HELEN HAYES
HOSPITAL

Helen Hayes Hospital, Route 9W, West Haverstraw, NY 10993
Ph: (845) 786-4000 TT: (845) 947-3187

Val S. Gray, Chief Executive Officer

State of New York, Department of Health
Richard F. Daines, M.D., Commissioner

January 28, 2009

Julie M. Stankivic
Health Insurance Specialist
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C5-06-27
Baltimore, Maryland 21244

Dear Ms. Stankivic:

We are submitting comments related to Medicare Classification Criteria for Inpatient Rehabilitation Facilities, specifically related to *whether IRF care is appropriate for certain other types of conditions which are commonly treated in IRFs, but are outside of the 13 conditions specified in the 75% rule.* Please forward these to RTI International to examine as they prepare their report for Congress. Please also consider reporting these at the Town Hall Meeting on February 2, 2009.

Overview:
Helen Hayes Hospital is one of the country's first rehabilitation facilities and is widely recognized as a leader in rehabilitation medicine and research. For over 100 years, we have helped restore function to individuals with catastrophic injuries and chronic disabling illnesses, enabling them to move on to active, productive, independent and fulfilling lives. As part of this mission, we have active and exemplary inpatient cardiac and pulmonary rehabilitation programs. However, it has been a challenge to deliver comprehensive IRF services to this population as a result of the 75/25 rule. Therefore, we appreciate the opportunity to participate in this Town Hall Meeting process and are submitting comments related to the benefits of acute inpatient rehabilitation for patients with cardiac and pulmonary disease. Based on both evidence in the literature and experience at our institution over the past 20 years, we strongly believe that rehabilitation in an IRF is appropriate for patients with significant decline in functional capacity following open heart or major thoracic surgery or after a complicated course related to a recent cardiac or pulmonary event.

Cardiac Patients:
Since the 75/25 rule was established, published data from the Society of Thoracic Surgeons (STS) national database indicate a gradual increase in the mean age of patients undergoing open heart surgery.[1] For example, between 2000 and 2002, 22% of patients undergoing coronary artery bypass surgery (CABG) were age >75 years,[2] and between 1997 and 2000, 9% of patients in the STS database were age 80 to 89 years.[3] Elderly patients undergoing open heart surgery are more likely to be female; to have diabetes, hypertension, renal failure, prior stroke, peripheral arterial disease, or prior open heart surgery; and to require urgent or emergent surgery. Post-operatively, they are more likely to develop renal failure or prolonged ventilation.[3]

Frequent and specialized medical and nursing management is crucial during the recovery period for these patients and includes:

- Fluid status management to avoid recurrent renal failure and/or congestive heart failure. This requires daily weights, examinations, and frequent serum chemistries.
- Patient education addressing long term self-care regarding the warning signs and symptoms of congestive heart. In our facility we have found that this is best performed by skilled rehabilitation nurses.
- Finger-stick glucose and blood pressure monitoring, medications adjustment to ensure target levels are reached prior to discharge, and nurses and nutritionists to work with patients to optimize their self-management skills.
- EKG telemetry monitoring as recurrent atrial arrhythmias are common in elderly patients after discharge from acute care.
- Medication education including anticoagulation regulation, with our case manager assuring that appropriate follow-up blood testing is arranged at discharge.

This collaborative specialized medical and nursing expertise and equipment is not available in sub-acute rehabilitation or skilled nursing facilities.

Elderly patients, particularly females, often live alone. Prior to surgery, many of these individuals already have poor physical function related to co-morbidities or progressive heart disease, and surgery further decreases that function. Intensive physical and occupational therapy in IRFs improve functional capacity by increasing endurance, strength, and balance, translating to improved gait and independence in self care and light home and food management activities. Although surgical and intra-operative monitoring techniques are improving, many elderly patients have post-operative cognitive deficits, requiring the intensive cognitive evaluation and treatment skills available in IRFs. Interdisciplinary team rounds, led by a physician and involving all disciplines, including case management, are needed to assure safe discharge planning and that therapy and medical needs are met in an efficient, yet individualized, way for these elderly patients. Finally, depression and anxiety are common in cardiac and post-operative patients, requiring availability of mental health professionals such as psychologists and psychiatrists. This constellation of skilled professionals is only found in IRFs.

Most of the issues related to functional independence and medical management mentioned above also pertain to elderly patients who have had a complicated acute care admission for a medical cardiac event, with subsequent significant medical deconditioning, unsteady gait and dependence

in self care. Those patients with pre-existing disabilities such as stroke, polio, Parkinson's disease, amputation, or other neurological or musculoskeletal disorders also require specialized medical, nursing, and therapy care as they recover from their cardiac event. These individuals will also benefit from admission to IRFs prior to return to home.

