Medication Management at Home:

Patient-Identified Processes and Risk Assessment

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"I can't remember as well as I did at one time….You have to have a system to keep track of your medicines."
Patient Quote

STRUCTURED ABSTRACT

Purpose: This exploratory and qualitative study endeavored to understand the patient experience and risks of managing medications at home.

Scope: Individuals living independently between the ages of 50 and 75 years with at least one chronic condition requiring a prescription for more than 3 months comprised the study population.

Methods: Participants were recruited by phone using a structured screening instrument and completed one-on-one interviews about their medication management routine. An analytic inductive process of transcript review identified common process maps and vulnerabilities. Focus groups reviewed these maps to validate the approach and to identify ways these processes might fail.

Results: Four high-level medication management processes were common among participants and provided a framework for discussion between patients and healthcare providers. Medication management methods used by patients were diverse and very individual. Over 300 risks were identified either by patients or by the clinical team reviewing the transcripts. The potential risks identified are from the patients' perspectives and have highlighted some possible areas in which interventions might improve medication management safety. A vital few represent areas for additional study and exploration with patients and their healthcare teams.

Keywords: Medication safety risks, patient-managed medication process, patient-reported vulnerabilities, and clinician-inferred vulnerabilities

PURPOSE:

This exploratory and qualitative study endeavored to understand the patient experience and risks of managing medications in the community setting. The research questions are:

1. What is the process by which patients manage medications (is there one common process or many different processes)?
2. What are the common failure modes associated with the patient process for managing medications, and which failure modes have the greatest negative impact on patient safety from the patients' perspectives?
3. Based on these risk assessment findings, what are the most viable opportunities for reducing patient medication management behavior risks that should be further explored by health systems?

Understanding patient processes will enlighten health systems and medical providers seeking effective methods for reducing the incidence of medication errors and ADEs that occur outside the control of traditional healthcare environments.

SCOPE

An increasing number of drugs are prescribed to mitigate the long-term risks of chronic conditions as well as their acute symptoms. Although studies have been conducted on medication management risks that occur within the healthcare system, relatively little is known about adverse drug effects (ADEs) in the ambulatory setting. Gurwitz et al. reported in a survey of ambulatory Medicare beneficiaries an incidence rate of 50.1 ADEs per 1,000 person-years and noted that 27.6% of them were considered preventable (1). A prospective cohort study in primary care practices showed that, of 661 patients interviewed, 24.5% had ADEs, of which 11% were preventable (2). Discrepancies among clinical office-recorded and patient-reported medications are common. Bedell et al. (3) found the discrepancy rate to be as much as 76% and noted that the two most significant predictors of medication discrepancy were older age and number of prescribed medications.

Our AHRQ Safe Practices Implementation study found a 20-40% discrepancy rate between the EMR medication list and the patient's list at baseline (4).

Outside the healthcare delivery environment, patients risk harm or injury as they fail to incorporate a medication change into their personal routines. In fact, 30-50% of patients with chronic disease might not take their medications as prescribed (5). Recent evidence has demonstrated that medication discontinuation can increase mortality risk post-MI (6) and is associated with adverse outcomes in patients with diabetes (7). Although healthcare professionals cite this as patient noncompliance, this characterization does not illuminate the process that patients and their families use to adhere to treatment recommendations from their doctors. A recent study by Davis et al. (8) showed that low health literacy and a greater number of prescription medications were associated with misunderstanding of instructions on prescription labels in as many as 48% of the study participants.

The Bedell study (3) revealed some patient concerns about medication management: 1) the desire for more information from providers; 2) concerns about adverse effects; 3) inconvenience of taking medications or cost of medications; and 4) multiple physician management. An Australian study (9) identified medication-related risk factors through home visits. Risk factors included multiple medication storage locations (8.3%), expired medications (22%), therapeutic duplications (25%), poor adherence to medication regimen (52%), hoarding of medications (21%), and confusion over generic and trade names (55%). Another study used root cause analysis to diagram patients' views of the causes of adverse drug events in ambulatory care (10). It found 164 causes of ADEs, which occurred through eight major pathways: medication nonadherence, prescriber-patient miscommunication, patient medication error, failure to read medication label/insert, polypharmacy, patient characteristics, pharmacist-patient miscommunication, and self-medication.

Patient Advisory Council

The PeaceHealth Medical Group Patient Advisory Council served as consultants throughout the research process by providing input and feedback regarding the relevance and approach used in all phases of the study. We sought their engagement because of a strong commitment to ensuring a patient-centered perspective and approach. We recognized as healthcare professionals that our bias could blind us to important insights and nuances that a patient perspective might find meaningful. They critiqued the study design and reviewed telephone recruitment scripts, individual and focus group interview questions, as well as visual depictions of the processes gleaned from 1:1 interviews. Two advisors participated in initial pilots of the one-on-one patient interviews and in a pilot Patient Focus Group. As a result of their engagement in the research, they initiated and produced a Patient Safety DVD, entitled *"Your Health Care and Safety - The Team Approach at PeaceHealth."* It contains a chapter on "Medication Safety" that is based on their learning from this study.

