

Environmental Scan Report

Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families

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Prepared by:

MedStar Health Research Institute
Kelly Smith, Ph.D.
Kelley Baker, M.A.
Deliya Wesley, Ph.D.
Lorri Zipperer, M.A.
Maureen D. Clark, M.H.S., M.L.I.S., LCPC, CADC
Rosie Hanneke, M.L.S.
Michael A. Stoto, Ph.D.
Christine A. Goeschel, Sc.D.

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Introduction

Background

Patient and family engagement (PFE) is an evolving concept in health care transformation in the United States and worldwide. Within the past 5 years, a number of frameworks have been developed that call for PFE as a way to achieve patient-centered care. This goal is based in medical ethics and human rights¹⁻⁴ and one of six aims set forth by the Institute of Medicine as fundamental to health care reform in the 21st century.⁵

A growing body of evidence suggests that PFE can improve the safety and quality of care delivery.^{4,6-9} Although the field of PFE in patient safety for hospitals and health systems is maturing, the use of PFE to improve patient safety in nonacute settings is in its infancy,^{10,11} but with a growing literature base.

Building sustainable processes and practice-based infrastructure is crucial to improving patient safety by PFE in primary care. The *Guide to Improving Safety in Primary Care Settings by Engaging Patients and Families* (hereafter referred to as the Guide), sponsored by the Agency for Healthcare Research and Quality (AHRQ), is being developed to provide primary care practices with interventions they can use to engage patients and families in ways that lead to improved patient safety. This comprehensive guide will include explicit instructions to help primary care practices, providers, and patients and families adopt new behaviors to increase patient and family engagement to improve patient safety.

We are using the Translating Evidence into Practice (TRiP) model^{12,13} as the conceptual framework for comprehensive guide development, implementation, and evaluation. We selected the TRiP model because it emphasizes intervention adoption and sustainability. The model is conceptually simple, is easy to relate to diverse audiences, and can be used to guide diffusion by establishing flexible work processes that can be customized to meet local practice demands and culture.¹⁴

The TRiP framework¹³ is composed of four discrete stages bundled together to:

1. Review the latest evidence;
2. Identify potentially effective and feasible interventions, test and refine practices with multidisciplinary team input, and implement interventions;
3. Measure performance; and
4. Spread and embed interventions into routine practice to meet the needs of all patients.

We performed an environmental scan to accomplish Stage 1 of the TRiP framework (Summarize the Evidence); this report documents the environmental scan.

Purpose

An environmental scan is an integral process for identifying, retrieving, and organizing information to enable health decisionmaking and has been used to foster knowledge translation in primary care.^{15,16} The purpose of the environmental scan was to identify:

- Descriptive, qualitative, and quantitative studies on methods to engage patients and families in their care in primary care settings and the impact of these methods on patient safety; roles that health care providers play in engagement; facilitators and barriers to engagement; and other contextual factors that affect engagement.
- Existing interventions and associated tools and materials for engaging patients and families in the primary care setting to improve safety.
- Gaps between existing tools and materials and those that need to be developed to ensure that the Guide is comprehensive in addressing the various ways patients and families can be engaged in a primary care setting.
- Examples of at least eight primary care practices that have succeeded in engaging patients and families in their care, which has led to improvements in patient safety.

The environmental scan included conducting a targeted review of the peer-reviewed literature, conducting a targeted review of the grey literature, and receiving input from domain experts in patient safety, primary care, and patient and family engagement.

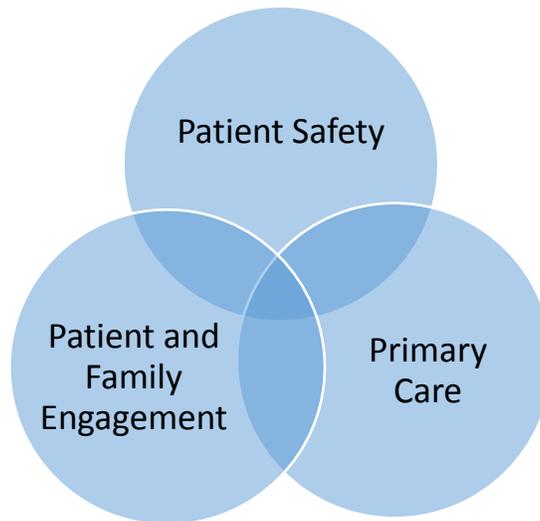
Conceptual Framework for Environmental Scan

While the goal of the environmental scan was to identify interventions that intersect all three domains (patient safety, primary care, and PFE), there was concern that interventions meeting this criterion would be rare. Therefore, the environmental scan aimed to identify and review interventions that covered at least two of the three domains and could meet the third with additional development.

PFE interventions that improved patient safety in acute care settings and could be applied to primary care were included. We also considered PFE interventions in primary care that were not evaluated for patient safety impact, but based on expert opinion could be modified or used to improve patient safety in primary care. Interventions in primary care that improved patient safety but did not explicitly include PFE were included if they could be expanded to incorporate PFE strategies with additional development.

Based on the purpose of the environmental scan, a simple conceptual framework emerged to describe the relationship between these three domains (Figure 1).

Figure 1. Conceptualization of Evidence for Environmental Scan



For the purposes of this environmental scan, the following definitions were used:

- **Patient Safety:** “*the freedom from accidental or preventable injuries produced by medical care.*” Practices to improve patient safety thus include those that reduce the occurrence of preventable adverse events.¹⁷
- **Patient Engagement:** “a set of behaviors by patients, family members, and health professionals and a set of organizational policies and procedures that foster both the inclusion of patients and family members as active members of the health care team and collaborative partnerships with providers and provider organizations.”^{1,18}
- **Primary Care:** “the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.”^{19,20}

Methods

The York framework²¹ for conducting scoping reviews was used to direct the environmental scan.^{22–25} Scoping reviews contextualize knowledge of the field by systematically mapping the literature on a topic; identifying key concepts, theories, and sources of evidence; and identifying gaps in current research. A scoping review analyzes a wide range of research and nonresearch material to provide greater conceptual clarity about the field.

The York framework for scoping reviews is composed of six phases to guide evidence synthesis. These include²¹:

1. Identifying the research question and setting a purpose for the study.
2. Identifying relevant research and nonresearch materials.
3. Selecting studies.
4. Abstracting data.

5. Collating, summarizing, and reporting the results.
6. Consulting with consumers and stakeholders to suggest additional references and provide insights beyond those in the literature.

Using this approach, our project team produced the following deliverables:

- Synthesis of research in the field,
- Inventory and description of current interventions being used to increase patient and family engagement in primary care settings to improve patient safety,
- Qualitative evaluation of effectiveness and usability of interventions identified, and
- Identification of gaps in the field and areas ready for intervention development.

Phase 1. Identifying Research Question and Purpose

The primary research question that the environmental scan addresses is:

What are effective and potentially generalizable approaches for engaging patients and families to improve patient safety in primary care settings?

Phase 2. Identifying Relevant Research and Nonresearch Materials

To have a comprehensive search, the York framework recommends searching several literature sources, including electronic databases, reference lists of relevant literature, key journals (hand search), and existing networks, relevant organizations, and conferences.²¹⁻²³ Informal interviews and surveys of subject matter experts help to inform the search strategies and identify Web sites for grey literature searching. Figure2 provides a high-level overview of our approach to identifying relevant research and nonresearch materials during phase 2.

Figure2. Process of Identifying Research and Nonresearch Materials



- Project Team
- Domain Experts
- Published Literature
- Grey Literature

Step 1. Informal Interviews and Surveys

We conducted informal interviews and surveys first with our project team and then with identified domain experts, including patients and family members. The interviews were designed to help us refine our definitions, search terms, and strategy, and identify interventions and resources pertinent to Guide development.

The informal interview questions are provided in Appendix A and include the following topics:

- Conceptualization of patient safety and patient engagement in primary care
- Identification of search terms and input on approach

- Advice on organizations, Web sites, and potential interventions
- Key constructs to assess usability, sustainability, and generalizability of interventions
- Recommended research (peer-reviewed and grey literature) to be reviewed
- Recommendations for other individuals to be included in interviews

The subjects of the informal interviews included:

- Project team members.
- MedStar Health's (MSH) network of patient and family advisory committees on quality and safety (PFACQS). This network includes nationally recognized patient and family advocates, community representatives from each of the 10 MSH hospitals and 3 PFACQS serving MSH's more than 238 practices.
- Domain experts, who are individuals with high-level expertise in areas pertinent to the project, such as patient engagement, patient activation, patient safety, health literacy, and primary care practice.

Due to the nature of the informal outreach as part of the environmental scan, a fast-track Office of Management and Budget (OMB) clearance and institutional review board approval were obtained before we conducted interviews and surveys.

Step 2. Electronic Literature Database Search

The project team devised a broad list of terms pertinent to patient safety, patient and family engagement, and primary care (Appendix B). These terms were combined to create keywords to search both peer-reviewed and grey literature electronic databases. We also reviewed Tanon and colleagues' (2010) paper on the appropriate search terms for identifying papers on patient safety in MEDLINE[®], Embase, and CINAHL.²⁶ In addition, we consulted with librarians to search Patient Safety Net (PSNet, psnet.ahrq.gov) to identify appropriate medical subject heading (MeSH) terms.

Appendix C outlines a sample search strategy for the peer-reviewed literature search. This strategy was modified and expanded to include search terms relevant to identifying "tools" or "interventions" conducted in "primary care" settings. Keywords were mapped to database thesauri search terms, where available, and also as text word terms in the databases as per protocol.²¹ Our goal was to conduct a sensitive search of the literature focused on identifying interventions at the intersection of patient safety, patient and family engagement, and primary care.

All literature database searches were limited to the English language and non-English articles with English abstracts, published between 2011 and November 2015. This date range was selected to build on the comprehensive outcomes reported in the environmental scan produced by AHRQ's *Guide to Patient and Family Engagement in Hospital Quality and Safety*.²⁷

To be comprehensive, we also reviewed reference lists of relevant articles, Web sites, and grey literature, along with specific journal issues to identify related published and nonpublished resources. These were validated through further consultation from domain experts and the project Technical Expert Panel (TEP).

We enlisted two clinical library scientists specializing in patient safety to support the electronic searching of the peer-reviewed literature. We gave the librarians five core readings from the field to validate the sensitivity of the search strategy. Once validated, the search strategies and approaches were modified to meet the variability of search string formats for the different peer-reviewed electronic databases. We ran the searches and removed duplicate articles to establish a core list of candidate articles to move forward for initial review and subsequent abstraction.

Table 1 summarizes the electronic databases used to search the peer-reviewed and grey literature.

Table 1. Electronic Databases

Type of Literature	Databases
Peer-Reviewed Literature	<ul style="list-style-type: none"> • Cumulative Index of Nursing and Allied Health Literature (CINAHL) • Cochrane Library • Web of Science • Embase • MEDLINE/PubMed®
Grey Literature	<ul style="list-style-type: none"> • New York Academy of Medicine's Grey Literature Report (http://www.greylit.org) • ProQuest Dissertations and Theses (http://www.proquest.com/products-services/dissertations/Find-a-Dissertation.html) • AHRQ Health Innovations Exchange (https://innovations.ahrq.gov/) • University of York Health – Centre for Reviews and Dissemination (http://www.crd.york.ac.uk/CRDWeb/) • McMaster University's Health Evidence site (http://www.healthevidence.org)

At least two trained searchers with differing backgrounds and expertise in the field of patient safety reviewed the de-duplicated list of candidate articles and nonresearch evidence for relevance. After initial review, the search strategy was further refined to focus on identification of “interventions” that have demonstrated effectiveness at improving patient safety and/or patient and family engagement. This provided a more focused listing for further review by abstraction teams. A final listing of peer-reviewed and nonresearch-related articles and reports was generated for review of inclusion and exclusion and abstraction.

Step 3. Web Site Search

After we selected relevant material from the electronic literature database search, we conducted a targeted review of select Web sites and social media sites to increase the capture of emerging approaches to improving patient safety in primary care. Through consultation with our stakeholders and members of the project team, we compiled a list of relevant organizations and Web sites to search (Appendix D).

We searched the Web sites in a systematic manner, allowing some variation in search strategies in response to varied Web site structures. Our approach included consulting the Web site’s site map to identify research, publication, or tool links to facilitate searching. Once we completed this hand search, we used the Web site’s search engine to uncover additional materials. For all Web sites, we searched the terms “patient and family engagement,” “patient safety,” “primary care,” “patient engagement,” and “medical error.” We kept a log of the Web site searches, saving

the links to relevant pages and tracking our progress through the Web sites, along with copies of all materials and resources obtained during these searches.

We also surveyed non-peer-reviewed resources in a process that paralleled the approach to the peer-reviewed literature in order to stretch beyond the established evidence base. The goal here was to identify individual clinics and other independent exemplars that may have promising locally developed tools and innovations to increase patient and family engagement in patient safety. We hypothesized that not all interventions that have been demonstrated to be successful at improving patient and family engagement would be represented in the peer-reviewed literature but may be disseminated by exploiting social media outlets.