Outcomes studies of acute inpatient rehabilitation for elderly patients with heart disease are sparse, but Audelin et al have summarized the existing literature.[4] Functional Independence Measure (FIM) scores increase significantly from admission to discharge, as do Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) scores. Of note, these improvements persist at 3-month and 1 year follow-up.

Data from our institution are consistent with these findings. During the years 2004-2008, average length of stay ranged from 10 to 12 days and average FIM score increased by 2.4 per day. Functional independence persisted at 3 months post discharge. Between 80 and 85% of our patients were discharged to home (rather than to acute care or a skilled nursing facility) and 94-98% of those patients remained at home at 3 months. Although no randomized controlled studies comparing IRF and alternative discharge destinations for elderly post open heart surgery patients has been published, these statistics are most likely more favorable than those from sub-acute rehabilitation facilities, where length of stay is closer to 4 weeks and readmission to acute care for medical management is common.

Pulmonary Patients:

Inpatient rehabilitation for pulmonary patients in an IRF typically includes medical and nursing management to optimize pulmonary medications, including inhaled bronchodilators, steroids, diuretics, and oxygen. Many of these patients have co-morbidities that require special attention, including steroid-induced diabetes, steroid myopathy, cardiovascular disease, or atrial arrhythmias. Therapy modalities include endurance and strengthening activities, breathing retraining techniques, stress management, balance and gait retraining, ADL and home and food management training. Exercise oximetry monitoring is used to optimize supplemental oxygen, and multidisciplinary team rounds, led by a physician, addresses patient specific goals and discharge planning issues. Mental health care specialists are a valuable part of the team and work with patients to address family issues as well as the depression and anxiety that frequently accompany chronic lung disease.

Short-stay comprehensive inpatient pulmonary rehabilitation has been shown to be effective for patients with chronic obstructive pulmonary disease (COPD) since the mid 1990's. Votto et al evaluated 38 patients with advanced COPD referred to inpatient pulmonary rehabilitation at their institution in 1994.[5] All patients were discharged to home after a mean length of stay of 9.9 days, increasing their 12-minute walk distance by 66% and significantly improving their dyspnea, functional activity, and psychosocial scores. This group also showed that these benefits are sustained at 1 year.[6] Stewart et al summarized six studies from 1994-98 and reported results from 157 patients with moderate to severe COPD admitted to an IRF over a 3 year-period.[7] Average length of stay was 21 days and significant improvements were noted in ambulation distance, quality of life and oxygen use. In addition, these patients spent less time in the hospital during

the 12 months after program completion compared with the 12 months before admission. Inpatient pulmonary rehabilitation has also been shown to improve psychological outlook and to decrease anxiety and depression,[8] even without addition of antidepressant medications.[9]

Similar results have been found in studies done outside the United States that evaluate short stay multidisciplinary inpatient pulmonary rehabilitation, similar to the IRF model. Baltzan et al demonstrated significant improvements in 6-minute walk test distance, number of stairs completed in 2 minutes, Borg dyspnea scores after exertion, and objective functional scores, including in octogenarians.[10] In Japan, Katsura et al showed that a 2-week inpatient pulmonary rehabilitation program improved quality of life, dyspnea, and exercise capacity and that these changes persisted over 12-months, especially in patients age 75 or older. Inpatient pulmonary rehabilitation studies in France and Italy also showed improvements in quality of life, exercise endurance, and mental health.[11-13]

ERehab reports composite national weighted outcomes for pulmonary patients undergoing rehabilitation in an IRF. From 2005-2008, after an average length of stay of 16-17 days, 74-80% were discharged to home rather than to acute care or a SNF, with 61-69% remaining home at 3 months post discharge. Average FIM gain per day ranged from 1.6-1.9, with continued increase in motor FIM at 3 months post discharge.

Comparison of Outcomes for IRF versus SNF Environments:

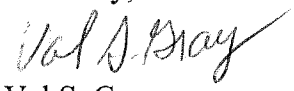
Unfortunately, there is no national registry that allows researchers or health policy specialists to evaluate inpatient rehabilitation for patients with heart or lung disease across different settings. For example, the discharge data point for the Society of Thoracic Surgery Registry does not differentiate discharge to an IRF versus to sub-acute rehabilitation, transitional unit or extended care. However, Vincent and colleagues recently published a preliminary comparison of functional and economic outcomes of cardiopulmonary patients in IRF versus SNF environments.[14] In this retrospective, study, participation in physical and occupational therapies were significantly different (72-78% in IRF and 48-51% in SNF), which translated to significant differences in all functional areas, including dressing and grooming, transfers, walking, problem solving, and comprehension. Although short term charges were higher in IRF versus SNF environments, more IRF patients than SNF patients were discharged to home (77.5% vs. 44.1%) and fewer IRF patients than SNF patients were discharged to acute care (15.8% vs. 23.2%) or expired (1.3% vs. 13.7%) during their stay. This study is consistent with clinical experience in our region.

