Title: Proactive Risk Assessment of Primary Care of the Elderly

Principal Investigator and Team Members:

Ben-Tzion Karsh, PhD (PI) Brian Arndt, MD John Beasley, MD Vicki Bier, PhD Roger Brown, PhD Pascale Carayon, PhD Sue Dovey, PhD Mary Ellen Hagenauer, BA Jamie Lapin, MS Paul Smith, MD Jon Temte, PhD, MD Tosha Wetterneck, MD

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University of Wisconsin

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1. Structured Abstracts

Purpose: The purpose of this study was to use proactive risk assessment methods to identify hazards and model the hazards' risk in the primary care of elderly patients. **Scope**: Fifteen primary care clinics throughout Wisconsin and Iowa (n=8 urban, 7 rural; 10 electronic health record (EHR), 5 non-EHR; 13 family medicine, 2 internal medicine) were recruited.

Methods: The proactive risk assessment first involved conducting observations of 50 patient-physician care episodes (70 hours), receiving 99 valid hazard reports (217 total hazards) to our hazard report website from the participating physicians, and conducting 12 hours of focus groups with physicians and 11 hours of focus groups with patients. Next, the raw data were analyzed using content analysis, failure modes and effects analysis and variance analysis.

Results: Major hazards identified included time pressure, lack of coordination between physician and outside care professionals, difficulties with medication management, missing or incomplete information, patient not following physician's recommendations or directions, patient – context of care misfit, burdens on memory, EHR usability problems, and unpredictable workflow. The main hazard identified we termed "information chaos," which we defined as the experience of some combination of information overload, underload, scatter, uncertainty, and erroneousness.

Key Words: primary care, elderly, patient safety, proactive risk assessment, mental workload

2. **Purpose** (objectives of study)

Though much has been learned about inpatient patient safety,¹⁻⁵ less is known specifically about ambulatory patient safety in general and primary care.⁶ Research indicates that the reasons for this stem from outpatients administering their own medications, the infrequency of communication between patients and physicians, and the inadequacy of outpatient care documentation⁷. We do know, however, that medical errors and preventable adverse events occur in ambulatory primary care settings and affect children, adults, and the elderly⁷⁻⁹. The incidence of preventable errors or adverse events in primary care is high, and evidence suggests that over half may be preventable.¹⁰⁻¹²

The causes and categories of errors in primary care are similar to those in inpatient care. Dovey and her colleagues identified administrative failures, investigation failures, treatment delivery lapses, miscommunication, payment system problems, errors in the execution of a clinical task, wrong treatment decision, and wrong diagnosis as causes of errors.¹³ Literature reviews found basically the same error categories and causes,^{10, 14} though recent reviews highlight the problem of missing clinical information, as well.¹⁵

Most of the research to date on primary care patient safety focuses on the adult population, often on the elderly. The focus on the elderly is logical because they consume about one-third of all medications in the US and are more susceptible to adverse drug events.¹⁶ Results from recent studies suggest that polypharmacy occurs in nearly 20% of patients aged 65 and older, at least one inappropriate prescription is given in 7%-10% of clinic visits, and the likelihood of having an inappropriate prescription increases as the number of prescriptions per visit increases.^{9, 16} Research on elderly outpatients shows that, of all reported adverse drug events (ADEs), 38% are life-threatening or fatal, and 42% of the life-threatening or fatal ADEs are preventable.¹⁷

From a safety engineering perspective,^{18, 19} this evidence, though informative, falls short of fully helping to improve the safety of care. The reason is that studying adverse outcomes and errors might only shed light on a fraction of safety problems; it leaves out what is considered to be the most important type of safety data: hazards.¹⁹⁻²³ "Hazard" is a safety term that that is analogous to "risk factor" in healthcare or epidemiology.¹⁹ Hazards do not necessarily lead to errors or harm, but they increase the risk of them. Some hazards increase the risk of errors, and errors themselves may be hazards for patient harm. Soon after To Err is Human¹ was released, it became apparent that focusing on only studying and mitigating patient harm was insufficient because there are underlying causes that should be studied. These underlying causes were identified as errors; recently, safety violations have also become a focus.²⁴⁻²⁶ Though few errors and violations lead to harm, they became the focus because of their potential to lead to harm.²⁷ It was realized, though, that underlying errors and violations were additional causes; these causes were identified as system problems, or problems related to components of healthcare delivery systems, such as technology, workflow, culture, and the physical environment. Now, dozens of articles state that medical errors are the result of system problems, require system analyses, and can only be addressed with system solutions.²⁸⁻³² Both these system problems and errors must be a major focus of safety efforts in healthcare because they are, collectively, patient safety hazards.^{18,19,33}

It is well recognized in safety engineering that the heart of safety lies not in injuries or errors but in hazards.^{20, 21} Hazards can vary by frequency, duration, location, predictability, and magnitude. Hazards can be located anywhere in a healthcare delivery system; they represent interactions between clinicians, patients, culture, workflow, and technology. These interactions increase the risk of an unwanted outcome, of which such an outcome is an error, a violation, clinician harm (e.g., needle stick) or patient harm. Once hazards are identified, they can be corrected before any unwanted outcome occurs. Hazard identification and analysis provide data for organizations to use to make sense of their safety situation and prioritize patient safety efforts. This is known as organizational sensemaking.²²

As noted in the original RFA, there is a need to identify hazards in all aspects of ambulatory care because such endeavors are rare. We chose to focus this application on identifying hazards in primary care, specifically in care of the elderly. The Specific Aims were as follows:

- 1. Identify patient care hazards for elderly patients.
- 2. Conduct a proactive risk assessment of the identified hazards.
- 3. Compile a report detailing the documented hazards, the proactive assessment results, and the suggested approaches for eliminating the identified hazards.
- 3. Scope (Background, Context, Settings, Participants, Incidence, Prevalence).

