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Medication Adherence: Staying within the boundaries of safety

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Abstract

An important domain of patient safety is the management of medications in home and community settings by patients and their caregiving network. This study applied human factors/ergonomics theories and methods to data about medication adherence collected from 61 older patients with heart failure and 30 informal caregivers living in the US. Seventy non-adherence events were identified, described, and analyzed for performance shaping factors. Half were classified as errors and half as violations. Performance shaping factors included elements of the person or team (e.g., patient limitations), task (e.g., complexity), tools and technologies (e.g., tool quality), and organizational, physical, and social context (e.g., resources, support, social influence). Study findings resulted in a dynamic systems model of medication safety applicable to patient medication adherence 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.

Practitioner Summary:

We describe situational and habitual errors and violations in medication use among older patients and their family members. Multiple factors pushed performance towards risk and harm. These factors can be the target for redesign or various forms of support, such as education, changes to the plan of care, and technology.

Keywords

Patient safety; resilience; medication adherence; chronic disease; human factors in healthcare

1. INTRODUCTION

For decades, medication safety has been the target of human factors/ergonomics (HFE) research and practice in the domain of healthcare and the area of patient safety (Karsh *et al.* 2006, Beuscart-Zéphir *et al.* 2010, Carayon and Wood 2010, Phansalkar *et al.* 2010, Flynn

2012). In fact, the earliest known application of HFE in healthcare was research by Safren and Chapanis (1960) on the types and causes of nurses' medication errors in a hospital.

By identifying medication errors as a major cause of patient harm, reports such as *To Err is Human* in the US (Kohn *et al.* 2000) and *An Organisation with a Memory* in the UK (Donaldson 2000) 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 (Xie and Carayon 2015).

Subsequent studies and reports, such as *Preventing Medication Errors* (U.S. Institute of Medicine 2007), 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 (Gandhi *et al.* 2003).

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 (Horne *et al.* 2005, Cramer *et al.* 2008). 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 (Cardenas-Valladolid *et al.* 2010, Naderi *et al.* 2012, Marcum *et al.* 2013) and is associated with increased mortality, disability, and reduced quality of life (Osterberg and Blaschke 2005, Sokol *et al.* 2005, Simpson *et al.* 2006, Fitzgerald *et al.* 2011). Studies also report self-medication error rates in older adults of 19% to 77%, and 12% to 26% of these errors resulted in harm (Lau 2008, Britten 2009, Mira *et al.* 2015).

Medication non-adherence can be intentional or unintentional, and from a safety science perspective can be classified as errors or violations, respectively (Barber 2002, Barber *et al.* 2005, Furniss *et al.* 2014). 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., taking the wrong pill) (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 omission or commission (cf. Reason, 1990; Reason *et al.* 1998). Literature suggests both intentional and nonintentional 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 (Horne and Weinman 1999, Piette *et al.* 2004, Forster *et al.* 2005, Hajjar *et al.* 2007, Gadkari and McHorney 2012).

Despite its evident importance and prevalence, medication non-adherence in home environments has not received the same attention of patient safety professionals as medication safety in hospital settings (Runciman *et al.* 2008, Masotti *et al.* 2010, Lang *et al.* 2015, Vincent and Amalberti 2015). This is also true of HFE research on medication safety, with several notable exceptions (Barber *et al.* 2004, Morrow *et al.* 2007, Liao *et al.* 2011, Furniss *et al.* 2014, Lim *et al.* 2016). 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 (Henriksen *et al.* 2009). 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 (Holden *et al.* 2016). 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 (Vincent and Amalberti 2015).

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 (1997) 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 (Cook and Rasmussen 2005). The forces “moving” a system relative to boundaries of risk and harm can also be called performance shaping factors (PSFs) (Hollnagel 1998). In systems models of safety, multiple PSFs interact over time and in specific incidents to produce action sequences and safety outcomes (Rasmussen 1997, Reason 1997, Hollnagel 2004). Lastly, although actual safety boundaries are uncertain and situational (Amalberti *et al.* 2006), organizations and other entities (e.g., regulators, professional societies) establish and enforce rules regarding tolerable behavior based on an estimate of those boundaries (Rasmussen, 1997). Rule transgressions, regardless of actual risk incurred or whether harm resulted, are regarded as safety violations (Reason 1997, Cook and Rasmussen 2005, Amalberti *et al.* 2006). 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?

