Technical Brief Disposition of Comments Report

Research Review Title: *Patient Safety in Ambulatory Settings*

Draft review available for public comment from November 24, 2015 to December 22, 2015.

Research Review Citation: Shekelle PG, Sarkar U, Shojania K, Wachter RM, McDonald K, Motala A, Smith P, Zipperer L, Shanman R. Patient Safety in Ambulatory Settings. Technical Brief No. 27. (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290- 2015-00010-I.) AHRQ Publication No. 16(17)-EHC033-EF. Rockville, MD: Agency for Healthcare Research and Quality; October 2016. www.effectivehealthcare.ahrq.gov/reports/final/cfm.

Comments to Research Review

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The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

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Commentator & Affiliation	Section	Comment	Response
KI Reviewer #1	Quality of Report	(did not state)	
KI Reviewer #2	Quality of Report	Good	Thank you
KI Reviewer #3	Quality of Report	Good	Thank you
KI Reviewer #4	Quality of Report	Good	Thank you
Peer Reviewer #1	Quality of Report	Good	Thank you
KI Reviewer #5	Quality of Report	Good	Thank you
KI Reviewer #6	Quality of Report	Superior	Thank you
KI Reviewer #7	Quality of Report	Superior	Thank you
Peer Reviewer #2	Quality of Report	Fair	Thank you
Peer Reviewer #3	Quality of Report	Good	Thank you
Peer Reviewer #5	Quality of Report	Good	Thank you
KI Reviewer #1	General	This is a very important subject, particularly as care continues to transition from acute hospital care to novel ambulatory /community-based models of care	No response needed
KI Reviewer #1	General	The report is overall sound largely confirming what is known by experts in this terrain - it is nonetheless useful to have this confirmed	No response needed
KI Reviewer #1	General	There are important opportunities for U.S. funders to synergize efforts with WHO and other international countries in building an evidence-base to baseline, intervene and scale-up approaches to improve the safety of ambulatory care	No response needed

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General	Overall, this report should be useful for AHRQ in designing a research agenda and useful for readers. The identification of a limited number of key ambulatory patient safety areas from a larger potential list of topics is useful. The summaries are helpful. Overall, I think the report "gets it right" in terms of identifying key safety areas and key issues, and in highlighting the lack of research in virtually all the key areas.	No response needed
Peer Reviewer #1	General	Comments above notwithstanding, I believe that this report is useful, and I found it interesting to read.	No response needed
KI Reviewer #5	General	Overall, the report seems to touch on most of the major issues and themes related to ambulatory safety.	No response needed
KI Reviewer #7	General	Excellent overview of patient safety problems in ambulatory settings. Nice contrast to inpatient settings. Good description of why outpatient settings are more difficult to track. Good specifics with diabetic patient example and insulin dosing.	No response needed
Peer Reviewer #2	General	This is a technical brief that looked at ambulatory care patient safety practices in the literature, their implementation and what contextual factors might affect their implementation. In addition to a literature scan, 8 key informants were interviewed. The goal is to inform AHRQ's research agenda in ambulatory patient safety. This is clearly an important topic which needs further growth and investment. The brief is well written. I have some concerns below for consideration in order to make this document more useful.	No response needed
KI Reviewer #6	General	The report is clear and thorough.	No response needed
Peer Reviewer #3	General	Overall, this is a comprehensive and well-written report on an important topic: ambulatory patient safety.	No response needed

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Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	The High Value Healthcare Collaborative (HVHC) is a provider-led network of 14 delivery systems across the United States. HVHC aims to transform the way we deliver and pay for care through data-driven shared learning. We welcome the opportunity to comment on this particular Technical Brief through our dedicated Patient Safety Program.	No response needed
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	We applaud AHRQ and its Evidence-based Practice Center (EPC) for focusing on patient safety practices in ambulatory settings and agree that a disproportionate share of our attention to patient safety has focused on inpatient care while we increasingly shift care to outpatient settings and home-based care. The report importantly notes the shift in patient safety perspective in ambulatory settings ranging from self-management through system-level interventions—an expanded improvement opportunity continuum. The HVHC Patient Safety Program views this improvement opportunity continuum as shared accountability—in terms of both the patient and the system and the patient and clinical team—and encourage "supported" self-management that includes collaborative treatment planning via patient education, shared decision making, and patient activation.	No response needed
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	Again, the HVHC Patient Safety Program recognizes the importance of this work and supports AHRQ and its EPC in shining a light on gaps in our knowledge of patient safety in ambulatory settings. Establishing a thoughtful research agenda for this area will be an important and useful contribution to the field and the health of our patients.	No response needed

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Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	General	The American Academy of Ambulatory Care Nursing (AAACN) has reviewed the AHRQ draft technical brief titled “Patient Safety in Ambulatory Settings”. It is a timely and important report that offers good insight into the ambulatory practice environment. AAACN, as the national organization devoted to and representing Ambulatory Care Nurses, appreciates the opportunity to submit comments.	No response needed

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Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	General	The American Pharmacists Association ("APhA") is pleased to provide feedback on the Agency for Healthcare Research and Quality (AHRQ) Draft Technical Brief, Patient Safety in Ambulatory Settings. Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, physician office practices, community health centers, managed care organizations, hospice settings, and the uniformed services. The goals of the Technical Brief are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future research. We have reviewed this document and provide the following comments based on input from APhA's members. Thank you for the opportunity to provide feedback on the Draft Technical Brief and for your consideration of our comments. We encourage AHRQ to use APhA as a resource, and we are happy to facilitate discussions between AHRQ and our members who are involved in patient safety efforts in the ambulatory setting, if that would be helpful.	No response needed

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Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	General	APhA strongly supports AHRQ's focus on identifying key issues to improve safety in the ambulatory setting, including the pharmacist's role in patient safety efforts. We believe that the draft document presents a comprehensive approach to addressing the intended goals and wish the panel great success in continuing work on this critically important issue.	No response needed
KI Reviewer #2	General	Overall, this is a clear and concise summary of the state of patient safety in ambulatory settings. The document can benefit, however, from more subheadings, bullet points and shorter paragraphs. At times many key points are included in a long paragraph (see page 17, 22 for examples) where they can easily get lost.	We have attempted to improve this by shortening paragraphs and adding bullets
KI Reviewer #3	General	The report could better consolidate the expert review findings and literature review findings. In the summary and implications, would focus on the five specific areas as well as on infrastructure issues such as culture, workforce safety, new models of care. Also test results and referrals are often including within diagnosis.	We have reorganized the conclusions based on the major themes and included both referrals and test results under diagnosis
KI Reviewer #4	General	Key opportunities for improving the completeness of the work: 1) include quantification of harms from ambulatory patient safety issues. Quantification of harms is important for identifying gaps in the evidence that matter the most for patient safety	We have added this to the future research agenda paragraph.
KI Reviewer #4	General	2) include perspectives other than "error"-based perspectives on preventing ambulatory patient harms.	We have added this to the future research agenda paragraph.
Peer Reviewer #1	General	The bibliography for the report (as opposed to for specific areas of patient safety) is very brief.	Since the majority of the text of the report is synthesizing Key Informant interviews, there are fewer references than a similar amount of text describing the results of a literature review.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General	The report actually provides very little specific information about what ambulatory patient safety practices are in use, though the bibliography and the list of practices are helpful in this regard. Matrix 1 is pretty sparse, perhaps simply reflecting the state of the literature.	We did a literature scan on the 28 selected practices and report what we found. If it is sparse, that is because it is the state of the published literature
Peer Reviewer #1	General	It can be difficult to say when one is talking about patient safety and when one is talking about quality, and at times the report seems arbitrary in its choices (but this may be inherent in the difficulty of distinguishing quality from safety). For example, medication adherence was considered a quality outcome and not a safety outcome. But hospital readmission was considered a safety outcome. And appropriate anti-- coagulation was not considered a safety issue, though patients are hurt badly every day by too much or too little anticoagulation in the outpatient setting.	We agree this is not a distinct boundary everyone agrees on and we tried to make clear for this report what we considered safety as opposed to quality.
Peer Reviewer #1	General	Some of the topics that appear to be included as ambulatory patient safety issues – if I understand correctly – seem odd – e.g. "life--sustaining treatment" and "mental health" and "multimorbidity"	This is how these topics were rated by our Key Informants, hence they were included in our report.
Peer Reviewer #1	General	Why exclude issues around telehealth? Seems like a prime area for safety issues.	The judgment of our Key Informants did not rate telehealth as important as many other safety interventions/targets.
KI Reviewer #5	General	Although not surprising, much of this is quite skimpy in terms of findings of articles of evidence-based interventions and hence the report itself. It felt like many more pages were devoted to methodology and what was not included, than actual useful findings. Thus my 1st several readings left me w/ a feeling that it seems to almost "end before it begins." (maybe this is a page limit constraint that was imposed for the body of the report; tho this is not stated).	This is a technical brief and is specifically focused on Key Informant interviews and literature scan. It is not a systematic review and is not supposed to reach conclusions about effectiveness of patient safety practices. This may be why it seems as if the findings are not "useful".

