Systems-Based Patient Work Analyses of Older Adults with Heart Failure

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This work is dedicated to my father, Lawrence Mickelson,

my greatest supporter,

whom I miss every day

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LIST OF ABBREVIATIONS

ADE   Adverse Drug Event

CHI   Consumer Health Informatics

CHIT   Consumer Health Information Technology

CDM   Critical Decision Method

CTA   Cognitive Task Analysis

CWA   Cognitive Work Analysis

EMA   Ecological Momentary Assessment

EHR   Electronic Health Record

IDA   Instant Data Analysis

IOM   Institute of Medicine

ISO   International Standards Organization

HBM   Habitual Prospective Memory

HFE   Human Factors Engineering

HIT   Health Information Technology

NP   Nurse Practitioner

PHR   Personal Health Record

PMMS Personalized Medication Management System

PSF   Performance Shaping Factor

QOL   Quality of Life

RITE   Rapid Iterative Testing and Evaluation

SD   Standard deviation

SM   Self-management

CHAPTER I

INTRODUCTION & BACKGROUND

Overview

This doctoral research explores the medication management work of older heart failure patients, with a focus on cognitive work amenable to tool and technology interventions. The goal was to gather the knowledge to guide the design of effective tools and technologies to improve medication management performance, medication adherence, and health outcomes. Medication mismanagement, adverse drug events, and medication non-adherence in heart failure patients are common, with devastating consequences for society, the healthcare system, patients, and their families. Technology and tools have the potential to improve medication management by patients, but only based on an explicit understanding of users, their tasks and their environments [1]. Insight into the work a tool is intended to support is the starting point for the design of effective tools [2]. Therefore, the design of tools and technologies to improve patient performance requires a deep understanding of their medication-related work activities and context. A literature review, however, yielded few studies addressing medication management as a goal-oriented process rather than an adherent/non-adherent behavior. Also, few tested methods to acquire this knowledge and few studies directed at the design of tools exist.

Statement of the Problem

The goals of medication treatment are to control symptoms, prevent complications and disability, and maintain quality and quantity of life [3]. Patients must administer medications continuously over time to maintain therapeutic levels and achieve optimal effects [4]. Not taking medications as prescribed is responsible for 30% to 40% of treatment failures [5, 6] and can bias the provider's evaluation of medication effects leading to unnecessary

increases in dose and raising the risk of adverse drug events (ADE) [7].

Heart failure is an example of a chronic disease prevalent in older adults characterized by high levels of medications non-adherence and medication mismanagement [8, 9] The natural course of the disease can only improve through optimal medication therapy to prevent cardiac changes and symptoms associated with the disease progression. However, typical medication non-adherence rates are high (40% to 60%), and increase the longer the patients have the disease [10].

Research primarily addresses the outcome medication adherence and medication management as a patient process is less understood. Medical and nursing research report over 200 medication non-adherence risk factors and few were consistently predictive, or account for much of the variance across studies [11-13]. Wu et al. [14] found 11% to 21% in medication adherence variance in heart failure patients explained by a few factors (forgetting, cost, frequency of dosage, and number of medications), all related to the medication management process. Interventions to improve medication adherence have primarily focused on patient factors [15-18] and report low to moderate effects on short-term adherence with little effect on chronic, long-term adherence [15, 16, 18]. A systematic review of medication adherence interventions in older adults found that only five percent based on theory and overwhelmingly involved educating the patient [19]. Interventions did not address common reasons voiced by older adults for not taking medications as prescribed: forgetfulness, frequent medication changes, complexity of regimen, daytime sleepiness, and routine disruptions [20]. These reasons involve barriers to the medication management process.

Patients describe managing medications as difficult work, requiring the help of others to accomplish [21-23]. In an ethnographic study of self-management behavior of lower income

diabetic patients, Hinder & Greenhalgh [24] described the "over-arching" theme as the patients' perception that self-management, a large part of which is managing medications, involved difficult physical, cognitive and emotional work.

There is a growing interest in the potential of technology to improve medication adherence in chronically ill older adults [25-27]. However, much of technology developed for older adults does not support their needs [28-33]. Older adults report a lack of perceived benefit, a lack of fit to their lifestyle, and report technology as cumbersome and confusing that adds rather than reduces cognitive work [26]. Current technology designed to improve medication adherence has not sufficiently considered the user and the work the tool should support [34]. Assumptions regarding how patient work is done, what is done, who does it, and functions that might be useful are common [35, 36]. As a result, research reports mixed effects of these technologies and tools in improving medication adherence in older adults [37, 38].

There are few studies that address the design of better tools and technologies to improve medication management in patients [17, 39]. The first principles of good design defined by the International Standards Organization (ISO) standard 924-210: Human-centered design for interactive systems is *design is based upon an explicit understanding of users, their tasks and their environments* (ISO, 2009). Insight into the work a tool is intended support is the starting point for the design of effective tools [2]. The Institute of Medicine (IOM) (2011) recommends a user-centered design approach to Health Information Technology development. The first step in the user-centered design process involves understanding the user, their tasks, and their environment.

Considering the dearth of medication management and design research, consequently there are few methods available to gather this kind of knowledge. Human factors engineering (HFE)

methods are best suited for this inquiry. As a practice and research discipline, HFE methods focus on improving performance and well-being through design [41, 42]. HFE methods have improved the safety and performance of work by healthcare professional such as physicians, nurses, and other allied health personnel across institutional settings [43] and can also improve patient performance. However, patient health work differs from the work of health professionals [44, 45] and there are few tested methods in current literature to capture and analyze the work of patients [44, 46].

Therefore, there are several gaps in knowledge to address. First, there is little research exploring medication management from a patient health work perspective. Second, there are few methods available to guide research investigating patient health work. Last, there is little research to guide the design of better tools to support patient medication management.

Significance

The Cost of Medication Mismanagement and Non-Adherence

The costs of medication non-adherence include increased mortality, disability, and reduced quality of life (QOL) [7, 47-49]. In a meta-analysis of 21 studies and 46,847 patients, non-adherent patients had a 50% increase in mortality risk compared to the adherent patients [48]. Indirect costs estimates include $1.5 billion in lost patient earnings and $50 billion in lost productivity [50]. In older adults, medication non-adherence is responsible for increased nursing home admissions (23%), loss of independence, and a reduction in QOL [13, 51]. The direct costs estimated for medication non-adherence range from $100 billion to $300 billion each year [52, 53]. Between 33% and 69% of medication-related hospital admissions in the United States are due to non-adherence to medications [7]. Factors related to medication adherence are present in 28% of hospital re-admissions [54]. For every dollar spent on facilitating adherence, medical

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costs would reduce by \$7 for people with diabetes, \$5.10 for people with high cholesterol, and \$3.98 for people with high blood pressure [53].

Growing Population of Older Adults

Due to the increased incidence of chronic disease and the aging population, the consequences of medication non-adherence will grow [55] The current U.S. population of adults over the age of 65 years old is 12.8%, and expected to be 20% by 2030 (U.S. Census Bureau, 2012). Research reported that 133 million (45%) Americans have at least one chronic disease, and by 2020, this number is expected to rise to 157 million, with 81 million having multiple conditions [10]. In older adults, 82% have at least on chronic condition, and 65% two or more [56]. Older adults are at greater risk for non-adherence due to limitations (physical, cognitive, perceptive) that may interfere with their ability to manage medications effectively. In addition, more healthcare is taking place in the home, placing more responsibility on older adult patients and their families [57].

Heart failure is one of the most rapidly growing chronic diseases in the U.S. and is the leading cause of hospitalization in older adults [58]. Non-adherence to medications is present in 50% of re-hospitalizations in the six months after discharge [8, 59] and a strong factor related to mortality in heart failure patients [60].

Changing Geographies of Care

The location where the majority of healthcare takes place is changing. The primary healthcare model is shifting from a focus on acute care in hospitals, to chronic care in homes due to the rising incidence of chronic disease and the growing number of aging adults [61]. Storni [62] refers to the changing *geographies of care* and healthcare activities transitioning from controlled clinical environments performed by professionals, to the uncontrolled environment of

the home performed by lay individuals. With this change, there is a critical need to support this work to assure safe delivery of treatments by persons with no professional training.

Older adults prefer to "age-in-place" and remain in their own homes for as long as they can take care of themselves [63]. This preference is cost-effective. Private residential living costs only 55% of the costs of full-time residential care in the United Kingdom [64]. The changing location of care and the older adult's desire to "age in place" creates a critical need to develop tools and technologies to support their health activities.

Healthcare Workforce Limitations

Last, the future healthcare workforce may not be meeting the growing demands for care. In the next decades, the supply of Registered Nurses in the U.S. will not meet the increasing demand for care [65, 66]. Physician numbers are also declining. Therefore, the delivery of care efficiently is a looming priority [67]. The design of technology support for patients to manage their own care would reduce demands on the limited workforce.

In conclusion, there are many forces increasing the magnitude of the problem of patient medication mismanagement and non-adherence. Tools of technologies can enable the successful performance of medication management by patients when designed with a thorough understanding of the users, their tasks and contexts.

Related Work

Historically, healthcare professionals viewed patient efforts to improve or maintain their health as behavior (adherent/non-adherent) and not work involving effort [68]. Considered a passive recipient of healthcare, activities performed by patients involved merely following the directions prescribed by the provider [69]. From this perspective, literature involving the health work of patients has primarily focused on the limitations of the patient and not patient health

activities in context [70]. First, a review of literature related to patient work in general is discussed (See Appendix A), followed by a review of medication adherence literature related to patient medication management (See Appendix B).

Sociology of Patient Work

Corbin and Strauss [3, 71] were early researchers that described patient health activities as work. Based on semi-structured interviews with patient/caregiver dyads, the *Trajectory of Chronic Illness* theory described chronic illness as a fragile balance of time and effort, shifting between illness work, everyday life work and biographical work. Corbin and Strauss identified many important characteristics of patient work. First, illness work takes place in everyday life context and cannot be studied in isolation. This distinguishes patient work from that of clinicians, which takes place in concrete time and space. Second, their work identified the importance of the interaction of work structure (context) and process (management) on outcomes. They proposed an imbalance between work structure and process creates issues with workloads and workflow. Third, patient work is cooperative and distributed, and includes the work performed by others for the patient. Last, patient work is often unrecognized by clinicians and is "invisible" to the outside world [3].

Self-Management and Self-care

Other researchers have expanded on the work of Corbin and Strauss [3]and developed the concept of *self-management*. Beginning with Thomas Creer's [72] work with asthmatic children, he defined self-management as the patient's active participation in treatment. Interventions focused on teaching patients illness management skills. Based on social learning theory [73] the underlying assumption is that patients are more likely to engage in their own healthcare if they have the knowledge, beliefs, abilities and self-efficacy to perform required behaviors [74]. The lack of skills and knowledge are the primary barriers to patient performance and the assumption

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is that all patients have an equal capacity to learn and perform.

Self-care is a similar concept, but self-care involves a broader set of activities. Self-care is a general term describing deliberate activities developed over time by the individual to ensure health and to maintain life [75, 76]. Context, culture, and individual capacity influence self-care performance, but self-care includes broader activities not prescribed or related to management of disease [74, 77]. Patients do not learn self-care through education, but these abilities are gained over time through experience [74] and influenced by capacity, resources, and limitations. Resource and demand imbalance causes problems with performance. Self-care research considers the contextual influences that enable and constrain process.

Medication Management

Medication management research focuses on the limitation in abilities (medication management capacity) of older adults, and the cognitive complexity of the medication regimen [78, 79]. This research is non-theoretically based and focuses on skill requirements. Author experience or assumptions define medication management tasks and processes [80, 81]. A systematic review of medication management assessment instruments devised a list of skills necessary for managing medications based on "author consensus" that included: (1) identify medications, (2) access medications from packaging, (3) comprehend and explain medication instructions, (4) recall information, and (5) administer medications [81]. The focus of interventions is improving these skills.

The Burden of Treatment

The *Burden of Treatment* theory recognizes that chronic disease medical treatments impose burden on patients [82, 83], similar to workload. Treatment burden is the workload imposed by medical treatments rather than demands from disease or symptoms. When demands

overwhelm patients and their networks (informal caregivers and the healthcare system), non-adherence to treatment and over and under-utilization of healthcare services can occur. Interventions to reduce treatment burden involve minimally disruptive medicine [84], a practice where practitioners minimize treatment burden and network capacity for action improved through care coordination. Improving network capacity and minimizing demand shifts the focus away from patient factors and motivational and educational interventions, placing the responsibility for improved patient performance on the healthcare system. Although not focused on optimizing the work system through design, treatment burden is a complementary concept that adds to the understanding of patient work.

Human Factors Engineering and Informatics

The primary focus for healthcare HFE has been the work of health professionals. However, applications of HFE methods and theories to the work of patients is a growing area of interest and often applied in the context of technology design.

Health work of older adults. Researchers applied HFE models and methods to gain an understanding of older adult unique design requirements. Concepts of abilities versus demands are primary. The Centers for Research and Education on Aging and Technology (CREATE) [85, 86] developed a model that emphasizes that technology designed for older adults must consider their reduced abilities in addition to task, technology, and contextual demands. Fisk et al. [86] used the model to synthesize research on aging and developed principles to guide the design of technology for older adults: (1) older adults are active users of technology; (2) they are less experienced with computers and cognitive decline often impedes performance; (3) environmental support through well-designed tools can improve performance; (4) simple design and less complexity is better; (5) if it cannot be seen, heard or manipulated, it can't be used; and (6) good design for older adults is good design for everyone.

Czaja and Sharit [87] identified the lack of ecological validity as a barrier to practical solutions to support the health activities of older adults. Laboratory research reported that cognition declines with age [88] yet health work related performance did not decline in real world settings [89]. Methods used in laboratory research failed to capture compensatory factors such as experience and environmental supports used by older adults in context. Clark, Czaja, and Weber [90] video recorded older adults performing 25 activities of daily living (ADLs) and using task analysis methods identified task demand as most problematic for older adults. Other researchers identified environmental supports as important factors in the health work performance of older adults. Morrell, Park, Kidder, and Martin [91] reported that older adults were more adherent to medications than younger adults despite evidence of cognitive decline and the greatest predictor of medication adherence was environmental demand. Older adults had more predictable environments, made fewer errors than younger adults, and structured their environments and lives around medication taking. These findings emphasized environment as a significant factor in successful medication management [92].

Invisible work. Informatics research identified patient health work as having characteristics of invisibility. Some types of work are difficult to observe and rarely mentioned in descriptions by workers themselves [93, 94]. A worker and their work are invisible when: (1) formal, indirect quantitative indicators that establish the criteria for successful performance live away from the work setting; and (2) others who never see the work first hand manipulate indicators for improvement [68]. Clinicians measure improvement in heart failure patients through numbers such as ejection fraction and brain natriuretic peptide (BNP) blood levels and infrequently see the work that goes on in patient's homes.

Unruh and Pratt [95] defined the invisible work of patients as activities done behind the

scenes amid multiple distributed actors, often involving communicating and coordinating. Their research uncovered the invisible work of breast cancer patients as: (1) maintaining state awareness, (2) bridging inter-institutional care, (3) managing dependencies, and (4) resolving inconsistent information. Invisible work occurred in irregular bursts and consumed patient resources. They proposed cooperation between providers and patients would reduce invisible work demand. This research also described patients using home structure and routines to organize health work.

Oudshoorn [96] described the invisible work of patients using a tele-monitoring device and technology design based on the assumptions of healthcare providers. Patients needed to decide when to take readings (patients lacked this knowledge) and manage the technology (patients lacked this knowledge and skills). Patient had difficulty becoming the "diagnostic agent." This was unrecognized by the technology developers and requirements focused on the needs of healthcare providers without considering patients.

Health information work. A significant amount of patient work research addresses information management. Moen and Brennan [97] used interviews, surveys and task analysis to explore the information management work of 49 households. They found information management strategies aligned with expected future use and the perceived importance of the health information and used the physical structure of homes and artifacts based on anticipated need. Zayas-Cabon [98] developed a method to acquire design requirement information for health information management tools through jointly constructed health information maps. Piras and Zanutto [99] explored the health information record-keeping work of 32 families and observed work practices that occurred in these households. Their findings emphasized the flow of documents in the home and that the emotional value of health documents impact the patient's

information management work.

Collaborative work. Research exploring the collaboration between patients and providers has focused on the provider role in the interaction [100-103]. Olson [104] described a "dual situation awareness" needed for patients and physicians to collaborate. This research concluded the goal of the patient provider collaboration is dual situation awareness to facilitate shared decision-making. Mickelson and Holden [105] discussed the distribution of tasks across locations, people, and artifacts. Patients and providers negotiated medication regimens using differing representations leading to inefficiencies in communication and difficulty reconciling medication regimens across people and locations.

Articulation work. Articulation work brings together elements of a system and coordinates effort and resources [106]. Coordination work is often invisible because there is no tangible product. Articulation work is especially important when disruptions or unintended events occur [107]. The field of Computer Supported Cooperative Work (CSCW) studies articulation work and the design of supportive technology [108]. Insights into articulation work occur through the study of worker created artifacts as artifacts that make articulation work visible [107]. Not considering articulation work creates a distorted understanding, leading to ineffective technology [68, 107].

Tool design requires the correct user perspective. Forsythe [109, 110] described the design of an information tool for patients with migraine headaches based on the physician and developer perspective rather than the patients. The resultant technology was not useful to patients, the targeted users of the technology.

Self-management work. Lippa et al. [111] evaluated self-management problem detection, functional relationship knowledge, and problem solving differences between diabetic

patients with different levels of glycemic control. Successful patients detected more cues, understood functional relationships to a higher degree, and had more strategies for problem-solving. Klein and Lippa [112] applied control theory and macrocognitive process theory to the self-management decision-making of patients with Type II diabetes. This research reported that teaching patients rules and procedures only assisted patients with planning routine, repetitive self-care activities, but was not helpful in decision-making or problem solving. The authors called for an educational strategy change for diabetic patients. They determined focus should be less on rules and procedures, and more on patient understanding of cues and functional relationships to assist with adaptive responses.

In an ethnographic study of 30 patients with diabetes, Hinder & Greenhalgh [24] found self-management behavior influenced by social position and resources, mediated through context. Patients who lacked material, cognitive, or social resources described self-management as hard work that required continual effort to maintain self-worth and physical well-being. The desire to act normally and lessen the visibility of their disease was also challenging for these patients.

Holden et al. [113] used the *Patient Work System* model to guide data collection and analysis of barriers to the self-care activities in 30 heart failure patients. Barriers included patient limitation factors such as medical condition, knowledge deficits, and preferences. Task barriers were also prevalent and included task difficulty and complexity. Tool barriers were related to both availability and access of tools and technologies and their design and usability.

Medication adherence work. Klein, Wustrack, and Schwartz [114] developed the *Adherence Loop* model of adherence motivation based on interviews with patients, professionals, and drug manufacturers. The essential processes important in motivating patients are: (1) to

believe the diagnosis and the potential effectiveness of the medication; (2) have *knowledge* and a mental model to decide what to do, when and how to do it; and (3) to *act* based on self-efficacy. Medication actions provides feedback to belief and knowledge. Klein and Meininger [115] viewed medication self-management as a challenging control task, with few available tools to assist patients. They explored decision-making demands by tracing the experiences of participants with one medication from the initial prescription to maintenance dosing. They found participants experienced many difficulties in medication management such as ambiguity of instructions and difficult decisions regarding timing and dosing.

Consumer Health Information Technology Design

Collaborative technology. Some studies explored the design of technology to assist collaboration between patients and providers. Morrow et al. [116] designed a paper tool to reduce cognitive load associated with collaborative patient-provider work. This tool reduced reliance on mental resources and improved problem solving. Liao et al. [117] developed a similar electronic tool integrated into an electronic health record. Other researchers described these artifacts as mediators of collaborative work and necessary when cognition distributed across many types of internal (mental) and external (artifacts) representations, people, tasks, and location [118].

Self-management technology. The patient perspective was absent in the design of self-management and self-care technologies. Few included a preliminary assessment of patient requirements before the development of the technology [2]. Jimison et al. [26] reviewed older adult consumer health information technology (CHIT) literature and concluded the most effective CHIT applications provided a complete feedback loop of functions: (1) monitoring, (2) interpretation of this data, (3) adjustment to treatment as needed, (4) communication from the

provider with recommendations, and (5) repetition of this cycle when needed. This study also reported patients used technology they perceived as useful. Storni [62] concluded the reasons behind the CHIT lack of usefulness were development in a clinical environment, input from clinical experts only, and CHIT design based on the medical model of health care.

Thompson, Hickson, and Burns [119] framed the design of information displays for Type I diabetic on a work domain analysis approach. The basis of this analysis was the model proposed by Hajdukiewicz et al. [120] that conceptualized the patient as the "system" and an "actor" in the system. Considering the patient's body as the domain system proved to be not very useful in defining requirements for displays due to the hidden nature of processes and outcomes within the body.

Medication adherence technology. Several studies investigated general requirements for adherence technology. Haverhals et al. [121] in a study of 32 older adults and their caregivers reported patients needed help getting reliable information and coordinating information from several providers. Ozok et al. [39] determined the kitchen as proper location for medication adherence technology because common memory cues depended on meals and food. Hernandez, Sommerich, and Woods [122] concluded a key requirement for medication adherence technology was the ability to communicate with caregivers, ease of use, and feedback about forgotten doses. Siek et al. [123] used participatory design methods to define requirements for a personal health record to help patients manage medications. This research reported that patients wanted autonomy in managing medication regimens, desired to understand why they were taking so many medications, and needed more information sources when faced with unusual events. Palen and Aaløkke [124] in an ethnographic study of older adults in Denmark developed insightful design principles. Medication adherence technology must support: (1) the distribution and use of

spaces in the home to support routines, (2) computation (such as tracking adherence rates), (3) increasing levels of help as needed, (4) "technology by invitation" meaning control over privacy and autonomy, and (5) support the administration of as needed medications.

Studies testing specific medication adherence applications rarely elaborated requirement origins. Chouvarda et al. [125] discussed several motivational medication adherence applications based on assumption that education and feedback improved the motivation to adhere, these applications provided no evidence for these assumptions. Other medication adherence technology evaluations also did not report requirement origins [126].

Conclusions

There are many gaps in knowledge regarding the medication management work system of patients. A common thread throughout self-management, self-care, and medication adherence literature is the assumption that the health activities of patients can be assumed and motivating and educating patients is the key to adherence. One striking gap in the literature is the lack of mention of patient tools.

Specific Aims

The aims of this study will be met using various HFE work analysis and cognitive task analysis methods to describe and analyze the medication adherence work system structure, process, tools, and strategies of older heart failure patients, and develop and test a methodology to accurately and feasibly capture and analyze these data.

Aim 1. Describe and analyze performance-shaping factors that enable and constrain medication management in older adults with heart failure.

Aim 2. Describe and analyze medication management work processes and workflow in older adults with heart failure.

Aim 3. Describe and analyze medication management tools used by older adults with heart failure to manage medications.

Aim 4. Describe and analyze the strategies adapted by older heart failure patients to attain their medication adherence goals.

Aim 5. Describe and assess a methodology that can be used to accurately and feasibly capture and analyze the medication management work system in older heart failure patients.

Conceptual Framework

The conceptual framework that underlies and guides each chapter of this study is a combination of the Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0) [127] and the Workflow Elements model [128]. The elements of work structure, the interacting attributes of persons, tasks, tools, interact and affect process (care and other processes) and outcomes (patient and organizational) [43]. A feedback loop exists between work system outcomes, process, and structure. The internal environment includes the physical and organizational structure of the patient's life and the external environment is outside of the work structure that includes "societal, economic, ecological, and policy factors" that influence work system elements [129]. The Workflow Elements Model (WEM) adds important pervasive elements in the background affecting the work system structure and processes [130]: temporality (scheduling, temporal rhythms, coordinating events), and aggregate factors (relationship and interactions between tasks and actors).

Figure 1-1. Conceptual Framework

#5 Method

#1
Performance
shaping
factors

Constrain
Facilitate

Enable

#3 Tools

Aggregation

Internal Environment

Tools
Artifacts

Tasks

Caregiver(s)

HCPs

Patient

External Environment
Temporality

#2
Medication
Management
Process

Individual
Collaborative

#4
Strategies
Adaptations

Produce

Proximal
Medication
adherence
0%

100%

Distal
Physical, Mental
& Social
Well-being

Structure
Input

Process,
Transformation

Outcome
Output

Zero to little current research   - - - - - - - -
Some research   ─────────
Large amount of research   ━━━━━━━

Dissertation Chapters

The next four chapters (2 - 5) are individual manuscripts directed at aims one through four guided by the conceptual model. These analyses are based on the interview, observation, survey, and medical record data from 61 older heart failure patients and 31 caregiver participants from the Caring Hearts study (PI: Richard J. Holden). Chapter two applies a systems safety framework to the analysis of the performance-shaping factors of medication management. The conceptual framework is expanded in chapter three by applying macrocognitive theory to patient medication management processes and workflow. Chapter four applies cognitive engineering concepts to an assessment of patient medication management tools. Medication management

strategies used by older adult heart failure patients to adapt to work system constraints and goal attainment are analyzed in chapter five.

Chapter six is a pilot study manuscript evaluating a digital diary data collection method for effectiveness, efficiency, and the satisfactoriness in assessing the medication management work system of older adults with heart failure. In this study, 15 older adults with heart failure and 2 caregivers recorded their medication management activities for one week using a tablet device. The challenges encountered using the method are also described.

Last, chapter seven summarizes my research trajectory given the results of the dissertation research and contributions to science and nursing.

CHAPTER II

MEDICATION ADHERENCE: STAYING WITHIN THE BOUNDARIES OF SAFETY

This chapter applies a systems safety framework to analyze the performance shaping factors that

influence the success or failure of the medication management processes of older adults with

heart failure. Study findings resulted in a dynamic systems model of medication safety applicable

to patient medication management in home and community settings. Findings and the resulting

model offer implications for future research on medication adherence, medication safety

interventions, and resilience in home and community settings.

Background

For decades, medication safety has been the target of human factors engineering (HFE)

research and practice in the domain of healthcare and the area of patient safety [131-135]. In fact,

apart from F.B. Gilbreth's [136] time-and-motion studies in the surgical theater, one of the

earliest known applications of HFE in patient safety was research by Safren and Chapanis [137]

on the types and causes of hospital nurses' medication errors.

By identifying medication errors as a major cause of patient harm, reports such as *To Err*

is Human in the US [138] and *An Organisation with a Memory* in the UK [139] catalyzed

national and international efforts to improve the safe use of medications in hospitals. Through

the application of HFE theories and methods, those efforts resulted in a greater understanding of

system factors that contribute to adverse events, shifting focus away from blaming front-line

healthcare practitioners to creating tools, improving processes and designing environments that

reduce the likelihood of errors [140, 141].

Subsequent studies and reports, such as *Preventing Medication Errors* [142], identified

medication safety as a challenge in hospitals but also in out-of-hospital settings, requiring

systems changes in hospital care, outpatient care, pharmacies, and among community-dwelling patients and informal caregivers (or carers). Home settings are important in part because more medications are administered by patients and families in home settings than in hospitals and clinics combined [143].

Patient self-administration in home and community settings is particularly challenging because many of the safety issues are related to nonadherence, defined as intentional or unintentional deviation from a prescribed and agreed upon medication plan [144, 145]. A systematic review of 29 studies of medication safety in ambulatory care concluded:

"[P]atient nonadherence was a frequent cause of error and also deserves more attention. Patient safety interventions, with their focus on hospital settings, have largely focused on errors in prescribing, dispensing, and monitoring of drugs. Nonadherence has received very little attention, probably because it is likely to be a minor problem in hospitalized patients under close surveillance by medical staff. However, in ambulatory care, where patients have greater responsibility for their drug therapy, improved adherence may offer an important means to reduce medication errors." (Thomsen et al., 2007, p.1423)

The medication non-adherence rate is estimated to be 20% to 60% among older adults with chronic disease [148-150] and is associated with increased mortality, disability, and reduced quality of life [48, 49, 151, 152]. Studies also report self-medication error rates in older adults of 19% to 77%, and 12% to 26% of these errors resulted in harm [153-155].

Medication non-adherence can be unintentional or intentional, and from a safety science perspective can be classified as errors or violations, respectively [156-158]. Unintentional

nonadherence can be viewed as poor execution of the right action (a slip – e.g., the wrong pill is taken), omission of the right action (lapse – e.g., forgetting to take a medication), or the execution of the wrong action (mistake – e.g., calculating the wrong dose) (cf. Reason, 1990). Intentional nonadherence can be viewed as a willful deviation from normative methods or rules (violations – e.g., intentionally taking a half dose or double dose of a medication); violations can be acts of ommission or commission (cf. Reason, 1990; Reason et al. 1998). Literature suggests both unintentional and intentional non-adherence may occur for a variety of reasons such as a patient's health beliefs, risk-benefit assessment, motivation, self-efficacy, forgetting, cost of medication, regimen complexity, and lack of instructions [161-165].

Despite its evident importance and prevalence, medication non-adherence in home environments has not received the same attention from patient safety professionals as medication safety in hospital settings [166-169]. This is also true of HFE research on medication safety, with several notable exceptions [116, 117, 158, 170, 171]. Understanding home-based medication adherence cannot be achieved by simply applying existing knowledge from hospital-based research. This is because the home setting presents unique HFE challenges [172]. Homes are not designed for healthcare delivery and occupants are often untrained, producing variable skill and knowledge levels (National Research Council, 2011). Patients also face macro-level physical, social, and organizational challenges such as financial difficulty, being judged by others, or physical distance from pharmacies [173]. Therefore, usual concepts, methods, and theories applied to the study of safety in the acute care setting must be adapted and expanded for safety research in homes and communities [169].

Accordingly, the purpose of this study was to investigate medication safety through the analysis of non-adherence events described by older patients with heart failure, a chronic illness

associated with multiple medication use. To accommodate its novel area of research, the study

adopts a general safety science framework, Rasmussen [174] dynamic systems model. The

model proposes that systems typically operate within acceptable boundaries of risk and harm, but

due to various forces such as production pressure, drift toward and sometimes cross those

boundaries. Counterforces such as safety campaigns compel the system away from the boundary

of risk, while resilient capacity prevents systems operating beyond the risk boundary from

resulting in harm [175]. The forces "moving" a system relative to boundaries of risk and harm

can also be called performance shaping factors (PSFs) [176]. In systems models of safety,

multiple levels of PSFs interact over time and in specific conditions to produce action sequences

and safety outcomes [174, 177, 178]. In the case of medication adherence, adherence is

constrained and enabled by multiple PSFs. For example, a patient's inability to drive might

'move' behavior towards the risk boundary of not retrieving their prescription medicine from

their retail pharmacy. Counterforces such as a mail-order drug delivery serve as defenses that

might move behavior away from this risk boundary as the patient begins to receive their

medications by mail. However, if mail-order shipping becomes overly expensive or

inconvenient, the patient's behavior may migrate towards the risk line and, as the patient more

routinely fails to receive their medication, behavior might cross the boundary of harm. This may

occur when, for example, routine medication non-adherence results in a hospitalization.

Lastly, although actual safety boundaries are uncertain and situational [179],

organizations and other entities (e.g., regulators, professional societies) establish and enforce

rules regarding tolerable behavior based on an estimate of those boundaries [174]. Rule

transgressions, regardless of actual risk incurred or whether harm resulted, are regarded as safety

violations [174, 175, 179]. Indeed, any deviation from the prescribed medication regimen is

usually considered non-adherent behavior regardless of reason or outcome [144]. Rasmussen's framework leads to these research questions:

- How do medication non-adherence events map onto unintentional and intentional migrations towards the boundaries of risk and harm (i.e., errors and violations)?

- What are the PSFs pushing patients towards the boundaries of risk and harm?

- What are PSFs pushing patients away from the boundaries of risk and harm?

- How do PSFs interact to produce safe and unsafe actions?

Methods

Sample and Setting

We analyzed cross-sectional data from interviews, observations, surveys, and medical record review collected from 61 patients living with heart failure accompanied by 31 informal caregivers in a study of heart failure self-care, 2012-2014. Informal caregivers were spouses (19, 60%) and adult children (11, 40%) of patients that participated during patient interviews. Patient participants were aged ≥ 65, diagnosed with heart failure with a documented status as mild to severe, and lived in a 200-mile radius of Nashville, Tennessee, USA. Half were recruited from an outpatient cardiology clinic specializing in heart failure. The other half were recruited within 60 days of discharge from a hospital admission for acute heart failure. Potential participants were contacted by phone with a non-participation rate of 30% due to disinterest, inability to contact and two withdrawals.

Observations were performed in outpatient clinics and patients' homes. Initial interviews took place in examination rooms, a private room in the clinic, or the patient's home. Most follow-up and extended interviews were conducted in the patient's home.

Data Collection

Data were collected through clinic appointment observations, short (30-min) initial semi-structured interviews, follow-up (90-min) interviews, and/or extended interviews (90-120 minutes). Observations of clinic visits involved non-interruptive note-taking and audio recording of the patient's entire formal encounter with a cardiologist, nurse practitioner, primary care physician, or other clinician. All initial interviews had the same general set of questions, extended with ad hoc probes, while follow-up interviews had some standard items and some questions that were created specifically for that participant, based on their initial interview responses. We asked questions from scripts specifically about medication processes such as daily administration routines, storing medications, management strategies, and difficulties with adhering to the medication regimen since the patient's heart failure diagnosis. After the initial interview, patients were given a standardized survey to return by mail (95% response rate) including assessment of heart failure health [180] and self-care behavior [181]. A heart failure knowledge survey [182] was completed by patients after the follow-up interview (79% response rate). Participants provided consent and received up to $65 for participation. The Vanderbilt University Institutional Review Board and Human Research Protection Program reviewed and approved the study. Detailed descriptions of data collection procedures and instruments are reported elsewhere [113].

Data Analysis

The specific data analysis method was descriptive qualitative content analysis with iterative category development [183]. This method systematically derives trends, patterns, and themes from large amounts of textual data revealing the underlying meaning [184]. It accommodates both deductive (conceptual model-driven) approaches and inductive (data-driven)

category development. To understand errors and accidents, all levels of the system must be analyzed, beginning with the error event itself, and moving backwards [159]. This is the first step in accident/event analysis as defined by The London Protocol (Taylor-Adams and Vincent 2004). During first-pass structural coding [185], researchers RSM & RJH identified broad passages of data mentioning medications. Second-pass coding RSM identified unsafe acts, the medication non-adherence events described by participants. A medication non-adherence event was defined as any instance where a patient did follow the prescribed medication regimen [144]. Non-adherence events included: taking a medication not prescribed; taking a greater or lesser dose; taking a medication at the wrong time, more or less frequently or for the wrong reasons; the wrong evaluation of effects; sharing medications; and omitting medications [186, 187]. Next, these events were iteratively categorized by error mechanisms (slips, lapses, mistakes, violations) [159] and error type [188]. Non-adherence events that resulted in known harm were identified with harm defined as "the impairment of the physical, emotional, or psychological function or structure of the body and pain or injury resulting therefrom" [188]. Non-adherence events were also categorized as recurring/routine or one-time/situational.

In the second step of analysis, performance-shaping factors (PSFs) for each non-adherence event were inductively coded from the data (interviews, medical record review) and categories iteratively defined. PSFs were factors that influenced or had the potential to influence medication performance including immediate conditions (environment, task, person, team), organizational factors, and defenses that prevented errors and violations [190, 191]. Next, PSF data-driven categories and subcategories were refined and informed concepts from healthcare and non-healthcare literature on errors [176, 192-196] and violations literature [159, 197, 198]. Final PSFs categories were identified as relating to person(s) (individual or team), task,

tool/technology, or organizational, social, or physical context [43, 129] using the Patient Work System model [113], an HFE systems framework. Cross-cutting themes regarding non-adherence events and PSFs were derived from the data. Authors RSM & RJH met regularly during coding discussions over a 10-month period, during which author RJH facilitated analytic agreement [199, 200].

Results

Table 2-1 describes the characteristics of the 61 older adult patients who participated in the study. All were diagnosed with heart failure and managing the disease with medications. Heart failure is one of the most rapidly growing chronic diseases in the U.S and the leading cause of hospitalization in older adults [201]. It occurs when the ability of the heart to eject or fill with blood is impaired from prolonged cardiovascular diseases, leading to a build-up of fluid and resulting symptoms such as shortness of breath, fatigue, and swelling [9, 202]. Treatment with medications is aimed to prevent further cardiac changes and to control symptoms [9]. Most patients were also managing other conditions such as high blood pressure, high cholesterol, and diabetes. Patients' regimens included a median of 16 medications (Mean=16.1, SD = 5.54), administered between one and six times per day.

Table 2-1. Demographics (N=61 patients)

Age, mean (SD, range)		73.31 (6.73, 65-86)
Gender	Male	31 (51%)
Education		
	Less than high school	9 (15%)
	High school	21 (34%)
	Some college	13 (21%)
	College graduate	18 (30%)
Heart Failure knowledge[a] (n=47)		

0-9	4 (8%)
10-13	38 (81%)
14-15	5 (11%)
Years since heart failure diagnosis	
Less than 1	14 (23%)
2 to 9	24 (39%)
10 and over	14 (23%)
Not known	9 (15%)
Number of medications, mean (SD, range)	16.9 (5.53, 3-34)
Heart failure specific health status[b] (n=58)	
Little to no disability	2 (3%)
Fair amount of disability	29 (50%)
Moderate amount of disability	25 (44%)
Severe disability	2 (3%)
Other medical diagnoses	
Hyperlipidemia (high cholesterol)	50 (82%)
Hypertension (high blood pressure)	55 (90%)
Diabetes Mellitus	37 (60%)
Living arrangements	
Alone	19 (31%)
With spouse	33 (54%)
With sibling	7 (11%)
With adult child/grandchild	2 (4%)
Retired	55 (90%)

[a] Dutch HF Knowledge Scale, theoretical range 0-15 [182]
[b] Kansas City Cardiomyopathy Questionnaire (overall summary scale) [180, 203].

In the following sections, we begin by identifying and describing the PSFs that support safe medication performance by patients. We then describe the medication adherence errors and

violations reported by patients and the PSF that defended against error and violation events emerging from our analyses. Lastly, we report on how PSFs often interact to shape medication adherence, including commonly identified interactions.

Safe Medication Management

Patients and informal caregivers described largely error-free performance while managing medications. Although the study could not quantify the "non-events" of safe performance, we identified seven major categories of PSFs supporting safe medication use: vigilance and monitoring; abilities and expertise; team communication and coordination; medication task support; error prevention and detection; ease of access; and tools and technologies (detailed in Table 2-2).

