### **PSYCHIATRY IN THE DIGITAL AGE (J SHORE, SECTION EDITOR)**



# Telehealth-Based Delivery of Medication-Assisted Treatment for Opioid Use Disorder: a Critical Review of Recent Developments

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Accepted: 16 June 2022 / Published online: 27 July 2022

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### Abstract

*Purpose of Review* Telehealth-delivered medication-assisted treatment for opioid use disorder (tele-MOUD) has received increased attention, with the intersection of the opioid epidemic and COVID-19 pandemic, but research on recent developments is scattered. We critically review recent literature on tele-MOUD and synthesize studies reporting primary data under four themes: clinical effectiveness, non-clinical effectiveness, perceptions, and regulatory considerations.

*Recent Findings* Despite increasing publications, most failed to include long-term comprehensive assessments. Findings indicate favorable outcomes such as improvements in retention and abstinence rates, positive experiences, and improved feasibility with the relaxation of regulatory measures. With increased adoption, clinician and patient perceptions appeared largely positive. Negative findings, albeit minor, were primarily associated with workflow adaptation difficulties and limited access of underserved populations to technology and internet connection.

*Summary* Additional financial, logistical, outreach, and training support for clinicians, patients, and support staff is recommended, in addition to permanent evidence-based regulatory reforms, to scale and optimize tele-MOUD services. Comprehensive recommendations to overcome limitations are expanded therein.

Keywords Telehealth · Opioid use disorder · Medication-assisted treatment · COVID-19 · Telebehavioral health

# Introduction

### Background

The United States (USA) has been facing an opioid epidemic for the past 2 decades. Over the past 2 years alone, over 9 million individuals have misused opioids, and close to

This article is part of the Topical collection on *Psychiatry in the Digital Age* 

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2.7 million have received a diagnosis of opioid use disorder (OUD) [1], a pattern of opioid use considered problematic and leading to significant impairment or distress [2].

Despite the opioid epidemic being declared a public health emergency (PHE) since 2017 [3], overdose deaths have been continuously increasing at record levels, with 100,000 annual overdose deaths, an increase of 28.5% during the 1-year period ending in April 2021, compared to the same period the prior year [4]. OUD is highly comorbid with (1) mental health conditions such as depression and anxiety, (2) health risk behaviors such as needle sharing which drastically increase risk of contracting blood borne infections such as HIV and hepatitis, and (3) physical health conditions such as chronic pain, endocarditis, and liver disease among others [5, 6]. Adding to populationlevel morbidity and mortality concerns, these challenges have resulted in staggering expenditures nationally related to healthcare services, in addition to major losses in productivity and costs to the legal system amounting to over 78 billion dollars annually [7]. Despite that, access to treatment has been limited, with only 20 to 40% of people struggling with OUD receiving care [8].

#### Medication-Assisted Therapy and Access to Services

Medication-assisted therapy (MAT) refers to the use of medications such as opioid agonists (methadone), antagonists (naltrexone), or partial agonists (buprenorphine or buprenorphine/naloxone), to treat OUD [9]. MAT is considered the gold standard for treating OUD, with consistently demonstrated superior clinical outcomes compared to abstinence-based approaches [10]. MAT mitigates withdrawal symptoms, limits cravings, and blocks some of the euphoric and sedating effects of opioids [9, 11]. Compared to standalone psychosocial treatment, the addition of MAT leads to reduction in opioid use and overdoses, reduced relapses, reduced incidence of infectious diseases, and higher retention rates [11, 12].

However, access to MAT for OUD (hereafter referred to as MOUD) is impeded by a combination of factors, including limited availability, widespread stigma, limited funding, treatment costs, and the burden and cost of traveling to access care [13]. Access issues are particularly profound in rural and remote areas, which experience disproportionately higher incidence of OUD compared to urban communities [8, 12]. While there have been national efforts to increase the number of buprenorphine-waivered prescribers [14], around 71% of counties nationally do not have publicly available MOUD prescribers, and close to 60% do not have any buprenorphine-waivered physicians [12, 15]. Indeed, the main barriers to accessing MOUD are the shortage and uneven distribution of addiction specialists [8, 12]. This is exacerbated by restrictions to prescribers' scope of practice and burdensome additional requirements such as special training and separate X Drug Enforcement Administration (DEA) waiver number to prescribe buprenorphine [16]. Furthermore, many prescribers who are buprenorphine-waivered may be treating very few to no patients with OUD [17].

Access issues were further expounded by the coronavirus disease 2019 (COVID-19) pandemic and subsequent PHE-related measures, which exacerbated health, psychosocial, and economic stressors, led to social isolation, and disrupted healthcare service delivery [18].

