

# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

## 1. TITLE PAGE

Project Title: Patient-Centric Risk Model for Medication Safety During Care Transitions

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# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

## 2. ABSTRACT

**Purpose:** This project was to develop a patient-centric risk model of medication related harms during transitions by (1) identifying hazards to medication safety using a patient work system framework, (2) developing a risk assessment tool, and (3) evaluating the risk assessment tool in a multi-site, prospective, longitudinal study.

**Scope:** The transition to home following hospital discharge is a high-risk period, with older adults being particularly vulnerable to adverse drug events. A human factors approach is needed to understand risks involved in medication use in ambulatory settings across care settings.

**Methods:** We conducted qualitative studies with healthcare professionals and patients at a community hospital and an urban academic safety-net hospital, including home observations after patient discharge, We then developed a risk assessment tool that captured information on patient home work system and patient-reported outcomes, in addition to chart review. Using this tool, we prospectively collected data from patients 65 years or older discharged from general medicine services.

**Results:** Top sources of hazards for medication related harms identified by professionals were defects in patient education and inadequate home work system, challenging medications, cost, and information inaccuracies. Medications most frequently cited were anticoagulants, insulins, diuretics, opioids, and antiplatelets. Challenging tasks reported by patients were making sense of medications and reconciling medications into home routines. Top risk factors identified based on longitudinal risk assessment of 376 patients were education, income, comorbidity, number of medications and types, lower quality of preparation for care transitions, number of prescribers, and self-efficacy for medication management.

**Keywords:** medication safety, care transitions, older adults, self-care, risk model, high risk medications, human factors, systems engineering

# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

## 3. PURPOSE

This project was to develop a patient-centric risk model of medication errors during transitions to ambulatory care, with the following aims: (1) Identify hazards and mitigating strategies to medication safety using a patient work system framework; (2) develop a patient-centric risk assessment tool through prospective qualitative studies; and (3) evaluate the risk assessment tool in a multi-site, prospective study of hazards and mitigating factors medication safety and their associations with medication discrepancies and potential adverse events.

## 4. SCOPE

Medication safety is a worldwide concern, and its improvement is the goal of the third World Health Organization patient safety campaign. In the US, adverse drug events (ADEs) in community settings accounted for 2.5-11.2% of all emergency department visits with unintentional injuries, nearly half judged as preventable (1, 2). After hospital discharge is a high-risk period,(3, 4) with 18.7% of patients developing ADEs within 45 days in one study (5).

Risks for medication-related harms in ambulatory care are multi-dimensional and complex (6, 7). Lack of comprehensive data on medication use, distributed nature of multiple providers, a multitude of care episodes, and chronic conditions are some of the challenges to study ambulatory medication use (8, 9). Led by human factors experts, this project took a systems engineering approach to understand risks involved in medication use in ambulatory settings, to consider patients and their home environments as critical elements for medication safety. This approach is in contrast with approaches that focus exclusively on patient’s demographic and disease conditions. The project was designed to inform an intervention to target modifiable risk factors related to managing medications safely after discharge. These factors include task difficulties in managing medications during care transitions and supporting systems at home (10-12).

Patient-centered perspectives are key to improving medication safety in ambulatory care settings, as medication management activities are self-directed. Studies have consistently demonstrated the benefit of patient engagement and support of medication use tasks through enhanced discharge medication education, timely medication adjustment and follow-up visit,(13, 14) and home-based medication management services (15). Human factors and systems engineering approaches and techniques are most suitable to study medication management from the patient’s perspective, to advance knowledge about patient’s and home caregiver’s role in medication safety during care transitions. Such knowledge should direct future research efforts, such as using emerging information technology to medication safety in community settings (e.g., medication reconciliation by a patient portal (16)) and developing new care delivery models (17). The epidemiology of hazards and risks and their association with medication errors based on the patient-centric risk model provided a first prospective, epidemiologic study of its kind in the ambulatory patient safety literature.

## 5. METHODS

### 5.1 Study design

This multi-site project contained theoretical modeling, qualitative studies with patients and care professionals, and epidemiological study of medication safety risks using a longitudinal, quantitative data collection approach at hospital and patient homes to develop a foundation for innovative interventions to improve patient safety in ambulatory settings.

Aim (1) Qualitative methods: individual semi-structured interviews with patients and care professionals, patient home visit observations, and focus group discussions using the nominal group technique to elicit individual and group opinions and perspectives pertaining to medication safety during care transitions.

Aim (2) Model development: literature review of instruments and concepts, guided by Aim 1 data, and pilot testing. The patient-centric aspect of the risk assessment tool was based on the consideration of the tasks of and capabilities for medication management during transition, especially at home.

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

Aim (3) Prospective data collection: structured data, based on the patient-centric risk model developed in Aim 2, from patient interviews, chart review, and at-home observation at four different time points (T1: before discharge, T2: immediately after discharge, T3: within 1-2 weeks after discharge with visits to patient’s home, and T4: 4-6 weeks after discharge with phone call).

### 5.2 Data sources/Collection

Data collection sites. During the risk tool development, data were collected from professionals at two health care systems (Baylor Scott & White Health based in Dallas, Texas, and Johns Hopkins Medicine in Baltimore, Maryland) and from patients and their home caregivers with a recent hospitalization at these two systems. During Aim 3, prospective data were collected from patients recruited at two hospitals from Johns Hopkins Medicine: one safety-net urban hospital, and one community hospital.

Study participants. Four groups of study participants were recruited. All data collection procedures were approved by relevant human subject review committees and administrative authorities.

Patient and home caregiver participants for qualitative studies. Qualitative data were collected from patients and caregivers. Older adult patients (65 and above) were enrolled into the study just prior to discharge and were visited in their homes on two different trips (within a week of discharge and about a month following discharge). Thereafter, they were contacted for a third time via phone call to conduct a follow interview. During the two home visits, research team members interviewed patients (and, when available, family caregivers) to assess their experience of the discharge and hospital-to-home transition process and elicit their perspectives on barriers to safe medication management after discharge. Photographs were taken when permitted to capture home environment, tools, and devices used to support medication management (e.g., discharge medication lists, pillboxes, medications storage locations). All interviews were audio recorded and professionally transcribed.

Healthcare professional participants. Healthcare professionals were enrolled to participate in both individual semi-structured interviews and focus group discussions. We enrolled hospitalists, primary care physicians, admission and discharge nurses, pharmacists and pharmacy technicians, case managers, social workers, care coordinators, transitional and home care nurses, and primary care providers. Individual interviews and some of the focus group discussions were audio recorded and professionally transcribed.

Pilot study participants. The risk assessment tool was pilot tested with 20 patients enrolled at one of the study site hospitals. Data collection using the risk assessment tool involved interviewer-administered surveys at three different points: First, patients were contacted in their hospital rooms and interviewed before being discharged to their homes. Second, patients were visited in their homes within a week of their discharge and interviewed for a second time, at which time the interviewer used the risk assessment tool to document medication safety risks during the transition period and in the home. Third, patients were interviewed via phone for a third and final time to assess and document any changes in medication management routines and barriers that might have developed since prior contact.

Risk assessment tool study participants. Inclusion criteria were age 65 years or older, home as discharge destinations, admitted for medical services, and a length of hospital stay longer than 24 hours at one of the recruitment units (three medical-surgical units in one hospital and all medical-surgical units in another hospital). Exclusion criteria were living more than 20 miles away from the hospital, unable to consent due to limited cognitive capabilities, and not English speaking. The risk factors as reflected in the risk assessment tool, demographics, medications, and adverse events were collected at four time points: interviews during hospital stay (T1), chart review upon discharge (T2), at-home interview and observation (T3, usually within 1-2 weeks of discharge), and a follow-up telephone interview (T4, usually 4-6 weeks of discharge).