**Table 2-2. Factors Shaping Patient-Caregiver Error-Free
Performance of Medication Management**

- Vigilance and monitoring: When performing medication-related tasks such as filling pillboxes, vigilance decreased the likelihood of slips. A patient's wife isolated herself when she filled the patient's pillbox to assure the activity had her complete attention. Also, close monitoring of symptoms, medication effects, and medication supply enabled safe medication use.
- Patient abilities and expertise: Patient physical, cognitive, and functional abilities enabled the safe performance medication-related tasks. For example, some participants described having "good" memories and never forgetting to take their medications. Some patients also described managing their medications "for years."
- Informal team communication and coordination: Sharing and reconciling information was vital to safe medication use. For example, accessible communication channels such as hospital portals or direct telephone contact allowed patients to request information, refill prescriptions, and request appointments easily.
- Task support: Internal and external contextual factors supported error-free medication use. For example, patients associated medication taking with structured events such as meals, bedtime and awakening in the morning. They also placed medications in visible locations to cue medication administration. Family members organized and administered medications for patients with physical and cognitive limitations. Pharmacies reminded patients when refills were due. Healthcare providers established rules to guide conditional

medication use and what to do when the patient experienced symptoms or problems such as forgetting a medication.

- Error prevention and detection strategies: Some patients devised their own error detection mechanisms.   For example, medications such as insulin could not be stored in pillboxes. One patient devised a system of counting syringes to assure he did not administer his insulin twice. Patients learned from errors and devised avoidance strategies. For example, a patient decided to break a medication in half to distinguish it from a look-a-like medication after confusing the medications and experiencing an adverse drug reaction.
- Ease of medication access: Medications and equipment access enabled uninterrupted medication use. Some pharmacies offered delivery services and other mail order options. Ninety-day refill intervals reduced the frequency of acquiring required refills. Generic medications were offered at reduced prices. Patients also kept extra supplies of medications, explained by a patient: "I have a cache."
- Tools and technologies: Patients used various tools to support memory and deal with complex medication regimens. A patient described the use of a pillbox: *"You've just got to have those daily box otherwise it's total chaos."* Two patients created alerts on their cellphone to remind them to take their medications. One patient used a left atrial pressure monitor that reminded him to take his medicine, told him the amount of medication to take, and stored this information over time.

Besides factors preventing errors, feedback and other cues that an error occurred contributed to timely error mitigation. Perceived medication effects were the primary source of feedback defending against omission errors. Several patients also used pillboxes—plastic containers with compartments for days of the week and administration times—to verify if they had taken their pills. As an example of both, a 68-year-old female patient realized she had forgotten her morning medications because she had not yet urinated, an expected medication effect. The presence of the medications in her pillbox verified the omission and she administered the medications within an acceptable time range.

Overview of Medication Adherence Errors and Violations

Thirty-seven of the 61 participants (61%) described at least one medication non-adherence event. A total of 70 unique events were described (mean of 1.89 events per participant, SD = 1.29, Range 1- 6), 35 (50%) involving unintentional errors (slips, lapses,

mistakes) and 35 intentional violations (50%). Errors were both situational one-time events (40%) and routine re-occurring events (60%), whereas violations were primarily routine and re-occurring (86%, 30/35). Eight events (11%) resulted in known harm to the patient either from an adverse drug events (ADE) or acute heart failure and condition deterioration. Table 2-3 summarizes medication non-adherence error and violation frequencies, specific non-adherence events increasing risk, and known events causing harm and hospitalization. Appendices C and D report illustrative quotes.

Table 2-3. Medication Management Violation and
Error Event Mechanisms, Risk and Harm

Mechanism	Non-adherence events increasing risk	Known harm
VIOLATIONS (50%, 35/70)	• Improper dose, (40%, 14/35) • Dose omissions (37%, 13/35) • Uninitiated medication (8%, 3/35) • Wrong time (6%, 2/35) • Wrong dosage form (3%, 1/35) • Wrong medication (3%, 1/35) • Wrong reason (3%, 1/35)	• Situational: Hospitalization resulting from a patient taking a double dose of a medication. • Routine: 3 hospitalizations resulting from routine omissions of medications.
LAPSES (24%, 17/70)	• Dose omissions (94%, 16/17) • Wrong time (6%, 1/17)	• Situational: ADE resulting from forgetting all morning medications.
MISTAKES (20%, 14/70)	• Dose omissions (43%, 6/14) • Wrong medication (22%, 3/14) • Wrong patient (14%, 2/14) • Improper dose (7%, 1/14) • Expired medication (7%, 1/14) • Wrong time & medication (7%, 1/14)	• Routine: Condition deterioration resulting from a delay in the delivery of a mail ordered medication.
SLIPS (6%, 4/70)	• Wrong time (50%, 2/4) • Dose omissions (25%, ¼) • Wrong medication (25%, ¼)	• Situational: ADE resulting from confusing two look-a-like medications.

Medication Adherence Errors: Lapses, Slips, & Mistakes

Some aspects of patients' home-based medication management, such as morning medication self-administration, became routinized over time. Routinized tasks were vulnerable to errors of execution: slips and lapses. For example, an 80-year-old male patient's morning breakfast routine changed and the next day forgot his morning medication. A 68-year-old female

patient described mistakenly putting an evening medication in the morning compartment while filling her pillbox. Other tasks were more thinking-intensive and vulnerable to mistakes such as errors in monitoring, planning, decision making, or application of rules. The most common medication adherence mistakes were related to the management of medication supplies and failures in responding to symptoms.

In the 35 described error events, eight categories of PSFs were commonly evident, presented in order of highest to lowest frequency of occurrence. These PSFs are summarized in Table 2-4.

Table 2-4. PSFs Shaping Non-Adherence Error Events (n=35)

TASK
Task complexity and workload (66%, 23/35)
The inherent difficulty of a task or process. For medications, this includes the number of pieces, steps, clarity, conditionality, urgency, or frequency.

- Number of medications & frequency of administrations, refills
- Sequence, number of steps
- Administration time of day

- Storage requirements
- Irregular dosing
- Frequent changes
- Medication appearance similarity

Quality of strategies and routines (57%, 20/35)

The presence, quality, and consistency of the set of practiced behaviors applied in anticipation or response to task requirements.

- Present/absent
- Number of strategies

- Adequacy in preventing, detecting errors

Quality of error cues (37%, 13/35)

The presence, salience, and timeliness of cues that enable/constrain error detection and recovery.

- Timing (immediate, delayed)

- Present/absent

PATIENT AND TEAM

Attention/inattention, vigilance (60%, 21/35)

The cognitive process of focusing attention and keeping careful watch for possible danger or difficulties

- Inattention after a change (e.g. in routine, medication regimen)
- Disruption in routines

- Assumptions of correctness

Patient abilities/limitations (46%, 16/35)

The abilities, knowledge, experiences, and attitudes of the patient.

• Functional	• Experience, familiarity
• Physical	• Knowledge
• Cognitive	• Attitudes

CONTEXT — ORGANIZATIONAL, PHYSICAL, SOCIAL

Access to supplies and equipment (40%, 14/35)

The availability and ease of access of medications and required equipment.

• Patient location (away from home)	• Distance to pharmacy
• Medication location (in the home)	• Stockpiling medications
• Delayed access	• Sharing medications
• Cost of medications, equipment	• Saving expired medications
• Insurance rules	

Communication & coordination (29%, 10/35)

Processes and systems in place for sharing information and collaborative medication tasks within teams.

• Lack of communication, coordination	• Speed of communication
• Inadequate information sharing	• Perceived need for communication, coordination
• Availability of communication channels	

Social support (14%, 5/35)

The availability and quality of support from one's social network, when needed.

• Lack of supervision	• Lack of procedural support

Organizational support (9%, 3/35)

The availability, quality, and utilization of organizational resources for assistance with medication use.

• Availability (e.g. rules, procedures, automation)	• Quality (e.g. mail order speed, reliability)

TOOLS AND TECHNOLOGIES

Quality of tools and technologies (31%, 11/35)

The availability and quality of tools to assist patients, family, or clinicians to perform tasks.

• Unintended consequences	• Inadequate tools
• Lack of tools	

Task complexity and workload. The complexity of medication regimens contributed to several error events (66%, 23/35). The average participant self-administered medications three times per day, and more if they were diabetic. In addition to the number, frequency, and route complexity (e.g. oral, sublingual, topical), administration times could be irregular and doses for certain medications such as Metformin and Coumadin continually changed. Some medications had special storage requirements and these were more easily forgotten. Certain medications were hard to differentiate by appearance. The wife of a 72-year-old patient described having to concentrate to avoid confusion: *"There's a lot of pills that are white and you just can't talk or do*

anything and, and give medicine (at the same time)." Medication names were difficult to say and remember: *"[To] tell you what I'm taking I would have to be a Yale professor. So I can't pronounce them"* (67-year-old male patient). The refill process also involved many steps and required patients to monitor the supply of multiple medications on different refill schedules.

Ambiguous symptoms, procedures, and rules also contributed to task complexity and workload. For example, two patients who interpreted chest pain as indigestion administered antacids in response. One patient took Tylenol for her shortness of breath and another cough drops. Rules about safe medication use were also unclear or unknown, resulting in stockpiling medications for later use, sharing medications with others, and the administration of expired medications. Events of under- or over-administration were also related to confusion about conditional medication administration rules, such as how much weight gain required the administration of a diuretic.

Quality of routines and strategies. Disrupted, weak, and inconsistent routines and strategies contributed to errors events (57%, 20/35) such as habitual forgetting. Although participants generally described having detailed and stable morning rituals, mid-day and bedtime routines were less fixed or non-existent. Several participants admitted routinely falling asleep and forgetting to take their medications. Other conditions also disrupted routines, as one 66-year-old man stated: *"Sometime I forget to take this shot, especially if I'm out."* Few participants described successful strategies for taking medications when away from home. Many tolerated occasional errors, up to a limit, even if they had happened more than once: *"If you miss one of those cholesterol pills, I mean, it's not gonna kill you. It's, if every day you mix 'em up, then, you know, then, you're looking at a little problem"* (84-year-old female patient).

Quality of error cues. There were few cues or error detection mechanisms to alert patients of errors, a contributing factor in 13 (37%) events. Although increasing symptoms or lack of anticipated medication effects were cues of possible errors, in many cases participant only became aware of the error hours, days, or weeks later. Those using the pillbox to verify self-administration sometimes did not realize their omission until the next scheduled administration. Participants who did not use pillboxes were sometimes unsure if they administered their medications: *"I haven't forgotten [necessarily] to take them — I can't remember if I've remembered"* (65-year-old male). In other cases, participants suspected, but could not verify if an error occurred. Undetected mistakes due to lack of knowledge led to habitual errors such as taking the wrong medication for a symptom (e.g., Tylenol for shortness of breath).

Attention/inattention. Inattention and lack of vigilance contributed to many error events (60%, 21/35) particularly lapses and slips. Medication management tasks became routine and cognitive effort attenuated over time. However, after a change such the addition of a new medication, attention was required. A 68-year-old patient took a double dose of a new medication after confusing it with a look-a-like medication he had taken for years. Another patient forgot his morning medications after his breakfast routine changed. He explained: *"I didn't have my drink in the morning, so I didn't get* [forgot] *my morning beta blocker."* Also, some patients did not double check a medication dispensed for accuracy. The daughter of a 72-year-old patient assumed an incorrectly dispensed medication from the pharmacy was correct and her mother took the wrong medication for several weeks before the error was discovered by her nurse practitioner.

Patient abilities/limitations. Limited abilities, skills, knowledge, and attitudes towards medications contributed to error events (46%, 16/35). Arthritis impaired an 84-year-old patient's

ability to take medications out of prescription bottles. She believed she sometimes dropped

medications on the floor without noticing. An 86-year-old patient who was unable to walk could

not access her medications stored in a high kitchen cabinet. The inability to drive was a factor in

two events. A 74-year-old patient was unable to find a family member to drive her home to

administer her medications. Lack of knowledge and experience also constrained the ability to

interpret symptoms and decide on the appropriate as-needed medication to administer.

Access to supplies and equipment. Organizational factors constrained the availability of

medications in multiple error events (40%, 14/35). Insurance rules restricted the timing of refills

in two events. A 74-year-old patient ran out of a vital medication due to slow mail order

delivery, leading to decline in his condition. Medication cost was a factor in two error events. A

68-year-old patient describing having to *"wait to get some money"* before acquiring her

medications. Medications were also inaccessible when patients went away from homes and did

not bring medications with them.

Communication and coordination. Absent, delayed, or incomplete communication,

information sharing and coordination of activities were factors in some events (29%, 10/35),

such as completely running out of out of a medication. Two of these events were initiated by the

delayed medication request of the patient to the pharmacy. The majority, however, involved

ineffective communication between the healthcare providers, pharmacies, and insurance

companies. For example, the wife of a 70-year-old patient explained running out of a medication

when the healthcare provider increased the dosage but did not write a new prescription or notify

the pharmacy. One patient was dispensed an incorrect medication from her local pharmacy after

a hospitalization and self-administered it for several weeks before the error was discovered by a

nurse practitioner. Also, patients did not always communicate with either family members or healthcare practitioners in situations where communication might have mitigated an error.

Social support. Inadequate social support from caregivers enabled error events (14%, 5/35). Three patients had physical and cognitive disabilities that constrained medication administration and required continual support and supervision when administering medications. In one case, an 84-year-old woman with two adult children living with her desired autonomy but sometimes inadvertently dropped medications on the floor without awareness. Families were not always aware of correct versus erroneous patient self-administration. Providing needed continual support was especially difficult for working caregivers.

Organizational support. Organizational support systems were also involved in errors (3/35, 9%). Mail order delivery systems were sometimes ineffective and medications ordered were delayed or did not arrive at all. A 74-year-old patient experienced shortness of breath after running out of one of his diuretics and explained: "[It] *can take two and a half weeks to get it to me."* Other patients were not aware of organizational support systems such as mail order delivery. A 72-year-old patient that could not drive ran out of her medication because she could not find a family member to drive her to the pharmacy but was unaware of medication delivery options.

Quality of tools and technologies. The consequences and inadequacy of medication tools were factors in error events (31%, 11/35). For the over half of patients who used pillboxes to organize medication administration, there was the risk of separating the medication from the name identifier on the prescription label. This was even riskier because of the similar appearance of pills mentioned above. Pillboxes also did not easily accommodate irregularly timed or non-routine medications, which were sometimes forgotten. Medication lists and hospital discharge

instructions were not always clear and easy to understand. Two error events were related to the print on prescription container labels being too small to read or having deteriorated with age. One patient described running out of a medication because he did not notice on the label that a refill authorization was required.

Medication Adherence Violations

Described violations were situational responses to specific conditions or, more often, routine patterns of behaviors under repeated circumstances. Situational violations (14%, 5/35) primarily involved acute symptoms and the perception that prescribed medications were ineffective, leading to additional self-medication. For example, a 68-year-old female patient experiencing chest pain took 3 additional nitroglycerin tablets after the prescribed dose was ineffective. As an example of routine violations (86%, 30/35), some participants (16%, 6/37) routinely omitted medications when they were traveling or away from home. Two violation events involved patients habitually taking extra doses of a diuretic after eating salty foods with friends. Others described ceasing all medication over days or weeks or regularly taking the wrong dose; these behaviors resulted in hospitalization for three participants.

Consistent with the notion of forces and boundaries in Rasmussen's (1997) dynamic systems model of safety, participants described intentional non-adherence as an attempt to achieve personal goals, shown in Figure 2-1. Most participants described violations positively, as necessary adaptations to prevent risk or retain control. Negative assessments of violations were expressed only if the patient experienced an undesired outcome. If no undesired outcomes were detected, violations often became habituated responses, depicted in Figure 2-1 as a case of "drift." In the 35 described violation events, ten categories of PSFs were commonly evident, presented in order of frequency and summarized in Table 2-5.

Figure 2-1. In Medication Adherence Violations, Individuals Pursued the Goals of Minimizing Risk and Preserving Autonomy
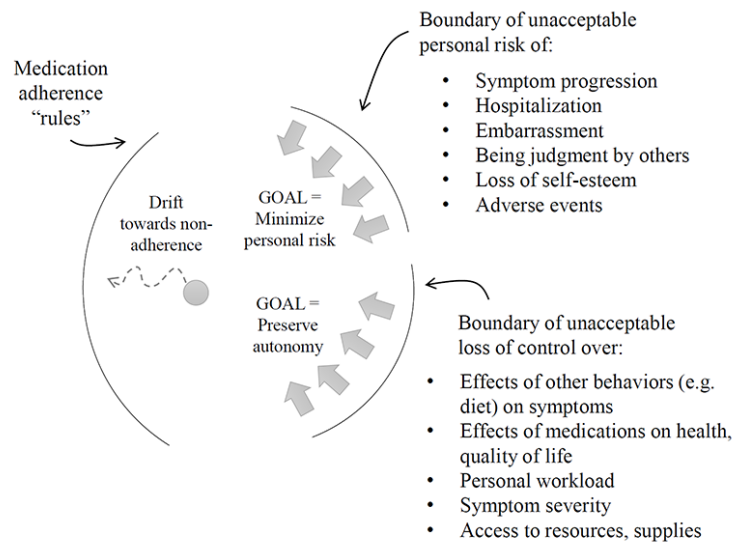
Goal agreement. Life goals such as comfort, rest, and enjoyment sometimes took precedence over medication adherence goals and led to violations (74%, 26/35). The long-term goals of medication adherence were sacrificed for other short-term goals. A typical example was the omission, reduction, or rescheduling of diuretic doses before bedtime or when away from home. One violation omission event involved a conflict with personal finances related to medication cost. Two patients expressed conflict between taking medications and their lack of will to live: *"I said let me go on…I don't wanna fight it no longer"* (74-year-old female). Other medication side-effects such as lethargy and weight gain or lack of medication effects resulted in the patient altering the dose or timing of a medication. Combined with a perception of urgency, the lack of medication effects led to the administration of extra doses in three violation events. A former surgeon, not satisfied with the effects of his laxatives, administered a second dose, leading to a hospitalization.

Violation consequences. The perceived consequences of a violation were a factor in its performance (69%, 24/35) and influenced whether the violation became habitual. If the violation

solved the problem without (perceived) unacceptable consequences it was considered successful. The daughter of a 70-year-old patient expressed pride in finding a solution to her mother's lethargy by giving her certain medications just once a day: *"during the day she's more alert."* Not all assessments of consequences were accurate. A patient completely discontinued his medications and claimed his blood pressure improved, *"it was good. I believe it checked it, I checked it, it was, uh, 198 over 136 (a very high value)."*

Communication and information sharing. An underlying factor in the majority (74%, 26/35) of violation events was the lack of or delayed communication with healthcare providers about patient-initiated medications changes. Routine violations, such as not taking medications while traveling or away from home, were *"never really discussed"* (81-year-old male) with providers. Some participants were reluctant to talk about adapting medication regimens with providers. A 70-year-old patient's daughter told her mother's nurse practitioner that she was giving her mother medications that made her "sleepy" only at night, yet several of her medications were to be given twice a day. When questioned further, the daughter said *"nothing has changed,"* leaving the practitioner unsure about how the medication was actually taken, once or twice a day. Actual medication administration, unless supervised by a formal or informal caregiver, was unknown to providers and known only to the patient.

Social influence. Many violations were strongly influenced by social factors (39%, 17/35). Avoiding embarrassment, loss of self-esteem, and the judgment of others were evident in several violation events. Some patients would omit medications or not pick up medications from the pharmacy to avoid asking informal caregivers for help. The social embarrassment of being symptomatic in public prompted overdosing, e.g., *"I can be standing at the checkout counter someplace and woman running, running the register says you're breathing awful hard"* (74-

year-old male). Being perceived by others as a sick person promoted omitting medications, *"you can tell people that take water pills cause they always running to the bathroom… Whoosh. But I, I don't do that"* (65-year-old female). An 81-year-old patient's cultural beliefs and mistrust of Western medicine led to frequent violations: *"in Trinidad, where I come from, you suffering high blood pressure. You have, you have couple leaves. You boil and you drink. Your pressure goes down."*

Rules. Rule ambiguity was a factor in violations (34%, 12/35). Providers gave patients instructions on the safe use of medications, for example, to not "double up" medications after missing a medication dose or to take as-needed diuretic medications if their body weight exceeded a threshold value. In many situations, however, the rules were not clear. When asked what she would do if her 70-year-old husband's oxygen saturation levels were abnormal, a wife vaguely stated, *"you know write it down and keep a check on it."* As another example, a 67-year-old male had an ambiguous perception of the rule of taking medication in response to weight gain: *"if it builds up over five pound or something, or whatever, if it start getting excessive…if I gain eight pounds or whatever, and then I, you know."* Rules were also interpreted flexibly, drifted from the original instructions, or were vague to begin with (e.g., take the medication and see if symptoms subside before calling an ambulance).

Resources. The quality of and access to resources enabled violations (34%, 12/35). Weekends and after working hours were described as difficult times to access healthcare providers, promoting violations such as taking more of an ineffective medication. Social support from informal caregivers was not always available, due to caregivers' working hours: this led to medication timing violations. Omission of diuretic medications away from home was in some cases related to the lack of bathroom availability.

Perceived risk. How patients and caregivers perceived and understood their disease and previous medication experiences were factors promoting violations (51%, 18/35). Underappreciating the health risk of heart failure contributed to four events of long-term intentional non-adherence, eventually leading to hospitalization. In two of these events, patients skipped medications if they did not *"see any outward signs"* of their effect (72-year-old female), despite instructions for daily medication use. Conversely, others self-administered medications prematurely, unnecessarily, or in greater or lesser amounts, out of anxiety and fear about symptoms or being hospitalized. For example, the wife of a patient reduced the dose of her husband's routine diuretic medication after he experienced acute renal failure, to avoid a recurrence Although in some cases non-adherence to avoid perceived risk may have been appropriate, as when one patient refused to take a new heart medication prescribed by an unfamiliar primary care physician, patients rarely communicated their adjustments to their medication regimens.

Self-confidence. Perceived self-confidence was a factor in several violation events (20%, 7/35). Some patients felt comfortable adjusting their medications because they were experts on the functioning of their own bodies. These patients violated rules and recommendations because they trusted their own knowledge and experience over the advice of their providers. An 81-year-old patient did not take the advice of his doctor stating, *"I've been sort of doing this at my own [discretion] and it seems to work."* Another patient described how he was *"in tune"* to his heart and trained himself to be alert to signs of fluid overload. This patient routinely took higher doses of diuretics after going to a Mexican restaurant or eating popcorn at the movies. Most self-confident patients monitored their condition very closely with tools such as blood pressures cuffs, pulse oximeters, and weight scales. Sometimes, a patient's perception of expertise was

inconsistent with medical expertise, as in the two events when patients discontinued medications after misattributing them as the cause of a deteriorating condition.

Tools and technologies. Interestingly, monitoring tools and technologies enabled some habitual violations (20%, 7/35). When patients were anxious or had a high level of perceived expertise, monitoring tools allowed them to closely follow the consequences of their violations, or to initiate medications earlier than the medication rule prescribed. One patient who described 3 violation events closely monitored his blood pressure and weight several times per day. Another patient who did not take medications when traveling and took higher doses of diuretics after eating salty foods closely monitored his blood pressure and left atrial pressure more often than prescribed by the providers. Other patients who described more than one violation did not closely monitor their condition. Monitoring devices could also be misused. A patient used a pulse oximeter threshold of 95 to dose his as-needed diuretic, although his provider recommended taking no action unless the value was 88 or less.

Table 2-5. PSFs shaping non-adherence violation events

TASK
Goal agreement (74%, 26/35)
A condition in which medication adherence objectives and other life objectives are incompatible and promote violations.
<table><tr><td>• Effects of medications</td><td>• Other responsibilities</td></tr><tr><td>• Comfort</td><td>• Motivation</td></tr><tr><td>• Rest</td><td>• Urgency</td></tr><tr><td>• Social activities</td><td></td></tr></table>
Violation consequences (69%, 24/35)
The consequences of a medication adherence violations on medication use, health and quality of life.
<table><tr><td>• Success/failure</td><td>• Acceptability of risk/benefit</td></tr></table>

CONTEXT — ORGANIZATIONAL, PHYSICAL, SOCIAL
Communication and information sharing (74%, 26/35)
Processes and systems in place for sharing information and collaborative medication tasks within teams.
<table><tr><td>• Lack of communication</td><td>• Unshared (hidden) information</td></tr></table>
Social influence (39%, 17/35)

The influence of real or imagined interactions with other people, either within patient's local social system (internal: e.g., family, home) or in the broader social environment.

- Judgment of others
- Perceived burden on others

- Cultural influences

Rules (34%, 12/35)

The quality of rules and established procedures that define and guide the safe use and medications.

- Lack of rules
- Rule ambiguity

- Rule drift

Resources (34%, 12/35)

The real or perceived quality and availability of organizational, social, and physical resources required for medication use and the effects of medication use.

- Perceived availability of healthcare provider

- Physical facilities

PATIENT AND TEAM

Perceived Risk (51%, 18/35)

The patient or caregiver's assessment of the potential for negative consequences due to disease, symptoms, treatments, or the actions of others.

- Lack of severity
- Perceived urgency
- Perceived negative effects of medications

- Previous experiences
- Attitudes towards medications

Self-confidence (20%, 7/3)5

The self-perception that a person possesses a high level of skill and expertise.

- Perceived expertise

- Lack of trust in healthcare providers

TOOLS AND TECHNOLOGIES

Tools and technologies (20%, 7/35)

The availability, quality, and consequences of tools and technologies.

- Perceived mitigating effects of monitoring tools   .

Performance Shaping Factor Interactions

Consistent with prevailing safety theory, errors and violations were often the result of a combination of factors, not isolated PSFs. Interacting error and violation PSFs acted together to increase or reduce safety, risk, and harm. For example, the risk of error for a visually impaired patient unable to read prescription labels is decreased if social support is available and a caregiver organizes the patient's medications using a tool such as a pill organizer. If a patient's perceived risk of non-adherence is low, monitoring of adherence by a family member or experiencing consequences such as hospitalization can reduce the risk of non-adherence. Table

2-6 presents common PSF interactions and Table 2-7 presents an illustrative event of several

errors and violations shaped by a combination of PSFs.

Table 2-6. PSF Interactions, Frequencies, and Examples.

Error event interactions	Frequency	Example
Weak routines and strategies, inadequate error cues, and high medication task complexity and workload	23%, 8/35	A 66-year-old patient sometimes forgot to take his bedtime medications and was unaware of the omission until the next morning. He did not develop a routine or strategy to prevent this error.
Patient limitations and inadequate social support	20%, 7/35	An 86-year-old patient could not reach her medications stored high in the kitchen cabinet (due to children in the home) and no one was home to assist her with retrieving them.
Inadequate communication and coordination and interrupted access to medications	17%, 6/35	A 72-year-old patient ran out of his medication after forgetting to call the pharmacy to re-order and a delay in receiving authorization from his healthcare provider.
Unintended consequences of tools and technologies, high medication task complexity, and inadequate error cues	9%, 3/35	A 68-year-old woman taking 15 routine medications daily confused 2 look-a-like pills while filling her pillbox. She was unaware of the error for several days until her unusual fatigue prompted her to check her medications.
Violation event interactions		
Lack of communication and information sharing, positive violation consequences, and goal conflicts	34%, 12/35	A 65-year-old patient took half of his prescribed diuretic dose before bedtime to reduce the frequency of urination at night. He did not reveal this to his healthcare provider.
Goal conflicts and the judgment of others.	20%, 7/35	An 81-year-old patient did not take his diuretic before going out with friends to avoid the embarrassment of frequent trips to the bathroom and the possibility of incontinence.
High self-confidence and the use of tools and technologies	14%, 5/35	An 84-year-old patient used a pulse oximeter to decide when he needed an extra diuretic rather than measuring his weight as prescribed by his healthcare provider. He observed the use of the tool in the hospital and saw other patients with the device in the waiting room of the clinic.

Table 2-7. Patient Scenario Illustrating PSF Interactions

A 74-year-old retired intelligence officer runs out of one of his medications (***access to medications***) after forgetting to re-order a refill until he only had only 2 pills remaining (***inattention, lack of vigilance***). He did not know the medication (Metolazone) was a diuretic (***patient limitations***) and thinks it is just one of his many "heart pills" (***medication complexity***) and thinks it is fine if he misses it for a few days. The medications did not arrive after one week (***inadequate organizational support***). He explains, *'I'll get a phone call from the computers, you know, your medication was mailed on, on the 8th of the month and uh this was the 10th of the month when I get the call. And uh I'm not going to see it until probably the 1st of the month.'*

He then called the mail order pharmacy to re-order the medication. He began experiencing shortness of breath and fatigue. He decided to call his primary care physician on Friday and attended an appointment the same day. Thinking it was unimportant (***patient limitation***), he did not bother to communicate to the physician that he was not taking one of his diuretics (***inadequate communication and information sharing***). The physician increased the dose of his other diuretic, Lasix, by one third and called a heart failure specialist by phone to discuss the patient. The physician set up an appointment for the patient with the heart failure specialist for the following Monday.

Over the weekend, the patient perceived the Lasix as having no effect (***risk perception***) and his condition continued to worsen. Not wanting to bother his primary care physician (***social influence***) and knowing it was difficult contact a physician on the weekend (***resources***), he doubled his dose of Lasix without consulting a physician (***self-confidence, lack of communication***). He sometimes took more Lasix without consulting his provider and his shortness of breath with positive results (***violation consequences***). He also closely monitored his weight and blood pressure over the weekend (***tools and technologies***).

He attended the Monday appointment with the heart specialist. Laboratory tests showed the patient's kidney function was declining (a side-effect of high doses of Lasix) and the specialist did not want to increase his Lasix dose any further. The heart failure specialist was unaware the patient was not taking the other diuretic (Metolazone) (***communication & coordination***) and ordered some additional testing to further evaluate the causation of the patient's condition decline.

Discussion and Conclusion

Consistent with other literature, we identified numerous events in which a patient's behavior deviated from the desired or prescribed medication regimen. The literature on medication adherence does not often focus on individual events, tending to assign labels of "adherent" or "non-adherent" patients, based on a somewhat arbitrary cutoff such as 80% overall compliance [144]. Unitizing non-adherence as events may reveal stronger relationships between non-adherence and outcomes of harm: for example, Wu, Moser [204] report $\geq 88\%$ as a cut-point for event-free survival, whereas we found that one non-adherence event could lead to harm in otherwise adherent individuals. This has major implications for the kind of interventions required—i.e., improving performance for all rather than targeting only the chronically non-adherent. Focus on events rather than individuals is also consistent with examining the factors shaping performance rather than "blaming and shaming" individuals who are non-adherent. The systems approach recommended for considering the work of healthcare practitioners [205, 206] needs to be reinforced when we begin to examine the work activity of patients and families [129].

Adherence Events vs. Adherent People

Although we could not reliably estimate the event occurrence rate, others estimate that 20-60% of older adults achieve less than 80% overall medication adherence and medication errors occur in 19-59% of patients [155]. Others estimate adverse drug events resulting from errors to occur in 19-30% of older adults discharged from the hospital [207, 208]. In our case, 61% could articulate at least one event of nonadherence which could be classified as an error, violation, or both, and on average about two events were reported per person. Both are likely underestimates, as many errors probably occurred but were not detected. Further, errors and

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violations may have been underreported due to their social undesirability, lack of perceived importance or relevance, and the nature of the interview (time-constrained and broadly focused). The study may have underestimated the rate of harm for similar reasons or because patients did not realize the relationship between an event and outcomes such as a subsequent hospitalization; such causality is even difficult for clinical experts to discover.

However, the strength of this study was not its ability to estimate event or harm rates. Unlike prior research, this study was uniquely designed to deeply investigate the specific types of medication non-adherence events and the PSFs promoting or preventing them. We identified seven PSF categories related to error-free performance, ten related to errors, and ten related to violations, with some recurring categories. In most cases, we found an interaction or combination of PSFs contributing to the non-adherence event.

A Dynamic Systems Model of Medication Non-Adherence

Rasmussen's [174] dynamic systems model provides a new lens from which to consider patient medication safety not previously applied to the health work of patients, as shown in Figure 2-2.

While the general parameters of the model apply, we found that the PSFs pushing patients towards or away from risk and harm were different in many ways from those involved in professional safety. Patients performed health work within the context of a messy everyday life, in which medication adherence competed with other life priorities. These included the desire for social acceptance, enjoyment, comfort, and control over various aspects of life. This is similar to the finding from an HFE study of patient falls that patients will act in a way that increases their fall risk for the sake of retaining autonomy, for example toileting alone [209].

Figure 2-2. A Dynamic Systems Model of Medication Non-Adherence. Based on Rasmussen [174] and Cook and Rasmussen [175]. PSFs influence behavior towards or away from the boundaries of medical risk, medical harm, personal risk, and personal control.
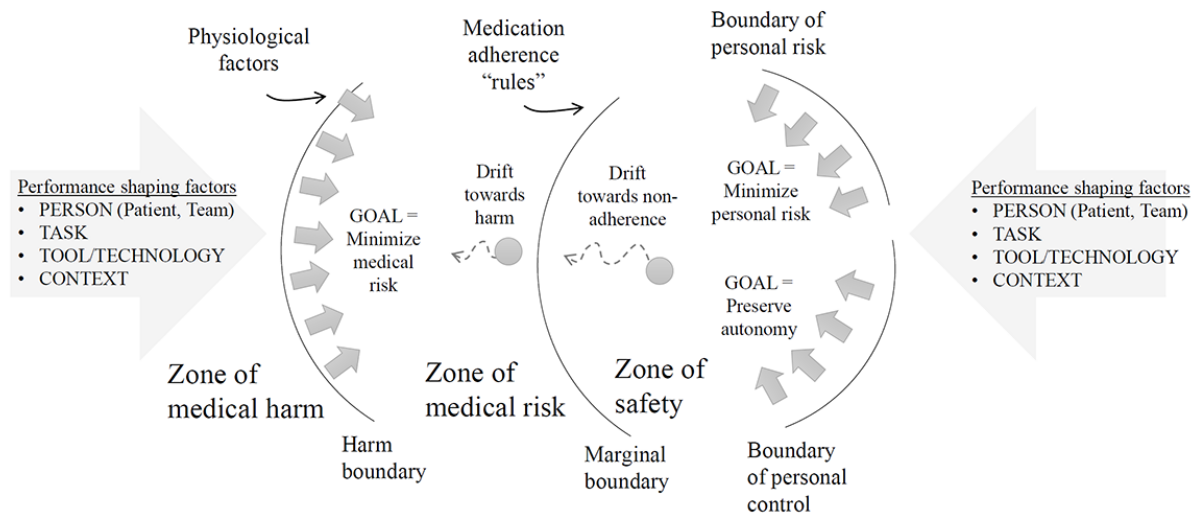
PSFs include both situational and stable influences at the level of the person and the broader system. In many cases, a patient's safety is largely outside of their control, as in events where personal limitations, medication regimen complexity, availability of formal or informal caregivers, or ambiguous rules were contributing factors. In those cases, patients may consistently operate closer to the boundary of risk, much as certain high-risk industries (e.g., petroleum, military aviation). For these, the reinforcement of rules or rejoinders about caution may serve little value compared to better risk assessment and reduction, event detection, and mitigation of harm from intentional or unintentional non-adherence [210]. For example, reducing polypharmacy, the use of five or more medications concurrently for treatment of multiple chronic conditions, can reduce the risk of non-adherence and ADEs [163, 211-213]. In other cases, such as those involving inadequate communication, miscalibrated perceptions, or a lack of strategies, a more preventive approach can be taken by the introduction of technologies, training, and practice with various strategies. Patients generally strive to achieve their personal goals without taking an unacceptable amount of risk, but at times they experience direct goal conflict.

In other cases, the boundaries of medication-related risk and safety are vague and difficult to define. They may even be situational or shifting over time. Furthermore, the forces compelling a patient towards or away from a boundary of risk or harm may be more immediate than the counterforces: this is evident when a patient seeks to resolve an immediate symptom in a way that contradicts general instructions given months or years ago.

Our data, findings from other studies of medication adherence, and a big body of literature in safety science all identify the dynamics of risk-related behavior, which in Figure 2-2 is depicted as "drift." Mirroring the increase in errors as systems become more complex [214], medication adherence errors may become increasingly probable over a patient's lifetime as the number and types of medications increase and cognitive or physical functions decline [149, 215, 216]. Just as compliance with safety rules declines with time [198], so do patients report lower medication adherence rates over time [217, 218]. This appeared to be especially likely in self-confident patients, mirroring Reason's [159] finding that self-rated "good drivers" performed more violations. However, it may be that individuals who are experts not only in their tasks but also in judging risk and the health consequences of various behaviors would be more judicious about when they violate, perhaps performing fewer violations overall [219]. Helping patients achieve such expertise would require much better clarification of the boundaries of safety than most patients appear to possess. The clarification of boundaries and instantaneous feedback on where one is relative to those boundaries are goals that are easier to articulate than achieve, requiring considerable research and design.

Further, as patients experience no ill effects, and perhaps perceive value in violations, non-adherent behaviors may become unspoken norms [220], making them less obvious to informal and formal caregivers. We note that drift is not a random phenomenon, but rather the

work of multiple forces depicted in Figure 2-2, which with enough feedback, learning, and restructuring of one's environment result in reinforced behavior, routines, and structural enablers. By implication, some of the drift can be carefully managed over time, rather than addressed during a specific event.

Implications for HFE and Safe Medication Use in Home and Community Settings

A major implication of the model in Figure 2-2 is that patients (and informal caregivers such as family members) are influenced by a variety of system factors *in the performance of meaningful, effortful, and deliberate activity* that may be called "patient work" [221]. As several recent models of healthcare HFE articulate, the patient is a key actor in patient safety, not a passive recipient [209, 222, 223]. Consequently, improving patient safety will require an understanding of patients' context and activity as well as interventions, technological and otherwise, to support this activity [224]. HFE is uniquely qualified to evaluate and support "human work" towards a better, healthier, and safer world [225], and "patient work" is as important an application as any [223].

As shown in Table 2-8, the safety of patient medication work could be improved using concepts from Safety I or Safety II, two systems-based approaches to safety science and practice [226, 227]. A Safety I approach might begin by building a system to identify error or violation events and analyze the events to better understand problematic PSFs and plan appropriate interventions [228]. Risks inherent to observed events, such the risk of medication omissions when one's medication regimen is complex, could then be mitigated through system redesign (e.g., by reducing the number of prescribed medications or adding reminder alerts) [229]. Event reporting could focus on only those errors or violations that led to harm or on all events with the potential to cause harm.

**Table 2-8. Examples of Safety I and Safety II Approaches to
Improving Safe Medication Use by Patients**

Applying Safety I to medication adherence could involve the following:

- Training and reinforcement of rules and procedures to safely manage medications.
- Manufacturing medications with distinct appearances to avoid confusing look-a-like medications.
- Technologies alerting patients to forgotten medications within a window of opportunity to safely correct the error.
- Dosing packets or systems that prevent or greatly reduce the probability of administering the wrong medication.
- Well-lit and low-distraction "workstations" where a person may take medications in their homes.
- Technological or human redundancies such as automatic refills or medication cross-check by a family member.

Applying Safety II approach to medication adherence could involve the following:

- Develop strategy training programs and design tools and technologies based on the strategies used by highly successful patients to manage medications and adapt to common constraints.
- Improving access channels to communicate with healthcare providers quickly as needed for decision-making.
- Providing patients with medication adherence feedback through electronic medication monitoring devices and graphical displays of the physiological response to medications.
- Educating patients and providing access to information on safe non-adherence practices (e.g. how often can a medication be skipped, safe delayed administration, administering extra doses).
- Automated capture and communication of biometric measurements to healthcare providers to detect condition decline early.