Participants

The study population comprised 50-75 year olds who had at least one chronic condition and had taken a prescribed medication for that condition during the past 3 months. Specifically, we used the following criteria to determine the study participants:

- 50-75 years old
- Speak English as their primary language
- Live in Lane County
- Live independently with only family support
- Have been diagnosed with diabetes mellitus, asthma or COPD, hyperlipidemia, hypertension, osteoarthritis, or heart disease and have at least one prescription medicine for that condition that has been prescribed for at least 3 months

More than 18,294 patients met the criteria listed above in the PeaceHealth data warehouse in October 2007. They represented individuals who had received services in the physician offices of PeaceHealth Medical Group
(PHMG) or South Lane Medical Group (SLMG) or were admitted to Sacred Heart Medical Center. The US Census 2006 indicated that 140,408 residents were living in Lane County who were age 45 or older. Potential study participants represented a subset of this broader age demographic (13%).

METHODS

To study the patient processes and risks involved in medication management, we used qualitative, one-on-one patient interviews. We explored methods and processes used by the participants to manage medications. We then used focus groups as a validation step to confirm the processes we found and to illuminate possible points of failure in each overall method. A rigorous inductive analytic approach was used by the research team in partnership with consultants experienced in these methods of data analysis.

Recruitment of Study Subjects

Using a randomly selected subset of the original population eligible (3,700), the principal interviewer began telephone screening to qualify patients to participate in 1:1 interviews. Of the 138 individuals contacted by phone, 36 qualified for one-on-one interviews and agreed to participate.

The same subset list above was used to recruit participants for the focus groups. Two additional lists of 30 each, representing rural participants in the 65-75 age range and individuals with non-Caucasian ethnicity in the 65-75 age range, were requested by the recruiter. Individuals meeting these specific criteria were randomly selected from the original list of 18,294. This allowed our study participants to meet the prevalence of these two groups in the Lane County population. The same telephone screening process was used to identify the 40 qualified participants for the focus group.

We recruited 38 patients for interviews with the goal of conducting enough interviews until no new medication management at-home processes were being identified. Two interviewees were Patient Advisors. Thirty-two interviews were completed, and two patient interviewees were disqualified due to inaudible transcription tape or not meeting screening criteria. The remaining recruited patients either self-canceled or were not needed to complete the interview phase goals. The study used one principal interviewer, who had interviewing and qualitative research experience.

1:1 PATIENT INTERVIEW PARTICIPANTS	
Patients Scheduled For Interviews	36
Patient Advisors Who Completed Interviews	2
Total Patients Recruited	**38**
Patient Interviews Completed	31
Patients Disqualified	2
Patients Not Interviewed	5
Total	**38**

Phase 1: Patient Interviews

The first part of this study aimed to describe the methods and processes used by the participants from the time they receive a prescription through the taking of the medications to getting the medication refilled. Jane Williams, of Williams Consulting, served as consultant for this phase of the research. We individually interviewed patients in a conference room or in their homes. The principal interviewer obtained the initial interview information either personally or with other trained interviewers. The interviews were taped. It was anticipated that there would be at least 10 and perhaps 30 interviews or more conducted until data saturation was reached. When no new methods or processes were identified by the participants, then the individual interviews concluded.

The interviews also collected demographic information. Demographic information included age, gender, ethnicity, highest level of education completed, residence status, (e.g., living alone or with spouse, etc.), insurance status, diagnosed condition(s), number of prescription medications patients are taking, length of time he or she has been on each medication, and the frequency of each medication.

Prior to participating in the interviews with the principal interviewer, a study coordinator collected informed consents and screened patients using the mini-mental survey. All participants completed this instrument and were determined to have cognitive skills needed to provide valid information during the interview or were disqualified based on their scores. Interviews averaged 1 hour each, during which a chart was compiled of all current prescribed medications, supplements, and over-the-counter medicines used by each patient. Respondents described how they manage medications at home, including filling and refilling prescriptions, obtaining information about prescription medications, organizing, taking and keeping track of medications, and managing changes.

We reviewed the interview transcripts and identified major steps in patient medication management process at home. Our analysis looked to verify if there was one process or many that patients use to manage their medications. We produced a visual depiction of the major and minor processes that patients use to manage their medication at home. Pamela Jull, of Applied Research Northwest, served as the consultant for this phase of the research. We used the following Applied Research Northwest's methodology to produce the visual depiction of the major and minor processes:

Reconciliation

Reconciliation involved reviewing the 31 flowchart patterns and identifying flowchart patterns for use in the

Failure Modes and Effects Analysis focus groups. To ground the analysis in the research plan, analysts referred to the research questions and language from the research plan (September 2007):

- "The objective of this study is to describe the medication process in the patient's language..."
- Produce "a visual depiction of the process(es) of medication management by patients."
- "An analytic inductive process will be used to organize the qualitative data."

The patient interview transcripts were randomly assigned to the team for coding and analysis. The goal was to produce no more than two to three different process models in anticipation of sharing the process diagrams with patients in focus groups. A three-step process of analysis and documentation was utilized.

1. The research team members individually reviewed of a subset of interviews using documentation forms developed for this purpose. The Coding Team members individually read, analyzed, and coded all transcripts assigned to their team.

2. Two teams were formed to analyze the transcripts. Each consisted of two team members with at least one member having a clinical background. Each team met together and produced a consensus flowchart for each transcript from the sharing of their individual work.

