

Multi-Center Study of Hospitalization for Heart Failure Using a Home Monitoring System in Managed Care and Hospital Facilities

EDWARD J. KRAMPER, M.D., A.B.F.P., and DANIEL L. COSENTINO, M.B.A.
Cardiocom, Minneapolis, Minnesota

ABSTRACT

Objective: To determine the hospital admission rate for heart failure within a large patient population using a home monitoring system in a group of managed care and hospital facilities.

Background: Hospital admission is a valuable measure of effectiveness when evaluating new management tools for heart failure. It reflects both the frequency of clinical decompensation and a major component of cost. Previous studies in small patient populations have provided evidence that heart failure disease management programs are effective in reducing hospital admissions and hospital stays.

Methods: This ongoing study reports data from a patient sample size ($N > 1,000$) from a diverse group of facilities using a new home monitoring system to obtain daily patient weight and symptom data for review and care plan adjustment for heart failure. The study group consisted of symptomatic heart failure patients from nine independent, managed care and hospital based facilities. This reporting period is for the 12 months beginning August 1, 2000 and ending July 31, 2001. Enrollment at this time in the study includes 1,026 patients for a total of 7,137 patient months.

Results: The mean hospital admission rate for heart failure per patient per year was found to be 0.234. The average length of stay for these admissions was 6.4 days.

Conclusion: New home monitoring technology offers patients and clinicians a cost-effective and efficient method to monitor large groups of heart failure patients. Using these devices in combination with close clinician management in diverse patient populations yields low heart failure hospital admission rates.

Heart failure (HF) is one of the predominant health problems in the United States today. There are approximately 5 million heart failure patients in the United States with an additional 450,000 new cases reported each year (1,12). Heart failure is the primary diagnosis in 872,000 hospitalizations and is the most common diagnosis in the Medicare population (2).

The direct cost of HF in the United States is \$19.6 billion per year (3). This represents the largest single current diagnosis related group (DRG) expenditure. The average cost per hospitalization is \$12,049 with an average stay of 9.1 days (4). It is a disease characterized by high hospital readmission rates. Data from several studies indicate that 30% to 50% of the patients hospitalized with heart failure will be readmitted within the following 3 to 6 month period (5,6).

Previous hospitalization for HF is the greatest predictor for subsequent HF admissions. Other important factors include smoking, weight, previous myocardial infarction, increasing age, gender, left ventricular wall motion score, use of digitalis or furosemide, diabetes mellitus, elevated systolic blood pressure, and increased blood urea nitrogen and serum sodium levels (7, 8).

Over the past decade, clinical studies have established that significant reductions (>50%) in hospitalizations and readmissions can be obtained with careful management of heart failure (5,9,10,11). A number of key warning signs occur before a patient becomes unstable and requires hospitalization. Management of HF is based on the titration of drugs, daily weight and symptom monitoring, dietary sodium restrictions and fluid intake in an outpatient setting.

There are a number of unique challenges in managing large groups of heart failure patients. These include:

- Determining which patients are in need of assistance.
- Obtaining accurate daily weights and symptoms from patients.
- Developing a central database to store, retrieve and maintain patient, lab and medication information.
- Hiring internal staff to monitor and manage a HF intervention program.
- Determining the return on investment for this type of outpatient program.

Over the past few years, a number of new home patient monitoring service groups have emerged. Most offer clinical monitoring to providers for their HF patients. Cardiocom® (Minneapolis, MN) offers equipment to a provider to monitor and manage their own patients. Each day, the patients' weight and symptom data is transmitted to a remote computer system that automatically identifies symptomatic patients and alerts clinicians for review and intervention as necessary.

This study investigated the effectiveness of the Cardiocom System in a large patient population within a group of managed care and hospital facilities to determine the rate of heart failure hospital admissions per patient per year.

METHODS

Patients

The study group consisted of patients from nine independent facilities. The facility types included three managed care and six hospital groups representing 64% and 36% of patients, respectively. The study period was for 12 months beginning August 1, 2000 and ending July 31, 2001.

Patient selection and enrollment was determined by the staff at each facility. In general, facilities selected the most symptomatic and costly patients first. Common enrollment and disenrollment criteria are listed below:

Enrollment

1. Inpatient admission or emergency room visit with HF as the primary diagnosis.
2. Left ventricular systolic dysfunction with an Ejection Fraction < 40%.
3. NYHA Class III - IV or rapidly deteriorating, unstable Class II.
4. Total liability for HF > \$10,000 in the past 12 months.
5. Physician referral.
6. On ACE inhibitor or documented intolerance.
7. Cognitively intact or available caregiver.
8. Reasonably adherent to medications and care plan.

