Patient Safety in Ambulatory Settings

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Patient Safety in Ambulatory Settings

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

This EPC evidence report is a Technical Brief. A Technical Brief is a rapid report, typically on an emerging medical technology, strategy or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Although Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions, the decision to request a Technical Brief is not solely based on the availability of clinical studies. The goals of the Technical Brief are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future research.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

If you have comments on this Technical Brief, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted a panel of Key Informants who represent subject experts and end-users of research. Key Informant input can inform key issues related to the topic of the Technical Brief. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Peer Reviewers

Prior to publication of the final Technical Brief, EPCs sought input from independent Peer
Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the
scientific literature presented in this report does not necessarily represent the views of individual
reviewers.
Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any
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Patient Safety in Ambulatory Settings

Structured Abstract

Background. Even though most medical care occurs in ambulatory settings, the patient safety movement originated in, and has been mainly focused on, adverse events in hospitalized patients. However, it is increasingly clear that the ambulatory setting is critically important. Ambulatory care differs substantially from inpatient care in ways that affect patient safety hazards and interventions. To better understand the scope of ambulatory care safety issues and the types of evaluations that have been reported for ambulatory patient safety practice (PSP), we have been tasked by AHRQ to provide an overview of key issues relating to the interventions.

Purpose. This Technical Brief had the following guiding questions:

What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

Methods. We integrated insights from discussions with eight Key Informants (KIs) with a literature scan of 28 safety topics/strategies.

Findings. KIs identified medication safety, diagnosis, transitions, referrals, and testing as important ambulatory care safety topics, and strategies that addressed communications, health IT, teams, patient engagement, organizational approaches, and safety culture as the most important strategies. The literature search found a moderate number of published intervention evaluations for e-prescribing, medication errors and adverse events, pharmacist-based interventions, and transitions from hospital to ambulatory care. There were few published evaluations of interventions for other targets/strategies. These results will assist AHRQ in developing a research agenda in ambulatory patient safety.

Summary and Implications. Both key informant interviews and the literature scan reveal important differences between inpatient and ambulatory safety. There are significant gaps in ambulatory safety research, including a notable lack of studies on patient engagement and timely and accurate diagnosis. Key informants recommend prospective, large-scale studies in diverse ambulatory settings to develop and test ambulatory safety interventions.

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Background

Introduction

The Institute of Medicine defines patient safety as "freedom from accidental injury" when patients receive health care. The goal of the patient safety movement is to prevent adverse events in health care. We employ the standard definition of adverse events, as previously adapted for ambulatory care: harm to patients arising from medical management, or patient self-management, rather than the natural history of disease.[1-4]

Even though most of medical care occurs in ambulatory settings, the patient safety movement originated in, and has been mainly focused on, adverse events among hospitalized patients. However, it is increasingly clear that the ambulatory setting is critically important; the National Academy of Medicine (Institute of Medicine) opined that adverse events may be more common in ambulatory settings than in acute care settings.[5] Like hospital care, ambulatory patient safety practices (PSPs) are probably somewhat or very sensitive to context, including size and complexity of the practice, financing, culture, and leadership.

Ambulatory care differs substantially from inpatient care in ways that affect patient safety interventions. First, ambulatory settings have traditionally lacked electronic health records and other technological tools that can be harnessed for safety. Paper records constitute an impediment to timely safety data management and reporting. Today, the HITECH (Health Information Technology for Economic and Clinical Health) Act, through which $30 billion of federal incentive payments were distributed to physicians and hospitals to promote digital adoption, has led to a marked increase in adoption of health Information Technology (IT)[6] in ambulatory settings. This makes it more feasible to employ technology-based safety interventions. However, ambulatory care remains fragmented, with the vast majority of care delivered in small practices that use different, and non interoperable, electronic platforms.

Next, the traditional visit-based model of ambulatory care, in which patients periodically have short visits with ambulatory providers, creates potential safety gaps. The time course of ambulatory care is longer; weeks or months can elapse between visits or referrals or diagnostic studies, creating additional challenges for patient safety. Ambulatory providers experience intense time pressure, with current incentives focused on seeing as many patients as possible in a given amount of time, and in small practices, lack support staff for coordination of care.[7] The presence and composition of team- including nurses, pharmacists, assistants, and others- in office settings varies greatly and can affect patient safety as well.

Most of the time, patients, especially those with chronic conditions, are actually self-managing.[8] The role of the patient is very different in ambulatory care settings than in the hospital.[9] In acute-care settings, patients are under close observation and often passively receive care. In ambulatory settings, patients must decide when to initiate medical care, interact with ambulatory health systems, follow provider recommendation and perform their daily health-related tasks. For those with multiple chronic diseases, this includes following a disease-specific medication, diet, and exercise regimen. Some also adjust their medication based on their measurements, such as using glucose monitoring to adjust insulin dosing. When patients have difficulty with these self-management activities, they are at risk for adverse events.

Moreover, human error in the hospital typically refers to errors committed by members of the health care team in a professional setting. When we consider error in ambulatory settings, we

must include the possibility of patient errors. The distinction between patient error and patient blame is critical. Errors in self-management can occur because providers or health systems do not provide patients or caregivers with the knowledge or skills that patients need to safely self-manage their health conditions. Patients themselves acknowledge that they can err in self-administering medications or interpreting symptoms.[10] Thus, patient safety issues encompass both the systems issues commonly studied in inpatient settings as well as broader, patient-centered concerns related to communication and shared decision-making.

Objective of This Technical Brief

In Fiscal Year 2015, the Agency for Healthcare Research and Quality (AHRQ) launched a multi-year initiative to expand the scientific evidence, strategies, and tools that are available for improving patient safety in all health care settings so that people can expect safe care whenever and wherever they receive it. AHRQ has focused on two health care settings—ambulatory care and long-term care facilities.

To better understand the scope of ambulatory care safety issues and the types of interventions that have been reported for ambulatory PSP, we were tasked by AHRQ to provide an overview of key issues relating to improve patient safety. We combined information we obtained from published literature, grey literature, and Key Informant (KI) discussions in order to examine what hospital-based PSPs are applicable to ambulatory care, what additional ambulatory care PSPs exist, what evaluations have been done of patient PSPs in the ambulatory care setting, what is the amount of, and quality of, the evaluations of PSPs in ambulatory care, and what is the evidence about spread and adoption of these practices. We also identified gaps in the current evidence base. Performing a systematic review of the effectiveness of ambulatory PSP interventions is not an objective of this Technical Brief.

Guiding Questions

The questions below guided the data collection for this Technical Brief. These guiding questions were developed by AHRQ prior to the start of the Technical Brief. Question 1 seeks to identify ambulatory care patient safety practices that have been studied and how widely they have been implemented. Question 2 seeks information on organizational settings and other factors that may influence uptake and effectiveness ambulatory care patient safety practices.

Guiding Question 1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

Guiding Question 2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

Methods

Overview

This Technical Brief integrates insights from discussions with Key Informants (KIs) with information extracted from the published literature and grey literature. Both KI discussions and literature scan were used to respond to guiding questions 1 and 2. A protocol for the conduct of this work was developed and filed with the Agency for Healthcare Research and Quality (http://effectivehealthcare.ahrq.gov/ehc/products/622/2104/ambulatory-safety-protocol-150724.pdf).

Key Informant Discussions

We identified eight KIs from major stakeholder groups such as developers of PSPs, policy makers, persons overseeing health plan or organization safety, and including a patient advocate. Key Informants were identified by a group process involving the project team members and the Task Order Officer. Due to government regulations, the number of KIs was limited to nine non-federal participants.

In order to help answer guiding question 1, before conducting the interviews the project team evaluated the 41 PSPs that were included in the Making Health Care Safer (MHCS) II report[11] and classified them into one of three categories:

- PSPs with a strong analogy to ambulatory care safety
- PSPs not relevant to ambulatory care
- PSPs with a "partial analogy" to ambulatory care

We also asked the project team and the Task Order Officer for input on any other practices that were not covered in MHCS II. This resulted in a list of 55 topics for which we would seek input from our KIs using an online questionnaire.

After the completion of the online questionnaire, we then scheduled teleconferences with our KIs. We sent the KIs the guiding questions, the protocol, and the list of included/excluded safety practices, and the following list of questions:

1. Are there important PSPs or targets left off the list of includes (in "PSP Survey Results")? Things on the list you would recommend dropping?
2. Do you have any information on organizational models of care that promote patient safety?
3. If you were in charge of the government agency responsible for funding research on patient safety, what is the most important, or the most 3 important, topics for which you would want to see proposals?
4. What are the big categories of patient safety problems, in terms of importance? For some or all of these, we'll ask you to flesh them out a bit in terms of the types of problems and the types of interventions that you think have promise.
5. When you think about patient safety in outpatient settings, what keeps you up at night?

The teleconferences were moderated by the lead investigator and included other members of the project team and, when available, the Task Order Officer (TOO). The discussion was informal while still asking for specific answers to each of the questions.

Analysis of Discussions

These KI teleconferences were audio recorded and transcribed with verbal consent from all participants. We reviewed the transcripts and identified themes inductively using open coding. One team member conducted initial coding, with a second team member reviewing codes. The team arrived at final themes through discussion and consensus. Although we had reached thematic saturation by the third discussion, we completed interviews with all KIs as pre-specified in our protocol. The summaries of these teleconferences can be found in Appendix B.

Literature Scan Search Strategy

We conducted searches in Medline (PubMed) from 2000 to August 11, 2015. In addition, we searched for grey literature from AHRQ Patient Safety Network (PSNet), the AHRQ Innovations Exchange, Institute of Medicine (IOM), the Joint Commission website, the Institute for Safe Medication Practices, Patient Safety Quality Healthcare, and the Pennsylvania Patient Safety Authority Site (PA-PSRS). A separate search was conducted for each of the included PSPs. The full search methodology by topic can be found in Appendix A.

Literature Scan Eligibility Criteria

Titles and abstracts were screened by one reviewer to identify studies meeting the following criteria:
1. Hypothesis-testing evaluation of a patient safety intervention
2. In ambulatory care
3. Targeted at safety
4. Reports a safety outcome
5. In a high income country, since the types of safety problems and patient/provider characteristics are probably context-specific.

Articles could have had more than one reason for exclusion, but only one was coded, and a hierarchy for exclusion reasons was not applied. Rather, the first obvious exclusion reason was chosen. Also, studies might appear in one particular PSP search but might be applicable for a different topic, for example a study might appear in a search about "monitoring" but consist of a pharmacist-led intervention to improve medication safety. On full text screening, studies meeting inclusion criteria were coded according to the actual PSP evaluated, and not the search from which it was identified.

There were 10 topics (diagnostic errors, health literacy, infection control, multimorbidity, patient engagement, pharmacists' role, radiation exposure, referrals, tracking test results, and workforce) for which our standard search retrieved large numbers of titles (758-3,022). In order to perform the literature scan within the timeframe and resources of the project, we developed an alternative search strategy for these 10 topics that reduced the number of titles by requiring the word "safety" be included in the title or abstract, OR the study was published in a leading general interest medical journal OR in a leading specialty journal for patient safety. We validated this "reduced titles" strategy by comparing titles selected thus to a 10% sample of the full search titles for the first three such topics, on patient engagement, the workforce, and infection control. No studies meeting inclusion criteria were missed using the "reduced titles" search. We thus

concluded that for this literature scan this was an acceptable method for estimating the number of available studies in those topics.

Abstracts potentially meeting these inclusion criteria had full text articles retrieved and assessed by one reviewer. Studies included at this stage were then classified by:

- The patient safety target or practice

- The study design, with the categories Systematic Review, Randomized Controlled Trial, or Other Hypothesis-Testing Study.

- Whether the intervention was tested in a single setting (single office-based setting or plan) or whether it was tested in multiple settings. Studies tested in multiple sites within a health care delivery system that shares characteristics across sites, such as Kaiser or the Veteran Affairs, were considered to be equivalent to "single site" implementations.

- Data from the title and abstract and full text screening were tabulated for ease of comparison.

Details about the inclusion and exclusion criteria for some specific recurring circumstances are explained below:

1. Hypothesis-testing studies included statistical testing of outcomes between two or more comparison groups. Studies reporting only descriptive results of implementation of an intervention were not included (for example, we did not include studies of the implementation of an intervention, such as medication reconciliation, that reported the proportions of patients who had certain kinds of reconciliations performed). Systematic reviews were identified by their use of that word in their title or by following the basic methods of systematic reviews (such as presenting the search strategy, the flow of titles and abstracts leading to articles meeting the eligibility criteria, and the inclusion of evidence tables).

2. Ambulatory care included office-based care only. Studies set in the Emergency Department were considered to be closer to hospital-based care than ambulatory care and were, in general, not included. Studies set in hemodialysis centers were not included, while studies set in free-standing chemotherapy centers were included. Studies of surgical procedures requiring an operating room were not included, even though the care was delivered in an ambulatory surgery center. Studies of labor and delivery were excluded.

3. Safety outcomes were, in general, defined similar to how they are defined for hospital-based patient safety: they had to be a result of the care given, and not a part of the natural history of disease. Medication adherence was considered a quality outcome and not a safety outcome. Hospital readmission was considered a safety outcome.

4. Interventions whose main target was to increase a process were excluded, unless that process was linked to an outcome. For example, interventions aimed at increasing the use

of medication reconciliation were excluded unless there was also an assessment of potential or actual adverse drug reactions.

5. Interventions whose aim was to increase constructs such as teamwork, safety culture, leadership, etc. were excluded unless they also reported a safety outcome.

6. Simulation studies that used students as study subjects were excluded.

7. Studies to improve care of a disease were in general excluded unless safety was the primary outcome. For example, the numerous studies of interventions to improve care of patients with diabetes, which in general use a measure of glucose control like HgbA1c as their principal outcome, were excluded even if they reported differences in hypoglycemic events.

8. Studies of different agents and different delivery models for anticoagulation were considered to be primarily quality and not safety and were excluded.

9. Many interventions could fall into more than one category. For example, studies of interventions to improve hospital-to-community transitions often used pharmacists and their primary goal was medication safety. We classified each study in only one category. Studies of transitions in care were all classified as transitions. Studies not about transitions where pharmacists were the only or principal intervention component were classified as pharmacist's role. Similarly, studies of e-prescribing usually have medication safety as their goal. We classified studies as e-prescribing if that term was used in the article or if it was described as computerized physician order entry (CPOE) in the outpatient/ambulatory setting. Such studies could include, and often did include, decision support. Studies of decision support for laboratory test monitoring were classified as medication safety.

Peer Review and Public Commentary

A draft version of the Technical Brief was posted for peer review on November 24, 2015, and revised in response to reviewer comments.

Findings

Overview

The results of the questionnaire survey and KI interviews identified 28 PSPs or targets, not mutually exclusive, that had relevance to the ambulatory care setting. Separate searches on each in PubMed yielded more than 20,000 titles. Titles, abstracts, and full text screening yielded 147 potentially relevant studies, which were mostly concentrated in a few PSPs. The KI interviews were analyzed for themes, which were summarized across two domains. We have included the table of themes in Appendix C.

Results of the Questionnaire Survey

After receiving input from our project team, an online questionnaire was sent out to our KIs to evaluate which PSPs should or should not be included in our list of practices to focus on. In addition, we asked the KIs to identify additional practices that were not on the list. Completion of the questionnaire by all eight KIs and the project team's input yielded a list of 28 PSPs relevant to ambulatory care settings and 27 excluded practices not relevant to PSPs in ambulatory care settings (see Table 1).

Table 1. Patient safety practices evaluated

PSPs included
Use of Simulation Exercises in Patient Safety Efforts
Obtaining Informed Consent From Patients
Team-Training in Health Care
Computerized Provider Order Entry With Clinical Decision Support Systems
Workforce issues (job satisfaction, environment, etc)
Transitions other than hospital to ambulatory care – care coordination
Self-management of high risk medications (insulin, anticoagulation, immunomodulatory therapy)
Chronic Opioid use
Tracking test results so things don't slip through the cracks (all diagnostic and prevention testing and screening)
Monitoring for medication safety beyond the initial decision to prescribe
Referring risks--Was the best referral made? Was information communicated well enough? Who is responsible for what? (Responsibility and accountability)
Issues of multimorbidity/frail elders beyond polypharmacy
Phone triage—Who staffs it? What support tools are used?
Mental health diagnosis/treatments in the context of integrated health (co-located primary care and mental health) – mental/psychological health across all ambulatory settings
Health Literacy
Infection control and prevention of office-based acquired infections (hand hygiene is on top but there are other issues)
The Joint Commission's "Do Not Use" List
Interventions To Improve Hand Hygiene Compliance
Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment
Human Factors and Ergonomics
Promoting Engagement by Patients and Families To Reduce Adverse Events/Responsibilities in safety practices
Promoting Culture of Safety
Patient Safety Practices Targeted at Diagnostic Errors
Interventions to Improve Care Transitions at Hospital Discharge
Clinical Pharmacist's Role in Preventing Adverse Drug Events
Medication Reconciliation Supported by Clinical Pharmacists
Monitoring Patient Safety Problems
Preventing Patient Death or Serious Injury Associated With Radiation Exposure From Fluoroscopy and Computed

Tomography
PSPs excluded
Identifying Patients at Risk for Suicide
Prevention of Venous Thromboembolism
Issues around Telehealth
Reducing Unnecessary Urinary Catheter Use and Other Strategies To Prevent Catheter-Associated Urinary Tract Infections
Prevention of Central Line-Associated Bloodstream Infections
Interventions To Allow the Reuse of Single-Use Devices
Use of Real-Time Ultrasound Guidance During Central Line Insertion
Interventions To Prevent Contrast-Induced Acute Kidney Injury
Administration of blood products
High-Alert Drugs: Patient Safety Practices for Intravenous Anticoagulants
Barrier Precautions, Patient Isolation, and Routine Surveillance for prevention of Healthcare-Associated Infections
Ventilator-Associated Pneumonia
Preoperative and Anesthesia Checklists
Use of Report Cards and Outcome Measurements To Improve Safety of Surgical Care: American College of Surgeons National Surgical Quality Improvement Program
Prevention of Surgical Items Being Left Inside Patient
Operating Room Integration and Display Systems
Use of Beta Blockers To Prevent Perioperative Cardiac Events
Preventing In-Facility Falls
Preventing In-Facility Delirium
Preventing In-Facility Pressure Ulcers
Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection
Rapid Response Systems
Strategies To Prevent Stress-Related Gastrointestinal Bleeding (Stress Ulcer Prophylaxis)
Effect of Nurse-to-Patient Staffing Ratios on Patient Morbidity and Mortality
Tubing Misconnections
Limiting Individual Provider's Hours of Service (this is in the context of physicians-in-training)
Smart Pumps and Other Protocols for Infusion Pumps

Table Note: PSPs=Patient Safety Practices

This list was reviewed during our KI interviews, and no substantive changes were made. The project team and KIs recognized that many of these included PSPs overlapped, and some published PSPs may fall into more than one category.