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KI Reviewer #5	General	One clear example/illustration of this skimpiness, is the repeated comments of the importance of diagnostic errors on one hand, and the absence of any evidence-based strategies that could be identified on the other hand. It is reasonable that the authors reference the recent Institute of Medicine report, although perhaps they could cull some of the key findings and integrate them into their framework and key informant matrix.	Unfortunately, the Kis did not cite any evidence-based strategies to improve diagnosis. Therefore we did not add them to the key informant matrix. We did add some more detail in the conclusion.
KI Reviewer #5	General	Another area that is obviously important yet seems to be treated too superficially was that of medication errors. In a scatter-shot way, a number of very important areas were touched upon ranging from as dosing errors, to medication reconciliation issues and even (an often overlooked but important error) failure of pharmacies to discontinue medications discontinued by the prescriber; but overall this did not feel like a very comprehensive list of the problems nor granular discussion of strategies to better address.	The Kis had a far-ranging discussion on medication safety, but it was not a comprehensive discussion. Again, we have added to the conclusion about this.

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KI Reviewer #5	General	The whole area of health IT is repeatedly mentioned, with appropriate critical comments of the current state-of-the-art. One needn't be an author of a best-selling book critical of health IT (as one of the informants obviously is) to identify these shooting-fish-in-a-barrel examples, and thus identify EMR's is a major current contributor to error-prone practices. What seems underemphasized, other than invoking their failed promise to do so, is a more detailed strategic discussion of how health IT could be reengineered to deliver on some of these promises. Since the evidence-based literature did not provide much (although I suspect more than was cited here related to more accurate order sentences, legible orders, medication list maintenance, some decision-support successes (allergies, renal dosing)), one would hope that the knowledgeable experts could fill in some of the gaps here. The entire workflow of ambulatory care is being reshaped by EMRs and HIT; we need more discussion of the negative and positive actual and potential impacts on ambulatory errors.	The KI discussion was more focused on unintended consequences than advantages, but we have added to the HIT section of the strategies section to provide specific examples.
KI Reviewer #5	General	One aspect of this report that would not really ring true for a primary care or other ambulatory care physician, is the lack of discussion of (for lack of a better word) "production pressure." Time is the currency of ambulatory care (particularly primary care) and if rushed or overloaded with patients, more error prone care is inevitable. A strategic, quality ambulatory practice would have a culture and praxis continual engagement of this issue, particularly with leadership being attentive and engaged with concerns of front line staff. Medical homes are invoked a number of times in this report, but not really in a way that inspires that much confidence of their ability to engage this issue.	We added this to the intro: Ambulatory providers experience intense time pressure, with current incentives focused on seeing as many patients as possible in a given amount of time. Added to summary and implications: The PCMH model holds appeal in part because KIs felt it conceptually supports safety better than the current fee-for-service structures.

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KI Reviewer #5	General	A somewhat related issue, experienced poignantly by patients, relates to access. While the larger topic is likely outside the scope of this report, having patients be able to access appointments in a timely ways or speak to providers for emergencies or more urgent questions, which seem to clearly impact on adverse outcomes and monitoring and diagnosis failures.	This is an important point but was not considered by our KIs or literature scans.
KI Reviewer #5	General	Appreciate the discussion of the difference between the ambulatory setting in the inpatient setting. This is important to emphasize and might be further dilated upon. Again the extreme time pressures seem to be a big factor here and lack of time to both be fully attentive to patients and their problems as well as follow-up on issues that arise. Lacking a well-developed risk management staff, small practices are particularly vulnerable here. In addition the chaos, and fragmentation, compounded by omnipresent insurance issues (patients switching plans, high co-pays and deductibles, formulary switches, etc.) all fertilize the soil for the nurturing of errors.	We have added to the introduction to emphasize this point further
KI Reviewer #5	General	How will we achieve a "QI culture" for more error-free outpatient care? This crosscutting need was touched on a number of places but seems to me to be so central that additional comments are warranted. This would include engagement and training of the staff, active use of various QI tools, a culture of low tolerance for defects, a highly attuned and sensitive mechanism from hearing back from patients about their experiences particularly with glitches and errors. Of course the role of leadership is key here. I don't see adequate discussion of these areas. Empowering and encouraging patients and staff to speak up and speak out about problems is a related critical aspect of this needed cultural shift.	We have added more detail about safety culture to the conclusions and research agenda

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KI Reviewer #5	General	Burnout. This very real phenomenon is mentioned a number of times in the report. What is burnout? Is it the stress of not having enough time to do the work that needs to be done? Is it feeling of loss of control over one's work, both in space and its content? Is it being alienated from the patient and the organization in which one is working? Is it being discouraged with the content of the practice not matching providers interests and skills (i.e. more bureaucratic and less clinically interesting)? Is it the added burden of after-hours clinical documentation? Or is it simply long hours, overly long hours? And how exactly does this connect with safer or less safe practicing and practices. And what are the safety implications of the answers to each of this series of questions? I appreciate there is only limited amount of space to deal with this here, but hard to overemphasize their importance.	I have added the definition of burnout to the strategies section. The Kis used the term without defining it, so we do not have much additional detail to add. We added to the research agenda more work on burnout
KI Reviewer #5	General	You mention communication related to patient instructions, and with specialists, but one aspect of communication that is critical and needs to be emphasized is communication within the ambulatory office. There is considerable opportunity for error related to communication failures within the care team in the office itself.	This did not come up in the KI interviews.
Peer Reviewer #2	General	The AMA released an important report on ambulatory safety in 2011 but this doesn't seem to be integrated or well-acknowledged anywhere except as a brief reference 7. In fact, that AMA report could have been very useful to this review in terms of concepts, gap areas, opportunities and next steps. On reading this, it often appeared that this brief was trying to reinvent the wheel.	The scope and methodology of the AMA report differed from this technical report, and the conclusions differ as well. That report does not propose a future research agenda. Nevertheless, we have fleshed out how our KI discussions related to the report in the conclusions.

