

Potential Harms Resulting From Patient-Clinician Real-Time Clinical Encounters Using Video-Based Telehealth: A Rapid Evidence Review

Rapid Review



Structured Abstract

Objectives. To review the evidence on harms associated with patient-clinician real-time encounters using video-based telehealth and determine the effectiveness of any related patient safety practices (PSPs). PSPs are interventions, strategies, or approaches intended to prevent or mitigate unintended consequences of healthcare delivery and improve patient safety. This review provides information that clinicians and health system leaders need to determine how to minimize harms from increasing real-time use of telehealth.

Methods. We followed rapid review processes of the Agency for Healthcare Research and Quality Evidence-based Practice Center Program. We searched PubMed, EMBASE, and Cochrane to identify eligible studies published from 2012 to 2022, supplemented by a search for unpublished evaluations and white papers. Outcomes of interest included: adverse events (any harm to patients due to medical care), other specified harms (i.e., preventable hospitalizations, inappropriate treatment, missed or delayed diagnoses, duplication of services, privacy breaches), and implementation factors for any PSPs.

Findings. Our search retrieved 7,155 citations, of which 23 studies (including 6 randomized controlled trials [RCTs]) were eligible for review. Fourteen studies reported on adverse events or unintended effects of telehealth; these studies were conducted in diverse settings, with four studies in behavioral health, two each in rehabilitation, transplant, and Parkinson's care, and one each in postoperative, termination of pregnancy, community health, and hospital-at-home settings. Adverse events such as death, reoperation, infection, or major complications were infrequent in both telehealth and usual care groups, making it difficult to find statistically significant differences. One RCT found telehealth resulted in fewer medication errors than standard care. Thirteen studies examined preventable hospitalizations or emergency department (ED) visits and reported mixed findings; six of these studies were in postoperative care and two were in urological care. Of the 6 RCTs, 3 showed no difference in risk of hospitalization or ED visits for telehealth compared to usual care, and 3 showed reduced risk for patients receiving telehealth. We found no studies on the effectiveness of PSPs in reducing harms associated with real-time telehealth.



Conclusions. Studies have evaluated the frequency and severity of harms associated with real-time video-based telehealth encounters between clinicians and patients, examining a variety of patient safety measures. Telehealth was not inferior to usual care in terms of hospitalizations or ED visits. No studies evaluated a specific PSP. More research is needed to improve understanding of harms associated with real-time use of telehealth and how to prevent or mitigate those harms.

Contents

1. Background and Purpose	4
1.1 Overview of the Patient Safety Practice.....	4
1.2 Purpose of the Rapid Review	5
1.3 Review Questions.....	5
2. Methods	6
2.1 Eligibility Criteria for Studies of Effectiveness	6
2.2 Literature Searches for Studies of Effectiveness.....	8
2.3 Data Extraction (Selecting and Coding).....	8
2.4 Risk of Bias (Quality) Assessment.....	8
3. Evidence Summary.....	9
3.1 Benefits and Harms	9
3.2 Future Research Needs.....	9
4. Evidence Base.....	10
4.1 Number of Studies.....	10
4.2 Findings for Review Questions	12
4.2.1 Question 1. What is the frequency and severity of harms associated with use of video-based telehealth in real-time clinical encounters between patients and clinicians?	12
4.2.2 Question 2. What patient safety measures or patient safety indicators have been used to examine the harms associated with use of video-based telehealth in real-time clinical encounters?	12
4.2.3 Question 3. What PSPs have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters, and in what settings have they been used?.....	26
4.2.4 Question 4. What is the reported rationale for the PSPs that have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters?	26
4.2.5 Question 5. What are the effectiveness and unintended effects of the PSPs?	26
4.2.6 Question 6. What are the most common barriers and facilitators (including cost and staff time) to implementing the PSPs?.....	26
4.2.7 Question 7. What toolkits are available to support implementation?	26
5. Discussion	27
5.1 Summary and Interpretation of Findings	27
5.1.1 The Frequency, Severity, and Measurement of Harms Associated with Use of Telehealth	27
5.1.2 PSPs to Reduce or Mitigate Harms Associated With the Use of Telehealth.....	28
5.2 Limitations	28
5.3 Implications for Clinical Practice and Future Research.....	29
6. References	30
Appendixes.....	36



1. Background and Purpose

Telehealth is broadly defined as the use of electronic information and telecommunication technologies to support clinical healthcare, patient and professional health-related education, health administration, and public health.¹ Telehealth comprises an increasingly wide range of tools to support interactions between clinicians and patients. While telehealth services existed in healthcare for decades, the adoption of telehealth increased dramatically since the onset of the Coronavirus disease 2019 (COVID-19) pandemic as a strategy to minimize spread of infection while continuing to care for patients. Reimbursement policies expanded the scope of services that could be conducted via telehealth, a change that benefited patient and workforce safety during the pandemic. Also, major governmental efforts sought to support rapid and safe adoption (telehealth.hhs.gov). While the benefits of telehealth are well established, 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,²⁻⁶ but little evidence existed about any harms associated with telehealth, and what patient safety practices (PSPs) or strategies are most effective in preventing and mitigating identified harms.

Past systematic reviews have concluded that telehealth can be safe and effective for care of orthopedic conditions⁷ and cardiovascular disease.⁸ An overview of 24 meta-analyses indicated that the use of telehealth did not increase mortality rates across a broad range of care settings.⁹ Studies in these meta-analyses cover a wide range of telehealth modalities including m-health, remote monitoring, and asynchronous communication portals and include many international studies. However, concerns about patient safety risks associated with telehealth care remain,¹⁰ particularly in real-time virtual encounters between patients and clinicians. A review and meta-analysis of the effect of telehealth on antibiotic prescribing, was inconclusive due to lack of high-quality research.¹¹ These real-time interactions via telehealth are becoming more common, but to date the literature about risks for this particular use of telehealth have not been reviewed.

1.1 Overview of the Patient Safety Practice

For this rapid review, we define PSPs 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.¹² We focus specifically on PSPs 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 physicians and other licensed healthcare professionals such as nurses, advanced practice providers, psychologists, social workers, and pharmacists. Examples of PSPs proposed for this purpose include

communication training, precharting (e.g., comprehensive reviews of patient histories), formalized patient escalation strategies, and education and reporting systems for adverse events.

1.2 Purpose of the Rapid 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.

1.3 Review Questions

1. What is the frequency and severity of harms associated with use of video-based 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 video-based telehealth in real-time clinical encounters?
3. What PSPs have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters, and in what settings have they been used?
4. What is the reported rationale for the PSPs that have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters?
5. What are the effectiveness and unintended effects of the PSPs?
6. What are the most common barriers and facilitators (including cost and staff time) to implementing the PSPs?
7. What toolkits are available to support implementation?



2. Methods

We followed processes proposed by the Agency for Healthcare Research and Quality Evidence-based Practice Center Program.¹³ The final protocol for this rapid review is posted on the AHRQ website at: https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/patient-safety-practices-rapid-protocol.pdf. The rapid review is intended to provide an assessment of evidence in a compressed timeframe to inform an end-user's decision. While the steps are similar to those of a "typical" systematic review, the methods are different (streamlined systematic review methods).¹³

For this rapid review, strategic adjustments were made to streamline traditional systematic review processes and deliver an evidence product in the allotted time. Adjustments included 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 conducted in the United States, and having each study assessed by a single reviewer who passed extracted data to a second reviewer to check accuracy without independent data extraction. This rapid review did not include a formal risk-of-bias or strength-of-evidence assessment because we did not find any studies of the effectiveness of a specific patient safety practice (PSP).

2.1 Eligibility Criteria for Studies of Effectiveness

We searched for original studies on the review questions according to the inclusion and exclusion criteria presented in Table 1. For this rapid review, we define a telehealth visit as a real-time clinical encounter involving two-way live video conferencing between a patient and clinician. Studies were excluded if there was no element of synchronous video communication between a patient and clinician. Studies including multiple telehealth modalities (e.g., text or phone-based interactions, remote-monitoring) were included if live videoconferencing between a patient and clinician was one part of these multicomponent interventions.

Outcomes of interest included three broad categories: adverse events (any study defined harm to patients due to medical care), other specified harms (i.e., preventable hospitalizations, inappropriate treatment, missed or delayed diagnoses, duplication of services, privacy/confidentiality breaches), and implementation barriers and facilitators for any identified PSPs.

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 nonclinical site (e.g., home setting) using telehealth to enable a real-time clinical encounter involving two-way live video conferencing between patient and clinician.	<ul style="list-style-type: none"> • Children (age < 18 years) and caregivers for children • Adults receiving inpatient or emergency department care • No element of synchronous video communication (remotely delivered, nonsynchronous medical services, such as remote monitoring, messaging, and email) • Use of mobile health apps without a two-way live video encounter • Audio-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 feedback in response to patient self-monitoring data
Intervention	PSPs to prevent or mitigate patient harms associated with use of video-based 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	<ul style="list-style-type: none"> • Usual care without PSP • Care involving a different PSP 	No clear description of intervention and comparator.
Outcome	<ul style="list-style-type: none"> • Adverse events <ul style="list-style-type: none"> ○ Any study-defined harm to patients caused by medical care • Other harms <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ The intervention (PSP), including time and cost ○ Outer setting—factors external to the healthcare organization such as regulatory requirements and financial pressures ○ Inner setting—characteristics of the local context where the PSP is implemented. ○ Individuals involved ○ Process 	No outcome of interest.
Timing	<ul style="list-style-type: none"> • Published 2012 to September 2022 	Published before 2012

Study Parameter	Inclusion Criteria	Exclusion Criteria
Setting	<ul style="list-style-type: none"> Clinical practices and healthcare systems in the United States 	<ul style="list-style-type: none"> No clinical site in the United States US healthcare included with other systems without data segregation by country
Type of studies	<ul style="list-style-type: none"> For Questions 1–4 and 6–7, include any study with original quantitative or qualitative data For Question 5, include randomized controlled trials, nonrandomized controlled trials, and observational studies with a comparison group 	<p>For Questions 1–4 and 6–7:</p> <ul style="list-style-type: none"> No original data <p>For Question 5:</p> <ul style="list-style-type: none"> No original data No original data or no comparison group

PSP = patient safety practice

2.2 Literature Searches for Studies of Effectiveness

We searched PubMed, EMBASE, and Cochrane, supplemented by a narrowly focused grey literature search for unpublished evaluations and white papers that were publicly available from governmental agencies or professional societies. These agencies or societies included the American Medical Association, the American Telemedicine Association, the Office of the National Coordinator, the Patient Safety Learning hub (pslhub.org), and the World Health Organization’s Global Patient Safety Network. We also checked ClinicalTrials.gov and PROSPERO for relevant unpublished work. For details of the search strategy, see Appendix A methods tables A-1 through A-3.

2.3 Data Extraction (Selecting and Coding)

The title and abstract of each citation were screened by a single team member. A second team member independently checked a 10 percent 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 was reviewed by a single team member to confirm eligibility and extract data. A second team member checked a 10 percent sample of the full-text reviews to verify that important studies were not excluded and confirm the accuracy of extracted data.

For all articles, reviewers extracted any available information on general study characteristics (e.g., author, year, study design), characteristics of the patient safety practice, rationale for the patient safety practice, outcomes, and implementation barriers and facilitators.

2.4 Risk of Bias (Quality) Assessment

We planned to assess the risk of bias of studies on the effectiveness of relevant patient safety practices, but no such assessment was performed because we did not find any effectiveness studies.



3. Evidence Summary

3.1 Benefits and Harms

For this review, we define patient safety practices (PSPs) 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.¹² We focused on telehealth in real-time clinical encounters involving two-way live video conferencing between a patient and clinician.

- This rapid review identified no specific interventions that could be characterized as a replicable PSP for addressing potential safety risks in real-time, synchronous video-based telehealth encounters between clinicians and patients in the United States.
- The majority of studies on the topic were limited to evaluation of the frequency and severity of harms associated with real-time video-based telehealth encounters between clinicians and patients, examining a variety of patient safety measures and indicators.
- Fourteen studies reported on adverse events or unintended effects of real-time use of video-based telehealth. Adverse events such as death, surgery, infection, or major complications were infrequent with telehealth or usual care, making it difficult to find statistically significant differences. Medication errors were the exception, with one study showing that a focused telehealth intervention resulted in *fewer* medication errors than standard in-person care.¹⁴
- Thirteen studies addressed preventable hospitalizations or emergency department (ED) visits as an outcome associated with the use of video-based telehealth in real-time clinical encounters between patients and clinicians. These studies reported mixed findings. Of the six randomized controlled trials (RCTs), three showed no difference in risk of hospitalization or ED visits for telehealth compared to usual care, and three showed reduced risk for patients receiving telehealth.

3.2 Future Research Needs

- More research is needed to improve understanding of specific harms associated with real-time use of telehealth and how to prevent or mitigate those harms.



4. Evidence Base

4.1 Number of Studies

Our search retrieved 7,155 unique titles and abstracts from which we reviewed 268 full text articles for eligibility (Figure 1). We only found 23 studies that met our eligibility criteria, including 14 studies on Questions 1 and 2 that addressed adverse events or unintended effects, 13 studies on Questions 1 and 2 that addressed preventable hospitalizations, and 1 study on Questions 1 and 2 that addressed misdiagnosis or delayed diagnosis. We did not find any studies that addressed Questions 3–7. A listing of studies excluded during full-text review is included in Appendix B, List of Excluded Studies, and information abstracted from each included study is provided in Appendix C, Evidence Tables. Figure 2 presents the publication year of the included studies.

