

ASSESSMENT OF ELECTRONIC COLLECTION
&
VISUAL DISPLAY OF ECOLOGICALLY VALID CLINICAL DATA
IN
PATIENTS WITH HEART FAILURE

by
Cubby L. Gardner

Dissertation submitted to the Faculty of the
Daniel K. Inouye Graduate School of Nursing Philosophical Doctorate Program
Uniformed Services University of the Health Sciences
In partial fulfillment of the requirements for the degree of
Doctor of Philosophy 2015

Distribution Statement

Distribution A: Public Release.

The views presented here are those of the author and are not to be construed as official or reflecting the views of the Uniformed Services University of the Health Sciences, the Department of Defense or the U.S. Government.



GSN

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
DANIEL K. INOUE
GRADUATE SCHOOL OF NURSING
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4712



September 8, 2015

MEMORANDUM FOR PRESIDENT, USU

THROUGH: CHAIR, BOARD OF REGENTS

Subject: Certification of Doctoral Student

The graduate student listed below is presented for certification to receive the Doctor of Philosophy effective upon your approval:

CUBBY LEE GARDNER

DOCTOR OF PHILOSOPHY

DOCTOR OF NURSING SCIENCE PROGRAM

Attached is the candidate's Certification of Successful Completion of the Final Examination. Also attached are the Certification of Authorized use of Copyrighted Materials, Dissertation Abstract, Dissertation Title Page and Curriculum Vitae.



Carol A. Romano PhD, RN, FAAN
Dean, Graduate School of Nursing

Attachments:
As stated



GSN PhD Program in Nursing Science

Dissertation Defense

Doctor of Philosophy Degree

NAME: CUBBY LEE GARDNER

TITLE: Assessment of Electronic Collection and the Visual Display of Ecologically Valid Clinical Data in Patients with Heart Failure

Date of Defense: 26 August 2015 from 1500 to 1700

The decision of the Dissertation Committee is:

PASS

- A. Both the dissertation and the oral defense are satisfactory: ✓ *aug 26, 2015 CR*
- B. Minor changes are recommended by the Dissertation Committee that is to be made to the satisfaction of the Dissertation Chairperson: ✓

DEFER

- A. Major changes in the dissertation are required. Changes must be made to the satisfaction of the Dissertation Chairperson: _____
- B. Major changes in the dissertation are required. Changes must be made to the satisfaction of the Dissertation Committee and at that time the oral defense will be rescheduled: _____

FAIL: Neither the oral performance nor the dissertation is adequate: _____

SIGNATURES OF THE COMMITTEE:

Chairperson: Carol A. Romano PhD, RN, FAAN Signature: _____

Member: Harry B. Burke MD Signature: _____

Member: Marla DeJong PhD, RN, COL, USAF Signature: _____

Member: Susanne Gibbons PhD, RN Signature: _____

Approval/Disapproval

Director, Doctoral Program: _____ Date: *26 Aug 2015*

Approval/Disapproval

Dean, Graduate School of Nursing: _____ Date: *28 Sept 2015*



UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

GSN PhD Program in Nursing Science
PhD Degree Certification

NAME: CUBBY LEE GARDNER

Degree Date: 5 October 2015

Total Course Units: [REDACTED]

Date passed dissertation proposal oral examination: 24 September 2014

Date passed dissertation oral defense: 26 August 2015

Date dissertation accepted by the GSN: 21 September 2015

I certify that the above named student has fulfilled all requirements for the PhD degree.

Chairperson:

Signature: [REDACTED]

Approval/Disapproval

Director, Doctoral Program: [REDACTED]

Date: 21 Sept 2015

Penny F. Pierce PhD, RN, FAAN

Approval/Disapproval

Dean, Graduate School of Nursing [REDACTED]

Date: 28 Sept 2015

Carol A. Romano PhD, RN, FAAN

COPYRIGHT STATEMENT

The author hereby certifies that the use of any copyrighted material in the dissertation manuscript entitled: *Assessment of Electronic Collection and the Visual Display of Ecologically Valid Clinical Data in Patients with Heart Failure* is appropriately acknowledged and, beyond brief excerpts, is with the permission of the copyright owner.



Cubby L. Gardner

August 26, 2015

DISCLAIMER

The views expressed herein are those of the author and do not reflect official policy or position of the Uniformed Services University of the Health Sciences, the Department of Defense, or the United States Government. All devices met Protected Health Information (PHI) and Personally Identifiable Information (PII) requirements. WRNMMC IRB Protocol number 400924-4.

**ASSESSMENT OF ELECTRONIC COLLECTION
&
VISUAL DISPLAY OF ECOLOGICALLY VALID CLINICAL DATA
IN
PATIENTS WITH HEART FAILURE**

**by
Cubby L. Gardner**

**Dissertation submitted to the Faculty of the
Daniel K. Inouye Graduate School of Nursing Philosophical Doctorate Program
Uniformed Services University of the Health Sciences
In partial fulfillment of the requirements for the degree of
Doctor of Philosophy 2015**

ABSTRACT

Title of Dissertation

**Assessment of Electronic Collection and the Visual Display of Ecologically Valid
Clinical Data in Patients with Heart Failure**

Cubby L. Gardner, Doctor of Philosophy, 2015

Dissertation directed by:

**Carol Romano, PhD, RN, FAAN, Professor & Dean, Daniel K. Inouye Graduation
School of Nursing**

Background: Accurate patient information is essential for patient management. Unfortunately, between-visit clinical information collection methods are incomplete and inaccurate leaving clinical information gaps. Patient recollected symptoms may not be sufficient accurate for disease management. This is a report of patient use of electronic devices to collect physiologic and subjective state data at night, their ratings of device usability, and whether clinicians rated the visual display of data as usable.

Methods: This was a descriptive exploratory study of 39 clinical patients with heart failure, mean age 68.1. Patients were provided with five electronic devices to record bodyweight, blood pressure, heart rate, blood oxygen saturation, physical activity, and subjective state data for six nights. Device use was assessed by calculating the ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected. Patients

rated the usability of each device using the System Usability Scale (SUS) and compared to the expected mean of 68 out of 100 using Student's t-test.

The author constructed a single-screen visual display of all variables using three stacked temporal dimensions: 24-hours in hours, 8-hours in minutes, and 30-minutes in seconds. The dimensions were dynamically linked so that clicking on one dimension displayed the dimensions below it. Fourteen clinicians rated the display using the SUS. Statistical tests were calculated using R version 3.1.3; significance was set at $p < 0.05$.

Results: Patients were able to use all devices. The body weight scale was used less than expected O/E 0.80; the blood pressure device, iPad, and oximeter were used as expected, O/E 1.03, 1.10, and 0.90, respectively; the actigraph was used more than expected O/E 1.93. The SUS grand mean score was 86.9 and the Intraclass Correlation Coefficient grand mean score was 0.73. For each device, the SUS mean score and the ICC score was: scale, 84.5, 0.66, respectively; blood pressure device, 89.7, 0.79, respectively; iPad-based subjective state application 85.7, 0.70, respectively; pulse oximeter 87.6, 0.61, respectively; and actigraph 85.2, 0.68, respectively, $p < 0.0001$. Fourteen clinicians evaluated the display and rated it significantly higher than the expected score of 68 from the literature.

Discussion: Patients rated devices used at home at night to collect clinical data as highly usable. This finding supports the feasibility of collecting large amounts of ecologically valid physiologic and subjective state data from patients at home overnight and organize it into a dynamic single-page of multiple temporal abstractions arranged hierarchically that is usable by clinicians.

**Board of Regents
Abbreviated Curriculum Vitae**

Name: Cubby Lee Gardner

Department: PhD Program, Daniel K. Inouye Graduate School of Nursing

Candidate for: PhD in Nursing Science

Citizenship: U.S.

Education:

M.S.N.	Texas Woman's University, Denton, TX	2006
B.S.N.	Texas Woman's University, Denton, TX	2005
A.D.N.	North Central Texas College, Gainesville, TX	1995

Military Assignments:

Year	Title	Institution
08/2012 to Present	PhD Student	Uniformed Services University of the Health Sciences Daniel K. Inouye Graduate School of Nursing Bethesda, MD
Apr 2010 to Jul 2012	Family Nurse Practitioner	633 rd Medical Operations Squadron Langley AFB, VA
Jun 2009 to Mar 2010	Senior Medical Officer	Provincial Reconstruction Team (PRT) Nangarhar, Jalalabad, Afghanistan
Aug 2008 to Mar 2009	Family Nurse Practitioner	1 Medical Operations Squadron Langley AFB, VA

Licensure:

1995-Present	Texas Board of Nurse Examiners	618132
--------------	--------------------------------	--------

Certification(s):

<u>Inclusive Years</u>	<u>Specialty</u>	<u>Certifying Body</u>
2007-Present	Family Nurse Practitioner	AANP

HONORS AND AWARDS

Award	Awarded By
Bronze Star Medal	U.S. Air Force
Air Force Commendation Medal	U.S. Air Force

Air Force Outstanding Unit Award
Air Force Good Conduct Medal
National Defense Service Medal
Afghanistan Campaign Medal
Global War on Terrorism Service Medal

U.S. Air Force
U.S. Air Force
U.S. Air Force
U.S. Air Force
U.S. Air Force

PUBLICATIONS

Papers submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Gardner, Cubby L., Burke, Harry B. (2015) Comparison of Clinic Versus Living Laboratory Assessment of Patients with Heart Failure (submitted to the Journal of Medical Systems on March 31, 2015)

Gardner, Cubby L., Flanagan, Michael C, Franklin, C, John-Sawyers, C, Walsh-Pouch, S, Bryant, F. Joyce, . . . Burke, Harry B. (2015). *Electronic physiologic and subjective data acquisition in home-dwelling heart failure patients: An assessment of patient use and perception of usability.* (submitted to the Journal of the American Medical Informatics Association on May 1, 2015)

Gardner, Cubby L., Liu, Fang, Fontelo, Paul, , Flanagan, Michael C. (2015), *Display and Usability of Patient-Collected Disease-Specific Clinical Information.* (submitted to Journal of the American Medical Informatics Association on September 5, 2015)

SCHOLARLY PRESENTATIONS

Podium Presentations

The Electronic Collection and Presentation of Nocturnal Heart Failure Information
Home Healthcare and Hospice Information Technology Conference, November 15, 2015, Washington DC

Poster Presentations

Reliability of Two Portable Heart Rate Measurement Devices
TriService Nursing Research and EBP Dissemination Course, September 16, 2014, San Antonio, TX

The Usability of Electronic Devices to Collect Nocturnal Heart Failure Information
Uniformed Services University of the Health Sciences, May 14, 2015, Bethesda, MD

The Integrated Display for Physiologic Monitoring
2015 Military Health Services Research Symposium, August 17-20, 2015, Ft Lauderdale, FL

Abstracts

The Application of Human Factors to Physiologic Monitoring
HFM-254 Symposium on Health Surveillance and Informatics in Missions: Multidisciplinary
Approaches and Perspectives, October 12-14, 2015, Paris, France

Electronically Collecting Nocturnal Heart Failure Information
2015 AMIA Annual Symposium, November 14-18, 2015, San Francisco, CA

External Peer-Reviewed Grant Awards:

Year	Role	% Effort	PI	Title	Funding Agency	Amount
2014	PI	80	Cubby Gardner	Electronic Collection and Presentation of Nocturnal Heart Failure Information	USUHS	\$2,500

APPROVAL SHEET

Title of Dissertation: Assessment Of Electronic Collection & Visual
Display Of Ecologically Valid Clinical Data In
Patients With Heart Failure

Name of Candidate: Cubby L. Gardner MS, RN, FNP-C

Dissertation and Abstract Approved:

Carol A. Romano, PhD., RN, FAAN, FACMI
Dean and Professor
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University of the Health
Sciences

Approval Date:

**Board of Regents
Abbreviated Curriculum Vitae**

Name: Cubby Lee Gardner

Department: PhD Program, Daniel K. Inouye Graduate School of Nursing

Candidate for: PhD in Nursing Science

Citizenship: U.S.

Education:

M.S.N.	Texas Woman's University, Denton, TX	2006
B.S.N.	Texas Woman's University, Denton, TX	2005
A.D.N.	North Central Texas College, Gainesville, TX	1995

Military Assignments:

Year	Title	Institution
08/2012 to Present	PhD Student	Uniformed Services University of the Health Sciences Daniel K. Inouye Graduate School of Nursing Bethesda, MD
Apr 2010 to Jul 2012	Family Nurse Practitioner	633 rd Medical Operations Squadron Langley AFB, VA
Jun 2009 to Mar 2010	Senior Medical Officer	Provincial Reconstruction Team (PRT) Nangarhar, Jalalabad, Afghanistan
Aug 2008 to Mar 2009	Family Nurse Practitioner	1 Medical Operations Squadron Langley AFB, VA

Licensure:

1995-Present	Texas Board of Nurse Examiners	618132
--------------	--------------------------------	--------

Certification(s):

<u>Inclusive Years</u>	<u>Specialty</u>	<u>Certifying</u>
<u>Body</u> 2007-Present	Family Nurse Practitioner	AANP

HONORS AND AWARDS

Award

Bronze Star Medal

Awarded By

U.S. Air Force

Air Force Commendation Medal	U.S. Air Force
Air Force Outstanding Unit Award	U.S. Air Force
Air Force Good Conduct Medal	U.S. Air Force
National Defense Service Medal	U.S. Air Force
Afghanistan Campaign Medal	U.S. Air Force
Global War on Terrorism Service Medal	U.S. Air Force

PUBLICATIONS

Papers submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Gardner, Cubby L., Burke, Harry B. (2015) Comparison of Clinic Versus Living Laboratory Assessment of Patients with Heart Failure (submitted to the Journal of Medical Systems on March 31, 2015)

Gardner, Cubby L., Flanagan, Michael C, Franklin, C, John-Sawyers, C, Walsh-Pouch, S, Bryant, F. Joyce, . . . Burke, Harry B. (2015). *Electronic physiologic and subjective data acquisition in home-dwelling heart failure patients: An assessment of patient use and perception of usability.* (submitted to the Journal of the American Medical Informatics Association on May 1, 2015)

Gardner, Cubby L., Liu, Fang, Fontelo, Paul, , Flanagan, Michael C. (2015), *Display and Usability of Patient-Collected Disease-Specific Clinical Information.* (submitted to Journal of the American Medical Informatics Association on September 5, 2015)

SCHOLARLY PRESENTATIONS

Podium Presentations

The Electronic Collection and Presentation of Nocturnal Heart Failure Information
Home Healthcare and Hospice Information Technology Conference, November 15, 2015, Washington DC

Poster Presentations

Reliability of Two Portable Heart Rate Measurement Devices
TriService Nursing Research and EBP Dissemination Course, September 16, 2014, San Antonio, TX

The Usability of Electronic Devices to Collect Nocturnal Heart Failure Information
Uniformed Services University of the Health Sciences, May 14, 2015, Bethesda, MD

The Integrated Display for Physiologic Monitoring
2015 Military Health Services Research Symposium, August 17-20, 2015, Ft Lauderdale, FL

Abstracts

The Application of Human Factors to Physiologic Monitoring

HFM-254 Symposium on Health Surveillance and Informatics in Missions:

Multidisciplinary Approaches and Perspectives, October 12-14, 2015, Paris, France

Electronically Collecting Nocturnal Heart Failure Information

2015 AMIA Annual Symposium, November 14-18, 2015, San Francisco, CA

External Peer-Reviewed Grant Awards:

Year	Role	% Effort	PI	Title	Funding Agency	Amount
2014	PI	80	Cubby Gardner	Electronic Collection and Presentation of Nocturnal Heart Failure Information	USUHS	\$2,500

ACKNOWLEDGMENTS

I would like to thank the members of my committee for their extraordinary patience, guidance and wisdom. I would also like to thank my fellow doctoral students “the warrior scholars” for their support, encouragement, and insights. I would also like to thank Dr. Paul E. Rapp, Dr. David O. Keyser, Dr. Dominic Nathan, and Ms. Kylee Bashirelahi for material support for data collection. I would also like to thank the Dr. Paul Ling for specialized instruction in R statistical software. Special thanks to the faculty and staff of the Uniformed Services University of the Health Sciences and the Daniel K. Inouye Graduate School of Nursing, administrative and other support and without whose help this research could not have been completed.

This investigation was supported by intramural funding from the Uniformed Services University of the Health Sciences through the Daniel K. Inouye Graduate School of Nursing.

DEDICATION

To, Jennifer Kay Gardner, my wife, best friend, coach, and cheerleader.

COPYRIGHT STATEMENT

The author hereby certifies that the use of any copyrighted material in the dissertation manuscript entitled: *Assessment of Electronic Collection and the Visual Display of Ecologically Valid Clinical Data in Patients with Heart Failure* is appropriately acknowledged and, beyond brief excerpts, is with the permission of the copyright owner.

— 

Cubby L. Gardner

August 26, 2015

DISCLAIMER

The views expressed herein are those of the author and do not reflect official policy or position of the Uniformed Services University of the Health Sciences, the Department of Defense, or the United States Government. All devices met Protected Health Information (PHI) and Personally Identifiable Information (PII) requirements. WRNMMC IRB Protocol number 400924-4.

ABSTRACT

Title of Dissertation

Assessment of Electronic Collection and the Visual Display of Ecologically Valid
Clinical Data in Patients with Heart Failure

Cubby L. Gardner, Doctor of Philosophy, 2015

Dissertation directed by:

Carol Romano, PhD, RN, FAAN, Professor & Dean, Daniel K. Inouye

Graduation School of Nursing

Background: Accurate patient information is essential for patient management. Unfortunately, between-visit clinical information collection methods are incomplete and inaccurate leaving clinical information gaps. Patient recollected symptoms may not be sufficient accurate for disease management. This is a report of patient use of electronic devices to collect physiologic and subjective state data at night, their ratings of device usability, and whether clinicians rated the visual display of data as usable.

Methods: This was a descriptive exploratory study of 39 clinical patients with heart failure, mean age 68.1. Patients were provided with five electronic devices to record bodyweight, blood pressure, heart rate, blood oxygen saturation, physical activity, and subjective state data for six nights. Device use was assessed by calculating the ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected.

Patients rated the usability of each device using the System Usability Scale (SUS) and compared to the expected mean of 68 out of 100 using Student's t-test.

The author constructed a single-screen visual display of all variables using three stacked temporal dimensions: 24-hours in hours, 8-hours in minutes, and 30-minutes in seconds. The dimensions were dynamically linked so that clicking on one dimension displayed the dimensions below it. Fourteen clinicians rated the display using the SUS. Statistical tests were calculated using R version 3.1.3; significance was set at $p < 0.05$.

Results: Patients were able to use all devices. The body weight scale was used less than expected O/E 0.80; the blood pressure device, iPad, and oximeter were used as expected, O/E 1.03, 1.10, and 0.90, respectively; the actigraph was used more than expected O/E 1.93. The SUS grand mean score was 86.9 and the Intraclass Correlation Coefficient grand mean score was 0.73. For each device, the SUS mean score and the ICC score was: scale, 84.5, 0.66, respectively; blood pressure device, 89.7, 0.79, respectively; iPad-based subjective state application 85.7, 0.70, respectively; pulse oximeter 87.6, 0.61, respectively; and actigraph 85.2, 0.68, respectively, $p < 0.0001$. Fourteen clinicians evaluated the display and rated it significantly higher than the expected score of 68 from the literature.

Discussion: Patients rated devices used at home at night to collect clinical data as highly usable. This finding supports the feasibility of collecting large amounts of ecologically valid physiologic and subjective state data from patients at home overnight and organize it into a dynamic single-page of multiple temporal abstractions arranged hierarchically that is usable by clinicians.