First, why focus on primary care? The IOM³⁴ defines primary care as "the provision of integrated accessible healthcare services by clinicians who are accountable for addressing a large majority of personal healthcare needs, developing a sustained partnership with patients, and practicing in the context of family and the community." Captured in the definition are the four essential components of primary care: first contact care ("accessible"), longitudinal care ("sustained partnership"), comprehensive care ("majority of personal health care needs"), and coordinated care ("context of family and the community").³⁴⁻³⁶ First contact care is not unique to defining primary care because not all first contact events represent primary care - for example cholesterol screening at a health fair or asking a friend with medical expertise for health advice are not examples of primary care encounters.^{34, 37} However, primary care is the entry way into, and patient's home in, the healthcare system. Longitudinal care indicates that continuity over time defines the care of the patient rather than care limited to a specific disease process (e.g., cancer) or disease episode (e.g., appendicitis).³⁶ Care continues through different stages of a patient's life and in various settings, ranging from hospital nurseries to clinics to nursing homes. The focus of care is on the individual, regardless of the type of care needed, and it is provided by a single individual or team of health professionals who must also act as advocates for their patients.³⁴ Comprehensive care is integrated care that is provided for most of the common problems in the population.³⁶ Primary care clinicians must be able to utilize other health professionals and resources when this would be helpful for evaluation and treatment. The *coordination function* is extremely important, and it consists of integrating care that takes place through referrals with different procedures or various therapies.³⁶ The necessity for coordination places additional demands on the primary care clinician.

For example, extra attention is required to ensure medical records are inclusive of pertinent information generated from other levels of care.³⁸ Well-coordinated care is critical if care is to be achieved in a cost-effective and safe manner³⁹.

These facts make primary care exceedingly complicated and put a great burden on the primary care physician in terms of coordination, information seeking, information need, mental workload and decision-making.⁶ In fact, Beasley et al.⁴⁰ recently found that primary care physicians dealt with an average of three problems per patient visit, and that figure rose with patients who had chronic diseases, such as diabetes. The need for clinicians and support staff to cope with a wide range of problems can lead to more chances of diagnostic and therapeutic errors. On the other hand, the nature of primary care also offers opportunities to minimize errors and hazards through coordination and planning of care for multiple problems over time.

Why study the elderly (defined as aged 65 and over)? First, over the past 50 years, the US population has aged and projections through 2050 show the trend continuing.⁴¹ Second, the elderly visit physician offices and outpatient departments at nearly double the annual rate of younger adult groups.⁴¹ Third, the elderly consume about one-third of all medications in the US and are more susceptible to adverse drug events.^{9, 16, 17, 42} Fourth, the elderly have, compared to other adult age groups, higher rates of diabetes, activity limitations caused by chronic conditions, vision and hearing limitations, selfreported poor or fair health, hypertension, heart disease, cancer, arthritis, and other conditions,^{41, 43} all of which means that they present to primary care with more problems. In fact, Beasley et al.⁴⁰ confirmed this by finding that primary care physicians deal with an average of 3.88 problems per patient encounter with elderly patients compared to an average of 3 problems per encounter for the entire sample; 30% of encounters with elderly patients addressed more than 4 problems compared to only 18% in the general sample. These additional problems likely increase the complexity of care for the clinician by increasing the number of decisions made regarding diagnosis and treatment. Fifth, the elderly are also at increased risk of disorders affecting their decision-making and memory, such as Alzheimer's disease.⁴⁴ Together, these facts demonstrate that the primary care visits with elderly patients are likely associated with more hazards than are encounters with other age groups. To verify that, safety engineering methods of proactive risk assessment are needed.

Karsh,¹⁹ Carayon.¹⁸ and Battles²³ proposed proactive methods for addressing patient safety. Each was consistent with safety engineering ideas of focusing on hazards. A hazard is anything that increases the probability of errors or of patient/ employee injury and is analogous to "risk factor" in healthcare or epidemiology. Because hazards occur in the real work environment, they typically interact with each other and can, therefore, lead to other hazards.²³ For example, the computer display of an electronic health record may be difficult to read because of poor contrast between the text and background in the display. The readability of the display could be even worse in situations where room lighting creates glare, further reducing the ability of the physician to read the record. These interactions among the physician, screen, lighting, and text are hazards in that they are potentially detrimental to different types of performance needed to be executed by the physician---in this case visual perception and decision-making. These, in turn, may impact patient safety and quality output goals.

In the current study, 15 primary care clinics throughout Wisconsin and Iowa (n=8 urban, 7 rural; 10 electronic health record (EHR), 5 non-EHR; 13 family medicine, 2 internal medicine) were recruited to identify hazards in the primary care of the elderly.