Figure 1. Results of the search and screening

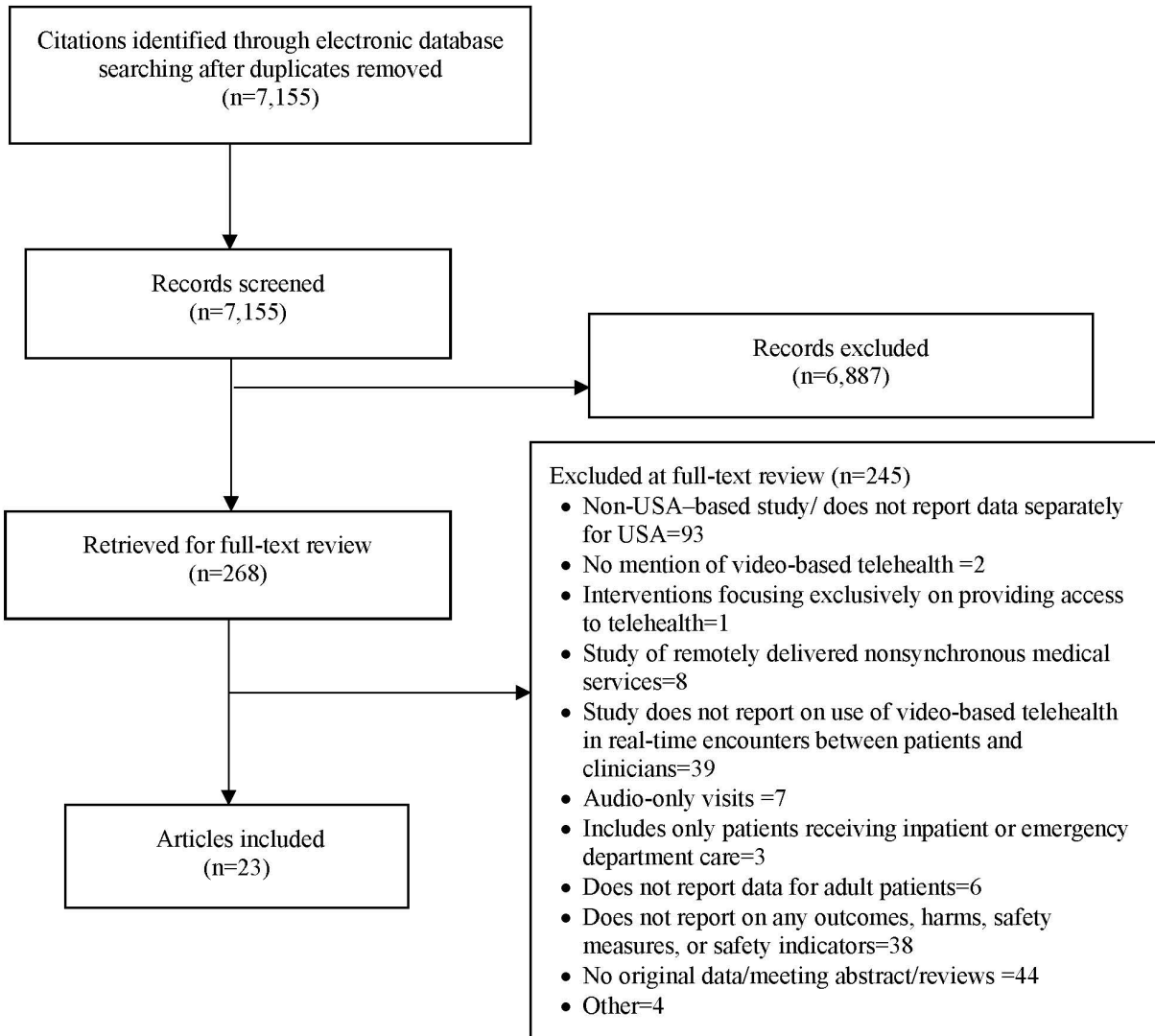
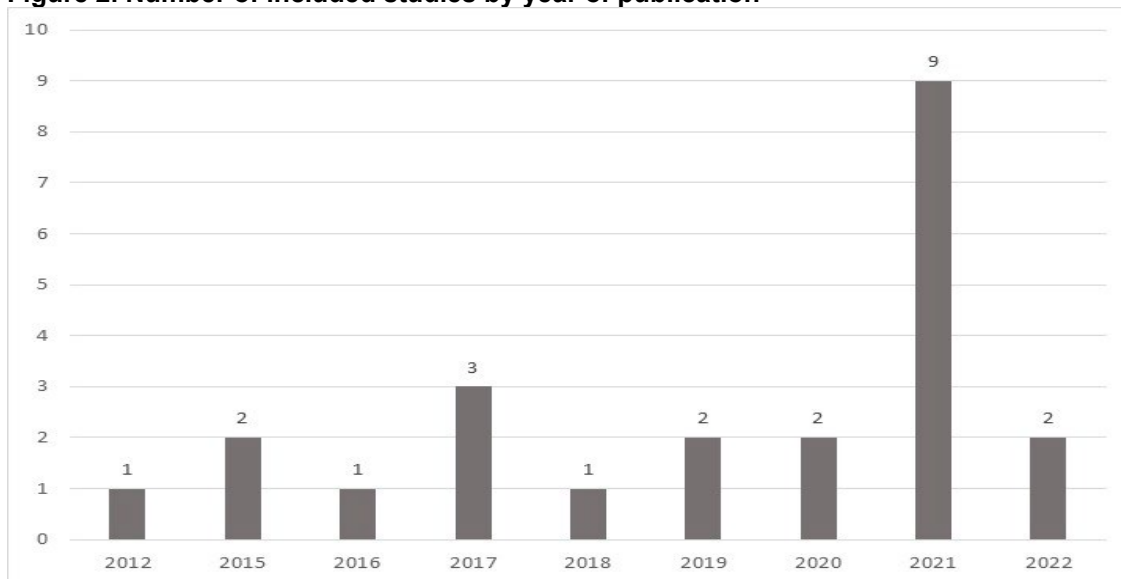


Figure 2. Number of included studies by year of publication



4.2 Findings for Review Questions

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

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

Questions 1 and 2 are tightly coupled, and therefore we present the findings together. Question 1 addresses any potential harms related to use of video-based telehealth, and Question 2 more narrowly addresses any standard measures for these harms that could be used by different stakeholders to understand, track, and reduce risk of harm. We present the outcomes by type of care delivery. The findings are summarized in Tables 2 and 3.

- Adverse events such as death, surgery, infection, or major complications were infrequent with telehealth or usual care, making it difficult to find statistically significant differences. Medication errors were the exception, with one study showing that a focused telehealth intervention resulted in *fewer* medication errors than standard in-person care.¹⁴

- Studies reported mixed findings on preventable hospitalizations or emergency department (ED) visits.

4.2.1.1 Adverse Events/Unintended Effects

A total of 14 studies reported information about adverse events or unintended effects of using video-based telehealth in real-time encounters between patients and clinicians.¹⁴⁻²⁷ These studies examined diverse types of care delivery, with four studies conducted in behavioral health: two each in rehabilitation, transplant, and Parkinson's care, and one each in postoperative, termination of pregnancy care, community health (e.g., using nonclinical means to improve health), and hospital-at-home services (Table 2). Details of this study can be found in Appendix C, Evidence Tables C-1 through C-5. Some of these studies used an active surveillance system to detect rates of targeted harms (e.g., pressure ulcers, infections, medication errors, falls), and others reported a broad category of adverse events. Table 2 describes the variety of adverse events reported across these studies.

4.2.1.1.1 Telehealth in Behavioral Health Care

Four studies reported adverse event outcomes for video-based telehealth in behavioral healthcare. A small feasibility and safety study focused on 10 active-duty members of the U.S. military receiving behavioral health treatment for posttraumatic stress and reported no adverse events, defined as psychiatric hospitalizations, suicides, and nonfatal suicide-related behaviors, number of times the patient support person was used during treatment, treatment adherence, and frequency of requests for patient or therapist technical support.²³ Following this safety study, a randomized controlled trial (RCT) compared telehealth or in-person delivery of behavioral activation treatment for depression with active-duty military personnel or veterans recruited from a military treatment facility and a Veterans Health Administration hospital.²⁴ Seven of 40 (17.5%) participants in the telehealth condition and 4 of 42 (9.5%) in the standard care condition experienced adverse events. None of these events (e.g., exacerbation of asthma) were determined to be related to the study.

Another small safety and feasibility study examined medication-augmented exposure therapy for posttraumatic stress in 11 participants from high-risk occupations and reported no safety events.²⁶ Seven of the 11 participants completed 12 to 15 sessions.

A randomized controlled feasibility study of mental health consultations for patients with depression or anxiety delivered through in-person or telehealth reported that 4 (of 22) participants in the telehealth condition reported at least 1 unintended consequence or adverse effect attributable to the telehealth intervention.²⁷ However, no adverse events were categorized as

serious, and data was not reported for the 27 participants in the usual care group.

All studies of video-based telehealth in behavioral health were small. Only one of the four studies provided a comparison of adverse events in telehealth and in-person care.

4.2.1.1.2 Telehealth in Rehabilitation

Two studies reported outcomes for video-based telehealth use in rehabilitation, one in followup after discharge from an intensive care unit (ICU) and one in cardiac rehabilitation. A small single-site randomized feasibility study focused on 21 medical/surgical ICU survivors with cognitive or functional impairment at hospital discharge and compared in-person to telehealth rehabilitation over a three-month period.¹⁹ Patients discharged to a nursing home or rehabilitation center were excluded from the study. One of the 13 participants in the telehealth group experienced an adverse event (i.e., a minor ankle sprain while conducting a walking exercise), while no patients receiving standard care did.

A second small RCT compared standard cardiac rehabilitation (21 participants) to hybrid care involving both in-person and telehealth care (26 participants).²¹ It reported no adverse events, including falls requiring hospitalization within 3 hours of completing a session, for either group.

While both studies in rehabilitation are small, each study provided comparisons between telehealth and in-person care.

4.2.1.1.3 Telehealth in Transplant Care

Two studies reported outcomes for video-based telehealth in transplant care, one applying telehealth to the evaluation and listing of patients for transplant and the other to post-transplant medication management. A retrospective study of 465 patients at one Veteran's Affairs Medical Center compared pretransplant mortality between those evaluated for liver transplant either in person (n = 233) or through telehealth (n = 232) and found no significant difference.²⁰

An RCT involved 136 kidney transplant recipients randomized to either usual care or a telehealth intervention including a mobile health app, remote monitoring of blood pressure and glucose, and video-based telehealth visits with a pharmacist.¹⁴ The total number of medication errors were significantly higher in the usual care control arm (1,385 versus 614, incident risk ratio 0.39, confidence interval 0.28 to 0.55, p<0.001). No significant differences were observed for rates of total infection or opportunistic infection. These studies suggest that telehealth may be no different than usual care in infections experienced by patients, and telehealth could reduce errors in post-transplant medication management compared to usual care.

4.2.1.1.4 Telehealth in Parkinson’s Disease Care

Two studies reported adverse event outcomes in Parkinson’s disease care involving use of video-based telehealth. One feasibility study of a virtual fall risk assessment involved 15 patients with Parkinson’s disease and reported no adverse events.¹⁵ A feasibility study of multidisciplinary care from speech therapists, physiotherapists, and pharmacists focused on 15 patients with Parkinson’s disease over 8 weeks and similarly reported no adverse events.¹⁸ Speech therapy, physiotherapy, and medication management sessions were delivered and supervised in real time by video telehealth.

Neither of these studies provided a comparison group, and both were small. Drawing conclusions about low-frequency adverse events is not appropriate.

4.2.1.1.5 Telehealth in Postoperative Care

A prospective cohort study included 718 surgical Veterans Affairs patients that self-selected video-based telehealth or traditional in-person care for post-operative followups.²⁵ The study reported no adverse events, including no significant differences in readmission or ED visits between the two groups.

4.2.1.1.6 Telehealth in Termination of Pregnancy Care

A retrospective study of 19,170 patients receiving termination of pregnancy care included 8,765 video-based telehealth visits and 10,405 in-person visits resulting in medical termination of pregnancy.¹⁷ Noninferiority for telehealth medical termination of pregnancy was confirmed with no significant difference in patients receiving a transfusion and no cases of death or surgery in either group.

4.2.1.1.7 Telehealth and Community Health Setting

One prospective cohort study of 13 men examined adverse events for video-based telehealth applied in the community health setting. A novel model of hypertension care, in which barbers refer men to hypertension care by pharmacists who use telehealth, reported no adverse events.¹⁶

4.2.1.1.8 Telehealth in Hospital-at-Home Care

One study examined adverse events associated with video-based telehealth in hospital care provided at home. An RCT compared adverse events in daily, in-home physician visits to initial in-home physician visits followed by subsequent video visits facilitated by an in-home nurse.²² A total of 172 patients were randomized, 84 to receive remote care and 88 in-home physician care. Adverse events included falls, pressure injury, and delirium,

with comparable rates suggesting noninferiority of telehealth care to in-person in-home care.

Table 2. Summary of studies reporting adverse events associated with video-based telehealth

Type of Care Delivery	Author, Year Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in behavioral care	Luxton, 2015 ²³ Feasibility study	Enlisted members of U.S. Army with PTSD	8	A behavioral activation treatment for PTSD delivered via synchronous (two-way) videoconferencing to the homes of U.S. military service members	Psychiatric hospitalizations, suicides, nonfatal suicide-related behaviors, patient support utilization, frequency of support requests, and treatment adherence	No adverse events reported
	Tönnies, 2021 ²⁷ RCT	Patients with depression or anxiety disorder	49 Control N=27 Intervention N=22	Web-based, real-time video consultations involving a 2-way interactive video to a primary care practice between mental health specialists and patients for up to 5 sessions	Self-reports of treatment leading to feeling worse, feeling hurt, fear of discovery of therapy	No serious major adverse events were reported although 4 of 22 patients in the treatment arm self-reported an unintended consequence or adverse event not otherwise serious. Adverse events were not reported for the control arm.
	Luxton, 2016 ²⁴ RCT	U.S. military personnel	121 Control N=59 Intervention N=62	8 sessions of behavioral activation treatment for depression in home via videoconferencing	Adverse events unrelated to treatment not defined except asthma attack. One safety protocol triggered by a previously unreported suicidal ideation.	No adverse events reported
	Olden, 2017 ²⁶ Prospective cohort	Survivors of trauma resulting from working in an occupation at risk for post-traumatic stress disorder	7	12–15 session exposure therapy protocol conducted weekly in 1.5-hour sessions through videoconferencing	None	No adverse events reported

Type of Care Delivery	Author, Year Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in rehabilitation	Jackson, 2012 ¹⁹ RCT	Patients discharged from medical intensive care unit or surgical intensive care unit	15 Control N=8 Intervention N=7	The rehabilitation intervention was provided over a 12-week period post-discharge in each patient's home and integrated both traditional "face-to-face" interventions as well as novel telephonic and video-based interventions	None	1 adverse event reported, an ankle sprain during walking exercise therapy. No adverse events were reported for the control arm.
	Keteyian, 2021 ²¹ RCT	Cardiac rehabilitation patients	47 Control N=21 Intervention N=26	Sessions completed remotely at-home or in the community using telehealth.	Falls requiring hospitalization	No serious adverse event or falls reported
Telehealth in Transplant care	John, 2020 ²⁰ Retrospective cohort	Liver transplant candidates	465 Control N=233 Intervention N=232	Telehealth visits with transplant hepatologist	Pre transplant mortality	No adverse events reported, no difference in pre-transplant mortality
	Gonzales, 2021 ¹⁴ RCT	Kidney transplant patients	136 Control N=68 Intervention N=68	Clinical pharmacist-led supplemental medication therapy monitoring and management, with risk-driven televisit and home-based blood pressure and blood glucose monitoring.	Medication error, total infection, and opportunistic infection rate	The total number of medication errors were significantly higher in the control arm. No significant differences were observed for other adverse events of total infection or opportunistic infection.

Type of Care Delivery	Author, Year Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in Parkinson's care	Afshari, 2021 ¹⁵ Feasibility study	Patients with Parkinson's disease	15	Four televisits every 2 weeks; televisits were performed on a HIPAA compliant secure video connect Epic platform.	Falls, near falls, and care partner intervention	No adverse events reported
	Hidecker, 2022 ¹⁸ Prospective cohort	Patients with Parkinson's disease	13	8-week telehealth program, consisting of speech therapy, physiotherapy, and pharmaceutical care	Falls, cardiac events, injuries, self-reported discomfort caused by therapy	No serious adverse events reported, 8 speech therapy patient reported hoarse voice of throat pain, 2 physiotherapy patients reported muscle soreness
Telehealth in postoperative care	Nikolian, 2018 ²⁵ Prospective cohort	Postoperative patients	718 Control N=485 Intervention N=233	2-week postoperative visit was conducted using telehealth (video).	None	No adverse events reported
Telehealth in termination of pregnancy care	Grossman, 2017 ¹⁷ Retrospective cohort	Pregnant women	19,170 Control N=10,405 Intervention N=8,765	Video discussion with patients, and if eligible for a medical termination of pregnancy, mifepristone and misoprostol were remotely prescribed	Hospital admission, surgery, blood transfusion, death, emergency department intravenous fluids or oral medication	No significant difference in adverse events for transfusion, no cases of death or surgery in either group
Telehealth and community health setting	Blyler, 2021 ¹⁶ Prospective cohort	Black men with stage 2 hypertension (systolic blood pressure ≥ 140 mm Hg)	13	Monthly virtual visits, connecting with the pharmacist via WebEx, Facetime, or standalone blood pressure monitors housed in the barbershops	Adverse events undefined	No adverse events reported

Type of Care Delivery	Author, Year Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in hospital-at-home care	Levine, 2022 ²² RCT	Patients who are home-health subscribers	172 Control N=88 Intervention N=84	Video visit daily after initial in-home visit (physician had option to see the patient in home again as needed)	Fall, pressure injury, delirium, thromboembolism, thrombophlebitis, catheter-associated urinary tract infection, new <i>Clostridoides difficile</i> infection, new methicillin-resistant <i>Staphylococcus aureus</i> infection, new arrhythmia, hypokalemia, acute kidney injury, transfer to hospital, unplanned mortality during or 30 days after admission	Adverse events included fall, pressure injury and delirium. Mean adjusted adverse events were 6.8 per 100 patients in the remote care arm and 3.9 per 100 patients in the control arm (difference reported as being within the range supporting noninferiority)

HIPAA = Health Insurance Portability and Accountability Act; PTSD = posttraumatic stress disorder, N= number of participants;

RCT = randomized controlled trial

*As reported in the included studies

4.2.1.2 Preventable Hospitalizations or Emergency Department Visits

A total of 13 studies addressed preventable hospitalizations or emergency department (ED) visits as an outcome associated with use of video-based telehealth in real-time clinical encounters between patients and clinicians. Seven of the studies reported on both outcomes,^{14, 17, 25, 28-31} three studies reported solely on preventable hospitalizations,³²⁻³⁴ and three studies reported on ED visits only.^{22, 35, 36} Table 3 provides a summary of findings for these studies. Details can also be found in Appendix C, Evidence Tables C-1 through C-3, and C-6 and C-7.

