Reducing Heart Failure Readmissions - Telemonitoring in Transitional Care

Eleanor R. Hethcox

NURS 6163 – Health Outcomes

Texas Woman’s University
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HF patients are often caught in the “revolving door” – the cycle of hospital admission to home care then discharged to the community then readmitted back to the hospital (Delany et al, 2013). Prevention of unnecessary hospital readmission of patients diagnosed with heart failure (HF) and avoidance of this “revolving door” has become a concerning topic for many healthcare institutions in terms of costs and patient quality of life. Several strategies and various programs have been implemented in hospitals across to the U.S. to reduce the readmission rates, including outpatient focused strategies, and inpatient and transition care-focused strategies. Despite the advances in evidence-based medical therapy, HF continues to contribute a substantial burden of mortality, morbidity and economic cost to the U.S. Healthcare system.

In 2009, the US Center of Medicare and Medicaid services began public reporting of all-cause readmission rates after heart failure hospitalization and in 2012, the Patient Protection and Affordable Care Act (PPACA) was signed into law which established financial incentives to reduce hospitalizations, but also penalizes them for having above national average readmission rates. Nearly half of the HF readmissions appear to be triggered by factors regarding diet and medical treatment, follow-up interventions, inadequate follow-up, poor social support and delays in seeking medical care (Desai, 2012). In terms of management, many HF specialists agree that HF management post-discharge from acute exacerbation requires diligent monitoring, patient self-care and seamless communication between provider and patient. Many different aspects of HF management have been the center of research, but one transitional care effort has not yet proven itself though this is the way of the future. Telemonitoring via wireless technology has the potential to impact HF from both the practitioner and patient perspectives by decreasing HF readmissions, decreasing mortality and increasing patients’ quality of life.
Background

Heart failure (HF) is the leading cause of hospitalization and health care costs in the United States. HF is a serious, yet common condition with a prevalence of 20 per 1000 in the general population and an incidence of over 500,000 new cases diagnosed annually (AHA). Hospital admissions for HF have steadily increased over the last decade. Approximately 5.7 million Americans are currently affected by heart failure and that number is expected to double over the next 25 years (Delaney et al, 2013). It is projected that by 2030, an additional 3 million people will have HF (Roger et al., 2011). HF patients represent a cohort of patients at high risk for poor outcomes resulting in substantial morbidity and mortality (Delany, 2013, Kleinpell, 2013). The mortality rate remains high – 50% of people diagnosed with HF will die within 5 years and approximately 20% will die within a year of HF diagnosis.

According to Roger et al, HF accounts for a large burden in rising health care expenditures – 3.4 million office visits, over 660,000 emergency room visits and 1.1 million hospitalizations per year (Roger et al., 2012). Direct and indirect costs associated with HF in the U.S. is now almost $40 billion annually which has increased from $29 billion in 2006. Over a million people are admitted to an inpatient setting for HF and 27% of these patients on Medicare are readmitted within 30 days (Hines, 2010). With an average length of stay (LOS) of 6 days, HF hospitalization is the largest single expense for Medicare and 33% of these patients are readmitted within 30 days of discharge.

Currently, the benchmark or key outcomes measures for HF is thirty-day mortality rates and 30-day re-hospitalization rates. Hospitals across the nation are struggling to meet these benchmarks as in 2012, CMS began penalizing facilities for unmet outcomes measurements – including the two benchmark rates for HF.
As part of the ongoing effort to reduce key outcome measures of HF, 5 key transitional care intervention categories have been identified. Transitional care intervention are those described as interventions designed to prevent readmissions among populations transitioning from one care setting to another (Feltner, 2014). These include: 1) Home-visiting programs, 2) Structured telephone support, 3) Telemonitoring, 4) Outpatient clinic-based and 5) Educational based programs. Home visiting programs are home visits by clinicians who educate, reinforce self-care instructions, perform physical examinations or provide other care. Structured telephone support includes monitoring, education, or self-care management using simple telephone technology after discharge in a structured format. Outpatient clinic-based interventions are those services provided in one of several types of outpatient clinics: multidisciplinary HF, nurse-led HF, or primary care. Educational programs are those that are delivered before or at discharge by various personnel or methods (2014).

In this synthesis, telemonitoring and its potential to reduce readmission rates and 30-day mortality and increase patient QOL will be the focus of interest. Telemonitoring is the use of communication technology to monitor clinical status (Chaudry et al, 2007). It has gained attention as a strategy to improve the care of patients with chronic illness – specifically those with heart failure. According to Chaudry et al, a system of frequent monitoring could alert clinicians to early HF decompensation thus providing the opportunity of early intervention.