Several conduits for this information include:

- Social media, such as Twitter activity associated with distinct hash tags (e.g., #PFAC2015, #patientvoice, #patientengagement) or organizational/ individual handles (e.g., @theNPSF or @CRICOstrategies);
- Meeting abstracts;
- Twitter feeds;
- Blog archives (e.g., KevinMD, Paul Levy “not running a hospital,” The HealthCare Blog, ePatient Dave, and Wachter’s World);
- Presentations from major patient safety and primary care conferences (e.g., National Patient Safety Foundation and American Academy of Pediatrics annual meetings);
- Newspaper databases;
- TED Talk archives; and
- Google news feeds.

Building on the use of published and widely available materials from the organizations listed above, the cognitive interviews and informal surveys of subject matter experts yielded the identification of membership organizations, existing tools, and specific primary care practices to include in the Guide.

Phase 3. Selecting Studies

The broad search terms resulted in a high yield of abstracts, interventions, and reports returned for preliminary review. To remove irrelevant material, we developed a screening protocol with specific inclusion and exclusion criteria based on the focus areas identified within our research question.

Table 2 outlines our inclusion and exclusion criteria.

Table 2. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • Documentation related to at least two of the three conceptual domains • Articles that describe elements of the organization, intervention, infrastructure, or processes related to the intersection of patient safety, primary care, or patient and family engagement • Studies using mixed methods or quantitative or qualitative methods, including meta-analyses and systematic reviews • Well described case studies of interventions 	<ul style="list-style-type: none"> • Non-English language articles (except when abstracts are in English) • Articles or reports without descriptions of interventions to improve patient safety or patient and family engagement • Studies that focus on patient and family engagement without addressing patient safety • Descriptive papers that outline theoretical constructs of patient safety and/or patient and family engagement

Operationally, we used the following guidance to decide which reports to include:

- Although the focus of this environmental scan was on resources related to interventions, other empirical studies that addressed critical issues in the intersection of patient safety, primary care, and patient and family engagement were also included. These included, for example, surveys of patients and providers about the issues and consensus processes to develop practice guidelines.
- Reports that explicitly addressed only two of the three conceptual domains (patient safety, PFE, primary care) were included *only if* they could plausibly be interpreted to include the third.
- Reports that focused on health promotion (e.g., smoking cessation, diet) and disease prevention (e.g., encouraging vaccination or cancer screening) were *not* regarded as addressing patient safety and were not included.
- Reports that focused on general safety issues (e.g., bicycle helmets, personal security) unrelated to medical treatment were *not* regarded as addressing patient safety and were not included.
- Reports that focused on falls in the home were *not* regarded as addressing patient safety *unless* the falls were explicitly related to medication errors or similar problems.
- Reports about outpatient care of patients with specific advanced diseases were *not* regarded as dealing with primary care *unless* the report explicitly mentioned that the intervention was used in a primary care setting.
- Reports about the management of patients with multiple chronic diseases in primary care settings were included *only if* reducing patient safety problems (e.g., medication management) was explicitly mentioned as a goal or outcome of the intervention.
- Reports about interactions (e.g., handoffs, medicine reconciliation systems) among caregivers (e.g., physicians and nurses, hospital and primary care staff, pharmacists, and primary care staff) without explicit mention of patients were generally *not* regarded as including patient and family engagement.
- Reports without explicit mention of patient and family engagement were included *only if* there was a potential for patient engagement (e.g., home visits or medication management).

Members of the project team piloted the inclusion/exclusion criteria with a subsample of abstracts retrieved from the MEDLINE database. Two groups of three reviewers were assigned 10 articles each to test the inclusion and exclusion criteria. The two groups met and developed a consensus approach to article/intervention inclusion (Table 2).

Once we developed the final set of inclusion/exclusion criteria, we trained a team of abstractors and worked with the abstractors until the interrater reliability was $\kappa \geq 0.6$. Abstractors then applied the accepted inclusion/exclusion criteria. In addition to peer-reviewed articles, we applied the inclusion/exclusion criteria to reports, theses, and policy analyses.

We used a similar screening process for literature and resources uncovered through Web site searching, reference lists, and key informant recommendations. We also included materials from Web sites representing less formal, interpretive descriptions of studies, programs, investigations, or interventions that were on Web pages and may or may not have been linked to report documents. A final list of resources, peer-reviewed and non-peer-reviewed sources, and resources meeting the inclusion criteria proceeded to Phase 4 for data abstraction.

Phase 4. Abstracting Data

According to the York methodology, the data abstraction process is multistaged, involving abstraction of information from individual articles or resources. Our abstraction process evolved throughout the project. The key criteria for preliminary abstraction included:

- Resource title.
- Brief description of resource, approach, intervention.
- Triad elements addressed (patient safety, patient and family engagement, primary care).
- Patient safety problem(s) addressed.
- Intervention identified (Yes/No).
- Include for further review (Yes/No).
- Publicly available resource.

We trained a team of six to conduct preliminary abstraction and categorization. At least two abstractors reviewed each resource. A senior researcher adjudicated differences between the reviewers relative to inclusion. We anticipated that there would be few if any randomized controlled trials (RCTs) addressing the effectiveness of interventions at the intersections of patient safety, patient and family engagement, and primary care. Thus, we adopted a “best evidence” approach, focusing on studies that met applicable methodological standards for qualitative studies, implementation science, case studies, and expert consensus panel reports.^{14,28–33}

Phase 5. Collating, Summarizing, and Reporting the Results

The purpose of this stage was to provide a structure to the literature and resources uncovered by the search. Due to the broad scope of our research question and the large volume of literature and resources uncovered in our searches, we constrained this final stage to a narrative synthesis. We organized the findings into specific categories, including patient safety, patient and family engagement, primary care, and the intersections therein.

The content team conducted thematic analysis of the evidence and assigned themes to the peer-reviewed literature, grey literature, and key informant survey results. Themes were organized around the following domains:

- Quality of evidence
- Conceptual domains (patient safety, patient and family engagement, primary care)
- Safety issues addressed
- Safety solutions

These domains were informed by a combination of our project team’s experience in the field and informal interviews and surveys with stakeholders, including:

- Patients and families;
- Primary care practice staff and providers; and
- Researchers in patient safety, communication, pharmacy, patient engagement, shared decisionmaking, quality and outcomes research, implementation science, and health care delivery systems science.

The abstractors independently coded each article for the quality of evidence, conceptual domain addressed, safety issue addressed, and safety solutions, using the categories outlined in Table 3. Our senior researchers reviewed and reconciled the categorizations. A report was assigned only one category for quality of evidence. It was then assigned at least two conceptual domains and could have multiple safety issues and safety solutions. We revised the categories to include safety issues and safety solutions that emerged as we reviewed the literature. The safety issues and solutions are defined and illustrated with examples in Appendix E.

Table 3. Reporting Categories and Codes

Category	Codes
Quality of Evidence	<ul style="list-style-type: none"> • Evaluated intervention • Well-described intervention (e.g., protocol, case study, toolkit) • Systematic review • Other
Conceptual Domains	<ul style="list-style-type: none"> • Patient safety • Primary care setting • Patient and family engagement
Safety Issues	<ul style="list-style-type: none"> • Fragmentation of the health care system and transitions between providers • Communication between patients and providers • Diagnostic errors • Medication prescription, management, drug interactions, adherence • Antibiotic, opioid, and other medication overuse • Other • Not addressed

Category	Codes
Safety Solutions	<ul style="list-style-type: none"> • Care team models, including pharmacists • Approaches to improve medication safety • Patient and family advisory councils • Educational interventions • Shared decisionmaking models • Family engagement in patient care • Chronic disease management • Other • Not addressed

Abstractors independently coded each resource for categories along the four domains. Once resources were categorized, a team of patient safety domain experts reviewed and identified interventions for further consideration for inclusion in Guide development.

Phase 6. Consulting With Consumers and Stakeholders

Stakeholder consultation was ongoing throughout the environmental scan process, informing each phase of the scan activities through informal and formal interactions with stakeholders.²¹ Stakeholders identified for the project included:

- Patients, family members, and lay caregivers.
- Primary care providers.
- Primary care practice staff.
- Practice administrators.
- Researchers.
- Pharmacists and other affiliated health care providers.
- Safety and quality improvement professionals.

Early involvement of stakeholders allowed us to seek guidance regarding the research question, search terms and strategy, and organizations and Web sites for review. We could also ensure that the results represented the interests of key stakeholder groups—patients, families, caregivers, primary care providers, and primary care practice staff—who were the intended audience for the deliverables to be developed and disseminated as part of the Guide activities.

We sought stakeholder input to inform both the environmental scan and to identify exemplar practices and interventions for consideration as case studies. To identify interventions that improve patient safety through patient and family engagement or within the primary care practice environment, we selected individuals with the knowledge, expertise, and experience in these areas to participate in our environmental scan activities. Our interviews with these key informants focused on identifying interventions from the peer-reviewed literature and non-peer-reviewed sources. The semistructured interview guides for patients, providers, and practice staff are available in Appendix A.

Individuals were invited to participate via email, in person, or telephone consultation with the project team members. Domains of interest for key informant input were:

- Feedback on research question and study purpose.
- Threats to patient safety in primary care.
- Identification of interventions to engage patients and families in primary care settings.
- Existing interventions, tools, and resources for patient engagement to improve patient safety in primary care.
- Barriers and facilitators of adoption of these interventions.
- Organizations or Web sites that should be reviewed.
- Approaches to dissemination of the Guide materials.

Data collection was conducted and reported in the REDCap™ database and summarized and synthesized using standardized approaches for content analysis and thematic review.^{34,35} Common themes emerging were validated by the key informants and additional subject matter experts as well as by members of the project’s Technical Expert Panel (TEP). TEP members also served as key informants in the identification process.

Results

Key Informant Interviews

We consulted 12 project team members early in the environmental scan to inform the initial search strategies, domains of interest, and conceptualization of the project goals and research question. From this input, we developed questions for key informants and stakeholders (Appendix A). Upon receiving OMB approval in December 2015, we conducted a survey of patients and patient advocates, primary care providers, and practice staff and selected researchers in patient safety and behavior change on the domains of interest. We also solicited input from TEP members.

A total of 23 individuals responded to our request for technical input. Table 4 lists stakeholder groups represented. We asked individuals to indicate all groups they were representing with their responses.

Table 4. Stakeholder Groups Providing Technical Input

Stakeholder Group	Number (N=23)
Patients	13
Family members	14
Caregivers	7
Nurses	3
Physicians	10
Pharmacist	1
Other providers*	2
Primary care practice staff	4
Researchers	4
Health care administrators	3
Patient safety or quality improvement officers	4
Policymaker	1

*Quality Improvement Network; patient safety advocate.

We recorded and categorized responses. We specifically sought common themes around conceptualization of patient safety and patient engagement in primary care to build on the evidence from AHRQ's *Guide to Patient and Family Engagement in Hospital Quality and Safety*⁸ and further inform the conceptual model for patient safety and patient and family engagement in primary care. The key themes that emerged along each of these conceptual domains are summarized below.

Conceptualization of Patient Engagement in Primary Care

One overarching common theme emerged around the concept of patient engagement in primary care—*partnership*.

From the perspective of our key informants, patients and providers reported similar characteristics of what patient engagement in primary care means and what it should look like. One provider defined patient engagements as *“a practice or behavior that allows and encourages the patient and their families to contribute in their medical care decision-making in an informed way that may exceed or even fall short of interventions and education that is offered by the caregiver.”* This provider specified that engagement occurs when the patient and provider discuss the different options and then come to an agreement on what is achievable given the individual patient's needs, values, and preferences, as well as the patient's confidence in his or her ability to achieve the plan and the goals.

Another primary care provider indicated that patient engagement means that patients are *“on top of their medications, treatments, and that they are actively keeping records of their care along with me as their primary care doctor.”* One provider stated this explicitly in that *“we have to move away from the no news is good new mentality to one of no news equals no news. When a patient calls saying that they haven't heard about a test, my call back starts with a **thank you for being a partner in your care.**”* An important patient-identified barrier to engagement, simply stated, is that *“engagement is useless without communication and being able to communicate concerns about their care and care experience to the doctor.”*

Conceptualization of Patient Safety in Primary Care

When asked about the concept of patient safety in primary care, our informants' responses focused on the primary care practice as the environment or setting for patient safety to be strengthened. Few identified the health care system (e.g., issues associated with fragmentation of care or continuity of care between acute and primary care settings) and community (e.g., issues associated with community pharmacy or other community-level health care professionals) as determinants of safety. Many identified the need to better understand patient-related factors (e.g., cost of medications) that affect a patient's ability to adhere to recommended treatments and therapies.

Most informants viewed factors related to the complex relationships among the key stakeholders within the practice setting—physician, patient, and practice staff—as the key to patient safety in primary care. Here, communication breakdowns, slips, and lapses were the most commonly reported determinants of patient safety in primary care. This referred not only to communication between the patient and the physician during the clinical encounter, but also to communication between primary and specialty care providers. It also included accurate specimen labeling,

medication reconciliation with the patient, and staff requests for two patient identifiers (e.g., check name and date of birth when confirming test results or sending medication orders to the pharmacy). Other related safety behaviors identified by key informants included openness, trust, transparency, and relationship-based care.