### **Telehealth-Based MOUD**

Despite calls for innovative solutions to improve MOUD access, the value of telebehavioral health (TBH) in this field has only recently been recognized. TBH is defined as the use of information and communication technologies, such as videoconferencing, to deliver behavioral health services remotely. TBH has received widespread support with regard to its effectiveness, efficiency, utility, and feasibility, and has demonstrated comparable clinical outcomes to in-person treatment in behavioral health [10].

The use of TBH to deliver MOUD, hereafter referred to as tele-MOUD, has been recognized as an approach to address the opioid crisis given its potential to overcome the shortage of MOUD prescribers, stigma, and geographical barriers [13, 16]. However, tele-MOUD implementation requires specific considerations, given the need to closely manage medications, track prescribing monitoring programs, test regularly, and follow strict prescribing regulations. In general, studies show favorable outcomes for the use of tele-MOUD such as improved abstinence and retention rates in comparison to in-person treatment [12], as well as high patient satisfaction with services. However, scaling tele-MOUD historically encountered multiple financial, regulatory, and legal barriers [19]. Some mirrored those encountered in implementing TBH programs more generally, such as reimbursement challenges, clinician and staff hesitancy, technology barriers, and challenges with workflows and implementation models [17, 20]. Others were more specific to regulatory restrictions to prescribing controlled substances remotely, regulations on prescribing buprenorphine specifically, and in-person visit requirements [21•].

# **The Present Review**

Evidence in the literature regarding tele-MOUD is dispersed and not well synthesized, especially given the surge of publications on the topic during recent years. This paper critically reviews the literature on tele-MOUD published since 2018 with the aim of summarizing the state of the field, including reported barriers, successes, and opportunities for improvement.

# Methods

#### Search Strategy

A review of the literature was conducted from January to April 2022 using Google Scholar database. The search included three main concepts: "Telebehavioral Health," "Medication-Assisted Treatment," and "Opioid Use Disorder." Accounting for interchangeable terms used for each concept, we developed one search string incorporating their multiple synonyms (see Table 1).

### **Inclusion and Exclusion Criteria**

Because this review focused specifically on the recent evolution of tele-MOUD, the search targeted articles published between 2018 and 2022. The search identified peer-reviewed

#### Table 1 Definitions of key concepts

Concept	Definition
Telebehavioral health	TBH is defined as behavioral health treatment delivered synchronously or asynchronously through telehealth means such as video- or audioconferencing. This definition excludes other forms of TBH and adjunct treatments such as text-based interventions, digital treatments, and others that do not center around video- or audio-based clinician-patient interactions
Medication-assisted treatment	MAT is defined as behavioral health treatment that centers around the prescription of medications, such as naltrexone, buprenorphine, and methadone, for the treatment of OUD
Opioid use disorder	OUD is defined as a substance use disorder as according to DSM-5 that specifically relates to opioid use
Search string	("Medication assisted treatment" OR "Opioid substitute treatment") AND ("Telepsychiatry" OR "Telemental health" OR "Telemedicine" OR "Digital treatment" OR "Telebehavioral health") AND ("Substance use" OR "Opioid" OR "Opioid use disorder")

articles examining the use of tele-MOUD through videoor audioconferencing, and reporting primary data. This included randomized control trials, case studies, program evaluations, cross-sectional studies, qualitative studies, retrospective studies, case reports, and others that reported the outcomes of tele-MOUD. We also included articles that reported the experiences or narratives of patients, clinicians, or support staff participating in tele-MOUD. We excluded review articles, opinion articles, commentaries, editorials, conference abstracts, and others not reporting a theme related to this topic, or not reporting primary data.

#### Data Collection, Management, and Analysis

Throughout the first phase of the search process, titles and abstracts of articles were reviewed for relevance. Next, fulltext versions of articles deemed relevant were read in detail to determine inclusion. For all included articles, specific data was extracted pertaining to the focus of this review and was placed in a table with pre-determined categories. These categories were initially guided by the authors' collective experience in researching, developing, and implementing TBH and tele-MOUD, and were further refined throughout the full-text review phase. Finally, this data was imported into the sheet, and authors met regularly to discuss the findings.

# **Results and Discussion**

Out of 962 hits that appeared on Google Scholar, and following the aforementioned phases, 30 articles met our inclusion criteria.

Almost all studies were published between 2020 and 2022, with the exception of two published in 2018 and 2019. Most commonly, studies employed a retrospective design (n=10) [8, 12, 22–29], a qualitative design (n=7) [10, 30 31, 32•, 33–35], or a case study design (n=6) [36–40, 41•]. The rest followed a mixed-methods approach (n=2) [16, 42], a prospective cohort design (n=1) [43],

non-randomized control trial (n = 1) [44], cross-sectional design (n = 1) [45], or a commentary approach narrating experience (n = 2) [46, 47].

We present findings of the review, including challenges, successes, and identified opportunities of included studies, and discuss them in relation to the literature under the following themes: (1) clinical effectiveness, (2) non-clinical effectiveness and feasibility, (3) perceptions and attitudes, (4) regulatory and contextual conditions.

