



When a pandemic and epidemic collide: Lessons learned about how system barriers can interrupt implementation of addiction research

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Abstract

Background

Telehealth technologies are now featured more prominently in addiction treatment services than prior to the COVID-19 pandemic, but system barriers should be carefully considered for the successful implementation of innovative remote solutions for medication management and recovery coaching support for people with opioid use disorder (OUD).

Method

The Centers for Disease Control and Prevention funded a telehealth trial prior to the COVID-19 pandemic with a multi-institution team who attempted to implement an innovative protocol during the height of the pandemic in 2020 in Tampa, Florida. The study evaluated the effectiveness of a mobile device application, called *MySafeRx*, which integrated remote motivational recovery coaching with daily supervised dosing from secure pill dispensers via videoconference, on medication adherence during buprenorphine treatment. This paper provides a participant case example followed by a reflective evaluation of how the pandemic amplified both an existing research-to-practice gap and clinical system barriers during the implementation of telehealth clinical research intervention for patients with OUD.

Findings

Implementation challenges arose from academic institutional requirements, boundaries and role identity, clinical staff burnout and lack of buy-in, rigid clinical protocols, and limited clinical resources, which hampered recruitment and intervention engagement.

Conclusions

As the urgency for feasible and effective telehealth solutions continues to rise in response to the growing numbers of opioid-related deaths, the scientific community may use these lessons learned to re-envision the relationship between intervention implementation and the role of clinical research toward mitigating the opioid overdose epidemic.

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Plain Language Summary: The COVID-19 pandemic coupled with the opioid overdose epidemic has resulted in compounded challenges to the fields of addiction treatment and clinical research. This manuscript describes a CDC (Centers for Disease Control and Prevention)-funded randomized control trial that was initiated prior to the COVID-19 pandemic and implemented during the height of the pandemic through 2020 in Tampa, Florida. The study evaluated the effectiveness of a mobile device application, called *MySafeRx*, integrating remote recovery coaching with the option of daily supervised buprenorphine dosing from secure pill dispensers via videoconference to reduce barriers and enhance support for medication adherence during treatment. With the sudden emergence of COVID-19, this research, already challenged by a research-to-practice gap and existing clinical system barriers to medications for opioid use disorder (MOUD) treatment (e.g., siloed service delivery, stigmatized staff and community perceptions of buprenorphine, and high staff burnout/turnover), was amplified by the rapidly changing protocols for standards of care during the implementation of an OUD treatment research intervention in the midst of the start of the pandemic. Lessons learned related to challenges from academic institutional requirements, boundaries and role identity, burnout, staff buy-in, and clinical protocols and resources are discussed, and recommendations for future research are provided. As urgency for feasible and effective solutions continues to rise in response to the growing numbers of opioid-related deaths, the scientific community may use these lessons learned to re-envision the relationship between intervention implementation and the role of clinical research toward mitigating the opioid overdose epidemic.

Keywords

implementation, opioid use disorder, system barriers, addiction treatment, telehealth

Introduction

The COVID-19 pandemic has likely contributed to yet another surge in the opioid overdose epidemic, with national trends indicating a spike in opioid-related overdose deaths in 2020 (Ahmad et al., 2021). This increase is largely due to the sudden shift in service provision, including social distancing requirements, a halt of in-person services, a quick transition to telehealth interventions, difficulty accessing medications, a decrease in rigidity of diversion protocols, the curtailing of harm reduction service programs (e.g., syringe exchange and naloxone distribution), and the unavailability of residential treatment (Bartholomew et al., 2020; Glick et al., 2020; Rodda et al., 2020).