Threats to Patient Safety in Primary Care Settings

Four common themes emerged from our key informants as threats to patient safety in primary care settings: breakdowns in communication, medication-related errors, factors influencing incorrect or incomplete diagnosis, and factors related to fragmentation of the health care system. Table 5 provides a summary of each domain and the informant-identified safety issues within that domain.

Table 5. Key Informant-Identified Threats to Patient Safety in Primary Care

Theme	Threats to Patient Safety
Communication	<ul style="list-style-type: none"> • Documentation errors, lack of documentation, limited sharing of information (e.g., medical record) • Divisive language, medical jargon, intimidating language • “Inept communication between patient and provider” • Health literacy • Lack of respect of time, privacy, confidentiality • Limited understanding of information • Sensitivity to culture and diversity
Fragmentation	<ul style="list-style-type: none"> • Care transitions (hospital, home, emergency department) • Primary care-specialist handoffs • Poor test followup, missed test results • Poor understanding of need for followup and expectations • Not enough time with patients
Medication issues	<ul style="list-style-type: none"> • Prescribing errors • Medication nonadherence • Adverse drug events and interactions • Overprescribing of opioids, antibiotics • Errors in medication reconciliation • Limited understanding of medications • Over-the-counter medications
Issues related to diagnosis and treatment	<ul style="list-style-type: none"> • Overuse and underuse of medical services • Missing contextual information in patient encounter • Specimen collection process lapses

Recommended Interventions To Improve Patient Safety and Patient Engagement in Primary Care

Our key informants identified interventions at the patient, provider, and practice environment level to improve patient safety.

Patients. Each of the 23 key informants reported that a major factor to improve patient safety in primary care was the need for patients to take a more active role in their care. Strategies identified by the informants to improve engagement and patient safety included:

- **Ask questions.** All informants identified preparing patients to ask questions at the office visit as an important first step. Providing opportunities to support question asking, including providers encouraging questions, should be considered as part of the Guide.
- **Take an active role in treatment decisions.** Having patients take an active role in treatment decisions is vital to improving patient safety. Active engagement in decisionmaking includes providing the physician with all the information needed to make a sound clinical judgment, listening to advice on lifestyle and behavioral factors that may influence poor health, and becoming “*information seekers*” rather than just “*passive recipients*” of care. Efforts within the Guide need to support a patient and provider team to encourage patient accountability in care. They also need to ensure that the patient’s voice is being heard.
- **Be prepared to be a patient.** Several individuals identified that ensuring that patients are aware of the expectations of being a patient is important. This includes knowing why they are at the doctor, being prepared for the appointment with questions, being open about problems and challenges in the care plan, and bringing a family member or friend with them to the appointment, particularly if expecting bad news.
- **Speak up.** The concept of partnership is tightly coupled with a patient’s role in the patient-provider relationship, shifting from a patient listening to a paternalistic doctor to being an active partner. One intervention prepares patients with the tools to speak up when something a provider says is unclear or when information is missing or incomplete. The intervention also helps providers make it easy for patients to speak up both when things are good and when they are not.
- **Improve medication understanding and use.** Our informants indicated that a comprehensive approach to patient medications is an important factor influencing patient safety and care quality in primary care. Patients need to know what they are taking, understand why they are taking it, and understand the implications of nonadherence.
- **Own your medical information.** Themes around patient ownership of their medical record were reported by patients, physicians, practice staff, and administrators. Making sure that patients had access to their medical records, most often recommended through a patient portal or other electronic means, was encouraged.
- **Communicate openly.** Patients and patient advocates often responded that the ability to have open electronic communication with primary care providers would yield higher levels of engagement and improve patient safety. Electronic communication types identified included email, communication through a patient portal, and the opportunity to text message the provider. Timely access to providers through the telephone was also encouraged.

Providers. Common provider-directed interventions and approaches aimed at improving patient safety and patient engagement in care included:

- **Motivational interviewing.** Informants emphasized the need for strategies to enhance the providers' skills and competencies at coaching, setting goals, and working with patients to agree on health priorities and set realistic expectations. The provider can be a coach or instructor to empower patients and family members to be engaged in their care and become partners. Informant recommendations included undergraduate and graduate medical education reform to include skills building around these topics as important first steps in the process.
- **Teach-back.** Patients and providers felt that an important approach to ensuring understanding of information and encouraging open communication is through the effective and consistent use of "teach-back." With teach-back, when a patient receives new information, the patient "teaches" that new information back to the provider. Informants recommended using teach-back whenever a new medication is prescribed, an old medication is renewed, or a new therapy is discussed. Teach-back can also be used to ensure understanding about why a test is being ordered to reinforce to the patient how important it is to get the test or adhere to the new medication.
- **Shared decisionmaking.** Patients and providers identified strongly with efforts to improve shared decisionmaking. Specific strategies or interventions to enable shared decisionmaking were not as common as the identified need for shared decisionmaking.
- **Contextualized care.** Many informants reported that interventions aimed at encouraging identification of patient-level barriers to implementing the care plan are critical to improving safety. These barriers include life preferences, health numeracy, context of care, socioeconomic pressures, and health literacy.
- **Appropriate language.** Changing the language used by providers in primary care from "medical jargon to living room language" was identified by several informants as a key feature to improve patient safety. This approach could help create a sense of equity in decisionmaking and allow patients to better engage in their care.

Practice Setting. Several approaches identified by our informants aimed to improve patient safety and patient engagement but required changes in operations, infrastructure, or organization in order to be adopted. We defined these approaches as interventions to be applied at the practice setting level, even though they may require individual patient, provider, or practice staff behavior change to be most effectively adopted.

- **Patient portals.** Patients, providers, and other health care stakeholders agree that a well-functioning, accessible, and usable patient portal is a critical feature that can cross the patient safety-patient engagement chasm in primary care. Information available through the portal should include "*all the patient's health information and NOT just selected parts.*" A patient portal has been identified as an important method of enhancing communication, a vehicle to identify potential errors in information, and a historical record of the plan of care. Informants suggested that a patient portal with access to test results would also allow patients and their family members or caregivers to know when test results arrive at the doctor's office and, more importantly, if they have not.

- **Patient and family advisory councils, boards, or committee models.** Our key informants overwhelmingly supported the idea of engaging patients and families in a structured way to improve the quality, safety, and effectiveness of care in the primary care setting. One physician indicated that it would be “*ideal for primary care practices to have a patient advisory group—not all can manage that process—but where they can, they should. Much insight is gained through listening to patients and having them in a leadership role.*”
- **Team huddles.** All key informants identified efforts to improve communication between physicians, patients, and practice staff as a critical factor to improve patient safety and patient engagement in primary care. Team huddles and other principles of high-reliability organizations were recommended to reduce the opportunity for errors in communication, enhance clinical teamwork and effectiveness, and establish practice resilience and ability to respond to unexpected emergencies.
- **Models of team-based care.** Approximately 35 percent of our informants identified team-based care as a critical factor that can improve both patient engagement and patient safety in primary care. Benefits of care teams in this context include allowing increased time with patients, fostering meaningful patient-provider relationships, and improving patient and provider satisfaction. Recommended models included nurse/ physician extenders, concierge practice model, team screening and taking of medical and social history, team documentation, and coaching and education done by an extended team. In these models, the patients engage with the full team and not just the physician.
- **Support for shared decisionmaking.** Patients and providers identified shared decisionmaking as important to improving patient safety and engagement in care. Approaches suggested to support shared decisionmaking included decision aids, option grids, patient and provider checklists, and other risk tools.
- **Previsit labs.** Obtaining lab tests before the visit encourages shared decisionmaking and limits the need for followup. Previsit labs reduce the risk associated with patients forgetting to have the tests done and the risk of the practice team or provider forgetting to follow up on test results.
- **Usable materials.** Informants indicated that providing patients with usable tools they can pick up and take home would help support open communication and decisionmaking. These include decision aids, patient educational materials, and access to their medical record. Providers cautioned, however, that in their experience “*...decision aids are great for the already activated and educated patient. Providers need to be sensitive to the less educated or health literacy challenged populations and develop strategies to encourage activation among all patient groups.*”

Literature Review

Peer-Reviewed Literature

The initial search strategies for the peer-reviewed literature yielded more than 11,000 indexed references in the PubMed database. To reach a more manageable and relevant selection of articles, the project team consulted with the medical library scientists to refine the search and filter the results to focus on identifying articles with interventions (and related concepts such as toolkits, processes, and process improvements). This more focused approach yielded 1,163

articles to undergo further review. The library scientists then conducted the additional searches using the Embase, CINAHL, Cochrane, and Web of Science databases.

As illustrated in Figure 3, the search of the electronic literature databases yielded the following numbers of reports:

- PubMed, 1,163,
- Embase, 913,
- CINAHL, 807,
- Cochrane, 538, and
- Web of Science, 531.

These were examined for duplicates, and 3,919 unique articles were identified. Six members of the research team, paired in teams of two (three teams of two reviewers), independently reviewed article abstracts to make initial determinations of whether the article addressed patient safety, patient and family engagement, or primary care. Of these, 336 reports met the predetermined inclusion criteria of reporting on an intervention that addressed at least two of the three conceptual domains.

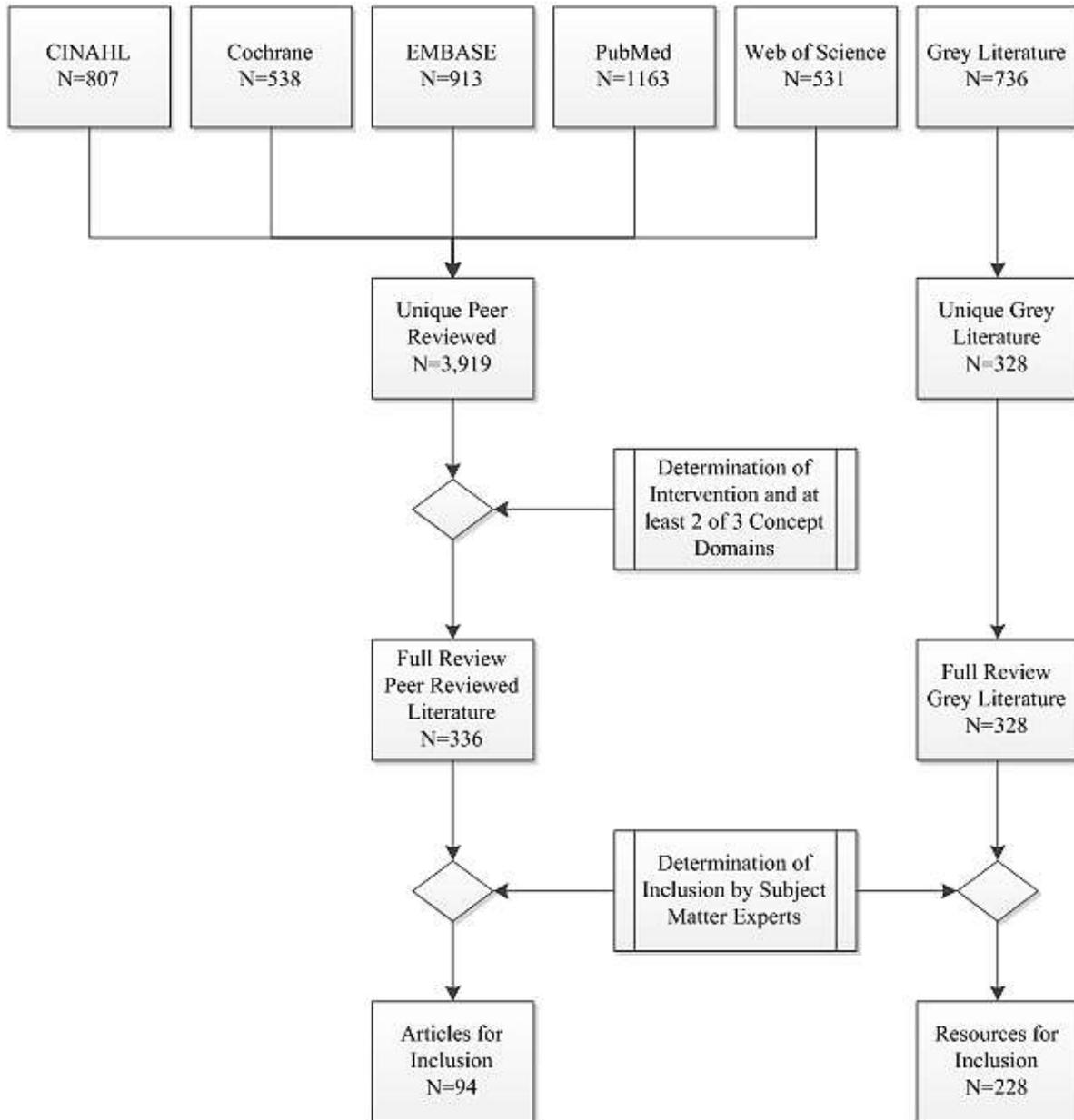
One of the senior researchers subsequently reviewed the 336 reports and identified 94 that met the predetermined inclusion criteria (see Table 2 for criteria). The 94 peer-reviewed articles were merged with the grey literature and key informant interview output to develop the inventory of interventions and inform the findings below.

