Evidence-based Practice Center Rapid Review Protocol

Project Title: *Making Healthcare Safer IV: Programs for Responding to Harms Experienced by Patients during Clinical Care*

Review Questions

How effective are programs for responding to harms experienced by patients during clinical care in terms of outcomes for patients, families, involved healthcare professionals, and healthcare systems?

Contextual Questions

1. How do such programs prevent or mitigate harms?
2. What are common barriers and facilitators to implementation?
3. What resources (e.g., cost, staff, time) are required for implementation?
4. What toolkits are available to support implementation?

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 patient safety practices (PSPs) 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).

Programs for responding after patients experience harm in the course of their health care were 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]

Overview of the Topic

How healthcare organizations respond after patients experience harm in the course of their clinical care has implications for the harmed patients and their families, the involved healthcare professionals, healthcare organizations, and future patients.[2, 3] The response can have associations with: the nature, prevalence, and duration of the emotional impact on patients, their trust, and their willingness to return to or recommend [4]the clinician(s)/organization, [2,3] clinicians' ability to learn and adapt after their patients experience harm, and respond more effectively after future events;[5, 6] organizations' culture of safety,[7] as well as their medicolegal experiences;[8-13] and the safety of future patients.[14] While healthcare organizations are required by regulatory and accrediting agencies to analyze harm events as part of their quality assurance and process improvement (QAPI) plans, there are relatively few requirements about how organizations respond to the patients, families, and healthcare professionals involved in harm events.

- Since 2001, the Joint Commission has required disclosure of any unanticipated outcomes to patients and families.[15]
- The National Quality Forum's Safe Practices for Better Healthcare state that "Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.[16]
- Leapfrog's Policy on Never Events (i.e., serious reportable events that ideally should never happen) asks hospitals to commit to nine actions if a never event occurs within their facility: 1) apologize to the patient and family; 2) report the event to an external agency; 3) conduct a root cause analysis of how and why the event occurred; 4) waive all costs directly related to the event; 5) provide a

copy of the hospital's policy on never events to patients upon request; 6) interview patients and families, who are willing and able, to gather evidence for the root cause analysis; 7) inform the patient and/or family of the action(s) that the hospital will take to prevent future reoccurrences of similar events based on the findings from the root cause analysis; 8) have a protocol in place to provide support for caregivers involved in Never Events, and make that protocol known to all caregivers and affiliated clinicians; and 9) perform an annual review to ensure compliance with each of element of Leapfrog's Never Events Policy for each Never Event that occurred. [17]

- The US National Steering Committee for Patient Safety's 'Safer Together: A National Action Plan to Advance Patient Safety' recommends that organizations 'implement and maintain programs for providing appropriate ongoing support in the aftermath of harm.[18]
- The WHO's 'Global Patient Safety Action Plan 2021–2030' emphasizes the need to 'Establish the principle and practice of openness and transparency throughout health care, including through patient safety incident disclosure to patients and families.'[19]

Programs for optimizing such responses go by a variety of names but are often referred to as communication and resolution programs or CRPs. Other names include disclosure programs, disclosure and offer programs, disclosure apology and offer programs, early resolution programs, CANDOR (Communication and Optimal Resolution),[20] BETA HEART® (healing, empathy, accountability, resolution and trust),[21] CARe (Communication, Apology, and Resolution)[22], and "Seven Pillars" program. Best practices go beyond event review and quality improvement, and include several components: proactive, honest, and transparent communication with patients and families; support for all parties including healthcare professionals; proactive offers of compensation when a medical error caused serious harm.

This topic was not addressed in previous MHS reports. In the prioritization process, the MHS IV TEP mentioned issues that called for further refinement of the definition of the topic to determine what outcomes to prioritize and whether to include studies describing perceptions of stakeholders (e.g., patients or physicians) without assessing an

intervention. For this rapid review, we plan to focus on studies that assess the effectiveness of interventional programs in improving outcomes for patients that experience harm in clinical care, and for their families, involved healthcare professionals, and healthcare systems.

Purpose of the Review

The overall purpose of this review is to synthesize the current literature on the effectiveness of programs used by healthcare organizations to respond after patients experience harm in the course of their care. The review will include programs that are intended to provide a transparent explanation of what caused the harm and support the patient and family afterwards, and that may also focus on investigating and learning from harm events to determine corrective actions.

