Safety of Telemental Healthcare Delivered to Clinically Unsupervised Settings: A Systematic Review

ARTICLE *in* TELEMEDICINE AND E-HEALTH · JULY 2010

Impact Factor: 1.67 · DOI: 10.1089/tmj.2009.0179 · Source: PubMed

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Safety of Telemental Healthcare Delivered to Clinically Unsupervised Settings: A Systematic Review

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Abstract

The safety of telemental healthcare delivered to clinically unsupervised settings, such as a personal residence, must be established to inform policy and further the dissemination of telemental health programs. The aim of this article is to provide an overview of safety issues associated with telemental healthcare and, through a systematic literature review, evaluate the safety of telemental healthcare delivered to unsupervised settings. The review resulted in a total of nine studies that specifically evaluated the delivery of telemental healthcare to unsupervised settings. Six of the nine studies reviewed explicitly described safety plans or specific precautions that could be used if necessary. Two of the nine studies reported events that required the researchers to use safety procedures to effectively respond to concerns they had regarding participant safety. In both of these studies, the issues were resolved with prescribed safety procedures. Recommendations and future directions for the development and evaluation of safety protocols are discussed.

Key words: *telehealth, telepsychiatry, policy*

Introduction

Advances in technology have outpaced policies regarding telemental health services. Regulations that often predate the widespread use and acceptance of telemental healthcare are now looked to for guidance to address specific concerns, including the safe provision of medical care to clinically unsupervised locations, such as a personal residence. Although these policies are designed to protect both consumers and providers, they may also create artificial barriers that limit progress and the ability to fully realize the benefits associated with telemental health. Establishing the safety of telemental healthcare is vital to inform policy decisions and increase the dissemination of a range of available services.

Although there is now little debate that telemental healthcare that uses two-way audio/visual equipment in clinically supervised environments is safe and effective when properly conducted,[1,2] the safety of telemental health delivered to clinically unsupervised settings, such as a patient's home, has not been documented. The aim of this article is to discuss the primary safety issues associated with telemental healthcare and, through a systematic literature review, begin to assess the safety of telemental healthcare that is delivered to clinically unsupervised settings. Our review focuses on available data from empirical research studies that evaluate telemental healthcare delivered to clinically unsupervised settings. For the purposes of our discussion and literature review, we define safety as the reduction and prevention of adverse reactions or events that might be experienced by patients who partake in care services. This definition extends to the protection of providers and collateral persons (e.g., family members and treatment staff) during the course of care. Safety plans are defined as predetermined procedures for reducing risk, preventing adverse reactions, and for responding to adverse events when they occur. These include appropriate screening processes for risk (e.g., suicidality), monitoring of patients during the course of treatment, and the establishment of safety protocols to ensure that the best methods for resolving adverse events are followed when they do occur.

TELEMENTAL HEALTH SAFETY CONCERNS

Telemental health services delivered to traditional clinically supervised settings, such as a hospital or outpatient clinic, have

appropriate treatment staff onsite who are immediately available to reduce or mitigate safety issues when they occur. For example, adverse emotional or behavioral reactions during therapeutic sessions can be immediately addressed by on-site staff; therefore, the risk that the patient will leave the site in an adverse state (e.g., suicidal or homicidal) is reduced. Telemental healthcare delivered to unsupervised settings, such as a patient's home, however, would not have clinical staff immediately available on-site to respond to adverse events. Thus, there are a number of unique potential risks with telemental healthcare delivered to clinically unsupervised settings that heighten concern compared to traditional care at locations with on-site clinical supervision.

One of the paramount concerns during the delivery of any mental health service is the risk of patient self-harm or harm to others. Similar to in-person treatments, providers should consider screening patients for self-harm or other risk before initiating treatment, and also continuously assess risk for harm to self or others during the course of care. Further, providers must maintain an awareness of safety issues with patients displaying strong affective or behavioral states throughout a protocol timeline and upon conclusion of treatment sessions. A well-defined safety plan (e.g., appropriate screening and routine suicide risk assessments) can mitigate the risk of a treatment.