A Safety II approach would further focus on 'things that go right' and identify ways to support safe and effective work performance [227, 230-232]. Safety II encourages making the system as robust as possible to unexpected or uncontrollable risks and stresses on the system. This idea has been recently applied to healthcare [227, 232] and is applicable to the domain of patient safety in home and community settings, including medication safety [158, 233]. The goal

of Safety II interventions—be they training, technology, or otherwise—would therefore be to develop resilience, which we define here as 'the ability of a patient, informal caregiving network, and formal caregiving network, to adjust their functioning prior to, during, or following changes and disturbances, so that they can sustain required medical and daily life operations under both expected and unexpected conditions' (based on Hollnagel [230]). This can be accomplished by identifying PSFs, strategies, and conditions under which medication management for a person or group of people is accomplished successfully, especially considering challenging circumstances such as complex medication regimens, travel, or medical disturbances (e.g., post-hospitalization, new diagnosis).

Descriptive statistics were provided for illustrative purposes only as this study was not designed to assess error or violation rates or to capture all possible safety events. The events described by participants may not be representative of true error and violation, but likely sheds light on common patterns and PSFs. The events described by participants were retrospective and recall bias may have influenced the accuracy of their description of non-adherence events. Although ours was a relatively large sample for a study of its kind, it was performed in one region of the US and was limited to older adults with heart failure. The data used for this analysis was gathered from a larger study of heart failure self-care, with only a subset of data collection methods designed to measure medication-related events. PSFs were extracted from narratives, rather than from structured assessment instruments, and we did not use a specific error/incident taxonomy because none applied directly to this domain; however, our PSF categories and their definitions were based on prevailing systems models and incident taxonomies.

Patient work related to medication management, and the typical home and community based settings where this work occurs, are important areas of focus for HFE and safety experts.

We argue that the domain of medication adherence is at least as deserving of HFE research and design as any other in the patient safety arena. While methods and models will need to be adapted to this domain, HFE provides a solid foundation on which to build.

CHAPTER III

MEDICATION MANAGEMENT: THE MACROCOGNITIVE WORKFLOW OF OLDER

ADULTS WITH HEART FAILURE

Macrocognitive processes are theorized as how people individually and collaboratively think in complex, adaptive, and messy non-laboratory settings supported by artifacts. This chapter applies a macrocognitive workflow framework to analyze medication management cognitive processes. Breakdowns were common and patients had little support for macrocognitive workflow from current tools. Recommendations for technology design to support the macrocognitive work of medication management are presented.

Background

For older adults with one or more chronic diseases, maintaining health typically requires continual management of complex medication regimens [234, 235]. These regimens involve multiple drugs, taken many times a day, on differing schedules, with complicated names, directions, and purposes [236]. Often constrained by age and disease-related cognitive and physical decline, multiple comorbidities, and having to navigate a complex healthcare system, it is no surprise that many do not take their medications as prescribed [53, 150]. Poor medication adherence is associated with poor outcomes, including increased rates of institutionalization, disability, and death [49, 152, 237].

Heart failure is one chronic disease with especially complex medication and lifestyle management components. Heart failure affects 5.7 million U.S. adults and 12% of older adults; it is the leading and faster growing cause of death in the U.S. [238]. Heart failure is characterized by impairment in the heart's ability to pump and expel body fluid. Treatment involves consistent medication administration to control fluid accumulation and prevent complications [239, 240].

Non-adherence to medications, however, is reported in 40% to 60% of heart failure patients, increasing the longer the patient has the disease [241]. Emergency room visits, hospitalizations, and the likelihood of survival are related to failing to take heart failure medications as prescribed [5, 151, 242].

Interventions to improve medication adherence have primarily involved educating and motivating the patient, with only moderate effects on short-term and little effect on long-term medication adherence [16, 243]. Innovative solutions are needed, and there is interest in the potential of consumer-facing health information technology (IT) to improve heart failure medication adherence [27, 244, 245]. Health information technology (HIT) developed for older adults, however, has inconsistently supported their health management needs [28-30, 246-248]. Older adults using technology for health management report a lack of perceived benefit, a lack of fit to their lifestyle, and that currently available technology is cumbersome and confusing, adding to rather than reducing the effort required to manage their health [26]. According to the principles and international standards for user-centered design, the above problems can be proactively addressed by basing HIT design on an explicit understanding of users, their activities, and their contexts [1, 249-252]. Understanding the actual work HIT is intended to support is the starting point for designing effective technology [2]. **Therefore, design of HIT to effectively promote medication adherence in older adults requires a deep understanding of the work activities and work context of medication management** [44, 253]. We define the concepts of patient work and medication management in Table 3-1.

Table 3-1. Patient Work and Medication Management Concepts Definitions

- **Medication management** is the process of implementing medication plans: the activities enabling optimal use of medicines to achieve maximum health benefits with minimal harm for a specific patient [254]. We avoid the term 'self-management,' which implies the patient acts alone.

- **Patient work** is the 'exertion of effort and investment of time on the part of patients or family members to produce or accomplish something' [255]. Health-related patient work bears some similarity to paid professional work (e.g., assessing symptoms, wound care) but includes unique tasks such as coping with disease progression, scheduling appointments, managing health finances, and preparing diet-appropriate meals [44, 256]. Patients also engage in collaborative work, in which both the patient (or family member) and at least one healthcare professional are active participants (e.g., in-visit communication and shared decision making) [223].

Prior research reveals that patient work related to medication management is complex, cognitive, and collaborative, rather than the linear execution of simple, standard tasks. Sensemaking, defined as the deliberate, continuous effort to understand relationships between people, places, and events to anticipate their path on which to base actions, is a foundational medication management activity [37] and is generally essential to chronic disease management [257]. Other medication management processes identified in prior research include tracking, collaborating, ordering, and organizing [38]. In the case of heart failure, some define patients' self-care (including medication management) as a process of naturalistic decision-making involving situation awareness, mental simulation, and outcome evaluation in the face of uncertainty, ambiguity, and time pressure [39]. Research on health IT functionality has described medication management activities such as seeking information, maintaining autonomy, reconciling medications across multiple providers [123, 234], planning, and creating reminders [258-260]. Nevertheless, these cognitive processes of medication management have not been studied simultaneously in a single group of patients. This has precluded an integrated, systematic categorization and modeling of cognition in medication management in its full complexity. Furthermore, to design effective tools and technologies for older adults with heart failure, it is necessary to understand the unique cognitive workflow of heart failure medication management as it occurs in actual practice.

Our present objective is to describe and analyze the work of medication management by older adults with heart failure, using a macrocognitive workflow framework to adequately capture the complexity of medication management work. Our research framework extends the Workflow Elements Model [128], which portrays workflow as a set of continually evolving and changing processes. Workflow can be planned, routine, and sequential, but often emerges based on situational factors and interaction between workflow elements. Those elements are *actions*, performed by *actors* using *artifacts*, producing *outcomes*, supported or constrained by the secondary elements of *context* (i.e., physical, social, cultural environments), *timing* (i.e., scheduling and coordination), and *aggregation* (i.e., interactions, combinations). Our study expanded the model to better operationalize the *actions* component of the model as a set of macrocognitive processes, such as sensemaking, re-planning, coordinating, problem detecting, and deciding [261, 262]. Macrocognitive processes are 'the collection of cognitive processes that characterize how people think in natural settings' [263]. Macrocognition is explicitly theorized as the type of cognition occurring in complex, adaptive, and messy non-laboratory settings, and can be accomplished by multiple people and supporting artifacts [261]. Thus, combining the Workflow Elements Model with macrocognitive processes facilitates the study of 'workflow in the wild' rather than 'workflow in a textbook.'

Methods

Between 2012-2014, we performed a study on the self-care of older adults with heart failure. Sixty-one patients and 31 informal caregivers were enrolled in the study. They were observed during clinic visits and at home and participated in either an extended interview lasting 90-120 minutes or in a short (30-min) interview followed by a longer interview (90-min). Data from electronic medical records and self-administered standardized surveys (97% response rate)

provided additional data. Interviews were semi-structured and probed about the actors, artifacts, actions, outcomes, and context of heart failure self-care in general and of medication management in particular. Interviews were structured on a model parallel to the Workflow Elements Model, the Systems Engineering Initiative for Patient Safety [SEIPS] 2.0 model [223], which includes: people; tasks; tools/technologies; social, physical, and organizational context; physical, cognitive, and social processes; and outcomes. A separate subset of questions was asked of each participant, including questions about the perceived efficacy and side-effects of medications, medication errors, and medication management tasks such as refills.

Patient participants were aged 65 or older and lived in a 200-mile radius of Nashville, Tennessee. Half were recruited from an outpatient cardiology clinic specializing in heart failure. The other half were recently discharged from a hospital with a diagnosis of acute heart failure. Participants provided informed consent and received up to $65 for participation. The Vanderbilt University Institutional Review Board and Human Research Protection Program approved the study. Detailed descriptions of sampling plans and data collection methods are reported elsewhere [256].

Analysis organized findings and major themes into the core elements of the Workflow Elements Model: actors, artifacts, actions, and outcomes. Within the actions element, data were analyzed according to five macrocognitive processes: sensemaking; planning; monitoring; decision making; and coordinating [262, 264]. The specific data analysis method was descriptive qualitative content analysis with iterative category development [183]. This method systematically derives trends, patterns, and themes from large amounts of textual data revealing the underlying meaning [184]. During first-pass structural coding [185], researchers RSM and RJH identified broad passages of data mentioning the management of medications as defined

above. Next, during second-pass analysis, author RSM assigned initial thematic codes related to actions and macrocognitive processes, actors, artifacts, and outcomes. For initial categorization, definitions of macrocognitive process were based on those established by Patterson and Hoffman [262] and Crandall, Klein and Hoffman [264]. Macrocognitive sub-processes were identified iteratively by constant comparison [265] of data to definitions from an extensive review of the macrocognition literature. Themes within and across categories were noted, for example, describing how macrocognitive processes were related or how a sub-process could break down. Authors RSM, RJH, and KMU met approximately every 2 weeks for a 10-month period to discuss coding and category development. Such coding discussions are a proven technique for facilitating analytic convergence among multiple coders [200, 266] but in our single-coder arrangement contributed to conceptual clarity and corrections of coding errors.

Results

Table 3-2 describes patient participant demographic characteristics, caregiver support, and living arrangements.

Table 3-2. Demographics

Age in years mean (SD)	65-86	73.31(6.73)
Gender	Male (n=31)	51%
Race	White (n=45)	74%
Annual Income (N=56)		
	< $25,000 (n=19)	34%
	$25,000-$49,999 (n=18)	32%
	$50,000-$99,999 (n=14)	25%
	≥ $100,000 (n=5)	9%
Reported years since heart failure diagnosis (N=52)		
	< 1 (n=14)	27%
	2-9 (n=24)	46%
	≥10 (n=14)	27%
Number of medications mean (SD, range)		16.9 (5.53, 3-34)
Comorbidities[a]		
	Hyperlipidemia (n=50)	82%
	Hypertension (n=55)	90%
	Diabetes Mellitus (n=37)	60%
Caregiver support		

None (n=32)	52%	
Spouse (n=18)	30%	
Adult child or children (n=11)	18%	
Living arrangements		
Alone (n=19)	31%	
With spouse (n=33)	54%	
With sibling (n=7)	11%	
With adult child or children (n=1)	2%	
With grandchild (n=1)	2%	
Other assistance		
Assisted Living (n=5)	8%	
Home health (n=7)	11%	
Retired (n=55)	90%	

[a]Commonly associated with CHF, not intended to be a list of all comorbidities of patients in our sample.

Overview

Medication management involved far more than administering pills on time, opening bottles, or binary decision-making on whether to take a medication. Behind individual tasks were a host of interacting cognitive processes, promoting a holistic understanding of what patients and caregivers need to do to manage medications in real world situations. Managing medications and the outcomes thereof involved a complex, interacting, and interdependent flow of actors performing actions enabled by artifacts (Figure 3-1).

Figure 3-1 Macrocognitive Workflow of Medication Management [130]
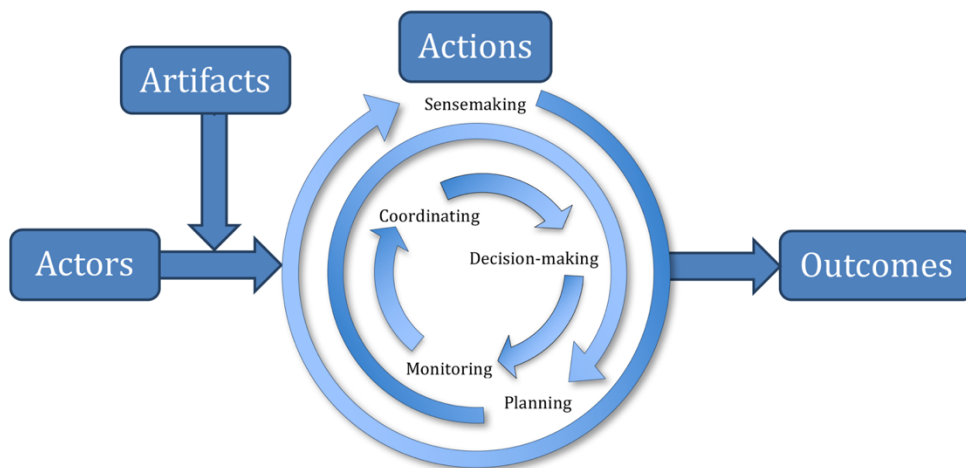
Our focus, the actions element of the Workflow Elements Model, and other elements are briefly described in the following sections.

Actors

A variety of laypersons and health care professionals participated alongside the patient in medication management activities (Figure 3-2). Informal caregivers, if present, included spouses, adult children, friends, and grandchildren. Their help was dynamic, far-reaching, and varied based on their availability and the needs and desires of the patient. The son of an 85-year-old woman explained how the family administered his mother's medications: *"It started out my sister did it primarily. Then she showed me, and then mom just wanted to do it herself sometimes, but we check."* Assistance sometimes included sharing medications. An 85-year-old man expressed comfort knowing *"my sister has some of the same medicine that I take...I can borrow some from there."* Informal team members varied widely in skills, abilities, knowledge, and motivation.

Figure 3-2. The actors comprising the formal and informal care teams
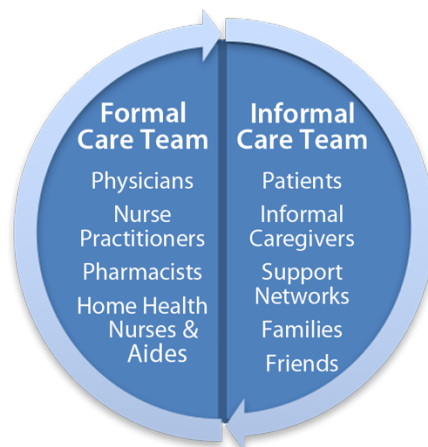
The number of health care professionals comprising the formal team varied with the patient's condition, comorbidities, and need for home health services. These individuals assisted the patient in a variety of clinical and nonclinical settings. Clinicians who prescribed medications

included nurse practitioners specializing in heart failure and physicians with specialties in primary care, cardiology, endocrinology, nephrology, neurology, and pulmonology. Some patients received medication-related assistance in their homes or assisted-living facility from nurses and aides. A 65-year-old patient described not having to leave her home for a blood test to determine the dose of a medication: *"It helps me a lot when the home health nurse can come and do my INR* [coagulation test] *...and then, she calls that into the Coumadin clinic."* Pharmacists also assisted patients. An 81-year-old patient consulted his pharmacist when his blood pressure was high: *"He (pharmacist) said, well now it should've gone down, but he says Norvasc is a tricky medicine, it may take it 3 hours to go down, but it will finally go down."*

Artifacts

Table 3-3. Artifacts Used by Older Adults with Heart Failure

(1) Patients and informal caregivers used tools for monitoring and measurement (e.g., blood pressure cuffs, scales), tracking and communication (e.g., vital sign logs, medication lists, online patient portals), organizing administration (e.g., pill organizers, baskets), and gathering information (e.g., Internet, books, brochures). Many patients (37/61, 61%) used pill organizers to decrease the effort of managing multiple medications and reduce the possibility of error. Some patients and informal caregivers used an online patient portal (20/61,33%) provided by their medical center and found the portal useful for communicating with health care professionals about refills and other needs.

(2) These tools did not always adequately support medication management activities. For example, some patients adapted medication lists received from the clinic. The son of an 84-year-old patient explained why his mother used an old medication list: *"And sometimes there's been a print out from them (clinic) around, but somehow or another this is just the one we have been using. Particularly because it will also help by telling me what it's for* [referring to hand-written annotations on purpose of each medication]."

(3) Personal devices including blood pressure cuffs used by some patients were originally designed for clinical use and patients and informal caregivers did not always understand the meaning of the raw numerical output. For example, a 68-year-old patient described his blood pressure reading to his nurse

practitioner: *"Well, let's see, the other night I was sitting there resting and it was good. I believe it checked it, I checked it, it was, uh, 198 over 136."*

(4) Multiple medication representations (e.g., medications, prescription labels, numerous medication lists, electronic health record lists) were difficult to reconcile across care settings. For example, a 65-year-old patient could not remember the name of a prescribed medication, but knew it's timing and appearance: *"I have to take it twice a day, it's supposed to be three times, I take it twice a day. It's orange and kind of brown."*

Artifacts—tools and technologies—facilitated patients' medication management. We have previously described the artifacts used by heart failure patients in this study [267]. Table 3-3 summarizes these findings.

Actions

For ease of presentation, we describe medication management actions in categories of discrete macrocognitive processes in Table 3-4. However, these processes interacted, overlapped, and were alternatively concurrent and sequential. For instance, when a patient gathered information about a medication (a subprocess of sensemaking), decision-making and planning were likely also taking place. Table 3-4 defines the macrocognitive processes and subprocesses reported in this study.

Table 3-4. Medication Management Process and Subprocess Definitions

Process	Subprocess	Definition
Sensemaking		**Deliberate, retrospective efforts to understand and explain events typically triggered by a change [268].**
	Information gathering	Exploratory activities to "gather, differentiate, interpret, evaluate, and aggregate" information from sources [269].
	Adapting mental models	Re-framing internal representations (how things work, mechanisms) on which to base future actions and expectations [270, 271].
	Storybuilding	The process of constructing narratives (stories, scripts, schema) to infer how a current situation might have evolved from an earlier state [272].
Planning		**Generating and adapting methods for action to transform current state into desired future state [264].**

	Generating plans of action	Generating options for methods by balancing available resources and existing constraints to achieve a specific goal [273].
	Adapting plans	Responding to changes in goals from a variety of sources such as peers, constraints, opportunities, events, or changes in anticipated plan trajectories [262].
	Anticipatory thinking	Preparing to respond to constraints, contingencies, and opportunities that could be encountered while implementing a plan [273, 274].
Monitoring		**Maintaining awareness of system state; to observe and check the progress or quality of (something) over a period of time; keep under systematic review [275].**
	Problem detection	Noticing when events may be taking an unexpected direction [262].
	Tracking	A control process that follows the course or progress of something to keep the system within safe and acceptable levels of performance [276].
Decision-making		**Commitment to one or more options or actions [262, 277].**
	Applying rules	Using a prescribed, explicit, and understood regulation as a guide for conduct or action [275].
	Pattern matching	Matching the circumstances of the present situation to similar events and clusters of cues from the past [274].
	Mental simulation	Imagining how a decision will play out [278].
	Making trade-offs	Losing one quality or aspect of something in return for gaining another quality or aspect [279].
Coordinating		**Managing interdependencies across members of a team with overlapping, common, and interacting activities, roles, and possible conflicting goals [264, 280].**
	Reconciling information	The process of bringing information or understanding into agreement (i.e., maintaining common ground) [280].
	Managing interdependencies	Managing the mutual reliance and dependencies between elements of a system [280].
	Negotiating	Coordinating competing roles, goals and plans in the "give and take" process by which team members agree on a common issue or solution [281].

Sensemaking. Sensemaking actions described by participants were retrospective, deliberate processes that integrated new information into existing understanding to guide future action. Sensemaking processes were foundational, contributing to all macrocognitive processes.

Due to the continuous flux in patients' health and medication regimens, punctuated by various health-related events (e.g., hospitalization, new prescription), participants perpetually

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searched for meaning and causal explanations by gathering information, adapting mental models, and storybuilding.

Information gathering occurred across actors, locations, and time. During clinical visits, most of the questions from observed participants were about verifying or executing an existing medication plan. They asked questions such as: How many do I take? [65-year-old male] You sent her refill in, didn't you? [daughter of 74-year-old female] and *Can I have a dental exam* [while on an anticoagulant]? [65-year-old male] These questions implied a concern for "what do I do" more than "why do I do it." Many patients (46/61, 75%) also gathered medication information from sources outside the clinical setting (Table 3-5). Reasons for gathering additional information included (1) a new diagnosis requiring medications, (2) an upcoming procedure, (3) a change in the medication regimen, (4) questioning the validity of medication choices made by clinicians, and (5) uncertainty or anxiety. Participants commonly gathered information from laypersons such as family, friends, or support groups. They sometimes shared this social network-sourced information with clinicians. A 65-year-old patient suggested to his physician: *"So, one of my friends said well maybe you just need a, a pap, what do you call it? Pa-, Paxil, is it?"* Participants who mentioned Internet or television information viewed it as valid and authoritative but had difficulty filtering and prioritizing it.

Table 3-5. Information Sources Outside of the Clinical Setting

Information source	%	Information type
Medical Center Portal (n=20)	33	laboratory tests, diagnostic tests, clinical summaries, lists of current medication regimen
Internet (n=25)	41	websites with health, disease, and medication information
Television (n=5)	17	commercials, TV shows (e.g., Dr. Oz)
Educational print materials (n=14)	23	medical books, medical brochures, information booklets

Educational classes (n=2)	3	organized diabetes, heart failure instruction
Prescription inserts (n=6)	10	medication indications, dosing, side effects, special instructions
Family, friends, support groups (n=27)	44	shared personal advice, experience, knowledge

Participants synthesized gathered information with previous experiences and current knowledge by adapting mental models or their personal understanding of "how things work." To illustrate, a 75-year-old patient revealed not taking her medications because she perceived they had no effects on her health, and did not like taking "so many" medications. She explained that after a hospitalization and conversation with her physician, she revised her mental model to view medications as like vitamins: *"Medication is a form of preparation, you know, and builds your system up to fight off what may come in the future."* After this mental model revision and a reduction in the number of daily medications prescribed by her physician, she subsequently began to take her medications regularly.

At times, participants developed inaccurate mental models, especially regarding functional or causal relationships between body systems, medications, and health events. A 75-year-old female patient contended, *"I don't have no heart failure medicine. I only have blood pressure medicine."* Several participants had difficulty connecting fluid retention to heart functioning. An 85-year-old female patient elaborated, *"I don't think it's (fluid) in the ankles or the hands or anything like that. I think it's the fluid in the heart area that would make the heart beat less."* Table 3-6 gives examples of participants' descriptions of causal factors contributing to past health events.

Table 3-6. Example Causes of Health Events Described by Patients and Informal Caregivers

Cause	Quotes
Prescribing decisions	*The rejection (heart transplant) and it was due to their neglecting, negligence of not resuming my appropriate therapeutic level of Procrit, my medication.* [68-year-old male patient] *They gave him an overdose of it (Lasix).* [wife of 72-year-old patient] [on why her husband experienced kidney failure] *My hair has fell out because they took me off my medicine.* [65-year-old female patient]
Medications	*Yeah, that's (medication) what made me mean. I kicked a t-, a tray out of the nurse's hands and stuff like that when I was in the, in the rehab.* [78-year-old male patient] *Well, all the other times, you know, I'd never had it* [diabetes]*... Some of the medication that they put me on would cause high sugar.* [68-year-old male patient]
Procedures	*Okay. Yeah, um, I think most of my health problems came after an open-heart operation, mitral valve repair in late 2001.* [81-year-old male patient] *Some of his memory problems...but he was put to sleep four times in two months and that really isn't very good.* [wife of 81-year-old male patient]
Genetics	*It's certain things and this is a genetical (sic) thing with a black man's diet and a white man's diet. See, uh, we grew up on pork that's the worst meat you can eat. Pork, half dog, half rat, half, and they eat anything, you understand?* [67-year-old male patient] [explaining the cause of his high blood pressure]
Comorbidities	*I think it (stroke) take a toll on my heart... That is why I have a pacemaker.* [79-year-old male patient]
Symptoms	*So I think all that pain and all may have caused heart trouble. I don't know.* [74-year-old male patient]
Environment	*That portion of when I look back now was a lot of just losing my breath, shortness of breath and all, came from the room fresheners.* [68-year-old male patient]

Storybuilding was a sub-process that enabled the creating and updating of mental models as well as organizing information and communicating one's mental model to others. A 69-year-old patient retold the story behind her pacemaker insertion: *"I was seeing a doctor and he had*

increased my medicine, Coreg, and the more he increased it the less my heart functioned so

that's when they decided they had to...so I came back, I moved my mother, came back down here

and, um, uh a doctor put in my pacemaker."

In summary, patient and informal caregiver sensemaking (1) combined information

gathered from multiple sources including sources outside health care settings and experience, (2)

developed causal models for health events, and (3) produced new or revised mental models often

expressed in personal stories.

Planning. Planning was the practical, prospective translation of instructions into

implementable actions under known constraints, with the goal of achieving a desired future state.

Generating plans of action provided the "how" of performing generic instructions such as "take

Lasix three times a day" in practice.

Participants expressed planning as an ambiguous process not well supported by their

formal care team. A 74-year-old male patient described the lack of guidance for planning:

"There's, there's not a, you know there's not a magic list of instructions that they lay out." A

recently discharged 65-year-old patient similarly conveyed the lack of guidance after her

hospitalization: *"When you go home, you're kinda on your own. You're kinda flyin by the seat of*

your britches."

As participants recognized changes in symptoms, medication regimen, available

resources, and existing constraints, they were continually adapting plans. To exemplify, a 66-

year-old patient explained how mixing up 2 look-a-like medications resulted in an adverse drug

reaction; consequently, he planned to break a newly prescribed medication in half to distinguish

it from other pills. As in this case, action plans often arose from new awareness of constraints

(look-a-like medications) based on feedback from implementing a prior plan (adverse drug

event). After experiencing severe shortness of breath that led to a hospitalization, an 84-year-old patient decided weight was not a sensitive indicator in detecting fluid retention. He instead planned to use a pulse oximeter to dose his conditional diuretic. He observed nurses using the device in the hospital and saw other patients with the device in the clinic waiting room. Although not directed by his clinicians to use the device, he explained his rationale, *"No, no one told me, but I know what happens when you don't have enough oxygen... I don't take any chances. When my oxygen gets down and doesn't come above 96, 95 or 96, I, I consider that a, uh, uh, a push a go button to do something."* This plan, however, was potentially unsafe and may have resulted in the diuretic overuse and resultant kidney damage.

Planning and re-planning often created new routines and leveraged known resources such as pillboxes [56] or a patient's "self-care workspace" [113].

> *You can put the daily dose in each (pillbox compartment) in advance so you don't overlook it. Because trying to open half a dozen containers twice a day, is impossible.* 81-year-old male patient

> *So it's all right there when he sits at the table where he can get to everything and that makes a difference too. You know that reminds him to do it.* Daughter of 80-year-old patient

Anticipatory thinking aided planning; projecting into the future possible consequences, constraints, and opportunities that might be encountered when implementing a plan. A 70-year-old patient explained a strategy he created in anticipation of forgetting whether he took his insulin: "*I've got a system for that now too anyway... I keep all, it takes ten syringes out of the little bag and I put them in, with the rest of my in-, with my insulin and stuff and if, if I've got an*

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even amount that means I haven't taken the morning one, but if I s-, if later on if I've got an odd

amount it means I didn't take that evening medicine."

Participants placed high value on planning as a method to cope with uncertainty and

anxiety. A 67-year- old patient emphasized the importance of filling pillboxes weekly to assure

she did not forget to take her medications: *"I don't, I don't forget that. That's my lifeline. How*

do you forget your lifeline?" This and other observations illustrate planning as a method of

control over complex medication management requirements.

Monitoring. Monitoring involved what participants called "listening" or "watching" for

changes. Endsley [282] and other researchers have previously described this concept as

maintaining situation awareness, defined as perceiving the current state, interpreting its meaning,

and projecting the future. Problem detection occurred when a participant noticed something

wrong with the current state whereas tracking occurred as people followed data over time to

identify patterns and trends indicating a potential future problem. To illustrate the distinction,

noticing that a medication bottle was empty involved problem detection, while documenting

medication refill dates involved tracking.

Problem detection required "noticing" an anomaly, yet many participants described

difficulty in distinguishing between symptoms and the effects of medications. A 68-year-old

patient recounted an instance of this confusion when she forgot to take a morning medication: *"I*

really didn't feel you know that bad. Um, of course it could have been one of those days I was

feeling not that good anyway." Not understanding the expected effects of medications

compounded ambiguity, as did the lack of perceivable problem cues. Patients developed their

own cues based on experience. Many patients (26/61, 43%) created a personal "sign" of fluid

retention. A 68-year-old woman described hers: *"I knew the signs of my congestive heart failure,*

and which mine is, I might get a little smother some and my irregular heartbeat and a little bit of discomfort in my chest." An 83-year-old retired physician shared his: "[It is] how much trouble I have getting in my pickup truck. If I'm short of breath after I do that, then, I know that I'm in failure."

Detecting medication administration problems such as forgetting or mixing up medications was important but unlike symptom detection, did not benefit from personal warning signs. Some participants recalled instances when they forgot or took the wrong medication and were not aware until the next administration time. A 68-year-old male patient recounted: *"I opened up the little box for my morning pills, the* [bedtime] *pills were still in there."* Some participants questioned the appropriateness of medication prescriptions and went to the Internet to "follow behind" and "check if it's right" or validated with other clinicians to verify if the right medication was prescribed.

Compared with problem detection, tracking was a longer-term, forward-looking function. Some information that participants tracked was very specific. One patient kept a list of medications he could not tolerate to assure an unknowing clinician did not prescribe them in the future. Another patient tracked refill information (e.g., prescription number, ordering clinician, refill date) in a self-made chart. Two patients documented when they administered an as-needed diuretic on their vital sign logs to prevent over-administering the medication. One patient tracked the cost of her medications at various pharmacies and switched pharmacies to avoid going into the "doughnut hole," a maximum yearly limit imposed by the Medicare insurance plan. Patients and caregivers also tracked information in a less purposeful manner or "just in case" it was needed. Some stored all the documents they received from their clinicians or hospital discharges. Information was also tracked as stories, adding to either an individual or shared narrative, as

illustrated by the following piecing together of a medication misadventure by a 74-year-old patient, her husband, and a nurse practitioner (NP):

Husband: *Well now, they give her, I can't even think. He give her one, one time, but that put her back in the hospital... It, it was just a little pill, but...*

Patient: *I lost my arms and legs, the use of 'em. I don't know how many times he's had to get up and pick me up. I, it was once a week.*

NP: *I think I remember that.*

Patient: *What doctor was it? Do you remember?*

Husband: *That one that shocked her heart... It was just four milligram. We took it once a week, but man, it put her down.*

Some participants assumed the electronic health record tracked their medical information and therefore they did not need to track this information themselves. A 65-year-old patient did not bring a copy of her medication list or the medications themselves to her cardiology appointment and dismissed the need: *"They always just get it off there* [electronic health record]. *Nothing has changed."* However, during the appointment several medication discrepancies were discovered.

Decision-making. Decision-making processes resulted in a variety of decisions, including calling a clinician, taking or skipping a medication, or modifying behavior (e.g., diet). Table 3-7 provides examples of how participants made decisions involving potential fluid retention, indicated by swelling or sudden weight gain. Some medication management problems had solutions pre-specified by a clinician and could be solved by applying rules for the appropriate situation. Some patients (12/61, 20%) had a clinician-provided rule to take an as-needed diuretic when their weight exceeded a threshold value. These rules were helpful but not all patients received rules and some had rules they did not follow. Participants also often

established their own rules and decision-making criteria based on their own or others'
experiences. For example, a patient did not begin taking a medication his primary care physician
prescribed until he spoke to his cardiologist; this rule stemmed from a negative experience with a
non-specialist prescribing cardiac medications in the past.

Table 3-7. Medication Decision-making for Fluid Retention

Process	Decision	Quote
Applying rules	Call clinician	*I mean I have instructions from (clinician) if your weight goes up this much in two or three days call me.* [74-year-old male patient]
Gathering information	Delay	*And it was, it (blood pressure) was an hour earlier, the difference in a hour uh so I take it again if it was, seemed to be off.* [80-year-old male patient]
Pattern matching	Seek assistance	*So, I monitor that (weight) fairly carefully. If it goes up, I usually call and say, 'What do I do now, daddy?* [80-year-old male patient]
	Use familiar action	*I just take an aspirin (for shortness of breath), or I take some Tylenol.* [83-year-old female patient]
	Do only as instructed	*They said to check it (blood oxygenation) and if it's a certain level then it's okay. But then when it's not, you know they said let, you know write it down.* [wife of 70-year-old patient]
	Use a familiar action for a similar symptom	*I used to have childhood asthma, occasionally I'll wake up at night with a slightly asthmatic tight feeling and sort of I'll walk it off.* [81-year-old male patient] [describing his response to heart failure symptoms]
Making trade-offs	Prioritize medication goals	*I just stayed home, you know. There was no (bladder) control at all.* [80-year-old male patient]
	Prioritize personal goals	*So I didn't take it (medication) then for several days in a week or two-week time... I didn't want to be, uh, be stopping on the road every fifteen minutes.* [67-year-old male patient]

Participants sometimes utilized pattern matching. The husband of a 65-year-old patient
explained how his wife (wrongly) matched her usual solution for coughing to her shortness of
breath from fluid retention: "I'll tell you what she does when she had, is having a problem
breathing... She's got on these menthol cough drops... and sometimes she'll take up to ten or
eleven of them." Participants also used mental simulation in making decisions. An 83-year-old

man responsible for the care of his debilitated wife did not contact a clinician when he experienced shortness of breath because he imagined it would result in hospitalization and consequently leave his wife unattended.

Making trade-offs was a decision-making sub-process that occurred when participants confronted conflicting goals and unclear solutions. *"I ended up having blood in the urine and this, this, well this creates a problem so, you know, you talk to them and they say drink lots of water, a lot of liquids, you know. Well I drink lots of water, a lot of liquids and what happened is it didn't stop bleeding right away but it sure filled me up with water. I couldn't breathe and I mean I had a heck of a time."* [74-year-old patient] Participant trade-offs sometimes involved going against medical advice. A compromised kidney function required the physician to discontinue a 74-year-old patient's gout medication. During an acute gout attack, however, she took the discontinued medication, *"They* [physicians] *took my gout medicine away from me and I told (husband), I said you just get that right back... I said if you don't want to give it to me, I'll take it from myself and so, so I did."*

Coordinating. Due to the distributed nature of the patient care team, coordinating information and activities across locations, actors, artifacts, and time required continual effort. Coordinating enabled and constrained other macrocognitive processes. Reconciling information brought actors and artifacts into agreement by updating one another and identifying discrepancies. For example, an 85-year-old patient described reconciling new medication information with his informal caregiver and a medication artifact: "[When] *I know they've changed my prescription, I make a note and call her* [daughter] *and tell her so she put it on her list and I write on my top* [of pill bottle]." During clinic visits, medical assistants reconciled the electronic health record medication list with the patient's paper list, prescription bottles, or

memory. Discrepancies were common and not all information was reconciled or shared. An 81-year-old patient stopped taking medications when he traveled but "never discussed it" with his physician. Coordination breakdowns at times stemmed from not reconciling clinician provided information with a patient's understanding. A good illustration was a 65-year-old man being unaware he recently suffered a heart attack based on information he received at the hospital: *"It (heart attack diagnosis) was a surprise cause it, they (just) told me, they told me my enzymes was elevated."*

Coordination was also accomplished by managing interdependencies (actions and information) between care team members across time and space. Timing of clinical appointments often depended on the availability of a family member to drive. A pending surgical procedure required an 81-year-old patient to inquire with his cardiologist about when to discontinue an anticoagulant: *"They (surgeon) want to know what I need to do about getting the okay to stop the Coumadin."* Participants did not always manage interdependencies effectively. There were many examples of communication breakdowns between care team members. In one example, a 72-year-old woman received the wrong medication from the pharmacy after a hospital discharge. Her frustrated daughter explained, *"She (pharmacist) said well they faxed it in, but you still got some on the other one so they ain't never filled that new prescription that he (physician) called."*

Coordination also required negotiating roles, treatment plans, and medication goals. A simple example of role negotiation was the wife of a 74-year-old patient informing the cardiologist she did not need him to refill prescriptions: *"I'll just get him (primary care physician) to do all of his prescriptions."* Roles were also dynamically negotiated between patients and family members. When asked who was responsible for administering her medications, an 85-year-old patient stated, *"Well everybody is really. If sometimes, you know I*

usually get it (medications) myself, but sometimes I'm just so tired I'll ask (for help)." Patients

negotiated medication regimens with their clinicians. A patient who did not like swallowing pills

negotiated with her cardiologist to decrease the number of daily pills from 8 to 4. In contrast,

some participants omitted, decreased, or increased medication doses without coordinating or

communicating with health care professionals. The son of a 79-year-old patient described the

medication "tinkering" practice of his father: *"He likes to play doctor for himself you know."*

Outcomes

The interactions between macrocognitive processes and other elements of the medication

management system produced successful and unsuccessful outcomes. Table 3-8 and Figure 3-3

present a patient scenario illustrating macrocognitive processes and their relationships to

outcomes based on one participant narrative.

Table 3-8. Scenario of Medication Management Outcomes

An 83-year-old retired surgeon is scheduled for a routine colonoscopy. Written instructions from the endoscopy clinic are given to him by his primary care physician and instruct him to administer a combination of laxatives the day before the procedure. The patient self-administered the laxatives in the morning the day before the procedure. He was anxious about the colonoscopy because he occasionally was incontinent of feces. He did not want to have an accident during the procedure. Hours after the administration of the laxative, he perceived no effect. He decided to administer an extra dose of the laxatives. Later he experienced a large amount of diarrhea and became lightheaded. He perceived himself to be dehydrated and drank several large glasses of water. Several hours after drinking the water, he became extremely short of breath. He called for assistance from the assisted-living facility he lived in. When she saw the patient, the medical assistant immediately called an ambulance. The patient was admitted to the hospital for pulmonary edema and acute heart failure.

Figure 3-3. Patient Macrocognitive Workflow Scenario

Discussion

Expanding the scope and frame of patient medication management uncovered insights into previously unexplored cognitive processes underlying performance. Broadening this lens confirmed the complex, cognitive, and collaborative nature of medication management workflow suggested by previous research. This analysis also provided new insights and implications for design of medication management tools and technologies, summarized in Table 3-6.

