STUDY FOR THE DEPLOYMENT OF AMERICAN HEART ASSOCIATION HEART FAILURE PROTOCOLS AND EDUCATIONAL CONTENT WITHIN THE INTEL® HEALTH GUIDE SYSTEM WITH A CONGESTIVE HEART FAILURE COHORT

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An Observational Study of Deployment of AHA Heart Failure Protocols and Educational Content within the Intel-GE Care Innovations™ Guide System Following Hospital Discharge

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Abbreviated title: AHA Heart Failure Protocols and Home Monitoring Post Discharge

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Abstract

Background: The rate of 30-day rehospitalization for patients with heart failure (HF) is of great concern. Published studies have emphasized the need for adequate care after hospital admissions and for early post-discharge visits with providers. The purpose of this study was to examine short-term (60-day) health-related quality of life and rehospitalization after implementation of the Intel® Health Guide System (HGS) deployed with American Heart Association (AHA) guideline-based HF protocols. **Methods:** This was a feasibility project of patients who were candidates for home care after a hospitalization for HF. The HGS system was delivered to patient homes. Protocols were deployed to the HGS for patients to assess key vital signs, and provide related educational content on a daily, weekly, or monthly basis for 60 days. Patients and caregivers could access the health education component and perform additional vitals assessments at any time. Utility of the system and adherence to scheduled sessions were measured. Health status was assessed pre and post monitoring periods. **Results:** Patients (n=26, 62% NYHA Class II) were enrolled, and were primarily older women with HF and preserved systolic function. Health status significantly improved between baseline and end of study. Utility scores and adherence were high. At 30 days, the all-cause and HF rehospitalization rates were 23% and 15%, respectively. Greater utility scores were correlated with improvements in health status. Adherence and utility for those not rehospitalized were significantly greater than for those rehospitalized. **Conclusion:** A telehealth system embedded with AHA education information on HF themes is feasible and may be a useful adjunct to homecare after a HF hospitalization. Utility and adherence to the use of the system was associated with a lower rate of rehospitalization. A larger trial is warranted.

Introduction:

Heart failure (HF) is the most common DRG among elderly people and is associated with substantial morbidity, mortality, and healthcare expenditures. [1;1] Despite adequate and efficient hospital care, the rate of 30-day rehospitalization for patients with HF is of great concern to health care providers and payers. Of over 11 million Medicare Beneficiaries, 19.6% are rehospitalized within 30 days and 34% within 90 days.[2] Readmission rate data have become available to providers and patients on CMS' Hospital Compare web site and notably vary geographically and within each state. As hospitals and healthcare providers attempt to improve early morbidity rates due to pending reimbursement cuts, transitioning patients to home from the hospital has taken on new importance. Published studies have emphasized the need for adequate care after hospital admissions and for early post-discharge visits with providers. [3-5] Unfortunately, there are many barriers that face patients after hospital discharge. Barriers include the ability to see a provider within 7-10 days, availability of transportation and confusion about complex medication regimens. Since a growing number of discharged patients are elderly and home bound, home health care has become a critical source of patient follow-up. In their own home setting, patients should be followed in parallel to actual outpatient visits. Skilled home care nursing becomes the "eyes" of the provider and, more recently, can be supplemented with telemonitoring. The telemonitoring field is rapidly expanding, but studies to date have produced mixed results in reduction of readmissions, symptom management, and mortality for patients with HF.[4-6] Irrespective of the type of monitoring system and whether implantable hemodynamic monitors are employed, outcomes were inconsistent.[7;8] A recent meta-analysis of over 8000 patients enrolled in various clinical studies found that the majority of technology assisted approaches used a home monitoring system rather than an implantable device or phone calls with decision support. [8] Remote monitoring was associated with lower number of deaths and hospitalizations, with the decrease in events greater in the cohort, non-randomized trials. In contrast Chaudry and colleagues failed to demonstrate improvement in outcomes in a randomized trial of a telephone-based interactive response system.[4]