The worsening of clinical symptoms or other emotional and behavioral crises that might occur during the course of treatment pose additional safety concerns. Treatments conducted in a supervised medical setting provide for more control over these situations than those delivered to unsupervised settings. For example, a provider can stop the treatment at any time to conduct risk assessments, or request further assistance from staff to help intervene. Patients who are in clinically unsupervised settings, however, can turn off the connection and thus leave the provider uncertain of the patient's status. This requires the development of alternative safety plans such as protocols that use collaterals to check on patients, or engage 911 in some situations.

Another potential safety concern of care delivered to clinically unsupervised settings is the possibility that patients might experience increased feelings of social isolation compared to patients in treatment programs that require in-person visits to a hospital, provider's office, or other healthcare facility. Although it is possible that patients with little or no social support might be at heightened risk, there is currently a dearth of data on the effects of nontraditional care locations on patient feelings of isolation. This suggests that providers and researchers should consider the evaluation of social isolation and availability of social support before and during treatment.

Technical standards and equipment infrastructure also have implications for telehealth safety. For example, if the telecommunications infrastructure is not reliable and there are not any redundancies built in, patients may be at risk if the system unexpectedly fails at critical times. Equipment failure could prevent completion of a suicide risk assessment or information gathering that is critical for the patient's safety. Equipment failures could also cause patients to feel abandoned. Back up plans, such as planned use of standard telephones in such situations, can help to reduce such risks. Further, providers and researchers should have basic knowledge and resources available to resolve technical issues when they occur. Adequate education and knowledge of modern information and telecommunications technologies is essential to quality care.

The quality of the communications connection also has implications for observation of symptoms during assessment and monitoring. For example, Zarate et al.[3] compared the reliability of observers' assessments of patients with schizophrenia at different bandwidths and found more reliable assessments at higher bandwidths (e.g., 384 kilobits/s (Kbps) compared to 128 Kbps) compared to in-person. These findings were presumably due to limited image-processing capability and artifacts caused by the limitations of lower bandwidth. Further, characteristics of the technology used and the setting might also create risks. Poorly lit rooms, small video monitors, or inadequate audio can cause eye strain or hearing problems. These problems can be reduced or eliminated by ensuring properly lit rooms, using larger video monitors, and ensuring patient control of audio volume. Further, technical malfunction has the potential to frustrate the patients and thus reduce treatment satisfaction and adherence.

Patient privacy is another issue that has implications for safety during the delivery of telemental health treatments. Those providing care should be sensitive to the potential adverse effect of disclosures made during emergency management on patient confidentiality and relationships in small communities. If the trust of patients is lost due to concerns about their privacy, patients may not continue treatment, or it may negatively impact the patient–provider alliance, treatment adherence and compliance, and, ultimately, treatment effectiveness.

Safety issues involved in the delivery of telemental healthcare consist of a variety of areas that are both common to traditional in-person care as well as unique to telemental healthcare. These include self-harm, harm to others, worsening of symptoms, adverse effects of the technology, and issues associated with patient privacy. Appropriate screening and routine suicide risk assessments for high-risk patients are integral for effective safety planning. Monitoring patients for worsening symptoms during treatment, protocols for

contacting collaterals in the case of an emergency, and consideration of privacy issues are also important.

To evaluate the safety of telemental healthcare delivered to clinically unsupervised settings, we conducted a systematic review of the literature to identify telemental health studies and review safety issues to include safety procedures or safety issues encountered. Our objectives were to (1) identify the number of empirical studies that specifically evaluated telemental health delivered to unsupervised settings, (2) identify those studies that specifically discussed safety planning, (3) review safety issues addressed and discuss reported adverse events that occurred during the studies, and (4) report how safety situations were resolved.