Examining processes at a level above individual microcognition allowed for a theoretical expansion of the actions element of Workflow Elements Model (Figure 3-1). A limitation of that and other workflow and work system models [43, 130, 283] has been their vague depiction of process (e.g., care vs non-care; cognitive, physical, or social-behavioral). Here, actions generically called "cognitive processes" in the past were systematically broken down into distinct functional processes and sub-processes.

Applying the expanded framework to heart failure medication management, we found that these cognitive processes were collaborative, with patients, informal caregivers, and clinicians all serving key roles in care [1,75,76]. Such findings further blur the lines between what is considered patient work versus the work of health professionals, especially as new technologies support patients in carrying out health work previously performed only by health professionals. Researchers now insist that patients and professionals are co-producers of care [77] and perform collaborative patient-professional work [129]. However, we found here and elsewhere [56] that patients and informal caregivers lacked the tools to support collaborative workflow around medication management both within households and across other settings (patient's home, caregiver's home, clinic). In addition, patients were not always willing to collaborate with formal caregivers and withheld information or made critical decisions without

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conferring with them. Openness to enhanced collaboration and communication will require a paradigm shift in the minds of formal and informal team members [284].

Based on the present analysis and prior research, we discuss three areas in dire need of well-designed technology: collaboration enables sensemaking, problem detection precedes decision-making, and planning requires implementation. Table 3-9 summarizes specific recommendations for technology supporting effective macrocognitive workflow during medication management, based on our findings.

Table 3-9. Summary of Findings and Recommendations for Design

Findings	Recommendations for Design
Collaboration and Sensemaking	
1. Patients or informal caregivers lacked the tools to support the collaborative workflow of medication management.	Design technology with shared access to all members of the care team to promote information sharing and reconciliation.
	Design technology to support mediated synchronous and asynchronous opportunities for interactions (e.g., telehealth technologies, text messaging, email, patient portals).
	Use structured, automated detection and record keeping of events (e.g., prescriptions) to facilitate reconciliation across care settings.
2. Patient or informal caregiver mental models were inconsistently shared with health care professionals.	Design structured tools to elicit patient/informal caregiver sensemaking of information and events during formal or informal team interactions.
	Support for the joint creation of explicit representations of "how things work" to support accurate team sensemaking.
3. Patients or informal caregivers struggled to synthesize large amounts of information and translate into actions.	Technology that supports the retrieval and visualization of information from multiple sources into meaningful displays of information.
	Personalized shared information dashboards editable by all team members.
Decision-Making and Problem Detection	
1. Patients or informal caregivers struggled with decision-making	Design decision-support tools for use by patients and informal caregivers in the home setting (e.g., clinical decision rules).

2. Patients or informal caregivers value the experiences and behavior of others for decision-making.	Support access through social media to heart failure support groups that include formal and informal team members for sharing stories, information, tips and tricks (e.g., Patients Like Me).
	Support access to individuals who can serve as model exemplars, for example, through discussion forums or lay coaching.
3. Patients or informal caregivers struggled to detect symptom and medication effect cues.	Collect or use available data (e.g., from cardiovascular implantable electronic devices, wearables, smartphone sensing, motion sensors) to automate cue detection or inform patients of the need to be vigilant for cues.
4. Patients or informal caregivers relied on electronic health records (EHR) for medical and medication history tracking.	Automate tracking to the extent possible, to counteract cumulative difficulty of tracking.
	Provide easy access to EHR information or a shared historical health record.
	Encourage EHR screen sharing during clinic visits.
Planning and Implementation	
1. Patient or informal caregivers lack support for planning and implementation of medication regimens into the context of their own lives.	Support for structured tools to facilitate collaborative medication planning (e.g., MedTable [78]) and strategy development.
	Use projection and simulation to help compare and validate plans.
	Offer planning tools for a variety of crises and other eventualities (e.g., Plan Your Lifespan [285]).

Support for Collaboration and Sensemaking

Coordination is the core of successful team performance [286] and "wraps" around other macrocognitive processes [262]. Sharing information towards the goal of establishing mutual understandings is a characteristic of high-performing teams [281, 287, 288]. Multiple comorbidities add to complexity and increase coordination requirements and the data to consider for sensemaking. With growing access to digital information, we found that patients gathered a large amount of data from multiple sources but struggled to synthesize them and translate data to actions. We also identified unidirectional information flow, with patients gathering but not always sharing information, or not sharing it clearly. This led to incongruous mental models

between patients and others, with minimal opportunity for making corrections. Our analysis demonstrates that the emerging role of the patient as actor can create silos of information and few guidelines for information sharing. Information technology can support collaborative information management towards the development of shared understanding and better coordination.

Support for Decision-Making and Problem Detection

While the majority of work related to clinical decision-support has focused on clinicians in professional settings, our study provided clear evidence that decision-support tools for patients and informal caregivers to use in home contexts are needed. Our results demonstrate that laypeople often make decisions based on their previous experiences and not by comparing options in a risk or benefit type analysis, in agreement with research in other domains [264, 289]. Mental simulation, situation awareness, and problem detection were crucial processes enabling decision-making about responding to symptoms. However, as with prior work, it was not clear whether these processes were effectively performed by everyone or only by a subset of patient "experts" [290, 291]. Participants also made decisions by modeling the behavior of others, suggesting that technology could help connect patients to individuals who can serve as model exemplars, for example, through discussion forums or lay coaching. Participants also indicated a clear desire for support in judging the appropriateness of decisions made by clinicians.

Support for Planning and Implementation

Implementing the medication regimen in a patient's specific life context is challenging. Others have reported that heart failure patients knew "what" to do but struggled with "how" to implement the medication regimen into their daily lives [21]. Having identified the patterns of patients' planning and execution of medication management in their natural context, we note

several implications for technology design in Table 3-9. In particular, we stress on technology to help patients with 3 key areas of work: develop and strengthen daily routines, plan specific behaviors (e.g., using goal setting methods), and compare different implementations of the same general plan (e.g., taking medications upon waking vs with breakfast).

Areas for New Research

This study highlighted important new areas of inquiry previously unexplored in patient medication adherence and management research. The collaborative, distributed nature of medication management calls for the application of team models and theories to the understanding of health management behavior. Improving knowledge building, knowledge transfer, and mental models sharing is a promising focus for interventions and technology design. More research is also needed in the area of patient expertise, how expertise is expressed in patient work, and how tacit knowledge develops in individuals and communities through information sharing and experience. Additional research is warranted into assessing the workload associated with cognitive work such as medication management, including better measures of cognitive demands, cognitive resources, and the balance of the two. Of great interest is the notion of articulation work, or the work needed to ensure processes such as medication management can be effectively performed. Articulation work such as managing one's health insurance and finances to maintain a supply of medication is often "invisible" and under investigated, but a necessary component from a macrocognitive perspective. More research is needed on how to integrate new technology with existing well-functioning artifacts and practices. There is a need for further research using ethnographic methods, cognitive task analysis, and other techniques adaptable to study the work of patients. Methods such as experience sampling methodology or day reconstruction method are needed to understand cognitive work contemporaneously without

disrupting patients' lives, but these methods have their challenges as well, including variability in the depth and accuracy of collected data.

Limitations

The analyzed research interviews had a broad scope of heart failure self-care, including specific questions about medication management. This breadth made it difficult to thoroughly examine medication management for an individual participant but patterns emerged when examining data across participants. The sample was limited to individuals in one region, with many receiving care at the same US academic medical center. This study did not collect data structured enough to develop quantitative workflow models capable of producing state transition probabilities, that is, the flow from one action to another. Finally, observation data were limited compared with interview data. A recent publication suggests the various methods that can be used to more rigorously study patient work phenomena such as medication management workflow [70], and how future work could incorporate additional methodologies. A single coder assumed primary responsibility for codebook development and application, due to resource limitations and institutional expectations of dissertation research projects. All the authors extensively discussed codebook development and used throughout the research, with the lead author presenting multiple examples of how codes were developed, underlying data, and rationale behind coding decisions to coauthors. Although every effort was made to address potential concerns about internal validity of the codebook through extensive and repeated discussions, the primary single coder approach remains a potential limitation of the analysis process. Involving multiple coders in the analysis process could strengthen future analyses.

CHAPTER IV

MEDICATION-RELATED COGNTIVE ARTIFACTS USED BY OLDER ADULTS WITH

HEART FAILURE

This chapter is applied human factors engineering concepts to the analysis of cognitive artifacts used by older adults with heart failure. Findings revealed cognitive artifacts were sometimes poorly designed, designed for healthcare providers, or not used optimally by patients. Artifacts designed for patients must support collaboration and communication and must fit their users' needs, limitations, abilities, tasks, routines, and contexts of use.

Background

The scientific and practice-based discipline human factors engineering uses data, theory, design principles, and various methods to optimize interactions between people and other elements of a system to improve human performance and well-being [41, 292]. Central to the human factors profession is a "systems" orientation, which states that human performance occurs within the context of a sociotechnical system [293]. Cognitive artifacts, tools and technologies that aid the mind in the performance of cognitive work, are an essential part of sociotechnical systems [271, 294] as are people, tasks, the organization, and the internal and external environments [223]. These elements all interact, are interdependent, and act together [295]. Emphasis on interactions in context, as opposed to isolated system elements, distinguishes human factors from other disciplines and professions [42, 296]. A human factors analysis of cognitive artifacts—our present aim—examines both the artifacts themselves and how they interact with different people, tasks, other artifacts, and organizational and environmental factors. To put it another way, a human factors analysis looks at how cognitive artifacts fit in

their surrounding sociotechnical system [228, 297] to inform system (re)design that optimizes performance and well-being [298, 299].

Human Factors and Patient Work Performance

Applying human factors methods and theories to health and healthcare dates back to the 1960s. It accelerated at the turn of the century due in part to the call by the Institute of Medicine for a human factors approach to achieving patient safety [299]. Healthcare professionals (i.e., clinicians) and their work have been the aim of the vast majority of applications of human factors in healthcare. Some have noted additional opportunity to apply human factors to understand and improve patient work [223, 300]. Patient work is effortful, goal-driven, health-related activity performed by patients, families, and other nonprofessionals [44]. The need to study and improve patient work stems from several converging factors:

(1) A realization that most care takes place in homes and communities, not in formal healthcare delivery settings [301];

(2) The rising volume and expense of clinical care and interventions, combined with concerns about a clinical workforce that will not match future demands [66];

(3) Perceptions of the financial value that patients and families can provide through self-care and preventive health behaviors [302];

(4) Increased expectations for patients and families to engage in health-related tasks such as information seeking and self-care [303]; and

(5) Newly available personal and clinical technologies that make it possible for people to manage health outside of formal clinical settings (e.g., home dialysis, mobile devices, tele-medicine, online medical knowledge bases) [304].

Cognitive Artifacts for Patient Work

We conceptualize cognitive artifacts as digital or non-digital artificial devices that maintain, display, or operate upon information through representations and that shape human cognitive performance [305]. Norman [271] describes cognitive artifacts bridging two gaps that jeopardize task performance. Artifacts bridging the gap of execution (action) provide alternative ways to act upon the real world (e.g., controls); representational artifacts bridging the gap of evaluation (interpreting effects) represent the real world (e.g., displays) [306]. Cognitive artifacts extended human performance by externalizing or offloading information processing to the environment [307]. They can also change the nature of the task itself [306]. Artifacts improve performance to the extent that they: a) address the important and leave out irrelevant information; b) fit the task, goals, and skills of their users; c) represent the properties or attributes of the represented entity; and d) use perceptual-spatial properties analogous to the real world [306].

Hutchins [308] argues that cognitive artifacts cannot be separated from the human operator, task, or the environment and have no inherent separate value. The emergent coordination and functioning of those elements together determine performance [309]. Thus, cognitive artifacts are best studied in a relational context, rather than by the analysis of individual attributes alone [2].

Cognitive Artifacts Used for Heart Failure Medication Management

This study used a human factors lens to examine the cognitive artifacts of older adults with heart failure. Specifically, identified cognitive artifacts in use, who used them, and how they facilitated or impeded successful medication management. In taking a human factors approach, we were attentive to how older adults' artifacts fit within the broader sociotechnical system.

Medication management for patients with heart failure is an important daily, lifelong process. However, reported heart failure medication adherence rates are 40-60% [310, 311]. Medication non-adherence can be intentional non-use of medications or unintentional errors such as lapses in medication taking, adding doses, or mixing up pills. Therefore, cognitive artifacts and other strategies that support memory and performance, mitigate errors, or help people recover from errors, could address medication non-adherence [312]. This may be particularly true among older adults, who are at risk for age-related cognitive decline and take a multitude of medications, including ones that may affect their cognition [313]. Several studies report patients with heart failure using cognitive artifacts, including paper records, notes, pillboxes, and kitchen cabinets, to manage medication-related activities [256, 314]. Studies have also introduced cognitive artifacts such as charts, organizers, that improved medication adherence among older adults [315]. However, there remains a need to describe patients' cognitive artifacts in more detail, examine how artifacts fit into patients' sociotechnical systems, identify their strengths and limitations, and propose consequent design and policy recommendations.

Methods

We conducted a secondary analysis of data from 30 patients, and 14 informal caregivers enrolled in a larger study of heart failure self-care. Patient participants were aged ≥65, lived in a 200-mile radius of Nashville, Tennessee, and received continuing outpatient care in a cardiology clinic specializing in heart failure. Table 4-1 describes participant characteristics (see also [256]). Participants provided consent and permission for scholarly use of audiovisual data. The study paid participants up to $65 for completing all study phases. The Vanderbilt University Institutional Review Board and Human Research Protection Program reviewed and approved the study.

Table 4-1. Patient Characteristics

Age	M=74.0 (SD=6.5) (range 65-86)
Sex	17 male / 13 female (57% / 43%)
Race	18 White non-Hispanic (60%), 10 Black (33%), 2 Mixed-race (7%)
Marital status	16 (53%) married, 7 (23%) widowed, 5 (17%) separated or divorced, 2 (7%) single
Caregivers	14 informal caregivers consented to participate: 6 spouses, 8 adult children
Education	10 (33%) completing 12 years, 11 (37%) >12 years, 9 (30%) <12 years
Annual household income[a]	7 (25%) ≤ $15,000, 15 (53%) ≤ $25,000, 21 (75%) ≤ $50,000
Employment[a]	26 (87%) retired, 3 (10%) disabled/unable to work, 1 (3%) part-time
Insurance[a]	100% Medicare, 17% Medicaid, 10% military, 87% private supplement
Heart failure type/severity[a,b]	9 (30%) systolic, 13 (43%) diastolic, 8 (27%) systolic and diastolic; NYHA Class: 11 (37%) II or "mild," 18 (60%) III or "mild/moderate"
Comorbidities	80% hyperlipidemia, 83% hypertension, 53% diabetes mellitus

[a]If known.
[b]NYHA Class=New York Heart Association functional classification; NYHA classes I and IV were excluded.

Data—originally collected in 2012-2013—included verbatim transcription of clinic visit observations, short (30-minute) interviews, and follow-up (90-minute) interviews. Photos of cognitive artifacts extracted from in-home and in-clinic video recordings, electronic medical records, and self-administered standardized surveys (100% response rate) provided additional data.

Nvivo 10 qualitative data analysis software was used for descriptive qualitative content analysis with iterative category development [316]. These methods systematically derive trends, patterns, and themes from large amounts of textual data revealing the underlying meaning [55]. Close analysis of words and photos directly depicting a participant's life is a way to achieve a rich, contextualized, participant-centered understanding of a phenomenon [317]. During first-pass structural coding [318], researchers identified broad passages of data mentioning a cognitive artifact used in medication self-management. We defined medication self-management as the

processes by which prescribed medications are administered by patients or their caregivers in a manner optimal for achieving treatment goals including activities related to planning, sensemaking, organizing, tracking, problem-solving, communicating and coordinating [3, 319, 320]. Next, during second-pass analysis, authors RSM and RJH assigned thematic codes to structurally coded passages related to the artifact's functional category [306], fit or misfit within the patient's broader sociotechnical [256], and observed advantages and disadvantages. The third pass involved data-driven, discussion-based thematic and category development using preliminary categories and exemplars [183]. The senior researcher (RJH) facilitated analytic convergence and presided over any analytic disagreements [200]. Passages and still photographs were selected to illustrate and enrich analytic themes [321]. In the final step, we assembled an illustrative case from one participant's data.

Results

We first describe observations about the nature of medication management and related knowledge gaps among participants. Next, we describe identified cognitive artifacts and their uses. Lastly, we discuss the fit between used artifacts and the patient's sociotechnical system and the artifacts' advantages and disadvantages.

Nature of Medication Management Among Older Patients with Heart Failure

Heart failure is a progressive disease prevalent in older adults [322], characterized by the heart's diminished ability to fill or to pump blood to the body resulting in symptoms such as shortness of breath, fatigue, and peripheral swelling [240]. The goals of pharmacologic therapy are to improve the pumping effectiveness of the heart and to control fluid build-up [323] achieved through a multitude of medications impacting a variety of physiological systems to

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control: blood pressure; heart rate and rhythm; fluid balance; clot formation; and lipid blood levels [240].

We observed that medication management in heart failure patients was complex, inseparable from other patient activities, and distributed across people, time, and place. These properties are described in Table 4-2 and elsewhere [105, 256, 314].

Table 4-2. Observed Properties of Medication Management

Complex

- Patients prescribed as many as 28 daily medications (M=15, SD = 5.7).
- Additional medications include over-the-counter products such as Tylenol and alternative therapies such as home-made cough syrup.
- Complex schedules (e.g., every other day, three times per day, every four hours).
- Multiple modes of administration (e.g., pills vs. drops vs. nebulizer).
- Multiple names and appearances for the same medication.
- Specific administration directions (e.g., with meals, 30 minutes after another medication).
- Conditions of use (e.g., contingent on weight gain).
- Changes in dose, frequency, schedule, and appearance based on continual adjustments by clinicians or surrounding a hospitalization or procedure.
- Multiple clinicians prescribe and change medication orders.

Inseparable from other patient activities

- Patients took more or less medications, depending on whether they had gained weight because of fluid retention or experienced fatigue, shortness of breath, or swelling.
- Medication administration could be disrupted or influenced by travel, dietary activity, daily physical activity, plans for intimacy, desire for sleep, fatigue, and mood.
- The cost and affordability of medications and availability of insurance affected patients' supply of and willingness to purchase medications.
- Perceived or expected effects or side-effects of medications were a basis for patient decisions.
- Additional tasks related to managing medications included looking up clinical information, reconciling the advice of multiple clinicians, managing the supply of medications, and organizing and planning the day around medication taking.

Distributed across people, time, and place

- Adult children, spouses, and friends assisted patients with medication tasks, sometimes taking total responsibility, and other times assisting as needed.
- This help was dynamic and ever changing, dependent on the limitations of the patient, patient preference, and resource availability.
- Family efforts assembled into a well-run system, with every member knowing their roles and responsibilities.
- Clinicians adjusted medications based on quality of life and contextual circumstances.
- Pharmacies assisted by reminding patients when refills were due and ready to be picked up.

| • Patients associated and connected medication administration to times of the day such as morning and bedtime, and events such as meals and medications became integrated with routine daily activities. |
| • Tasks performed ahead of time reduced daily cognitive effort. |
| • Patients used places and objects in their homes to organize medications and remind them when medications were due. |

Knowledge Gaps Related to Medication Management

A striking observation was that many patients, caregivers, and clinicians had incomplete or incompatible knowledge regarding medication management. Patients do not always know what medications they were taking, their medications names, directions for use, or what effects to expect (Table 4-3a). Several patients lacked knowledge about the relationship between medications and symptoms, and, therefore, when it was appropriate to take medications. Informal caregivers also lacked knowledge about symptoms, medications, and the relationship between the two.

Clinicians could not guarantee patients were taking their medications as directed. Clinicians struggled to get accurate accounts of patients' current medications. Few patients brought their medications or medication lists to clinic visits as requested, and over half relied on memory (Table 4-3).

While patients often represented their knowledge of medications based on pill size, shape, and corresponding condition or organ (water pill, kidney medicine), clinicians almost always used the brand or generic medication names when speaking to patients (Table 4-3c).

Table 4-3. Selected Examples of Observed Knowledge Gaps

a) Patients and informal caregivers lack knowledge

- A 65-year-old White male states, *"So they got me, they put me on this, I forget the name of the drug I take…And they got me on, uh, Spironolactone, which is a, it's something for your heart, I don't know."*
- A 79-year-old Afro-Caribbean male describes experiencing multiple symptoms of worsening heart failure and fluid retention, but was reluctant to take an extra diuretic medication because he perceived there was nothing wrong with his heart.
- The daughter of a 74-year-old White female states, *"I didn't recognize it as heart either when you swelled up. I thought it was gout."*

b) Clinicians lack knowledge about patients' medication-related behavior

- An 81-year-old White male patient describes not taking diuretics when he travels but that he *"never really discussed it"* with his physician.
- A 65-year-old Black female adjusts the frequency of her medication without consulting her doctor: *"I have to take it twice a day, it's supposed to be three times, I take it twice a day."*
- A nurse and 71-year-old Black male attempt to communicate about a medication.
  Nurse: *"Um, using your sp-, in-, Spiriva inhaler?"*

  Patient: *"Yeah."*

  Nurse: *"How many times a day?"*

  Patient: *"Tha-, that's blue, ain't it?"*

  Nurse: *"I don't know."*

  Patient: *"I got, I got inhaler, I got one … use it sometimes."*

  Nurse: *"Just when you need it?"*

  Patient: *"Yeah, only though, not like the blue one all the time. What you call it?"*

  Nurse: *"I don't know. I don't, I don't know what those look like."*

c) Patients/caregivers and clinicians represent medication-related knowledge differently

- A cardiologist attempts to identify which prescribed medication a 65-year-old Black female patient is taking.
  Cardiologist: *"So mom says she needs Sedia and Bumax and something else, but she doesn't know which one."*

  Patient: *"Maximillistine, I can't say it, you know."*

  Cardiologist: *"Well, it's Maxaltine, but you're not on that."*

  Patient: *"I, well, it's the pill, I'm on it, but I…"*

  Cardiologist: *"I don't know which one, you know."*

  Patient: *"—its M, it's uh, I can't say it…it's, it's a, I have to take it twice a day, it's supposed to be three times, I take it twice a day. It's orange and kind of brown."*

Cognitive Artifacts Used by Older Adult Patients with Heart Failure

Patients and their caregivers used multiple cognitive artifacts to achieve medication

management goals of measurement and evaluation, tracking and communication, organization

and administration, and information and sense making. Table 4 provides a case example of artifacts used by one patient.

Artifacts used for monitoring and measurement helped externalize the patient's condition and provided data for interpretation and action, including medication taking. These artifacts resembled those used by clinicians, were rarely modified, and were embedded in daily routines. Most patients owned scales (97%) and weighed themselves daily (77%). Most used their scales during their morning routine and in the bathroom. Clinicians instructed patients to use scales to monitor for weight gain over time (e.g., 5lbs in 3 days) or above a personal threshold value (e.g., >185lbs) and to either take extra diuretic medication (33%) or call the clinician.

Table 4-4. Case Example of a Patient and his Family Using Multiple Artifacts (underlined)

Bill Smith is retired firefighter in his 80s who lives in the city with his wife of 60 years. He developed heart failure about 5 years ago following a heart attack and cardiac bypass surgery. He is also diabetic and has poor vision. Bill has difficulty walking due to his shortness of breath and chronic vertigo. He uses a walker at home and a wheelchair when away from home. One of his adult children lives nearby and helps Bill and his wife with their medication management tasks such as picking up medications, maintaining medication lists, and accompanying them to clinic appointments.

Because Bill's wife also has several chronic illnesses, the kitchen table is the center of health-related activities for both. Bill regularly uses various devices to measure his blood pressure, weight, and blood sugar. He records these measures on a paper log. Bill is visibly upset by the frequent burden of these activities and says he does not see their benefit. "It aggravates the fool out of me," he tells his nurse practitioner (NP). "I started coming out here, taking my blood pressure, taking my weight, and sugar count, so forth 'til I feel like a secretary." Recently, he bought a new digital weight scale because he could not see the numbers on the old scale. He does not appear to view rapid weight gain as a seriously concerning indicator of fluid retention. When his NP asks what he would do if he rapidly gained weight, he replies, "I'd stop, I'd back off from the table (is) the first thing." Bill does not know his medications by name and depends on a medication list maintained by his adult child. When his NP asks if he is taking Lasix, he responds, "Whatever, whatever it (medication list) says, yeah." His child keeps track of medication changes and once a week helps Bill set up his pillbox, which he uses to administer his daily medications.

Bill's poor vision makes it difficult for him to read prescription drug labels. Also, different family members fill Bill's pillbox at different times. Therefore, Bill has developed a strategy for labeling the tops of prescription pill bottles. For each medication, Bill used a bold marker to write the number of pills to take and an abbreviation indicating the time of administration (M for morning, N for noon, B for bedtime). He explains, "When I get my prescription filled from the drug store, I take (its) top off. I put (the marked top) on the new bottle." This way, he can use the same tops even after refilling the medications. This strategy has simplified the process of identifying medications and filling his pillbox, as his child explains: "We done it too because there was two or three of us at one time trying to fill his pill bottle and (his wife's) pill bottles and when they were both down, we were trying and I would be over there and I would try to do it vice versa, so when he come up with this system here, it just really made it easy."

Bill uses his social support system and a spatial arrangement strategy for medication refills. "If I get a pill bottle and I look into there and I say, uh, well I've got six pills. I've got pills filled out for this week. I set it over here

on the turntable… on my little table and my wife calls the drugstore and says fill this prescription. And, and, and then she picks it up you know, if it has to be called in (authorized), it tells me on the bottle. They'll call in and when it gets filled, my pharmacy, they will call and tell us your, your prescription is ready… She (child) goes and picks it up or (wife) will come by and go get it. And I, then I'll take the top off of this one and change the top, I got it marked."

Bill's case is an example of a system of people, cognitive artifacts, and places that assemble and adapt to accomplish medication management goals in the context of limitations, challenges, and available resources.

Many patients (70%) owned blood pressure (BP) cuffs, and some (60%) used them daily for BP and heart rate readings. Patients kept BP cuffs in various places in their homes. Some models were portable for travel. Three patients (10%) used pulse oximeters, which are small sensors that clip to the index finger or earlobe and display indirect measures of oxygen in the blood. Two patients used these on physician recommendation. The other purchased one after observing its use in others; he used it several times per day and took his extra diuretic at oxygen saturation < 96%. Two patients (7%) participated in a left atrial pressure (LAP) monitoring clinical trial. Patients placed a patient advisor module (PAM) on the chest over an implanted sensor twice a day. The PAM would give a LAP measure and recommended to patients the diuretic dose for that time. The device also wirelessly transmitted data such as weight and temperature to the clinic.

Tracking and communication artifacts were among the most useful types of patient artifacts. Because months separated clinic visits, clinician awareness of patients' status and event occurrences depended on patients tracking, detecting, and communicating trends and deviations. Fewer than half of patients documented weight (43%) and BP (37%) daily. Clinicians gave patients a paper form for this task, but some used homemade forms. Patients modified the forms to fit their needs (See Figure 4-1). One added his weight and BP measurements to a form designed to record blood sugar. Patients kept logs in the area of their home where they took the measures. Logs gave patients feedback on their condition over time and allowed them to follow

trends and note changes such as taking additional medications. A 68-year-old White female

described using her log (Figure 4-1): *"You see how my weight constantly kept going down… You*

can see here where I went up a little bit and took those pills and dropped."

All patient received a printed medication list at the end of each clinic visit from the

reconciled electronic health record (EHR) medication list. Patients added handwritten notes to

these lists depending on what information was important to the patient.

EHR-generated medications lists did not always meet the patient's needs. The listed

medications were uncategorized and ordered by when last prescribed, listed along with

alternative names, dose, frequency, route, and directions. In contrast, patients organized

medication administration by time. Consequently, some patients (23%) made their own

computer-generated or handwritten medication lists and revised the EHR-generated list (Figure

4-2).

Figure 4-1. A Completed Weight, Blood Pressure, and Heart Rate Log. The patient
has noted extra medications taken and absolute daily changes in her weight.

Figure 4-2. Patient-made Medication List Ordered by Time, Updated and Annotated
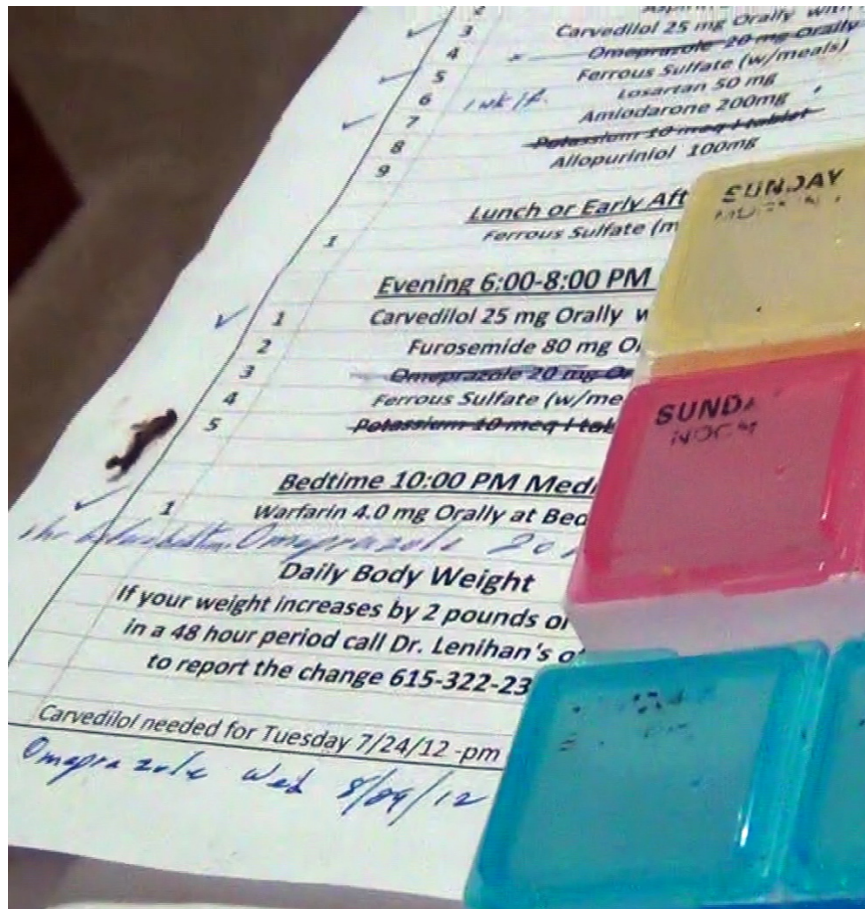
Two patients tracked their medication history: one patient made a list of medications he had issues with; and one made a chart of all the medications he had ever taken, discontinue date (if applicable), the name of the provider that wrote the prescription, the prescription number, and when the next refill was due. Hand-made lists gave insights into informational gaps in EHR-generated lists.

Patients brought a medication list to 37% of observed clinic appointments and medication bottles to 17%. These helped communicate the current medication regimen to clinicians. Over half (60%) relied on memory alone to communicate about medications. Some patients (17%) also carried notepads or other portable objects like appointment books to note the information

they needed to communicate to clinicians or to track information. One patient's wife used a calendar to track changing Coumadin doses.

All patients had access to the medical center's web-based patient portal, and 27% used it. Users had access to secure messaging with clinicians, appointment scheduling, laboratory and test results, clinical summaries, and problem lists including current medications. Some were unaware the portal existed (13%), some did not own a computer (27%), and some (13%) did not like to use computers, or felt they had insufficient computer skills.

Patients organized medication administration using unique systems that fit their regimen, lifestyle, skills and limitations, and circumstances. Pharmacies put medications in labeled plastic containers. Labels could deteriorate over time: one patient described taking a medication she thought was for constipation, but could not read the name on the label. Sometimes patients used these labels as an organizational system, arranging bottles by administration time in a cabinet or drawer. However, 73% used pill organizers (pillboxes) to reduce the burden of reading labels, opening bottles, and taking medications out of bottles several times a day (Figure 4-3). Patients would fill the pillboxes on a most often once a week, regular schedule, thus batching what would otherwise be a twice-daily cognitive activity. Pillboxes had various separate compartments for time of day (e.g., morning, noon, night). Some patients checked whether these compartments were empty or full to verify if they took their medications. Patients also used paper bags dividing morning and evening medications, tinfoil bags when traveling outside the house, and a variety of containers such as toiletry bags, baskets, drawers, and cabinets (Figure 4-3). Pillboxes were located in an area of the house dedicated to health-related activities, the place of one's morning routine (e.g., in the bathroom), and in a visible area to serve as a reminder. Baskets, drawers, and cabinets also served to separate medications taken by cohabitants.

Figure 4-3. A Typical Pillbox (left) and Medications Stored in a Kitchen Drawer (right).

The main source of information for patients regarding medications was their clinician or pharmacist, but some used additional information artifacts to make sense of their medications and condition. Some patients (27%) described using written information such as booklets and brochures provided by clinicians. Most received a binder containing patient-centered educational information about heart failure and self-care. One patient had medical and pharmaceutical books in his home. Some patients (10%) mentioned reading package inserts from the pharmacy that came with their medications. A third of patients looked up information about their disease and medications on the Internet. Some did this daily and others infrequently. Patients (17%) mentioned receiving health and medication information from television shows and advertising. Some did not trust the information and others considered it reliable and useful. After hearing on a television advertisement that all heart patients should take aspirin a patient taking an anticoagulant consulted his clinician and learned this did not apply to him.

Fit Between Artifacts and the Patient's Sociotechnical System

We observed several instances of "misfit," in which artifacts were incompatible with patients, other artifacts, routines, and environments of use. Instances of artifact-artifact misfit included differences between patients' and clinicians' artifacts. For example, patients' scales or

BP cuffs produced readings different from their clinics'. Patients' homemade or modified medication lists often differed from those generated by the EHR. Artifact-person misfit occurred when cognitive artifacts were ill-suited for older users, their experiences, mental models, limitations, and daily routines. For example, prescription labels using small text or websites with multiple navigation options were challenging for those with visual acuity and less computer experience, respectively. Artifact-task misfit occurred when daily measures were taken at home but not communicated directly to clinicians, except in summary form during visits spaced months apart. Another example was medication lists that were not organized by time of day or were missing information on indication or brand name. Artifact-context misfit included lack of access and portability. For example, patient portals required computer, Internet, and e-mail access, but 27% of patients did not own a computer. Pillboxes, scales, and other artifacts were not portable.

Advantages and Disadvantages of Cognitive Artifact Use

For each of the 15 artifacts identified, Table 4-5 summarizes their advantages and disadvantages. We identified three major advantages. First, cognitive artifacts facilitated clinician-patient communication, particularly outside of clinic appointments. With daily electronic transmission of patient data, interpretation and action were no longer dependent only on patients' knowledge, memory, and skills. Clinicians could intervene early, and patients could receive rapid feedback. Through the patient portal, patients could review past health information, upcoming appointments, and medication list with ease and email clinicians with questions and refill requests.

Second, artifacts engaged patients in medication management. Patients using logs could identify abnormalities or trends as well as explore possible causes and solutions. When artifacts

were used with knowledge of action or decision rules, such as extra medications taken above a certain threshold, patients could be more active rather than passive recipients of care.

Third, when cognitive artifacts were easy to use, they reduced complexity and task burden. Electronic transmission of measures eliminated daily logging and the need to bring logs to appointments. Pillboxes helped to batch cognitive activity and may have reduced the risk of error. They also supplemented memory and calculations regarding administration and refills. Patient portals made information retrieval and refill requests less effortful.

There were also four major disadvantages. The first was related to integrating or reconciling multiple representations. Clinic visit communication was rarely structured around patient artifacts such as personal medication, lists and both clinicians and patients showed difficulty understanding each other's lists. The multitude of lists and frequent updates was challenging, with some patients using outdated or incorrect lists. Once a pillbox was filled, it took effort to verify and identify the dispensed medications; patients described medication errors due to similar-looking medications or misfiling the pillbox.

Second, patients used cognitive artifacts designed for clinicians. Patients accessed information with clinician-oriented language and formatting. Information important to the patients (e.g., a medication's purpose) was sometimes overlooked, and patients and caregivers needed to add it later. Some misperceived or misunderstood the implications of clinical device data; for example, one patient self-administered extra diuretics based on oxygen saturation values deemed "normal" by his cardiologist.

Third, artifacts did not always filter or sort information based on attributes such as importance or accuracy. Although most patients regarded clinicians as the primary source of medication information, some relied on other pervasive sources such as television advertising

and the Internet. The challenge for the patient was judging the credibility and interpreting this

information. Some patients accepted television advertising as credible but misunderstood the

information presented. Patients had few opportunities to validate this information with the

clinician and could omit or start medications based on misinformation.

Fourth, data were sometimes lost when, as described earlier, they were not recorded or

communicated between patients and clinicians.

Table 4-5. Advantages and Disadvantages of Fifteen Types of Cognitive Artifacts Used by Patients

Artifact	Advantages	Disadvantages
Blood pressure cuff	Easy to use, numbered scale	Need to interpret, calibration issues
Scale	Familiar; available; easy to use; numbered scale; clear rules for action (if known)	Rules for action not always known; difficult to use if physical disability or vision problem; calibration issues
Pulse oximeter	Numbered scale, small and portable	Need to interpret; reliability issues
Left atrial pressure monitor	Suggests action; uses real time, personalized, and longitudinal data	Requires surgical implant; must be trained to use; may promote overdependence
Health telemetry	Real time output; efficient and low-burden	Requires special equipment, training, and staff effort
Paper weight & blood pressure logs	Adaptable; longitudinal; inexpensive	Burdensome; rely on memory and motivation; can be lost; not real time; provide no action/decision support
Paper medication lists (printed, handwritten)	Useful; flexible; portable; easily updated or recreated	Legibility issues; multiple versions; not always clear; must be updated; may promote overdependence
Appointment books, calendars, notes	Easily available; flexible; personal	Not permanent; not standardized; not easily shared; hard to search
Patient portal/personal health records	Speed of access; fast, secure communication; connected to verified health data	Requires computer skills; access issues; use of clinical language
Prescription medication bottles	Accurate; up to date; standardized	Difficult to open; label visibility and legibility
Pill Organizer	Reduces effort; provides feedback; simplifies refill planning	Not adaptable; feedback is delayed, passive; pills in box become separated from original containers

Other containers: baskets, bags, drawers, cabinets	Flexible; sometimes portable; usually available; personalized	Large, take up space; larger containers are less portable
Medication inserts; books; brochures	Available; inexpensive; sometimes accurate	Can be out-of-date; can be lost, damaged; require health literacy
Internet	Flexible; useful; high volume of information; potential for interaction	Credibility issues; access and cost issues; requires skills; not personalized; unfiltered; commercial
Television advertisements	Accessible; clear; often repeated	Credibility issues; not personalized; hard to interpret; commercial

Discussion

We used a human factors lens to focus on cognitive artifacts and explore older adults' management of medications, a phenomenon of particular importance among those living with heart failure. Patients used multiple artifacts for multiple functions, yet artifacts were not always well designed, appropriately used, or compatible with patients' broader sociotechnical systems. Consequently, artifacts appeared to be both helpful for coping with complex regimens and knowledge gaps and potentially harmful by increasing the risk of misinformation, misinterpretation, and overdependence.