### 5.3 Interventions

The project was observational and did not implement any interventions.

# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

## 5.4 Measures

Observational measures were collected through the risk assessment tool, medication discrepancies, causes, any self-report adverse drug events, hospital visits, and patient-reported outcomes of medication safety.

## 5.5. Data Analysis

Qualitative analysis. We used NVivo to code transcript data and to develop themes through a consensus process.

Bivariate Correlation Analysis. Given that most of our primary and secondary outcome variables were ordinal or nominal in nature, we used Spearman's rank correlation coefficient for more conservative assessment.

Regression Modeling. We used forward stepwise regression (with p value of 0.1 as forward selection criterion, with no exit criterion) as our modeling technique due to the innovative and in-depth nature of our work and lack of previously established models in the literature based on such in-depth, rich data on work systems and care processes. Due to the difficulty in reaching out and scheduling a home visit within the ideal targeted time window of 14 days or so, we also included home visits (T3) conducted outside of the 14-day time window and analyzed accordingly. As part of sensitivity analyses, we conducted separate regression analysis with different subsets of patients. The second set of regression analysis included only those patients with T3 completed within 30 days, and the third regression analysis included only those with T3 being completed within 14 days.

## 5.6. Limitations

The project was limited in terms of patient population studied, the sites included, and data collected. As with any studies using observational study design, findings were associations.

We recruited 376 patients, lower than the planned recruitment target of 440. After making multiple recruitment related meetings at both participating hospitals, the number of patients not discharged directly to home was much higher than initially estimated. We engaged with experts and the Project Officer (Dr. Bartman) on recruitment goals. Because the power calculation suggested that the study power (measured by errors of margin in estimating medication discrepancies) was relatively insensitive to the number of recruited patient study participants above N=150 patients for this observational study, we believe that our model evaluation efforts achieved the needed recruitment goal with N=376.

## 6. RESULTS

### 6.1 Principal findings

6.1.1. Theoretical framework (Aim #1). We conducted literature review and developed a framework to characterize hazards/risks for medication safety during transition from hospital to home as a result of mismatches (“Fit?”) between the task burden imposed on the patient's home work system and this system's capabilities (Figure 1). The framework informed our development of a patient-centric risk assessment tool (described below under Aim 2 and 3 in more detail) by identifying potential risk factors in characterizing a patient's home-based work system, taking into account the tasks confronting the patient's home work system when the patient is during transition.

6.1.2. Defining patient-centered approaches to medication safety (Aim #1). We reviewed literature through the lens of patient-centered care and identified commonly used health system-oriented medication safety measure concepts, and we assessed evidence of their appropriateness for patients and how they could be adapted to be more patient centered (18). We contrasted these with newer measurement concepts designed to be more patient centered but not yet developed into measures or widely used for interventions, such as patient-reported adverse events, and discussed the potential for developing measurement concepts based on significance to patients, such as goal-oriented medication lists (Table 1). Studies to improve ambulatory medication safety in healthcare generally have focused on healthcare system-oriented measures, such as medication discrepancies and readmissions. However, such measures may not meaningfully reflect the patient perspective. Design and evaluation of interventions to enhance self-management of medications throughout healthcare settings should consider approaches to increase patient-centeredness in medication safety.

# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

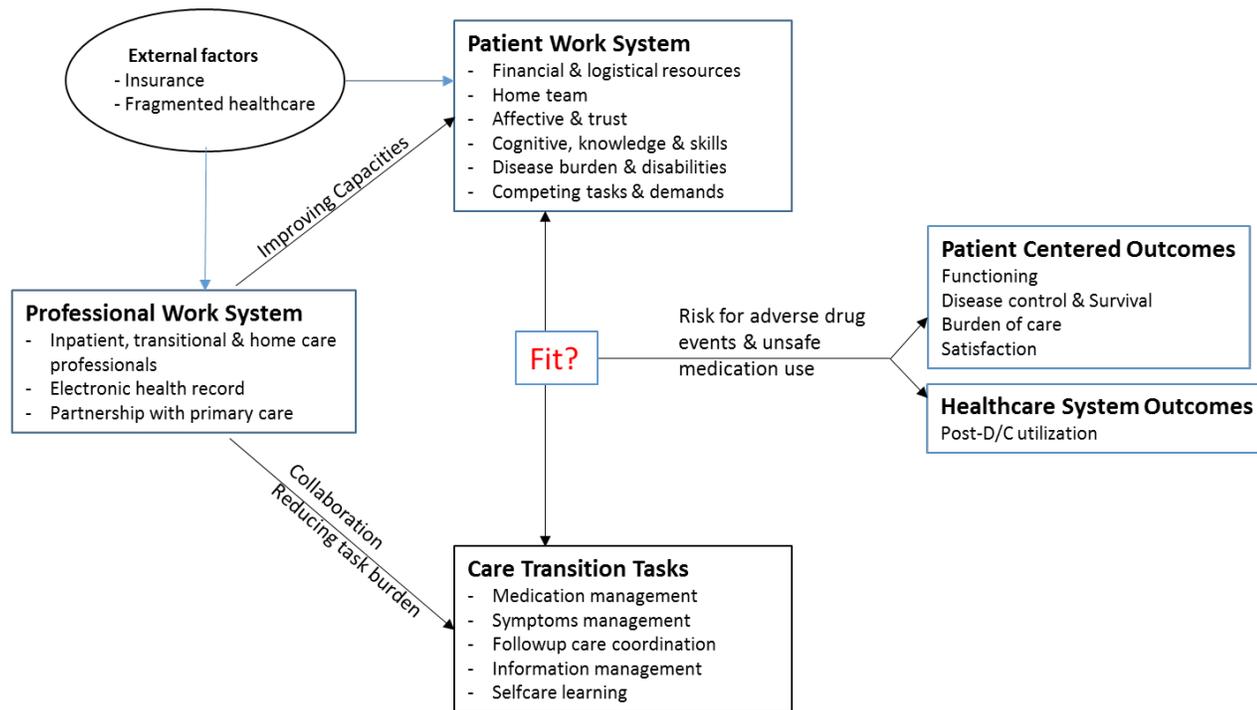


Figure 1. A theoretical framework of risks and hazards for medication-related adverse events.

Table 1. Health system-oriented and patient-oriented medication safety measurement concepts

Measures	Healthcare system-based data	Patient-reported data	Approaches to increase patient-centeredness
<b>Health system-oriented medication safety measures</b>			
<b>Medication discrepancies</b>	Medication lists, as listed in health records (reconciliation by providers)	Patients' own medication records or personal health records	Include patient reporting of importance of adherence to specific medications
<b>Drug-drug interactions</b>	Medical or pharmacy records or computer systems	Patient concerns, including interactions and side effects	Include patient reporting about drug-drug interactions with risk of adverse events and side effects; notation of patient preferences
<b>Medication errors (commission and omission)</b>	Medical records documentation; provider reporting	Patient reporting of perceived errors; patient reporting of capacity to manage complex regimens	Include patient preferences for medication use, side effects, cost
<b>Appropriateness</b>	Comparison with best practice or guidelines using medical or pharmacy records, such as the Beers Criteria	Patient reporting of health priorities and treatment burden	Include patient reporting of treatment burden and medications patient want to take
<b>Adverse drug events</b>	Medical records (as documented by providers)	Patient reporting of adverse drug events	Include data on preferences, side effects and long-term adverse effects in records
<b>Nonadherence</b>	Medical or pharmacy records	Patient reporting of medication adherence, including reasons for non-adherence, rationale for medications	Collect and include data on health priorities for patients, including preferences for medications and side effects in records
<b>Patient centered medication safety measures</b>			
<b>Quality of communication regarding medication management process</b>	Medical record documentation of patient understanding or deficits in knowledge	Patient survey on knowledge about medication risks and comfort with taking medications	Collect and include data on patient preferences in communication with providers (e.g., telephone or electronic, language of choice) in records