As the development of evidence-based practices across the continuum of care for opioid use disorder (OUD) has progressed, the forces driving the opioid overdose epidemic have also shifted over time, and its severity has increased since the first wave in the early 2000s (Centers for Disease Control and Prevention, 2021). In response, researchers and practitioners have attempted to match the heterogeneous nature of the epidemic with a set of complex and individualized OUD treatment services, including both pharmacological and psychosocial supports (Dugosh et al., 2016; Fraser & Hawkins, 1984; Koh, 2017; van Dommelen-Gonzalez et al., 2015; Veilleux et al., 2010; Wells et al., 2018). Three Food and Drug Administration (FDA)-approved medication options exist to treat OUD, including buprenorphine (BUP), methadone, and naltrexone (Fullerton et al., 2014; Hser et al., 2014; National Institute on Drug Abuse [NIDA], 2012; Sullivan et al., 2019). BUP was introduced in the year 2000 as an office-based alternative to methadone, requiring fewer prescribing

precautions and regulatory restrictions. As the opioid overdose epidemic persisted, accessible treatment options became a priority, and BUP emerged as the preferred medication for OUD (MOUD) option (Abraham et al., 2020; Kelly et al., 2012; Schwartz et al., 2008; Yarborough et al., 2016). When implemented with fidelity, BUP has been shown to reduce the risk of opioid overdose by 50% (Pierce et al., 2016); unfortunately, national averages for retention in outpatient BUP treatment are low, with less than 50% remaining in treatment at 6 months (Hser et al., 2014). The low rates of adoption and retention in these medication programs negatively affect recovery outcomes (Ndegwa et al., 2016; Timko et al., 2016).

Several factors can limit the utilization and implementation of MOUD interventions, such as lack of access, lack of knowledge and awareness of resources, negative beliefs about the use of MOUD by both providers and patients, and social determinants of health (SDOH) and geographic location (Abraham et al., 2013; Kelly & Daley, 2013; Knudsen et al., 2011; Magura & Marshall, 2020; Pollack et al., 2021; Probst & Rehm, 2018; Rhee & Rosenheck, 2019; Rigg & Monnat, 2015; Roman et al., 2011; Stevens et al., 2015; Volkow et al., 2014). Treatment outcomes also depend largely on the specific nature and degree of the client's issues, the appropriate fit of treatment services, and the quality of the interactions and communication between the client and their providers (NIDA, 2012). Meaningful treatment and functional recovery are possible with support from MOUD, but policy, practice, and infrastructural resources must align for MOUD programs to be effectively implemented (Ndegwa et al., 2016; Timko et al., 2016; Warden et al., 2012).

As emphasized by NIDA Director, Dr. Nora Volkow, research efforts need to shift from showing/examining MOUD effectiveness (i.e., something that is well known) and move toward examining how to increase the accessibility and practical implementation of MOUD in real-world settings (Volkow, 2022). This manuscript offers a deep look into the implementation of a CDC (Centers for Disease Control and Prevention)-funded randomized control trial focused on the delivery of MOUD and offers lessons learned to improve future interventions through an implementation science lens.

Method

The Study

MySafeRx was a technology-based Android device application, integrating remote motivational enhancement (RME) sessions, with daily supervised BUP dosing from secure electronic pill dispensers via videoconference to encourage medication adherence. This study was a randomized control trial, which originally aimed to examine the effect of RME sessions versus standard of care on treatment engagement during the transition from inpatient detoxification to daily outpatient supervised dosing of BUP, with a target sample size of 160 people. Potential participants were considered eligible for the study if they were (1) currently in inpatient detoxification for OUD, (2) over the age of 18, (3) misusing opioids, (4) not pregnant, (5) stably housed, and (6) interested in using MOUD to treat their OUD. Informed consent was obtained from eligible participants prior to their enrollment in the study. When the study was initiated at the beginning of 2020, telehealth services were rarely incorporated into addiction clinical practices, and medication policies for BUP dosing were restrictive (e.g., daily in-person dosing at this site). In comparison to this standard of care, the study's intervention was an innovative approach for this treatment facility and its region. However, due to the COVID-19 pandemic, standard care at this treatment facility suddenly shifted toward practices that more closely resembled the remote care delivery model of *MySafeRx* (e.g., weekly take-home BUP medication with regular telehealth staff contact). As a result, the contrast between the intervention and control planned in the original study design quickly evaporated due to the blurring of the experimental and control conditions and the original study design needed to change. The team rapidly redesigned the study, with support from the CDC, and implemented a pilot study in the summer of 2020 that would assess differences in engagement impacted by different algorithms for the use of the locked electronic pill dispenser. The pilot was designed to enroll 30 people, but only 19 participants joined the study, between February 2020 and June 2021, before it was closed to enrollment. An interim analysis showed significant differences in engagement, retention,

and opioid use but inconsistent systems of care and research-to-practice gaps deterred study implementation. The substantial study challenges and lessons learned that impacted implementation are described below.