3. Then, the 31 interview flowcharts were combined into process models. Two team members independently reviewed the 31 consensus flowcharts and synthesized these into one to three dominant models/processes consistently mentioned by the patients. They produced a consensus on four high-level visual maps to share with the research team. The entire team then reviewed and confirmed the process models.

Phase 2: Patient Focus Groups

We intended to use a Failure Mode and Effects Analysis (FMEA) to identify the most serious risk factors associated with the processes patients' identified from the time they receive and fill prescriptions. Patient Advisors participated in a pilot Focus Group to provide feedback on the proposed focus group process. As a result, the FMEA Flow Charts for use in the Focus Groups were simplified in accordance with input from the patient advisors. We conducted four patient focus groups between April 21 and May 29, 2008. Jane Williams, of Williams Research, served as consultant for this phase of the research.

The focus groups reviewed the four consensus model flow charts from the Phase 1 interviews, which showed the most common steps involved in how those patients managed medications at home. Participants were asked to analyze each step, identifying potential failures. They shared their ideas in the larger group; each possible failure was captured on a flip chart. Each individual then rated each step using Failure Modes Effects Analysis (FMEA) five-point rating scales for "severity," "frequency" and "detection." This rating method was simplified based on patient advisor feedback that a 10-point scale was too complex and easily overwhelming.

During the analysis of the FMEA ratings, variability and gaps in ratings suggested a problem with the application of the methodology and its usefulness for identifying and prioritizing risks. There did not appear to be any correlation between their ratings and the numerous ways they indicated the process step might fail, including a correlation between steps they had highlighted as greatest risk and their scoring of severity, frequency, or detection. We concluded, after a discussion with Erik Stalhandske and Joseph DeRosier of the VA National Center for Patient Safety, that the FMEA process we utilized did not have face validity. If we were to have conducted a traditional FMEA, we would have done it with one patient and those who support and have expert knowledge of that unique patient's medication management processes. It would have gone to a much higher level of specificity and granularity in probing the patient's subprocesses. They believed, however, that the study's value was in the granularity of the individual interviews and the unique ways that patients manage their medications and the vulnerabilities uncovered during the interview process. Although the FMEA did not yield a ranking of the key risks, the groups did identify failures that could occur in the patient's processes for medication management.

Phase 3: Patient-Identified Vulnerabilities

In order to identify risks and vulnerabilities related to medication management patient processes, we reviewed the transcripts more closely for nuances among the individual interviews, identifying the stories and vulnerabilities noted as part of the experience of patients in managing their medications. This rigorous analytic inductive process was led by Carmit McMullen, PhD, of Kaiser Permanente.

1. Team members read assigned transcripts individually and coded them for stories and vulnerabilities. A *story* has a beginning and an end, has a point, may be interrupted by a question, and may continue beyond one response. We only coded stories about medication management. *Vulnerability* is defined as the potential for something to go wrong, the potential for harm, or a snippet of words indicating risk.

2. An *inferred vulnerability* was defined as a patient describing a scenario that may lead to an undesirable outcome, but this outcome was not stated explicitly by the patient. It was noted by the research team member. On the other hand, a *reported vulnerability* was the patient describing behaviors, such as stopping medication or being forgetful, that produced an undesirable outcome. The undesirable outcome is self-reported by the patient.

3. Using the definition above, teams of two readers reviewed coded transcripts for the purpose of reaching a consensus agreement with regard to coding. The team then wrote a case summary for each transcript reviewed to summarize issues that may be missed when looking at individual stories and vulnerabilities. The summary posed unanswered questions, recorded ideas for intervention, and summarized what is most important in the transcript.

4. All transcripts that had not been reviewed by clinical staff (i.e., Ron Stock, MD, or Betsy Ovitt, RN) during the initial coding were reviewed by one of these team members for clinical vulnerabilities that could be overlooked by nonclinical members of research team.

5. Dr. McMullen, a medical anthropologist, led the project team through the methodology work of sorting identified vulnerabilities into categories. A brainstormed list of broad categories was created, and each of the over 400 vulnerabilities were sorted into the identified categories.

Limitations of Study

This study was conducted with a small subset of patients in a predominately Caucasian population. Although it attempted to verify the application of these medication management processes more broadly, it can only provide a framework for additional exploration. The FMEA rating process with the focus groups was cumbersome, and time limitations prevented us from reviewing all the process flows with each focus group.

We present all the results of this qualitative analysis in this report.

RESULTS

Phase 1: In-depth Interviews
We conducted 31 one-on-one, in-depth interviews, during November 2007. Overall, 37 patients participated in four focus groups; two patients were disqualified. During the recruitment phase, 380 qualified patient contacts were attempted, 102 patients participated in the screening process, and 36 patients completed the screening process and agreed to be an interview participant.

Profile of study participants

Chronic Conditions

Chronic Conditions	Number of Patients	Percent of Total
Diabetes	10	11.76%
Asthma	5	5.88%
COPD	5	5.88%
Hyperlipidemia	20	23.53%
Hypertension	22	25.88%
Arthritis or Osteoarthritis	13	15.29%
Heart Disease	10	11.76%

Participants had a range of one to six chronic conditions. The mean number of chronic conditions per patient was 2.8.