Synthesis of the Key Informant Interviews

The KIs provided wide ranging views on numerous topics related to ambulatory patient safety, which we have organized into the following areas: the need for more fundamental formative work on the implementation of interventions and better measures of safety, specific ambulatory PSPs and concerns (which we refer to as safety issues), and cross-cutting patient safety strategies. We have summarized the interviews in Figure 1 as a matrix encompassing ambulatory care safety (a row for each of six safety issues) and strategies typically considered to address these vulnerabilities (a column for each of six cross-cutting strategies).

Figure 1. Matrix of key informant themes

	General comments	Communication	Health IT	Teams	Patient-engagement	Organizational Approaches	Measurement
Safety Issues	General comments → ↓	Problem: Cross-cutting vulnerability / Intervention: PCMH has better communication built in which may promote safety	Problem: - Alert fatigue - Work arounds - Poor EHR usability → burnout / Intervention: - Potential to be transformative - Health information exchanges	Problem: NPs underutilized / Intervention: - Mix of skills promotes safety - PCMH has teams and this may promote safety	Intervention: - Shared decision making - Health literacy	Problem: Lack of infrastructure and skills to deal with safety issues / Intervention: - Care coordination - Improved Information flow PCMH	Problem: Lack of validated measures / Intervention: Need multiple ways to measure
Prescribing and Medication Errors	Definition: Prescribing, dispensing, interactions, monitoring Non-adherence as safety problem / Intervention: - National action plan - Anti-biotic stewardship - Allergy documentation	Intervention: - Clear, consistent medication instructions - Changes made to Rx in writing for consistency from electronic order to pharmacy to bottle	Intervention: - Decision support - Changes made to Rx in writing for consistency from electronic order to pharmacy to bottle	Intervention: Pharmacist on team (PINCER trial, now in practice in UK)	Problem: Lack of patient engagement	Problem: Current systems don't support ongoing monitoring / Intervention: - Prescribing checklist - Educate patients about self-management of meds	N/A
Diagnostic Errors	Knowledge Gap: Lack of epidemiologic data	Intervention: Three-way or more consultation amongst specialists	Intervention: Decision support	N/A	Problem: Lack of information and tools for patients to improve diagnosis	Problem: Little tracking and reporting, awareness / Intervention: real time investigative procedures	N/A
Transitions	Definition: - In/out of hospital care - In/ out of social services - Multi-morbidity - Pediatrics to adults	Intervention: Need for synchronous communication when patient transitions	Intervention: Interoperability needed	Intervention: Make sure information moves with patient during transitions	Problem: Lack of effective patient education / Intervention: Self-care training	N/A	N/A
Referrals	Problem: Challenge to reach correct person in timely fashion / Intervention: Follow-up/continuity	N/A	N/A	N/A	N/A	Problem: - Perverse financial incentives - Unclear referral reasons	N/A
Culture	Problem: - Fear of speaking up about perceived safety concerns - Uncertainly about safety event reporting	N/A	N/A	N/A	N/A	Problem: Complacency issues	N/A
Testing	Problem: - Ordering the wrong tests - Poor interpretation of tests / Intervention: Standard procedures	N/A	N/A	N/A	N/A	Problem: Lack of systemization for the testing process in current practice	N/A

Formative Work

- Prioritization
- Intervention Development Process
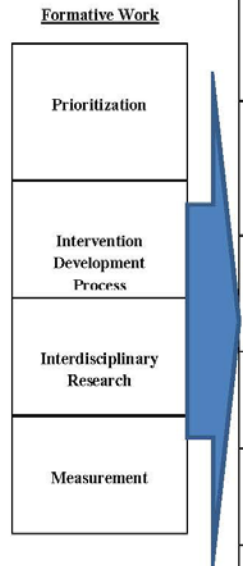- Interdisciplinary Research
- Measurement

Figure notes: IT=Information Technology; PCMH=Patient-Centered Medical Homes; gray boxes represents intersections of issues and strategies that KIs did not discuss.

KI Topic Area 1: Formative Work

KIs emphasized the importance of additional formative work in ambulatory safety in addition to testing and implementation of interventions. This formative work would inform the entire range of safety issues discussed. Several of the KIs recommended that AHRQ convene a consensus process of some kind to prioritize ambulatory safety issues that would lend consistency to local efforts. Several predicted that inquiry into intervention development would increase the uptake and effectiveness of patient safety promotion activities. During KI calls, the importance of interdisciplinary perspectives, including medicine, nursing, human factors, and the social sciences, was mentioned several times. Lack of validated measures remains a pervasive problem. Because ambulatory care is decentralized, KIs recommended use of multiple measures that can be triangulated in order to establish the burden of ambulatory safety problems. One emphasized the importance of developing consensus for measures in order to bring consistency and comparability across studies. The field could also benefit from consistent definitions of safety topics.

KI Topic Area 2: Safety Issues

The KIs reflected on the wide range of safety practices included. Multiple KIs felt there was a distinction between PSPs that reflected concrete patient safety issues, such as hand hygiene, and PSPs that represented cross-cutting patient safety strategies, such as "promoting a culture of safety." One KI urged us to consider patient safety strategies separately from specific patient safety issues, because different sets of interventions are needed to address cross-cutting strategies than to address specific patient safety topics. Another recommended considering the strategy and the topic jointly during the intervention design phase. Figure 1 provides some examples of such joint consideration (e.g., decision support as an intervention representing an health IT strategy, and directed at two safety topics).

Across all the discussions, KIs mentioned 5 concrete safety issues relevant to ambulatory settings: medication safety, diagnosis, transitions among providers in ambulatory settings, referrals from one provider to another, and management of test results. There was agreement that each of these issues is complex, multi-faceted, and important for patient safety. They began with general comments about each issue. Briefly, medication safety was defined broadly to include any deviation from optimal medication use, including errors in prescribing, dispensing, and monitoring, as well as failure to note medication interactions or appropriately discontinue medications. Some aspects of medication non-adherence were also seen as safety problems. Multiple KIs gave the same example: a non-adherent patient whose physician adds more antihypertensive agents to his regimen, causing the patient to become over-medicated when he finally does adhere. Delayed or missed diagnosis was felt to be a significant problem needing additional formative and descriptive work on a large scale. Participants noted that ambulatory care is rife with transitions, and recommended looking at transitions broadly, as interactions between all parties involved in patients' health. The referral process also is vulnerable to safety gaps; patients and subspecialty providers often do not know the reason for a visit, and the primary care provider may not receive timely information and feedback. Diagnostic testing exhibits widespread problems in notification and tracking of test results, and patients are variably aware of clinically relevant results.

KI Topic Area 3: Strategies

KIs also discussed strategies that can be used to improve safety across multiple specific topics. Patient engagement is an example of a safety strategy that could address both diagnostic and medication safety. Six cross-cutting safety strategies emerged from the KI discussions: communication, health information technology (IT), teams, patient and family engagement, organizational approaches, and safety culture. These six areas can be both facilitators of ambulatory safety and, if lacking or sub-optimal, barriers to safety. KIs provided both general input about each area and topic-specific input, which we discuss below.

Communication is clearly critical to ambulatory safety. KIs view current communication processes as vulnerable to safety problems. One specific vulnerability was the lack of implementation of clear medication instructions, despite the availability of evidence-based medication instructions that enhance comprehension. Similarly, the lack of group communication among multiple providers was viewed as a barrier to timely and accurate diagnosis. Experts reported an unmet need for synchronous communication at times of transition in ambulatory settings. One KI suggested that the communication practices embedded in the Patient-Centered Medical Home (PCMH) have the potential to enhance patient safety.

Health IT was cited as both a strategy to improve safety and a barrier to safety. KIs considered poor usability of current electronic health records (EHRs) to be a safety vulnerability and a source of clinician burnout. Burnout includes symptoms and signs such as emotional exhaustion, cynicism, perceived clinical ineffectiveness, and a sense of depersonalization in relationships with colleagues and/or patients.[12] They cited the increasing reports of alert fatigue, in which the proliferation of meaningless alerts leads to clinicians ignoring automated alerts. There was also concern about the quality of communication in visits when the physician or provider is focused on the electronic health record. However, there was agreement among KIs that health IT has potential to improve safety in ambulatory settings broadly and for specific safety issues like transitions in care and diagnosis. They saw potential in using decision support to enhance diagnosis, and believed that interoperable health IT platforms could eventually address medication reconciliation. Technology also has the potential to engage patients, especially between visits.

How work roles within teams are constructed, workflow managed, and teamwork monitored all can influence patient safety. For ambulatory care, the KIs envisioned increasing the role of nurse practitioners, physician assistants, and other health care team members in order to foster safety. Including pharmacists on ambulatory teams was specifically mentioned, as was employing a team approach to transitions.

KIs consistently highlighted the importance of patient engagement since ambulatory encounters are rare and brief compared with daily self-management. KIs discussed the need for evidence to inform optimal patient engagement strategies. KIs believed is critical that patient engagement strategies address the needs of populations with limited health literacy, limited English proficiency, and other social vulnerabilities. Making the health system easier for patients to navigate was felt to confer safety benefit.

KIs expressed concern about the notable lack of existing organizational approaches in current practice that support ambulatory safety. They also expressed concern about "complacency" about errors in ambulatory practice and believed that strengthening reporting and feedback mechanisms would help. KIs felt that the patient-centered medical home (PCMH) approach had

promise, and recommended further study of how PCMH transformation affects adverse event incidence.

Measurement remains a challenge for ambulatory safety. Currently, we do not have effective measurement strategies. KIs believed that multiple modes of measurement including EHR-derived measures, patient and clinician reports, and record review, would need to be used in combination to effectively detect and measure the spectrum of ambulatory safety gaps.

Finally, an overarching theme that emerged from the discussions was the current rapid transformation of the ambulatory environment, and the need to take this rapidly changing context into account when examining safety hazards and interventions to improve ambulatory safety. Much of the current literature is derived from traditional ambulatory care models, and these are likely to be replaced by new models in the future. Thus, there is an urgent need for rapid-cycle evaluation of the impact of new care delivery models on safety.

Results of the Literature Scan

Figure 2 presents the results of the screening of the titles, abstracts, and full text articles. The searches of PubMed on the 28 topics yielded a total of 21,927 titles with an additional 61 titles coming from grey literature. Some titles appeared in more than one search, and as we did not de-duplicate these 28 searches the total number of unique titles is somewhat less. From these titles, one reviewer screened the titles, abstract, and full text articles. The majority of studies excluded at abstract screening were because they were not hypothesis-testing studies of patient safety interventions, or not about patient safety, or not based in ambulatory care (see Figure 2).

Of the 3,039 abstracts selected at full text screening, 361 articles were retrieved and reviewed. Two hundred and fourteen articles were rejected on further review, most because they were not hypothesis-testing studies of PSPs. One hundred and forty-seven studies met our eligibility criteria.

We also identified a number of authoritative reports and commentaries, such as the CDC Infection Prevention Resources for outpatient settings and the AMA report on Ambulatory Patient Safety.[13,9] However, these reports and commentaries were rejected because our literature scan was restricted to hypothesis-testing studies.

Figure 2. Overview of screening

Total titles screened
N=21,988

Total titles rejected
N=18,949

Total abstracts screened
N=3,039

Total abstracts rejected
N=2,678

-No abstracts, N=81
-Abstract/Protocol only, N=18
-No safety outcomes, N=165
-Not a high income country, N=10
-Not a hypothesis-testing evaluation of a patient safety practice intervention, N=995
-Not a PSP or PSP intervention, N=105
-Not ambulatory care, N=354
-Not human study, N=6
-Not on topic, N=4
-Not original research, N=4
-Not safety, N=848
-Not a safety intervention, N=8
-Not a systematic review, N=4
-Background, N=24
-Duplicates, N=52

Total articles screened
N=361

Total articles rejected
N=214

-Protocol only, N=4
-No safety outcomes, N=31
-Not a high income country, N=5
-Not a hypothesis-testing evaluation of a patient safety practice intervention, N=85
-Not ambulatory care, N=12
-Non-systematic review, N=5
-Background, N=20
-Not safety, N=2
-Not one of our patient safety targets, N=4
-Duplicates, N=46

Total included studies
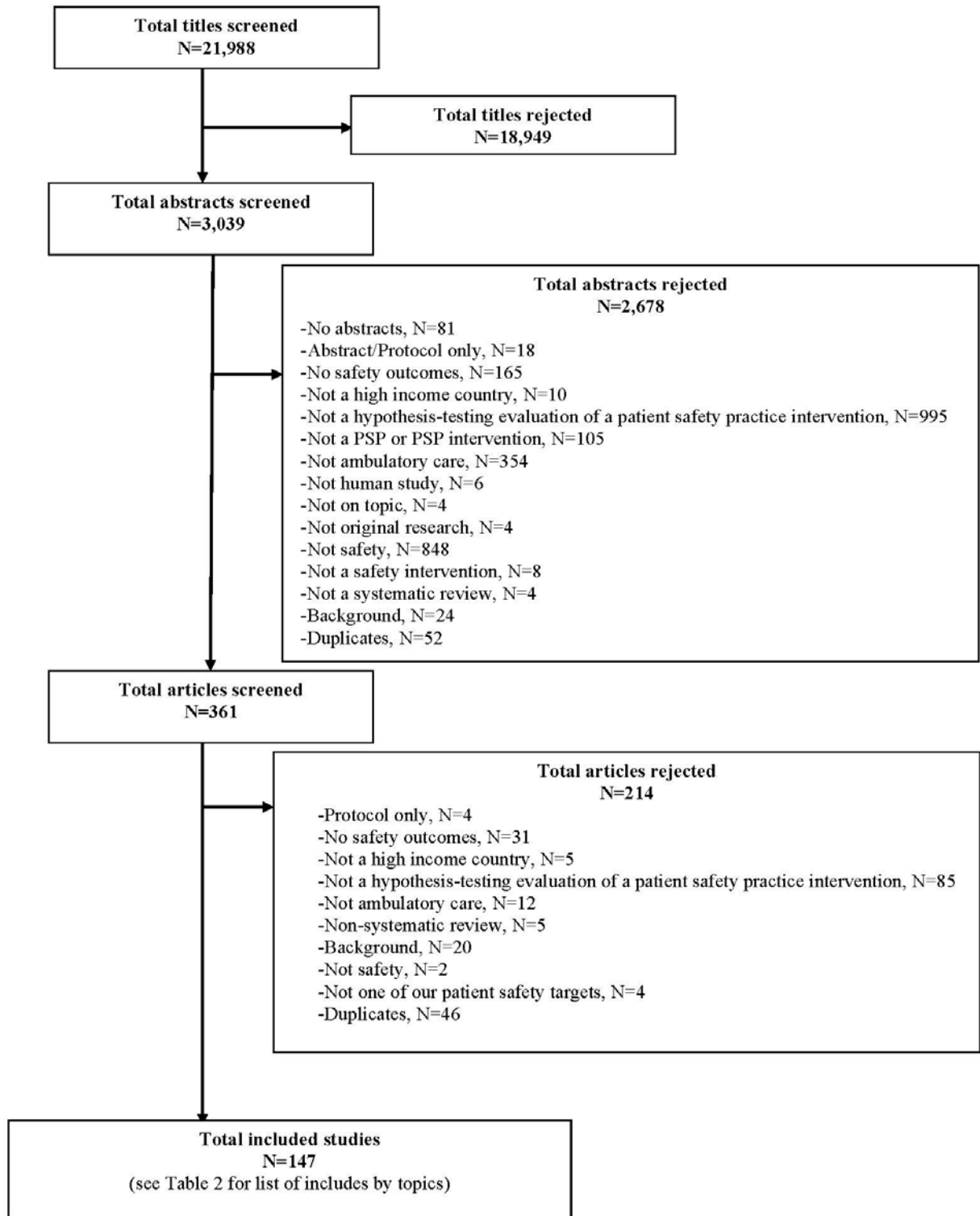N=147
(see Table 2 for list of includes by topics)

Figure notes: PSP(s)=Patient Safety Practice(s)

Of the studies meeting eligibility criteria, the PSPs that were the subject of the greatest number of studies were e-prescribing, medication safety, pharmacist-led interventions, and transitions of care (see Table 2). These PSPs also all already have systematic reviews of their effectiveness (60 percent published within the past two years), although not all the reviews are exclusively focused on ambulatory care-based versions of these interventions. However, even within the PSP that had the most identified studies, medication safety, the published studies have a relatively narrow focus and setting. Table 3 shows the intervention and setting for the 28 medication safety studies that were not systematic reviews. These are dominated by studies of computerized decision support and/or alerts as part of CPOE or the electronic health record and implemented in academic health care settings or large managed care organizations.