TABLE OF CONTENTS

LIST OF TABLES	xiv
LIST OF FIGURES	xv
CHAPTER 1: Introduction	16
Background	17
Clinical information gap between visit	17
Electronic collection of patient data	18
Electronic presentation of patient information	20
Conceptual Framework	21
Purpose	22
Significance	22
Nursing significance	23
Operational Definitions	24
Research Questions	26
Research Question 1	26
Research Question 2	26
Research Question 3	27
Research Design	27
Setting and sample	27
Electronic data collection procedures	28
Electronic display procedures	29
Assumptions	30
Organization of the document	31
CHAPTER 2: Comparison of Clinic Versus Living Laboratory Assessment of Patients with Heart Failure	35
Abstract	35
Introduction	36
Current approach to the acquisition of clinical heart failure information	37
Clinic-based assessment	37
Retrospective assessment	37
Subjective assessment nonconcurrent with objective measures	38
An effective approach to the acquisition of clinical heart failure information	39
In-home assessment	40
Real-time collection	40
Subjective assessment with concurrent objective measures	41
Additional benefits with data transmission and storage	41
Conclusion	43

CHAPTER 3: Electronic Physiologic and Subjective Data Acquisition in Home-Dwelling Patients with Heart Failure: An Assessment of Patient Use and Perception of Usability 45

Abstract	45
Introduction	46
Methods	47
Setting and participants	47
Procedure	48
Data collection devices	49
System Usability Scale	51
Statistical methods	52
Results	52
Discussion	55

CHAPTER 4: The Display and Usability of Patient-Collected Heart Failure-Specific Information 66

Abstract	66
Introduction	67
Methods	68
Setting and sample	68
Procedure	68
Heart Failure Variables	69
Single Screen Display	71
System Usability Scale	74
Statistical Methods	75
Results	76
Discussion	77

Chapter 5: Conclusion..... 87

Introduction	87
Summary of the study	87
Overview of the problem	87
Purpose statement	88
Methodology	89
Major findings.....	89
Discussion	91
Clinical information gap between visit	93
Electronic collection of patient data	95
Electronic presentation of patient information	97
Strengths and Limitations	99
Recommendations	99
Conclusion	100

REFERENCES 103

Appendix A 112

Appendix B	114
Appendix C	124
Appendix D	129
Appendix E	136

LIST OF TABLES

Table 1.	Cleveland & McGill (1985) rank order of perceptual tasks by accuracy.	32
Table 2.	Description of patient populations	59
Table 3.	Patient device use.....	60
Table 4.	The mean System Usability Scale (SUS) scores and 95% confidence interval (CI) by device and the intraclass correlation coefficients (ICC) and 95% confidence interval by device. All scores were significantly different than expected by chance ($p < 0.0001$).....	61
Table 5.	Comparison of mean use observed-expected ratio (O/E) and overall System Usability Scores (SUS) by device and by New York Heart Association functional classifications (NYHA).....	62
Table 6.	Subjective state assessment statements from iPad-based subjective state assessment application	81
Table 7.	Demographics of clinician sample (N=14)	82
Table 8.	Clinician System Usability Scale mean scores and confidence intervals (CI) for electronic display of clinical information compared to mean score of 68.....	83
Table 9.	Patient device use.....	101
Table 10	The mean System Usability Scale (SUS) scores and 95% confidence interval (CI) by device and the intraclass correlation coefficients (ICC) and 95% confidence interval by device. All scores were significantly different than expected by chance ($p < 0.0001$).....	102

LIST OF FIGURES

Figure 1.	Data, information and knowledge model according to Choo (20).	33
Figure 2.	Graphical representation of patient data collection tasks.	34
Figure 3.	Graphical representation of patient data collection tasks.	63
Figure 4.	Devices for collecting heart failure data	64
Figure 5.	iPad-based subjective question assessment application.	65
Figure 6.	iPad-based subjective question assessment application	84
Figure 7.	Electronic display of nocturnal heart failure information showing the interactive 24-hour view (arrows 2-4), 8-hour view (arrow 5), and 30-minute view (arrow 6-8), arrayed onto a single screen.....	85
Figure 8.	Additional detail showing subjective question set (arrow 9), and discrete values for 1-second level data on vertical cursor (arrow 10).....	86

CHAPTER 1: Introduction

Patient reported information about signs and symptoms and subjective states is a critical part of patient assessment and the diagnostic process. However, patient reported information during a healthcare encounter is often dependent on memory and lacks clarity and accuracy about trends or patterns of symptoms patients experience at home between clinic visits. In addition, there is little or no information available to a clinician regarding patient signs and symptoms experienced at night. This clinical information gap between healthcare encounters is difficult for clinicians to fill with complete and accurate clinical information upon which to base clinical management decisions. This is particularly true of patients with heart failure resulting from the complexity of heart failure and its management. One proposed solution to improve the accuracy of assessing patient signs and symptoms and subjective states, specifically those experienced at night, is to have patients use patient-facing electronic devices (devices used by patients to collect clinical information in non-clinical settings) to collect data at home for review by the clinician at the next visit. What is not known is: 1) how well patients will collect physiologic data (weight, blood pressure, heart rate, blood oxygen saturation, and physical activity) and subjective state data (symptoms and subjective states) at night, at home using electronic devices, and 2) if a visual data display can be designed that will present large amounts of patient-collected clinical data in a way that is usable to clinicians. In this investigation the researcher assessed whether patients diagnosed with heart failure will collect data at home overnight for up to six nights, whether a temporally abstracted hierarchical display of those data can be created, and whether clinicians find the display usable.

BACKGROUND

Clinical information gap between visit

Accurate between-visit clinical information is essential for the optimal management of patients. In current practice, between-visit clinical information is obtained when the patient visits the clinic and the clinician acquires an interval history, either orally or using a written instrument. Until recently, patient-collected data were essentially limited to subjective paper-based logs and diaries that patients maintained between clinic visits (55; 102). Often, between-visit clinical information collection methods are incomplete and inaccurate (88; 100). Recalling complete and accurate clinical information is particularly difficult for patients with heart failure because of memory problems associated with heart failure itself (32; 72) and advancing age (77). Additionally, many patients with heart failure suffer a tremendous burden of nighttime symptoms including sleep-disordered breathing (74), of which they may not be aware, leading to a spiral of clinical deterioration that may go undetected until the exacerbation is severe (67; 83).

Efforts to close the temporal distance between visits have been attempted through close follow-up disease management programs; which have been associated with reduced mortality, hospitalization, and patient care cost (42; 73). Before the advent of Internet communications, close follow-up programs included such interventions as outpatient-based telephone follow-up, outpatient clinic follow-up, and home care (42; 73). Advances in telecommunication technologies have led to the use of patient-facing devices to collect physiologic and subjective state data from patients and have demonstrated positive effects on clinical outcomes in terms of all cause mortality, all cause hospital admission, heart failure

related hospital admission, health related quality of life, and health care costs (21). Devices used for this purpose are often referred to as home telemonitoring programs or remote patient monitoring.

Home telemonitoring program outcomes have been well studied in patients with heart failure and have been associated with reductions in mortality and hospitalization when compared to usual care (21; 42; 49; 51). Telemonitoring virtually reduces the temporal distance between clinic visits by creating a virtual visit. In common telemonitoring scenarios, an intermediating clinician, usually other than the patient's primary care clinician, reviews one day's worth of the patient-collected data and decides whether or not to contact the patient (6; 26; 36; 53; 54; 64; 82; 89; 94; 99). The introduction of an intermediate clinician may reduce the fidelity of patient information received by the primary care clinician. Developing a way for the primary care clinician to quickly and personally review patient collected clinical data since the last visit would improve the quality of patient information available for clinical decision-making.

Electronic collection of patient data

Noninvasive home telemonitoring devices have been seen as a way to bridge the between-visit clinical information gap by having patients collect clinical information at home between clinic visits. Clinical data collected by patients at home is more ecologically valid than data collected in the clinic because patients collect the data while performing their routine activities of daily life. Throughout the United States (U.S.) nearly 70% of adults routinely track a health indicator, such as weight, diet, exercise, blood pressure, sleep patterns, headaches for themselves or a loved one (31).

Even though there has been much research on the home telemonitoring outcomes, researchers have failed to adequately describe use and usability of devices. Many researchers fail to adequately describe the number and type of devices used to electronically collect patient data (49). The few researchers reporting remote monitoring devices use have found mixed results. Zan and colleagues (107) found that in younger patients with heart failure (age 53 ± 17 years) patient-facing mobile device use, assessed by self-report of use, is feasible for improving patient engagement; while Svagard and associates (93) found that in a small sample of patients with heart failure smart phone technologies were reported as too difficult to use.

A number of researchers classify home telemonitoring systems into four categories, including 1) automated device-based telemonitoring, 2) mobile telemonitoring, 3) automated interactive voice response systems, and 4) video consultation with vital signs transmitted over standard telephone lines (11; 21; 49). Automated device-based systems are electronic devices such as scales or blood pressure devices that record and transmit data to a central location. Mobile telemonitoring systems employ patient-facing devices to collect and transmit data over the wireless Internet through smart phones, and other such devices. Automated interactive voice response systems allow patients to enter data by touch-tone keypad in response to computer generated voice prompts from the telephone system. Video consultation involves the use of video telecommunications equipment to establish a two-way link between the patient and a clinician; these systems may or may not be able to transmit physiologic data. Kitsiou and colleagues (49) report that automated device-based systems can be further sub-categorized as systems that transmit only numeric data such as weight and

blood pressure, systems that transmit responses to symptom questionnaires, and systems that do both.

Electronic presentation of patient information

Frequent or continuous automated data collection can result in large data sets. These data must be organized and presented in a way that is usable to clinicians. Systems that visually display real-time patient data are commonly used in critical care environments. Such systems are capable of simultaneously displaying multiple temporal streams of clinical information and tabular numeric and waveform data in real time (68).

Powsner and Tufte (71) developed an early version of patient data visualization by graphically representing a patient medical record. However, this display was limited to statically representing numerical information from the patient's record. Plaisant and colleagues (69) devised LifeLine™, a time-oriented method to create a broadly applicable display of a personal history on a common timeline. Their methods involved visual graphics depicting points along a timeline representing significant events of an individual's history, in effect creating a temporal index of events. Innovative work on TimeLine™ by Bui and Aberle (17) found a way to contextually combine numeric and categorical data to provide contextual information aligned to a common timeline. TimeLine, mapped and reorganized data from multiple sources into a graphical user interface, and provided improved data source integration, the ability to see more detail in the overview screen, and an overall improved graphical user interface. The data sources for these displays are from electronic health records rather than patient-collected clinical data sources.

Temporal abstraction is the process of simplifying the representation of data over time by compressing it into smaller less detailed time segments (25). Temporally abstracting

data promotes rapid visual decoding (22), and reduces cognitive burden (96). This arrangement enables clinicians to simultaneously access data at multiple levels of temporal granularity (i.e., seconds, minutes, hours, days) on the same page. The goal of this visual display of patient-collected data is to provide the patient's primary care clinician with a way to quickly evaluate the enormous amounts of patient-collected data obtained between clinic visits to see how the patient's condition has progressed over time.

CONCEPTUAL FRAMEWORK

The conceptual framework for this study is the knowledge hierarchy of data, information, knowledge, which is sometimes referred to as the wisdom hierarchy, information hierarchy, or knowledge pyramid (79). The framework is widely recognized, with some slight variations in modeling. The framework illustrates the relationship between data, information and knowledge; variations of this have included the concepts of understanding, intelligence and wisdom, and the processes for transforming one element to another. The concepts of data, information, and knowledge are described in the context of clinical information systems by Blum (1986), and in the context of nursing science by Graves and Corcoran (1989). Various models of this framework agree in the definition of the main concepts (13; 20; 37; 79) that include: 1) data are individual facts or discrete symbols that objectively describe a phenomenon; a datum in isolation does not provide information; 2) information results from the collection, structure and organization of data in such a way that information is conveyed to the user; and 3) knowledge results from information that has been synthesized so that relationships can be identified and formalized; knowledge can be transformed into discoveries and to support decisions (37).

The conceptual model for this study is best illustrated in Figure 1, in the interpretation by Choo (20) in which data, information and knowledge are shown to correlate with increasing data organization on the y-axis and increasing human agency on the x-axis. The concepts in the knowledge hierarchy are arranged to provide a context and relationship.

Graphical visual displays give structure to data to reveal information (96); they provide a way to simultaneously perceive quantitative and qualitative aspects of information (22). Visualizations are used to distill data and transform it into information that is clinically useful to the viewer (91). There are a number of principles that underlie effective visual design to represent data clearly, simply, and concisely, while adhering to visual hierarchy, visual flow, and grouping (61). Cleveland and McGill (22) empirically developed and proposed a hierarchy of the perceptual task accuracy of the human visual system. Their hierarchical rankings of perceptual tasks by accuracy for specific aspects that were judged are shown in Table 1.

PURPOSE

The purpose of this study is to determine if patients diagnosed with heart failure will collect physiologic and subjective state data at home overnight and if the patient-collected data can be displayed in a way to create information that is usable to clinicians.

SIGNIFICANCE

The current dominant, visit-based clinical care model limits the amount and kind of patient information that clinicians routinely access; it is a reactive care model that makes it difficult for clinicians to adequately incorporate large amounts of patient information from outside of clinical care environments (4). Clinicians often rely on patient-provided reports of health behaviors, adherence, and assessments of the severity of symptoms upon which they

must base their clinical decision-making. Improving the way clinicians acquire, integrate and review this patient-collected personalized clinical information has the potential to improve care (58; 98).

The Military Health System (MHS) patient population and the treatments provided are analogous to the general population, and the treatments provided them (35; 46-48). Improving the way military clinicians acquire, organize and display clinical data for one patient as well as for large groups of patients has the capacity to support the shifting focus in healthcare from a disease-centric model of care to one that is population health and prevention-oriented (9). Organizing patient-collected data over time can provide clinicians with meaningful clinical information to enhance the accuracy and quality of the knowledge that informs their medical decisions.

Nursing significance

This research is significant to nursing practice and to advanced practice nursing because collecting personalized clinical information from patients in their homes is essential to improving our understanding of patients' interaction with their environment (27).

Advance Practice Registered Nurses are a major provider of ambulatory care in clinical environments where periodic and ongoing evaluation of patients is conducted.

Understanding patterns of health and illness over time is essential for creating and evaluating interventions for patients, families, and communities (41). Obtaining more ecologically valid information can improve the creation and evaluation of patient care plans. Patient-collected personalized clinical data are more ecologically valid because patients collect it as they perform their routine activities of daily life.

OPERATIONAL DEFINITIONS

Ecological validity is defined as ability to generalize information to real-life settings, such as when the patient is at home performing routine activities of daily life (81).

Measurements taken in the patient's home environment are more ecologically valid than in a clinic because the clinic is not the natural, real-life setting of the patient.

Patient-facing devices are devices intended for use by the patient to collect clinical data in non-clinical settings. Common examples of patient-facing devices include body weight scales, blood pressure devices, and pulse oximeters.

Device use is defined as the observed use divided by expected use, where 1 represents observed use equal to expected use.

Expected device use is defined for each device:

- Scale – once daily, in the evening
- Blood pressure device – twice daily, morning and evening
- iPad-based subjective state assessment – at least twice daily, and during the night if awoken with symptom change
- Pulse oximeter – overnight (8 hours)
- Actigraph – overnight (8 hours)

Usability is an abstract concept, defined within a specific context, which Brooke briefly describes as “appropriateness to a purpose” (16). The International Organization for Standardization (ISO) defines usability as “[the] extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context.”(45) In this investigation, the investigator evaluated patients' rating of usability of five patient-facing devices for collecting physiologic and subjective state data at

home overnight. The investigator also evaluated clinicians' ratings of usability of a personalized clinical information display constructed from patient-collected personalized clinical data.

Overall System Usability is defined as the overall System Usability Scale (SUS) score as calculated according to Brooke (16). The SUS is a validated 5-point Likert scale instrument anchored on either end by "1 = strongly disagree" and "5 = strongly agree" for each of ten items that measured the usability concepts. The System Usability Scale is scored producing a single overall usability score between 0 and 100. To score the System Usability Scale, each item must be transformed producing a value between 0 and 4. For odd numbered items the score contribution is calculated as scale position minus 1. For even numbered items the score contribution is calculated as 5 minus the scale position. The sum of all items is multiplied by 2.5 producing 41 possible unique scores between 0 and 100, the average score expectation was 68 (16; 56; 80). The instrument has become widely used for general usability testing because it has demonstrated reliability and internal-consistency greater than 0.90 (56). Lewis and Sauro (56) report that the factor structure of the System Usability Scale represents two subscales, namely usability and learnability. The usability subscale is comprised of eight factors that load on usability, and is calculated by multiplying the sum of items 1, 2, 3, 5, 6, 7, 8, and 9 by 3.125 to derive the usability subscale score. The learnability subscale is comprised of two factors that load on learnability and is calculated by multiplying the sum of items 4 and 10 by 12.5 to derive the learnability subscale score (56). The author selected the System Usability Scale to evaluate the display because it is easy to administer, reliable with small samples, and can differentiate usable from unusable systems (97). Additionally, the original author published the instrument as freely available for use (16).

Moreover, one study suggests that other instruments, such as the Technology Acceptance Model questionnaire may be less suitable for measurement of health information technology use among physicians (108). The SUS has two subscales: usability and learnability. Factor analysis of the SUS with two datasets conducted by Lewis and Sauro (56) reveals two subscales, namely, usability and learnability having reasonable reliability with coefficient alpha of 0.91 and 0.70 respectively. The subscales are highly correlated with the overall SUS score, 0.985 for the usability subscale, and 0.784 for the learnability subscale. Lewis and Sauro (56)

RESEARCH QUESTIONS

Research Question 1

Will patients use selected patient-facing devices to collect physiologic and subjective state data at home overnight? Device use was operationalized as the number of measurements recorded by each device (observed) over the number of expected measurements for each respective device (expected). The ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected, was recorded as use for each device per patient. The expected use was defined for each device.

Research Question 2

Will patients report the devices used at home overnight to be usable? Usability was operationalized as the overall System Usability Scale score as described by Brooke (16).

Research Question 3

Will clinicians report the electronic display of patient-collected clinical information to be usable? Usability was operationalized as the overall System Usability Scale score as described by Brooke (16).

RESEARCH DESIGN

Setting and sample

This descriptive exploratory study was conducted between December 2014 and June 2015 in a United States Military Health System (MHS) heart failure clinic. The institutional review board (IRB) of affiliated university and institution for research approved this study (Appendix A). The heart failure clinic is staffed with a cardiologist and three nurse practitioners, and operates primarily one day per week, with an average schedule load of 16 patients.

All participants were military retirees or dependents, recruited as a convenience sample between December 2014 and May 2015. Patients were eligible if they had a clinical diagnosis of heart failure, were between 21 and 90 years of age, could speak, read and understand English, and were able to operate study devices. All New York Heart Association Functional Classification (NYHA) patients were eligible to participate. Patients who were unable to operate the devices, by virtue of limited cognitive ability were excluded. The recruitment goal was at least 37 patients to have an 85% chance to detect a 10-point difference in usability scores at medium effect size, 0.5 (23), calculated with G*Power (<http://www.gpower.lhu.de/en.html>).

The investigator recruited clinicians as a convenience sample from the cardiology clinic to evaluate the single-page display of patient-collected clinical information. All

clinicians were eligible to participate. The sample included cardiology staff physicians, cardiology fellows, nurse practitioners, physician assistants, and medical residents.

Clinicians were recruited in June 2015.

Electronic data collection procedures

The study was designed to complement what occurs in an active clinic under usual conditions. The investigator approached patients in the examination room before their clinician encounter, showed the patient the devices and described the purpose of the study, and obtained informed consent. Once patients signed the informed consent, they were enrolled in the study. The investigator then trained patients for up to one hour on how to use the electronic devices (body weight scale, blood pressure device, pulse oximeter, actigraph, and an iPad-based sign, symptom and subjective state questionnaire) selected to collect physiologic and subjective state data. When the enrolled patients knew how to wear and to use the devices were issued the devices to collect data at home for the next six consecutive nights.

Patient participants were asked to use the scale once at night when preparing for bed; to use the blood pressure device twice daily, once before going to bed and once when getting up; the iPad at least twice each day, once at bedtime and upon awakening, and when getting up during the night. The investigator asked patients to wear the pulse oximeter and the actigraph all night, which the investigator expected to be 8 hours. The sequence of data collection is graphically illustrated in Figure 2. Patients were contacted by telephone after the first night and asked if they had questions. Seven days after enrollment, patient participants returned to the heart failure clinic to return the devices and complete a usability assessment for each device. The investigator downloaded the device-collected data using

device-specific software, cleaned the data using the R statistical language, and uploaded the data into the study's MySQL study database. All devices met Protected Health Information (PHI) and Personal Identifiably Information (PII) requirements. All data use was Health Insurance Portability and Accountability Act (HIPAA) compliant.

Electronic display procedures

The display screen was constructed to display multiple temporally abstracted views arranged hierarchically. The levels of temporal abstraction were dynamically linked so that clicking on one level updated the next level. The investigator constructed mock-ups and models of the clinical information display, and assisted by collaborators, developed a single-page, web-based display application employing a MySQL, Apache web server, PHP script language, Scalable Vector Graphics (SVG), AJAX, and JavaScript. The single-page display is open source and freely available.

Experts programmed the visual display using client-server architecture. User information requests were made through a browser, sent to a web server, passed to an application server, which queries a database, and retrieves the data. The application server returns the data to the web server that sends the web page code back to the browser. This simultaneous temporally abstracted visual display was constructed with the following open source software. MySQL is popular open source database software used for constructing relational databases in which the patient data are stored. The data schema includes two tables per patient, one for episodic data and one for continuous data, for each patient. Apache web server is open source software that provides an interface between the browser and the data source. It is robust and can be run on the most common computer operating systems. PHP is open source software used in web development that handles the web server requests to the

database. When a query is passed from the web server, PHP generates the content that is returned to the web server. SVG is a method for rendering graphical elements that can be infinitely scaled in size without losing resolution or clarity. SVG allows content to be displayed on a wide range of device with varying screen sizes while retaining the clarity of the typeface. AJAX stands for Asynchronous JavaScript and XML (extensible markup language); it is a technique to improve the performance of dynamic web pages. The process permits updating portions of a web page without requiring a reload of the entire web page. JavaScript is a client-side scripting language that permits the display of dynamic web page elements. The JavaScript codes are built into the web page programming and are executed by the client web browser when the web page is loaded locally. JavaScript is commonly used to perform actions such as validating web form entries (e.g., e-mail address, age, phone number) or performing calculations with user input.

After completing the informed consent, clinicians were provided with an iPad-based single screen display of individual patient clinical information. The investigator described the arrangement of the data on the screen to the clinician. The clinicians then used the device to review a patient's six days of patient-collected data. After viewing the display, clinicians completed the System Usability Scale (SUS).

ASSUMPTIONS

The investigator assumed that subjective patient responses were valid at the time. An additional assumption was that patients who demonstrated the ability to operate each patient-facing device would continue to use them in the manner demonstrated upon enrollment, and that devices would perform as intended without undetected malfunction.

The investigator assumed that clinicians credentialed to practice in the heart failure clinic had the necessary knowledge, skills and experience to assess the usability of the electronic display of personalized clinical information. The clinicians were not using the information for clinical treatment decisions, but evaluating the usability of the information display.

ORGANIZATION OF THE DOCUMENT

Chapter 2 is a manuscript submitted to the Journal of Medical Systems documenting a literature review emphasizing some important limitations on the current approach to acquiring heart failure information and suggested an alternative method for collecting personalized clinical information. The manuscript was submitted to the Journal of Medical Systems.

Chapter 3 is a manuscript submitted to the Journal of American Medical Informatics Association documenting investigation of patient use and assessment of usability of selected patient-facing devices for collecting physiologic and subjective state data at home.

Chapter 4 is a manuscript prepared for submission to the Journal of the American Medical Informatics Association documenting the development of a single-page hierarchical temporally abstracted display of patient collected clinical data, and the clinicians' assessment of the usability of the display.

Chapter 5 provides a unifying discussion of the study findings, relating them to the relevant literature supporting the original study question. Additionally the investigator provides recommendations for application of the study findings regarding patient-collected personalized clinical data to provide the clinicians caring for patients with heart failure with better clinical information to make better clinical decisions.

Table 1. Cleveland & McGill (1985) rank order of perceptual tasks by accuracy.