Grey Literature

The process for identification of resources within the grey literature followed a similar approach to that used with the peer-reviewed literature (Figure) and yielded 536 source documents that met the inclusion criteria of reporting on two or more of the conceptual domains of patient safety, patient and family engagement, and primary care. An additional 200 resources were identified through searches of Google, Twitter, and other social media outlets or through the social networks of the project team and the AHRQ contracting officer. These resources were reviewed independently by two senior patient safety researchers for consideration.

After review, deduplication, and consideration of relevance of the reports and resources to the goals of the Guide, 328 unique resources were identified for full review. One of the senior researchers subsequently reviewed these 328 resources and identified 228 that met the predetermined inclusion criteria (see Table 2 for criteria).

Figure3. Peer-Reviewed and Grey Literature Flowchart



Overall Analysis

Each unique article or resource was independently coded for the quality of evidence, conceptual domain addressed, safety issue addressed, and safety solutions, using the categories first provided in Table 3. The number of reports in each of the categories for both the peer-reviewed and grey literature are presented in the tables below (Table 6, Table 7, Table 8, Table 9).

Table 6. Number of Reports by Report Type, Safety Issues, and Safety Solutions Addressed

Report Type	Peer-Reviewed Literature		Grey Literature	
	N (94)	%	N (328)	%
Evaluated intervention	33	35.1	68	20.7
Well-described intervention	28	29.8	292	89.0
Systematic review	18	19.1	11	3.4
Other	15	16.0	31	9.5

Table 7. Number of Reports by Conceptual Domain

Conceptual Domains Addressed	Peer-Reviewed Literature		Grey Literature	
	N (94)	%	N (328)	%
Patient safety	85	90.4	310	94.5
Primary care setting	92	97.9	292	89.0
Patient and family engagement	65	69.1	291	88.7

Table 8. Number of Reports by Safety Issue Addressed

Safety Issues Addressed	Peer-Reviewed Literature		Grey Literature	
	N (94)	%	N (328)	%
Fragmentation of the care system and transitions between providers	24	25.5	250	75.3
Communication between patients and providers, health literacy	34	36.2	280	85.4
Diagnostic errors	2	2.1	129	39.3
Medication prescription, management, drug interactions, adherence	54	57.4	119	36.3
Antibiotic, opioid, and other medication overuse	10	10.6	7	2.1
Other	16	17.0	62	18.9
Not addressed	10	10.6	0	0

Table 9. Number of Reports by Safety Solution

Safety Solutions	Peer-Reviewed Literature		Grey Literature	
	N (94)	%	N (328)	%
Care team models, including pharmacists	40	42.6	187	57.0
Medications, medication lists, reconciliation	38	40.4	133	40.5
Family advisory councils	0	0.0	79	24.1
Educational interventions	44	46.8	243	74.1
Shared decisionmaking models	10	10.6	89	27.1
Family engagement in patient care	5	5.3	97	29.6
Chronic disease management	19	20.2	0	0
Other	14	14.9	0	0
Not addressed	17	18.1	0	0

Peer-Reviewed Literature

Slightly more than one-third of the published articles that met the inclusion criteria reported on an evaluated intervention (33 articles, or 35.1%; Table 6). The level of rigor of the evaluations varied, and some evaluations revealed negative effects of the intervention on outcomes assessed.

Another 18 articles (19.1%) included systematic reviews of the literature. Many of these reviews included only a small number of medium- or high-quality articles and relatively few strong conclusions about effective interventions. Another 28 articles (29.8%) provided good descriptions of interventions but focused on protocols, case studies, or toolkits and did not report the results of evaluations.

The remaining 15 articles (16.1%) did not include descriptions of interventions. They reported on surveys of patients and providers about the issues, consensus processes to develop practice guidelines, and other empirical studies that addressed critical issues in the intersection of patient safety, primary care, and patient and family engagement.

Most studies reviewed explicitly addressed patient safety (85 articles, or 90.4%; Table 7) in primary care settings (92 articles, 97.9%). However, only 65 articles (69.1%) directly addressed patient and family engagement.

The most common safety issues addressed were medication prescription and management, drug interactions, and adherence (54 articles, or 57.4%; Table 8). An additional 10 articles covered the related area of antibiotic, opioid, and other medication overuse, for a total of 64 articles (68.0%) on medication issues. Other frequent patient safety issues addressed were communication between patients and providers, including health literacy (34 articles, 36.2%) and fragmentation of the care system and transitions between providers (24 articles, 25.5%). Two articles (2.1%) addressed diagnostic errors. The remaining reports either addressed a different patient safety issue (16 articles, 17.0%) or did not explicitly address patient safety at all (10 articles, 10.6%).

The most common patient safety solutions identified in the peer-reviewed literature were educational interventions (44 articles, or 46.8%; Table 9); care team models including pharmacists (40 articles, 42.6%); and health information technology (IT), including medications, medication lists, and reconciliation (38 articles, 40.4%). There were also articles on chronic disease management models (19 articles, 20.2%), shared decisionmaking models (10 articles, 10.6%), and family (beyond patient) engagement in patient care (5 articles, 5.3%).

No articles discussing family advisory councils in the context of primary care were identified by this search. The remaining reports either addressed a different patient safety solution (14 articles, 14.9%) or did not explicitly address patient safety solutions at all (17 articles, 18.1%).

Grey Literature

The grey literature search yielded 328 tools, interventions, reports, and other resources aimed at improving patient safety and patient and family engagement in primary care settings that met our initial inclusion criteria. Of the reports identified, about 20% met the threshold for being well evaluated, including 11 systematic reviews (Table 6). These reports also included consensus panel reports that may or may not have identified interventions for consideration. Most of the reports were defined as well-described interventions, approaches, processes, or reviews with

consensus panel recommendations for improving patient safety and patient engagement in primary care settings.

Most of the resources identified by our grey literature search addressed our conceptual domains of patient safety (94.5%), primary care (89%), and patient and family engagement (88.7%; Table 7). Of these, 273 (83.2%) addressed all three domains.

The most common safety issues addressed in the grey literature included communication breakdowns (85.4%; Table 8), fragmentation issues (75.3%), diagnostic errors (39.3%), and issues around medications (38.4%). This profile is somewhat similar to the peer-reviewed literature search where communication, medication, and fragmentation issues were the top three patient safety concerns identified.

In the grey literature, solutions to overcoming patient safety concerns in primary care were often multifactorial in nature, with few interventions focused on only one problem (Table 9). Care team models, including approaches to frame the patient and family members as part of the care team, were the most commonly reported interventions in the grey literature to target patient safety and patient engagement in primary care. Other commonly reported interventions included medication reconciliation and medication lists, models and decision aids to support shared decisionmaking, and strategies to engage patients and family members as advisors, board members, or active participants in their care.

One feature common across most of the interventions, tools, and reports was education. Education was included as a key strategy to foster the adoption of interventions and enabling technologies. Activities aimed at educating patients were replete throughout the grey literature. Educational activities for providers and practice staff were also represented but to a much lesser extent. Our search also identified reports aimed at engaging the academic and policy communities in the dialogue around patient safety and patient engagement in primary care.

Interventions

Subject matter experts, including patient representatives, a health literacy expert, a systems delivery scientist, patient safety experts, a human factors specialist, and safety scientists, independently reviewed the 422 reports considered for inclusion in the Guide. Of the 328 resources identified in the grey literature search, 251 described interventions in sufficient detail to warrant review and usability considerations. Of these, experts determined that 228 should be considered for inclusion in the Guide. Similarly, 72 interventions identified within the peer-reviewed literature were included in the intervention inventory. Appendix F contains a table of the interventions identified for consideration for inclusion in the Guide.

Discussion of Findings

Reduced patient safety in primary care is influenced by patient-related, provider-related, and health system or practice-related factors. (Policy-related factors have also been identified but are beyond the scope of this project.) Factors influencing patient safety within primary care seldom occur in isolation but are part of a complex matrix within the health care environment.³⁶

In this environmental scan, four key threats to patient safety in primary care emerged. These were validated through our key informant interviews and by our Technical Expert Panel. The four threats are:

- Communication breakdowns (among patient, provider, and practice staff).
- Medication management (reconciliation, prescribing, adherence, overuse).
- Diagnosis and treatment (decisionmaking, information transfer, missed diagnosis, delayed diagnosis).
- Fragmentation and environment of care (identification issues, transfers, care coordination, safety culture, reporting, and error management).

These findings have been confirmed in recent systematic reviews and technology assessment reports on patient safety in ambulatory care.^{37–41}

Of these, factors related to communication breakdowns and fragmentation of the care process were the highest sources of safety issues identified in the peer-reviewed and grey literature. These were followed by issues surrounding medication prescribing, management, and adherence and diagnostic error. Our environmental scan revealed that each of these threats to patient safety is multifaceted, with no single solution rising to the top as the catalyst for improvement. Barriers to improving patient safety are reported at the patient, provider, and practice staff levels.

We have organized the findings of our environmental scan along the four threats to patient safety in primary care settings. We examine strategies identified to close the gaps in safety and those specifically linking enhanced patient and family engagement to improved patient safety in primary care. Appendix F includes a full list of interventions and resources identified during the environmental scan.

Patient Safety Issues in Primary Care

Communication

The issue of communication slips and lapses leading to medical error, near-misses, and unsafe conditions in primary care was the most widely reported problem. It underlies other issues related to medication management, diagnosis and treatment, and organizational structure and safety (e.g., fragmentation of care).^{42–49} Communication errors between the patient and the care provider, the patient and practice staff, and providers and practice staff have all contributed to medical error in primary care.

Extending beyond the local practice setting, errors related to communication breakdowns between the primary care practice and other health care settings (e.g., hospital, home care, emergency departments, community pharmacy) have also been reported as contributing to the patient safety landscape of primary care.^{39,43,46,50–56} Errors within this domain may include errors in referral and errors in communicating test results.

Given its ubiquitous relationship to patient safety in primary care environments, strategies to improve communication are at the forefront of patient safety efforts. The target audiences for the interventions have primarily been patients and physicians.

Education is the most common approach to encouraging adoption. Patient education focuses on providing detailed brochures on how to be a safe patient,⁵⁷⁻⁶¹ guidance on being prepared for an appointment,⁴ and guidance on asking questions⁶⁰⁻⁶⁶ and generating lists of medications⁶⁷⁻⁷⁰ to support shared decisionmaking and open communication with the care team. Provider education has focused on training in motivational interviewing, coaching, and other supportive approaches to engage in shared decisionmaking^{6,7,58,60,71-73} with patients.

Recently, communication approaches more commonly associated with acute health care settings and high reliability have emerged in the peer-reviewed and grey literature for ambulatory care settings, including primary care. Examples include elements of the TeamSTEPPS[®] approach, including SBAR (situation, background, assessment, recommendations)⁷⁴⁻⁷⁷; daily huddles⁷⁸⁻⁸⁰; and other approaches to team-based care.^{42,81-85}

Another key emerging trend is using the electronic medical record as a tool for communicating with patients and communicating through patient portals (e.g., Open Notes).^{60,86-90} For physicians managing patients with chronic disease, supportive tools and technologies to guide discussions with patients around therapeutic options and treatment decisions continue to evolve in complexity and usability (e.g., option grids, decision aids).^{60,91-93} A recent systematic review on the use of text messaging in primary care resulted in increased adherence to medications, demonstrating strong evidence for its use as an adjunct to traditional communication strategies to improve care.⁶⁰ Additional educational strategies around literacy, health literacy, and cultural and contextual competency were also reported.^{60,81,94-96}

Our environmental scan findings detail a complex web of communication within the primary care environment. Engagement of patients and families in overcoming communication breakdowns has the potential for broad-reaching improvements in patient safety in primary care. The peer-reviewed and grey literature is replete with strategies to enhance communication between patients and providers around therapeutic options, medications, and chronic disease management.

Many of the strategies were confirmed through consultation with our key informants and members of the Technical Expert Panel. Efforts to improve patient awareness of existing strategies to improve communication are warranted. In addition, increasing usability of the interventions is needed to enhance adoption into routine practice. Encouraging communication between patients, providers, and practice staff is central to improving patient safety in primary care. Improved communication has the potential to affect all identified patient safety issues that surfaced during our environmental scan. Thus, strategies to enhance patient-provider partnerships in communication should be considered a key element of the Guide.

Medication Issues

One of the most widely studied sources of medical error in both acute and nonacute health care settings is medication errors.^{39,70,97-101} Errors occur at the prescribing, filling, and administration stages of medication management. Prescribing errors included prescribing the wrong medication, prescribing medications with drug-drug interactions, and making errors related to transcription of written prescription orders.