Methods

LITERATURE SELECTION CRITERIA

Our focus was to identify telemental health studies reported in peer-reviewed journals that specifically focused on clinical care delivered to clinically unsupervised settings such as the patient's home. We performed a comprehensive search by using the following search engines: PsychINFO, EBSCOhost (1982–2009), and MEDLINE. A variety of search terms were used to include, but not limited to, telemental health, tele-behavioral health, telepsychiatry, telemedicine, and e-mental health. Reference lists of all relevant articles were searched for additional potential sources. We limited our review to published studies that involved mental health outcomes to include treatments and assessments, but excluded treatment studies that focused on physical health issues and outcomes. We further limited the search to published clinical case studies and empirical studies. On the basis of the inclusion and exclusion criteria, the search resulted in a total of 76 articles that met our initial search criteria. We then further reviewed these articles to verify that the studies were all telemental health studies and conducted in an unsupervised setting (e.g., a patient's home). We then determined the type of study (i.e., research design), the primary outcome variable(s), whether any adverse events that occurred during the study were reported, and if safety plans were described or used. Our final literature review yielded a total of nine studies that specifically involved the delivery of telemental healthcare to clinically unsupervised settings. We also found four additional studies that did not explicate the level of supervision provided during the therapy sessions.

Results

DESCRIPTION OF STUDIES

The nine studies are described in *Table 1*. The studies were undertaken in three countries to include seven in the United States, one in Spain, and one in Germany. Of these nine studies, six were classified as randomized control trials (RCTs), one as a non-RCT with a dependent groups design, one as a non-RCT with an independent groups design, and one case study. Treatments in these studies included cognitive-behavioral therapy, depression home monitoring, administration of psychological tests, and tracking of alcohol consumption. The treatment providers in these studies consisted of licensed doctoral-level psychologists, masters-level therapists, and nurse care managers. None of the protocols reported physical (i.e., in-person) supervision of patients by any clinical or nonclinical persons. Most of the studies used standard telephones to deliver treatment, a few employed some type of voice-recording technology, and one used a written form of therapy via the Internet. The goal of most of these studies was to investigate the efficacy of specific therapies or validity of clinical assessments conducted via a particular telemodality compared to their "in-person" analogs.[4–6] Outcome variables included symptom reduction, duration of treatment effects, patient satisfaction, and validity of assessment method.

SAFETY PLANS

Six of the nine studies that we reviewed explicitly described safety plans or precautions that could be deployed in the event that a participant or researcher became at risk. The most common safety plans described across these studies were exclusion criteria intended to prevent participants from becoming at risk. For example, Aziz and Kenford[6] compared telephone administration of structured clinical interviews for depression and posttraumatic stress disorder to traditional face-to-face administrations. These researchers described a screening plan that would exclude potential participants if the participants were concerned whether a family member's presence might hinder the free disclosure of information or if the participant felt that discussing the trauma over the phone might be too overwhelming and difficult. In a different study, Knaevelsrud and Maercker[7] excluded potential participants who reported dissociation, psychosis, or suicidality.

Several other studies reported specific safety plans that called for the monitoring of symptoms during the treatment protocol. For example, Dobscha et al.[8] and Turvey et al.[9] both administered depression screens (the patient health questionnaire [PHQ]) to veteran patients via Viterion™ Telehealth monitors and telephone-based interactive voice-recording home monitors. In both studies, nurse care managers analyzed the depression scores outputted to them via the in-home monitors. In the event that scores were too high—indicating severe depression—or if scores fluctuated irregularly, care managers would follow a safety plan. Depending on the individual

Table 1. Description of Telemental Health Studies in Clinically Unsupervised Settings