4.2.1.2.1 Telehealth in Postoperative Care

Six of the 13 studies focused on the use of video-based telehealth in postoperative care for a variety of surgical procedures including transplants (Table 3).

A small RCT of 30 patients in an enhanced recovery after surgery (ERAS) program (including postoperative telehealth) showed that 2 of 14 patients in the telehealth program were rehospitalized compared to none of 16 in usual care.²⁸ Also, 2 of 14 patients in the telehealth program had an ED visit compared to 1 of 14 patients receiving usual care. Significance was not reported for hospitalization or ED visit outcomes. The study was small, and the intervention included other components such as accelerated discharge which may have impacted rehospitalization rates in the telehealth program.

Another RCT randomized 136 kidney transplant recipients to usual care or a telehealth intervention including a mobile health app, remote monitoring of blood pressure and blood glucose, and telehealth visits with a pharmacist.¹⁴ The trial showed a significantly lower rate of hospitalizations for patients receiving the telehealth bundle.¹⁴ A nonrandomized study of 341 thoracic surgery patients showed that patients opting out of a telehealth followup visit had increased ED visits (odds ratio (OR) 8.7, $p \leq 0.05$) and 30-day readmissions (OR 5.1, $p \leq 0.05$) compared to patients opting for telehealth care.³⁰

One study assessed the impact of a range of practice changes to adapt liver transplantation services during the pandemic, including postoperative telehealth followup visits.³⁴ That study showed a trend toward increased readmission rates for patients receiving the redesigned care bundle during the pandemic (41.9% pre-pandemic versus 61.5% of peripandemic patients, $p = 0.09$). The study was small, and the intervention had multiple components.³⁴ The authors did not directly speculate on the causes of increased readmissions but described the complex effects of the pandemic on transplantation including decreases in referrals and delays in patient listings resulting in a likely increase in disease progression of patients receiving transplants during the pandemic.

A prospective cohort study of 718 surgical Veterans Affairs system patients showed no significant differences in postoperative readmissions or ED visits between standard of care and a postoperative intervention including telehealth.²⁵

Lastly, a randomized noninferiority trial for postdischarge virtual visits after low-risk surgeries showed that virtual followups were noninferior to in-person care for readmissions.³² Thus, postoperative interventions involving telehealth care were associated with varying differences in readmissions or ED visits compared with usual care.

4.2.1.2.2 Telehealth in Urological Care

Two studies examined the use of video-based telehealth in urological care. In a retrospective study of a telehealth program in male prisoners in Iowa, no patients required ED visits.³⁶ In a retrospective study of a telehealth program in the Veterans Affairs system, 1 percent of patients (1 of 97) had an ED visit within 30 days after the telehealth encounter.³⁵ It is difficult to draw conclusions from these two studies because they did not have a comparison group.

4.2.1.2.3 Telehealth in Hospital Discharge

In a RCT of 102 patients being discharged from the hospital, there were no significant differences in ED visits or readmissions between a tele-

discharge program (including virtual visits and telemonitoring) and standard in-person care after controlling for age, gender, and number of diagnoses.²⁹ The authors reported that the study was underpowered to statistically evaluate hospital admissions and ED visits.

4.2.1.2.4 Telehealth in Palliative Care

One quality improvement study integrated pharmacists into an interprofessional palliative care team in a single Veterans Affairs medical center and tracked ED visits and hospital admissions, but it did not report any comparative data between their video and telephone groups.³¹

4.2.1.2.5 Telehealth in Termination of Pregnancy Care

In a retrospective study of 19,170 patients receiving termination of pregnancy care, there was no significant difference in ED visits or hospitalizations between video-based telehealth or in person care.¹⁷ Six of 8,765 telehealth patients (0.07%) experienced a hospitalization compared to 13 of 10,405 in-person patients (0.12%). Thirteen telehealth patients (0.15%) experienced an ED admission with treatment compared to 22 in-person patients (0.21%).

4.2.1.2.6 Telehealth for Hospital-Level Care at Home

In an RCT of 172 patients receiving hospital-level care at home, 3.6 percent of patients randomized to remote video-based physician care were transferred back to the hospital compared with 2.3 percent of patients receiving in-person physician care.²²

4.2.1.2.7 Telehealth in Burn Care

In a retrospective study of 52 patients receiving video-based telehealth followup burn care, no readmissions were reported.³³

Table 3. Summary of preventable hospitalizations or emergency department visits associated with video-based telehealth

Type of Care Delivery	Author, Year Study Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in postoperative care	Bednarski, 2019 ²⁸ RCT	Colonic or rectal cancer patients	30 Control N=16 Intervention N=14	Accelerated discharge with televideo conference on the second postoperative day with a physician assistant.	Readmissions and ED visits within 30 days of surgery were monitored according to the Clavien–Dindo classification.	Telehealth was associated with a small increased rate of readmissions and ED visits compared to usual care that

Type of Care Delivery	Author, Year Study Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
						was not statistically significant.
	Gonzales, 2021 ¹⁴ RCT	Kidney transplant patients	136 Control N=68 Intervention N=68	Clinical pharmacist led supplemental medication therapy monitoring and management, with risk-driven televisits and home-based blood pressure and blood glucose monitoring.	Hospitalizations were defined as admission to a hospital with at least one overnight stay	Telehealth was associated with reduced readmissions.
	Tham, 2021 ³⁰ Retrospective cohort	Thoracic surgery patients	341 Control N=46 Intervention N=295	Postoperative telehealth visits.	ED visit and readmission within 30 days post discharge	Telehealth was associated with reduced risk for readmissions and ED visits.
	Delman, 2021 ³⁴ Prospective cohort	Transplant waitlisted patients	344 Control N=274 Intervention N=70	Virtual selection meetings and telehealth follow-up.	Readmission within 30 days post-transplant and Indications for readmission	Telehealth was associated with increased risk for readmissions.
	Nikolian, 2018 ²⁵ Prospective cohort	Post-operative patients	718 Control N=485 Intervention N=233	2-week post-operative visit was conducted using telehealth (video).	Length of stay, readmission, reoperation, and ED visits and deaths within 30 days of surgery	Telehealth was no different than usual care in readmissions and ED visits.
	Harkey [†] , 2021 ³² RCT	Postoperative patients	236 Control N=101 Intervention N=135	Video-based visits with a certified medical assistant & video-based virtual visits with a surgeon	Patients were emailed a survey 30 days after surgery to assess for adverse events, including readmission to other facilities. Electronic reminders were sent if surveys were not returned within a week, and 2 attempts were made to contact the patient by telephone	Virtual followups were noninferior to in person care for readmissions

Type of Care Delivery	Author, Year Study Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
Telehealth in urological care	Sherwood, 2019 ³⁶ Retrospective cohort	Prisoners with urologic complaints/ conditions	376	Video-based visit with a urological advance practice provider	Safety was assessed by analyzing the number of patients in which an ED visit was required after telehealth visit and missed or delayed cases of malignancy	No ED visits were reported for telehealth, but there was no comparison group
	Chu, 2015 ³⁵ Retrospective cohort	Veterans	97	Conducted telemedicine visits 9 half-days per month via a videoconferencing system over a virtual local area network between tertiary medical center and 2 outpatient primary care clinics	Examined the urologic conditions, patient satisfaction, and emergency department visits within 30 days of the telehealth visit	1% of patients (1 of 97) had an ED visit within 30 days post telehealth encounter, but there was no comparison group
Telehealth in hospital discharge	Noel, 2020 ²⁹ RCT	Patients with two or more chronic conditions	102 Control N=57 Intervention N=45	Provision of a telehealth kit; telehealth patients measured their vitals daily using the tele-equipment and had weekly virtual visits with a transition of care physician (i.e., teledoc)	Hospital readmissions and emergency department visits within 30 days of the index hospitalization discharge	No difference in ED visits or readmissions between a tele-discharge program (including virtual visits and tele monitoring) and standard in-person care
Telehealth in palliative care	Shirley, 2021 ³¹ Quality improvement	Veterans with cancer	25	Pharmacist-integrated telemedicine palliative care team clinic to optimize prescribing practices for Veterans receiving palliative care services	Emergency department visits and hospitalizations data was collected for the 6 months following clinic visits	No comparison group, but the average number of ED visits after telehealth visits was 0.16, and the number of hospitalizations for the same time period was 0.36
Telehealth in termination of pregnancy care	Grossman, 2017 ¹⁷ Retrospective cohort	Pregnant women	19,170 Control N=10,405 Intervention N=8,765	Video discussion with patients, and if eligible for a medical termination of pregnancy, mifepristone and misoprostol are	Assessed whether a patient required hospitalization, surgery, blood transfusion, or treatment in the emergency department	No significant difference in ED visits or hospitalizations between telehealth and in-person care

Type of Care Delivery	Author, Year Study Design	Study Participants	N	Telehealth Intervention*	Measures	Study Results
				remotely dispensed		
Telehealth in hospital at home care	Levine, 2022 ²² RCT	Patients who are home-health subscribers	172 Control N=88 Intervention N=84	Video visit daily after initial in-home visit (physician had option to see the patient in home again as needed)	Readmission 30-days after discharge from an acute care episode; additionally measured ED visit (unrelated to readmission) within 30 days or a primary care visit within 14 days	No significant difference in readmission rates between telehealth and in-person care
Telehealth in burn care	Hickey, 2017 ³³ Retrospective cohort	Burn Victims	31	Problem focused video-directed virtual physical exam	No specific definition for readmission	No comparison group, but no readmissions were reported

ED = emergency departments, N= number of participants; RCT = randomized controlled trial

* As reported in the included studies

† Harkey, 2021³² included 432 participants in the trial, but only 236 participants completed the allocated intervention. This report used the rate from the participants who completed the allocated intervention.

4.2.1.3 Misdiagnosis or Delayed Diagnosis

One study reported on diagnostic safety in telehealth. A retrospective comparison of diagnostic accuracy in video-based telehealth versus in-person care in 276 unique and 154 repeat telehealth visits showed 90 percent diagnostic concordance.³⁶ This study reviewed the safety and effectiveness of a urologic telehealth program in the Iowa prisoner population for over a decade. While no adverse events were reported, the results indicated that telehealth visits eliminated the need for in-person care in most cases. Details on this study can also be found in Appendix C, Evidence Tables C-1 through C-3, and C-8.

4.2.1.4 Results From the Grey Literature

This grey literature search focused on patient safety and adverse events in respect to the use of video-based telehealth technologies in delivering healthcare services. We identified seven reports from four sources relevant to this rapid review.³⁷⁻⁴³ The findings from these reports suggest that although telehealth has the potential to create operational efficiencies, there remains work to be done in standardizing protocols and procedures for conducting televisits and telehealth encounters. The authors proposed implementation strategies that include educational material for identifying patient safety concerns and developing standards for conducting telehealth encounters. We did not find any eligible

unpublished studies or work by searching ClinicalTrials.gov and PROSPERO. Appendix D provides details of the results of the grey literature searches.

4.2.2 Question 3. What PSPs have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters, and in what settings have they been used?

No studies met our inclusion criteria for this question.

4.2.3 Question 4. What is the reported rationale for the PSPs that have been used to prevent or mitigate the harms associated with use of video-based telehealth in real-time clinical encounters?

No studies met our inclusion criteria for this question.

4.2.4 Question 5. What are the effectiveness and unintended effects of the PSPs?

No studies met our inclusion criteria for this question.

4.2.5 Question 6. What are the most common barriers and facilitators (including cost and staff time) to implementing the PSPs?

No studies met our inclusion criteria for this question.

4.2.6 Question 7. What toolkits are available to support implementation?

No publicly available tools were found.



5. Discussion

5.1 Summary and Interpretation of Findings

This rapid review synthesized the literature evaluating patient safety issues and practices associated with real-time, synchronous video-based encounters between clinicians and patients. This is the first review to focus on patient-clinician real-time clinical encounters using video-based telehealth. The studies were systematically examined for questions about the safety of telehealth including any reporting of: the frequency and severity of harm, the usage of patient safety measures or indicators to examine harm, what safety practices and settings were used to prevent or mitigate harm, what was the rationale for their usage, the effectiveness and unintended effects of the of patient safety practices (PSPs), common barriers and facilitators to implementation, and any toolkits to support implementation. The majority of included studies were limited to evaluation of the frequency and severity of harm, using a variety of patient safety measures and indicators.

5.1.1 The Frequency, Severity, and Measurement of Harms Associated with Use of Telehealth

The most frequently reported patient safety outcomes in the identified studies were either adverse events or healthcare utilization (i.e., preventable hospital admissions, emergency department [ED] visits). Study size and quality varied greatly, with only 9 studies (of 23) identified as randomized controlled trials (RCTs).

Most other adverse events such as death, surgery, infection, or major complications were few, making it difficult to find statistically significant differences. Medication errors were the exception¹⁴ with a focused telehealth intervention resulting in *fewer* medication errors *than* standard in-person care. Additionally, one retrospective study in a prisoner population showed a relatively high level of concordance (90%) between telehealth and in-person diagnoses in urologic care.³⁶ This is particularly notable as missed or delayed diagnoses are considered one of the more likely harms associated with telehealth use.

The largest group of studies reporting utilization outcomes were in postoperative care. Three randomized controlled trials (RCTs) indicated either reduced risk^{14, 28} or no difference in risk³² of 30-day readmissions. Three cohort studies had mixed results with one study showing reduced risk of readmission and ED visits,³⁰ one showing no difference with usual care for readmissions and ED visits,²⁵ and one showing increased risk of readmissions.³⁴ An RCT of telemedicine in hospital discharge showed no difference in risk of readmissions or ED visits between telehealth and care as usual.²⁹ An RCT in hospital-at-home care showed no significant difference in readmissions between in-person and telehealth visits with a

doctor.²² A retrospective cohort study in termination of pregnancy care showed no significant difference in hospital admissions or ED visits between telehealth and in-person care. The remaining studies, which spanned a wide range of care settings, were difficult to interpret as there was no comparison group.^{31, 33, 35, 36}

5.1.2 PSPs to Reduce or Mitigate Harms Associated With the Use of Telehealth

This rapid review identified no specific interventions that could be characterized as a replicable PSP for addressing potential safety risks in real-time, synchronous video-based telehealth encounters between clinicians and patients. Appendix D details the grey literature reports that communication training, precharting (e.g., comprehensive reviews of patient histories), formalized patient escalation strategies, and education and reporting systems for adverse events have been proposed as PSPs for telemedicine.³⁷⁻⁴³ However, this rapid review identified no studies that evaluated the impact of any of the proposed PSPs. Consequently, there is no evidence-base to understand their effectiveness (Question 3), unintended effects (Question 5), or implementation processes (Question 6).

5.2 Limitations

As shown in Figure 2, half of the studies identified in this review were from 2021 or later, indicating the science of safety for telehealth is a new and active area of research. The widespread adoption of telehealth during the pandemic may have generated innovations that have not yet made their way into the scientific literature. Telehealth interventions are frequently multicomponent, and coupled with other technology (e.g., mobile health, telephone visits, patient portals, remote monitoring) or care delivery changes (e.g., the adoption of telemedicine as a component of hospital at home care, or as part of a broader redesign of perioperative care). This makes isolating the effects of telehealth difficult.

Rapid reviews use streamlined processes to complete the effort in a narrow timeline. In this review, we limited the studies to published works since 2012, performed within the clinical practices and healthcare systems of the United States, and evaluating video-based telehealth use with real-time encounters between patients and providers. We excluded studies related to asynchronous encounters, audio-only encounters (i.e., telephone visits), encounters using image analysis such as photography, teleconsultation, and remote monitoring of electrical devices. Interactions intended for synchronous video and audio could have reverted to audio only for a variety of reasons (e.g., network bandwidth, patient preference), but this was not systematically evaluated in this review. Additionally, many standard evidence standards and patient care practices were affected by the Coronavirus disease 19 (COVID-19) pandemic and the rapid changes in regulatory standards of care related to telemedicine.