Studies meeting eligibility criteria for the other PSPs or safety targets were few. Those PSPs that have systematic reviews have been implemented in more than one setting, although frequently the exact nature of the PSP differs from study to study (for example, studies of pharmacist-led interventions vary in exactly what the pharmacist does and when). PSPs for which published studies are few have, in general, only been assessed in a single setting. The list of included studies by topic can be found in Appendix D.

We did not identify any studies, focusing on Guiding Question #2, concerning organizational models that promote the uptake and spread of ambulatory PSPs.

Table 2. Included studies by topic

Included studies, N=147

Safety Practice	Study Design				
	Systematic Review	RCT	Other hypothesis testing study	Practice guideline	TOTAL
Diagnostic errors					0
E-prescribing	6	2	22		30
Hand hygiene			2		2
Health literacy			1		1
Human factors		1			1
Infection control			2	1	3
Informed consent			1		1
JCAHO "Do Not Use" list					0
Life-sustaining treatment					0
Medication safety	5	12	16		33
Mental health					0
Monitoring			1		1
Multimorbidity					0
Opioid use			3		3
Patient engagement		4	2		6
Pharmacists' role	2	1	14		17
Radiation exposure			1		1
Referrals					0
Safety culture		1			1
Self-management					0
Simulation			7		7
Team-training			1		1
Telephone triage	3		3		6
Tracking test results		1	2		3
Transitions	7	10	13		30
Workforce					0
TOTALS:	**23**	**32**	**91**	**1**	**147**

notes: PSP(s)=Patient Safety Practice(s)

Table 3. Settings for medication safety

Author, Year	Intervention	Setting
Armstrong, 2014[14]	Fax alert Computer-assisted	Providers in two large health plans
Bhardwaja, 2011[15]	Computer alert	Pharmacists in a large managed care organization
Boyle, 2013[16]	"Standardized CQI" that includes computerized decision support	Community pharmacists
Bundy, 2012[17]	EHR assisted paper drug bulletins	Two federally qualified health centers
Collins, 2011[18]	CPOE with decision support	Ambulatory cancer center
Gabe, 2014[19]	Standardized symptom questionnaire	Ambulatory respiratory care clinic
Glassman, 2007[20]	Provider feedback added to EHR with CPOE and decision support	Veterans Affairs ambulatory care clinic
Griesbach, 2015[21]	EHR Drug Alerts	780 physicians in an Accountable Care Organization
Harrison, 2015[22]	Computing-assisted warfarin dosing	15 community pharmacists
Hsu, 2014[23]	CPOE alert	Academic medical center with 2.5 million ambulatory visits per year
Kansagra, 2011[24]	Registry of chemotherapy toxicity admission	Ambulatory cancer facility
Lau, 2013[25]	EHR with decision support	400 physician medical group
Lukasweski, 2012[26]	Web-based tool for patients to identify potential medication safety concerns	29 members of a community-based organization devoted to healthy aging
Lopez-Picazo, 2011[27]	EHR with decision support	All primary care physicians in a region of Spain
Matheny, 2008[28]	EHR with decision support	Primary care physicians at 20 clinics
Palen, 2006[29]	EHR with decision support	16 ambulatory sites in a managed care organization
Raebel, 2005[30]	Computerized alerts	A large managed care organization
Raebel, 2006[31]	Computerized alerts	A large managed care organization
Raebel, 2007[32]	Computerized alerts	A large managed care organization
Raebel, 2007[33]	Computerized alerts	A large managed care organization
Ryan, 2013[34]	Two methods for medication reconciliation	Ambulatory clinic at an academic medical center
Singh, 2012[35]	Web-based QI program	Eight primary care practices
Smith, 2006[36]	CPOE with decision support	One health maintenance organization
Stock, 2008[37]	EHR and web-based methods for medication reconciliation	A large health plan
Tanner, 2015[38]	EHR	209 primary care practices
Touchette, 2012[39]	Medication therapy management programs	Three geographically disparate academic health care systems
Wessell, 2013[40]	A multi-method quality improvement intervention	20 primary care practices
Willis, 2011[41]	In house medication reconciliation by trained health care students	111 patients aged 65 or older who consented to a home visit

notes: CPOE=Computerized physician order entry; CQI=Continuous Quality Improvement; EHR=Electronic Health Record

Summary and Implications

These results shed light on the current state of ambulatory safety evaluation. Most PSPs have few or even zero studies evaluating use in ambulatory care. Even for PSPs with a moderate evidence base, if the experience of hospital-based PSPs is any guide, there will still be a host of context and implementation issues that remain and require additional study. The combination of input from KIs and the literature scan demonstrates that, although there is some overlap in the hospital-based and ambulatory safety topics, the ambulatory environment has many distinct safety issues, most notably medication safety, safety culture, transitions among providers in ambulatory settings, and timely and accurate diagnosis, which includes issues arising from referrals from one provider to another, and management of test results. While the labels given these safety issues are similar or even identical to some hospital safety issues, the targets, the time course, and types of interventions may be substantially different.

In terms of medication errors and adverse drug events, the results of our literature scan showed a few PSPs, such as e-prescribing and pharmacist-led interventions, have a moderate evidence base. Practices such as pharmacist-led medication reconciliation and review of high-risk medication use[42, 43] are two evidence-based solutions that have a persistent implementation gap; this is worthy of further study. However, KIs observed that current health IT solutions do not adequately support medication safety, and echoed earlier calls for large-scale studies in this area,[9] particularly in real-world implementation and examining unintended consequences such as alert fatigue.

Patient safety culture seems to be an area of challenge for ambulatory safety. As an example, KIs described a general acceptance of sub-optimal results reporting and tracking. Reporting systems for errors are under-developed, and it is not clear what feedback results from such systems. It seems the fear of speaking up persists as well. Notably, KIs did not bring up or discuss widely used safety culture surveys or team training. There is a need to elucidate effective strategies to enhance ambulatory safety culture,[44] because the successful implementation of all ambulatory safety interventions requires a strong safety culture as a foundation.

While there was clear consensus about the importance of patient engagement, concrete best practices did not emerge from either the literature scan or interviews. Another key consideration in patient engagement is patient characteristics, such as educational attainment, health literacy, English proficiency, cognitive impairment/ disability, and health care access, as social determinants of health which are likely to affect ambulatory safety. However, there are few data to support these perceptions or inform ambulatory safety interventions.

The term "transitions in care" has come to imply post-hospital discharge, but the KIs identified many other unsafe transitions: among ambulatory providers, between ambulatory providers and the emergency department, between health care and social services, and managing pediatric to adult transitions for the chronically ill. Most of these transitions have not been the subject of a single PSP evaluation.

Interviews also emphasized the need for more research on diagnosis, including epidemiologic approaches to capture the incidence of diagnostic errors in the population, as well as in-depth behavioral and cognitive studies to improve the diagnostic process, as described in the 2015 IOM report on improving diagnosis.[45]

In addition to the specific safety issues, the literature scan and KI interviews revealed both the possible safety advantages and many unintended consequences of health IT, as with a prior

expert panel on ambulatory safety.[9] Some advantages include safety improvements from computerized physician order entry in medication prescribing and medication list maintenance. KIs perceived advantages such as widespread information-sharing through health information exchanges as theoretical rather than actually functioning today. Many KIs mentioned struggles with poorly designed, expensive, cumbersome electronic health records as a source of physician burnout, which they see as a safety hazard. Health IT implementation emerged as a needed area of study, because of the concerns about alert fatigue and "workarounds" that may worsen safety. The entire workflow of ambulatory care is being reshaped by EMRs and health IT; we need more discussion of the negative and positive actual and potential impacts on ambulatory errors.

There are some limitations to our approach. We identified 8 KIs; although we felt we reached thematic saturation with this group, it is possible that results would have changed with inclusion of additional patient safety leaders, though this remains a small field. We performed a literature scan rather than a full systematic review, because of the sparse literature in this area and the desire to address a large number of applicable PSPs.

Both the literature scan and the KI interviews point to significant knowledge and implementation gaps. Current evidence does not permit the quantification of harms from ambulatory safety issues; the magnitude of problems remains unknown. Other than the medication-related and care transition practices mentioned above, few of the PSPs have significant evidence in ambulatory settings, and fewer still have been widely implemented. The KI interviews highlighted the lack of large-scale epidemiologic studies and multi-center interventions across all topics. Epidemiology using an injury prevention perspective rather than an error-based framework was also felt to be lacking.[46, 47] We did not identify literature indicating specific organizational models of care to support ambulatory safety, although our KIs suggested that patient-centered medical home and team-based care models may hold promise. The PCMH model holds appeal in part because KIs felt it conceptually supports safety better than the current fee-for-service structures. In addition, care coordination with a multi-disciplinary team was seen as an asset for the PCMH compared with traditional ambulatory practice.

These results inform a significant future research agenda. First, measurement development efforts are needed, directed at each of the safety topics the KIs focused on: medication safety, diagnosis, transitions, referrals, and testing. There should be multiple measures that can serve as outcomes for research, and there should be efforts made to support development of performance measures. Measures are critical for the quantification of harms. In turn, the quantification of harms will allow the prioritization of ambulatory safety issues. Second, research in patient safety needs to incorporate multiple disciplines with appropriately diverse methods. This would inform non-"error" based approaches to ambulatory safety. KIs felt that more rigor needs to be brought to the science of intervention development before those interventions are evaluated in well-designed hypothesis-testing studies. There should also be further emphasis on implementation studies to understand what promotes implementation, sustainment, and spread of successful ambulatory safety practices. Third, it is clear that there is a need to invest in improving the safety of the diagnostic process. The IOM report on diagnosis mentions several evidence-based strategies such as cognitive training and systematic feedback on diagnostic accuracy, which could be tested and implemented on a larger scale.[45] Several KIs emphasized the need for collection of primary, descriptive data in order to understand diagnostic accuracy. Fourth, epidemiology of adverse events in various types of ambulatory transitions warrants further study

in preparation for developing effective patient, provider, and system-level interventions. Fifth, health IT is reshaping the workflow of ambulatory care, and research is needed on how this can enable PSP interventions and act as a barrier to safe practice; and ways to increase the former and decrease the latter. Finally, there are a host of safety culture measures, tools, leadership efforts, and interventions that have proliferated, but concerns with safety culture remain. This suggests the need for long-term, large-scale efforts not only to characterize, but improve safety culture. One approach to enhancing safety culture may be to develop interventions to treat and prevent health care provider burnout.

Because our results demonstrate multiple possible areas of focus in ambulatory safety, prioritization via a Delphi panel or process could help with a formal research agenda. Taken together, our results suggest the need for large-scale, prospective descriptive and intervention studies across multiple ambulatory environments in order to establish real-world evidence to support safer care in ambulatory settings.

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Acronyms and Abbreviations

AHRQ   Agency for Healthcare Research and Quality
IT   Information Technology
IOM   Institute of Medicine
KI(s)   Key Informant(s)
PA-PSRS   Pennsylvania Patient Safety Authority Site
PCMH   Patient-Centered Medical Homes
PSP(s)   Patient Safety Practice(s)
RCT   Randomized Controlled Trial
SR   Systematic Review
TOO   Task Order Officer

Appendix A. Search Methodology

PATIENT SAFETY IN AMBULATORY CARE

The search methodologies included here are by topic:

DIAGNOSTIC ERRORS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/11/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Diagnostic Errors"[Mesh] OR diagnostic error* OR misdiagnos* OR false positive* OR false negative* OR "errors in diagnosis"

NUMBER OF RESULTS: 1998
===
E-PRESCRIBING

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/4/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
e-prescription* OR e-prescrib* OR electronic prescription* OR electronic prescrib*

NUMBER OF RESULTS: 481
===
HAND HYGIENE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:

English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Hand Hygiene"[Mesh] OR ((hand OR hands) AND (hygien* OR wash OR washing OR disinfect*))

NUMBER OF RESULTS: 80
==
HEALTH LITERACY

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/7/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Health Literacy"[Mesh] OR "health literacy"[tiab] OR patient educat*

NUMBER OF RESULTS: 1172
==
HUMAN FACTORS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:

"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives

OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Human Engineering"[Mesh] OR human factor* OR ergonomic*

NUMBER OF RESULTS: 264
==
INFECTION CONTROL

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
"Infection Control"[Mesh] OR "Infection Control Practitioners"[Mesh] OR (infection* AND (prevent OR prevents OR preventing OR prevention OR control OR controlling OR Controlled))

NUMBER OF RESULTS: 2271
==
INFORMED CONSENT

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error* OR safety management
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
"Informed Consent"[Mesh] OR "informed consent"[tiab]

NUMBER OF RESULTS: 228
==

JCAHO "DO NOT USE" LIST

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:
joint commission OR jcaho
AND
"do not use" OR do-not-use OR abbreviation*

NUMBER OF RESULTS: 35
===
LIFE-SUSTAINING TREATMENT

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Advance Directives"[Mesh] OR "Resuscitation Orders"[Mesh] OR "life support" OR life sustain* OR advance directive* OR living will* OR "power of attorney" OR resuscitat* OR "do not resuscitate" OR "do-not-resuscitate"

NUMBER OF RESULTS: 366
===
MENTAL HEALTH

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/7/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND

"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
"Mental Health Services"[Mesh] OR "Mental Health"[Mesh] OR "Mental Disorders"[Mesh] OR mental health* OR mental* ill OR mental illness OR psychological health* OR psychosis OR psychotic* OR schizophren* OR bipolar
AND
integrated OR co-locat* OR primary care

NUMBER OF RESULTS: 490

==
MONITORING MEDICATIONS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
monitor*[ti] OR reporting[ti]
AND
medication* OR medicine* OR pharmaceutical* OR prescription* OR drug OR drugs

NUMBER OF RESULTS: 377

==
MONITORING PATIENT SAFETY PROBLEMS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/11/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND

monitor* OR track*
AND
problem*

NUMBER OF RESULTS: 463
==
MULTIMORBIDITY

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/6/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
multimorbid* OR multi-morbid* OR multi morbid* OR complex patient* OR complex disease* OR complex condition* OR multiple chronic disease* OR multiple chronic condition* OR "Comorbidity"[Mesh] OR comorbid* OR co-morbid*

NUMBER OF RESULTS: 1381
==
OPIOID USE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
opioid*
AND
use OR abus* OR addict* OR overuse OR over-use

NUMBER OF RESULTS: 207
==

PATIENT & FAMILY ENGAGEMENT

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Patient Participation"[Mesh] OR ((patient[ti] OR patients[ti] OR family[ti] OR families[ti] OR spouse*[ti] OR consumer* OR caregiver*) AND (engag* OR participat* OR involv* OR responsib*))

NUMBER OF RESULTS: 2096
===
PHARMACISTS' ROLE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/11/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Pharmacists"[Mesh] OR clinical pharmac*

NUMBER OF RESULTS: 758
===
RADIATION EXPOSURE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/11/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Radiation Injuries"[Mesh] OR "Radiography/adverse effects"[Mesh] OR "Radiography/complications"[Mesh] OR "Radiography/contraindications"[Mesh] OR "Radiography/radiation effects"[Mesh] OR radiation injur*[tiab] OR radiation expos*[tiab] OR ((radiation OR x-ray* OR x ray* OR xray* OR fluoroscop* OR tomograph*) AND (injury OR injuries OR harm* OR death OR mortality))

NUMBER OF RESULTS: 1136
==
REFERRALS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/6/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
"Referral and Consultation"[Mesh] OR refer[ti] OR referring[ti] OR referral*[tiab] OR consult*[ti] OR consulting[tiab] OR gatekeep*[tiab] OR gate keep*[tiab] OR second opinion*

NUMBER OF RESULTS: 1389
==
SAFETY CULTURE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/10/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND

"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care" OR "Outpatients"[Mesh] OR outpatient*[tiab]
AND
"Organizational Culture"[Mesh] OR organization* culture* OR organisation* culture OR corporate culture* OR shared value* OR "culture of safety" OR safety culture*

NUMBER OF RESULTS: 276

===

SELF-MANAGEMENT OF MEDICATIONS

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
self-manag* OR self manag*
AND
medication* OR medicine* OR pharmaceutical* OR prescription* OR drug OR drugs

NUMBER OF RESULTS: 279

===

SIMULATION

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error* OR safety management
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
simulation

NUMBER OF RESULTS: 447

==
TEAM-TRAINING

DATABASE SEARCHED & TIME PERIOD COVERED:
 PubMed – 1/1/2000-7/30/2015

LANGUAGE:
 English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
((team OR teams OR teamwork OR collaborat*) AND train*) OR team-training

NUMBER OF RESULTS: 358
==
TELEPHONE TRIAGE

DATABASE SEARCHED & TIME PERIOD COVERED:
 PubMed – 1/1/2000-8/6/2015

LANGUAGE:
 English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
triage
AND
telephone OR phone