Disenrollment

1. Transfer to a nursing home for long-term care.
2. Significant decrease in mental capacity and/or inability to comprehend the program.
3. Amputations that affect patient's ability to stand.
4. Significant improvement in the patient's condition whereby daily monitoring is no longer beneficial.
5. Patient expiration.
6. Patient choice.

Study device

Each patient was provided with a Telescale® home monitoring device, which was used to record the patient's daily weight and symptoms. Each facility was provided with a Cardiovisor® heart failure disease management hardware and software system to receive and analyze this data. All facilities participating in the study were current Cardiocom customers. No reimbursement or free product was provided to any of the study participants.

Cardiocom offers two monitoring options: a hardware/software system operated by facility staff, or an outsourced nursing service. All data in this study is based on the in-house program operated by staff clinicians at each facility.

The Telescale is an automated, precision, electronic scale, integrated with a simple visual and audio display to query the patient. The device is placed in the patient's home to measure their weight and to ask them a series of questions about their symptoms. Telescale is accurate to ±0.1 lb and has a maximum weight capacity of 500 lbs. Telescale's precise measurement provides early detection of as little as 45 cc's of fluid gain. Telescale provides instant feedback to patients about their current weight, variance from previous day's weight, and specified dry weight.

Cardiocom provides a Cardiovisor® custom-configured server at no additional charge as part of the program. The Cardiovisor server includes an 8-channel modem and CD-RW backup. Cardiocom is responsible for all hardware and software, and provides an all-inclusive warranty.

Daily symptom and weight reporting

Each day, the patient's weight and symptoms were measured at the patient's home and automatically transmitted to the monitoring facility in less than 20 seconds.

Symptoms

Each facility used a standard set of questions and scoring system provided by Cardiocom as shown in Figure 1. If the patient's total symptom score is ≥ 10, the patient is automatically flagged as an "Exception".

Symptom	Score
Dyspnea at rest	7
Cough	3
Pedal edema	5
Abdominal fullness	3
Chest pains	7
Decreased urine output	5
Fatigue	2
Hypotension	5
Medication compliance	7
Sodium intake	1
Fitness (Exercise)	1

Figure 1. List of symptoms and corresponding weighted scores. A patient score of ≥ 10 triggers an Exception.

Weight

Clinicians also set weight limits for each patient. If the patient weight exceeds the pre-set limit, the patient is automatically flagged as an Exception. Clinicians can also set minimum weight and trended weight parameters for each patient.

Reporting

Practitioners at each facility call Exception patients to verify reported data and gather additional information. If physician intervention is necessary, a detailed Exception report is sent to the physician's office. The physician then can determine the best course of treatment for their patient.

The Cardiovisor software program contains patient demographics, healthcare and emergency contacts, medications, labs, clinical notes, daily weights, and symptom data. Cardiovisor also includes individual and population reports and graphs for detailed analysis.

In addition to receiving the standard Exception reports, triggered only when the weights or symptoms fall outside predetermined parameters, practitioners may print symptom and weight updates on patients who are unstable, have recently been hospitalized, or are undergoing medication titration.

Study endpoints and data collection

The primary endpoint was the number of HF hospital admissions as a primary diagnosis and hospital days associated with those admissions. All patients were followed until disenrollment. Patient data was compiled from each facility's Cardiovisor database. Additional subjective data was collected from three facilities on patient acceptance of this program.

RESULTS

Base-line characteristics

The study started on August 1, 2000, with 257 patients and grew steadily over 12 months ending July 31, 2001, with 1,026 patients as shown in Figure 2. There were 7,137 cumulative patient months.

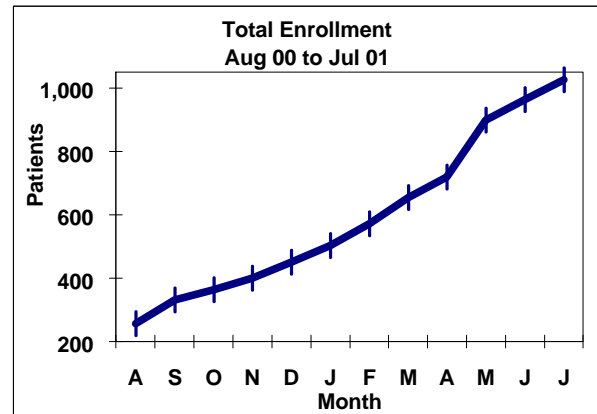


Figure 2. Total enrollment for all nine facilities. There were 257 patients at the beginning and 1,026 patients at the end of the study period.