5.3 Implications for Clinical Practice and Future Research

The scope of telehealth includes a wide variety of care models including real-time encounters between patients and providers, asynchronous encounters, image-based diagnostics, teleconsultation, and remote telemonitoring. Studies have evaluated the frequency and severity of harms associated with real-time video-based telehealth encounters between clinicians and patients, using a variety of patient safety measures. Studies suggest that telehealth was not inferior to usual care in terms of hospitalizations or ED visits. That is, studies generally reported no statistical differences between telehealth and usual care for patient safety outcomes. No studies have evaluated a specific PSP for reducing potential harms. We cannot make any conclusions about related implementation barriers and facilitators.

This review clearly identifies a gap in the literature and calls for more research to improve understanding of the specific harms associated with real-time use of video-based telehealth and how to prevent or mitigate identified harms. Future research should investigate the existing gaps in evidence, specifically developing and evaluating PSPs for reducing patient safety risks in telehealth. Even though there is no evidence that telehealth poses increased risk compared to usual care, risk remains in care processes and different PSPs may be required in telehealth settings from those used in usual care. This research will need to account for the observed complexity and multicomponent nature of many of the telehealth interventions reported on in this review. Future research should also explore further potential patient safety benefits of telehealth (e.g., if telehealth reduces the no show rate for appointments, does this translate into fewer delays in diagnoses or care?).

Excess utilization and adverse events were impacted by real-time video-based telehealth encounters. We suggest researchers address the evidence gaps by explicitly detailing how proposed telehealth interventions might impact patient safety and including the reporting and frequency of harm to control for confounding variables between intervention and control groups. Patient safety measures and indicators should be explicitly detailed to examine harm and explore how interventions might prevent or mitigate harm. Impactful studies should review barriers and facilitators and provide toolkits to support implementation.



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Authors

Michael Rosen, M.A., Ph.D., C. Matthew Stewart M.D., Ph.D., Hadi Kharrazi, M.H.I., M.D., Ph.D, Ritu Sharma B.Sc., Montrell Vass, B.S., Allen Zhang, B.S., and Eric B. Bass, M.D., M.P.H.

Peer Reviewers

Prior to publication of the final evidence report, the Evidence Based Practice Center (EPC) sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers. Peer Reviewers must disclose any financial conflicts of interest greater than \$5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The AHRQ Task Order Officer (TOO) and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers follows:

Brian William Hasselfeld, M.D.
Senior Medical Director, Digital Health and Innovation
Johns Hopkins Medicine
Baltimore, MD

Bob McNellis, M.P.H., P.A.
Senior Advisor for Disease Prevention
Office of Disease Prevention
National Institutes of Health
Bethesda, MD

Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Susan Henderson, M.D., M.P.H., Medical Officer in the AHRQ Division of Healthcare Associated Infections, who reviewed the report as a subject matter expert, and Ryan Tam and Christin Ko, who helped with screening and abstraction.

Disclaimers

This report is based on research conducted by the Johns Hopkins University under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 75Q80120D00003). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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A representative from AHRQ served as a Contracting Officer's Representative and reviewed the contract deliverables for adherence to contract requirements and quality. AHRQ did not directly participate in the literature search, determination of study eligibility criteria, data analysis, interpretation of data, or preparation or drafting of this report.

AHRQ appreciates appropriate acknowledgment and citation of its work. Suggested language for acknowledgment: This work was based on an evidence report, Potential Harms Resulting From Patient-Clinician Real-Time Clinical Encounters Using Video-Based Telehealth: A Rapid Evidence Review, by the Evidence-based Practice Center Program at the Agency for Healthcare Research and Quality (AHRQ).

Suggested citation: Rosen M, Stewart CM, Kharrazi H, Sharma R, Vass M, Zhang A, Bass EB. Potential Harms Resulting From Patient-Clinician Real-Time Clinical Encounters Using Video-based Telehealth: A Rapid Evidence Review (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 75Q80120D00003.). AHRQ Publication No. 23-EHC019-2. Rockville, MD: Agency for Healthcare Research and Quality; September 2023. Posted final reports are located on the Effective Health Care Program [search page](#). DOI: https://doi.org/10.23970/AHRQEPC_MHS4TELEHEALTH.

Afterword

Recognized for excellence in conducting comprehensive systematic reviews, the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) Program is developing a range of rapid evidence products to assist end-users in making specific decisions in a limited timeframe. AHRQ recognizes that people are struggling with urgent questions on how to make healthcare safer. AHRQ is using this rapid format for the fourth edition of its Making Healthcare Safer series of reports, produced by the EPC Program and the General Patient Safety Program. To shorten timelines, reviewers make strategic choices about which processes to abridge. However, the adaptations made for expediency may limit the certainty and generalizability of the findings from the review, particularly in areas with a large literature base. Transparent reporting of the methods used and the resulting limitations of the evidence synthesis are extremely important.

AHRQ expects that these rapid evidence products will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to AHRQ. If you have comments related to this report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to MHS@ahrq.hhs.gov.

Robert Otto Valdez, Ph.D., M.H.S.A.
Director
Agency for Healthcare Research and Quality

Therese Miller, D.P.H.
Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Craig A. Umscheid, M.D., M.S.
Director
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

David W. Niebuhr, M.D., M.P.H., M.Sc.
Evidence-based Practice Center Program Liaison
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Erin N. Grace, M.H.A.
Acting Director, Healthcare-Associated Infections
Division
Deputy Center Director
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality

Margie Shofer, B.S.N., M.B.A.
Director, General Patient Safety Program
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality

Jennifer Eskandari
Task Order Officer
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality

Farzana Samad, PharmD, FISMP, CPPS
Health Scientist Administrator
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality

Appendixes

Appendix A. Methods

Search Strategies for Published Literature

Table A-1. PubMed search strategy

#	Concept	Search Terms
1	Telehealth	Telemedicine[mh] OR telemedicine[tiab] OR "tele medicine"[tiab] OR telehealth [tiab] OR "tele health"[tiab] OR videoconferencing[mh] OR "video conferencing"[tiab] OR videoconference*[tiab] OR "video conference"[tiab] OR "video consult"[tiab] OR "videophone"[tiab] OR "video visit"[tiab] OR "virtual visit"[tiab] OR "virtual consult"[tiab] OR televisit* [tiab] OR "tele visit"[tiab] OR teleconsult*[tiab] OR "tele consult"[tiab]
2	Patient safety/harms	"patient safety"[mh] OR "patient safety" [tiab] OR "Patient Harm"[mh] OR "Patient Harm"[tiab] OR "patient risk"[tiab] OR "quality care" [tiab] OR "adverse event"[tiab] OR "undesired event"[tiab] OR "medical errors"[mh] OR "medical error"[tiab] OR "Diagnostic Errors" [mh] OR "diagnostic error"[tiab] OR "Medical mistake"[tiab] OR "Diagnostic mistake"[tiab] OR "Healthcare error"[tiab] OR "Health care error"[tiab] OR "erroneous diagnos"[tiab] OR "failure to diagnose"[tiab] OR "false diagnos"[tiab] OR "faulty diagnos"[tiab] OR misdiagnos*[tiab] OR "mistaken diagnos"[tiab] OR "wrong diagnos"[tiab]
3.	1 AND 2	Telehealth AND Patient safety
4.	Publication limit 2012 - September 2022	

Table A-2. Embase search strategy

#	Concept	Search Terms
1	Telehealth	Telemedicine/exp OR telemedicine:ti,ab OR 'tele medicine':ti,ab OR telehealth:ti,ab OR 'tele health':ti,ab OR videoconferencing/exp OR 'video conferencing':ti,ab OR videoconference:ti,ab OR 'video conference':ti,ab OR 'video consult':ti,ab OR 'videophone':ti,ab OR 'video visit':ti,ab OR 'virtual visit':ti,ab OR 'virtual consult':ti,ab OR televisit:ti,ab OR 'tele visit':ti,ab OR teleconsult:ti,ab OR 'tele consult':ti,ab
2	Patient safety/harms	'patient safety'/exp OR 'patient safety':ti,ab OR 'Patient Harm'/exp OR 'Patient Harm':ti,ab OR 'patient risk':ti,ab OR 'quality care':ti,ab OR 'adverse event':ti,ab OR 'undesired event':ti,ab OR 'medical errors'/exp OR 'medical error':ti,ab OR 'Diagnostic Errors'/exp OR 'diagnostic error':ti,ab OR 'Medical mistake':ti,ab OR 'Diagnostic mistake':ti,ab OR 'Healthcare error':ti,ab OR 'Health care error':ti,ab OR 'erroneous diagnos':ti,ab OR 'failure to diagnose':ti,ab OR 'false diagnos':ti,ab OR 'faulty diagnos':ti,ab OR misdiagnos:ti,ab OR 'mistaken diagnos':ti,ab OR 'wrong diagnos':ti,ab
3.	1 AND 2	Telehealth AND Patient safety
4.	Publication limit 2012 - September 2022	

Table A-3. Cochrane search strategy

#	Concept	Search Terms
1	Telehealth	Telemedicine(MESH) OR telemedicine:ti,ab,kw OR 'tele medicine':ti,ab,kw OR telehealth:ti,ab,kw OR 'tele health':ti,ab,kw OR videoconferencing(MESH) OR 'video conferencing':ti,ab,kw OR videoconference:ti,ab,kw OR 'video conference':ti,ab,kw OR 'video consult':ti,ab,kw OR 'videophone':ti,ab,kw OR 'video visit':ti,ab,kw OR 'virtual visit':ti,ab,kw OR 'virtual consult':ti,ab,kw OR televisit:ti,ab,kw OR 'tele visit':ti,ab,kw OR teleconsult:ti,ab,kw OR 'tele consult':ti,ab,kw
2	Patient safety/harms	'patient safety'(MESH) OR 'patient safety':ti,ab,kw OR 'Patient Harm'(MESH) OR 'Patient Harm':ti,ab,kw OR 'patient risk':ti,ab,kw OR 'quality care':ti,ab,kw OR 'adverse event':ti,ab,kw OR 'undesired event':ti,ab,kw OR 'medical errors'(MESH) OR 'medical error':ti,ab,kw OR 'Diagnostic Errors'(MESH) OR 'diagnostic error':ti,ab,kw OR 'Medical mistake':ti,ab,kw OR 'Diagnostic mistake':ti,ab,kw OR 'Healthcare error':ti,ab,kw OR 'Health care error':ti,ab,kw OR 'erroneous diagnos':ti,ab,kw OR 'failure to diagnose':ti,ab,kw OR 'false diagnos':ti,ab,kw OR 'faulty diagnos':ti,ab,kw OR misdiagnos:ti,ab,kw OR 'mistaken diagnos':ti,ab,kw OR 'wrong diagnos':ti,ab,kw
3.	1 AND 2	Telehealth AND Patient safety
4.	Publication limit 2012 - September 2022	

Appendix B. List of Excluded Studies Upon Full-Text Review

1. Adly AS, Adly AS, Adly MS. Effects of laser acupuncture tele-therapy for rheumatoid arthritis elderly patients. *Lasers in Medical Science*. 2022;37(1):499-504. doi: 10.1007/s10103-021-03287-0. - **Non-USA based study or does not report data separately for USA**
2. Aiken A, Lohr PA, Lord J, et al. Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study. *Bjog*. 2021 Aug;128(9):1464-74. doi: 10.1111/1471-0528.16668. PMID: 33605016. - **Non-USA based study or does not report data separately for USA**
3. Aiken ARA, Romanova EP, Morber JR, et al. Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study. *Lancet Reg Health Am*. 2022 Jun;10doi: 10.1016/j.lana.2022.100200. PMID: 35755080. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
4. Anderson T, McClintock AS, McCarrick SS, et al. Working Alliance, Interpersonal Problems, and Depressive Symptoms in Tele-Interpersonal Psychotherapy for HIV-infected Rural Persons: evidence for Indirect Effects. *Journal of clinical psychology*. 2018;74(3):286-303. doi: 10.1002/jclp.22502. PMID: CN-01794391. - **Audio only visits**
5. Bakas T, Sampsel D, Israel J, et al. Using telehealth to optimize healthy independent living for older adults: A feasibility study. *Geriatric nursing*. 2018;39(5):566-73. doi: 10.1016/j.gerinurse.2018.04.002. PMID: CN-02416995. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
6. Banner D, Lear S, Kandola D, et al. The experiences of patients undertaking a 'virtual' cardiac rehabilitation program. *Studies in health technology and informatics*. 2015;209:9-14. PMID: CN-01215258. - **Non-USA based study or does not report data separately for USA**
7. Batalik L, Konecny V, Dosbaba F, et al. Cardiac Rehabilitation Based on the Walking Test and Telerehabilitation Improved Cardiorespiratory Fitness in People Diagnosed with Coronary Heart Disease during the COVID-19 Pandemic. *Int J Environ Res Public Health*. 2021 Feb 24;18(5)doi: 10.3390/ijerph18052241. PMID: 33668304. - **Non-USA based study or does not report data separately for USA**
8. Bauer MS, Krawczyk L, Miller CJ, et al. Team-Based Telecare for Bipolar Disorder. *Telemed J E Health*. 2016 Oct;22(10):855-64. doi: 10.1089/tmj.2015.0255. PMID: 26906927. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**

9. Bellsmith KN, Gale MJ, Yang S, et al. Validation of home visual acuity tests for telehealth in the COVID-19 era. *Investigative Ophthalmology and Visual Science*. 2021;62(8). - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
10. Benvenuti F, Stuart M, Cappena V, et al. Community-based exercise for upper limb paresis: a controlled trial with telerehabilitation. *Neurorehabil Neural Repair*. 2014 Sep;28(7):611-20. doi: 10.1177/1545968314521003. PMID: 24515928. - **Non-USA based study or does not report data separately for USA**
11. Bera R, Franey E, Martello K, et al. Presence of Caregivers at Telehealth Visits Significantly Improves Virtual Assessment of Drug-Induced Movement Disorders. *Movement Disorders Clinical Practice*. 2022;9(SUPPL 1):S12-S3. doi: 10.1002/mdc3.13411. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**
12. Bera R, Franey E, Martello K, et al. TeleSCOPE: A Real-World Study of Telehealth for the Detection and Treatment of Drug-Induced Movement Disorders. *CNS Spectrums*. 2022;27(2):250. doi: 10.1017/S1092852922000621. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**
13. Bernocchi P, Vitacca M, La Rovere MT, et al. Home-based telerehabilitation in older patients with chronic obstructive pulmonary disease and heart failure: a randomised controlled trial. *Age and ageing*. 2018;47(1):82-8. doi: 10.1093/ageing/afx146. PMID: CN-01425738. - **Non-USA based study or does not report data separately for USA**
14. Bisno DI, Reid MW, Berget C, et al. Group appointments (GA) via home telehealth (HT) for young adults (YA) with type 1 diabetes (T1D) may improve psychosocial functioning. *Diabetes*. 2019;68doi: 10.2337/db19-801-P. PMID: CN-01995844. - **Conference, meeting, poster abstract only**
15. Bond A, Taylor M, Abraham A, et al. Successful implementation of remote video consultations for patients receiving home parenteral nutrition. *Gut*. 2018;67:A230-A1. doi: 10.1136/gutjnl-2018-BSGAbstracts.459. - **Conference, meeting, poster abstract only**
16. Bourdon H, Jaillant R, Ballino A, et al. Teleconsultation in primary ophthalmic emergencies during the COVID-19 lockdown in Paris: Experience with 500 patients in March and April 2020. *J Fr Ophtalmol*. 2020 Sep;43(7):577-85. doi: 10.1016/j.jfo.2020.05.005. PMID: 32564983. - **Non-USA based study or does not report data separately for USA**
17. Bowen DJ, Robbins R, Bush N, et al. Effects of a web-based intervention on women's breast health behaviors. *Translational behavioral medicine*. 2017;7(2):309-19. doi: 10.1007/s13142-016-0439-z. PMID: CN-01403718. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**

