

Designing and Implementation of a Heart Failure Telemonitoring System

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ABSTRACT

Introduction: The aim of this study was to identify patients at-risk, enhancing self-care management of HF patients at home and reduce the disease exacerbations and readmissions. **Method:** In this research according to standard heart failure guidelines and Semi-structured interviews with 10 heart failure Specialists, a draft heart failure rule set for alerts and patient instructions was developed. Eventually, the clinical champion of the project vetted the rule set. Also we designed a transactional system to enhance monitoring and follow up of CHF patients. With this system, CHF patients are required to measure their physiological measurements (vital signs and body weight) every day and to submit their symptoms using the app. additionally, based on their data, they will receive customized notifications and motivation messages to classify risk of disease exacerbation. The architecture of system comprised of six major components: 1) a patient data collection suite including a mobile app and website; 2) Data Receiver; 3) Database; 4) a Specialists expert Panel; 5) Rule engine classifier; 6) Notifier engine. **Results:** This system has implemented in Iran for the first time and we are currently in the testing phase with 10 patients to evaluate the technical performance of our system. The developed expert system generates alerts and instructions based on the patient's data and the notify engine notifies responsible nurses and physicians and sometimes patients. Detailed analysis of those results will be reported in a future report. **Conclusion:** This study is based on the design of a telemonitoring system for heart failure self-care that intends to overcome the gap that occurs when patients discharge from the hospital and tries to accurate requirement of readmission. A rule set for classifying and resulting automated alerts and patient instructions for heart failure telemonitoring was developed. It also facilitates daily communication among patients and heart failure clinicians so any deterioration in health could be identified immediately.

Keywords: heart failure, telemonitoring, telemonitoring system, design.

1. INTRODUCTION

The prevalence of heart disease including chronic heart failure (CHF) in developing countries such as Iran is increasing and the burden of cardiovascular disease and its consequences are significant (1). Our Center is a center of excellence for cardiovascular medicine and heart failure programs in Tehran, Iran (www.rhc.ac.ir). In this center, more than 9000 heart failure patients are visited annually in outpatient clinic which a third of them are new cases. A study in acute heart failure in this center showed, 167 (58.2%) of 287 patients with acute heart failure were readmitted and 5 (1.7%) patients died during 3 months of follow up.

Currently, chronic diseases have a significant impact on the quality and life expectancy of many people in the

world. On the other hand the rising average age of the population engaged considerable financial and human resource of governments in the field of health. One of the most important of these diseases is heart failure due to the prevalence in the population (1, 2, 3).

According to statistics released by the Ministry of Health and Medical Education in Iran annually 33 to 38 percent of deaths are due to heart disease. Also 167 cases from thousand cases of heart disease lead to patient's death (4). Based on the results of epidemiological researches in Iran emergence of heart disease occurs approximately 20 years earlier than European and American countries. The average age of the heart diseases patients in Iran is about 55 years, while in Europe and America heart disease patients are 73 to 76 years

old, which imposes treatment costs to patients and health care systems and also reduces manpower from active and economic part of society which has significant effects on the economics (4, 5, 6). In this research we decided to have cooperation with the Tehran University of Medical Sciences and Research and Research and Ethics Committee of the Rajaie Cardiovascular Medical and Research Center, which is a tertiary center for cardiovascular medicine and heart failure programs in Tehran, Iran in order to develop a remote home care system to decrease loads from healthcare system. Rajaie Cardiovascular Medical and Research center is one of the largest cardiovascular hospitals in Asia and the center of Cardiovascular Medicine in the country.

Remote care means automatic health related data transfer to health care centers (9). This process makes facilities for health centers to monitor greater number of patients, regardless of location restrictions. This system is appropriate specifically for high-risk patients who need urgent care, older people who are at home and those who are in remote areas.

In a study conducted by the Ministry of Health of America which was a remote surveillance programs intended to provide health care to wounded war veterans suffering diabetes, heart failure, hypertension, health related data was collected and sent to the related centers. Results shows promising evidence of a decrease of 21% required repeatedly hospitalizations; re-hospitalizations decreased 19% and also average of 86% satisfaction after registration (10).

Although heart failure is not curable but some lifestyle changes (diet and daily exercise) can increase the quality and life expectancy of patients, followed by a continuous and careful monitoring of daily vital signs such as weight, blood pressure, etc. (11). However most of the patients have heart failure in hospitals and also most occupied beds. During a review specified that 21% of heart failure patients returned to the after a period 30 days after discharge. The governments in many developed countries monitor the performance of the heart centers, and the heart centers with high return of discharged patients will be penalized.