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

<b>Engagement</b>	Medical record documentation of providers’ perceptions of engagement in their medication safety	Patient survey, patient use of medication safety tools	Ask patients about preferences in their engagement with providers, ask questions and discussing goals of medications
<b>Medication safety-related quality of life</b>	Medical records documentation of issues related to quality of life and medication safety	Patient reporting of relevant quality-of-life issues	Ask patients about healthcare and safety goals and medication approaches appropriate for achieving these goals
<b>Patient concerns about safety</b>	Patient concerns about safety documented in the medical record	Patient- and family-reported healthcare concerns and priorities in the visit	Collect and report information outside of provider visits, relate information to patient goals
<b>Patient-reported experience</b>	Patient reporting of healthcare satisfaction related to medication discharge management in existing hospital surveys	More detailed satisfaction survey with medication safety issues (e.g., medication education or reconciliation process)	Include discussion or survey of patient goals, preferences, and medications they are willing to take

6.1.3. Work system approach to understanding partnership between professionals and patients during care transitions (Aim #1). Based on human factors principles and inspired by observations at patient’s homes after hospital discharges, we developed a set of recommendations on ways to engineer work system components to support partnership with patients and their caregivers at different stages of a care episode. These recommendations were aimed to enable productive interactions among work systems that are distributed and are often limited in their ability to exchange information and co-align their interests (19). There are major gaps and barriers for patients and caregivers after hospital discharge to achieve safe medication use. Patients and caregivers are often not ready to take on the responsibility for medication management when transitioned from inpatient care. Current approaches tend to focus on adding isolated strategies. A system thinking can enable a fundamental transformation to redesign professionals’ interactions with patients and caregivers with an explicit goal to develop patients and caregivers into true partners, with targeted roles, skills, attitude, knowledge, and tool support. Our recommendations were built on the fact that medication safety during care transition and, more so, at patient homes is the property of a “work system,” in which the patient and caregivers are at the center, with collaboration with health professionals.

6.1.4. Identifying barriers and facilitators for medication management tasks after discharge (Aim #1). We conducted a total of 10 focus group sessions using the nominal group technique (NGT) approach (eight at BSWH sites and two at JHU sites) with clinicians to delineate barriers/risks to and facilitators for medication management tasks following hospital discharge. We also interviewed 46 healthcare professionals (inpatient nurses, hospitalists, pharmacy techs, discharge nurses, transition guides, social workers, and care managers) at the two organizations. These interviews and focus groups supported some of the known risk factors usually classified as systems related (e.g., errors in discharge medication list) or patient related (e.g., intentional medication nonadherence) and also led to identification of new risk factors (e.g., time-sensitive mediations) and further insights regarding how an intervention study in the future can be developed to mitigate these risks. We used these interviews and focus groups to identify the frequently mentioned risk factors that have high potential for adverse drug events. The risk factors identified based on preliminary analyses of these qualitative data were used in iterative development of the planned patient-centric risk assessment tool.

We identified the collective perspectives of multidisciplinary healthcare providers to better understand the factors affecting the safety of medication management process during transitions of care from hospital to home, using a nominal group technique to collect data and analyses about processes and emergent issues most critical in assessing patients at risk for preventable adverse drug events. A total of 34 professionals of case coordinators, case managers, hospitalist providers, nurses, pharmacists, and social workers from the two study systems participated in focus groups. Analysis of the data revealed several emergent themes relevant to barriers in the medication management process. With a focus group technique, we identified the collective perspective of multidisciplinary healthcare providers to better understand the ergonomics of medication management during transition of care.

6.1.5. Work system analysis of barriers for patient self-management after discharge (Aim #1). Framing the care transition as a collaboration between healthcare and patient “work systems,” we conducted semi-structured interviews with 33 clinicians, representing 10 different roles directly involved in providing care for patients

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

during this transitional period. Analysis of interviews identified key barriers that clinicians felt impeded preparing patients to self-manage their medications safely in the home environment: (1) streamlining and coordinating clinical management of medication reconciliation across care settings; (2) building patient capacity and engagement in self-management of medications; and (3) redesigning the transitional process. Our research highlights the value in framing care transition goals of professionals when preparing patients and their caregiver(s) to self-manage medications upon discharge.

**6.1.6. Hazards that increase the risk for preventable harms.** Care transitions pose high risk for adverse drug events. Frontline clinicians working with patients and family members during care transitions may provide insights on hazards that increase the risk for preventable harms. We analyzed the interviews for hazards mentioned and categorized by their sources, along with medications mentioned.

Interviews analyzed were from 25 healthcare professionals at two healthcare systems (n=3 hospitalists, n=17 nurses - bedside or case managers, n=3 clinical pharmacists, n=1 pharmacy technician, and n=2 social workers). The professionals were asked about risks for adverse drug events during care transitions among older adults.

Five sources of hazards were identified: education and home work system, challenging medications, cost, information inaccuracies, and system gaps. Medications most frequently cited were anticoagulants, insulins, diuretics, opioids, and antiplatelets (Table 2). Anticoagulants and insulins were cited in four of the five sources of hazards. Top hazards associated with education and home work system were regimen change related (e.g., unaware of importance of newly prescribed discharge medications or confusion with generic names). Complex dosing was cited as the top hazard category associated with challenging medications. Duplications in discharge medications (either same medications or medications with similar actions) were the top hazard associated with information inaccuracies. Using or switching to medications with nonsustainable cost, especially with large price differences among choices, was the leading cost-related hazard. Unavailability in the community settings was the top hazard associated with system gaps, mostly for asthma or chronic obstructive pulmonary disease medications.

**Table 2.** Top 10 medication classes cited in describing hazards for ADEs, by number of citations by study participants

<i>Medications</i>	<i>Education &amp; home work system</i>	<i>Challenging medications</i>	<i>Cost</i>	<i>Information inaccuracies</i>	<i>System gaps</i>	<i>Total</i>
Anticoagulant	12	10	10		1	33
Insulin	3	11	7			21
Diuretic	8	3		5		16
Opioid		8		4	2	14
Antiplatelet	8	2	1	2	1	14
Bronchodilator/inhaled corticosteroid	2		1	2	2	7
Beta blocker	4			3		7
ACE inhibitor	4		1	1	1	7
Antiarrhythmic		2		4		6

**6.1.7. Ethnographic observations and cognitive engineering interviews (Aim #1).** We used the Systems Engineering Initiative for Patient Safety (SEIPS) model and Wagner’s Chronic Care model to guide observations and interviews. We visited 36 patient homes at both study sites to conduct in-depth, semi-structured interviews and observations after discharge (Table 3). Each enrolled patient was visited twice at his/her home (first visit within a week of discharge; second visit about 30 days from discharge). We took pictures of key cognitive artifacts (e.g., pill bottles, medication management systems developed by patients such as medication schedules). Example photos are in Figure 2. A follow-up phone call interview was also made 2 to 3 months after discharge. In total, 36 participants were enrolled between the two study sites (18 at each site). 229 photographs were taken from 27 of the enrolled participants, which included photographs of discharge medication lists for 17 participants. Photographs were not taken for eight participants, because patients did not provide permission, items were unavailable, or items were located in a room different from the site where interviews were conducted.