4. **Methods** (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Study Design

Practices were recruited by emailing an invitation to participate in the study to physician members of the Wisconsin Research and Education Network (WREN), a practiced-based research network. Interested physicians were contacted by study coordinators to provide details. The first 15 physicians from 15 different clinics that responded to the email and who routinely saw elderly patients were accepted. Each participating physician was compensated \$100. From each of the 15 clinics, one primary care physician was recruited. From the primary care physician's panel of patients, we recruited "participating" and "nonparticipating" patients. "Participating patients" were those who consented to having our data collector follow them throughout their visit, from arrival to leaving the clinic, and consented to participate in the patients of the participating physician who consented to allowing us to observe their encounter with the physician, but were not involved in more extensive observations or a focus group. They were not compensated. The study was approved by the University of Wisconsin IRB and the IRBs of all clinics.

Data Sources / Data Collection

Three methods of hazard identification were employed: observing of 50 patientphysician care episodes (70 hours), receiving 99 valid hazard reports (217 total hazards) to our hazard report website from the participating physicians, and conducting 12 hours of focus groups with physicians and 11 hours of focus groups with patients.

Two types of observations were conducted: one in which the participating physician was followed and one in which the patient was followed. When the physician was followed, observations started when the physician arrived at clinic or began preparation for the day or half-day and ended with final tasks at the end of the day. It included observations of elderly patient visits during the day, but not of any other type of visit. Observations of "participating" patients began upon their arrival at clinic and ended when they left the clinic. In both cases, the trained data collector recorded observations freehand with pen and paper and then transcribed the notes within 24 hours. The data collector was trained to record observations using an ethnographic approach, which included recording content and methods of conversations, content and methods of interactions with computer systems, body language, etc.

Teleconference focus groups were conducted separately with physicians and patients. Physician focus groups were scheduled by a study coordinator, each lasting 90 minutes. Based on availability and desired focus group size, the physicians were divided into two focus groups, one meeting Tuesday evenings at 8pm and the other meeting Thursday evenings at 8pm. Each group had four focus group meetings, for a total of 12 hours between the two groups. When physicians were unable to participate, the study coordinator emailed them a list of questions covered in the focus group so that they could email responses to the topics covered.

The patient focus groups were scheduled by a study coordinator at a time convenient to the patients. Each focus group meeting lasted 1 hour. Based on availability, the patients were divided into three groups: Mondays at 9am, Mondays at 5:30pm, and Thursdays at 9am. Depending on patient preference, they could dial into the conference call on their own or have the operator call them. Each group was scheduled for six meetings (18 total); however, only 11 were needed to get through all the topics we sought to cover.

For the physician hazard reports, an industrial engineering graduate student gave each physician a two-page document that defined a hazard, described the process for reporting hazards, and provided three sample scenarios that included hazards. Physicians were given the following definition of a hazard:

"Hazard" is a safety term that is analogous to "risk factor" in healthcare or epidemiology. Hazards do not necessarily lead to errors or harm, but hazards increase the risk of them. Some hazards increase the risk of errors, and errors themselves may be hazards for patient harm. For example, smoking is a risk factor for lung cancer; it won't necessarily lead to it, but it could. And in primary care, not being able to find information in the electronic health record or in a paper chart might not necessarily have a negative outcome, but it could. Put simply, a hazard is anything that frustrates you, is a barrier to care, might lead you to make a mistake or error, or affects your ability to provide the exact kind of care you want to provide."

The sample scenarios were created by the research team to describe an ambulatory elderly patient encounter and identified hazards. Possible consequences to the patient and to the physician or care processes were identified as well. Physicians were also given a printed copy of the hazard reporting webpage that was filled in with a sample scenario, which the industrial engineering student used to review the website reporting process with the physician. Physicians received a daily emailed reminder from a research coordinator that contained a unique identifier they could use on the website and a link to the reporting webpage.

Upon logging in, the website asked, "Did anything occur that frustrated you, that was a barrier to providing care, or that affected your ability to provide the exact kind of care that you wanted to provide?" The next four questions were asked with regard to each elderly patient encounter reported that day. The questions were as follows: (1) What were the hazards you encountered today related to this patient and what was the context in which they occurred? (2) What were the potential consequences to you or the patient care processes? (3) What were the potential consequences to the patient? (4) What change(s) do you think could be made in order to prevent the hazards that you reported from happening again?

Analysis

The raw data were subjected to hazard analyses using content analysis, failure modes, and effects analysis (FMEA) and variance analysis. The content analysis for all data sources used an inductive approach, starting with a thematic analysis⁴⁵ to understand and identify the types of hazards. QSR NVivo⁴⁶ facilitated data analysis.

The content analysis was led by a graduate research assistant trained in qualitative methods and hazard analysis through extensive graduate coursework and research experience. Terms not understood by the graduate research assistant, because they were clinical, were discussed with a physician team member who explained the concept. After refining the themes, the theme names, definitions, and codes under the theme were separately reviewed for face validity by both a professor of industrial and systems engineering with expertise in safety engineering and a physician on the research team with expertise in primary care. Disagreements were reconciled through discussion.