Medication Use

	Mean #	Median #
Medications (all) listed during screening	5.033	4
Medications (all) brought to interview	11.937	12
Prescription medications brought to interview	7.937	7.5
Over-the-counter medications brought to interview	1.843	1.5
Supplements brought to the interview	2.125	1

The number of medications (including prescriptions, over-the-counters, and supplements) that the patient was currently taking ranged from a minimum of two to a maximum of 42. We analyzed the number of medications the patients stated they were taking during the screening compared with the number of medications they brought to the interview, compared with the number of medications listed on the electronic Rx pad (if they were a PHMG patient). Over-the-counter medications and supplements were identified separately. In a majority of cases, there was a discrepancy between our medical records, their self-report, and the actual medications brought to the interview.

Demographics

Our small study made every effort to represent the demographics of our county. The table below shows how closely we were able to adhere to this target.

Characteristics of Study Participants	Percent of Interviewees	Lane County Demographics
Age		
50-59 years old	30%	n/a
60-69 years old	46.67 %	n/a
70-75 years old	23.33 %	n/a
Male	46.67 %	47%
Female	53.37 %	53%
Ethnicity		
Caucasian	86.67 %	87%
Hispanic/Latino	6.67 %	1%
Asian/Asian American	3.33 %	3%
African American	3.33 %	1.1%
Education Level	For age 45-64/65 and older	
Less than High School	6.67%	7%/18.8%
High School Graduate	46.67	93%/81.2%
College Grad or higher	46,67%	29.8%/23.9%

Insurance Information

Payor Information	Commercial	Medicare	Medicaid	Other	Not Available
Patient Reported	73.33%	16.67%	3.33%	3.33%	3.33%
Initial Data Query	40%	40%	3.33%	3.33%	13.33%

We were surprised that the self-reported payor information was so different than what our data source had reported in our initial query. In discussing this with the billing office, they indicated that many patients on Medicare have selected commercial plans as their Medicare Advantage programs. We do not know if they erroneously reported Medicare plans as commercial to account for this significant discrepancy.

Systems and Routines for Managing Medications at Home

Patients interviewed for this study described some kind of system or "routine" for how they organized, consumed, and kept track of their medications, ranging from apparently very organized and efficient to rather more haphazard and random. Few respondents seemed to lack any kind of system at all for managing their medications.

A wide variety of systems were described, each including a range of different variables. The following components, however, often featured as factors in individual systems:

- Medication storage: where patients keep medications, prescription and otherwise, in the home
- Container usage: whether patients transfer medications to a weekly organizer or some other type of container

- Use of routine and memory triggers: how patients remember to take medications, and how they keep track of what they have taken
- Usage methods: laying out medications before taking, taking them one at a time, or some other system

Medication Storage

The majority of respondents found it important to <u>keep their medications "visible,"</u> often in a "high-traffic area," such as the kitchen table or counter, coffee table, or bedside table. They found this helped them remember to take their medications. As was frequently noted, when it comes to remembering to take your medications, often it is "out of sight, out of mind."

A common idea around medication storage was the notion of <u>keeping medications "all together," "all in one place</u>." The location of that one place varied widely between respondents: the kitchen (table, counter, drawer, or cabinet), the dining or living room, the bathroom (counter, medicine cabinet, or drawer), or the bedroom.

However, the preference for keeping medications <u>in close proximity to where and when they will be</u> <u>taken was mentioned just as frequently</u>. Thus, a large proportion of respondents divided their medicines between two or more places (e.g., the bedside table for use first thing in the morning/last thing at night, the bathroom for medications taken when brushing teeth, taking a shower, etc., or the kitchen for mealtime medications).

Although some respondents kept medication bottles loose on a kitchen/bathroom counter, many kept them inside some other kind of container.

Container Use or Weekly Pill Organizers

Although a majority (27 of 31) of respondents took their medications directly from the original containers on each dosage occasion, <u>a substantial minority (15 of 31) of respondents used some type of weekly pill organizer</u> to help manage all or some of their medications. Most popular of these was the kind with two slots per day: one for AM medications, the other for PM. A few respondents used weekly containers with more or fewer slots per day, used more than one weekly container at a time, or used a kind with detachable days.

Most respondents using weekly pill organizers tended to include over-the-counter medicines (a daily aspirin, for example), supplements, and vitamins in the organizer along with their prescription medications, so long as space allowed.

The majority of those using weekly organizers typically had a particular day when they filled them. A few said they filled organizers "when empty" or "running low." Most of those who used one or more weekly organizers felt the absence of pills in a particular slot indicated that they had taken their medications. (NOTE: A few respondents did not use a weekly organizer because, they said, there was no proof that a pill really had been taken.)

Use of weekly pill organizers did not necessarily appear to correspond to number of medications taken; although some individuals commented that they had started using an organizer once their medications had increased beyond a certain point, many respondents who were taking a considerable number of medications were not using an organizer. (Likelihood to use an organizer seemed to relate more to individual style and preference/personality rather than to number of medications being taken.)