# **Clinical Effectiveness**

Studies commonly examined clinical effectiveness using abstinence rates and retention rates as the primary measures. The majority of studies reported improved rates, although much variability was observed, potentially due to differences in data collection timepoints and the socio-demographic characteristics of target groups. For instance, some studies found retention and abstinence rates that are comparable or superior to in-person treatment rates [12, 22, 24, 27, 28, 41•]. Others reported significantly lower risk of treatment discontinuation among patients using tele-MOUD compared to those using in-person treatment [23, 26, 46].

Clinical effectiveness was also observed in integrated care settings such as reports of maternal and newborn outcomes being comparable to in-person care as determined by retention rates, urine drug screen, and neonatal abstinence syndrome diagnoses [44].

Most of these studies, reflecting research conducted during COVID-19, attributed their success to relaxation of regulatory measures, which allowed them to transition to tele-MOUD, especially given access challenges associated with mobility restrictions. Tele-MOUD provided an ideal alternative to in-person treatment, by increasing patients' ability to attend treatment where no other options were available.

Despite that, most studies reviewed did not have longterm follow-up data demonstrating support and failed to report long-term clinical effectiveness, with data typically extending to only 3 to 6 months. Also, while most concluded that tele-MOUD was effective, others reported lower retention rates in comparison to in-person treatment. These findings may be related to confounding factors associated with the COVID-19 PHE among others. For instance, some authors found lower retention and treatment adherence rates in their samples and subsequently argued that due to COVID-related fatigue, financial challenges, and psychosocial distress, patients found it difficult to maintain treatment [34, 36, 40]. However, these authors also highlighted other challenges impacting the effectiveness of tele-MOUD, such as patients having trouble accessing functioning devices and reliable internet connection, privacy concerns, and lower digital literacy, which contributed to treatment discontinuation. They also alluded to patients' limited engagement with clinicians and limited willingness to use technology in their treatment course as potential contributing factors to negative clinical outcomes. Finally, Rahman et al. [24] reported decreased adherence to medication regimens and decreased use of toxicology screenings, which may have affected objective assessment of sobriety and substance use.

# **Non-clinical Effectiveness and Feasibility**

Reviewed studies examined important aspects related to effectiveness but that addressed non-clinical aspects such as access to care, implementation feasibility, and workflow adaptations.

Seeing the publication time period, perhaps the most reported non-clinical outcomes related to improving access to care in the context of mobility restrictions, especially among hard to reach and rural populations. For instance, some authors reported improved outreach with vulnerable patients, reduced wait times, and improved access to treatment upon transitioning to tele-MOUD [10, 23, 25, 37, 40]. Authors attributed these findings to the ability of tele-MOUD to bypass issues such as childcare, work commitments, transportation challenges, stigma, and increased flexibility in scheduling. This was especially true in studies focusing on remote, rural, and disadvantaged populations. Importantly, it was reported that multiple forms of tele-MOUD may be suitable options, ranging from low-threshold audio-only modality to videoconferencing [31, 36]. Others reported additional benefits to having tele-MOUD services integrated within their organizations such as being able to avoid outgoing referrals, maintaining integrated approaches, increasing their capacity to treat more patients, and avoiding medical data fragmentation [32•].

In a survey of primary care centers that provided MOUD during COVID-19, most clinics reported operational adaptations in response to the pandemic [45]. The most significant adaptations included changing billing codes for virtual visits, implementing stronger outreach strategies, and decreasing barriers for patients to enroll and continue their medication course. Almost half reported that medical and behavioral health visits became exclusively virtual. Most reported increased duration of buprenorphine prescriptions, reduced urine toxicology screening, and increased patient demand for treatment. The survey also demonstrated that most clinicians reported easier experience in retaining patients.

The main feasibility concerns were associated with patient access to devices and internet connection, whereas facility-level challenges included resistance to adaptation to new workflows [40, 41•]. That said, other studies such as in Hunter et al. [34] found that clinicians required additional support and flexibility when prescribing medications, expressed concerns about medication diversion and potential overdose, and called for additional funding to be able to sustain tele-MOUD services.

As for factors affecting implementation, tele-MOUD adoption was facilitated by a sense of mission regarding fighting the opioid epidemic, control over referral processes, and previous experience with tele-MOUD. Other facilitating factors included perceived effectiveness and the availability of an operational toolkit to guide implementation. Barriers included the perception of tele-MOUD as a complex intervention, and it being perceived as external to the core mission of the clinics [30]. This is in line with previous findings in the literature, whereby facilitators to tele-MOUD implementation included having strong tele-MOUD advocates within the facilities and having feasible and operationalized tele-MOUD [48].