When a person is discharged from the hospital Despite having some physical limitations, debilitating effects of the disease, lack of understanding and knowledge, The patient should keep track of his/her health plan (7). So the empowerment of patients to keep track of their health is very important. Thus heart failure patients can be monitored by creating a comprehensive system of remote home care and heart disease risk classification system. High-risk patients will be specified before worsening their disease symptoms and prevent early death by timely actions, also prevent from repeatedly hospitalizations and decreasing their quality of life (8). Hence the advice of many research centers and treatment is caring, supervision, management and distance learning have significant influence on the treatment and control of chronic heart failure patients, thus main purpose of this research is proposing such a system.

Effective management of heart failure patients requires a lifestyle change, such as continuous monitoring of the disease, weight losing and low sodium diet programs. A healthy life style was presented in (12), this model indicates that the behavior of any person results from their behavioral control and intention. It is also stated that every person decisions are

affected by social norms and their behavior control. This conceptual model has wide use in explanation and prediction of individual behaviors in a way that it is widely used in health literature.

Theoretically proven that changing individual behaviors needs three elements of motivation, ability and stimulus at the same time and in the absence of above elements behavioral changes will not be possible. In most cases, people have low motivation to change their behaviors, thus another purpose of developing the remote homecare of heart failure patient's system is to increase their motivation and ability by providing right educational self-care hints and also providing timely appropriate messages (13).

Previous studies have shown that providing better support for patients in the home could have a theatrical effect on the cost and efficacy of healthcare (14). Such remote self-care systems have been developed to assist CHF patients (15), for example a system named WANDA were developed, The system aimed to help clinicians monitor patients remotely, align with individual lifestyles, aid in decision making by automatically analyzing patients data, and provide flexibility to address the needs of various patient groups (16).

2. AIM

The purpose of this study is to provide the system of remote home care for patients with heart failure, in this study three phases of study, design and optimization of the prior model and final model were described, finally was completed by evaluating the capacity of the system usability by the users.

3. MATERIAL AND METHODS

The first phase consists of assessment of factors needed in remote homecare and system functionality required for patients with chronic heart failure. In this phase, a questionnaire was designed based on applied clinical studies, American Heart Association criteria, credible management guidelines (17, 18), diagnostics self-care for heart failure patients in America and Europe and Australia (19, 20), Information from cardiologists and residents of Rajaie hospital about data items and capabilities of the remote self-care system. The questionnaire consists of four sections (Total of 51 questions): 14 questions related to patient's demographic information, 17 questions related to patient's clinical information, 8 questions related to physician and nursing and 12 questions about system functionalities. The questionnaire was designed based on research and was evaluated by five experts. The answers for each question were "the importance" of each item (value of 1 to 10) and "not necessary" (zero value), along with each closed questions an open question were considered for each item to have comments from examiners. The validity of the questionnaire was confirmed in decision group consisting five cardiologists and medical informatics and health information management professors. The reliability of the questionnaire was calculated by Cronbach's alpha test with the resulting value of 85%.

The second phase contains designing a prototype for remote home care system based on requirements from the questionnaire in the first phase of the study. To implement the system Java technologies, Android, XML, SQLite, MVC

