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Congestive Heart Failure Home Monitoring Pilot Study in Urban Denver

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***Abstract*—With a growing number of low-income patients developing Congestive Heart Failure in urban Denver, accessible and affordable solutions are needed to provide home management options. A multidisciplinary team evaluated currently available options for telemonitoring and developed a solution for an initial pilot study. This system is currently used in the Denver Metro area (Colorado) for 44 CHF patients. Preliminary results show this approach is effective and has reduced the patients' average length of stay at the hospital compared to historical data and control patients who do not use a remote monitoring system.**

Keywords – chronic illness management, home health monitoring, low-income patients

I. Introduction

Currently, nearly one in two Americans has a chronic medical condition [1]. The total number of individuals with chronic illness is projected to increase by more than one percent per year by 2030 – mainly because of the baby boomers generation – resulting in an estimated chronically ill population of 171 million [1]. One such disease is Congestive Heart Failure (CHF). According to a study in the Journal of the American College of Cardiology, one in six members of the population will develop CHF [2]. A study performed in 2004 [3] shows that the risk of CHF is high in the elderly population and nearly 80% of the 5 million CHF cases in the US occurred in a population that is 65 years and older.

Use of telehealth monitoring (THM) for CHF patients has matured and become widely adopted in the last few years. For instance, Johnston et al. [4] reported the outcomes of the Kaiser Permanente Tele-Home health research project on several diseases such as CHF, chronic obstructive pulmonary disease using remote video technology in the home health care setting to evaluate the quality, patient satisfaction, and cost savings using this technology. As results, no differences in the quality indicators, patient satisfaction, or use were seen.

Woodend et al. [5] studied the effect of THM in patients with cardiac diseases (heart failure and angina) who are at risk of readmission using video conferencing with a nurse, daily transmission of weight and blood pressure, and periodic transmission of a 12-lead electrocardiogram. They reported that there was a 51% reduction in the number of hospital admissions and 61% reduction in the number of days spent in the hospital per patient with angina who received THM compared with those with usual care.

The contribution made by this team is the creation and deployment of a home-health monitoring system for CHF patients in the Denver metro area. The goal is to improve outpatient care through the use of a home monitoring system to measure body vital parameters. Researchers in engineering and medicine at the University of Denver created a pilot study with the initial goal of enrolling 65 participants to enhance out-patient care through the use of an off-the-shelf telemonitoring system to capture and transmit daily weight measurements. For this initial pilot study, daily weight measurements are taken with a wireless bathroom scale and transmitted through a dedicated home telemonitor to the hospital for monitoring and diuretic prescription modification. This approach, shown in Fig. 1, is believed to improve patient outcomes through daily weight monitoring and medication adjustments when deviations occur over a three to five day period as described below [6][7].

The remainder of this paper is organized as follows. We present Congestive heart failure symptoms in Section II. Participants are presented in Section III. Study results are

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explained in Section IV followed by Conclusion and future work in Section V.

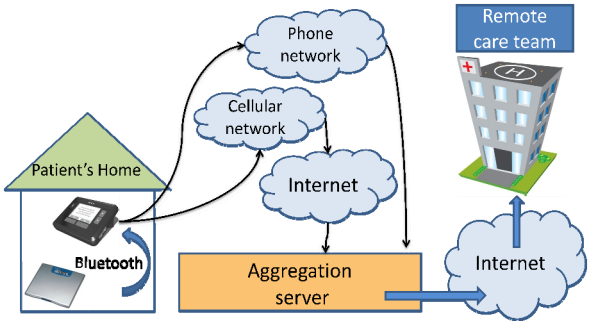

Fig.1 Proposed Home Telemonitoring System

II. CHF Symptoms

Both locally and nationally the treatment of CHF and other diseases of the elderly population are creating new and growing challenges for the health care system. The most common cause of hospitalization and re-hospitalization in CHF patients is difficulties in breathing caused by water in the lungs. This condition occurs due to diminished effective blood flow to the kidneys which results in salt and water retention. This results in an increase in intracardiac pressures and ultimately an increase in lung water. As shown in Fig. 2, the cardiac output decrease may be due to a variety of causes which include valvular heart disease, high blood pressure, and myocardial infarction. The kidneys and the lungs are affected through decreased blood flow and increased pressure [8].