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Peer Reviewer #5	General	Overall a good review of the state of where we are in patient safety in primary care. I did find it a bit narrow in its scope in terms of requiring a safety outcome and in not adapting the in hospital safety practices to primary care in ways that made sense	The need for a safety outcome was our operationalization of Guiding Question #1 "What are the ambulatory patient safety practices that have been studied in the literature?" We judged that an "outcome" was needed to count as being "studied". Also, we did try and adapt the hospital practices to the ambulatory setting, and did make some change to make them sensible for outpatient care.
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	• It was unclear whether or not reports of spread/adoption were gleaned from QIO/QIN reports, the Community-based Care Transitions Program, and/or reports and websites produced by the CMMI-funded HENs.	While the HEN / QIO materials in general are valid resources, their general focus on quality-focused hospital-based interventions made reviewing them outside our scope
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	• A table that compared the CMMI Partnership for Patients 14 priority areas (HEN 1.0 and 2.0) with those included/excluded would be useful. For example, early elective delivery and pre-eclampsia were not noted but were adverse event areas for HENs that clearly crossed to outpatient care; others include but are not limited to pressure injuries, patient falls, MRSA, undue radiologic testing (i.e., unnecessary and unwarranted duplicative testing).	These topics were not identified by our Kis
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	• We were surprised that remote patient monitoring to avoid unnecessary readmissions particularly for congestive heart failure and asthma were not identified as there is a literature in this area. Ambulatory sensitive admissions are a longstanding, recognized adverse event that reflect breakdowns in ambulatory service delivery.	The Kis did not mention ambulatory-sensitive conditions.
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	• We would have liked to have seen results from a modified Delphi approach among key informants to prioritize a final list of patient safety areas in focusing future work. This together with identification of the key informants would help to interpret the validity of the final list of 28 PSPs relevant to ambulatory care.	We have included in our discussion that prioritization may be a next step

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Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	• A clear gap in the literature and practice has been direct patient/caregiver engagement in the design and study of implemented practices. This is particularly important given the important recognition in this report of the expanded improvement opportunity continuum highlighted above.	We added the following to the KI section: KIs discussed the need for evidence to inform optimal patient engagement strategies.
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	General	In reviewing the 28 patient safety practices (PSP) there is a distinctly "academic medicine" feel to the topics. Non- academic office-based care tends to be somewhat isolated, not impacted by Joint Commission standards, non-standardized in staffing roles, responsibilities and education, and somewhat insulated from important PSP topics such as medication reconciliation and a "culture of safety".	We acknowledge this comment, and note it does not seem to require a response
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	General	Clinical Pharmacists rarely exist outside of hospital-sponsored ambulatory care so "medication reconciliation supported by clinical pharmacists" is not likely to be achievable for the office-setting practitioner. The provider performs the medication reconciliation at the time of the visit or point of service and commercial clinical pharmacists (e.g., CVS) interact with the patient at the point of purchase. Utilization of pharmacy benefit manager databases is a helpful technology that supports the medication reconciliation process.	This practice was not identified by our Kis or literature scan. Also, there is evidence in our local market that clinical pharmacist use is expanding, for example UCLA medical group now has clinical pharmacists in 40 outpatient care areas geographically separated from the hospital.
KI Reviewer #1	Abstract	Methods (lines 33-34)- Give details of how key informants were selected	They were selected by the project team with AHRQ input and intended to reflect the diversity of stakeholders
KI Reviewer #1	Abstract	Methods (lines 33-34)- I'm unclear what a literature scan means	A literature scan is not a complete systematic review, for example no attempt is made to extract data about effectiveness or reach conclusions about effectiveness
KI Reviewer #1	Abstract	Methods (lines 33-34)- Explain how the interview and literature scan data were integrated?	These were combined by the project team in a narrative way
KI Reviewer #1	Abstract	Findings (lines 41-42)- Mention of undertaking a targeted review of 28 subjects really belongs in the Methods	We moved this to the method section

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KI Reviewer #1	Abstract	Findings (lines 41-42)- Explain what is meant by 'medication safety' as vague at present	We have changed to medication errors and adverse events
KI Reviewer #1	Abstract	It would be useful to have some conclusions	We have added a "Summary and Implications" heading to the abstract: Both key informant interviews and the literature scan reveal important differences between inpatient and ambulatory safety. There are significant gaps in ambulatory safety research, including a notable lack of studies on patient engagement and timely and accurate diagnosis. Key informants recommend prospective, large-scale studies in diverse ambulatory settings to develop and test ambulatory safety interventions.
KI Reviewer #6	Background	The Background appropriately describes the need to focus on patient safety practices for ambulatory care and why/how ambulatory care differs from inpatient care where most PSP work has focused previously.	No response needed
KI Reviewer #7	Background	Yes, adequately describes clinical problem and compares to inpatient setting to provide contrast. Describes driving factors clearly and in an organized fashion.	No response needed
Peer Reviewer #5	Background	I thought this set the stage nicely. I liked bringing the patient aspects into the discussion	No response needed
Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	Background	The Draft Technical Brief presents a fairly balanced literature evaluation of pharmacists' roles, responsibilities, and results related to patient safety.	No response needed
KI Reviewer #1	Background	Intro Pg. 7- Should IOM not now be referred to as the National Academy of Medicine? (line 8) In any case, please reference the source of the definition	We have revised this so that IOM Is now referred to National Academy of Medicine except when referring to past IOM reports

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KI Reviewer #1	Background	Intro Pg. 7- I don't think it's helpful to refer to a 'patient safety movement' as this conjures up images of trade unions and special interest groups – patient safety is the collective responsibility of all who manage and work in health systems (line 9)	We think this may be a difference in the meaning of the same words in the US and the UK. In the US "movement" will not have this connotation.
KI Reviewer #2	Background	I think the background rings true for me (a primary care provider and researcher). I think a key piece missing however, is the role of the team, especially the office based team, which often includes physicians/providers, medical assistants, office staff, and maybe nursing staff as the minimum -- integration with behavioral/mental health, pharmacy and others is occurring within the office setting, but all these individuals WITHIN the office setting are key players in error and safety.	We have revised this by adding the following: The presence and composition of team- including nurses, pharmacists, assistants, and others- in office settings varies greatly and can affect patient safety as well
KI Reviewer #1	Background	Intro Pg. 7- Please give a glossary of key terms including 'adverse events' (line 11)	Technical briefs normally do not include a glossary of terms. We have tried to define terms when they are first used.
KI Reviewer #4	Background	There is no quantification of the harms from ambulatory patient safety issues? Is this a big problem affecting patients? Which issues cause the most patient harm?	We added the following to summary/ implications: Current evidence does not permit the quantification of harms from ambulatory safety issues; the magnitude of problems remains unknown.
KI Reviewer #1	Background	Intro Pg. 7- Please reference more fully – for example, the IOM report referred to stating that the burden of adverse events may be higher in ambulatory settings than in acute care settings (lines 17-19)	We have added a citation
KI Reviewer #1	Background	Intro Pg. 7- Please spell out all abbreviations with first use e.g. HITECH (line 23)	We have spelled out the abbreviations with first use
KI Reviewer #1	Background	Intro Pg. 7- I think the $30bn is an under-estimate (line 25)	We double checked this number and it is what is reported in the cited reference.
KI Reviewer #1	Background	Intro Pg. 7- Explain the difference between outpatient settings and ambulatory care (line 27); lines 32-33 seem to imply that these terms are being used as synonyms – id that correct?	We changed this to ambulatory throughout

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KI Reviewer #1	Background	Intro Pg. 7- These activities may be indicated depending on the nature of the conditions (lines 39-40)	We agree they are probably indicated in many patients and the point is that, whereas in the hospital setting such "advice" can be formalized in the diet that is ordered, or exercise therapist visit, in the ambulatory setting the patient must take control of these.
KI Reviewer #7	Clarity & Usability	p. 8, line 36/37: "In ambulatory settings, patients must decide when to seek medical care..." This line implies that patients decide on their own, decide independently of clinicians. Maybe it could be, "Patients must choose whether to follow their providers' recommendations about follow up." Or add that sentence. Yes, patients initiate to seek care initially, but generally follow the clinician's advice or decide not to. This is nicely contrasted with inpatient care.	We hanged as follows: In ambulatory settings, patients must decide when to initiate medical care, interact with outpatient health systems, follow provider recommendation and perform their daily health-related tasks.
KI Reviewer #3	Background	May want to define "ambulatory". Does the scope of this report focus on primary care/specialty practices or include ASCs, dialysis centers, home care, nursing homes?	The scope of "ambulatory" is defined later in the methods in point #2.
KI Reviewer #4	Background	Introduces key issues (paucity of data; different patient role in the ambulatory setting from inpatient setting; new changes in HIT; additional perspectives to consider for "errors"). However, a key limitation is the restriction to an "error"-focused perspective. Although mention of the patient role is included, no mention is made of an epidemiologic/injury prevention perspective that has be the successful model for reducing healthcare acquired infections (Wachter RM, Patient safety at ten: unmistakable progress, troubling gaps. Health Aff (Millwood). 2010 Jan-Feb;29(1):165-73) and that has been suggested for outpatient medication safety interventions (Budnitz DS1, Layde PM. Outpatient drug safety: new steps in an old direction. Pharmacoepidemiol Drug Saf. 2007 Feb;16(2):160-5).	We added text to the summary/ implications section