Methodologic Approach

For this rapid review, 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 Evidence-based Practice Center (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), restricting the search to studies published in English, and having each study assessed by a single reviewer. We also plan to limit the search to studies published in 2010 or after for several reasons: increased relevance to the contemporary healthcare environment (versus studies published prior to 2010); because that was the first year a published paper referred to an organization's program for responding after patients experience harm as being fully integrated with the organization's patient safety efforts (as opposed to being primarily described as a risk management strategy); and for feasibility.[8] The EPC team plans to use the artificial intelligence (AI) feature of DistillerSR (AI Classifier Manager) as a second reviewer at the title and abstract screening stage, as described below in the section on Data Extraction.

We will search for *good or fair* quality systematic reviews published since 2010, using the criteria developed by the United States Preventive Services Task Force Methods

Workgroup for assessing the quality of systematic reviews.[23]

- **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.

We will rely primarily on the content of any good or fair systematic review that is found. We will not perform an independent assessment of original studies cited in any such systematic review.

For contextual questions 1 (rationale), 2 (barriers and facilitators), and 3 (resources), we will draw on information reported in the studies identified by the Review Question.

For contextual question 4, we will identify publicly available patient safety toolkits developed by AHRQ or other organizations that could help to support implementation of the PSPs. To accomplish that task, we will review AHRQ's Patient Safety Network (PSNet) (https:/psnet.ahrq.gov) and AHRQ's listing of patient safety related toolkits (https://www.ahrq.gov/tools/index.html?search_api_views_fulltext=&field_toolkit_topics=14170&sort_by=title&sort_order=ASC) and we will include any toolkits mentioned in the studies we find for the Review Question. We will identify toolkits without assessing or endorsing them.

Eligibility Criteria

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

Table 1. Inclusion and Exclusion Criteria

Study Parameter	Inclusion criteria	Exclusion criteria
Population	All patients who experience harm (as defined by the original study) in the course of their clinical care for example as defined by any of the following criteria: • CANDOR event criteria: an event that involves unexpected patient harm (physical, emotional, or financial)[24] • PACT criteria[25] and MACRMI criteria[26] o All events with temporary major or greater harm (aka NAIC 4+, or NCC-MERP level physical harm (called E+) events or higher (E+ = temporary but "significant" physical harm defined as harm whose management is anticipated to require an invasive medical procedure or three or more additional visits to a health care center) o Serious reportable event/Sentinel event (any event that may need reporting to Board of Registration in Medicine or Department of Public Health) o Any event for which a patient, family member, or provider requests a CRP be used o Any event reported by patient/family claiming significant harm (as defined above) o Any event involving a claim or pre-litigation notice	None
Intervention	Programs for responding after patients have experienced harm that include: • Transparent communication with patients/families after qualifying events AND • Event review AND/OR • Post-event review communication o When an error caused harm, this includes an apology, taking responsibility, and an action plan to address the underlying cause, with a commitment to make it less likely to happen again.	Studies limited to investigation strategies or corrective action strategies without post-event review communication with patients or family members; Studies limited to compensation strategies
Comparator	Usual care, pre- and post-implementation comparison, same intervention with varying settings or harm events	No clear description of the comparator
Outcome	• Patient safety outcomes • Malpractice experience (e.g. number of new claims, resolution time) • Financial outcomes (e.g. total indemnity payments, defense costs) • Quality of or satisfaction with communication and the overall response, according to the patient, family, and/or clinicians • Implementation of changes in specific patient safety practices • Changes in the program for responding to harms	None
Timing	Original studies and systematic reviews published since 2010	Published before January 1, 2010
Setting	Any setting in which care is being delivered, including healthcare setting or outside of healthcare setting	None

Study Parameter	Inclusion criteria	Exclusion criteria
Type of studies	Systematic reviews, randomized controlled trials, and observational studies with a comparison group, including pre-post studies	• Narrative reviews, scoping reviews, editorials, commentaries, abstracts • Not published in English

CANDOR=Communication and Optimal Resolution; CRP=Communication-And-Resolution Program; MACRMI=Massachusetts Alliance for Communication, Apology, and Resolution; NAIC=National Association of Insurance Commissioners; NCC-MERP=National Coordinating Council for Medication Error Reporting and Prevention; PACT=Pathway to Accountability, Compassion, and Transparency

Literature Searches

Our search strategy will focus on databases expected to have the highest yield of relevant studies, including PubMed and the Cochrane Library, supplemented by a narrowly focused search for unpublished reports that are publicly available from AHRQ, the Centers for Medicare & Medicaid Services, the Patient Centered Outcomes Research Institute), or professional organizations (i.e., Institute for Healthcare Improvement, and the Pathway to Accountability, Compassion, and Transparency [PACT] Collaborative, Betsy Lehman Center for Patient Safety) having a strong interest in the topic.