Setting

This study took place at a substance use disorder treatment facility in Tampa, Florida. The facility provides inpatient detoxification, stabilization services, and outpatient aftercare treatment using both psychosocial and pharmacological treatment methods. Prior to the COVID-19 pandemic and social distancing regulations, the MOUD clinical program at the study site consisted of two options for people with OUD upon discharge after 3–5 days of detoxification: (1) monthly long-acting naltrexone injections (Vivitrol) or (2) daily, in-person, onsite supervised BUP dosing. At the onset of this study, when daily onsite supervised BUP administration was the standard, the overwhelming majority of patients exiting inpatient detoxification did not successfully transition to continued “aftercare” involving either kind of MOUD. During the pandemic, the standard of care for BUP treatment shifted to allow for “take-home” prescriptions upon discharge from detoxification rather than the required daily in-person supervised dosing. The low baseline engagement and retention rates in MOUD at this site provided a rationale for the study intervention's goal of improving these rates with innovative technology, remotely supervised self-administration of medication, and individualized mobile recovery coaching support for patients.

Case Example

In examining the complex implementation challenges faced in this study intervention, consider the case of Jenna (her name has been changed to protect her identity), a 36-year-old female patient with an extensive history of polysubstance use, including illicit opioids, who was identified as an eligible candidate for the *MySafeRx* study. At the time of enrollment, she presented with significant post-traumatic stress disorder and social phobia symptoms derived from the results of the Psychiatric Diagnostic Screening Questionnaire. She had her first experience with drug use at the age of 11, with a history of being unstably housed, and had been sleeping on the street for over a year when she entered detox. She had experienced sexual trauma as a child by her family members and again as an adult while she was unhoused. Jenna had local family members willing to let her live with them if she was actively enrolled in a treatment program. Unfortunately, the housing support offered by her family came at the expense of continued exposure to her past abusers. The *MySafeRx* study presented an opportunity for her to receive flexible treatment that seemed suitable for her social anxieties and transportation challenges to the treatment facility for in-person, daily BUP dosing, allowing her to still take medication daily and receive support remotely.

Upon enrollment into the *MySafeRx* study and beginning her BUP treatment with daily mobile recovery coaching at home, Jenna described the hardships of her living environment and the recurring anxieties from remembering past abuse. She began self-harming behaviors such as hitting, scratching, and burning and, despite wanting to obtain OUD treatment, was torn between continuing to stay with her family or going back to live on the streets. Her options felt limited due to not having an ID, not having insurance, and residential facilities not accepting her if she received MOUD treatment. Additionally, she was experiencing these issues during the beginning of the COVID-19 pandemic, at a time in which the treatment facility was experiencing a COVID-19 outbreak and thus functioning with fewer staff and a lower treatment capacity. *MySafeRx* coaches attempted to guide her toward ancillary support resources which were difficult to navigate and often led to dead ends.

When the clinical team did not address the mounting needs of the participant or respond to her requests for additional counseling or medication supports, coaching and research staff felt compelled to advocate for her at the study site for clinical appointments and follow-up from her treatment providers. Finally, despite differing opinions by her treatment providers, she was eventually prescribed medication to help with her psychological distress. After only a few days on this medication, on a videoconference recovery coaching call (as part of the study intervention), it was revealed that she was experiencing serious adverse side effects from one of the new psychiatric medications, which required immediate attention. She had fallen multiple times and experienced contusions to her head and body. Her mental status was impacted and reported leaving lit cigarettes around the house and leaving the stove on throughout the night, forgetting what day it was, and being unable to answer basic questions. She reported not being able to get ahold of her clinical treatment team over the phone despite continuous calls because it was a weekend. According to *MySafeRx* coaching protocols, upon learning of these negative side effects, the coach contacted the study's on-call manager and medical director of *MySafeRx*. The study's medical director, out of concern for Jenna's immediate safety, recommended she cease the use of this medication until she could be assessed and stabilized in-person by her provider.