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Peer Reviewer #3	Background	The Introduction is strong; however, I would suggest that the authors consider several additional reasons why error in the ambulatory setting may be prevalent and problematic. For example, ambulatory care involves multiple providers often across healthcare settings. In these situations, communication between providers may be difficult and inefficient making care prone to errors. In addition, ambulatory care is delivered longitudinally and errors may occur because of the time lapse between visits. More thoughtful consideration of unique attributes of the ambulatory setting is important to conceptualize patient safety in this setting.	We have added the time course to the introduction
KI Reviewer #5	Background	Does this section adequately describe the clinical problem that the new intervention is meant to address and discuss current medical practice as it relates to the clinical problem? What are the contextual factors that may be driving the perceived need for this intervention?	We have added the following to the intro: Like hospital care, ambulatory patient safety practices are probably somewhat or very sensitive to context, including size and complexity of the practice, financing, culture, and leadership.
KI Reviewer #5	Background	Good contextualization of ways ambulatory differs from in patient safety. Again I found this section a bit skimpy though perhaps the authors are being constrained by length limits (that I'm not aware of)	We have added more detail to the introduction
Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	Background	The Draft Technical Brief recognizes medication safety as one of 5 concrete safety issues. Medication safety is described as "doing no harm" or at times the somewhat more expanded view of "preventing harm." To address medication safety in a comprehensive manner consider re-framing the "medication safety" dialogue to focus on "safe and optimal medication use."	Per other feedback we have changed to a focus on medication errors and adverse events. "Optimal use" was felt to be too broad for the scope of this report
KI Reviewer #2	Guiding Questions	These are clearly defined and well presented	No response needed
KI Reviewer #3	Guiding Questions	n/a	No response needed
KI Reviewer #4	Guiding Questions	No changes noted	No response needed

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #3	Guiding Questions	The guiding questions are strong and stable throughout the brief. The authors do not note any changes to the guiding questions.	No response needed
KI Reviewer #7	Guiding Questions	No changes made.	No response needed
Peer Reviewer #2	Guiding Questions	Appropriate	No response needed
Peer Reviewer #5	Guiding Questions	Reasonable questions	No response needed
Peer Reviewer #2	General	I also thought the scope was too narrow. The goal was to identify an ambulatory safety research agenda for AHRQ, but then why only focus on interventions (or PSPs)? On page 9 objective, it appears that 'scope of the issue' was also to be better understood but I see that the emphasis is only on available interventions, their evaluation and adoption (and authors note this isn't an effectiveness review?). It should have been an opportunity to identify areas where research to both understand and improve patient safety issues would have been useful.	These guiding questions were given to us as part of the contract and were not changed during the project
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	Guiding Questions	The authors identify that the research was focused on office-based care. Within the context of ambulatory care, this scope could be viewed as too narrow. Ambulatory care encompasses primary care, outpatient specialty services, rehab and other social programs, and includes private office-based care as well as clinics. Ambulatory surgery centers and dialysis centers are also considered ambulatory care.	These guiding questions were given to us as part of the contract and were not changed during the project

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Guiding Questions	The guiding questions were focused on what ambulatory patient safety practices exist and how much they have been studied. But it seems to me that a key question should be what are the key areas in which there may be problems with ambulatory patient safety – this needs to be known before it makes much sense to investigate ambulatory patient safety practices. In fact, most of the report does focus on identifying the key areas of ambulatory patient safety, and relatively little on ambulatory patient safety practices/processes. But since only hypothesis--testing studies were included in the environmental scan, the key areas seem to be identified only from a mere 8 KI interviews. This seems to me to be less than desirable, though I in fact agree with the ambulatory patient safety areas identified. The guiding questions may not be as good as they could be. Would like to know what patient safety problems have been identified and what is being done about them and whether there is a conceptual framework about patient safety problems. In addition, patient safety practices should be aimed at causes of likely errors – e.g. diagnostic errors – but, presumably because of the exclusion of all but hypothesis-- testing errors, there is little discussion of this kind of thing. By only including hypothesis testing studies, the report missed things that could be important ideas to test.	The guiding questions specified patient safety practices and not the epidemiology of ambulatory patient safety harms, hence the report focus on practices
KI Reviewer #6	Guiding Questions	The guiding questions and the reasons for them are stated. There is no mention of whether or not they changed over the course of the work.	No changes were made to the guiding questions

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #5	Guiding Questions	The 2 questions posed seemed a bit awkward and perhaps limiting: (pasted phrases below that I found so; my caps) What are the evidence-based hospital patient safety practices that MAY BE APPLICABLE to the ambulatory care setting tool....MAY INFLUENCE the implementation and spread of ambulatory I might have liked to seen language that was a bit more direct. Perhaps language such as "has been show" or "has been applied" or even "could be promising" although perhaps the questions would lead to the same interventions in any case	The Guiding Questions specified this language. As a technical brief, it is out of scope to conclude that PSPs "have been shown" to be applicable because this requires conclusions of effectiveness which are not in the scope of a technical brief. We used the KI input to identify the hospital based PSPs that may be applicable to the ambulatory care setting, and those 28 practices are presented in the table. Going further and performing a systematic review of effectiveness for those 28 was outside the scope of the technical brief. We identified no studies that assessed how various organizational structures or strategies may influence the spread of ambulatory PSPs, so could not reach any conclusions on this.
KI Reviewer #3	Methods	N/a	No response needed
KI Reviewer #6	Methods	Descriptions of data collection and Key Informant engagement are both concise and thorough.	No response needed
KI Reviewer #7	Methods	1. Yes, clearly describes how data for this report was gathered.	No response needed
KI Reviewer #7	Methods	2. Clearly describes who key informants were, how questions were sent	No response needed
KI Reviewer #7	Methods	3. Clearly describes how questionnaire was sent	No response needed
KI Reviewer #7	Methods	4. Clearly describes discussion, interview	No response needed
Peer Reviewer #3	Methods	The authors use satisfactory methods of key informant interviews with strong guiding questions. The report describes the number of key informants and their role in shaping the report.	No response needed
KI Reviewer #5	Methods	Details of the methodology are very well described and defined as well as clearly detailed in the summaries of each of the calls	No response needed
KI Reviewer #1	Methods	(page 9) Overview - Interchanging between ‘gray’ and ‘grey’ literature (line 9)	We have fixed this and refer to it as "grey" literature rather than "gray"

