Evidence-based Practice Center Rapid Response Protocol

Project Title: Making Healthcare Safer IV: Patient and Family Engagement

Review Questions

1. What is the frequency and severity of harms addressed by the patient and family engagement PSPs?

2. What measures or indicators have been used to examine the harms associated with the target of the patient and family engagement PSPs?

3. What patient and family engagement PSPs have been used to prevent, report, or mitigate harms to patients, and in what settings have they been used?

4. What is the rationale for the patient and family engagement PSPs that have been used to prevent, report or mitigate the harms

5. What studies have assessed the effectiveness and unintended effects of the patient and family engagement PSPs that have been used to prevent, report, or mitigate harms to patients and what new evidence has been published since the MHS III report of 2019?

6. What are common barriers and facilitators to implementing the patient and family engagement PSPs?

7. What resources (e.g., cost, staff, time) are required for implementation?

8. What toolkits are available to support implementation of the patient and family engagement PSPs?

Context and Domain Being Studied

The Agency for Healthcare Research and Quality (AHRQ) Making Healthcare Safer (MHS) reports consolidate information for healthcare providers, health system administrators, researchers, and government agencies about practices that can improve patient safety across the healthcare system—from hospitals to primary care practices, long-term care facilities, and other healthcare settings. In Spring of 2023, AHRQ launched its fourth iteration of the MHS Report (MHS IV). Patient and family engagement as a PSP was identified as high priority for inclusion in the MHS IV reports using a modified Delphi technique by a Technical Expert Panel (TEP) that met in December 2022. The TEP included 15 experts in patient safety with representatives of governmental agencies, healthcare stakeholders, clinical specialists, experts in patient safety issues, and a patient/consumer perspective. See the MHS IV Prioritization Report for additional details.[1]

Patient-centeredness is a core component of healthcare delivery and is required to ensure patients receive care that is aligned with their values and preferences. Patients and their families are the ones who experience safety events and are often most equipped to detect their occurrence, particularly when the safety events are due to breakdowns in coordination of care across components of the health system.[2-4] Additionally, it is important to engage with patients and their families when safety events occur because safety events can undermine trust in the system (i.e., violating patients' trust that healthcare providers are responsible for protecting patients from harm,[5] or that healthcare providers are not forthcoming or forthright with information about safety events when they do occur)[6] and lead to patients becoming disengaged with their care.[7, 8] Consequently, their perspective on and engagement with care delivery processes is critically important. By promoting active engagement of patient and family members with their care and authentic collaboration with healthcare professionals, unique patient and family perspectives can be incorporated into patient safety, ultimately reducing risks for adverse events and preventable harms. Numerous organizations have advocated for patient and family engagement to be a key strategy for reducing preventable patient harm.[9-11]

Overview of the Patient Safety Practice (PSP)

Patient and family engagement involves a broad spectrum of practices intended to promote partnerships between patients, their loved ones, and health professionals. Prior literature discusses patient and family engagement as a general or overarching philosophy that can be

applied to many PSPs as a specific component of PSPs (e.g., inclusion of a mechanism for patients to report concerns in a rapid response system), or as a contextual moderator of the effectiveness of a PSP.[12] Furthermore, patient and family *engagement* (i.e., creating active partnerships) has been differentiated from simply *informing* patients about aspects of their healthcare. Engagement consists of empowering patients with skills and tools to work with their care team, partnering patients with their care team to impact care decisions, including about patient safety, and fully integrating patients and families as members of the care team.[13]

For the purposes of this review, we define PSPs focused on patient and family engagement as any intervention that is specifically designed to promote engagement of patients and/or family members in reporting and reducing patient safety events and associated harms. This definition excludes interventions having the goal of solely informing patients and their families about their care or PSPs (e.g., patient education interventions) lacking an intent to engage and partner with them.

Purpose of the Rapid Response

The overall purpose of this rapid response is to summarize the most relevant and recent literature on PSPs focused on patient and family engagement and how these PSPs can be implemented.

Methodologic Approach

For this rapid response, strategic adjustments will be made to streamline traditional systematic review processes and deliver an evidence product in the allotted time. We will follow adjustments and streamlining processes proposed by the AHRQ EPC Program. Adjustments include being as specific as possible about the questions, limiting the number of databases searched, modifying search strategies to focus on finding the most valuable studies (i.e., being flexible on sensitivity to increase the specificity of the search), and restricting the search to studies published recently (i.e., since 2019 when the search was done for the MHS III report) in English and performed in the United States, and having each study assessed by a single reviewer. Depending on the expected volume of literature, the EPC team may opt to have a randomly selected 10% sample checked by a second reviewer or use the artificial intelligence (AI) feature of DistillerSR (AI Classifier Manager) as a second reviewer at the title and abstract screening stage.

For this topic, we may need to consider a number of different PSPs that focus on the targeted harms.

We will search for recent high quality systematic reviews and will rely primarily on the content of any such systematic review that is found. We will not perform an independent assessment of original studies cited in any such systematic review.