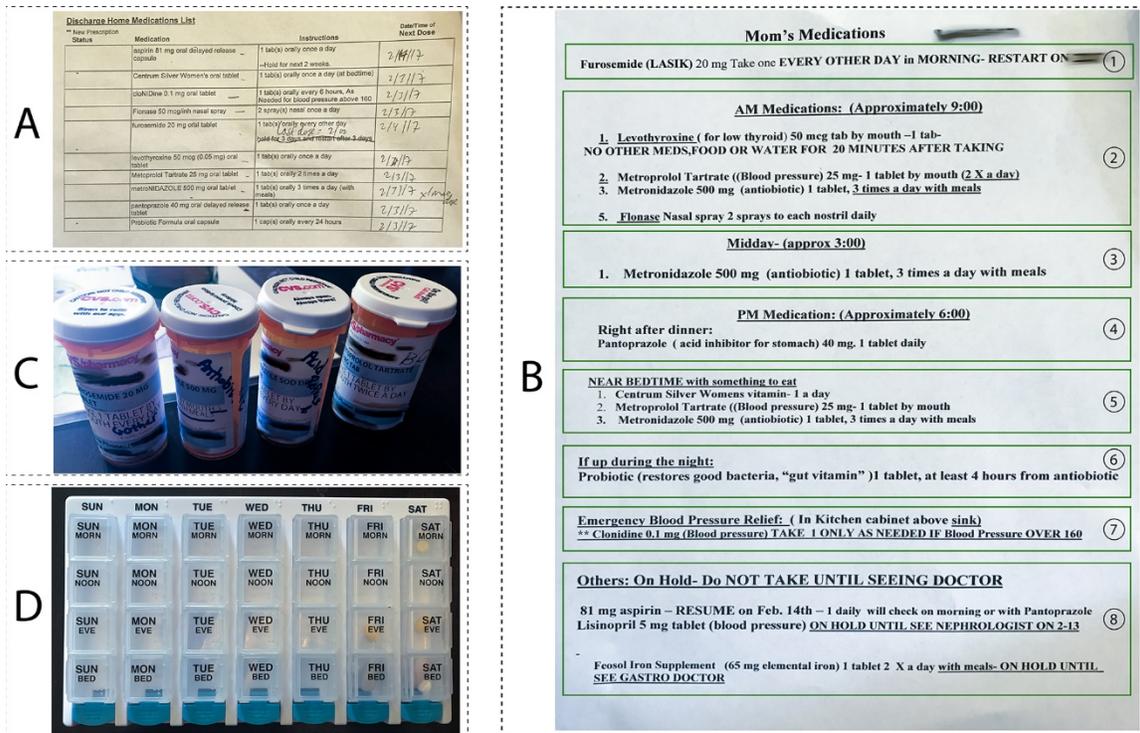
# Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

6.1.8. Opportunities for support “Home Teams” (Aim #1). During the home visits, we identified numerous opportunities to engage and support “home teams” (patient, family, informal caregivers) and any other during and after hospital stays: (a) Patients and families reported receiving a large amount of information at discharge, generally not individualized to their immediate needs and difficult for them to use to communicate with post-discharge professionals (e.g., community pharmacists, home care nurses); (b) Patients and families usually did not have a clear understanding of what they need to do to maximize safe medication use; (c) Interactions with multiple professionals at hospitals were not coordinated (e.g., hospitalist and discharge nurse), often resulting in communicating seemingly conflicting information to patients and families; (d) Patients and families were confused about who to contact for help or for clarifying any questions/concerns.

**Table 3:** Characteristics of enrolled participants and medication list information

Variable	Study Site A (n=18)*	Study Site B (n=13)*
<b>Participant Characteristics</b>		
Age (median, range, in years)	71 (67-83)	81 (65-93)
Sex (Females) (%)	56%	69%
<b>Race/Ethnicity</b>		
White	67%	92%
Black/African American	33%	8%
<b>Medication List Information</b>		
Median # of medications in medication list (range)	12 (6-22)	12.5 (11-20)
AVS number of pages (median, range)	6 (4-12)	3 (3-4)

\* Total number of participants for whom demographic information was available (total=31 patients). Medication list information is based on 17 patients for whom photographs of discharge medication lists were available. AVS: after visit summary.



**Figure 2:** Tools and devices examined at patient homes. A: Medication list at discharge; B: medication schedule created by a family caregiver; C: annotated prescription drug labels to emphasize indication; D: pillbox used by patient.

6.1.9. Medication management tasks during care transitions (Aim #1). Our analysis generated a set of tasks (Table 4), most of which were not recognized and consequently were not supported. As one example, patients and family caregivers performed the tasks of making sense of medications provided, versus the traditional view of following physician orders. They needed to understand how the medications work for them and needed to believe the indicated benefits of the medication through personal experiences, versus via a purely intellectual comprehension task (Box 1 for an example). As another example, reconciling discharge medication

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

instructions with medication routines as home is not a trivial task, such as adjusting medication routines based on current patient conditions and new medication regimens developed at discharge.

### Box 1: Emma’s Work System

Emma’s daughter, Becky, was managing her mom’s medications and records at home. When Emma was hospitalized, Becky visited every day and communicated with the doctors and nurses about her mother’s condition and medication regimen. Each day, the doctors and nurses shared their thoughts and Becky discussed the insomnia and nausea medications prescribed by different doctors, which were making her mother drowsy in the morning. These conversations enabled Becky to better manage her mother’s conditions at home after discharge. Becky always used the same community pharmacy and knew the pharmacist well. She picked up all the discharge prescriptions and worked with the pharmacist to develop a new medication schedule, which included a “taper” with dose adjustment that meant a change in Emma’s daily life routines. The first day, Becky woke her mother up early to take the morning medications and realized that her mother was sleepy most of the day from a new allergy medication. As a proactive caregiver, Becky held one sleeping aid until her mother’s next doctor’s appointment (which was only a few days later). Becky started using a large file folder provided by the doctor to organize the drug brochures and other documents (Emma had been in the hospital three times in the past year and had visited the offices of three different specialists). She also started logging her mother’s medications in a notebook, a strategy she learned from one of the home health nurses.

**Table 4.** Themes related to medication management tasks

1. **Hospital (Inpatient) Tasks:** patient fully under the care of inpatient clinicians
  - 1.1. **Advocate for safety:** asking questions about medications, sharing previous experience with a medication,
  - 1.2. **Make sense of hospital administered medications and clinician actions:** understanding actions of hospital clinicians, learning names and actions of medications administered in hospital
  - 1.3. **Mediate information across inpatient clinicians:** serve as information safety net across frequently changing hospital clinicians
2. **Transitional Tasks:**
  - 2.1. **Admission-related transitional tasks:** during home/community to hospital transition-tasks during the peri-admission period, first few days before and after the immediate admission day.
  - 2.2. **Discharge-related tasks:** during hospital to home transition-peri-discharge period and first few days to first weeks of post-discharge period
3. **Maintenance Tasks:** tasks during maintenance phase in home/community, following the immediate post-discharge period
  - 3.1. **Make sense of medication regimen:** learn when to take, how to take, if should take or not, consequences of taking or not taking medication; understanding changes in medication regimen
  - 3.2. **Manage medication supplies:** anticipate and monitor home medication stock, navigate insurance/medication cost, make phone calls, fill prescriptions, arrange for pickup/delivery of medications, store medications, discard unused/expired medications
  - 3.3. **Mediate information across outpatient clinicians:** asking questions about medication; sharing information between primary care provider and specialty care providers; filling information gap across providers
  - 3.4. **Organize medications and supplies:** identify appropriate pillbox; fill pillbox container, situate medications for timely administration
  - 3.5. **Prepare final medication doses:** perform dose/dosage form manipulations and prepping before administration (e.g, shake inhalers, cutting pills into appropriate size)
  - 3.6. **Administer medicines:** remembering to take medicines, taking medicines at the right time, dose, and frequency
  - 3.7. **Monitor medication effects:** measure, document, and track self-monitoring values (e.g., blood pressure, glucose, weight, urine output); infer effect in relation to medication use; track/become aware of positive or adverse medication outcomes
  - 3.8. **Routinize medication management tasks:** strategize for common and odd schedule medications, integrate new medications into existing medication regimen

6.1.10. A patient-centric risk assessment tool through prospective qualitative studies (Aim #2). We developed, refined, and pilot tested the risk assessment tool based on qualitative studies and guided by the project framework (Figure 1). The tool assesses risk factors at three time points. Whenever possible, we used validated measures reported in the literature.

