

Title:

Assessing Risk in Ambulatory Medication Use after Hospital Transitions.

Wetterneck, Tosha MD, MS	PI, Department of Medicine, University of Wisconsin School of Medicine and Public Health (UWSMPH)
Brennan, Patti PhD	Mentor, Department of Industrial and Systems Engineering, University of Wisconsin - Madison
Carayon, Pascale PhD	Primary Mentor, Department of Industrial and Systems Engineering, University of Wisconsin - Madison
Holman, G. Talley PhD,	Research Scientist, Department of Industrial Engineering, University of Louisville, Kentucky
Karsh, Ben-Tzion PhD	Mentor, Department of Industrial and Systems Engineering, University of Wisconsin - Madison
Linzer, Mark MD,	Mentor, Division of General Internal Medicine at Hennepin County Medical Center, Minnesota
Smith, Maureen MD, PhD, MPH	Mentor, Department of Population Health Sciences and Family Medicine, UWSMPH
Smith, Paul MD	Mentor, Department of Family of Medicine, UWSMPH; Director of the Wisconsin Research Education Network (WREN)

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1. Structured Abstract

Purpose: Evaluate medication information management (MIM) at patient transitions of care from the hospital setting to the ambulatory setting from a primary care perspective.

Background: Primary care providers (PCP) rely on information transfer at hospital transitions to manage their patient's ongoing care. Failures and errors related to the transfer and management of medication information occur despite electronic health record implementation and impact the quality and patient safety.

Methods: We performed a prospective risk assessment of the MIM process across transition of cares from hospital to primary care from the PCP's perspective. We interviewed and observed nurses, physicians, and patients and evaluated electronic information systems at 3 primary care clinics and 2 hospitals. We identified the failures or risk of, their causes, and the effects of failures on the MIM process and patient care. We also evaluated error recovery mechanisms, the ways that failures and errors get detected and subsequently corrected.

Results: MIM process failures are common at transitions of care and in primary care in general, despite the use of electronic health records. All components of the work system, people, tools & technologies, organizational policies, training & relationships between organizations, task design and performance, and the environment of care contribute failure occurrence. Clinicians view failures as typical occurrences in the process. Error recovery mechanisms to prevent harm from failures in medication information transfer are commonplace. Cross-clinic analyses are ongoing.

Key words: medication information management, primary care, transitions of care, proactive risk assessment, error recovery, patient safety, health information technology

2. Purpose

The Specific Aims we pursued were as follows:

To assess transitions of care from hospital to ambulatory primary care from a primary care perspective, we aim:

Specific aim #1: To analyze the system failures in the medication information management (MIM) process. We will implement a human factors risk assessment of the MIM process in the primary care clinic using an integrated prospective risk assessment (PRA) approach with failure modes and effects analysis (FMEA) and fault tree analysis (FTA) techniques. These techniques provide a complementary bottom-up (FMEA) and top-down (FTA) approach to model risks and associated hazards during transitions of care from hospital discharge to the PCP. The risk assessment will consider the contribution of the organization, environment, technology, human and tasks on failures in the MIM process.

Specific aim #2: To evaluate the methods for detection of failures and the subsequent correction of failures in the MIM process. We will explore the methods by which primary care providers and clinic staff detect and correct failures in the MIM process. Error recovery results when a failure has been corrected in a manner that reduces or eliminates patient harm or the potential for harm. Methods of detecting failures will be identified from the FMEA and explored further using PCP and clinic staff interviews and focus groups. The contribution of the organization, environment, technology, human and tasks on error recovery in the MIM process will again be determined.

3. Scope

3.1 Background

Medication errors and adverse drug events (ADEs) are a significant problem in ambulatory care.¹⁻⁴ Only recently have medication errors and ADEs related to transitions of care from the hospital to the ambulatory primary care setting been studied. Multiple agencies and organizations involved in patient safety, including the World Health Organization (WHO) Collaborating Centre on Patient Safety, the Joint Commission (JC), the Agency for Healthcare Research and Quality (AHRQ), the Commonwealth Fund, and the Institute for Safe Medication Practices⁵⁻⁸ have acknowledged the risky nature of transitions of care and recommend further study of transitions to provide recommendations on interventions to improve the safety of medication use across transitions.

Primary care is characterized by four components: it is longitudinal, coordinated, comprehensive and a point of first-contact care.⁹ Achieving comprehensive and coordinated care primary care is dependent upon the integration of health care provider knowledge about the patient across care settings and is thus reliant upon the transfer of information.¹⁰ Changes in the delivery of hospital care, from PCPs managing their patient's care to hospitalists and subspecialists taking over inpatient care duties have added to the complexity of primary care delivery by creating new transitions of care.¹¹ The transfer of information between providers at these transitions is therefore essential for PCPs to integrate the care episode into the longitudinal patient plan of care and to avoid harm to patients resulting from the 'gap' in care.¹²⁻¹³ Research evaluating the transfer of information from hospitals to PCPs at hospital discharge shows great potential for improvement. One study found that hospital discharge summaries were available at only 15% of PCP hospital follow-up visits due to not sending the summary to the PCP (51%) or not dictating it in time for the follow-up visit (20%).¹⁴ Preliminary results from a large, US, academic multicenter study found that 77% of PCPs knew their patient had been admitted to the hospital but only 41% had seen a discharge summary within 2-3 weeks of discharge.¹⁵ Failures in information transfer across transitions more commonly occur when there: 1) are differences in hospital and PCP networks of care; and 2) is a lack of assistive information technology.¹⁶

Indeed, the design of healthcare systems directly influences care delivery and thus the quality and safety of patient care.¹⁷⁻¹⁹ Human factors is concerned with understanding the interactions of humans and other elements of the system with the goal of designing systems that optimize human performance and safety.¹⁹⁻²⁰ The Systems Engineering in Patient Safety (SEIPS) model, based on the Balance Theory of Job Design© and the concept of Healthy Organizations as well as Donabedian's framework for quality of care assessment is a human factors model used to better understand how the design of work systems influences outcomes.²¹⁻²⁵ It proposes direct relationships between the healthcare system, processes and outcomes. This model is needed to understand the complexity of the work system and to determine what elements influence the occurrence of failures and errors. There are at least five elements that interact to produce a healthcare work system: people (the patient and healthcare providers), tasks, technologies and tools used by people to complete tasks, the organization and the environment. The work-system elements interact to perform patient care processes that ultimately affect patient, healthcare provider and organization outcomes.