We will answer Review Questions 1 and 2 by focusing on the harms and patient safety measures or indicators addressed in the studies identified for Review Question 5. For Review Question 2, we will focus on identifying relevant measures included in the Centers for Medicare & Medicaid Services (CMS) patient safety measures, AHRQ's Patient Safety Indicators, or the National Committee for Quality Assurance (NCQA) patient safety related measures. For Review Question 3, we will focus on interventions identified in Review Question 5 (i.e., those interventions with studies evaluating their effectiveness). We will ask our content experts to answer Review Question 4 by citing selected references, including explanations of the rationale presented in the studies we find for Review Question 5. For Review Questions 6 and 7, we will focus on the barriers, facilitators, and required resources reported in the studies we find for Review Question 5. For Review Question 8, we will search publicly available patient safety toolkits developed by AHRQ or other organizations that could help to support implementation of the PSPs, including AHRQ's Patient Safety Network (PSNet) (https:/psnet.ahrq.gov) and AHRQ's listing of patient safety related toolkits (see https://www.ahrq.gov/tools/index.html?search_api_views_fulltext=&field_toolkit_topics=14170&sort_by=title&sort_order=ASC). We will include any toolkits mentioned in the studies found for Review Question 5. We identified toolkits without assessing or endorsing them.

Eligibility Criteria for Studies of Effectiveness

We will search for original studies and systematic reviews on Review Question 5 according to the inclusion and exclusion criteria presented in Table 1.

Table 1. Inclusion and Exclusion Criteria

Study Parameter	Inclusion criteria	Exclusion criteria
Population	Adult and pediatric patients and their family members	Patient representatives or public representatives who are not patients or family members
Intervention	Any intervention intended	Patient education interventions

Study Parameter	Inclusion criteria	Exclusion criteria
	primarily to focus on patient and/or family member engagement in reporting and reducing patient safety events and associated harms.	(e.g., interventions solely providing patients with information about their care or patient safety).
Comparator	Usual practice or other type of PSP	• No concurrent or historical comparison group • No clear description of intervention
Outcome	**Safety** • Adverse events and incidents of harm **Quality of care measures** **Utilization of health care services** (focusing on the main utilization measure reported in the study) **Implementation** • Barriers and facilitators • Resources (cost, staff, time)	• Measures of patient knowledge or engagement levels only • No outcome of interest
Timing	Original studies published since 2019, the year of the search done for the MHS III report on this topic	Published before 2019
Setting	Inpatient and outpatient care settings in the United States	Setting outside of the United States
Type of studies	Systematic reviews [last 3 years] Original studies [2019 -present]: Randomized controlled trials or observational studies with a comparison group, including pre-post studies	Narrative reviews, scoping reviews, editorials, commentaries, and abstracts

MHS = Making Healthcare Safer; PSP =patient safety practices

Literature Searches for Studies of Effectiveness

We will search PubMed and the Cochrane Library for systematic reviews published in the last 3 years that address the review questions. If no recent high quality systematic review is identified that will adequately address the review questions, we will conduct searches of PubMed for original studies published since 2019 that address the review questions. To efficiently identify articles that meet the eligibility criteria, we will distribute citations from the literature search to team members, with plans to have the title and abstract of each citation reviewed by a single

team member. Each team will decide whether it has enough time and resources to ask a second team member to check a 10% sample of citations to verify that important studies were not excluded after the review of titles and abstracts. Alternatively, the team may opt to use the DistillerSR AI Classifier Manager as a semi-automated screening tool to conduct the review efficiently at the title and abstract screening stage. In that case, the title and abstract of each citation will be reviewed by a team member, and then the AI Classifier Manager will serve as a second reviewer of each citation.

Description of Included Studies

To efficiently describe eligible studies, the full text of each potentially eligible article will be reviewed by a single team member to confirm eligibility and prepare a summary of the study, including author, year, study design, number of study participants, and main findings relevant to each of our review questions. Since Review Question 5 calls for identification of studies on the effectiveness of PSPs focused on patient and family engagement, we will describe the objectives and basic characteristics of those studies without conducting a detailed analysis of the findings of those studies. The team will decide whether it has enough time and resources to ask a second team member to check a randomly selected 10% sample of the articles to verify that important studies were not excluded and confirm the accuracy of extracted data.

To describe eligible systematic reviews, a single team member will prepare a summary including the author, year, number of studies by study design, and main findings relevant to each of our review questions. For Review Question 8, we will create a table to record the source of each relevant toolkit along with a 1-2 sentence description of each toolkit. We will not endorse any specific toolkit.

Risk of Bias (Quality) Assessment

For studies that address Review Question 3 about the effectiveness of PSPs, the reviewer will use the Cochrane Collaboration's tool for assessing the risk of bias of randomized controlled trials (RCTs) or the ROBINS-I tool for assessing the Risk Of Bias In Non-randomized Studies – of Interventions.[14, 15] When assessing RCTs, we will use the 7 items in the Cochrane Collaboration's tool that cover the domains of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other biases.[14] When assessing non-randomized studies, we will use specific items in the ROBINS-I tool that assess bias due to confounding, bias in selection of

participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported results.[15] The risk of bias assessments will focus on the main outcome of interest in each study.