#### T1 - During inpatient stay: risk factors associated with patient work system

- Home team assessment (project developed)
- Assessment of self-administration of medications (modified from MedMaIDE (20))

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

- PROMIS Self-Efficacy Managing Medications (21)
- Family caregiver activation in transition (22)
- Medication access and affordability (project developed)

### T2 - Upon discharge: risk factors associated patient transition tasks

- Medication Regimen Complexity Index (23)
- Medication changes (project developed)
- High-risk medications (24)

### T3- Transitioned to home: risk factors associated with patient work system

- Professional support (project developed)
- Transitional care activities (project developed)
- Tools and practices of medication management at home (project developed)

We refined and pilot tested the patient-centric assessment tool in 20 patients in two cohorts, resulting in minor modifications of the tool for wording and workflow.

6.1.11. Evaluation of the risk assessment tool in a multi-site prospective study to identify hazards and mitigating factors for medication safety during care transitions (Aim #3). We used three groups of variables as outcome measures for evaluation of the risk assessment tool:

#### Care process outcomes

- Medication discrepancy tool (25)
- Transitional care measure (26)

#### Patient-reported outcomes

- Medication-related problem survey (27)
- Post-discharge ED or hospital visits
- Professional support (project developed)

The overall data collection plan is in Table 5. We collected data from a total of 376 patients (Table 6)

from the two participating hospitals between October 2018 and August 2019. The patients were recruited with inclusion and exclusion criteria described earlier.

Two research pharmacy technicians, trained on the use of patient-centric risk assessment tool by the research team, were situated at the hospitals (one each) to recruit eligible patients before discharge and then collect data from each patient at four different time points using a variety of methods (patient interviews, EHR chart review, structured observations at patient homes, and telephone call): T1 - before discharge (in hospital room), T2 - immediately after discharge (EHR chart review), T3 - home visit-based data collections after discharge, and T4 - phone call follow-up patient interview approximately 4 weeks after T3 (Table 6, last three columns). REDCap was used for a secure electronic entry and storage of data in compliance with IRB and HIPPA regulations. The REDCap database was hosted at the Johns Hopkins Institute for Clinical and Translational Research Center.

**Table 5.** Data collection overview, including variables for Patient-Centric Medication Safety Risk Assessment Tool, outcome measures, medications, and patient demographics

Construct (# of items)	Measure (example construct, Cronbach’s alpha-if applicable)	Data collection time and source	Source	
Identifier (2)	e.g., MRN			
Patient demographics (4)	(e.g., age, sex, gender, race)	T1/EHR	Developed based on literature and Aims 1&2; pilot tested with 20 patients	
Demographics/ background info (10)	(e.g., transportation mode, education level, income, primary care physician)	T1/patient interview		
Patient basic medical info	(e.g., admission diagnoses, LOS, # of admissions, Charlson Comorbidity Index)	T1/EHR		
Caregiver info and tasks (6)	(e.g., caregiver at home, tasks caregiver help)			
Medication access (2)	(e.g., Have you skipped filling your prescriptions due to problems with insurance .....?)	T1/patient interview		
Self-efficacy for med manag (4)	(e.g., I can follow directions when my doctor changes my medications); Cronbach’s alpha=0.75			PROMIS Self-Efficacy for Managing Medications(21)
Patient capability of how to take medications (3)	(e.g., “Can you pls read the drug name in the medication bottle?” in a simulated test)	T1/patient interview		MedMalDE <sup>5</sup> (20)

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

Admission medication list	Medication name, dose, strength, frequency, dosage form, special instructions (for each medication)	T2/EHR	
Discharge medication list	Medication name, dose, strength, frequency, dosage form, special instructions (for each medication)		
Complexity of medication regimens	form (e.g., oral-capsule); frequency (e.g., twice daily); additional instructions (e.g., relation to food)		Medication Regimen Complexity Index (MRCI)(28)
High-alert medications (3)	Number, name		(24)
Medication changes (4)	(e.g., # of medication changes from one generic to another, # of new medications to start after discharge)		(29)
Patient contact attempts (5)	(e.g., total # of attempts, reason if not successful)	T3	
Medication discrepancies – in transitions from acute care	(e.g., discrepancies exist?, types, causes)	T3/comparing discharge medication list & medications at home	Medication Discrepancy Tool (30)
Major events since discharge	(e.g., Since the patient came home, did the patient go to the emergency department or hospital? [Y/N])	T3/patient interview at home	Developed based on literature and Aims 1&2; pilot tested.
Transitional care activities at home	(e.g., Have you reviewed written discharge instruction materials after coming home?)		
Medication-related workload (2)	(e.g., Were you overwhelmed in the first few days after coming home with the new medication regimen?)		
Quality of preparation for post-hospital care (3)	(e.g., When I left the hospital, I clearly understood the purpose of taking each of my medications); Cronbach's alpha=0.74		Transitional Care Measure (26)
Medication-related problems (MRP) (9)	(e.g., My medication interferes with my routine daily activities); Cronbach's alpha=0.79		Medication-related problems scale (MRP) (27)
Home work system	(e.g., storage location, methods, types, schedule helpers, tasks & task distribution)		Developed based on literature and Aims 1&2; pilot tested.
Patient contact attempts at T4 (5)	(e.g., total # of attempts, reason if not successful)	T4	
Major events since T3 visit (5)	(e.g., Since my last visit with you on [DATE], have you been to the ED or admitted to a hospital?)	T4/ phone interview	Developed based on literature and Aims 1&2; pilot tested.
MRP (9)	See above		MRP (27)

<sup>§</sup> Adapted/ modified (as opposed to 'used exactly as reported in the existing literature)

**6.1.12. Medication management task burdens and home work system capacities.** The number of tasks to be performed by patients during immediate transition was high. On discharge, the IQR number of medications per patient was 8-16, including one high-alert medication, and the median MRCI was 26 (IQR: 16.5-38).

Among the patients recruited (Table 6), 38% were 75 years or older, over one quarter were non-White, and a third had annual income less than 25K. One half reported having three or more prescribers, almost all reported having a primary care provider, and approximately a third had three or more hospital admissions within the last year. Almost all had health insurance, but approximately a quarter reported skipping medications in the past year due to problems with insurance or paying coverage. Notably, most (80%) of the patients did not have a family caregiver at home (Table 7); those who had a family caregiver reported having/using caregiver help for a subset of medication management tasks (Table 7). Only half of the patients reported that they or their caregiver brought medication list/bottle to hospital at admission. Simulated evaluation of patient capability by pharmacy technicians using a fake medication bottle and label revealed that only 82% of our sample could complete all the three basic tasks (i.e., reading medication label, describing how to take medication, and opening the bottle) necessary to be able to take medications correctly based.