Patient adherence to medication intake, dietary restrictions and lifestyle changes is a key component of managing HF and reducing unnecessary exacerbations. Delivery of education and assurance of understanding of HF care expectations are key factors to adherence. To date, home telemonitoring systems have not always integrated delivery of relevant and credible patient education. Furthermore, telemonitoring systems have not consistently allowed for assessment of health status and symptoms. The SPAN-HF trial failed to show any additional improvements to health status by adding an automated home monitor to a nurse-driven system.[9;10]

The purpose of this study was to examine short-term (60-day) health-related quality of life and rehospitalization after implementation of the Intel-GE Care Innovations™ Guide (formerly the Intel® Health Guide) deployed with American Heart Association guideline-based HF protocols for assessment of clinical status and symptoms and delivery of relevant patient education to enhance home-bound patients' and caregivers' understanding of and management of HF.

METHODS

This was a single center, unblinded, non-randomized feasibility study of telemonitoring with embedded patient education. The University Hospitals Home Care Services program is a large home care agency in Northeast OH. It was chosen as the site for implementing the study and was the source of referrals and enrollment. This nurse-driven program was available to CMS recipients who were discharged home and met eligibly criteria for home care services. The study was approved by the Institutional Review Board of the University Hospitals Case Medical Center, Cleveland OH. The trial was registered in www.clinicaltrials.gov Protocol ID #AHA100602.

All nurses from the home program had been trained in HF by the National Heart Failure Training Program (N-HeFT™) (www.NHeFT.org).[11] At the study initiation, a refresher course on symptoms, signs and medical therapy of HF was administered. Patients were consented following hospital discharge with a HF diagnosis and were home bound, thus they qualified for the home care nursing program. The Care Innovations Guide (Guide) was delivered to patient homes with American Heart Association (AHA) HF patient education content on many topics embedded into the unit. Based on the patient's health status, AHA-recommended HF protocols were deployed to the Guide for patients to assess key vital signs, health questions and provide related educational content on a daily, weekly, or monthly basis for 60 days. Patients and caregivers were trained in use of the Guide and related peripherals (that included blood pressure monitors, weight scales, glucose monitors (for diabetics), and pulse oximeters), response to scheduled sessions, and access of educational content and assessing vital signs independent of scheduled sessions. Patients and caregivers could access the health education component and perform additional vitals assessments at any time.

Patients were included if they had a diagnosis of NYHA Class II-IV heart failure and had been hospitalized for an acute decompensation in the previous 30 days and could complete the monitoring process alone or with a caregiver. Patients also needed to have a telephone line or broadband internet availability to connect to the Guide. Patients who had a life expectance of < 6 months or were living in an extended care facility were not eligible.

Utility was defined as days of activity and interaction of the patient with the monitor / days of actual monitoring possible. *Adherence* was defined as the percent of actual completed sessions from the number of scheduled sessions offered. Re-hospitalization data were acquired directly from patients or caregivers and primary care physicians. Health status was assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ) pre and post monitoring periods. [12] Baseline medications were recorded; however, medications were adjusted by the patient's primary care provider as needed during the study period. Post

Guide monitoring, patients and clinicians completed surveys on satisfaction with the use of the Guide with the embedded AHA HF protocols and educational content.

The Intel-GE Care Innovations™ Guide PHS6000 was used in this study (See Figure 1). It allows health care providers to remotely access vital sign measurements of patients at home. The Guide collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Health care providers were able review the transmitted information and select education and reminders to send to patients using software interface. Patients were also able to review their stored vital sign measurement information and review educational and motivational content deployed to the unit separate from their scheduled sessions.

Analysis:

Percentages, means ± SD are presented. A paired Student's t-test was used to compare the KCCQ score at baseline and 60 days. We compared the change in KCCQ Clinical and Overall scores to compliance (completing scheduled sessions) and utility (days with activity per monitored days) using ANOVA and generalized estimating equations (GEE). Medians (distributions) of compliance and utility were compared across rehospitalization status using Wilcoxon Rank Sum test. Utility scores were calculated using the days of recorded activity compared to the actual days of monitoring, i.e, how well and often the patients or caregivers used the system. Rehospitalization rates were determined using product-limit survival tables and tested using log-rank test. SAS (SAS Institute, Inc.) version 9.1 was used.