Rank	Aspect Judged
1	Position along a common scale
2	Position on identical but nonaligned scales
3	Length
4	Angle slope (with θ not too close to 0, $\pi/2$, or π radians)
5	Area
6	Volume, density
7	Color saturation, color hue

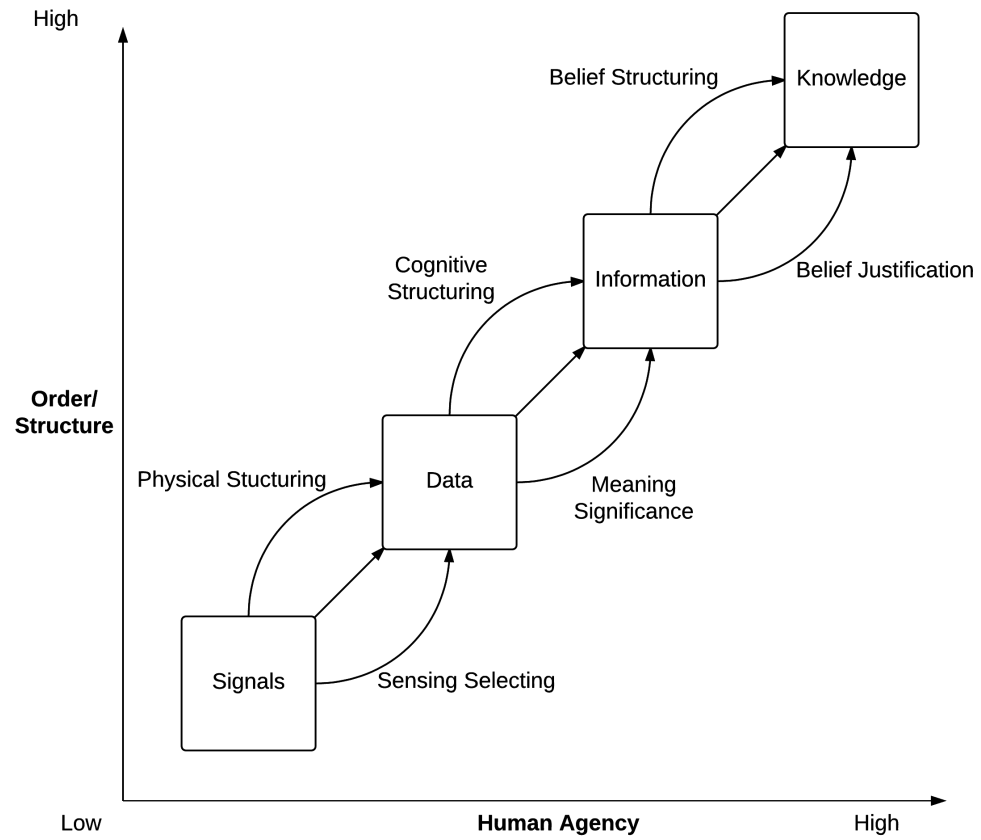
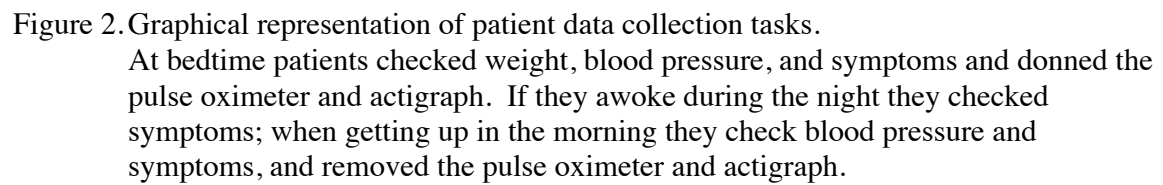


Figure 1. Data, information and knowledge model according to Choo (20).



CHAPTER 2: Comparison of Clinic Versus Living Laboratory Assessment of Patients with Heart Failure

ABSTRACT

The focus of this paper is how to use patient-facing devices to obtain better information for patients with heart failure. The current approach to the outpatient management of heart failure involves the clinician combining patient retrospective self-reports of symptoms and activity, their physical examination, and the patients' laboratory values during routine office visits at varying time intervals. There are three difficulties with the current approach. First, the quality of the information depends on patient recall. Second, patient-provided data are not necessarily complete (key details may be omitted) or accurate. Third, the information provided may not be clinically relevant. Therefore, the current approach to heart failure symptom assessment may not provide clinicians with sufficiently complete and detailed information to properly manage their patients. Technologies exist that can overcome these difficulties and provide clinicians with accurate real-time objective and subjective data that are ecologically valid. Approaches used to collect objective and subjective patient information have successfully been employed in the behavioral sciences, but this methodology has not been applied to the assessment of heart failure. Allowing patients to use their homes as living laboratories; use objective and subjective instruments; communicate objective, ecologically valid real-time information to their clinicians can potentially empower patients, enhance medical management, and improve clinical outcomes.

INTRODUCTION

The focus of this paper is how to use patient facing devices to obtain better information for patients with heart failure. The current approach to the outpatient management of heart failure involves the clinician combining patient retrospective self-reports of symptoms and activity, their physical examination, and the patients' laboratory values during routine office visits at varying time intervals (90). Patient reported information has long been the main component of clinical assessment because it is essential to constructing the chronology of the patient's disease. There are difficulties with current symptom assessment methods, which are predicated upon retrospective patient self-report rather than real-time physiologic and subjective state information collected in an ecologically valid manner e.g., in a living laboratory. First, the quality of the information depends on patient recall (88; 100). Second, the data provided by the patient are not necessarily complete (key details may be omitted) and accurate (65). Third, the information provided may not be clinically relevant (32; 72; 77). Therefore, the current approach to heart failure symptom assessment may not provide clinicians with sufficiently complete and detailed information to optimally manage their patients.

Ecologically valid, real-time physiologic and subjective state data collected and transmitted from the patients' home environment can provide actionable information that clinicians can use to improve their management of patients with heart failure. The purposes of this paper are to: (1) review how heart failure symptom information is currently acquired, and (2) describe an improved approach to acquiring information about the signs and symptoms of heart failure.

Current approach to the acquisition of clinical heart failure information

Clinic-based assessment

Patient assessment typically occurs in clinics and hospitals when patients are seen for routine follow-up or when being treated for an exacerbation of symptoms. An assumption is that clinic-based measurements approximate similar measures if they were taken in patients' home. But clinical observations do not necessarily reflect the patients' state at home environment. Ayman and Goldshine (5) found that patient-recorded blood pressure at home differed significantly from clinic-based measurements and better represented average blood pressure.

Retrospective assessment

Current assessment methods require patients to recall and recount, either orally or with a written instrument. Retrospective subjective patient data collection carries a high risk of recall bias, systematic error in which the respondent incompletely or inaccurately recalls past experiences or events (65). Moreover, patient report accuracy is affected by time; accuracy decreases as the recall interval increases (15). Additionally, patient retrospective symptom report accuracy is affected by mood (10).

Willis and associates (103) presented a cognitive model of the survey response process that describes the major cognitive processes involved when a subject is asked to respond to a survey question. When a question is asked the respondent must: 1) comprehend the question being asked, 2) make a decision or judgment on the feasibility of accessing the information, 3) retrieve the information from memory as factual recall or estimation, and 4) recode the information into a response to the question. When respondents are unable to

retrieve factual information from memory, estimation of the information prevails, as seen in diet history reporting. Dietary self-reporting detail is lost and reports more resemble diet history estimates as the target period becomes more remote (14). Additionally, Wang and colleagues (100) found that self-reported compliance with hypertension medication shows very poor agreement when compared with prescription refill records.

The risk of recall error is compounded in subjects who are cognitively impaired. Mild cognitive impairment is prevalent among patients with heart failure, even those without dementia (32; 72) and cognitive impairment appears to increase with age (77). It may be difficult for many patients with heart failure to accurately complete some retrospective recall tasks, even assisted by caregivers, due to poor memory. Pressler (72) reported that 25% - 50% of patients with heart failure suffer at least mild cognitive impairment, making it more difficult for patients to accurately recall and recount symptoms, particularly if the time period is long. As a result, retrospective reported outcomes might provide unreliable information about the patient's symptom history.

Subjective assessment nonconcurrent with objective measures

Subjective data are generated from an individual's experience, opinion or perception of a phenomenon. From a clinical perspective, subjective data include any patient-reported condition, experience or opinion. In contrast, objective data are observable, measureable phenomenon perceived by someone other than the subject. Although various subjective assessment instruments for heart failure are available, they are infrequently used during and office visit. Often, clinicians obtain an interval history simply by asking patients how they have been; with the expectation that the patients will accurately recall and recount significant

changes in symptom occurrence. Consequently there is no way to accurately associate subjective measures with physiologic data.

To mitigate these problems, clinicians occasionally ask patients to complete paper diaries to augment their recollection. Unfortunately, paper diaries may be as ineffective as retrospective recall. Stone and colleagues (92) asked 80 patients with chronic pain to record pain scores at three time points during the day in either paper diaries or electronic diaries. They found that even though patients using paper diaries reported 90% compliance with diary entries, actual recorded compliance was only 11%, calling into question their validity. Patients assigned to the electronic diary group had a 94% compliance rate.

An effective approach to the acquisition of clinical heart failure information

The living laboratory is a research paradigm whereby end-users are integrated into the research (30). Incorporating patient facing technologies into the patient's home environment effectively creates a living laboratory that provides patient-facing, ecologically valid, data. Patients have input into the process through rating scales, surveys, and focus groups. Two thirds of seniors desire to access health services from home, and more than half currently access their medical information online (66). Understanding how patients can best use these technologies in their home environment is essential for successful assimilation. Greenhalgh and colleagues (38) found that older adults with assisted living desired telehealth technologies that fostered connectedness and individual productivity. User engagement in living laboratories may also provide motivation for the collection and transmission of clinical data from patients to clinicians.

In-home assessment

Ecological validity refers to the ability to generalize information to real-life settings, such as when the patient is at home performing routine activities of daily life (81).

Measurements taken in the patient's home environment were more ecologically. Therefore, obtaining measurements of patients' symptoms in the patient's home environment may provide a more accurate picture of symptom occurrence.

Some researchers have reported that home monitoring of patients with heart failure results in decreased re-hospitalization and mortality (21; 42; 44; 50; 51). In a review of technologies used to monitor patients with heart failure at home, Conway, Inglis and Clark (24) found that structured telephone calls and physiologic monitoring systems demonstrated significant effects on all-cause mortality (RR = 0.87; 95% confidence interval [CI], 0.75–1.01; $p = 0.06$) and heart failure related hospitalization (RR = 0.77; 95% CI, 0.68–0.87; $p < 0.0001$).

Furthermore, Howell and colleagues (43) found that actigraphic measurement of patient's 6 most active minutes of daily activity demonstrated high correlation (correlation coefficient (r)=0.613, $P<.001$) with the clinic-based six-minute walk test. Although higher for patients aged 65 years and older the correlation was also statistically significant for younger patients. Modern actigraphy devices can be worn continuously for several days permitting continuous quantitative measurement of patient activity, creating a way to collect data equivalent to a daily six-minute walk test.

Real-time collection

In real-time assessment, subjects are asked to rate the subjective phenomenon in the moment, as they occur. Collecting subjective state data in real-time greatly decreases the risk

of recall bias and promotes the collection of ecologically valid data. The data are ecologically valid because they are collected while patients are performing the activities of daily life.

The ecologically valid, real-time assessment method is well known in behavioral sciences but has not yet been widely applied to heart failure symptom assessment. For example, Anestis and associates (3) sought to evaluate whether ecologically valid, real-time assessment would correlate with outcomes for patients with eating disorders. They found that for women diagnosed with bulimia nervosa real-time assessment of affective lability predicted frequency of bingeing.

Subjective assessment with concurrent objective measures

Real-time subjective assessments can be performed in parallel with continuous physiologic measures such as movement, pulse rate, and blood oxygen saturation. Patients with heart failure experience a high symptom burden, typically experiencing 15 ± 8 symptoms daily (106). But not all symptoms are equally useful in determining if there has been a deleterious clinical change that requires intervention. For example, the occurrence of shortness of breath is ubiquitous in patients with heart failure of all classifications (1); hence, assessment of its presence or absence may not be beneficial. However, knowing that a patient is experiencing increasing anxiety with shortness of breath is associated with decreased blood oxygen saturation and decreased systolic blood pressure and may suggest an important clinical deterioration.

Additional benefits with data transmission and storage

Telemonitoring of patients with heart failure can result in significantly improved outcomes such as decreased all-cause mortality, decreased all-cause hospitalization,

decreased heart failure-related hospitalization, health-related quality of life, cost (21; 24; 42; 44; 50; 51). Additionally, wireless technologies can feasibly support telemonitoring programs for heart failure management (104). Furthermore, the real-time electronic collection and transmission of ecologically valid patient data can produce high quality clinical databases for patient management and research (12).

Recording symptoms when they occur (event-contingent) and at certain fixed time points (time-contingent) may facilitate better detection of acute symptom changes. Patients with heart failures frequently ignore, misinterpret or misattribute symptoms, such as increasing shortness of breath, until they are in extremis and require hospitalization (67; 83). Knowing that a patient is experiencing increasing shortness of breath over several hours may alert patients, caregivers, or clinicians to clinical deterioration that may be addressed in hours rather than days. Determining which symptoms best provide indications of worsening heart failure is an important next step in developing ecologically valid assessment instruments that can be used to improve patient care.

Equally important is the determination of data collection frequency. Once clinical variables have been selected, an appropriate sampling method must be developed to balance the data collection and respondent burden. It may be effective to ask patients hourly if they are experiencing shortness of breath, but patients may consider the task so onerous as to dissuade them from participating in collection. An event-driven model, where patients report shortness of breath whenever it occurs may be less sensitive if patients do not accurately attend to their symptoms or have trouble recognizing a change from baseline. A combination of event-contingent, and time-contingent sampling may provide the most flexibility. Combining real-time subjective reporting with physiologic monitoring, such as pulse

oximetry, may detect patterns of deterioration that symptom surveillance alone may not disclose.

In addition, the ability to conveniently and longitudinally collect ecologically valid, real-time patient data can result in large data sets over time. Such data sets are amenable to knowledge discovery and data mining (KDD) techniques. Classifiers can be used to detect only data that fall outside established thresholds, so that abnormal values can be more easily analyzed. Temporal pattern mining can be used to identify patterns for instances of abnormal data over greater periods of time to reveal seasonal or annual variations, for example. Identification of individual patterns of response permits clinicians to personalize therapy based on patients' individual response. Ultimately, temporal patterns might be used to anticipate potentially deleterious clinical changes.

CONCLUSION

Current approaches to clinical management that rely on the reporting of patients with heart failure information during clinical visits results in biased, incomplete, and inaccurate clinical data; data that physicians, nurse practitioners, clinical nurses, and physician assistants use to manage the patient. Furthermore, these methods do not provide ecologically valid, real-time information. Modern technology provides a means for electronically acquiring ecologically valid, real-time patient objective and subjective data. Physiologic data acquisition devices, such as body weight scales, blood pressure devices, pulse oximeters, actigraphs, and iPad-based assessment applications can provide the accurate and objective information about clinical severity of illness information that is necessary for clinicians to properly manage of the patient. Electronically strategies facilitate comprehensive and coordinated collection of objective and subjective data. Allowing patients to use their homes

as living laboratories; use objective and subjective instruments; communicate objective, ecologically valid real-time information to their clinicians can potentially empower patients, enhance medical management, and improve clinical outcomes.

CHAPTER 3: Electronic Physiologic and Subjective Data Acquisition in Home-Dwelling Patients with Heart Failure: An Assessment of Patient Use and Perception of Usability

ABSTRACT

Background: The current approach to the outpatient management of heart failure involves patients recollecting what has happened to them since their last clinic visit. But patients' recollection of symptoms may not be sufficiently accurate to optimally manage their disease. This is a report of the investigation of whether patients will use electronic devices at night to collect physiologic and subjective state data and whether they rated these devices high in usability.

Methods: This was a descriptive observational study of home-dwelling patients with heart failure, between 21 and 90 years of age, enrolled in the heart failure clinic. Patients were provided with five electronic devices, namely, body weight scale, blood pressure device, an iPad-based subjective question set, pulse oximeter, and actigraph. These devices recorded patient bodyweight, blood pressure, heart rate, blood oxygen saturation, physical activity, and subjective state data for six nights.

Results: Patients were able to use all devices. The body weight scale was used less than expected O/E 0.80, $P < 0.001$; the blood pressure device, iPad, and oximeter were used as expected, O/E 1.03, 1.10, and 0.90, respectively; the actigraph was used more than expected O/E 1.93, $P < 0.001$. The SUS grand mean score was 86.9 (CI = 84.8, 90.0) and the ICC grand mean score was 0.73 (CI = 0.56, 0.90). For each device, the SUS mean score and the ICC score was: scale, 84.5 (77.3, 91.6), 0.66 (0.46, 0.87), respectively; blood pressure device, 89.7 (85.8, 93.6), 0.79 (0.64, 0.93), respectively; iPad subjective questions 85.7 (80.8,

90.6), 0.70 (0.51, 0.89), respectively; pulse oximeter 87.6 (83.5, 91.7), 0.61 (0.61, 0.92), respectively; and actigraph 85.2 (79.8, 90.7), 0.68 (0.50, 0.88), respectively. All the SUS and ICC scores were significantly different from what would be expected by chance, $p < 0.0001$.

Discussion: The investigator concluded that patients with heart failure can use electronic devices to collect clinical data at home during the night. This finding indicates the ability to collect highly accurate ecologically valid objective and subjective information that can be used to better manage patients with heart failure. To our knowledge, researchers have not quantitatively assessed the use and usability of electronic objective and subjective data collection devices in patients with heart failure' homes overnight.

INTRODUCTION

The current approach to the outpatient management of heart failure combines patients' retrospective self-reports of symptoms and activity with a physical examination and laboratory results during a routine office visit (90). Clinicians expect that patients will accurately recall significant changes in symptoms and activity since the last clinic visit. Unfortunately, there is a great deal of variability in patient's self-reports and in subjective assessment instruments (55). Recall is, many times, not veridical with past events and it may be especially difficult for patients with heart failure because of the prevalence of mild cognitive impairment due to both heart failure itself (32) and advancing age (77). Thus, retrospective objective and subjective information recalled at clinic visits may not provide the accurate, complete, and detailed information that clinicians require for the optimal management of their patients.

Until recently, methods to improve patient-collected data have been limited to recordings entered into logs and diaries maintained by the patient between clinic visits. This

situation has changed with the introduction of portable electronic technologies that are capable of collecting, storing, and transmitting physiologic and subjective state data from patients' homes. They have the potential to dramatically improve the information that clinicians have available to them when making clinical decisions.

Most of what is known about heart failure is related to patients' diurnal symptoms and activities; for example, the New York Heart Association Functional Classification (NYHA) is predominately a daytime system. Little is known about what happens to patients with heart failure during the night, yet many patients with heart failure present to the emergency department at night (83). Some portable electronic technologies can operate continuously to collect data from the time patients go to bed until they get up in the morning. These data can fill in a vital clinical information gap regarding heart failure as a disease.

The investigator was therefore interested in patients with heart failure using patient-facing devices (intended to be used by patients to collect clinical information in non-clinical settings) to collect nocturnal health information in their homes. The research questions are: 1) Will patients use selected patient-facing devices to collect physiologic and subjective state data at home overnight? 2) Will patients report the devices used at home overnight to be usable? To our knowledge, researchers have not quantitatively assessed the use and usability of electronic objective and subjective patient-facing devices in patients with heart failure' homes during the night.

METHODS

Setting and participants

This descriptive observational study was conducted between December 2014 and June 2015 in a United States Military Health System (MHS) heart failure clinic. The

institutional review board (IRB) of affiliated university and institution for research approved this study.

Patients were included for consideration if they had a clinical diagnosis of heart failure, were between 21 and 90 years of age, and able to operate study devices. All New York Heart Association Functional Classification (NYHA) patients were eligible to participate. Patients who were unable to operate the devices, by virtue of limited cognitive ability were excluded from consideration. The investigator sought to recruit at least 37 participants to detect a 10-point difference in usability scores at medium effect size, 0.5. The participants were all retirees and their families. The MHS population and care has been shown to be similar to the general population (35; 46-48).

Procedure

The study was designed to complement what occurs in a practicing clinic. The primary investigator approached patients in the examination room before their clinician encounter, showed the patient the devices and described the purpose of the study, and obtained informed consent (Appendix B). Enrollment, device training and device issue took place in the clinic at the time of the patients' scheduled visit. The investigator trained patients for up to one hour on how to use the electronic devices selected to collect physiologic data (body weight scale, blood pressure device, pulse oximeter, and actigraph) and subjective state data (an iPad-based subjective state assessment) so that all the enrolled patients knew how to wear and to use the devices. Patients were then issued devices to collect their physiologic and subjective state data at home for the next six consecutive nights.

Patients were asked to use the scale once at night when preparing for bed; to use the blood pressure device twice daily, once before going to bed and once when getting up; the

iPad at least twice each day, once at bedtime and upon awakening, and when getting up. The investigator asked patients to wear the pulse oximeter and the actigraph all night, which the investigator expected to be 8 hours. The sequence of data collection is graphically illustrated in Figure 3. Patients were contacted by telephone after the first night and asked if they had questions. Seven days after enrollment, patients came back to the heart failure clinic. At that time, they returned the devices and completed a usability assessment for each device (Appendix C). The device-collected data were downloaded using device-specific software, cleaned using the R statistical language, and uploaded into the study's MySQL study database. All devices met Protected Health Information (PHI) and Personal Identifiably Information (PII) requirements. All data use was Health Insurance Portability and Accountability Act (HIPAA) compliant. Seven days after enrollment, patients came back to the heart failure clinic to return the devices and completed the System Usability Scale for each device.

Data collection devices

The investigator selected six clinical variables based on their clinical and prognostic value in patients with heart failures, namely, body weight (105), systolic and diastolic blood pressure (60), heart rate, blood oxygen saturation (60), physical activity (105), and subjective symptom (105). To collect these data, the investigator selected the following electronic device to measure and record variables (Figure 4):

Patients measured body weight using the American Weigh Scales (AWS) Bioweigh USB Body Fat Scale. Patients weighed themselves each evening before going to bed.