For example, pillboxes reduced the burden of daily medication administration but separated medications from important information such as name, dose, prescribing clinician, and special instructions. Not surprisingly, many patients knew what their medications looked like and when to take them, but not their names or uses. Clinical practice could accommodate these common representations through the use of visual identifiers, written or pictorial, in medication lists and instructions. Informational pharmacy-printed stickers could be included for affixing to the bottom surface of a pillbox. These suggestions could also improve clinical medication reconciliation. Any newly introduced cognitive artifacts should be usable and acceptable to older

adults; they must therefore consider physical (manual dexterity, ability to stand, walk), sensory (vision and hearing), cognitive (working memory and attention), and skill (computer literacy) limitations of older adults as well as their tasks (goals, strategies, constraints) and environments of use [324, 325]. They should also be flexible enough to accommodate customization and ad-hoc data entry, to supports users' needs and mental models [271, 306]. New systems must also focus on affordability, compared to comprehensive, subscription-based medication management products such as the Philips Medication Dispensing Device.

We noted missed opportunities for artifact use for (1) monitoring and recording data in a timely—if not real time—manner and (2) bidirectional communication between patients and clinicians about new data, interpretation, and related actions. Data often ended up unused or communicated based on memory in summary fashion. A promising solution is remote health monitoring with well-calibrated telemetry devices, proper training, and timely feedback from clinicians [326]. Self-management software applications using self-directed learning or intelligent agents (e.g., avatars) may be a more patient-engaged and cost-efficient solution. We suggest that these patient-facing technologies should not only deliver education but also support problem-solving, sensemaking, and communication. There is also growing potential to harness home-based sensor technology and commercial wearable health-monitoring devices as part of a model of connected health.

Patient work, especially among patients with heart failure, is a distributed and cooperative activity delegated among patient, informal caregivers, clinicians, and artifacts [105, 314]. Designers of artifacts and information systems should be aware that everything designed for the patient may also include that patient's family members or close friends. The work is also situated in the larger context of life, in which symptoms and health status may compete for time

and priority [44]. For new artifacts to integrate into this context and support daily living, as opposed to adherence to discrete disease-management tasks, designers and policy makers will need to be aware of the full complexity of so-called patient work system and work processes that govern patients' lives [44, 223, 256]. The data from this study supports the view of cognitive artifacts as effective or ineffective mediators of patient and collaborative work [54], bridging the barriers to the execution and evaluation of the goal-related activities. For medication management. these activities include measurement and evaluation, tracking and communication, organization and administration, and information and sense making (Figure 4-4).

Figure 4-4. Cognitive Artifacts Bridge Gulfs of Evaluation and Execution in Patient and Collaborative Medication Management Work
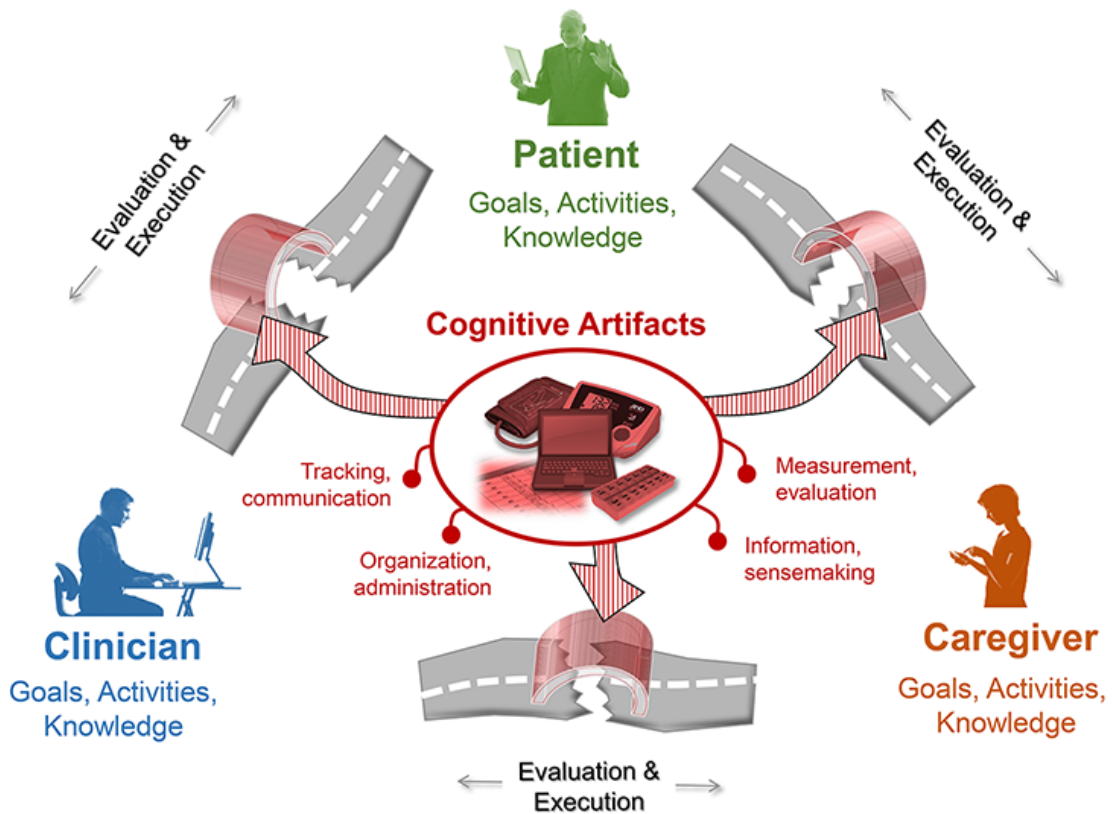
As patients in our study performed the bulk of their health-related activity at home yet relied considerably on their clinicians, our findings support continued efforts to promote patient-centered care and appropriately balanced patient-clinician relationships. We endorse the metaphorical "pilot's role" for patients, as articulated by Wagner et al. [327]. Under this view, patients with chronic disease work with "co-pilot" caregivers and "air traffic controller" clinicians. They also require appropriate "cockpit technology" to connect these actors, especially when separated by time and space. The role of technology in patient-centered care can be transformative [304, 328]. Processes such as shared decision-making could co-evolve with shared cognitive artifacts used by both patients and clinicians and therefore a sort of common ground. Coordinated care could be better achieved if plans of care, changes, and communications were centralized in one system, accessible to all stakeholders. Patients' goals could be better managed and accessed if they were electronically available and modifiable by patients and shareable with clinicians. In short, there are limitless opportunities for technology to support new and emerging models of care.

Methodological Considerations and Future Directions

A limitation of the study was that the older heart failure patients and informal caregivers were from one region of the US recruited from clinics at one academic medical center. The basis of findings was extensive interviewing and short periods of nonrandom observation; therefore, findings are limited to what patients could or would self-report and shown researchers. Furthermore, the data represent patient and caregiver perspectives, but not clinicians'. The effectiveness and usability of observed artifacts were not assessed objectively because the study objective was to identify and describe, not formally evaluate, artifacts. A clinical view of patient medication work dominated the design of artifacts used by patients in this study. The use of

ethnographic [31], cognitive task analysis [14], and participatory ergonomics methods [53] for patient medication work research would be useful for uncovering needs and goals from a patient perspective.

Additionally, our participant sample consisted of adults with heart failure. The ways in which this group of patients uses objects and artifacts may limit the findings of this study. It is unknown if the properties of cognitive artifacts described here extrapolate to other patient groups with complex routines, such as those with dementia, diabetes, cancer, or pediatric patients. Follow-up research should test the transferability of our findings and investigate the ways, if any, that use of cognitive artifacts varies by treatment, disease, or patient type.

Another promising direction is to consider the patient's broader life context and consider technologies and artifacts with which patients interact that are not always directly related to treatment. This might include, for example, personal phones, diaries, wearable sensor systems, and the Internet, whose functions may not be cleanly divided into health-related or unrelated-to-health. This perspective may be especially important for considering primary prevention and treatment during early disease onset, as personal technologies become increasingly used for health. Additionally, other social actors in the patient's immediate network, besides primary caregivers and clinicians, are worth investigating in future studies of cognitive artifacts for patient work. A clear takeaway from our findings is that multiple roles that artifacts and objects play, and that these objects can be seen as a bundle of values and potential uses. This concept can be advanced through future research unpacking what design decisions influence specific values and uses by a patient. For example, an experiment using A/B testing where the same cognitive artifact (e.g., a digital bodyweight scale) with different design choices are compared. The

different uses of experimentally assigned artifacts may reveal a lot about the nature of artifacts and their use.

Additional future research might focus on unbundling the requirements of cognitive artifacts. We show that an artifact like the personal health record has many implicit requirements: Internet access, computer access, health literacy, and computer literacy, to name a few. These requirements might not be explicit to healthcare professionals, policy makers, or designers.

An interesting finding worth further exploration is the concept of the configuration [223] or assemblage [329], illustrated in the case of "Bill Smith" (Table 4-4), whose medication management relied on an apparently coincidental but likely purposeful combination of tools, routines, and human relationships. These heterogeneous human and non-human elements assemble to form a meaningful whole maintained through repeat enacted practices and stabilizing and destabilizing forces [329]. Future studies may further examine the nature of these assemblages and how they form, evolve, and support or jeopardize medication management. Other research directions include systematic examination of specific strategies patients develop to use or modify artifacts for specific purposes, from common techniques such as annotating EHR-generated medication lists to creative strategies such as labeling medication bottle tops. Such an examination would identify how patients, to use a human factors saying, "finish the design" started by artifact developers [330]. A final direction is to explore combinations of patient- and clinician-facing information technology and sensor-based data toward a vision of connected, coordinated, and closed-loop health and disease management.

CHAPTER V

MEDICATION MANAGEMENT STRATEGIES USED BY OLDER ADULTS WITH HEART

FAILURE: A SYSTEMS-BASED ANALYSIS

This chapter uses an empirical strategies analysis method to analyze the medication management

strategies of older heart failure patients. Strategies are behavioral adaptations that allow patients

to achieve medication management goals despite constraining conditions. Strategies were either

stable or situational. Stable strategies modified the participants' medication processes, their

socio-technical environment, or themselves. Ad hoc situational strategies often increased risk.

Non-adherence was sometimes a strategic adaptation to conflicting goals. The healthcare system

was a common source of constraints but did not offer adequate strategic support. Supporting

strategic adaptations and the use of tools and technologies is an under researched avenue to

improve medication management in patients.

Introduction

The health—i.e., physical, mental, and social well-being [331]—of older adults with

heart failure requires them to manage often complex medication regimens. Many experience

problems as research reports 40 to 60% do not take medications as prescribed [14]. Multilevel

constraints are known to impede the safe and effective use of medications by patients with heart

failure. These constraints, or barriers, can be attributes of persons or their surrounding system, as

summarized in Table 5-1 [14, 113, 332-336]. Over time, patients and their informal caregivers

develop adaptive methods and strategies to cope with these constraints [337]. When strategies do

not exist, are ineffective, or are maladaptive, medication performance and health outcomes are at

risk. While extensive current literature addresses patients' constraints, specific strategies used by

patients for the safety-critical processes of medication management are less well described and understood.

Table 5-1. Medication Management Constraints [113, 123, 173, 320, 332-334, 338-341]

Patient

- **Sleep quality**
- **Coping and emotional response**
- **Cognitive, physical, perceptual abilities**
- **Experience, time since diagnosis**
- **Multiple comorbidities**

Task

- **Medication regimen complexity**
- **Medication effects**
- **Frequent medication changes**
- **Conflicting goals**

Tool

- **Portability**
- **Accuracy**
- **Durability**
- **Usability**
- **Effectiveness**

Organizational environment

- **Living arrangements**
- **Disruptions**
- **Financial, healthcare, and family resources**
- **Rules, roles, routines**
- **Communication channels**
- **Other workload**

Social environment

- **Interpersonal influence**
- **Judgement of others**
- **Cultural beliefs, norms**
- **Social resources and engagement**

Physical environment

- **Distance to pharmacy**
- **Workspace attributes**

Constraints and Strategies

In systems science and engineering, constraints are obstacles that threaten goal achievement by blocking workflow, or decreasing the effectiveness or increasing the effort required to carry out a goal-directed process [342-344]. Systems models classify constraints as interacting attributes of structural factors such as persons, tasks, tools, and the environment [43, 129]. Constraints can be stable and continually present, or situational, irregularly occurring, and unexpected [345]. These obstacles make reaching a goal 'impossible, difficult, or unsatisfying in light of standards for timely and effective performance' [344] p. 284. Defined as desired

objectives, goals are judged as successfully achieved by performance criteria that set boundaries of an acceptable outcome [346] to the system, team, or individual pursuing the goal. Success criteria and goals of the healthcare system, health team, and families may differ from those of the patient. Goals and constraints guide the selection of strategies.

Strategies are behavioral adaptations that allow goal achievement despite constraining conditions [342-344, 347]. Similar to constraints, strategies can be stable and pre-planned (Figure 5-1a) or 'in the moment' responses (Figure 5-1b) to unexpected situations and conditions [342, 344, 348]. Strategies involve short term fixes or long term habits and remove, manipulate, or work around a constraint [344]. Workarounds involve going outside of a usual, accepted process of goal achievement and increasing risk [349].

Figure 5-1. The Relationship between Constraints, Strategies, and Goals

(a) Stable Constraints & Strategies   **(b) Situational Constraints & Strategies**
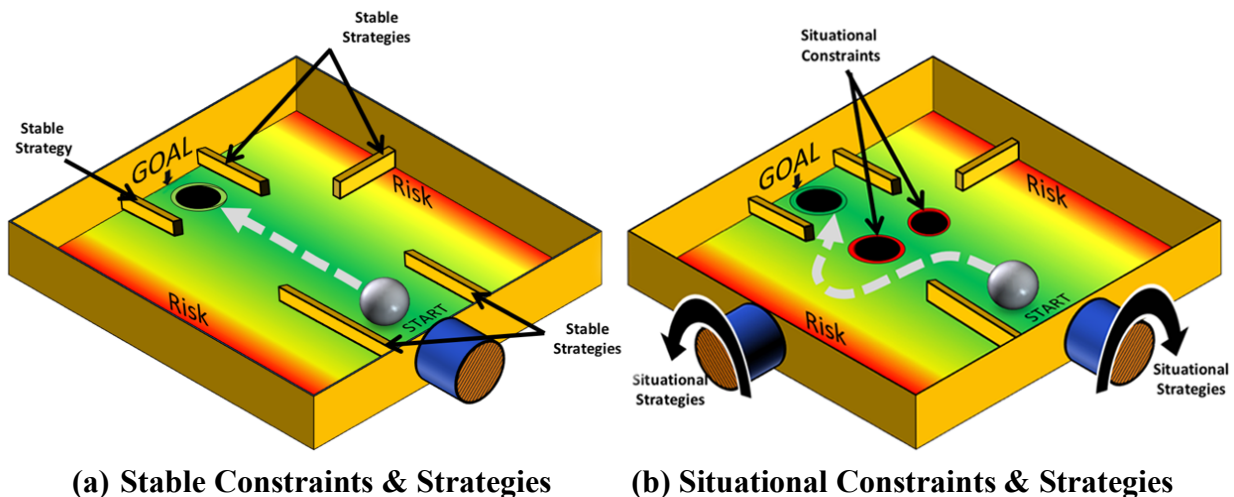
Medication Management in Heart Failure

Medication management is the most commonly performed self-care behavior of patients with heart failure [350]. Heart failure is a chronic condition affecting primarily older adults and is the leading cause of death among cardiovascular diseases [351]. Heart failure patients' adaptation to medication constraints and the development of strategies is regarded as a

naturalistic decision-making process [291, 337] relying on previous experience, situational factors, and whether self-care goals conflict with personal goals [291].

There is a dearth of research, however, addressing the medication management strategies of patients in response to constraining factors. Harkness et al. [352] identified two categories of strategies for heart failure self-care: perception- and action-based. Swanlund [320] described general strategies successfully used by older adults with cardiovascular disease to administer medications: help from others, cues, simplification, determination, routines, knowledge, education, and alertness. Other research addressed memory constraints and successful strategies to remember medication administration [158, 258, 353, 354]. These studies have provided high-level categories and descriptions but have lacked detail and a theoretical underpinning. We identify a need for detailed, analysis of strategies specifically related to medication management, including how the use of strategies affects patient performance and health outcomes. This chapter explores the nature of strategies that older adults with heart failure use to manage medications. We adopt cognitive systems engineering concepts to interpret our data [355, 356]. This approach introduces a new way to understand the ubiquitous heart failure self-care phenomena of managing medications.

Methods

This study employs an empirical strategies analysis method [347, 357] using a qualitative descriptive design to assess the nature of patients' and informal caregivers' medication management strategies. The empirical strategies analysis method elicits strategies individuals use in natural settings and describes patterns across cases [347, 357].

Sample and Setting

We analyzed data from 61 patients living with heart failure and 31 informal caregivers in a study of heart failure self-care, 2012-2014. Patient participants were aged $\geq$ 65 and lived in a 200-mile radius of Nashville, Tennessee, USA. Half were recruited from an outpatient cardiology clinic specializing in heart failure. The other half were recruited within 60 days of discharge from a hospital admission for acute heart failure.

Data Collection

Data were collected through: (1) clinic appointment observations; (2) either a short (30-min) interview with a follow-up (90-min) interview or one extended interview (90-120 minutes); (3) self-administered surveys; (4) photographs extracted from in-home or in-clinic video-recordings; and (5) a researcher review of the medication list from the electronic medical record. Interviews made up the bulk of strategy-related data. Scripted interview questions specifically addressed medication processes such as daily administration routines, storing medications, refill management, organizational strategies, and difficulties with adhering to the medication regimen. Patients completed and returned by mail a standardized, self-administered paper survey (n= 58, 95% response rate). The survey assessed cardiovascular health via the Kansas City Cardiomyopathy Questionnaire [180] and self-care behavior via the Self Care of Heart Failure Index [358]. The Dutch Heart Failure Knowledge Scale [182] was completed by patients at the follow-up or extended interview (n=48, 100% response rate). Follow-up interviews took place approximately one week after the initial interview, though not all patients completed a follow-up. Participants provided consent and received up to $65 for participation. The Vanderbilt University Institutional Review Board and Human Research Protection Program reviewed and approved the

study. Detailed descriptions of data collection procedures and instruments are reported elsewhere [359, 360].

Data Analysis

The specific data analysis method was descriptive qualitative content analysis with iterative category development [183]. This method systematically derives trends, patterns, and themes from large amounts of textual data revealing the underlying meaning [184]. It accommodates both deductive (conceptual model-driven) approaches and inductive (data-driven) category development. During first-pass structural coding [318], researchers RSM & RJH identified broad passages of data mentioning medication management in the interviews. During second-pass coding, RSM identified strategies described by participants to manage medications. Patient medication management was defined as the process and related activities required for the optimal use of medications to achieve the maximum health benefits with the minimal harm for a specific patient [254]. Strategies were defined as any method used by a patient or informal caregiver to adapt to medication management constraints to achieve goals [346, 347]. Constraints identified in illustrative instances of strategy use were categorized using the Patient Work System model [113], a systems engineering framework including person(s) (individual or team), task, tool/technology, organizational context, social context, and physical context factors [43, 129]. Sub-categories and cross-cutting themes regarding strategies and constraining factors were derived from the data and informed by concepts from extensive literature review of strategies from medical and non-medical sources [158, 344, 346-348, 361-363]. Authors RSM & RJH pursued analytic agreement regarding themes, subthemes, and core category emergence using regular coding discussions [199, 200].

Results

All patient participants had a diagnosis of heart failure and were managing the disease
with medications. Table 5-2 describes detailed demographic information and selected survey
results from the 61 older adult participants. Patients had on average 16.9 medications including
prescribed, over the counter, and herbal supplements documented in the medical record. All
patients had at least one comorbidity and the majority reported fair to moderate amounts of
disability from their disease. Analysis of data revealed four overarching themes: the nature of
stable strategies, the nature of unstable strategies, strategies involving non-adherence, and the
healthcare system as a source of constraints and potential provider of strategies. Participant IDs
identify individuals, detailed in Appendix E.

**Table 5-2. Demographics, Self-report Health Status,
Knowledge, Adherence (N=61)**

Age, mean (SD, range)		73.31 (6.73, 65-86)
Gender	Male	31 (51%)
Race	White, non-Hispanic	45 (74%)
Annual Household Income		
	Less than $25,000	19 (31%)
	$25,000 to $49,999	18 (30%)
	$50,000 to $99,999	14 (23%)
	$100,000 and over	5 (8%)
	Did not report	5 (8%)
Education		
	Less than high school	9 (15%)
	High school	21 (34%)
	Some college	13 (21%)
	College graduate	18 (30%)
Years since heart failure diagnosis		
	Less than 1	14 (23%)
	2 to 9	24 (39%)
	10 and over	14 (23%)
	Not known	9 (15%)
Other medical diagnoses		
	Hyperlipidemia (high cholesterol)	50 (82%)
	Hypertension (high blood pressure)	55 (90%)
	Diabetes Mellitus	37 (60%)

Number of medications, mean (SD, range)	16.9 (5.53, 3-34)

Living arrangements	
Alone	19 (31%)
With spouse	33 (54%)
With sibling	7 (11%)
With adult child/grandchild	2 (4%)
Retired	55 (90%)
Heart failure specific health status [a] (n=58)	
Little to no disability	2 (3%)
Fair amount of disability	29 (50%)
Moderate amount of disability	25 (44%)
Severe disability	2 (3%)
Heart failure knowledge [b] (n=47)	
0-9	4 (8%)
10-13	38 (81%)
14-15	5 (11%)
Memory strategies [c] (n=56)	
Use a system to help you remember your medications?	
Rarely	5 (11%)
Sometimes	2 (4%)
Frequently	3 (5%)
Always	46 (82%)
Remember medications [c] (n=56)	
Forget to take one of your medications?	
Always	6 (11%)
Sometimes	12 (21%)
Frequently	0 (0%)
Rarely	38 (68%)

[a] Kansas City Cardiomyopathy Questionnaire (overall clinical summary scale) **[180, 203]**
[b] Dutch Heart Failure Knowledge Scale, range 0 (low)-15 (high) [182]
[c] Self-care of Heart Failure Index [358]

Theme 1: The Nature of Stable Strategies

Participants developed and proactively used various stable strategies. These strategies became integrated, even automated, into people's routines and were relatively successful under standard conditions. Stable strategies were adaptive responses to the consistent presence of stable constraints such as medication management task difficulty, healthcare system complexity, and lacking resources (e.g. tools, social support, access to medications). Stable strategies were further

classified according to the target of participants' adaptation: the medication management process; the environment; or the self.

Sub-theme 1a: Strategies adapting medication management process. A common strategy (90%, 55/61) was to simplify, reorganize, or otherwise modify the medication management process itself. For example, filling a pillbox could be simplified by marking prescription bottles with pertinent information: *'Do you see on top of those bottles? you've got the BM, that's* [means] *bedtime and AM... all I have to do is look at the top and… take them out of here and put them in my little container.'* [S005] Referring to medications as a 'heart' pill or a 'fluid' pill was another simplification strategy. Many participants (43%, 26/61) also used a specific cue or trigger to help know when to self-administer an extra diuretic, for example, based on *'how much trouble I have getting in my pickup truck.'* [S020] Similarly, participants simplified tasks by adapting their timing (67%, 41/61). Medications were synchronized into daily events such as meals, waking, or bedtime and physically arranged according to sequence of administration. Consolidating medication tasks (e.g., the weekly pillbox filling ritual) or pre-completing tasks (e.g. preparing medications at bedtime for morning administration) eased the memory and execution burden of medication management: *'I put my medicine out at night, what I'm gonna take the next morning. All I have to do is just get me some water.'* [S031]

Another process-related adaptation was managing scarce or limited medication supplies (49%, 30/61). This was accomplished by borrowing medications from family members, stockpiling unused or discontinued medications (*'I have a cache'* [V025]), or finding alternative supply sources: *'Our druggist we've been there so long now they'll give me two or three pills to get me by till I get my prescription comes in.'* [V005]

Sub-theme 1b: Strategies adapting the sociotechnical environment. Participants operated in a *sociotechnical system* or environment, which they often adapted to accomplish goals.

These strategies included offloading medication management tasks onto other people (84%, 51/61), physical spaces (57%, 35/61), or tools and technologies (77%. 47/61) in one's environment (Table 5-3). For instance, patients recruited others' assistance, for example having a spouse track one's medications: *'I really don't keep up with how many I take and all that, I just depend on her to do that.'* [V008] In doing so, participants used strategies to manage their scarce supplies of social support, being careful to not overtax informal caregivers and other assistants: *'I mean my daughters have to take me you know* [to the pharmacy]. *Everybody's busy and I feel you know, I don't wanna impose on everybody's schedule.'* [S008] Other people were also relied on for information, including learning from non-professionals: '[My sister] *has had heart problems for a long time… and she knows all the tricks, all the tricks of the trade.'* [S028]

Physical spaces were also exploited, often used as memory aids: '*I just keep water right there by the bed because when I roll over, take the shots, then reach back and get the pills and then I can get up.'* [S020]

Table 5-3. Examples of Strategies Leveraging People, Physical Space, and Tools and Technologies in One's Environment

People	
• **Outsourcing tasks to family members**	*'She, she* [wife] *keeps all my medication up. She knows more about now what I take than I do. I used to take, know what I done, but she keeps it in a little, uh, what do you call those things?'* [S006]
• **Community assistance**	*'We have one of our members* [church] *is a med student so she made that chart for him so that helps a lot… it's been a, a team effort to keep him, to get him stable.'* [son of S013]

• **Pharmacists and healthcare provider assistance**	*'I think they* [physicians and nurses], *they keep everything pretty straight for me, you know like the medicine and stuff and if they feel like there needs to be a change or something other they take care of that* [send change to pharmacy]*'.* [S030]

Physical Space

• **Home structures to organize medication administration (e.g. cabinets, drawers, tables)**	*'I've got, I've got a, got a little plastic basket I've got all my bottles and meds in, and I've got one for me and one for my husband.'* [S007]
• **A medication management space proximate to place of administration**	*'So in the morning time when I roll over…I just keep water right there by the bed because when I roll over, take the shots, then reach back and get the pills and then I can get up.'* [S021]
• **Spatial and visual cues indicating an action was completed**	*'I keep all, it takes ten syringes out of the little bag and I put them in, with the rest of my in-, with my insulin and stuff and if, if I've got an even amount that means I haven't taken the morning one, but if I s-, if later on if I've got an odd amount it means I didn't take that evening medicine.'* [S030]

Tools and Technologies

• **Tools to externalize memory requirements (e.g., medication lists, mobile phone reminders)**	*'I just always keep a list because I can't remember all that, there's so many of them* [medications]*.'* [S007]
• **Tools to evaluate fluid status based on numerical values (e.g., bathroom scales, pulse oximeters)**	*'The doctor won't tell you to buy one of these* [pulse oximeter] *Uh, but I used it as a trigger* [for diuretic administration]*, you know. I don't want to go through another thing like I went down in Birmingham.'* [S028]
• **Tools to detect and prevent errors (e. g. post-administration checklists, problematic medication lists)**	*'I've got another list that ha-, that had medications I take and that did have side effects… like I'm allergic to penicillin. Then, uh, the Metformin that I used to take for my diabetes, that stuff messed with my kidneys. So, I st-, had to stop taking that. A couple other ones start giving me, uh, make me, making my muscles weak.'* [S010]
• **Tools to communicate with providers about refills (e.g. secure messaging).**	*'When I need a prescription or something I can write in"* [through patient portal]*.'* [S009]
• **Tools to acquire medication information (e.g., portal, websites, medication package inserts).**	*'Well if, if I'm there if I'm at an appointment I, I ask him* [provider]*, otherwise if I have questions I would do it* [at] *My Health At Vanderbilt.'* [V026]
• **Tools that facilitate refills, maintaining medication supply**	*'I can drive to it and I have driven to it, but they, they will automatically deliver it, no problems at all.'* [68/M/patient]

A pervasive strategy was to create and use tools and technologies. For example, participants created charts and other tools to reduce workload and reliance on memory: *'That was confusing to try to keep everything. Did I take it or didn't I take it? And so we made a little chart.'* [V029] One patient used post-it notes to communicate information from her primary care physician to her cardiologist: *'I know [primary care physician] told me, I left me a note on one of these papers.'* [S002] Some participants also carried medication lists in their wallets for communicating across healthcare providers and settings. In using tools, patients also had to combine or modify existing tools to achieve their goals, for example, combing several logs into one:

> *'I've got just got a little chart I write it all down on. Cause they gave it to me up in diabetes. But then I've sort of added some things* [weight, blood pressure]. *Didn't have room, but I sort of added some things to write it down and everything.'* [S030]

Sub-theme 1c. Strategies adapting the self. Although less common than strategies adapting the process or environment, multiple patients described adapting themselves, including their thinking and mental models. For example, patients reframed how they viewed things, as illustrated by a patient who rather than begrudging his frequent trips to the bathroom, accepted them as a sign that his diuretic was working: *'I know what it's doing, and to me, that's something good pretty much. And so, it doesn't bother me.'* [S010] A previously non-adherent patient became adherent after this cognitive reframing of the purpose of her medications:

'I'm realizing medication is a form of preparation, you know, and builds your system up to fight off what may come in the future. So after this last hospitalization I became a little bit more devoted in taking my meds.' [S008]

Theme 2: The Nature of Situational Strategies

While stable strategies were adequate for typical medication management situations, various changes to their routines required patients to devise situation-specific strategies. Examples of disruptions included eliminating a step (consuming a nutritional supplement) from a morning medication-taking routine or being prescribed a new look-a-like medication. In both cases, the patients experienced a medication-related adverse event, but in many other cases, patients developed situational strategies to prevent disruptions from causing harm. These situational strategies were sometimes planned and used in recurring situations. Other times, these strategies were created ad-hoc.

Sub-theme 2a. Planning for the situation. For expected or recurring situations, many patients (67%, 41/61) had rules-based strategies, allowing them to deploy the specific strategy when a condition was met. The most common examples of this were rules-of-thumb about not 'doubling up' when medications were forgotten or taking an as-needed diuretic upon detecting weight increases: '*Yeah, it's, what, what the doctor's instructions are if, if you gain three pounds, uh, in a short period of time, take a diuretic. Well, I don't let it wait that [long].'* [S028] Many patients learned these rules from healthcare professionals.

On the other hand, patients also developed situational strategies based on personal experience. For example, patients brought extra medications while on vacation in case they were

delayed in returning home: *'You always wonder if you're going to be stranded while you're traveling. I always have a few extra days' supply.'* [S028]

Sub-theme 2b. Responding to the unexpected. In responding to unexpected and unplanned for situations, patient participants described a variety of spontaneous strategies. Some (25%, 15/61) applied (or misapplied) a strategy from the past to the new situation, as one caregiver described: *'I'll tell you what she does when she had, is having a problem breathing-She's got on these menthol cough, cough drops----and sometimes she'll take up to Ten or eleven of them.'* [husband of V013] In other cases (10%, 6/61), they experimented with strategies they observed from healthcare practitioners, for example, adjusting diuretic dosing:

> *'I was foolin' around with it [Lasix] trying to say, well, I, I won't bother anybody... I observe and I read and what have you, but, uh, being in the hospital, I can pick up quick... I'm not a dummy... I can pick up things like that.'* [V002]

Other spontaneous situational strategies were to seek help (48%, 29/61) from family, friends, and healthcare providers: *'I could see that I was getting out of breath and everything so I called my daughter up and I told her.'* [V005] Yet others avoided a decision or delayed their response (16%, 10/61) until further evaluation: *'I could feel it come on and usually I run around in denial for about four or five days. You know, then finally I say yeah, this, this is, you know, a problem now.'* [S024]

The selection of a situational strategy appeared to be a complex process, depending on patients' awareness and interpretation of the situation as well as preferences. For example,

concerned that contacting her physician would result in hospitalization, a patient administered

twice the dosage of nitroglycerin, citing: *'I did not want to be going to the* [hospital].' [V016]

Theme 3. Strategic Non-adherence

Patients sometimes faced situations wherein personal goals conflicted with their or the

provider's medication adherence goals. In some cases (57%, 35/61), patients would implement a

strategy to achieve the personal goal, resulting in nonadherence from a medical point of view.

Table 5-4 provides several examples, including cases of patients reducing and skipping doses or

self-administering additional doses of medications in response to acute symptoms, perceived

medication ineffectiveness, or after consuming salty foods. In some cases, patients were aware of

the goal conflict and trade-offs; this patient who skipped diuretic medication to avoid disruptions

to personal travel goals was clearly aware of the consequences: *'And when we're traveling I just*

don't take it [medication]… *Well, for several days I can notice edema in my leg. Gain some*

weight, so I, it's a balance.' [S009]

Table 5-4. Example Task Strategies Involving Non-Adherence

Patient Goal	Constraint	Strategy	Example Quote
Minimize the intensity of medication side-effects	• Frequent waking at night due to increased urine volume • Fear of falling • Desire for rest	Reduced the dose of a diuretic before bedtime.	*'Half one? So, I don't have to get up so many times. It puts you up about three times if you take a whole one, and if you just take a half one, you don't have to get up about twice.'* [V020]
	• Increase in urine volume • Availability of bathroom facilities • Difficulty walking	Spread the medication dose over time.	*'I take the Furosemide in the morning usually. Well right now [when away from home] I took part of it and I'll take the rest [later]. Stretching it out seems to work better.'* [S009]
	• Perceived negative medication side-effects • Difficulty speaking up • Desire for autonomy	Reduced the frequency of administration.	*'I have to take it twice a day, it's supposed to be three times, I take it twice a day… I couldn't take it 3 times a day because it was making me sick.'* [S021]
	• Anxiety about medication effects (kidney damage) • Cultural beliefs (distrust of Western medicine) • Lack of knowledge	Administered medications only when symptoms occurred.	*'If I'm not swelling, I'm not holding water, and I'm watching my weight on the scales then I don't take it* [Lasix].' [S013] *'He doesn't take those water pills as often since you told him it will affect his kidney. So he doesn't take them like every week.'* [son S013]

	• Lethargy due to medications • Medication task difficulty (insulin management) • Recent hypoglycemic events • Lack of social support	Administered twice a day medication once a day to avoid daytime sleepiness.	*'We took it upon ourselves to change it where everything she takes that makes you sleepy you take it at night and she's sleeping more at night.'* [daughter] [S015]
Symptom relief or avoidance	• Acute symptoms • Lack of expected effects • Anxiety	Administered an extra dose of a medication.	*'So this morning I took two doses instead of one and still waiting for it to kick in.'* [S024]
	• Acute symptoms • Lack of prescribed medication to control symptoms • Pain	Administered a discontinued medication.	*'They took my gout medicine away from me and I told (husband), I said you just get that right back and said it out there, I said if you don't want to give it to me I'll take it from myself and so, so I did, because I can feel it coming on.'* [S016]
	• Eating high-salt food the previous evening • Eating preferences	Administered a larger dose of a medication.	*'It's only when I've been a bad boy and gone out to a Mexican restaurant that I have to take the 60* [mg of Lasix].* '* [S004]
	• Anxiety • Recent hospitalization	Administered a medication early.	*'So it was so close [to the weight threshold] and it was bothering me so I knew the signs of my congestive heart failure...[and took medication early]'* [S002]
Avoid social judgement, incontinence	• Perceived ineffective bowel prep • Patient history of bowel incontinence • Next day colonoscopy	Administered an extra dose of a medication.	*'I got prepped, it, uh, I didn't think I got a good reaction so I doubled up on it and took an extra package of that laxative* [resulting in hospitalization].* '* [S020]
Avoid effects on job performance	• Increased urine volume • Time pressure • Availability of bathroom facilities	Omitted multiple doses of a medication.	*'So I didn't want to be, uh, be stopping on the road every fifteen minutes. So I didn't take it then for several days in a week or two-week time.'* [V017]
Preserve financial resources	• Income limitations • High cost of medications • Family responsibilities	Omitted multiple doses of a medication.	*'I get through down through the money I don't have anything left. So that's why I felt like the tablet wasn't going to be that important to me.'* [S021]

Patients also described events of strategic nonadherence while pursuing goals of comfort or quality of life:

> *'But my other goal is what I call palliative… it doesn't matter how much diet, how much*
>
> *medication, how much exercise, how much this, that or the other, I am not gonna get*
>
> *through this, I am dying of heart disease. So … whatever I can do to physically feel better*

on a daily basis whether that means sleeping, whether that means getting up and walking around, whether that means taking a ride out to the Buddhist temple for recre-, whatever, palliative makes me feel better that day.' V018

Theme 4. The Healthcare System as a Source of Constraints and Potential Provider of Strategies

The healthcare system was often (92%, 56/61) a source of stable and situational constraints due to its complexity, inadequate informational integration, complex medication regimens, limited access to resources, insurance rules, and medication costs. These prompted various, sometimes very effortful strategies:

'I'm real careful with my meds as far as I've got about 4 medications that are on $4, um, drug list and I get them at Wal-Mart like that, they're not filed through my insurance so that's not accounting toward my doughnut hole but so I keep, check to see what I've got that's not you know that is on a $4 list somewhere, um, the rest of them I get, I get through my, um, regular drug store. But, um, um, I do my research on that.' S007

However, the healthcare system offered few new strategies or assistance implementing existing ones. Nevertheless, some strategy support was reported by patients (51%, 31/61) in the form of refill reminder calls, mail-order delivery, 90-day refill intervals, secure messaging with providers, and health information access through a patient portal.

Healthcare professionals also provided some strategic support. A few patients (8%, 5/61) expressed that this help was minimal. A patient explained: *'There's not a magic list of*

instructions that they lay out.' [S024] Clinic observations, however, offered several examples of

nurse practitioners helping patients adapt their medication management process to their context.

For example, an 86-year-old disabled patient would not take her diuretics until the evening when

family assistance was available. As a result, she was awake all night. The nurse practitioner

worked with a family member to devise a strategy adjusting the timing of her medication to late

afternoon and involving family help earlier in the day.

Discussion

These results suggest the support of strategic adaptations as an important new priority for

research to improve the medication management performance of older adults. There is little

research addressing patient strategies, especially the strategies of older adults, and more work is

needed to expand our understanding of the relationship between patient strategies and health

outcomes.

The Importance of Strategies to Medication Management Performance

In this study, participants often adapted the environment or the task, rather than the self.

Participants streamlined processes and used structural supports to make medication management

easier, quicker, and less effortful. Stable strategies also aimed to prevent known and potential

errors such as forgetting medications or confusing look-a-like medications.

Other research validates strategies as important elements of successful medication

management in older adults. Laboratory research reports cognition declines with age [88], yet

work related performance did not decline in real world settings [89.] Methods used in laboratory

research failed to capture compensatory factors such as environment supports and strategies used

by older adults in real world settings. Lippa et al. [364] in a study of the self-management

practices of 18 diabetic patients found the number of problem cues mentioned, knowledge of

functional relationships, and the *number of strategies mentioned* as related to improved diabetes treatment adherence. Other research reports a greater number of medications improved medication adherence [365-367] suggesting increasing complexity necessitates more attention and stronger strategies. A lack of or weak stable strategies may enable medication mismanagement, and improving strategy use by patients is an important focus for practice and future research.

