Project Title: *Potential Harms Resulting from Patient-Clinician Real-Time Clinical Encounters using Video-based Telehealth: A Rapid Evidence Review*

Review Questions

1. What is the frequency and severity of harms associated with use of telehealth in real-time clinical encounters between patients and clinicians?

2. What patient safety measures or patient safety indicators have been used to examine the harms associated with use of telehealth in real-time clinical encounters?

3. What patient safety practices have been used to prevent or mitigate the harms associated with use of telehealth in real-time clinical encounters, and in what settings have they been used?

4. What is the reported rationale for the patient safety practices that have been used to prevent or mitigate the harms associated with use of telehealth in real-time clinical encounters?

5. What are the effectiveness and unintended effects of the patient safety practices?

6. What are the most common barriers and facilitators (including cost and staff time) to implementing the patient safety practice?

7. What toolkits are available to support implementation?

Context and Domain Being Studied

Telehealth is broadly defined as "the use of medical information that is exchanged from one site to another through electronic communication to improve a patient's health".[1] Telehealth comprises an increasingly wide range of tools to support interactions between clinicians and between clinicians and patients as well as patient self-monitoring. While telehealth services existed in healthcare for decades, the adoption of telehealth has increased dramatically since the

onset of the Coronavirus disease 2019 (COVID-19) pandemic as a strategy to minimize spread of infection. Changes to reimbursement policies during this time expanded the scope of services that could be conducted via telehealth, a change that benefited patient and workforce safety during the pandemic. However, major concerns exist about telehealth, specifically preventable harm due to missed or delayed diagnoses, ineffective communication, and disparities due to technology access. Governmental agencies and professional societies worked diligently to produce guides and resources for rapid adoption and use of telehealth, but little evidence existed about what patient safety practices or strategies would be most effective for whom in preventing and mitigating the risks of patient harm. For this project, we define patient safety practices as interventions, strategies, or approaches intended to prevent or mitigate unintended consequences of the delivery of healthcare and to improve the safety of healthcare for patients.[2] We will focus specifically on patient safety practices intended to prevent or mitigate harms associated with use of telehealth in real-time clinical encounters involving two-way live video conferencing between patient and clinician, where clinicians are defined as including physicians and other licensed health care professionals such as nurses, advanced practice providers, psychologists, social workers, and pharmacists. Telephone only visits will not be included in this Rapid Review because the safety concerns with a telephone encounter are considerably different from a video-based telehealth session. Telephone only encounters are not the desired norm for telehealth visits, they vary widely in their length and purpose, and they do not meet the requirements for reimbursement for a telehealth visit in all states or for all health insurance plans. Given the very tight timetable for completing a Rapid Review, we recommend deferring consideration of patient safety practices intended to prevent or mitigate harms associated with telephone only encounters for a future Rapid Review.

Purpose of the Review

The purpose of this rapid review is to assess the evidence on the potential harms associated with real-time use of video-based telehealth for encounters between clinicians and patients and determine the effectiveness of any PSPs targeted at reducing identified harms. The review is intended to give clinicians and health system leaders the information needed to minimize harms from increasing real-time use of telehealth. Also, this rapid review summarizes evidence that can help organizations determine how to implement telehealth programs effectively, with attention to

strategies for continuously improving the safety and quality of care delivered via telehealth.

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 Evidence-based Practice Center 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 performed in the United States, and having each study assessed by a single reviewer who will pass extracted data to a second reviewer to check accuracy without independent data extraction.

Study Eligibility Criteria

We will search for original studies on the review questions according to the inclusion and exclusion criteria presented in Table 1. We also will search for systematic reviews of studies that meet the eligibility criteria.

Table 1. Inclusion and Exclusion Criteria

Study Parameter	Inclusion criteria	Exclusion criteria
Population	Adults receiving clinical care for acute or chronic conditions or health maintenance issues (i.e., preventive care) from a non-clinical site (e.g., home setting) using telehealth to enable a real-time clinical encounter involving two-way live video conferencing between patient and clinician	• Children (age < 18 years) and caregivers for children • Adults receiving in-patient or emergency department care • Remotely delivered, non-synchronous medical services, such as remote monitoring, messaging, and email • Use of mHealth apps without a two-way live encounter • Telephone only visits • Interactions between clinicians without real-time inclusion of a patient • Computerized decision support without an interaction between a patient and a clinician • Systems that provide only automated, computer-driven,