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #1	Methods	(page 9) Key informant discussions - More information is needed on how they were selected (line 18) (page 9) Key informant discussions - Please explain how/why you chose to undertake 8 interviews – in particular, was saturation reached (line 18)	U.S. government rules specify only nine people can be interviewed. One of our selected Key Informants did not return the needed paperwork in time, so we ended up with only eight Key Informants. KIs were selected to include a diversity of stakeholders. AHRQ had input into selection of KIs.
Peer Reviewer #5	Methods	I am surprised that a Delphi process was not used to answer the guiding questions. This would have allowed a broad perspective from an international group of stakeholders experienced in the topic.	This was not possible within the rules of the program, which require no more than nine participants as Key Informants
Peer Reviewer #1	General	I was surprised to see such a small number of key informant interviews. This is particularly important in this case, because there isn't much research to rely on, and the report's conclusions about what are the key ambulatory patient safety areas are based primarily on the key informant interviews. Also, I would have liked to know more specifically what organizational positions the key informants occupy – not necessarily what organization, but what type, what size, etc. That said, the appendix with detail about what the KIs said is useful.	Federal rules restrict us to no more than nine Key Informants and one Key Informant did not return the needed paperwork in time, hence we weren't able to get more Key Informants. Also, AHRQ rules require at the draft report stage that we ne not list the names and affiliations of the Key Informants. This will be done for the final report
KI Reviewer #5	General	Clearly the interviews yielded more meaty and substantive and diverse ideas, but here again I wonder if interviewing only eight stakeholders constitutes a full enough breadth and depth tapping into knowledge and ideas that are out there. It just simply didn't feel like "saturation" had been fully reached in this qualitative exercise, although perhaps the authors perceived otherwise, and should discuss why they felt so. And as mentioned below I don't get a good feeling of these key informants were. Were the key informants different from the people listed as investigators? I would've assumed there would be more information yet provided if both the investigators and the key informants views were added to these tables (as the investigators must have a wealth of ideas of their own)	We are limited to only nine Key Informants and one of our selected Key Informants did not return the needed paperwork in time, so we ended up with only eight Key Informants. The Key Informants are not the project team members and AHRQ requires they be de-identified for the draft report. At the final report they will be identified which will make it clear to readers what stakeholders are included.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	General	I assume 8 key informants to keep it under 9! But how were they chosen?	Key Informants were chosen to represent a diversity of stakeholder and perspectives on ambulatory patient safety. In the final report they will be identified and that will make it more clear to readers what perspectives were represented
KI Reviewer #5	Methods	Key informants are described in fairly general terms, and is not clear if they are closely in touch with front line practices versus leaders in larger organizations with less front line daily experience. I assume that keeping them anonymous at this stage is standard practice, but it would help to have a better sense of how to interpret their input.	It is AHRQ practice to keep them anonymous at the draft stage. At the final report stage they will be named along with their roles and professional affiliations which should help readers judge how to interpret their input.
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	General	In reviewing the report, there were several areas where additional information would have been beneficial, including: • We would have liked to have seen a list of key informants to understand the balance of perspectives represented. With 8 informants and one of these a dedicated patient advocate, the 7 remaining informants were spread across developers of PSPs, policy makers, and persons overseeing health plan or organizational safety. - For example, two areas that are not reflected in the report are the role of patient reported measures and identification of social determinants (e.g., housing and food security) that directly impact adverse events such as readmissions, mortality, and complications.	The list of Key Informants will be included in the final report. While social determinants of health are critically important in outpatient care, there is simply a lack of data linking them to patient safety. We have added this to the summary and implications as an area for further study.

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #4	Methods	Clearly explained. However, in searching for relevant "gray" literature it may make sense to include professional or governmental guidelines or recommendations. Although these are not necessarily hypothesis-testing evaluations, they may be quite informative and be the basis for existing ambulatory safety activities. For example, CDC Infection Prevention Resources for Outpatient Settings: http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html CDC's Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care, with accompanying Checklist: http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist_508_11_2015.pdf Include existing relevant professional and governmental recommendations (e.g., CDC's Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care, with accompanying Checklist: http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist_508_11_2015.pdf Additional information on infection control in outpatient settings should be added. Good starting point are these 2 links: CDC Infection Prevention Resources for Outpatient Settings: http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html CDC's Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care, with accompanying Checklist: http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist_508_11_2015.pdf	We have added to the report these citations, however since the guiding questions specified "studied in the literature" we restricted inclusion to hypothesis-testing studies.

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #1	Abstract	Methods (lines 33-34)- Explain how the data from key informant interviews were analysed	We have added the following to the methods: These KI teleconferences were audio recorded and transcribed with verbal consent from all participants. We reviewed the transcripts and identified themes inductively using open coding. One team member conducted initial coding, with a second team member reviewing codes. The team arrived at final themes through discussion and consensus. Although we had reached thematic saturation by the third discussion, we completed interviews with all KIs as pre-specified in our protocol.
KI Reviewer #2	Methods	Literature scan is well described, as are the interviews with the KIs. However, the KI interview analysis description is weak, consisting of one sentence on page 10-11.	We have added additional text to the methods.
KI Reviewer #1	Methods	Eligibility criteria (pages 10-13)- It would be helpful to know to what extent these operationalizing criteria were prespecified	The operationalization criteria were mostly pre-specified (hypothesis-testing study, safety target, safety outcomes) but "setting" was defined iteratively with AHRQ as new questions about settings appeared we checked with AHRQ about their importance

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	Methods	Eligibility Criteria: • On page 11, included and excluded ambulatory clinical settings are listed with little rationale. - Clinics (those that are integrated hospital outpatient departments vs independent as well as those that are primary care and specialty care where some procedures are performed) are important to sort out as different types of settings. It is not clear why Emergency Departments (EDs) were excluded and we would strongly recommend ED inclusion given the amount of primary care that occurs in these settings. For both hospital-based vs. independent practices, urgent care, and EDs, is important clarification. As a provider-based clinics must share a common medical record with the hospital, patient safety via care coordination and handoffs should have a higher chance of success than stand alone, ambulatory clinics where electronic records are not interoperable with other clinics or hospitals. Thus the multiple complex patient would be at highest risk of harm it would seem. - Other settings not noted for inclusion/exclusion are urgent care facilities, pharmacies, and dental care clinics. A cross-tabulation of included literature to depict this expanse of setting-specific representation would be informative and serve to highlight important gaps in our understanding.	Emergency departments were (generally) excluded because safety in the ED is already assessed as part of the hospital quality and safety assessment programs. We have created a new table 3 for the settings of the intervention for medication safety which had the greatest amount of studies.
Peer Reviewer #2	Methods	Under eligibility criteria, some of them appear to be arbitrary. Example: No ED or hemodialysis center but inclusion of chemo centers. Some of this rationale needs to be justified—I think there is plenty of similarity between outpatients and ED for example.	We agree that drawing a boundary between clinical sites "included" and "excluded" resulted in decisions that not everyone agrees with, but these boundaries were developed with AHRQ input and reflect their information needs. Hemodialysis, for example, was excluded because it is already a subject of its own particular quality and safety monitoring program. Chemotherapy centers were not which is why they were included.

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #5	Methods	The "inclusion/exclusion" exercise seems in retrospect a bit sterile and arbitrary and fear it may not have contributed as much as hoped (other than perhaps limiting the lit review work of the panel; but seem didn't shed a lot of additional light of what were the key areas)	The literature scan was not meant to answer question about "Key" areas, rather it was meant to answer Guiding Question #1, "What are the ambulatory patient safety practices that have been studied in the literature?"
Peer Reviewer #3	Methods	This section clearly and concisely describes how data for the report was gathered and integrated. The description of the literature review is excellent – particularly the description of the inclusion and exclusion criteria. There were a few exclusion and inclusion criteria that should be explained.	No response needed
Peer Reviewer #3	Methods	a. It is unclear why hemodialysis centers and outpatient surgical centers excluded. These types of settings are likely important for ambulatory safety.	They were excluded by AHRQ because other safety initiatives cover these areas
Peer Reviewer #3	Methods	b. It is unclear why hospital readmissions were considered safety outcomes. This outcome has not traditionally been specified as a safety outcome.	Readmissions was included as a safety outcome because of the perception that is a preventable adverse event.
Peer Reviewer #3	Methods	c. It is unclear what the authors meant by, “simulation studies that used students were excluded.” Perhaps they can describe this type of study.	There were some early interventions tested as simulations on students rather than an actual provider, for example Cioffi, J., N. Purcal, et al. (2005). "A pilot study to investigate the effect of a simulation strategy on the clinical decision making of midwifery students." J Nurs Educ 44(3): 131-4.
Peer Reviewer #3	Methods	d. Given earlier discharges home with urinary catheters and central lines in place, nosocomial infections related to these lines and catheters seem important and relevant to the ambulatory setting.	Such settings and interventions were not excluded
Peer Reviewer #2	Methods	How was Criteria 4 (Reports a safety outcome) defined?	A safety outcome is defined in point #3 on page 12

