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## Is necessity also the mother of implementation? COVID-19 and the implementation of evidence-based treatments for opioid use disorders

### ARTICLE INFO

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### ABSTRACT

Opioid-related overdoses and the coronavirus disease 2019 (COVID-19) represent two of the deadliest crises in United States' history and together constitute a syndemic. The intersecting risks of this syndemic underscore the urgent need to implement effective opioid use disorder (OUD) treatments that are sustainable amid COVID-19 mitigation strategies. In response to new federal guidance released during the pandemic, opioid treatment programs (OTPs) have quickly innovated to implement new systems of medication delivery. OTPs rapid implementation of new medication delivery models defies conventional wisdom about the pace of research transfer. As part of an ongoing cluster-randomized type 3 hybrid trial evaluating strategies to implement contingency management (CM), select staff of eight OTPs had been trained to deliver CM and were in the midst of receiving ongoing implementation support. As COVID-19 emerged, all eight OTPs mirrored trends in the addiction field and effectively adapted to federal/state demands to implement new methods of medication delivery. However, over the past few months, necessity has arguably been the mother of implementation. We have observed greater variance among these OTPs' success with the additional implementation of adjunctive CM. The speed and variability of innovation raises novel questions about drivers of implementation. We argue that the mother of the next innovation should be a public call for a progressive, thoughtful set of public health policies and other external setting levers to address the needs of those with OUD and the OTPs that serve them.

### 1. Implementation of evidence-based treatments for opioid use disorder during COVID-19: is necessity also the mother of implementation?

Opioid-related overdoses and the coronavirus disease 2019 (COVID-19) represent two of the deadliest crises in United States history. More than 770,000 Americans have died of overdose since 1999, and in recent years, about 70% of such deaths were due to opioids (Centers for Disease Control and Prevention, 2019). Impacts of the COVID-19 pandemic have been similarly profound, claiming more than 225,000 American lives as of October 2020.

Lethal overdoses and COVID-19 now constitute a syndemic, for which public health challenges are tragically interacting. Individuals who use opioids are at increased risk for the adverse consequences of COVID-19 due to direct (e.g., slowed breathing due to therapeutic opioid use, chronic respiratory disease) and indirect (e.g., housing instability, incarceration) pathways (Volkow, 2020). Notably, Black and Hispanic individuals experience amplified consequences due to structural inequities and systemic racism (Arasteh, 2020). Intersecting risks of this syndemic underscore the need for effective strategies to implement medications for opioid use disorder (MOUD) that are sustainable amid COVID-19 mitigation strategies.

Opioid treatment programs (OTPs) that provide FDA-approved agonist medications (i.e., methadone, buprenorphine) are on the front lines, implementing novel MOUD delivery methods in response to calls for social distancing. On March 16, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) released emergency "Opioid Treatment Program (OTP) Guidance" about dispensing

methadone and buprenorphine during the COVID-19 pandemic. For decades, OTPs have operated under tightly controlled federal regulations regarding dosing frequency, urinalyses, and take-home medication doses. In response to new guidelines, OTPs needed to quickly implement new MOUD delivery systems. As paired examples of policy adaptation, patients deemed "less stable" who previously required daily, in-clinic dosing are now allowed up to 14 days of take-home doses, whereas "stable" patients who required in-clinic dosing 5–6 days per week are allowed up to 28 days of take-home doses (SAMHSA, 2015, 2020). Concurrently, regulations for reimbursement of telehealth sessions were loosened (Centers for Medicare & Medicaid Services, 2020), allowing OTPs to deliver counseling remotely. The speed with which SAMHSA and the health care industry relaxed regulations and with which practitioners implemented changes to MOUD delivery was exceptional.

### 2. What can implementation science learn during COVID-19 circumstances?

The rapid implementation of new MOUD delivery models defies conventional wisdom, which suggests that it takes 17 years to implement 14% of research findings into routine practice (Green et al., 2009). This raises a salient question regarding implementation drivers: What enabled OTPs to implement new MOUD delivery systems so quickly? The crude answer is the necessity of responding to federal demands. A more nuanced answer may derive from considering the multiple factors that compose the Consolidated Framework for Implementation Research (Damschroder et al., 2009), which includes factors of the outer setting (i.e., federal/state regulations, reimbursement procedures) and OTP-

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specific factors of the inner setting (i.e., structural characteristics, organizational culture). Relative to outer setting factors, inner setting factors receive far more scientific attention—perhaps due to their seeming malleability. COVID-19 underscores the importance of the outer setting, and offers an unprecedented window through which to view the interacting effects of the inner and outer settings on MOUD implementation.

