Evidence-based Practice Center Rapid Review Protocol

Project Title: *Making Healthcare Safer IV: Engaging Family Caregivers with Structured Communication for Safe Care Transitions*

Review Questions

1. What is the frequency and severity of harms associated with care transitions?
2. What patient safety measures or indicators have been used to examine these harms?
3. What patient safety practices (PSPs; including Engaging Family Caregivers with Structured Communication for Safe Care Transitions) have been used to prevent or mitigate the harm and in what settings have they been used?
4. What is the rationale for these PSPs?
5. What are the effectiveness and unintended effects of these PSPs?
6. What are common barriers and facilitators to implementing these PSPs?
7. What resources (e.g., cost, staff, time) are required for implementation?
8. What toolkits are available to support implementation of these 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). Engaging Family Caregivers with Structured Communication for Safe Care Transitions 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 Making Healthcare Safer IV Prioritization Report[1] for additional details.

Care transitions, particularly those from an inpatient or emergency setting to an outpatient setting, represent a critical point in patient care due to potential disruptions in the continuity and coordination of care that often lead to adverse outcomes such as new hospitalizations and readmissions, emergency department (ED) visits, and exacerbations of health conditions.[2,3] The presence of family caregivers throughout the transition process can potentially help prevent such adverse outcomes. Furthermore, if healthcare professionals use structured communication approaches, patients and caregivers may better understand what to expect, next care steps, and available resources during inpatient and emergency care and after patients return to an outpatient setting (e.g., home).

Overview of the PSP

Caregivers are individuals who assist others with social or health needs, supporting others in a number of ways including bathing and eating, providing community and health-related transportation, medication management, ongoing care coordination and communication, and/or managing a chronic condition.[4,5] *Family caregivers* are informal or unpaid adult caregivers providing support to a family member or friend[6] and includes relatives, friends, partners, or others who have a close personal relationship with the individual they are supporting.[5,7] As of 2020, approximately 53 million American adults (21.3%) reported being a caregiver with 14.1 million (5.7%) and 41.8 million (16.8%) caring for an individual aged less than 18 years or more than 49 years, respectively.[6]

Care transitions refers to when patients move between healthcare practitioners or settings as their care needs change.[8] This rapid review focuses on care transitions involving family caregivers either within or between healthcare settings (e.g., intensive care unit to hospital; hospital to skilled nursing facility), or from an inpatient or emergency setting to an outpatient setting where family caregivers are primarily responsible for continuing care for the patient.

Clear communication between healthcare professionals and between caregivers and patients is an important aspect of delivering quality healthcare at points of care transitions[9] and is a key component of frameworks to improve patient safety during transitional care.[10-12] Patients and caregivers desire and may benefit from better communication at transitions of care.[11,13-15]

Structured communication is an approach to improve communication via use of standardized procedures, tools, or templates, with the goal of facilitating clear and complete sharing of relevant information and better understanding by all parties. Healthcare professionals use structured communication techniques to deliver information between each other and to caregivers and patients. Further, the structured communication is not necessarily a one-time event; instead the communication protocols can extend beyond the initial care transition through ongoing communication and interaction.

Examples of structured communication tools and approaches include, among others, the Teach-Back Method,[16,17] checklists,[18] computer-assisted programs,[19,20] and modules embedded within electronic health records. For discharge to the home, the communication to caregivers can include content such as medication administration, wound care, and the timing of followup appointments. Structured communication approaches help healthcare professionals establish communication processes and instruments to guide a conversation to ensure other individuals (e.g., other healthcare professionals, caregivers, patients) comprehend the next steps in care and know how and when to access additional support from the healthcare system. These approaches may improve direct health and utilization outcomes for patients, but may also impact the experience of posttransitional care for family caregivers who often experience additional stress and burden due to their caregiving responsibilities.

This rapid review topic, which was not covered in previous Making Healthcare Safer (MHS) reports, differs from the concurrent MHS IV rapid response on **Person and Family Engagement**. This rapid review is specific to ***structured communication*** related to ***care transitions***. Consequently, it can involve an intervention that only provides information to family caregivers

(unlike the rapid response on Person and Family Engagement, which excluded information-only interventions). Secondly, it only addresses care transitions in multiple healthcare settings, whereas the scope of the rapid response on Person and Family Engagement included interventions within a single setting. Third, unlike the rapid response, this topic includes interventions targeted at caregivers who are neither patients nor family members and does not include interventions targeted at patients without the presence of a family caregiver, whereas the rapid response only included those two groups of caregivers. In the prioritization process, the Making Healthcare Safer IV TEP noted that it may be beneficial to refine how structured communication is defined for this PSP.