NUMBER OF RESULTS: 60
==
TRACKING TEST RESULTS

DATABASE SEARCHED & TIME PERIOD COVERED:
 PubMed – 1/1/2000-7/30/2015

LANGUAGE:
 English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
screen* OR mass screening OR ((laboratory OR laboratories) AND (test OR tests OR testing))
AND
track* OR follow-up OR "follow up" OR follow* up OR notify* OR notification OR monitor* OR lost OR missed OR delay* OR correct OR incorrect OR wrong OR communicat* OR testing process*
AND
result OR results OR diagnosis OR diagnoses OR diagnostic

NUMBER OF RESULTS: 931

===
TRANSITIONS OTHER THAN HOSPITAL TO AMBULATORY CARE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
transition* OR care coordinat* OR care co-ordinat* OR "coordination of care" OR "co-ordination of care"

NUMBER OF RESULTS: 482

===
TRANSITIONS AT HOSPITAL DISCHARGE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-8/11/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND

transition* OR care coordinat* OR care co-ordinat* OR "coordination of care" OR "co-ordination of care"
AND
"Patient Discharge"[Mesh] OR hospital discharg* OR patient discharg*[tiab] OR discharge plan*

NUMBER OF RESULTS: 253
===
WORKFORCE

DATABASE SEARCHED & TIME PERIOD COVERED:
  PubMed – 1/1/2000-7/30/2015

LANGUAGE:
  English

SEARCH STRATEGY:
"Patient Safety"[Mesh] OR Safety management OR safety[tiab] OR accident*[tiab] OR harm*[tiab] OR complication* OR error*
AND
"Ambulatory Care"[Mesh] OR "Ambulatory Care Facilities"[Mesh] OR ambulatory[tiab] OR nurse practitioner* OR minute-clinic* OR minute clinic* OR community pharmac* OR dentist* OR midwives OR midwife* OR hospice* OR telehealth OR telemedicine OR "home care"
AND
"job satisfaction" OR job dissatisf* OR workforce OR workload OR "safety culture" OR "culture of safety" OR handoff* OR hand-off* OR professional competence OR competen* OR whistleblower* OR retaliat* OR collaborat* OR "safety climate" OR "climate of safety" OR interrupt* OR work environment*

NUMBER OF RESULTS: 2756

FURTHER FILTERED IN ENDNOTE AS FOLLOWS:

ALL FIELDS:
job satisfy*
work stressor*
staffing
turnover*

workplace
culture
interrup*
safety climate
workload
handoff
competen*
whistleblower
retaliate*

NUMBER OF RESULTS AFTER FILTERING: 1764

Appendix B. Summary of Key Informant Interviews

Meeting Notes:
Patient Safety Practices in Ambulatory Settings Key Informant Meeting

Wednesday, July 8, 2015
7:00 – 8:00AM PT

Attendees and Introductions

Four project staff members and one key informant attended this meeting. The meeting attendees briefly introduced themselves. Two project staff members were unable to attend.

Orientation to the Project

Project Staff 1 (PS-1) then oriented Key Informant A (KI-A) to the project. The US government is to begin funding research in ambulatory patient safety and they want to know where to go. PS-1 sent 3 documents to KI-A in advance of the meeting; the first one is the one with the two short guiding questions from AHRQ, which are listed here:

> 1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

> 2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

PS-1 further explained that the term "Patient-Centered Medical Home" is an American phrase that is meant to describe a sort of virtual organization of primary care where a GP-equivalent or a GP-practice equivalent would take ownership for all of the care patients are going to receive even if they don't receive it in any kind of system like Kaiser or the VA or the UK NHS. The idea is to try to improve the coordination of care and hopefully increase the quality of care and be less wasteful of resources. What AHRQ is looking for, therefore, are organization of care strategies that can help improve patient safety practices.

The second item sent prior to this meeting was the protocol for the project, which explains how we plan to do this, and it involves collecting information from what our government agency calls Key Informants and because of federal rules we are limited to 9 people in this group.

KI-A asked PS-1 to give a bit more explanation of the term "ambulatory care" because this term is not used in the UK. PS-1 stated that in a Venn diagram it would overlap greatly with what KI-A knows as GP care. In America it would also include all outpatient specialty care; anything happening in an office and not on the inpatient ward of a hospital. For example, it would include sending somebody to a cardiology consultant or sending someone to the rheumatology consultant. It also includes ambulatory surgical procedures, so surgical procedures that do not require an overnight stay in the hospital. For our project, however, the federal government has said that they do not want to include anything that involves an operating room. PS-1 added that there are many rather complex surgeries in the US that do not involve overnight stays, but those will not be part of this study, but in a broad definition of ambulatory care they would be included in the US. Project Staff 3 (PS-3) added that sometimes when people say "ambulatory care" in this context it is code for anything other than the hospital. This may include other institutions that are not hospitals, but one of the things that they have had to do is clarify what is and isn't an ambulatory care setting. PS-1 confirmed to KI-A that primary care is subsumed under ambulatory care. KI-A also asked if "Patient-Centered Medical Home" would also be subsumed under that and PS-1 replied yes, but it is also meant to encompass that the primary care clinician knows about or is involved with any of the patients that they are responsible for during their hospitalization. PS-3 added that in many cases it is a concept that the patient has a system of care that is taking care of them that is not necessarily hinged to a visit to a doctor in an office so it includes home care, telemedicine, coaches that help the patient along while they're at home or in a workplace. PS-3's sense is that it's both a thing (the clinic with new teams and data systems taking care of patients) and also a concept of how we think about care of patients

outside of hospitals. Project Staff 2 (PS-2) added that as a primary care physician, you would not only be responsible for patients that come in for visits, but you would be responsible for a panel of patients and the quality of their care regardless of whether they come and see you. The idea is that what they need may not be tied to some periodicity of them being in your office and so there's a responsibility for the quality of their care that's more all-encompassing. Sometimes that can be tied to different payment models. It's variably tied to when they go into the hospital, but there is some disagreement, but she agreed with PS-3 that it is a re-envisioning of the mandate of primary care and it is also used synonymously with the idea of team-based care so that the GP does not do everything but everyone works at "the top of their license," doing the most complex tasks they can which frees up the physician to do the things that only the physician can do. That is kind of the "holy grail" of Patient-Centered Medical Home. PS-1 added that, outside of a few organized systems of care here in the US, the traditional view of the responsibility of the primary care doctor to a patient is only if that patient happened to walk in the door. Once they walked out the door, there was no responsibility to them per se, so the idea of trying to actively manage a group of patients to get flu shots, mammograms, etc., was not a part of primary care, which is quite a bit different from the UK's NHS.

PS-1 received an OK from KI-A re: the recording of this call for our meeting notes. He then moved on to the questions that the team has for KI-A. Responses to PS-1's questions follow including the areas where there are problems or issues and those where interventions show some promise to improve safety.

> **What are the broad, main categories of patient safety problems?**
>   1) Prescribing and medication errors
>   2) Diagnostic errors
>   3) Administrative and communication errors
>   4) Boundaries and transitions, interfaces of care issues "Errors that are being introduced as a result of things that are trying to improve patient safety; informatics errors

Regarding prescribing and medication errors, KI-A elaborated that the problems can be the actual prescription being issued at the time, drug interaction or morbidity, and contraindications. There is also a whole piece around monitoring of certain classes of drugs, such as lithium, ACE inhibitors, and electrolytes. There are other issues as well but they may be related more to quality, than safety, such as drugs not being taken as intended or adherence issues. Also, there are issues with informatics related tools, and shared decision making approaches. The informatics are really around decision support roles but there's also been some work around introducing skill mix interventions into the primary care team; introducing pharmacists who are working more closely with the family physician than would otherwise be the case. There's also some work being done around prescribing-related checklists, but it needs more development.

Regarding diagnostic errors, PS-1 asked KI-A to elaborate on this issue since it is a very broad category. KI-A noted that this has been far less studied in the ambulatory context, so we're still at the stage of describing problems, including wrong diagnoses, missed diagnoses, not appropriately stratifying patients within a diagnosis and then the whole chain of problems that can ensue subsequently. Particularly where cancer is concerned, delays can have major effects (lung cancer, ovarian cancer specifically). A bit of work is being done – still in the discussion phase - with the IBM Watson team to see whether we can try to make some of that real time decision support available into the mix, so there is high-level discussion going on across Scotland in that respect building on some of the work that has been done at Kettering. Another opportunity would be ready access to real time investigative procedures in house in ambulatory care, such as ultrasound, CT, or MRI or second opinions (being institutionalized at KP). PS-2 commented that the other areas that KI-A mentioned interface with diagnostic errors and the challenge with diagnostic errors is that it is really different and is a category of its own. However, it interfaces so much with boundaries, health IT, and decision support. She wanted to know how KI-A thinks about that because they do seem to overlap. KI-A responded that decision support is going to be quite valuable in this respect, as it can be useful in a variety of ways. One is real time decision making. The other important issue that we would potentially benefit from is the time involved in getting a second opinion, which can take 2-3 months to get. Three-way consultations are now quite feasible and we have communications thru scribe or teleconference, electronic health record, etc. and this is beginning to be more institutionalized. There are a number of ways of pursuing this and he's had some interesting discussions with two experts on these fronts, but the world is crying out for some real answers in this respect. PS-2 asked him to say a little more about boundaries so that she can be clear on it. The interfacing errors can be on both sides so part of it is the reconciliation piece, for example, what is being communicated, for example there's quite a bit of work around drugs. When patients go into hospital and are then discharged

how is that being communicated effectively? There are wider issues as to the kinds of messages the patients are taking away, particularly in chronic disorders where this is absolutely fundamental because ideally we want the generalist, the specialist and the patient to all be on the same page and not to be speaking as cross purposes. Shared records can help, but if there was synchronous communication taking place, that can help. He mentioned the US model where the primary care physician follows the patient into the hospital when they're admitted can also help, as they don't really have that in the UK. There are other boundaries – between primary care and other ambulatory care and another big one is the social care dimension, long term care or post-acute care sector which is an interface that doesn't work very well because there are very different infrastructures, different training models, different conceptual models. It's virgin terrain really in terms of thinking about some of these issues. The UK has tried to set up seamless integrated models of care for our dementia patients, but the infrastructure isn't there to begin to support that thinking. The other piece that he has not yet mentioned is the self-care agenda, considering patients are caring for themselves 98-99% of their lives. That's another boundary that we could do so much better on. PS-2 agreed and said that it sounded like KI-A was referring to different organizational systems of care as well as different information technology systems. KI-A said yes and PS-2 also added the issue of responsibility at the time of transition. KI-A agreed that transition is very important and it has been conceptualized quite narrowly and it is a much bigger piece than that. PS-1 followed with a comment about IT, and asked if KI-A considers the health IT to be its own category or is it distributed across all of the categories? PS-1 asked him to expand on his views about IT in terms of a conceptual framework of ambulatory patient safety problems and their interventions. KI-A sees IT as an underpinning infrastructure that is increasingly in so much of what we do, but it is not a panacea or "magic bullet." The whole human organizational dimension is incredibly important. It's an enabler, it's a corporative infrastructure, but it's not a panacea, certainly not most of the time. IT does introduce its own problems and its own safety risks, particularly in the socio-technical dimension that is not adequately conceptualized, considering the IOM report that David Classen and colleagues put together. The alerts that the systems put out can cause frustrations and defensiveness. They may not be accurate but there is the wider issue that it has not been appropriately integrated and people are not appropriately trained in its use, and there's a whole class of work-arounds that are introduced which undermine the safety systems that are in practices.

PS-1 then moved on to the next question for KI-A from PS-2:

➢ **What's the area that worries you most or keeps you up at night thinking about it?**
  • From a clinical perspective, the thing that worries KI-A most is the increasing number of patients living with multi-morbiditiy. We've got some of our patients living with 10-15 conditions and the whole gamut of services that go with that; the diagnostic tests, the prescribing, the monitoring. It is becoming such a complex area affecting such a large patient base in primary care and it's only going to increase and KI-A thinks we're really struggling in that respect.

  • The other category would be those things where you get one opportunity not to miss it and they're pretty rare occurrences, such as missing the kid who collapses because of meningitis, for example. That end of the spectrum is what also worries KI-A and it's a very difficult piece when you're dealing with undifferentiated disease early on and you're not particularly trained in that in our clinical skills because so much of what we learn is driven by specialist models and perspectives and they're looking at things much further down the line.

  PS-2 confirmed that the two main areas are 1) undifferentiated symptoms and rare diseases for which there is a limited time window and 2) unforeseen complications of people with multi-morbidity who are being monitored by many people for separate conditions.

PS-1 then moved on to some specifics. One of the documents sent showed the combined results from the Survey Monkey, except one person from whom we do not yet have results. KI-A responded that he is pretty happy with the way things have panned out and most of the things that have dropped out he would more naturally associate with inpatient care. The one area that is currently excluded is around telehealth, which is currently receiving a lot of attention in the UK and he would relate it more to the ambulatory space than to the inpatient space and so you may want to think about it again. From what he has seen at the VA, he expects it to expand from the way it is being used, so it surprises him that it was dropped. Other than that, he's happy with it.

PS-1 then asked KI-A if he thinks there are organizational models of care that promote patient safety. KI-A responded that having a family physician responsible for coordinating care certainly has the potential to promote patient safety because the fragmentation that must be dealt with organizationally can be a disaster. Having appropriate skill mix in the team can also help, as well as having ready access to a range of specialist opinions as we've been talking about. Fundamentally, though, it's having somebody who can be the coordinator of care. Once you have that, there are a variety of tools and approaches that can be brought into the mix. Some of the approaches that are currently being used in the UK are reaccreditation every five years for doctors, the regular running of significant event audits, complaint mechanisms, etc.

Since both Scotland and England already have what we would consider to be some of the features of what America is trying to do in terms of the Patient Centered Medical Home, PS-1 then asked KI-A if there have been innovations in the primary care level or the organization of care in either of those countries that you think are helping to promote either patient safety practices themselves or the spread of patient safety practices across care delivery sites. KI-A responded that there have been some, for example the Quality and Outcomes work helps in that respect. A lot of it comes from guidelines and then standards and indicators, a lot of which are quality related, but there are some safety related ones as well. The whole process is intended with regular monitoring, appraisals and benchmarking across primary care sites, which helps to raise the bar in many respects. The other thing that is happening is the patient safety incident databases, particularly in England, where there are actual patient safety events or near misses which are reported and attempts are made to learn lessons from them and they are shared across the physician community, which can be helpful. Having that kind of core infrastructure can help in that respect. Then there is a fair amount of research going on that builds on that kind of interface that is dependent upon having a lead provider. For example, the PINCER trial that KI-A did which looked at trying proactively to introduce pharmacists to practices to try to identify prescribing and medication management errors and then deal with those in a practiced fashion. It was a successful intervention and has now found its way into NICE guidelines. It's being sort of scaled up across regions of England at the moment. That kind of infrastructure can help and in the US you have phenomenal innovation in some of your health systems, but scaling up beyond individual health systems is much more challenging. We're far less good at innovating, but when we do innovate there is a rational structure in place to support that scaling up piece. There's a trade-off there. PS-1 agreed.

PS-1's final question to KI-A:

> **Pretend you have the control of the pot of money for health care in your country. What would you fund in patient safety research?**
>
> KI-A responded by saying he would answer that in a convoluted way. One issue that really needs to be sorted out is adequate baselining and the trouble with the original IOM reports was there wasn't really any adequate baselining and it was the same with our organization with the report that Liam Donaldson put together. If you don't adequately baseline you never know if you're making an improvement or not. That is crucial bit of the mix and within that it's also more complicated because most errors, in KI-A's opinion, don't matter but there are a subset of errors that really do matter that translate into patient harm. It's actually drilling down and baselining in that respect that is important and we have been funded to do that work through the Department of Health in England, so that work is now going, even though it's probably 10 years too late.
>
> The other bit that we probably need to do is focus much more on intervention development. In the UK we tend to use the MRC's complex intervention framework for developing interventions – appropriate systematic review evidence, theory, feasibility testing, piloting, randomized controlled trials – and then scaling up. We recognize the kind of errors that most frequently translate into harm – a subset of drugs that are particularly important, a subset of diagnostic errors that are particularly important – and so in those areas really catalyzing the development of interventions. KI-A believes in collaborative models and the way he would do it is to develop a network with a view to intervention development.
>
> PS-1 asked if what KI-A means by "intervention development" is that there's been too much emphasis or a displaced emphasis on intervention evaluation without proper development of the interventions so that you end up testing interventions that either may not have had a good chance to work to begin with or even if they did work in a particular situation they have not been thought through so that they would be scalable from the get go. Yes, KI-A agreed and referred to the PINCER trial, which involved 10 years of developmental work. That is a lot of work involved but

interventions have the potential to be both protective and cost effective. Appropriate conceptualization and looking at the theoretical dimensions is important and then another big charge with a complex intervention is the generalizability piece. Thinking those issues through up front is very important. Evaluation in the ambulatory space may be a little premature and we probably just need to invest and do the hard grind and hopefully reap some of the rewards in the hospital setting.

PS-2 followed up with two things that she finds challenging with interventions: 1) we have an under-ascertainment problem in ambulatory care in terms of errors, and 2) when you have an intervention and the goal is to intervene before harm occurs there is a counterfactual hurdle to convince people that this would have led to harm had we not intervened. She asked KI-A to respond to those two issues. KI-A responded that, in part, this is why baselining is so important. If we use any single approach, then we're always going to underestimate. His conclusion is that we need a triangulation of approaches, which will involve the interrogation of records, but also reporting mechanisms and the patient or the carer are important pieces of that equation. Part of the reason we're in the state that we're in is because a lot of original estimates suffer from under-ascertainment issue and so he would imagine that the original IOM estimates were really underestimates.