Project MIMIC (Maximizing Implementation of Motivational Incentives in Clinics) is an ongoing NIDA-funded cluster-randomized trial (R01-DA046941), which evaluates strategies to implement contingency management (CM)—an empirically supported behavioral intervention that incentivizes patients for meeting treatment goals—as an MOUD adjunct. Prior to the onset of COVID-19, research staff had trained staff of eight OTPs to deliver a prize-based CM protocol (Petry et al., 2000) and they were in the midst of receiving implementation support. As COVID-19 emerged, all eight OTPs effectively adapted to federal/state demands to implement new MOUD delivery methods, though we observed variance in their interpretation of guidelines. Six of the eight OTPs defined “stable” patients narrowly and continued daily dosing of new patients and those with positive urine screens within the past 30 days. These OTPs focused on risk mitigation through distanced dosing, assigned pick-up time blocks, use of protective personal equipment, and daily temperature/symptom checks. They provided counseling sessions via telephone, videoconferencing, or on-site on opposite sides of a window. One of the OTPs dosed new patients or those with positive urine screens twice per week, and allowed patients established in treatment to have up to 14 days of take-home doses. On the other end of the spectrum, one OTP stopped admitting new patients and assigned all current patients 28 days of take-home doses.

We observed even greater variance among these OTPs’ implementation of adjunctive CM. Specifically, two OTPs discontinued delivery of CM sessions with no plan for resumption, four OTPs paused CM delivery and developed plans to resume services once social distancing guidelines were relaxed, and the two remaining OTPs adapted to deliver CM via telehealth sessions without service disruption. One of these latter OTPs developed a service innovation of having patients come to the OTP and sit in a “virtual pod” with a computer to enable videoconference access to a counselor on the premises. The other of the two OTPs delivered CM fully via telehealth sessions and created a novel workplan such that the front desk manager, who continued to work on-site, would join CM sessions via three-way calling to administer prize draws. As of October 2020, social distancing guidelines are still stringent in New England and OTPs have maintained their initial adjustments to MOUD prescribing and CM delivery.

It would be premature for us to presume generalizability of these OTPs’ pandemic response regarding MOUD delivery, given a regional sample of eight settings and ever-evolving COVID-19 circumstances. Acknowledging those caveats, however, we have clearly observed capacity among these OTPs to rapidly adapt to new circumstances—with our collective OTP sample implementing flexible MOUD dosing practices, and two of the OTPs in our sample adapting delivery of a prize-based CM protocol via telehealth. Organizational decisions about implementation did not appear to vary systematically as a function of geographic region or patient sociodemographic characteristics. To better understand continuing trajectories of MOUD adaptations, our team will assess both inner and outer setting factors, using data collected at multiple timepoints prior to and after the onset of COVID-19 mitigation measures. Such analyses may help to elucidate those specific factors that differentiate the two OTPs that were able to sustain CM delivery without service disruption.

### 3. A persisting question about outer setting influences

A question that remains elusive for the addition health services

research community is whether implementation strategies can leverage other outer setting pressures (e.g., provider incentives, legislation for service reimbursement) to accelerate the uptake of both MOUDs and adjunctive behavioral health practices such as CM. That two of our trial’s participating OTPs were able to rapidly implement new MOUD dosing practices and adjunctive CM via a telehealth format is certainly a basis for optimism. Further, their action offers evidence of what is possible if external pressures in the outer setting are put in place. A key challenge for implementation researchers is to identify scalable ways to modify the outer setting that do not require the gravity and range of circumstances that this global pandemic has posed.

Since the emergence of COVID-19, necessity has arguably been the mother of implementation. We hope that the impetus for the next innovation is public call for a progressive, thoughtful set of public health policies that incorporate outer setting levers to better address the needs of those with opioid use disorder and the OTPs that serve them.

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