Situational constraints are less easily planned for or anticipated. In this study, some of the acute situational strategies tested the boundaries of safety. Taking a greater dose of a medication in response to a perceived lack of effect resulted in hospitalization for one participant. Supporting resilience, the ability to adapt and respond to change, disruptions, and disturbances [231], can be a focus for new interventions and tool and technology design. For example, improving the speed and quality of communication channels between patients and healthcare professionals may reduce the need to make unsafe decisions without provider input. Decision-support tools for patients could also offer guidance to patients when situations are difficult to interpret and act on. Improving a patient's repertoire of safe situational strategies by providing patients more rules and "what to do if" scenarios as guidance.

Strategic Non-Adherence

The results reveal medication management to be a goal-driven process aimed to control a complex system of people, tasks, tools, and environments to achieve and maintain physical, mental, and social well-being for that patient. This description is not unlike patient centered care: 'Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions' [368]. Patient health work is similar to the work of healthcare professionals and share common goals often constrained by

system factors [344, 369, 370]. Patient work also involves complex interdependencies that require integration and coordination. Unlike the work of health professionals, patient work takes place within the messy context of everyday life, where conflicting goals and dynamic, complex, multilevel constraints impede patient health goals.

Work is never performed as perfectly imagined by processes and procedure manuals because constraints and conditions require adaptation [227]. Rather than trying to control behavior with a rigid pre-defined path, parameters of performance made explicit and strategies adapted to keep patient behavior within these parameters would improve safety [174]. In aviation research, air traffic controllers switched strategies and relaxed performance criteria when the number of planes to track increased in number [347]. Similarly, when situational demands of medication management increased (e.g. being away from home, experiencing acute symptoms), patients described relaxing adherence criteria as a strategy, increasing risk. However, patients were not always able to judge 'safe' boundaries. Decision support tools could improve safe decision-making.

Healthcare System as a Source of Strategies

As a major source of constraints**,** the healthcare system could also offer more tools, technologies, and strategies to support effective and efficient medication management. Participants appreciated pharmacy tools such as mail-order delivery and automatic refills. They also mentioned the patient portal as a source of information and an easy communication tool. There are many potential areas of improvement when the support of medication management becomes a priority. Participants in this study had difficulty tracking information over time such as medication history or the cost of medications across pharmacies. Crowd-sourcing and social media tools facilitating sharing of strategies between patients could also go far to improve

medication management performance.

Limitations

Although ours was a relatively large sample for a study of its kind, it was performed in one region of the US and was limited to older adults with heart failure. The data used for this analysis was gathered from a larger study of heart failure self-care, with only a subset of data collection methods designed to measure medication-related strategies. Infrequently used strategies were not identified, and the situational strategy descriptions were limited. The long-term effects of strategy use were unknown as patients were not followed over time. Also, descriptive statistics document participants mentioning the particular strategy or constraint. Other participants' medication management may also be constrained by those factors, and they may use strategies they did not mention.

Conclusion

Patient work has more in common with professional work than previously assumed, and likely could benefit from the same tools and research methods used in professional work settings. Patients strived to control their system and achieve goals; they are not simply adherers/non-adherers and followers of directions.

CHAPTER VI

DIGITAL DIARY METHOD TO ASSESS THE PATIENT WORK SYSTEM: A PILOT

STUDY OF MEDICATION MANAGEMENT AMOUNG OLDER ADULTS WITH HEART

FAILURE

Chapter six documents the results of a pilot test aimed to evaluate a digital diary data collection

method for effectiveness, efficiency, and satisfactoriness in capturing patient work system data.

Challenges using the method were also analyzed. Fifteen older adult heart failure patients

recorded their medication management activities for one week using a tablet device followed by

a follow-up interview. Results illustrated the methods as effective in capturing the barriers and

resources of medication management, required little participant and researcher time and effort,

and participation was a satisfactory experience for participants. Computer inexperience and

usability attributes of the technology were the primary barriers to effective use of the method.

The method holds promise for HFE patient work data collection.

Introduction

As the paradigm of healthcare shifts from hospitals to homes and acute to chronic care,

patients and their families are increasingly responsible for implementing and managing their own

care [371, 372]. Although patients participating in their own care is not new, we now cannot

ignore that patients, families, and other laypersons perform effortful, goal-driven, health-related

activities that can even be considered a type of work [44, 113, 339, 360]. Scholars label these

activities as "patient work" [3], though informal caregivers and other nonprofessionals may also

participate [129]. As "co-producers" of healthcare [284], patients individually and in

collaboration with health professionals perform health work that produce important health-

related outcomes. Improving patient work performance, however, is an under-explored approach

to improving healthcare delivery. To study and improve work done by patients, researchers suggest using and adapting work-study methods used in other domains of activity [70]. In particular, a recent national report [46] and subsequent publications [373] propose the use of human factors engineering (HFE) methods, which have been used to systematically study and improve work systems in domains such as aviation, manufacturing, energy, consumer products, medical devices, surgery, and e-commerce [374]. This research study pilot tests an innovative method to perform an HFE work system analysis [375] of patient health work. More specifically, we applied and evaluated a digital diary method to study barriers and facilitators in the medication management work systems of older adults with heart failure. Based on this pilot study, we contend that the digital diary method can be used to inform HFE studies and, more generally, the design of tools and technologies to improve patients' performance of health work.

HFE Approach to Patient Work

The academic and practice discipline HFE, or ergonomics (Greek for "the science of work"), aims to optimize the interaction of human and non-human elements in complex sociotechnical systems to improve performance and well-being through human-centered design [41, 42]. HFE applications have improved safety and performance in healthcare and other settings, in part through more user-centered design of tools and technologies [43]. Technology and other tools can improve the health work performance of patients as they have for healthcare professionals [26, 376, 377], but only if they are based on an understanding of and designed to align with users, their tasks, and contexts [2, 378]. HFE methods and theories are generally suitable to the study of any work or leisure activity [379, 380] including patient work, yet must be adapted for each work domain [70, 381]. This includes adapting HFE and related methods to assess and analyze the work of patients [44, 46] which differs from the work of health

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professionals [44, 45]. Patient work takes place in a highly personal space, is integrated with other daily activities, and can be difficult to study in context [113, 382]. Patients are not paid, have little training, highly variable abilities, and shifting motivations to perform or not perform health work [45].

Challenges of the Assessing Patient Work

The study of patients in home and community settings impose unique challenges to implementing HFE methods of data collection, including the following [70, 147, 381, 383, 384]. Access to a participant's home can be difficult, as participants may misunderstand the purpose of the research study and distrust the researchers' intentions and motives. Participants may feel the presence of researchers as intrusive in personal spaces. They may have different priorities (e.g. socializing, asking advice) impeding the efficient and minimally biased collection of data. Older adults may be hesitant to allow researchers into their homes, especially if they live alone. Participants can live far away from research centers, become disinterested, cancel appointments, and be difficult to contact. The reliability and quality of data can be limited as patients may have incomplete or inaccurate memories of past events in addition to wanting to provide socially desirable answers. Patients may be hesitant to disclose socially undesirable or less than ideal health-related practices, fearing judgement from the researcher. They may also "sugarcoat" the situation if they wrongly believe the researcher to represent or report to their medical team. Further, some forms of health-related work may be inherently difficult to assess. For example, medication management is cognitive, sometimes implicit, and often distributed across multiple people and places, over prolonged periods of time, and at all times of the day and night [267, 360]. These challenges make it difficult and resource-intensive to assess patient work cross-sectionally or through longitudinal in-person observation.

Participant Driven Diary Methods

Participant driven diary methods may achieve a balance between sometimes conflicting patient work data collection requirements and challenges. Researchers have utilized diary methods for decades to capture activities and experiences from the perspective of the participant [385-387]. These methods involve repeated daily recording of researcher specified information by a participant in a natural setting over a specified time interval [388, 389]. Early diary instruments were limited to paper-based written logs, requiring significant effort from the participant. Recent technological advances and digital methods of data capture have permitted diary methods to include photographs and audio and video recordings. These innovations have increased the use of diary methods in recent years [390].

Diary methods are useful for several types of research objectives. First, diary methods can produce accurate, detailed information about activities of individuals [391]. Second, diary methods are useful in understanding variations within and between individuals over time [385]. Third, diary methods can capture the experiences of vulnerable populations such as older adults [392, 393], low-income adults [394], children [395], and adults with chronic illness [391, 394]. Last, diary methods are useful in capturing multilevel factors (e.g. person, day, event, team) [385, 389] facilitating multiple-levels analyses.

HFE data collection methods capture the interaction of humans and context in a complex system [41, 42] and previous HFE research benefitted from diary methods. Palen and Salzman [396] used voice-mail diaries to capture the difficulties novice mobile phones users encountered and re-designed the interface to better suit the novice user. Church, Cousin, & Oliver [397] explored mobile search in social settings through online diaries and found users wanted an easier means to share search results with others. Other examples include eliciting requirements for

assisted living technology for older adults [398, 399], learning in the workplace [400], ridesharing applications [401], and mobile information needs [402].

Time or events can trigger participant data capture and structure sampling design. Some studies used fixed time intervals (e.g. every 2 hours) specified by the researcher [385, 403]. Time-based methods are useful when capturing continually changing conditions (e.g. engagement, self-esteem) [403], or when the researcher is interested in multiple diverse variables [387]. Event-based designs instruct participants capture data for every instance that meets the researcher's definition of the event (e.g. medication administration) [385, 403]. Event-based diary sampling is appropriate for the capture of discrete activities or events that are not ongoing (e.g. use of a cell phone, exercise) [385, 387] and research of an exploratory, descriptive nature [391]. Ecological momentary assessment (EMA) methods are sampling strategies aimed to capture a phenomenon or event close to moment it occurs in a natural setting [404]. EMA [405] adds an experience based sampling method where participants are signaled at random times and directed to record their experiences in that moment [404, 405].

Digital Diary Method to Assess Patient Work

Digital methods can address many of the patient health work data collection challenges described earlier [70]. First, these methods allow the analysis of medication work across time at multiple levels of analysis. Second, these methods permit for the capture of medication work as close to real time as practical without continuous observation, reducing retrospective bias and normative description. Third, these methods can capture the collaborative nature of medication work by documenting the involvement of others in activities. Fourth, these methods allow the participant to play an active role in data collection, equalizing power dynamics, encouraging trust, and facilitating information sharing. Fifth, these methods involve continued researcher-

participant interaction over the course of the study improving validity and credibility through

continual member checking. Sixth, visual media elicit different types of information such as tacit

knowledge, and information about which participants may not be consciously aware. Last,

participants in other studies have enjoyed the process of taking photographs, improving their

motivation and protocol compliance.

This study pilot tested a digital diary method to gather data about patients' medication

management work systems, namely system barriers to and resources for medication

management. Diary methods have not been applied to assess the work systems of patients.

Methods including patients as active participants in the research process are identified as well-

suited for patient contexts [70], but digital diary methods are as yet untested in patient work

research. Using the proposed method, patients are the data collectors, capturing their medication

activities using photographs and audio and video recording uploaded in real time for researcher

evaluation. The method involves an ongoing patient-researcher interaction over a period of one

week. It is unknown, however, if this is a feasible and effective data collection method for

patient work systems analysis.

The first study aim was to evaluate the effectiveness, efficiently, and satisfactoriness of

using a digital diary method for data collection in capturing the medication management work of

older adults with heart failure. These three evaluation criteria were selected and operationalized

based on the definition of usability International Organization for Standardization [1] definition

of usability. Effectiveness refers to the ability to achieve goals, in this case to collect rich data on

the medication management work system. Efficiency refers to the reasonable use of resources

such as time and effort. Acceptability refers to participants' satisfaction with the method. The

second aim was to describe challenges encountered using the method by both researchers and

participants.

Methods

  This pilot study took place August through October 2016 within the context of a larger

project evaluating the self-care of older adults with heart failure. The study consisted of a

sequence of data collection (See Table 6-1) and analysis methods: (1) digital diary (photographs,

video and audio recordings, photographs annotated with text) captured by participants for one

week and uploaded in real time to a secure cloud-based data repository, (2) ongoing analysis of

transmissions, (3) satisfaction survey completed by participants, (4) a follow-up interview

informed by transmitted recordings, (5) and the analysis of data collection methods for

effectiveness, efficiency, participant satisfaction, and method challenges. Vanderbilt University

Institutional Review Board approved this study.

Setting and Sample

  The study was conducted with patients from a heart and vascular outpatient clinic at a

large medical center in the Southeast US. One physician specializing in heart failure assisted the

researcher to identify prospective participants who fit eligibility criteria: (1) aged ≥ 65, (2)

diagnosed with heart failure in NYHA functional classes II and III, (3) not on a cardiac

transplant list, (4) currently patients at the medical center, (5) living at home or in assisted living,

but not in a nursing home, (6) English speaking, (7) able to provide consent, and (8) living within

a 90-mile radius of the medical center. Initial interviews and instruction took place in the clinic

research room. Follow-up interviews took place in the research room of the clinic (8/15, 53%),

participant's homes (6/15, 40%), and a community setting (1/15, 7%).

  Twenty-five eligible patients with an upcoming appointment were contacted by

telephone. Sixteen agreed to participate. One participant dropped out of the study one day after

recruitment citing anxiety about using the diary technology. Analysis was ongoing during data

collection and the researcher recruited participants until data saturation for the purpose of this

pilot was established. Fifteen participants completed all data collection phases. Two

accompanying caregivers agreed to help the participant gather the data and were consented.

Patient participants received an honorarium of $75 U.S.

Data Collection

Detailed data collection procedures are documented in Table 6-1. After recruitment,

participants (and caregiver, when applicable) met the researcher in the clinic for 20 to 30

minutes. During this meeting, detailed information about the study was communicated, informed

consents signed, and demographic information gathered. An iPad Air tablet computer was given

to the participant and detailed instructions about devise use, login, and software use were

verbally communicated. The participant then demonstrated the use of the tablet (photographs

with text annotations, video recording, and audio recording) to the researcher. Detailed written

instructions (See Appendix F) were also given to the participant to reference at home. The

tablets were equipped with access to cellular networks, so participants did not need to have an

internet connection.

Table 6-1. Study Data Collections Procedure

1. Initial Encounter (clinic) 30 minutes

- Explain study purpose and protocols
- Answer questions
- Obtain consent
- Device distribution
- iPad Air tablet set-up and training
  - o Login, general use
  - o Use of software (photographs with annotations, video recording, audio recording
  - o Teach back by participant
- Give written instructions for iPad and data collection (See Appendix A)

2. Data capture by participant (home, community) 1 week

- Photo/Video/Audio/Photo with annotations diary recordings of medication activities by participants using an iPad Air tablet
- Real-time transmission upload to secure cloud based data repository

- Phone conversations with field note documentation for 3 days, then as needed
- Ongoing analysis, field note documentation, preparation for follow-up interview
- Digital Diary Satisfaction survey completion by participant at the end week

3. Follow-up interview (clinic, home, or community) 1 hour
- Follow-up interview
- Collection of device

Participants were instructed to capture medication activities using the tablet for a one-week period spending no more than 15 minutes a day. A one-week duration allowed enough time for data collection without undue burden on the participants. Other research recommended that the frequency of data collection each day should not exceed five events of two to three minutes each [406]. The event-based sampling method was preferable because medication activities do not occur continually or at pre-specified times [385, 387]. Examples of medication activities were affixed to the back of the iPad (e.g. obtaining refills, information, medication administration) (See Appendix F).

Using the Capture (Box, Inc.) application loaded on the iPad, participants had the choice of video recording, audio recording, photographs, and photographs with typed text annotations to record their medication activities. Many digital diary studies gave participants a choice between written, audio, photo, or video [391, 392]. Allowing for flexibility enabled participants to fit diary methods to their lives and circumstance [391]. The recorded files were uploaded in real time to a secure cloud based server via a cellular network.

The researcher contacted the participants daily by phone for three days and then as needed to discuss their progress and any issues encountered. Other researchers recommended daily contact with participants during diary studies [391, 392, 396]. Diary follow-up was reported to increase the volume of data by reminding participants and increased motivation and engagement [392]. Field notes were recorded following these conversations and throughout the

data collection time period. The follow-up interview was scheduled during phone conversations and participants were reminded to complete the Digital Diary Satisfaction Survey (See Appendix G) and bring it to the follow-up interview.

The survey assessed from the participant's perspective about the experience of taking part in the digital diary data collection process. It included 8 questions assessing satisfaction, comfort, time, effort, clarity of instructions, learning, enjoyment, and preferred mode of data capture. Responses were structured in a seven point Likert scale (strongly agree, agree, agree slightly, neither agree nor disagree, disagree slightly, disagree, and strongly disagree) and a free text area to write in comments followed each structured question.

Follow-up interviews occurred after each participant's completion of the digital diary week. An interview guide (See Appendix H) was individualized based on an initial analysis of the digital diary recordings. Participant questions probed for details about barriers and facilitators in their work system (person, task, tool, context) [43, 113, 129]. They were also questioned about processes and strategies related to medication management although the analysis of these data is outside the scope of this paper. Transmitted photographs or stills extracted from video recordings were printed and used to prompt participant memory and elicit work system details, based on stimulated recall methodology [407]. Mean interview duration was 54 minutes (SD 18, range 22-92).

Data Analysis

Survey, digital dairy, and interview data were used to evaluate the effectiveness, efficiency and satisfactoriness of the digital data collection process. Effectiveness was evaluated through descriptive qualitative content analysis with iterative category development [183] of transcribed diary and interview data for work system barriers and facilitators to medication

management. Efficiency and satisfactoriness of the diary data collection method was evaluated through satisfaction survey results, transmission descriptive statistics. Field notes were analyzed for challenges encountered by the researcher during the data collection period.

Analysis of effectiveness. Verbal and textual data from the digital diary transmissions and interviews were transcribed verbatim, de-identified, and imported into NVivo software for qualitative content analysis combined with interview data. Photographs and video recordings were analyzed for attributes of visual representations including activities, context, tools, and people. We performed descriptive content analysis of interview data imported into NVivo software. In a first pass analysis, researcher RSM identified passages related to medication management. Next, through focused coding RSM identified and iteratively categorized text relating to medication management barriers and facilitators within the broad predetermined categories of person, task, tool, and contextual factors, based on the Patient Work System model [113, 129, 359, 408]. Barriers were defined as attributes or conditions of work system elements that make it impossible, difficult, ineffective, inefficient, or unsatisfying to carry out a goal-directed process [113]. Facilitators were defined as attributes or conditions making it easier, more efficient, more effective or more satisfying. The next steps involved iterative subcategory development and intra- and inter-category theme identification related barriers and facilitators to medication management. Analytic agreement was reached through author discussions [199].

Analysis of efficiency and satisfaction. The purpose of this analysis is to assess the participant's experience of method burden and satisfactoriness. Survey question categorical Likert responses were aggregated and described through descriptive summary statistics. Open-ended survey responses were entered into NVivo software for qualitative content analysis and provided support for categorical responses. Comments made during digital diary transmissions

and interviews about the participants' experience with the tablet or method were included in the analysis. We calculated the total and per-participant number of recording transmissions, type of transmissions (video, audio, photograph, and photographs with annotations), number of days each participant sent transmissions, duration of transmissions (audio and video recordings), and preferred transmission type.

Analysis of method challenges. Field notes were imported into Nvivo software for qualitative content analysis. Challenges were categorized as relating to person, task, tool, and context previously described.

Results

Table 6-2 describes the fifteen patient participants' demographics, medication regimen information, and technology experience. All were diagnosed with heart failure, a chronic disease affecting older adults. Heart failure occurs when the heart is ineffective in pumping blood, resulting in fluid accumulation and symptoms such as shortness of breath, peripheral edema, and fatigue [9, 202]. Participants were using a mean of fifteen medications to control symptoms of heart failure, progressive cardiac changes, and other comorbid conditions.

Table 6-2. Demographics (N=15)

Age, mean (SD, range)		72.4 (5.6, 65-85)
Gender	Male	7 (47 %)
Race	White, non-Hispanic	13 (87%)
Annual household Income		
	Less than $25,000	7 (47%)
	$25,000 to $49,999	3 (20%)
	$50,000 to $99,999	2 (13%)
	$100,000 and over	3 (20%)
Education		
	Less than high school	2 (13 %)
	High school	4 (27%)
	Some college	5 (33%)
	College graduate	4 (27%)
Retired		13 (87%)
Years since heart failure diagnosis mean (SD, range)		12.3 (5.4, 4-22)
Comorbidities		

Hyperlipidemia (high cholesterol)	10 (67%
Hypertension (high blood pressure)	11 (73%)
Diabetes Mellitus	5 (33%)
Number of medications, mean (SD, range)	15.0 (4.2, 7-26)
Experience with technology (computers, smart phone, or tablet)	
No experience	5 (33%)
Experience using computers	4 (27%)
Experience using computers, smartphones	5 (33%)
Computers, smartphone, iPad	1 (7 %)

Participants used a mixture of transmission formats to capture their medication management activities (See Table 6-3). Photographs were the format type most frequently used, followed by audio, then video recordings. The preferred format overall was photographs with audio-recordings.

Table 6-3. Transmission Format Totals, Frequencies, and Participant Preferences (N=15)

Transmissions per participant mean (SD, range**)**	15.6 (10.1, 0-39)
Total Transmissions	219
Total Audio (N = 10)	64
Audio duration (minutes) mean (SD, range)	2.82 (2, 0.42-10)
Total Video (N= 9)	46
Video duration (minutes) mean (SD, range)	1.5 (1.2, 0.22-3.8)
Total Photo (N=10)	107
Photos per participant mean (SD, range)	10.7 (7.7, 2-25)
Number of days sent mean (SD, range)	4 (2, 0-7)
Preferred Media Transmission Type (N=11)	
Audio alone	1 (9%)
Video alone	3 (27%)
Photos with typed comments	2 (19%)
Photos and audio	5 (45%)

Table 6-4 details transmission subject categories including tasks (process and medications), tools (organizational tools and equipment), and physical spaces involved in medication management. Notably, the topics of transmitted data varied by media type. Some participants 3/15) used video recordings to document process performance such as filling

pillboxes or administering medications. Participants also documented process using a series of

photographs (27%, 4/15). Photographs were used to capture places (67%, 10/15), tools (100%,

15/15), equipment (33%, 5/15), and medications (100%, 15/15). Audio recordings described

processes and strategies in addition to underlying thoughts and feeling about medication

management.

Table 6-4. Transmission Subject (N=15)

Subject	N (%)
Process	
Patient administering medications	3 (20)
Patient filling pillboxes	4 (27)
Places	
Administration areas in the home	7 (47)
Medication storage areas	3 (20)
Organizational Tools	
Medication lists	11 (73)
Pillboxes	10 (67)
Other organizational devices (e.g. plastic bags,)	5 (33)
Equipment	
Monitoring equipment (e.g. glucometer)	3 (20)
Administration equipment (e.g. syringes)	2 (13)
Medications	
Medication bottles	11 (73)
Medications (pills)	6/15

Effectiveness

Digital diary recording and follow-up interview data revealed multifaceted and interacting barriers and facilitators of medication management (See Table 6-5). Digital diary transmissions elicited intra-participant factors. Some participants struggled daily with their medication regimens, regularly omitting, adjusting, or delaying medications. Other participant's managed medications consistently without many difficulties.

Table 6-5. Barriers & Facilitators of Medication Management

Factor	(-) Barrier (+) Facilitator	N=15 (%)
Patient	- Attitude towards medications	7 (47)
	- Cognitive Limitations	7 (47)
	+ Experience, knowledge	6 (40)
	- Difficulty speaking up	4 (27)
	+ Anxiety	4 (27)
	- Hopelessness	3 (20)
Task	+ Use of multiple strategies	9 (60)
	- Negative effects of medications on life & health	8 (53)
	- Negative effects of non-adherence on life & health	7 (47)
	- Precision requirements	7 (47)
	+ Regimen stability	6 (40)
	- Cost of medications	4 (27)
	- Irregular timing	4 (27)
Tool	- Lack of portability	6 (40)
	- Lack of clarity, feedback	6 (40)
	+ Appropriate for patient task	5 (33)
	+ Reduces time and effort	5 (33)
	- Not up to date	4 (27)
	- Lack of permanence, durability	3 (20)
	+ Adaptable	2 (13)

Organizational	− Non-routine schedule/events	11 (73)
	− Communication/Coordination Difficulties	10 (67)
	− Insurance rules	7 (47)
	+ Use of organizational tools	7 (47)
	+ Mail order prescriptions	5 (33)
	+ Automatic refills	6 (40)
	+ Secure messaging	6 (40)
	+ Healthcare system integration	6 (40)
	+ Support from healthcare professionals	6 (40)
	+ Medication samples	2 (13)
	+ Strategies support	4 (27)
	+ Medication information	5 (33)
Social	− Judgement of others	6 (40)
	+ Social support	6 (40)
	+ Relationship with pharmacy/pharmacist	5 (33)
	− Influence of TV ads	3 (20)
Physical	− Lack of bathroom facilities	7 (47)
	− Resources distances (pharmacy, provider)	3 (20)

Patient. Patient factors that emerged were primarily cognitive and affective. Patient attitudes towards medications emerged ("All this medication is just killing me" [76/M/patient]) as a factor that sometimes resulted in taking less medication than prescribed ("I started popping the pills in two, and only taking a half a dose… still didn't have a problem" [68/F/patient]). Daytime sleepiness and declining memory ("Guess I'm going to have to start doing that… Keep it wrote down. Since I had this heart attack, I forget" [65/F/patient]) interfered with medication management. A 66-year-old patient feel asleep with a lancet in her hand and cut herself while asleep. Hopelessness interfered with the motivation to take medications accurately ("I'd almost rather go like that is to die a slow death with this stuff, I'm going to feel this bad all the time" [76/M/patient]). Some patients expressed a hesitancy to voice medication concerns to their providers and altered their medication regimen on their own or remained silent but concerned ("I think it's too much to

just cut back. He cuts it back in half" [73/M/patient]). High anxiety about their condition or a recent hospitalization facilitated patients to develop strategies and adhere more closely to their prescribed regimen ("I learned my lesson" [73/F/patient]).

Task. Task barriers were addressed through a combination of strategies and tools. Patients with ineffective strategies struggled to accomplish medication tasks ("I tried everything like Wile Coyote, trying to come up with some way to remember that pill" [76/M/patient]). Use of physical space and home structure were common strategies to reduce effort ("I keep them all together" [76/F/patient]) and improve accuracy ("They are lined up in this fashion on the counter and then the one that I need to take next I move to the front" [76/M/patient]).

Medication management required continual attention ("It's an effort every day" [66/F/patient]). Patients took an average of 15 (4.2, 7-26) medications administered as many as five times a day. Medications changes disrupted the usual routine and regimen stability re-enforced routines and eased the effort required to manage medications ("It just seems so easy for me because I'm so regimented and have been taking the same medications so long" [76/F/patient]). Precision requirements and irregular timing of medications added to the burden of managing medications. Diuretic side effects were a frequent cause of non-adherence when away from home ("If I'm going out, I don't take it" [75/F/patient]). Conversely, experiencing negative effects from omitting or adjusting medications discouraged non-adherence ("I just got pissed off one day… so I stopped taking it [medication]… this kicks in [defibrillator]… it's like you've been kicked by a horse… and I ended up in the hospital" [70/M/patient]). Cost-related non-adherence was mentioned by some

Figure 6-1. Self-Made Medication List with Highlighted Changes and Indications Added

Medications – As of 08/25/2016
R/X Highlighted   Change as of this date
MORNING 8 AM
 Losartan Hctz 100/12.5 mg (BP)
 Pantoprazole 20 mg (Acid Reflux)
 Fish Oil (1) -1400 mg (Heart)
 Senior Multi-Vitamin
 Calcium 600 mg (Bone Density)
NOON: 11:30 AM
 Magnesium 400 mg Supplement
 Fish Oil (1) -1400 mg (Heart)
 Iron 65 mg (Blood)
 Vitamin D3 5000 IU (Bone Density)
 Calcium 600 mg (Bone Density)
EVENING: 7 PM
 Amlodipine-Benaz 10/20 mg (BP)
 Warfarin Sodium 2.5- 5mg (Blood Thinner)
 Atorvastatin 10 mg (Cholesterol)
 Pantoprazole 20 mg (Acid Reflux)
 Calcium 600 mg (Bone density)
WEEKLY: THUR AM
 Clonidine-Transdermal Patch
    0.3 mg/Day (BP)
AS NEEDED
 Alprazolam (Xanax) 0.5 mg
Change
 Stopped Metoprolol and
 AM & PM dose of 0.1 mg Clonodine

participants due to the price of certain non-generic medications ("I have on my own cut out the Bumex, to one from two when I get into the doughnut hole. It cost so much for that" [76/M/patient]).

Tool. Patients appropriated objects and developed their own tools to fit medication management task requirements. For example, some patients developed medication lists that were wallet sized and organized by time (See Figure 6-1). Medication bottles were re-labeled with time of administration (See Figure 6-2) and medication name abbreviations written on tops for easy retrieval from storage containers (See Figure 6-2).

Adapted and uniquely developed tools highlighted tool requirements such as the need for portability. Text box 1 narrates a participant's development of a unique tool to manage her medications illustrating barriers, facilitators, processes, strategies and tools.

Organizational. Organizational factors described by participants were numerous sources of barriers and facilitators. A lack of routines, frequent non-routine events or activities, and disruptions were the most commonly described barrier interfering with medication management ("I take my last shot at... well, before my medication has run out, they send me some more" [81/F/patient]). Some patients were even oversupplied with medications ("When I stopped taking the metformin, I had about 6 bottles of that up there. Because every, every time you turn around, [pharmacy] was calling saying, your prescription's ready" [76/M/patient]). Healthcare providers

Figure 6-2. Medication Bottle Labeling

(physicians and nurse practitioners) provided samples of costly medication and helped participants with strategies and provided informational support.

Social. Social ties facilitated and social influence impeded medication management. Caregivers were a valued source of procedural and emotional support ("I do all of his medications" [73/M/wife]). Patients often developed relationships with their pharmacists who provided information and extra medications in a pinch. Fear of being judged and social pressure ("I have a sister that thinks I can go [out], handle it and be okay, she don't know what they [diuretics] are cause she ain't never been on them" [70/F/patient]) encouraged patients to skip medications when away from home. Two patients discussed worrying about medication side-effects after seeing television advertisements ("Then they start telling you it's going to kill you after you ... It gives you 100 ways to die if you take it" [76/M/patient]).

3.1.6 Physical. The physical environment interfered with access to medications. Distances to pharmacies and healthcare provider offices increased the effort and cost required to obtain medications and regimen adjustments ("It's an hour and a half… In my car I was worried about pushing it that far every day" [71/M/patient]). Some patients did not take their diuretics when

they were away from home because bathrooms were difficult to find ("It's not always that easy to find a bathroom" [71/M/patient]).

Table 6-6 and Figure 6-3 illustrate a patient's development of tool and requirements.

Table 6-6. Patient medication management scenario

> *"That's what you would call Aggie Engineering. You know what we used to call it, but that's not politically correct. Or, as we used to say, as two of my Texas Aggie's used to say, 'I MacGyvered it."* [65/F/patient]

A 65-year-old female heart failure patient developed a unique method to organize her twice daily medication administration. She required a tool that gave her clear feedback if she took her medications or not. This patient had a very active lifestyle and often needed to take her medications with her when she was away from home. She wanted to be able to grab the medications she needed quickly and easily and put them in her purse. Any storage container would need to fit in her purse and not spill the contents when jostled around. She took several large dietary supplements capsules that would not fit into the slots of a usual pillbox. Grandchildren were frequently around and she took care of her daughter's children several times a week. Any tool was required to be childproof. She also liked to organize her medications once a week in front of the television. Any organizational device was required to be stable and not spill if she suddenly moved while she was holding the device on her lap.

The tool and strategy she devised met all of her requirements. She obtained two 18 count egg cartons and cut a third of the bottom off one of the cartons. She then sewed the two cartons together and then gathered old prescription bottles and re-labeled each bottle and cap with either AM or PM (See Figure 2). These bottles were prepared several weeks at a time by putting her morning medications in AM bottles and dinner medications in the PM bottles.

In the morning when she got up, she took one A.M., and one P.M. bottle and put them on the table by her reclining chair. Once administered, the empty bottle was put into a container storing empty bottles. This way, she could tell by glancing at the table that she had taken her medications. The bottles were large enough for all of her medications, childproof, and easily fit into her purse without spilling. This strategy required no extra effort if she needed to be away from home and take her medications with her. Also, the egg carton containers did not allow the bottles to spill while she was filling them.

Figure 6-3. Scenario Self-Made Medication Organizational Tool

Efficiency and Satisfaction

"It was not as bad as I thought it would be. I believe the method is a good idea." [76/M/patient]

All participants completed the Digital Diary Satisfaction survey assessing their experience participating in the study and collecting information using the digital diaries. Figure 6-4 summarizes the satisfaction survey data.

Efficiency. Most patients reported the time (80%, 12/15) and effort (93%, 14/15) required for digital diary data collection was satisfactory ("Only added a minute or so to each step of my overall process" [65/F/patient]). For some participants learning to use the iPad took time ("Once you figure out how to work the iPad it's not bad" [71/M/patient]) and extra time requirements were primarily related to the use of the iPad ("it was an iPad unfamiliarity issue" [71/M/patient]).

Several participants (6/15, 40%) had family members help them with recordings ("I needed my uh, nice, ten-year-old grandson to help me… he was going to do my videotaping" [65/F/patient]).

Figure 6-4. Digital Diary Satisfaction Survey Results
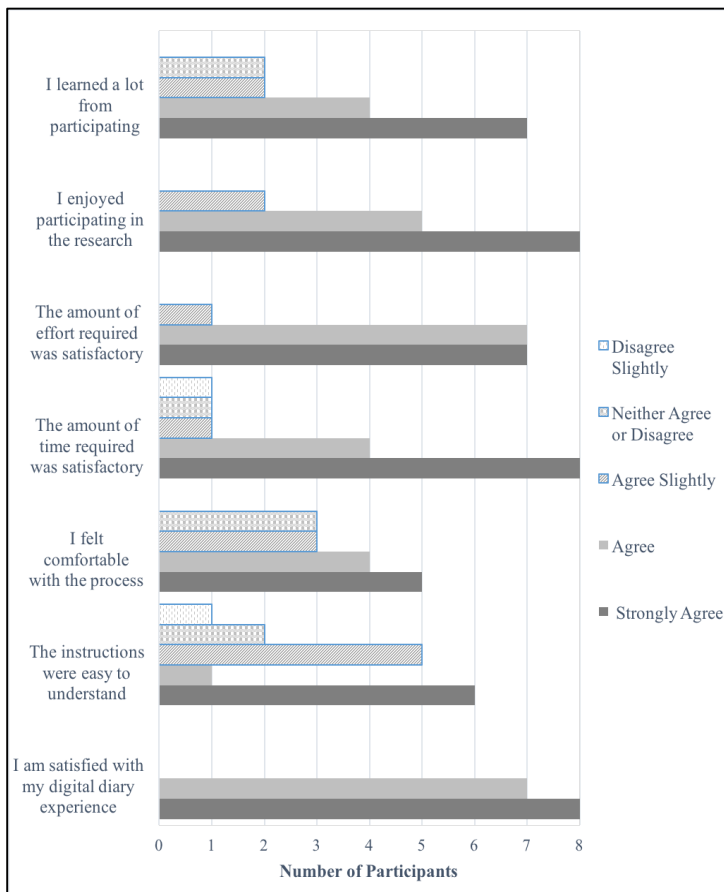
From a researcher perspective, the method was an efficient use of resources. Total preparation and interview time per participant was on average 2 hours. Time spent per participant per day varied widely dependent primarily on the difficulty the participant had using the iPad. The most common problem prompting phone calls to the researcher from the participant was getting lost on a different screen and the inability to return to the recording screen. Real time upload of participant recordings allowed the researcher to analyze data continuously and detect participant issues quickly. The follow-up interviews were then informed and efficient.

Satisfaction. Overall, all participants (100%, 15/15) reported a satisfying experience participating in the study. Participants made comment indicating they were engaged ("I really got into it. My dog liked it" [76/M/patient]) and enjoyed participating ("I'm, I'm rather enjoying it" [66/F/patient]). Others commented that focusing on their medications made them more aware of their process ("This did make me think about the methods I use to take my meds" [73/M/patient]), the value

of their medications ("I thought most about how important my meds were to my health… they keep me alive" [70/M/patient]), the effort required ("It just makes you more aware of how much time you do spend in keeping everything together" [76/F/patient]) and how others might struggle ("I becha medications is a problem for a whole bunch of people" [76/M/patient]). Many participants (73%,11/15) reported learning from the digital diary experience. One participant did not realize how often he delayed or skipped his diuretics when away from home ("How can I explain this… this week it was a lot." [76 /M/patient]). Participants also enjoyed feeling they were helping other patients ("It was, it's very helpful to me, and most of all I wanted to do it to help someone else" [75/F/patient]) and health providers ("They done so much for me" [76/M/patient]).

Digital Diary Method Challenges

Certain barriers posed challenges and interfered with the effectiveness, efficiency, and satisfactoriness of the digital diary data collection method. These barriers involved functional and non-functional attributes of the technology, the research process, and attributes of the participants.

Technology challenges. Lower comfort levels with the method were due to the use of technology. These challenges related to the actual functioning of the technology and non-functional issues that surrounded use [409].

More than half (9/15, 60%) of participants (See Table 6-1) had no tablet or smartphone experience, including many (5/15, 33%) who had no experience using computers. These participants expressed frustration in the first few days using the iPad ("That was the most frustrating part for me and that's why a couple of times I called you… just the iPad itself, how it operated" [76/M/patient]). After some additional phone instruction and practice, most of these participants were successful in transmitting diary information ("Not having worked with an iPad

before, I got a little confused at first. Working more evened the process out" [69/M/patient]). One

participant dropped out of the study due to anxiety about using the iPad and two participants'

media transmissions included little useful data (e.g. video of an object for 10 seconds with no

sound).

All digital diary data uploaded via a cellular network. The strength of this signal varied,

and some participant data took a long of time to upload, especially video data. If the participant

closed the iPad prior to upload completion, the data would not upload completely until the

participant opened the iPad for the next recording. This made it difficult to assess the time that

the media was sent. In one instance, the researcher had not received transmissions from the

participant prior to the follow-up interview because the video uploads failed due to the large file

size.

One participant described written instructions as too detailed to be useful for trouble-

shooting ("Provided more info/detail than I felt I would need and when I errored I called versus

trying to re-read the instructions" [76/M/patient]). Others shared this assessment reflected in the

neutral and unsatisfactory survey scores for the clarity of the instructions (47%, 7/15). Other

participants just didn't refer the written instructions ("I didn't use them a lot" [71/M/patient]).