Data Extraction

To efficiently identify studies 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. The team will use the DistillerSR AI Classifier Manager as a semi-automated screening tool to conduct the review efficiently at the title and abstract screening stage. 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. The full text of each remaining potentially eligible article will be reviewed by a single team member to confirm eligibility and extract data. The team will 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.

Information will be organized according to the review questions, and will include author,

year, study design, types of harms, characteristics of the programs for responding to harms, rationale for the programs, outcomes, unintended consequences, implementation barriers and facilitators, required resources, and description of toolkits.

In the results section of the report, the following information will be presented:

1. Care setting;
2. Patient population;
3. Description of the intervention studied, including program components;
4. Outcome measures;
5. Outcomes;
6. Findings
7. Risk of bias or study quality.

To streamline data extraction, we will sort eligible studies by specific type of program, and focus on extracting information about characteristics, outcomes, and barriers/facilitators most pertinent to a specific type of program.

Risk of Bias Assessment

For studies that address the Review Question about the effectiveness of programs, the primary 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.[27, 28] 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 bias.[27] 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.[28] The risk of bias assessments will focus on the main outcome of interest in each study.

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

Data Synthesis

Selected data will be compiled into evidence tables and synthesized narratively. We will not conduct a meta-analysis. For the Review Question about the effectiveness of programs, we will record information about the context of each study and whether the effectiveness of the program differs according to characteristics of the programs or characteristics of the targeted patients (e.g., age, sex, race, or ethnicity) if such information is reported in the original studies. If any of the programs have more than one study of effectiveness, we will grade the strength of evidence for those programs using the methods outlined in the AHRQ Effective Health Care Program (EHC) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[29] Evidence grading would not add value for programs that do not have more than one available study.

Analysis of Subgroups or Subsets

We will assess whether the effectiveness of programs differs according to characteristics of the programs or characteristics of targeted patients,.

Registration

We will submit the protocol to AHRQ and to the PROSPERO international prospective register of systematic reviews.

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. The investigators do not have any related financial conflicts of interest that would disqualify them from participation in the review.

External Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does not necessarily represent the views of individual reviewers.

We will ask at least one clinical content expert and one methodological expert to review the draft report. Potential peer reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited peer reviewers may not have any financial conflict of interest greater than $5,000.

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.

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.

2. Prentice JC, Bell SK, Thomas EJ, et al. Association of open communication and the emotional and behavioural impact of medical error on patients and families: state-wide cross-sectional survey. BMJ Qual Saf. 2020 Nov;29(11):883-94. doi: 10.1136/bmjqs-2019-010367. PMID: 31959717.

3. Sokol-Hessner L, Dechen T, Folcarelli P, et al. Associations Between Organizational Communication and Patients' Experience of Prolonged Emotional Impact Following Medical Errors. Jt Comm J Qual Patient Saf. 2024 Mar 7. doi: 10.1016/j.jcjq.2024.03.002. PMID: 38565471.

4. Fisher KA, Gallagher TH, Smith KM, et al. Communicating with patients about breakdowns in care: a national randomised vignette-based survey. BMJ Qual Saf. 2020 Apr;29(4):313-9. doi: 10.1136/bmjqs-2019-009712. PMID: 31723017.

5. Plews-Ogan M, May N, Owens J, et al. Wisdom in Medicine: What Helps Physicians After a Medical Error? Acad Med. 2016 Feb;91(2):233-41. doi: 10.1097/ACM.0000000000000886. PMID: 26352764.

6. Etchegaray JM, Gallagher TH, Bell SK, et al. Error disclosure: a new domain for safety culture assessment. BMJ Qual Saf. 2012 Jul;21(7):594-9. doi: 10.1136/bmjqs-2011-000530. PMID: 22562878.