18. Bowman A, Denehy L, Benjemaa A, et al. Feasibility and safety of the 30-second sit-to-stand test delivered via telehealth: An observational study. *Pm r*. 2022 Feb 9doi: 10.1002/pmjr.12783. PMID: 35138036. - **Non-USA based study or does not report data separately for USA**
19. Brahier M, Baker K, Penne M, et al. Patient-Perceived Breakdowns in Telehealth-Diagnosis Early in the COVID-19 Pandemic. An Exploratory Mixed Methods Study. *Diagnosis*. 2022;9(2):eA76-eA7. doi: 10.1515/dx-2022-0024. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**
20. Brasen CL, Madsen JS, Parkner T, et al. Home Management of Warfarin Treatment Through a Real-Time Supervised Telemedicine Solution: a Randomized Controlled Trial. *Telemedicine journal and e-health*. 2019;25(2):109-15. doi: 10.1089/tmj.2017.0260. PMID: CN-01793289. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
21. Brocki BC, Andreasen JJ, Aaroe J, et al. Exercise-Based Real-time Telerehabilitation for Older Adult Patients Recently Discharged After Transcatheter Aortic Valve Implantation: Mixed Methods Feasibility Study. *JMIR Rehabil Assist Technol*. 2022 Apr 26;9(2):e34819. doi: 10.2196/34819. PMID: 35471263. - **Non-USA based study or does not report data separately for USA**
22. Buvanendran A, Burns JW, Moric M, et al. Telemedicine delivered cognitive behavioral therapy (CBT) reduces pain catastrophizing. *Regional anesthesia and pain medicine*. 2016;41(5) PMID: CN-01333648. - **Conference, meeting, poster abstract only**
23. Buvik A, Bergmo TS, Bugge E, et al. Cost-Effectiveness of Telemedicine in Remote Orthopedic Consultations: randomized Controlled Trial. *Journal of medical Internet research*. 2019;21(2):e11330. doi: 10.2196/11330. PMID: CN-01791048. - **Non-USA based study or does not report data separately for USA**
24. Caccese M, Imbevaro S, Feltrin A, et al. Cancer Patient-Reported Experience Measures (PREMs) Regarding the Policies Implemented to Contain the Spread of Sars-CoV-2 and Vaccination Campaign at Veneto Institute of Oncology. *Patient Prefer Adherence*. 2022;16:353-62. doi: 10.2147/ppa.s351771. PMID: 35173420. - **Non-USA based study or does not report data separately for USA**
25. Capin JJ, Jolley SE, Morrow M, et al. Safety, feasibility and initial efficacy of an app-facilitated telerehabilitation (AFTER) program for COVID-19 survivors: a pilot randomised study. *BMJ Open*. 2022 Jul 26;12(7):e061285. doi: 10.1136/bmjopen-2022-061285. PMID: 35882451. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
26. Casten R, Rovner B, Chang AM, et al. A randomized clinical trial of a collaborative home-based diabetes intervention to reduce emergency department visits and hospitalizations in black individuals with diabetes. *Contemporary Clinical Trials*. 2020;95doi: 10.1016/j.cct.2020.106069. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**

27. Cerdan de Las Heras J, Balbino F, Catalán-Matamoros D, et al. Effect of a Telerehabilitation program in sarcoidosis. *Sarcoidosis Vasc Diffuse Lung Dis.* 2022;39(1):e2022003. doi: 10.36141/svld.v39i1.12526. PMID: 35494172. - **Non-USA based study or does not report data separately for USA**
28. Cha YH, Riley J, Gleghorn D, et al. Remotely Monitored Home-Based Neuromodulation With Transcranial Alternating Current Stimulation (tACS) for Mal de Débarquement Syndrome. *Frontiers in Neurology.* 2021;12doi: 10.3389/fneur.2021.755645. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
29. Check DK, Winger JG, Jones KA, et al. Predictors of Response to an Evidence-Based Behavioral Cancer Pain Management Intervention: an Exploratory Analysis From a Clinical Trial. *Journal of pain and symptom management.* 2021;62(2):391-9. doi: 10.1016/j.jpainsymman.2020.12.020. PMID: CN-02251010. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
30. Chen WL, Chiu WT, Wu MS, et al. Translational research of telecare for the treatment of hepatitis C. *BioMed Research International.* 2014;2014doi: 10.1155/2014/195097. - **Non-USA based study or does not report data separately for USA**
31. Cheville A, Moynihan T, Herrin J, et al. Collaborative Tele-Rehabilitation Among Patients With Advanced Stage Cancers: a Randomized Controlled Trial. *Archives of physical medicine and rehabilitation.* 2019;100(10):e18-. doi: 10.1016/j.apmr.2019.08.035. PMID: CN-01985203. - **Conference, meeting, poster abstract only**
32. Cheville AL, Moynihan T, Herrin J, et al. Effect of Collaborative Telerehabilitation on Functional Impairment and Pain Among Patients With Advanced-Stage Cancer: a Randomized Clinical Trial. *JAMA oncology.* 2019;5(5):644-52. doi: 10.1001/jamaoncol.2019.0011. PMID: CN-01937468. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
33. Cho JH, Kim HS, Yoo SH, et al. An Internet-based health gateway device for interactive communication and automatic data uploading: Clinical efficacy for type 2 diabetes in a multi-centre trial. *J Telemed Telecare.* 2017 Jul;23(6):595-604. doi: 10.1177/1357633x16657500. PMID: 27381040. - **Non-USA based study or does not report data separately for USA**
34. Choi H, Lee SK. Failure mode and effects analysis of telehealth service of minority elderly for sustainable digital transformation. *Comput Biol Med.* 2022 Sep;148:105950. doi: 10.1016/j.combiomed.2022.105950. PMID: 35973373. - **Non-USA based study or does not report data separately for USA**
35. Chong E, Shochet T, Raymond E, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. *Contraception.* 2021 Jul;104(1):43-8. doi: 10.1016/j.contraception.2021.03.019.

PMID: 33781762. - **Does not report data for adult patients or cannot extract information separately**

36. Choudhary N, Chakravarty K, Kharbanda PS, et al. Satisfaction and effectiveness of tele-medicine in follow-up of people with epilepsy in a resource-poor setting during COVID-19. *Epilepsy Behav.* 2022 Mar;128:108569. doi: 10.1016/j.yebeh.2022.108569. PMID: 35104733. - **Non-USA based study or does not report data separately for USA**
37. Chowdhury M, Birns J, Rudd A, et al. Telemedicine versus face-to-face evaluation in the delivery of thrombolysis for acute ischaemic stroke: A single centre experience. *Postgraduate Medical Journal.* 2012;88(1037):134-7. doi: 10.1136/postgradmedj-2011-130060. - **Includes only patients receiving in-patient or emergency department care**
38. Christiansen CL, Miller MJ, Kline PW, et al. Biobehavioral Intervention Targeting Physical Activity Behavior Change for Older Veterans after Nontraumatic Amputation: A Randomized Controlled Trial. *PM r.* 2020 Oct;12(10):957-66. doi: 10.1002/pmrvj.12374. PMID: 32248638. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
39. Clarke AL, Roscoe J, Appleton R, et al. Promoting integrated care in prostate cancer through online prostate cancer-specific holistic needs assessment: a feasibility study in primary care. *Supportive care in cancer.* 2020;28(4):1817-27. doi: 10.1007/s00520-019-04967-y. PMID: CN-02124059. - **Non-USA based study or does not report data separately for USA**
40. Comer JS, Furr JM, Kerns CE, et al. Internet-delivered, family-based treatment for early-onset OCD: A pilot randomized trial. *J Consult Clin Psychol.* 2017 Feb;85(2):178-86. doi: 10.1037/ccp0000155. PMID: 27869451. - **Does not report data for adult patients or cannot extract information separately**
41. Cooper I, Brukner P, Devlin BL, et al. An anti-inflammatory diet intervention for knee osteoarthritis: a feasibility study. *BMC Musculoskelet Disord.* 2022 Jan 13;23(1):47. doi: 10.1186/s12891-022-05003-7. PMID: 35027029. - **Non-USA based study or does not report data separately for USA**
42. Cordova FC, Ciccolella D, Grabianowski C, et al. A Telemedicine-Based Intervention Reduces the Frequency and Severity of COPD Exacerbation Symptoms: A Randomized, Controlled Trial. *Telemed J E Health.* 2016 Feb;22(2):114-22. doi: 10.1089/tmj.2015.0035. PMID: 26259074. - **Study of remotely delivered, non-synchronous medical services**
43. Cortes-Penfield NW, LeMaster M, Alexander B. Implementation of a Telehealth-based OPAT Early Post-Discharge Clinic May Reduce Hospital Readmission. *Open Forum Infectious Diseases.* 2021;8(SUPPL 1):S405. doi: 10.1093/ofid/ofab466.804. - **Conference, meeting, poster abstract only**

44. Cox NS, McDonald CF, Hill CJ, et al. Telerehabilitation for chronic respiratory disease. *Cochrane Database of Systematic Reviews*. 2018;2018(6)doi: 10.1002/14651858.CD013040. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**
45. Creadore A, Tkachenko E, Li D, et al. 17915 Determining accuracy of teledermatology diagnosis of cellulitis. *Journal of the American Academy of Dermatology*. 2020;83(6):AB87. doi: 10.1016/j.jaad.2020.06.436. - **Conference, meeting, poster abstract only**
46. Crump CA, Wernz C, Schlachta-Fairchild L, et al. Closing the Digital Health Evidence Gap: Development of a Predictive Score to Maximize Patient Outcomes. *Telemed J E Health*. 2021 Sep;27(9):1029-38. doi: 10.1089/tmj.2020.0334. PMID: 33170109. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
47. Cuaron JJ, Gillespie EF, Shaverdian N, et al. Safety and Satisfaction of Patients Opting for Fully Remote Consultation and On-Treatment Management Visits During COVID-19. *International Journal of Radiation Oncology Biology Physics*. 2021;111(3):S111. doi: 10.1016/j.ijrobp.2021.07.256. - **No original data (opinion, descriptive data, letters, editorial, commentary, protocols)**
48. Daly B, Kuperman G, Zervoudakis A, et al. InSight Care Pilot Program: Redefining Seeing a Patient. *JCO Oncol Pract*. 2020 Oct;16(10):e1050-e9. doi: 10.1200/op.20.00214. PMID: 32468925. - **Study of remotely delivered, non-synchronous medical services**
49. Danila M, Outman R, Rahn E, et al. The activating patients at risk for osteoporosis (apropos) study: a randomized trial within the glow cohort. *Journal of bone and mineral research*. 2017;31doi: 10.1002/jbmr.3107. PMID: CN-01462255. - **Conference, meeting, poster abstract only**
50. Davis LE, Harnar J, LaChey-Barbee LA, et al. Using Teleneurology to Deliver Chronic Neurologic Care to Rural Veterans: Analysis of the First 1,100 Patient Visits. *Telemed J E Health*. 2019 Apr;25(4):274-8. doi: 10.1089/tmj.2018.0067. PMID: 30016207. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
51. De Souza MA, Fioretti AC, Vincentin AH, et al. Effectiveness of telemedicine in response to the COVID-19 pandemic. *Revista da Associacao Medica Brasileira*. 2021;67(10):1427-31. doi: 10.1590/1806-9282.20210611. - **Non-USA based study or does not report data separately for USA**
52. Der-Martirosian C, Griffin AR, Chu K, et al. Telehealth at the US Department of Veterans Affairs after Hurricane Sandy. *J Telemed Telecare*. 2019 Jun;25(5):310-7. doi: 10.1177/1357633x17751005. PMID: 29384428. - **Does not report on any outcomes, harms, safety measures, or safety indicators**
53. Desai C, Pearce I, Modgil V. Performing sensitive clinical examinations during urological telemedicine visits: How to avoid pitfalls? *Research and Reports in Urology*.

- 2021;13:739-44. doi: 10.2147/RRU.S313881. - **Study does not report on use of telehealth in real-time encounters between patients and clinicians**
54. Dickinson R, Hall S, Sinclair JE, et al. Using technology to deliver cancer follow-up: A systematic review. *BMC Cancer*. 2014;14(1)doi: 10.1186/1471-2407-14-311. - **Relevant but review (systematic/narrative/scoping)**
 55. Dobrzanskiy O, Kondratskiy Y, Kolesnik A, et al. Role of minimally invasive surgical procedures in treatment of gastric cancer. *European journal of surgical oncology*. 2019;45(2):e78-. doi: 10.1016/j.ejso.2018.10.282. PMID: CN-01792915. - **No mention of telehealth**
 56. Dunkerley S, Thelwall C, Omiawele J, et al. Patient care modifications and hospital regulations during the COVID-19 crisis created inequality and functional hazard for patients with orthopaedic trauma. *International Orthopaedics*. 2020;44(12):2481-5. doi: 10.1007/s00264-020-04764-x. - **Non-USA based study or does not report data separately for USA**
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Appendix C. Evidence Tables

Evidence Table C-1. Study characteristics of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Afshari, 2021 ¹⁵	KQ1	To determine if the telehealth application of two observer-based, objective measures of fall-risk in PD—Five-Times-Sit-To-Stand (FTSTS) and 360 Rapid-Turns-Test (RTT)—is feasible and safe	Study name: NR Main study: NR	NR	Feasibility study	All participants had an initial in-person clinic evaluation, followed by four televisits every 2 weeks and then a final in-person visit. Televisits were performed on the HIPAA compliant secure VidyoConnect Epic platform. Participants used their own or a loaned Apple iPad and connected to their home WiFi to participate in televisits. At the baseline in-person visit, the study physical therapist demonstrated the FTSTS and RTT measures and obtained baseline scores. Participants learned how to execute measures at home, and care partners were instructed on stand-by assistance measures.	NR	10 Week

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Bednarski, 2019 ²⁸	KQ1	To determine whether the combination of MIS, ERP and a structured telemedicine program (TeleRecovery) could shorten total 30-day LOS by 50 per cent	Study name: RecoverMI Main study: Phase II of RecoverMI	1/7/2016 to 8/22/2017	RCT	Accelerated discharge on postoperative day (POD) 1 with or without evidence of bowel function and a teleVideo-conference on POD-2. Physician assistants within the colonic and rectal surgery section at MDACC conducted the teleVideo-conferences.	Routine postoperative management care	NR
Blyler, 2021 ¹⁶	KQ1	Tested whether virtual visits could be substituted for in-person visits after blood pressure (BP) control was achieved.	Study name: NR Main study: Los Angeles Barbershop Blood pressure Study	NR	Prospective cohort	Participants' barbers promoted follow-up with a specialty-trained pharmacist who initially met each patron in the barbershop for bimonthly in-person visits. Once BP goal of $\leq 130/80$ mmsHg achieved, participants were transitioned to monthly virtual visits, connecting with the pharmacist via WebEx, Facetime, or stand-alone BP monitors housed in the barbershops.	No comparator	NR
Chu, 2015 ³⁵	KQ1	To report the use of telemedicine to deliver general urologic care to remote locations within the Veterans Affairs Greater Los Angeles Healthcare System.	Study name: NR Main study: NR	9/1/2013 to 3/1/2014	Retrospective cohort	Conducted telemedicine visits 9 half-days per month via a videoconferencing system over a virtual local area network between tertiary medical center and 2 outpatient primary care clinics.	No comparator	9.5 Day

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Delman, 2021 ³⁴	KQ1	To report our center's (University of Cincinnati Medical Center, Cincinnati, OH) protocolized response to the COVID-19 pandemic	Study name: NR Main study: NR	3/1/2020 to 8/1/2020	Prospective cohort	COVID-19 era: virtual selection meetings, coronavirus disease 2019 negative donors, pretransplant symptom screening, rapid testing on presentation, telehealth follow-up, and weekly community outreach town halls.	Pre-COVID-19 era: usual care	NR
Gonzalez, 2021 ¹⁴	KQ1	To examine the efficacy of improving medication safety through a pharmacist-led, mobile health-based intervention.	Study name: NR Main study: NR	NR	RCT	Received clinical pharmacist-led supplemental medication therapy monitoring and management, utilizing a smartphone-enabled mobile health app, with risk-driven televisits and home-based BP and blood glucose monitoring.	Usual care	12 Month
Grossman, 2017 ¹⁷	KQ1, KQ2	To compare the proportion of medical termination of pregnancy with a clinically significant adverse event among telemedicine and in-person patients at a clinic system in Iowa during the first 7 years of the service	Study name: NR Main study: NR	7/1/2008 to 6/30/2015	Retrospective cohort	Video discussion with patients, and if eligible for a medical termination of pregnancy, mifepristone and misoprostol are remotely dispensed.	In-person medical termination of pregnancy services	NR