Previous literature had documented the importance of cost-effectiveness and funding for sustainability of tele-MOUD programs, including needing funding for initial startup costs and for established reimbursement structures [48]. However, in our review, although many studies had received specific funding to implement their tele-MOUD programs, surprisingly few examined financial considerations in their research. Weintraub et al. [12] noted that financial feasibility and sustainability of their tele-MOUD program was primarily attributable to tele-MOUD being covered by insurance whereby the originating site and prescribers are eligible for reimbursement. Himelhoch et al. [41•] reported financial challenges associated with transitioning towards tele-MOUD during the initial phases of their operations. Despite identified financial challenges, tele-MOUD consequently resulted in higher retention rates and positive clinical outcomes in their target population  $[41 \bullet]$ .

# Clinical Vignette 1: Bypassing Geographical Barriers in Alaska

A seasonal fisherman in a remote village in Alaska offers an example of how the telehealth modality provides access to treatment for the most vulnerable and underserved populations. This individual's family had suffered with addiction for generations. Living in such a remote area and dependent on sea planes for goods, the supply of opioids was inconsistent making opioid withdrawal a chronic and disabling condition. Accessing treatment meant spending upwards of \$1,000 monthly on flights to Anchorage, leading to job loss due to travel and time away.

Without the requirement for an in-person examination to initiate treatment, due to the COVID-19 PHE, an X-waivered provider with an Alaska medical license was able to meet with this individual on video and safely prescribe buprenorphine-naloxone for treatment of OUD. Medications were shipped from a commercial pharmacy in Anchorage, offering the stability of life-saving treatment. With the challenge of shipment delays, judicious and advanced prescribing ensured no gaps in treatment occurred. Medication adherence was confirmed though monitored doses and pill counts, as well as videoobserved oral fluid drug tests that were mailed directly to the laboratory

### **Perceptions and Attitudes**

As for findings concerning perceptions and attitudes, results are categorized under those related to clinicians and patients.

Among a nationwide sample of addiction medicine physicians, most believed that tele-MOUD was more effective than other telemedicine services, including remote psychotherapy, and that patients should use tele-MOUD at a clinical site as opposed to at home. Physicians also reported that they would require technology compliant with Health Insurance Portability and Accountability Act (HIPAA), urine screening at patient sites, and local counseling to be available for patients, before feeling comfortable to deliver tele-MOUD services [16]. The survey found that only 38% provided tele-MOUD but 62% were willing to provide it, indicating barriers to adoption. Legal barriers, such as cross-state practice restrictions and local tele-MOUD regulations, rather than clinical or logistical barriers, were identified as the most prominent challenges needing policy reforms. Accordingly, physicians also expressed more interest in gaining information on local telemedicine and prescription policies rather than ongoing support from telemedicine experts. Moreover, non-tele-MOUD prescribers reported more perceived barriers than their counterparts, and they tended to provide stronger ratings for each barrier, indicating that experience and education in tele-MOUD are correlated with adoption rates. It is important to note that this study reflected views before COVID-19. Results may have changed over the past

2 years due to multiple factors such as increased adoption of telemedicine, increased publications and educational material on remote care delivery, and an appreciation of telemedicine as the only option for care delivery, especially early during the pandemic.

In a survey of physicians working in opioid treatment programs (OTP), 82% reported that patients were satisfied with using tele-MOUD, mostly due to the flexibility and safety it provided, along with reduced transportation barriers [34]. Although most physicians reported positive impact of remote care delivery on their patients, such as being more comfortable in-home environments, and although they reported that it might be a suitable long-term option, many worried that it decreased the quality of care they were giving due to their limited ability to assess patient status adequately. Added convenience and comfort, along with removal of transportation barriers, were also echoed in other studies [45, 32•].

Feasibility barriers to tele-MOUD implementation cited by Uscher-Pines et al.  $[32\bullet]$  included operational issues related to workflows such as getting in-person vitals, coordinating lab testing, and sending results to remotely located waivered prescribers  $[32\bullet]$ . Only one health center offered tele-MOUD to patients in their homes via a mobile app in this study. Even so, treatment still required patients to travel (e.g., urine toxicology testing must be completed in a medical setting).

While the literature on patient satisfaction with tele-MOUD pre-COVID-19 is scarce, some studies had indicated that patients were satisfied with videoconferencing despite most preferring in-person care over tele-MOUD. In this review, patient satisfaction was explored by some authors [10, 34] who found that despite technical glitches and minor difficulties, participants were satisfied with improved access to care, reduced barriers such as for childcare and transportation, and improved flexibility in scheduling online appointments. Participants felt safer and more satisfied with the seemingly less "formal or medicalized" format of tele-MOUD compared to in-person sessions. Anecdotal evidence from Clark et al. [46] echoes similar feelings, with many of their patients acknowledging having accessed OUD treatment due to their 24/7 buprenorphine hotline service.