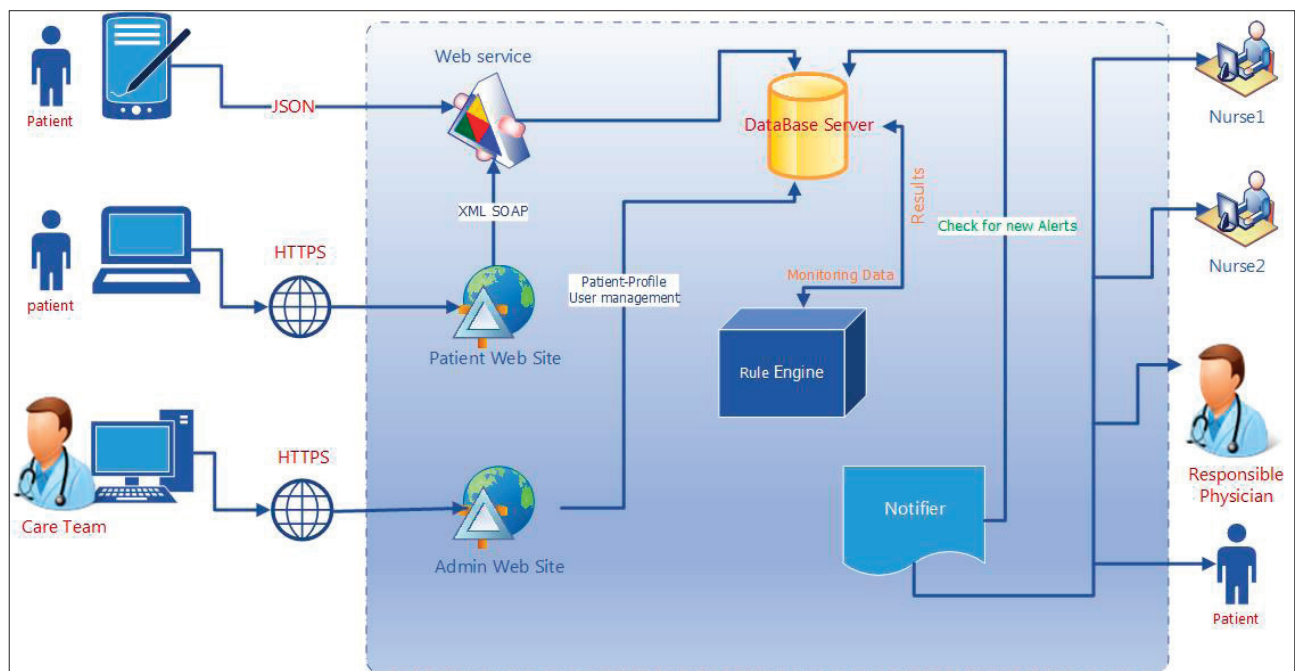


Figure 1. Modules of the prototype system

Code-first entity framework, Html5 and visual studio IDE were used. The prototype was temporarily available for the users through Internet. To optimize the prototype system 10 cardiologists and 5 residents were invited to use the system and were asked to have their comments and feedbacks.

In the third phase the final system was completed based on feedbacks from using the prototype system by users (physicians, nurses, patients) and its usability and user's satisfaction were evaluated. After requested modifications from evaluation phase the final system were setup on the hospital server and was available for cardiologists through internet. In order to evaluate usability of the final system the questionnaire for user interaction satisfaction were used.

4. RESULTS

This study was conducted to design and implement remote homecare system for heart failure patients. Requirements of this study was gathered by a questionnaire designed from clinical studies, diagnostic and credible management guidelines, information from cardiologists and residents. In this section analysis of data related to evaluation of the system by the users will be provided.

Architecture of the homecare prototype system

Based on results from needs assessment, a conceptual method was designed then a prototype in the form of mobile application for data gathering, sending to the hospital server and receiving alerts and their related instructions were implemented, and also a web based system for monitoring and management of the disease and a database specific for parameters and patient's symptoms were designed and implemented.

The conceptual model for the remote homecare system for patients with chronic heart failure disease is shown in (Figure 1), as it is shown the prototype consists of six modules, each of these modules will be described in the proceeding sections.

Care Team Module

In this module demographic and clinical information and other information related medical conditions of pa-

tients with defined profiles for each patient will be collected and facilities such as adding patient's medical history, Viewing and management of generated alerts related to current state of the patient and other information needed to manage and monitor the status of patients are provided. In order to implement the objectives of this module a web based administrative system were designed and implemented.

Data collector module

Since the patients with chronic heart failure should be able to send parameters and clinical symptoms daily through system from home, this module contains a mobile-based application and a website where patients can use any of these platforms to send the measured required parameters and clinical symptoms that have been identified in the needs assessment.

Data receiver module

To receive data sent by the patients from various platforms a module for receiving and evaluating the received data for their accuracy based on formats defined for each data element was provided. After evaluation the correct data will be saved to the database. To implement this module Web Service technology is used.

Rules engine module (data analysis module)

After needs assessment of the system and identifying the required parameters of the heart failure patient's homecare system, in order to have optimized management and control of the system and also facilitate healthcare staff to monitor and care patients it is essentially needed to have an instruction based expert system, in order to estimate patient's risks based on received parameters. Instructions for the risk assessment of the expert system were extracted from studies, management guidelines, diagnosis and self-care of heart failure patients and also questionnaires were asked from Rajaei Hospital cardiologists. The instruction decision group includes 3 cardiologist, 4 residents and 3 fellowships.

In the interview with experts, they were asked to identify parameters, important symptoms and their priorities.