Once she was able to meet with the prescribing physician, they made attempts to adjust her medication and achieve stabilization, but Jenna returned to self-harming behavior and suicidal ideation and attempted to self-medicate using the same medication that caused the initial side effects. Again, unable to reach her treatment team, the recommendation was made, due to strong suicidal ideation, that she should enter emergency crisis stabilization. With efforts from the research team, she agreed to bring herself voluntarily into the emergency crisis stabilization service but upon being admitted to an examination room, she banged her head against a wall.

The crisis stabilization unit recommended that because of the severity of her case and her possible head injury, she needed medical emergency evaluation prior to mental health inpatient care. However, instead of transferring her to the medical emergency room, she was discharged to the street and required to obtain her own transportation to the emergency room. Due to her lack of health insurance and fear for a bill she could not pay, she left the stabilization unit without a ride home or money. She slept on the street for the night where she exchanged sexual acts for drugs. The following day, she attempted to re-enter detox at which point, due to her drug use slip up the night before, was told by clinical staff that she would have to revert to in-person daily dosing for 2 weeks. This rigid "step-up" protocol was residual from pre-COVID-19 standards and did not reflect the transition to more flexible telemedicine procedures. It was also unsustainable due to her limited familial support and lack of transportation resources. After about 2 weeks of intermittent dosing and spurts of communication, the study team and clinical team lost contact with Jenna.

This series of unfortunate events highlights the challenges of the research-to-practice gap, clinical system issues, and barriers for participants that were amplified by the COVID-19 pandemic. It is in recognition of the complexity of severe cases like Jenna's that effort must be made to improve responsiveness to unanticipated change and unpredictable needs with more effective and comprehensive collaboration between both research and clinical teams during the implementation of new interventions.

Findings

The challenges that emerged during the implementation of this study intervention were twofold. First, they were grounded in a research-to-practice gap that manifested in differing priorities between academic and clinical stakeholders. Second, they were based on existing clinical system issues that were exacerbated by the changing protocols brought on by the COVID-19 pandemic response.

Implementation Challenges— Research-to-Practice Gap

While addiction researchers and clinicians may share the same ultimate goal of improving the well-being of those they serve, each is met with discordant challenges along the way which interrupt the potential for collaboration. The research-to-practice gap is a well-established concept in implementation science and has resulted in dozens of implementation science theories, models, and frameworks that attempt to support implementation research and practice within different service settings (Nilsen, 2015). However, even these implementation science strategies, intended to bridge this gap, become exclusive by nature, often relying on specific vernacular and training that causes the relationship between institutional research and clinical practice to

remain mutually exclusive (Institute of Medicine et al., 1998). Researchers and clinicians often have different viewpoints of substance use and recovery and tend to believe that the opposite perception is flawed on a fundamental level (Marinelli-Casey et al., 2002). For instance, researchers may be reliant on stringent methodology and exact processes that are often seen as unrealistic in a real-world setting where people and circumstances are unpredictable or difficult to control. Clinicians, on the other hand, are often faced with changing processes and staffing, historic policies or procedures that can restrict change, sparse resources and funding limitations, personnel shortages, and/or training and documentation demands that may impede the application of evidence-based practices (Vroom & Massey, 2022). This already challenging relationship was strained by the COVID-19 pandemic, wherein circumstances, procedures, and expectations of all parties involved were forced to change rapidly and without warning within a short period of time.

The lessons learned related to the “research-to-practice gap” implementation challenges have been narrowed to three categories: (1) academic institutional requirements, (2) boundaries and role identity, and (3) burnout.