RESULTS

Twenty six patients were consented and enrolled within a 6-month period. All had been discharged home after a hospitalization with a primary diagnosis of decompensated HF**.** For 15% of the patients, the admission was for new onset HF. Demographics are shown on Table 1**.** Patients were older, and the majority were women and had non-ischemic HF. More than half of patients had HF with preserved ejection fraction (HF-PEF) and 80.8% had a history of hypertension. At baseline, 62% were considered New York Heart Association (NYHA) functional class II in the home care nurse's assessment. The mean left ventricular diastolic diameter (LVIDD) was 4.85 + 1.27 cm and therefore, not dilated. Although the mean blood pressure was 125 mmHg ± 22 mm Hg, the RVSP mean, 52 mm Hg ± 11 mm Hg was indicative of pulmonary hypertension. Medications at baseline are noted in Table 1. Most patients were on loop diuretics, and only 7 (26.9%) received an aldosterone antagonist. None of the patients were receiving angiotensin receptor blockers (ARB) and only 10 were on angiotensin converting enzyme (ACE) inhibitors. Of the 9 patients with EF ≤ 40%, only 6 were prescribed an ACE inhibitor and none were prescribed an ARB. There was no documentation of the reasons for not being on guideline recommended vasodilator therapy. Beta blocker therapy was prescribed with similar frequency as diuretic therapy. Baseline laboratory values are also depicted in Table 1. Renal function was relatively well preserved; however, the majority of patients were anemic.

Health-Related Quality of Life

The KCCQ scores at baseline and 60 days are shown in Table 2. KCCQ Clinical Summary score significantly improved (p=0.039) and the Overall Summary score trended toward improvement (p=0.077; Figure 1). Patients scored high on the self-efficacy domain (1-item) at baseline and approached a perfect standardized score of 100 at 60 days. *Utility* scores were high, with a mean of 86.4% ±5.61 (median=88.8). Mean patient *adherence* was also high at 73.4% ±31.7 (median=89.4) (Figure 2).

Hospitalizations

Thirteen patients (50%) were rehospitalized within the 60-day follow-up period, four for HF and nine for other reasons. Therefore, at 30 days, the all-cause and HF rehospitalization rates were 23% and 15%, respectively. Mean days hospitalized at follow-up was 16 ± 5 days. Using generalized estimating equations, greater utility but not adherence scores were correlated with improvements in health status by KCCQ Clinical Summary score (p=0.013) and Overall Summary score (p=0.0056). Less patient utility and adherence were associated with rehospitalization. Median adherence and utility for those not rehospitalized (97.2% and 96.9%, respectively) were greater than for those rehospitalized (67.4% and 82.2%: p=0.013, p=0.006, respectively; Figure 3).

DISCUSSION

This pilot study has demonstrated the feasibility of adding AHA Heart Failure guideline protocols and educational content within the Care Innovations Guide. Health status, as shown by the KCCQ Clinical and Overall Summary Scores improved after hospitalization; however, all-cause hospitalization rate was still above 20%, similar to those in the state of Ohio. [1] It is notable that only 6 out of 10 patients with EF <40% were prescribed ACE inhibitors in spite of adequate blood pressures and renal function. This finding further reinforces the existing gap between Guidelines and clinical care. Nurses, in spite of training, could not change medications without a physician's order.

Clinical and overall health status measures were found to improve over the course of the study. Further, patients who had greater improvement in health-related quality of life were more likely to utilize the Guide monitoring system. In addition, there was a statistically significant association noted between utility, adherence, and rate of rehospitalization. The findings of this study, although based on a small number of patients and requiring testing in prospective randomized controlled studies, highlights the potential for home monitoring with AHA guideline-based HF protocols and educational content to impact HF disease burden, progression and health care expenditures.

