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Care of Patients With Heart Failure

# Testing a novel pictorial medication sheet to improve adherence in veterans with heart failure and cognitive impairment

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ABSTRACT

*Objectives:* (a) To evaluate efficacy of a pictorial medication sheet to improve adherence in veterans with heart failure (HF) and cognitive impairment (CI); (b) to describe acceptance of the intervention.
*Background:* CI is prevalent in HF and is associated with worsened medication adherence. The Veteran's Administration has developed a medication image library; however, use of images to improve adherence has not been tested.
*Methods:* Thirty-six veterans with HF and CI were enrolled and provided pictorial medication sheets and an optional alarmed pillbox. Adherence pre-and post-intervention was determined by 30-day pill counts. Acceptance was assessed from interviews.
*Results:* Twenty-seven veterans (75%) completed the study. Overall medication adherence was poor, however there was significant improvement from pre-intervention ($M = 79.74$, SD $= \pm 16.98$) to post-intervention ($M = 84.74$, SD $= \pm 10.00$) adherence ($t(26) = 2.16$, $p < .05$, Cohen's $d = .42$).
*Conclusions:* This pilot study provides preliminary evidence that medication images improve adherence with complex medication regimens. The intervention was well received by patients.


## Introduction

Searching for ways to prevent heart failure (HF) readmissions has received increasing attention over the past decade.[1] In October 2012, the Centers for Medicare and Medicaid Services (CMS) instituted the Hospital Readmissions Reduction Program, reducing reimbursement to hospitals identified as having excess readmissions for the diagnoses of HF, myocardial infarction, and pneumonia.[2] Understandably, this sharpened the focus upon finding methods to reduce or prevent hospital readmissions for HF, particularly within large health care organizations such as the Veteran's Administration Healthcare System (VA). In the VA, the HF readmission rate has remained static at 20% within 30 days, and in the general Medicare population, 27% of patients with HF are readmitted within 30 days, contributing to excessive health care spending.[3,4] Although many readmissions may reflect progression of illness and thus be less preventable than previously thought, the preponderance of HF readmissions have been linked to medication non-adherence, and as a result are considered avoidable.[3,5,6] Therefore, improving medication adherence remains fundamental to reducing readmissions and improving outcomes for persons with HF.

### *Medication adherence*

Acceptable medication adherence has been expressed as taking 80% of prescribed medications, a figure likely derived from pharmaceutical trials that reported adherence only to the investigational drug under study.[7] However, adherence of at least 88% to all prescribed cardiac medications has been associated with event-free survival in persons with HF, and adherence to <80% of HF medications has been related to all-cause mortality.[8,9] Persons with HF tend to be older, with multiple co-morbidities and complex medication regimens; adherence to medication is poor in this population, estimated to be as low as 40–50%.[10]

Conceptual models and theoretical frameworks contextualize medication adherence as part of the recursive decision-making

*Abbreviations:* BNP, B-type natriuretic peptide; CI, cognitive impairment; CMS, Center for Medicare and Medicaid Services; EMR, electronic medical record; HF, heart Failure; HgbA1c, glycated hemoglobin; LVEF, left ventricular ejection fraction; SLUMS exam, St. Louis University mental status examination; TSH, thyroid stimulating hormone; VA, Veteran's Health Care Administration.

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process inherent to successful self-care in HF.[11,12] The ability to make a series of thoughtful decisions resulting in adherence to complex self-care and medication regimens is particularly important as HF is primarily managed by the patient at home. Chronic HF usually presents with co-morbid illnesses, and complexity of care is increased by polypharmacy prescribed from multiple providers in a fragmented health care delivery system.[13,14]

An important factor that affects decision-making capability in HF patients and yet remains clinically under-recognized is the presence of cognitive impairment (CI).[15,16] A person with mild CI may have problems with memory, attention, planning, and problem solving, all of which impede a patient's ability to make decisions needed to adequately comply with medication regimens.[17] Compared to the general population, HF patients have up to a four-fold risk of developing CI.[18] A recent study of outpatient veterans with HF demonstrated a high prevalence (58%) of clinically unrecognized CI that was significantly associated with poorer medication adherence.[19] In this study, the cognitive domains most affected proved to be verbal learning and verbal memory. Effectively, patients experienced difficulty understanding and remembering medication instructions communicated during office visits. Hence, an intervention that increases retention of medication instructions provides an attractive target for improving adherence.