Human factors analysis methods are increasingly being adapted for use in healthcare to identify potential and actual systems failures and their causes.^{17,18, 26-28} One such method is prospective risk assessment, which typically identifies the failures that occur in processes, the risk of failures, and the causes and effects of the failures.¹⁸ The prospective nature of the assessment refers to prospective risk assessment's emphasis on error prevention by analyzing the potential failures and prioritizing them for action (e.g. system redesign) before a failure occurs that

causes harm. Risk refers to the severity of the situation if a failure occurred and the likelihood of the failure to occur. A risk assessment method commonly used in healthcare is failure modes and effects analysis (FMEA).^{29,30}

Most safety efforts in healthcare have focused on error prevention; however, not all errors can be prevented. Therefore, recovery from error and improving the reliability of error recovery is an important complement to error prevention programs.^{31,32} Error recovery is a process by which an error that has been committed is detected and corrected. The end result of recovery is the avoidance or reduction of negative consequences associated with the error. In healthcare, we commonly think about error recovery in terms of “near miss events” or “error interception”, in which errors occur and are caught before reaching the patient, e.g. a pharmacist reviews a medication order and notes the patient is allergic to the medication and calls the physician to change the order. These near miss events provide a rich source of data as the causes of these events are usually similar to the causes of errors that do reach the patient and cause harm.³¹

Error recovery in health care is usually thought of as a mechanism to prevent errors that have occurred before they reach the patient. Examples include pharmacist or nurse interception of errors in the medication use process, attending physician detection of errors on an inpatient teaching service, blood transfusion errors detected by human or machine double checks,^{88,89} information technology detecting errors, e.g. barcoding for patient identification and medication verification and computer provider order entry preventing medication errors. Error recovery can be ‘planned’ into the process, e.g. standard checking of work by others or limiting functions or barriers to detect errors or unplanned.³² In healthcare, where gaps in care frequently occur, e.g. information exchange at transitions, clinicians compensate by creating informal (unplanned) processes and documents that may in time become ‘formalized’ by routine or policy (planned).^{13,32,33} Given the frequent lack of needed information and the common occurrence of medication errors and preventable adverse drug events after hospital discharge, we expect to find both planned and unplanned error recovery in the MIM process in primary care clinics.

3.2 Setting

Three ambulatory primary care clinics and two associated hospitals in Wisconsin were recruited to participate (Table 1). Recruitment was performed by the Wisconsin Research Education Network (WREN), a Practice-Based Research Network of more than 90 health care providers at primary care clinics in 35 communities and from 21 different health care organizations scattered throughout and representative of practices in Wisconsin. Clinics were recruited based on variability in 3 criteria: 1) organizational structure and clinic relationship with the referral hospital, 2) electronic health record (EHR) use in the clinic, and 3) provider continuity of care from the hospital to clinic setting. Human subject committee approval was obtained from all clinic and hospital institutional review boards before the research ensued.

3.3 Participants

Table 2 outlines the study participant characteristics at the 3 primary care clinics and 2 hospitals studied. All clinic providers and staff were invited to participate in the study. Only one physician opted to not participate (clinic 3) and also nurses and ancillary staff that were approached agreed to participate. Verbal consent was given for participation after review of an information sheet about the study. Of note, many persons were observed in this study who were not enrolled in the study as participants. For example, patients observed during physician and nurse observations were not considered participants by the IRB. In addition, clinic and hospital staff that interacted with the person being observed were also not considered study participants. There were information sheets available for patients and staff that were observed but not considered study participants.

Table 1. Participating Primary Care Clinic and Hospital Characteristics

Clinic Characteristic	Participating Clinics		
	Clinic 1	Clinic 2	Clinic 3
Name			
Clinic Type	Community clinic affiliated with large health system	3 Community clinics, one of which was connected to critical access hospital and staffed by all group physicians	University-based clinic associated with affiliated with large health system (same as clinic 1)
Clinic specialty	Family Medicine	Family Medicine	Internal Medicine
EHR	Yes, integrated with hospital 3. Internet access to hospital 1 EHR	No	Yes, integrated with hospital 3. Some internet access to hospital 1 EHR
Hospital affiliation	<u>Primary:</u> Hospital 1: mid-size, urban, community, tertiary care teaching hospital. <u>Secondary:</u> Hospital 3: academic tertiary care center	<u>Primary:</u> Hospital 2: rural critical access hospital attached to clinic. <u>Secondary:</u> Hospital 3	<u>Primary:</u> Hospital 3; <u>Secondary:</u> Hospital 1
Location (rural / urban)	Suburban	Rural	Urban
Hospital care / continuity	1 physician (alternating) in clinic practice rounds on all clinic patients in hospital 1, occasionally is patient's PCP = clinic continuity with occasional PCP continuity. Hospitalist care at Hospital 3 = no continuity.	Patient's PCP rounds on patients in Hospital 2 = PCP continuity. Hospitalist care at Hospital 3 = no continuity.	Hospitalist care at Hospital 1 and 3 = no continuity.