It has become increasingly apparent that better strategies for monitoring HF geared towards identifying sub-clinical congestion, enhancing self-care, improving treatment adherence, and addressing comorbid conditions would be of value. Instead of being episodic and reactive, care could then become proactive through continual home observation and patient and caregiver education and assistance designed to slow or prevent further deterioration. Interventions to better monitor the patient with HF at home range from increasing self-care and structured telephone support to telemonitoring and remote monitoring of implantable devices. In individual studies and meta-analyses, researchers have suggested that telemonitoring in ambulatory HF patients can improve mortality by 17 to 47% during six to twelve months of follow-up, with similarly significant reductions in hospitalizations varying from 7 to 48%. [8] However, two recent multicenter randomized controlled trials failed to demonstrated benefit with telemonitoring for HF. In Telemonitoring to Improve Heart Failure Outcomes (TELE-HF), a telephone-based interactive voice-response system that obtained symptom and weight information provided no significant benefit over usual care in all-cause rehospitalization rates or death. [4] Similarly, Telemedical Interventional Monitoring in Heart Failure Study (TIM-HF) did not demonstrate a significant impact of remote monitoring by telemedicine on HF related rehospitalization rates or mortality.[13]

These studies highlight the complexity of home monitoring interventions. TELE-HF relied on patient-initiated communication: patients had to use a toll-free telephone system in which an automated voice then asked a series of questions to which patients had to respond by keypad. Fourteen percent of patients assigned to the telemonitoring arm never used the automated call-in system, and only 55% were still regularly using the system by the end of the study period. Loss of adherence in the intervention arm highlights the need to make an intervention palatable to patients. Furthermore, nurses in TELE-HF were not empowered to change the medication regimen without physician consultation, adding a layer of communication or collaboration and delay. Home management of HF ideally involves multiple components, of which monitoring is only one. There needs to be timely transmission of data, receipt of the information by the appropriate care team members who can analyze and act upon it, a feedback loop to the patient and/or caregiver with directions, and sufficient patient and caregiver empowerment to understand and implement the instructions. Monitoring alone may not have been sufficient to produce desired outcomes. Also, although telemonitoring promises to reduce the need for in-person follow-up, it may actually increase the workload involved. In the TELE-HF study, while there were only 25 patients per site on average, there were 884 incidents per site requiring responses. Managing the volume of information transmitted through a telehealth system increases the need for mid-level personnel with adequate HF training, expertise and licensure to provide HF treatment independently of or in collaboration with the patient's physician. Patient adherence to scheduled Guide system sessions in our study was high, although the observation time was short. It is possible that in our study, the addition of patient education embedded into the Guide, and accessed during and outside of scheduled sessions, encouraged better adherence and improved self management.

Patient education is essential in the management of HF and is strongly encouraged in Guidelines. Accurate information and buy-in from patients and their caregivers can often prevent decompensation and even hospital admission. [14;15] Although multiple agencies and societies have patient education tools and information, responsibility for dissemination of education materials is left to the provider. The provider must guide patients to review materials independently or actually provide the education in-person. Education is traditionally delivered via printed material and enhanced when providers review material with patients. Web sites are replete with information that may not only be inaccurate, but potentially harmful. Even when accurate, patients may not understand and be able to utilize what they read. Materials for education used during a hospitalization may be different than those used in the outpatient setting. Further, in the hospital setting, multiple healthcare providers may deliver short bits of information on multiple HF related themes that may be inadequate in terms of breadth or depth. In patients who are home-bound, delivery of relevant patient education to facilitate disease management is usually managed by a home-care nursing team that may or may not be adequately trained in delivering HF self-care information. A telehealth system embedded with accurate, credible AHA education information on HF themes may be a useful adjunct in that the materials are standardized, accurate, have adequate breadth and depth and use both words and pictures to provide information. The value of patient education in optimizing self-management has not been consistently assessed; further research is needed.

Limitations

Limitations of this study included that, due to available funding, the study was limited to a very small patient sample size (25) from a single center enrollment in Northeast Ohio with a short monitoring period (60 days). An additional limitation to the outcomes analysis was that the study did not have a control group for comparative purposes and was non-randomized. Finally, the patients and/or caregivers were capable of self-selecting to choose to view or ignore the educational content that was provided within the protocols. Home care nurses, in spite of training could not alter medications without the express order of the treating physician. It is not known whether medication adjustments by nurses could have decreased rehospitalizations.