Memory Triggers

<u>Use of routine and "triggers"</u> were commonly used to help respondents remember to take their medications and keep track of what they have taken. The majority of respondents mentioned tying medication consumption to their "daily routine" until it became "automatic." Typical examples included:

- first thing in the morning and last thing at night
- right before/after brushing teeth
- right before/after a daily shower
- with the morning coffee/juice
- with breakfast/lunch/dinner
- before a morning walk

Several respondents also described the effectiveness of sandwiching medications between two routine, daily activities. For example:

- after morning shower, before putting on make-up
- after brushing teeth, before putting in/taking out contacts

Respondents also detailed the importance of using "memory triggers," "cues," or a "memory device," be it something that is performed (e.g., brushing teeth), something that is consumed ("a glass of Cran-Raspberry juice"), or both (always taking a glass of iced water to bed). Many respondents felt that being "creatures of habit" helped them with their medications. They noted the importance of recognizing how critical their medications were to their well being and of being "consistent."

Reliance on memory. When asked how they keep track of which medications they have taken, a substantial proportion of interview participants noted that they "just do"; most felt that they could reliably remember if they had taken their medications or not. (Just a few respondents noted that they "can't do it from memory" and need to have some other method of keeping track.)

Notebooks and other written notes/records. These were relatively common, particularly for new medications, for medications with varying dosage or irregular days, and for recording blood sugar or other levels. Several participants used notebooks, pieces of paper, or backs of envelopes for these purposes. Others used entries on wall calendars or "Post-Its" on cabinet doors, a bathroom mirror, or bedroom window to remind them about new medications or varying dosages.

Physical reminders. Several participants noted that they "just feel it in my body" if they have forgotten to take their medications. This seemed to apply to pain medications, sleeping pills, and inhalers in particular.

Usage Methods

For those with weekly organizers, medications were typically taken from a specified daily slot at the appropriate time of day and consumed directly.

As mentioned, a majority of respondents did not use a weekly pill organizer, generally taking medications directly from the original pill bottles. These respondents were divided between:

a) Those who "line-up" all their pills for one occasion, placing them all together in their hand, on a napkin, or on the counter; check visually that all are present; and then take all at once. (A few respondents noted that they double checked the label as they removed each pill from its bottle.)

b) Those who take each pill out of the bottle one at a time and consume individually, working through bottles in some systematic way. Examples of this latter approach included working from left to right (or right to left); taking all bottles out of a basket/drawer/from shelf and so on, returning as taken; or using "bottle positioning," upright bottles indicates yet to be taken, on their side indicates one more pill to be taken that day, upside down indicates all done for the day.

Incorporating Medication Changes

When asked how they manage changes in medications, most respondents said they simply <u>include new medications in their current system</u> at the appropriate time, adding them to the daily/weekly pill container for the week or placing a new pill bottle with other medication bottles, for example.

Most study participants said they simply <u>remove discontinued medications</u> from their weekly container, current drawer, or shoe box. Some stored these medications in a separate drawer, for example, in case they were needed later; others disposed of them.

Several respondents said they used <u>additional reminders,</u> such as a note on a prominent bulletin board or wall calendar, or a Post-It on the bathroom mirror or kitchen cabinet, until a new medication was automatically incorporated into their system.

The respondents who were relatively new to medications or new to a larger number of medications appeared to find changes more challenging, reporting a fair amount of "trial and error" initially. Several noted the importance of remembering to take medications, figuring out a system that works for them. In general, prescription medications took priority over supplements and over-the-counter medications.

Respondents mentioned that travel and unexpected changes in their routine caused by illness and/or stress had caused them to forget their medications or to take them at a time much later than recommended. Recognition of this pattern caused some individuals to develop additional reminders or systems to prevent the failure from reoccurring.

Overall Patient Processes for Medication Management

Based on patient interviews, a high-level flowchart was developed, depicting the key areas necessary to develop a system for managing medications:
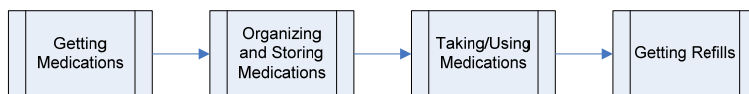
Based on the interviews, detailed flow charts were developed, showing the most common steps involved in how patients managed medications at home. These four flow charts incorporated the major pathways patients used to manage their medications as well as significant minor pathways patients also used.
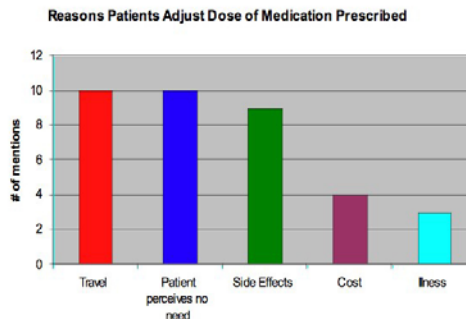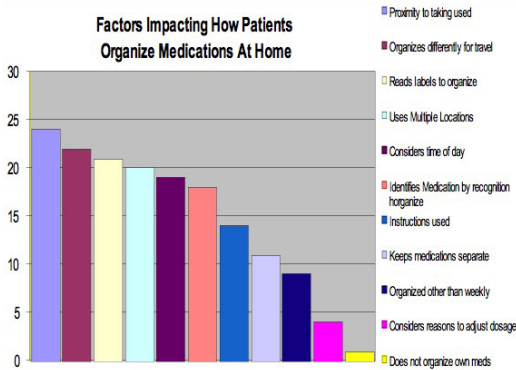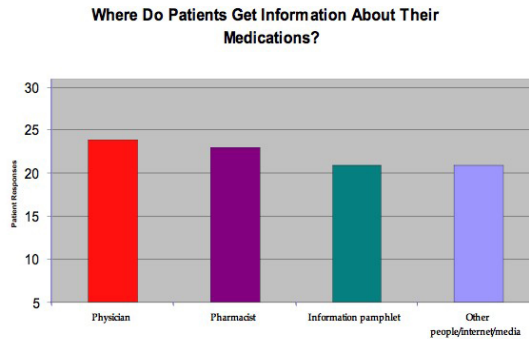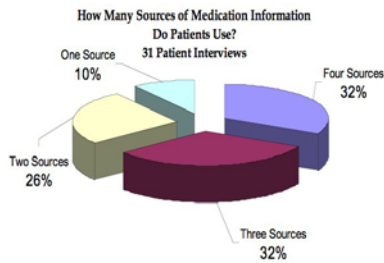
Other Interview Findings

