently showed that resistance exercise training is essential for preventing/ reversing the glucocorticoid-induced bone loss.

CR after cardiac transplant improves measures of exercise tolerance, cardiopulmonary responses to exercise, and body composition (fat, muscle, and bone), with data demonstrating that these improvements are best attained in a supervised CR program.[8]

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G. Congestive heart failure

Randomized, single-site clinical trials conducted over the last 15 years demonstrate that CR that includes prescribed exercise training favorably improves exercise tolerance, disease-related symptoms, and quality of life. Preliminary data also suggest that clinical outcomes may be favorably influenced as well.

As of 2005, over two dozen controlled trials had assessed the effects of exercise training in patients with heart failure, the vast majority of which included subjects ≥65 years of age.[1,3-5,7,10,12-15,17,19,21,22] Each trial showed that prescribed exercise contributed to a reduction of the fatigue- and dyspnea-limiting exercise intolerance that is common in these patients. Using peak oxygen uptake to measure exercise capacity, the magnitude of the reported improvement ranged from 15%-30%. Such improvement is greater than or equal to the gains in exercise capacity observed in most clinical device and drug trials.

The mechanisms responsible for the improved exercise performance are both central and peripheral adaptations. Central factors include exercise training-induced increases in peak cardiac output, heart rate, and stroke volume. Adaptations in peripheral function are demonstrated by improved flow mediated vasodilatation in metabolically active muscles and increased cellular oxidative capacity within the skeletal muscles.

Evidence to date suggests that exercise training does not worsen heart function or increase left ventricular chamber size in patients with heart failure.[1,9,21] On the contrary, a 1997 trial showed that regular exercise training resulted in a small but significant improvement in left ventricular ejection fraction (34% to 38%).[9] More recently, Giannuzzi et al.[10] showed that not only is ejection fraction improved, but reverse re-modeling occurred as well, as evidenced by a 5% decrease in end-diastolic volume. Trials of exercise training in heart failure were generally 8-24 weeks in duration and were *conducted in a physician-supervised CR setting*. Data derived from these trials indicate that regular exercise partly reverses the exercise intolerance that plagues patients with heart failure and that this exercise training can be done safely in a CR setting without adversely impacting left ventricular function.

Numerous randomized or randomized crossover trials have also assessed quality of life after exercise training in patients with heart failure.[1] Using both general and disease-specific instruments, improvements in shortness of breath, ability to perform activities of daily living, anxiety, depression, and general well-being were measured. The magnitude of the improvement in each variable ranged between 15% and 50%.[5,7,10,16] Again, these gains match or exceeded benefits reported in many drug trials.

The European Heart Failure Training Group reported the combined results of randomized clinical trials completed at seven separate centers involving 134 stable patients with heart failure.[7] They observed no adverse exercise training-related side effects. However, it is important to point out that, similar to patients with coronary artery disease, patients with heart failure who exercise can experience complications during training. This is not surprising given their pre-existing left ventricular dysfunction, abnormal neurohumoral regulation, and an over-active sympathetic system, which can predispose them to significant arrhythmias, abnormal hemodynamic response to exercise and abnormal fluid status regulation. Consistent with this, the heart failure exercise trials reported to date required physician involvement to help monitor, evaluate, and care for patient-related complications.

In 1999, a single site trial involving 99 patients evaluated hospital re-admission and subsequent cardiac mortality and showed a 67% decrease (relative risk = 0.33) in risk for cardiac events with exercise training,[5] whereas a trial reported in 2002 showed no exercise training-related effect on clinical outcomes.[22] A 1999 meta-analysis involving single site training experiences showed a significant reduction in total mortality or combined mortality or hospitalization (hazard ratio = 0.72), respectively.[8] These findings, although preliminary, are consistent with observed exercise training-induced changes in the pathophysiology of heart failure. Specifically, exercise training down-regulates sympathetic nervous system activity and plasma and tissue cytokine concentrations, all of which are typically increased and associated with a poorer prognosis and worsening disease in patients with heart failure.[2,6,11,18,23]

As the trials to date have been small and the benefit/risk ratio of cardiac rehabilitation in patients with heart failure remain unclear, an NIH-funded multi-site, randomized clinical trial is now underway to evaluate the impact of exercise training on morbidity and mortality in patients with heart failure and will also assess a large number of secondary endpoints including exercise safety, impact on exercise capacity and quality of life, and cost-effectiveness. Called HF-ACTION (Heart Failure – A Controlled Trial Investigating Outcomes of Exercise TraiNing), this trial is due to report its findings in 2008.