2. Method

2.1 Sample and Setting.

We analyzed cross-sectional data collected from 61 patients living with heart failure and 30 informal caregivers in a study of heart failure self-care, 2012–2014. Patient participants were aged 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.

2.2 Data Collection

Data were collected through clinic visit observations, short (30-min) interviews, follow-up (90-min) interviews, and/or extended interviews (90–120 minutes). 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. 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 (Holden *et al.* 2015).

2.3 Data Analysis

The specific data analysis method was descriptive qualitative content analysis with iterative category development (Miles *et al.* 2013). This method systematically derives trends, patterns, and themes from large amounts of textual data revealing the underlying meaning (Krippendorff 1989). It accommodates both deductive (conceptual model-driven) approaches and inductive (data-driven) category development. During first-pass structural coding (Saldana 2009), researchers RSM & RJH identified broad passages of data mentioning medications. During second-pass coding, RSM identified non-adherence events described by participants. Medication non-adherence was defined as any instance where a patient did not take a medication as prescribed (Cramer *et al.* 2008). 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 (Ferner and Aronson 2006, Field *et al.* 2007). Next, these events were iteratively categorized by error mechanisms (slips, lapses, mistakes, violations) (Reason 1990) and error type (National Coordinating Council for Medication Error Reporting and Prevention 2001b). 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” (National Coordinating Council for Medication Error Reporting and Prevention 2001b). Non-adherence events were also categorized as recurring/routine or one-time/situational.

For each non-adherence event, performance-shaping factors (PSFs) were identified from reported data. PSFs were defined as attributes of work systems (Carayon *et al.* 2006, Holden *et al.* 2013) enabling or constraining safety and increasing or decreasing the likelihood of errors, violations, error recovery, and error mitigation. Identified PSFs were categorized using the Patient Work System model (Holden *et al.* 2015), an HFE systems framework including person(s) (individual or team), task, tool/technology, organizational context, social context, and physical context factors (Holden *et al.* 2013, Holden, Schubert, and Mickelson 2015). Sub-categories and cross-cutting themes regarding non-adherence events and PSFs were derived from the data and labeled using concepts from healthcare and non-healthcare literature on errors (Biebuyck *et al.* 1990, Hollnagel 1998, Vincent *et al.* 1998, LeBlanc *et al.* 2011, Groth and Mosleh 2012, Lawton *et al.* 2012) and violations (Reason 1990, Alper and Karsh 2009, Hale and Borys 2013). Authors RSM & RJH met regularly during coding discussions over a 10-month period, during which author RJH facilitated analytic agreement (Barbour 2001, Berends and Johnston 2005).

3. Results

Table 1 describes the characteristics of the 61 older adult patients and 30 informal (family) caregivers who participated in the study. All were living 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 (Roger *et al.* 2012). 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 (Rich 2001, Yancy *et al.* 2016). Treatment with medications is aimed to prevent further cardiac changes and to control symptoms (Rich 2001). 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.

3.1. Safe Medication Management

Patients and informal caregivers described largely error-free performance in the course of managing medications. Although the study could not quantify the “non-events” of safe performance (Weick 1987), 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).

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 about 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 was able to administer the medication.

3.2 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 an unintentional error (slips, lapses, mistakes) and 35 intentional violations (50%). Errors were both situational (40%) and routine (60%), whereas violations were primarily routine (86%, 30/35). Three times (4%) the event resulted in direct harm to the patient and in four cases (6%) routine medication omissions resulted in hospitalization. Table 3 summarizes medication non-adherence error and violation frequencies, types, and PSFs. Appendices A and B report illustrative quotes.

3.3. 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.

3.3.1. 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). 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 participants 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.

3.3.2. 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 woman).

3.3.3. Patient Abilities/Limitations—Limited abilities, skills, knowledge, and attitudes towards medications contributed to error events (46%, 16/35). Arthritis impaired an 84-year-old woman’s ability to take medications out of prescription bottles. She believed she sometimes dropped medications on the floor without noticing. An 86-year-old woman 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.

3.3.4. 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.

3.3.5. 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 an 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).

3.3.6. 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.

3.3.7. 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.

3.3.8. 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.

3.4. 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 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 1 as a case of "drift." In the 35 described violation events, ten categories of PSFs were commonly evident, presented in order of frequency.

3.4.1. 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.

3.4.2. 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.

3.4.3. 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)."*

3.4.4. 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.

3.4.5. 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.*”

3.4.6. 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).