Additionally some questions about sending conditional surveillance instructions in emergency conditions to patients were asked. After preparing the instructions draft a second round of interviews and questionnaires were done to assess the efficiency and effectiveness of the instructions with some other Cardiologist from Rajaei Hospital. During the interviews, each expert was asked to review the prepared parameters, messages and warnings and write their comments. Finally, the senior program specialist collects the opinions of other physicians and made final amendments to ensure the accuracy of instructions: Finally the extracted important parameters to identify heart failure patients remotely includes weight, blood pressure, heart rate and blood sugar As well as a list of symptoms that are shown in the Table 1.

Symptom
Feeling pain in your chest
Waking up at night because you could not breathe
Feeling more tired than usual
Having shortness of breath
Feeling Anorexia
Feeling Muscle cramps
Decreased urine volume

Table 1. List of symptoms in patients in our sample

The performance of analysis module is based on events, means that for every change in the patient’s clinical records or inserting new information and changing daily care, the patient data analysis module determines status of the patient and finally results of analysis will be stored in the database in the form XML data, the final output is classified in three stages of normal, alert and emergency.

Database module

Sending patients data online and store medical records and other personal information based on a unique identification for each patient requires database module. In this module all information related to heart failure patients, including medical history, demographic information and patient care data from patient registration system will be stored. Also, the result of Rule Engine analysis will be stored in the database.

Notifier module

This module is responsible for the control and alerts. After saving the analysis of disease surveillance data in the database, this module checks the database timely or on events, If there were any change in patients condition the module will generate alerts based on basic definitions which identified by the healthcare team, This module produces messages or warnings tailored to the patient’s condition and send these alerts to patients, physicians and medical care. The definitions are shown in (Table 2).

The patient's condition	Patient	The first nurse	The second nurse	The doctor in charge
Normal	□	□		
Warning	□	□	□	
Emergency	□	□	□	□

Table 2. Basic Definitions care team Implementation of remote homecare system for patients with chronic heart failure

Web-based surveillance system

Web-based surveillance system is the proposed system interface for patients, nurses and cardiologists. This system requires a healthcare technician (One of trained hospital

nurses) to monitor and register patients data. The technician after login to the system, in the home page will see a list of registered patients. When a patient was asked by the doctor to register in the system, the patient will be referred to the nurse, the nurse will login to the system and then by clicking “New Patient” and filling the required patient data, the process of registering the patient will be completed. The system has three levels information for each patient, patient’s demographic information (first level), patient records and medical records (level II) and daily healthcare information (third level).

Patient’s demographic information registration on the first level: for registering first level of patient information the nurse responsible for the registration system of patients on the home page that shows the patient list Clicks a link titled “Level 1” and completes the requested patient information. The first level contains information such as education, employment status, disease start year, cause of heart failure, and level of sensitivity due to heart failure care. Care sensitivity level is divided into two levels of high-sensitivity and low-sensitivity, for high sensitive data the patient should enter the requested information on a daily basis and otherwise will receive a warning from the system.

Patient’s medical records on the second level: The second level of information contains medical and laboratory records for the patient, Information at level cause of admission, pregnancy, disease classes (NYHAF Function-Class), co-morbidities, used medications, the type of heart rhythm and laboratory parameters. Since the process of changing the items in the second level of clinical information with respect to time is very valuable for doctors in monitoring the disease, the patient’s clinical information in the second level on each patient visit to the medical center will be recorded as new information and previous information of the patient at this level on earlier won’t be editable.

Daily healthcare information recorded in the third level: The third level of the patient’s clinical records includes vital parameters and symptoms that should be sent by the patients on daily basis through a website or a mobile application system, in this level data will be sorted by date and prepared in order to be visited by doctors and processed by data analysis module.

Dashboard to check the status of patients

In the dashboard page which is available for physician and healthcare team members, by entering the desired date and clicking the Search button, a list of patient’s states will be shown from the date to a week after. There are different graphs in the dashboard that all of them have period of a week in horizontal axis at intervals of 4 hours a week.

As shown in Figure 2, the first graph is the results of the analysis of daily patient healthcare data at intervals of 4 hours a week that are drawn in 3 colors. Green means normal and yellow means caution and red means the state of emergency. The vertical axis of the graph contains outputs of analyzer module as well as an unregistered mode for the time in which data was not recorded.