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Methods	Page 12—titles were screened by requiring the word 'safety' –but why was 'error' excluded from titles? Areas where this methodology was validated included topics such as patient engagement, workforce and infection control where the word error will likely not even show up. Seems like an overly broad exclusion.	"Safety" did not need to be in the title for any of 18 topics and only needed to be in the title for the 10 topics that generated thousands of titles if the article was not published in a major general interest journal or a journal with a focus on patient safety. We validated this method with three of the topics and are therefore confident that our methods were adequate for a literature scan. Studies aimed at decreasing "error" (in the title) were certainly included, for example e-prescribing titles #1, 5, 8, and 11.
Peer Reviewer #5	Methods	Limiting the lit search to papers that reported a safety outcome has severely limited what has been included. This may be necessary to make the review feasible but it seems to me that it also causes the loss of the complexity of what is being tried in primary care.	We did not well explain these methods and have revised this. We are confident these methods are adequate for a literature scan.
Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	Methods	Restricting the search so as to only include those studies with "safety" in the title seems overly limiting especially when the panel would allow for interventions in which potential drug interactions was an outcome (pg. 11/24, #4). If "safety" in the title is a requirement, it appears to erroneously exclude studies involving relevant issues such as "potential drug interactions" unless "safety" is also included in the title.	We did not well explain these methods and have revised this. We are confident these methods are adequate for a literature scan.
Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	Methods	Please consider expanding the pharmacists' role in medication safety to include safe and optimal medication use. It is our opinion this approach would permit inclusion of examples where pharmacists are involved in proactively identifying an optimal medication regimen for a patient in advance of medication administration/prescribing (thereby preventing a medication error) or identifying opportunities for medication modification to prevent unnecessary harms.	We did not expand this section because our view is that it gets into the domain of "quality" and our technical brief concerns "safety".

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #3, Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA, Exec VP and CEO American Pharmacists Association (APhA)	Methods	APhA recommends including the search term “pharmac” in addition to “community pharmac” in the relevant search strategies. This addition would potentially capture additional studies.	We judged adding the limiter about "community" to be a reasonable one given the focus on outpatient care, and that using just "pharmacy" would have included a voluminous literature in in-hospital pharmacy use
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Methods	It is noted that studies of labor and delivery were excluded from this report. AWHONN is not sure why this is included because usually the term labor and delivery doesnt apply to ambulatory care.	Labor and delivery were mentioned as excludes since on the literature scan we did identify studies about midwives and about free-standing "birthing centers", which did not include in our scan
KI Reviewer #7	Findings	Excellent recap of communications problems, fragmented care, pros and cons of EHRs, health literacy issues, social vulnerabilities, patient compliance, and complacency on the part of out patient providers about medical errors.	No response needed
Peer Reviewer #3	Findings	The description of the findings from the key informant interviews is very helpful. The matrix of themes is excellent.	No response needed
KI Reviewer #5	Findings	Seeing the tables with derived from the Key informant their interviews with their conceptual layout and their big holes was quite useful	No response needed
KI Reviewer #1	Findings	Findings (page 13) - Overview - Text on analysis belong in the Methods (lines 13-14)	This is an overview and we would prefer to leave this unchanged, to orient the reader about what to expect in the coming text
KI Reviewer #1	Findings	Findings (page 13) - Questionnaire matrix - Details of data collection belong in the Methods (lines 18-22)	These are included to refresh the readers memory
KI Reviewer #1	Findings	Findings (page 15) - Figure 1 matrix- I found this very difficult to follow	We have improved the readability of the figure.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	Findings	Page 16 - Results of the Questionnaire matrix • Figure 1 is unreadable.	We have revised the figure so that it is easier to read
Peer Reviewer #5	Clarity & Usability	I found this easy to read and except for Figure 1, easy to understand.	We have revised the figure so that it is easier to read
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	Findings	The PSP identifies "referral risks". This is called out in the matrix on p16 of the technical brief but could be more fully developed. Timely referral execution and result review is a daily topic and a component of the patient-centered medical home (PCMH). The provider initiates the referral, but the patient may or may not follow thru. Processes need to be enacted to establish a 30 day or similar window for follow up and receipt of consultant or referral report. Compliance outside of the 30 day window falls off steeply and could result in a negative patient outcome.	There is debate about the optimal window for referral completion, and while we agree with the reviewer that delayed referrals are a safety hazard, the evidence are not strong enough today for us to recommend a specific time frame such as 30 days
Peer Reviewer #5	Findings	I had a very hard time understanding figure 1. I am confused that most of the boxes under measurement are blank when I thought measurement was identified as an important area. The table does not seem to match the text. I think that there needs to be more explanation in the text and in the titles to explain what this figure is showing.	We have changed the figure legend so it is clear that blank areas were intersections of strategies and issues that were not discussed
KI Reviewer #6	Findings	Findings are generally integrated and balanced. NP under-utilization is listed in the matrix in Figure 1 but is not mentioned in the text of the findings.	We believe the figure captures this issue adequately
KI Reviewer #2	Findings	The key informant Matrix is nice, however, are the blank boxes areas in which there was no conversation? Or conversation but no concern? More details needed here.	We have changed the figure legend so it is clear that blank areas were intersections of strategies and issues that were not discussed
KI Reviewer #1	Findings	Literature scan (page 18) - The text on numbers of studies needs to be rewritten so it is more logically presented; on first reading it is for example completely unclear where 'the remaining 62 articles' comes from (lines 23-28)	We have revised the flow and the description of those studies.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #1, Lucy A. Savitz, PhD, MBA, High Value Healthcare Collaborative (HVHC)	Findings	Page 19 - Literature scan, line 20 • The report states that one exclusion criteria was that, "…studies were excluded at this stage were because they were not hypothesis-testing studies of patient safety interventions (page 19)." We would suggest that systematic approaches to improvement science would be important to include. There are multiple improvement science methodologies. For the last decade, many health systems have been utilizing improvement science methodologies like Six Sigma, Lean, PDSA, and discrete event simulation for process improvement. Further, incorporating industrial engineers or improvement science specialist into the ambulatory setting to assist with the selection of the proper methodology and mentoring sites on the application of the tools have yielded measurable results. Our concern is that this body of work was excluded from the Technical Brief; several peer-reviewed journals have emerged over the last decade that have increased visibility of this work—e.g., Implementation Science, BMJ Quality and Safety.	Guiding Question #1 concerned patient safety practices. If we identified a patient safety practice that used one or more of these generic methods (PDSA, Six Sigma, etc) we included it, but we did not include studies about these generic methods as a general topic, just as we included studies of PSPs that used a randomized trial design but did not include articles about randomized trials.
KI Reviewer #1	Findings	Summary (page 21)- I think you mean 'care transitions'? (line 31)	We have corrected the typo
KI Reviewer #5	Findings	P 21 typo noted: Other than the medication-related and car transitions practices mentioned-assume you mean CARE transitions.	We have corrected the typo
KI Reviewer #7	Clarity & Usability	p. 22, line 30-31, spelling error. "Car" should be "care."	We have corrected the typo
KI Reviewer #3	Findings	I think you should mention the importance of safety culture more here	We have added more detail about safety culture in the findings.