**Synthesis of Literature: HR Management Strategies**

To evaluate the impact telemonitoring has on HF outcomes, a review of evidence-based literature was performed using the following databases: CINAHL, Medline, and the Cochrane Library using the search terms heart failure, telemonitoring and readmissions. The limits set were from January 2007 to July of 2014 and randomized controlled trials. Thirteen articles were
generated. From these studies, references were also scanned and abstracts reviewed to find other studies pertinent to the literature synthesis.

In a Meta-Analysis of Outcomes of Heart Failure care management programs, B. Wakefield et al described and quantified individual interventions used in multicomponent outpatient heart failure programs. Most of the programs reviewed were delivered using traditional methods including face-to-face, clinic and home visits and telephone calls. The results yielded 35 studies including 8071 subjects who were typically older with an average age of 70.7 years and 59% were male. They found that the most commonly used intervention was patient education and symptom monitoring by study staff and by patients. The conclusion was that the multicomponent HF management programs have positive effects on patient outcomes, but the contribution of the individual interventions remains unclear. It is further suggested that future studies of these chronic disease interventions must include descriptions of recommended key program comments. They do however recognize that home-monitoring technologies are emerging to improve patient outcomes and HF is a frequently targeted condition for home technology monitoring. In another systematic review by Takeda, Taylor, Khan & Underwood published in 2012, several databases were searched and RCTs with at least six months follow up, comparing disease management interventions were examined. Twenty-five trials were included and interventions were classified as case management, clinic interventions, multidisciplinary interventions (holistic approach bridging the gap between hospital admission and discharge home delivered by a team). They found that case management interventions were associated with reduction in all cause mortality at 12 months follow up, CHF clinic interventions revealed non-significant reductions in all-cause mortality or CHF related admissions, and CHF related and all-cause readmissions were reduced by multidisciplinary interventions.
In another systematic review published in 2014, Feltner et al. assessed the efficacy, comparative effectiveness, and harms of transitional care interventions to reduce readmission and mortality rates for adults hospitalized with HF. Their review included 47 trials and looked at specific interventions including home-visiting programs, STS, telemonitoring, outpatient clinic based interventions and primarily education interventions. They concluded that home-visiting programs and multi-disciplinary interventions reduced all-cause readmission and mortality, structured telephone support reduced HF-specific readmissions and mortality and should receive the greatest consideration by systems or providers seeking to implement transitional care interventions for persons with HF.

In a RCT conducted by Seto et al, 2012 entitled Mobile Phone-Based Telemonitoring for Heart Failure Management, researchers investigated the effects of a mobile phone-based telemonitoring system on heart failure management and outcomes including hospitalization, mortality, and ED visits. They found no significant differences between the telemonitoring and control groups, but did not exclude the potential benefits that telemonitoring can have the HF cohort. They concluded that although their study showed no significant differences, this technology improved QOL through improved self-care and clinical management and may be more statistically significant in a larger study.

Another study by Kulshreshtha et al looked at the use of remote monitoring to improve outcomes in patient with heart failure. This study was a pilot trial that looked at a remote monitoring intervention examining re-hospitalization rate, re-hospitalization rate for HF, mortality, ER visits, length of stay and participant satisfaction. Their results demonstrated a trend towards a lower all-cause readmission rate in the RM group versus the control group. Their study also demonstrated that not only can RM be successfully employed to deliver follow-up care, but
extending its use to a larger population may be potentially of great value to both patients and providers. The successful implementation of their RM program, high degree of patient satisfaction and the trends suggest that RM may reduce hospitalizations which they say warrants further study.

In the CHAMPION study, a randomized, controlled trial, in which selected patients were equipped with a wireless implantable hemodynamic monitoring system, showed promising results for patient outcomes. In a 6 month period, 83 heart failure related hospitalizations were reported in the treatment group compared to 120 in the control group. The treatment group had a 39% reduction in heart failure related hospitalization compared with the control.

In a systematic review and network meta-analysis by Pandor et al, researchers found that remote monitoring (RM) strategies have the potential to deliver specialized care and management and may be one way to meet the growing needs of the HF population. The study design was a systematic review and meta-analysis of RCTs or observational cohort studies with a control group. RM interventions included home telemonitoring (TM) including implanted monitoring devices with medical support provided during office hours or 24/7 and structured telephone support (STS) programs delivered via human-to-human contact (HH) or human-to-machine (HM) interface.