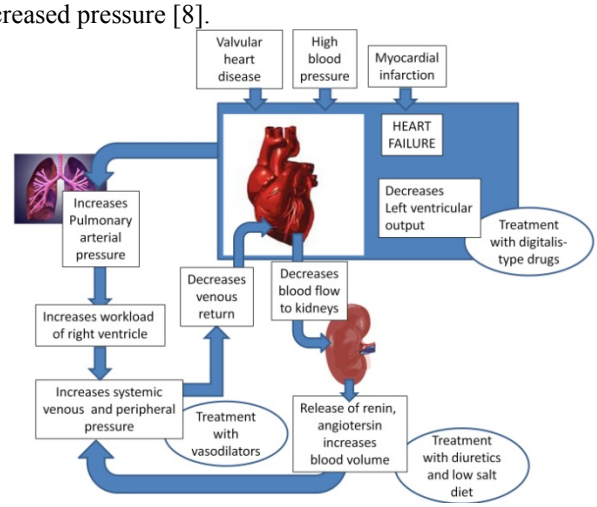

Fig. 2 Heart Failure Overview

Monitoring body weight is identified in the ACC/AHA Clinical Performance Measures [9] as a leading indicator of assessing CHF risk. In fact, CHF patients can gain 3 lbs over night or 5 lbs in three days. If weight gain is detected three to five days before an event, symptoms are most commonly treated with diuretic medications [7].

This study initiated in the summer of 2009 with a planned duration of two years. Recruitment of five subjects per month is planned to complete the study group while also recruiting similar numbers of control group participants. A full 365 days of monitoring is necessary to determine if hospitalization is reduced by 28% for a power factor of 95%. Technology for interfacing with patients initially focused on a dedicated telephone line service (PSTN) to remove the need for a home based computer. The device used for the interface is the RTX3370 from Tunstall Telehealth paired with the UC-321PBT bluetooth bathroom scale from A&D, Fig. 3. Based on a survey of available telemonitoring devices at the time, this device did not require a computer interface and has configurable menus that can be programmed in English and Spanish so that patients receive feedback on the weight measurement and confirm transmission to the hospital.

Fig. 3 RTX3370 device paired with the UC-321PBT scale

However, the use of a PSTN device created an obstacle for recruitment since many participants only had cell phone based communication. This became evident a few months into the recruitment of subjects. As soon as the FDA approval of the GSM/GPRS wireless version for the telemonitor was available in the Fall of 2010, the study switched over to the RTX3371.

The new devices utilize a cell phone sim card to communicate data to the server for monitoring. Cell phone companies offer low data rate plans for telemetry applications and can sell the sim cards in batches for applications of this type. The average cost per month on these plans is relatively low on the order of 12 dollars per customer so with a business plan the minutes can be pooled since some patients may have more activity than others. Adoption of the new telemonitoring devices added about three additional months to the recruitment phase; however the short fall in subjects with access to telephone lines was overcome in about three months with this new technology solution.

Collection of the data from each home is one of the challenges in this study. The bathroom scale stores all readings so the telemonitor uploads all data stored in the external devices. This causes potential variability in communication from patient to patient but generally does not exceed one megabyte of data per month since readings are only required on a daily basis. Patients are encouraged to remove their clothing, void themselves, and take the readings early in the morning at approximately the same time each day so that a consistent body weight is observed. Transfer of the data from all of the homes in the morning creates a potential for server congestion. In order to overcome this limitation, two dedicated modem lines are used for interface to the telemonitoring devices. If the home based system can't get through, it will continue to redial until a confirmation is received. The patient only needs to stand on the scale once and send information then the