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Harkey, 2021 ³²	KQ1	To evaluate the outcomes of all-cause 30-day hospital encounter proportion among patients who have a post-discharge video-based virtual visit follow-up compared with in-person follow-up.	Study name: NR Main study: NR	8/1/2017 to 3/1/2020	RCT	Completing a video-based visit with the certified medical assistant who confirmed patient location, identification, and reviewed demographics and home medications. Patients were then placed in the virtual waiting room until the surgery team member picked them up and a separate video-based virtual visit was performed.	In-person visits	NR
Hickey, 2017 ³³	KQ1	The objective of this study is to review our experience incorporating Interactive Home Telehealth (IHT) visits into follow-up burn care	Study name: NR Main study: NR	3/1/2015 to 6/1/2016	Retrospective cohort	Typical encounters included a brief follow-up discussion, with a review of any changes in clinical status, as well as a problem focused video-directed virtual physical exam. Changes to the outpatient burn plan of care were communicated directly to the patient.	NR	15 Month
Hidecker, 2022 ¹⁸	KQ1,	This study aimed to test the feasibility, safety, and signal of efficacy of a coordinated telehealth program, consisting of speech therapy, physiotherapy, and pharmaceutical care, for people with PD living in some rural US communities.	Study name: NR Main study: NR	11/1/2017 to 12/1/2018	Prospective cohort	8-week telehealth program, consisting of speech therapy, physiotherapy, and pharmaceutical care, using a single cohort of people with PD living in rural Wyoming and Nevada, USA.	Patients at Baseline	8 Week

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Jackson, 2012 ¹⁹	KQ1	To overcome the current reality in which patients receive inadequate rehabilitation, we devised a multi-faceted, in-home tele-rehabilitation program implemented using social workers and psychology technicians with the goal of improving cognitive and functional outcomes.	Study name: The Returning to Everyday Tasks Utilizing Rehabilitation Networks (RETURN) Study Main study: NIA-sponsored BRAIN-ICU cohort	8/1/2008 to 2/1/2009	RCT	The comprehensive, multicomponent, in-home rehabilitation program delivered to the intervention patients was developed with a specific focus on the remediation of characteristic deficits among ICU survivors (i.e., limitations in cognition, strength and endurance, and functional ability).	In-person care	3 Month
John, 2020 ²⁰	KQ1	We investigated the effects of telehealth on the liver transplant evaluation process.	Study name: NR Main study: NR	1/1/2005 to 12/31/2017	Retrospective cohort	The telehealth visit with the transplant hepatologist included a detailed history of the patient's liver disease, co-morbidities, social history particularly substance abuse and social support, counseling about the transplant listing process, waiting list, MELD scores, transplant procedure, immunosuppression, complications and posttransplant outcomes.	In-person (usual care)	NR

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Keteyian, 2021 ²¹	KQ1	To compare exercise training intensity during standard cardiac rehabilitation (S-CR) versus Hybrid-CR (combined clinic- and remote home-/community-based).	Study name: iATTEND Main study: Phase II of iATTEND	3/1/2019 to 3/1/2020	RCT	Were asked to complete ≥ 1 and ≤ 12 of their 18 sessions in the CR clinic facility, with the remaining sessions completed remotely at-home or in the community using telehealth.	Completed all sessions in the hospital's early-outpatient Phase II, clinic-based program.	NR
Levine, 2022 ²²	KQ1, KQ2	To compare remote and in-person [hospital at] home physician care	Study name: NR Main study: NR	8/3/2019 to 3/26/2020	RCT	Video visit daily after initial in-home visit (physician had option to see in home again as needed).	In-home visit by physician daily	NR
Luxton, 2015 ²³	KQ1,	The purpose of this preliminary study was to evaluate the feasibility and safety of providing U.S. military service members with a behavioral health treatment delivered directly to the home using videoconferencing	Study name: NR Main study: NR	NR	Feasibility study	A behavioral activation (BA) treatment for PTSD8 delivered via synchronous (two-way) videoconferencing to the homes of U.S. military service members.	Patients at Baseline	NR
Luxton, 2016 ²⁴	KQ1	The purpose of this randomized controlled noninferiority trial was to compare the safety, feasibility, and effectiveness of home-based telebehavioral health to care provided in the traditional in-office setting among military personnel and veterans.	Study name: NR Main study: NR	8/1/2012 to NR	RCT	8 sessions of behavioral activation treatment for depression (BATD) in the home via videoconferencing.	8 sessions of behavioral activation treatment for depression in a traditional office (same room) setting	8 Week

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Nikolian, 2018 ²⁵	KQ1, KQ2	This pilot study was performed to investigate the safety, feasibility, and financial implications of providing postoperative care using an electronic clinic (eClinic) at a university hospital	Study name: NR Main study: NR	3/1/2017 to 1/1/2018	Prospective cohort	2 week postoperative visit was conducted using telehealth (video).	2 week postoperative visit was conducted in person (traditional)	2 Week
Noel, 2020 ²⁹	KQ1	Evaluated Telehealth feasibility in improving transitions of care.	Study name: Telehealth Transitions of Care Main study: NR	6/1/2017 to 6/1/2018	RCT	Provision of a telehealth kit,. Telehealth patients measured their vitals daily using the tele-equipment and had weekly virtual visits with a transition of care physician (teledoc).	Standard transitions of care	NR
Olden, 2017 ²⁶	KQ1	Investigate the feasibility of conducting a research trial with exposure therapy delivered via videoconferencing.	Study name: NR Main study: NR	NR	Prospective cohort	12–15 session exposure therapy protocol conducted weekly in 1.5 hour sessions through video-conferencing.	No comparator	15 Week
Sherwood, 2019 ³⁶	KQ1,	We reviewed the safety and effectiveness of our hospital's urologic telemedicine (TM) program that has been utilized for the Iowa prisoner population for over a decade.	Study name: NR Main study: NR	6/1/2007 to 7/1/2014	Retrospective cohort	urologic complaints provided to the APP, the eventual diagnosis (or differential diagnosis) provided by the APP to the patient, management suggested including diagnostic tests ordered, medications and/or treatments provided, and suggested follow-up.	In-person visit	NR

Author, year	KQ	Purpose	Study	Study Dates (m/d/y)	Study Design	Telehealth Intervention	Comparator	Intervention Duration
Shirley, 2021 ³¹	KQ1	To pilot a pharmacist-integrated palliative care team clinic utilizing telemedicine to optimize palliative prescribing for Veterans and to describe CPS outcomes related to pharmacotherapy changes implemented	Study name: NR Main study: NR	12/1/2019 to 5/31/2020	Prospective cohort	The palliative care CPS completed a comprehensive medication regimen review, assessed symptoms, addressed medication-related concerns, evaluated medication compliance, and provided medication education. They also utilized the VA's VIONE deprescribing tool to identify potentially inappropriate medications and make deprescribing recommendations.	No comparator	NR
Tham, 2021 ³⁰	KQ1	To determine the impact of postoperative telehealth visits (PTV) on reducing emergency department visits (EDV) and readmissions within 30 days post-discharge (30DR).	Study name: NR Main study: NR	9/1/2017 to 7/1/2019	Retrospective cohort	Postoperative telehealth visits are scheduled by the institution's telehealth department within 72 hours post-discharge.	Usual care without post-operative telehealth visit	NR
Tönnies, 2021 ²⁷	KQ1	The study aims to evaluate the feasibility of mental health specialist video consultations with primary care patients with depression or anxiety disorders.	Study name: NR Main study: PROVIDE-B	3/1/2017 to 10/1/2017	RCT	Web-based, real-time video consultations involving a 2-way interactive video to a primary care practice between mental health specialists and patients for up to 5 sessions.	Treatment-as-usual	2 Week

APP = advanced practice provider; BA = behavioral activation; BATD = behavioral activation treatment for depression; BP = blood pressure; BRAIN-ICU = Bringing to Light the Risk Factors and Incidence of Neuropsychological Dysfunction in intensive care unit; CPS = clinical pharmacy specialists; CR = cardiac rehabilitation; d = day; EDV = emergency department visits; ERP = enhanced recovery protocols; FTSTS = Five-Times-Sit-To-Stand; HIPAA = Health Insurance Portability and Accountability Act; iATTEND = improving

ATTENDance to cardiac rehabilitation; ICU = intensive care unit; IHT = Interactive Home Telehealth; KQ = Key Question; LOS = length of stay; m = month; MDACC = University of Texas MD Anderson Cancer Center; MELD = Model of End Stage Liver Disease; MIS = minimally invasive surgery; mmHg = millimeters of mercury; NIA = National Institute of Aging; NR = not reported; PD = Parkinson’s disease; POD = postoperative day; PROVIDE-B = improving cross-sectoral collaboration between primary and psychosocial care: an implementation; PTV = postoperative telehealth visits; RCT = randomized controlled trial; RTT = Rapid Turns Test; S-CR = standard cardiac rehabilitation; study on video consultations-B; TM = telemedicine; VA = United States Department of Veterans Affairs; VIONE = Vital, Important, Optional, Not needed, Every medication has an indication program; y = year

Evidence Table C-2. Patient condition and geographic location of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, year	Specific Patient Condition	Patient Safety Practice Description	Patient Location	Clinical Focus	Patient Required To Be in State	Geographic Location
Afshari, 2021 ¹⁵	Specific condition: Parkinson Disease Specific population: Patients identified as likely to benefit from PT and OT to reduce fall-risk	None	Home Community type: NR	Physical Therapist	Yes	Illinois
Bednarski, 2019 ²⁸	Specific condition: Colonic or rectal cancer Specific population: Colonic or rectal cancer patients	None	Home or hotel Community type: NR	Physician assistant	Yes	Texas
Blyler, 2021 ¹⁶	Specific condition: Stage 2 hypertension (systolic BP ≥140 mm Hg) Specific population: Black men	None	Home Community type: Urban	pharmacists	Yes	California
Chu, 2015 ³⁵	Specific condition: Urology patients Specific population: Veterans	None	Outpatient care center Community type: Rural	Urologists	Yes	California
Delman, 2021 ³⁴	Specific condition: Orthotopic liver transplantation Specific population: Transplant waitlisted patients	Safety culture, clinical decision support, teamwork and team training	Not specified, assuming Home Community type: NR	Surgical	Unclear	Ohio
Gonzalez, 2021 ¹⁴	Specific condition: Kidney transplantation Specific population: Kidney transplant patients	None	Home Community type: NR	pharmacists	Unclear	NR
Grossman, 2017 ¹⁷	Specific condition: Termination of pregnancy Specific population: Pregnant women	None	Home Community type: NR	Primary care	Yes	Montana

Author, year	Specific Patient Condition	Patient Safety Practice Description	Patient Location	Clinical Focus	Patient Required To Be in State	Geographic Location
Harkey, 2021 ³²	Specific condition: Appendectomy and cholecystectomy Specific population: Post-operative patients	None	Home Community type: NR	Surgical	Yes	North Carolina, South Carolina
Hickey, 2017 ³³	Specific condition: Burn Victims Specific population: Patients discharged from an inpatient admission or the emergency department with barriers to follow-up such as distance from hospital on discharge, inability to drive or obtain a driver, or significant comorbidities that made traveling difficult, were offered an IHT encounter	None	Home Community type: NR	Burn Surgeons, Physiatrists & Psychiatrists	Unclear	NR
Hidecker, 2022 ¹⁸	Specific condition: Parkinson Disease Specific population: NR	None	Home Community type: Rural	Speech- language pathologist; physio- therapist; clinical pharmacist	Unclear	NR
Jackson, 2012 ¹⁹	Specific condition: Not specified Specific population: Patients discharged from medical intensive care unit (MICU) or surgical intensive care unit SICU	None	Home Community type: NR	Social workers and psychology technicians	Unclear	NR
John, 2020 ²⁰	Specific condition: Liver transplantation Specific population: Liver transplant candidates	None	Veterans Associate Medical Center Community type: NR	Transplant hepatologist	No	USA (across 29 states)
Keteyian, 2021 ²¹	Specific condition: Cardiac rehabilitation patients Specific population: Cardiac rehabilitation patients	None	Home Community type: NR	Cardiac rehabilitation staff	Yes	Michigan
Levine, 2022 ²²	Specific condition: Infection, Heart Failure, COPD, Asthma, cellulitis OPD, malignant pain etc, Specific population: Patients who are home-health subscribers	None	Home Community type: NR	Presumably Hospitalists	Yes	Massachusetts
Luxton, 2015 ²³	Specific condition: Post-Traumatic Stress Disorder (PTSD) Specific population: Enlisted members of U.S. Army	None	Home Community type: NR	Psychologist, postdoctoral fellow	Unclear	NR

Author, year	Specific Patient Condition	Patient Safety Practice Description	Patient Location	Clinical Focus	Patient Required To Be in State	Geographic Location
Luxton, 2016 ²⁴	Specific condition: Depression Specific population: US military personnel	None	Home Community type: NR	Mental health	Yes	Washington, Oregon
Nikolian, 2018 ²⁵	Specific condition: laparoscopic cholecystectomy, appendectomy, ventral/umbilical hernia repair (open or laparoscopic), Inguinal hernia repair (open or laparoscopic) Specific population: Post-operative patients	None	Home Community type: NR	Surgical	No	Michigan and surrounding states (not specified) Patients in surrounding States to Michigan were included in study (not quantified)
Noel, 2020 ²⁹	Specific condition: Not specified Specific population: Patients with two or more chronic conditions	None	Home Community type: NR	Primary care	Yes	New York
Olden, 2017 ²⁶	Specific condition: PTSD Specific population: Survivors of trauma resulting from working in an occupation at risk for PTSD	None	Home Community type: NR	Mental health	Yes	Vermont
Sherwood, 2019 ³⁶	Specific condition: Urologic complaints/conditions Specific population: Prisoners	None	Prison Community type: Rural	Urologic advanced practice provider (APP)	Yes	Iowa
Shirley, 2021 ³¹	Specific condition: Cancer Patients Specific population: Veterans	De-prescription	Home Community type: NR	Palliative Care Physicians	Unclear	NR
Tham, 2021 ³⁰	Specific condition: Thoracic surgery patients Specific population: Thoracic surgery patients	None	Home Community type: NR	Surgical	Unclear	NR
Tönnies, 2021 ²⁷	Specific condition: Primary care Specific population: Patients with depression or anxiety disorder	None	Home Community type: NR	Mental health	Not applicable (Germany)	NR

BP = blood pressure; COPD = chronic obstructive pulmonary disease; IHT = Interactive Home Telehealth; MICU = medical intensive care unit; mmHg = millimeters of mercury; NR = not reported; OPD = obstructive pulmonary disease; OT = tele-occupational therapy; PT = tele-physical therapy; PTSD = post-traumatic stress disorder; SICU = surgical intensive care unit