Over 95% of the patients who were informed that their nurse or physician were being observed agreed to have their clinic visit observed. All enrolled participants were over age 18. As this study was not a clinical trial or intervention testing study and only limited information was collected on participants, the race and ethnicity of the participants was not collected. Given the lack of diversity of race and ethnicity seen in healthcare professionals working in primary care clinics and hospitals in Wisconsin (outside of Milwaukee), healthcare professionals, patients or the clinics studied may also have been identifiable by race/ethnicity identification of the participants. A targeted enrollment table is therefore not provided.

4. Methods

The specific aims of the study are:

Specific aim #1: To analyze the system failures in the medication information management (MIM) process.

Specific aim #2: To evaluate the methods for detection of failures and the subsequent correction of failures in the MIM process.

Table 2. Primary Care Clinic & Hospital Participant Characteristics

	Clinic 1 & Hospital 1	Clinic 2 & Hospital 2	Clinic 3
# Clinic Attending Physicians	4	6	6
# Mid-level providers	2	0	0
# Nurses-Medical Assistants	9	6	5
Clinic Directors	1	1	1
Other clinic personnel	6	4	0
Patients at follow-up	10	12	10
Hospital Pharmacists or technicians	2	2	n/a
Hospital based physician	1	0	n/a

4.1 Study Design

The study is theory-based and uses a case-study design to collect and analyze data. In this design, each clinic site is considered a ‘case.’ Data collection and analysis is performed one clinic at a time, sequentially and separately. The analysis of data from one clinic is called ‘within case’ analysis. When all three clinics have undergone data collection and the data analyzed within case, the data from the FMEA and error recovery analyses will be reviewed together, across each technique, for cross-case analysis. Cross-case analyses will compare and contrast data and combine data when feasible as we know which results are unique and similar across clinics. This study design is a strength of the proposed research as it increases the data inputs available for a combined analysis to help ensure that all failures and error recovery mechanisms have been identified and addressed, a so-called ‘macro-system view’, while still analyzing data at the clinic level for the micro-system view. This multiple case study design will also improve the generalizability of the results to other ambulatory primary care clinics, the ability to draw conclusions about the data, and will allow hypothesis generation to explain differences across clinics.

4.2 Data Sources/Collection

The goals of data collection were to:

1. Understand the medication information management (MIM) process in primary care clinics after a patient transition from the hospital setting to the primary care clinics. The work system perspective is used and the data supports the performance of the prospective risk assessment and process redesign.
2. Record error recovery methods in the MIM process.
3. Allow comparison of the MIM process, prospective risk assessment and error recovery methods across three primary care clinics settings.

Data were collected from multiple sources to better understand the medication information process and the failure/error recovery methods employed within this process for the clinic being studied. These data sources include, 1) interviews with clinic personnel (physicians, mid-level providers, nurses, medical assistants, clinic directors and other relevant ancillary staff including receptionists, medical records personnel and lab technicians; and clinic hospital follow-up

patients; 2) observations and embedded interviews of the general work of clinic personnel; 3) specific observations of the patient during a follow-up clinic visit after hospital discharge to observe interactions between patients, providers and clinic staff during the patient's; and 4) document review e.g. paper or electronic forms and templates used for medication management, job descriptions (org, tasks, error recovery) clinic policy & procedures relating to MIM.

Data collection began with an interview of the clinic director. We then completed observations of nurses/medical assistants (heretofore referred to as nurses) providers (physicians and mid-level providers, heretofore referred to as physicians) performing their typical work during and between patient visits. Once a good understanding of clinic processes was developed, we began observations of patient follow-up visits and patient interviews. We finished data collection with provider, nurse and clinic staff interviews.

4.2.1 Observation Protocol

An observation protocol was developed and piloted at Clinic 1 to collect data relevant to the specific aims. The observation protocol was based on the SEIPS model to ensure data collection from all elements of the work system that contribute to information flow as well as the communication literature to better document communications to understand their meaning. The following items were intended to be collected:

1. **Tools** (charts, templates, forms) or **technologies used to record or manage medication related information:** e.g. Electronic medical record, fax machines, phone messages, verbal; Problems with using the forms or technologies; automation surprises; alarms or alert messages triggered in computer).
2. **General work environment:** e.g. space organization; clinic layout (ease of communication and flow between staff, providers & patient rooms; location of computers, forms, charts; noise levels, workplace atmosphere: Calm, busy but professional, chaotic).
3. **Tasks, general:** e.g. pace of work / perceived time pressure to complete tasks, interruptions, number of tasks & workload; typical day: average number of patients per provider; patients waiting in reception area; patients waiting in exam rooms.
4. **Tasks, medication information specific:** e.g. Document steps in process; problems that are encountered and how they are dealt with: errors or failures, failure/error recovery: detection, explanation & correction, other pertinent information that may influence how a task is performed (apparent reasons for variations).
5. **People:** e.g. Observed communication and professionalism between providers and staff; who they interact with / communicate with, ability of providers and staff to communicate with patients (language barriers & communication barriers); context of interactions – problems, information transfer, routine patient care; method of communication: verbal vs. phone vs. electronic vs. written message contact; behavioral cues: frustration, lack of understanding; detailed conversations about medication-related information including medication names, doses, etc; comments made by staff pertinent to data collection; comments made by patients pertinent to data collection (understanding of information presented, questions asked); comments made by caregivers.
6. **Organization:** e.g. supervision required for a task; protocols in use; insights into organization and safety culture; problem solving, communication norms, task prioritization.

Observations were performed by either a human factors engineer or a human-factors trained physician. These were direct, non-participatory observations. Free-hand notes were taken and transcribed after the visit. Transcribed notes were reviewed by both researchers and information added as needed to understand information flow.