Summary

Based on our facility's experience and the evidence outlined above, we emphatically believe that selected patients with cardiac and/or pulmonary disease are appropriate candidates for acute inpatient rehabilitation and should not be denied this opportunity based on the 75/25 rule. Those of us who work in the field observe, on a day-to-day basis, the impact of the 75/25 rule on our patients. Any criteria which limits access to inpatient rehabilitation for patients with cardiac and pulmonary diagnoses makes a profound and permanent impact on the health of these individuals.

Thank you for the opportunity to comment about this question. Please feel free to contact us if you have any questions about IRF care for patients with heart and/or lung disease.

Sincerely,



Val S. Gray
Chief Executive Officer

Nancy Ferrato, RN
Director, Utilization Management

John Pellicone, MD, FCCP, FACP
Medical Director

Marjorie King, MD, FACC, FAACVPR
Director, Cardiac Services

References

1. Haan CK, Chiong JR, Coombs LP et al. Comparison of Risk Profiles and Outcomes in Women Versus Men ≥ 75 Years of Age Undergoing Coronary Artery Bypass Grafting. Am J Cardiol 2003;91:1255-1258
2. Ferguson TB, Peterson ED, Coombs LP et al. Use of Continuous Quality Improvement to Increase Use of Process Measures in Patients Undergoing Coronary Artery Bypass Graft Surgery: A Randomized Controlled Trial. 2003 JAMA;290:49-56
3. Bridges CR, Edwards FH, Peterson ED et al. Cardiac Surgery in Nonagenarians and Centenarians. J Am Coll Surg 2003;197:347-357
4. Audelin MC, Savage PD, Ades PA. Exercise-based Cardiac Rehabilitation for Very Old Patients (≥75 Years) J Cardiopulmonary Rehabilitation and Prevention 2008;28:163-173
5. Votto J, Bowen J, Scalise P et al. Short-Stay Comprehensive Inpatient Pulmonary Rehabilitation for Advanced Chronic Obstructive Pulmonary Disease. Arch Phys Med Rehabil 1996;77:1115-1118
6. Bowen JB, Thrall RS, ZuWallack RL, Votto JJ. Long-term benefits of short-stay inpatient pulmonary rehabilitation in severe chronic obstructive pulmonary disease. Monaldi Arch Chest Dis 1999;54:189-192
7. Stewart DG, Drake DF, Robertson C et al. Benefits of an Inpatient Pulmonary Rehabilitation Program: A Prospective Analysis. Arch Phys Med Rehabil 2001;82:347-52.

8. Goldberg RT, Hillberg R, Reinecker L, Goldstein R. Evaluation of Patients with Severe Pulmonary Disease Before and After Pulmonary Rehabilitation. Disability and Rehabilitation 2004;26:641-648
9. Alexopoulous GS, Sirey JA, Raue PJ et al. Outcomes of Depressed Patients Undergoing Inpatient Rehabilitation. Am J Geriatr Psychiatry 2006;14:466-475
10. Baltzan MA, Kamel H, Alter A, et al. Pulmonary Rehabilitation Improves Functional Capacity in Patients 80 Years of Age or Older. Can Respir J 2004;11:407-413
11. Katsura H, Kanemaru A, Yamada K et al. Long-term Effectiveness of an Inpatient Pulmonary Rehabilitation Program for Elderly COPD Patients: Comparison between Young-Elderly and Old-Elderly Groups. Respirology 2004;9:230-6
12. Fuchs-Climent D, Gallais D, Varray A et al. Quality of Life and Exercise Tolerance in Chronic Obstructive Pulmonary Disease: Effects of a Short and Intensive Rehabilitation Program. Am J Phys Med Rehabil 1999;78:330-335
13. Garuti G, Cilione C, Del'Orso D et al. Impact of Comprehensive Pulmonary Rehabilitation on Anxiety and Depression in Hospitalized COPD Patients. Monaldi Arch Chest Dis. 2003;59:56-61
14. Vincent HK, Vincent KR. Functional and Economic Outcomes of Cardiopulmonary Patients. A Preliminary Comparison of the Inpatient Rehabilitation and Skilled Nursing Facility Environments. Am J Phys Med Rehabil 2008;87:371-380