Patients measured blood pressure using the Omron 10 Series+ Blood Pressure Monitor (Model BP791IT). Patients measured blood pressure twice daily, once when going to bed and when getting up in the morning.

Patients measured heart rate using the Nonin WristOx2 model 3150 pulse oximeter. The pulse oximeter was configured to automatically record when placed on the patient's finger. Patients put the device on when going to bed, wore it continuously overnight, and took it off when they got up.

Patients measured blood oxygen saturation using the Nonin WristOx2 model 3150 pulse oximeter. The pulse oximeter was configured to automatically record when placed on the patient's finger. Patients put the device on when going to bed, wore it continuously overnight, and took it off when they got up.

Patients measured physical activity using the ActiSleep+ actigraph monitor; a micro-electro-mechanical system based accelerometer that collects triaxial movement data at a rate of 30Hz. Patients wore the device on their wrist overnight. Wear time was validated using the algorithm developed by Choi and Liu (19); segments calculated as non-wear segments were removed. The investigator created a physical activity threshold to separate normal daily physical activity from low physical activity, such as what occurs during sleep, by averaging a convenience sample of 30-minute segments of normal activity and dividing the grand mean of vector magnitudes by four.

Patients collected symptoms and subjective states data using a custom-built iPad-based application that presented patients with a list of 10 symptom statements and recorded their responses (Figure 2). The investigator implemented symptom and subjective state prompts for the iPad-based application developed from signs and symptoms common to

patients with heart failure (1). The ten subjective statements were: I am more short of breath than usual; I am in more pain than usual; I feel my heart beating fast; I feel more tired than usual; my feet are more swollen than usual; I feel sicker than usual; I am more unhappy than usual; I have less appetite than usual; I am confused; and I feel alone. Degree of agreement was on a 3-point scale: “no” = 0, “a little” = 1, or “a lot” = 11. This scoring system was devised to permit rapid visual decoding of the score. The scores were summed and an overall score was calculated. A score between 1 and 10 indicates that the patient was experiencing at least one symptom. A score equal to, or greater than 11 indicates that the patient was experiencing one or more significant symptoms. The patients were asked to use the iPad-based subjective state application when going to bed, if they awoke during the night, and when they got up in the morning. The iPad-based subjective state application collected time-stamped, scored entries for each patient and displayed the score to the nearest hour in which the symptom was experienced. These data were not used clinically; rather, they were used to assess patient usability of the iPad-based subjective state assessment application.

It is important to note that while the variables were selected for the clinical and prognostic value in the management of patients with heart failure; the data collected in this study were not used clinically. Device use was operationalized as the number of measurements recorded by each device (observed) over the number of expected measurements for each respective device (expected). The ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected, was recorded as use for each device per patient. The expected use was defined for each device.

System Usability Scale

Usability was operationalized as the overall System Usability Scale score as described by Brooke (16). The System Usability Scale, developed by John Brooke (16) is a validated 5-point Likert scale instrument anchored on either end by “1 = strongly disagree” and “5 = strongly agree” for each of ten items that measured the usability concepts. Raw scores are transformed resulting in scores between 0 and 100 with a global average of 68 ± 12.5 ; it has high reliability (Cronbach’s alpha .85 to .90) (80).

Statistical methods

Device use was assessed by calculating the ratio of observed over expected (O/E) device use, where 1.0 is observed equals expected. The investigator assessed significance of device use by comparing O/E ratio to the hypothetical mean of 1.0 using Student’s t-test. Further, the investigator assessed significance of overall System Usability Scale (16) by applying Student’s t-test against a hypothetical mean score of 68, based on the literature (56). Inter-rater agreement of raw system usability scores was assessed by calculating the Intraclass Correlation Coefficient (ICC) with 95% confidence intervals (87). Statistical tests were calculated using R version 3.1.3 (Comprehensive R Archive Network, <http://cran.r-project.org>) with the significance probability threshold set at $p < 0.05$.

RESULTS

Patients were recruited from December 2014 to May 2015, to evaluate the consistency of the sample the investigator created two cohorts. The first cohort (original) consisted of the first 29 consecutive patients enrolled in the study and the second cohort (validation) consisted of the next 10 consecutive patients enrolled in the study. The investigator screened 58 patients, 42 enrolled, one patient died, one withdrew, and one

person did not return the equipment; the completed sample consisted of 39 patients. The demographics of the patients are presented in Table 2.

The investigator compared the demographics, New York Heart Association Functional Classification, actual use, usability, and inter-rater agreement between the two cohorts. The investigator did not find any significant differences so the investigator combined the two cohorts, resulting in a final cohort of 39 patients.

The investigator was interested in the objective time each device was used and whether the devices were used for the expected length of time. These results are shown in Table 3.

A day's use of a device was defined as each day the device recorded any data. The mean days used was the number of days used divided by six days. The least used device was the body weight scale, 4.50 days (4.02, 4.98). Furthermore, these results reflect only 24 patients; 15 patients did not use the scale and were not included in the mean days used result. The mean use of the blood pressure device, iPad-based subjective state application, and oximeter were approximately the same, 5.58 days (5.22, 5.95), 5.56 days (5.14, 5.99), and 5.51 days (5.20, 5.82), respectively, although their range of days did differ. The actigraph was used the most days; mean 5.79 days (5.56, 6.00).

The ratio of observed use to expected use (O/E) is significantly less than expected for the scale, O/E 0.80, $P < 0.001$. The observed use did not differ significantly from the expected use for the blood pressure device, iPad-based subjective state application, and oximeter, O/E 1.03, 1.10, and 0.90, respectively. The actigraph was used twice as much as expected, O/E 1.93, $P < 0.001$. Overall, with the exception of the scale, the evidence

supports that patient will use electronic devices at night to collect physiologic and subjective state data.

After the devices were returned, each participant was given the System Usability Scale (SUS) for each device (Table 4). The SUS measured the participant's perception of the usability of the device. The investigator was also interested in how correlated the participant's scores were for each device.

The SUS grand mean score was 86.9 (CI = 84.8, 90.0) and the ICC grand mean score was 0.73 (CI = 0.56, 0.90). For each device, the SUS mean score and the ICC score was: scale, 84.5 (77.3, 91.6), 0.66 (0.46, 0.87), respectively; blood pressure device, 89.7 (85.8, 93.6), 0.79 (0.64, 0.93), respectively; iPad-based subjective state application 85.7 (80.8, 90.6), 0.70 (0.51, 0.89), respectively; pulse oximeter 87.6 (83.5, 91.7), 0.61 (0.61, 0.92), respectively; and actigraph 85.2 (79.8, 90.7), 0.68 (0.50, 0.88), respectively. All the SUS and ICC scores were significantly different from what would be expected by chance, $p < 0.0001$.

The investigator was also interested in whether the severity of illness affected the patient usability scores. Table 5 shows the O/E ratios and SUS scores by device, and further divided by NYHA class.

There were no significant differences in the O/E use by device and NYHA class. There was a consistently significant SUS difference across all devices between NYHA class II and III patients. The class III patients found the devices significantly easier to use than the class II patients, $p < 0.05$. The grand mean SUS scores, by NYHA classification I, II, and III, were 88.67 (81.68, 95.67), 83.74 (78.67, 88.81), and 94.88 (91.88, 97.87) respectively. This class II vs. class III difference in SUS was also significant when comparing across all devices, $p < .001$.

DISCUSSION

Overall, the investigator found that, other than the scale, patients were able to use electronic devices to measure, store, and transmit nocturnal physiologic and subjective state information and they found them highly usable. Patient-facing information reflecting the patient's status at home can be important for clinicians' understanding of patients' wellbeing at home (40). A number of paper-based instruments have been developed to collect subjective patient-generated data, but they vary in terms of which symptoms they assess, number of assessment items, and time range over which patients report; they are not very accurate (55).

Patients with heart failure who used body weight and symptom diaries experienced better clinical outcomes after six months compared to matched controls (28). However, in this study, 15 patients did not use the study-provided body weight scale. This may be due in part to patients using their own scale rather than the study scale to measure body weight. There were no significant differences in age, gender balance, race/ethnicity composition, or NYHA functional class distribution between those patients who used the body weight scale and those who did not. Among those who used the scale, it had the lowest mean days used, the lowest O/E ratio, the lowest SUS score, and the correlation of its SUS scores was the second lowest in the study. There are a number of factors that may have affected the scale's low use and usability. The scale required user setup with each use and this may have made it inconvenient. Because the operation of the scale required users to bend down to activate the device, the scale may also have been affected by some patient's physical limitations, e.g., obesity, limited flexibility, or impaired balance. Furthermore, some patients expressed

concern about falling when engaging in this activity, and so declined to use the scales provided.

The blood pressure device was used as expected given that it had the highest usability user agreement. When examining difference between NYHA classes in terms of use and usability scores. There was no significant difference for use, but there was a significant difference in usability score between NYHA class II and class III patients, with class III patients rating devices higher. Anecdotally, most patients were experienced in manual home blood pressure monitoring. This familiarity may be the reason for the high usability score and usability agreement.

The pulse oximeter used was less than expected, but not significantly less so. It had the fourth highest usability, and ranked lowest in terms of consistency of agreement. When comparing NYHA class patients, there was no significant difference for use ratio between classes, but there was a significant difference in system usability score between class II and III, with the highest scores provided by class III patients. Most patients indicated familiarity with the pulse oximeter from their clinic visits. Many patients expressed curiosity about, and interest in, continuous recording of blood oxygen saturation. Nearly a quarter of patients had been diagnosed with sleep apnea. Additionally, since shortness of breath is a common heart failure symptom (35), patients may place a higher value on collecting this data due to symptom familiarity.

The actigraph was the most used device; it ranked fourth in its overall usability, but third in usability across patients. Observed use did not differ significantly between patients with different NYHA classifications, except for class II and class III patients where there was a significant difference between usability scores. The high use score is attributable to

patients simply putting on the wristband and not being required to do anything else. Patients often said that they did not understand the purpose of the actigraph, but they were nonetheless willing to wear it.

The iPad-based subjective state assessment application delivered and recorded subjective state assessment, and was used more than expected. It ranked third in usability and second in consistency of agreement of usability. There was no significant relationship between patient NYHA classification and use; however, there was a significant difference in usability between class II and class III patients. The results suggest that patients are willing to use the device to report symptoms that are present at bedtime, that occur during the night, and that are present upon awakening.

One of the goals of this study was to determine if patients could use these devices at night so that the investigator could collect nocturnal information. Although much is known about daytime heart failure, there is little objective information about nocturnal heart failure. The investigator found that patients were able to use these devices at night and were able to collect high quality nocturnal heart failure information.

A study limitation is that this was a sample of convenience, which may affect generalizability of the results. During the course of this study, little changed in the heart failure clinic from which patients were recruited and there were no patient interventions that might have affected the results of this study. Over two-thirds of the clinic patients contacted agreed to participate and, apart from three patients, all completed the study. The reasons patients gave for not participating were that they were not interested, it was too much work, and that they were in a hurry to leave the clinic. On the other hand, although many studies of patient-facing devices used in patient's homes have high drop out rates (50%) the

investigator had a minimal drop out rate (54). In other words, similar to other studies like this one, most patients agreed to use the devices and they used them the entire time of the study.

In conclusion, the investigator found that patients with heart failure in this particular study were able to use electronic devices in their homes at night to collect clinical data relevant to the management of their disease. To our knowledge, no study has assessed the in-home, nocturnal use and usability of electronic objective and subjective data collection devices with patients who have heart failure.

Table 2. Description of patient populations

	Original cohort	Validation cohort	Combined sample
N	29	10	39
Age mean (SD)	69.4 (10.9)	64.2 (15.7)	68.1 (12.3)
Gender n (%)			
Male	21 (72.4%)	7 (70.0%)	28 (71.8%)
Female	8 (27.6%)	3 (30.0%)	11 (28.2%)
Race/ethnicity n (%)			
African American	18 (62.1%)	6 (60.0%)	24 (61.5%)
Caucasian	11 (37.9%)	4 (40.0%)	15 (38.5%)
NYHA functional class n (%)			
I	8 (27.6%)	2 (20.0%)	10 (25.6%)
II	16 (55.2%)	6 (60.0%)	22 (56.4%)
III	5 (17.2%)	2 (20.0%)	7 (18.0%)

Note. New York Heart Association (NYHA) functional classification

Table 3. Patient device use.

Episodic devices	Days used		Average number measurements taken			
	Mean (95% CI)	Range	Observed	Expected	O/E ¹	p-value
Body weight scale ²	4.50 (4.02, 4.98)	2 - 6	4.87	6	0.80	<0.001
Blood pressure device	5.58 (5.22, 5.95)	1 - 6	12.54	12	1.03	0.77
iPad-based subjective state app	5.56 (5.14, 5.99)	0 - 6	13.58	12	1.10	0.16
Continuous devices	Days used		Time used (hours)			
	Mean (95% CI)	Range	Observed	Expected	O/E ¹	p-value
Pulse oximeter	5.51 (5.20, 5.82)	3 - 6	43.71	48	0.90	0.05
Actigraph ³	5.79 (5.56, 6.00)	2 - 6	95.58	48	1.93	<0.001

¹Ratio of observed over expected (O/E) device use where 1.0 is observed equals expected.

²The results are based on the 24 patients who used the scale.

³Three patients used a Zephyr device for activity; they are not included in the activity results.

Table 4. The mean System Usability Scale (SUS) scores and 95% confidence interval (CI) by device and the intraclass correlation coefficients (ICC) and 95% confidence interval by device. All scores were significantly different than expected by chance ($p < 0.0001$).

Device	SUS Mean (95% CI)	ICC (95% CI)
Body weight scale	84.5 (77.3, 91.6)	0.66 (0.46, 0.87)
Blood pressure device	89.7 (85.8, 93.6)	0.79 (0.64, 0.93)
iPad-based subjective state app	85.7 (80.8, 90.6)	0.70 (0.51, 0.89)
Pulse oximeter	87.6 (83.5, 91.7)	0.61 (0.61, 0.92)
Actigraph	85.2 (79.8, 90.7)	0.68 (0.50, 0.88)
Grand Mean	86.9 (84.8, 90.0)	0.73 (0.56, 0.90)

Table 5. Comparison of mean use observed-expected ratio (O/E) and overall System Usability Scores (SUS) by device and by New York Heart Association functional classifications (NYHA)

Device	NYHA class	n	O/E mean (95% CI)	SUS mean (95% CI)
Body weight scale	I	6	0.81 (0.60, 1.01)	81.25 (65.97, 96.53)
Body weight scale	II	13	0.81 (0.66, 0.96)	80.58 (69.75, 91.40)*
Body weight scale	III	5	0.77 (0.65, 0.88)	97.00 (90.27, 100.00)
Blood pressure device	I	10	1.02 (0.79, 1.26)	91.50 (82.26, 100.00)
Blood pressure device	II	22	0.92 (0.79, 1.05)	87.05 (81.93, 92.16)*
Blood pressure device	III	7	1.37 (0.34, 2.40)	96.07 (91.10, 100.00)
iPad-based subj. states	I	10	1.09 (0.94, 1.24)	86.75 (77.83, 95.67)
iPad-based subj. states	II	22	1.18 (0.95, 1.42)	82.84 (75.80, 89.88)*
iPad-based subj. states	III	7	0.87 (0.52, 1.22)	93.57 (85.58, 100.00)
Pulse oximeter	I	10	0.95 (0.72, 1.18)	88.25 (80.52, 95.98)
Pulse oximeter	II	22	0.88 (0.74, 1.02)	85.00 (79.17, 90.83)*
Pulse oximeter	III	7	0.88 (0.67, 1.09)	96.07 (90.93, 100.00)
Actigraph	I	10	2.12 (1.51, 2.72)	90.25 (81.63, 98.87)
Actigraph	II	20	1.72 (1.29, 2.14)	79.75 (71.83, 87.67)*
Actigraph	III	6	2.34 (1.47, 3.21)	92.50 (85.08, 99.92)
Grand Mean	I	10	1.24 (1.10, 1.37)	88.67 (81.68, 95.67)
Grand Mean	II	22	1.11 (0.97, 1.25)	83.74 (78.67, 88.81) *
Grand Mean	III	7	1.25 (0.90, 1.59)	94.88 (91.88, 97.87)

Note. *II vs. III, $p < 0.05$

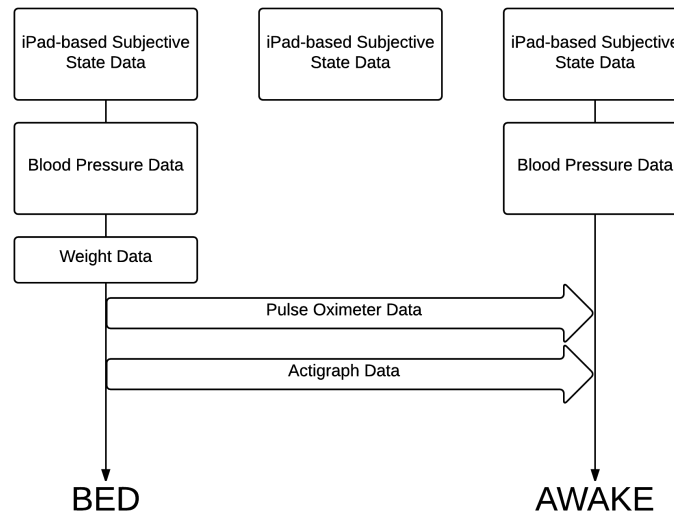


Figure 3. Graphical representation of patient data collection tasks.

At bedtime patients checked weight, blood pressure, and symptoms and donned the pulse oximeter and actigraph. If they awoke during the night they checked symptoms; when getting up in the morning they check blood pressure and symptoms, and removed the pulse oximeter and actigraph.

- Nonin WristOx2 model 3150 Pulse Oximeter

- Actigraph ActiSleep+

- AWS BioWeigh USB Body Fat Scale

- Omron Series 10+ Blood Pressure Monitor

- iPad 3 (iOS 8.1) running Hypnos


Figure 4. Devices for collecting heart failure data

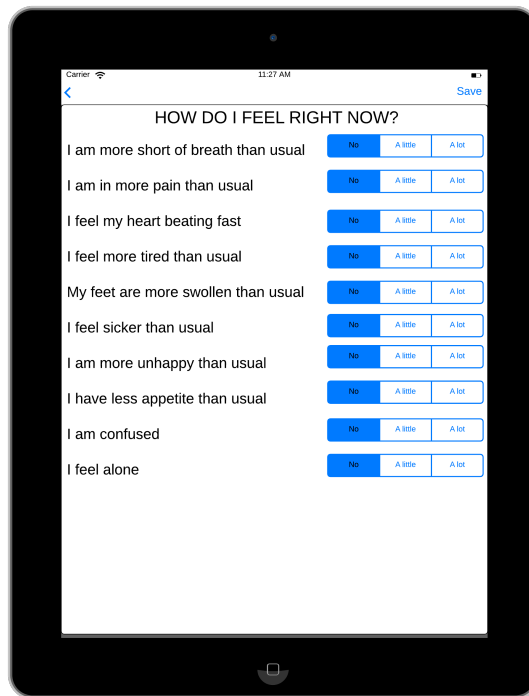


Figure 5. iPad-based subjective question assessment application.

CHAPTER 4: The Display and Usability of Patient-Collected Heart Failure-Specific Information

ABSTRACT

Background: Accurate patient information is essential for the optimal management of patients. Unfortunately, between-visit clinical information collection methods have demonstrated limited completeness and poor accuracy. The recent introductions of patient-facing devices that store and transmit physiologic and subjective state data have the potential to improve patient care. The purpose of this study was to investigate how clinicians will rate the usability of a novel display of patient-collected disease-specific clinical information.

Methods: Patients used five devices to collect six clinical variables with clinical and prognostic value in patients with heart failure, namely, body weight, systolic and diastolic blood pressure, pulse rate, blood oxygen saturation, and physical activity, as well as subjective symptom states. The author constructed a single-screen that displayed all variables using three stacked temporal dimensions: 24-hours in hours, 8-hours in minutes, and 30-minutes in seconds. The dimensions were dynamically linked so that clicking on one dimension displayed the dimensions below it.

Fourteen clinicians rated the display using the System Usability Scale, a ten item, 5-point Likert scale anchored at either end with “1=strongly disagree” and “5=strongly agree”. The System Usability Scale score was calculated according to the procedure described by Brooke and compared to the expected mean of 68 out of 100 using Student’s t-test. Additionally, subscale scores for usability and learnability were calculated as described by Lewis and Sauro. The author compared clinicians’ System Usability Scale scores to the expected score of 68 from the literature. The author calculated the Intraclass Correlation

Coefficient (ICC) of clinician responses. Statistical tests were calculated using R version 3.1.3; significance was set at less than 0.05.

Results: Fourteen clinicians evaluated the display and rated it significantly higher than the expected score of 68 from the literature. The overall System Usability Scale score and 95% confidence interval was 91.96 (86.77, 97.16), significantly higher than expected ($p < 0.0001$), and usability and learnability subscale scores were 91.74 (85.92, 97.56) and 92.86 (87.48, 98.13), respectively, also significantly higher than expected ($p < 0.0001$). Intraclass Correlation Coefficient 0.89 (0.79, 0.97) shows significant agreement between clinician ratings ($p < 0.0001$).

Conclusion: patient collected data can be organized into a dynamic single-page of multiple temporal abstractions arranged hierarchically. Clinicians reported the visual display to be highly usable. These findings support that clinicians can use this display to view large amounts of clinical data collected by patients between visits.

INTRODUCTION

Accurate patient information is essential for the optimal management of patients. In current practice, medical information is obtained when the patient visits the clinician and the clinician acquires an interval history, either orally or using a written instrument. Until recently, patient-collected data were essentially limited to subjective paper-based logs and diaries that patients maintained between clinic visits (55; 102). Between-visit clinical information collection methods have demonstrated limited completeness and poor accuracy (32; 65; 72; 77; 88; 100).