Respondents were asked how they get information about their prescriptions, such as what they are, why they are taking them, how to take them, side effects, and which of these sources they find most helpful and useful. Significant findings include:

- Two thirds of respondents use three or more sources to get information on their medications.
- One third of patients mentioned travel as a reason to adjust their dose of medications.
- One third made changes when they perceived no need for the medication or they could not feel any difference when they took the medication. Side effects, cost, and illness were mentioned less frequently.

- 75% of patients mentioned the physician and pharmacist equally as the most common source of information.

Below are charts that show these results:

How Many Sources of Medication Information Do Patients Use?
31 Patient Interviews

- One Source 10%
- Four Sources 32%
- Two Sources 26%
- Three Sources 32%

Where Do Patients Get Information About Their Medications?

Factors Impacting How Patients Organize Medications At Home

- Proximity to taking used
- Organizes differently for travel
- Reads labels to organize
- Uses Multiple Locations
- Considers time of day
- Identifies Medication by recognition horganize
- Instructions used
- Keeps medications separate
- Organized other than weekly
- Considers reasons to adjust dosage
- Does not organize own meds

Reasons Patients Adjust Dose of Medication Prescribed

Phase 2: Focus Groups

Nine or 10 patients took part in each group, for a total of 37 participants, as follows:

- Group One: 65 to 75 year olds
- Group Two: 50 to 64 year olds, currently unemployed
- Group Three: 50 to 64 year olds, employed
- Group Four: 65 to 75 year olds

As part of the focus group exercise, each group reviewed the high-level flow charts created through the synthesis of the individual interviews. The focus groups confirmed that the processes described and visually depicted were accurate and meaningful. This served as a validation of the analysis of the interviews in Phase 1 of the study.

The team learned that FMEA analysis in a community setting proved challenging to the patient focus groups. Frequent questions about how to apply the ratings emerged in each group. Comments about how this process is a very different way of thinking about behaviors related to medication management were common. We do not know what value the FMEA analysis provided to the individuals participating. The level of patient understanding of the FMEA process and the level of individual participation varied widely

among patients in the focus groups. The context and ways participants thought each step might fail, rather than actual numbers, may have been the most useful part of the group interactions. The scores of individuals and the three focus groups had tremendous variance.

Some of the risks identified by at least three of the focus groups are:

Getting new prescription approval from the doctor

- Patient forgets to pick up prescription order, leaves at doctor's office

Getting the prescription order to the pharmacy

- Office doesn't fax prescription to pharmacy – forgets, too busy, delays
- Computer/fax machine error – doesn't go through, pharmacy doesn't receive
- Faxed to wrong pharmacy – e.g., Walgreen vs. Walmart, wrong location

Getting medication from the pharmacy

- Can't afford to pick it up, no money
- Pharmacy doesn't have in stock
- Pharmacy closed, inconvenient hours/work schedule, holiday

Organizes and stores pills only in original containers

- Keeping track of whether taken or not – issues included easier to misplace bottles, grab wrong container, pills may look similar, remembering how many to take, confusion about current and discontinued, keeping track of refill dates

Transfers pills from original container to pill box or other organizer

- Put pills in wrong slot – e.g., forget what time pill should be taken – might take at wrong time
- Not enough time slots for daily meds – e.g., pills get combined and confused; once out of pill bottles, similar looking pills are easily confused
- Pill organizer tops are not secure, if organizer gets dropped pills mixed up/lost
- Lose track of what you've transferred – e.g., if you get interrupted, if you run out midweek and forget to fill later, leave one out/forget one pill

Keep medications where they will be taken

- Safety issues – pills are within reach of other people, children, and animals
- Improper storage conditions might damage pills – e.g., heat/sunlight, moisture/damp bathroom
- Easier to lose/get covered up

Stores medications in various other locations

- Easier to forget to take them; "out of sight, out of mind"
- Forget where they are stored, forget to find all locations

Uses daily routine to remember to take medications

- Change in routine – e.g., meal times, sleeping habits, work schedule, illness, rushed/running late, traveling or out for the day
- Routine gets interrupted, get distracted – e.g., phone call, visitors

Uses visual prompt or sound alert to take medications

- Forget to look at visual prompt, don't notice it – e.g., poor location, gets bypassed

Remember to take medications (no cues/reminders)

- Don't remember/just forget

- Get distracted – e.g., have company over, occupied, busy

<u>Takes medication as directed</u> or <u>Takes more/less or not at all</u>

- Patient doesn't understand effects around skipping/taking later/double/overdosing – e.g., side effects, maintaining medication levels

<u>Notices a refill is needed</u>

- Don't notice you're out soon enough – e.g., additional time needed for mail order, or just don't notice soon enough

<u>Ordering the refill</u>

- Insurance company restrictions – e.g., limiting number allowed, date of refill, wont cover/pay for refill, issues cause delays

Additional FMEA analysis showed that missing data was significant and, therefore, numerical ratings were inconclusive. Instead, the team pursued a qualitative analysis to identify vulnerabilities and risks (as discussed in the Methods section), the results of which are presented below.