Other charts that were plotted just below the results of the analysis of patient’s data are mapped to parameters of a patient’s daily healthcare such as heart rate, weight, blood pressure, blood sugar and symptoms. These diagrams, for



Figure 2. Evaluation Dashboard

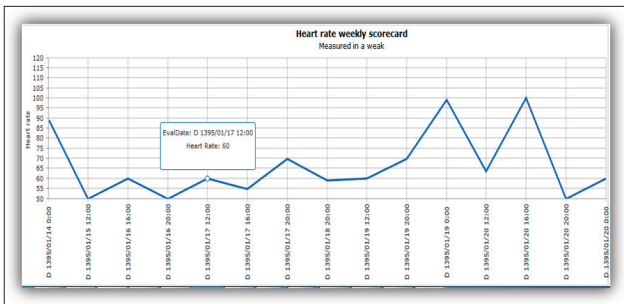


Figure 3. Evaluation Dashboard

example results diagram, plot values within an interval of 4 hours in a week. The charts are drawn below each other so that the physician can easily investigate the process of changing patient’s condition and its effective parameters. For example, when at a certain time in the results chart the patient’s condition is emergency, the doctor can check the parameters of daily healthcare charts of that time or even earlier time and find the parameters that are the cause of current state of the patient (Figure 3 to 4).

Posting patient’s daily healthcare information of the third level through the website

After registering the patient in the remote homecare system by the personnel, the patient can login to the system by their national code and record needed information.

Posting patient’s daily healthcare information of the third level through mobile application

To facilitate registering data by heart failure patients in the remote homecare system of chronic heart failure patients, a mobile application is developed. Healthcare personnel after registering the patient in the system install the application on the patient’s smart phone. After running the application a login page will be shown (Figure 5) to enter username and password, the personnel will enter the requested data and then the main menu of the system will be shown. In this way there will be no need to enter authentication information in future and the main menu will be shown after running the application. The patient

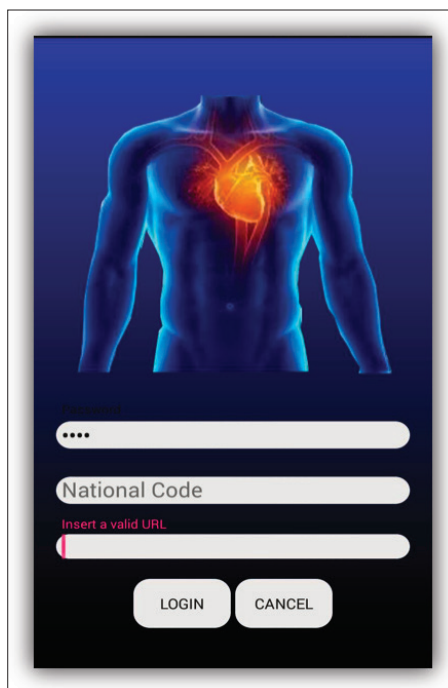


Figure 5. Telemonitoring Application

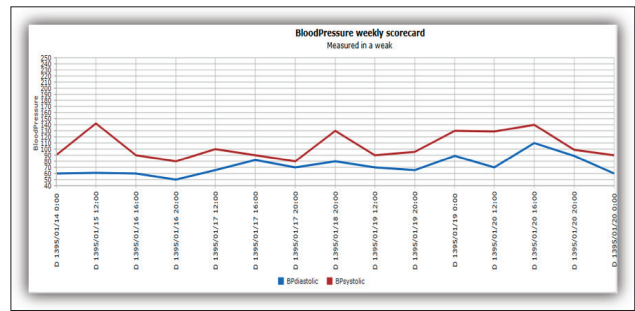


Figure 4. Evaluation Dashboard

can enter healthcare information in the application and send them through internet. By using this application the patient disease will be under the control and monitoring of healthcare team. The application includes sending daily healthcare information, education information (life style, self-care notes), some information about heart failure and daily alerts and reminders for referring to the clinic.

5. DISCUSSION

As discussed earlier, identifying individuals at risk while they are at home is very valuable because it has the potential to reduce emergency hospital admissions and provide a just-in-time intervention that helps a patient better understand the cause of deterioration and the action he or she needs to take to overcome it (21).

While the literature on expert systems, suggests using ontologies and machine learning to learn and predict rules (22, 23, 24), this study found that a fixed set of simple rules to generate alert messages was what the users requested and, hence, they were incorporated in the design.

However, after using the system and experiencing the number of alerts generated, the nurses requested customizations to the rules. For instance, they suggested having a capability to store a “dry weight” for each patient rather than the values implemented in the system, and flexibility to change the rules to accommodate new research that suggests that

weight variances of four pounds or more are an indication of high risk.