The FMEA was moderated by the PI, and the analytical team was composed of four primary care physicians from the research team. A graduate research assistant kept real-time notes. The FMEA began with each physician on the team completing the online tutorial at http://www.va.gov/ncps/SafetyTopics/HFMEA (2 hours). Next, we held a two-hour meeting to review the raw data and select a first topic on which to conduct the FMEA. We decided that information hazards were the main problem identified and selected the step in patient care we termed "obtain information from an external provider" to start with. This was defined as information about a visit with any provider other than the primary care provider (PCP) that was not available at the time it was needed by the PCP. Next, three 3-hour (9 hours) meetings were held during which we held additional FMEA training and reached consensus on scoring criteria and on our cutoff score to proceed. Neither the traditional HFMEA scoring method, which was developed for inpatient care, nor the traditional industry FMEA scoring measures were judged appropriate for our study. Instead, we developed our own scoring tailored to primary care. Also unique to our study, we supplemented "severity to patient" as a criterion with severity to physician, severity to finances, severity to time, severity to legal/regulatory, and severity to information. Our final scoring for the FMEA was

r requency.								
	Per face-to-face visit	Equivalent						
	with an elderly patient							
	(assuming 5 elderly							
	patient visits per day)							
10	Multiple times per visit							
9	1 / visit							
8	Every other visit	Multiple times per day						
7	1 / 5 visits	1 / day						
6	1 / 25 visits	1 / week						
5	1 / 50 visits	2 / month						
4	1 / 100 visits	1 / month						
3	4-6 / 1200 visits	4-6 times / year						
2	2-4 / 1200 visits	2-3 times / year						
1	1 / 1200 visits or less	1 / year or less frequent						

Frequency:

Detectability:

10 Unlikely to detect					
5	Might detect				
1	Highly likely to detect				

Severity to Patient

		Examples								
10	Death	-Wrong med prescribed, patient dies.								
		-Child with asthma exacerbation receives wrong med and dies. (Real								
		example: a pregnant woman at St. M's gets wrong medication and dies								
		during labor).								
		-88 year old with end-stage heart disease is not adequately monitored,								
		develops dysrhythmia and dies.								
9	Permanent	- Prescription of prostate med for nocturia. Patient gets dizzy after first								
	loss of	dose, falls, breaks hip and ends up in nursing home for rest of life.								
	independence	- Too much blood thinner, patient has hemorrhagic stroke and lives with								
	or significant	permanent partial paralysis in nursing home for rest of life.								
	permanent	- Patient with atrial fib is cardioverted without prior anticoagulation and								
	disability	develops hemiplegic paralysis and needs full assist with nursing home								
		placement.								
		- Patient with atrial fibriliation is cardioverted without prior								
0	Major	Dreagulation, has stroke, and becomes aphasic.								
0	intonyoption /	- Prescription of prostate med for nocluna. Patient gets dizzy after first								
		uose, fails, fills field, fesuling in subdural fieldatoma. Surgically drained,								
	torm	- Med causes fall, heads shoulder that results in frozen shoulder with								
	discomfort*	moderate pain requiring daily pain meds and restriction of activity for rest								
	OR loss of	of life								
	function that	- Patient has surgical treatment that results in permanent incontinence								
	does not result	and impotence.								
	in loss of	- Permanent dialysis								
	independence	- Major surgery with general anesthesia								
	•	- PTSD								
		- Prolonged hospitalization								
7	Minor	-Short hospitalization with quick return to function. Antibiotic causes C.								
	intervention	diff diarrhea, require 2 days hospitalization and then returns home to full								
		function.								
		-Patient has exacerbation of asthma due to erroneous administration of								
		beta-blocker and requires short-term hospitalization to stabilize								
		-Cardiac cath								
		-Short-term dialysis								
6	Tomporony	-invasive procedure but no general anestnesia required								
0	loss of function	-rescription of prostate medifor nocturia. Fattern gets utzzy after hist								
	without	for cooking/cleaning/etc_ but fully recovers								
	hospitalization.	-Patient received an antibiotic that was not indicated and develops C-								
	it is reversible.	diffical diarrhea and misses 3 days of work without compensation.								
		-Minimal or no chronic problems								
		-Orthopedic injury without hospitalization and no chronic problems related								
		to it								
5	Severe short-	-Prescription of prostate med for nocturia. Patient gets dizzy after first								
	term	dose, falls, breaks ribs that causes significant pain and sleep disturbance								
	discomfort*	for 5 weeks, but complete recovery and no loss of function.								
		-Sutures removed too soon after minor surgical procedure and wound								
		dehiscence, which requires 6 weeks of outpatient care.								
		-Severe short-term mental discomfort								
		-No loss of function								
<u> </u>		-Repeated outpatient visits for treatment								

4	Minor discomfort that is permanent	 Prescription of prostate med for nocturia. Patient gets dizzy after first dose, falls, breaks ankle, but has persistent pain requiring Tylenol daily for life. No loss of function. Patient develops chronic but non-disabling shoulder pain after slipping on ice in front of clinic. Sleep disturbance
		- Some loss in range of motion after ankle fusion
3	Annoyed, minor temporary discomfort*	 Prescription of prostate med for nocturia. Patient gets dizzy after first dose, falls gets black eye, minor aching that resolves in a few days and embarrassed by black eye. Due to error in lab order, patient has to return for another visit for
_		another lab draw. This requires short time off from work and lost income.
2	Extra patient workload or time, but no discomfort*	 Prescription of prostate med for nocturia. Patient gets dizzy after first dose, falls, but no injury and stops med. Annoyed about money wasted on medication that will be trashed. Patient has to call back to inquire about a medication error when doctor writes wrong script. No pain involved No lost time at work
1	No harm	 -Prescription of prostate med for nocturia. Nocturia improves. -Things do go right at times. -No harm, discomfort, annoyance.