Study Parameter	Inclusion criteria	Exclusion criteria
		feedback in response to patient self-monitoring data
Intervention	Patient safety practices (PSPs) to prevent or mitigate patient harms associated with use of telehealth in real-time clinical encounters between patients and clinicians, such as adverse events, misdiagnosis, inappropriate treatment, loss of privacy, or duplication of services.	Interventions focusing exclusively on providing access to telehealth.
Comparator	• Usual care without PSP • Care involving a different PSP	No clear description of intervention and comparator

Outcome	• Adverse events
	• Preventable hospitalization
	• Inappropriate treatment
	• Misdiagnosis or delayed diagnosis
	• Delayed care
	• Duplication of services (telehealth followed immediately by an in-person visit)
	• Privacy/confidentiality breaches
	• Implementation barriers and facilitators, including characteristics and resource needs related to:
	    o The Intervention (PSP), including time and cost
	    o Outer Setting
	    o Inner Setting
	    o Individuals Involved
	    o Process
		No outcome of interest

Timing	• Published 2012 to present	Published before 2012
Setting	• Clinical practices and health care systems in the United States	No clinical site in the United States
Type of studies	• **For Questions 1-4 and 6-7**, include any study with original quantitative or qualitative data • **For Question 5**, include randomized controlled trials, non-randomized controlled trials, and observational studies with a comparison group	**For Questions 1-4 and 6-7:** • No original data **For Question 5:** • No original data • No original data or no comparison group

Literature Searches

Our search strategy will focus on databases expected to have the highest yield of relevant studies, including PubMed, , EMBASE, and Cochrane), supplemented by a narrowly focused search for unpublished evaluations and white papers that are publicly available from governmental agencies or professional societies having a strong interest in the topic, including AHRQ, American Medical Association, American Telemedicine Association, Office of the National Coordinator, Patient Safety Learning hub (pslhub.org), and World Health Organization's Global Patient Safety Network. We will check ClinicalTrials.gov and PROSPERO for relevant unpublished work.

Data extraction (selection and coding)

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. A second team member will check a 10% sample of citations to verify that important studies were not excluded after the review of titles and abstracts. 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 check a 10% sample of the full text reviews to verify that important studies were not excluded and confirm the accuracy of extracted data.

Data extraction categories will include author, year, study design, characteristics of the patient safety practice, rationale for the patient safety practice, outcomes, and implementation barriers and facilitators. To streamline data extraction, we will sort eligible studies by patient safety practice, and then focus on extracting information about characteristics, outcomes, and barriers/facilitators most pertinent to that practice.

Risk of Bias (Quality) Assessment

For studies that address Question 5 about the effectiveness of PSPs, the primary reviewer will assess the risk of bias using Cochrane's Risk of Bias 2 (ROB 2) tool[3] for randomized controlled trials (focusing on the randomization process, deviations from intended interventions, missing data, outcome measurement, and selection of reported results), and the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool for non-randomized studies (focusing on

biases due to confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, outcome measurement, and selection of reported results).[4] Another team member will review that assessment to verify no major disagreement with that assessment. Any major disagreements will be resolved through discussion with the Task Leader.

Strategy for Data Synthesis

Data will be compiled into evidence tables and synthesized narratively. We will not conduct a meta-analysis. For Question 5 about the effectiveness of PSPs, if any of the PSPs have more than one study, 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.[5] It is unlikely that evidence grading would add value for PSPs that do not have more than one available study.

Analysis of Subgroups or Subsets

For this rapid review, no subgroup analyses will be conducted.

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 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. The EPC will complete a disposition of comments document that will provide a high-level summary of the response to peer review comments.

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. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

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References:

1.	Tuckson RV, Edmunds M, Hodgkins ML. Telehealth. New England Journal of Medicine. 2017;377(16):1585-92.

2.	Shekelle PG, Pronovost PJ, Wachter RM, et al. Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria (Prepared under Contract No. HHSA-290-2009-10001C). AHRQ Publication No. 11-0006-EF. Agency for Healthcare Research and Quality. Rockville, MD: 2010.

3.	Sterne J, Savović J, Page M, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ. 2019;366:14898.

4.	ROBINS-I tool. The Cochrane Collaboration; 2022. https://methods.cochrane.org/methods-cochrane/robins-i-tool. Accessed on September 9, 2022.

5.	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