Phase 3: Patient-Identified Vulnerabilities

Through a rigorous analysis of the 31 interview transcripts, 485 vulnerabilities were identified. Patients reported 172 vulnerabilities, and 313 inferred vulnerabilities were noted by the research team. In order to make meaning, we looked for patterns or themes among them. This resulted in the identification of 40 **vulnerabilities types.** They are listed below:

- Care Setting Transitions
- Cost
- Distrust
- Dosing Schedule
- Healthcare Errors (Rx'ing, Labs, Pharmacy)
- Identifying Medications (Look Alike)
- Patient Honesty/Disclosure with Physician
- Medications Are Dangerous
- Dangerous Organization System (Complexity, Storage)
- Perceived Trusted Information Sources (May Be Unreliable or Help Access Needed Info)
- Multiple Pharmacies
- Confusing Instructions

- Error Awareness
- Low Literacy
- Low Vision
- Memory
- No Patient System to Remind to Take Medications
- Missed Doses
- Number of Medications (Cognitive and Physiological Vulnerability)
- Insurance Companies
- Patient Self-Experimentation (Self-Dosing)
- Insufficient Information (Patient Desires More Information)
- Multiple Providers
- Someone Else Manages

- Old/Expired Medications
- Refills
- Splitting Pills
- Away From Home Locally
- Busy Times/Changes of Routine
- Change Medications Without Telling Physician
- Change of Prescribed Use for Reliability/Tolerance (Compromise)
- Travel (Away From Home)
- Transferring Medications-Containers/Pill Boxes
- Can Not Sense Therapeutic Effect (Does Not Comprehend Reason, Cues-Retakes Dose)
- Medications Hard to Take
- Mobility/Access

(Verbal/Written)	Medications	(Physical/scheduling)
• New Medications (Not Fully Tested, Recalled)	• Low Health Literacy (of Own Health/General Health Information)	• Reluctance to Take Medications
		• Side Effects

A comparison between patient-reported vulnerabilities and the research team's inferred vulnerabilities yielded the following observations:

- New Medications (Untested/Withdrawn) and Dangerous Medications were only identified by the research team and not by patients
- The Research Team noted twice as many vulnerabilities than were reported by patients (313 vs. 172)
- Despite a difference in rank order for vulnerabilities, there was agreement on seven of the vital few on each list

Patient-Reported Vulnerability (58% of Total)	Inferred Vulnerability by Research Team (50% of Total)
Memory	Low Health Literacy
Side Effects	Dangerous Organizational System
No Patient Reminder System to Take Medications	Side Effects
Busy Times/Changes to Routine	Memory
Dangerous Organizational System	Identifying Medications
Healthcare System Errors	Patient Self Dosing/Experimentation
Identifying Medications	Refills
Refills	Number of Medications
Number of Medications	Confusing Instructions
Low Health Literacy Insufficient Information	

In order to provide useful ways to understand the risks associated with the patient's experience in managing medications, we offer two models for review. Model A organized the 40 vulnerabilities around nine useful categories related to the patient (4), their routines/system (3), medications (1), and the healthcare system (1). Model B analyzed the vulnerability categories around the question: Who can make this safer and is accountable for any change to make this safer? Vulnerabilities were clustered in three areas: the Patient (Internal Factors), the Healthcare System (External Factors), or Both in Partnership.

Below is a summary of vulnerability frequency related to the demographics of patient profiles.

Table Summary of Vulnerabilities (Inferred and Reported) by Patient Demographics

Summary Report of Demographics		Reported	Inferred
Vulnerabilities by Demographic Grouping		**Frequency**	**Frequency**
	Males (14)	118	260
	Females (17)	138	315
	Fewer Than 5 Medications Total at Interview	10	56
	5-10 Medications Total at Interview	73	153
	More Than 10 Medications Total at Interview	173	365
	Fewer Than 5 Rx Medications at Interview	69	155
	5-10 Rx Medications at Interview	138	253
	More Than 10 Rx Medications at Interview	48	166
	Ages 50-59 (30%)	69	180
	60-69 (46.67%)	122	224
	70-75 (23.33%)	63	170
	2 or Fewer Chronic Conditions (16 Pts)	103	229
	3 or More Chronic Conditions (15 Pts)	153	345

Vulnerability Analysis Findings

Overall, in reviewing the identified vulnerabilities, twice as many vulnerabilities were identified (inferred) by the coding team than were reported by patients.
We also found the following:

- No difference was found between our identification of vulnerabilities for Medicare-age patients compared with patients not of Medicare age.
- No vulnerability categories were identified by patients (reported) and not by coders (inferred).
- Patients on more medications did not identify different vulnerabilities than other patients.