Filling and administration errors include patients not filling their prescription, patients not understanding why they are on a new or different medication, and patients not taking the medications as prescribed. Each of these gaps in medication safety has yielded different approaches to reduce opportunity for error. Efforts to reduce medication errors in the ambulatory care setting, including primary care, have focused on:

- Medication reconciliation,^{102–105}
- Patient medication lists,^{67,69,70,106–109}
- Pharmacist-led interventions,^{60,110–114}
- E-prescribing, and
- Computerized physician order entry.^{115,116}

Education and training has accompanied most interventions, except for those directed toward patients specifically.

Two recent systematic reviews of safe medication use in primary care acknowledged that much of the research aimed at reducing medication errors has focused on single interventions. The authors contend that co-implementation of interventions may provide the most effective options to improve medication safety in primary care.^{98,117}

Our environmental scan yielded several important findings about strategies to improve medication safety in primary care. Medication lists were the primary strategy aimed at patients, family members, and caregivers. Our team identified no fewer than 40 medication lists, pill cards, and smart phone applications available to patients to keep track of their medications (for a complete list, see Appendix F).^{18,58,102,114,118–120}

Despite a field with numerous interventions to improve medication adherence and medication safety by engaging patients through medication lists, few of these strategies have seen widespread adoption. More recently, patient-facing strategies such as sharing medical notes¹²¹ and providing automatic refill reminders¹²² have been associated with higher levels of medication adherence among patients.

Strategies aimed at the provider and practice levels were also reported, although with much less frequency. Interventions such as innovative approaches to medication reconciliation, e-prescribing^{60,114}, and integration of community pharmacists into the extended care team^{110,111,113,123,124} all appeared to improve medication safety in primary care. Emerging strategies such as group visits and engaging the extended health care team to provide coaching and conduct teach-back around new medications were described in the literature and validated by our key informants.^{125–127}

Results of the environmental scan suggest that errors in medication management within primary care represent a significant threat to patient safety. Engagement of patients in improving safety through adherence and education are the core strategies currently used. Patient-directed interventions rely highly on patients already being activated in their care to seek and use the wide variety of tools and techniques available for maintaining medication records.

Most of these interventions are geared toward individuals taking more than one medication and those with complex chronic conditions.^{128–130} However, limited evidence is available on whether these patient populations were included in the development of the approaches. At the same time, the role of primary care providers and practice staff is expanding in supporting medication management in their patients. Strategies for practices to support and engage patients in medication adherence and management should be considered in developing the Guide.

Diagnostic Error

Estimates of diagnostic error in outpatient care suggest that approximately 1 in 20 adult patients in the United States is affected, resulting in significant costs to patients, families, providers, and the health system.^{131–133} Diagnostic error has been operationally defined as “diagnoses that are unintentionally delayed (sufficient information to make a diagnosis was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was made).”¹³⁴ A recent study found that of the closed claims occurring in primary care over a 5-year period, 72.1% were related to alleged diagnostic error.¹³⁵

Despite its estimated prevalence, evidence on the epidemiology and potential interventions to reduce diagnostic error in primary care are only now emerging.^{50,131,136–140} Some of this challenge is due to how primary care is delivered.^{134,141} Diagnostic error in primary care is a complex process with implications for patients and providers, as well as practices and health systems.

Ultimately, diagnostic error relates to the principle of uncertainty inherent in the diagnostic process.^{131,139,142,143} Most diagnostic errors in primary care are related to process breakdowns in the patient-practitioner clinical encounter.³⁸ Thus, efforts to improve the patient-provider interaction, specifically those that involve data gathering (e.g., pre-labs, testing followup), have the greatest potential for influencing patient safety in primary care.

Recent systematic reviews and consensus reports identified patient safety strategies targeting diagnostic errors.^{37,39,50,133,134,139,142–144} Emerging evidence suggests that solutions focusing on patient, physician, and practice-related factors can have the greatest impact on reducing diagnostic error.^{39,134,142,144} One recent study found that to prevent diagnostic errors and improve patient safety, interventions needed to be context specific and targeted to:

- The needs of the patient population being served (i.e., socioeconomic and demographic characteristics),
- The environment of the clinical care site (urban, rural, or suburban), and
- The practice setting (acute, ambulatory care, primary care, or home care).

Each of these factors needs to be considered when designing interventions and approaches to overcoming diagnostic error.

Opportunities to integrate patients, families, and caregivers into the process of preventing diagnostic error may occur at several levels within the primary care environment. These include more actively engaging patients in the diagnostic process and monitoring of outcomes, engaging patient and family stakeholders in the health system environment, and engaging patients and advocates in research and policy development.^{141,145,146}

For primary care settings, strategies to more actively engage patients and families in the diagnostic process could include:

- Shared decisionmaking,^{73,92,147,148}
- Enhanced previsit planning, including pre-labs,^{87,149,150}
- Structured patient-provider communication, including asking questions,^{47,151,152}
- Sharing of provider notes,^{86,88–90}
- Use of mobile, text, and secure electronic mail messaging to enhance adherence to the therapeutic plan and monitor health status,^{153–155} and
- Use of patient portals,^{60,124,156} among others.^{58,136,137,144,157}

Providers and the practice environment need to be supportive of patient engagement in these activities, overcoming fears, powerlessness, and vulnerability inherently related to illness.¹⁵⁸ Enabling behaviors include avoiding dismissive or disrespectful behavior, encouraging patients to ask questions and listening to their responses, setting expectations for followup of diagnostic tests, and making efforts to streamline often uncoordinated care.^{56,67,141}

These findings are consistent with the recommendations of our Technical Expert Panel members and key informants, as well as the more than 130 articles, resources, tools, and reports that have identified strategies aimed at improving the diagnostic process. Resources to support patients in more actively engaging in their care continue to surface.

Our work suggests that active engagement of patients and families throughout the diagnostic process may yield important improvements in the safety and quality of health care. Several promising interventions and intervention bundles to support engagement in the diagnostic process emerged during our environmental scan and should be considered for Guide development. The feasibility of integrating these interventions into the standard of practice in primary care will require a comprehensive approach to behavior change for physicians, patients, family members, and practice organizations.

Fragmentation

Fragmentation has been defined as the “lack of standardization and innovation, dissemination, trust, and a safety culture,” and is seen as a threat to safety in health care systems.⁴³ In our environmental scan, we have operationally defined fragmentation as breakdowns in the transition of patients between providers (or health care settings) with a resulting loss of critical information and valuable time on behalf of the provider and the patient.

Like communication breakdowns, fragmentation can have far-reaching outcomes. Approaches to overcoming the impact of fragmentation in primary care practices have yielded two primary foci: improving the standardization of care delivery and providing relationship-based care.

In the words of one of our Technical Expert Panel members, standardization from the patient’s perspective simply means “*every patient, every time.*” Adopting team-based approaches to care encourages standardization of practice workflow and efficiencies.^{77,80,101,159} Recent evidence suggests that standardizing structured communication and patient experiences in primary care through the adoption of checklists may be one way to improve safety.^{43,159} Continuity of relationships in primary care, in which a patient has one primary care provider who manages his

or her care over a long period of time, is another approach suggested to improve decisionmaking and engagement in primary care.^{82,160,161}

Patients also have a role in reducing the impact of fragmentation. Our key informants indicated that setting expectations for the patient for the completion of diagnostic tests and setting timelines for followup either via phone or in person are important steps patients can take immediately to improve care. Engaging and empowering patients through partnership was identified as a crucial step to increase patient safety.¹⁶²⁻¹⁶⁴

Our findings indicate that increased engagement from patients and families could help address fragmentation issues. Promising interventions for improving the standardization of care delivery and providing relationship-based care, to reduce the impact of fragmentation, should be considered for the Guide.

Strategies To Engage Patients and Families and Improve Safety

The environmental scan revealed that while the field of patient safety in primary care is new, several important innovations aimed at improving patient safety in primary care have emerged.^{43,48,83,141,161,165} Interventions exist that focus on providers, patients, and practices as the target audience, with varying strength of evidence of effectiveness, impact, and demonstrated usability.

Table 10 outlines the common themes of interventions and approaches that have demonstrated success or have received strong recommendations from our key informants for consideration for inclusion in the Guide. The interventions are organized by target audience.

Table 10. Recommended Interventions

Target Audience	Intervention Themes	Specific Interventions
Patient Provider Practice staff	Team approach to patient care	<ul style="list-style-type: none"> • Expand the health care team (e.g., pharmacists). • Increase the amount of time for each encounter/appointment. • Allow team documentation and followup. • Create an environment for comprehensive shared decisionmaking. • Form patient and family advisory committees and councils.
Patient Practice staff	Culture of safety and respect	<ul style="list-style-type: none"> • Foster open two-way communication between patients and practice staff: <ul style="list-style-type: none"> ○ Celebrate positive behaviors such as empathy and respect. ○ Correct negative behaviors. • Communicate with empathy, respect, and flexibility. • Set clear expectations for following up on test results. • Have patients complete any blood work, laboratory tests, and screenings before the visit (“pre-visit labs”) to foster shared decisionmaking and optimize clinic time. • Routinely conduct double identification protocols.

Target Audience	Intervention Themes	Specific Interventions
Patient Provider	Relationship-based care	<ul style="list-style-type: none"> • Provide clear, concise, contextual, and compassionate care. • Engage in shared decisionmaking, ensuring values and preferences are discussed and agreed on. • Acknowledge uncertainty. • Embrace transparency (communication, clinic notes, etc.). • Routinely conduct double identification protocols.
Provider Practice staff	Regular structured communication	<ul style="list-style-type: none"> • Use routine and structured communication. • Flatten hierarchy and institute a just culture approach. • Conduct daily huddles to discuss plan of the day, complex patients, and potential threats to safety; create a resilient primary care experience. • Institute a system to report and investigate threats to patient and provider safety.
Provider	Culture of transparency and open communication	<ul style="list-style-type: none"> • Make it easy for patients, family members, and staff to speak up when care breakdowns occur. • Create a culture of safety for staff and patients. • Be fair and institute a just culture approach to problem solving and accountability. • Conduct huddles to enhance teamwork and get the team on the same page for the plans of the day.
Practice Practice staff	Team-based resilient care models	<ul style="list-style-type: none"> • Actively participate in team huddles. • Prepare for the unexpected. • Capitalize on expanded team. • Allow team documentation.
Patient	Active partner in care	<ul style="list-style-type: none"> • Be ready to discuss key problems. • Keep a list of medications and bring it to appointments. • Bring a family member or patient advocate to appointments.

Below, we review specific interventions that cut across multiple domains of safety issues in primary care, briefly describe factors affecting their usability, and discuss their effectiveness.

Shared Decisionmaking

Our environmental scan yielded strong evidence from peer-reviewed and grey literature and from patients, family members, and primary care providers on the importance of shared decisionmaking to improving patient safety in primary care.^{4,36,41,58,60,71–73,84,91–93,114,123,124,130,141,145,147,148,163,166–215} Shared decisionmaking has established effectiveness for improving decisionmaking around medications, alternative treatments, chronic disease management, and self-management strategies. Toolkits and resources such as the SHARE Approach from the Agency for Healthcare Research and Quality, decision aids, and option grids support the patient-provider partnership in care decisions.^{91,147,178}

Factors influencing the impact of shared decisionmaking from the provider perspective include quality of the patient-provider relationship, importance of quick patient recovery, and physician knowledge of treatment options. Concurrently, patient’s influencing factors include ensuring a

correct diagnosis from the provider; getting information on treatment options, including perceived harms and benefits; and getting a clear explanation of the care trajectory.²¹⁶

The field of shared decisionmaking continues to evolve and approaches to enhance patient-provider partnership in primary and specialty care continues to grow. We found several study protocols describing new approaches to supporting shared decisionmaking. For example:

- An intervention aimed to improve shared decisionmaking between patients and providers to enhance diabetes management among Mexican Americans.²¹⁷
- Another protocol aimed to improve medication adherence in older adults.¹³⁰
- One intervention that promotes shared decisionmaking between family physicians and their patients led to a reduction in antibiotic overprescribing and had no effect on patient satisfaction.^{60,114,147,148,178,218}

Although shared decisionmaking interventions can be beneficial, there is heterogeneity in their application and further data are needed to show they can improve health outcomes.⁶⁰

Despite the encouraging evidence of the impact shared decisionmaking could have on patients, several barriers to adoption were also reported. The primary barrier to shared decisionmaking is the limited time providers have for deep and meaningful conversations with patients.^{48,149,219} The provider's time pressures and the patient's needs in the relationship are factors that need to be considered when evaluating the inclusion of shared decisionmaking as an intervention in the Guide.

Patient and Family Advisory Councils, Boards, and Committees

Patient and family advisory councils, boards, and committees were identified through the grey literature search and in consultation with our Technical Expert Panel and key informants as an important strategy for improving patient safety.^{2,6,7,10,41,58,65,85,161,181,184,196,197,204,205,220–228}

Strategies for engaging patients as advisors in the acute care setting are quite mature, and several toolkits are available. Patients as advisors in the hospital setting have emerged through our environmental scan, including several supported by the Agency for Healthcare Research and Quality.^{8,229} A recent addition to the field has come from the Institute for Patient- and Family-Centered Care and is specific to advisory committees in the ambulatory care setting.