**Table 6.** Patient Characteristics (in percentage). Hospital 1: Urban safety-net; Hospital 2: Suburban community

	TOTAL N=376 (100%)	Hospital 1 N=156 (41%)	Hospital 2 N=220 (59%)
<b>Sex</b>			
Female	61.7	69.2	56.4
<b>Age</b>			
65-69	30.3	35.9	26.4
70-74	31.1	31.4	30.9
75-79	17.8	15.4	19.6
80-84	13.8	11.5	15.5
85+	6.9	5.8	7.7
<b>Ethnicity</b>			
Non-Hispanic	98.1	98.1	98.2

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

Hispanic	1.1	1.3	0.9
<b>Race</b>			
White	73.7	74.4	73.2
Black/African American	21.8	24.4	20.0
Asian	2.4	0.0	4.1
Other	2.2	1.2	2.8
<b>Education</b>			
Below high school	13.6	24.4	5.9
High school graduate	20.7	29.5	14.6
<b>Income</b>			
Under \$25K	34.5	57.1	18.7
\$25K- \$50K	22.3	24.4	20.9
\$50K+	39.4	15.0	55.9
Not reported	3.7	2.6	4.6
<b>Insurance</b>			
Medicare only	10.1	12.2	8.6
Medicaid only	0.5	0.6	0.5
Commercial only	3.5	1.9	4.6
Medicare + Medicaid	12.5	14.7	10.9
Medicare + Commercial	68.4	62.8	72.3
All three	4.0	6.4	2.3
No insurance	1.1	1.3	0.9
<b>Transportation</b>			
Car	66.0	51.3	76.4
Friend	27.9	35.3	22.7
Public transportation	11.4	16.7	7.7
Other	4.0	8.3	0.9
<b># of prescribers in the past year</b>			
None	3.5	5.1	2.3
1	22.9	32.1	16.4
2	23.4	23.7	23.2
3+	48.9	35.9	58.2
Not reported	1.3	3.2	0.0
<b>Length of hospital stay, days</b>			
1	4.3	8.3	1.4
2	15.2	15.4	15.0
3+	80.5	76.3	83.6
<b>Documented allergy</b>			
Yes	55.6	56.4	55.0
<b># of hospital admissions in the past year</b>			
0	0.3	0.0	0.5
1	45.7	48.1	44.1
2+	54	51.9	55.4
<b>Time 3 (T3): # of days between hospital discharge and home-based data collection</b>			
T3<=14 days	28.5	59.2	11.4
15<=T3<=30 days	37.6	29.6	42.1

**Table 7.** Patient and family caregiver home work system characteristics as evaluated while in the hospital

	N=376	%
<b>Having a caregiver at home, N (%)</b>		
No	303	80.6
<b>Tasks caregiver helps (for those who have a caregiver (N=73))</b>		
Read discharge instructions	42	57.5
Explain to you how to take your medications	46	63.0
Create a medication schedule for when to take what medications	40	54.8
Fill pillboxes	41	56.2
Make changes to medications as a result of hospitalization	33	45.2
Remind you to take your medications	53	72.6
Update your list of medications	50	68.5
Help you with medical appointments and other needed tasks	63	86.3

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

<b>Caregiver/patient brought medication list or bottles to the hospital</b>		
Yes	201	53.5
<b>Medication access challenges, N (%)</b>		
Pick up new medications prescribed at discharge	342	94.2
Skipped medications due to problems with insurance or with paying coverage	85	22.6
<b>Self-efficacy for med management,<sup>1</sup> mean (SD) &amp; % positive responses<sup>2</sup></b>		
I can follow directions when my doctor changes my medications	4.53 (0.67)	96.8
I can manage my medications without help	4.35 (0.88)	89.4
I can list my medications, including the doses and schedule	3.74 (1.11)	65.7
I can take my medication when there is a change in my usual day	4.27 (0.74)	92.5
<b>Barriers due to patient limitations, N (%)</b>		
Correctly read the drug name on the medication bottle	334	89.3
Correctly tell how to take the medication	329	88.0
Open the bottle	335	89.6

<sup>1</sup>Response options are on a five-point Likert scale ranging from "Strongly Disagree" to "Strongly Agree," coded as 1-5

<sup>2</sup>Positive responses include "Agree" or "Strongly Agree"

<sup>3</sup> Patient knowledge/capability of how to take medications evaluate by three items adapted from MedMaIDE (20)

The most commonly used storage methods included pillboxes, tabletops, cabinets, and drawers (Table 8). Medication lists and pillboxes were, by far, the most frequently used tools to support timeliness of medication intake. A very high percentage of patients (88%) reported receiving their medications through community pharmacies.

**Table 8.** Medication management activities

Medication type	N	%
Pills/Tablets	270	98.5
Capsules	178	65.0
Inhalers	64	23.4
Total number of types reported, mean (SD)	2.32 (0.99)	
How to obtain medications	N	%
Community pharmacies	242	88.3
Mail-order pharmacy	67	24.5
Outpatient pharmacies	82	29.9

**6.1.13. Patient-reported and process outcomes.** At the home visit, almost 10% of patients reported an ED visit or hospital admission and 40% had their medications changed. A significant number of patients reported experiencing trouble with filling prescription after discharge (16%), being overwhelmed with the changes to the medication regimen (15%), spending considerable time dealing with insurance (9%), and worrying about medication costs after discharge (27%).

A high majority of patients rated the quality of discharge process as positive. However, a substantial portion of patients reported concerns about their medications: taking too many medications (45%), side effects (31%), and drug interactions (26%). Means (standard deviation) of medication related concerns (range 9-45) were 20.71 (5.11) and 20.87 (4.34) for hospitals 1 and 2, respectively.

**6.1.14. Evaluation of the risk factors for medication discrepancies.** The Spearman’s rank correlation ( $\rho$ ) analysis identified the following risk factors for medication discrepancies: lower education level ( $\rho=-0.17$ ,  $p<0.01$ ), lower income ( $\rho=-0.19$ ,  $p<0.001$ ), higher Charlson comorbidity index ( $\rho=0.12$ ,  $p<0.05$ ), higher number of medications on discharge ( $\rho=0.17$ ,  $p<0.01$ ), higher medication regimen complexity ( $\rho=0.20$ ,  $p<0.001$ ), and higher number of medication types (e.g., pill, capsules) ( $\rho=0.39$ ,  $p<0.001$ ).

Those patients who experienced a lower quality of preparation for care transitions ( $\rho=-0.33$ ,  $p<0.001$ ), who had a larger number of prescribers ( $\rho=0.29$ ,  $p<0.001$ ), who had lower self-efficacy for medication management ( $\rho=-0.24$ ,  $p<0.001$ ), who had a higher number of medications ( $\rho=0.22$ ,  $p<0.001$ ), and who had higher medication complexity at discharge ( $\rho=0.17$ ,  $p<0.01$ ) also reported higher medication-safety related concerns after hospital discharge.

Regression analysis (Table 9) identified the variables in the risk assessment tool that were predictive of medication discrepancies: number of medication storage methods, number of medication types, and hospital

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

doctors making changes to medications. For this analysis, only those patients participated in home visit data collection (N=236) were included.

**Table 9.** Stepwise Poisson regression model to identify factors related to the number of medication discrepancies at Time 3. Three variables excluded due to high multi-collinearity (VIF>3): education, income, and Medication Regimen Complexity Index (MRCI). The variables “patient has allergy” and “number of medication changes from one generic to another generic” were statistically significant when sample of T3<=30 and T3<=14 days were used.