3.4.7. 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.

3.4.8. 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.

3.4.9. Tools and Technologies—Interestingly, monitoring tools and technologies enabled some habitual violations (20%, 7/35). In particular, 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.

3.5 PSF Interactions

Consistent with prevailing safety theory, errors and violations were often the result of a combination of factors, not isolated PSFs. Table 4 presents common PSF interactions and Table 5 presents an illustrative event of several errors and violations shaped by a combination of PSFs.

4. DISCUSSION

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 (Cramer *et al.* 2008). Unitizing non-adherence as events may reveal stronger relationships between non-adherence and outcomes of harm: for example, Wu *et al.* (2009) report 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 (Reason 2000, Holden and Karsh 2007) needs to be reinforced when we begin to examine the work activity of patients and families (Holden *et al.* 2013).

4.1. 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 (Mira *et al.* 2015). Others estimate adverse drug events resulting from errors to occur in 19–30% of older adults discharged from the hospital (Hanlon *et al.* 2006, Kripalani *et al.* 2007). 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 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, eight 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.

4.2. A dynamic systems model of medication non-adherence

Rasmussen's (1997) 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.

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 (Hignett *et al.* 2015).

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, event detection, and mitigation of harm from intentional or unintentional non-adherence (Dekker 2014). 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 is depicted as "drift." Mirroring the increase in errors as systems become more complex (Amalberti 2001), 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 (Gray *et al.* 2001, Ownby *et al.* 2006, Marcum *et al.* 2013). Just as compliance with safety rules declines with time (Hale and Borys 2013), so do patients report lower medication adherence rates over time (Butler *et al.* 2004, Wu *et al.* 2012). This appeared to be especially likely in self-confident patients, mirroring Reason's (1990) 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 (McKeon *et al.* 2006). 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 (Vaughan 1996), 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, 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.

4.3. Implications for HFE and safe medication use in home and community settings

A major implication of the model in Figure 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” (Strauss *et al.* 1982). As several recent models of healthcare HFE articulate, the patient is a key actor in patient safety, not a passive recipient (Carayon *et al.* 2013, Holden *et al.* 2013, Hignett *et al.* 2015). Consequently, improving patient safety will require an understanding of patients’ context and activity as well as interventions, technological and otherwise, to support this activity (Valdez *et al.* 2015). HFE is uniquely qualified to evaluate and support “human work” towards a better, healthier, and safer world (Wilson and Sharples 2015), and “patient work” is as important an application as any (Holden *et al.* 2013).

The notion of supporting work as opposed to eliminating specific safety events is also a hallmark of the Safety II approach or orientation to the “things that go right,” which contrasts with the Safety I approach of finding and fixing the “things that go wrong” (Hollnagel *et al.* 2007, Hollnagel *et al.* 2013, Hollnagel *et al.* 2015, Wears *et al.* 2015). Safety II encourages making the system as robust and resilient as possible, rather than correcting or eliminating supposedly faulty aspects of the system. This idea has been recently applied to healthcare (e.g., Hollnagel, Wears, & Braithwaite, 2015; Wears, Hollnagel, & Braithwaite, 2015) and is applicable to the domain of patient safety in home and community settings, including medication safety (Furniss *et al.* 2014, Schubert *et al.* 2015). Both approaches are associated with medication adherence research and interventions, but Safety I predominates.

Applying a Safety I approach to medication adherence includes better education or training, supervision by informal or formal caregivers, and identification and remediation of specific “risky” conditions such as patient attitudes towards medications or having a complex medication regimen (Schmaling *et al.* 2001, Hajjar *et al.* 2007, Rossi *et al.* 2007, Nieuwlaat *et al.* 2014). Other Safety I error prevention mechanisms could include manufacturing medications with distinct appearances, technologies alerting patients of forgotten medications, dosing packets or systems that prevent or greatly reduce the probability of dispensing the wrong medication, reinforcement and practice of safe medication use strategies, well-lit and low-distraction “workstations” where a person may take medications, and technological or human redundancies such as automatic refills or medication cross-check by a family member. Although we strongly oppose it, a conceivable Safety I approach to medication adherence violations would identify and chastise people for intentional non-adherence.

In contrast, applying Safety II to medication adherence could involve the following:

- Providing feedback on performance as patients manage their medications and other self-care tasks. Wu *et al.* (2012) found feedback to heart failure patients about their own rates of medication adherence improved performance. Similarly, understanding when a person is at risk, the value a medication provides, or when a problem has occurred, are important targets for feedback (and anticipatory feedforward, when possible).