There were three managed care and six hospital groups representing 64% and 36% of patients respectively. The largest group was a managed care organization with approximately 500 patients enrolled by the end of the study. The smallest managed care group had 26 patients. Data across the managed care groups is clearly biased by the large group with 3,861 patient months. Distribution of patient months for the three managed care groups is shown in Figure 3.

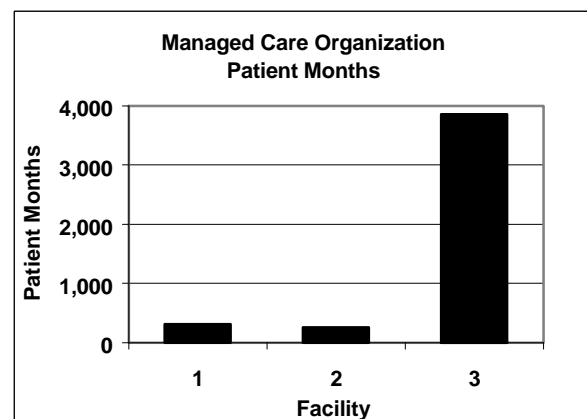


Figure 3. Distribution of patient months in three managed care organizations.

The distribution of patient months among the six hospital based facilities is shown in Figure 4. The largest hospital group had 120 patients enrolled at the end of the study period. The smallest group had 25 patients enrolled at the end of the study. Patient months ranged from a high of 866 to a low of 143.

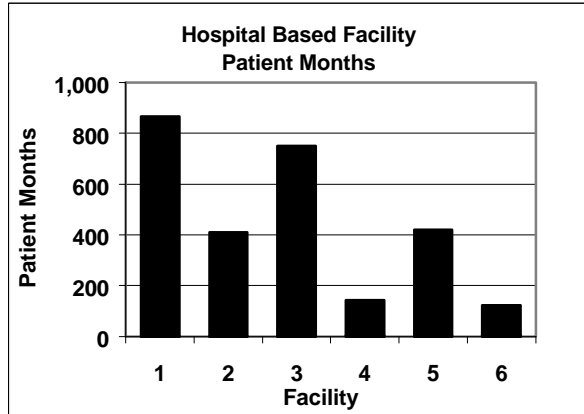


Figure 4. Distribution of patient months in six hospital facilities.

HF hospital admissions

There were 139 admissions for HF as a primary diagnosis during the study period. Hospital admission by month for all groups are shown in Figure 5. Admissions increased approximately in proportion to the increase in enrollment over the period.

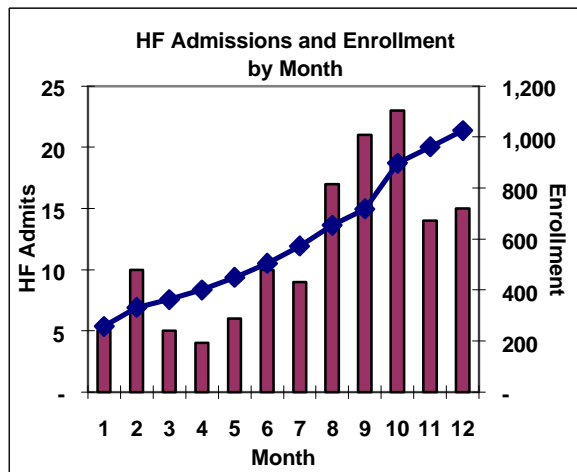


Figure 5. HF admissions and enrollment by month.

HF admissions normalized for patient enrollment are shown in Figure 6. **The mean HF admission per enrolled patient per month is 0.0195. On a yearly basis this is 0.234 HF admissions per enrolled patient per year.** Admissions ranged from 0.010 to 0.030 for all groups.

