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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.

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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 other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential non-financial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential non-financial conflicts of interest identified.

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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.

Contents

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

Formative Work
- Prioritization
- Intervention Development Process
- Interdisciplinary Research
- Measurement

	General comments → ↓	Communication	Health IT	Teams	Patient-engagement	Organizational Approaches	Measurement
Safety Issues		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

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

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┌─────────────────────────┐
│  Total titles screened  │
│      N=21,988           │
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            │────────────────────►┌─────────────────────────┐
            │                     │  Total titles rejected  │
            │                     │       N=18,949          │
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│ Total abstracts screened│
│       N=3,039           │
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            │────────────────────►┌──────────────────────────────────────────────────────────────────┐
            │                     │               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                                                │
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│ Total articles screened │
│        N=361            │
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            │                     │                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                                                │
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│      Total included studies         │
│            N=147                    │
│ (see Table 2 for list of includes   │
│           by topics)                │
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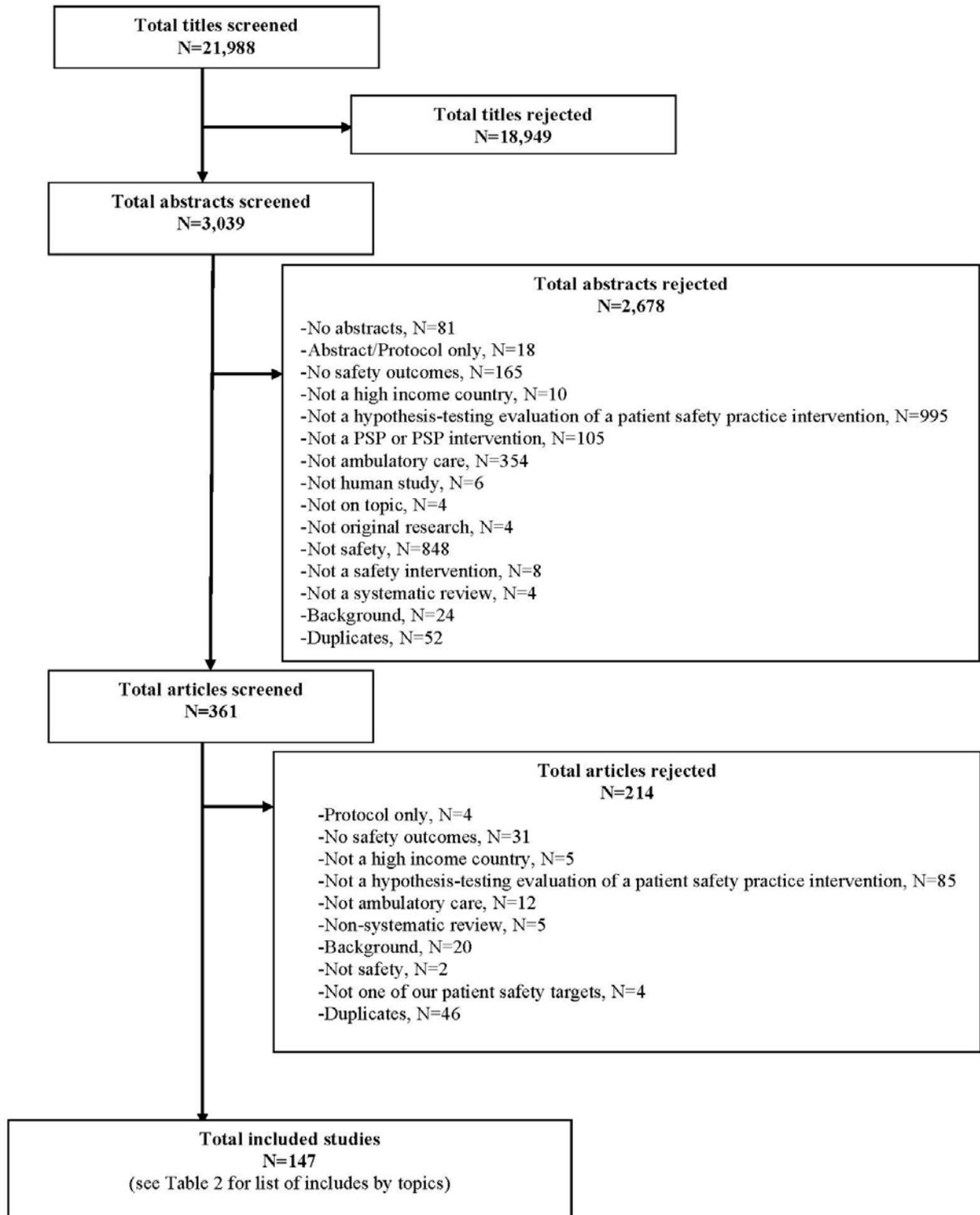
Figure notes: PSP(s)=Patient Safety Practice(s)

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