Academic Institutional Requirements

The research study team was comprised of personnel from two academic institutions in two different states, which resulted in unanticipated and significant administrative barriers. These constraints required significant and unexpected efforts from the research staff, influenced the study timeline, and caused continuous changes to study protocols. Navigating two separate sets of institutional requirements, regulations, and preferences ultimately delayed the start of the enrollment phase of the study. Given the national transition to the requirement of single Institutional Review Board (IRB), the IRB relationship between institutions needed to change from the initial planned study to a new pilot under the auspice of single IRB. However, it was the first study at the primary institution to require this ceding process through SMARTIRB for single IRB management, resulting in substantial delays. These delays had an impact on staff buy-in at the study site, where staff turnover was already high, and caused a loss of momentum initiated by several clinical staff training earlier in the process. Training had to be repeated and protocols reformatted multiple times to address IRB requirements, contributing to the perception by clinical staff that the study was disorganized and sluggish.

Boundaries and Role Identity

The study was designed to be an adjunct to standard clinical care. However, differences in alignment emerged between research and clinical stakeholders, as both clinical staff and participants were confused about whether the study’s intervention should be an independent entity separate from treatment or as a supplement to standard care. This

overlap created a complicated dynamic and unsustainable environment.

Due to the highly interpersonal nature of the intervention (motivational interviewing [MI] recovery coaching), participants learned to lean on the empathy of the study staff. Since the MI coaches were regularly more available to them than their clinical team, which was short on case management and nurses, participants often attempted to engage MI coaches when they could not reach clinical staff. The study staff felt ethically compelled to respond to desperate participant outreach and requests for support for scheduling appointments, getting in touch with a nurse about symptoms, or medication refills, which resulted in the research team members going beyond their expected responsibilities to take initiative related to case management and care coordination duties for the study participants. The ambiguity of roles and responsibilities ultimately led to resentment and division between the research team and the clinical/treatment team.

Burnout

As research protocols changed and the ambiguity of roles emerged as an operational challenge, the needs of study participants remained high. Due to the nature of this study, the researchers and the study’s recovery coaches were exposed to the intimate details of participants’ lives including ongoing daily challenges and historic traumas. In this process of establishing therapeutic rapport and improving the quality of and engagement in MOUD services central to the study intervention objectives, research team members felt invested in the well-being of participants. However, the intervention was embedded in a system of care that was ineffectively supporting the multi-dimensional needs of participants, especially those with significant co-occurring disorders and trauma. Burnout and moral injury occurred when study staff were repeatedly exposed to clinical dysfunction and unresponsiveness that prevented participants from receiving what they felt was appropriate care. The study staff reported feelings of despondence and powerlessness when attempts to affect change or advocate for participants were unsuccessful. The repeating patterns of systemic detachment from the trauma of patients and an inability to effect change have been shown to cause even altruistic staff to disengage or feel hopeless in their work (Johnson et al., 2006). In contrast, the treatment facility’s clinicians felt frustrated that gaps were being exposed, that clinical judgment and actions were being questioned, that participant’s responsibility for treatment difficulties and their behaviors were not the sole focus of discussion, that their efforts to address the systemic and logistical challenges for meeting the needs of the entire population were not being appreciated by research staff, and that research team members were getting overly involved in what they viewed to be clinical aspects of care.

Burnout was also a burden for clinical staff. In behavioral health settings, especially in addiction services, clinical staff are shown to experience burnout at higher rates than other healthcare industries (Paris & Hoge, 2010; West et al., 2018) due in part to the low rates of compensation and high stress environments (Lacoursiere, 2001). The extremely limited clinical resources and turnover of clinical team members made it especially difficult for agency staff to accommodate a research team, equipment, and a new set of procedures. In addition to treatment-related challenges, both clinical and research staff were burdened with the constant pressure to adhere to strict protocols, maintain and secure funding sources, complete tedious documentation, and report to internal and external leadership, all of which contributed to burnout in this study.