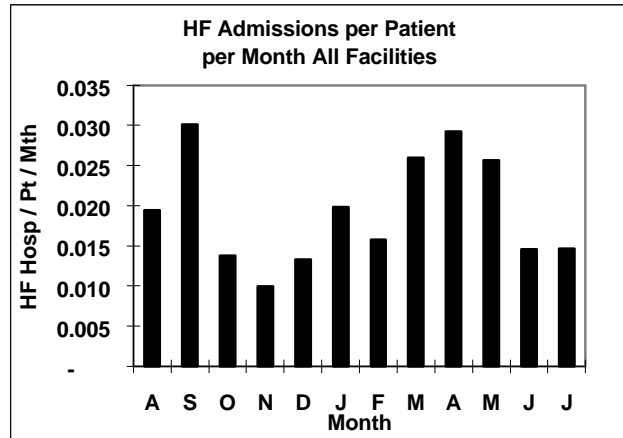


Figure 6. HF Admissions per Patient per Month for All Facilities.

Hospital admissions per enrolled patient per year for managed care organizations are shown in Figure 7. Facility 3 with approximately 500 enrolled patients had the largest number of admissions per patient per year. The range was 0.038 to 0.236.

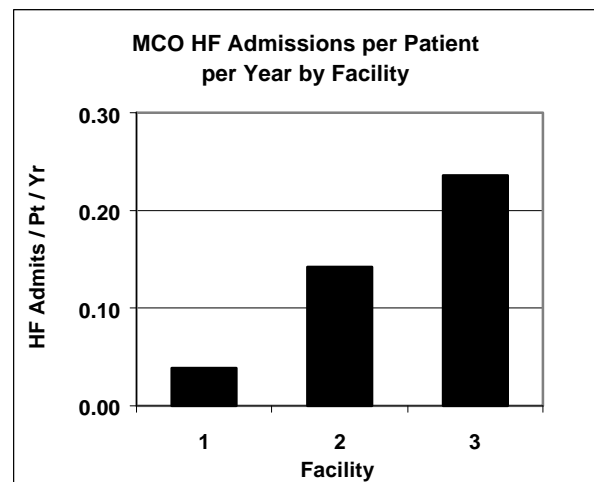


Figure 7. Managed Care Organization HF Admissions per Patient per Year by Facility.

HF Hospital admissions per enrolled patient per year for hospital groups are shown in Figure 8. The range was 0.084 to 0.401.

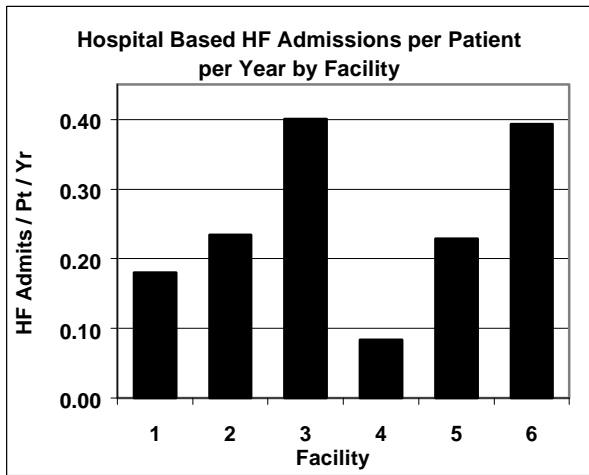


Figure 8. Hospital based HF Admissions per patient per year by facility.

Length of Stay

Length of stay for HF admissions was compiled for all groups. The average length of stay for each facility is shown in Figure 9. The range was 1.7 to 7.6 days. The mean value for all groups was 6.4 days.

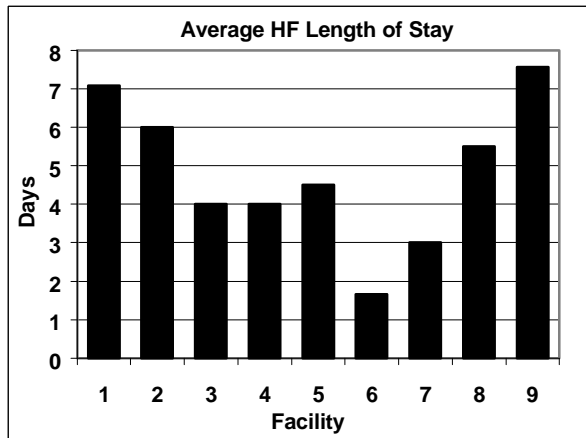


Figure 9. Average HF Length of Stay.

Length of stay for the three managed care organizations is shown in Figure 10. The range was 3.0 to 7.6 days. The mean value was 4.1 days.