The recent introduction of patient-facing clinical devices, devices used by patients to collect information in non-clinical settings, that store and transmit continuously collected

physiologic and subjective state data in naturalistic settings has the potential to improve care (58; 98). The author noted that patients found these devices highly usable (34). However patient-collected data needs to be organized and displayed to the clinician in a way that is usable for the management of patient care. Currently, the author does not know of a single-screen visual display that simultaneously presents hierarchical temporally abstracted patient-collected, disease-specific medical information to the clinician.

The purpose of this study was to investigate how clinicians will rate the usability of a single-page visual screen display of patient-collected heart failure-specific clinical information. The author describes the construction of an electronic single interactive screen that displays each patient's continuously collected ecologically valid objective and subjective heart failure information to answer the research question: Will clinicians report the electronic display of patient-collected clinical information to be usable?

METHODS

Setting and sample

This descriptive exploratory study was conducted in a United States Military Health System (MHS) heart failure clinic. The institutional review board (IRB) of affiliated university and institution for research approved this study. All credentialed clinicians in the clinic were eligible to participate and were included; there were no exclusion criteria.

Procedure

Once clinicians completed the informed consent (Appendix D), they were provided with an iPad-based single screen visual display of patient clinical information. The investigator described the features of the display and the clinician reviewed one patient's six days of data, after which the clinician completed the System Usability Scale (SUS),

(Appendix E). The display was populated with an historical de-identified data set; data collected for this study were not used for clinical treatment decisions. Clinicians were asked to review the data set to assess usability of the visual display for rapidly reviewing large amount of patient-collected data.

Heart Failure Variables

The author selected six clinical variables based on their clinical and prognostic value in patients with heart failure. These variables are: body weight (105), systolic and diastolic blood pressure (60), heart rate, blood oxygen saturation (60), physical activity (105), and subjective symptoms (105).

Body weight was measured using the American Weigh Scales (AWS) Bioweigh USB Body Fat Scale. Patients weighed themselves each evening before going to bed.

Blood pressure was measured using the Omron 10 Series+ Blood Pressure Monitor (Model BP791IT). Patients measured blood pressure twice daily, once when going to bed and when getting up in the morning.

Heart rate was measured using the Nonin WristOx2 model 3150 pulse oximeter. The pulse oximeter was configured to automatically record when placed on the patient's finger. Patients put the device on when going to bed, wore it continuously overnight, and took it off when they got up.

Blood oxygen saturation was measured using the Nonin WristOx2 model 3150 pulse oximeter. The pulse oximeter was configured to automatically record when placed on the patient's finger. Patients put the device on when going to bed, wore it continuously overnight, and took it off when they got up.

Physical activity was measured using the ActiSleep+ actigraph monitor; a micro-electro-mechanical system based accelerometer that collects triaxial movement data at a rate of 30Hz. Patients wore the device on their wrist overnight, and wear time was validated using the algorithm developed by Choi and Liu (19); segments calculated as non-wear segments were removed. The author created a physical activity threshold to separate normal daily physical activity from low physical activity, such as what occurs during sleep. The investigators constructed an activity threshold by averaging a convenience sample of 30-minute segments of normal activity and dividing the grand mean of vector magnitudes by four, or 25% of known active measurement.

Symptoms and subjective states data related to heart failure were collected using a custom-built iPad-based application that presented patients with a list of 10 symptom statements and recorded their responses (Figure 6). The symptoms were selected from the most common heart failure signs and symptoms (1). Subjective states were assessed with ten subjective statements developed by the authors from common clinical management questions, and consistent with clinical practice guidelines (105). The ten subjective statements are listed in Table 6. Patients rated their degree of agreement with each statement on a 3-point scale where “no” = 0, “a little” = 1, or “a lot” = 11. This scoring system was devised to permit rapid visual decoding of the score. The scores were summed and an overall score was calculated. A score between 1 and 10 indicates that the patient was experiencing at least one symptom. A score equal to, or greater than 11 indicates that the patient was experiencing one or more significant symptoms. The patients were asked to use the iPad-based subjective state assessment application to rate their subjective states when going to bed, if they awoke during the night, and when they got up in the morning. The

author collected time-stamped, scored entries for each patient and displayed the score to the nearest hour in which the symptom was experienced. These were not used clinically; rather, they were used to assess patient usability of the iPad-based subjective state assessment application.

Single Screen Display

The single-page display is a web-based application employing a MySQL database for storing patient-collected data, an Apache web server for handling data requests, PHP script language to generate web content, Scalable Vector Graphics (SVG) to create visual elements, AJAX a technique for requesting and retrieving content without requiring a full screen refresh, and JavaScript for producing dynamic web elements. Our single-page display is open-source and freely available.

MySQL is popular open source database software used for constructing relational databases in which the patient data are stored. The data schema includes two tables, one for episodic data and one for continuous data, for each patient.

Apache web server is open source software that provides an interface between the browser and the data source. It is robust and can be run on the most common computer operating systems.

PHP is open source software that handles the web server requests to the database. When a query is passed from the web server, PHP generates the content that is returned to the web server.

SVG is a method for rendering graphical elements that can be infinitely scaled in size without losing resolution or clarity. SVG allow content to be displayed on a wide range of devices with varying screen sizes while retaining the clarity of the typeface.

AJAX stands for asynchronous Javascript and XML, it is a technique to improve the performance of dynamic web pages. The process permits updating portions of a web page without requiring a reload of the entire web page.

Javascript is a client-side scripting language that permits the display of dynamic web page elements. The Javascript codes are built into the web page programming and are executed by the client web browser when the web page is loaded locally. Javascript is commonly used to perform actions such validating web form entries (e.g., e-mail address, age, phone number) or performing calculations with user input.

The author, assisted by technical experts, constructed a single screen that displayed all the variables using three stacked temporal dimensions: 24-hours in hours (top section), 8-hours in minutes (middle section), and 30-minutes in seconds (bottom section) (Figure 7). The dimensions were dynamically linked so that clicking on one dimension displayed the dimensions below it. Arrows shown in Figure 7 and Figure 8 are for illustrative purposes only.

The top section of Figure 1, representing 24-hours in hours, has four lines. The first line (Arrow 1) points to the patient's name and the day. Day 1 means the first day of the patient display and its associated date. Days 2 – 6 represent successive days for which there is data. The author collected and displayed 6 days of collected data. In terms of the capability of the display, any number of days can be displayed; the line can scroll to the right.

Line 2 (Arrow 2) points to the blood pressure reading and the time it was taken. There are two blood pressure readings displayed on this screen. In terms of capability of the display, any number of blood pressure readings, and their associated times, can be displayed.

Line 3 (Arrow 3) points to the body weight and the subjective assessment scores, and times they were taken. Selecting the shaded block (grey if monochrome, blue if shown in color) associated with the subjective score provides additional detail for that score (Figure 8, Arrow 9). In terms of capability of the display, any number of subjective scores, and their associated times, can be displayed.

Line 4 (Arrow 4) points to the 24-hour time interval that comprises Day 1. The heavier darker line superimposed on the thin line of the time scale (dark grey if monochrome, blue if shown in color) represents the period of pulse oximeter wear. If the pulse oximeter is not worn, the pulse oximeter line would be absent. The shaded band over the numbered portion of the time scale (grey shading if monochrome, red if shown in color) represents the 8-hour time interval that is displayed in the section below. The line can be moved anywhere on the 24-hour time interval and the section below will display that 8-hour interval. Clicking on an hour on this time line will update the next section, which is an exploded view of the shaded 8-hour segment.

The middle section of the display (Arrow 5) depicts oxygen, heart rate and physical activity, in 30-minute increments of data exploded from the highlighted section in line 4. If a block is present it represents a threshold violation. There were thresholds for three variables, namely, oxygen saturation whose threshold is 92%, heart rate whose upper threshold is 100 beats per minute and lower threshold is 60 beats per minute, and physical activity whose upper threshold is 12 vector magnitude units. When one clicks on a block, the 30-minute window for that block is shown in the lower section of the display. Clicking one of the threshold violation markers (boxes) changes the color attribute to red and updates the section below with an exploded view of the 30-minute segment selected (Figure 7, Arrows 6, 7, 8).

Shown in Figure 8, upper section of the display (Arrow 9) is the result of clicking one of the subjective score blocks to see an itemization of the patient's reported subjective state score. Clicking the shaded box produces an exploded view of the non-zero subjective state responses (i.e., fatigue, swelling, appetite, etc.).

The lower section of the display (Figure 8, Arrow 10) has a vertical cursor that allows the clinician to view the exact values on the graph for the three variables blood oxygen saturation, heart rate and activity at each moment in time.

System Usability Scale

The System Usability Scale was originally developed by John Brooke (1986) to rate the usability of computer programs (16). It is a validated instrument that employs a 5-point Likert scale anchored at either end with "1=strongly disagree" and "5=strongly agree" for each of ten items measuring the concept of usability. The System Usability Scale is scored producing a single overall usability score between 0 and 100. To score the System Usability Scale, each item must be transformed producing a value between 0 and 4. For odd numbered items the score contribution is calculated as scale position minus 1. For even numbered items the score contribution is calculated as 5 minus the scale position. The sum of all items is multiplied by 2.5 producing 41 possible unique scores between 0 and 100, the average score expectation was 68 (16; 56; 80). The instrument has become widely used for general usability testing because it has demonstrated reliability and internal-consistency greater than 0.90 (56). Lewis and Sauro (56) report that the factor structure of the System Usability Scale represents two subscales, namely usability and learnability. The usability subscale is comprised of eight factors that load on usability, and is calculated by multiplying the sum of items 1, 2, 3, 5, 6, 7, 8, and 9 by 3.125 to derive the usability subscale score. The learnability

subscale is comprised of two factors that load on learnability and is calculated by multiplying the sum of items 4 and 10 by 12.5 to derive the learnability subscale score (56). The author selected the System Usability Scale to evaluate the display because it is easy to administer, reliable with small samples, and can differentiate usable from unusable systems (97). Additionally, the original author published the instrument as freely available for use (16). Moreover, one study suggests that other instruments, such as the Technology Acceptance Model questionnaire may be less suitable for measurement of health information technology use among physicians (108).

Statistical Methods

Clinicians assessed the usability of the information display with System Usability Scale and, the author reports the overall score, as well as the usability and learnability subscales. The author calculated the System Usability Scale overall score according to the procedure described by Brooke (16). The author compared clinicians' System Usability Scale scores to the expected score of 68 from the literature (16; 80) using Student's t-test. Additionally, the author calculated subscale scores for usability and learnability as described by Lewis and Sauro (56). The author calculated the Intraclass Correlation Coefficient (ICC) of clinician responses to each item of the System Usability Scale according to the procedure described by Shrout and Fleiss (87) to assess agreement of clinician ratings. The author calculated statistical tests using R version 3.1.3 (Comprehensive R Archive Network, <http://cran.r-project.org>). The author considered a P value of < 0.05 to be statistically significant.

RESULTS

Clinicians were recruited over two days. To assess the consistency of the sample, the investigator compared the original cohort that consisted of the first nine consecutively enrolled clinicians, with the second (validation) cohort that consisted of the next 5 consecutively enrolled clinicians. The author compared the two cohorts of clinician using Student's t-test for continuous variables and Chi-squared test for categorical variables; there were no significant differences between the groups so the cohorts were combined, resulting in final sample of 14 clinicians. Fourteen clinicians participated in the study (see Table 7).

The author, with the assistance of technical experts, developed a single-page screen to display heart failure-specific information from patient-collected data. The display is organized, so that information at the top of the display has lower temporal granularity and information near the bottom of the display has higher temporal granularity. For example, 24-hours in hours (top section), 8-hours in minutes (middle section), and 30-minutes in seconds (bottom section) (Figure 7).

After using the display, clinicians completed the System Usability Scale (Table 8). The mean and 95% confidence interval for the System Usability Scale overall score was 91.96 (86.77, 97.16), this was significantly higher than the expected mean of 68, $p < 0.0001$. The means and 95% confidence intervals for usability and learnability subscale scores were 91.74 (85.92, 97.56) and 92.86 (87.40, 98.13), respectively, both of which were significantly higher than their expected mean of 68, $p < 0.0001$.

The author was also interested in how correlated the clinician's ratings were for each item in the System Usability Scale. The Intraclass Correlation Coefficient of the clinician's ratings was 0.89 (CI = 0.79, 0.97), $p < 0.0001$.

DISCUSSION

The display constructed for this study is a single-page hierarchical temporally abstracted display of patient-collected data that provided clinicians structured data that they rated to be highly usable. A purpose of this display is to allow clinicians to quickly evaluate large amounts of clinical data collected by patients between visits, in a single page format that facilitates recognition of abnormal values in relationship to all the other data.

Previous researchers have focused on representing information from the electronic health record; constructed from data collected in clinical environments. Powsner and Tufte (71) developed a method to statically represent the numeric data from a single patient record. Plaisant and colleagues (69; 70) described the visual representation of record elements on a common time line with a product they called LifeLines™. Early work in exploring electronic records by temporal abstraction was reported by Shahar and Cheng (84), who describe a framework for knowledge-based navigation of abstractions for visualization and explanation (KNAVE). Further developed by Shahar and associates (85), KNAVE-II is an interactive query interface for exploration of multiple patient records at selectable levels of absolute and temporal abstraction for identification of patterns. Klimov and Shahar (52) further developed a framework for visualizing temporally derived information *VISITORS* (*VisualizatIon of Time-Oriented RecordS*) from multiple patient records which allows for interactive exploration of raw data and abstracted concepts across multiple patient records. All of these methods visually display data from the electronic patient record. The visual display constructed for this study is designed to show data for a single patient at a time, similar to other systems such as LifeLine™ and KNAVE; it does not allow for simultaneous display of multiple patient records like KNAVE-II and VISITORS. These systems have

demonstrated utility for applying specific research queries upon electronic medical records; yet, they are not adapted to the point-of-care needs of the clinician taking an interval history. The display constructed for this study is interface that clinicians find usable in the clinic environment at the time of the patient visit to rapidly review data collected by the patient since the last visit.

Between clinic visits, wearable patient-facing devices can collect enormous amounts of clinical data some of which are virtually meaningless when displayed solitarily in their raw form (i.e., activity data). Similarly, a single daily reading may not provide enough data (i.e., a single blood oxygen saturation) to be transformed into meaningful information (i.e., a visual relationship between blood oxygen saturation and activity level). Temporal granularity refers to the relevance of a specific unit of time in relationship to the problem under consideration; in other words, it refers to the selection of a contextually appropriate time scale (25). Information-overload results when individuals must analyze more variables than cognitively possible (39; 59). The employment of techniques to visually represent data to enhance interpretation of complex data have the potential to reduce information overload that is widespread in healthcare (18). There is increasing interest in the visualization of electronic health records; West and Borland (101) report that, among other lessons learned, users valued single-screen functionality that provided temporal data and represented mixed data types. The display developed for this study combines physiologic clinic variables selected for their clinical prognostic value and subjective state data. The data are arranged in a temporally abstracted hierarchy that presents multiple levels of temporal granularity simultaneously; thus, allowing clinicians to quickly recognize abnormal clinical information in relation to all the other data.

Martins and associates (57) asked 6 residents, fellows, and MD/PhD Students to compare KNAVE-II to electronic spreadsheets and paper records using the System Usability Scale. Participants were asked to complete a set of ten clinical query tasks of varying complexity from among three clinical scenarios, they report overall System Usability Scale scores for KNAVE-II, 69.1; paper records, 46.8; and electronic spreadsheets, 48.1. The conclude that clinicians can more quickly and accurately find meaningful information in large amounts of time-oriented clinical data using KNAVE-II than with paper records or electronic spreadsheets. The overall System Usability Scale score of 91.96 for the hierarchical temporally abstracted display constructed for this study was significantly higher than noted for KNAVE-II.

Applying the adjectival rating scale devised by Bangor and colleagues (7; 8), the overall System Usability Scale score of 91.96 is considered a “best imaginable” score. Additionally, subscale scores for usability and learnability, as described by Lewis and Sauro (56), were similarly high at, 91.74 and 92.86, respectively. The results of this investigation support that clinicians find the electronic display of patient-collected information usable.

CONCLUSION

The study was designed to collect clinician feedback in a setting that would mirror what occurs in a practicing clinic environment. The MHS clinic patient population and the treatments provided are similar to the general population (35; 46-48). A study limitation is the restricted number of clinicians who work in the cardiology clinic. The investigator recruited a convenience sample of clinicians from a single MHS cardiology clinic; which may limit generalizability of the results to other heart failure clinicians. Another study limitation is that its population consisted of consecutive heart failure patients seen at one

heart failure clinic, but we believe that these patients are representative of heart failure patients.

In summary, the author created a single page interactive display that communicated complex time-denominated heart failure-related information to clinicians. Clinicians reported that they found the system to be usable and that it provided clinical information regarding patients' medical status. The author suggests that the simultaneous hierarchical temporally abstracted display may be an efficient way for clinicians to rapidly evaluate multiples days of clinical data collected by patients at home between visits, providing ecologically valid information upon which to base clinical decision making. This study supports that a visual display can be constructed that increases the organization and structure of patient-collected data in a way that is usable to clinicians. Future studies need to assess the clinical usefulness of visual displays to support clinical decision-making.

Table 6. Subjective state assessment statements from iPad-based subjective state assessment application

1.	I am more short of breath than usual
2.	I am in more pain than usual
3.	I feel my heart beating fast
4.	I feel more tired than usual
5.	My feet are more swollen than usual
6.	I feel sicker than usual
7.	I am more unhappy than usual
8.	I have less appetite than usual
9.	I am confused
10.	I feel alone.

Table 7. Demographics of clinician sample (N=14)

Age (Mean ,SD)	40.4 (8.6)
Gender n (%)	
Female	8 (57.1%)
Position n (%)	
Staff Physician	4 (28.6%)
Fellow	4 (28.6%)
Medical Resident	1 (7.1%)
Nurse Practitioner	4 (28.6%)
Physician Assistant	1 (7.1%)
Practice years n (%)	
Less than 1 year	0 (0.0%)
1-3 years	2 (14.3%)
4-6 years	2 (14.3%)
7-9 years	1 (7.1%)
10 or more years	9 (64.3%)

Table 8. Clinician System Usability Scale mean scores and confidence intervals (CI) for electronic display of clinical information compared to mean score of 68.

Score	Mean $\pm$ SD	(95% CI)	P-value
Overall usability	91.96 $\pm$ 9.00	(86.77, 97.16)	p<0.0001
Usability subscale	91.74 $\pm$ 10.08	(85.92, 97.56)	p<0.0001
Learnability subscale	92.86 $\pm$ 9.45	(87.40, 98.13)	p<0.0001

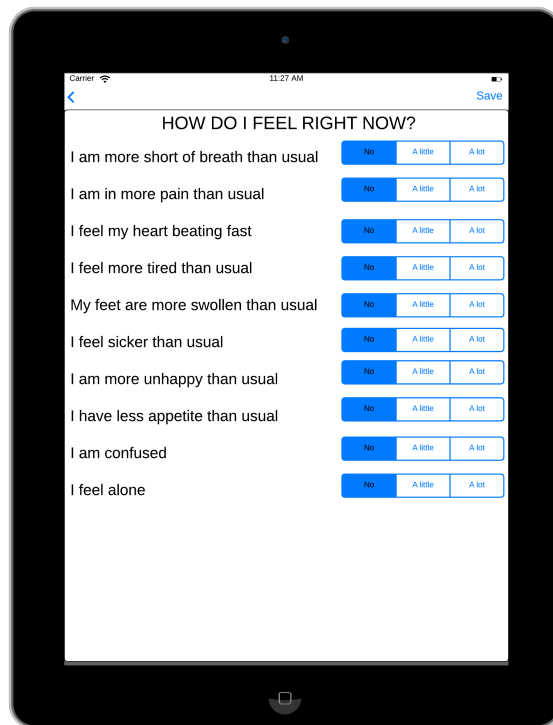


Figure 6. iPad-based subjective question assessment application



Figure 7. Electronic display of nocturnal heart failure information showing the interactive 24-hour view (arrows 2-4), 8-hour view (arrow 5), and 30-minute view (arrow 6-8), arrayed onto a single screen

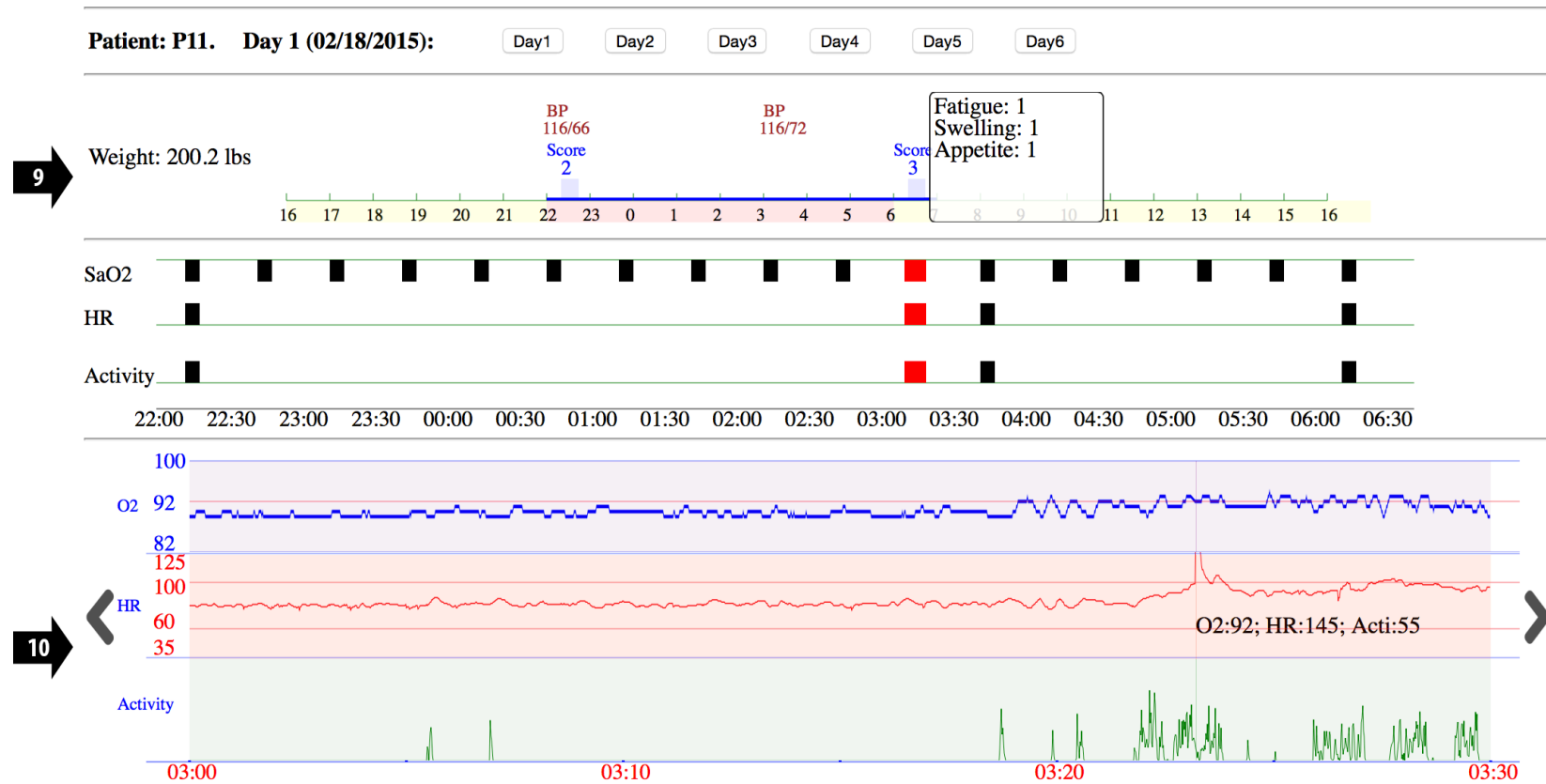


Figure 8. Additional detail showing subjective question set (arrow 9), and discrete values for 1-second level data on vertical cursor (arrow 10).