Wiley et al, 2012, performed a critical appraisal of the literature concerning HF disease management, Prevention and Control. In their meta-analysis they also concluded that prevention of HF re-hospitalizations requires comprehensive disease management. This includes interventions such as structured telephone support along with telemonitoring interventions. In the MOB1le Telemonitoring in Heart Failure Patients Study (MOBITEL) by Scherr et al, 2009, the goal was to evaluate the impact of home-based telemonitoring using Internet and mobile phone...
technology on the outcome of HF patients after acute decompensation. There were 120 patients in the study that were randomly placed in control and interventional arms. Patients in the interventional arm were equipped with mobile phone-based patient terminals for data acquisition and transmission to the monitoring center. The results were that 33% of the control group reached the primary end point – 1 death and 17 hospitalization, compared with 11 tele group patients which was 17%, 0 deaths and 11 hospitalizations. They also report that the tele group patients had a significantly shorter length of stay of 6.5 days vs. the control of 10.0 days. They conclude that telemonitoring using mobile phones as patient terminals has the potential to reduce frequency and duration of HF hospitalizations (Scherr et al, 2009).

In a special report published in Circulation, a Journal of the American Heart Association, Desai & Stevenson, 2012, investigate whether rehospitalization for HF is something that can be predicted or prevented. Challenges in predicting exacerbation are numerous. Desai & Stevenson identify cardiac biomarkers including natriuretic peptides and cardiac troponins may signal potential readmission within the 30 days and that circulating catecholamines and renin-angiotensin system metabolites or lower levels of serum can also identify patients at risk for early readmission. Desai & Stevenson briefly describe the CHAMPION trial in which wireless transmission of directly measured left atrial pressures were transmitted wirelessly to physicians which empowered them to self-adjust medications. They state that for patients at risk for recurrent decompensation, this approach may allow optimal titration and empower patients to have more control and increase their perceived QOL.

They further elaborate that beyond clinical and laboratory parameters, the overall level of disability as reflected in measures of functional limitation, frailty, and patient reported QOL seems to be a particularly important predictor of the overall readmission rate (Desai &
They suggest that prevention of readmission is a 3-phase strategy that must exploit opportunities for management across the full continuum of care from hospital to home. They believe that integration of an active ambulatory intervention model with the medical home could improve management of comorbid medical illness that contributes to 50% of the rehospitalizations (2012).

Three RCTs also emphasize telemonitoring with education as a tool to improve communication between HF teams and their patients. In a study conducted by Delaney et al, researchers found that the primary outcomes including re-hospitalization, QOL and HF knowledge in the intervention group which had both telemonitoring of vital signs and symptoms and education was significantly better than those in the control group. They suggest that home care agencies may benefit from continuing telemonitoring and providing self-care education and state that those agencies not currently using telemonitoring or other types of teleheath may consider adding this technology into chronic disease protocols (Delany, 2013). In a similar study by Black et al, 2014, a remote monitoring and telephone nurse coaching intervention are being conducted that measure blood pressure with and without symptoms, heart rate, weight and symptom questionnaires. Their primary outcome measure is the 180-day all-cause readmission rate and secondary outcomes are the 30-day readmission rate, mortality, ED visits, hospital days, costs and HRQOL. The BEAT-HF study differs from other telemonitoring programs in that nurses respond proactively after a trigger is generated. A trigger is a significant change in biological parameters. The study is ongoing but researchers thus far feel that telemonitoring along with coaching and consistent education will have a large impact in outcome measures. In another study published by the European Journal of Heart Failure, 2012, Dendale et al describe the effect of a telemonitoring-facilitated collaboration between practitioner and heart failure
Reducing Heart Failure Readmission Rates

Clinic on mortality and rehospitalization rates entitled TEMA-HF1. This RCT showed that all-cause mortality and number of hospitalizations was significantly lower in the experimental group and compared to the control (Dendale, 2012). They state however that their findings need confirmation in a large trial.

Conclusion

The synthesis review for telemonitoring of HF and its effects on readmission and QOL are mixed. Some studies show no significant changes in selected outcomes whereas others do show some significance, but warrant either further study or larger cohorts of study. Improving patient outcomes requires a new approach that undoubtedly requires a multidisciplinary team effort with focus on diligent monitoring on patient and practitioner sides. For select HF patients, a remote monitoring via wireless technology may prove worthy in terms of increased QOL and reduction in 30 day readmission rates only in conjunction with other established interventions. For those facilities, identification of high risk for readmission patients in combination with wireless telemonitoring may be the answer to improving outcomes across the board.