REFERENCE	STUDY TYPE	SAMPLE DESCRIPTION	PRIMARY OUTCOME(S)	MODALITY	SETTING	ADVERSE EVENTS
6	RCT	Veterans ($n = 34$) who were patients of the VAMC	Scores for PTSD and depression assessed via telephone vs. in-person	Telephone	Remote location, unsupervised	No
8	Case study	Veterans ($n = 5$) taken from a larger depression study	Depression severity, pain severity	Telehealth monitors	Home, unsupervised	Yes
5	RCT	Patients ($n = 600$) beginning antidepressant treatment	Depression, patient health	Telephone	Remote location, unsupervised	No
7	RCT	Participants ($n = 96$) with PTSD	Severity of PTSD	Internet (online writing assignments)	Home, unsupervised	No
9	Dependant groups, convenience sample	Patients ($n = 34$) enrolled in a telehealth heart monitoring program	Depression severity	Telephone-based interactive voice recorder	Home, unsupervised	Yes
21	Independent groups	Patients seeking medical assistance ($n = 289$) and medical staff ($n = 57$)	Depression severity assessed via telephone vs. in-person	Telephone	Remote location, unsupervised	No
20	RCT	Community sample ($n = 546$) residing in the Los Angeles area	Depression severity assessed via telephone vs. in-person	Telephone	Home, unsupervised	No
22	RCT	Patients ($n = 98$) in early recovery from alcohol use disorder	Alcohol consumption assessed via telephone vs. self-report	Interactive Voice Response telephone monitoring	Home, unsupervised	No
4	RCT	Individuals ($n = 120$) with depression and PTSD	Efficacy of cognitive-behavioral therapy vs. supportive emotion-focused therapy	Telephone	Home, unsupervised	No

RCT, randomized control trial; PTSD, posttraumatic stress disorder; VAMC, veterans affairs medical center.

case, the nurse would contact the participant to confirm their safety or they would alert the study clinicians with recommendations. In both of these studies, no participants were withdrawn due to concerns regarding depression severity.

REPORTS OF ADVERSE EVENTS

Two of the nine studies reviewed reported events that required the researchers to use safety procedures to effectively respond to concerns they had regarding participant safety. In one of these studies, Turvey et al.[9] used interactive voice-recording home monitors to administer two forms of the PHQ to assess severity of depression. One study participant expressed suicidal ideation on the PHQ-9, which was noted by the study staff nurse care manager. The researchers report that they were unable to contact the patient or the emergency collaterals, so the nurse contacted the local police who visited the participant to confirm safety. In addition, three other participants scored high on depression severity, which prompted the implementation of precautionary measures, including consultation with physician and initiation or adjustment of an antidepressant regimen. The researchers concluded that the use of voice-recording home monitors was a feasible method of screening for potentially depressed patients and that their preestablished safety plan for the assessment of suicidality was successful.

In the second study that reported an adverse event, Dobscha et al.[8] tested the use of Web-based remote access health monitors to assess patient depression symptoms. Five patients used in-home telehealth

monitors weekly for 24 weeks to complete the PHQ-9. After detecting an increase in symptom severity for two participants, the study care manager sent out alerts to advise the study clinicians. One patient also stopped entering data into their monitor, which prompted the manager to confirm the patient's safety via telephone. The patient reported no problems and continued to use the monitor after the reminder. The results of the study provided support for the use of home health monitors to regularly assess patient depression symptoms. In both of these studies, safety contingency plans were able to resolve the situations and mitigate potentially serious outcomes. Thus, the aforementioned studies demonstrate that predetermined safety plans are instrumental to the successful delivery of telemental healthcare.

TECHNICAL ISSUES

Two studies reported limitations of telehealth equipment that might have had implications for safety. Dobscha et al.[8] reported that the Web-based remote access system monitors they used did not adequately display all of the PHQ-9 information. In particular, there was an insufficient amount of characters that the monitor was able to display on at least one of the PHQ items, which resulted in the deletion of a few patient responses. The monitor systems were also incapable of scoring the questionnaire or entering the results in a database; this had to be done manually by the care manager. In addition, one of the participants preferred to use his monitor at work, but experienced connection difficulties because of his employer's network firewall. Knaevelsrud and Maercker[7] reported that the most frequent reasons why participants dropped out of their study were computer and network technical problems as well as emotional distress associated with writing about stressful events.