However, patients did express reservation about certain aspects of tele-MOUD. For instance, participants in Moore et al. [10] reported increasing feelings of isolation with remote care. Tele-MOUD requires little to no inperson interactions compared to in-person sessions, group meetings, and counseling sessions. This is concerning for many patients who self-isolated not only because of the COVID-19 pandemic but also due to the stigma associated with OUD treatment and the lack of understanding and supportive family members. In Brunet el al. [30], some clinicians reported that their patients preferred in-person meetings over remote care, perceiving in-person as more conducive for building rapport. Similarly, in Hunter et al. [34], a few clinicians expressed that their patients did not prefer tele-MOUD because it felt "impersonal."

#### **Regulatory and Contextual Conditions**

As a precursor to discussing this review's findings regarding the regulatory conditions in the past few years, we first describe the evolving context followed by current findings.

Prior to COVID-19, a combination of federal and state regulatory restrictions created barriers to scaling tele-MOUD. These included the Drug Addiction Treatment Act of 2000, Title 42 of the Code of Federal Regulations Part 8 (42 CFR 8) for OTPs, and the Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008. These regulations restricted prescribing and dispensing controlled substances for tele-MOUD and included requirements for in-person encounters to prescribe MOUD [49]. In addition, reimbursement restrictions and variations across public and private payers created significant complexities. For example, Medicare reimbursed TBH services only when patients were at an originating site located in a zip code designated as rural or professional shortage area [50]. Also, there were significant variations among states with regard to Medicaid and private payer reimbursement regulations, including originating site requirements [51]. Concerns about the opioid epidemic led to passing the 2018 SUPPORT Act, which expanded Medicare reimbursement for telehealth services delivered to treat substance use disorders, by removing the originating site requirements, expanding coverage for MOUD to patient homes. The SUPPORT ACT also directed the attorney general to issue final regulations to allow for special registration, which would permit tele-prescribing controlled substances, including buprenorphine, without requiring in-person evaluations [32•].

The PHE declared in response to COVID-19 facilitated the suspension of policies and regulations that had been regarded as barriers to the expansion of tele-MOUD [18]. The DEA implemented the PHE exception, under the Ryan Haight Act, to lift the restriction on tele-prescribing controlled substances throughout the PHE, thus suspending requirements for in-person evaluations previously needed for buprenorphine initiation [18]. In addition, the DEA allowed using audio evaluations to initiate and maintain buprenorphine prescribing. The Centers for Medicare and Medicaid Services (CMS) expanded reimbursement to audio-only sessions, during the PHE (now becoming permanent for behavioral health). Additionally, the Department of Health and Human Services (HHS) relaxed the enforcement of HIPAA-related videoconferencing privacy requirements [52]. Some states permitted cross-state practice, easing licensure requirements, and suspended or reduced administrative and financial burdens such as prior authorizations and copays, and limitations on take-home MOUD [53].

The above changes helped facilitate large-scale adoption of TBH. For example, TBH Medicare visits rose from 1% of behavioral health visits in 2019 to about 38% for 2020. Towards the end of 2020, TBH made up 50% of all Medicare behavioral health services [54]. Specifically for OUD, CMS reports that the number of fee-for-service members receiving telehealth services increased to 39% in April 2020 compared to 2% in 2019 [55].

Further regulatory changes took place in April 2021, with guidance provided by HHS to allow eligible prescribers to prescribe buprenorphine for OUD for up to 30 patients at any given time, while being exempt from certain federal requirements, such as having to certify to certain training and to being able to provide ancillary services and counseling [56]. While these guidelines do not eliminate the requirement for the X waiver, they aim to expand access to MOUD by easing the barriers reported by prescribers with regard to training requirements for prescribing buprenorphine [56].

As for findings of the present review, a comparison of research conducted pre- and post-COVID-19 indicates that while earlier publications cited stringent restrictions on tele-prescribing and inability to treat out-of-state patients as major barriers to tele-MOUD implementation, post-COVID-19 publications reported that relaxed measures facilitated tele-MOUD implementation. For example, pre-COVID-19 regulatory barriers were cited by clinicians who were both adopters and non-adopters, including the Ryan Haight Act requirement that patients meet with waivered prescribers in-person for their first visit to prescribe buprenorphine [32•]. Another study found that Ryan Haight was not well understood, leading to concerns about legality of tele-prescribing controlled substances [30]. At state level, a "patchwork" of telehealth regulations was described as hindering not only telehealth adoption but also innovation in health. These include state regulations prohibiting telehealth practice across state lines or limiting access to prescription drug monitoring programs to local prescribers, creating concerns about high-risk prescribing [16]. The complex regulations led clinicians to identify needing support and resources, including guidance on conducting at-home tele-MOUD, tele-prescribing, and mailing controlled medications [30]. Findings of this review indicated that the regulatory context was a critical factor in determining the success of programs. Most articles reporting positive outcomes attributed their success primarily to relaxation of regulatory measures and advocated for them to be permanent as opposed to temporary  $[22, 23, 27, 37, 41^{\bullet}, 46].$ 