Another condition associated with less than adequate self-care, including medication adherence, in persons with HF is the presence of depression.[20,21] Studies have shown depression to be common in persons with HF, with prevalence rates conservatively estimated at about 26%, or 2 to 3 times higher than in the general population.[21] This condition may also remain frequently clinically under-recognized.[21] For example, a study of 251 veterans with HF found the average subject to be mildly depressed, yet only 30% of the sample had been formally diagnosed.[19]

### *Interventions to improve adherence*

The healthcare community recognizes the need to identify those HF patients most at risk for poor adherence, and thus poor outcomes.[22] Developing screening tools for common conditions that may affect adherence, such as CI, depression, sleep-disordered breathing, poor health literacy, and socioeconomic burden has been suggested.[23–25] There remains a paucity of tested interventions designed specifically to target these underlying determinants of poor adherence, even when identified.[26] Ideally, such interventions would be readily implemented, acceptable to patients, and not resource-intensive. Interventions that have shown improvement in HF medication adherence to date have been relatively complex, often requiring repeated contact from pharmacists or nurses, and did not result in sustainable outcomes once the intervention ceased.[27–30]

### *Medication reconciliation*

One proposed intervention to improve medication adherence and patient safety, as well as reduce pharmacy cost, is to conduct accurate medication reconciliation at each clinic visit.[31,32] Indeed, the VA has included medication reconciliation as a performance measure, and has launched a system-wide medication reconciliation initiative.[33] However, meaningful medication reconciliation takes substantial clinic time and requires the patient to be cognizant of their current medication regimen. HF patients may have difficulty in accurately recalling their medication schedule, and may be able to identify their medications visually (color, size, shape) rather than by name or indication. The clinician, however, usually has access only to the pharmacy profile with the name and indication of the drug, and may not know the color, size, or shape of the pill the patient has received.

Adding to the problem, the VA and other large health maintenance organizations provide generic medications from centralized mail-out pharmacies. Frequent changes in vendors result in changed appearance of the tablets.[19] Finally, HF patients require repeated dosage titrations, and medication regimens are frequently changed with each care transition, particularly hospital readmission and discharge.

As part of the medication reconciliation initiative, the VA has assembled a digital library of 30,000 full color individual medication images.[34] These images could potentially be incorporated into a printed or virtual (digital) pictorial medication sheet, allowing ready access to an accurate and user-friendly pharmacy profile for patients, their caregivers, providers, and pharmacists. However, use of such medication images to improve adherence by helping patients remember medication instructions and facilitating accurate medication reconciliation has not been tested in veterans with HF and CI.

The purpose of this pilot study was to evaluate the efficacy of a pictorial medication sheet to improve medication adherence in veterans with HF and CI.

The specific aims of this study included:

Aim 1. To evaluate efficacy of a pictorial medication sheet in improving medication adherence in veterans with HF and CI.

Aim 2. To describe patient's acceptance of the intervention.

## Methods

This pilot study was an interventional, within-subjects design conducted at a large metropolitan Veterans' Administration facility that serves an ethnically mixed urban population of 246,000 veterans in southern California. Approval was obtained from the institutional review board (IRB), and all subjects provided written informed consent prior to enrollment.

### *Study population*

Clinical providers and research coordinators screened eligible patients for the study who presented to the outpatient VA HF clinic. Patients were eligible for enrollment if they were 18 years old or older, had an established clinical diagnosis of HF, and had screened positive for CI using the Saint Louis University Mental Status (SLUMS) exam prior to entrance into the study.[35] The SLUMS exam is a 30-point, education-adjusted screening tool for CI that categorizes impairment as none, mild, or impairment consistent with dementia. A score of $<27$ in a person with a high school diploma, or $<25$ in a person who did not complete high school is considered positive for mild CI. A score of $<21$ for persons with a high school diploma or $<20$ for those who did not complete high school is considered positive for severe impairment consistent with dementia.[36] The SLUMS exam was compared to the Mini Mental Status Exam (MMSE) and found to be more sensitive in detecting mild CI with a sensitivity of 94% versus 67% for persons with a high school diploma or above, and 93% versus 67% for patients with less than high school education.[37]

Although identified as having at least mild CI by SLUMS exam, none of the study subjects had been formally diagnosed with impaired cognitive abilities or dementia. All study subjects were independent, community dwelling persons who managed their own affairs, and were deemed able to provide informed consent by the investigators. In order to participate in testing the pictorial medication sheet and optional alarmed pillbox, participants were