Chapter 5: Conclusion

INTRODUCTION

Chapter 1 was an introduction in which the primary investigator presented important background to the research question, the specific research problem, and the purpose of the study, as well as a brief description of the materials and methods employed to answer the research question. Chapter 2 was a submitted manuscript in which the investigator recognized some important limitations of the current approach to acquiring accurate and complete clinical information between clinic visits, particularly in patients with heart failure; then suggested an alternative method for collecting ecologically valid personalized clinical information. Chapter 3 was a submitted manuscript in which the investigator described the investigation of device use and assessment of usability in a sample of Military Health System (MHS) patients with heart failure. Chapter 4 was a prepared manuscript in which the investigator described, and evaluated, the usability of a display of patient-collected clinical information. Clinicians credentialed to practice in an MHS heart failure clinic evaluated the display. Chapter 5 provides a summary of the study, a discussion of the results, and recommendations for future study.

SUMMARY OF THE STUDY

Overview of the problem

Patient reported information about signs and symptoms and subjective states is a critical part of a clinician's assessment and evaluation of a patient's condition and diagnosis. However, patient reported information during a healthcare encounter is often

dependent on memory and lacks clarity and accuracy about trends or patterns of symptoms patients experience at home between clinic visits. In addition, there is little or no information available to a clinician regarding patient signs and symptoms experienced at night. This clinical information gap between healthcare encounters, especially for patients with heart failure, makes it difficult for the clinician to obtain complete and accurate between-visit clinical information upon which to base clinical management decisions. One proposed solution to improve the accuracy of assessing patient signs and symptoms, specifically those experienced at night, is for patients to use patient-facing electronic devices, devices intended to be used by patients to collect clinical data in non-clinical settings, to collect data at home for review by the clinician at the next visit. What is not known is: 1) how well patients collect physiologic and subjective state data at home, and 2) if a display can be designed that will present large amounts of patient-collected clinical information in a way that is usable by clinicians. This study assessed whether patients diagnosed with heart failure will collect data at home overnight for up to six nights and whether a temporally abstracted hierarchical display of that information can be created that is usable to clinicians.

Purpose statement

The purpose of this study was to determine if patients diagnosed with heart failure will collect physiologic and subjective state data at home overnight, if patients will find selected devices for collecting data overnight usable, and if the patient-collected data can be displayed in way that is usable to clinicians.

Methodology

This descriptive exploratory study was conducted between December 2014 and June 2015 in a MHS heart failure clinic. The institutional review board (IRB) of affiliated university and institution for research approved this study.

Patients included for consideration had a clinical diagnosis of heart failure, were between 21 and 90 years of age and able to operate study devices. All New York Heart Association Functional Classification (NYHA) patients were eligible to participate. Patients who were unable to operate the devices, by virtue of limited cognitive ability were excluded from consideration. The investigator sought to recruit at least the 37 participants needed to detect a 10-point difference in usability scores at moderate power. The participants were all retirees and their families. Participants were 39 clinical patients with heart failure, mean age 68.1 (SD, 12.3), 71.8% male, 61.5% African American, New York Heart Association (NYHA) classification: 25.6% class I patients, 56.4% class II patients, and 18.0% class III patients.

To evaluate the visual display of clinical information, the investigator recruited credentialed clinicians practicing in the heart failure clinic to use and rate the usability of a single-page display of patient-collected clinical information. The electronic display of patient-collected information was evaluated by fourteen clinicians age 40.6, SD 8.6, 57.1% female, including 4 staff cardiologist, 4 cardiology fellows, 4 nurse practitioners, 1 physician assistant, and 1 internal medicine resident.

Major findings

Question 1: Will patients use the selected patient-facing devices to collect physiologic and subjective state data at home overnight?

In this study, patients were asked to use a body weight scale, a blood pressure device, a pulse oximeter, an actigraph, and an iPad-based subjective state assessment application to collect physiologic and subjective state data at home overnight for six consecutive nights. Device use is shown in Table 8. The least used device was the body weight scale 4.50 days out of 6 days (4.02, 4.98). These results reflect only 24 patients, 15 patients did not use the study provided body weight scale and they are not included in the mean days used result. The mean use of the blood pressure monitor, iPad, and oximeter were approximately the same, 5.58 days (5.22, 5.95), 5.56 days (5.14, 5.99), and 5.51 days (5.20, 5.82), respectively, although their range of days did differ. The actigraph was used the most, mean 5.79 days (5.56, 6.00).

Use was defined as the ratio of observed use to expected use (O/E), where 1.0 is observed use equals expected use. The data show that the body weight scale was used O/E 0.80, significantly less than expected, $p < 0.001$. The observed use over the expected use for the blood pressure monitor, iPad, and pulse oximeter, O/E 1.03, 1.10, and 0.90, respectively, did not differ significantly, $p = 0.77$, $p = 0.16$, $p = 0.05$, respectively. The actigraph was used twice as much O/E 1.93, significantly more than expected, $p < 0.001$.

Question 2: Will patients report the devices used at home overnight to be usable?

Patients returned the devices after seven days and completed the System Usability Scale for each device, to assess device usability. Mean usability score and intraclass correlation coefficients are shown in Table 9. The System Usability Scale (SUS) grand mean overall score was 86.9 (84.8, 90.0) and the Intraclass Correlation Coefficient (ICC) of grand mean score was 0.73 (0.56, 0.90). For each device, the SUS mean score and the ICC score were: body weight scale, 84.5 (77.3, 91.6), 0.66 (0.46, 0.87), respectively;

blood pressure monitor, 89.7 (85.8, 93.6), 0.79 (0.64, 0.93), respectively; iPad subjective questions 85.7 (80.8, 90.6), 0.70 (0.51, 0.89), respectively; pulse oximeter 87.6 (83.5, 91.7), 0.61 (0.61, 0.92), respectively; and actigraph 85.2 (79.8, 90.7), 0.68 (0.50, 0.88), respectively. All the SUS and ICC scores were significantly different from what would be expected by chance, $p < 0.0001$.

Question 3: Will clinicians report the electronic display of patient-collected clinical information to be usable?

A single-page hierarchical display of temporally abstracted patient data was developed for this study, and clinicians were asked to rate the usability of the display for quick review of a patient's six-day collection of physiologic and subjective state data. In summary, the temporally abstracted hierarchical display is a single-page web-based application employing: a MySQL, Apache web server, PHP script language, Scalable Vector Graphics (SVG), AJAX, and JavaScript.

Clinicians used the display running on an iPad 3 to review a patient's six day of patient-collected data. After using the display clinicians completed the SUS. The mean and 95% confidence interval for the overall SUS score was 91.96 (86.77, 97.16); this was significantly higher than the expected mean, $p < 0.0001$. Additionally, the investigator calculated subscales for usability and learnability and found the mean and 95% confidence interval for usability and learnability to be 91.74 (85.92, 97.56), and 92.86 (87.40, 98.13), respectively.

DISCUSSION

The main findings of the study are that patients diagnosed with heart failure will, apart from the body weight scale, use selected patient-facing electronic devices to collect

physiologic and subjective state data at home overnight for up to six nights, and they reported all of the devices to be usable. Furthermore, a small sample of MHS clinicians from this heart failure clinic found that a temporally abstracted hierarchical display of patient-collected clinical information was usable. While use was not studied, it is proposed that usability may be a prerequisite for use.

The focus of this study was to determine if patients could use these devices at night so that nocturnal heart failure information could be collected. Although a great deal is known about daytime heart failure, there is little objective information about nocturnal heart failure. This study provides support for patients' ability to use these devices at night to collect high quality nocturnal heart failure information. More than two thirds of patients approached for the study agreed to participate, suggesting that among this sample, interest in home monitoring was high. There was no strong correlation between use scores and usability scores.

Additionally, this study was designed to mirror what would occur in a practicing clinic. Patients were shown the devices and over two-thirds agreed to participate and, all but three completed the study. The reasons patients gave for not participating were that they were not interested, it was too much work, and that they were in a hurry to leave the clinic. Although many studies of patient-facing devices used in patient's homes have high drop out rates, some nearly fifty percent (54), this study had a minimal drop out rate. It is acknowledged that these results may not be generalizable to all patients with heart failure.

This study provides new information about how to fill the gap in clinical information that occurs between clinic visits with ecologically valid clinical data

collected by patients at home overnight. In this sample, patients collected data overnight in addition to the diurnal measurements that are normally collected in clinic settings. The temporally abstracted hierarchical display of patient-collected clinical data provided clinicians with a way to quickly review large amounts of ecologically valid clinical data collected by patients between visits. It is acknowledged that the sample of clinicians was small and may not be generalized; however, the study provided some evidence for the feasibility of such nested temporally abstracted hierarchical visual display.

Clinical information gap between visit

Many patients with heart failure suffer a tremendous burden of nighttime symptoms including sleep-disordered breathing (74), of which they may not be aware. Overnight physiologic data collection does not typically occur outside the context of a formal sleep study.

Circadian patterns have been closely associated with cardiac function (33). Sleep disturbance in heart failure impacts daily function, mood, and quality of life (29; 62). Nonetheless, heart failure symptoms are not typically assessed at night. There is very little literature on the nocturnal aspects of heart failure. More than 70% of patients with heart failure report sleep disturbance (2; 74; 75). It is estimated that between 42% (95) and 51% (76) of patients with heart failure have moderate to severe sleep disordered breathing, a term used to describe abnormal breathing patterns during sleep. Subjective sleep assessment does not necessarily correlate with objective sleep assessment, meaning that patients may not realize the severity of impact of their symptoms (76; 86). Heart rate and blood oxygen saturation are also important clinical considerations in patients with heart failure. Shortness of breath is a ubiquitous heart failure symptom, regardless of

NYHA functional classification (1). Milo-Cotter and colleagues (60) found that in patients with heart failure admitted for acute exacerbations, those with lower blood oxygen saturation (<90%) were at increased risk of worsening heart failure and death. In this study, patients were willing to wear the pulse oximeter and the actigraph overnight to collect data on physical activity, heart rate, and blood oxygen saturation.

Methods for collecting between-visit clinical information have demonstrated limited completeness and accuracy (88; 100). Efforts to close the temporal distance between visits have been attempted through close follow-up monitoring (42; 73), including home telemonitoring, which has been well studied in patients with heart failure and has demonstrated benefits in terms of mortality, hospitalization and cost (21; 42; 49; 50). Telemonitoring virtually reduces the temporal distance between clinic visits by creating a virtual visit aided by telecommunications technologies. In common telemonitoring scenarios, an intermediary clinician, usually other than the patient's primary care clinician, reviews patient-collected data and determines whether or not to contact the patient (6; 26; 36; 53; 54; 64; 82; 89; 94; 99). Unfortunately, the introduction of an intermediate clinician for monitoring may reduce the fidelity of patient information received by the primary care clinician. Developing a way for the primary care clinician to quickly and personally review patient multiple variables of collected clinical data since the last visit would improve the quality of patient information available for clinical decision-making. The display developed for this study is designed to allow the clinician to rapidly review enormous amounts of patient-collected clinical data and recognize specific clinical information in relation to other clinical information simultaneously; the findings provide support for the feasibility of using such a visual display in the future.

Electronic collection of patient data

Overall the results demonstrate that, apart from the body weight scale, patients were able to use the selected patient-facing electronic devices for collecting physiologic and subjective state data at home overnight for up to six nights, and that patients found the devices to be highly usable. Studies of home telemonitoring devices often refer to telemonitoring as a singular intervention and fail to adequately describe the number and type of devices used for electronic data collection (49). While the outcomes associated with automatic devices-based home telemonitoring have been well studied, use and usability of the devices used have not been a specified outcome measure (49).

The body weight scale was used significantly less than expected. It ranked lowest in usability score and next lowest in terms of agreement in usability scores across patients. Fifteen patients did not use the study provided body weight scale in this study. There were no statistically significant difference in age, gender balance, race/ethnicity composition, or NYHA functional class distribution between those who used the study provided body weight scale and those who did not. Among those who used the study provided body weight scale, it had the lowest mean days used, the lowest O/E ratio, the lowest SUS score, and the second lowest agreement in usability scores across patients. The difference in body weight scale use may be partially due to patients weighing on their own home weight scale instead of using body weight scale provided by the study. Because the operation of the study body weight scale required users to bend down to activate the device, the study body weight scale use may have been affected by some patient's physical limitations (i.e., obesity, decreased flexibility, or impaired balance). Some patients expressed concern about falling while engaging in this activity, and so

declined to use the study provided body weight scale. A possible explanation may be patients with heart failure many times do not fully appreciate the risks associated with weight gain, and so adhere poorly to weight monitoring recommendations (63).

The blood pressure device was used as expected; it had the highest usability scores and its ICC score demonstrated the highest user agreement across patients. When examining the differences between NYHA classes, there was no significant difference in use score, but there was a significant difference in usability score between NYHA class II and class III patients. Most patients reported experience with blood pressure monitoring devices and many reported already having a similar device at home. This familiarity may be the cause for such high usability scores and usability score agreement.

The iPad-based subjective state assessment application was used slightly, but not significantly more than expected. It ranked third in usability score and second in usability agreement across patient. When examining difference between NYHA classes, there was no significant difference in use, but there was a significant difference in usability scores between NYHA class II and class III patients. Patient experience with tablet computers varied with some reporting ownership of a device and some reporting not. A few patients (those with lower NYHA classification ratings) reported that they felt some of the sign, symptom, and subjective state questions did not apply to them.

The pulse oximeter was used as expected, $p = 0.05$. It ranked next highest in terms of usability, but lowest in terms of score agreement across patients. When examining difference between NYHA classes, there was no significant difference in use, but there was a significant difference in usability scores between NYHA class II and class III patients in this study with class III patients reporting higher usability scores.

The actigraph was used significantly more than expected. It had the next lowest usability scores and ranked third in terms of agreement in usability scores across patients. When comparing NYHA class patients, there was no significant difference for use ratio between classes, but there was a significant difference between NYHA class II and class III patients in terms of usability rating. The actigraph was the simplest device to use, and the simplicity of operation may have facilitated higher use. Patients were informed that if they wished, they could wear the actigraph continuously. A few patients stated that even though they did not completely understand the purpose of the actigraph, they were willing to wear it.

Electronic presentation of patient information

The single-page nested temporally abstracted hierarchical display of patient-collected clinical information that clinicians evaluated was found to be highly usable. The results of this investigation provide evidence that clinicians will find the electronic display of patient-collected information usable.

The employment of techniques to visually represent data to enhance interpretation of complex data have the potential to reduce information overload that is widespread in healthcare (18). Information-overload results when individuals must analyze more variables than cognitively possible (39; 59). There is increasing interest in visualization of electronic health records (101). In a review of innovative information visualizations for electronic health records, West and colleagues (101) report that, among other lessons learned, users valued single-screen functionality that provided temporal data and represented mixed data types.

Displays capable of presenting multiple temporal streams of data are common in critical care setting (68). These data displays show data as it is happening. To bridge the between-visit clinical information gap, patient-collected data must be organized and displayed in a way that permits rapid assessment of large amounts of data collected over time, showing how the patient has progressed to their current state since the last visit.

Methods for single patient clinical information visualization systems can be grouped into four categories: displaying numerical data over time, displaying categorical data over time, displaying heterogeneous data on a common time scale, and displaying a snapshot of a patient's state (78). The display screen constructed for this study simultaneously displays multiple temporally abstracted views arranged hierarchically. Temporal abstraction is simplifying the representation of time series data by compressing it into smaller less detailed time segments (25). Temporally abstracting data promotes rapid visual decoding (22), and reduces cognitive burden (96). This arrangement enables clinicians to simultaneously access data at multiple levels of temporal granularity on the same page.

Temporal granularity refers to the relevance of a specific unit of time in relationship to the problem under consideration; in other words, it refers to the selection of a contextually appropriate time scale (25). For example, it would be virtually impossible to review a patient's blood oxygen saturation for an 8-hour period on the scale of sections. The display constructed for this study uniquely addresses the issue of temporal granularity by arranging the display dimension in a temporal hierarchy so that clinicians can focus on detailed sections of data while preserving the overall context without distorting the relationships between the variables.

The main finding is that clinicians rated the usability of the display significantly higher than the expected score. Applying the adjectival rating scale devised by Bangor and colleagues (7; 8), the score of 91.96 is considered a “best imaginable” score. Additionally, subscale scores for usability and learnability, as described by Lewis and Sauro (56), were similarly high at, 91.74 and 92.86, respectively.

STRENGTHS AND LIMITATIONS

An important strength of this study is that it was conducted in a small, controlled environment. During the course of this study there were no major changes in the heart failure clinic operation or staffing. The patient population was stable and there were no interventions that might have affected the results of this study. The conditions limited the number of confounding variables permitting the focus on feasibility. Additionally, the System Usability Scale is standardized measure with well-documented reliability (16; 56; 80).

One limitation is that subjects represented a convenience sample of only one site. This may limit generalizability for both patients and clinicians. Another limitation is that, by design, the study enrolled only patients who demonstrated the cognitive and psychomotor ability to operate the study devices. Physical limitations may have led some patients to use the weight scale less than expected.

RECOMMENDATIONS

The results of this study support that patients will use patient-facing devices to collect their clinical information and that clinicians find a hierarchical visual display of temporally abstracted patient-collected data to be usable in providing clinical information. On possible next step would be to assess the clinical use and usefulness of

the visually displayed information. This would require a study in which clinicians' patients collected their clinical information and sent it to their clinician. The clinician could either review their information in real time or they could review it at the time of the patient's next visit to their clinic. The goal of this study would be to test whether there was any difference in the management and outcomes of the patients who used the devices compared to the patients who did not use the devices.

CONCLUSION

In this study, researchers investigated how patients will use and rate the usability of selected patient-facing devices for collecting physiologic and subjective state data at home overnight, and how clinicians rate the usability of a novel electronic visual display of patient-collected clinical information. These results support the feasibility of collecting and displaying the between-visit clinical information that can fill the gap clinicians find at subsequent patient visits to the clinic. Patient-facing electronic devices can capture enormous amounts of patient-collected clinical data; data that was not previously available to clinicians in a way that could be rapidly integrated during a clinic visit. Being able to rapidly review enormous amounts of ecologically valid, patient collected data that is organized into a meaningful visual display that communicates useful information for making clinical decisions can provide clinicians with a clearer understanding of how a patient's condition has developed over time. Results from this study provide evidence for the feasibility of achieving that outcome.

Table 9. Patient device use.

Episodic devices	Days used		Average number measurements taken			
	Mean (95% CI)	Range	Observed	Expected	O/E ¹	p-value
Body weight scale ²	4.50 (4.02, 4.98)	2 - 6	4.87	6	0.80	<0.001
Blood pressure device	5.58 (5.22, 5.95)	1 - 6	12.54	12	1.03	0.77
iPad-based subjective state app	5.56 (5.14, 5.99)	0 - 6	13.58	12	1.10	0.16
Continuous devices	Days used		Time used (hours)			
	Mean (95% CI)	Range	Observed	Expected	O/E ¹	p-value
Pulse oximeter	5.51 (5.20, 5.82)	3 - 6	43.71	48	0.90	0.05
Actigraph ³	5.79 (5.56, 6.00)	2 - 6	95.58	48	1.93	<0.001

¹Ratio of observed over expected (O/E) device use where 1.0 is observed equals expected.

²The results are based on the 24 patients who used the scale.

³Three patients used a Zephyr device for activity; they are not included in the activity results.

Table 10 The mean System Usability Scale (SUS) scores and 95% confidence interval (CI) by device and the intraclass correlation coefficients (ICC) and 95% confidence interval by device. All scores were significantly different than expected by chance ($p<0.0001$).