Few published reports exist on the impact of patient advisory councils on patient safety that include tests of change. One published report indicated that an advisory committee-led intervention resulted in a significant improvement in the number of accurate medication lists for patients in ambulatory care practices in Wisconsin.^{226,227} Here, the number of patients with accurate medication lists improved from 55 percent of patients to 72 percent of patients.

Another narrative report of the impact of a patient advisory council on family medicine practices transitioning toward patient-centered medical homes indicated that the advisory council had “changed the conversation.” Improvement efforts of this council have focused on improving communication and access, redesigning the practice and signage, helping redesign the patient portal, and holding the practice accountable for quality and experience data.¹⁸⁴

Interviews with practices and leaders in patient engagement from across the country indicate that the approach to engaging patients and families as advisors in primary care is similar to the approach used in the acute care setting. Models in primary care exist, developed as part of statewide practice improvement collaboratives or by patients in a grassroots approach to improving care.

Evidence of impact is suggestive, primarily consisting of case studies and individual reports. But when it is designed to focus on quality and safety of care, a patient advisory council may be an effective approach to engaging the community to overcome practice challenges.

Team-Based Care

Team-based models of care can help reduce medical errors related to communication breakdowns, diagnostic errors, and medication management issues and are a key driver of increasing standardization (thus reducing fragmentation) within primary care settings.^{4,7,43,53,54,56,58,82,101,118,123,136,141,164,179,195,200,203,205,230–239} Strategies to improve team-based care within primary care settings include:

- Team documentation,
- Daily team huddles,
- Expanded care teams,
- Care navigators/case managers, and
- Inclusion of the patient and family members as part of the team.

Strategies such as the patient-centered medical home and patient-centered care coordination have yielded important improvements in team culture of safety and willingness to speak up and have also been associated with improved patient and professional satisfaction. While still emerging, strategies for enhancing teamwork can significantly affect all domains of safety lapses in primary care environments. Challenges to implementation include organizational readiness, payment structure (fee for service versus bundled payments), infrastructure, staff and physician readiness, and patient acceptance of the team approach.

Interventions To Support Medication Safety

Approaches to improve medication safety in primary care include:

- Patient-focused applications for medication lists,
- Team documentation,
- Efforts to partner with patients on medication reconciliation activities,
- Access to medication history through an electronic patient portal, and
- Other technology-mediated processes to support medication adherence.^{7,39,41,43,45,52,53,58,60,70,82,85,90,98,101,104,110–112,114,115,117,118,120,126,129,135,164,169,179,202,204,224,232,237,238,240–256}

More than half of the medication-related interventions identified in our environmental scan included approaches to ensure accurate medication lists for patients. Evidence of effectiveness of the medication lists was limited, and they were of questionable usability. Smart phone

applications aimed at maintaining records of medications and providing medication reminders have emerged over the past several years. Patient reviews of these applications were scarce.

Medication reconciliation remains an important approach to improving patient safety in the acute, primary, and long-term care settings. Medication reconciliation is limited in the primary care setting by the quality of information from patients and family members about not only what patients are taking but also how they are taking it. Over-the-counter medications are often not routinely reported by patients despite the risk of contraindications. Overall, efforts to improve medication safety in primary care should improve not only safety, including reductions in adverse drug events, but also quality of care.

Family Engagement in Care

Family engagement has been proposed as a potential solution to improving patient safety. Since patients are often cared for or influenced by their families, caregivers, and social networks, integrating the family into safety and quality of care activities may be an important strategy to consider. One study found that for short-term interventions, integration of the family increased medical adherence through simple interventions such as check-ins with a family member or daily documentation. However, the study was inconclusive on the effect on management of chronic health issues.⁶⁰

In another study, families were trained to participate in medical triage, making calls following a carefully designed protocol. Results were mixed as family activations were not taken as seriously as those from a practitioner, yet families were often accurate in identifying medical needs at home.⁶⁰ These studies suggest that to take full advantage of patient partnerships in primary care to improve safety, providers should also consider the family an integral part of the relationship.

Structured Communication for Patients, Families, and Primary Care Providers

Strategies to support structured communication for patients, family members, and providers have been proposed as important to improving patient safety in primary care. Many of the educational resources for patients and families encourage patients to:

- Have a checklist to prepare for their doctor's visit,
- Bring a list of questions,
- Write out their symptoms if they have trouble communicating with the doctor during the visit, and
- Bring a family member or friend to visits, particularly when significant health concerns are being discussed.^{41,43,57,58,60,62,141,177,179,204,222,225,257-260}

Evidence of the impact of tools to support question asking is suggestive and case based at best. A recent consensus report from the United Kingdom recommended a checklist for primary care providers to structure communication within the patient encounter.⁴³ This checklist was generated following a comprehensive synthesis of evidence pertaining to patient safety errors in primary care and strategies to overcome them. Checklists for patients and providers may support broad adoption of information seeking within the patient-provider relationship and are worth consideration.

Model of Patient Safety in Primary Care

As patient safety expert Robert M. Wachter stated in a 2006 editorial in the *Annals of Internal Medicine*:

*...We now understand that the ambulatory environment is so different from the hospital environment that expertise in hospital care might not predict excellent outpatient care and might even create skills and instincts that are harmful in the ambulatory environment.*²⁶¹

During our environmental scan, we were challenged to identify the structures, processes, and interventions by which patient safety in primary care may be influenced, improved, and further accelerated by the engagement of patients and families. Input from our case study practices, Technical Expert Panel, and other key informants helped frame how to achieve safe care in primary care settings. Based on our work, we propose a new conceptual model leading to improved patient safety in primary care with engagement of the patient, family, and community at its core (Figure 4).

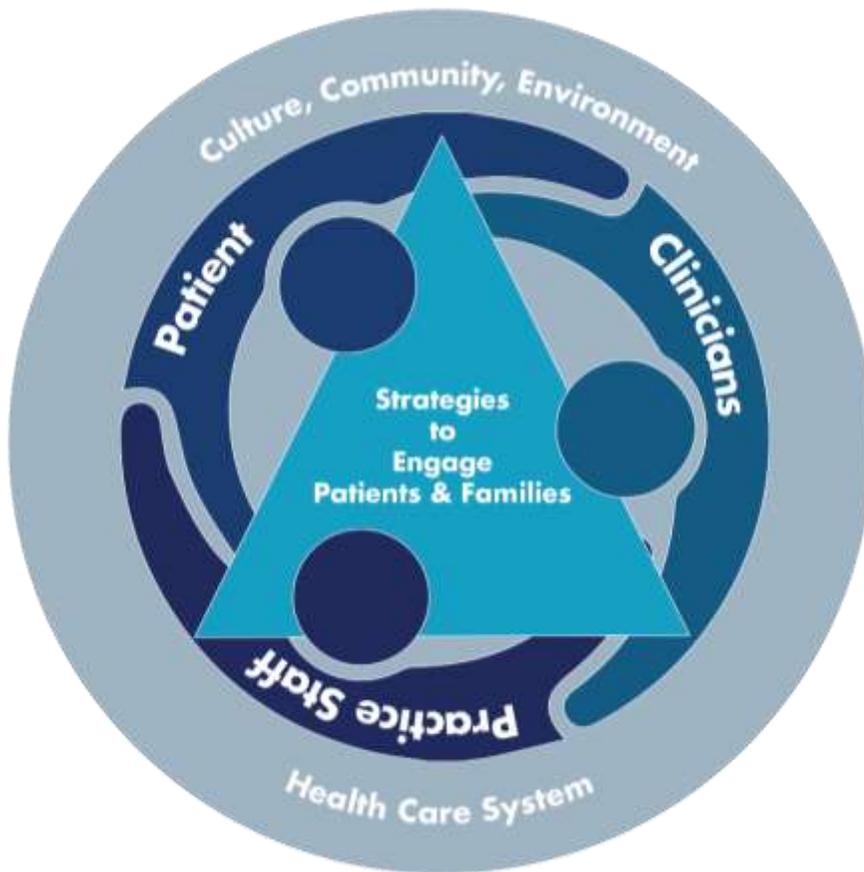
In the model, partnership is key. The patient, clinician, and practice staff member are linked together in a relationship based on communication, respect, and trust. Enabling patient and family engagement strategies (triangle) are mechanisms for patients, providers, and practice staff to enhance this relationship with open flow of information. The model also reflects that primary care practice does not exist in isolation but is part of a broader, complex health care system and is subject to the tensile forces of culture, community, and external environment.

Our model, the “Cycle of Safety,” is predicated on four simple concepts:

1. **Partnership:** Partnership refers to the relationships forged between the patient, provider, and practice staff within the primary care practice. Safe care is greatest when the relationships between these actors are strong. All three groups together represent the “primary care team,” moving away from the traditional paternalistic model of medicine into one of collaboration, mutual respect, and trust.
2. **Teamwork:** Strategies to improve teamwork and inclusion of the patient and family as part of the health care team are safety imperatives in primary care. As a team, all partners know their roles and what is expected of them in order for the team to perform effectively. The model recognizes that patient engagement is a continuum from disengaged to activated and empowered. In a resilient team, the other members adapt and accommodate individual differences while pursuing a common goal. In the case of a disengaged patient, bringing in additional support networks, within the patient or provider nodes, may be required to move the patient onto the path toward activation.
3. **Community:** Another key component of our model is the concept of community. Here, community influences, including practice location, sociodemographic characteristics of the patients, and community-based resources (including grocery stores, pharmacies, and safe places for children to play and adults to exercise) are all contributing factors to safety in primary care. Attention to the health of communities is vital to developing a safe culture.

4. **Health care environment:** The model also recognizes that the practice of primary care is strongly influenced by external forces, including policy, health reform, and practice transformation efforts. By establishing the core values of the practice around partnership, teamwork, and community, a primary care practice will create a resilient microsystem within which to promote patient safety.

Figure 4. Model of Patient Safety in Primary Care



Gaps Identified

Gaps in Strength of Evidence

Evidence Gap 1: Few Well-Evaluated Studies on Patient Engagement To Improve Patient Safety in Primary Care

The evidence base for improving patient safety in primary care settings by engaging patients and families is overall suggestive or modest at best. Our team identified several gaps in evidence that could serve for further study and attention in further developing the Guide. Of note is how few of the interventions we reviewed were carefully evaluated. Only 33 (35.1%) of the peer-reviewed literature and 68 (20.7%) of the grey literature reports described an evaluated intervention. The lack of rigorous evaluation and the limited approaches to standardized evaluation through validated surveys or other means represent gaps in the literature.

In terms of safety issues addressed, the grey literature is much more focused on studies addressing fragmentation of the care system (75.3%) and communication between patients and providers (85.4%). The corresponding percentages for the peer-reviewed literature are 25.5% and 36.2%, respectively. This suggests a gap in the peer-reviewed literature addressing fragmentation and communication between patients and providers.

On the other hand, medication prescription, management, drug interactions, and adherence (57.4%) and antibiotic, opioid, and other medication overuse (10.6%) are relatively more common in the peer-reviewed literature; the corresponding percentages for the grey literature are 36.3% and 2.1%, respectively.

Gaps in Practice Patient Safety Infrastructure

Infrastructure Gap 1: Limited Evidence on Infrastructure To Support Safety in Primary Care

The environmental scan revealed gaps in primary care practices to identify, review, and disclose medical errors.^{262,263} Organizational and operational structures that exist in hospital settings such as patient safety event reporting systems, patient safety officers, peer review committees, and other structures for safety are rare in individual primary care practices. Instances of these structures appear limited to those practices affiliated with large health care systems, but attention within these systems often focuses on acute care settings.

AHRQ's efforts on consumer reporting may be one strategy to support primary care practices in identifying common causes of error in the practice environment. However, a practice's inability to support the infrastructure of a robust safety program may limit detecting, addressing, and learning from medical errors in primary care. Future research is needed to address optimal approaches to event review/root cause analysis, and failure modes and effects analyses, as well as the costs associated with safety improvements in primary care.

Gaps in Measurement

Measurement Gap 1: Limited Evidence of Measures To Assess Patient Safety in Primary Care

While not a focus of our environmental scan, our work did reveal a dearth of outcome measures for patient safety in primary care. Assessment of patient safety in primary care is limited not only in the small number of validated measures of safety but also by practices' inability to conduct routine measurement of traditional safety outcomes. Discrete tests of change in patient safety in primary care are rare.²⁶⁴ With few measures of patient safety available specific to primary care, evidence of improvement in patient safety within primary care settings is inherently anecdotal, case based, and ripe for transformation.

AHRQ's survey on medical office safety is one of the strongest and most widely used assessment tools currently available to measure safety culture in practices.²⁶⁵ Another surrogate measure of safety has been through the evaluation of malpractice claims.¹³⁵ As attention in the field of patient safety continues to shift focus to the ambulatory care setting, several new measures of safety have recently emerged. One promising measure is the Patient Measure of Safety for use within the acute and primary care settings.^{266,267} Until these measures are

implemented to scale, surrogate measures of patient safety such as patient satisfaction and claims will continue to dominate the field.^{165,268}

Measurement Gap 2: Limited Measures To Assess the Impact of Engagement on Patient Safety

Another gap identified during our environmental scan was in the assessment of patient and family engagement. Most of the literature assessed engagement of patients and families using surrogate measures such as health outcome improvements and patient satisfaction, and through qualitative reports of satisfaction with engagement approaches.^{7,58,67,269} To this end, the evidence base for improving patient safety by engaging patients and families is thin.