Severity to PCP

		Examples							
10	Suicide	-Physician administers wrong medication, patient dies, suit results, and							
		physician commits suicide.							
9	Quit medicine	-Physician administers wrong medication, patient dies, suit results, and							
		physician leaves practice of medicine before normal retirement age.							
8	Leave current	-Doc does acceptable, but suboptimal, management of shoulder dystocia during							
	job	delivery, baby dies, and doc becomes insurance company medical director.							
		-Physician misses cervical fracture in busy emergency room, stops doing full-							
		scope family practice, and takes up much more limited sub-specialty. Fatigue							
		may be a factor. (actually in all!)							
		-Doctor may still be in medicine but is not seeing patients.							
7	Restrict	-Doc does acceptable, but suboptimal, management of shoulder dystocia during							
	practice / cut delivery, baby has partial arm paralysis. Stops practicing OB.								
	back hours	-Physician misses problem of acute coronary syndrome in hospitalized patient and							
		patient dies, doctor stops doing hospital work.							
6	Major stress /	-Doc does acceptable, but suboptimal, management of shoulder dystocia during							
	frustration /	delivery, baby has partial arm paralysis. Doctor worries about being sued,							
	anxiety	increases alcohol use, and ends up with DUI and court-ordered substance							
		abuse treatment.							
	-Physician realizes error in adjustment of anticoagulation medication (base								
		computer problem), is subject to criticism by colleagues, suffers transient							
		depression, and loses sleep.							
		-Doctor gets sued.							
		-Psychosocial issues for which doctor seeks treatment.							
		-Psychosocial impairment for which doctor does not seek treatment.							
		-Doctor thinks about problem for more than 1 month.							

	-	
5	Moderate stress / frustration / anxiety	 Doc does acceptable, but suboptimal, management of shoulder dystocia during delivery, baby suffers fractured clavicle but recovers completely. Doc does not sleep well and has recurrent intrusive thoughts about delivery events for 3 weeks (mild PTSD) Physician sends ill adult/child patient with chest pain home during busy day at clinic and suffers stress for the next week related to concern that he/she may have missed something. Thinks about issue for between 3 days and 1 month. Doctor changes way s/he practices because of error (ordering more tests, staying later in the office to make sure nothing was missed).
4	Minor stress / frustration / anxiety	 -Doc does acceptable, but suboptimal, management of shoulder dystocia during delivery, baby suffers transient weakness of the arm and recovers fully. Doc worries about baby's recovery over the weekend, calls on Monday and everything is okay. -Physician prescribes medication not normally covered by formulary; patient irritated at increased cost, increased work needed to try to obtain (unsuccessfully) needed prior authorization. -Stress associated with issue does not last more than 3 days (or a weekend).
3	Annoyed	 -Doc does acceptable, but suboptimal, management of shoulder dystocia during delivery, baby is fine after delivery. Doc has intrusive thoughts about delivery events for a few days, but sleeps well. -Physician is called after hours by pharmacy for clarification of order that was problematic because of the pick-list in the computer. -Minimal impact on day. -Intrusive thoughts because of the issue. -Physician has to call back pharmacies or patients multiple times to clarify order(s).
2	A little more work or time required, but no stress	-Physician has to call back one pharmacy or patient to clarify order. (note that 10 of these in an evening could push this up to a 4!) -No mental stress.
1	No consequence	-Doc does optimal management of shoulder dystocia during delivery, baby is fine after delivery. Discusses teaching points with resident and goes home to a good night's sleep.

Process Severity

Process Consequence	Clarification	1	2	3				
Cost	-system cost only, does not include patient cost	Less than \$200	ess than \$200 - \$2000					
Time/Efficiency	-system only	small or no impact	medium impact	severe impact				
Legal/Regulatory	-egal/Regulatory -regulatory (internal or external) - incident reports (usually internal)			severe impact				
Information Information availability now, in future		Small or no impact (moderate delay or none)	Medium impact (temporarily missing or unknown information)	Severe impact (Lost or unknown information)				

We decided that our cutoff score would be a criticality of 32 or higher for patient or PCP, or a criticality of 12 or higher on process measure. We decided not to base decisions on the risk priority number. Our rationale for ignoring Detectability (and therefore the risk priority number) was that whether or not we can easily detect a failure, such as information missing from a patient's chart we know *should* be there, has nothing, necessarily, to do with whether or not that failure is fixed.

The HFMEA method says that, if a failure is so obvious and readily apparent that a control measure is not warranted, you don't have to proceed with analysis. However, we found that flawed logic. Being able to detect a failure and being able to fix or control it are two different things. Missing information in a chart is a perfect example – if you expect it and it is not there, you obviously detect that failure; but without controlling that problem, it keeps happening, every day, unchecked.

Our rationale for the cutoffs was to use the smallest product that seemed important. For example, regarding Patient or PCP criticality, the smallest product that seemed important was 32, because it is the product of an 8 multiplied by 4. An 8 was deemed very important ,but only if it was combined with at least a 4. An 8 combined with a 3 seemed more trivial. The reason 4 felt like a good cutoff was that, in Frequency, 4 equals 1/month, whereas 3 equaled 4-6/year (more trivial). Similarly, on PCP severity, 4 was permanent/stress whereas 3 was temporary discomfort or just annoyed. We did not choose 7x4 or 6x4 as the lower cutoff for the practical reason of that leading to too many hazards.