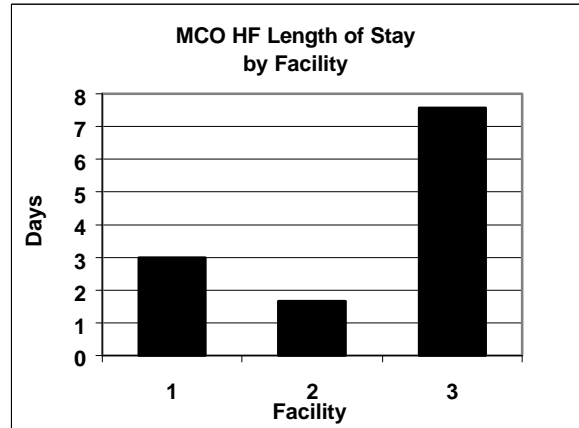


Figure 10. Managed Care Organization Length of Stay by Facility.

Length of stay for the six hospital groups is shown in Figure 11. The range was 4.0 to 7.1 days. The mean value was 5.2 days.

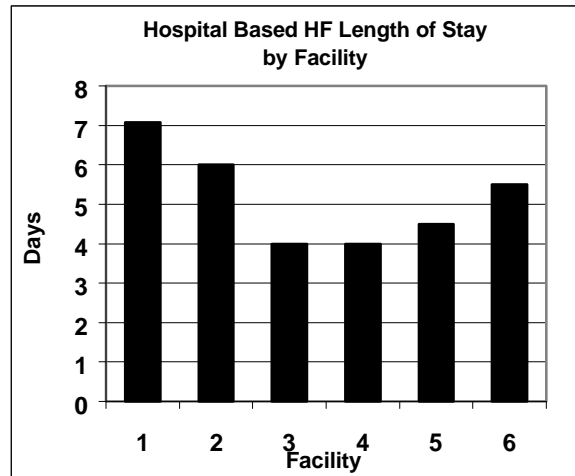


Figure 11. Hospital Based HF Length of Stay by Facility.

Daily management issues

The facilities had a number of specific concerns about providing a monitoring device to the patients' homes, including:

- Delivery and set-up
- Patient acceptance
- Telescale losses

Delivery and set-up

Some facilities were concerned about the patient's ability to set-up the Telescale because of the patient's age and/or physical condition. In the study population, 95% of Telescale units were sent directly to the patients' homes from Cardiocom. More than 99% of the patients in this group set-up the Telescale with no additional assistance. The remaining 5% of deliveries were made by practitioners who used home delivery of the Telescale as an opportunity to review the patient's care plan in person.

Patient acceptance

A written survey of a subset of three facilities was performed to determine patient acceptance. The survey gathered data about ease of Telescale use, confidence in recognizing symptoms of heart failure, and willingness to make changes in self-care because of the program. 100% of the patients surveyed agreed the Telescale was easy to use; 86% were more confident about recognizing their symptoms of heart failure; and 92% made changes in their self-care because of the Telescale device and HF monitoring program.

Telescale losses

No Telescale units have been lost to date. This is most likely due to the practitioner being immediately notified by Cardiovisor when a patient is not using his or her Telescale.

DISCUSSION

This is a preliminary report on a large body of data collected from nine diverse groups. Further data collection and a detailed statistical analysis are underway. At this point we can reach some reasonable conclusions from this information.

Hospital admission

Hospital admission is a valuable measure of effectiveness when evaluating new management tools for heart failure. It reflects both the frequency of clinical decompensation and a major component of cost (11). Previous studies in small patient populations have provided evidence that heart failure disease management programs are effective in reducing hospital admissions and hospital stays (10).

An observational study of comprehensive management by a heart failure / transplant team was performed by Fonarow et al. (11) with a total enrollment of 214 patients and follow-up duration of 6-months. The 6-month hospital admission rate for the 179 non-transplant patients in the Fonarow study declined from 1.9 ± 1.3 to 0.21 ± 0.48 . Rich et al. (10) performed a nurse-directed, multidisciplinary randomized trial with 282 patients and follow-up duration of 90 days. According to a leading disease management journal, the average national rate of heart failure admissions per patient per year is 2.0 (14).

The results of this study using the Cardiocom System in nine independent centers with N = 1,026 patients over a 12 month period show 0.234 HF hospital admissions per enrolled patient per year. This is a very low rate for HF admissions when compared with the reported unmanaged incidence of approximately 2.0 HF admissions per patient per year (11,13,14). This clearly demonstrates the effectiveness of the Cardiocom System. Results from managed care organizations and hospital groups were similar 0.217 and 0.261 respectively on a weighted average based on total patient months.