Purpose of the Review

The overall purpose of this review is to assess the effectiveness of using structured communication with family caregivers for safe care transitions. We will also report unintended harms of this PSP as described in relevant studies.

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 Agency for Healthcare Research and Quality (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 in English and performed in the United States, and having each study assessed by a single reviewer. We will use the artificial intelligence (AI) feature of DistillerSR (AI Classifier Manager), such that we will re-review the top 30 percent of excluded citations that the AI Classifier Manager notes as potentially includable. For this topic, we may need to consider a number of different PSPs that focus on the targeted harms.

For this topic that focuses on preventing or mitigating harms associated with care transitions, we will ask our content experts to answer Review Questions 1 and 2 by citing selected references that best answer the questions without conducting a systematic search for all evidence on the targeted harms and related patient safety measures or indicators.

For Review Question 2, we will focus on identifying relevant measures that are 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.

We will ask our content experts to answer Review Questions 3 and 4 by citing selected references, including PSPs used and 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 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 Review Question 5. We will identify 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	Patients and family caregivers experiencing care transitions within or between inpatient and emergency settings or from a care setting to an outpatient setting. If the inpatient literature includes 10 or more studies, we will focus only on transitions to outpatient settings.	• Care transitions that do not include a family caregiver
Intervention	Structured communication with patients and/or caregivers for care transitions	• Nonstructured communication • Structured communication only with patients • Communication between healthcare professionals
Comparator	Any comparator, including pre-intervention measurements	No comparator

Study Parameter	Inclusion criteria	Exclusion criteria

Outcome	• Post care transition:
	  ○ ED utilization
	  ○ Hospital admission/readmission
	  ○ Symptom/condition exacerbation
	  ○ Mortality
	  ○ Continuity of care measures
	  ○ Medication errors in transitioned setting
	• Caregiver burden/stress
	• Patient/caregiver satisfaction
	• Quality of care
	• Unintended consequences and harms of structured communication with family caregivers for care transitions
		Other outcomes

Timing	Original studies and systematic reviews published since 2010	Before 2010
Setting	Any care setting or transition to an outpatient setting	No exclusions
Followup	Any followup	No exclusions
Study Design	RCTs, non-randomized trials, and observational studies with a comparison group	• Unspecified study designs or comparison group not described • Comparator group is not appropriate (would not have equivalent exposure to the intervention) • Qualitative studies

Abbreviations: ED = emergency department; RCT = randomized controlled trial.

Literature Searches for Studies of Effectiveness

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 governmental agencies (e.g., AHRQ) or non-profit research organizations (e.g., Patient-Centered Outcomes Research Institute) having a strong interest in the topic. We will search databases for relevant studies published in 2010 or later, in order to complete this rapid review in a timely manner, and also capture all recently published studies. A 2020 review[21] of a similar topic included 40 studies, and only 2 were published before 2010.

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. We will use the DistillerSR AI Classifier Manager to identify potentially highly relevant studies excluded during the initial screening. To accomplish this, after a single team member reviews each citation, we will re-review the top 30 percent of abstracts noted by the AI Classifier Manager as potentially relevant. The full text of each

remaining potentially eligible article will be reviewed by a single team member to confirm eligibility and extract data. A second team member will review a randomly selected 10 percent 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, frequency and severity of the harms, measures of harm, characteristics of the PSP, rationale for the PSP, outcomes, implementation barriers and facilitators, required resources, and description of toolkits. To streamline data extraction, we will sort eligible studies by specific PSP (if the report covers more than one specific practice), and focus on extracting information about characteristics, outcomes, and barriers/facilitators most pertinent to a specific PSP.

Risk of Bias (Quality) Assessment

For studies that address Question 5 about the effectiveness of PSPs, 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.[22,23] 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.[22] 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.[23] The risk of bias assessments will focus on the main outcome of interest in each study.

If we identify a recently published eligible systematic review, the primary reviewer will use the criteria developed by the United States Preventive Services Task Force Methods Workgroup for assessing the quality of systematic reviews.[24]

- **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.

Strategy for Data Synthesis

Selected data will be compiled into evidence tables and synthesized narratively. We will not conduct a meta-analysis. For Review Question 5 about the effectiveness of PSPs, we will record information about the context of each study and whether the effectiveness of the PSP differs across patient subgroups. If any of the PSPs have more than one study of effectiveness, we will grade the strength of evidence for those PSPs using the methods outlined in the AHRQ Effective Health Care Program (EHC) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[25] Evidence grading would not add value for PSPs that do not have more than one available study.

Analysis of Subgroups or Subsets

No subgroup analyses will be conducted except as noted above for Review Question 5.

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. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

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. 75Q80120D00003/75Q80123F32011 from the Agency for Healthcare Research and Quality, 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 the Agency for Healthcare Research and Quality 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

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