Conclusions: This observational study showed the feasibility of adding AHA Heart Failure guideline-based protocols and educational content within the Care Innovations Guide. As expected, this home-bound population of patients with HF were older and primarily women. In spite of nurse training, health care providers did not prescribe ACEI or ARB therapies at expected rates, although many patients had HF-PEF. Health-related quality of life, as shown by the KCCQ Clinical and Overall Summary Scores improved after hospitalization; however, all-cause hospitalization rate was still higher than desired. Clinical and overall health status measures improved during the study, and were associated with greater patient utilization of the Guide. In addition, there was a statistically significant association noted between compliance, utility, and rate of rehospitalization. These preliminary observations need to be confirmed in a larger, randomized clinical trial. Future trials should also test the ability of trained, HF mid-level provider nurses (licensed independent practitioners) to adjust medications and apply other management decisions based on recommended evidence-based national or local guidelines or protocols.

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Figure Legends:

Figure 1: Key components of the Intel–GE Care Innovations™ Suite

Figure 2: KCCQ Scores at baseline and end of study

Figure 3: Adherence and Utility Scores

Figure 4: Relationship of Adherence and Utility with Rehospitalization

Table 1: Demographics of the patient population, laboratory and medications at baseline

Parameter	Value
Number of Patients	26
Gender (% women)	61
Age (mean ± SD)	75 ± 10
Race (% African American)	39
BMI kg/m^2	29.5 ± 6.5
Etiology (% ischemic)	23
Ejection Fraction (EF %)	47 ± 16
EF > 40% (%)	62
LVEDD (cm) (mean ± SD)	4.85 ± 1.3
Right Ventricular Systolic Pressure (RVSP mm Hg, mean ± SD)	52 ± 11
NYHA Class II (%)	62
NYHA Class III (%)	29
Systolic Blood Pressure (mm Hg, mean ± SD)	125 ± 22
Diastolic Blood Pressure (mm Hg, mean ± SD)	69 ± 10
Sodium mmol /L	137 ± 4
Potassium mmol /L	4.2 ± 0.6
BUN mg/dL	29 ± 18
Creatinine mg/dL	1.46 ± 0.9
Hemoglobin g/dL	11.2 ± 2.1
Albumin g/dL	3.14 ± 0.5
ACE inhibitor dose n=10 (mg enalapril equivalents, mean ± SD)	25.5 ± 15.7
Beta Blocker, n=23 (mg metoprolol equivalents, mean ± SD)	89.3 ± 51
Loop diuretic (mg furosemide equivalents, mean ± SD)	91.4 ± 78
Aldosterone inhibitor (spironolactone equivalents, mean ± SD)	23.2 ± 4.7
Angiotensin Receptor Blocker, n=0	0
Digoxin, n=4 (mg, mean ± SD)	0.16 ± 0.06

Table 2:

Kansas City Cardiomyopathy Questionnaire (KCCQ) baseline and 60 days with domains and the overall and clinical summaries.

	Physical Limitation	Symptom Stability	Symptom Frequency	Symptom Burden	Total Symptom Score	Self-Efficacy	Quality of Life	Social Limitation	Overall Summary	Clinical Summary
Baseline	46 ± 25	67 ± 30	51 ± 33	59 ± 29	55 ± 29	79 ± 24	50 ± 31	43± 36	49 ±25	51 ± 23
60 days	58 ± 24	63 ± 31	71 ± 27	75 ± 29	73 ± 27	92 ± 12	68 ± 31	54 ± 44	63 ±26	65 ± 22