Device	SUS Mean (95% CI)	ICC (95% CI)
Body weight scale	84.5 (77.3, 91.6)	0.66 (0.46, 0.87)
Blood pressure device	89.7 (85.8, 93.6)	0.79 (0.64, 0.93)
iPad-based subjective state app	85.7 (80.8, 90.6)	0.70 (0.51, 0.89)
Pulse oximeter	87.6 (83.5, 91.7)	0.61 (0.61, 0.92)
Actigraph	85.2 (79.8, 90.7)	0.68 (0.50, 0.88)
Grand Mean	86.9 (84.8, 90.0)	0.73 (0.56, 0.90)

REFERENCES

1. Albert N, Trochelman K, Li J, Lin S. 2010. Signs and symptoms of heart failure: are you asking the right questions? *American journal of critical care : an official publication, American Association of Critical-Care Nurses* 19:443-52
2. Andrews LK, Coviello J, Hurley E, Rose L, Redeker NS. 2013. "I'd eat a bucket of nails if you told me it would help me sleep:" Perceptions of insomnia and its treatment in patients with stable heart failure. *Heart & lung : the journal of critical care* 42:339-45
3. Anestis MD, Selby EA, Crosby RD, Wonderlich SA, Engel SG, Joiner TE. 2010. A comparison of retrospective self-report versus ecological momentary assessment measures of affective lability in the examination of its relationship with bulimic symptomatology. *Behaviour research and therapy* 48:607-13
4. Asch DA, Muller RW, Volpp KG. 2012. Automated Hovering in Health Care — Watching Over the 5000 Hours. *New England Journal of Medicine* 367:1-3
5. Ayman D, Goldshine AD. 1943. Blood-Pressure Determinations in Patients with Essential Hypertension. *New England Journal of Medicine* 229:799-811
6. Balk AH, Davidse W, Dommelen P, Klaassen E, Caliskan K, et al. 2008. Tele-guidance of chronic heart failure patients enhances knowledge about the disease. A multi-centre, randomised controlled study. *European journal of heart failure* 10:1136-42
7. Bangor A, Kortum P, Miller J. 2009. Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of usability studies* 4:114-23
8. Bangor A, Kortum PT, Miller JT. 2008. An empirical evaluation of the system usability scale. *Intl. Journal of Human-Computer Interaction* 24:574-94
9. Barr L. 2015. New plan will dramatically change today's Air Force health system. In *Inside Maxwell AFB*
10. Ben-Zeev D, Young MA. 2010. Accuracy of hospitalized depressed patients' and healthy controls' retrospective symptom reports: an experience sampling study. *The Journal of nervous and mental disease* 198:280-5
11. Bhimaraj A. 2013. Remote monitoring of heart failure patients. *Methodist Debaque Cardiovasc J* 9:26-31
12. Black N. 1999. High-quality clinical databases: breaking down barriers. *The Lancet* 353:1205-6

13. Blum BI. 1986. Clinical information systems—a review. *Western Journal of Medicine* 145:791
14. Bonow RO, Bennett S, Casey DE, Jr., Ganiats TG, Hlatky MA, et al. 2005. ACC/AHA clinical performance measures for adults with chronic heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Heart Failure Clinical Performance Measures) endorsed by the Heart Failure Society of America. *Journal of the American College of Cardiology* 46:1144-78
15. Broderick JE, Schwartz JE, Vikingstad G, Pribbernow M, Grossman S, Stone AA. 2008. The accuracy of pain and fatigue items across different reporting periods. *Pain* 139:146-57
16. Brooke J. 1996. SUS-A quick and dirty usability scale. *Usability evaluation in industry* 189:194
17. Bui AA, Aberle DR, Kangarloo H. 2007. TimeLine: visualizing integrated patient records. *IEEE transactions on information technology in biomedicine : a publication of the IEEE Engineering in Medicine and Biology Society* 11:462-73
18. Caban JJ, Gotz D. 2015. Visual analytics in healthcare--opportunities and research challenges. *Journal of the American Medical Informatics Association : JAMIA* 22:260-2
19. Choi L, Liu Z, Matthews CE, Buchowski MS. 2011. Validation of accelerometer wear and nonwear time classification algorithm. *Medicine and science in sports and exercise* 43:357-64
20. Choo CW. 2005. The Knowing Organization. In *The Knowing Organization*, pp. 1-29
21. Clark RA, Inglis SC, McAlister FA, Cleland JG, Stewart S. 2007. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *BMJ (Clinical research ed.)* 334:942
22. Cleveland WS, McGill R. 1985. Graphical perception and graphical methods for analyzing scientific data. *Science (New York, N.Y.)* 229:828-33
23. Cohen J. 1992. Statistical power analysis. *Current directions in psychological science*:98-101
24. Conway A, Inglis SC, Clark RA. 2014. Effective technologies for noninvasive remote monitoring in heart failure. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association* 20:531-8

25. Cousins SB, Kahn MG. 1991. The visual display of temporal information. *Artificial intelligence in medicine* 3:341-57
26. Dar O, Riley J, Chapman C, Dubrey SW, Morris S, et al. 2009. A randomized trial of home telemonitoring in a typical elderly heart failure population in North West London: results of the Home-HF study. *European journal of heart failure* 11:319-25
27. Donaldson SK, Crowley DM. 1978. The discipline of nursing. *Nursing outlook* 26:113-20
28. Eastwood CA, Travis L, Morgenstern TT, Donaho EK. 2007. Weight and symptom diary for self-monitoring in heart failure clinic patients. *The Journal of cardiovascular nursing* 22:382-9
29. Erickson VS, Westlake CA, Dracup KA, Woo MA, Hage A. 2003. Sleep disturbance symptoms in patients with heart failure. *AACN clinical issues* 14:477-87
30. European Network of Living Laboratories. 2015. *About us*. <http://www.openlivinglabs.eu/aboutus>
31. Fox S, Duggan M. 2013. Tracking for Health.
32. Gallagher R, Sullivan A, Burke R, Hales S, Gillies G, et al. 2013. Mild cognitive impairment, screening, and patient perceptions in heart failure patients. *Journal of cardiac failure* 19:641-6
33. Gallerani M, Manfredini R, Ricci L, Cappato R, Grandi E, et al. 1993. Sudden death may show a circadian time of risk depending on its anatomo-clinical causes and age. *Japanese heart journal* 34:729-39
34. Gardner CL, Flanagan MC, Franklin C, John-Sawyers C, Walsh-Pouch S, et al. 2015. *Electronic physiologic and subjective data acquisition in home-dwelling heart failure patients: An assessment of patient use and perception of usability*. Dissertation Chapter. Uniformed Services University of the Health Sciences
35. Gimbel RW, Pangaro L, Barbour G. 2010. America's "undiscovered" laboratory for health services research. *Medical care* 48:751-6
36. Goldberg LR, Piette JD, Walsh MN, Frank TA, Jaski BE, et al. 2003. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. *American heart journal* 146:705-12
37. Graves JR, Corcoran S. 1989. The study of nursing informatics. *Image--the journal of nursing scholarship* 21:227-31

38. Greenhalgh T, Wherton J, Sugarhood P, Hinder S, Procter R, Stones R. 2013. What matters to older people with assisted living needs? A phenomenological analysis of the use and non-use of telehealth and telecare. *Social science & medicine* (1982) 93:86-94
39. Halford GS, Baker R, McCredden JE, Bain JD. 2005. How Many Variables Can Humans Process? *Psychological Science* 16:70-6
40. HealthIT.gov. 2014. Patient-Generated Health Data. ed. NL Consortium
41. Henly SJ, Wyman JF, Findorff MJ. 2011. Health and Illness Over Time: The Trajectory Perspective in Nursing Science. *Nursing research* 60:S5-S14
0.1097/NNR.0b013e318216dfd3
42. Holland R, Battersby J, Harvey I, Lenaghan E, Smith J, Hay L. 2005. Systematic review of multidisciplinary interventions in heart failure. *Heart (British Cardiac Society)* 91:899-906
43. Howell J, Strong BM, Weisenberg J, Kakade A, Gao Q, et al. 2010. Maximum daily 6 minutes of activity: an index of functional capacity derived from actigraphy and its application to older adults with heart failure. *Journal of the American Geriatrics Society* 58:931-6
44. Inglis SC, Clark RA, McAlister FA, Ball J, Lewinter C, et al. 2010. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. *Cochrane database of systematic reviews (Online)*:Cd007228
45. International Organization for Standardization. *usability*.
[https://www.iso.org/obp/ui/- iso:std:iso:9241:-11:ed-1:v1:en](https://www.iso.org/obp/ui/-iso:std:iso:9241:-11:ed-1:v1:en)
46. Jackson JL, Cheng EY, Jones DL, Meyer G. 1999. Comparison of discharge diagnoses and inpatient procedures between military and civilian health care systems. *Military medicine* 164:701-4
47. Jackson JL, O'Malley PG, Kroenke K. 1999. A psychometric comparison of military and civilian medical practices. *Military medicine* 164:112-5
48. Jackson JL, Strong J, Cheng EY, Meyer G. 1999. Patients, diagnoses, and procedures in a military internal medicine clinic: comparison with civilian practices. *Military medicine* 164:194-7
49. Kitsiou S, Paré G, Jaana M. 2015. Effects of Home Telemonitoring Interventions on Patients With Chronic Heart Failure: An Overview of Systematic Reviews. *Journal of medical Internet research* 17
50. Klersy C, De Silvestri A, Gabutti G, Raisaro A, Curti M, et al. 2011. Economic impact of remote patient monitoring: an integrated economic model derived from

a meta-analysis of randomized controlled trials in heart failure. *European journal of heart failure* 13:450-9

51. Klersy C, De Silvestri A, Gabutti G, Regoli F, Auricchio A. 2009. A meta-analysis of remote monitoring of heart failure patients. *Journal of the American College of Cardiology* 54:1683-94
52. Klimov D, Shahar Y. 2005. A framework for intelligent visualization of multiple time-oriented medical records. *AMIA ... Annual Symposium proceedings / AMIA Symposium. AMIA Symposium*:405-9
53. Konstam V, Gregory D, Chen J, Weintraub A, Patel A, et al. 2011. Health-related quality of life in a multicenter randomized controlled comparison of telephonic disease management and automated home monitoring in patients recently hospitalized with heart failure: SPAN-CHF II trial. *Journal of cardiac failure* 17:151-7
54. Kulshreshtha A, Kvedar JC, Goyal A, Halpern EF, Watson AJ. 2010. Use of remote monitoring to improve outcomes in patients with heart failure: a pilot trial. *Int J Telemed Appl* 2010:870959
55. Lee KS, Moser DK. 2013. Heart failure symptom measures: critical review. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology* 12:418-28
56. Lewis JR, Sauro J. 2009. The factor structure of the system usability scale. In *Human Centered Design*:94-103: Springer. Number of 94-103 pp.
57. Martins SB, Shahar Y, Galperin M, Kaizer H, Goren-Bar D, et al. 2004. Evaluation of KNAVE-II: a tool for intelligent query and exploration of patient data. *Studies in health technology and informatics* 107:648-52
58. McDonald K, Wilkinson M, Ledwidge M. 2015. Role of Monitoring Devices in Preventing Heart Failure Admissions. *Current heart failure reports*
59. Miller GA. 1956. The magical number seven, plus or minus two: some limits on our capacity for processing information. *Psychological Review* 63:81-97
60. Milo-Cotter O, Cotter G, Kaluski E, Rund MM, Felker GM, et al. 2009. Rapid clinical assessment of patients with acute heart failure: first blood pressure and oxygen saturation--is that all we need? *Cardiology* 114:75-82
61. Myatt GJ, Johnson WP. 2008. Data Visualization. In *Making Sense of Data II*:19-66: John Wiley & Sons, Inc. Number of 19-66 pp.
62. Naughton MT, Lorenzi-Filho G. 2009. Sleep in heart failure. *Progress in cardiovascular diseases* 51:339-49

63. Ni H, Nauman D, Burgess D, Wise K, Crispell K, Hershberger RE. 1999. Factors influencing knowledge of and adherence to self-care among patients with heart failure. *Archives of internal medicine* 159:1613-9
64. Noel HC, Vogel DC, Erdos JJ, Cornwall D, Levin F. 2004. Home telehealth reduces healthcare costs. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association* 10:170-83
65. Ottawa JMLPEU. 2000. *A Dictionary of Epidemiology*. Oxford University Press, USA
66. Pai A. 2015. Survey: 67 percent of seniors want to access healthcare at home. In *mobihealthnews*
67. Patel H, Shafazand M, Schaufelberger M, Ekman I. 2007. Reasons for seeking acute care in chronic heart failure. *European journal of heart failure* 9:702-8
68. Philips. 2014. *IntelliVue MP60 and MP70 patient monitors*.
http://www.healthcare.philips.com/main/products/patient_monitoring/products/intellivue_mp70_mp60/index.wpd
69. Plaisant C, Milash B, Rose A, Widoff S, Shneiderman B. 1996. LifeLines: visualizing personal histories. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, pp. 221-7. Vancouver, British Columbia, Canada: ACM
70. Plaisant C, Mushlin R, Snyder A, Li J, Heller D, Shneiderman B. 1998. LifeLines: using visualization to enhance navigation and analysis of patient records. *Proceedings of the AMIA Symposium*:76-80
71. Powsner SM, Tufte ER. 1994. Graphical summary of patient status. *Lancet* 344:386-9
72. Pressler SJ. 2008. Cognitive functioning and chronic heart failure: a review of the literature (2002-July 2007). *The Journal of cardiovascular nursing* 23:239-49
73. Quaglietti SE, Atwood JE, Ackerman L, Froelicher V. 2000. Management of the patient with congestive heart failure using outpatient, home, and palliative care. *Progress in cardiovascular diseases* 43:259-74
74. Redeker NS. 2008. Sleep disturbance in people with heart failure: implications for self-care. *The Journal of cardiovascular nursing* 23:231-8
75. Redeker NS, Hilkert R. 2005. Sleep and quality of life in stable heart failure. *Journal of cardiac failure* 11:700-4

76. Redeker NS, Muench U, Zucker MJ, Walsleben J, Gilbert M, et al. 2010. Sleep disordered breathing, daytime symptoms, and functional performance in stable heart failure. *Sleep* 33:551-60
77. Riegel B, Dickson VV, Cameron J, Johnson JC, Bunker S, et al. 2010. Symptom recognition in elders with heart failure. *Journal of nursing scholarship : an official publication of Sigma Theta Tau International Honor Society of Nursing / Sigma Theta Tau* 42:92-100
78. Rind A, Wang TD, Aigner W, Miksch S, Wongsuphasawat K, et al. 2011. Interactive information visualization to explore and query electronic health records. *Foundations and Trends in Human-Computer Interaction* 5:207-98
79. Rowley J. 2007. The wisdom hierarchy: representations of the DIKW hierarchy. *Journal of Information Science* 33:163-80
80. Sauro J. 2011. A Practical Guide to the System Usability Scale: Background, Benchmarks, and Best Practices. Denver, CO: Measuring Usability, LLC
81. Schmuckler MA. 2001. What is ecological validity? A dimensional analysis. *Infancy* 2:419-36
82. Schwarz KA, Mion LC, Hudock D, Litman G. 2008. Telemonitoring of heart failure patients and their caregivers: a pilot randomized controlled trial. *Progress in cardiovascular nursing* 23:18-26
83. Shafazand M, Patel H, Ekman I, Swedberg K, Schaufelberger M. 2012. Patients with worsening chronic heart failure who present to a hospital emergency department require hospital care. *BMC research notes* 5:132
84. Shahar Y, Cheng C. 1999. Intelligent visualization and exploration of time-oriented clinical data. *Topics in health information management* 20:15-31
85. Shahar Y, Goren-Bar D, Boaz D, Tahan G. 2006. Distributed, intelligent, interactive visualization and exploration of time-oriented clinical data and their abstractions. *Artificial intelligence in medicine* 38:115-35
86. Short MA, Gradisar M, Lack LC, Wright H, Carskadon MA. 2012. The discrepancy between actigraphic and sleep diary measures of sleep in adolescents. *Sleep medicine* 13:378-84
87. Shrout PE, Fleiss JL. 1979. Intraclass correlations: uses in assessing rater reliability. *Psychological bulletin* 86:420-8
88. Smith AF, Jobe JB, Mingay DJ. 1991. Retrieval from memory of dietary information. *Applied Cognitive Psychology* 5:269-96

89. Soran OZ, Pina IL, Lamas GA, Kelsey SF, Selzer F, et al. 2008. A randomized clinical trial of the clinical effects of enhanced heart failure monitoring using a computer-based telephonic monitoring system in older minorities and women. *Journal of cardiac failure* 14:711-7
90. Spertus J, Peterson E, Conard MW, Heidenreich PA, Krumholz HM, et al. 2005. Monitoring clinical changes in patients with heart failure: a comparison of methods. *American heart journal* 150:707-15
91. Stacey M, Salvatore J, Jorgensen A. 2013. Visual Intelligence: Microsoft Tools and Techniques for Visualizing Data. Wiley
92. Stone AA, Shiffman S, Schwartz JE, Broderick JE, Hufford MR. 2002. Patient non-compliance with paper diaries. *BMJ (Clinical research ed.)* 324:1193-4
93. Svagard I, Austad HO, Seeberg T, Vedum J, Liverud A, et al. 2014. A usability study of a mobile monitoring system for congestive heart failure patients. *Studies in health technology and informatics* 205:528-32
94. Tompkins C, Orwat J. 2010. A randomized trial of telemonitoring heart failure patients. *J Healthc Manag* 55:312-22; discussion 22-3
95. Trupp RJ, Hardesty P, Osborne J, Shelby S, Lamba S, et al. 2004. Prevalence of sleep disordered breathing in a heart failure program. *Congestive heart failure (Greenwich, Conn.)* 10:217-20
96. Tufte ER. 2001. *The visual display of quantitative information*. Graphics press Cheshire, CT
97. U.S. Department of Health and Human Services. 2014. *System Usability Scale (SUS)*. <http://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html> - PAGE_4
98. Varma N, Piccini JP, Snell J, Fischer A, Dalal N, Mittal S. 2015. Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients. *Journal of the American College of Cardiology*
99. Wade MJ, Desai AS, Spettell CM, Snyder AD, McGowan-Stackewicz V, et al. 2011. Telemonitoring with case management for seniors with heart failure. *The American journal of managed care* 17:e71-9
100. Wang PS, Benner JS, Glynn RJ, Winkelmayr WC, Mogun H, Avorn J. 2004. How well do patients report noncompliance with antihypertensive medications?: a comparison of self-report versus filled prescriptions. *Pharmacoepidemiol Drug Saf* 13:11-9

101. West VL, Borland D, Hammond WE. 2015. *Innovative information visualization of electronic health record data: a systematic review*. 330-9 pp.
102. White MM, Howie-Esquivel J, Caldwell MA. 2010. Improving heart failure symptom recognition: a diary analysis. *The Journal of cardiovascular nursing* 25:7-12
103. Willis GB, Royston P, Bercini D. 1991. The use of verbal report methods in the development and testing of survey questionnaires. *Applied Cognitive Psychology* 5:251-67
104. Winkler S, Schieber M, Lucke S, Heinze P, Schweizer T, et al. 2011. A new telemonitoring system intended for chronic heart failure patients using mobile telephone technology--feasibility study. *International journal of cardiology* 153:55-8
105. Writing Committee M, Yancy CW, Jessup M, Bozkurt B, Butler J, et al. 2013. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation* 128:e240-327
106. Zambroski CH, Moser DK, Bhat G, Ziegler C. 2005. Impact of symptom prevalence and symptom burden on quality of life in patients with heart failure. *European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology* 4:198-206
107. Zan S, Agboola S, Moore SA, Parks KA, Kvedar JC, Jethwani K. 2015. Patient engagement with a mobile web-based telemonitoring system for heart failure self-management: a pilot study. *JMIR Mhealth Uhealth* 3:e33
108. Zheng K, Padman R, Johnson MP, Diamond HS. 2007. Evaluation of Health IT Applications: The User Acceptance Perspective. *Studies in Computational Intelligence* 65:49-78

Appendix A

**WALTER REED NATIONAL MILITARY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD**
8901 WISCONSIN AVENUE
BETHESDA MARYLAND 20889-5600

December 4, 2014

MEMORANDUM

FROM: WRNMMC IRB
TO: LTC Brian Hemann, MC, USA
SUBJECT: WRNMMC IRB REVIEW OF New Project

PROJECT TITLE: The Electronic Collection and Presentation of Nocturnal Heart Failure Information
REFERENCE #: 400924-1
ACTION: APPROVED
APPROVAL DATE: December 3, 2014
EXPIRATION DATE: December 3, 2015
REVIEW TYPE: Expedited Review
RISK LEVEL: Minimal Risk

1. Your New Project materials have been APPROVED by expedited review IAW 32 CFR 219.110 and 32 CFR 219.111. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All future research must be conducted in accordance with this approved submission.
2. This is an IRB approval. Please check with your local command to ensure you have met all Command requirements.
3. Prior to initiating your research study, you, as the Principal Investigator, must ensure all applicable agreements are in place to comply with institutional requirements. These agreements must be uploaded into IRBNet so that they are available in the regulatory file.
4. The IRB approved, stamped consent/HIPAA authorization forms enclosed are to be duplicated and used to enroll subjects. Keep the signed, original consent forms in your project file; give each subject a signed copy of the consent form.
5. If collection and or analysis of data for your project are to continue beyond one year, you must submit a report for continuation. In order for ongoing human subject research projects to be reviewed, approved and processed by the IRB within this time constraint, you will be sent an automatic reminder from IRBNet

approximately 60 days prior to your review date. You are reminded that it is also your responsibility to maintain your research files in a secured, locked location.

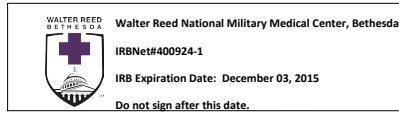
6. You are reminded to provide all amendments, unanticipated problems involving risks to subjects or others, deviations, related serious adverse events, and any other relevant information through IRBNet for reporting to the IRB.

7. You are reminded that any presentations or publications regarding this project must be appropriately cleared through the publication clearance process.