Originally, we intended on observing and interviewing 3 physicians and 3 nurses at each clinic as well as other clinic staff relevant for information flow in the clinics and to use theoretical saturation as a guide to knowing if more data needed to be collected. We elected to instead interview all physicians, nurses and relevant staff and observe them all at least once for 2-5 hours depending on profession type. We found that this strategy led to saturation in observation data with few physicians and nurses needing to be observed a second time.

We started observing nurses and physicians one at a time in the clinic with one observer doing observations at a time to minimize clinic burden. After analyzing the first two observation notes we found that we were not adequately capturing failures of information flow and recovery efforts because we were not observing both the work of the physician and the nurse before, during and after the visit. To overcome this issue, we changed our observation strategy to one of simultaneous tandem observations.

4.2.1.1 Tandem Observation Protocol

This observation method uses two observers to evaluate the work of and information flow across a physician or mid-level provider–nurse team in a primary care clinic. Tandem observations were conducted by a human factors engineer and a human-factors trained physician, one person observing the nurse and the other observing the physician. The observations started at the beginning of the morning or afternoon session of seeing scheduled patients and ending 3-5 hours later, either at lunch time or the end of the work day. We observed eighteen provider-nurse teams, six each at three different primary care clinics in Wisconsin for a total of 140 hours of observation time. Observation notes were taken free-hand and transcribed by the researchers for analysis. Both sets of observation notes were reviewed by the observers for completeness.

4.2.2 Interview Protocol

Interview protocols were developed using an iterative process of question formation, review by the research team and outside experts and testing using pilot interviews and cognitive interviewing. We originally intended on performing 2 interviews with each physician, nurse and other relevant clinic staff, one to discuss failures in information flow and the other to discuss failure/error recovery mechanisms. We found, however, that we could accomplish both in one interview. Physician and clinic directors interviews generally took 60 minutes while nurse interviews took 20-45 minutes.

The clinic director interview focused on: 1) learning about (& requesting) the policies and procedures governing medication information management in the clinic, 2) discussing at a 'high level' the process of medication information management for a patient who comes to the clinic for follow-up after hospital discharge, 3) understanding (& requesting) what alternatives types of data may be available on information flow in the clinic (e.g. incident reports on problems with information flow, quantitative studies on resource availability (chart)).

4.2.3 Patient Follow-up Observations and Interviews

Patients were identified by clinic staff by reviewing the physician schedules for "hospital follow-up" visits (noted by the receptionist as the chief complaint when the patient scheduled the appointment). Patients were called by the clinic staff for permission to release their contact information to the research team who then called the patient and obtained assent over the phone and consent in person to observe their visit and partake in a short interview afterwards. Patients were compensated monetarily \$25 for their time. Although detailed records were not kept, we estimate that between 50% and 75% of the patient's that were identified on the

schedule agreed to participate and completed the study. The resultant patient sample for follow-up visits was a convenience sample based on patient identification on the schedule, patient consent, patient attendance at the visit, and observer availability / ability to travel to site for the observation and interview.

Table 3. Summary of Data Collection from Primary Care Clinic & Hospital Participants

	Clinic & Hospital 1		Clinic & Hospital 2		Clinic 3	
	Interviews	Observations	Interviews	Observations	Interviews	Observations
Attending Physicians	4	4	6		5	6
Mid-level providers	2	2	0	0	0	0
Nurses-Medical Assistants	8	9	6	8	5	6
Clinic director	1	n/a	1	n/a	1	n/a
Other clinic personnel	6	5	1	4	0	0
Patient follow-up	9	10	12	12	10	10
Hospital pharmacists	2	2	1	2	0	0
Hospital physicians*	1	3	0	2	0	0
Total time spent	17 hours	77 hours	15 hours	>72 hours	9.5 hours	>60 hours

*Note: hospital physicians included clinic attending physicians

4.3 Intervention

There was no intervention in this study.

4.4 Measures

4.4.1 Qualitative Data Analysis

The data collected in this study were not only used to gain a better understanding of the current MIM process in the clinic, they will be used to generate the initial prospective risk assessment process tool in an effort to streamline the PRA process and the time required of clinic personnel performing the PRA with the research team. The following elements are coded from the interview and observation data:

- a. Process steps, ideal
- b. Process steps, actual
 - i. Common process
 - ii. Major process variations & why they vary
- c. For each process step:
 - i. Who is involved
 - ii. What task is accomplished and what is needed to accomplish the task
 - iii. What tools / technologies are used
 - iv. Where it occurs
- d. Process step failures, known and potential (failures)
- e. Risk of failure
 - i. Likelihood of occurrence

- ii. Severity of event if failure occurs
- iii. Likelihood of detecting a failure
- f. Causes of process step failures (causes)
- g. Effects of process step failures (effects)

A heuristic review of documents led to the development of contributing factors or causes related to information failures and failure recovery or lack of recovery. Tandem observations were analyzed separately and together this pre-determined coding structure to identify failures in medication information flow and recovery mechanisms occurring across the paired observations.

4.5 Limitations

There are multiple limitations in this study. First is the study design which uses case studies of the MIM process across transitions of care. These results may not be generalizable to other settings. We attempt to overcome this by performing a cross-case analysis to look for common problems across the sites as well as to identify systems factors which may differ across the sites and result in differences in failures, causes and recovery methods. Second, we are using interviews and observations to document failures and recovery methods. It is very difficult to quantify failures and their causes for the FMEA analysis. Some failures may be witnessed and are rare while other common errors may be missed. We attempted to achieve saturation in data by observing and interviewing all clinic personnel and 10 patients at each clinic. It is possible we did not achieve saturation of patient data given the small numbers but we were limited in performing more observations based on personnel resources, travel time to clinic sites and hospitals and burden on the clinic to identify and call patients. Additionally, we noted that some staff had problems identifying problems in the MIM process as there tended to be a “normalization of deviancy” in which staff perceived problems in information transfer as commonplace and part of the normal system rather than failures in the system and recovery efforts. Last, none of the clinics had medication error databases or cases readily available to share and few examples of actual MIM process failures across transitions were identified during the interviews, moreso by physicians than other clinic staff, hence some failures and harm related to these failures were likely missed in the analysis.