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Question 2:
What is the appropriate level of physician supervision for cardiac rehabilitation services?

Current Medicare coverage requirements for cardiac rehabilitation (Coverage Issues Manual 35.25) state, *"Services of nonphysician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible."* This coverage manual requirement contradicts other current Medicare requirements regarding physician supervision, particularly the Medicare Intermediary Manual at 3112.4 A which state, "*The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises…"*

A review of reports by the Office of the Inspector General (OIG) during its audits of hospitals in 2003-2004 clearly highlights the confusion that arises from these contradictory CMS requirements. OIG auditors came to different conclusions about virtually identical programs and whether the physician supervision of those programs was adequate. Additionally, in response to the diverse individual OIG reports, a growing number of Medicare contractors have tightened their own policies regarding cardiac rehabilitation, requiring physician presence at all times that services are provided to Medicare beneficiaries. Some contractors have also made a determination that only hospital-based physicians can meet the "incident to" requirements – a policy that is not supported by any existing Medicare policy and is contrary to some state laws that preclude physician employment by hospitals.

We agree with Medicare policy that states, *"The physician supervision requirement is generally assumed to be met when the services are performed on the hospital premises."* When cardiac rehabilitation is provided in a physician office or in a free-standing facility such as a comprehensive outpatient rehabilitation facility, it is reasonable to require that a physician be immediately available during the hours of operation of the Phase II cardiac rehabilitation program.

It is important to note that there is no clinical logic to maintaining a requirement unique to cardiac rehabilitation for such physician presence in the hospital area where stable, monitored outpatients are participating in cardiac rehabilitation. **Hence, for a hospital-based program, because there is no clinical basis for Medicare's current requirement that a physician be in the proximate area of the exercise room, we urge the removal of this requirement from current policy.**

Thus, we propose another, more clinically appropriate approach to physician supervision of cardiac rehabilitation services. We recommend that a Phase II cardiac rehabilitation program, have two levels of physician involvement and supervision – program medical direction and emergency supervision/consultation.

This approach supports the provision of safe and effective patient care by both assuring appropriate program management and the adherence to sound clinical practices.

Although Medicare does not currently require a cardiac rehabilitation program to have a "medical director," formal establishment of such a role would help to ensure high quality care and the organized and effective delivery of cardiac rehabilitation services. The physician medical director is responsible for ensuring that the program meets established standards of care. This physician would function not only as an administrator but also as a clinician, educator, consultant, and, most importantly, as a liaison with the medical community and the facility's administration. Specifically, it is the physician medical director whose responsibility it would be to ensure that each patient has a plan of care, including an exercise prescription that is individualized and medically appropriate, and that information concerning the patient's clinical status and progress is communicated to the referring physician. There should not be a requirement, however, that this physician be physically present during all hours of operation of the program.

While it would be ideal for this physician to have extensive experience in cardiology and cardiac rehabilitation programs, we recognize that a mandate for such a qualification would impose a burden on some programs, most notably those located in rural areas of the United States. Likewise, it would be reasonable to expect some hospitals to contract with a physician practice to provide "medical direction" on an ongoing basis, with a specific physician identified as the "medical director" for a specified time. There are a number of professional organizations that support ongoing education and training for physicians in cardiac rehabilitation. These include the American College of Cardiology, the American Association of Cardiovascular and Pulmonary Rehabilitation, the American College of Sports Medicine and the American Heart Association.

The second level of physician supervision that should be provided is emergency supervision/consultation. The program's medical director or his/her designee could provide this level of supervision. In fact, one of the physician medical director's responsibilities would be to ensure that at all times the program is operating, one or more physicians are immediately available in the event of an emergency and, when necessary, available to the cardiac rehabilitation staff for necessary consultation. CMS should allow the emergency supervision to be provided in the same way in which hospitals provide medical support for emergencies for other services, for instance, by relying on the hospital's emergency department medical staff, through the hospital's regular "code" team, or through another approach that assures the immediate availability of a physician in the event of a patient emergency.