### Limitations and Identified Gaps

The present review shows that in the past 2 years, there has been a surge in publications on tele-MOUD, even though it is a narrow topic. This indicates an increasing interest in tele-MOUD, especially following COVID-19. Nevertheless, limitations in the reviewed literature were identified, including the uncontrolled, retrospective, and cross-sectional design of many studies [8, 12], the inability to generalize findings due to their single setting design, the narrow specialty of care they cover, or the small population size among others [10, 12, 24–26, 28, 30, 43–45], potentially missing data and short-term follow-up [8, 12, 28, 31, 42–44], and the potential for selection bias [10, 44]. Finally, the majority of the studies included in this review focused on the clinician experiences, with only few studies reporting on patient experiences through direct patient interviews [10].

Consequently, there is a need for prospective randomized studies comparing tele-MOUD with in-person MOUD. Moreover, most reviewed studies failed to draw comprehensive evaluations of their programs. For instance, almost none of the studies reviewed examined (1) long-term effectiveness of tele-MOUD treatment, (2) clinical outcomes beyond retention and abstinence rates such as overdose and comorbidities, (3) financial considerations for implementing and maintaining tele-MOUD programs, or (4) non-clinical outcomes beyond anecdotal feedback.

Some programs appeared to have been largely implemented to support rural populations, recognizing that patients had little-to-no options to access MOUD in their communities or having to travel outside of their communities for treatment [12, 30, 57]. Other programs appeared to address patient needs in urban settings [24, 26] and patients experiencing homelessness [25]. Findings call for studies to focus on a range of populations to include more geographical, demographic, and clinical diversity [8, 12, 33].

In general, most programs reported positive findings primarily associated with recent relaxation of regulatory measures, which ultimately facilitated transitioning towards tele-MOUD. This is especially true when regarding tele-MOUD as a feasible and practical alternative in the context of ubiquitous technology to overcome access barriers to treatment such as mobility restrictions. That said, the potential of tele-MOUD based on reviewed studies seems to only be scratching the surface, especially since studies adopted very basic implementation methodologies that mostly utilized videoand audioconferencing.

Importantly, recent literature appears to continue to examine tele-MOUD from a relatively traditional perspective, as an approach to delivering MOUD remotely that mirrors inperson care. We recognize the value this research offers, particularly at a time of massive scaling of tele-MOUD that occurred with COVID-19. We also appreciate that some research was conducted during the COVID-19 PHE, during which the focus was on examining the effects of COVID-19 on healthcare delivery and on the feasibility and effectiveness of transitioning to tele-MOUD. However, doing so may have ignored opportunities to explore the innovation potential of tele-MOUD in further expanding access, advancing quality of care, decreasing costs, and improving populationlevel health outcomes.

### Recommendations

With significant research and practice experience, evidence supporting the feasibility, acceptability, and scalability of tele-MOUD, current and future research should focus on implementation science, quality, cost, and evaluation approaches. This could include leveraging technology inherent to tele-MOUD delivery to collect both process and outcome data, optimizing and diversifying care delivery models, and addressing care access disparities as follows:

#### 1. Tele-MOUD modality and technology

Our review found little research on non-traditional approaches to tele-MOUD delivery. For example, only one study mentioned asynchronous use of text and voicemail in the context of supporting engagement for synchronous tele-MOUD sessions. If we continue to regard tele-MOUD as a virtual replica of in-person care, the benefits will eventually plateau. That is because tele-MOUD helps mitigate the uneven distribution of prescribers but does not increase the workforce per se. Therefore, there is value in incorporating asynchronous, consultative, and hybrid healthcare delivery models, to optimize access, quality, and cost-efficiency of care. It is necessary to conduct further formative and implementation studies examining innovative, tailored approaches to delivering tele-MOUD for effectiveness, feasibility, and cost-effectiveness [25]. Such research should extend beyond synchronous videoconferencing, to include texting, email, or audio-only care delivery in tele-MOUD to examine impact and develop best practices.

Data on the effectiveness of digital solutions that support tele-MOUD delivery, such as remote monitoring, digital therapeutics, and other online tools, continues to be limited. Some evidence supports the potential for wearable sensors for remote monitoring of opioid withdrawal [58] and for internet-based community reinforcement tools in supporting treatment engagement and reduction in opioid use [59]. More studies are needed to examine the effectiveness awareness and utility of mobile health solutions and adoption rates [58] especially for patient engagement peer support and selfnavigated modules used to complement tele-MOUD.