5. Results

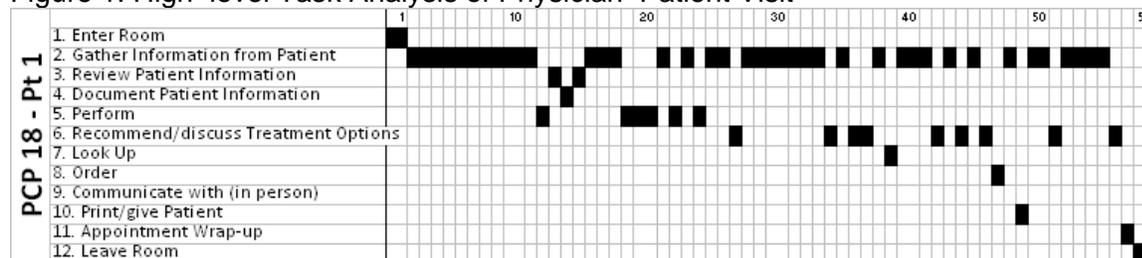
5.1 Principal Findings / Outcomes

5.1.1 PCP Task analysis list development (Aim 1)

We used multiple strategies to analyze the observation data. A literature search of PCP tasks found few usable task lists, most of which were very high level, to analyze data. We partnered with Dr. Karsh at UW who recently completed an AHRQ-funded study to evaluate hazards in the primary care of the elderly (1P20HS017115) to use our observations in primary care clinics to create and validate and master task list for PCPs during a patient encounter. The final task list has 12 major tasks, 189 subtasks, and 191 total tasks. The major tasks are: Enter Room, Gather Information from Patient, Review Patient Information, Document Patient Information, Perform, Recommend / Discuss Treatment Options, Look Up, Order, Communicate, Print / Give Patient, Appointment Wrap-up, and Leave Room. To better understand the use of the EHR and paper information sources during an physician-patient visit, additional task coding was included (either as a third level code or as a fourth level code using a lowercase letter) to identify the data source for the task, e.g., the EHR, paper chart or a patient source (e.g., patient or caregiver memory, or paper source maintained by them). The use of source codes adds an additional 198 codes to the task list. We also found it valuable to note the presence of someone else in the room besides the physician and the patient who was involved in the care delivery, e.g., a patient caregiver (-C) or a medical student (-S). This was noted during coding by adding (-C) at the end

of a code for patient caregiver and (-S) for a medical student (-S). The use of such modifiers can assist evaluation of information flow. The complete task list is available from the study PI. An example of the high-level task analysis applied to this study's observation data is shown in Figure 1.

Figure 1. High-level Task Analysis of Physician-Patient Visit



5.1.2 FMEA (Aim 1)

The task list proved to be much too detailed to perform an FMEA using these process steps. We determined a common set of MIM process steps across all three clinics performed by nurses and physicians using the interview, observation and document/EHR review data, and coded the patient and tandem observations using these process steps. This was done to facilitate cross-clinic data analysis. We then identified actual failures in the MIM process, apparent cause of those failures, i.e. contributing factors, and the actual or potential effects of the failures on patient care. We also coded failure recovery including the mechanism of detection of the failure and the full or partial correction of the failure (see 5.1.4). Failures were judged to be related or not related to the hospital transition of care. We then used the above coding structure (see 4.4.1) to code the patient observations process steps, failures, causes and recovery mechanisms. The patient interviews followed by the physician, nurse and relevant staff interviews were coded to supplement these data. Finally, the document review provided additional causes of failure and mechanisms for recovery. The list of process steps is as follows:

Pre-Patient follow-up visit with PCP

1. Hospital makes changes to pre-admission medications.
2. Hospital makes discharge medication list, does medication reconciliation & counsels patient.
3. Patient follows discharge medication list instructions at home.
4. Patient medication list is present at clinic for patient follow-up visit and reconciliation.

Patient follow-up visit with PCP from hospitalization

1. Nurse records information about the chief complaint(s) and recent hospitalization.
2. Nurse gathers, reviews, verifies & updates the medication list to achieve an accurate list.
3. Nurse compares and reconciles discharge medication list and the clinic medication list.
4. Nurse reviews, verifies & updates allergy list with patient.
5. Nurse conveys issues about inability to achieve an accurate medication list with the PCP.
6. PCP reviews the discharge summary and other hospitalization related information.
7. PCP gathers, reviews, verifies & updates the medication list to achieve an accurate list.
8. PCP compares and reconciles discharge medication list and the clinic medication list.
9. PCP reviews, verifies & updates allergy list with patient.
10. PCP gathers and reviews medication-related information (adverse drug events, efficacy, compliance/adherence, options for continued use of medications).
11. PCP makes decisions regarding medication use (change, add, discontinue, keep the same)
12. PCP documents medication changes made during the visit on the patient medication list.