Commentator & Affiliation	Section	Comment	Response
KI Reviewer #3	Findings	In the lit review, there are no articles on referrals but there have been studies showing IT tools that help with referral mgmt	Our literature search identified observational evaluations of health IT referral systems (e-referrals) but the assessed outcomes were not safety outcomes, rather they included variables about the quality of the referral like “difficulty in identifying the clinical question” and “appropriateness of referral”. Such studies were not included in our literature scan because we judged them to be more about quality than safety.
KI Reviewer #5	Findings	See my general comments above I would say that in general the studies are clearly identified , and balanced. The reviewers cast a broad net and picked up most of the relevant evidence-based literature. How well they did in integrating these bits and pieces is hard to say. Certainly they were limited by the nature of the fragmentary data that is out there, but one would've hoped that given the expertise on the panel they could have done a bit more weaving together of these disparate pieces of cloth.	We have added substantially to the summary/ implications to address this.
Peer Reviewer #3	Findings	The description of the findings from the literature is good. The authors describe the types of studies for each safety domain. This section, however, could be improved with more synthesis of the evidence. The authors state that medication safety was the most highly studied domain but do not describe the types of interventions used and whether these interventions were effective.	We have added some additional detail about medication safety. Describing effectiveness is outside the scope of a Technical Brief.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Findings	1. The report mentions referral risks on page 14 Table 1 p. 17 and p. 21 relating these to referrals from one provider to another ambulatory provider. However the report doesnt make mention of referral from the ambulatory setting to the emergency department. This is a dimension of referrals that is critical to explore not only from our vantage point of caring for pregnant women but for all patients who may be referred to go to the hospital in a nonemergent manner e.g. a woman who is told to go to labor and delivery for decreased fetal movement and doesnt need an ambulance.	We include this in our discussion of transitions of care in the summary/ implications
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Findings	2. Triage in the ambulatory setting is another issue not explored. Telephone triage is mentioned in Table 1 p. 14 but not triage in the ambulatory setting to prevent a potentially emergent patient from waiting longer than indicated.	We agree that this is important, but the Kis did not discuss it
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Findings	3. Communication and patient engagement are identified as issues on page 18 but aspects of impaired ability to engage or communicate due to disability or dementia and the need for resources and support ate not called out.	We agree that this is important, but the Kis did not discuss it- we added it as worthy of further study
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Findings	4. There is only one mention of care coordination in Table 1 on page 14. This issue is closely related to referrals and could be explored as a dimension of the larger issue of how patients get the comprehensive care they need from their care team inclusive of all components of that team.	We mention this in the context of the patient centered medical home in the summary/ implications
Public Reviewer #4, Kerri Wade Association of Womens Health Obstetric and Neonatal Nurses	Findings	5. One of the most frequent safety events are patient falls. Among other elements fall prevention programs should explore safety for those with physical limitations or impairments.	Falls were considered but not included

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #5	Findings	I am interested that issues around telehealth were excluded as a category. In rural settings this is often used for referrals. Excluding in facility falls could easily become preventing in home falls but this does not seem to have been considered.	Both of these were considered but did not receive enough support from the Kis to take the place of the 28 PSPs that were assessed

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	General	Patient falls screening, assessment, diagnosis and care planning is noticeably absent from the PSP. Consideration should be given to the integration of the American Geriatric/British Geriatric Fall Prevention Guidelines for Ambulatory Care (2001, updated in 2010). This patient safety practice has already been adopted by NQF's Patient Safety Measures in 2007, approved in 2012 and again in 2015. NQF measure 0101 is a 2 part measure noted as PQRS # 154- Falls Risk Assessment and PQRS # 155 – Falls Plan of Care. A falls risk screening using a validated tool or process assists in the identification of patients who require a more complete assessment and plan. Additionally, since the AHRQ report addresses the IOM Patient Safety Definition "Freedom from accidental injury", the report fails to include focus on protection from fall-related injury (i.e., there is no emphasis from the Key Informants on Fall-related Injury Risk or History). The TJC Sentinel Alert "Preventing Falls and Fall-related Injury in Healthcare Facilities" (Sept 28, 2015) identifies fall and injury prevention strategies that could be modified to be applicable in the ambulatory environment. Another major omission is patient safety practices that are age-adjusted, risk adjusted, or population-based (diagnosis, gender, ethnicity, frailty, etc). The CDC has gained national attention for its community-based, ambulatory care practice focused STEADI program (Stopping Elderly Accidents, Deaths and Injury). The program uses 3 simple questions for screening patients who may need further fall-risk assessment. Inclusion of fall risk screening (regardless of program or tool) for patients 65 years and older is the corner stone of a falls risk and injury prevention strategy.	Falls were explicitly considered and were not included in the list of PSPs to be covered in this technical brief

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing (continued)	General (continued)	As the office practice setting is not regulated, the environment of care (EOC) often contributes to fall risk. Cluttered environments, torn carpets, uneven flooring, exam table injuries (e.g., patients falling off tables or having difficulty stepping on or off the table) and parking lot maintenance (e.g., ice, delayed snow removal, potholes, uneven curbs) contribute to potential patient injuries in the ambulatory environment. Variability in the education and training of unlicensed assistive personnel (commonly referred to as Medical Assistants) can lead to poor technique in many aspects of office care such as point of care testing, point of service tests, e.g., EKG and documentation and collection of vital signs. Medical Assistants education ranges from “on the job trained” to graduation from an Associate’s degree program. To assure safe practice in ambulatory care, minimal education and training recommendations along with competency assessment should be stressed. In relating this to falls risk, improper assessment of BP for orthostatic hypotension may provide a false sense of security and could lead to a fall with injury. A second example of the impact of inadequate education and training is related to point of care testing. More and more providers rely on point of care testing to adjust medications and treatment plans. The medical assistant usually conducts this testing and has little or no laboratory training to ensure the provision of accurate test results. This contributes to the diagnostic errors identified in the PSP list. The assessment, analysis, and decision making of the registered nurse in ambulatory care are critical to the quality of care provided.	

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2, Nancy May, MSN, RN-BC, NEA-BC American Academy of Ambulatory Care Nursing	General	In summary the AAACN would offer that the definition, scope and research context of ambulatory care be broadened to be more inclusive; the referral section be expanded; that falls risk screening, assessment, diagnosis and care planning be added as well as consideration to the environment of care, and minimal standards for education and training of unlicensed assistive personnel. Thank you for the opportunity to comment on this important technical brief.	We appreciate the comment but stayed within the agency's scope for defining ambulatory care Our section on referrals includes all KI input we received Falls were explicitly considered and not included by the KIs so we cannot include them now
Public Reviewer #5, Tosha Wetterneck, MD University of Wisconsin School of Medicine and Public Health	Findings	my research group has completed AHRQ funded research studying the impact of previsit planning in primary care with positive results on physician situation awareness and perceptions of safety. I did not see previsit planning as an intervention but it should be considered. I can forward abstract results.	With regard to the abstract our lit scan was only including published literature and grey literature, not abstracts, but that we would pass along this information to our AHRQ Task Order Officer
KI Reviewer #6	Summary & Implications	The summary seems appropriate given the nature of the findings.	No response needed
Peer Reviewer #5	Summary & Implications	Good summary of the findings and future directions for guiding question 1.	No response needed
KI Reviewer #2	Summary & Implications	Bullet points might make this section easier to follow.	We didn't use bullet points but we re-organized the section and hope it is easier to follow
KI Reviewer #3	Summary & Implications	Need research on the five areas but also on areas such as culture and workforce safety/burnout and what strategies exist to improve these. Might want to cite the recent NPSF report Free from Harm that has a recommendation about improving safety across the continuum of care.	Thank you for this suggestion- added
KI Reviewer #4	Summary & Implications	A key gap that is not addressed is the population burden (number of patients affected, severity of the harm among those affected) that may be impacted by patient safety interventions in ambulatory settings. This may not have been "in scope" for the project; however, without relative quantification of harms across domains of ambulatory patient safety, we may become focused on a very narrow problem that may have trials on effective interventions, but it is a problem that causes little ham in few patients.	This is an important point that was outside the scope of this Technical Brief, but we have added it to the Summary and Implications section

