



Dissemination of Contingency Management for the Treatment of Opioid Use Disorder

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Accepted: 27 January 2022 / Published online: 10 February 2022
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Abstract

Contingency management is an intervention for substance use disorders based on operant principles. The evidence base in support of contingency management is massive. It is effective in treating substance use disorder in general and opioid use disorder in particular. Dissemination has remained slow despite the urgency created by the opioid epidemic. Key barriers include a lack of expertise, time, and money. Implementing contingency management with smartphones eliminates the need for special training. It also solves logistical issues and requires little time on the part of clinicians. Thus, remaining barriers relate to cost. Federal anti-kickback regulations complicate solutions to the cost barrier. Other important regulatory challenges related to cost include the lack of billing codes and the difficulty of obtaining FDA approval for digital therapeutics. Even after the cost barrier is overcome, provider adoption is not guaranteed. Incentivizing providers for collaborative care may increase adoption and generate referrals. Recently proposed legislation and governmental policy statements provide optimism regarding the near-term large-scale adoption of contingency management in the treatment of opioid use disorder.

Keywords Motivational incentives · Public policy · Behavioral health · Digital health technology · Smartphone-based intervention

Opioid use is a significant long-term behavioral health problem in the United States. According to the Centers for Disease Control and Prevention (CDC), over 840,000 people have died of a drug overdose since 1999, and in 2019 over 70% of drug overdoses involved opioids (CDC, 2020). Opioid use also represents an immense economic cost. The combined cost of addressing opioid use disorder and opioid overdose death was over \$1 trillion in the United States in 2017 alone (Florence et al., 2021).

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A critical part of the public health response to the opioid epidemic is medication-assisted treatment. Medications such as methadone and buprenorphine (Suboxone®) are effective in promoting abstinence from illicit opioids and preventing drug overdose (Sordo et al., 2017; Strain et al., 1994). However, despite their robust effectiveness, medication-assisted treatments are not perfect solutions. Treatment retention and drug use while in treatment are significant problems (Hser et al., 2014). In fact, between 50% and 80% of people discontinue medication-assisted treatment prematurely (Williams et al., 2020), such that of 130,300 episodes of medications for opioid use disorder treatment, only 36% lasted beyond 6 months (Krawczyk et al., 2021). For individuals who do remain in treatment, ongoing opioid use and concurrent stimulant use are common problems (e.g., Daniulaityte et al., 2020; Strug et al., 1985).

It is fortunate that there is a behavior analytic intervention that has broad beneficial effects when combined with medication-assisted treatment for opioid use disorder: contingency management (CM). In CM interventions, a putatively reinforcing consequence (hereafter, “incentive”) is made contingent upon the objective measurement of one or more target behaviors. For example, monetary vouchers may be provided contingent upon verification of drug abstinence (e.g., Higgins et al., 1994). Decades of laboratory research guided by operant principles and procedures has demonstrated that illicit drugs are reinforcers and that drug reinforcement is biologically normal (Bigelow, 2001; National Institute on Drug Abuse, 1978.) From an operant perspective (e.g., Silverman, 2004), drug taking and related behaviors are determined in large part by the consequences of available options, with the immediate consequences exerting substantially more control than the distal outcomes (Bickel et al., 2014; Bickel & Marsch, 2001). In particular, physiological and subjective effects of drugs are immediate and thus potent reinforcers, whereas outcomes such as improved family and social relationships and better health take months or years to develop and are thus sharply discounted. CM helps address this temporal imbalance by providing incentives immediately upon submission of drug tests that indicate recent drug abstinence.