The counterfactual issue is also challenging and KI-A thinks that really trying to figure out which errors matter most is important and he would be much more interested in those errors which are much clearer and have a direct pathway leading to harm; for example, non-steroidals being given to those with a history of GI bleed without appropriate GI protection. There's a pretty direct causal mechanism there and those are the things he would preferentially focus in on. PS-2 clarified that that would argue for pre-specifying and honing in on specific, high-yield issues and KI-A replied that for a trial you'd have to; there's no other way to pilot a trial appropriately otherwise. PS-2 added that even with intervention development, this is something that comes up a lot: whether it is for one high-yield safety situation vs. trying to improve primary care cognition across clinicians in a health system across conditions. For the latter, KI-A feels that you probably need other kinds of evaluations quite a lot of the time, and so it may it may be more programmatic where you might move into a QI kind of approach for quality improvement. PS-2 asked how KI-A would prioritize those and he replied that there is merit in both, but he thinks more focusing probably lends itself more to formal experimental studies in randomized controlled trials. It is a more generic package than the effect when they need particular individual outcome is so diffuse that trying to measure in a trial is probably a bit of a non-starter.

PS-3 responded that this discussion has been terrific and this is making him think about the organization of our work and he wonders whether we can think about safety hazards and opportunities in the traditional organization of ambulatory care and then maybe have a different section that looks at new models, whether it's Patient Centered Medical Home or telemedicine or patients who are self-monitoring. There's kind of the old set of hazards ahead of opportunities and now we have the world moving very quickly and it's raising new opportunities for improvement, but also new potential hazards with new players and new members of the team. He's not sure how to organize that in the report, but we might want to bat it around a little later.

PS-1 asked for any final thoughts from PS-2 and she thanked KI-A for his input and said that it was very informative. Project Staff 5 (PS-5) stated that all had been covered administratively. PS-1 wished KI-A a great holiday and thanked him for his input.

Meeting was adjourned.

<u>**Meeting Notes:**</u>
Patient Safety Practices in Ambulatory Settings Key Informant Meeting

Thursday, July 23, 2015
7:00AM – 8:00AM PT

Attendees and Introductions

Four project staff members and two key informants attended this meeting along with the Task Order Officer from AHRQ for this project. There was also a representative for one of the key informants on the call who took notes only. The meeting attendees briefly introduced themselves. There were two project staff members who were unable to attend.

Orientation to the Project

The Evidence Based Practice Center does systematic reviews and other evidence products on various topics on contracts given to us by AHRQ. For each individual topic the EPC needs to bring in people who have content expertise in that area in order to help inform us. This particular topic is not a systematic review per se. This is what AHRQ describes as a technical brief, the difference being that there will not be a formal synthesis of evidence about patient safety practices that work or don't work. The content experts are called key informants. Project Staff 1 (PS-1) sent 3 documents in advance of the meeting; the first one is the one with the 2 short guiding questions from AHRQ, which are listed here:

1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

The second document sent prior to this meeting was the protocol for the project, which explains how we plan to operationalize this for the technical brief, and it includes input from the key informants. Part of that is the Survey Monkey that was completed, and those results will be discussed later on in the call. These teleconferences with the Key Informants are the more free floating way of collecting information, and then we are also in the process of doing literature scans to identify titles and to gather some amount of information from studies that look relevant to ambulatory patient safety practices. We will produce a draft report which will go to AHRQ and be sent out for peer review to you and other key informants. The report will then be revised based on the peer review comments and a final will be submitted to AHRQ.

PS-1 then asked AHRQ-1 to clarify AHRQ's intention with respect to the report in order to help the key informants think about the context of this. AHRQ-1 briefly stated that AHRQ is moving its resources to the ambulatory setting. This project serves as the underpinnings of future work that AHRQ is going to do in terms of developing funding opportunity announcements and to write contracts. This is an important first step to get the lay of the landscape of ambulatory safety practices in developing future long term work that AHRQ intends to get involved with in looking at making improvements in patient safety practices in the ambulatory setting.

PS-1 then moved on to the questions for the key informants, first asking for a response from Key Informant B (KI-B).

➢ **What are the broad, main categories of patient safety problems?**
KI-B prefaced her comments by stating that her focus is almost entirely inpatient care, so she wanted the team to consider that when listening to what she has to say. KI-B said that to summarize what has been learned over time, many of the problems remain the same:

1) Communication

2) Organizational leadership and the patient's role in that. This is much more highlighted in the ambulatory settings. The patient should always be central to what we're thinking about, but in the ambulatory setting so much more of what we are trying to accomplish is

driven or managed by the patient, that we need to make much bigger strides in terms of: patient engagement, shared decision making, thinking about how behavior changed theory needs to underpin the patient, clinician and organization in terms of how we organize what we are trying to do.

3) Referrals and how patients get connected to the right care, whether it's in the community or in a tertiary center or something in between. How are we insuring that they're getting to the right people for the right things and getting that follow-up and continuity? We have a lot of perverse incentives that interfere with that on multiple different levels.

Key Informant C (KI-C) then responded to the same question and briefly stated that he agreed that when you transition to ambulatory safety the patient plays a key role that is much less than in that played in the inpatient or nursing home setting. He focuses on medication safety but a key theme that he feels would overlap is:

1) Problems which are frequent, serious, measureable and feasibly prevented. This is the rubric that they use with respect to medication safety in order to focus on the big categories that are the most important issues.

Then, turning to medication safety and using that same rubric, he said that there are a few federal initiatives for guidance.

2) Opioid safety and abuse. He mentioned the National Action Plan for Adverse Drug Prevention that used the above rubric to initiate or consolidate federal actions around 3 issues: anticoagulation safety, hypoglycemia from insulin and other diabetes management, and opioid safety. Opioids crosses both issues of patient safety and abuse and so there is a whole other set of federal initiatives and action plan around safe use and preventing opioid abuse, so he would focus on that as well.

3) Antibiotic stewardship. The final issue crosses 'what is patient safety' and 'what is healthcare quality' issue but maybe antibiotic stewardship would prevent antibiotic resistance and may reduce adverse events from unnecessary antibiotic use.

PS-1 then asked the team to make any comments. Project Staff 4 (PS-4) had none and said that these all sounded reasonable, and he turned it over to Project Staff 3 (PS-3). PS-3 agreed and stated that the two Key Informants bring different perspectives to the table. He agreed with KI-B that even though her focus has been on the inpatient, the issue of teamwork and reliability is highly relevant to what we're trying to do. For KI-C, he said that the focus on medication safety is valuable and one of the things we want to do is to see if there are lessons from trying to improve medication safety in the ambulatory environment that may be relevant to other domains that we're looking at. In some ways it's a very specific issue, but in some ways it has the usual issues around reliability and communication and has a particular twist in the ambulatory side with patients having a real role in both protecting themselves but at the same time sometimes being part of the problem if they don't get it right.

PS-4 then followed up about the opioid issue, saying it is not a regular patient safety topic since it doesn't necessarily involve errors or failure to monitor or the usual types of things and wondered what the group thought about that as a patient safety problem. KI-C responded that it depends upon what your definition is for patient safety. Obviously, a dosing error of an opioid is a serious medication error, and then you get into the issue of patients seeing multiple providers with overlapping prescriptions for opioids is a patient safety problem. PS-4 referred to some of KI-C's publications and stated that the point KI-C made in those papers was that it wasn't the Beers medications and the high risk medications, but drugs like insulin and anticoagulants that cause the vast majority of adverse drug events. He added that you can't stop someone from having diabetes and so the point KI-C made in the paper(s) was that these are just drugs with a narrow therapeutic range, but you can stop people from the epidemic of overprescribing or sort of a low threshold for prescribing opiates. Even though he knows it is not a typical patient safety problem, it does seem like a preventable harm that the medical establishment is contributing to. PS-4 continued this discussion noting that there have been some internal discussions about whether or not to think of this as a patient safety issue. It is such a special case and we're not really sure what to do with it. KI-C responded that he shares the final part of PS-4's comment that we're not really sure what to do with it, so he avoids it. He knows how to feasibly prevent a large number of anticoagulation complications and hypoglycemia from insulin in the outpatient setting because

there are specific, concrete things that can be done which have demonstrated efficacy. KI-C does not know what that is for opioids other than things directed at the obvious errors and things directed at abuse. PS-4PS-4 asked for others to chime in and wondered why that would differ from antibiotic stewardship. Why wouldn't we have more opioid stewardship instead of just reflexively prescribing pain meds for people with chronic pain for conditions that may not benefit from opiates? KI-C's response was that antibiotic stewardship is easier to do and you have tests. We're not so good at testing for pain, but we do have antimicrobial testing. PS-4 responded that that's fair.

KI-B agreed with all of the difficulty and kind of quagmire of chronic opioids, but if we think about it in terms of misuse and overuse, it seems that there are a lot of people working in this area around opioid use and improving chronic pain management and people are dying and having a high burden of harm. So it might not be achievably managed right now, but I don't know that it shouldn't be on the radar. It seems to be a problem that's exploding in the country. PS-3 added a comment that we should probably move on because this is one of those topics we could talk about for an hour. He added that some of the differences are that there's no test to know whether it's being used appropriately or inappropriately, and it's got sort of a moral frame to it, and one of the interesting things about it is there's a risk with an aggressive look at it that we'll end up with the opposite problem of underuse, which may be true with anticoagulation and diabetes agents, but it would feel like a major risk. Antibiotics have a little of the same flavor, although they don't have the moral ethical framework applied to it. In some ways there is a spectrum and if you push hard you can see that this is fundamentally different from the others, but there are a couple of parts of it that may be different and we'll have to work through that as we figure out where it lives in our report.

KI-C brought it back to the patient and stated that generally patients are not trying to abuse insulin or antibiotics, and certainly not anticoagulants. There is that component for opioids that is fundamentally different.

PS-1 then moved on to the Survey Monkey results.

➢ **Are there important PSPs or targets left off the list of includes (in "PSP Survey Results")? Things on the list you would recommend dropping?**

The project team started with all of the things that were included in Making Healthcare Safer II plus a few other things that the project team thought of and then we had the Key Informants vote on whether each item should be included or not. From there we drew a line and things with more enthusiasm were included above the line and those with less stayed below. These lists are included on the handout "Patient Safety Practices in Ambulatory Settings – Survey Results," and there are currently 28 items included and 27 excluded. PS-1 asked whether there is anything important that we have not included or if they wanted to make a case to move something from the include list to the exclude list. PS-1 said that there is nothing magical about this and it can certainly be tailored in order to make it better fit the interests of the stakeholders.

KI-B responded that she thought the list mostly looked good but considering the scope and what can reasonably be done, she does wonder about the suicide risk piece. It seems to her that ambulatory care is the place where you would have traction on that, more so than inpatient with a chance to do some preventive work and make a difference there, but she can be argued out of this as well. PS-1 responded that this particular item has come up on other calls and is on the radar screen and it moves up and down depending upon who is making the case for it at any particular time.

KI-C responded that it is a reasonable list, but that #17 "The Joint Commission's 'Do Not Use' List" on the include list is rather outdated these days, referring to pediatrics in particular, and there might be some updates to this decade-old list. That prompted KI-B to add that something that frames some of this towards pediatrics might be very important, especially in terms of medication because of the level of complexity that is involved. PS-1 responded that this is a good point and noted that there is nothing in the search strategies that is restricting it to adults only, but he wondered if KI-B thought that the list seems "adult-centric" and is there something pediatric that isn't there or some twist on it that we should make sure to include to capture pediatric safety issues. PS-4 jumped in to say that there are a couple on the list that you would want to tweak (#15 Health Literacy and #21 Patient Engagement) for patients and families, but it could be

specified; one example that isn't on the list that may be a bit of a QI safety grey zone is the whole thing about pediatric patients with major chronic illnesses getting transitioned to adult care. He has several pediatric colleagues that this is their whole focus – what to do with the diabetic or the rheumatology patient or the CF patient – it's a very high risk transition period when they're in their mid-late teens. There may be some topics we haven't thought of because we haven't asked a pediatrician, just as is true for geriatrics. PS-4 added that we might want to ask a pediatric specialist. KI-B responded that the main thing that was coming to mind for her is medication dosing and the issues that can cause problems there. There's more literature now than there was before. PS-4 agreed that there are medication safety issues in pediatrics that have a wrinkle that we don't deal with in adults and the dosing, etc. so maybe we should flag it a little bit more. PS-1 then asked KI-C if the medication dosing in pediatrics shows up in what he does at the CDC. KI-C responded that 5% of the adverse events involve dosing errors in pediatrics, but the majority involves children getting medication when they are not supposed to; traditionally considered poisonings. PS-4 asked if KI-C meant medications lying around the house and KI-C said exactly. KI-C added whether they're medications meant for pediatric use or over the counter medications or prescription adult medications, it's the #1 medication safety problem for kids; 1 in 67 kids end up in the emergency department each year by the age of 5 because they got into a medication. That's far higher than any other medication error or other adverse effect. PS-4 responded that in a way it's a safety practice that we would want to target adults; like when prescribing medication to think of whether or not there are kids in the house. KI-C responded positively and did not want to go in an entirely different direction, but the issue is which is more important when there are kids in the house – having the diabetes medication on the kitchen table for their diabetes management so they remember to take it or preventing their kid from taking it? Is there a happy medium? They have a communication campaign to do that. For pediatric medication safety, unsupervised child ingestions are far and away the most impactful problem that is measurable in the outpatient setting. PS-1 had not realized that and commented that this is a very interesting observation.

PS-1 then moved on to the organizational care question relating to the second of AHRQ's guiding questions and he mentioned the discussion on the first call regarding skill mix.

➢ **Do you have any information on organizational models of care that promote patient safety?**

He first asked KI-B to comment and she did not know about literature about it in ambulatory care and had not really considered the question before and PS-1 asked her to extrapolate from her hospital-based experience. She responded that there is plenty of association with nurse staffing and patient outcomes, so how much of the right kind of care you're getting would matter, but she does not know how that would look in the outpatient ambulatory environment except maybe it's more about how much time people have for their visits. That seems to be an ongoing source of stress, compression, work flow, work force burnout – sort of a lot packed into that time and caseload for providers. We certainly have a lot of data that nurse practitioners are underutilized in many contexts and that if nurse practitioners were practicing to their full scope in most settings we could have more primary care available to more people at a high quality level.

PS-1 asked KI-C if this comes up in the CDC work that he is involved in and he responded not directly, but he infers from the data that we have where most medication-related harms occur in the ongoing monitoring stage that we have to think about what is the organizational model that supports the ongoing safe monitoring of coagulants of folks taking insulin. However that disease management is happening, incorporating a measure of medication safety makes sense. It has been going on for decades, but we need to focus.

PS-4 added that this must be a 'large vs. small' issue, too, since the resources may be there in a hospital to monitor safety problems, but not in a small practice, and that must be a huge issue. KI-B added that we can monitor things to death without necessarily making improvement and said we need ways to integrate information, make it flow better, push better, create portals for people to communicate more seamlessly without overloading both the patient and the provider. We haven't quite yet developed the level of technological imagination that we need. KI-C clarified that when he used the term 'monitoring' what he meant to describe is when the patient themselves are monitoring their blood glucose, etc., there's probably some monitoring that should be going on. PS-4 added that what KI-C said does confirm that the dominant medication safety problem is not at the initial prescribing stage, but what happens when the patient has been on the

medication for a year or two and following the patient over time. PS-1 said that this brings up a point that he and the team has been discussing internally: do you put medication adherence into safety or quality? KI-C responded that he puts that in quality, not safety, because in simplistic terms the harm is not due to the drug when one is non-compliant. The harm is the disease process. KI-B always finds that that line is challenging and PS-1 agreed. PS-4 added that once a patient is under our care it is a bit of a safety problem if what you're giving them is adding more meds because you think the disease is not under control, but in fact they're just not adhering to their meds. That's probably the easiest way to sell it as a safety problem, but it is a big problem, and it might be one of those cases where, ideologically, it would be nice to have it get more attention. It's a major problem in the ambulatory setting and not in the hospital, so it would be nice to have a topic that is unique to the ambulatory setting. He sees where KI-C is coming from, namely that it does seem more like a QI problem, but one could make a case for people with hypertension, etc., who are getting more intensive regimens just because no one is addressing the adherence problem from the original prescriptions. PS-3 added that there is a classic struggle as to why failure to give someone their DVT prophylaxis in the hospital is a safety problem but he guesses it is because the disease they're at risk for is iatrogenic in some ways because they're in the hospital, but it is a very subtle line.

PS-3 also commented on a prior discussion about organizational models to say that the literature is going to be helpful, but this is one that is going to be changing so radically over the next 5 years that we are going to have to be very thoughtful about the early literature around telemedicine, patient self-monitoring using new IT tools, all of which are potential opportunities to improve safety, but also create their own new hazards. The way a diabetic monitors his/her glucose in the future and the way people remember to take their medicines – all of that is going to be so technologically diffuse that it has got to be on our radar screen in thinking about these issues. KI-B added that she is frustrated that we haven't had the kind of resources for some of the technologies in terms of thinking of new ways of doing things rather than replicating our old ways in an electronic format. It is outside the scope of this in a big way, but it is also a significant problem that we haven't reimagined how.

PS-1 then moved on to question #5 on the agenda.

> **When you think about patient safety in outpatient settings, what keeps you up at night?**

KI-C responded first by stealing a quote from Brian Strom that it is "older medications, poorly used." We still haven't optimized use of anticoagulants, diabetes drugs or opioids. It is a problem that we all know, but we haven't optimized how we can manage our patients on those 3 classes of medications.