2. Evaluation of tele-MOUD services and programs

Synchronous video-based tele-MOUD is as effective as in-person treatment in retaining patients across several studies employing non-randomized designs; however, controlled comparisons continue to be lacking [60, 61]. Future research needs to incorporate long-term data collection more diverse and larger sample sizes medications beyond buprenorphine and a range of clinical and nonclinical outcomes. In addition studies should more consistently track satisfaction over time in a manner that is valid and generalizable as such data may hold value in predictive modeling for treatment retention and engagement [57]. Finally, reviewed studies primarily examined abstinence and retention rates as measures of treatment effectiveness, yet other clinical outcome measures warrant focus, including reduced use, safer use, and harm reduction.

Reviewed studies did not evaluate using remote consultative models to support delivery of MOUD in primary care settings. However, different models have demonstrated benefits in supporting OUD treatment in primary care settings, such as the Collaborative Care Model, or in enhancing clinicians' self-efficacy, such as Project ECHO [62]. Given the shortage of MOUD prescribers, further research is needed to examine evidence for scalability, cost-effectiveness, patient outcomes, and practices of clinicians supported through these programs [62].

3. Care integration

Given the healthcare system's fragmentation, tele-MOUD scaling may risk replicating this fragmentation. For example, clinical guidelines for treating OUD emphasize the importance of offering psychosocial needs assessment and the option for mental health treatment in addition to MOUD [63]. But only about 25% of people with both OUD and mental health conditions receive treatment for both [64]. In turn, there is a need to examine technology's use not only to expand access to care, but to also support integration between MOUD and mental health treatment, as well as OUD with physical health. The literature appears to recognize the value of such integration with tele-MOUD [8, 21•].

4. Health equity

It is worth noting that the opioid epidemic had been declared a PHE since 2017, yet it took another PHE related to COVID-19 for stronger measures to be taken to facilitate the expansion of tele-MOUD. In our opinion, this indicates that behavioral health and, more specifically, substance use disorders continue to be stigmatized and may lack the response otherwise provided to other aspects of health and healthcare. Data analytics and predictive modeling can assist tele-MOUD programs to better assess protective and risk factors, in order to tailor treatment approaches to the needs of patients. It is recommended that tele-MOUD programs implement targeted outreach to patients deemed at increased risk of medication non-adherence or treatment disengagement [24, 25].

There are concerns about the possibility of tele-MOUD exacerbating the digital divide and perpetuating access inequities, especially that limited access to Wi-Fi, smartphones, and private spaces is a major barrier to engaging in tele-MOUD [22]. Therefore, concerted efforts need to be directed towards expanding access to high-speed internet across the country, and to Lifeline Programs, also known as "Obama phones," to bridge the digital divide [22]. It is also recommended to make audio-only care available and reimbursable for individuals with no video access [22]. Finally, research should further incorporate social determinants of health contributing to health inequities when examining tele-MOUD [33].

### Clinical Vignette 2: Easing Access by Removing Barriers in an Urban Setting

The case of a 48-year-old man in an urban setting without housing illustrates how tele-MOUD may improve retention in care. With untreated PTSD and decades of stimulant and opioid use disorders, this individual had been in and out of multiple treatment facilities, both inpatient and outpatient, but had been unable to maintain significant time without use. He was discharged from a number of treatment programs due to his inability to attend required clinical and counseling visits or due to reported behavioral issues and conflicts with staff members

When the COVID-19 pandemic began, he was at high risk of poor health outcomes or death from overdose as local shelters limited admissions, and treatment became scarce. He fortunately had access to a smartphone through a federal program. Utilizing Wi-Fi at a public coffee shop, he was able to establish care with a tele-MOUD clinician, covered under his Medicaid plan, eventually stabilizing on 16 mg of buprenorphine-naloxone. When his medication had been stolen in the past, he was forced to return to opioid use as he awaited an in-person visit to restart medication. As a vulnerable individual living on the streets, his medication was inevitably stolen again, and this time, he was able to message his care team on his phone app. He requested a visit and received an early refill instead of returning to illicit opioid use. Also on the treatment app, he read educational materials about PTSD, and he began to understand how this condition might be the cause of his sleep disturbance and anxiety. He discussed this with his provider and was started on treatment that improved his quality of life. Without the barrier of having to make travel arrangements for every required visit, he was able to be timely and consistent with video follow-up visits. He no longer has to navigate the challenging interactions with front desk staff and busy support staff in a clinic setting that were often triggering and resulted in conflict. If he returns to substance use, he no longer has to face the shame or judgment of entering a treatment facility and asking to return to care—he can message his provider and easily return to treatment.

#### 5. Regulatory considerations

Calls for regulatory overhaul of licensure and prescribing requirements to facilitate tele-MOUD expansion predated COVID-19 [45]. At the time of preparing this review, the future regulatory landscape of telehealth after the PHE is over remains uncertain. There are concerns that the end of the PHE may roll back some of the advances seen in tele-MOUD adoption.