Validation of Vulnerability Analysis

To further validate our methodology, Focus Group Transcripts underwent the same coding for vulnerabilities as the individual interviews. That analysis did not uncover any reported vulnerabilities not already listed in our taxonomy.

CONCLUSIONS

Understanding the medication management process from the patient perspective yielded a rich picture of what behaviors and practices patients use everyday. Sometimes, those practices fail, and medication is not taken as planned or as prescribed. At times, patients are aware of the potential risk, and at other times they learn about the risk only after a significant life-changing event. That was the case for one man in his 50s who shared the story of the increasing number of medications he had been given by his doctor over the past few years. In some cases, he didn't know what the medication was for. He said that he didn't believe they made a difference; they were expensive; and he "didn't feel" any different. So he quit all medications because he could and because he was used to doing what made sense to him. Two weeks later, he was admitted to the hospital with a heart attack and nearly died. As he described his current medication

management process now, he stressed how he had a process that was simple, easy to remember, and supported by his daily routines. He had learned why he needed each medication and made a habit to take his medications every day. He let his wife and kids know that taking the medications were important to him and he needed their support. His story was compelling, as were others we heard.

The common framework and process maps provide a picture of steps that create a method to manage medications. It could apply to a vast number of patients who live at home and are responsible for managing their medications. This is a significant finding, because it provides a picture of steps that help promote medication safety from the patient perspective.

The stories shared by these patients emphasized the importance of building on their individual strengths. They employed strategies to keep themselves safe and increase the likelihood they would take the medication as directed. How often does a professional in the healthcare system provide some guidance or a framework for patients to think about as they join the many who take medications as a way to stay healthy while living with a chronic condition? For example, one gentleman in his 70s, interviewed in his home, told the story of how he had "forgotten to take all his meds" and as a result ended up in the Emergency Room. As he shows the interviewer a large sign, he comments, "Oh yeah, I've forgotten. I put this big old sign in my bedroom window that says, Do Not Forget to Take your Pills, All your Pills!"

Although there was a common framework – the high-level processes of getting, organizing, taking, and refilling medications for every patient interview – we learned that patient methods are diverse and very individualized. A common theme was the use of visual cues for the taking of medications. How people put this strategy into practice was unique for the individual. One retired engineer used the positioning of his bottles to indicate whether he had taken his medications and at what time. He relied on his routine of having orange juice each morning to remember to take his morning dose when his glass was half full.

The process maps provide a picture of what can happen in medication management and could be used to begin conversations with patients whose adherence to medication routines has been haphazard. They could see what others do and develop their own plan. Focus group members commented on the value of the picture and in thinking together about ways the process could fail. As they identified those potential failures, they began to share ideas for how to prevent or mitigate the risk. It was a reminder of how important having safety conversations is in preventing harm.

In discussions with primary care clinicians, they often share frustrations about the noncompliant patient. In our analysis of vulnerabilities, it was encouraging to note the common vital few vulnerabilities that both patients and clinicians agree are areas of risk. These shared areas are ripe for discussion between patients and providers as they work together to make medication use safer in both the healthcare setting as well as the home setting, where most medications are taken. Additional study/discussion with both pharmacists and primary care clinicians about why the discrepancy between what patients report as risk and their perceptions could yield new insights.

The purpose of this study was to understand medication management so that insights could help both patients and healthcare professionals improve safety and reduce risk. The two models that came out of our vulnerability analysis may be helpful in identifying interventions in three specific domains – with the patient, with the healthcare system, and through collaboration between the two. In Model B, there were five vulnerabilities that cannot be mitigated without the collaboration of both patients and healthcare professionals.

One intervention that was a result of the study is a Patient Safety Program created by patients for patients. The chapter on Medication Safety highlights some patient "medication management" best practices and ways of thinking and interacting with a healthcare provider to promote medication safety. The potential

risks identified have highlighted some possible areas, such as where interventions might improve medication management safety.

List of Publications and Products:

Johnson, B., Abraham, M., Conway, J., et al. (In press). *Partnering with Patients and Families to Design a Patient- and Family-Centered Health Care System: Recommendations and Promising Practices.* Bethesda, MD: Institute for Family-Centered Care. *Note:* A profile of the AHRQ Medication Management grant is included in a chapter entitled Creating Partnerships in Ambulatory Care.

PHMG Patient Advisory Council,. *"Your Health Care and Safety - The Team Approach at PeaceHealth."* 2009 September 13. Eugene, OR http://www.peacehealth.org/Oregon/PHMGClinics/PHMGVideos.htm

Conference Presentations

Minniti, MM Stock, R Ovitt, B. Medication Management at Home: Patient Identified Processes and Risk Assessment. Sacred Heart Foundation 4th Annual Clinical Research Recognition Event, 2009 October 13; Eugene, OR.

Minniti, MM. Involving Patients in Quality Improvement. Institute for Family-Centered Care Seminar, 2009 October 26-29; Minneapolis, MN.

Minniti, MM, Stock, R. Medication Management at Home. Institute for Family-Centered Care Seminar; 2009 October 26-29; Minneapolis, MN.

Minniti, MM. Medication Management at Home: Patient Identified Processes and Risk Assessment. AHRQ Annual Conference m*AHRQ*et Place Café Poster; 2008 September 7-10; Bethesda, MD.