Question 3:
To which physician (referring or hospital clinic) should the cardiac rehabilitation services be "incident to"?

Both the Medicare Hospital Manual and the Intermediary Manual attempt to define "incident to" services. For example, the Intermediary Manual states, "*To be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a non-physician need also be the occasion of the actual rendition of a personal professional service by the physician. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.*

Using this regulatory definition of "incident to" services, there are actually three appropriate options for determining the physician to whom the services are "incident to." During the course of cardiac rehabilitation treatment, this physician would be responsible for assessing the course of treatment and the patient's progress and, where necessary, changing the treatment regimen. It also is appropriate for the designated "incident to" physician to change through the course of cardiac rehabilitation treatment, as long as such a change is noted in the patient's medical record (see below).

a. A beneficiary may choose to see his/her own **primary care physician.** . <u>Medicare should not preclude a beneficiary's right to see a physician of his/her choice.</u>

b. A beneficiary may choose to see his/her **referring physician.** We believe that this is the most common scenario in cardiac rehabilitation, with the patient returning to his/her cardiologist for these services.

c. A beneficiary may choose to see the **rehabilitation program's medical director or program-affiliated physician.** This scenario is often the easiest for the hospital-based program.

Under each of these options, it is imperative that the beneficiary be informed at the beginning of cardiac rehabilitation treatment that he/she will need to see a physician during the course of treatment in order to assess patient progress and, when necessary, modify the plan of care.

In addition, a critical aspect of validating that cardiac rehabilitation is "incident to" a physician' service is through documentation within the cardiac rehabilitation program's medical records. In each option above, there should be specific documentation in the cardiac rehabilitation program's medical record indicating that a physician (or physicians) did personally see the patient in order to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. It is reasonable to expect the cardiac rehabilitation program to establish processes and policies to validate that each patient has at least one encounter with his/her designated "incident to" physician.

Question 4:
What are the individual components that comprise a cardiac rehabilitation program?

Cardiac rehabilitation is an essential component of the comprehensive care of patients with cardiovascular disease. Consensus statements from the American Heart Association (AHA),[5,11] the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR),[1] and the Agency for Health Care Policy and Research[18] conclude that cardiac rehabilitation should include a multidisciplinary approach to overall cardiovascular disease risk reduction. Although the core therapeutic modality is monitored and supervised exercise training, cardiac rehabilitation programs should contain specific components aimed at optimizing cardiovascular risk reduction, fostering healthy behaviors, and improving functional capacity and quality of life in patients with heart disease.[6]

The components necessary for a comprehensive cardiac rehabilitation program have been delineated by the AHA and AACVPR[6] (Table 1) and emphasize the processes of evaluation, interventions, and expected outcomes. Inherent in these recommended components is the understanding that successful risk factor modification and the maintenance of a physically active lifestyle is a lifelong process. It is essential to the success of any program that each of these interventions is provided in concert with the patient's primary care provider and/or cardiologist, along with other specialists and appropriate healthcare professionals who will subsequently supervise and refine these interventions over the long term. Presently, these core components form the basis of a national program certification process established by the AACVPR.[2] Comprehensive and detailed guidelines regarding cardiac rehabilitation programs have been published by AACVPR[1] and endorsed by the American Heart Association. Detailed guidelines for specific risk factor modification are also available.[3,4,7-10,12-15,17] Outcome assessment to track individual patient progress and to monitor program effectiveness is outlined in an AACVPR consensus statement.[14]

Table 1.
Individual Components Comprising A Cardiac Rehabilitation Program

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- Patient Assessment
- Exercise Training
- Education/Counseling
    - Physical Activity Counseling
    - Nutritional counseling
    - Lipid Management
    - Blood Pressure Management
    - Smoking Cessation
    - Weight Management
    - Diabetes Management
    - Psychosocial Management

Individual Components Comprising a Cardiac Rehabilitation Program

Patient Assessment [1,14,16]