Evidence Table C-3. Patient characteristics of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	N at Baseline	Gender	Age	Race
Afshari, 2017 ¹⁵	Overall	Telemedicine	15	Female: 5 (33.3) Male: 10 (66.7)	Mean: NR (SD NR) Median: 67 (IQR 64-73) Range: 60-73	White: 11 (73.3) Black or African American: 1 (6.7) Asian: 3 (20)
Bednarski, 2019 ²⁸	Arm 1	Control	16	Female: 6 (37.5) Male: 10 (62.5)	Mean: 59.3 (SD 10.2) Median: NR Range: NR	White: 10 (62.5)
Bednarski, 2019 ²⁸	Arm 2	RecoverMI	14	Female: 8 (51.14) Male: 6 (42.86)	Mean: 58.7 (SD 12.6) Median: NR Range: NR	White: 10 (71.43)
Blyler, 2021 ¹⁶	Overall	Overall	10	Female: NR Male: 10 (100)	Mean: 57.3 (SD 5.9) Median: NR Range: NR	Black or African American: 10 (100)
Chu, 2015 ³⁵	Overall	Overall	97	Female: NR Male: 97 (100)	Mean: 65.8 (SD NR) Median: NR Range: 29-90	White: 78 (80) Black or African American: 3 (3) Other (Hispanic, Native American, Unknown): 16 (17)
Delman, 2021 ³⁴	Arm 1	Pre-COVID-19	274	Female: 105 (38.3) Male: NR (NR)	Mean: 53.2 (SD 17.1) Median: NR Range: NR	Non-Hispanic-White: 251 (91.6) Black or African American: 13 (4.7)
Delman, 2021 ³⁴	Arm 2	COVID-19	70	Female: 20 (29) Male: NR	Mean: 56.2 (SD 10.9) Median: NR Range: NR	Non-Hispanic-White: 63 (91.3) Black or African American: 6 (8.7)
Gonzalez, 2021 ¹⁴	Overall	Overall	136	Female: 59 (43) Male: 77 (57)	Mean: 51 (SD 13) Median: NR Range: NR	White: 46 (34) Black or African American: 87 (64) Other (Hispanic): 3 (2)
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	68	Female: 26 (38) Male: 42 (62)	Mean: 51 (SD 14) Median: NR Range: NR	White: 19 (28) Black or African American: 47 (69) Other (Hispanic): 2 (3)
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	68	Female: 33 (49) Male: 35 (52)	Mean: 50 (SD 12) Median: NR Range: NR	White: 27 (40) Black or African American: 40 (59) Other (Hispanic): 1 (2)

Author, Year	Arm	Arm Name	N at Baseline	Gender	Age	Race
Grossman, 2017 ¹⁷	Arm 1	In-Person	10405	NR	NR	NR
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	8765	NR	NR	NR
Harkey, 2021 ³²	Arm 1	In-Person	143	Female: 89 (62) Male: 53 (38)	Mean: 37.4 (SD 14.4) Median: NR Range: NR	White: 72 (54) Black or African American: 58 (44) Other (Not specified): 3 (2)
Harkey, 2021 ³²	Arm 2	Virtual visit	289	Female: 186 (64) Male: 103 (36)	Mean: 38.4 (SD 14) Median: NR Range: NR	White: 167 (64) Black or African American: 84 (32) Other (Not specified): 12 (4)
Hickey, 2017 ³³	Overall	Interactive Home Telehealth (IHT)	31	Female: 4 (12.9) Male: 27 (87.09)	Mean: 44 (SD NR) Median: NR Range: 18-83	NR
Hidecker, 2022 ¹⁸	Overall	Telemedicine	15	Female: 8 (47.06) Male: 7 (41.18)	Mean: 73.3 (SD NR) Median: NR Range: 57-93	NR
Jackson, 2012 ¹⁹	Arm 1	In-person usual care	90	Female: 5 (62) Male: 3 (38)	Mean: 50 (SD NR) Median: NR Range: 46-69	White: 7 (88) Black or African American: 1 (12)
Jackson, 2012 ¹⁹	Arm 2	Telemedicine	90	Female: 5 (38) Male: 8 (62)	Mean: 47 (SD NR) Median: NR Range: 41-59	White: 6 (86) Black or African American: 1 (14)
John, 2020 ²⁰	Arm 1	In-person evaluation	465	Female: 10 (4.29) Male: 223 (95.7)	Mean: NR Median: 57 (IQR 7) Range: NR	White: 146 (62.66) Black or African American: 42 (18.03) Other (Hispanic, Other): 37 (15.88)

Author, Year	Arm	Arm Name	N at Baseline	Gender	Age	Race
John, 2020 ²⁰	Arm 2	Telehealth evaluation	465	Female: 7 (3.02) Male: 225 (96.98)	Mean: NR Median: 61 (IQR 7) Range: NR	White: 139 (59.91) Black or African American: 59 (25.43) Other (Hispanic, Other): 26 (11.4)
Keteyian, 2021 ²¹	Arm 1	Standard cardiac rehabilitation (S-CR)	21	Female: NR (24) Male: NR	Mean: 58 (SD 11) Median: NR Range: NR	White: NR (19) Black or African American: NR (76) Other (Not specified): NR (5)
Keteyian, 2021 ²¹	Arm 2	Hybrid cardiac rehabilitation (Hybrid-CR)	26	Female: NR (35) Male: NR	Mean: 63 (SD 13) Median: NR Range: NR	White: NR (23) Black or African American: NR (73) Other (Not specified): NR (4)
Levine, 2022 ²²	Arm 1	In-Person	88	Female: 46 (52.3) Male: 42 (47.7)	Mean: 66.5 (SD 18.9) Median: NR Range: NR	Black or African American: 17 (19.5) Other (Latinx): 18 (20.7) White: 45 (51.7)
Levine, 2022 ²²	Arm 2	Telemedicine	84	Female: 51 (60.7) Male: 33 (39.3)	Mean: 72.1 (SD 16.6) Median: NR Range: NR	Black or African American: 16 (19) Other (Latinx): 21 (25) White: 32 (38.1)
Luxton, 2015 ²³	Overall	Telemedicine	10	Female: 0 (0) Male: 10 (100)	Mean: 31.8 (SD 7.44) Median: NR Range: 21-45	NR
Luxton, 2016 ²⁴	Arm 1	In-Person	59	Female: 12 (20.34) Male: 47 (79.66)	Mean: NR Median: NR Range: 19-65	Non-Hispanic-White: 41 (69.49) Non-Hispanic-Black or African American: 10 (16.95) Other (Hispanic, non-Hispanic Asian, Native American, Other): 8 (13.55)
Luxton, 2016 ²⁴	Arm 2	In-Home	62	Female: 10 (16.13) Male: 52 (83.87)	Mean: NR Median: NR Range: 19-65	Non-Hispanic-White: 44 (70.97) Non-Hispanic-Black or African American: 8 (12.9) Other (Hispanic, non-Hispanic Asian, Native American, Other): 10 (16.13)

Author, Year	Arm	Arm Name	N at Baseline	Gender	Age	Race
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	485	Female: 273 (0.56) Male: 212 (0.44)	Mean: 42.3 (SD 17.1) Median: NR Range: NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic clinic	233	Female: 145 (0.62) Male: 88 (0.38)	Mean: 40.9 (SD 15.9) Median: NR Range: NR	NR
Noel, 2020 ²⁹	Arm 1	Standard care	57	Female: 35 (63) Male: NR (NR)	Mean: 63.67 (SD 14.78) Median: NR Range: NR	Other (Non-Caucasian): 10 (18)
Noel, 2020 ²⁹	Arm 2	Treatment (teledoc)	45	Female: 29 (64) Male: NR (NR)	Mean: 65.66 (SD 13.24) Median: NR Range: NR	Other (Non-Caucasian): 6 (1.3)
Olden, 2017 ²⁶	Overall	Overall	11	Female: 2 (18.2) Male: 9 (81.8)	Mean: 42.82 (SD 13.53) Median: NR Range: NR	White: 7 (63.6) Black or African American: 1 (9.1) Other (Hispanic): 2 (18.2)
Sherwood, 2019 ³⁶	Overall	Telemedicine (TM) diagnosis	376	Female: 0 (0) Male: 376 (100)	Mean: 42.3 (SD 13.2) Median: NR Range: NR	NR
Shirley, 2021 ³¹	Overall	Telemedicine	25	Female: 0 (0) Male: 25 (100)	Mean: 81 (SD NR) Median: Nr Range: 58-96	NR
Tham, 2021 ³⁰	Overall	Overall	341	Female: 151 (44.3) Male: 190 (55.7)	Mean: 62 (SD NR) Median: NR (IQR 50-70) Range: NR	Non-Hispanic-White: 263 (77.1) Non-Hispanic-Black or African American: 59 (17.3) Other (Asian, Alaskan native/American Indian, Hispanic White): 19 (5.6)
Tönnies, 2021 ²⁷	Arm 1	Control (standard care)	27	Female: 19 (70.4) Male: 8 (29.6)	Mean: 51.2 (SD 15.46) Median: 56 (IQR NR) Range: 18-72	NR
Tönnies, 2021 ²⁷	Arm 2	Intervention (Video-conference)	23	Female: 16 (69.6) Male: 7 (30.4)	Mean: 45.9 (SD 15.86) Median: 48 (IQR NR) Range: 22-72	NR

CR = cardiac rehabilitation; IHT = Interactive Home Telehealth; IQR = interquartile range; N = sample size; NR = not reported; S-CR = standard cardiac rehabilitation; SD = standard deviation; TM = telemedicine

Evidence Table C-4. Adverse event or unintended effects outcomes (categorical) of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Afshari, 2022 ¹⁵	Overall	Telemedicine	Fall, or other adverse events	NR	NR	15	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Blyler, 2021 ¹⁶	Overall	Video-conference	No treatment-related serious adverse events	NR	NR	13	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Grade 3 adverse events	NR	12 months	68	Patients with events: NR N of events: 107	NR	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Grade 3 adverse events	NR	12 months	68	Patients with events: NR N of events: 75	NR	Comparator: Arm 1 p-value only: p=0.18	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Grade 3 or higher adverse events	NR	12 months	68	Patients with events: NR N of events: 134	NR	Ref	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Grade 3 or higher adverse events	NR	12 months	68	Patients with events: NR N of events: 80	NR	Comparator: Arm 1 Incidence rate ratio: 0.55 (95% CI: 0.30 to 0.99), p=0.05	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Infections	NR	12 months	68	Patients with events: NR N of events: 86	Rate per patient-year: 1.26 (95% CI: 0.76 to 1.76)	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Infections	NR	12 months	68	Patients with events: NR N of events: 90	Rate per patient-year: 1.32 (95% CI: 0.92 to 1.72)	Comparator: Arm 1 p-value only: p=0.75	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Opportunistic infections	NR	12 months	68	Patients with events: NR N of events: 10	Rate per patient-year: 0.14 (95% CI: 0.01 to 0.30)	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Opportunistic infections	NR	12 months	68	Patients with events: NR N of events: 13	NR	Comparator: Arm 1 p-value only: p=0.47	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Total adverse events	NR	12 months	68	Patients with events: NR N of events: 1446	NR	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Total adverse events	NR	12 months	68	Patients with events: NR N of events: 1406	NR	Comparator: Arm 1 p-value only: p=0.85	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Total medication errors	NR	12 months	68	Patients with events: NR N of events: 1385	NR	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Total medication errors	NR	12 months	68	Patients with events: NR N of events: 614	NR	Comparator: Arm 1 p-value only: p<0.001	NR
Grossman, 2017 ¹⁷	Arm 1	In-Person	Any major adverse event (not including death or surgery)	NR	NR	10405	Patients with events: 13 (0.12) N of events: NR	NR	Ref	NR
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	Any major adverse event (not including death or surgery)	NR	NR	8765	Patients with events: 8 (0.09) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.483	NR
Grossman, 2017 ¹⁷	Arm 1	In-Person	Any major adverse event or ED visit with treatment	NR	NR	10405	Patients with events: 33 (0.32) N of events: NR	NR	Ref	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	Any major adverse event or ED visit with treatment	NR	NR	8765	Patients with events: 16 (0.18) N of events: NR	NR	Comparator: Arm 1 Difference in prevalence (%): 0.0013 (95% CI: -0.01 to 0.28), p=0.066	NR
Grossman, 2017 ¹⁷	Arm 1	In-Person	Hospital admission	NR	NR	10405	Patients with events: 13 (0.12) N of events: NR	NR	Ref	NR
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	Hospital admission	NR	NR	8765	Patients with events: 6 (0.07) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.216	NR
Grossman, 2017 ¹⁷	Arm 1	In-Person	Transfusion	NR	NR	10405	Patients with events: 7 (0.07) N of events: NR	NR	Ref	NR
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	Transfusion	NR	NR	8765	Patients with events: 6 (0.07) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.975	NR
Hidecker, 2022 ¹⁸	Overall	Telemedicine	Hoarse voice, sore throat, strained neck, or unusual coughing	NR	NR	13	Patients with events: 9 (6; 1;1;1) (69.23) N of events: NR	NR	NR	NR
Hidecker, 2022 ¹⁸	Overall	Telemedicine	Medication-related adverse event	NR	NR	13	Patients with events: 0 (0) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Hidecker, 2022 ¹⁸	Overall	Telemedicine	Strain/sprain and muscle soreness	NR	NR	13	Patients with events: 2 (15.38) N of events: NR	NR	NR	NR
Jackson, 2012 ¹⁹	Arm 1	in-person usual care	Adverse events (including sprained ankle)	NR	3 months	8	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Jackson, 2012 ¹⁹	Arm 2	Telemedicine	Adverse events (including sprained ankle)	NR	3 months	7	Patients with events: 1 (14.28) N of events: NR	NR	NR	NR
John, 2020 ²⁰	Arm 1	In-person evaluation	Mortality	NR	NR	233	Patients with events: 90 (NR) N of events: NR	NR	NR	NR
John, 2020 ²⁰	Arm 2	telemedicine evaluation	Mortality	NR	NR	232	Patients with events: 67 (NR) N of events: NR	NR	NR	NR
Keteyian, 2021 ²¹	Arm 1	Standard cardiac rehabilitation (S-CR)	Adverse events or falls requiring hospitalization	NR	3 hours	21	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Keteyian, 2021 ²¹	Arm 2	Hybrid cardiac rehabilitation (Hybrid-CR)	Adverse events or falls requiring hospitalization	NR	3 hours	26	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Levine, 2022 ²²	Arm 1	In-Person	Delirium	CMS patient safety measures	30 days	88	Patients with events: 4 (4.8) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Levine, 2022 ²²	Arm 3	Telemedicine	Delirium	CMS patient safety measures	30 days	84	Patients with events: 1 (1.1) N of events: NR	NR	NR	NR
Levine, 2022 ²²	Arm 1	In-Person	Fall	CMS patient safety measures	30 days	88	Patients with events: 1 (1.2) N of events: NR	NR	NR	NR
Levine, 2022 ²²	Arm 2	Telemedicine	Fall	CMS patient safety measures	30 days	84	Patients with events: 2 (2.3) N of events: NR	NR	NR	NR
Luxton, 2015 ²³	Overall	Telemental Health	Patient safety	NR	NR	8	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Luxton, 2016 ²⁴	Arm 1	In-Person	Adverse events	NR	NR	59	Patients with events: 4 (6.78) N of events: NR	NR	NR	NR
Luxton, 2016 ²⁴	Arm 2	In-Home	Adverse events	NR	NR	62	Patients with events: 7 (11.29) N of events: NR	NR	NR	NR
Luxton, 2016 ²⁴	Arm 1	In-Person	Distress/suicidal ideation	NR	NR	59	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Luxton, 2016 ²⁴	Arm 2	In-Home	Distress/suicidal ideation	NR	NR	62	Patients with events: 1 (1.61) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: surgical site: deep	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: surgical site: deep	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication pneumonia	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication pneumonia	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: bowel obstruction	NR	30 days	485	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: bowel obstruction	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: bowel perforation	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: bowel perforation	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: choledocholithiasis	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: choledocholithiasis	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: constipation	NR	30 days	485	Patients with events: 4 (0.82) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: constipation	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: cystic duct leak	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: cystic duct leak	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: Gastrointestinal Bleeding	NR	30 days	485	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: Gastrointestinal Bleeding	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: ileus	NR	30 days	485	Patients with events: 4 (0.82) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: ileus	NR	30 days	233	Patients with events: 2 (0.86) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: intra-abdominal abscess/hematoma	NR	30 days	485	Patients with events: 3 (0.62) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: intra-abdominal abscess/hematoma	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: surgical site: superficial	NR	30 days	485	Patients with events: 3 (0.62) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: surgical site: superficial	NR	30 days	233	Patients with events: 1 (0.43) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: total	NR	30 days	485	Patients with events: 21 (4.33) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: total	NR	30 days	233	Patients with events: 10 (4.29) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Complication: urinary tract infection	NR	30 days	485	Patients with events: 1 (0.21) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Complication: urinary tract infection	NR	30 days	233	Patients with events: 2 (0.86) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Death within 30 days	NR	30 days	485	Patients with events: 1 (0.2) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Death within 30 days	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Reoperation	NR	30 days	485	Patients with events: 4 (0.8) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic Clinic	Reoperation	NR	30 days	233	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Olden, 2017 ²⁶	Overall	Overall	Safety issues	NR	NR	7	Patients with events: 0 (0) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Tönnies, 2021 ²⁷	Arm 1	Control (standard care)	Unintended consequences and adverse effects	NR	16 weeks	27	Patients with events: NR N of events: NR	NR	NR	NR
Tönnies, 2021 ²⁷	Arm 2	Intervention (Video-conference)	Unintended consequences and adverse effects	NR	16 weeks	22	Patients with events: 4 (18.18) N of events: NR	NR	NR	NR