KI-B responded that the fundamental thing that worries her across all settings is when someone knows that something isn't quite right and they can't figure out how to get that addressed, whether it is a patient who doesn't want to ask questions or doesn't feel comfortable doing it or a provider, medical assistant, new doctor, or nurse that understands that something isn't quite right in a situation, but can't figure out how to get that resolved – a fundamental communication and safety culture issue.

PS-1 then moved to the last of the questions.

> **If you were in charge of the government agency responsible for funding research on patient safety, what is the most important, or the most 3 important, topics for which you would want to see proposals?**

KI-B responded first by stating that she made a list, but it comes back to what we talked about in the beginning: patient engagement, shared decision making, looking at motivation adherence and behavior change theory. She would want a patient safety implementation science center that involved people from many disciplines working together to test out different ideas. PS-1 asked if she is saying that what is missing now is a more fundamental or conceptual framework for how to make changes happen? Is your concern here how to actually get things working in the varied contexts that are out there? KI-B referred to a talk that Mary Dixon Woods gave at UCSF recently in which she talked about the tension between 'all improvement is local' and having too many different approaches to improvement from a patient safety perspective, so that we don't have a sort of baseline consistent approach and that it's clear what the core intervention is and what the

adaptable periphery is. She also thinks that there is so much fantastic work going on but there are also so many cases where things just get applied on top of without really understanding the environment and the problems that need to be solved in that environment. Are we solving the right problems? Are we generating the most innovative solutions to those problems? We've been constrained by the way things are in a certain way and by the number of little silos in which that care is being delivered. It's very challenging to break out of that but to have more space for bringing people from different places together so that the framework is not 100% - so this is how we do it at UCSF and this is what our problems are – but there is a broader base of understanding our problems. We need more ways of bringing together and sparking creativity across disciplines, including design; cognitive support – how do we better address some of those other components that would ultimately be part of the safest possible care.

KI-C responded that he would be a hypocrite if he didn't list some of things that they are planning to fund or trying to get funded and he points to the National Action Plan for Adverse Drug Event Prevention which came out at the end of last year. It tries to direct federal resources to align their initiatives around anticoagulation, diabetes management, and opioid safety. Particularly in the area of pediatrics, he would like to see funding or changes made to the prescription writing so that it is consistent, from the electronic order entry screen to the pharmacy to the bottle. Finally, he would like to design a better bottle, and he feels there are better options for safety that would keep children from getting into them and they would touch on medication adherence, which he did not mean to say is not a problem. It is a major problem.

PS-4 responded that, relative to funding, there is interest in diagnostic errors and it is an area where ambulatory care is probably more important than in the hospital. In the hospital there are so many tests and specialists that eventually they get the diagnosis. You have more chance to intervene in the outpatient setting so it would be crazy not to have some synergy with the interest in that right now. The other big movement going on right now is Choosing Wisely and overuse and he thinks there are safety problems associated with that. The other nice thing is that a lot of those issues involve some patient engagement too, like the classic ones involving antibiotic use and opiate use that was mentioned earlier, but also PSA testing and other issues. It would be nice to highlight overuse and diagnostic errors as particularly relevant to the outpatient setting and patient safety.

PS-3 commented that it was a rich conversation and he is glad that PS-4 added that because diagnostic errors is very large. Also, regarding the meta-issue that KI-B brought up as to how do we get better, how do we learn, how do we implement practices, PS-3 feels that the ambulatory world is going to change in some ways more drastically than the hospital world in terms of the basic paradigm. There will be many new entrants to the field; new models, outsiders coming into the field, new technology, mechanisms for self-care and self-engagement and so some of our focus has to be on capturing that and capturing the opportunities and future hazards that emerge under these new models. Everybody practicing at the top of their license is good, but what happens when patients do more and more self-management aided by apps, etc. saying you can do this the way you manage your travel? There will be emerging issues there and we will have to figure out where it lives.

PS-1 then asked for final comments. KI-C's final comment was to second PS-3's last point to say that it's ironic that we have spent so much time focusing on inpatient safety issues and now we are moving to outpatient clinician support, but a large portion of the issues and problems really go back to when the patient is not sitting in our offices and are on their own doing self- management.

KI-B's final comment was that the problem of perverse incentives is very real and people don't get paid for the time that they perhaps should be spending to engage patients in these important self-management issues. In some types of care, such as OB, there are incentives financially not to refer your patients, which can be problematic for those patients who are more complicated. That financial alignment oriented towards the patient's needs and making that smooth can become a safety issue and should be on the radar somewhere as a policy issue.

AHRQ-1's final comment from the AHRQ perspective was to say that this has been very helpful and he thanked everyone for their participation. He liked giving some thought to the comment "serious, preventable and measurable" perspective knowing that 300 to 1 ratio of ambulatory visits to inpatient visits and he wonders if the cumulative effect of error in the ambulatory environment has a bigger impact when we look at serious or sentinel events long term on a

patient. The other challenge we have is the measurable piece since we can't determine if we're doing well at preventing things or identifying common errors in the ambulatory setting if we can't measure them. He doesn't know if we're there yet, but thinking about future and funding opportunities on helping them to do a better job of identifying and measuring potential near miss events.

PS-1 ended the call by saying that we will collate all of this, add it to all of the other key informant calls, go through the titles and at some point there will be a draft report and we will be sending that out to them for comment. We will be in touch sometime around the end of summer.

Meeting was adjourned.

Meeting Notes:
Patient Safety Practices in Ambulatory Settings Key Informant Meeting

Friday, July 24, 2015
11:00AM – 12Noon PT

Attendees and Introductions

There were four project staff members and two key informants in attendance at this meeting along with the Task Order Officer from AHRQ. The meeting attendees briefly introduced themselves. There were three project staff members unable to attend this meeting.

Orientation to the Project

The Evidence Based Practice Center does systematic reviews and other evidence-based products on various topics that are assigned to us by AHRQ. Most are systematic reviews and meta-analyses including current work we are doing on gout and osteoarthritis and other topics. We have people within the EPC who are librarians, statisticians, methodologists who are skilled in the methods of systematic reviews and literature analysis, but for each of the individual topics the EPC needs to bring in people who have content expertise in that area in order to help inform us. This particular topic is not a systematic review per se. This is what AHRQ describes as a technical brief, which in AHRQ's definition explicitly is not a review that is going to say the evidence suggests that patient safety practice X is effective and should be done and patient safety practice Y is not effective and should not be done. That is not what they are looking for. What AHRQ is looking for is to expand their funding in ambulatory patient safety practices and they are looking for this paper to sort of be the underpinnings of what they choose to send out solicitations on. As AHRQ-1 has previously said, "What is the lay of the land?" That's what they are hoping to get out of this and for a technical brief the content experts that we recruit are not called technical experts, but Key Informants. PS-1 asked Key Informant E (KI-E) and Key Informant D (KI-D) if they had any fundamental questions at this point and they did not, so he moved on to AHRQ's guiding questions.

PS-1 sent 3 documents to KI-E and KI-D in advance of the meeting; the first one is the one with the 2 short guiding questions from AHRQ, which are listed here:

1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?

2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

The second item sent prior to this meeting was the protocol for the project, which will not be discussed in detail. First, in terms of what are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting, the Key Informants have already received and responded to the Survey Monkey that we sent out which dealt with this issue. We included the patient safety practices that were included in Making Healthcare Safer II plus a few other things that we thought of, plus some others suggested by AHRQ, and then we had the Key Informants make that assessment about whether each item is relevant or whether there was a strong analogy to relevance for ambulatory patient safety. In the second part of this call we're going to talk about that list, which is the third document that was sent out. Currently librarians are running searches on these patient safety practices that are included to see whether anything has been published on them and, if so, how much, and how many have just been done once. The second part of the operationalization is gathering this more free form input rather than survey input from you folks and the other key informants.

PS-1 then moved on to the set of questions that he and Project Staff 2 (PS-2) will be asking KI-E and KI-D.

➢ **What are the broad, main categories of patient safety problems?**
   KI-E responded first.
   1) Diagnostic errors

2) Healthcare associated infections

3) Lack of patient education, such as medication treatment adherence, for instance if a patient is on warfarin or another medication that needs monitoring, etc. It was nowhere on the list so she is not sure if it is applicable in this context.

PS-1 said he would come back to her in a second, but KI-D then responded to the same question.

1) Diagnostic errors are still a big issue

2) Medication errors, especially polypharmacy, medication interactions, adverse events, especially when there are multiple prescribers

3) The whole issue around communication is a key underlying problem of most of these, not just physician-patient communication, but also provider-provider, provider-other health care personnel, so issues of communication and lack thereof continues to be a very big patient safety concern.

4) Testing process errors; ordering the wrong tests, poor interpretation of tests, not notifying patients of test results, and most importantly not following up of important, urgent, abnormal or normal that shouldn't be normal test results with patients.

Regarding 'lack of patient education' PS-1 mentioned to KI-E item #21 - Promoting Engagement by Patients and Families – which is included on the PSP list and asked if what KI-E was describing in terms of patient education is different from that item. KI-E agreed that maybe it is the same as item #21, but PS-1 said if she decides later that it really is not the same, to let us know because nothing is final.

PS-1 then turned to PS-2 and she mentioned to KI-E that she thinks of healthcare associated infections to be largely an inpatient problem in the hospital rather than a problem with outpatients. KI-E said that is fine except that most operations are conducted in outpatient surgical centers and she was thinking of those in particular. PS-2 agreed that those are very important, but asked PS-1 if those are outside of the scope of this project. PS-1 responded that it is a little bit grey but he thinks AHRQ would like everything, if possible. When the project team posed this question to AHRQ, their response was that even though there are many quite complex surgeries that are now considered as outpatient procedures, things that required an operating room were out, but surgical things that could be done in the context of an office would be in, even if they were done in the ambulatory surgical centers, such as putting in a central line, etc. Bottom line is that it is a little unclear where the line is drawn and PS-1 was sorry he couldn't be more explicit about that.

KI-E then went back to the question about item #21 and asked whether it would include educating the patient about medication self-management, such as if they were on Coumadin or educating the patient about following up with the physician or other provider? PS-1 responded that this is a good question and said that in this list of 28 there is a certain amount of overlap and he pointed to #7 - Self-management of high risk medications - so we have the self-management issue as its own specific topic, but whether we ultimately aggregate these 28 into a smaller number of broader topics is something still under discussion, but what KI-E is asking about would fall under #7 if not under #21. PS-2 agreed with KI-E that self-management is a very important topic and where a lot of her own work has been done and that we will certainly be including that topic, but we will have to figure out how to label it and give it the prominence that it needs. PS-1 added that it came up on an earlier call with other key informants whether adherence per se is a patient safety issue or a patient quality issue and at least one key informant viewed it as a quality issue because if you didn't take the drug, the adverse effect was the disease progression or the consequences of the disease and that where this person drew the quality and safety issue is that it's the drug if you take it wrong is actually causing the problem. So this person had insulin, opioids, anti-coagulants, things like that, on the list of self-management whereas self-management can obviously apply to other aspects of care. PS-1 asked if that distinction resonated with either KI-E or KI-D. KI-E said it did and made perfect sense. KI-D added that you can define it and then people have a better understanding of what you mean. There are safety issues around adherence and it is not just all quality, including some of the things around transitions of care, such as adding a drug to a patient's regimen not knowing that the patient did not take the original prescription. However, she suspects that such issues would be caught in some of the other categories. PS-1 agreed that hypertensive medications would be the same thing, but at any rate the line between quality and safety is one that is not precise and will have to be defined for each project. The best advice we have is to try to be clear as to what will be going on

either side of that line so the people know what we included, whether or not they agree with where that quality and safety line is. PS-2 added that David Bates defines an adverse event as "harm that occurs to the patient as a result of medical management rather than the natural history of the disease" and that we have somewhat modified this for the outpatient setting to say that "harm to the patient resulting from medical management or patient self-management rather than the natural history of the disease is one way in which people have distinguished safety from quality."

Just as PS-1 was about to move on to the Survey Monkey results, AHRQ-1 joined the call. He briefly introduced himself, but did not want to take time away from the discussion. KI-E and KI-D also briefly re-introduced themselves to AHRQ-1 and PS-1 brought AHRQ-1 up to speed on what had been discussed thus far on the call. PS-1 also asked AHRQ-1 to chime in regarding healthcare associated infections and where the line would be drawn regarding what kinds of surgical things would be in and out with respect to operations in ambulatory surgical centers. AHRQ-1 responded that there has been previous work done by AHRQ around surgical safety issues and there has been a lot of collaboration with Peter Pronovost and much of his work is around OR safety. AHRQ's been intimately involved in this and felt that a lot of the OR issues were going to be the same in the ambulatory surgery centers as they would be in the hospital ORs so they didn't want to get into issues of blood products and surgical sites, etc. since those would be very similar to what they have already looked at in the hospital OR. They wanted to move toward the medical office-based kinds of ambulatory issues in safety rather than looking at surgical or oncology outpatient delivery of chemotherapeutic agents. To a lesser degree they are interested in dialysis centers because they have come up in other reviews. Big picture is that they want to focus more on the medical office perspective, understanding that surgeons do have a medical office, too, but they really want to get away from what happens in the operating room for this particular task order.

> **Are there important PSPs or targets left off the list of includes (in "PSP Survey Results")? Things on the list you would recommend dropping?**

KI-D first asked if the plan is to combine some topics and split apart some others and PS-1 confirmed that there will be a separate search on each of the 28 topics on the include list, so there will be a search strategy for each one that will come up with some number of titles and then we will de-duplicate them and see what the total is. PS-1 and PS-2 will look at them to try and identify things that are evaluations of interventions done in an outpatient setting. PS-1 added that how we then put it together in a way that is most useful to readers is still an open question and will depend upon what we actually find. As we already talked about #7 and #21 have some obvious overlaps; do you overlap it on the patient role or do you overlap #7 on the other medication role? How we lump and split remains to be seen.

KI-D said that as she looks at the list she sees opioid use could be lumped in with high risk medications. She also feels that some are too broad and vague. The whole issue around clinical pharmacists is one that is going to need a lot of work. If we're talking about large healthcare systems that have their own pharmacists that are available to primary care, that's a relatively small subset; or the primary care offices at academic health centers that have access to a clinical pharmacist, or are we talking about the pharmacist who fills a patients' prescriptions at the CVS? Whether or not that's going to be very applicable for the role of #25 and #26, especially #26, she has questions about and wonders where it will go. She also thinks that the whole issue of multimorbidity is so large that you could go with that forever. PS-1 responded regarding KI-D's earlier response about communication that this underlies probably half of these on the list, if not more, and KI-D agreed. She added that when you look at the primary care patient safety literature, communication is a key factor in all of it, and she doesn't know quite where you're going to put that. The issue about not including surgery also makes her think about #28 on the list. She doesn't do a lot fluoroscopies or CTs in her primary care office, so this is mainly whether or not she reminded her patients on certain medications to stop their medicines before they go and have a procedure done? She feels it is very narrow and she's not sure how important it is.

KI-E responded to the same question that it is a comprehensive list. There are a few that are just so big and broad. She was thinking about #27, monitoring patient safety problems; it sounds vague to her and she's not sure how it would be done and also #22, promoting a culture of safety; it's just so huge. Are we talking about at the time of service? How would we be monitoring the patient safety problems? Following up with the patients? Asking the patients to report back? PS-1 responded that when we did the hospital version of that, one of the conclusions that came out of Making Healthcare Safer II was the importance of having multiple systems to monitor patient

safety problems and not to try to rely on just one thing. PS-1 imagines that, looking at ambulatory patient safety, there may be some analogy there as KI-E indicates; safety problems could be monitored by talking to patients, through the electronic medical record, patient portals, etc. KI-E really likes the mention of communication because it is so connected to not only provider-provider issues, provider-patient issues, but also communication that is connected to the patient's health literacy, their ability to engage in the healthcare context. She feels that patient education is a key component.

PS-2 asked for confirmation from KI-E and KI-D that the challenge is that some on the list seem much narrower conceptually and some seem broader and some seem more like content areas while others seem more like methods. KI-E responded that it is going to be much more of a challenge for those doing the literature review. PS-2 understands and she agrees that some of the topics are enormous and some are smaller and this is partly a reactive list to the way that these are talked about in the literature if that's helpful in thinking about why it is not internally consistent. She also asked both of them if anything is missing or if there is anything important out there that wouldn't be captured by this list. KI-E responded regarding #22, promoting a culture of safety, whether we're going to be looking at what is happening in the outpatient setting between providers, like what is happening; is it an absence of a collaborative team effort to promote safety, like what is causing some of these safety errors or are we talking about how the patient is connected? It's just such a huge term and she's trying to grasp more detail on it. PS-1 explained that in the hospital area there actually are groups that have tried to have interventions that would promote a culture of safety and they usually use something like the AHRQ Patient Safety Culture survey as their outcome measure. Those are mostly all focused on provider level kinds of things with no patient involvement, but he asks whether one of the things she is getting at is referred to in the second of the guiding questions that we got from AHRQ, which is about new organizational models of care, such as Patient-Centered Medical Home or team-based care, in terms of improving safety or the uptake of safety practices. PS-1 can imagine that what might promote a culture of safety may be things like team-based care or like accountable care organizations.

PS-2 then moved on to the next question. She stated that part of what is harder to find in the literature are successful examples of things going right in terms of outpatient safety, and this is some of the input that we are hoping to get from the key informants. Part of the challenge is that successful examples of practices that improve safety are not always disseminated. In both of your work, we would love to hear practices, initiatives or efforts that promote patient safety, specifically in medical office settings.