Intervention

Currently, UTMB utilizes a heart failure team that staff as consults and works the heart failure clinics that are located in Galveston with several satellite clinics in the surrounding area. Upon discharge from the hospital, cardiology nurses and dedicated heart failure APRNs give discharge teaching including medication compliance, diet and sodium restrictions and symptom recognition. Follow-up occurs in the outpatient setting within a 2 week period. The proposed intervention will occur at discharge for HF patients. The RCT will have 2 arms – the control will be usual care and the intervention will be usual care plus the mobile device, phone or tablet, with a one touch HF application. Patients in the intervention arm will be given 2 thirty minute
instruction modules that will show patients how to utilize their mobile app. Patients will be instructed to measure daily weight using a hospital issued scale, blood pressure and answer a questionnaire regarding their symptoms. Specifications and use of the Smart Band-aid non-invasive sensor will also be performed. The information including cardiac rhythm, oxygen saturation, and temperature will be transmitted wirelessly through their apps to the dedicated CHF team of physicians, nurse practitioners, physician assistants and nurses.

Data input will be downloaded to a secure internet site for review by HF clinicians and analyzed for variances from discharge baselines. Clinicians will respond to the variances according to a developed protocol and schedule immediate assessments to determine severity of variance and appropriate next step interventions.
# SYNTHESIS OF LITERATURE AND LEVELS OF EVIDENCE

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**Key to Evidence Levels:**

- **Level I Evidence:** From systematic review or meta-analysis of all relevant randomized controlled trials (RCT’s), or evidence-based clinical practice guidelines based on systematic reviews of RCT’s.
- **Level II Evidence:** From at least one well-designed RCT.
- **Level III Evidence:** From well-designed controlled trials without randomization.
- **Level IV Evidence:** From well-designed case-control and cohort studies.
- **Level V Evidence:** From systematic reviews of descriptive and qualitative studies.
- **Level VI Evidence:** From single descriptive or qualitative study.
- **Level VII Evidence:** From the opinion of authorities and/or reports of expert committees.

Intervention

To implement this project, the design utilized will be a randomized clinical trial conducted at John Sealy Hospital, Cardiology Unit at the University of Texas Medical Branch in Galveston, TX. Patients whose diagnosis is CHF exacerbation will be screened for inclusion of the study. A control group and intervention group will be followed for a period of 30 days post discharge. A study by Arbaje et al supports that certain factors contribute to early hospital readmission. These include the following factors: being unmarried, living alone, lacking “self-management” skills, and having an unmet activity of daily living and lower level of education. LACE index will also be utilized for inclusion and exclusion.

Variables significantly associated with readmission included lack of cardiology consult during admission, living status, point of entry of index admission, receiving Medicare, and having pulmonary hypertension (Hamner, 2005). Therefore, inclusion criteria are as follows:

- Medicare recipients (Medicare as primary insurance)
- Diagnosis of congestive heart failure
- Ages between 65yrs and 75 years
- Cognitively intact
- Currently admitted to hospital for CHF exacerbation as primary problem
- Education level – some college, high school graduate or below
- Ability to use smart phone application
- Living alone or single

Exclusion criteria include:

- TDCJ inmate, prisoner or
- Diagnosed with dementia or with limited cognitive abilities
Major medical insurance as primary insurance
24/7 caregiver
Age less than 65 years or greater than 75 years of age
Patients discharged to LTAC facilities or hospice care

The control group will receive standard of care for discharge per CHF protocol. Intervention group will be given protocol plus classes, smartphone, and wi-fi access or dedicated data plan service through ATT. All members of the interventional arm will receive the Smart Bandage, an adhesive patch containing an array of sensors that measure vital signs including blood pressure, oxygen saturations, heart rate and rhythm, weight changes, etc. The wireless transmitters in the bandage send readings to the smartphone app creating a “body-area network” that continuously monitors those patients at high risk for hospitalization (Versel, 2011).

