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# Electronic physiologic and subjective data acquisition in home-dwelling heart failure patients: An assessment of patient use and perception of usability

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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 their symptoms may not be sufficiently accurate to optimally manage their disease. Most of what is known about heart failure is related to patients' diurnal symptoms and activities. Some mobile electronic technologies can operate continuously to collect data from the time patients go to bed until they get up in the morning. We were therefore interested to evaluate if patients would use a system of selected patient-facing devices to collect physiologic and subjective state data in and around the patients' period of sleep, and if there were differences in device use and perceptions of usability at the device level

*Methods:* This descriptive observational study of home-dwelling patients with heart failure, between 21 and 90 years of age, enrolled in an outpatient heart failure clinic was conducted between December 2014 and June 2015. Patients received five devices, namely, body weight scale, blood pressure device, an iPad-based subjective states assessment, pulse oximeter, and actigraph, to collect their physiologic (body weight, blood pressure, heart rate, blood oxygen saturation, and physical activity) and subjective state data (symptoms and subjective states) at home for the next six consecutive nights. Use was defined as the ratio of observed use over expected use, where 1.0 is observed equals expected. Usability was determined by the overall System Usability Scale score.

*Results:* Participants were 39 clinical heart failure patients, mean age 68.1 (SD, 12.3), 72% male, 62% African American. The ratio of observed over expected use for the body weight scale, blood pressure device, iPad application, pulse oximeter and actigraph was 0.8, 1.0, 1.1, 0.9, and 1.9, respectively. The mean overall System Usability Scale score for each device were 84.5, 89.7, 85.7, 87.6, and 85.2, respectively.

*Conclusions:* Patients were able to use all of the devices and they rated the usability of all the devices higher than expected. Our study provides support for at-home patient-collected physiologic and subjective state data. To our knowledge, this is the first study to assess the use and usability of electronic objective and subjective data collection devices in heart failure patients' homes overnight.

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## 1. 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 [1]. 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 [2]. 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 [3] and advancing age [4]. Thus, retrospective objective and

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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 mobile electronic technologies that are capable of collecting, storing, and transmitting physiologic and subjective state data from patients' homes. Diurnal remote patient monitoring devices [5,6] have shown improved patient outcomes. [7–9]. Mobile technologies that can be used at home 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 [10]. Some mobile 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, if patients can and will use selected devices to collect the data.

We were therefore interested to evaluate if patients would use a system of selected patient-facing devices (devices intended to be used by patients to collect clinical information in non-clinical settings) to collect physiologic and subjective state data in and around the patients' period of sleep. Additionally, we were interested to see if there were differences in device use and perceptions of usability at the device level, and so collected quantitative data from patients by asking them to complete the System Usability Scale [11]. The research questions are: (1) Will patients recruited under normal clinic operating conditions use selected patient-facing devices to collect physiologic and subjective state data at home overnight? (2) Will patients trained under normal clinical operating conditions report the devices used at home overnight to be usable? To our knowledge, researchers have not quantitatively assessed the use and usability of patient-facing electronic devices for collecting objective and subjective data in homes overnight for patients with heart failure.

## 2. Methods

### 2.1. 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 as determined by the patient's clinician were excluded from consideration. Based on the literature, we sought to recruit at least 37 participants in order to have an 85% power to detect a 10-point difference in usability scores at medium effect size, 0.5 [12 p. 157]. The participants were all retirees and their families. The MHS population and care have been shown to be similar to the general population [13–16].

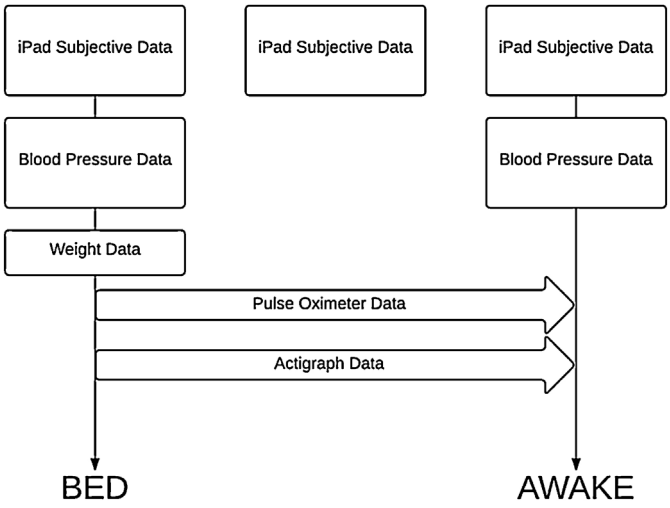


**Fig. 1.** Graphical representation of patient data collection tasks.

### 2.2. Procedure

The study was designed to be congruent what occurs in clinic. The lead author 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. Enrollment, device training and device issue took place in the clinic at the time of the patients' scheduled visit. The lead author 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, shown in Table 1. 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 lead author asked patients to wear the pulse oximeter and the actigraph all night, which the lead author expected to be 8 h. The sequence of data collection is graphically illustrated in Fig. 1. 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 to return the devices and completed the System Usability Scale for each device. When patients returned the equipment the lead author asked patients to complete a 10-item System Usability Scale (SUS) survey for each device. To minimize potential ordering effects, the presentation order of device questionnaires was pre-determined by generating five-number sets of random numbers from 1 to 5, each representing one device. Sets of 5 SUS questionnaires were placed in sealed envelopes marked with the study numbers in sequential order, each envelope contained questionnaires presented in random order according to the generated table of numbers. When patients returned equipment, the received the envelope matching their respective enrollment number, at which time they completed and returned the surveys.

The device-collected data were downloaded using device-specific software, cleaned using the R statistical language, and uploaded to the 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.