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KI Reviewer #5	Summary & Implications	I appreciate and like the conceptual framework that the authors have used to try to tie together both the themes and the strategies. The gaps are mainly in the depth rather than the breath of what they have done here (as discussed above).	No response needed
KI Reviewer #7	Summary & Implications	Excellent summary of 5 pt safety issues: -medication safety -diagnosis -transitions among providers in ambulatory settings. -referrals from one provider to another. -management of test results. -post hospital discharge. and the need for more patient and family engagement. Also the need for strategies to assist accurate diagnosis.	No response needed
KI Reviewer #5	Summary & Implications	Even the few PSP's that they cite have evidence (e.g. e-prescribing, medication safety, transitions from hospital to the ambulatory setting, and pharmacist-led interventions) are sufficiently complex, underdeveloped, and controversial in how to best apply them that authors need to explicitly call out these issues generically (rather than implied all is well and solved even on these fronts).	Since we did not review the primary studies at this level of detail we can only comment generally on this, and have added a sentence to the text
KI Reviewer #5	Summary & Implications	Calling HIT "disruptive" may be the wrong word since this has more positive connotations nowadays (although getting somewhat tarnished from overuse and misuse), especially in light of the negative consequences to date that the report nicely emphasizes.	We have re-phrased this to avoid using this term.
KI Reviewer #5	Summary & Implications	I worry that there may be an insufficient number of clearly distilled recommendations to propel work in this field more solidly forward. Mostly just general calls for research	Thanks for this- we have added more specific recs into the summary and implications

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Peer Reviewer #2	Summary & Implications	I found this to be a bit shallow given the importance and breadth of this topic and its potential for impact on future AHRQ funded work. For example, on page 22, line 12, the language is so generically written "moderate evidence base" followed by mention of some broad areas such as e-prescribing, medication safety, etc. In a document like this I would expect to find more depth than broad statements such as patient safety culture is a challenge.	It is difficult to be more specific about recommendations where there is a lack of evidence. We have added recommendations and citations as far as the data have led us.
KI Reviewer #7	Clarity & Usability	p. 22, line3 20: Who? healthcare workers or patients or both? Who does this refer to? Please make clear.	We cannot find this text. The revisions along the way have deleted this sentence.
Peer Reviewer #2	Summary & Implications	In sum, while the document is a conversation starter, we know some of this stuff already and rather than repeating the obvious, the technical brief needs to lay a strong foundation for future work using more specific direction. It could be that the intent of the document is the way it is now and in that case, I missed the point. However, it doesn't seem that the way this brief is written it informs the field in a very meaningful way over and above what we know now. I was expecting to see a blueprint for future work but didn't see a lot of new concepts and next steps outlined. In fact, much of this could have been gleaned from the AMA report.	We have added detail to the report throughout, especially to the summary and implications. We were charged by AHRQ to base our conclusions on KI interviews and on the literature scan rather than to develop a "blueprint for future work." We have added more direct reference to the AMA report, but it does not include much of this literature, and the scope was quite different (includes ambulatory surgery, as an example.)
Peer Reviewer #3	Summary & Implications	This section is well written. The comprehensiveness and depth of this section can be improved.	Without any specifics on how this section should be improved, we are unable to respond to this comment
Peer Reviewer #5	Summary & Implications	I feel that guiding question 2 was not really explored in ways that can be used by the community. What aspects of the medical home promote safety and how? not all medical homes are the same so this woudl be a useful finding from this report.	We were limited by the total lack of published studies evaluating the medical home's role in patient safety
KI Reviewer #3	Next Steps	n/a	No response needed

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KI Reviewer #7	Next Steps	Excellent summary of strategies to improve patient safety with communication, health info technology, patient and family engagement, organizational approach, safety culture. Successfully ties together claims and questions and summarizes important points. Great point about few studies evaluating patient safety in ambulatory setting and the general acceptance of sub-optimal results of reporting and tracking.	No response needed
KI Reviewer #1	Next Steps	HIT will prove fundamental going forward; there was however little in the next steps section on how the usability and usefulness of EHRs and other related technologies might be improved	We agree but the role of the technical brief is to provide an overview and information on future research needs. Making specific policy recommendations about how EHR use might be improved is beyond our scope.
KI Reviewer #2	Next Steps	Is included within the summary and implications, but could easily be a heading for the last paragraph in that section that outlines a future research agenda - I would like to see this include the need for patient centered outcomes that matter as ultimate research goals. That is missing in this section.	Thank you- added to the summary/ implications
KI Reviewer #1	Next Steps	It would be useful to suggest some initial prioritization for next steps based on considering the burden of harm and the extent to which these issues are considered tractable – that way, it may be possible for AHRQ and other funders to initiate both short-term and longerterm funding strategies	Thank you- added to the summary/ implications
KI Reviewer #4	Next Steps	A missing next step should be relative quantification of harm from different ambulatory patient safety issues. The focus should be on measurable patient harms (not "errors") and serious patient harms.	Thank you- added to the summary/ implications
KI Reviewer #5	Next Steps	see above It would appear that some of the important patient safety culture and leadership issues have gotten lost from this set of recommendations.	We have reinforced these in the summary.

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KI Reviewer #5	Next Steps	The ability for staff to speak up, be engaged improvement, feel supported in this set of reflexes is perhaps more important in the long run than all the other specifics since it is likely drive the others and without it any specific interventions are likely to be unsuccessful in unsustainable. This also relates to above comments related to pace of work and production pressures.	We have reinforced these in the summary.
KI Reviewers #1, 5 and 6	Next Steps and Clarity & Usability,	Next steps statement is quite broad - this can be seen as a benefit - leaves considerable flexibility; or as a limitation - open to wide-ranging interpretations. The conclusions clearly point the way to the need for future research and informants in mostly adequate but general directions. Would be even more helpful if there could be more specificity in these recommendations. I think it achieves its overall purpose of highlighting the need for much greater work in this area; it is however lacking on defining critical next steps and the timescales for these. Yes- though a table with key research final recs might be helpful	In this revision we have somewhat increased the specificity of future research suggestions but developing highly specific suggestions was beyond our scope.
Peer Reviewer #3	Next Steps	More details on the authors' recommendations would be helpful.	Thank you- added to the summary/ implications
Peer Reviewer #5	Next Steps	I think there could have been more exploration of settings and tools that help in reducing safety events in primary care that could help the community moce forward in this area	We have reported what we found in the literature and what our KIs told us, if this did not include the settings or tools the reviewer was looking for we cannot do anything about it.
KI Reviewer #6	Clarity & Usability	The report is clear and the matrix figure and tables are useful.	No response needed
KI Reviewer #7	Clarity & Usability	The report is very well structured and organized. Points are clearly presented. Conclusions will definitely inform future research.	No response needed
KI Reviewer #1	Clarity & Usability	The report is reasonably clear; the above suggestions will however help to improve the reproducibility of the methods	Thank you, we have incorporated many changes as a result of peer review

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KI Reviewer #1	Clarity & Usability	It would benefit from a section on limitations so as to minimize the risk of its findings/conclusions being over-interpreted	We have added some limitations
KI Reviewer #2	Clarity & Usability	The report is well structured and organized and the main points are presented well. As noted, better use of subheadings and bullet points would improve the usability of the document. The conclusions address future research needs well.	Thank you, we have made some changes to help satisfy this request
KI Reviewer #4	Clarity & Usability	"Summaries" in Appendix B appear to be more of a "transcript" rather than synthesis. Would highlight the key concepts or themes brought up by the Key Informants. Appendix C does put some themes in a matrix, but these should be framed in Appendix B or at least precede the verbatim Appendix B.	We have revised the figure and hope that it now serves the purpose of being a synthesis of the transcripts in Appendix B
Peer Reviewer #3	Clarity & Usability	The report is clear but would benefit from more detail.	We have added additional data in response to peer reviewers comments, that hopefully help address this concern
Public Review #6, Patient	n/a	Da Vinci Robot is a very dangerous operational device (title of 780 word comment from the reviewer)	Surgical safety is outside the scope of this technical brief and no response is needed