> **Do you have any information on organizational models of care that promote patient safety?**

KI-D asked if we meant at a system level, like Patient-Centered Medical Home or accountable care organizations or do we mean at a smaller, micro-system level, such as what is happening in one physician's office. PS-2 responded that either would be interesting and added that when we wrote the question we were thinking about the ways in which accountable care organizations and Patient-Centered Medical Homes support safety, but it would also be useful to hear what happens really at a micro-system level. KI-D responded that there is a lot out there on the PCMH but she hasn't seen a lot on PCMH and patient safety together; PCMH is usually linked to other things like communication. She is in the process of writing a paper that compared monitoring of chronic opioids in PCMH vs. non-PCMH practices. PS-1 thought that sounded interesting and wanted to hear a "teaser trailer" about it. KI-D responded that the PCMH practices do better in a number of things. She thinks that using the PSPs you're going to find things around some of the data that's present is about things like PCMH, but maybe not ACOs so much because the literature is not as robust. She thinks it is going to be harder - not that it's not there - to find some of the little micro-system things. How little staff meetings take place speaks to communication between medical assistants and physicians in an office; whether or not you've got people who are set up to follow the test tracking; or whether or not they're monitoring for health literacy. It's often down to an individual MA-physician small group type thing. PS-2 responded that she's getting a sense from KI-D that the team-based workflow and the better lines of communication in the PCMH could support patient safety but you're sharing our sense that there actually isn't too much written about it. KI-D agreed and added that we're finding more literature in the last 5-10 years around PCMH, but you're going to have to look for it through some of the topics on the list to find the patient safety piece in it, as she doesn't think they are focused on patient safety as such in the titles or writing. PS-2 responded this makes her think that we should take a harder look at the

PCMH literature and KI-D said that this is where it might be, especially in primary care outpatient settings, which she knows the best.

KI-E was then asked to respond to the same question and PS-2 provided this example: If people have a community pharmacist who does medication reconciliation on a regular basis and medication counseling, that would support patient safety and reduce adverse events. She made up this example, but KI-E said it is accurate. PS-2 asked if there are other specific things like this that are helpful that we should go out and look for in the literature. KI-E responded that continuity of care and the lack thereof would be important. If a patient sees several different physicians who are not in an organization like Kaiser or Mayo Clinic or the Cleveland Clinic and medical records are not being transferred to each individual provider or a patient goes to an urgent care center, there's no continuity of information and it becomes up to the patient to provide that information. She wonders if there could be some research how to get more continuity of care if they are not in an HMO type situation. KI-D followed up on KI-E's comments by saying that you will get that information in your care transitions literature so it's important because she raises such good points that a lot of safety issues happen with breakdowns in communication and loss of information and 'information chaos' as Beasley calls it – overload, under-load, misinformation, all the kinds of information that go around. The care transitions literature may be a place that looks at the care transition sets and because they may be very focused on a quality issue like readmissions to the emergency room or no readmissions within 30 days, etc. but they may have as mid-level markers some of these patient safety issues that you've got on your list. PS-2 responded to KI-E that it sounds like if people do get care from an integrated health system that their care – at least their information continuity – is improved and so we should make sure that we try to get at that through the literature if we can, the extent to which the information flows with them, which she agrees is really, really important in the ambulatory setting.

PS-2 then moved on to the next question.

➢ **What's the area that worries you most or keeps you up at night thinking about it?**
KI-E responded first.

- Diagnostic error and she hopes when the new IOM report is released it will shed some light. PS-2 said that she is on that panel and the report will be released soon.

KI-D was then asked to respond to the same question. She said things that are important and which bother her most are:

- The things that happen so often in primary care or outpatient settings that clinicians just consider them to be standard operating procedure. Regarding working in the testing process, there was no system in place. Nobody could track whether the order had a result that came back and they just waited for the patient to call them about it. Nobody thought of it as an error. They just thought of it as a crummy system that they had to live with. The same issue surrounds diagnostic errors because they claim they can't pick up everything and we just have to live with it. There are in the outpatient setting so many problematic areas, but the harms that come from the adverse events are often minimal (as compared to death) so we minimize how important it is. There are enough really bad things that happen that the harm can be very high, however, and because it happens so often we have a significant number of those high harm events, even though the high harm events per the number of bad things that happen is pretty low. But it happens so often, hundreds of thousands of times, that we need to move from "I just have a really crappy system for that" or "nobody worries about that" to the fact that "yes, I have a really bad EHR and it is causing safety problems for my practice and my patients." What keeps her up is how we move people further along that line. PS-2 restated her point that it is complacency around seemingly inconsequential errors without thinking about the totality and what that says about the system. KI-D agreed and added that for the most part doctors don't even think of them as errors because it's hard to go to work every day if you realize that 20 medical errors were made every day in your practice. However, depending upon how broad a term you want to use, we probably make 20 errors a day in our medical practices. Beyond complacency, we have blinders on and we don't even call them errors. KI-E added about diagnostic errors that it is not being tracked or reported and physicians and patients aren't really informed about what it is, where it occurs most often and they aren't given tools to help prevent it or to help assist a more accurate diagnosis, and

if there is not an accurate diagnosis, how is there going to be an accurate treatment plan? PS-2 agreed completely.

PS-1 then moved on to the last question.

> **If you were in charge of the government agency responsible for funding research on patient safety, what is the most important, or the most 3 important, topics for which you would want to see proposals?**

KI-D responded first:

1. Care transitions, both at the patient level as well as the information level; what's going on with the patient between places as well as what's going on with their data and information.

2. Teams and PCMH and really focus it more on the actual safety outcomes, rather than using a lot of these in-between markers. We need to go all the way and tie all of these team-based care, Patient Centered Medical Home and care transition projects to the outcomes that matter in patient safety.

KI-E then responded to the same question:

1. She agreed with KI-D on care transitions

2. Diagnostic error; mis-diagnosis, missed diagnosis, delayed diagnosis

PS-1 finished up by stating what the next steps would be. We will take all of this information and add it to the information gathered from the other key informant calls, and there is still one more call to happen, and we'll pull out the main themes. Then we will add that to the information collected from the literature scan process. In due course there will be a draft report that will provide the conclusions that we find. At that point it will go out for review and I hope that all of you will be able to give it a good hard critical review of it as well. After we get all of those reviews back plus the reviews from other reviewers there will be a final report, which will be released later this year or early next year.

PS-1 thanked everyone and said we will be in touch as we go on down the line. Meeting was adjourned.

Meeting Notes:
Patient Safety Practices in Ambulatory Settings Key Informant Meeting

Monday, August 3, 2015
8:00AM – 9:00AM PT

Attendees and Introductions

There were four project staff members and two key informants in attendance at this meeting along with the Task Order Officer from AHRQ. There were two project staff members unable to attend the meeting. The meeting attendees briefly introduced themselves.

Orientation to the Project

PS-1 gave a brief orientation to the EPC program. In terms of this project, what AHRQ wants here is a technical brief, which is explicitly not a systematic review and it is not supposed come up with conclusions to say that patient safety practice A works and should be implemented and patient safety practice B does not work and should not be implemented. The timeline for this project is different from what we're used to on systematic reviews. The draft report is actually due by the end of this month. Information will be collected from the key informants and a literature scan will be performed, which we will talk about in a few minutes.

AHRQ-1 had stated that the input of the key informants is extremely valuable as AHRQ moves some of its interest from the hospital area of patient safety to the ambulatory environment, and he added that because the arena of patient safety in the ambulatory environment is so new, the role of the key informants is going to help AHRQ develop a long-term strategy both with funding opportunity announcements and grants on where we need to go, so the key informants' knowledge and expertise in this area is going to push the envelope for AHRQ and what their next steps are.

PS-1 then asked if there were any fundamental questions at this point and they did not, so he moved on to AHRQ's guiding questions.

PS-1 sent 3 documents to Key Informant G (KI-G) and Key Informant F (KI-F) in advance of the meeting; the first one is the one with the 2 short guiding questions from AHRQ, which are listed here:

> *1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?*

> *2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?*

First, in terms of *'what are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting'*, PS-1 noted that the Key Informants have already received and responded to the Survey Monkey that we sent out which dealt with this issue, and we'll be looking at those results shortly. The next part of #1, *'What are the ambulatory care patient safety practices that have been studied in the literature?'* involves a literature search, and librarian experts from UCSF and RAND are currently running searches on these patient safety practices for which we intend to come up with counts. Regarding '*which ones have not been broadly implemented or studied beyond a single ambulatory care center?'* those will again come from the literature search which will tell us here's something that has been done once or something that has been done at a lot of places. For #2, '*What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?',* we will combine information received from the key informants and information found through the literature scan.

PS-1 then moved on to the set of questions that they will be asking. KI-F first asked PS-1 for clarification on what is meant by 'ambulatory' since it can be anything from dialysis centers to primary care to specialist practices, etc. She asked if there was a particular setting that we're most interested in or are we interested in it all. PS-1 asked AHRQ-1 to also respond to this question, since this has been an ongoing discussion, but PS-1 stated that he believes ultimately AHRQ is interested in the whole thing but that certain ambulatory sites mirror what hospital patient safety already is and for which a lot has already been

done; outpatient surgery, for example. Therefore, ambulatory surgery centers are off our list, even though they are technically ambulatory care. The majority of the focus, according to PS-1, would be office-based ambulatory care, but the boundaries aren't precisely defined. AHRQ-1 added that they're not so interested in the dialysis center or infusion center because they feel there are a lot of similarities to the hospital. Of more interest is the connection between that dialysis center or infusion center to the primary care or specialty care practice and how that, in fact, impacts the patient as a whole from a safety perspective; again, the communication, the record keeping, the transmission of information, is an important part of that, hopefully, in the context of looking at the primary care basis, but also looking at the interaction with the specialty care, but not necessarily the delivery of the surgery in an ambulatory surgery center, the delivery of the chemotherapy in an infusion center, or the dialysis that goes on in a dialysis center.

> **What are the broad, main categories of patient safety problems?**

KI-F then responded:

1) Transitions of care – There are a lot of transitions within ambulatory care that we need to learn a lot more about, even thinking about a rehab to home or nursing home back to the hospital, etc. including the medication management issues that come up and other things that fall through the cracks.

2) Medication safety - Adverse drug events are common, medication errors, prescribing systems and unintended consequences, and medication adherence is a huge issue.

3) Diagnostic error – Cognitive error and well as test result management, referral management and all of those pieces.

4) Plus things that span across all of these topic areas like patient engagement and health literacy, work force safety, particularly issues around psychological safety and burnout, which we know is a huge issue in primary care.

KI-G then responded to the same question.

1) Diagnoses – He's thinking of it in a little narrower way, and what would be thrown into that category would depend; the way KI-F described it is one way of thinking about it.

2) Medications – same issues as KI-F brought up

3) Lab follow-up – It could be considered a diagnostic issue, but there are a lot of issues around laboratory and radiology not being followed up.

4) On the overarching front, he would include communication, which KI-F mentioned. It seems to have a role in all of the main types of errors that occur and it's a big issue with transition problems. Also, one that KI-F did not mention is lack of measurement. Although we've some experience at measuring how safe care is in the inpatient setting, we haven't measure it at all in the outpatient setting and that's a place where there is a lot of room for improvement.

Project Staff 2 (PS-2) responded that these are great lists with some overlap, but some differences in conceptualization. Project Staff 6 (PS-6) commented that it sounded like KI-G wanted to say a little bit more about diagnoses and measurement. KI-G responded on the diagnosis front that the IOM report will be coming out soon that will have some recommendations, but he's not sure it will come out in a timely way so that it can be folded in to what we're doing. Both PS-2 and PS-6 are on the committee so they are aware of that. Diagnoses and ambulatory care and failure to make certain diagnoses are clearly a big problem and a big cause of harm and one that we haven't been able to quantify and I would like to see AHRQ support some more work in that area. Regarding measurement, he added that doing some primary data collection in some of the big areas, like the diagnostic area, would be very helpful. He also thinks it would be useful to do some more work in the medication area now that we've made this investment in health IT. We still don't have a lot of information about how safe they are today, and his own empiric experience suggests that there are opportunities to improve further, compared to where we were in the past.

KI-F agreed with KI-G's focus on measurement and she also feels that the issue of optimizing health IT is a really important one because of the errors created with e-prescribing. She also noted that when we started in hospitals approximately 15 years ago, we spent a lot of time talking about culture change and

while this has not been solved in hospitals, there should be some focus on this in the ambulatory setting. She is aware that AHRQ has the Ambulatory Culture Survey tool, etc., but in terms of really how to create that culture in the ambulatory setting, which is quite different from the inpatient setting, we probably need more work given that we think culture is so fundamental to everything else that we are trying to do.

PS-1 then moved on to the list that was generated by the Survey Monkey results. The project team included the patient safety practices that were included in Making Healthcare Safer II plus a few other things that they thought of, plus some others suggested by AHRQ, and then the Key Informants made that assessment about whether each item is relevant or whether there was a strong analogy to relevance for ambulatory patient safety. We tabulated those results and drew a line. There are 28 above the line and 27 below the line. We are already beginning to conduct literature searches on the 28 that are included. We recognize clearly that there's a lot of overlap with the topics and that some of the topics seem very broad and some very narrowly focused and it's not yet clear to us exactly what is going to be the best organizational strategy for reporting the results of this; whether we're going to put things in large groups or whether we'll keep things sort of granular like this.

> **Are there important PSPs or targets left off the list of includes (in "PSP Survey Results")? Things on the list you would recommend dropping?**

KI-G responded that everything that he can think of is basically there. He didn't see diagnostic error called out, and it was determined that he was looking at an old list, so once he was looking at the right list, PS-1 gave him some time to look it over while KI-F responded to the question.

KI-F thought the list looked directionally correct, but has a few things that she wanted to make sure are incorporated somewhere; for example, medication adherence. Self-management of high risk medications is on the list as #7, but she was wondering if the general topic of adherence is included somewhere and she is just missing it. Maybe it's part of Monitoring for medication safety (#10)? Also, issues like decision support optimization – you've got #4, Computerized Provider Order Entry With Clinical Decision Support Systems, which she is assuming involves e-prescribing in the outpatient setting, but wants to clarify that. She's glad that the culture one, #22, is there but she wonders whether the necessary infrastructure to support this embedded within it or should there be a bucket around infrastructure. You can have a list of 28 great practices, but there needs to be infrastructure in place to implement it, such as expertise around QI, around process redesign, around doing root cause analyses, around safety reporting, and is there a mechanism for staff to report issues, etc. If something bad happens in the practice, do they know about it and, if so, do they have the knowledge, expertise, and tools to think about it from a systems perspective and do a root cause analysis or whatever is needed to design an improvement, which she thinks a lot of practices really struggle with.

PS-2 responded to KI-F regarding the issue of medication adherence and asked whether we think about that as a safety issue vs. a quality issue or a health behavior issue? KI-F responded that the distinction between safety and quality is very grey, but she thinks about it in terms of a patient being prescribed a medication and if not taken as intended could lead to adverse drug events, not to mention clinical complications, etc. She definitely has been considering it in the safety bucket. PS-2 then referred back to KI-G's definition about an adverse event being something that occurs as a result of medical management and not the natural history of the disease, and said that this is where she struggles the most with adherence. There are challenges in adherence that lead to incorrect medication self- administration which clearly has safety concerns and then there's just non-adherence, which clearly leads to poor health outcomes. She agreed that it is grey, but it is an area that they have struggled with because there is huge literature around medication adherence and, reading it, it didn't feel like it all related to safety, so if we were able to draw a line that would be helpful. KI-G added that from his perspective it is more quality than safety, but he would also like to see some of it in, because people do get in trouble if they stop medications or take them erratically and this is what he would like to focus on. PS-1 added one thing related to this from KI-C told us when he was on a similar call with us a week or two ago. What he told us is that in the pediatric world, unintentional ingestions of their parents' medications account for something like 7 to 10 times the number of ED visits for children than adverse drug reactions to prescriptions being taken by the child for a given illness. Where does that fit into this do you think? KI-G thinks of that as a different issue. He thinks of that as pediatric ingestion. He added that KI-C knows this area very well, but our primary data collection suggested that an even bigger issue was the parent having trouble understanding the instructions about what to give the child

and getting the dosage wrong. KI-F lumps this into the same bucket of adherence because the medication is not being taken as prescribed. Going back to PS-2's issue, PS-1 said we can certainly put something along this line into the conceptual paper, but for the literature scan we don't want to go into trying to make sure that people take their beta blockers or statins, or any number of different kinds of chronic medications, the main reason being that there is gigantic literature on that and we'll end up swamping everything else. We can certainly include the general discussion of this issue and its interaction or segue into quality as one of the issues in ambulatory patient safety practices.

The other thing that KI-G did not see on the list is dispensing of medicine. He stated that there is the clinical pharmacist's role in preventing adverse drug events, but getting dispensing right is a fairly big issue. He thinks that there are a moderate number of problems and some very clear things that should be done to prevent some of them, such as getting people to actually use the stop medication order. While it is standard for him to send a stop medication order to the pharmacist, the pharmacies have not started recognizing them and they have systems in place to keep people taking their drugs. Often when people's drugs are stopped they keep taking them because the pharmacy keeps after them. PS-1 did not realize that and KI-F agreed that this is a very important issue, along with allergy information. She added that if a medication is stopped due to anaphylaxis it would be useful for the pharmacy to know that and right now they don't know it was stopped and they don't know that the patient could get a really bad allergy. KI-G added that sometimes they just dispense the wrong thing, too. The big commercial pharmacies have been a little sensitive to having any studies done of how frequent that problem is, but it is still happening a lot more than we desire. KI-G did one of the biggest studies on this but had to do it in a smaller pharmacy that would allow them to come in and study them.