Participants encountered several usability issues primarily due to Capture (Box, Inc.)

software. When and if a file was recorded was unclear and no feedback followed completed

actions ("I don't know if it when through" [66/F/patient]). Also, some participants described having

difficulty knowing when the audio or video recording was recording or not ("I been doing all this

talking and I don't think I recorded a word of it. So that is disheartening" [76/M/patient]). Some

participants got lost on different screens and had difficulty getting back to the recording screen

("I touched something and lost the scroll bar at the bottom the gives me the selection for voice-

photo-video" [70/M/patient]). Navigation to the recording review screen was difficult for some

participants. Icons differentiating the different screen options were not easily apparent (e.g.

mountain icon for recording library).

Process challenges. Some participants commented that they were not always sure what

to record ("Take a picture, well if I can think of something to take a picture of" 76/M/patient).

Subsequent phone conversations with the researcher assuaged some of this confusion. The

balance between specificity and flexibility was a challenge, informing the participant enough yet

giving them the ability to add information they thought was important and the researcher might

not know. This lack of research process clarity contributed to the large amount of irrelevant

information recorded by some participants (5/15, 33%). One participant talked about food and

eating more often than her medication process.

Participant challenges. Other challenges involved participant factors. The researcher

had difficulty contacting some participants by telephone. Participants were not always truthful.

One patient took credit for authoring her medication list on her computer when her provider had

developed the list for the patient. Two participants expressed depressive thoughts due to the

intense focus on their medications ("I realized they are between me and death" [70/M/patient]). Others

expressed that they did not like the way they looked or sounded ("That was a fat face." [66/F/patient])

and subsequently avoided audio or video recording.

Discussion

Patient work is a growing area of interest for healthcare focused HFE research. Data

collection challenges "in the wild" present numerous barriers given the uncontrolled, messy

context of patient work. The findings from this pilot suggest digital diaries can be one effective,

efficient, and satisfactory field research method to gather patient work data. Diary recordings

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were rich in detail and the method did not impose undue burden on participants or researchers.

Patients in this study reported personal benefits from participation in the research process.

Evaluation of Effectiveness, Efficiency, and Satisfaction

Effectiveness was measured by the method's ability to capture rich, detailed data about medication management work system barriers and facilitators. Karsh et al. [283] defined work system barriers and facilitators of healthcare professional work. Comparing results to the barrier/facilitator categories defined by Karsh et al., the digital diary data collection method elicited detailed categories specific to patient work (See Table 6-7). Several categories are notable. First, patient medication management work depended more on cognitive than physical abilities. Many patient work barrier/facilitator categories involved collaborative, team, and interactional attributes of patient work. Some patients were hesitant to speak up to providers about disagreements they had about their medication regimen due to the hierarchal nature of the patient-provider relationship, or fear of being labeled a "bad patient.". Barriers related to communication, coordination, and integration of care were prominent patient medication management work barriers. Developing relationships with healthcare professionals such as pharmacists were important facilitators. Other research has noted the cognitive, collaborative nature of patient medication management work [360]. These results also emphasize the importance of strategies, tools, and technologies to successful medication management. We can conclude that the method was effective in capturing detailed patient work system data.

Table 6-7. Barrier and Facilitator Category Comparison

Category	Current study	Karsh et al. 2006
Patient	- Attitude towards medications - Cognitive limitations + Experience, knowledge - Difficulty speaking up + Anxiety	+ Skills, knowledge training, education + Size, weight, reach strength + Physical abilities +/- Needs, biases, beliefs, mood

	- Hopelessness	
Task	+ Use of multiple strategies	- Task demands, complexity, difficulty
	- Negative effects of medications on life & health	+/- Time and sequence demands
	- Negative effects of non-adherence on life & health	
	- Precision requirements	
	+ Regimen stability	
	- Cost of medications	
	- Irregular timing	
Tool	- Lack of portability	+ Availability of usable technology
	- Lack of clarity, feedback	+/- Technology
	+ Appropriate for patient task	functions/features
	+ Reduces time and effort	
	- Not up to date	
	- Lack of permanence, durability	
	+ Adaptable	
Organizational Environment	- Non-routine schedule/events	+/- Policies, priorities
	- Communication/Coordination Difficulties	+/- Organizational structure
	- Insurance rules	+ Extra-organizational rules, standards
	+ Availability and use of organizational tools	+ Financial resources
	+ Mail order prescriptions	+/- Management structure
	+ Automatic refills	+/- Rewards structure
	+ Secure messaging	+ Training provided
	+ Healthcare system integration	
	+ Support from healthcare professionals	
	+ Medication samples	
	+ Strategies support	
	+ Medication information	
Social Environment	- Judgement of others	+/- Social norms and pressures
	+ Social support	+/- Social climate/culture
	+ Relationship with pharmacy/pharmacist	+ Staffing levels
	- Influence of TV ads	+/- Industry social influence
		+/- Industry workforce characteristics
Physical Environment	- Lack of bathroom facilities	+/- Physical layout and geography
	- Resources distances (pharmacy, provider)	

The method was able difficult to capture work system attributes of such as time and invisible, articulation work. The semi daily recording of real behavior added a time dimension

not commonly captured medication adherence research. Also, documenting activities in real elicited some of the automatic, skills level work that patients may not remember to talk about in interviews.

Efficiency of the method was demonstrated through survey results, digital diary transmissions, and interview comments. Patients reported the method as requiring little time and effort. Other diary studies struggled with the burden of the method on participants [384, 389, 406]. The tablet recorded and transmitted recordings with a minimal amount of effort on the patients' part when the technology itself was not a barrier.

Satisfaction using the method was also demonstrated. Other research has shown older adults enjoyed participating in photo diary studies [147, 410, 411]. Participants mentioned the satisfaction derived from helping other patients and "giving back" to their provider. Other studies similarly found altruism and gratitude as a strong driver of research participation in older adults [147, 412] and they were hesitant to criticize providers.

Patient Work Data Collection Challenges

This pilot study demonstrated that a digital diary method addressed several patient work data collection challenges and mirrored advantages and disadvantages reported in other diary studies. The method mitigated some of the logistical and privacy challenges reported in field studies involving patients [147, 383, 410, 411]. More than half of patients preferred not to be interviewed in their homes. Choice of interview location enabled patients to control personal space access. Real time recordings enhanced the credibility and quality of data, an advantage reported in other diary research [413]. Validation opportunities with repeated contact between the researcher and the participant also enhanced credibility. The short time frame and frequent researcher-participant contact mitigated difficulties with motivation and engagement. Other diary

studies reported high levels of participant commitment and motivation as a barrier to method use [389, 404]. Socially desirable responses were more difficult to maintain over the course of a week, exampled by the participant who initially expressed how easy medication management was and in the next recording spoke of the "hassle" and his distaste for taking medications. Other research reported diary methods as effective in gathering variability within and between individuals [385, 403]. Participants revealed sensitive information such as cost and inconvenience related to non-adherence during interviews. Underlying attitudes were revealed in audio recordings that may not be expressed in face-to-face interactions. These advantages are documented in other research using diary data collection methods (See Table 6-8).

Table 6-8. Literature Review - Advantages and Disadvantages of Diary Data Collection Methods

Advantages	Disadvantages
• Ecological validity, captured during or close to real experience **[403]**	• Participant burden [384, 389, 406]
• Reduction in retrospective bias **[413]**	• Motivational issues [404]
• Allows for the study of processes that underlie behavior **[414]**	• Requires a high level of participant commitment [389]
• Captures situational context **[387, 389, 413]**	• Omissions – participants may not capture all events when they occur (event-based) [385, 417]
• Captures longitudinal variability and relationships **[385, 403]**	• Reactivity – events altered by the process of data capture [404]
• Allows the capture of multi-level data and interactions (e.g. person, day, event, team) **[389]**	• Participant confusion about what data to capture [391, 396, 410]
• Resource efficiency **[385]**	
• Minimizes the effect of the observer **[410]**	
• Can be used when observation is not possible or impractical **[415]**	
• Useful structure for interviews **[416]**	
• Participant enjoyment **[410]**	

Digital Diary Challenges

This pilot study also encountered diary method challenges. This pilot gave participants wide freedom in terms of what, when, and how to record information due to the exploratory nature of the pilot. Some participants recorded large amounts of information unrelated to medications. Some patients had a limited perception of medication management activities, focusing primarily on administration and not considering other tasks such as obtaining refills, gathering information, or communicating with pharmacies as part of the process. Other diary studies reported confusion about what to record and omissions [385, 391, 396, 410, 417]. Activity omissions and the inconsistent data across participants is also a reported disadvantage of diary method use [385, 417]. Clearer event definitions or the use of time-based data sampling such as Ecological Momentary Assessment methods [404, 405] may improve the consistency and comparability of data across patients.

Recommendations

As a data collection method, the experience of this pilot study resulted in some recommendations for other researchers interested in using digital diaries to capture the health work of patients. Table 6-9 documents these recommendations.

Table 6-9. Recommendations for Future Digital Diary Research

• **Computer experience and self-efficacy:** Other diary methods had participants use disposable cameras to capture their experiences, however, data was not available in real time for analysis prior to interviews [410]. The trade-off to acquire immediate access to transmitted digital data is a minimal level of participant computer skills and computer self-efficacy for success. In a similar population Holden et al. [113] reported 30% of older participants did not own computers or have computer skills. A screening survey prior to recruitment such as the Computer Self-Efficacy Scale [418] may be useful.

- **Clear action feedback from device:** Feedback when the device was recording, when instances were successfully recorded, and when recordings were sent was unclear causing participant confusion and frustration. Also, navigation between screens was unclear. Any device chosen for digital diary recordings needs to have clear feedback: (1) when the device is recording, (2) when an instance was recorded, (3) functionality to enable reviewing of recordings, (4) and clear screen navigation options.
- **Clear event or time definition:** Patients in this study were sometimes unclear about what activities to record and a limited perspective about what activities were considered "medication management." Participants need clear event or time definitions of when and what to capture. Ecological momentary assessment (EMA) [404, 405] may be a useful method to augment event or time captured data. EMA could reduce the confusion about what to capture and avoid the need for lengthy instructions.
- **Partner with healthcare providers and staff:** In this study, partnering with a provider facilitated recruitment of participants. Over half (64%) of participants contacted agreed to participate. Considering the technology involved, the older population, and the somewhat unfamiliar nature of the data collection process, this was a notable recruitment percentage. Others research has emphasized networking as important in gaining access to participants in healthcare settings [419].
- **Encourage assistance from family members:** Family members assisted some of the participants with recordings which eased the anxiety and burden of the diary collection method.
- **Flexibility:** Communities and homes are uncontrolled environments. Research does not always go as planned and building flexibility into the diary protocol is necessary.

There were several limitations to this study. By design the small sample size limits generalizability of results, but this study was intended as a pilot study prior to the application of the method to a larger sample. Also, the participants in this study were from a single medical center, recruited from a single provider's patients, and from one geographic location. An

assessment of the time of day digital diary media was sent was not possible due to the limitations of data transfer speeds over cellular networks. Therefore, some interviews were not informed by digital diary data. Some participants struggled significantly with the technology and the quality of data received from these participants was not high. Researcher interactions with participants in the form of phone calls during the data collection process is a potential source of bias. Data was coded by one researcher although coding discussions with exemplars regularly took place.

Implications

The digital diary method has a potentially wide applicability across a range of ages, diseases, income levels, and ethnic groups. This method could be very useful in capturing observational data in difficult to reach populations such as children, low income adults, and older adults. The credibility and quality of data is improved as data is recorded in real time by the participants themselves in the comfort of their usual environment. Participant consequences were enjoyment, a positive feeling of helping others, and greater insight into their own behavior. Patient involvement in the research process is a form of patient engagement and may have therapeutic consequences. More research in application of this method are needed to further adaptions to the requirements of patient work capture.

CHAPTER VII

IMPLICATIONS FOR RESEARCH TRAJECTORY

The goals of this dissertation were to explore the structure and process elements of the medication management work system of older adults with heart failure and to pilot test a method to gather work system data for future research. This knowledge can inform the design of tools and technologies to improve the performance of patient medication management and guide future patient work research efforts. There is an urgent need for this knowledge as the scope of healthcare performed by patients expands and the population of older adults grows beyond the capacity of the healthcare system to absorb. The costs of medication mismanagement to the healthcare system, society, patients, and their families will continue to demand available resources. Low cost paper or technology tools require few healthcare human resources, can be applied widely across populations, and are cost effective. In older adults, cognitive, perceptual, and physical limitations can reduce the effectiveness of purely educational or motivational interventions. Optimizing the work system is therefore a valuable focus for future research aimed at improving the performance of patients.

Gaps to Address

Although patient work is a growing interest in HFE healthcare community, there is currently little research directed towards understanding the medication activities of patients in context. This lack of evidence has led to the development of ineffective technologies that impede rather than support medication management processes. Many current frameworks to guide research are adapted from the work of healthcare professionals and require modification to include attributes of patient work and new research findings. Further development of data collection tools applicable to broad, diverse patient populations is needed to generalize findings

beyond a small local population and specific health condition. There are many questions to answer in the growing field of patient work research including those resulting from this work.

Each chapter in this dissertation highlighted an element of the sociotechnical system of patient medication management with implications for future research and system design. Chapter two examined performance shaping factors that influenced error and violation events. These results illustrated a dynamic systems model of medication management where patients drift between safety, risk, and harm. This research suggests the need for research aimed at improving performance – e.g. defining safe boundaries of medication use, rather than focusing only on extreme cases of the chronically non-adherent. Chapter three highlighted the collaborative and cognitive nature of medication management and suggests the need for systems, tools, and technologies to facilitate the co-production of care. Chapter four analyzed the use of cognitive artifacts by older heart failure patients and found patient tools designed for healthcare providers rather than patients and a lack of tools to support the collaborative nature of medication management. Chapter five examined medication management strategies and highlighted the importance of strategies to the successful medication management. Chapter six pilot tested a method that addresses many of the current challenges to the collection of patient work data.

Short Term Research Trajectory

My first goal is to further refine the digital diary method and expand the pilot research include a larger sample from diverse locations health systems. Expanding the study of patient medication management beyond heart failure patients is also a priority.

Long Term Research Trajectory

The application of team models as frameworks to guide research aimed at improving the collaboration between patients, families, providers, and health systems is a future avenue for

research. Effective or ineffective team functioning such as sharing information may have impact the effectiveness of medication regimen optimization. The understanding of roles between team members and the building of a shared mental models between diverse health team members is important to overall team functioning. Considering the patient as an active member for the health team poses many interesting new areas of research. Further expanding participatory research and the inclusion of patients in the research process is another priority for future research.

The relationship between expertise, engagement, and non-adherence to treatment is an important are for future research. Increased engagement and expertise in some patients may increase non-adherence to medications as patient's feel capable of modifying their own treatment. Are engaged patents more or less likely to adhere and what are the effects on medication performance and outcomes? There are many questions to answer.

Contributions to Science and Nursing

The results from the five studies produced several overarching themes valuable to science and nursing. First, patient work in many ways has more in common with professional work than previously assumed, and likely could benefit from the same tools and research methods used in professional work settings. Patients strived to control their system and achieve goals; they are not simply adherers/non-adherers and followers of directions. This involves moving beyond adherence as the primary goal of interventions but rather the optimization the work system for that patient. Second, patient work is distributed and collaborative. Patient work does not occur in isolation but in combination with the work of health professionals and family members. Interventions, tools and technologies must include the collaborative nature of patient work. Third, modifying the task or the environment may be a more effective in the long term than modifying the person. This emphasizes the potential role of tools and technologies as a strategy

to improve patient medication performance and directs focus away from the individual patient as the source of the problem. Fourth, in adapting to constraints, patients are often unsure of the boundaries of safety. When goals conflict, those boundaries are tested, increasing the risk of harm to the patient. This research found even one instance of non-adherence can result in harm. This has major implications for the kind of interventions required—i.e., improving performance for all patients rather than targeting only the chronically non-adherent. Last, patients and research benefits from patient participation in the research process. Including patients and communities in research facilitates a mutually beneficial partnership with untapped potential in moving the understanding of patient health activities and the design of supportive systems forward.

Nursing as a profession can benefit from the incorporation of HFE theories and methods into research and new model and framework development. Expanding the domain of nursing interventions to include the design of tools, technologies, processes, and environments is within the scope of nursing practice and yet an untapped means to improve patient performance and outcomes. HFE models and theories are truly patient-centered, reflecting the values and priorities of nursing as a discipline. They also further move the paradigm beyond the "patient as the problem" and towards a systems-focused perspective.

APPENDIX A

Results of Literature Review – Patient Work

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
Medical, Nursing, Sociology									
Self-care, Self-management									
Corbin & Strauss 1985 [3]	Sociology Nursing Trajectory of Chronic Illness Theory	Describe what is involved in the work of managing illness	Qualitative Unit of analysis: patient/ caregiver dyads	60 patient caregiver dyads with various chronic diseases	Unstructured interviews, Grounded theory analysis	1. Planning 2. Monitoring work performance workflow, problems and complications; 3. Distributing tasks 4. Prioritizing 5. Information work 6. Establishing routines 7. Making arrangements 8. Securing, allocating, and maintaining resources 9. Managing time 10. Scheduling, pacing, fitting together; and the juggling.			1. Illness involves trajectory that changes over time. 2. Context and process interact to produce consequences that upset balance. 3. Strategies are used to maintain equilibrium.
Granger et al. 2009 [21]	Nursing Trajectory of Chronic Illness Theory		Qualitative description Unit of analysis: patient/ provider dyads	6 patient-physician dyads	Structured interviews Directed content analysis	1. Learning new information 2. Remembering medicines 3. Thinking and acting in response to symptoms 4. Attending appointments 5. Sharing responsibilities 6. Monitoring 7. Deciding when to report symptoms 8. Changing behaviors 9. Reliably participating in the ritual of the regimen.	1. Lack of knowledge of strategies to perform tasks		1. The work of adherence is cognitive. 2. Patient knew what but not how to perform tasks. 3. Requires 2-3 people to accomplish the patients' work.
Willems et al. 2006 [420]	Medical Trajectory of Chronic Illness Theory	To identify the work involved in end-stage heart failure	Qualitative, Longitudinal Multiple Case Study	31 heart failure patients	Structured Interview	1. Organizing medicines and other aspects of care. 2. Balancing demands of treatment and lifestyle, rules and routines 3. Conserving energy 4. Managing resources	1. Fatigue		Following regimens is hard work for patients.
Ryan & Sawin 2009 [74]	Nursing Individual and Family SM Theory	To identify gaps in the science of SM and present a descriptive mid-range SM theory.	Literature Review			1. Enhancing knowledge and beliefs (self-efficacy, outcome expectancy, goal congruence) 2. Regulating skills and abilities			Combines individual and family perspective of self-care into "system."

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
						(goal-setting, self-monitoring, reflective thinking, decision making, planning and action, self-evaluation, emotional control) 3. Social facilitating (i.e., influence, support, collaboration).			
Lorig and Holman 2003 [421]	Sociology	Describe the historical development of SM	Literature review			1. Problem solving 2. Decision making 3. Resource utilization 4. Formation of a patient–provider partnership, 5. Action planning 6. Self-tailoring			Teaching skills improves SM through perceived self-efficacy, improvement in motivation.

Schulman-Green et al. 2012 [422]	Nursing	Describe processes of SM in chronic illness.	Qualitative Systematic Review	101 studies of SM	Meta synthesis of studies done between 2000 and 2011	1. Focusing on illness needs
						  a. Learning
						  b. Taking ownership
						    i. Recognizing managing responses
						    ii. Completing tasks
						    iii. Becoming expert
						  c. Health promotion
						2. Activating resources
						  a. Healthcare,
						  b. Psychological
						  c. Spiritual,
						  d. Social
						  e. Community
						3. Living with chronic illness
									There has not been a comprehensive exploration of self-management from the perspective of individuals living with a chronic illness.

Bayliss et al. 2003 [423]	Medical	Identify perceived barriers to self-care among patients with comorbid chronic diseases	Qualitative	16 adults with 2 or more chronic condition	Semi structured interviews		1. Compound effects of conditions. 2. Physical limitations 3. Compound effects of medication 4. Schedule and coordination of medication 5. Side effects 6. Burden of medications 6. Lack of knowledge 7. Financial constraints 8. Low self-efficacy 9. Inadequate communication		Self-management interventions may need to address interactions between chronic conditions as well as skills necessary to care for individual diseases.

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
							10.Lack of social support		
Moser & Watkins 2008 [424]	Nursing	Identify barriers to self-care decision making in heart failure	Literature review				1. Cognitive impairment 2. Comorbidities 3. Low functional status 4. Sensory impairment 5. Low-Level pro-inflammatory state 6. Depression, anxiety 7. Lack of control 8. SES 9. Lack of social support 10. Health literacy		1. Researchers have not thoroughly examined the role of decision-making in self-care. 2. Lack of systematic research. 3. Lack of comprehensive and multi-dimensional viewpoints.
Bennett et al. 2000 [425]	Nursing	Identify self-care strategies to detect symptoms in heart failure patients	Qualitative	23 heart patients 18 family members	Focus groups			1. Changing the level of physical activity 2. Waiting 3. Completing activities at a slower pace 4. Resting staying quiet 5. Changed the schedule or skipped a dose when leaving the house 6. Pillboxes 7. Medications prepared before needed 8. Carrying an extra dose of medications carried at all times 9. Measuring and recording weight, BP	Patients use a variety of strategies to cope with symptoms.
Human Factors, Informatics									
Older Adults									
Mitzner et al. 2013 [382]	Human factors Capabilities Limitations Self-efficacy Control	Describe SM within the context of aging	Literature Review			1. Goal selection 2. Information collection and interpretation, 3. Decision making, 4. Action 5. Coordination between components of the care network	Barriers 1. Healthcare Demands 1. Technology Demands Resources 1. Abilities (motor, perceptual, cognitive, literacy and numeracy) 2. Socio-emotional (self-		Critical need to develop tools for self-management.

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
							efficacy and control; motivation; attitudes; stress, perception of risk 3. Care network, social support, technology		
Klein & Lippa 2008 [112]	Human Factors Macrocognition Control Theory	Investigate cognitive barriers to control in Type II diabetes	CTA	18 adults with type II diabetes	Critical incident interviews	1. Problem detection 2. Sensemaking, 3. Decision making, 4. Planning/ re-planning.			1. Dynamic control challenge requiring complex processes, including the mismatch between most patient training and the dynamic demands.
Rogers, Meyer, Walker & Fisk 1998 [426]	Human Factors	Factors that impede ADLs	Qualitative	59 older adults	Focus groups		68% Cognitive or physical factors 26% Environmental	1. Stopping the activity (51%) 2. Perseverance (22%), 3. 3. Using tools or altering the environment (21%).	Older adults need tools to support the accomplishment of ADLs.
Clark, Czaja, & Weber 1990 [90]	Human factors	Demonstrate human factors techniques in analyzing performance of daily living activities. Focus on physical tasks	Ethnographic	60 older adults living at home	Video and audiotaped activities Task analysis	Problems in performance 1. Lift/lower and push/pull movements are the most frequent motions performed 2. Standing	1. Task Demands		Older adults need tools to support the accomplishment of ADLs.
Invisible Work									
Unruh & Pratt 2008 [95]	Informatics	Uncover the invisible work breast cancer patients	Longitudinal	18 breast cancer patients	Interviews, Survey Critical incident interviews Patient diaries Photos	1. Obtain and maintain state awareness 2. Bridge inter-institutional care 3. Manage dependencies 4. Resolve inconsistent information	1. Unclear communication channels a. Lack of responsiveness b. Ambiguous answers and information gatekeeping c. Duplicate effort 2. Lack of Integration a. Variations in organizations. b. Lack of		1. Patient work occurs in reactive bursts. 2. Consumes patient resources 3. Difficult to study 4. Requires cooperation with patients Recommendations 1. Common information spaces 2. Ease the work of collaborating with HCPs through explicit representations

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
							procedural information c. Inefficient communication 3. Managing Dependencies a. Discover dependencies during emergent events, with no time to plan in advance 4. Resolving inconsistencies a. Lack of explicit justifications for clinical recommendations b. Lack means to discuss details of competing recommendations		
Oudshoorn 2007 [96]	Sociology	Examine the role of patients in a tele-monitoring application	Mixed Methods	65 patients that completed EKG monitoring	11 semi-structured interviews Survey		1. Capture the right moment to record without clear guidance 2. Become diagnostic agents and trust their own abilities t make choices. 3.Shift responsibility to patient becomes observer	1. Patients used EKG recorder as a tool to gain mastery of the situation they faced	1. Need to help patients become diagnostic agents.
Information, Articulation Work									
Piras and Zanutto 2010 [99]	Informatics CSCW	Describe the management of personal	Qualitative	32 families	Semi-structured interviews	1. Organization and transportation of documents to appointments as		1. Crossroads 2. Archives 3. Archives-in-use	The findings emphasize the flow of documents that

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
		medical documentation				expected by providers 2. Annotations important to patient understanding 3. Use of spaces in the home to organize health information 4. Management of emotional meaning health documents represent			patients use and how documents have emotional value to patients, which has an impact on patients' information management work.
Moen & Brennan 2005 [97]	Human Factors, Nursing	Explore health information management in the home through the lens of the primary self-identified information manager	Task Analysis	49 Information managers in a household	Interviews, questionnaire, Artifact collection, Photographs Content analysis Task analysis	1. Observing, assessing, and surveying household members health conditions 2. Organizing, separating, and differentiating information types according to perceived importance or relevance 3. Obtaining, retrieving, and keeping track of health information according to household needs		Storage Strategies 1. Just-in-time 2. Just-at-hand 3. Just-in-case 4. Just-because	Laypeople develop robust, complex strategies to store health information or artifacts guided by how they think they might use the information in the future.
Klasnja, Hartzler, Unruh, and Pratt 2010 [427]	Informatics	Describe unanchored work activities of patients to inform design	Ethnographic	15 Away from home breast cancer patients	In home interviews, Clinic observations Telephone interviews Context analysis	Unanchored Information work 1. Information capture 2. Information retrieval.	1. Diminished attention 2. Lack of familiarity, 3. Necessity for mobility 4. Inadequate work environments		Unanchored information activities are difficult, and patients have few tools. There is a need design guideline to help patients with this work.
Unruh, Skeels, Civan-Hartzler, & Pratt 2010 [428]	Informatics	Observe information exchange work in clinic and describe barriers	Ethnographic	14 breast cancer patients Clinic	In home interviews, clinic observations telephone interviews		1. Awkward physical positions 2. Bursts of information exchange 3. Separation from information artifacts 4. Lack of advance information 5. Heightened stress inhibit capacities to access, use, learn, communicate, and remember informatio		Clinic environments do not help patients with information work – more research and development of tools are needed.

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
							n effectively		
Unruh & Pratt 2008 [429]	Informatics	Uncover barriers to information management	Qualitative	18 breast cancer patients in homes	35 in-depth interviews, 17 surveys, 227 critical incident interviews, 49 PHI reviews Photo diaries.		1.Emotional responses to information 2. Amount of information 3. Lack of time 4. lacked an understanding of how to use that information in the future		1. Prevent unorganized collections from accumulating through electronic tools. 2. Leverage assistance from others. 3, Incorporate emotion into research and design.
Chen 2010 [430]	Informatics	Information crucial to patients, ways patients use health information to direct disease management	Qualitative	29 patients with Type II diabetes	Interviews Clinic observations	1. Understanding typical life routine 2. Accommodating atypical activities 3. Disproving & discovering healthy tips 4. Reevaluating personal expectations		Information derived from outside sources and experience	1. HIT must address physiological, social and psychological activities within the process of disease management. 2. Account for individual differences, encouraging positive patient involvement.
Self-Management Work									
Storni 2013 [62]	Human Factors	Look at what diabetics really do in dealing with their condition, and not necessarily at what they are supposed to do from an academic perspective to inform design of technology	Ethnography	14 diabetic patients	Observations of support group meetings Semi-structured interviews "Shadowing" at home	1.Diabetes is a lifestyle, not just a disease 2. Different diabetes for different people 3. Limitation of treatment to the biomedical aspects of the disease and not social		1. Journaling to keep track of values	
Lippa, Klein, & Shalin 2008 [364]	Human Factors Control Theory	To assess the relationship between decision making and successful SM to support the design of interventions	CDM	18 adults with diabetes	Critical Incident interview	Expert versus novice differences 1. Problems detection (detected more cues) 2. Knowledge of functional relationships 3. Problem solving		1. Problem solving strategies	
Klein & Lippa 2008 [112]	Human Factors Control theory Macro-cognition	To understand the interplay of rules, functional relationships knowledge, and adherences as an expression of expertise	CTA	12 adult patients with Type II diabetes	Critical decision interviews	Macrocognitive Processes 1. Sensemaking 2. Problem detection 3. Decision-making 4. Planning			
Zayas Cabon 2009	Human Factors	To provide a holistic framework	Literature Review				1. Physical: reduced vision, hearing,		Macrocognitive functions must be considered in the design of

Author	Perspective Theoretical	Purpose	Design	Sample	Method	Work Processes	Barriers Resources	Strategies Tools	Conclusions
	Macro Cognition	for design and/or evaluate CHI interventions.					motor function 2. Cognitive: lack of training, diminished perception, attention, memory 3. Communication low health literacy, language		technology for consumers. Approaches such as task analysis, function analysis, and flow charting can help designers understand health workflow.
Thompson, Hickson, & Bums 2003	Human Factors Ecological Interface Design	Design and implement mobile and desktop information displays for insulin-dependent (Type 1) diabetics and their health care team.	CWA	Human physiology textbooks, Anatomical charts, Scientific papers and diabetic patient teaching resources	Work domain analysis (WDA)	Physiologic Processes Anabolic and Catabolic processes	Feedback from system difficult to continuously measure by the patient (blood sugar)		1. Patients think of the system from a very high level whereas medical professionals may think of the system from a more detailed point of view. 2. WDA may have limited use in designing displays for patients.

Results of Literature Review – Patient Medication Management Work

Author Year	Theoretical Perspective	Purpose	Design	Sample	Methods	Work Processes	Barriers Resources	Strategies Tools	Conclusions

Swanlund et al. 2008 [79]	Nursing
	
	Orem's (2001) self-care deficit theory
		To explore medication SM as perceived by community-dwelling elderly.	Qualitative	19 older adults with chronic disease	Interviews	Self-Managing
						1. Establishing habits
						2. Adjusting routines
						3. Tracking, simplifying, valuing medications,
						4. Collaborating
						5. Managing costs
						6. Living Orderly
						  a. Ordering and Organizing routines
						  b Integrating Medications into daily life
						7. Aging well
									Successful medication management involves ability to be organized and age well.

Swanlund 2010 [320]	Nursing	Identify perceived medication management strategies in older adults.	Qualitative Naturalistic inquiry	27 older adults in an independent living facility	Interviews		1.Decreased mental or sensory alertness 2. Out-of-routine 3. Not feeling well/falls 4. Complicated routine 5. Decreased gross or fine motor ability	1. Simplification 93% 2.Visual and tactile cues 78% 3. Routine 74% 4. Knowledge and education 40% 5. Mental alertness 30% 6. Determination 15% 7. Caregiver set-up 15%	
Bajcar, 2006 [431]	Pharmacy Trajectory of Chronic illness	Describe medication-taking tasks and how these tasks relate to patients' medication information needs	Qualitative CTA	10 patients aged 18-65 on at least one long term medication	Semi-structured interviews Grounded theory Task analysis	1. Making sense of medication taking 2. Medication-taking acts 3. Mediation-taking self-assessment			Participants self-regulate their medications, with and without their physicians' knowledge.
Ryan & Wagner 2003 [340]	Sociology	Explore contextual factors that lead to episodic non-adherence	Qualitative	27 AIDS patients	Interviews		1 Away from home 2. Not morning 3. Unpredictable social life Resources 1. Routine		Routines facilitated medication adherence.
Knafi & Reigal 2014 [332]	Nursing	Assess condition and patient factors and interactions	Prospective cohort	242 heart failure patients	1 medication MEMs over 6 months Patient diaries Survey		1. Higher number of comorbid conditions 2. Higher total number of daily medicines 3. Older age with poorer sleep quality 4. Fewer months since diagnosis		Newly diagnosed, with comorbid conditions, poly pharmacy, and poor sleep are at risk for poor medication adherence.
Mickelson & Holden 2013 [105]	Human Factors Nursing	Describe the distribution of medication tasks across people and artifacts.	Qualitative	30 older heart failure patients	Interviews Observation Survey Medical record review				

Author Year	Theoretical Perspective	Purpose	Design	Sample	Methods	Work Processes	Barriers Resources	Strategies Tools	Conclusions
Hickman et al. 2006 [338]	Human Factors	Explore the nature of communication problems older adults experience in the context of healthcare communications.	Qualitative	24 older adults 65 to 80 years old	Structured Interviews		1. Difficulty comprehending verbal information (54%) 2. Difficulty seeing and hearing (29%) 3. Difficulty remembering (21%).	1. Ask for written instructions was the most suggested strategy (46%) for comprehension related problems in a high severity situation 2. Clarification was the strategy in a low severity situation (58%).	
Morrow et al. 2007 [116]	Human Factors	Develop an external support to reduce the cognitive load involved in collaboration with providers.	RCT Outcome: problem-solving performance	64 community dwelling older adults.	Simulation of tasks with 3 conditions: Med table Blank paper No support			External representations	External representations assisted older adults in collaborative process
Nichols, Sanchez, & Mitzner 2004 [353]	Human Factors	Describe the relationship between memory strategies in older adults	Cross sectional		Survey	Prospectively remembering to take medications	1. Internal resources 2. External resources		
Vedhara et al 2004 [432]	Human Factors	Describe the relationship between habitual prospective memory (HBM) and medication adherence	RCT Longitudinal 10 days	48 diabetic patients	Electronic dose event monitors	Task conditions: 1. No cue 2, Visual cue, 3. Auditory cue 4. dual cue (auditory and visual cue)			HPM task performance was optimal in the dual cue condition
Boron, Rogers, & Fisk 2006 [258]	Human Factors	Describe strategies used by older adults to remember their medication	Cross sectional	366 older residents in large southeastern city	Survey	Prospectively remembering to take medications		Location Visibility Association Pill caddy Mental Planning Physical Pain Physical reminders (alarms)	
Sanchez, Nichols, Mitzner, Rogers, & Fisk 2006 [354]	Human Factors	Explore if strategies were adopted from external sources or whether they were self-generated.	Qualitative	9 older adults	Interviews		Barriers 1, Atypical conditions 2. Early in treatment Resources 1. pill caddy	1. Association 2. Location 3. Visibility 4. Retrospective reminder 5. Physical symptom	The strategy in which there was the highest number of non-adherence instances was location. All reported episodes of non-adherence.
Sanders & Oss 2013 [433]	Nursing	How do older adults taking four or more medications remember to take medications	Qualitative	149 older adults taking more than 4 medications	Semi-structured interviews			1. Associate with waking up, meals and bedtime	
Haverhals et al. 2011 [121]	Pharmacy	Elucidate the medication self-management needs and strategies of older adults and their adult caregivers that could be addressed through	Qualitative	32 older adult patients and 2 adult family caregivers	Semi-structured interviews	1. Seeking reliable medication Information 2. Maintaining autonomy in medication decisions 3. Worrying about taking too many medications			PHA should 1. Provide links to authoritative and reliable information on side effects, drug interactions, in a way that is clear, concise, and easy to navigate 2. Facilitate communication between patients

Author Year	Theoretical Perspective	Purpose	Design	Sample	Methods	Work Processes	Barriers Resources	Strategies Tools	Conclusions
		effective Personal Health Application design				4. Reconciling information discrepancies 5. Tracking and coordinating health information between multiple providers			and doctors and pharmacists 3. Provide patients the ability to selectively disclose medication information.
Ozok, Patel, Wu & Gurses 2011 [39]	Human Factors	Understanding the medication adherence related practices and barriers in older adults. Determining the feasibility of introducing a medication adherence technology.	Cross sectional	65 older adults living independently and taking at least one medication per day	Survey			1. Developing a medication routine 2. Location 3. Cues 4. Time 5. Self-deployed external tools (pillboxes)	The kitchen area is the primary medication storage location. A stationary technology connected with speakers, directing the older adults to the kitchen to take their medications can be one sample technology solution and time released pillboxes
Klein & Meininger 2004 [115]	Human Factors Control theory	1.Compare standard paper based written instructions to human factors based design 2. Describe how diabetic patients are educated	Mixed methods	62 college students 41older adults age 58-87yrs 39 retail pharmacy customers	CDM interviews Process tracing	.		1. Medication information sheets 2. Procedural and medical models of educating patients	1. Many problems with mediation adherence stem from the difficulty understanding poorly written information. 2. Patients should be taught to understand medication adherence as a function of balance and control, not rules and procedures
Verdezoto & Olsen 2012 [341]	Computer science	Describe the design of a personalized medication management system (PMMS) to support senior citizens at home.	Review	120 compliance technologies			1. Takings medications more frequently 2. Forgetting 3. Lack of knowledge	1.Do something special to remember their medicine 2. Take their medicine in connection with meals 3. Have a visible medicine stored 4. Pill dispensing box system	1. 34% unintentionally non-compliant 2. 23% intentionally noncompliant. 3. Non-compliance increases with frequency 3. The intentionally non-compliant have greater need for information 4. Recommend participatory design methods
Chiou et al. 2014 [259]	Human factors Prototype development	Identify cognitive and emotional challenges of self-managing complex medication regimens		4 Older adults	Contextual Inquiry	1. Empowerment in health and lifestyle, 2. Separation of medication, 3. Strategic placement of memory aids 4. Need for timely medication information 5. Coordination		1. Patients checked number and look of pills before administration 2. Adapted medication regimens to routines 3. Relied more on memories and	

Author Year	Theoretical Perspective	Purpose	Design	Sample	Methods	Work Processes	Barriers Resources	Strategies Tools	Conclusions
						between self and care network, 6. Work environment conditions.		habits than technology 4. Motivation through empowerment 5. Stored meds out of sight near a water source 6. Objects served as reminders	
Palen and Aaløkke 2006 [260]	Medical Sociology	Describe how elders manage their medication with the objective of informing the design of in-home assistive health technology to support "medication adherence"	Qualitative	10 older adults 66 to 88 years old	Ethnography Photos	1. Process involves socially distributed cognition. 2.Structure of home and temporal rhythms help with planning, organization and prospective remembering		1. Medication knowledge is embedded in environment, physical features of medications	They conclude that the participants use their home infrastructure of spatial, temporal relationships to form a home distributed cognition; elders also had computers installed in their homes to document medication intake and other health measures.
Aarhus, Ballegaard, & Aaløkke 2010 [434]	Medical Sociology Boundary framework of Nippert-Eng (1996)	Explore strategies patients use to establish boundaries for medications for technology development	Case study Participatory design	Qualitative	Ethnography Content analysis Grounded theory	Balance between visibility/invisibility and segmentation or integration	1. Seriousness of a condition, comorbidities effects if can integrate, segment, disclose or hide 2. Invisibility may interfere with medication adherence (no visual cues) 3. Segmenting may influence desire to carry medications outside of the home.		Flexibility of the technology should give the patient a choice in terms of mobility and appearance of where to place it as to maintain the order of the home.
Siek & Haverhals 2011 [123]	Human Factors Computer science	Identify requirements for the a PHR to help older adults manage medications	Case study Participatory design	4 Focus groups 2 confirm interviews 21 interviews older adults and their caregivers	User Review Expert Review Needs assessment in situ Interviews Rapid Iterative Testing and Evaluation (RITE) Instant Data Analysis (IDA)	1. Gather medication information from multiple sources depending on the urgency 2. Autonomy of their medication regime 3. Integrate conventional and alternative medications into their regimes 4. Reasons for taking too many medications.	1. Paper copies of med list from EHR cannot be altered 2. Paper medication list illegible 3. Paper medication list difficult to share 4. Paper medication list out of date 2. Forgetfulness (when and how to take)		1. Users want more functionality as they become comfortable with technology 2. Need a balance of textual and metaphor information 3.Design of PHAs for older adults should have automated mechanisms that require minimal interaction steps to perform basic medication management tasks. 4. HCPs and patient have different understandings of medication management 5. Explore PHI management issues with all the stakeholders

Author Year	Theoretical Perspective	Purpose	Design	Sample	Methods	Work Processes	Barriers Resources	Strategies Tools	Conclusions
									to avoid any preconceived notions from creeping into PHAs' design. 6. Explore target populations' different practices regarding specific PHI management tasks. The success of future PHAs will lie in their ability to correctly interpret different input permutations.