Table 4. Selected Medication Information Failures and Causes from Clinic 1

PS#	Failure	Cause 1	Cause 2
Pre 1	Med stopped / changed during hosp that should have not been (per PCP)	Discontinuity of care	
Pre 2	Discharge med list has wrong dose of one med (vitamin B12)	EHR med list is incorrect ? Used for reconciliation	
Pre 3	2 meds listed on the clinic EHR med list twice	Generic vs. brand name use - EHR allows duplicate meds on list	
Pre 4	PT did not take insulin at hosp discharge as prescribed	Pt uncertain about change; hospital nurse told pt to read up on it before switching over	Pt wanted to talk to his diabetes doctor before making the change
2	Pt is taking an OTC prn med (Aleve) that is not on medication list	Nurse did not ask pt about other as needed medication use	OTC med
2	Nurse does not verify type and dose of insulin and the dose and/or frequency of 7 of the other 9 meds on med list	Nurse reconciled from recent d/c list but list changed after d/c	
2	Pt did not know name of antibiotic (for UTI) and therefore nurse did not put on medication list	Prescribed by different physician (other than PCP) at hospital discharge	Hospital and clinic EHRs are different, different med lists
2	Pt did not remember to tell the nurse about 5 medications the patient was taking during the initial medication reconciliation	Family member forgot to bring his medication list	
2	Spiriva was added to the medication list but the wrong medication form was chosen, the capsules rather than the inhaler form.	Newer medication. Nurse may be unfamiliar with it and dose forms	The new nurse in clinic did not verify the form with the pt.
2	Nurse does not review EHR med list with pt - notes that it has been updated since d/c	Pt said she did not bring her med list when asked about meds	List appeared to have been updated since d/c with d/c med list
3	Nurse did not complete full medication reconciliation using discharge summary	Only asked about meds on current EHR list but pt also prescribed a bowel regimen and polymyxin cream on d/c med list	Nurse did not ask "anything else" as prompt to pt about additional medications
3, 8	Both the nurse & PCP attempt medication reconciliation with the discharge summary and patient but unable to perform.	Lots of changes to meds in hospital at once - pt cannot remember changes; pt has long list of meds	Meds were changed btw hospital d/c & f/u appt so discharge list not correct
4	Nurse does not verify allergy info with pt	Omitted task in computer workflow	
7	EHR med list has nicotine patch - pt not taking and MD does not delete	Nurse didn't review med list w/ pt	MD does not update med lists
7	Pt does not know 2 meds by name - lisinopril (the BP one I cut in half) and sertraline (knew Zoloft)	Generic vs. brand name confusion	Knows med condition / characteristic but not name
8	PCP did not complete med rec - PCP noted meds on d/c summary & discussed with pt, did not look at clinic med list	PCP using 2 different EHRs, clinic med list not available in this emr	
9	Med not added to pt allergy list (prev ADR)	MDs do not routinely change this info	Not true allergy
12	MD discontinues 3 medications during the visit but does not change the EMR med list	MD is not in the habit of changing the EMR medication list	
12	MD restarts med that was stopped at d/c (and d/c'd on med list by nurse during med rec) but does not add it to the medication list	MD is not in the habit of changing the EMR medication list	MD does not reorder the med (automatically populates med list)
12	MD stops metoprolol for suspected ADRs but does not delete from EHR med list	MD does not update med lists	

MD=physician, Pt=patient, d/c=discharge or discontinue, med=medication

The full FMEAs for each clinic are too large and extensive to be shown in this document. Table 4 above shows a snapshot of selected failures and causes from clinic 1 analyses.

Themes of failures that were common across the clinics are as follows. Failures in medication information transfer at hospital discharge were commonly seen; information was commonly missing for either the nurse or the physician to use during the visit or the information had changed by the time the follow-up clinic appointment had arrived such that the discharge summary medication list was not the current, accurate medication list. Patients and family members relied on memory the majority of the time when discussing medications. Few patients and families brought actual pill bottles, more brought a medication list or the discharge medication list from the hospital with them to the clinic appointment, however, this information did not always make it to the nurse or physicians hands to be used during the appointment. While nurses stated in interviews that they performed medication reconciliation at the beginning of the visit by verifying the current medication list with the patient when present by reading all of the medication information to the patient (name, dose form, dose, frequency) and then asking the patient if there were any additional prescription medications, over-the-counter medications or as needed medications. Yet in actual practice, they commonly only read the medication name to the patient and it was not always clear that the patient response that they were taking the medication correlated with the patient's actual knowledge about taking the medication or the patient's adherence to taking it. Most physician nurse pairs did not have a special procedure in place for hospital discharge follow-up visits to ensure that all of the information was present before the patient visit nor did they routinely contact the patient before the follow-up visit. Some nurses described changing the patient medication list based on the discharge medication list in the discharge summary before the visit, however, this new list was not always confirmed with the patient to ensure that they were still taking the medications and that there were not any changes after discharge. Many physicians did not actively update the patient medication list in the chart or the EHR during or after the visit to record changes. The changes were usually dictated or typed into the clinic note and some physicians felt it was not their job to maintain the medication list or that it would be updated at the next visit. At the clinic with an integrated hospital-clinic computer system, the outpatient medication list was updated to the hospital discharge medication list automatically at discharge. While the discharge summary usually showed the medication list and which medications were changed, stopped or added during the hospital stay, the patient medication list itself did not show these changes so reconciliation in the clinic was more difficult for the physicians. At the clinic that was not using EHRs for documentation less medication information failures were seen during the observations than at the other clinics with EHRs. We believe this is related to the fact that the clinic did not routinely keep up the medication list or perform medication reconciliation at each clinic visit. Usually medications were discussed as needed based on the clinic condition of the patient and the reason for the visit so there were less discussions about medications and medication use and therefore less opportunities for failures. Looking at the numbers of failures observed during the patient follow-up visits at clinic 1 and clinic 2, for example, clinic 1 had 36 total failures with 21 of these related to failures of medication information transfer at the transition of care and clinic 2 had 20 failures with 8 related to the transition of care.

The causes of failure were listed and analyzed according to the SEIPS model to classify them into one of the five elements of the model (see table 6). This analysis shows that the causes span the range of the systems' elements and our FMEA shows that most failures have more than one cause, and many of the causes are similar across the failures. This shows that in order to effectively manage and prevent failures of medication information transfer at transitions of care, changes will need to be made to all parts of the work system – there isn't a simple fix to the information management problem. Also, EHRs, which have been proposed to fix failures in medication information management, actually contribute to failures as well.