8. Please do not hesitate to contact the WRNMMC Department of Research Programs staff at (301) 295-8239 for any assistance or concerns.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

Appendix B



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Research Study Entitled: *The Electronic Collection and Presentation of Nocturnal Heart Failure Information*

Principal Investigator:

Brian Hemann, MD
LTC, MC, USA
Assistant Chief
Department of Cardiology
Walter Reed National Medical Military Center
8901 Wisconsin Ave
Bethesda, MD 20889-5600
301-319-3480 (office)
brian.hemann@med.navy.mil

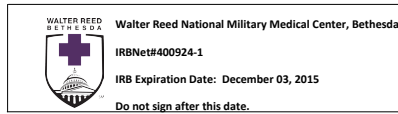
Study site: ☒ WRNMMC, ☐ FBCH, ☐ USUHS, ☐ WRAIR, ☐ NMRC, ☐ JPC,
☐ OTHER

Are you participating in any other research studies? ☐ Yes ☐ No

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you have been diagnosed with heart failure and are currently receiving care in the Heart Failure Clinic at Walter Reed National Military Medical Center (WRNMMC).

Taking part in this study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. Leaving the study will not affect your medical care. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

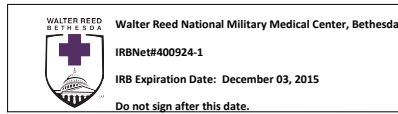
2. PURPOSE OF THE STUDY:

The purpose of this study is to assess our ability to collect data about your heart failure signs and symptoms that occur during the night and create an electronic display summary. The data we collect will only contain the nighttime signs and symptoms of heart failure. This collected data will not be monitored in real time by the investigators or your clinical team; which means the data will not be transmitted to the clinic by the investigators and the data will not be screened, reviewed, or used by your clinicians. The data will be stored in the devices and downloaded after you return the equipment. During the study period, you should follow all routine care and treatment instructions as provided by your clinical team. If you develop a new concern about your health during the study period, please contact your healthcare clinician as you normally would. If you feel you have a medical emergency, you should dial 911.

3. PROCEDURES TO BE FOLLOWED:

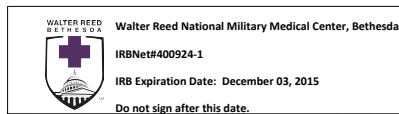
As a participant, you will be asked to do the following things:

- At the beginning of the study (enrollment period):
 - Meet with the associate investigator to complete a demographics form.
 - Receive equipment and training on how to use the equipment. You will be given a daily activity list and equipment operating instructions form. To ensure you are comfortable with the equipment, you will demonstrate how to use the devices to the associate investigator after the equipment training. Then, you will sign an equipment check-out form for the 5 study devices and a carrying bag.
 - If you are unable to transport the devices to your home, the associate investigator will make arrangements to deliver the devices.
 - You will schedule a follow-up visit with the investigator which will take place the following week in order to return the 5 study devices at WRNMMC Heart Failure Clinic. If you are unable to transport the devices to WRNMMC, the associate investigator will make arrangements to pick up the devices at your home.
 - The enrollment period will be approximately two hours of your time.
- During the study period:

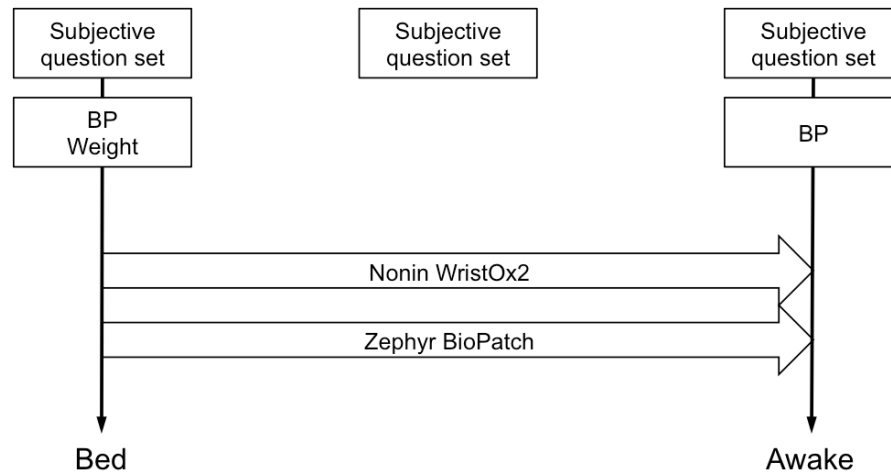


Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

- You will wear an electronic device on your chest with standard ECG adhesive pads from the time you go to bed until the time you wake up the next day. The device will automatically record your heart rate, respiratory rate and motion.
 - You will wear an electronic device on your wrist and finger from the time you go to bed until the time you wake up the next day. The device will automatically record your pulse rate and oxygen saturation.
 - At bedtime, you will weigh yourself with the provided scale and check your blood pressure.
 - At bedtime, you will use the iPad to fill out a subjective question set to answer a few questions about your signs and symptoms.
 - If you wake up during the night, you will use the iPad to fill out the subjective question set every time you wake up.
 - Upon awakening for the day, check your blood pressure and use the iPad to fill out a subjective question set to answer a few questions about your signs and symptoms.
 - After the first night of using the devices, you will be contacted the next day by the associate investigator in order to answer any questions you may have.
 - We anticipate that you will spend approximately 15 minutes in the evening and morning on study related tasks.
- After the 7 day study period:
 - The day before your follow-up visit, you will be contacted by the associate investigator to confirm the meeting time and date of your scheduled follow-up visit.
 - You will meet the associate investigator in the WRNMMC Hearth Failure Clinic for the follow-up visit in order to return the 5 study devices and carrying bag and answer a set of questions.
 - If you are unable to transport the devices to WRNMMC, the associate investigator will make arrangements to pick up the devices at your home.
 - We will answer any study related questions that you may have. The follow-up visit will take approximately 30 minutes.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014



4. ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study is your alternative to participating for the study.

5. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

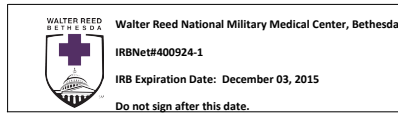
You will be part of this study for 7 days. During this time, you will be asked to visit with the associate investigator two times: one time at enrollment, and the second time after you completed the seven day period for the study. The first visit will last approximately 2 hours and the final visit will last approximately 30 minutes.

6. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

A total of 60 subjects are expected to take part in this study.

7. POSSIBLE RISKS AND DISCOMFORTS FROM BEING IN THIS STUDY

There is no known risk associated with this study other than the possibility of skin irritation from the Biopatch adhesive pads attached to the chest. For those male participants who have an excessive amount of chest hair, shaving part of the hair from the chest area may be required in order to apply the Biopatch adhesive pads.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY:

You will not benefit from taking part in this study, but the information we collect may help us learn more about heart failure that occurs during the nighttime and assist clinicians in the future by improving the way clinicians look at signs and symptoms of heart failure.

9. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the Walter Reed (WRNMMC) Department of Research Programs, the Walter Reed (WRNMMC) Institutional Review Board (IRB), the DoD Higher Level Review, and other government agencies.

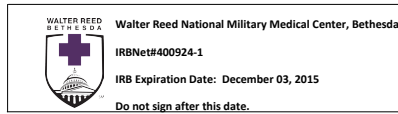
These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your research records may be disclosed outside of WRNMMC, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

stopped without your consent if the military mission requires it, or if you lose your right to receive medical care at a military hospital.

The study investigator may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the study staff
- The study investigator decides that continuing your participation could be harmful to you
- The study is cancelled
- Other administrative reasons
- Unanticipated circumstances

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.

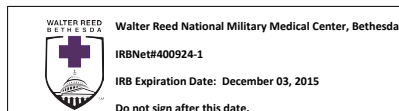
12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the study investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator, Department of Research Programs, at Walter Reed National Military Medical Center at 301-295-8273.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study. You will not be held financially liable for lost, broken, or damaged equipment.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the study investigator as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care and there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled.

Data already collected will be retained and analyzed until the study closes even if you choose to withdraw from the study.

Should you choose to withdraw, you must contact the investigator and return the 5 study devices to the Heart Failure Clinic.

15. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

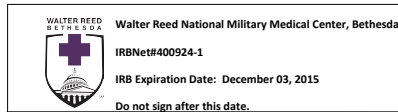
The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used. This authorization is effective until the end of the research study.

(1) What information will be collected?

For this research study, we will be collecting subjective information about your signs and symptoms as well as blood pressure, weight, blood oxygen saturation, and activity level. We will also collect demographic information such as gender and age, and clinical information such as heart failure classification.

(2) Who may use your PHI within the Military Healthcare System?

The members of the research team will have access to your health information in order to find out if you qualify to participate in this study, to administer research procedures, to monitor your progress, and/or to analyze the research data. Additionally, your PHI



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

may be made available to groups such as the WRNMMC Department of Research programs and the WRNMMC Institutional Review Board.

(3) How long will the researchers keep your PHI?

This consent form and HIPAA authorization will be maintained for a period of six years after the study is completed.

(4) Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The study information collected prior to this cancellation will be used by the research team. No further data will be collected.

If you want to cancel your Authorization, please contact the Principal Investigator in writing:

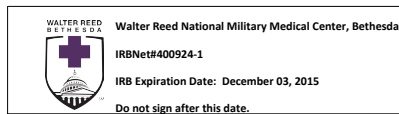
Brian Hemann, MD
LTC, MC, USA
Assistant Chief
Department of Cardiology
Walter Reed National Medical Military Center
8901 Wisconsin Ave
Bethesda, MD 20889-5600
301-319-3480 (office)
brian.hemann@med.navy.mil

(5) What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

(6) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

(7) Who should you contact if you have any complaints?

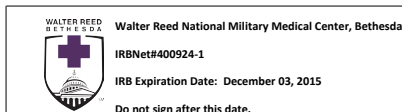
If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775.

Your signature at the end of this document acknowledges that you authorize WRNMMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

16. CONTACTS FOR QUESTIONS ABOUT THE STUDY:

If you have questions about the study, or if you think you have a study-related injury you should contact Brian Hemann, MD at 301-319-3480. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at (301-295-8273) or WRNMMC Staff Judge Advocate Office at 301-295-2215.

A signed copy of this consent form will be given to you.



Protocol No. 400924-1
Current Version: #2
Participant
November 25, 2014

SIGNATURE OF PARTICIPANT

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

Printed Name of Participant

Signature of Participant

Date (must be same as subject)

Time

SIGNATURE OF RESEARCH TEAM MEMBER OBTAINING CONSENT

I certify that the above signed research subject has freely and voluntarily provided written consent to participate in this research study.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date (must be same as subject)

Time

Appendix C

System Usability Scale

Patient Version 1.0

INSTRUCTIONS: We are interested in your assessment for each piece of equipment that we asked you to use for this study. Considering only the BioPatch, please mark only one response for each of the 10 items listed here.



	Strongly Disagree			Neutral			Strongly Agree
	1	2		3	4		5
1. I think that I would like to use this system frequently	☐	☐		☐	☐		☐
2. I found the system unnecessarily complex	☐	☐		☐	☐		☐
3. I thought the system was easy to use	☐	☐		☐	☐		☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐		☐	☐		☐
5. I found the various functions in this system were well integrated	☐	☐		☐	☐		☐
6. I thought there was too much inconsistency in this system	☐	☐		☐	☐		☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐		☐	☐		☐
8. I found the system very cumbersome to use	☐	☐		☐	☐		☐
9. I felt very confident using the system	☐	☐		☐	☐		☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐		☐	☐		☐

© Digital Equipment Corporation, 1986

System Usability Scale

Patient Version 1.0

INSTRUCTIONS: We are interested in your assessment for each piece of equipment that we asked you to use for this study. Considering only the WristOx2, please mark only one response for each of the 10 items listed here.



	Strongly Disagree			Neutral			Strongly Agree
	1	2		3	4		5
1. I think that I would like to use this system frequently	☐	☐		☐	☐		☐
2. I found the system unnecessarily complex	☐	☐		☐	☐		☐
3. I thought the system was easy to use	☐	☐		☐	☐		☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐		☐	☐		☐
5. I found the various functions in this system were well integrated	☐	☐		☐	☐		☐
6. I thought there was too much inconsistency in this system	☐	☐		☐	☐		☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐		☐	☐		☐
8. I found the system very cumbersome to use	☐	☐		☐	☐		☐
9. I felt very confident using the system	☐	☐		☐	☐		☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐		☐	☐		☐

© Digital Equipment Corporation, 1986

System Usability Scale



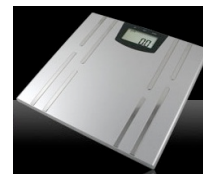
Patient Version 1.0

INSTRUCTIONS: We are interested in your assessment for each piece of equipment that we asked you to use for this study. Considering only the Blood Pressure Monitor, please mark only one response for each of the 10 items listed here.

	Strongly Disagree			Neutral		Strongly Agree
	1	2		3	4	5
1. I think that I would like to use this system frequently	☐	☐		☐	☐	☐
2. I found the system unnecessarily complex	☐	☐		☐	☐	☐
3. I thought the system was easy to use	☐	☐		☐	☐	☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐		☐	☐	☐
5. I found the various functions in this system were well integrated	☐	☐		☐	☐	☐
6. I thought there was too much inconsistency in this system	☐	☐		☐	☐	☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐		☐	☐	☐
8. I found the system very cumbersome to use	☐	☐		☐	☐	☐
9. I felt very confident using the system	☐	☐		☐	☐	☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐		☐	☐	☐

© Digital Equipment Corporation, 1986

System Usability Scale



Patient Version 1.0

INSTRUCTIONS: We are interested in your assessment for each piece of equipment that we asked you to use for this study. Considering only the Weight Scale, please mark only one response for each of the 10 items listed here.

	Strongly Disagree			Neutral			Strongly Agree
	1	2	3	4	5		
1. I think that I would like to use this system frequently	☐	☐	☐	☐	☐		☐
2. I found the system unnecessarily complex	☐	☐	☐	☐	☐		☐
3. I thought the system was easy to use	☐	☐	☐	☐	☐		☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐	☐	☐	☐		☐
5. I found the various functions in this system were well integrated	☐	☐	☐	☐	☐		☐
6. I thought there was too much inconsistency in this system	☐	☐	☐	☐	☐		☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐	☐	☐	☐		☐
8. I found the system very cumbersome to use	☐	☐	☐	☐	☐		☐
9. I felt very confident using the system	☐	☐	☐	☐	☐		☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐	☐	☐	☐		☐

© Digital Equipment Corporation, 1986

System Usability Scale

Patient Version 1.0

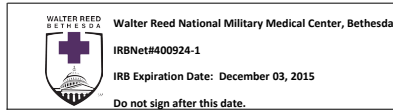
INSTRUCTIONS: We are interested in your assessment for each piece of equipment that we asked you to use for this study. Considering only the iPad, please mark only one response for each of the 10 items listed here.



	Strongly Disagree			Neutral			Strongly Agree
	1	2		3	4		5
1. I think that I would like to use this system frequently	☐	☐		☐	☐		☐
2. I found the system unnecessarily complex	☐	☐		☐	☐		☐
3. I thought the system was easy to use	☐	☐		☐	☐		☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐		☐	☐		☐
5. I found the various functions in this system were well integrated	☐	☐		☐	☐		☐
6. I thought there was too much inconsistency in this system	☐	☐		☐	☐		☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐		☐	☐		☐
8. I found the system very cumbersome to use	☐	☐		☐	☐		☐
9. I felt very confident using the system	☐	☐		☐	☐		☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐		☐	☐		☐

© Digital Equipment Corporation, 1986

Appendix D



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Research Study Entitled: *The Electronic Collection and Presentation of Nocturnal Heart Failure Information*

Principal Investigator:

Brian Hemann, MD
LTC, MC, USA
Assistant Chief, Heart Failure Clinic
Department of Cardiology
Walter Reed National Medical Military Center
8901 Wisconsin Ave
Bethesda, MD 20889-5600
301-319-3480 (office)
brian.hemann@med.navy.mil

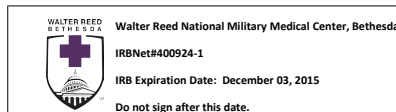
Study site: X WRNMMC, ___ FBCH, ___ USUHS, ___ WRAIR, ___ NMRC, ___ JPC,
___ OTHER

Are you participating in any other research studies? ___ Yes ___ No

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you are a clinician who provides medical care for patients who have been diagnosed with heart failure and are currently practicing in the Heart Failure Clinic at Walter Reed National Military Medical Center (WRNMMC).

Taking part in this study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. Leaving the study will not affect your position at WRNMMC. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

2. PURPOSE OF THE STUDY:

The purpose of this investigation is to collect ecologically valid nocturnal physiologic and subjective data from heart failure participants in order to present this collected data in an electronic display. For this study, you will assess the usability of the electronically displayed nocturnal heart failure information.

3. PROCEDURES TO BE FOLLOWED:

When the nocturnal heart failure data has been collected from the heart failure participants, the de-identified data will be electronically displayed on an iPad. As a participant, you will be asked to assess the electronic display of nocturnal heart failure information. Once the electronic data has been reviewed, you will complete a question set about the usability of the electronic display.

4. ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study is your alternative to participating for the study.

5. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

You will be part of this study for approximately 60 minutes in order to assess the electronic data display and complete the question set.

6. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

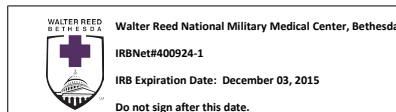
60 participants with heart failure and 4 clinicians are expected to take part in this study.

7. POSSIBLE RISKS AND DISCOMFORTS FROM BEING IN THIS STUDY

There is no known risk associated with this study.

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY:

You will not benefit from taking part in this study, but the information we collect may help us improve the electronic display of nighttime heart failure signs and symptoms



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

and provide feedback about the usefulness of the electronically displayed nocturnal heart failure data.

9. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the Walter Reed (WRNMMC) Department of Research Programs, the Walter Reed (WRNMMC) Institutional Review Board (IRB), the DoD Higher Level Review, and other government agencies.

These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your research records may be disclosed outside of WRNMMC, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

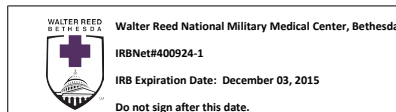
This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if the military mission requires it, the study is cancelled, or unanticipated circumstances arise.

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. You should understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the study investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator, Department of Research Programs, at Walter Reed National Military Medical Center at 301-295-8273.

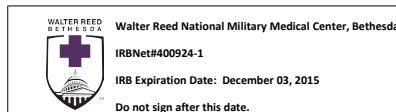
13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the study investigator as soon as possible. By leaving this study at any time, you in no way risk your position as a clinician at WRNMMC and there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled.

Data already collected will be retained and analyzed until the study closes even if you choose to withdraw from the study.



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

15. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used. This authorization is effective until the end of the research study.

(1) What information will be collected?

For this research study, we will be collecting questionnaire information about the usability of electronically displayed nocturnal heart failure data.

(2) Who may use your PHI within the Military Healthcare System?

The members of the research team will have access to your status as a credentialed clinician at WRNMMC in order to find out if you qualify to participate in this study and/or to analyze the research data. Additionally, your PHI may be made available to groups such as the WRNMMC Department of Research programs and the WRNMMC Institutional Review Board.

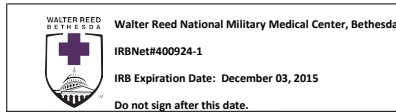
(3) How long will the researchers keep your PHI?

This consent form and HIPAA authorization will be maintained for a period of six years after the study is completed.

(4) Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The study information collected prior to this cancellation will be used by the research team. No further data will be collected.

If you want to cancel your Authorization, please contact the Principal Investigator in writing:



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

Brian Hemann, MD
LTC, MC, USA
Assistant Chief, Heart Failure Clinic
Department of Cardiology
Walter Reed National Medical Military Center
8901 Wisconsin Ave
Bethesda, MD 20889-5600
301-319-3480 (office)
brian.hemann@med.navy.mil

(5) What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

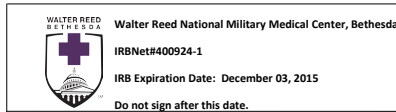
(6) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(7) Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775.

Your signature at the end of this document acknowledges that you authorize WRNMMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.



Protocol No. 400924-1
Current Version: #2 - Dr
October 8, 2014

16. CONTACTS FOR QUESTIONS ABOUT THE STUDY:

If you have questions about the study, or if you think you have a study-related injury you should contact Brian Hemann, MD at 301-319-3480. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at (301-295-8273) or WRNMMC Staff Judge Advocate Office at 301-295-2215.

A signed copy of this consent form will be given to you.

SIGNATURE OF PARTICIPANT

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

Printed Name of Participant

Signature of Participant

Date (must be same as subject)

Time

SIGNATURE OF RESEARCH TEAM MEMBER OBTAINING CONSENT

I certify that the above signed research subject has freely and voluntarily provided written consent to participate in this research study.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date (must be same as subject)

Time

Appendix E

System Usability Scale

Clinician Version 1.0

Demographic Information:

Gender: ☐ Female ☐ Male

Position: ☐ Physician ☐ Advance Practice Nurse ☐ Physician Assistant

Number of years in practice: ☐ less than 1 ☐ 1-3 ☐ 4-6 ☐ 7-9 ☐ 10 or more

Survey #: _____

Age: _____

INSTRUCTIONS: We are interested in your assessment of usability for the nocturnal heart failure information display. You will complete one questionnaire after reviewing all the displays. Considering the display system, please mark only one response for each of the 10 items listed here.

	Strongly Disagree			Neutral			Strongly Agree
	1	2		3	4		5
1. I think that I would like to use this system frequently	☐	☐		☐	☐		☐
2. I found the system unnecessarily complex	☐	☐		☐	☐		☐
3. I thought the system was easy to use	☐	☐		☐	☐		☐
4. I think that I would need the support of a technical person to be able to use this system	☐	☐		☐	☐		☐
5. I found the various functions in this system were well integrated	☐	☐		☐	☐		☐
6. I thought there was too much inconsistency in this system	☐	☐		☐	☐		☐
7. I would imagine that most people would learn to use this system very quickly	☐	☐		☐	☐		☐
8. I found the system very cumbersome to use	☐	☐		☐	☐		☐
9. I felt very confident using the system	☐	☐		☐	☐		☐
10. I needed to learn a lot of things before I could get going with this system	☐	☐		☐	☐		☐

© Digital Equipment Corporation, 1986