The in-person analytical team meetings were supplemented with considerable online discussion. Following these preliminary meetings, we held eight 3-hour meetings (24 hours) to complete the FMEA of just "obtain information from an external provider." After the FMEA was complete, we conducted the variance analysis using the tasks and processes identified from the observations and major hazards identified through all methods, including the FMEA.

Limitations

- a. Because patients and physicians were geographically distributed throughout Wisconsin and Iowa, we needed to conduct telephone focus group meetings. This proved successful with the physicians, but only partially successful with patients. Some patients did not always attend their focus groups, some did not understand the concept of a teleconference, and others struggled to participate because of hearing limitations. Those who did not understand a teleconference could not grasp that multiple people could be on a telephone conversation at once. They kept asking "who is talking" or "who is there"? These were patients who were, according to their physicians, mentally capable of participating, but they had no mental model of a conference call. Fortunately, we were able to explain to them what a conference call was and keep them in the focus group. Patients who struggled to hear were dropped.
- b. In our proposal, we planned to complete process maps from our data. Instead, we compiled process steps and tasks, but did not convert them into traditional process maps, as we could not. The reason was that we could not identify workflows per se; the workflow of each encounter was unique to the physician-patient-problem-time interaction. As such, the true nature of primary care does not lend itself to sequence diagrams or maps. This was a critical finding of the study, and we have published and presented on this topic. It has significant implications for safety interventions and the design of health information technologies. This did not, however, prevent any subsequent analyses.

- c. In our proposal, we planned to conduct hazard analyses on three main topics: medication management, diagnostic and laboratory testing, and medical records. We believed, based on past work, that we could complete hazard analyses on each in 6 hours, or 18 hours total. Instead, we focused our FMEA on missing information, which was not originally proposed. After completing the process of hazard identification and conducting a preliminary review of the data, it became clear to us that, despite conclusions in the literature that medication management, diagnostic and laboratory testing, and medical records would be the most hazardous processes, this was not the case. Instead, it was problems with information that led to problems with medication management, diagnostic and laboratory testing, and medical records. That is, underlying hazards in those three were information problems. For that reason, we felt we needed to follow our data and deviate from our proposal. The reason we did not complete the hazard analysis for information hazards and the proposed topics was that we grossly underestimated the time required to complete a single FMEA. The FMEA of just the step "obtain information from an external provider" required eight meetings, each lasting 3 hours (24 hours total), and that did not include three preliminary meetings, each 3 hours long (9 hours total), for training and agreeing upon scoring metrics or the estimated 6 hours that each participating physician contributed to the online methods we used. Not counting the 9 hours of preliminary meetings, that means each physician contributed at least 30 hours to the completion of just one step: "obtain information from an external provider." This still does not include the time spent on the variance analysis or the content analysis. Looking back, the team agrees that no time was wasted and, in fact, the team desired much more time for even the one hazard tackled in the FMEA. The reason it took so long, even with an experienced FMEA moderator (the PI), is that the physician team needed to consider failures and hazards faced by any primary care physicians caring for any elderly patients. This is in stark contrast to the typical FMEA or hazards analysis that involves a single clinic or hospital where the failures and causes are specific to the organization and all team members are part of that organization.
- d. It was not practical to involve the participating physicians in the hazard analysis, given how long it took simply to complete one analysis. Instead the hazard analyses were conducted by the research team. It also became apparent that we could not involve the participating physicians, because the data were so variable between clinics. An EMR hazard was not relevant to a participating physician with no EMR. Instead, the analyses were conducted by our team because we had a broad view of the problems from all clinics.
- e. We proposed to analyze our data using FMEA, variance analysis, and HAZOP. Instead, we used FMEA, variance analysis, and content analysis. The reasons for the substitutions were that (a) content analysis was an appropriate first step for analyzing all of our raw data and complemented well our other methods and (b) HAZOP proved too restrictive in its use of property and guide words. The combinations of property and guide words did not provide us with additional benefit beyond what the FMEA already provided, and the existing word taxonomy was too limited.

5. **Results** (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications).

A summary of all results were shared with all participating physicians, patients, and IRBs.

Principle findings

The content analysis of the three hazard identification methods yielded many hazards in the primary care of the elderly, including time pressure, lack of coordination between physician and outside care professionals, difficulties with medication management, missing or incomplete information, patient not following physician's recommendations or directions, patient – context of care misfit, burdens on memory, EHR usability problems, inappropriate trust in EMRs, patients not understanding what was important for them to bring to an appointment, financial burdens preventing patients from filling prescriptions or other treatments, and unpredictable workflow.

Observations yielded 716 tasks and subtasks (32 main tasks and their subtasks) that formed the basis of the FMEA and variance analysis. The FMEA of "obtain information from an external provider" yielded seven main failure modes:

-Don't know information exists when you make relevant decision

-Information not available when you make the decision

-Failures/Errors of omission/commission in information that was sent

-Information available, but PCP not certain of reliability

-You think you looked at the information, but in reality you did not (you looked at the wrong info, but believed it to be what you needed) - info was not actually received by the clinic or doc

-Reliance on incorrect memory

-Misinterpreting or misreading (includes not seeing something that is there, cognitive slip, a failure in cognitive execution). You intended to do the right thing but did the wrong thing.

