

Evidence-based Practice Center Protocol

Project Title: Patient Safety in Ambulatory Settings

I. Background and Objectives for the Technical Brief

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

We will examine what hospital-based patient safety practices are applicable to ambulatory care, what additional ambulatory care patient safety practices exist, what evaluations have been done of patient safety practices in the ambulatory care setting, what is the amount of, and quality of, the evaluations of patient safety practices in ambulatory care, what is the evidence about spread and adoption of these practices. Particular attention will be paid to organizational models of care, such as the Patient Centered Medical Home.

II. Guiding Questions

The questions below will guide the data collection for this technical brief.

1. What are the evidence-based hospital patient safety practices that may be applicable to the ambulatory care setting? What are the ambulatory care patient safety practices that have been studied in the literature? Which ones have not been broadly implemented or studied beyond a single ambulatory care center?
2. What tools, settings, and other factors (such as implementation of Patient-Centered Medical Home and team-based care) may influence the implementation and spread of ambulatory care patient safety practices?

III. Methods

We will integrate insights from discussions with Key Informants with information extracted from the published literature and grey literature in this Technical Brief.

1. Data Collection

A. Discussions with Key Informants

We will identify nine non-federal Key Informants from major stakeholder groups such as developers of patient safety practices, policy makers, persons overseeing health plan or organization safety, and including a patient advocate. We will begin with interviews of Key Informants (KIs), both individually as well as in a small group setting via phone conference. Interview discussions will focus both on guiding questions, focusing

particularly on topics specific to the KI's area of expertise. Under Guiding Question 1, we will seek insight from Key Informants and AHRQ on which patient safety practices (PSPs) covered in Making Health Care Safer (MHCS) II¹ may be applicable in ambulatory care. We will also gather KI input on ambulatory PSPs not already considered and implementation issues. Lastly, we will gather Key Informant input on organizational models, tools, and settings that may influence ambulatory patient safety and practices.

B. Grey Literature search

We will then conduct our literature search, using methods similar to those used in MHCS II. We will include grey literature from sources such as PSNet and the AHRQ Patient Safety Organization program (PSO) website, the New York Academy of Medicine's Grey Literature Report, Internet searches (e.g., Google Scholar), and government websites, as well as from other resources identified through discussions with our Key Informants.

C. Published Literature search

We will search in Medline (Pubmed), Embase, the Cochrane Collection, PsycInfo, CINAHL, Clinicaltrials.gov, WorldCat, and the Web of Science. Searches will begin with the year 2000. In addition, we will "reference mine" articles of relevance. We will ask the Key Informants to provide references for any studies they believe would be relevant. An updated search will be conducted after submission of the draft technical brief.

The search strategy will use terms such as ambulatory OR outpatient* OR out-patient* OR clinic OR clinics AND "patient safety" OR harm* OR accident* OR complication* OR error* OR discontinuit* OR continuity OR hand-off* OR medication safety OR medical staff fatigue OR medical staff sleep deprivation, in addition to the names of the specific patient safety practices identified by the Key Informants.

Preliminary inclusion criteria include hypothesis-testing studies of interventions in the ambulatory setting in high income countries judged sufficiently same as to the U.S. to be applicable.

2. Data Organization and Presentation

A. Information Management

The DistillerSR software package will be used to manage the search outputs, screening, and abstraction of the study level details. Titles and abstracts identified by the searches, reference mining, and key informants will be dually screened by two literature reviewers against established inclusion criteria, and all selections will be accepted without reconciliation for further, full-text review. Full-text articles will be dually reviewed; disagreements regarding inclusion at the full-text stage will be reconciled. Included studies will go on for dual abstraction of study-level details based on the previous MHCS review, including intervention description, context, implementation, study design, spread, and any other variables determined after input from the KIs.

While the draft report is being peer reviewed, an update search will be conducted, and studies identified in this search will undergo the same review process.

In addition, we will also use an interview guide for discussions with the KIs of the guiding questions and collect information using paper-and-pencil, and then extract from these notes themes relevant to the guiding questions.

B. Data Presentation

We will prepare a draft technical brief report and appendices following AHRQ publication guidance. We will summarize the collected data in tables and figures with explanatory text.

IV. References

1. Shekelle PG, Wachter RM, Pronovost PJ, et al. Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Comparative Effectiveness Review No. 211. (Prepared by the Southern California-RAND Evidence-based Practice Center under Contract No. 290-2007-10062-I.) AHRQ Publication No. 13-E001-EF. Available at: www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html Agency for Healthcare Research and Quality. Rockville, MD: March 2013.

V. Definition of Terms

Not applicable.

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient of policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

IX. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

X. Role of the Funder

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