Evaluation. Upon physician referral, a medical history, physical examination, and appropriate testing will be performed. The history, physical examination, and testing may be performed by the primary care physician, the referring physician, or the cardiac rehabilitation program Medical Director or designated program-affiliated physician. The medical history will include a review of current and prior cardiovascular medical and surgical diagnoses and procedures (including assessment of left ventricular function, measures of myocardial ischemia and coronary anatomy); co-morbidities; symptoms of cardiovascular disease; medications; and cardiovascular risk profile. The physical examination will assess cardiopulmonary systems; post-cardiovascular procedure wound sites; and any pertinent orthopedic and neuromuscular abnormalities.
Interventions/Goals. Based upon documented assessment information, an initial treatment plan prioritizing goals and details of interventions will be developed and implemented. Similarly, a plan for long-term secondary prevention and improvement in quality of life, will be developed with the patient.

Exercise Training[1,3,10,13,17]

Evaluation. An assessment of exercise capacity is strongly recommended prior to participation in an exercise-based cardiac rehabilitation program, and should be repeated as changes in clinical condition warrant. Depending on functional and clinical status, this evaluation may include maximal stress testing (with or without assessment for myocardial ischemia) or an assessment of sub-maximal function such as a six minute walk or a sub-maximal exercise test.
Interventions/Goals. Based on patient assessment, individual goals, and the exercise test, if performed, an individualized exercise prescription will be developed for aerobic and resistance training. [1,3] Individualized exercise prescription will define the frequency, intensity, and modality to achieve aerobic, muscular, flexibility, and energy expenditure goals. Patients will participate in supervised, ECG monitored, exercise training sessions. Periodic updates to the exercise prescription should be provided and modified if the clinical status changes.

Education/Counseling

Physical Activity Counseling[1,17]
Evaluation. Patients should be assessed for current physical activity level and domestic, occupational, and recreational needs. Readiness to change should be evaluated along with level of self-confidence, barriers to increasing physical activity, and social support.
Interventions/Goals. Advice, support, and counseling will be provided regarding physical activity needs at initial evaluation and follow-up, based on national standards and guidelines for physical activity [3]. Individual patient needs should be met, but all patients should be encouraged to achieve the optimal level of physical activity allowed by the limits of their underlying disease.

Nutritional Counseling[12]
Evaluation. Current dietary behavior should be assessed including dietary content of fat, cholesterol, sodium, caloric intake, eating and drinking habits.
Interventions/Goals. An individualized prescribed diet should be provided, based on initial needs assessment and patient's previous success adhering to therapeutic diets. Group or individual education sessions should be provided if needed, including family members when appropriate. Referral to a registered dietician or appropriately trained health professional can be made for patients who are unable to reach goals without additional assistance.

Lipid Management[9,12]
Evaluation. Fasting values of total cholesterol, high density lipoprotein-cholesterol (HDL-C), low density lipoprotein-cholesterol (LDL-C), and triglycerides will be documented along with assessment of any current treatment and compliance. Evaluation and subsequent intervention can be done by the primary or referring physician or as a consultation service by the program Medical Director or program affiliated physician.
Interventions/Goals. Nutritional counseling should be provided as needed in all patients. Drug therapy should follow recognized clinical practice standards and should be managed by one of the physicians listed above. Emphasis should be placed on non-pharmacological interventions to increase HDL-C including exercise, and smoking cessation, with drug therapy based on National Cholesterol Education Program (NCEP) guidelines. Interventions to reduce triglycerides include exercise, nutritional counseling and weight management, with drug therapy as needed based on NCEP guidelines.

Blood Pressure Management[15]
Evaluation. Blood pressure will be assessed at program entry and after initiation or adjustments of antihypertensive drug therapy. Compliance with the therapeutic regimen should be determined and reinforced. Blood pressure should be checked periodically during exercise training sessions.
Interventions/Goals. Cardiac rehabilitation sessions provide an ideal opportunity to assess patients for suboptimal blood pressure control both at rest and during exercise, and to communicate this information to the physician managing the pharmacological regimen. National standards derived from evidence based medicine for management of blood pressure control should be followed. Assessment of patient compliance with the medication regimen and lifestyle modification should be done until BP target goals are reached.