- Making the goal of interventions—be they training, technology, or otherwise—the development of 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 2013).
- Identifying PSFs, strategies, and conditions under which medication management for a person or group of people is accomplished successfully, especially in light of challenging circumstances such as complex medication regimens, travel, or medical disturbances (e.g., post-hospitalization, new diagnosis).

5. LIMITATIONS

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. 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.

6. CONCLUSION

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.

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Appendix A.: 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>"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."</i> 72/M/wife
Patient Abilities and Limitations	1. <i>"I don't have a problem trying to remember to take my pills. That's just not a problem with me."</i> 84/F/patient 2. <i>"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."</i> 66/M/patient 3. <i>"The drugstore's right up the street you know? I mean my daughters have to take me you know. 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?"</i> 72/F/patient 4. <i>"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."</i> 84/F/patient 5. <i>"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."</i> 65/F/husband
TASK	
Task Complexity and Workload	<i>"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."</i> 81/M/patient <i>"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."</i> 66/F/patient <i>"[The] calcium has to be stored in a different place. It's easy to forget that."</i> 81/M/patient <i>"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."</i> 81/M/patient
Strategies	<i>"... 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]."</i> 80/M/daughter <i>"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."</i> 65/F/patient <i>"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."</i> 66/M/patient <i>"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."</i> 70/M/patient
Quality of error cues	<i>"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."</i> 68/F/patient <i>"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."</i> 68/F/patient <i>"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."</i> 80/M/patient
TOOLS AND TECHNOLOGIES	
	1. <i>"Also on my cell phone...I have reminders on there even you were on there today."</i> 68/M/patient 2. <i>"It [left atrial pressure device] will tell you when you need to take your medicine, that way you won't forget it."</i> 66/M/patient 3. <i>"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]."</i> 71/M/wife 4. <i>"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."</i> 81/M/wife
CONTEXT - ORGANIZATION, PHYSICAL, SOCIAL	
Communication & Coordination	1. <i>"When I need a prescription or something I can write in" [through patient portal]."</i> 80/M/patient 2. <i>"I have not been taking the Glyburide, Glipiparide, uh, the uh prescription ran out and had to be refilled, there was communication difficulty between my pharmacy and my doctor."</i> 66/M/patient

PATIENT AND TEAM	
3. "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}	
4. "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}	
5. "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}	
6. "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}	
7. "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	
1. "I've done it so much it's just total engrained in my thinking I guess." ^{83/M/patient}	
2. "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}	
3. "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}	
4. "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}	
5. 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	
1. "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}	
2. "Well, I just, and fortunately [daughter] lives with me so wherever I need to go, she takes me." ^{86/F/daughter}	
3. "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}	
4. "I sign up for automatic refills at CVS and you know they text me when they're ready." ^{67/M/patient}	
5. "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}	
6. "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	
1. "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}	
2. "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}	
3. "I don't have my pens. I got the insulin, but the pens left over there." ^{74/F/patient}	
4. 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}	
5. "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}	
6. "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}	
7. "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}	
8. "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}	
9. "...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 B.: 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	<p>1. "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}</p> <p>2. "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}</p> <p>3. "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}</p> <p>4. "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}</p> <p>5. "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}</p> <p>6. "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}</p> <p>7. "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}</p> <p>8. "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}</p> <p>9. "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}</p>
Self-confidence	<p>10. "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}</p> <p>11. "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}</p> <p>12. "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}</p> <p>13. "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}</p> <p>14. "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}</p>
TASK	
Goal agreement	<p>"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}</p> <p>"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}</p> <p>"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}</p> <p>"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]</p> <p>"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}</p> <p>"I thought about it [taking bedtime medications], but I was down in my bed good and warm." ^{74/F/patient}</p> <p>"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}</p> <p>"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}</p> <p>"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}</p> <p>"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}</p> <p>"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}</p>