The end of the PHE exception of the Ryan Haight Act would reinstate previous restrictions on tele-prescribing controlled substances, which may disrupt access to medications, particularly as guidelines on telehealth registration under the SUPPORT Act have not been issued. There has been some legislative movement, with the introduction of the TREATS Act in 2021, which supports prescribing certain controlled substances for TBH, specifically supporting the tele-prescribing of MOUD, without requiring an in-person evaluation [65]. In addition, the American Telemedicine Association, supported by hundreds of professional organizations and telehealth stakeholders, in January 2022 urged Congress to [1] extend telehealth waivers through 2024, [2] require HHS to finalize telehealth evaluations in order to inform telehealth legislation before the end of 2023, and [3] introduce permanent telehealth legislation that is evidence based in 2024 [66].

Meanwhile, it is crucial to maintain ongoing regulatory support and guidance to optimize and mitigate barriers to tele-MOUD implementation [45]. Updates on policies and associated processes must be communicated clearly and regularly to avoid confusion and misinterpretation. Additionally, processes towards compliance with these policies should be clear, uncomplicated, and low cost [32•]. Concomitantly, healthcare centers should develop workflows and logistical solutions that comply with regulations to facilitate tele-MOUD delivery [32•]. Also, it is recommended to develop and disseminate toolkits outlining relevant training requirements, implementation protocols, policies on tele-prescribing, and federal and state regulations that facilitate tele-MOUD adoption [16, 30].

From a cross-state practice perspective, participation in the Interstate Medical Licensing Compact has been expanding, facilitating physician cross-state licensure. Currently, the Compact includes 34 states, Guam, and the District of Columbia [67], and there are calls for further adoption [16]. Other calls supporting cross-state practice include increasing access to and interoperability of state Prescription Drug Monitoring Programs to allow out-of-state tele-MOUD prescribers comprehensive access to patient history across jurisdictions [16].

Further research is needed to assess the impact of regulatory changes on tele-MOUD, including possible risks and benefits of such changes, in order to inform future regulations and models of care delivery [22].

The coverage of telehealth by Medicare for both video- and audio-based sessions has become permanent, for behavioral health conditions, regardless of geographical location or originating site [52]. However, state-specific telehealth coverage mandates for both public and private insurance programs vary and may expire at different points in time, possibly disrupting access to care. Since cost-effectiveness is necessary for feasibility, states and payers will need to be involved and incentivized to cover tele-MOUD after the PHE ends.

Finally, as innovations in the delivery of MOUD remotely continue to be introduced, it is essential to have clearer regulatory guidance on digital health. For example, it is difficult to determine currently under the FDA regulatory definitions whether a mobile health (mHealth) app is considered a medical device or not. With increased innovations in tele-MOUD provision, the more the need will be for clearer guidance from the FDA and clearer messaging on approval processes and requirements for mHealth applications (58).

# Conclusion

As the USA continues to grapple with the opioid epidemic and COVID-19 pandemic, and as patients continue to face numerous barriers in accessing MOUD, the necessity to adopt and expand tele-MOUD is more evident than ever. This is illustrated by the rapidly expanding literature on tele-MOUD, which is adding to the wealth of knowledge and support for its effectiveness in different settings and populations. Needless to say that tele-MOUD is not the only solution for the reduction of the MOUD care gap; rather, it should be regarded as one component of a larger, more comprehensive and concerted effort to enhance access to quality MOUD treatment, especially for vulnerable and underserved populations. In addition, tele-MOUD holds potential to grow the role of technology beyond care delivery and towards data collection, predictive analytics, risk stratification, and targeted care. It offers opportunities to go beyond merely mirroring in-person care to enhance care coordination, mitigate care fragmentation, improve quality and integration, and decrease costs. It can also serve as a vehicle to implement more innovative approaches to healthcare delivery that overcome the clinician shortage. As we continue to navigate this phase of the COVID-19 pandemic with significant uncertainty, one thing that has become clear is that the conversation around tele-MOUD must evolve from whether it is effective, feasible, and scalable to how information and communication technologies can be effectively leveraged to deliver high-quality care, decrease costs, and implement newer models of care.

## Declarations

**Conflict of Interest** Hossam Mahmoud does not have existing conflict of Interest. Nothing to disclose. Hady Naal does not have existing conflict of Interest. Nothing to disclose. Emile Whaibeh does not have existing conflict of Interest. Nothing to disclose. Alyson Smith does not have existing conflict of interest. However, she used to be employed as medical director for a telehealth company that delivered tele-MOUD. For full transparency, she reports the following in her ICMJE disclosure form: "I was Medical Director (a paid employee) of Boulder Care, a telehealth MAT provider until March 2022. There is no financial connection between Boulder Care and this publication."

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