Implementation Challenges—Clinical System Issues

The study intervention was designed with an understanding that existing clinical system issues prevent equitable MOUD services across regional cultural norms. In a prior qualitative study evaluating the perspectives of patients conducted at the same treatment facility by this study team, findings showed that overall infrastructural challenges included the cost of medication, lack of transportation, continuity of care between stages of treatment, the lack of shared decision-making in treatment plans, family and social network stigma, and a lack of mental health treatment integration (Sharp et al., 2021). In response to those findings, at the onset of the current study, the team anticipated such challenges would require attention but that ultimately the intervention would supplement barriers to care and exemplify a more accessible and person-centered approach to MOUD implementation. It was not anticipated, however, that despite the clinical relevancy and best practices integrated into the study design, the infrastructure of the clinical setting and the innovation of the intervention would be discordant, especially under the pressure of unexpected and mandated procedural changes from a pandemic.

Even before the onset of the COVID-19 pandemic, the existing system of care for addiction treatment has been a barrier for the implementation of innovative treatment solutions (Mathis et al., 2018). The lessons learned related to the clinical system challenges in this study consist of two subcategories: (1) clinical staff buy-in and (2) clinical protocols and resources. The following sections are a description of these issues.

Clinical Staff Buy-in

During study preparation, there were preliminary administrative and infrastructural barriers that made adapting the existing clinical environment for research challenging. A lack of project implementation buy-in from

clinical staff was prompted by logistical complications related to establishing internet connection, allocating office space for study staff, and integrating study protocols into the daily operations of the treatment facility. While there was a partnership with the study site established contractually, which included financial compensation to the facility for the use of their space, the research team was met with resistance as they attempted to incorporate themselves into the clinical environment.

The study team initiated several methods for intentionally enhancing a collaborative relationship, which were received with lukewarm enthusiasm or never embraced by their clinical partner counterparts. For example, to create a more seamless and transparent system of intervention documentation, the clinical staff were provided with *MySafeRx* account login credentials for access to participant intervention notes, which included recovery coach and on-call manager notes. Clinical staff were trained on the *MySafeRx* application and the screening assessments, equipping them with instructions on how to share appropriate study information with potential participants. Study staff also facilitated MOUD education sessions, so clinical staff could be prepared to answer questions from patients in detox who may be considering MOUD as part of their treatment plan. However, engagement in the MOUD education sessions was typically tepid. When screening processes were implemented into the online intake assessment, the form was often skipped or left incomplete. Clinical staff reported feeling overburdened by the additional documentation and screening of study participants rather than feeling like it was supplementing their work in a positive way.

Additionally, there was a difference between the application of person-centered care communication styles embraced by the study team versus the clinical team. The nature of the study intervention was based on the core concepts of MI that emphasized empathy, support for autonomy, compassion, and validation of challenges—qualities which were consistently praised as benefits of the study intervention by the participants. However, this approach was contrary to the status quo of the treatment facility staff's communication style, which was more directive in nature, and about which participants often complained to MI-trained study coaches. To mitigate this difference early in the study, and to establish clinical staff buy-in for person-centered language and communication, clinical staff were offered free MI training workshops. Unfortunately, only three clinical staff members attended, only one of whom eventually interacted with study participants or engaged in the recruitment process at all.

Clinical Protocols and Resources

Structure and flexibility of care are needed simultaneously for people with OUD and especially for people experiencing co-occurring mental health and substance use issues (Sacks et al., 2008) to account for the individual

and circumstantial needs of clients. Procedural changes in response to the COVID-19 pandemic included the ability to provide more flexible take-home BUP dosing after shorter periods of observed in-person daily dosing, options for telehealth appointments, and fewer urine toxicology tests. The rapid changes to the standard of care made in response to the pandemic, however, were not clearly defined for all clinical staff, causing treatment decisions often to be made on a case-by-case basis that was inconsistent between participants. For example, the study intervention was originally designed to mitigate transportation barriers by providing more options for autonomous remote support and daily medication dosing. However, even after the onset of the COVID-19 pandemic, the treatment facility still required at least 2 weeks of in-person dosing as a diversion prevention strategy for the most “high-risk” study participants to establish stability and prove their trustworthiness for take-home prescriptions. This requirement was stricter than the study team’s preference since those who were “highest risk” were often also those with the most transportation, employment, and housing insecurity who may have benefited most from fully remote and flexible services.