PATIENT AND TEAM	
Violation consequences	<p><i>"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."</i>^{76/M/patient}</p> <p><i>"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."</i>^{70/F/daughter}</p> <p><i>"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]."</i>^{68/M/patient}</p> <p><i>"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."</i>^{81/M/patient}</p>
TOOLS AND TECHNOLOGIES	
	<p>30. <i>"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."</i>^{68/M/patient}</p> <p>31. <i>"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."</i>^{84/M/patient}</p>
CONTEXT – ORGANIZATION, PHYSICAL, SOCIAL	
Communication & Coordination	<p>32. <i>"Never discussed it" [referring to medication non-adherence while traveling].</i>^{81/M/patient}</p> <p>33. Patient: <i>"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."</i></p> <p>Interviewer: <i>"Did Dr. Doe tell you to do that?"</i></p> <p>Patient: <i>"No."</i>^{68/M/patient}</p>
Social influence	<p>34. <i>"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"</i>^{66/M/patient}</p> <p>35. <i>"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."</i>^{65/F/patient}</p> <p>36. <i>"I take insulin. And you know sometimes you just don't want to be telling everybody your business."</i>^{65/F/patient}</p> <p>37. <i>"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."</i>^{72/F/patient}</p> <p>38. <i>"I think that a lot of people are hesitant to bother their doctors."</i>^{81/M/wife}</p> <p>39. <i>"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."</i>^{81/M/patient}</p>
Rules	<p>40. <i>"There's, there's not a, you know there's not a magic list of instructions that they lay out, okay."</i>^{74/M/patient}</p> <p>41. <i>"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."</i>^{68/M/wife}</p> <p>42. <i>"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."</i>^{67/M/patient}</p> <p>43. Interviewer: <i>"Did somebody tell you you should get an ox-, something to measure your oxygen?"</i></p> <p>Patient: <i>"No, no one told me, but I know what happens when you don't have enough oxygen."</i>^{84/M/patient}</p> <p>44. <i>"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."</i>^{66/M/patient}</p>
Resources	<p>45. <i>"You know I would not [call the doctor], unless it's an emergency, a life or death."</i>^{72/F/patient}</p> <p>46. <i>"It seemed like everything happened on a weekend, you know, when nobody's in the office."</i>^{65/M/patient}</p> <p>47. <i>"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."</i>^{74/F/patient}</p> <p>48. <i>"[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."</i>^{72/F/patient}</p>

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Figure 1.

In medication adherence violations, individuals pursued the goals of minimizing risk and preserving autonomy.

Figure 2.

A dynamic systems model of medication non-adherence, based on Rasmussen (1997) and Cook and Rasmussen (2005). Performance-shaping factors influence behavior towards or away from the boundaries of medical risk, medical harm, personal risk, and personal control.

Table 1.**Demographics (N=61 patients)**

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

Table 2.**Factors shaping error-free performance of medication management**

- **Vigilance and monitoring:** When performing medication-related tasks such as filling pillboxes, vigilance decreased the likelihood of slips. Three error events occurred during this process. 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 a "good" memories and never forgetting their medications. Some patients also described managing their medications "for years."
- **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 and refill prescriptions easily.
- **Task support:** Medication regimens and medication access systems were complex. Internal and external contextual factors supported error-free medications use. For example, patients associated medication taking with events such as meals, bedtime and awakening in the morning and placed medications in visible locations. Family members administered medications to 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.
- **Error prevention and detection strategies:** Detecting errors enabled learning to prevent their occurrence in the future. Some participants devised their own of 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 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. Patient 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 the complexity of 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.

Table 3.