Publication of the psychometric properties of the Patient Health Engagement Scale is a good first step in improving measures of engagement.²⁷⁰ Assessment of patient activation is also a potential measure that may be linked to patient safety improvements. However, widespread adoption of measures of activation have not yet been described in primary care.^{181,271–273} Whether these measures are directly related to improvements in patient safety is also an area requiring further study.

Gaps in Usability of the Tools Identified

Usability Gap 1: Limited Evidence of Patient Involvement in Intervention Development

The peer-reviewed and grey literature demonstrates a significant number of tools, resources, and interventions targeting patient engagement in health care. Many of these tools, however, have limited evidence of end-user (i.e., patient) input into development of the tool or involvement in usability and dissemination activities. The scan revealed little information on usability of common tools such as medication lists or tools that support patient readiness for doctor visits.

Instructions for how to use and get started using the interventions were also limited. In addition, many of the tools, toolkits, and resources reviewed appeared appropriate for patients who were already activated, engaged, and empowered. We found cases of minimal attention to less engaged patients. This gap has significant implications for the Guide and the Guide development process.

Usability Gap 2: Culturally Sensitive and Culturally Appropriate Tools

Overall, our environmental scan revealed that despite the diversity of health care settings and recipients of care across the Nation, there is a general lack of culturally appropriate or culturally specific tools for patients and families. We found few tools that were tailored to specific populations or that addressed or acknowledged the need to accommodate specific cultural, racial, ethnic, or religious needs of patients and families. There is also little evidence to suggest the effectiveness of existing tools for differing cultural needs.

Specific gaps in the tools reviewed include little attention to interventions addressing limited English proficiency, the need for translators or other language support services within primary care settings, and barriers to health literacy. Few of the patient-focused tools catered to patients and families with lower or limited health literacy. Related to this issue, there does not seem to be a consensus on what would be an appropriate way to test or assess the health literacy level of existing tools in order to modify them appropriately.

Limitations of the Environmental Scan

The strength of evidence supporting patient safety improvement through intervention varies. Our approach sought to triangulate evidence, wherever possible, from the peer-reviewed literature,^{6,198,274} domain experts (patients, providers, practice staff/leaders, policy and research experts), and a robust grey literature search. Our findings indicate a lack of strong evidence of the effectiveness of patient and family engagement strategies on improving patient safety in primary care settings. Much of the work identified draws on expert panel recommendations, technical expert panel reports, and well-described case studies of interventions. Large-scale demonstration projects in the field have not yet emerged for many of the recommended practices.

Our review depended heavily on targeted searching of the grey literature through Web sites, conference proceedings, and social media outlets to identify practices to improve patient safety. Many organizations used source documents, such as AHRQ's "Questions are the Answer"⁶³ or the National Patient Safety Foundation's "Ask Me 3"²⁷⁵ program materials, and tailored them to their specific audiences' needs. Thus, while many tools are available, evidence on the usability and feasibility of implementing them in practice was limited.

We continue to receive emails on a near daily basis about new and emerging tools within the domains of patient safety, primary care, and patient engagement. Our plan is to review these interventions on an ongoing basis and incorporate the findings into Guide development.

Implications for the Guide

Implication 1: Patient Safety in Primary Care Continues To Evolve

The fields of patient safety and patient and family engagement in primary care settings are evolving at a tremendous rate. Our initial environmental scan focused on literature, reports, and resources published between 2012 and November 2015. Since that time, our team has received almost daily notifications of emerging tools, technologies, interventions, toolkits, and consensus reports that continue to frame the state of the evidence within the field. Where possible, we have included these resources and integrated them into the narrative.

It is anticipated that the fields of patient safety and patient engagement in primary care will continue to outpace our ability to identify, review, and synthesize the evidence during our work and that our interventions themselves will emerge at a time of increased readiness for change in the health care landscape. In addition, multiple initiatives are competing for provider and practice attention for implementing change at the practice level. Coupled, these forces may affect Guide development and dissemination, as well as practice recruitment efforts for field testing the Guide.

Strategies to mitigate the impact of competing priorities and environmental pressures include maintaining awareness of competing initiatives and looking for areas of synergy where appropriate. Our project team members are actively engaged in other projects within the fields of patient safety and patient and family engagement, including the Centers for Medicare and Medicaid Innovations Transforming Clinical Practice Initiative and the Centers for Medicare & Medicaid Services next iteration of Partnership for Patients.

These initiatives focus on improving patient outcomes with clinical transformation in the practice environment through engagement of patients and families. Dissemination of the Guide case studies, interventions, and implementation strategies within the full Guide are happening early in the development of these initiatives. This approach presents significant opportunities to have our work incorporated into these large-scale demonstration and implementation projects.

Implication 2: Engagement Interventions Need To Focus on the Patient as Change Agent

Our environmental scan found a significant body of work on approaches to engage patients and families in their care. Those interventions that also aimed to improve patient safety were targeted toward changing the patient's individual behaviors. These include interventions to encourage patients to speak up, ask questions, maintain and carry comprehensive medication lists, and act as a champion for safety and quality in their own care. Challenges in patient adoption of these interventions stem from vulnerability of the patient, illness, literacy and health literacy, activation, empowerment, and confidence to speak up.

For Guide development, we will need to ensure that we provide guidelines and implementation strategies for each stakeholder in the model of safety to support adoption. Patient-focused materials will also need recommendations and guidelines for providers and practice staff in how to support patients in adopting these tools and interventions as part of complex behavior change activities. This approach will require additional development to complement existing materials revealed during the scan.

Implication 3: Education Alone Is Unsustainable

The preponderance of evidence revealed during our environmental scan included “education” as a key driver in behavior change to improve patient safety by engaging patients and families. Evidence and experience in patient safety, however, demonstrate the limitations of education to support widespread adoption of health behaviors or to integrate sustainable programs, processes, and practices into daily workflow.²⁷⁶

Implications for the Guide development process include bringing our human factors and safety specialists, health behavior change experts, and adult learning specialists together with our patients and primary care providers and practice staff to build robust processes to support adoption in practice. Feasibility of implementation will be guided by practice stakeholders and experts in establishing patient-centered medical homes.

Our Technical Expert Panel will also engage in development efforts, lending their experience and expertise to the work. This innovative and comprehensive approach to intervention and Guide development should yield sustainable processes and practices for patients, family members, providers, and practices to adopt to improve patient safety.

Implication 4: Evidence Is Limited on Usability of Identified Resources

While the environmental scan identified more than 300 tools, toolkits, interventions, and resources to support improvement of patient and family engagement and patient safety in primary care, usability of these approaches varied quite a bit. We found the strongest evidence

of usability in tools and toolkits that were multifocal and provided several methods and mediums from which providers, practice staff, and patients could learn how to use and adopt the tools in practices.

To overcome issues with end-user adoption of the interventions developed as part of the Guide, our Guide development team will use a multimodal strategy for reviewing the interventions with all three stakeholder groups (patients, providers, and practice staff). We will identify barriers and facilitators of adoption in practice and will validate our assumptions with these stakeholders in a process of participatory action.^{277,278} Our team's experiences with these approaches, coupled with the opportunity to engage experts in health care complexity, influence, simulation, behavior change, human factors, and usability, should yield sustainable and usable interventions.

Implication 5: Health Equity and Literacy Need To Be Addressed

Health literacy is a major concern affecting usability of the tools, techniques, and resources identified, but few of the materials we reviewed for this scan were at a literacy level or health literacy level that would influence adoption for many of AHRQ's priority populations. An additional consideration for our Guide is that one size does not and will not fit all, especially when we consider the diversity of the patients and families who will use it.

To overcome this potential gap, special consideration from a health equity perspective will be given. The goal will be to understand the end users (race/ethnicity, age, gender, sexual orientation, social status, place of residence, educational attainment, etc.) and their unique needs in terms of how the Guide would realistically serve them.

The Guide (and interventions) will need to be adapted to address specific population groups' needs and circumstances in order for the Guide to have its intended and optimal impact, fairly and equally for all users. Our team of subject matter experts includes expertise in health equity, literacy, and community action at the patient level and the scientific perspective. Efforts to develop culturally sensitive and appropriate approaches to reaching patients at all literacy levels will be considered.

Next Steps

Over the coming months, we will continue to work with our project partners, AHRQ team, and Technical Expert Panel members to identify and prioritize interventions to include in the *Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families*. The field of patient safety in primary care continues to evolve. Our work is emerging at a time of tremendous transformation within the health care system as organizations across the country take up the banner of population health.^{279–281}

At no other time in history has primary care been so central to the long-term sustainability of our population's health. Our model (Figure 4) will aid in translating our thinking of patient safety in primary care and will guide our efforts to ensure that each intervention selected addresses the needs of patients and families, primary care providers, and practice staff. Our team will remain vigilant in efforts to be informed of changes in policy and practice in the primary care domain to promote interventions that are feasible, achievable, and sustainable.

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Appendix A. Informant Interview Guide

Key Informant Interview Guide - Telephone

Interviews will be conducted by telephone and will be audio recorded with participant consent.

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At the time of the interview, interviewer will ask participant over the phone if he or she agrees to be interviewed and audio taped. A waiver of documentation of informed consent will be obtained from MedStar Health Research Institutes Institutional Review Board.

Interviews will take approximately 60 minutes each.

Interview Protocol for Domain Experts

[bracketed text will depend on interviewee or topic]

INTRODUCTION

Thank you for agreeing to do this interview! My name is [Insert Name of Interviewer] and I will be asking you questions today about patient safety, health literacy, and what you have done to improve these conditions in primary care settings.

As you know, this project is being funded by the Agency for Healthcare Research and Quality, which is a federal agency that works to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

The purpose of today's interview is to learn about your experiences with [the tool that you were involved in that helps patient safety in primary care settings.] We will take about an hour or so.

[Interviewer will read the key informant the study description and request a consent to participate in the interview. Oral agreement to audio record will be recorded. If consent submitted, ask if the individual has any questions about how the input will be used and mention that once the interview has been transcribed the audiotape will be destroyed.]

Thank you!

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0179), AHRQ, 5600 Fishers Lane, Mail Stop Number 07W41A, Rockville MD 20857.

Concept: Research Question

Stem Question: Please review the proposed research question. Given the task that we have been asked to achieve, do you think we have the correct research question?

Probes: What other questions do you think we should ask?
What might help us to better define the research question for this project?

Concept: Patient and Family Engagement

Stem Question: What does patient and family engagement mean to you?

Probes: How would you define it?
What other terms would you use to describe engagement?
Are there examples of how engagement could be accomplished in physician offices?

Stem Question: How would you describe the differences or similarities between patient-centered care and patient and family engagement in care?

Probes: Could you describe optimal engagement?
How about activation? How is activation different than engagement?

Stem Question: Can you describe how patient and family engagement might be leveraged to improve patient safety?

Probes: Is this from personal experience? If yes, can you describe that experience?
What type of settings has this been used in?

Concept: Patient Safety in Primary Care

Stem Question: Can you describe any patient safety problems in primary care settings?

Probes: Are there solutions or interventions that could prevent these safety issues?
Can you describe the interventions?
Have you experienced any of these approaches?

Concept: Dissemination to Primary Care Practices and Patients

Stem Question: We would like your help in identifying the best approaches to engaging patients, primary care providers, and primary care practice staff in adopting this work. Do you have any suggestions on how we might achieve this?

Probes: Do you think social media campaigns may be beneficial?
How about presentations?
Which conferences would be best suited to these interventions?
What about new outlets? Radio? Television? Web sites?

Key Informant Interview Guide – In Person

Interviews will be conducted in person and will be audio recorded with participant consent.

At the time of the interview, interviewer will ask participant if he or she agrees to be interviewed and audio taped. A waiver of documentation of informed consent will be obtained from MedStar Health Research Institutes Institutional Review Board.

Interviews will take approximately 30 minutes each.

Interview Protocol for Domain Experts

[bracketed text will depend on interviewee or topic]

INTRODUCTION

Thank you for agreeing to do this interview! My name is [Insert Name of Interviewer] and I will be asking you questions today about patient safety, health literacy, and what you have done to improve these conditions in primary care settings.

As you know, this project is being funded by the Agency for Healthcare Research and Quality, which is a federal agency that works to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

The purpose of today's interview is to learn about your experiences with [the tool that you were involved in that helps patient safety in primary care settings]. We will take about a half hour or so.

[Interviewer will read the key informant the study description and request consent to participate in the interview. Oral agreement to audio record will be recorded. If consent submitted, ask if the individual has any questions about how the input will be used and mention that once the interview has been transcribed the audiotape will be destroyed.]

Thank you!

Public reporting burden for this collection of information is estimated to average 30 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0179), AHRQ, 5600 Fishers Lane, Mail Stop Number 07W41A, Rockville, MD 20857.