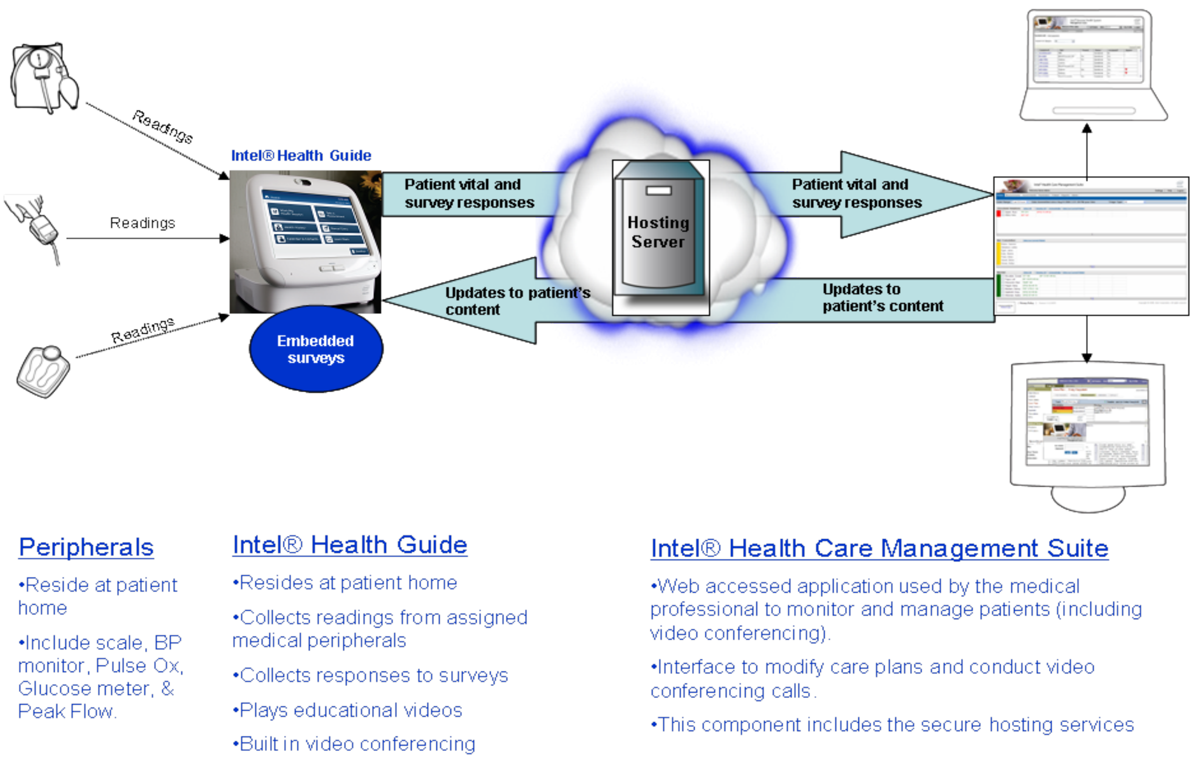
Readings
Readings
Readings
Intel® Health Guide
Embedded surveys
Patient vital and survey responses
Updates to patient's content
Hosting Server
Patient vital and survey responses
Updates to patient's content
Peripherals
•Reside at patient home
•Include scale, BP monitor, Pulse Ox, Glucose meter, & Peak Flow.
Intel® Health Guide
•Resides at patient home
•Collects readings from assigned medical peripherals
•Collects responses to surveys
•Plays educational videos
•Built in video conferencing
Intel® Health Care Management Suite
•Web accessed application used by the medical professional to monitor and manage patients (including video conferencing).
•Interface to modify care plans and conduct video conferencing calls.
•This component includes the secure hosting services