These seven failure modes were associated with 65 causes of those failure modes, categorized into five main causes:

-Information not sent (mail, email, phone, via patient, verbal face-to-face) [16 sub-causes, such as information not ready to be transmitted at the time it is needed by the PCP or outside provider did not know which PCP to send information about the visit].

-Information is sent but not received at PCP's site (relevant department or unit) when needed [5 sub-causes, such as mode of transmission was too slow (e.g., snail mail) or information was mailed to patient but patient did not receive it]. -Information received by unit, but it is not available to the PCP during the visit [21 sub-causes, such as the information was not yet filed/scanned or information was put into the medical record (electronic or paper) but in the wrong place]. -Information is available at the time of the visit, but PCP does not or cannot mentally process it appropriately [18 sub-causes, such as PCP cannot find the data or there is so much information in the record that the PCP does not see the information from the outside provider]. -Misplaced confidence in memory [no sub-causes].

All the causes were linked to one or more failure modes. Of the 65 causes, only 6 were considered widely under control and, therefore, did not need ranking on the scoring criteria. The remaining 59 causes were ranked using our scoring measures and criticalities were calculated. Each cause yielded six criticalities: one for patient, physician, time, finances, legal/regulatory, and information. If any of the six exceeded the cutoff, it was considered an important cause on which to focus; 28 exceeded our cutoff, and so, as proposed, we discussed the types of solutions that would control these 28 causes. Our discussion of solutions was guided by the hierarchy of hazard control from safety engineering, which states that the best solutions eliminate the hazard, the next best reduce exposure to safe levels and guard or block against the hazard, followed by administrative solutions, such as new policies and behavioral controls (e.g., warning and training). We also focused on solutions that could help PCPs recover from failures, if they happened. Finally, we were guided by the safety philosophy that it is best to control problems at their source. Examples of causes on which we focused and potential solutions are as follows:

Cause 1b. External provider does not know to which PCP to send information. Possible solutions.

- Better: Nationally linked electronic information exchange that alerts the PCP that the patient had a visit with another provider and makes the information from the external provider visible to the PCP.
- Not as good / external provider-focused: Create a policy to always confirm the patient's PCP and have a system that automatically forwards the information from the visit to the PCP.
- Not as good / external provider-focused: Use reminders to remind the external provider to send the information to the PCP.
- Not as good / patient-focused: Educate patients on the importance of telling external providers who their PCPs are and train them to do so. Train patients to bring in all information from external visits.

Cause 3r. Information in paper form was reviewed by PCP at a time other than during the visit, but then was left/filed/stored and then not available during the visit

- Better: have electronic access to all information during the visit.
- Not as good: have a policy to bring records into the room.

The variance analysis yielded a 189x189 cell matrix composed of the 32 main tasks observed and their specific hazards. A snapshot of the variance matrix is below. The power of the variance matrix is that it complements more traditional methods, like FMEA, by providing a graphical view of hazard interactions. It is read as the column can cause the row to happen. For example, in the figure below, computer problems at an EHR clinic can cause patient records not to be available, accuracy failures throughout all steps, and failures to complete steps during the present visit and at subsequent visits, because the computer problems could affect timeliness of data input.

	LEGEND:				General daily responsibilities						Prepare for appointment							
	X= same visit, N=Next visit with same patient, S=subsequent visits that day		outer problems	s missing information	uter schedule inaccurate	s in paper in-box missing	s not available	accuracy throughout process step tion	e to completely execute process step	:d alert that patient is ready to be seen	ng or inaccurate patient intake nation from nurse	te to locate patient	outer problems	not available	iplete information on purpose of nts visit	accuracy throughout process step tion	e to completely execute process step	
Patient/Doctor/ Both	Process Step	Variance	Comp	Chart	Comp	Form:	Chart	Poor : ex ect	Unab	Misse	Missi infor	Unab	Comp	Chart	Incon patier	Poor	Unab	
Doctor	General daily responsibilities	Computer problems Charts missing information																
		Computer schedule inaccurate																
		Forms in paper in-box missing																
		Charts not available	X/S															
		Poor accuracy throughout process step execution	X/S	X/S		X/S	X/S											
		Unable to completely execute process step	X/S				X/S											
	Prepare for appointment	Missed alert that patient is ready to be seen Missing or inaccurate patient intake information from nurse																
		Unable to locate patient								x	x		x					
		Computer problems																
		Chart not available											x					
		Incomplete information on purpose of patient's visit		x	x		x				x		x	х				
		Poor accuracy throughout process step execution					X/S				x		x	х				
		Unable to completely execute process step					X/S				х		х	х				

The main hazard identified from hazard analyses we termed "information chaos," which we defined as the experience of some combination of information overload, underload, scatter, uncertainty, and erroneous information. That is, underlying many of the hazards we identified and analyzed was an information problem. Time pressure was a hazard because it prevented the patient and PCP from discussing all relevant information and caused information to be missed. EHR usability was a hazard because usability problems made it more likely that information would be missed.