Error and violation mechanisms, outcomes, and performance shaping factors

Mechanism and outcome ^I	Performance shaping factor and definition
ERRORS (N=35) Lapses (49%, 17/35) • Dose omissions (94%, 16/17) • Wrong time (6%, 1/17) Slips (11%, 4/35) • Dose omissions (25%, ¼) • Wrong time (50%, 2/4) • Wrong medication (25%, ¼) Mistakes (40%, 14/35) • Dose omissions (43%, 6/14) • Wrong patient (14%, 2/14) • Wrong medication (22%, 3/14) • Expired medication (7%, 1/14) • Wrong time & medication (7%, 1/14)	PATIENT AND TEAM Attention/inattention, vigilance • Checking accuracy • Monitoring supplies, resources • Monitoring assumptions Patient abilities/limitations • Functional • Physical • Cognitive • Experience, familiarity • Knowledge • Attitudes TASK Task complexity and workload • Frequency • Sequence, number of steps • Time of day • Appearance similarity • Improper dose (7%, 1/14) • Storage requirements • Irregular dosing • Workload (# refills) • Burden on informal caregiver Quality of strategies • Present/absent • Effective error prevention Quality of error cues • Timing (delayed) • Absent • Clarity TOOLS AND TECHNOLOGIES Quality of tools and technologies • Unintended consequences • Lack of tools • Inadequate tools CONTEXT - ORGANIZATIONAL, PHYSICAL, SOCIAL Communication & coordination • Lack of communication • Poor information sharing • Communication channel availability • Speed of communication • Lack of coordination Quality of routines • Inadequate routines • Routine disruptions • Routine change • Absence of routines Social support • Lack of supervision • Lack of support Organizational support • Availability (e.g. rules, procedures, refill reminders) • Quality (e.g. mail order speed, reliability) • Utilization of resources Access to supplies and equipment • Patient location • Medication location • Delivery delays
	<i>The cognitive process of focusing attention and keeping careful watch for possible danger or difficulties.</i> <i>The abilities, knowledge, experiences, and attitudes of the patient.</i> <i>The inherent difficulty of a task or process. For medications this includes the number of pieces, steps, clarity, conditionality, urgency, or frequency.</i> <i>The set of practiced behaviors applied in anticipation or response to task requirements.</i> <i>The presence, salience, and timeliness of cues that enable/constrain error detection and recovery.</i> <i>The availability and quality of tools to assist patients, family, or clinicians to perform tasks.</i> <i>Processes and systems in place for sharing information and collaborative medication tasks within teams.</i> <i>The presence, quality, and consistency of regularly followed habits that structure behavior.</i> <i>The availability and quality of support from one's social network, when needed.</i> <i>The availability, quality, and utilization of organizational resources for assistance with medication use.</i> <i>The availability and ease of access of medications and required equipment.</i>

Mechanism and outcome ¹	Performance shaping factor and definition
VIOLATIONS (N=35) <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Cost • Insurance rules • Distance to pharmacy • Stockpiling medications • Sharing medications • Expired medications <p>PATIENT AND TEAM</p> <p>Perceived risk</p> <ul style="list-style-type: none"> • Lack of severity • Perceived urgency • Perceived negative effects of medications • Previous experiences • Attitudes towards medications <p>Self-confidence</p> <ul style="list-style-type: none"> • Perceived expertise • Lack of trust in healthcare providers <p>TASK</p> <p>Goal agreement</p> <ul style="list-style-type: none"> • Effects of medications • Comfort • Rest • Social activities • Responsibilities • Motivation • Urgency. <p>Violation consequences</p> <ul style="list-style-type: none"> • Success/failure • Acceptability of risk/benefit <p>TOOLS AND TECHNOLOGIES</p> <p>Tools and technologies</p> <ul style="list-style-type: none"> • Perceived mitigating effects of monitoring tools <p>CONTEXT - ORGANIZATIONAL, PHYSICAL, SOCIAL</p> <p>Information sharing</p> <ul style="list-style-type: none"> • Lack of communication • Unshared (hidden) information <p>Social influence</p> <ul style="list-style-type: none"> • Judgment of others • Perceived burden on others • Cultural influences <p>Rules</p> <ul style="list-style-type: none"> • Lack of rules • Rule ambiguity • Rule drift <p>Resources</p> <ul style="list-style-type: none"> • Perceived availability of healthcare provider • Quality of care • Physical facilities <p><i>The patient or caregiver's assessment of the potential for a negative consequences due to disease, symptoms, treatments, or the actions of others.</i></p> <p><i>The self-perception that a person possesses a high level of skill and expertise.</i></p> <p><i>A condition in which medication adherence objectives and other life objectives are incompatible and promote violations.</i></p> <p><i>The consequences of a medication adherence violations on medication use, health and quality of life.</i></p> <p><i>The availability, quality, and consequences of tools and technologies.</i></p> <p><i>Processes and systems in place for sharing information and collaborative medication tasks within teams.</i></p> <p><i>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.</i></p> <p><i>The quality of rules and established procedures that define and guide the safe use and medications.</i></p> <p><i>The real or perceived quality and availability of organizational, social, and physical resources required for medication use and the effects of medication use.</i></p>

¹Error outcomes are based on *Taxonomy of Medications Errors* (National Coordinating Council for Medication Error Reporting and Prevention 2001) error types. These error types describe the inaccuracies that result from the medication error.

Table 4.

Performance-shaping factor interactions, frequencies, and examples

Error interactions	Frequency of occurrence	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 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 5.

Patient scenario illustrating performance-shaping factor (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.