Evidence in Support of Contingency Management

The broad utility of contingency management has been borne out in more than 100 randomized controlled trials and hundreds of other studies. Success in promoting drug abstinence has been observed across a wide range of drugs of abuse, including opioids (Jarvis et al., 2019), cocaine (Higgins et al., 1994), amphetamines (Brown & DeFulio, 2020), marijuana (Kadden et al., 2007), nicotine (Notley et al., 2019), and alcohol (Koffarnus et al., 2018). Likewise, CM has been successful in a variety of populations including adults in typical outpatient treatment settings (Petry & Carroll, 2013), adolescents (Stanger & Budney, 2010), and individuals who are pregnant (Higgins et al., 2010) or homeless (Milby et al., 1996). CM is effective whether the incentives are delivered as vouchers (Lussier et al., 2006), in prize-based systems (Benishek et al., 2014), or as access to employment (Silverman et al., 2001) or

housing (Milby et al., 1996).¹ CM is effective in initiating drug abstinence, and in maintaining drug abstinence over long time periods (Silverman et al., 2012). Overall, several meta-analyses have found superior clinical outcomes relative to other psychosocial approaches (e.g., Ainscough et al., 2017; Dutra et al., 2008; Prendergast et al., 2006).

As an intervention for opioid use disorder, CM is especially effective in initiating and maintaining drug abstinence when combined with medication-assisted treatment (Carroll & Rounsaville, 2007; Castells et al., 2009; Griffith et al., 2000). It is similarly effective in promoting attendance to and retention in drug abuse treatment (Weinstock et al., 2007), including opioid pharmacotherapy (DeFulio & Silverman, 2012; Jarvis et al., 2017; Timko et al., 2016).

CM Dissemination Barriers Overcome by Technology

Given the enormous evidence base supporting CM, there is an incommensurate lack of availability of CM services for individuals and families who could benefit from them. Adoption of CM practices by outpatient substance abuse treatment clinics has been much slower than what would be expected if efficacy was a sufficient driver. Health-care specialists are usually the first to push to test and adopt new agents, devices, and procedures as evidence emerges. This has not been the tradition in substance abuse treatment (Abraham et al., 2010; Heinrich & Hill, 2008; McGovern & Carroll, 2003). Decades of effort in disseminating CM through specialized outpatient substance abuse treatment clinics have met with little success. In fact, most treatment professionals have never delivered a CM intervention or received training regarding CM concepts and procedures (Benishek et al., 2010; Hartzler, Jackson, Jones, Beadnell, & Calsyn, 2014; Kirby et al., 2006; Rash et al., 2012). Many studies have examined the causes of this disconnect. In some cases, provider beliefs can interfere with adoption (Hartzler & Rabun, 2013; Kirby et al., 2006). However, most clinicians have a favorable view of the use of incentives as an adjunct to treatment (Timko et al., 2016). Further, increased exposure to CM increases positive beliefs and acceptability of CM interventions (Bride et al., 2010; Ducharme et al., 2010; Hartzler et al., 2014; Kirby et al., 2012). Thus, beliefs do not appear to be potent barriers to CM dissemination. Instead, the key barriers appear to be practical in nature. Outpatient clinics simply lack the expertise (Kirby et al., 2006; Oluwoye et al., 2020), time (Petry, 2010), and money (Higgins et al., 2019; Petry, 2010) necessary to adopt CM in their practices. These barriers are not likely to change, thus an alternative pathway for dissemination is required if the well-documented benefits of CM are to become accessible to the thousands—or perhaps millions—of people who might benefit from them.

¹ Dallery et al. (2015) and Andrade and DeFulio (2017) offer chapter-length coverage of CM including descriptions of procedural differences across variants. For a book-length treatment, see Higgins et al. (2007). For instructions regarding CM design and implementation considerations see Meredith et al. (2014), and for a book-length treatment of this topic, see Petry (2011).

Smartphone technology supplies an alternative path to rapid dissemination of high-fidelity CM services that entails minimal burden to providers and is maximally convenient for anyone using the service (Dallery et al., 2019). It also enhances access to CM by eliminating the need to travel to a clinic to receive services. In the treatment of opioid use disorder, this intervention typically includes measuring drug taking by selfie videos that show a drug test conducted with oral fluid. All contingencies and the randomization of the drug testing schedule are programmed and controlled by computer. An automated reminder system also provides relevant SMS text messages or push notifications. Cash-like incentives are delivered to a reloadable gift card that can be used like a credit card at approved locations. Necessary materials such as drug tests are shipped directly to locations specified by program enrollees. Additional support services, such as automated self-paced cognitive-behavior therapy modules or community reinforcement approach therapy can be integrated into the same app environment as the CM program (see DeFulio, Rzeszutek, Furgeson, Ryan, & Rezanian, 2021b, for a fuller description).