Figure 1

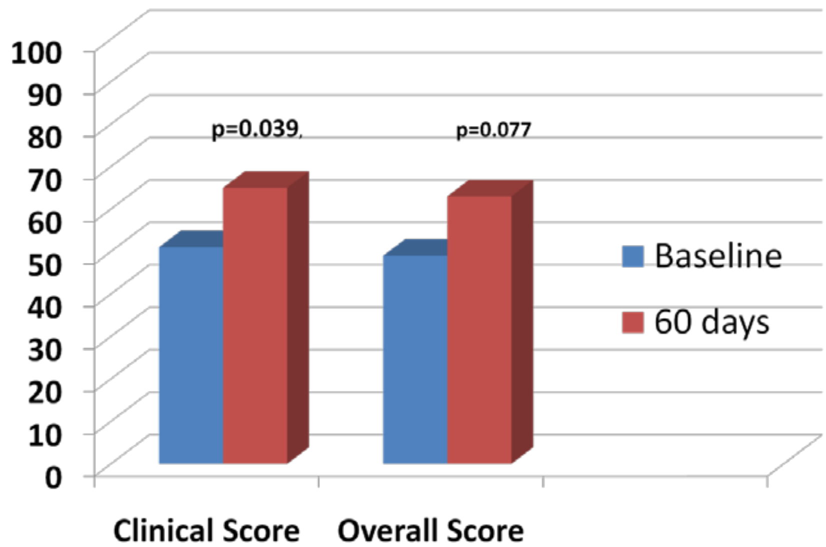
100
90
80
70
60
50
40
30
20
10
0
p=0.039
p=0.077
Baseline
60 days
Clinical Score
Overall Score

Figure 2

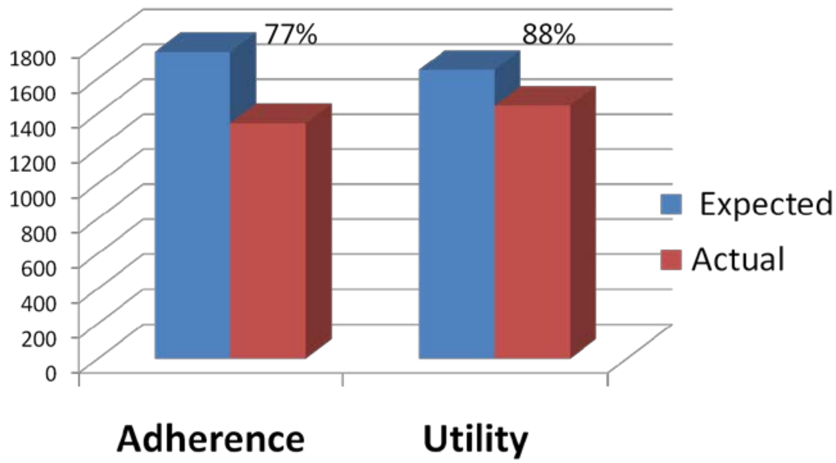
1800
1600
1400
1200
1000
800
600
400
200
0
77%
88%
Expected
Actual
Adherence
Utility

Figure 3

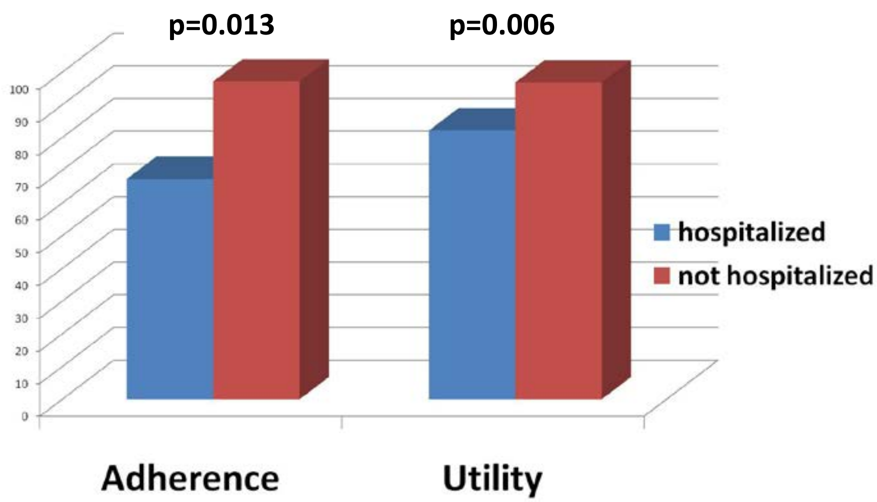
p=0.013
p=0.006
100
90
80
70
60
50
40
30
20
10
0
hospitalized
not hospitalized
Adherence
Utility

Figure 4