CI = confidence interval; CMS = Centers for Medicare & Medicaid Services; CMV = cytomegalovirus; ED = emergency department; N = sample size; NR = not reported; p = p-value; Ref = reference

Evidence Table C-5. Adverse event or unintended effects outcomes (continuous) of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Results	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Grade 3 adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 1.57 (SD 0.34)	NR	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Grade 3 adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 1.1 (SD 0.22)	NR	Comparator: Arm 1 p-value only: p=0.19	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Grade 3 or higher adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 1.97 (SD 0.46)	NR	Ref	NR
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Grade 3 or higher adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 1.18 (SD 0.25)	NR	Comparator: Arm 1 p-value only: p=0.04	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Results	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez , 2021 ¹⁴	Arm 1	Usual care	Overall adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 21.26 (SD 25.24)	NR	Ref	NR
Gonzalez , 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Overall adverse events rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 20.68 (SD 18.35)	NR	Comparator: Arm 1 p-value only: p=0.83	NR
Gonzalez , 2021 ¹⁴	Arm 1	Usual care	Overall medication error rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 20.4 (SD 14)	NR	Ref	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Results	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Overall medication error rate	NR	12 months	Baseline: 68 Followup: 68	Baseline: NR Followup: Mean 9 (SD 5.9)	NR	Comparator: Arm 1 Incidence rate ratio: 0.39 (95% CI: 0.28 to 0.55), p<0.001	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics
Levine, 2022 ²²	Arm 1	Telemedicine	Fall	CMS patient safety measures	30 days	Baseline: 84 Followup: 84	Baseline: NR Followup: Mean 6.8 (95% CI 2.9-15.7)	NR	Comparator: Ref Difference represents the remote care group minus the control group.: 2.8, p=NR	Age, sex, race or ethnicity, HOSPITAL score
Levine, 2022 ²²	Arm 1	In-person	Transfer back to hospital	CMS patient safety measures	30 days	Baseline: 88 Followup: 88	Baseline: NR Followup: Mean 3.9 (95% CI 1.4 - 11.0)	NR	Comparator: Ref Difference represents the remote care group minus the control group.: 2.8, p=NR	Age, sex, race or ethnicity, HOSPITAL score

CI = confidence interval; CMS = Centers for Medicare & Medicaid Services; CMV = cytomegalovirus; HOSPITAL = hemoglobin at discharge, discharge from an oncology service, sodium level at discharge, procedure during the index admission, index type of admission, number of admissions during last 12 months, and length of stay; N = sample size; NR = not reported; p = p-value; Ref = reference; SD = standard deviation

Evidence Table C-6. Preventable hospitalizations or emergency department visits outcomes (categorical) of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Bednarski, 2019 ²⁸	Arm 1	Control	ED visit	NR	30 days	16	Patients with events: 1 (6.25) N of events: NR	NR	NR	NR
Bednarski, 2019 ²⁸	Arm 2	RecoverMI	ED visit	NR	30 days	14	Patients with events: 2 (14.29) N of events: NR	NR	NR	NR
Bednarski, 2019 ²⁸	Arm 1	Control	Readmission	NR	30 days	16	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Bednarski, 2019 ²⁸	Arm 2	RecoverMI	Readmission	NR	30 days	14	Patients with events: 2 (14.29) N of events: NR	NR	NR	NR
Chu, 2015 ³⁵	Overall	Overall	Emergency department visit	NR	30 days	97	Patients with events: 1 (1.03) N of events: NR	NR	NR	NR
Delman, 2021 ³⁴	Arm 1	Pre-COVID-19	Readmission	NR	30 days	274	Patients with events: 26 (41.9) N of events: NR	NR	Ref	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Delman, 2021 ³⁴	Arm 2	COVID-19	Readmission	NR	30 days	70	Patients with events: 20 (61.5) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.09	NR
Gonzalez, 2021 ¹⁴	Arm 1	Usual care	Total hospitalizations	NR	12 months	68	Patients with events: NR N of events: 74	Rate per patient-year: 1.08 (95% CI: 0.6 to 1.6)	Ref	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Gonzalez, 2021 ¹⁴	Arm 2	Intervention (mobile app/televisit)	Total hospitalizations	NR	12 months	68	Patients with events: NR N of events: 44	Rate per patient-year: 0.65 (95% CI: 0.4 to 0.94)	Comparator: Arm 1 Incidence rate ratio: 0.46 (95% CI: 0.27 to 0.77), p=0.005	Age, sex, race, history of diabetes, years on dialysis, calculated panel reactive antibody, cold ischemic time, induction therapy, delayed graft function, cytomegalovirus (CMV) serostatus, and donor characteristics
Grossman, 2017 ¹⁷	Arm 1	In-Person	ED visit with treatment	NR	NR	10405	Patients with events: 22 (0.21) N of events: NR	NR	Ref	NR
Grossman, 2017 ¹⁷	Arm 2	Telemedicine	ED visit with treatment	NR	NR	8765	Patients with events: 13 (0.15) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.308	NR
Harkey, 2021 ³²	Arm 1	In-Person	All-cause Hospitalization encounter	NR	30 days	101	Patients with events: 16 (15.8) N of events: NR	NR	Ref	NR
Harkey, 2021 ³²	Arm 2	Virtual visit	All-cause Hospitalization encounter	NR	30 days	135	Patients with events: 15 (11.1) N of events: NR	NR	Comparator: Arm 1 2-sided effect: -4.7, p=0.29	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Hickey, 2017 ³³	Overall	Interactive Home Telehealth	Unintended readmission	NR	30 days	31	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Levine, 2022 ²²	Arm 1	In-Person	Transfer back to hospital	CMS patient safety measures	30 days	88	Patients with events: 3 (3.6) N of events: NR	NR	NR	NR
Levine, 2022 ²²	Arm 4	Telemedicine	Transfer back to hospital	CMS patient safety measures	30 days	84	Patients with events: 2 (2.3) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	ED visits within 30 days	NR	30 days	485	Patients with events: 19 (3.9) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic clinic	ED visits within 30 days	NR	30 days	233	Patients with events: 11 (4.2) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 1	Traditional clinic	Readmission within 30 days	NR	30 days	485	Patients with events: 14 (2.8) N of events: NR	NR	NR	NR
Nikolian, 2018 ²⁵	Arm 2	Electronic clinic	Readmission within 30 days	NR	30 days	233	Patients with events: 6 (2.7) N of events: NR	NR	NR	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Noel, 2020 ²⁹	Arm 1	Standard care	ED visit	NR	30 days	57	Patients with events: NR N of events: NR	NR	Ref	Age, gender, number of diagnoses
Noel, 2020 ²⁹	Arm 2	Treatment (teledoc)	ED visit	NR	30 days	45	Patients with events: NR N of events: NR	NR	Comparator: Arm 1 OR: 0.75 (95% CI: 0.18 to 3.11), p=0.691	Age, gender, number of diagnoses
Noel, 2020 ²⁹	Arm 1	Standard care	Readmission	NR	30 days	57	Patients with events: NR N of events: NR	NR	Ref	Age, gender, number of diagnoses
Noel, 2020 ²⁹	Arm 2	Treatment (teledoc)	Readmission	NR	30 days	45	Patients with events: NR N of events: NR	NR	Comparator: Arm 1 OR: 2.65 (95% CI: 0.4 to 17.33), p=0.311	Age, gender, number of diagnoses
Sherwood, 2018 ³⁶	Overall	Telemedicine (TM) diagnosis	ED visit	NR	NR	376	Patients with events: 0 (0) N of events: NR	NR	NR	NR
Tham, 2021 ³⁰	Arm 1	Without postop telehealth	Emergency department visit (30 days post-discharge)	NR	30 days	46	Patients with events: 8 (17.4) N of events: NR	NR	Ref	NR

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Tham, 2021 ³⁰	Arm 2	With postop telehealth	Emergency department visit (30 days post-discharge)	NR	30 days	295	Patients with events: 7 (2.4) N of events: NR	NR	Comparator: Arm 1 p-value only: p<0.0001	NR
Tham, 2021 ³⁰	Arm 1	Without postop telehealth	Readmission (30 days post-discharge)	NR	30 days	46	Patients with events: 7 (15.2) N of events: NR	NR	Ref	NR
Tham, 2021 ³⁰	Arm 2	With postop telehealth	Readmission (30 days post-discharge)	NR	30 days	295	Patients with events: 10 (3.4) N of events: NR	NR	Comparator: Arm 1 p-value only: p=0.0006	NR

CI = confidence interval; CMS = Centers for Medicare & Medicaid Services; CMV = cytomegalovirus; ED = emergency department; N = sample size; NR = not reported; OR = odds ratio; p = p-value; Ref = reference

Evidence Table C-7. Preventable hospitalizations or emergency department visits outcomes (continuous) of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Results	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Levine, 2022 ²²	Arm 1	In-person	Transfer back to hospital	CMS patient safety measures	30 days	Baseline: 88 Followup: 88	Baseline: NR Followup: Mean 3.43 (95% CI 1.11-10.07)	NR	Comparator: Arm 1 Difference represents the remote care group minus the control group.: 2.28, p=NR	Age, sex, race or ethnicity, hospital score
Levine, 2022 ²²	Arm 2	Telemedicine	Transfer back to hospital	CMS patient safety measures	30 days	Baseline: 84 Followup: 84	Baseline: NR Followup: Mean 5.7 (95% CI 2.28-15.56)	NR	Comparator: Arm 1 Difference represents the remote care group minus the control group.: 2.28, p=NR	Age, sex, race or ethnicity, hospital score
Shirley, 2021 ³¹	Overall	Telemedicine	VA ED visit	NR	6 months	Baseline: 25	Baseline: NR Followup:	NR	NR	NR

						Followup: 12	Mean 0.16 (Range 0-3)			
Shirley, 2021 ³¹	Overall	Telemedicine	VA hospital admission	NR	6 months	Baseline: 25 Followup: 12	Baseline: NR Followup: Mean 0.36 (Range 0-3)	NR	NR	NR

CI = confidence interval; CMS = Centers for Medicare & Medicaid Services; ED = emergency department; N = sample size; NR = not reported; p = p-value; Ref = reference; VA = United States Department of Veterans Affairs

Evidence Table C-8. Misdiagnosis or delayed diagnosis outcomes (categorical) of studies addressing harms from patient-clinician real-time clinical encounters using telehealth

Author, Year	Arm	Arm Name	Outcome Definition	Patient Safety Measures	Time Point at Analysis	N at Analysis	Outcome	Within-Arm Comparison	Between-Arm Comparison	Adjusted Factors
Sherwood, 2019 ³⁶	Overall	Subsequent in person follow-up	Non-concordance	NR	NR	210	Patients with events: 22 N of events: NR	NR	NR	NR

N = sample size; NR = not reported

Appendix D. Grey Literature Search Results

Table D-1. Grey literature search results from governmental agencies and professional societies

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
American Medical Association (AMA) (https://www.ama-assn.org/) retrieved: 1/6/2023	AMA Digital Health Research [2016 – 2020] (report) ³⁷	PSP	Televisits & Telemedicine tools – monitoring/care management and clinical decisions support.	Most physicians find that adopting these methods improve patient safety and work efficiency.	This report is focused on survey results of physician's motivation and requirements for adopting telemedicine into their practices. Physicians were surveyed to determine how many adopted these methods and how they've effected patient care
	AMA Return on Health Report [2021] (case reports) ³⁸	Emergency department (ED) visits, readmissions rates, mortality	Televisits & Telemedicine	Many of the case studies report findings that telemedicine works to improve patient safety compared to traditional care alone. Including, lowering mortality, ED visits and reducing readmission rates.	Authors proposed a "framework for measuring the value of digitally enabled care". Several organizations report research efforts guided by this framework to measure the impact of their telemedicine implementation.

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
Patient Safety Learning hub (https://www.pslhub.org/) retrieved: 1/9/2023	Telemedicine: Ensuring Safe, Equitable, Person-Centered Virtual Care (white paper) ³⁹	PSP	Televisits & Telemedicine	Authors recommend inviting/engaging patients and patient advocates (e.g., family/friends), provide training for tele-visits and limited physical exams, and to incorporate ancillary support in virtual care practices; Recommendations included improved communication skills (also an element in framework, discussed further in report), and to be cognizant of patient's emotional/psychological state by inviting patient to share their concerns related to telemedicine versus in-person care.	The Lucian Leape Institute developed and published a telemedicine implementation guide. Using their framework, authors define its elements in the clinical context and provide recommendations for the how to improve telehealth implementation in respect to patient safety

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
<p>World Health Organization's Global Patient Safety Network (https://www.who.int/teams/integrated-health-services/patient-safety)</p> <p>retrieved: 1/9/2023</p>	<p>Consolidated telemedicine implementation guide (implementation guide)⁴⁰</p>	<p>PSP</p>	<p>Televisits & Telemedicine</p>	<p>This guide solely focused on privacy and data protection for patients. And insist on training and accreditation for health works to maintain the safety for patients.</p>	<p>The World Health Organization developed an implementation guide for the use of telemedicine. The guide is organized into phases and steps within each phase. The most relevant to this is the phase 02 (plan the implementation) and step 06 (enforce mechanism for patient and health worker safety and protection)</p>

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
Agency of Healthcare Research and Quality (https://www.ahrq.gov/) retrieved: 1/11/2023	Telehealth and Patient Safety (primer) ⁴¹	PSP	Telehealth & telehealth care models	Authors propose potential implementation strategies to enhance patient safety. Strategies include clinician education on patient safety considerations and evidence-based strategies for conducting telehealth encounters, coordinate care with medical home staff, integrating protocols and safety reports to prevent adverse events, utilize remote and accessible technologies for patients and caregiver	Reports emerging concerns related to the use of telemedicine (and its modalities) on patient safety. The concerns outlined are diagnostic errors, medication safety, escalation of care and health equity. Attributing adverse events to poor communication, limited physical examination, and reliance on patient to report vitals or symptoms. The rapid adoption of telemedicine into medical practices has led to disparities in access in care access, especially among the elderly, ethnic minorities and 'less-resources' individuals.

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
	Telemedicine and Patient Safety (perspectives) ⁴²	Adverse events, treatment-related errors, & PSP	Telemedicine	Authors report that telemedicine has worked to help identify and prevent both treatment-related errors and treatment-related adverse events	Authors of this article propose that the adoption of telemedicine in health care has the potential to improve patient health outcomes and overall clinical operations. They acknowledge the emerging concerns for patient safety and emphasizes that patient safety should 'permeate' through all phases of telemedicine implementation and uses

Source (Link)	Document's Title (type)	Relevant Outcomes	Telehealth Intervention	Results	Summary
	Telehealth and Patient Safety During the COVID-19 Response (perspectives) ⁴³	Diagnostic errors & PSP	Telemedicine	Authors propose precaution measures to take for implementing and using telehealth. For namely, escalation protocols which determine when a patient should transition to urgent care for follow-up or receive emergency care. Also, pre-charting, which will allow providers to conduct a detailed review of patients to determine whether telehealth is appropriate for their care. Conduct quality assurances for telehealth visits to discuss positive and negative patient safety concerns. Lastly, authors encourage that providers receive telehealth training for effective communication and best practices for tele-visits.	Presents an overview of the role of the COVID-19 pandemic's role in the rapid adopting of telehealth in healthcare delivery. Reporting its positive effect on patient and provider safety from the spread of the COVID-19 virus. Authors acknowledge emerging patient safety concerns related to the use of telemedicine. Namely, the limitations of remote care, potential diagnostic errors, and effective communication.

AMA = American Medical Association; ED = emergency department; PSP = patient safety practice