Outcome variable: # of medication discrepancies (N=236)			
	IRR	95% CI	P value
Number of medications on discharge medication list <sup>§</sup>	1.07	(1.04 – 1.10)	<0.001
Number of approaches to obtaining medications <sup>§</sup>	0.41	(0.30 – 0.57)	<0.001
Number of medication storage methods <sup>§§</sup>	0.71	(0.56 – 0.90)	0.005
Number of completed tasks for examining patient limitations	0.65	(0.51 – 0.81)	<0.001
Patient is worried about medication cost	1.17	(0.82 – 1.66)	0.394
Someone from hospital or home care agency helps the patient after discharge <sup>§</sup>	2.21	(1.56 – 3.14)	<0.001
Length of stay of index hospitalization	0.90	(0.84 – 0.97)	0.004
Number of medication types <sup>§§</sup>	1.67	(1.40 – 2.00)	<0.001
Hospital doctors make changes to medications <sup>§§</sup>	0.47	(0.32 – 0.69)	<0.001
Number of providers writing prescriptions in the past 12 months <sup>§</sup>	0.82	(0.75 – 0.91)	<0.001
Patient is overwhelmed in the first few days after coming home <sup>§</sup>	1.84	(1.21 – 2.79)	0.004
Having a caregiver at home, n (%)			
No	1 (ref)		
Yes, spouse	0.86	(0.47 – 1.56)	0.617
Yes, others	0.27	(0.11 – 0.64)	0.003
Number of changes to medication regimen	0.81	(0.70 – 0.93)	0.004
Patient also picks up new prescribed medications at discharge	0.31	(0.13 – 0.75)	0.009
Insurance			
Medicaid	1 (ref)		
Medicare without Medicaid	1.82	(1.09 – 3.04)	0.022
Other	3.56	(1.44 – 8.78)	0.006
Skip filling prescriptions due to problems with insurance or paying for medications	1.73	(1.20 – 2.49)	0.003
Charlson comorbidity index	1.06	(1.00 – 1.13)	0.052
Medications are changed by a doctor or a pharmacist after discharge	1.33	(0.95 – 1.85)	0.097

§: variable remained in the regression model when only a subset of sample (sample of T3<=30 days) used (N=156).

§§: variable remained in the regression model when only a subset of sample (sample of T3<=14 days) used (N=65).

Pseudo R<sup>2</sup>=0.33 (p<0.001) for original, 0.41 (p<0.001) for sample of T3<=30 days, 0.27 (p<0.001) for sample of T3<=14 days.

**6.1.15. Evaluation of the risk factors for patient-reported outcomes (medication-related concerns and visits to ED and hospitals).** We used stepwise multiple linear regression to identify the risk factors in the risk assessment tool for increased medication-related concerns (patient-reported outcomes) measured at home visits (T3) and in telephone follow-up (T4). Those patients who experience a high quality of preparation for care transitions also reported significantly fewer medication related concerns (Table 10). Risk factors for increased medication related concerns were documented allergy, a higher number of prescribers within past 12 months, and lower self-efficacy for medication management. Seemingly counterintuitively, increased number of changes to medication regimens was associated with lower number of medication-related concerns.

**Table 10.** Stepwise multiple linear regression models to identify factors related to medication-related concerns (A) at Time 3 & (B) at Time 4

A. Outcome measure: Medication-related concerns* at Time 3 (N=235)			
	Coef.	SE	P value
Care transition measure (scale) <sup>§§</sup>	-1.76	0.46	<0.001
# of providers writing prescriptions in the past 12 months <sup>§</sup>	0.52	0.13	<0.001
Patient has allergy <sup>§</sup>	1.91	0.57	0.001
Self-efficacy for managing medications (scale) <sup>§</sup>	-1.81	0.52	0.001
Patient capability of how to take medications (# of completed tasks)	1.30	0.43	0.003
Patient is worried about medication cost	1.21	0.63	0.057

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

Time from discharge to Time 3 interview, days	0.62	0.31	<b>0.044</b>
# of changes to medication regimen <sup>§</sup>	-0.47	0.24	0.056
<b>B. Outcome measure: Medication-related concerns* at Time 4 (N=223)</b>			
	Coef.	SE	P value
# of medications on discharge medication list <sup>§§</sup>	0.13	0.05	<b>0.020</b>
Self-efficacy for managing medications (scale) <sup>§</sup>	-1.57	0.48	<b>0.001</b>
Patient is overwhelmed in the first few days after coming home <sup>§</sup>	2.05	0.75	<b>0.007</b>
# of medication types (e.g., tablet, inhaler, eye/ear drop) <sup>§</sup>	0.92	0.30	<b>0.003</b>
Number of changes to medication regimen <sup>§</sup>	-0.55	0.23	<b>0.018</b>
Household size	-0.49	0.22	<b>0.025</b>
# of providers writing prescriptions in the past 12 months*	0.19	0.12	0.111
Medications are changed by a doctor or a pharmacist after discharge	0.91	0.54	0.093
Patients skip filling prescriptions due to problems with insurance/cost*	1.33	0.62	<b>0.033</b>
Time from discharge to Time 3 interview, days	0.51	0.29	0.079

§: variable remained in the regression model when only a subset of sample (T3<=30 days) used (N=155 and 64, respectively).

§§: variable remained in the regression model when only a subset of sample (sample of T3<=14 days) used (N=65).

\* The variables “# of prescriber within 12 months” and “patient skipping filling medications” remained in regression model when sample of T3<=14 days was used.

For A: Pseudo R<sup>2</sup>=0.31 (p<0.001) for original, 0.34 (p<0.001) for sample of T3<=30 days, 0.36 (p<0.001) for sample of T3<=14 days.

For B: Pseudo R<sup>2</sup>=0.29 (p<0.001) for original, 0.28 (p<0.001) for sample of T3<=30 days, 0.65 (p<0.001) for sample of T3<=14 days.

The risk factors in the risk assessment tool for increased odds of visits to ED and hospitals after discharge during the study period (Table 11) were number of hospital visits in the last 12 months, number of medication storage locations, male patients, Asian patients, and patients who do not have a clear understanding of when the next dose of medication is due coming home right after the discharge.

**Table 11.** Stepwise logistical regression models to identify factors related to ED/hospital admission after discharge (A) at Time 3 & (B) at Time 4

<b>A. Outcome measure: ED/Hospital admission after discharge at Time 3 (N=221)</b>			
	OR	95% CI	P value
# of hospital visits in the past 12 months	1.25	(1.05 – 1.49)	<b>0.013</b>
# of medication storage locations	3.35	(1.47 – 7.66)	<b>0.004</b>
Patient gender			
Female	1 (ref)		
Male	4.25	(1.42 – 12.71)	<b>0.010</b>
Race			
Caucasian	1 (ref)		
Black or African American	2.26	(0.77 – 6.67)	0.140
Asian	16.99	(2.16 – 133.96)	<b>0.007</b>
It was clear to patient when the next dose of medication is due after coming home	0.03	(0.00 – 0.44)	<b>0.011</b>
Time from discharge to Time 3 interview, days	1.93	(1.00 – 3.74)	<b>0.050</b>
# of new medications to start after discharge	0.69	(0.48 – 1.01)	0.054
<b>B. Outcome measure: ED/Hospital admission after discharge at Time 4 (N=214)</b>			
	OR	95% CI	P value
Transportation			
Car	1 (ref)		
Friend and/or public transportation	3.11	(1.08 – 9.01)	<b>0.036</b>
Other	8.14	(2.49 – 26.55)	<b>0.001</b>
Insurance			
Medicaid	1 (ref)		
Medicare without Medicaid	0.79	(0.26 – 2.39)	0.672
Other	9.14	(1.32 – 63.13)	<b>0.025</b>
# of medication storage methods	1.65	(0.99 – 2.74)	0.054
Medications are changed by a doctor or a pharmacist after discharge	0.33	(0.12 – 0.95)	<b>0.039</b>
Self-efficacy for managing medications (scale)	0.52	(0.24 – 1.11)	0.091

For A: Pseudo R<sup>2</sup>=0.25 (p<0.001) for the original sample. The model did not converge for other subgroups due to low sample size. For B: Pseudo R<sup>2</sup>=0.18 (p<0.001) for the original sample. The model did not converge for other subgroups due to low sample size.