remainder of the communication is automated since the RTX devices have storage capability. Simplicity in the implementation is important since Denver Health is a safety-net institution where the patients served have, on average, the equivalent of a third grade education. Once the data is captured by the home based unit, it is sent to an intermediate server before going to the hospital for better technical maintenance and support at the school for this pilot study. As shown in Fig. 4, an aggregation server is used to collect the data from all of the remote devices during the daytime through an encrypted connection using SSL to protect our data security. Transfer to the hospital occurs once a night through a secure FTP connection. Data is then handled from the medical side for presentation in the patient electronic medical record (EHR) for review by a nurse practitioner. The study nurse at DHMC reviews patient weights on a daily basis, except for weekends. Anytime a patient has a weight gain that is greater than or equal to 3 lbs overnight, the nurse calls the patient. The nurse will assess the patient for signs and symptoms of heart failure, (leg swelling or shortness of breath). The nurse will notify the patients' doctor or a supervising cardiologist who will make clinically appropriate changes to their medications or the patient will be advised to schedule an appointment. Conversely, the nurse will call patients if a weight is not registered.

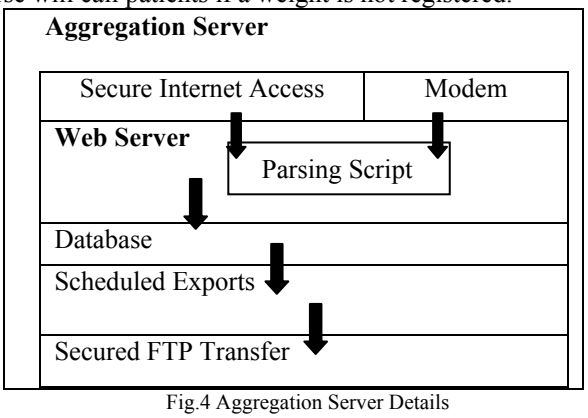

Fig.4 Aggregation Server Details

III. Participants

DHMC is considered a "safety-net provider" and serves predominantly indigent, inner-city minority populations. At Denver Health, half of the patients are of Hispanic ethnicity and 29% are African American. Additionally, over 50% of patients lack health insurance. CHF is consistently in the top 10 list of ICD-9 coded primary admissions. On average 300 patients are admitted with a heart failure diagnosis annually. The readmission rate for CHF patients is 20% at 30 days, 45% at 6 months, and 67% at one year.

In 2007, DHMC treated approximately 250 CHF patients at a cost of nearly $5,000,000. According to our medical partners, CHF patients staying in the hospital for an average of 4.5 days cost $4,000 per day exclusive of physicians' fees. Additionally, hospital re-admittance is high, ranging from 1 to 8 admissions per CHF patient per year, with an average of 1.5 hospital stays per CHF patient annually. Thus, CHF patient care costs approximately $20,000 per patient per year

In this pilot study, patients are selected from the pool of inpatients admitted to DHMC for Heart Failure (HF) or outpatients scheduled for an appointment in the Denver Health Cardiology Clinic. Selection and exclusion criteria are listed below.

Inclusion Criteria:

a. Denver Health patients who have Hospital admission with a primary diagnosis of heart failure during index hospitalization and/or are patients seen by ER, Internal Medicine and Cardiology clinics.
b. The absence of pulmonary congestion (scant or no crackles upon lung auscultation) confirmed by the attending physician and the cardiac nurse specialist at the time of enrollment.
c. $\geq$ 18 years of age.

Exclusion Criteria:

a. Pregnant or lactating women
b. End stage liver disease
c. Renal disease requiring dialysis
d. Dementia
e. Co-morbid illness with life expectancy less than 12 months
f. Active, illicit substance abuse
g. Acute myocardial infarction at index hospitalization
h. Hemodynamically significant primary cardiac valve disease
i. Anticipated CABG within the next 6 months

Enrolled patients are assigned to two groups, one active and one control. The first group includes patients who meet the inclusion criteria and have been willing to actively participate and send their weight data to DHMC. The second group includes patients who do not wish to be monitored but agreed to allow a review of their medical records. Enrollment started in August 2009. By the end of January 2011, 44 CHF patients had consented to actively enroll in the study. 28 of them were assigned the RTX3370 and 16 of them were assigned wireless teledevice RTX3371. The race/ethnicity of the active group is: 19 are African-American, 13 are Caucasian, and 12 are Hispanic. The male to female ratio is 15:7. By contrast, there are 16 patients in the control group, 10 of them are African American, 2 are Caucasian, 3 are Hispanic, and 1 is Asian. The male to female ratio is 7:1.