If we identify a recent eligible systematic review, the reviewer will use the criteria developed by the United States Preventive Services Task Force Methods Workgroup for assessing the quality of systematic reviews.[16]

- **Good** - Recent relevant review with comprehensive sources and search strategies; explicit and relevant selection criteria; standard appraisal of included studies; and valid conclusions.
- **Fair** - Recent relevant review that is not clearly biased but lacks comprehensive sources and search strategies.
- **Poor** - Outdated, irrelevant, or biased review without systematic search for studies, explicit selection criteria, or standard appraisal of studies.

The Task Leader will review the risk of bias assessments and any disagreements will be resolved through discussion with the team.

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 from participation in the review.

Role of the Funder

This project is funded under Contract No. 75Q80120D00003/75Q80122F32009 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The AHRQ Task Order Officer will review contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by AHRQ or the U.S. Department of Health

and Human Services.]

Format and Content of Report

The report will follow the most recent template approved by AHRQ at the time of approval of the protocol.

References:

1. Rosen M, Dy SM, Stewart CM, Shekelle P, Tsou A, Treadwell J, Sharma R, Zhang A, Vass M, Motala A, Bass EB. Final Report on Prioritization of Patient Safety Practices for a New Rapid Review or Rapid Response. Making Healthcare Safer IV. (Prepared by the Johns Hopkins, ECRI, and Southern California Evidence-based Practice Centers under Contract No. 75Q80120D00003). AHRQ Publication No. 23-EHC019-1. Rockville, MD: Agency for Healthcare Research and Quality. July 2023. DOI: https://doi.org/10.23970/AHRQEPC_MHS4PRIORITIZATION. Posted final reports are located on the Effective Health Care Program search page. .

2. Harrison R, Walton M, Manias E, et al. The missing evidence: a systematic review of patients' experiences of adverse events in health care. Int J Qual Health Care. 2015 Dec;27(6):424-42. doi: 10.1093/intqhc/mzv075. PMID: 26424702.

3. Giardina TD, Haskell H, Menon S, et al. Learning From Patients' Experiences Related To Diagnostic Errors Is Essential For Progress In Patient Safety. Health Aff (Millwood). 2018 Nov;37(11):1821-7. doi: 10.1377/hlthaff.2018.0698. PMID: 30395513.

4. Ozavci G, Bucknall T, Woodward-Kron R, et al. A systematic review of older patients' experiences and perceptions of communication about managing medication across transitions of care. Res Social Adm Pharm. 2021 Feb;17(2):273-91. doi: 10.1016/j.sapharm.2020.03.023. PMID: 32299684.

5. Burrows Walters C, Duthie EA. Patients' Perspectives of Engagement as a Safety Strategy. Oncol Nurs Forum. 2017 Nov 1;44(6):712-8. doi: 10.1188/17.ONF.712-718. PMID: 29052666.

6. Entwistle VA, Quick O. Trust in the context of patient safety problems. J Health Organ Manag. 2006;20(5):397-416. doi: 10.1108/14777260610701786. PMID: 17087402.

7. Khullar D. Building Trust in Health Care-Why, Where, and How. JAMA. 2019 Aug 13;322(6):507-9. doi: 10.1001/jama.2019.4892. PMID: 31305868.

8. Rhodes P, Campbell S, Sanders C. Trust, temporality and systems: how do patients understand patient safety in primary care? A qualitative study. Health Expect. 2016 Apr;19(2):253-63. doi: 10.1111/hex.12342. PMID: 25644998.

9. Guide to Patient and Family Engagement in Hospital Quality and Safety. Content last reviewed March 2023. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/patient-safety/patients-families/engagingfamilies/index.html.

10. Enhance patient and family engagement for the provision of safer health care. WHO Meeting Report. 2019 https://www.who.int/publications/m/item/enhance-patient-and-family-engagement-for-the-provision-of-safer-health-care-the-expert-consultation-meeting-report.

11. Centers for Medicare & Medicaid Services. Person and Family Engagement. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Person-and-Family-Engagement.

12. Berger Z, Flickinger TE, Pfoh E, et al. Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. BMJ Qual Saf. 2014 Jul;23(7):548-55. doi: 10.1136/bmjqs-2012-001769. PMID: 24336575.

13. Kim JM, Suarez-Cuervo C, Berger Z, et al. Evaluation of Patient and Family Engagement Strategies to Improve Medication Safety. Patient. 2018 Apr;11(2):193-206. doi: 10.1007/s40271-017-0270-8. PMID: 28795338.

14. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011 Oct 18;343:d5928. doi: 10.1136/bmj.d5928. PMID: 22008217.

15. Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016 Oct 12;355:i4919. doi: 10.1136/bmj.i4919. PMID: 27733354.

16. U.S. Preventive Services Task Force Procedure Manual. Appendix VI. Criteria for Assessing Internal Validity of Individual Studies. U.S. Preventive Services Task Force. July 2017. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual/procedure-manual-appendix-vi-criteria-assessing-internal-validity-individual-studies.