A lack of cohesion between care systems also contributed to incongruent services and unmet participant needs that interrupted their pursuit of treatment and their involvement in the study. When participants found themselves in urgent need of daily support to manage scheduling, cravings, mental health issues, or even medical problems, they were typically unable to receive immediate attention from the clinical treatment team at this facility. For example, while there was a psychiatrist on staff at this treatment facility, this person was only on-site to see patients once per week. Additionally, psychiatric medication prescribing practices were often reported as subjective and preferential, leaving participants confused about what services they could or could not receive from this one facility and requiring them to go elsewhere to seek out multiple providers, leaving them vulnerable to unmet mental health needs. When a problem, such as mental/physical health emergencies, fell outside the jurisdiction or abilities of the treatment facility staff, participants were directed to the local hospital, crisis center, or higher levels of care. These alternatives were often infeasible due to participants’ inability to pay, a lack of health insurance coverage or primary care, lengthy wait times for an open bed at an inpatient or residential facility, and rules banning the use of MOUD in transitional housing, residential facilities, and faith-based organizations. When faced with a lack of support options, adverse events occurred, and participants dropped out of care and the study.

Discussion

Implementation Science Integration

In the clinical case presented here, the urgent conditions created by the COVID-19 pandemic pre-empted changes

out of necessity, and the old system was neither deconstructed nor prepared appropriately before a new approach was applied. The field of implementation science has developed critical concepts and methodological guidance that aims to support high-quality implementation research (Proctor et al., 2011; Sweetnam et al., 2022). In retrospect, the study and its corresponding adaptations would have benefited from the use of different implementation science methods, strategies, and expertise. The following sections will provide an overview of implementation science–related recommendations for future MOUD intervention studies.

First, more attention and time should have been devoted to developing and nurturing a collaborative partnership between the research team, support staff, and clinical site, including active discussion on topics related to the identification and integration of role differentiation in the initial preparation phases of the study. Especially in a setting where staff turnover is high, concrete delineation of responsibilities should be more transparently identified for the clinical and research teams. Implementation research has shown role clarity to be significantly correlated with staff burnout and organizational climate (Green et al., 2014; Rogers et al., 2020).

Organizational readiness and the attitudes and behaviors of treatment staff were equally important to successful treatment outcomes in this study. The implementation of new innovative practices relies heavily on the climate and culture of the inner processes of the treatment-providing organization (Jacobson et al., 2020). System-based resistance to innovation may originate from differences between traditional treatment values that prioritize abstinence and punitive protocols, as compared to a wave of unconventional technology and more patient-centric flexible approaches. Multiple implementation resources and tools exist that identify and assist with examining and combatting barriers to organizational climate and staff buy-in that are critical for ensuring organizational readiness and successful implementation. For example, the Implementation Climate Scale (Ehrhart et al., 2014) and/or the Evidence-Based Practice Attitude Scale (Aarons et al., 2012) may be used to assess staff attitudes toward new interventions to understand how change is anticipated and facilitated by an organization. In turn, these scales can assist with the identification of factors that may influence the uptake and implementation of a new intervention within the target organization, including staff capacity, resources, and buy-in (Scaccia et al., 2015).

Given the study’s challenges during the redesign, there was also a missed opportunity for co-creation, where both parties (i.e., academic and community) are invested in the development and decision-making of the intervention and the knowledge of the support staff and treatment organization is prioritized (Greenhalgh et al., 2016). This may have assisted with building mutual trust and addressed barriers related to roles, expectations, and necessary resources.

The case example presented in this manuscript (i.e., Jenna's story) highlights barriers clients faced during the pandemic that may be related to a general lack of preparedness of the treatment organization and clinicians. For example, would Jenna have been sent to the emergency department on her own in the midst of a hurricane—a common Florida public health emergency? These structural/system issues show the importance of the treatment organization and researchers' problem-solving for barriers through active and intentional collaboration and discussion before active implementation occurs. Contingency planning that considers both internal and external factors can potentially mitigate challenges with study validity due to historical events, which highlights the importance of close collaboration with the treatment organizations and clinicians as well as the clients themselves to fully understand the needs of the target population (Birken et al., 2017).