PS-6 then came back to KI-F regarding the culture of safety and infrastructure issue and how it gets operationalized in the ambulatory care setting. She wondered if KI-F has seen communities of practice that are able to get together around patient safety or is it more within a doctor's practice and asked if she knows where we might look for such practices. KI-F responded that we have seen pilots of things like Lean and Six Sigma, etc. in ambulatory settings, especially in medical homes, thinking about things like medical reporting and it doesn't have to be a fancy electronic system. It can be huddles and paper-based reporting systems, training and root cause analysis. It's kind of all over the place to be honest with you. Medical homes is probably where the most has been done to create some of that infrastructure.

PS-1 then segued to the next question:

> **Do you have any information on organizational models of care that promote patient safety?**

PS-1 mentioned that skill mix would also be included in this, so we're looking for organizational models which include clinical pharmacists or include advance practice nurses or other types of providers. KI-F responded first that with ACOs you see a much stronger representation of case managers and those kinds of folks to track patients with complex diseases. Those models help with patient safety as well, especially for transitions of care, medication management, and all of those kinds of things. She also thinks that the Patient Safety Organization piece may be related here because in theory it did bring some protection to ambulatory settings and so we might see more sharing across ambulatory practices because of innovations that are in PSOs so we might think of it as a lever, at least.

KI-G responded by saying KI-F had covered it pretty well. PS-1 then asked KI-G about HIT in this area, specifically about Health Information Exchange, which is something he has helped us with in the past. Certainly, in theory, Health Information Exchange should have a large role in this. How close are we to getting there and what are the big barriers? KI-G responded that we are a ways from getting there. We only have Health Information Exchange in a small proportion of the country at this point and the places where we do have it people feel totally overwhelmed by actually trying to find things that are relevant. Whether it will actually make a lot of things better is an open question at this point, and an awful lot of the things that you have to do from an HIT perspective is closing of loops; for example, making sure that when you send an important referral that the person shows up, and when you get an important result that it gets followed up. A lot of those things do end up being open and with Health Information Exchange, for example, we

don't have an approach for underscoring which things are really critical, so there's this vast quantity of stuff that becomes available once you have it and providers just don't know what to do to go through it.

PS-2 came back to KI-F on the PSO question and asked about their current work and what they could do to make more of a dent in ambulatory patient safety. KI-F responded that her experience with this comes from the PSO that they had at the Harvard hospitals and there definitely was interest from the ambulatory settings because in the past they had felt excluded from the peer review protection and other things that existed here but now they had that overriding peer review to help protect any conversations they would have and then the convener of our PSO was definitely interested in things across the ambulatory setting and trying to get cases from the ambulatory setting and having that protection helped with that. That was one example and she doesn't necessarily think that this has spread strongly across the US, where it's been a strong way for practices to share in other settings, but she thinks there is potential there. In talking about the issues of lack of transparency and the lack of sharing across practices, etc., one of the big barriers has always been the fact that there is not this protection. It's an opportunity area in terms of using the PSO to hopefully facilitate that, but she doesn't think it has taken off yet. PS-2 confirmed that it is a potential mechanism for sharing cases and getting feedback and in that way allowing systems to investigate adverse events and use that to improve their systems. KI-F agreed and added that it could be used for identifying trends; if a system of 20 practices scattered all over the place, it could be a mechanism by which you could identify trends across that broad swath of practices where right now things are quite "siloed." AHRQ-1 added that he is intrigued by the PSO and it's an area that hasn't even come up in discussions at AHRQ around the ambulatory environment and he will need to look more into it. He thinks it may be because the challenges around measurement and reporting and the epidemiology of errors in the ambulatory environment is probably complicating the issue of looking for trends or identifying best practices.

➢ **What's the area that worries you most or keeps you up at night thinking about it?**

KI-G responded first.

- Referrals that get lost. KI-F did some of the first work on this and what we found was that when patients show up at the provider's office where they have been referred, the provider only has a sense of what's wrong with them about half the time and many of the referrals end up not getting closed. When we look at our malpractice cases many are issues in which the primary care provider did recognize there was an issue and did try to send someone to another provider, but there was an incomplete path. Systems just really haven't developed good approaches for managing that. It shouldn't be impossible, but it has been with us for more than 10 years.

KI-F was then asked to respond to the same question.

- KI-F responded that she has a long list of things that keep her up at night. She asked this question to clinicians when she was at the Brigham and their first response was test results falling through the cracks; things that they should have seen, but they didn't see.

- In addition to that and the referral issue that KI-G mentioned, she's learning more and more about the burnout in primary care and she is just very worried about how are we going to improve the safety and quality of primary care when the clinicians are barely making it through their days. That's an issue that's really going to affect any of our ability to make other kinds of improvements, and now we're seeing data that the EHRs may be worsening this rather than helping it, so it is a huge issue that we're going to need to figure out how to address.

  PS-2 agreed and asked about gaps in the literature on burnout and safety as KI-F sees them. KI-F responded that she is definitely not an expert on that piece, but she knows that there are researchers like Brian Sexton at Duke who just got an RO1 to study interventions around burnout and she wonders if there is actually literature out there in other fields and industries that we could bring into healthcare. What we really do need are real interventions and she thinks some of the new care models are interventions, but there also might be resiliency training and other things that can be done at the individual level to help with this. Rather than throwing our hands up, we need to come with tactical, practical things that we can do about it.

PS-2 responded that that makes sense and not just looking at the relationship of burnout to safety but also looking at how improving clinicians' levels of burnout changes safety in outpatient settings. KI-F recently read an article about burnout and how it impacts clinicians' abilities to do the cognitive thinking to avoid diagnostic error, for example. She added that these things are all very interrelated and Brian Sexton talks about this intervention where he asked people to think about 3 good things at the end of every day and to write them down and he had some interesting data on how this helped healthcare workers. Although it seems rather simple, it focuses on the positive rather than the negative. Especially in safety, instead of always talking about the worst case and the bad errors that are made, is there a way to put it in a more positive context to help with this? There are things that we need to study and learn from. What kind of interventions can we implement and then does it really have an impact.

PS-2 then went back to what KI-G said about referrals and even though KI-G and KI-F's paper on this subject came out about 10 years ago, this problem is not fixed. She wonders if KI-G feels there is a good model that should be followed in that way. KI-G does not know what the model is, but he thinks it is time to fix it. He added that we certainly have systems that are more electronic in place now than we did then since most referrals are done electronically now, but we still don't routinely ask providers whether this is a critical thing that they absolutely want to make sure happens, which is one solution that ought to be tested. It's just much more complicated to making this work in the usual American healthcare scene, which is a very open environment. Trying to figure out how to handle that issue is a pretty important one from the policy perspective. AHRQ-1 added that he sees a lot of room for improvement in that area, both from an IT perspective and as a provider, but when looking at ambulatory safety he wondered what the patient's role would be, if any, in this. KI-G responded that they should very definitely play a role and it should be a big role because they're driving most of the time in the ambulatory setting. At the same time, the legal system doesn't consider what the patient does and doesn't do, but he thinks that we could probably make much of the greatest improvement by getting patients more involved and coming up with approaches that make it easy for the patients to do the right sort of sets of things. KI-F agreed and added that there are so many reasons why a patient may not follow through on a referral; for example, they didn't understand what the referral was for or why it was important or didn't agree with it, etc. or they called and couldn't get through to schedule the appointment, or they couldn't get a ride. There are a lot of reasons that they might not have gone so it needs to be a partnership of patient engagement, and also having some of those tools so that patients can follow through on those referrals. The providers need to make sure that they understand why they need to go, especially since they are sometimes walking out the door with 10 things to do. From a health literacy standpoint, we need to do a better job of having that information in an appropriate format in a way that helps them to manage their care.

PS-1 then moved on to the last question.

> **If you were in charge of the government agency responsible for funding research on patient safety, what is the most important, or the most 3 important, topics for which you would want to see proposals?**
> KI-F responded first:

1. Developing better measures of ambulatory safety since we can't improve what we can't measure. That would span a lot of these areas.

2. Diagnostic error and all of the facets within that.

3. Optimization of technology in the ambulatory setting and EHRs, since they're here and they're being used and we need to make sure that they are achieving the safety benefit.

KI-G then responded to the same question:

1. Leveraging EHRs just because we now have everyone using EHRs but they're not really getting the safety benefits and they're really very frustrated by that.

2. Diagnoses in the ambulatory setting, and he would do a primary care data collection that looks across multiple diagnoses in the ambulatory setting and look for diagnostic errors.

3. Medications, even though this may overlap somewhat with leveraging EHRs (#1). The biggest safety issue is medications so it is low-hanging fruit, but he has the sense that we're falling far short across the board.

4. Building better measurement tools

PS-1 finished up by stating what the next steps would be. This is the last of these calls and we will take all of this information and synthesize it into some kind of narrative with the information gathered from the other key informant calls. Then we will add that to the information collected from the literature scan process and produce a draft report. At that point we will send it out to you and all of the key informants and other peer reviewers for you to give it a good hard critical look at it. Then we will incorporate those comments into a revised report, and we'll send that in to AHRQ whenever that's done. Between now and then we may email for clarification on things as we go through the notes.

PS-1 thanked everyone and said we will be in touch as we go on down the line. Meeting was adjourned.

Appendix C. Table of Themes in Key Informant Discussions

Table C1. Safety Practices

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Communication	CROSS-CUTTING VULNERABILITY Administrative and Communication Errors*			PCMH has better communication built in which may promote safety			
HIT	Underpinning infrastructure that is increasingly in so much of what we do, but it is not a panacea or "magic bullet." - alert fatigue - work-arounds	We are replicating old ways of doing things in an electronic format rather than transforming the way we do things				- Poor EHR usability exacerbating burnout - GAP: EHR optimization to improve safety	HIEs not implemented meaningfully yet. Still with unprocessed data that is not usable to clinicians in real-time, not helping loops be closed.
Teams	Skill mix promotes safety	- Can extrapolate from inpatient that nurse staffing might help - NPs may be under-utilized		PCMH has teams and this may promote safety			
Patient Engagement		Need to make much bigger strides in terms of: patient engagement, shared decision making, thinking about how behavior changed theory needs to underpin the patient, clinician and organization	Patient more important in outpatient setting		Lack of patient education, such as medication treatment adherence, for instance if a patient is on warfarin or another medication that needs monitoring	Includes health literacy	
Organizational Approaches	- Care coordination - Regular monitoring, appraisals and benchmarking across primary care sites	- Burnout pervasive and unsafe*		- PCMH - Needed study: examine whether/ how PCMH improves safety	Care contained within a single system (information flow) important for safety	- Need to study burnout and safety - Current lack of infrastructure/ skills: there needs to be infrastructure in place to implement it, such as expertise	

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
						around QI, around process redesign, around doing root cause analyses, around safety reporting, and is there a mechanism for staff to report issues, etc. If something bad happens in the practice, do they know about it and, if so, do they have the knowledge, expertise, and tools to think about it from a systems perspective and do a root cause analysis or whatever is needed to design an improvement. PCMH often includes this. -PSOs have potential esp b/c peer review protection and potential for feedback, though not fully realized.	
Measurement	Needs adequate baselining and triangulation- single measurement approach will always under-estimate, need to include patient and caregiver reports.	Measurement is not the same as improvement. Source of frustration if there's no mechanism to improve.					Current lack of validated measures is a barrier to improvement*

Table C2. Prescribing and Medication Errors - "low-hanging fruit"

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy	Problems can be the actual prescription being issued at the time, drug interaction or morbidity, and contraindications. monitoring of certain classes of drugs, such as lithium, ACE inhibitors, and electrolytes. - quality not safety, such as drugs not being taken as intended or adherence*		- Opioids, anticoagulation, insulin (Natl Action Plan)- funding specifically for these. - Antibiotic stewardship (safety or quality) - Unsupervised child ingestions - Most harm occurs in monitoring. Formative work needed re: opioids: how does it relate to medication safety more broadly? What interventions beyond addressing obvious errors and abuse prevention would work? Kaveh's comparison to abx stewardship flawed per Dan b/c easier to establish need for abx than need for pain meds.			Allergy documentation	Should include medication dispensing, including dispensing of meds MD has stopped
Communication			Changes made to the prescription writing so that it is consistent, from the electronic order entry screen to the pharmacy to the bottle.				
HIT	Intervention: decision support		Changes made to the prescription writing so that it is consistent, from the electronic order entry screen to the				

C-3

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
			pharmacy to the bottle.				
Teams	Intervention: Pharmacist on team (PINCER trial, now in practice in UK-PharmDs identify and rectify errors)						
Organizational approaches	Intervention: Prescribing checklist		Current systems don't support ongoing monitoring well		Need to educate patients about self-management of meds		

Table C3. Diagnostic Errors

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy	Includes wrong diagnoses, missed diagnoses, not appropriately stratifying patients within a diagnosis and then the whole chain of problems that can ensue subsequently - Rare/serious undifferentiated conditions with limited window for action (meningitis, stroke)				Martine: need to prioritize dx	Cognitive error and well as test result management, referral management and all of those pieces.	Need primary data collection around diagnosis*
Communication	Three-way consultation amongst specialists						
HIT	Intervention: decision support						
Organizational approaches	Intervention: ready access to real time investigative procedures in house in ambulatory care, such as ultrasound, CT, or MRI or second opinions (being institutionalized at KP)				Martine added about diagnostic errors that it is not being tracked or reported and physicians and patients aren't really informed about what it is, where it occurs most often and they		

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
					aren't given tools to help prevent it or to help assist a more accurate diagnosis, and if there is not an accurate diagnosis, how is there going to be an accurate treatment plan?		

Table C4. Transitions/boundaries

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy .	In/ out hospital, primary care and other ambulatory care and another big one is the social care dimension, long term care or post-acute care sector -Multi-morbidity (when recommendations and treatments for one condition adversely affect another)						
Communication	Need for synchronous communication when patient transitions						
HIT							Interoperability needed
Teams				Needed intervention: Make sure information moves with patient during transitions			
Patient-engagement	"Wider issues as to the kinds of messages the patients are taking away, particularly in chronic disorders where this is absolutely fundamental because ideally we want the generalist, the specialist and the patient						

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
	to all be on the same page and not to be speaking as cross purposes." - Self-care agenda, considering patients are caring for themselves 98-99% of their lives						

Table C5. Referrals

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy		How are we insuring that they're getting to the right people for the right things and getting that follow-up and continuity? We have a lot of perverse incentives					
Organizational approaches		Perverse financial incentives can interfere with referrals					-Unclear referral reasons. Provider only has a sense of what's wrong with them about half the time and many of the referrals end up not getting closed. When we look at our malpractice cases many are issues in which the primary care provider did recognize there was an issue and did try to send someone to another provider, but there was an incomplete path. Systems just really haven't developed good approaches for managing that

Table C6. Culture

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy		Fear/ Inability to speak up: when someone knows that something isn't quite right and they can't figure out how to get that addressed, whether it is a patient who doesn't want to ask questions or doesn't feel comfortable doing it or a provider, medical assistant, new doctor, or nurse that understands that something isn't quite right in a situation, but can't figure out how to get that resolved					
Organizational approaches				Complacency: we need to move from "I just have a really crappy system for that" or "nobody worries about that" to the fact that "yes, I have a really bad EHR and it is causing safety problems for my practice and my patients." What keeps her up is how we move people further along that line.			

Table C7. Testing process*

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Strategy				Ordering the wrong tests, poor interpretation of tests, not notifying patients of test results, and most importantly not following up of important, urgent, abnormal or normal that shouldn't be normal test results with patients.			
Organizational approaches				Lack of system for the testing process in current systems			

Table C8. General Comments

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
Formative scientific work	DIAGNOSTIC ERRORS Dx errors need formative science		DIAGNOSTIC ERRORS and PRIORITIZATION Problems which are frequent, serious, measureable and feasibly prevented				
Intervention development	Need to focus on intervention development process-MRC's complex intervention framework for developing interventions – appropriate systematic review evidence, theory, feasibility testing, piloting, randomized controlled trials – and then scaling up. We recognize the kind of errors that most						

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
	frequently translate into harm – a subset of drugs that are particularly important, a subset of diagnostic errors that are particularly important – and so in those areas really catalyzing the development of interventions.						
	KI-A believes in collaborative models and the way he would do it is to develop a network with a view to intervention development. Appropriate conceptualization and looking at the theoretical dimensions is important and then another big charge with a complex intervention is the generalizability piece. Two processes						
	1. Pre-specifying and honing in on specific, high-yield issues and moving from intervention development to RCTs 2. If targeting a broad PSP like improving cognition, use other kinds of evaluations quite a lot of the time, and so it may it may be more program-matic where you might move into a QI kind of						

	KI-A	KI-B	KI-C	KI-D	KI-E	KI-F	KI-G
	approach for quality improvement.						
Interdisciplinary		Need the broad, interdisciplinary theoretical work to drive improvement: bringing together and sparking creativity across disciplines, including design; cognitive support – how do we better address some of those other components that would ultimately be part of the safest possible care.					

*indicates agreement/mention by another person

Appendix D. List of Included Studies by Topic

E-Prescribing

1. Abramson EL, Barron Y, Quaresimo J, et al. Electronic prescribing within an electronic health record reduces ambulatory prescribing errors. Jt Comm J Qual Patient Saf. 2011 Oct;37(10):470-8. PMID: 22013821.

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