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

6.1.16. Prevalence of medication discrepancies. Medication discrepancies were identified in 82% of the patients visited at home (N=236). Top 10 classes contributed to 85.4% (Table 12).

**Table 12.** Top 10 medication classes involved in medication discrepancies (total 1932 in 194 patients)

Medication Classes	Discrepancies	Percentage
Nutrients/supplements	361	18.7%
Gastrointestinal tract	206	10.7%
Cardiovascular	187	9.7%
Respiratory tract	147	7.6%
Antibiotics/anti-infectives	115	6.0%
Nonopioid analgesics	103	5.3%
Steroids	80	5.1%
Antihyperlipidemic	69	4.1%
Opioids	66	3.6%
Antiseizure	55	3.4%

### 6.2. Outcomes

The project team achieved proposed aims. In addition to the risk assessment tool development, the project team has published two articles on patient-centered medication safety and on partnership for medication safety. The team expanded the scope to include other outcomes (such as clinical review of medication discrepancies) and anticipated reports of findings in peer-reviewed journal articles on medication safety in ambulatory settings after care transitions. The project also developed a foundation for future work on ways to support and engage patients in a distributed healthcare system environment, including an AHRQ-funded patient safety learning lab on partnership to improve medication safety in ambulatory settings.

### 6.3. Discussion

A patient-centered perspective to medication safety has generated insightful findings on barriers and facilitators for medication safety at home. We believe that the framework and the risk assessment tool should provide guidance for future research and practical improvement. We highlight several areas based on our study.

*Patient medication management tasks during care transition.* Our study findings addressed a critical gap in our understanding of patient-centric risks for medication related harms. We identified a number of tasks performed by many patients as active participants of medication management, in comparison with the relatively passive view of patients as care recipients (e.g., fill, understand, organize, take, monitor, and sustain), with the goal to guide interventions.(31) Most of the tasks identified (Table 4) are poorly supported because of lack of appreciation of these tasks. For example, a patient is often asked to provide medication history without memory support or without understanding limitations in current EHR. Isolated interventions, such as bringing “brown bags” of medications (32), engagement phone calls for filling prescriptions (33), and post-discharge phone-calls (34), may fail to address underlying risk factors associated in performing the identified tasks (35). In particular, given the high percentage of patients with discrepant medications, medication safety based on the assumption of accurate medication lists should be re-examined. Medications taken by patients are highly dynamic, as 40% of the patients when visited at home had their medications changed.

*Partnership with patients and their family caregivers in managing medications.* Most patients (88%) filled their discharge medications through community pharmacies, indicating the significant (and largely untapped) role they can play in partnering with patients and their family caregivers to support safe medication use. The risk assessment tool expands the current information gathered about the patient home work system and thus provides a better view about ways to partner with patients based on their capabilities. Older adult patients in the studies hospitals mostly manage medications themselves, another reality that must be taken into account in address risk factors.

*Patient work system.* Historically, patient engagement in inpatient settings has narrowly focused on their goals of care in hospitals rather than supporting the entire patient journey; there is little perceived responsibility and specific organizational infrastructure in working with patients in their expected work systems at home, with few safety guards against errors and system flaws in comparison with hospital medication management system. For example, it may be valuable to reconceptualize the time in the hospital as a window of opportunity to further support patient’s journey beyond the inpatient care, rather than only focusing on timely

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

and safe discharge of patient care that seems to be myopically interpreted as preventing 30-day readmissions and ED visits.

*Patient-centered risk factors.* We identified a several factors in patient work system that were associated with increased risks for potential medication related harms. High number of prescribers, allergies, high number of discharge medications, high number of types (e.g., patch and inhalers), and high number of storage places are indicative of high medication management task burdens during transitions. We did not find that number of changes in medication regimens was associated with increased risk, perhaps due to adjustment that may lead to better patient-reported outcomes. Whereas much research on transitional care has been on professional services and on collaboration among healthcare professionals, our study findings fill some of the conceptual gaps on how to build systems that view care transitions as handoffs of care from acute care professionals not only to ambulatory and primary care professionals but also to patients and caregivers at home, who function in a patient work system.

### 6.4. Conclusions

Risks to medication safety during transitions care may be understood as a mismatch between medication management tasks and capabilities in successfully accomplishing the tasks in ambulatory environment. The project provided a way to prospectively assess the risks that go beyond patients’ clinical condition and provide practical ways to develop patient-specific risk reduction strategies by redesigning the work system.

### 6.5. Significance

The project developed a risk assessment tool that may be implemented to reduce risks of patient harms due to medication use, misuse, or nonuse. The project refined a framework for developing patient partnership, which may be used for research and for practical solutions and technology development.

### 6.6. Implications

Future research should focus on developing interventions based on the significant risks and sources of risks identified in this project. Possible recommended interventions include patient-centric discharge planning and education (especially with respect to cardiovascular drugs, diuretics, insulin, antiplatelets), restructuring of the medication reconciliation process to focus on medications with potential for severe adverse events, and supporting medication safety through redesigning work systems to support effective interactions between care professionals and patients.

## 7. List of Publications and Products

### 7.1 Publications

Lee JL, Dy SM, Gurses AP, Kim JM, Suarez C, Berger ZD, Brown R, Xiao Y. Towards a More Patient-Centered approach to Measuring Medication Safety [commentary]. *Journal of Patient Experience* 2018, 5(2):83-87 [DOI: [10.1177/2374373517727532](https://doi.org/10.1177/2374373517727532)].

Xiao Y, Abebe E, Gurses AP. Engineering a Foundation for Partnership to Improve Medication Safety during Care Transitions. *Journal of Patient Safety and Risk Management* 2019, 24(1): 30-36 [DOI: [10.1177/2516043518821497](https://doi.org/10.1177/2516043518821497)]

### 7.2 Presentations

Abebe E, Hannum S, Gurses AP, Xiao Y. Identifying gaps for patient-centric model of medication management during care transitions. Academy Health Annual Research Meeting. June 24-26, 2018, Seattle, WA.

Gurses AP, Abebe E, Xiao Y. Patient-centric risk model of medication safety among elderly patients: Transitioning from hospital to home. Human Factors and Ergonomics Society Meeting, 2018, Philadelphia, PA.

Abebe E, Gurses AP, Xiao Y. Cognitive artifacts supporting medication management tasks during the hospital-to-home care transition: Implications for Design. International Symposium on Human Factors and Ergonomics in Health Care, Chicago, IL.

## Final Progress Report of “Patient-Centric Risk Model for Medication Safety During Care Transitions”

### 7.3 Mentorship

Ephrem Abebe, PhD, MPharm, MS; Present Position: Assistant professor (tenure-track) Purdue College of Pharmacy, West Lafayette, IN; Degrees received under Dr Gurses’s supervision: Postdoctoral research fellowship, Research focus: Medication safety in care transitions from hospital to home among older adult.

### 7.4. Product

Patient-centric risk assessment tool

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