Research has indicated several barriers to adopting treatments for OUD in community treatment settings at both the organizational and clinician levels, especially related to proper training and conflicting priorities (Ducharme et al., 2007; Hartzler et al., 2014; Helseth et al., 2018). Since MI and support for MOUD were core components of the study intervention, implementation may have been more successful if the clinical team had embraced opportunities for MI training and MOUD education or had been given more opportunities to engage in training. These specific recommendations may be enhanced through the use of implementation strategies such as enhanced monitoring and feedback and didactic webinars. Monitoring and feedback can provide the opportunity for sharing treatment outcomes with clinical staff, reasons for decision-making, and suggestions for improvement (Cheng et al., 2022; Gould et al., 2014). In addition, didactic webinars have been shown to significantly affect the uptake and use of MOUD and may be a particularly effective method to engage providers in additional training during events that limit in-person training opportunities (e.g., COVID-19) (Caton et al., 2020). Both strategies may also provide the space to engage in meaningful discussion and develop effective communication approaches and mutual trust between study staff and clinical staff. Future research focused on developing and implementing interventions for OUD would benefit from utilizing study designs (e.g., user-centered or human-centered designs) that root the essential components of an intervention in the characteristics and knowledge of the stakeholders that will use and/or receive the intervention (Dopp et al., 2019).

The most valuable interventions tend to be those that effectively serve the most people. The most meaningful opioid treatment interventions should also focus on serving populations burdened with co-morbidities, poverty, and trauma, which account for treatment disparities and system-based inequities. This study and its lessons learned serve as an example of the importance of these characteristics in the adoption and implementation of OUD interventions. In addition to co-creation, the

current study may have also been improved by the utilization of an implementation science framework to assist with identifying critical constructs and domains that support and/or hinder the uptake and implementation of an innovation. More specifically, future MOUD research would benefit from the guidance of frameworks that emphasize health equity and the incorporation of SDOH in health outcomes, systems, sectors, and policy (Brownson et al., 2021)—for example, the Health Equity Implementation Framework (Woodward et al., 2019). These frameworks can aid with the identification of strategies that address SDOH with the goal of improving access to and outcomes of MOUD interventions in community-based service settings (Vroom & Sharp, in press).

Lastly, it is recommended that research teams developing research initiatives related to opioid treatment interventions incorporate health equity and implementation science experts to guide the conceptualization and selection of strategies/approaches from the onset of project development. Including individuals that can serve as “implementation support practitioners or facilitators” in implementation projects has been identified as a promising implementation strategy (Metz et al., 2021). These individuals will be able to provide support and expertise in how to best integrate and translate knowledge of health equity and implementation science research into real-world practice settings (Kerkhoff et al., 2022).

Conclusion

The study discussed here provides an example of how a system of care that is already fractured and susceptible to outside influence may provide an unstable foundation on which to test the statistical rigor of new innovative approaches without the support of clearly defined implementation strategies. However, in a time when viable solutions for MOUD treatment are desperately needed, it offers lessons learned to inform future technology-based and telehealth interventions. Successful implementation lies in a study design that prioritizes early collaboration between clinical and research staff, ensures basic commitments to resources and adequate provision of clinical care, considers organizational culture and readiness to change, models adaptive strategies to account for unpredictable change, and allows for flexibility based on the needs of the individuals it seeks to serve. As researchers and practitioners struggle to find ways in which they may utilize best practices in an applied setting, implementation science strategies are needed as the glue to fortify the connection and enable both sides, but especially the recipient of care, to succeed.

Clinical Trial Registration

The clinical trial described in this manuscript is registered at ClinicalTrials.gov, titled “Evaluating Adaptive Dispenser Initiation

Protocols for MySafeRx During Post-detox Buprenorphine Treatment—A Pilot Study,” with the identifier (NCT number: NCT04449744).

Declaration of Conflicting Interests


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