Participant quotes illustrating performance shaping factors involved in errors or error prevention. Superscripts denote the patient's age, patient's gender, and identity of the person quoted, such that [68/F/patient] is a quote from a 68-year-old female patient and [72/M/wife] is a quote from the wife of a 72-year-old male patient.

PATIENT AND TEAM

Attention and Vigilance

1. *'I never ever do his medicine in the tray with anybody around me. I just, that's something, because there's a lot of pills that are white and you just can't talk and, and, and, or do anything.'* [72/M/wife]
2. *'I've forgotten that I can remember one time and that was this one morning I got up in a hurry and having to go somewhere and, uh, just forgot it.'* [68/F/patient]
3. *'... it dawned on me I didn't have my drink in the morning, so I didn't get my morning beta blocker… I know precisely, what caused it* [forgetting] *was the change in routine, uh and uh without thinking, I only changed part of the routine, not all of it.'* [80/M/patient]

Patient Abilities and Limitations

1. *'I don't have a problem trying to remember to take my pills. That's just not a problem with me.'* [84/F/patient]
2. *'I really don't consult with it* [the medication list] *because I've been taking those so long I know what I need to take.'* [66/M/patient]
3. *'The drugstore's right up the street you know? I mean my daughters have to take me you know* [patient does not drive]. *Everybody's busy and I feel you know, I don't wanna impose on everybody's schedule and I'm staying at home all day and they working, you know?'* [72/F/patient]
4. *'You know, I mean, if you miss one of those cholesterol pills, I mean, it's not gonna kill you. It's, if every day you mix 'em up, then, you know, then, you're looking at a little problem.'* [84/F/patient]
5. *'I'll tell you what she does when she had, is having a problem breathing…She's got on these menthol cough, cough drops… and sometimes she'll take up to… Ten or eleven of them.'* [65/F/husband]

TASK

Task Complexity and Workload

1. *'I know more or less the shape and color. And of course, those can change…. white and pink are common colors… and each brand has a different color and shape…sometimes I have a hard time telling which is smaller and larger.'* [81/M/patient]
2. *'They have suggested that to me but what I try to do is get all my prescriptions primarily due, I mean at the same time so I may even wait you know 2 or 3 days before I have one filled so just so I can get them, pick them all up at the same time and if I get a new prescription I start with my crusade of trying to get that you know eventually it's gonna match up with the dates of filling the other ones.'* [66/F/patient]
3. *'*[The] *calcium has to be stored in a different place. It's easy to forget that.'* [81/M/patient]
4. *'A for example, uh, Metformin, one tablet daily, but two on Monday, Wednesday, Friday. Well, it's easy to forget Monday, Wednesday, Friday one week.'* [81/M/patient]

Strategies

1. *'… they've got all their medicines and stuff right there in the drawer, so that's the first thing they do, you know… so it's all right there when he sits at the table where he can get to everything. And that makes a difference too. You know that reminds him to do it* [take medications]. *'* 80/M/daughter
2. *'So in the morning time when I roll over… I just keep water right there by the bed because when I roll over, take the shots, then reach back and get the pills and then I can get up.'* 65/F/patient
3. *'They're both white, one's just smaller than the other. So what I'm thinking about doing is breaking the statin in half so I see the 2 half pills, put that at night so I can distinguish 'em. '* 66/M/patient
4. *'I keep all, it takes ten syringes out of the little bag and I put them in, with the rest of my in-, with my insulin and stuff and if, if I've got an even amount that means I haven't taken the morning one, but if I s-, if later on if I've got an odd amount it means I didn't take that evening medicine.'* 70/M/patient

Quality of error cues

6. *'I did, just as soon as I got home* [administered medication]. *You can tell when, when you haven't taken your diuretic. If you know by 10 o'clock if you're not going* [to the bathroom] *you need to, it kind of is a thing that reminds me. '* 68/F/patient
7. *'One time I did put a, really it wasn't a mix up except that it was something I normally take, uh, at night and I put it in the morning box, part of it… I usually take it at bedtime cause the, my blood pressure gets so low. And that's, that really makes me feel bad. '* 68/F/patient
8. *'I got ready to go to bed to take my pills, uh I took my pills and set out my morning pills separately and when I opened up the little box for my morning pills, the pills were still in there. I had missed. '* 80/M/patient

TOOLS AND TECHNOLOGIES

9. *'Also on my cell phone… I have reminders on there even you were on there today.'* 68/M/patient
10. *'It* [left atrial pressure device] *will tell you when you need to take your medicine, that way you won't forget it. '* 66/M/patient
11. *'They* [clinic] *do a print out every time we go in there… we keep that sheet current and on the counter and of course I have one folded up, but, um, uh, and, and I just about know by heart what he takes, but just not trusting my own mind I always, because it is so important look at that* [printed medication list].' 71/M/wife
12. *'I think that a lot of people are hesitant to bother their doctors and to me that's the best thing about the* [patient portal] *because you can send an email and you know that the doctor looks at it on, at their convenience. '* 81/M/wife

CONTEXT – ORGANIZATION, PHYSICAL, SOCIAL

Communication & Coordination

13. *'When I need a prescription or something I can write in* [through patient portal]. *'* 80/M/patient
14. *'I have not been taking the Glyburide, Glimiparide, uh, the uh prescription ran out and had to be refilled, there was communication difficulty between my pharmacy and my doctor.'* 66/M/patient
15. *'They gave her her old prescription instead of giving her the prescription that he called in… She* [pharmacist] *said well they faxed it in, but you still got some on the other one so they ain't never filled that new prescription that he called. '* 72/F/daughter

16. *'And like when they [*health provider] *double it* [the prescription] *they don't write a new prescription though, even though they've doubled it, cause* [then] *insurance won't pay for it if it's just been filled, you know.'* [70/M/wife]

17. *'That's something I need to talk to him about, too, about the Metoprolol. I had a doctor that increased it on me and I didn't, I've got a few, but I didn't want to start taking it.'* [70/M/patient]

18. *'I got confused one time. They gave me a prescription for one size and the drugstore didn't have that size so they changed it to something else. Instead of taking one 4mg, is it 4? I had to take two 2mg twice a day and I got confused by that.'* [70/M/patient]

19. *'It* [hospitalization] *gets my medicine all messed up because you know when I'm in the hospital they don't give me all that medicine They-they don't let me take a lot of it. But, uh. I just, but when I get home I just have to sit down and figure it out, you know.'* [68/M/patient]

Routines

20. *'I've done it so much it's just total engrained in my thinking I guess.'* [83/M/patient]

21. *'I ne-, don't even have to look at the bottles. I know I'm used to taking it. I take about; I think I take about six pills in the morning and three in the afternoon and three at night.'* [89/F/patient]

22. *'I have a few times, not a whole lotta time, but I have maybe like at night, if I lay down and rest something a little while, I might forget to take my medicine.'* [70/M/patient]

23. *Patient:* *'Or we'll go away and be away all day'*
    Daughter: *'And she'll forget to bring 'em* [medications] *with her.'*
    Patient: *'And I'll forget to bring 'em with me. And then, I'll forget 'em when I get home. I just go to sleep and forgetting about the night pills… because you come home and kind of go to sleep.'* [74/F/patient]

Social and Organizational Support

24. *'both of my daughters, they see to me take my medicine… I get it on time, and, and it's, it's, it's right and everything, you know, which it used to be, I didn't take it on, on time, you know. But now that, uh, since they, uh, is helping me with it, I do take it on time.'* [86/F/daughter]

25. *'Well, I just, and fortunately* [daughter] *lives with me so wherever I need to go, she takes me.'* [86/F/daughter]

26. *'I just go pick it up. They call when, when they say 'this is Rite-Aid, your prescription has been filled. Come pick it up.'* [75/M/patient]

27. *'I sign up for automatic refills at CVS and you know they text me when they're ready.'* [67/M/patient]

28. *'I'll weigh and I know I weigh 160 and my weights going up, then I know there's something wrong… And like this is where she* [nurse practitioner], *she told me to take the metolazone.'* [68/F/patient]

29. *'Well, one thing though, her medicine wasn't being taken properly. She was living alone and her medicine wasn't being, she wasn't taking her medicine properly.'* [86/F/daughter]

Access to Supplies and Equipment

30. *'I can drive to it and I have driven to it, but they, they will automatically deliver it, no problems at all.'* [68/M/patient]

31. *'I know like my $4 ones* [medications] *I get at* [name, pharmacy]*… I get those for 90 days. Um, the, um, the ones I get for 30 days, um, I just kind of keep a watch on it* [cost]' [68/F/patient]

32. *'I don't have my pens. I got the insulin, but the pens left over there.'* [74/F/patient]

33. *Patient:* *'Sometimes I can't even get 'em when I run out.'*
    Wife: *'His Medicare only pays once a month. So, he's gotta wait 'til the time runs out before he gets 'em or they won't fill 'em.'* [76/M/patient and wife]

34. *'The only time that we forget is if we happen to be in between paychecks and don't have the money at that time.'* 67/M/patient

35. *'And, and their mail system is not, they don't, you know. It's slow. I'll get a phone call from the computers, you know, your medication was mailed on, on the 8th of the month and uh this was the 10th of the month when I get the call. And uh I'm not going to see it until probably the 1st of the month.'* 74/M/patient

36. *'I've got about three or four extra bottles of that. They just constantly givin' me medicine, you know. And I let it pile up.'* 75/M/patient

37. *'Well, the, the one thing that I have to watch is don't run out, you know. On some medicines, uh, I can go down, shoot, my sister has some of the same medicine that I take, uh, like on the Warfarin, I, I can borrow some from there.'* 84/F/patient

38. *'... they're* [medication] *old we can't hardly see what it is. But this is what was given her originally for diarrhea and it works. We can hardly see it* [medication label].*'* 86/F/daughter

APPENDIX D

Participant quotes illustrating performance shaping factors involved in violations.

Superscripts denote the patient's age, patient's gender, and identity of the person quoted, such that [68/F/patient] is a quote from a 68-year-old female patient and [72/M/wife] is a quote from the wife of a 72-year-old male patient.

PATIENT AND TEAM
Perceived Risk
39. *'Well see I've, I've not ever really, maybe didn't have you know really heart trouble because I mean she, they, she says I had a heart attack, but I don't know that I had a heart attack, so, um, Dr. Neptune said I did, but I just don't think, uh, I don't necessarily think I did.'* [78/M/patient]
40. *'They just tell me I had it and I'm convinced I do because I've been hospitalized several times for it… I have congestive heart failure you know and I don't see any outward signs… it's a silent thing for me.'* [72/F/patient]
41. *'That was um, the meds was the biggest thing. Um, I, I guess I didn't really understand the seriousness of it.'* [72/F/patient]
42. *'But I'll tell you what, for, uh, almost 2 years, I couldn't hardly go back and forth to the mailbox. They had me on 24 pills. And I started getting rid of 'em.'* [68/M/patient]
43. *'If I'm not swelling, I'm not holding water, and I'm watching my weight on the scales then I don't take it because you know it's harder on my kidneys to take it* [concern about side effects], *so if I don't have to take something I won't take it.'* [68/M/patient]
44. *'I said I'm not giving you this much m-, uh, Lasix no more… we went back to the doctor… I told them I said y'all giving him way too much of that and then went into kidney failure. You know they just bottomed out on him.'* [72/M/wife]
45. *'Well, you know, I don't take any chances. When my oxygen gets down and doesn't come above 96, 95 or 96, I, I consider that a, uh, uh, a push a go button to do something to something* [administer medications]. *'* [84/M/patient]
46. *'When he wants to and I think the last, the last trip to the hospital scared him… that time made him pay more attention to the medication, but he, he just categorically don't like taking medications.'* [81/M/son]
47. *'I feel the-, I feel there's something, but I go try something, you know. I will try something, yeah? I taking them diuretics every day 'til I dead? No, sir. I go try something* [altering medication regimen]. *'* [81/M/patient]
Self-confidence
1. *'I said I'm gonna quit taking it and then when I get to Vanderbilt I'll see about it and all. Well Doctor name said it was not the medicine, he's never had anybody to have any trouble with it you know. Well my heart doctor here said the same thing and I-I just was for sure that it was the medicine you know?'* [68/F/patient]
2. *'So I know what is good to me, what's not good to me after a while and I have to tell them no, I need that* [medication] *because if I don't all my hair is going to fall out. It, it only affects my hair and I know when it, it'll grow out and then after a while they'll take me off something and there it go, it's always in my hair.'* [65/F/patient]
3. *'One time when my blood pressure was rising, Dr… emailed me and I had told him that I had backed off the Furosemide because my weight was going down below 150 and he said, 'Well, we'll double the Furosemide to get rid of water, but you want to be on it.' But I've been sort of doing this at my own discretion and it seems to work.'* [81/M/patient]

4. *'I'm gonna be presumptuous, but I've already had congestive heart failure and multiple heart attacks and so forth, my theory is that the patient sometimes kinda develops an awareness of their body.'* [68/M/patient]

5. *'We said we're not taking it till we go talk to Dr. [cardiologist]… There was a doctor that put me on that, and I was having trouble with low blood pressure and he put me on that. I got a new name for him, an undertaker.'* [72/M/patient]

TASK

Goal agreement

1. *'I stayed tired. I didn't feel like doing anything* [when taking medications-side effect]. *So, I just threw all them away.'* [68/M/patient]

2. *'Tried that two mornings, didn't work. This morning I took two 80 milligram pills* [not prescribed]. *It hasn't kicked in yet.'* [74/M/patient]

3. *'I have to take it twice a day, it's supposed to be three times, I take it twice a day… I couldn't take it 3 times a day because it was making me sick, so I got off of it, but uh, I have to take it.'* [65/F/patient]

4. *'You'd be sittin' on the commode all night, wouldn't you? He'd be sittin there, wouldn't ever get up.'* [70/M/wife] [when asked why the patient did not take his prescribed dose of medication]

5. *'What I take before breakfast, the breakfast. Mid-morning. The only thing I didn't take today was, uh, Lasix. Because we were-- traveling.'* [70/M/patient]

6. *'I thought about it* [taking bedtime medications], *but I was down in my bed good and warm.'* [74/F/patient]

7. *'I don't like what they do for me, you know make me go to the bathroom and uh, I'd like to crawl in my bed and get a full night's sleep.'* [72/F/patient]

8. *'Well, then the only, the only problem I have is with um, this, this one. like we're eating food over the weekend. I know uh, I have salt in the food... so I know well, eat what I want to eat up. So what I'll do, what uh, I don't do it regular. It's not a regular thing. I take one* [extra] *of these tablets in the night.'* [79/M/patient]

9. *'I have seriously thought at times in the last week or so, completely stopping all medication. So the only thing I would hesitate, I, I would possibly do it if I could reach just some guarantee and it's not possible that I wouldn't die from suffocation.'* [68/M/patient]

10. *'I can go anytime. I would go anytime. In fact, I told* [Dr. Bond], *not the last time I seen him, but the time before that I said, if I'm bad, I said let me go on. I said, I mean, I don't wanna fight it no longer, you know I'm just, I know a lot, a lot of people have put up with this problem for longer you know and everything, but I, I've told him, my husband he was sitting right there but I told him, I said, if I'm in a bad shape and you see that I'm getting my last breath, I said let me go on, but he's in the business to save lives not to you know not watch 'em die.'* [74/F/patient]

11. *'One day I'll jump four pounds, the next day I'll lose it, the next day, you know it's just there. my pills and fluid pills and the druggist said well you're going to run out, you're going to run out, but I can't afford to get that weight back on my, that, that fluid back on me.'* [65/M/patient]

Violation consequences

1. *'So, I don't have to get up so many times. It puts you up about three times if you take a whole one, and if you just take a half one, you don't have to get up about twice.'* [76/M/patient]

2. *'So what we know, but a lot of her medicine that she was taking made her sleep and she was taking it during the day. So we took it upon ourselves to change it where everything she takes that makes you sleepy you take it at night and she's sleeping more at night. And during the day she's more alert during the day.'* [70/F/daughter]

3. *'And like I said, I've been doing great. Everybody, couldn't nobody believe, uh, how good I was doing* [positive feedback from others during his period of medication non-adherence].*'* [68/M/patient]

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4.	*'And when we're traveling I just don't take it…. Well, for several days I can notice edema in my leg. Gain some weight, so I, it's a balance. You know, after a couple of days travel, we went to Europe, generally, I have edema.'* [81/M/patient]

TOOLS AND TECHNOLOGIES

1. *'If I'm not swelling, I'm not holding water, and I'm watching my weight on the scales then I don't take it.'* [68/M/patient]
2. *'If you're laying on a sofa and can't catch your breath, there won't be a better motivator, that's why I bought the little oxygen meter which I, I, I check mine* [blood oxygenation] *probably 10-15 times a day.'* [84/M/patient]

CONTEXT – ORGANIZATION, PHYSICAL, SOCIAL

Communication & Coordination

1. *'Never discussed it'* [referring to medication non-adherence while traveling]. [81/M/patient]
2. Patient: *'Half one? So, I don't have to get up so many times. It puts you up about three times if you take a whole one, and if you just take a half one, you don't have to get up about twice.'*
   Interviewer: *'Did Dr. Doe tell you to do that?*
   Patient: *'No.'* [68/M/patient]

Social influence

1. *'I said I really don't want the popcorn from here cause it's dang salty. I said I'd rather get the Carmel corn, she* [younger girlfriends] *said well it's got a lot of sugar. I said the sugar I can control a lot easier than the salt. I can take a little extra insulin but I can't take the salt out of my system without taking Lasix… So I had the regular popcorn cause you know we never win a battle'* [66/M/patient]
2. *'Because you sure look at people, you can tell people that take water pills cause they always running to the bathroom. All of my friends every time they come in they, they say, 'Hey, girl.' Whoosh. But I, I don't do that.'* [65/F/patient]
3. *'I take insulin. And you know sometimes you just don't want to be telling everybody your business.'* [65/F/patient]
4. *'That aggravates me becau-, I mean, I don't like to holler at him all the time… I thought about it* [medications], *but I was down in my bed good and warm and I just didn't wanna, I didn't wanna worry you* [husband] *with it.'* [72/F/patient]
5. *'I think that a lot of people are hesitant to bother their doctors.'* [81/M/wife]
6. *'We have root bark, or something. I always love eat, and I think that what keep me up, you know. Eat that. Man, I went back, I saw him* [shaman] *four months, the ulcer gone clean. Yeah. There* [they give] *us medicine over there to, to, to cure all them illness.'* [81/M/patient]

Rules

1. *'There's, there's not a, you know there's not a magic list of instructions that they lay out, okay.'* [74/M/patient]
2. *'They said to check it and if it's a certain level then it's okay. But then when it's not, you know they said let, you know write it down and keep a check on it.'* [68/M/wife]
3. *'I weigh every day, so the fluid, if it builds up over five pound or something, or whatever, if I start getting excessive, I can tell if, you know, if I gain eight pounds or whatever, and then I, you know, if the next day I take a lot of Lasix, and it might go down some or things, so I don't bother to call unless it's real high on a day, and that way, I mean I can control it.'* [67/M/patient]
4. Interviewer: *'Did somebody tell you you should get an ox-, something to measure your oxygen?*

Patient: 'No, no one told me, but I know what happens when you don't have enough oxygen.'
84/M/patient

5. *'I've been trained and that's why they get angry with me cause I, I bought a scale because they told me to but I never use it because I, you know I can gain 4 or 5 pounds in a day and lose in a day. It* [weighing] *doesn't make much difference and really it's for the concern of the water gain.'* 66/M/patient

Resources

1. *'You know I would not* [call the doctor], *unless it's an emergency, a life or death.'* 72/F/patient
2. *'It seemed like everything happened on a weekend, you know, when nobody's in the office.'* 65/M/patient

3. *'They took my gout medicine away from me and I told* [husband], *I said you just get that right back and said it out there, I said if you don't want to give it to me I'll take it from myself and so, so I did, because I can feel it coming on, I can feel that.'* 74/F/patient

4. *'*[They] *don't have a place to go to the bathroom… can't find a bathroom everywhere you know? And most generally some places you won't use, use it no way.'* 72/F/patient

APPENDIX E

Participant ID Details

Case	Age	White	Sex
S002	67	yes	Female
S003	81	yes	Male
S004	66	yes	Male
S005	80	no	Male
S006	72	yes	Male
S007	68	yes	Female
S008	73	no	Female
S009	81	yes	Male
S010	66	no	Male
S011	85	yes	Female
S012	65	no	Male
S013	79	no	Male
S014	69	yes	Female
S015	70	yes	Female
S016	74	yes	Female
S017	71	no	Male
S018	79	yes	Male
S019	65	yes	Male
S020	81	yes	Male
S021	65	yes	Female
S022	72	no	Female
S023	74	no	Female

S024	74	yes	Male
S025	80	no	Female
S026	86	no	Female
S027	82	yes	Female
S028	84	yes	Male
S029	68	yes	Male
S030	70	yes	Male
S031	74	no	Male
V001	65	yes	Female
V002	80	no	Male
V003	67	no	Female
V004	83	yes	Male
V005	68	yes	Female
V006	74	yes	Female
V007	86	yes	Male
V008	70	yes	Male
V009	84	yes	Female
V010	69	no	Female
V011	81	yes	Female
V012	80	yes	Male
V013	65	yes	Female
V014	83	yes	Female
V015	66	yes	Male
V016	65	yes	Female
V017	67	yes	Male

V018	68	yes	Male
V019	72	yes	Male
V020	76	yes	Male
V021	84	yes	Female
V022	68	yes	Male
V023	67	yes	Female
V024	67	yes	Female
V025	68	yes	Female
V026	75	yes	Female
V027	67	yes	Male
V028	65	yes	Female
V029	70	yes	Male
V030	77	no	Male
V031	74	yes	Female

Written Instructions for iPad and Data Collection

iPad Overview

Home Screen

Connection status of cellular

Battery Indicator

1:21
Sunday, July 10

Slide to Enter 6 digit code

Touch Screen

Home button

Back of iPad

Microphones

camera

Volume buttons

iPad

Speakers

Re-charging connection
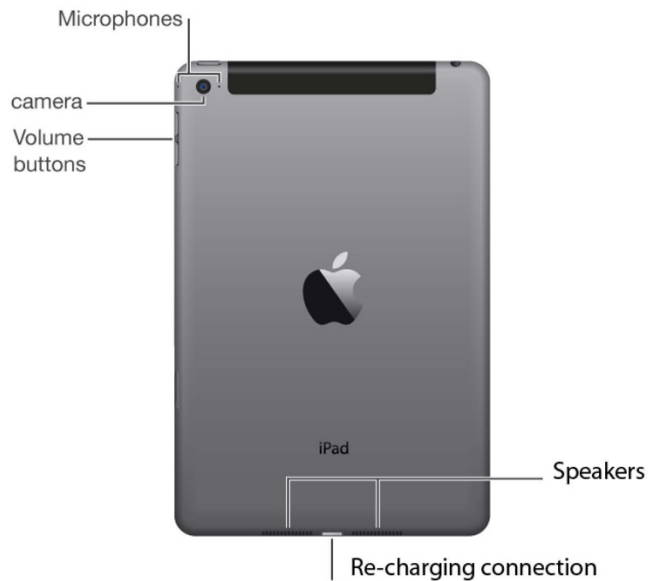
Turn on the iPad
Turn on the iPad by pushing the the small round button at the bottom of the iPad called the Home button. When you push the Home button, the Home Screen will appear.

1

Touch Screen

All you have to do to use the iPad is touch the screen. You can tap or slide the screen with your fingers.
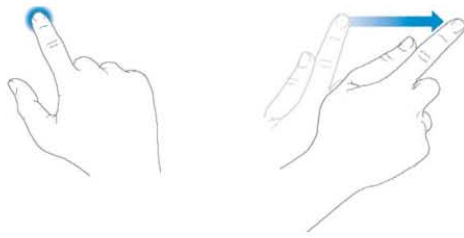
Log in to the iPad

To log in to the iPad slide the arrow at the bottom of the Home Screen with your fingers. A screen will appear with numbers. Tap the numbers of your 6 number code (098890) on the screen with your finger.

Capture

Capture is the application you will use to create audio or video
recordings and take photographs with comments. To open Capture, just tap the "C" box with your finger.
The screen on the far right will open.

2

Ways to Record

You can make a video, take a photo and add comments, or make an audio recording of your medication activities. All you do is touch the word you want (Video, Photo, or Audio) at the bottom of the Capture Home screen and slide the word until it is above the red or blue circle.

Take a Photo

Slide the word Photo to the center of the bottom. The circle will turn blue. When you are ready to take a photo, tap the blue circle one time and you will hear the clicking sound when the photo is recorded.

Review, Delete, or Add a Comment to a Photo

Touch the circle with the "L" [icon] at the upper left corner of the Capture Home Screen. This action will switch the screen to the Capture Review screen.

Tap the photo you are interested in and it will open.
Review: If you are happy with the photo, Tap the "X" in the upper right corner of the photo.
Delete: Select the trash can icon in the lower right corner of the photo.
**Add a Comment:** Select "Add Comment" at the bottom of the photo. A keyboard will open and type your comment into the box. Select "Post."
Return to the Capture Review screen: Tap the "X" in the upper left corner of the photo to close the phoo.
Return to the Capture Home screen: Tap the camera icon [icon] in the upper right corner of the screen.
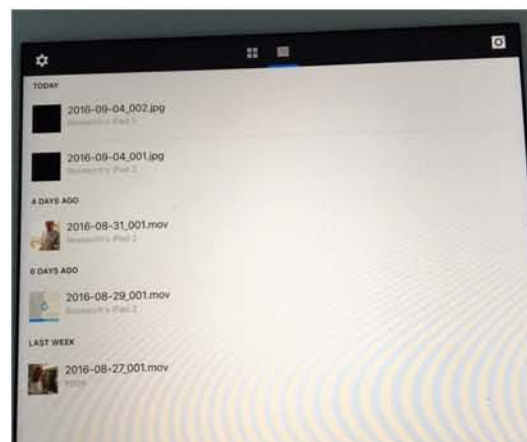
Capture Review Screen

3

Record Your Voice

Slide the word "Audio" to the center. The circle will turn red. To start recording, tap the red circle. The circle will turn into a red square and will stay a square until you choose to stop recording. Tap the red square to stop and it will turn back into a red circle.

Not Recording

Recording

Record a Video

A video records both photos and your voice. Slide the word "Audio" to the center.The circle will turn red. To start recording, tap the red circle. The circle will turn into a red square and will stay a square until you choose to stop recording. Tap the red square to stop and it will turn back into a red circle.
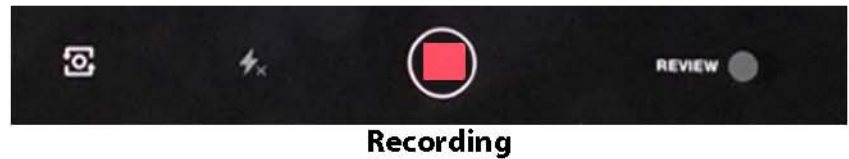
Switch the camera between front facing (take video or photos of yourself) and rear facing (take video or photos of something else) by tapping the [icon] icon.

Do not turn on the **Review Button** or you will have to save each recording you take. The review button is on if the circle is blue.

Double Checking

To be sure your recording was sent, check the Capture Albums screen. This screen will give you a summary view of all the recordings you have made. From the Caprure Home Screen, tap the icon in the upper right corner that looks lide a mountain in a square. Tap the type of recording you want to chaeck. Tap "Close" to return to the Capture Home screen.

Opens
Album View

4

Uploading recordings. All of the recordings that you create will automatically be uploaded to the Vanderbilt research server. Especially for photos and video recordings, this may take a few seconds.

Assuring upload. After you create a recording make sure that it gets uploaded by waiting for the numberin the upper left corner of the screen disappear.

Charge and monitor the battery
The best way to charge the iPad battery is to connect iPad to a power outlet using the included cable and USB power adapter. The battery icon in the upper-right corner of the status bar shows the battery level or charging status.

5
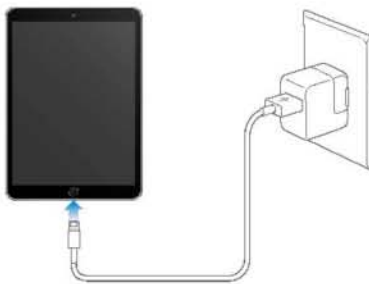
Troubleshooting

1. How do you turn the iPad off when I am not using it?
The iPad turns off when you close the cover. When you open the cover, you need to log back in.

2. What if I can't Log in?
Check that you are using the right code (098890). Be sure you are not tapping other numbers at the same time by tapping only with your index finger.

3. What if I can't see the Capture icon when I log in?
If you are logged into Capture, it will remain open and you will see the screen with the recording options and not the Capture icon.
If Capture is closed, you may be in the second iPad screen. There are 2 screens available on the iPad.
If you accidently slide the screen to the left you will see a different application icons. To get back to the screen with the Capture icon, slide the screen to the right and the Capture icon will be visable.

4. How can I tell how much battery power is left on the iPad?
The battery power is displayed as a percentage in the upper right corner of the screen.

5. What if the Capture screen is just black when I am trying to take a picture?
First, be sure the iPad has not run out of battery power (see #4).
Second, be sure the camera is not covered up. The camera for the iPad is actually on the back in the upper right corner. If you open the case and flip it directly backwards, it will cover the camera. You need to fold part the case to expose the camera. Also, if you have the iPad lying face up on a flat surface, the camera will be covered and the screen will appear black.

6. How do I take a picture of myself with the iPad?
You can switch the camera to front or rear facing by tapping the [icon] icon on the recording screen.

6

Troubleshooting (continued)

7. What if the iPad is no longer saving my recordings?

Check if the REVIEW button is turned on. If the REVIEW button is slid to the right, it will appear blue and is on. This means that the iPad will no longer save a recording until after you have reviewed it. You will have to tap SAVE or CANCEL. We do not recommend using the review button, as it just adds an extra step to the recording process.
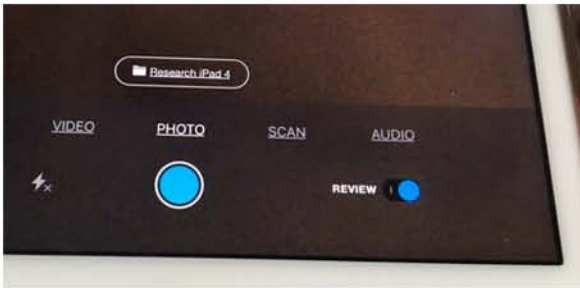
8. How can I review what I have recorded?

Tap the clock icon [ ] in the left upper corner of the screen. This will open a screen that displays thumbnails of all of the photos, video and audio recordings you have captured.

Tap the recording you would like to review. The recording will open. If you do not like the recording, click the little trash can icon in the lower right corner of the screen. You will be asked if you want to delete the recording tap the delete option in the pop-up box.

If you do not want to delete the recording, tap on the X in the upper left corner of the screen. You will return to the thumbnail screen.

Return to the record screen by tapping the camera icon in the upper right corner of the screen. [ ]

9. What do I do if I end up on the Settings screen?

First, don't change any of the settings! Save to Library and Upload using Cellular Data should be green. Tap the clock icon in the upper right corner of the screen which will take you to back to the thumbnail view screen. Next tap the camera in the upper right corner to return to the recording screen of Capture.

7

Label Attached to the back of the iPad Air Cover

We want to know what kind of activities you (and others)

have to DO related to your medications

Some Examples:

Administering medications

Organizing medications

Detecting problems

Preventing problems

Finding information

Keeping track of medications

Refilling medications

Communicating about medications

Adjusting to situations

THANK YOU!

CARING HEARTS – DIGITAL DIARY INSTRUCTIONS

Purpose

The purpose of giving you the iPad is for you to record bits of information about the kinds of activities you do to manage your medications. Think about it like telling a story, or keeping a diary about your medication activities and routines. What makes these medication activities harder or easier to do? What special ways have you figured out to make these activities easier, safer, or more effective?

Recording Guidelines

Please spend a 5 to 10 minutes each day for 1 week either recording short videos (no more than 3 minutes), taking photos with comments, or recording your voice alone about your medication activities and routines.

Activities

The following list contains examples of things you could record but there are many others:

- Administering your medications. Examples: preparing any equipment, how you schedule your medications around other activities.
- Communicating with your doctor or nurses about your medications. Examples: emailing, calling on the telephone, sending information about your blood pressure or weight.
- Organizing your daily pill taking. Examples: using tools such as pillboxes, placing your medications in a cabinet or box.

- Remembering to take your medications or to get refills. Examples: putting your medications where you see them, setting an alarm on your cell phone.

- Adjusting routines when you are away from home. Examples: taking your medications with you, taking them late, skipping a dose.

- Learning about medications. Examples: the internet, asking friends and family, talking to your pharmacist.

- Noticing problems with your medications. Examples: side effects, when errors occur.

- Deciding what do if there is a problem with your medications. Examples: call your doctor or a family member, wait and see if the problem goes away.

- Knowing when to take extra medications. Examples: taking medications for chest pain or when your weight goes up.

- Keeping track of your medications and changes. Examples: using a medication list, keeping track of past medications.

- Communicating with family members about your medications. Examples: when you need a refill picked up, when a doctor or nurse practitioner changes your medications.

General Information

- We would like you to record your medication activities in your home and away from home if possible. You can just record your voice if you are in a place where it is uncomfortable to take photos or video.

- If you later decide you are uncomfortable with anything you record, you can delete the recording from the device (See iPad Overview).

- Once you have taken a picture or recording on the iPad, it automatically goes to our encrypted database. No other person other than the researcher in this study will have access to the information you share.

- You're in control, but there is 1 privacy rule - Try not to take pictures of strangers. If there are family members or friends that have signed our consent, it is fine to take pictures of them. If not, please do not take pictures of other people.

- We will be collecting the iPad at the end of the week and would like to interview you about your experiences. We can come to your home or we can meet at the clinic.

- For the first few days we will call on the telephone at the time of your choosing to see how things are going unless you prefer not to be called. You can contact the researcher at any time by phone, email, or text.

Thank you for your participation!

Researcher contact information

Email

phone

APPENDIX G

Digital Diary Satisfaction Survey

The following questions will ask you important information about your experience collecting photo/videos for this study. The questions ask about the how difficult this was and how much and your comfort in answering the questions in the interview. Choose the alternative that best describes your response. Add your personal comments for each response is encouraged.

1. Overall, I am satisfied with my experience with the photo diary process.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

2. The instructions for the photo diary were easy to understand.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

3. I felt comfortable with the photo diary process.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

4. The amount of time required for this photo diary process was satisfactory.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

5. The amount of effort required of me for the photo diary process was satisfactory.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

6. I enjoyed participating this photo diary research.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

7. I learned a lot participating this photo diary research.

Strongly Agree	Agree	Agree Slightly	Neither Agree or Disagree	Disagree Slightly	Disagree	Strongly Disagree
1	**2**	**3**	**4**	**5**	**6**	**7**
Comments						

8. Which did you like the best and why? Photos, video, or audio

APPENDIX H

Interview Guide

Date:

Time begin:

Time end:

Participant(s) ID:

A. Goal: Elicit process with timeline, barriers and facilitators, and strategies

1. Routine process. Ask about barriers, facilitators strategies tracking, problem detection, decision making, adapting, communicating, sensemaking.

Go through sequences of day, week, month:

    a. What makes this hard, easy?

    b. What do you need to know?

    c. Who helps?

    d. How do you decide?

    e. What do you think about?

    f. What other ways might you do this?

2. Continue for all identified processes and places

    a. Refill process

    b. Tracking medications

    c. Storing medications

    d. Organizing medications

e. Remembering medications

f. Accessing information

g. Communication with providers

h. Cost

3. Asks adaptations for:

a. Away from home and traveling

b. Irregular medications

c. Special requirements

d. Side effects

4. Individualized Questions

Time check – 30 minutes

B. Goal: Elicit mental model of a critical Incident

1. Now we want to talk about the interesting and challenging experiences you have had.

a. If mentioned an incident in the initial process-tracing interview, mention it.

b. If no incident was mentioned ask about

i. An event that was especially challenging?

ii. A time when you had trouble deciding what to do?

iii. A event that if you could do over, you would?

iv. If can think of no event, use scenario of making an administration mediation error.

2. Could you tell me more details about that? From beginning to end?

   OK so this is what happened (recount story) ……Tell me if I have it right or if there are
   other things that should be added.

3. Now I'd like to go through the event again and this time we will try to create a timeline of
   the important occurrences--when things happened, what you saw, the decisions or
   judgments you made, and the actions you took.

4. Let us go through it again and I want to ask you about some details

   Ask about:

Cues & Knowledge:	What were you seeing?
Analogues:	Were you reminded of any previous experience?
Standard Scenarios:	Does this case fit a standard or typical thing that happens?
Goals:	What were trying to achieve or what was most important to you in making a decision?
Options:	What other courses of action were available or considered?
Basis of Choice:	How was this option selected/other options rejected? What rule was being followed?
Mental Modeling:	Did you imagine the possible consequences of this action? Did you imagine the events that would unfold?

Experience:	What specific training or experience was necessary or helpful in
	making this decision?
	What training, knowledge, or information might have helped?
Decision-Making:	How much time pressure was involved in making this decision?
	How long did it take to actually make this decision?
Aiding	If the decision was not the best, what training, knowledge, or
	information could have helped?
Situation	
Assessment:	If you were asked to describe the situation at this point,
	how would you summarize the situation?
Errors:	What mistakes are likely at this point?

5. Ask about "What ifs"

   What might have happened differently at this point?

   What were the alternative decisions that could have been made here?

   What choices were not made or what alternatives were rejected?

6. So let's go through this again (Recount details for correct understanding, correction of errors and additions by participant) VALIDATION.

Adapted from: Crandall, Klein & Hoffman [264]; Hoffman [435]; Hoffman, Crandall & Shadbolt, [436]

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