Table 6. Selected Causes of Failures of Medication Information Transfer Categorized by the SEIPS Model

Actual Cause	SEIPS model category
OTC med, pt did not bring up the change when asked in general about med list	Medication-related
clinic EHR had old dose of med too (used for med rec at hosp?)	EHR
generic vs. brand name use	Med-related
Aleve not on Allergy list (prev ADR)	EHR People: healthcare provider
OTC med: not a Rx med so does not have to order via computer system	Med-related EHR
MDs do not usually change med list	People: PCP Task
Nurse reconciled from recent d/c list – not expecting changes but pt saw different doctor since visit	Task
Nurse at hospital told him he should read up on it a little bit before switching over to understand it better	People: Hosp nurse
Pt wanted to talk to his diabetes doctor before making the change to insulin- pt took insulin after seeing DM doctor	People: patient pref Organization
Prescribed at hospital discharge - different EMR so not on med list automatically	EHR – lack of integration
Pt cannot remember med changes after d/c and exactly what she is taking	People: patient
Nurse is rushed for time checking in pt	Task – time pressure
Nurse did not ask "anything else" when reviewing med list	Task – med rec
Discontinuity of hospital and clinic care	Organization
confusion between what to discontinue and what to just not "check as taking" on med list	Task
Nurse chose the most common dose but the patient was prescribed a smaller dose (likely for geriatric considerations) based on the d/c summary. The nurse did not ask the dose the patient was taking when entering the med.	Medication related- less common dose People - nurse Task – med rec
The long list of EHR choices for docusate and docusate combos	EHR – design of pick-lists Medication-related
Generic-brand name issue - pt used the brand name "senna" and the combo pill listings used the generic name "casanthrol"	Medication-related
Family member forgot to bring pt medication list	People – family member
The nurse did not verify the drug form with the pt.	Task – med rec

5.1.3 Fault-tree analysis (Aim 1)

We originally intended to use fault-tree analysis (both qualitative and quantitative) to provide a different approach to looking at medication information failures and recovery in the primary care clinics and across transitions of care. Fault-trees start with an adverse event, in our study perhaps a medication error or information failure leading to patient harm. Unfortunately, our extensive interviews and observation data did not produce enough harm level data examples to create reliable fault-trees for analysis. We intend, instead, to perform a HAZOP, a hazard and operability study, which will use the FMEA data as inputs to identify and evaluate failures and

hazards across the MIM process and transition of care to look for common themes and problems across the entire process. This is currently underway.

5.1.4 Failure (error) recovery mechanisms (Aim 2)

We also coded failure recovery including the mechanism of detection of the failure and the full or partial correction of the failure. There were many examples of failure recovery and missed opportunities for failure recovery seen in the observations and discussed in the interviews. Recovery occurred before, during and after the patient follow-up visit. Failures that were committed by the patient, nurse, physician or hospital were also recovered by the patient, nurse or physician and sometimes by the same person committing the failure. Examples of failure recovery (both detection and correction) include the following. The physician and nurse would discuss the patient visits for the day and the physician would ask the nurse to gather information for the visit ahead of time and during the visit (discharge summary) if the needed information was not present. Nurses at times had problems completing medication reconciliation and would ask the physician to review the medication list and complete the medication review instead. Patients would forget to tell the nurse about a new medication or a medication change and remember this while speaking to the physician about the medication or the related medical condition. Patients often knew their medications by something other than the medication name, for example, by the brand name (instead of the trade name on the medication list), or by the color of the pill, or how often they take it every day, or the condition it treats (e.g. blood pressure pill) or the effect on the patient (e.g. water pill or diuretic). The nurse or the physician could work with this patient recall and the medication list to match like items together. Looking at the number of occurrences failure recovery across clinics at patient follow-up visits, clinic 1 had a total of 36 failures, 11 of which were recovered from (6 only partially) while clinic 2 had 20 total failures, 15 of which were recovered from (5 only partially). So the observed failure recovery rates during the visit were much higher at clinic 2 than clinic 1.

The following excerpt is an example of partial error recovery during a patient follow-up visit (observation text shortened for brevity and effect). "Pt discharged after heart surgery. Sees PCP 2 3 weeks later. Nurse tries to review clinic EHR med list with pt, pt unsure of what she is taking saying, "they changed everything and missed meds". Nurse is rushed for time and leaves note for MD that med list not correct. MD reviews med list from d/c summary with pt. Pt still uncertain – she has been told to stop some meds by the surgeons but unsure which ones. MD unsure why surgeon did not increase Warfarin dose with last subtherapeutic INR. Outside docs on different computer system. MD able to refill Warfarin (blood thinner) and checks level that day in clinic with plans to call pt about dose to take. MD arranges for pt to schedule an appt with nurse the next day and pt will bring all med bottles and info from home." In this example, the PCP partially recovers from the failure of not knowing what medications the patient is taking or what dose she is supposed to be taking by asking more questions about the warfarin dosing and checking laboratory levels for monitoring. He also has the patient bring in pill bottles at a future visit to fully recover from this failure. The obvious effects are delays in care and potential misdosing of medication based on the lack of accurate data.