Length of stay

The average length of stay (LOS) for these HF admissions was 6.4 days with a range from 1.7 days to 7.6 days. This compares favorably with reported values of 7.0 to 9.1 days (15) although a more detailed statistical analysis is indicated.

Identification of symptomatic patients

Clinicians noted a number of key advantages using an objective weight and symptom monitoring system. The first benefit was the accuracy and reproducibility of the patient's daily weight and automated tracking and trending of this data. This system eliminated the subjectivity of self-reported weights. Objective measurements coupled with detailed reports, which include labs and medication regimen, provide clinicians with greater confidence when adjusting and titrating medications.

An additional benefit was the elimination of random outbound, telephone calls. Prior to this study, many patients were called on a weekly and sometimes bi-weekly basis to obtain self-reported weight and symptom data. This random outbound calling process was time-consuming and inefficient. A primary advantage of the Cardiocom technology is its ability to rapidly and objectively identify symptomatic patients.

This “management by exception” process allows clinicians to direct their time and attention to patients in need of assistance.

The centralized database of information allows the clinician to review objective and subjective clinical data trends, current medications, blood chemistries and previous case notes prior to contacting the patient so a complete diagnosis can be made. In this study, all patients were managed by in-house staff either at the managed care companies or hospital based facilities. No outside contractors were required and all data was sent directly to the staff at each monitoring facility.

Patients also preferred being the initiator of daily information instead of the receiver of frequent, untimely calls for daily information. The most commonly reported patient feedback was that the home device and daily clinical monitoring makes them feel more confident, independent and secure in managing their heart condition.

Other observations

- Enrollment rates in the first 30 days for each facility ranged from as few as 8 to as many as 74 patients.
- All Cardiovisor central computer and client installations, both in a networked or stand alone environment, were completed in one day.
- All facilities received Telescale patient data within 48 hours of the Cardiovisor central computer installation. Cardiocom provided all hardware and software required for daily monitoring as part of the contract fee.

CONCLUSION

New home monitoring technology offers patients and clinicians a cost-effective and efficient method to monitor large groups of heart failure patients. Using these devices in combination with close clinician management in diverse patient populations yields low heart failure hospital admission rates. A mean admission rate for heart failure of 0.234 per patient per year can be expected using this system.

REFERENCES

1. American Heart Association: 1998 Heart and stroke statistical update. American Heart Association. Dallas. TX. 1998.
2. National Heart, Lung, and Blood Institute, National Institutes of Health. Congestive heart failure in the United States: a new epidemic. [Data fact sheet]. 1999.
3. O'Connell, et al. Economic impact of heart failure in the United States: time for a different approach. *J Heart Lung Transplantation*. 1993;13(suppl):S107-S112.
4. Mills RM Jr, Young JB. *Practical Approaches to the Treatment of Heart Failure*. Baltimore: Williams & Wilkins; 1998.
5. Rich, et al. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med*. 1995; Nov 2.:1190-1195.
6. Krumholz, et al. Readmission after hospitalization for congestive heart failure among Medicare beneficiaries. *Arch Intern Med*. 1997;157:99-104.
7. Brophy, et al. The hospital course and short-term prognosis of patients presenting to the emergency room with decompensated congestive heart failure. *Can J Cardiol*. 1993;9:219-224.
8. Hoffman, et al. Modifiable risk factors for incident heart failure in the coronary artery surgery study. *Arch Intern Med*. 1994;154:417-423.
9. Roglieri, et al. Disease management interventions to improve outcomes in congestive heart failure. *Am J Managed Care*. 1997;3:1831-1839.
10. Rich, et al. Heart failure disease management: a critical review. *J Cardiac Failure*. 1999;5;1:64-75.
11. Fonarow, et al. Impact of a comprehensive heart failure management program on hospital readmissions and functional status of patients with advanced heart failure. *JACC*. 1997;Vol.30.,No.3:725-732.
12. Rose EA, Stevenson LW. *Management of end-stage heart disease*. Philadelphia: Lippincott-Raven;1998.
13. The Advisory Board Company, *Cardiology Roundtable Annual Meeting*, Nov. 9-10, 1998.
14. National Health Information, LLC. *Disease Management News*:2001;Vol.6.,No 15:8.
15. Robbins MA, O'Connell JB. *Economic Impact of Heart Failure, Management of end-stage heart disease*. Philadelphia: Lippincott-Raven;1998.