ADDITIONAL LITERATURE SEARCH

Given the paucity of studies that specifically evaluated telemental healthcare delivered to clinically unsupervised settings, we broadened our search criteria to include empirical studies that used telehealth technologies for mental health monitoring and clinical assessments during and as follow-up to primary and psychiatric care treatment. We excluded studies that only involved telephone contacts for medication monitoring or those that reported brief follow-up phone contacts that did not involve a clinical symptom assessment (i.e., use of a standardized measure or interview). Out of more than 23 additional studies reviewed, we identified a total of 10 studies that conducted mental health follow-up assessments to unsupervised settings. Of these, four studies described telemental health contacts that were a follow-up to a primary care treatment.[10–13] The remaining six studies specifically focused on telemental health follow-up contacts, usually as a form of relapse prevention for psychiatric disorders.[14–19] The majority of these studies assessed depressive symptoms via standardized measures, and all of these studies reported the use of telephone technology to contact patients in-home. For instance, Katon et al.[19] contacted participants via telephone to administer the symptom checklist for depression (SCL-20) in a study that evaluated the effects of a collaborative care intervention among depressed primary care patients. None of these studies described safety plans for the telephone contact portion of the study, or reported the occurrence of adverse events during the study.

Discussion

This review was conducted to identify and review safety issues associated with telemental healthcare delivered to clinically unsupervised settings. As anticipated, we identified a limited number of published articles that described results or procedures conducted in these settings. Specifically, our review of the literature resulted in the identification of nine telemental health studies conducted in settings without direct onsite clinical supervision. Six of the studies reported the existence of a safety plan and only two reported the occurrence of adverse events—all of which were resolved with prescribed safety procedures. Two studies reported technical issues that occurred during the delivery of care; however, this did not result in any adverse safety events. In addition, none of studies in our additional literature search that used telephone contacts for secondary mental health monitoring and assessments reported adverse events. Overall, the data suggest that the use of safety plans in these studies, including those focused on prevention of adverse effects, was effective.

Our review provides initial evidence that telemental health services delivered to clinically unsupervised settings can be safely managed. The limited data and low count of peer-reviewed studies, however, limit our ability to make generalized conclusions about the safety of these treatments. This review is limited to published studies only, and thus we are unable to evaluate the safety of treatments that are not reported in the literature. There is also not enough data available to adequately evaluate potential differences in safety based on the type of telehealth technology used. Further, several of the studies did not have sufficient detail regarding study methods necessary to adequately assess safety plans or outcomes. In several of the studies, safety procedures were only discussed if an adverse event occurred during the course of the study, thus making it unclear whether these actions were part of preplanned safety protocols or not. Although it is likely that safety plans were required

by institutional review boards before study initiation, there is no requirement to report safety plans in journal articles. It would therefore be wrong to assume that a safety plan was not available if not explicitly reported in an article. Finally, adverse events were presumed to have not occurred by virtue of them not being reported. It is conceivable, however, that adverse events did take place but were not classified as such or were effectively managed with an existing safety plan.

Conclusions

The current review suggests that telemental health safety concerns can be effectively managed in clinically unsupervised settings. This suggestion is based on a limited review, and caution must be taken before attempting to generalize results. It is anticipated, however, that these initial findings will ultimately guide additional work in this area because the limited safety data available at this time constrain the development of telehealth standards of care as well as policy. Studies that specifically focus on the evaluation of safety of telemental health are necessary to address this issue and additional research is needed on adverse events that might occur when different telehealth modalities (telephone, Internet-based, etc.) are used. Researchers and policy experts should use these results as a precedent to encourage the investigation of telehealth delivery into clinically unsupervised settings. As telehealth continues to gain acceptance, we expect that more data will emerge to support the safety, standardization, and widespread dissemination of telemental healthcare programs to include those delivered to clinically unsupervised settings.

Acknowledgments

The authors wish to thank Gregory A. Gahm, Ph.D., and Mark A. Reger, Ph.D., for their assistance with this article.

Disclosure Statement

No competing financial interests exist.

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Received: December 15, 2009
Revised: February 2, 2010
Accepted: February 2, 2010