Smoking Cessation[8]
Evaluation. Inquiries should be made regarding smoking status, amount and years of cigarette smoking or use of other tobacco products, and exposure to second-hand smoke. Readiness to change should be determined and the patient should be assessed for psychosocial factors that may impede success. Status should be updated at each visit during first 2 weeks of cessation and periodically thereafter.
Interventions/Goals. A patient who smokes should be educated about adverse effects of tobacco use on cardiovascular health, referred back to the managing physician for pharmacological intervention, and/or referred to a smoking cessation program, if available, with adherence monitored and reinforced.

Weight Management[7]
Evaluation. Weight, height, and body mass index will be determined at program entry and periodically throughout the program.
Interventions/Goals. If weight risk is identified, short-term and long-term goals will be established for each patient for weight loss. In conjunction with prescribed exercise, a diet will be suggested to reduce total caloric intake and maintain appropriate intake of nutrients and fiber. Referral for more intensive dietary intervention may be needed, depending on clinical status and initial results. Long-term adherence to diet and exercise programming aimed toward attainment and maintenance of established weight goal will be encouraged.

Diabetes Management[4]
Evaluation. Presence or absence of diabetes will be confirmed for all patients. If the patient has been diagnosed with diabetes, a history of complications including vascular disease, problems with eyes, kidneys, or feet; or autonomic or peripheral neuropathy will be documented. Patients will be assessed for a history of episodes of hypoglycemia or hyperglycemia and for symptoms/signs of vascular, ophthalmologic or neurologic disease that may complicate exercise programming. The physician managing the patient's diabetic condition will be identified. Previous diabetes education and medical nutrition therapy should be assessed to identify further patient needs in self-care.
Interventions/Goals. Reinforcement regarding self-monitoring skills will be provided. A glucometer should be available to monitor pre- and post-exercise finger blood glucose when indicated, based on clinical practice guidelines. Suboptimal glycemic control will be communicated to the treating physician. When appropriate, referral should be made to a registered dietitian for medical nutrition therapy or to a certified diabetic educator for skill training, medication instruction, and support.

Psychosocial Management[1,16,18]
Evaluation. Using interview and/or standardized measurement tools, psychological distress (eg. depression, anxiety, sexual adjustment issues, etc) and social functioning (eg. social isolation) should be assessed. Community resources to enhance the patient's and family's level of social support should be identified.
Interventions/Goals. When psychological distress is identified, this should be communicated to the patient's physician and, when medically appropriate, patients should be referred to mental health specialists for further evaluation and treatment. Group education and counseling regarding adjustment to heart disease, stress management, and health related lifestyle change can be offered by the cardiac rehabilitation facility. Family members, domestic partners and/or significant others may be included in these sessions.

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Question 5:
What is the appropriate number of cardiac rehabilitation sessions needed to achieve a net health benefit?

The majority of the scientific literature demonstrating the effectiveness of cardiac rehabilitation has been based upon the 36-session Medicare model where services are concentrated over a 12-week period of time. The duration of cardiac rehabilitation programming in Canada is more flexible, allowing studies to explore the optimal duration of programming. Reid et al. randomly assigned patients to either standard (33 sessions for 3 months) or distributed cardiac rehabilitation (33 sessions for 12 months) and found that both program formats showed improvements over time in cardiorespiratory fitness, daily physical activity, low-density lipoprotein cholesterol, generic and heart disease quality of life and depression symptoms.[4] Hamm et al. found that the greatest percentage of patients (30%) achieved their highest exercise capacity at 38 weeks of outpatient cardiac rehabilitation and, in addition, 80% of the patients achieved their peak exercise capacity after 12 weeks (at 26, 38, or 52 weeks) of rehabilitation.[2] Morrin et al. also demonstrated that significant improvements in health related quality of life outcomes can require longer than the traditional 12-week intervention model.[3] Thus, there is growing evidence that spreading sessions out over a longer timeframe can be equally beneficial and may even enhance effectiveness for some clinical parameters.

These studies support the AHCPR recommendation that cardiac rehabilitation programs provide the most consistent benefit "with exercise training at least three times per week for 12 or more weeks' duration."[1] Because an individual patient's progression toward desired health outcomes is variable, we recommend that CMS clarify that the 36 monitored supervised sessions are not limited to a 12 week time frame, but should be individualized for each patient, with the duration of programming up to a maximum of 52 weeks.

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