Still, the study was effective in identifying eight deteriorating cases, even with the simple rule set it used. Three of the events resulted in admissions and five were completely controlled while the patient was at home.

Specifically, the rule categories that were effective in identifying patients at high risk were:

- a) High Heart Rate Alert;
- b) High Blood Pressure Alert;
- c) Weight Gain;
- d) Shortness of Breath.

Furthermore, strategies that were effective in managing these conditions included:

- a) Taking missed medications;
- b) Increasing diuretics;
- c) Reducing salt intake.

Overall, meaningful patient interactions occurred at various stages of the self-care model. First, device usage statistics illustrate that patients monitored their vitals more frequently after using the system. Frequency of monitoring is very important; because it allows patients to recognize precursors to deterioration sooner and, hence, act faster. Patient reports confirmed that the system was instrumental in helping them see patterns especially for the parameters they have not monitored before such as heart rate. Furthermore, patients stated that, through self-monitoring, they were able to take corrective actions even before the HF nurse called them. Findings also show that there was an improvement in the quality of life for patients, who were actively using the system, with the exception of one patient.

5.1. STUDY IMPLICATIONS

The implications of this research on Information Systems research and practice are as follows. As design science research, this study described the requirements and process for developing a home telemonitoring system that was accepted and used in context. Even though this system had basic features, it was able to identify cases in which patients' conditions deteriorated. In addition, evaluation of the system showed an improvement in the quality of life for patients, this finding suggests that improvements in technology could have a positive impact on telemonitoring systems.

Results of this work elevate the importance of continued research in developing systems to monitor patients for possible signs of deterioration. Such technology may be extremely useful in alerting patients and nurses to high-risk symptoms. The use of this system demonstrates potential to also impact populations that struggle with their conditions and wish to avoid hospital readmission (23). While a limited number of cases were identified and managed in the three-month study, the impact on patients was significant since emergency hospital admissions place a burden on patients and providers.

5.2. LIMITATIONS

There are several limitations to this study. First, the setting and sample size affect generalizability of findings because it focuses a specific instantiation in a single healthcare institution, hence, the size, status, culture and resources of the hospital influence the adaptation processes. However, Nielson and Lauder (1993) argue that 3-5 participants is a sufficient

sample size to test the usability of a system. It is also expected that the findings will motivate future research to replicate the artifact and test the design in other healthcare contexts.

Second, recruitment and participation were problematic. Reasons cited for recruitment challenges included fear of change, privacy concerns, and limited physician buy-in (25).

Third Gaps in data were also a major challenge because nurses didn't know how to interpret the data after days of missing values. For example, it was difficult to identify whether a weight gain of five pounds occurred gradually over several days or suddenly. Findings showed that these gaps occurred for several reasons such as patients forgetting to measure, technical issues with phone or devices, traveling, being admitted to the hospital or undergoing rehabilitation.

6. CONCLUSION

This paper described the design of a telehealth system for heart failure self-care that aims to: 1) overcome the gap that occurs when patients transition from the hospital to home environment, and 2) reduce readmissions. The system builds on the behavior model such that it sends messages to patients that potentially trigger behavior change. It also facilitates daily communication among patients and heart failure clinicians so any deterioration in health could be identified immediately and helps to prevent any deterioration in patient's health by taking just in-time interventions due to daily monitoring of HF parameters.

Furthermore, patients and providers articulated the challenges they faced with the system and opportunities to enhance future designs. Suggested improvements included additional communication mechanisms, customization of rules and alerts, more charting capabilities.

Overall, the research shows that the rule-based home monitoring system supported heart failure self-care. Patients used the devices to monitor themselves, identify deterioration, and treat their condition. Results showed an improvement in the quality of life for three patients and the system is still in use by Rajae Health center and the patients. In addition, nurses used the system to identify patients at-risk and suggest treatments. Deteriorations were identified and cases were managed accordingly. Communication also improved and occurred between visits, when needed.

Future work will focus on incorporating feedback from the patients into the design of the system. A predictive analytics module is also under development for trend analysis and to predict blood pressure, weight, HGA1C levels in advance. A larger clinical trial is also planned to demonstrate the impact of the system on health outcomes and readmissions.

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- Author Contribution: R.S., M.J. M.M. made substantial contribution to conception and design (acquisition of data, analysis and interpretation of data). R.S., M.J., N.N. revised it critically and gave final approval of the version to be submitted.

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