Discussion

The discussion focuses on information chaos, the main hazard we identified. It should not be surprising that this is the main hazard, because primary care of the elderly is an information intensive process. PCPs rely on information to diagnose and treat their patients. And, it is *information* that is central to the success of many cognitive tasks⁴⁷ that support diagnosis and treatment. Examples of such cognitive tasks include, among many others, sensing, perceiving, searching, remembering, focusing attention, forethought, analyzing, problem-solving, pattern matching, assessing, and learning. The mere existence of needed information is important, but more important is the easy availability, presentation, arrangement, and access of that information at the time it is needed to support task performance. The reason information is so central is that, for a range of cognitive tasks, such as decision-making, information must be found, arranged, coordinated, communicated, and stored.^{47, 48}

Information chaos has important implications because it can reduce PCP situation awareness and increase PCP mental workload. Under conditions of degraded situation awareness and increased mental workload, the likelihood of successful completion of the aforementioned cognitive tasks is reduced. That means that patient care may be directly affected by information chaos.

Conclusions, Significance, and Implications

Our study identified dozens of hazards using three different hazard identification methods; 65 hazards were identified for just the PCP step we called "obtain information from an external provider." However, the most important hazard we identified was what we called "information chaos," which we defined as the experience of some combination of information overload, underload, scatter, uncertainty, and erroneous information. That means that improving the safety of primary care of the elderly will require solutions that specifically reduce information chaos for PCPs. This has never before been a target for primary care patient safety. We acknowledge that many primary care redesign efforts have been proposed, but we argue that none of them specifically targeted information chaos or its proximal outcomes of reduced situation awareness and increased mental workload.

For example, others have recommend primary care interventions, such as clinical teams, better information technologies, open-access scheduling, new chronic care models, better patient training to self-manage chronic conditions, and group medical visits.^{49, 50} We agree that many of those interventions may improve primary care, but our data suggest that redesign must begin with better information management to support SA and reduce MWL, or the interventions may fail. In fact, a recent meta-analysis of primary care interventions to reduce ADEs and hospital admissions found little evidence that existing interventions work.⁵¹ And currently proposed primary care teams, such as the teamlet or huddle, do not address the fundamental hazard of information chaos. The teamlet is designed to improve patient self-management, delegate routine processes away from physicians, develop health coaches, and cut healthcare costs⁵². Those are all admirable outcomes, but none address the information chaos. The teamlet^{52, 53} model specifically involves trying to gather data upon patient arrival so that it can be shared with the physician when the physician enters the exam room, but our data show that the timing would be too late to collect missing medications and missing tests (especially if they reside outside the clinic). The huddle model⁵⁴ suffers similar problems, and the larger program within which huddles were developed, called TransforMED,⁵⁵ does not focus on the underlying hazard we identified. Therefore, information chaos is not addressed. Health information technology (HIT) interventions may yield the greatest rewards, but our data show that current clinic EHRs (which were all off-the-shelf vendor products) contribute to reducing SA and raising MWL instead of the reverse. Well-designed technology can greatly enhance situation awareness as it has done in the military and aviation,⁵⁶ but this has not happened yet in primary care. This is a new avenue for future research and one that should be addressed in the design of EHRs.

6. List of Publications and Products

Publications

- Smith, M. W. ,Russ, A., Wears, R. L., Patterson, E., Miller, A., Militello, L., Anders, S., Karsh, B. (2009). Medical informatics: what contributions can human factors make? <u>Proceedings of the Human Factors and Ergonomics Society 53st Annual</u> <u>Meeting</u>
- Karsh, B. Dierks, M., Nemeth, C., Wears, R., Wetterneck, T., Alvarado, C. (2009). Beyond the Hospital: Human Factors and Ergonomics Issues in the Ambulatory/Outpatient Care Setting. <u>Proceedings of the Human Factors and</u> <u>Ergonomics Society 53st Annual Meeting</u>

Presentations and Posters

- Lapin, J. Hazards in the Primary Care of Elderly Patients: A Qualitative Analysis of Physician Hazard Reports. Wisconsin Primary Care Research and Quality Improvement Forum. November 12-13, 2009.
- Karsh, B. "CDS integration with workflow: but what is the workflow? A human factors engineering perspective" CDS Collaboratory, Office of the National Coordinator and Agency for Healthcare Research and Quality, Washington DC, November 12, 2009.
- Karsh, B. "Designing decision support systems that fit into clinical workflow" Academic Medical Center Collaborative of Eclipsys Users, Dallas, TX, October 14, 2009.
- Karsh, B. Proactive risk assessment of primary care of the elderly. Wisconsin Research and Education Network Spring Convocation of Practices. May 8-9, 2009.
- Karsh, B. What Health Hazards do the Elderly Face in Primary Care Settings: an AHRQ Funded Study. Wisconsin Primary Care Research Forum. November 1-2, 2008.
- Lapin, J. Proactive risk assessment of primary care of the elderly. 2008 AHRQ Annual Conference: Promoting Quality...Partnering for Change, Bethesda, MD, September 7-10, 2008.
- Lapin, J. Proactive risk assessment of primary care of the elderly. University of Wisconsin Institute for Clinical and Translational Research Meeting on Creating Collaborative Research Conversations. April 17, 2008.
- Beasley J, Prochinske K, Kietzer L, et al. Proactive Risk Assessment of Primary Care of the Elderly. Paper presented at: American Academy of Family Physicians National Network; Colorado Springs, CO. March 7, 2008.
- Prochinske K, Kietzer L, Smith P, et al. Proactive Risk Assessment of Primary Care of the Elderly: A Wisconsin Research and Education Network Study. Paper presented at: Agency for Healthcare Research and Quality Annual PBRN; Bethesda, MD. June 11-13, 2008.

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