IV. Study Results

Analysis of patients who have been monitored for six months does show an overall reduction in length of stay. This result is assessed by using historical data from the hospital as the control group. The length of stay (LoS) of the enrolled patients at the hospital is recorded by DHMC. A comparison of the two groups of patients' LoS is performed by running T-Test analysis to investigate whether there is a significant change in the average hospitalization days (i.e., LoS) between the two groups of patients.

For the T-Test analysis, the LoS of the control and active groups are assumed to have a normal distribution with unequal variance and unequal number of samples per group. The T-Test analysis assesses whether the means of the two groups are statistically different from each other. The risk level (α) is set at 0.05. As the result shows in table I, there is an 18.9 % reduction in the mean LoS: from 4.02 to 3.26 (mean difference = 0.76) days for at least six months of participation. The probability of rejecting the hypothesis is 0.74.

Since there are an insufficient number of patients in the control group, the confidence in the result is very low. By evaluating the available historical data from 5 years of encounters (2004 to 2008) from patients as a control group, the study results improve. As shown in table II, there is a 39.96% reduction in the mean LoS (from 5.43 to 3.26) days for at least six months of participation. The probability of rejecting the hypothesis of significant difference between mean LoS values is 0.19.

TABLE I. RESULT OF T-TEST ANALYSIS FOR THOSE PATIENTS WHO ARE IN THE PROJECT AT LEAST 6 MONTHS

	Control	Active
Mean	4.02	3.26
Variance	53.98	23.92
Observation	12	37
P(T<=t)two-tail	0.74	

TABLE II. RESULT OF T-TEST ANALYSIS FOR THOSE PATIENTS WHO ARE IN THE PROJECT AT LEAST 6 MONTHS IN ACTIVE GROUP USING HISTORICAL DATA FOR THE CONTROL GROUP

	Control(Historical)	Active
Mean	5.43	3.26
Variance	9.99	23.92
Observation	4463	37
P(T<=t)two-tail	0.19	

One of the goals of this study is to reduce the cost of hospitalization. Based on the information in table I and table II, $3,040 and $8,680, respectively will be saved per patient during 6 months of remote monitoring.

An investment of approximately $1,000 in monitoring hardware plus about half an hour of installation time along with routine maintenance and monitoring in the ball park of $200 to $500 per patient depending upon the frequency of contact is much less than a single night in the hospital at $3,000 to $5,000 without physician fees. This analysis agrees with a recent large study reported in the New England Journal of Medicine that home monitoring alone will not significantly reduce hospitalization in CHF patients [10]. Further investigation is necessary to understand the dynamics in a safety-net population.

V. CONCLUSIONS AND FUTURE WORK

This study demonstrated the ability to configure and deploy a home-based telemonitoring system for use by patients in the urban Denver area. Low recruiting patterns signaled the need for an upgrade in technology to provide greater access to the patient population. This change provided the necessary access to complete recruitment and initiate a full year of home monitoring.

Technology has the potential to transform the patient doctor relationship by providing more detailed insight into daily patterns and risk factors. Currently, the office visit is the primary mode of gathering knowledge but many patients show symptoms due to anxiety or suppress symptoms unknowingly. With regular monitoring in a quantitative manner through technology, it is strongly believed that patient engagement is improved and hospitalization will be reduced for effective self-management of chronic illness.

We plan to extend the project by monitoring other vital symptoms of the disease such as blood pressure and oxygen level. By providing such information to nurses, they can make better decision regarding the health of CHF patients.

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