Concept: Research Question

Stem Question: Please review the proposed research question. Given the task that we have been asked to achieve, do you think we have the correct research question?

Probes: What other questions do you think we should ask?
What might help us to better define the research question for this project?

Concept: Patient and Family Engagement

Stem Question: What does patient and family engagement mean to you?

Probes: How would you define it?
What other terms would you use to describe engagement?
Are there examples of how engagement could be accomplished in physician offices?

Stem Question: How would you describe the differences or similarities between patient-centered care and patient and family engagement in care?

Probes: Could you describe optimal engagement?
How about activation? How is activation different than engagement?

Stem Question: Can you describe how patient and family engagement might be leveraged to improve patient safety?

Probes: Is this from personal experience? If yes, can you describe that experience?
What type of settings has this been used in?

Concept: Patient Safety in Primary Care

Stem Question: Can you describe any patient safety problems in primary care settings?

Probes: Are there solutions or interventions that could prevent these safety issues?
Can you describe the interventions?
Have you experienced any of these approaches?

Concept: Dissemination to Primary Care Practices and Patients

Stem Question: We would like your help in identifying the best approaches to engaging patients, primary care providers, and primary care practice staff in adopting this work. Do you have any suggestions on how we might achieve this?

Probes: Do you think social media campaigns may be beneficial?
How about presentations?
Which conferences would be best suited to these interventions?
What about new outlets? Radio? Television? Web sites?

Appendix B. Search Terms

Concept Domain	Search Terms
Patient and Family Engagement	Patient engagement Family engagement Caregiver Patient centered care Engagement Activation Empowerment Social support Patient and Family Advisory Committees Shared decision making Decision making Patient advocacy Patient advisors Patient champions Family participation Patient participation Patient satisfaction Customer service
Patient Safety	Patient safety Safety Safety culture Safety climate Medical error Disclosure Adverse events Just culture Error reporting Reporting culture Communication Error Harm Diagnostic error Defensive medicine Testing Leadership Safe care Sentinel event Serious safety event High reliability
Primary Care	General Internal Medicine Internal Medicine Family Practice Pediatrics Geriatrics Pediatrician Geriatrician Family Medicine Prevention Services Care management Physician Nurse Nurse practitioner

Concept Domain	Search Terms
	Physician assistant Primary practice General practice General Practitioner
Change Theories	Organizational change Process management Transtheoretical model Stages of change
Intervention	Intervention Tool Toolkit Approach Protocol Process Procedure

Appendix C. Sample Search Strategies

The following represent sample search strategies used by AHRQ to identify published literature in Patient Safety Net (PSNet):

“medical errors”[MeSH Terms] OR “iatrogenic disease”[MAJR] OR “sentinel event*”[tw] OR “disclosure”[MeSH Terms] OR (“Safety”[MeSH] OR “Safety Management”[MeSH]) OR “Systems Theory”[All Fields] OR teamwork[All Fields] OR “crew resource management”[All Fields] OR “learning organization”[All Fields] OR “high reliability”[All Fields] OR HRO[All Fields] OR mindfulness[Text Word] OR “patient safety”[All Fields] OR “safety culture”[All Fields] OR “systems approach”[All Fields] OR “medical error*”[All Fields] OR “medical mistake*”[All Fields] OR “adverse event*”[All Fields] OR checklist

((medical error [mh] OR Diagnostic errors [mh] OR iatrogenic disease [mh] OR sentinel surveillance [mh] OR safety [mh] OR (adverse [ti] AND (drug* [ti] OR event* [ti])) OR (medication* [ti] AND (error* [ti] OR safety [ti])) OR iatrogenesis [ti] OR iatrogenic [ti] OR ((medical [ti] OR treatment [ti] OR care [ti]) AND (injury [ti] OR injuries [ti])) OR mishap* [ti] OR (root [ti] AND cause* [ti]) OR (failure* [ti] AND mode* [ti]) OR RCA* [ab] OR FMEA [ab]) OR (((hospital information systems [mh] OR decision support systems, clinical [mh] OR drug therapy, computer-assisted [mh] OR Clinical Pharmacy Information Systems [mh] OR Medical Records Systems, Computerized [mh] OR ((computerized [ti] OR computerised [ti] OR computer [ti] OR computer-based [ti]) AND (order* [ti] OR entry [ti]))) OR ((human [ti] AND factor* [ti] OR ergonomic* [ti] OR human engineering [ti] OR Communication OR judgment [mh] OR Problem solving [mh] OR disclosure [ti] OR (incident* [ti] AND (report* [ti] OR critical [ti])) OR Work Schedule Tolerance [mh] OR Workload [mh] OR sleep [ti] OR fatigue [ti] OR teamwork [ab] OR disclosure [ti] OR accreditation [ti]) OR (Cross Infection [mh] OR Infection Control [mh] OR nosocomial [ti] OR hospital-acquired [ab] OR Drug Resistance, Microbial [mh] OR (Infection [ti] AND Control [ti]) OR handwashing OR (hand [ti] AND (hygiene [ti] OR disinfection [ti] OR wash [ti]))) OR (Accidental Falls [mh] OR (fall* [ti] AND (preventing [ab] OR prevention [ab] OR reducing [ab] OR reduction [ab] OR aged [mh] OR elderly OR geriatric)) OR Decubitus Ulcer [mh] OR ((pressure [ti] OR decubitus [ti]) AND ulcer* [ti]) OR decubiti [ti])) AND (((Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR Comparative [ti] OR effectiveness [ti] OR Evaluation [ti] OR Feasibility [ti]) AND (trial [ti] OR Studies [ti] OR study [ti] OR Program [ti] OR Design [ti])) OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh] OR systematic [sb]))

This strategy served as a basis for the peer-reviewed literature searches and was tailored for the primary care setting.

Appendix D. Organizations and Web Sites

AHRQ literature and Web sites searched included the following (in alphabetical order):

- A Decisionmaker’s Guide to Adopting Innovations
- AHRQ Innovations Exchange
- Comprehensive Patient Safety and Medical Liability Communication and Program Resolution Education Toolkit (CANDOR)
- Designing Consumer Reporting Systems for Patient Safety Events
- Detecting, Addressing, and Learning from Patient Identified Breakdowns in Care (aka - We Want to Know)
- Engaging Patients and Families in the Medical Home
- Five Steps to Safer Health Care
- Guide for Developing a Community-Based Patient and Family Advisory Council
- Guide to Patient and Family Engagement in Hospital Quality and Safety (the “hospital report”)
- Guide to PFE in Hospital Quality and Safety
- Patient and Family Engagement Module of the CUSP Toolkit
- Planning and demonstration projects under the Medical Liability Reform and Patient Safety Initiative such as The Seven Pillars: Crossing the Patient Safety—Medical Liability Chasm
- PSNet
- Workshop on Consumer Engagement in Selected Patient Safety Topics

Other organizations that address patient safety and/or patient and family engagement (in alphabetical order):

- AARP
- Accreditation Council for Graduate Medical Education
- Alliance for Continuing Medical Education
- American Academy of Cardiology
- American Academy of Orthopedic Surgeons
- American Academy on Communication in Healthcare
- American Academy on Physician and Patient
- American Cancer Society
- American Case Management Association
- American College of Chest Physicians
- American Health Insurance Plans
- American Heart Association
- American Hospital Association
- American Lung Association
- American Medical Association
- American Organization of Nursing Executives
- America’s Health Insurance Plans
- Anthem

- Association of State and Territorial Health Officials
- Australian Commission on Safety and Quality in Health Care
- Axiom Action
- Be Med Wise
- California HealthCare Foundation
- Canadian Patient Safety Institute
- Care Transitions Program
- Case Manager Society of America
- Center for Advancing Health
- Center for Advancing Health Engagement framework
- Center for Patient Partnerships
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Cincinnati Children's Hospital Medical Center
- Citizens for Patient Safety
- Commonwealth Fund
- Consumer Med Safety
- Consumers Advancing Patient Safety
- Consumers Union
- Dartmouth-Hitchcock Medical Center
- Department of Defense
- DHHS Partnership for Patients Campaign
- diagKNOWsis
- Empowered Patient Coalition
- Every Patient's Advocate
- Gordon and Betty Moore Foundation
- Harvard School of Public Health, Health Literacy
- Health Care for All
- Health Literacy Now
- Health Research and Educational Trust
- Health Resources and Services Administration
- Informed Patient Institute
- Institute for Family-Centered Care
- Institute for Health Care Communication
- Institute for Healthcare Improvement
- Institute for Patient- and Family-Centered Care
- Institute of Medicine
- Josie King Foundation
- Kaiser
- Leapfrog Group
- Malcolm Baldrige Quality Award
- Manitoba Institute for Patient Safety
- Maryland Patient Safety Center
- Massachusetts Coalition for the Prevention of Medical Errors

- Maximus Center for Health Literacy
- Medically Induced Trauma Support Services
- Medicare and Medicaid patient and family education/engagement materials
- Medicare Rights Center
- Minnesota Alliance for Patient Safety
- National Academy for State Health Policy
- National Association of Children’s Hospitals and Related Institutions
- National Association of County and City Health Officials
- National Center for Cultural Competence
- National Committee for Quality Assurance
- National Family Caregivers Association
- National Initiative for Child Healthcare Quality
- National Institutes of Health
- National Patient Safety Agency (United Kingdom)
- National Patient Safety Foundation
- National Transitions in Care Coalition
- New Health Partnerships
- Partnering for Patient Empowerment through Community Awareness Partners
- Partnership for Healthcare Excellence
- Partnership for Patient Safety
- Patient Centered Outcomes Research Institute
- Patient/Family Safety Council—Calgary, Alberta
- Patients are Powerful
- Patients.About.Com
- Persons United Limiting Sub standards and Errors in Health Care
- Persons United Limiting Sub standards and Errors of America
- Persons United Limiting Sub standards and Errors of NY
- Picker Institute
- Picker Institute Europe
- Planetree
- Quality and Safety Education for Nurses
- RAND
- Robert Wood Johnson Foundation
- Save the Patient
- Society of Critical Care Medicine
- Society to Improve Diagnosis in Medicine
- State hospital associations
- The Joint Commission
- UC Berkeley (CA program on access to care)
- United States Pharmacopeia
- Voice for Patients
- Winnipeg Patient Safety Council
- World Health Organization—Patients for Patient Safety

Health care providers (in alphabetical order):

- Aurora Health Care
- Carilion Clinic
- Children's Hospital of Philadelphia
- Christiana Care
- Dana Farber Cancer Institute
- Emory Health System
- Genesys Health System
- Group Health
- Health Systems of Eastern Carolina
- Lucile Packard Children's Hospital at Stanford, CA, Magnet in Nursing Excellence
- MCG Health, Augusta, GA
- MedStar Health
- Memorial Health System of Hollywood, Florida
- Prince George's County Health Department
- U.S. Department of Veterans Affairs
- University of Colorado Medical Center, Denver
- University of Washington Medical Center
- Vermont Oxford Network

Appendix E. Category Definitions

Safety Issues

1. Fragmentation of the care systems and transitions between providers

Definition: The transition of patients between providers is fragmented, at times resulting in the loss of critical information and valuable time on behalf of the provider and the patient.

2. Communication between patients and providers, health literacy

Definition: Communication of necessary health information (diagnostic, treatment, prevention, etc.) between patients and providers can be fragmented, infrequent, or nonexistent. In addition, patients who are health illiterate cannot understand critical information about the management of their own care and well-being.

3. Diagnostic errors, management of test results

Definition: Errors in diagnosis, medication, and communication/management of test results on behalf of the provider can have serious patient safety consequences. Reporting such errors is critical to ensuring patient safety and provider accountability.

4. Medication prescription, management, drug interactions, adherence

Definition: Medication management on behalf of the patient is often a safety issue when patients do not correctly manage their medications or adhere to treatment guidelines.

5. Antibiotic, opioid, and other medication overuse

Definition: The overuse of antibiotics and opioids can pose long-term safety consequences for the individual as well as the community in terms of antibiotic resistance and opioid addiction.

Safety Solutions

1. Care team models, including expanded care teams

Definition: Collaborative teams of providers work together to integrate new models of care to combat fragmentation, particularly with pharmacists.

2. Medication lists, reconciliation, programs to enhance adherence

Definition: Health information technology can include mobile messaging, telemedicine, electronic health records, etc., to improve communication between patients and providers and exchange of critical health information.

3. Patient and family advisory councils, boards, committees

Definition: A group consisting of patients, providers, and practice or hospital staff and/or administrators engaged together to improve the function, structure, and processes of the health care organization.

4. Educational interventions

Definition: Educational interventions seek to fill in knowledge gaps for patients about critical aspects of the care, including (but not limited to) information about diagnosis, treatment, prevention, and illness self-management.

5. Shared decisionmaking models

Definition: A shared decisionmaking model prompts the provider and patient to share available evidence in order to make an informed decision together that best fits the patient's needs and preferences.

6. Family engagement in patient care (*patient engagement is a given*)

Definition: Family engagement in patient care occurs when families are prompted by health care providers to engage to provide additional support, particularly when it comes to treatment adherence and prevention.