7. Carvalho R, Bates DW, Syrowatka A, et al. Factors determining safety culture in hospitals: a scoping review. BMJ Open Qual. 2023 Oct;12(4). doi: 10.1136/bmjoq-2023-002310. PMID: 37816540.

8. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Annals of internal medicine. 2010 Aug 17;153(4):213-21. doi: 10.7326/0003-4819-153-4-201008170-00002. PMID: 20713789.

9. Adams MA, Elmunzer BJ, Scheiman JM. Effect of a health system's medical error disclosure program on gastroenterology-related claims rates and costs. Am J Gastroenterol. 2014 Apr;109(4):460-4. doi: 10.1038/ajg.2013.375. PMID: 24698856.

10. Lambert BL, Centomani NM, Smith KM, et al. The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes. Health Serv Res. 2016 Dec;51 Suppl 3(Suppl 3):2491-515. doi: 10.1111/1475-6773.12548. PMID: 27558861.

11. Mello MM, Greenberg Y, Senecal SK, et al. Case Outcomes in a Communication-and-Resolution Program in New York Hospitals. Health Serv Res. 2016 Dec;51 Suppl 3(Suppl 3):2583-99. doi: 10.1111/1475-6773.12594. PMID: 27781266.

12. Mello MM, Kachalia A, Roche S, et al. Outcomes In Two Massachusetts Hospital Systems

Give Reason For Optimism About Communication-And-Resolution Programs. Health Aff (Millwood). 2017 Oct 1;36(10):1795-803. doi: 10.1377/hlthaff.2017.0320. PMID: 28971925.

13. Kachalia A, Sands K, Niel MV, et al. Effects Of A Communication-And-Resolution Program On Hospitals' Malpractice Claims And Costs. Health Aff (Millwood). 2018 Nov;37(11):1836-44. doi: 10.1377/hlthaff.2018.0720. PMID: 30395501.

14. Brenner MJ, Hickson GB, Rushton CH, et al. Honesty and Transparency, Indispensable to the Clinical Mission-Part II: How Communication and Resolution Programs Promote Patient Safety and Trust. Otolaryngol Clin North Am. 2022 Feb;55(1):63-82. doi: 10.1016/j.otc.2021.07.018. PMID: 34823721.

15. Joint Commission International -"Patient Safety Systems" (PS) Chapter. https://www.jointcommission.org/standards/patient-safety-systems-ps-chapter/.

16. NATIONAL QUALITY FORM-Safe Practices for Better Healthcare. https://www.qualityforum.org/News_And_Resources/Press_Kits/Safe_Practices_for_Better_Healthcare.aspx.

17. THE LEAPFROG GROUP-Giant Leaps for Patient Safety, "Never Events", 2016. https://www.leapfroggroup.org/influencing/never-events.

18. Institute for Healthcare Improvement- National Action Plan to Advance Patient Safety, 2020. https://www.ihi.org/initiatives/national-steering-committee-patient-safety/national-action-plan-advance-patient-safety.

19. World Health Organization -Global Patient Safety Action Plan 2021-2030. https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan.

20. Communication and Optimal Resolution (CANDOR). Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html.

21. BETA HEART (healing, empathy, accountability, resolution and trust). https://betahg.com/risk-management-and-safety/beta-heart/.

22. Communication, Apology and Resolution (CARe). Betsy Lehman Center for Patient Safety. https://betsylehmancenterma.gov/initiatives/communication-apology-and-resolution-care.

23. 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.

24. Module 1: An Overview of the CANDOR Process. Content last reviewed August 2022. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/patient-safety/settings/hospital/candor/modules/notes1.html.

25. PACT: Pathway to Accountability, Compassion, and Transparency. PACT Process Map. https://www.ariadnelabs.org/pact/. https://www.ariadnelabs.org/wp-content/uploads/2023/02/PACT-Process-Map-and-Exercise_2.25.22.pptx.

26. The Massachusetts Alliance for Communication, Apology, and Resolution (MACRMI) https://betsylehmancenterma.gov/assets/uploads/TrackedEvent_Sample.pdf.

27. 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.

28. 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.

29. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(14)-EHC063-EF. R Agency for Healthcare Research and Quality. Rockville, MD: 2014. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-methods-guide_overview.pdf.