A dedicated CHF team will be assembled including a medical assistant, registered nurse, nurse practitioner, respiratory therapist and cardiologist to provide transitional and episodic care. The groups will be randomized. For 30 days following discharge, all patients in intervention group will “check-in” daily via smart phone application that will measure blood pressure, oxygen saturation, weight and subjective symptoms. Data will be analyzed and RNs will assess the likelihood of exacerbation. Cardiologist will be notified of potential readmission cases and RN and NP will visit the patients and per MD protocol will provide care in the home as pre-determined by the heart failure team.

Raw data will be analyzed by a statistician with no vested interest in the project. The outcomes of interest will be 30-day readmission rates from the control and interventional arms, 30-day mortality of both control and interventional arms and finally, pre and post surveys of QOL utilizing the
Model

The framework that will guide this project is that of Rosswurm & Larabee – the model for Evidence based practice change. This is a 6 step model to facilitate a shift from traditional and intuition driven practice to implement evidence-based changes into practice (White, 2012). The steps include: 1. Assessing the need for change in practice, 2. Linking the problem interventions and outcomes, 3. Synthesizing the best evidence, 4) Designing practice change, 5) Implementing and evaluating the change in practice and finally, 6) Integrating and maintaining change in practice. See Figure 1.0.

Currently, the 30 day readmission rate for UTMB Galveston is 24.8 % which is the national average (Webfrational, 2014). Any deviation above this will place the University in jeopardy of being penalized by CMS. Therefore, efforts to reduce the 30-day readmission and mortality rates are crucial for the University in terms of monies saved and for improvement in patient QOL and patient satisfaction.

The process for implementation will be a randomized clinical trial within John Sealy Hospital in Galveston, TX. The first step will be to receive IRB approval from both UTMB and TWU Dallas. Next, selection of patients with admitting diagnosis of CHF or CHF exacerbation will be performed according to inclusion and exclusion criteria set forth by primary researchers. The next step in the process is to secure equipment including 40 Samsung, android based tablets with wifi and 4G capabilities to be donated by AT&T. The app will be the Smart Bandage application that will be pre-loaded onto the tablets. Short and succinct educational guides will be added to the existing CHF discharge protocol booklet to address interventional details.
The patient population of interest will be randomized into the groups. Discharge instruction will be performed by 2 advance practice RNs. APRNs and RN teams will be responsible for ensuring adequate teaching and responsible for ensuring connectivity to a wireless, secure server within patient’s homes.

For a period of 30 days from date of discharge, interventional patients will transmit information from their sensors by updating their information through a one-touch system. The data will be wirelessly transmitted to the HF team and interpreted by CHF APRNs and cardiology physicians on the heart failure team. From the physiological parameters including blood pressure, temperature, heart rate and rhythm, oxygen saturations, and questionnaire, the CHF team will decide whether hospitalization will occur versus other interactions including outpatient visit, medication adjustment or home health visit by the team.

**Proposed Outcomes**

The outcomes that are of interest include the 30-day readmission rate, the QOL and 30 day mortality of both interventional arm and control groups. It is hypothesized that the interventional arm will yield a lower rate of readmission, higher QOL and a lower 30 day mortality than the control group.

The 30 day readmission rate will be calculated as follows: per-enrollee readmission rates will be computed as the number of readmissions divided by the number of enrollees. A per-enrollee rate will almost always be lower than a per-admission rate. Readmission rates will also be reported on a per-admission basis – the readmission rate for a group of people will be the number of readmissions counted divided by the total number of admissions.
Next, QOL will be determined using the Minnesota Living with Heart Failure Questionnaire which is designed to measure the effects of heart failure and its treatments on an individual’s quality of life. This measure the effects of symptoms, functional limitations, and psychological distress on an individuals’ QOL and consists of questions that assess the impact of frequent physical symptoms, the effects of heart failure on physical/social functions, and side effects of treatments, hospital stays, and costs of care. Both arms will take the survey during hospitalization, prior to discharge and 30 days post discharge and will be compared to baseline.

Finally the third outcome measurement will be the 30-day mortality measure for HF. This will be completed by using a hierarchical logistic regression model. This approach models data at the patient and hospital levels to account for variance in patient outcomes within the hospital. The calculation is a ratio of the number of “predicated” deaths to the number of “expected” deaths at the institution, multiplied by the national observed mortality rate. The numerator of the ratio is the number of deaths within 30 days predicted based on the UTMB’s performance with its observed case mix, and the denominator is the number of deaths expected based on the nation’s performance with UTMB’s case mix. A lower ratio will indicated lower-than-expected mortality rates or better quality, while a higher ratio indicated higher-than-expected mortality rates or worse quality.
References