5.1.4 Example of Tandem Observation: Failures in Information Flow at a Patient Visit (Aim 1&2)

Table 1 shows an example of lack of medication information flow between the nurse, patient and physician during a patient visit. For purposes of brevity, the text in Table 1 is a summary of the actual observation text. The analysis of the paired observation reveals that physician plan for the patient to take two tablets of sleeping medication for sleep will fail based on information the patient provided to the nurse that the physician did not have. This information would not

have been available if the observer were only observing the physician. There were multiple contributing factors evident from the observation including: 1) the lack of documentation by nurse of pt taking 20mg for MD, 2) time pressure to see a new patient in a short visit and the need to address other issues like high blood pressure, 3) the focus on the nurse obtaining a list of medications with no mechanism to easily indicate on the list that the patient is taking more medication, 4) patient expectations that the nurse documented their conversation about the Ambien dose for the physician to see, 5) the nurse comment to the patient which may have prevented the patient from the admitting higher dose to the physician. From interview data we also know that the physician-nurse team has not discussed expectations for documenting patient medication history, and related information.

Table 5: Example of Failures in Information Flow at a Patient Visit

Nurse observation: Nurse checks in new pt	Physician observation: Clinic appointment
<ul style="list-style-type: none"> • Pt called 1 wk earlier for appt, got Rx for Ambien 10mg nightly over phone for insomnia • Nurse reviews med list in EHR (ambien) & checks that pt is taking med, reviews allergies, smoking hx & chief complaint • Pt states Ambien not working well, took double dose x 2 days and still not sleeping • Nurse tells pt he should not take more med than prescribed. Does not document conversation. 	<ul style="list-style-type: none"> • MD greets new pt and reviews pt's medical hx, social hx • MD notes pt's BP is high (not on meds) and that he smokes & discusses implications with pt • MD discusses insomnia and Ambien use (MD now running behind for 15 min visit) • Pt states medication not working well • MD tells pt to take 2 tablets nightly to see if this helps • MD tells pt to f/u in a few weeks with longer visit to discuss multiple problems

Pt = patient, EHR=electronic health record, MD= physician hx=history, BP=blood pressure

We found many similar examples of failures in information flow between the nurse, patient and physician. In addition, we found many examples of recovery from information flow failures. Recovery was seen from failures in information flow prior to the clinic visit and failures during the visit. Nurses, physicians, and patients recovered from their own failures and each others failures and worked together to recover from failures of information flow across the care transition. Tandem observations were generally well accepted by both patients and primary care clinicians.

Conclusions

- 1) Simultaneous, tandem observations of physician-nurse teams provided a more complete view of the work being performed before, during and after patient care visits. This method allowed us to observe information flow between the team members and with the patient, and identify failures in information flow, and how these failures were (or were not) recovered from during the patient care session. This method should be useful to analyze physician-nurse teams and their workflows to assist the design and implementation of patient centered medical homes in primary care.
- 2) A PCP task list was created using physician observation data which can aid the determination of physician workflows in the outpatient setting with regards to patient visits. This workflow / task analysis can assist with the design and implementation of EHRs to fit the physician workflow in addition to other quality improvement efforts.

- 3) Failures of medication information flow during transitions of care are common and may not be detected or recovered from during the patient visit.
- 4) Failures of medication information flow at routine patient visits is also common and may be a cause of failures during patient hospitalization or at patient follow-up visits.
- 5) Most nurses and medical assistants do not receive standard training in medication reconciliation at the clinic visit or at hospital follow-up visits.
- 6) EHRs allow creation of a patient medication list but do not allow documentation of uncertainty regarding the list or certain medications on the list, thus other mechanisms are needed to allow this exchange of information between providers and over time.
- 7) EHRs alone will not solve the failures of medication information transfer at transition of care and their design and implementation may contribute to failure occurrence as well.
- 8) Healthcare providers continue to normalize failures of information transfer in primary care clinics due to the common nature of this problem. This prevents recognition of the problem and taking action to find a solution.
- 9) Hospital discharge follow-up visits are often treated like other routine clinic visits. Needed information about the hospitalization is often not sought until immediately before or during the appointment leading to delays in care and may not be available until after the appointment leading the delays and rework. Instituting processes to routinely obtain needed information ahead of the visit (i.e. moving failure recovery processes to earlier in the process before the patient visit) should make information available during the visit and decrease delays in care and rework.

6. List of Publications and Products:

6.A Publications

Wetterneck TB, Holman GT. Use of tandem observations in ambulatory primary care to evaluate physician—nurse teamwork. In: *Healthcare Systems Ergonomics and Patient Safety Conference Proceedings*, Oviedo, Spain, 2011. In press.

Wetterneck TB, Lapin JA, Karsh BT, et al. Human Factors and Ergonomics in Primary Care. In: Carayon P, editor. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*. Taylor & Francis; 2011. In press.

Wetterneck TB. Error recovery in health care. In: Pascale Carayon P, editor. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*. Taylor & Francis; 2011. In press.

Wetterneck TB, Karsh B-T. Human Factors Applications to Understanding and Using Close Calls to Improve Health Care. In: Wu A, editor. *Using Near Misses and Close Calls to Improve Patient Safety*. Oakbrook Terrace, IL: Joint Commission Resources; 2011. p. 39-54.

6.B Additional Dissemination of Research Knowledge and Findings

Wetterneck TB, Holman GT. Medication information management and error recovery in primary care clinics. Wisconsin Primary Care Research & Quality Improvement Forum, November 2009.

Lapin JA, Krueger DJ, Wetterneck TB, et al. Workflow Schmerkflow. Wisconsin Primary Care Research & Quality Improvement Forum, September 2010.

Wetterneck TB. Human Factors and Ergonomics Society 54th Annual Meeting. Panel speaker for Beyond the Hospital: Human Factors and Ergonomics Issues in the Ambulatory/Outpatient Care Setting. "Error Recovery and Medication-related Information Management," San Francisco, CA, September 2010.

Wetterneck TB. Human Factors and Ergonomics Society 53rd Annual Meeting. Panel speaker for Beyond the Hospital: Human Factors and Ergonomics Issues in the Ambulatory/Outpatient Care Setting. "Error Recovery and Medication-related Information Management: Failures and Recovery," San Antonio, TX, October 2009.

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