The automation of nearly all elements of a contingency management intervention eliminates (1) the need for clinicians who have CM expertise and specialized training; (2) the need for clinicians to procure and store material incentives and drug tests; (3) substantial staff time required to administer the programs; and (4) related manual financial accounting. Further, nascent evidence supports the effectiveness of CM in the treatment of opioid use disorder when delivered via smartphone. In particular, two retrospective studies show that a CM-based smartphone intervention increases drug abstinence and clinic attendance (DeFulio, Furgeson, Brown, & Ryan, 2021a; DeFulio et al., 2021b) and a secondary analysis of a randomized controlled study shows that a combination of CM and the community reinforcement approach delivered via a digital platform increased drug abstinence and treatment retention (Maricich et al., 2021). There is also substantial evidence of the effectiveness of digitally implemented CM in the treatment of other substance use disorders (Kurti et al., 2016). This is not to say that these interventions are perfect. For example, there is an ongoing need to ensure accurate salivary drug toxicology for relatively newer opioids (e.g., Fentanyl; Palmquist & Swortwood, 2021). Nevertheless, now that several companies are currently providing CM services to the general public, the stage is set for rapid dissemination, but two key barriers remain.

The Cost Barrier

Cost is an important and ubiquitously cited barrier to adoption of CM. Outpatient treatment providers lack the revenue margins to pay for CM interventions. In general, even low-value reward approaches have not been sustained. Like all other evidence-based services in modern health care, it seems more appropriate for payers to pay for CM services. This includes insurers, self-insured employers, and government programs such as Medicaid. Smartphones may also reduce costs. Nevertheless, there is no way to completely eliminate the cost of CM intervention. This fact positions cost at the front of the critical policy barriers that have the potential to further

delay the dissemination of CM, despite its efficacy and the urgency created by the ongoing opioid crisis.

On April 1, 2021, the Biden White House formally called on the Office of Drug Control Policy (ONDCP) to “identify and address policy barriers related to contingency management interventions [i.e., motivational incentives],” and “explore reimbursement for motivational incentives and digital treatment for addiction” (ONDCP, 2021). The most salient cost-related policy barrier to the dissemination of CM intervention is the anti-kickback statute in U.S. Code, Title 42, which makes it illegal to provide remuneration for referral or receipt of medical services that are billed in whole or in part to the federal government. A strict reading of the original policy would appear to render federal payment for CM services an impossibility. However, clarification on this point has been provided by the Department of Health and Human Services (2020) in the Office of Inspector General December 2020 Final Rule (i.e., the OIG Final Rule).

The OIG Final Rule provides modifications to policies designed to prevent fraud in Medicaid and state health-care programs. It relates to the anti-kickback statute mentioned above. The OIG Final Rule specifies various “safe harbors,” which are exceptions to the anti-kickback statute that are acceptable and protected under the law. Of greatest interest here is the fact that CM is explicitly and extensively considered and described in the OIG Final Rule.

The consideration of CM within the OIG Final Rule begins with the acknowledgement that CM is a highly effective and well-researched intervention for people with substance use disorders and that CM has the potential to help combat the opioid epidemic. Nevertheless, the OIG Final Rule describes that CM interventions are expressly not protected under the patient engagement and support safe harbor. However, this does not mean that CM intervention is illegal. Instead, the OIG Final Rule declares that CM payments, “would be subject to case-by-case analysis,” under the relevant policies, including the patient engagement and support safe harbor (Department of Health & Human Services, p. 77791).

The specific criteria that are applied to determine whether a specific CM program is legal are extensive and certainly require professional legal counsel to navigate successfully. Even then, support for CM services as legally acceptable is equivocal. There is a chance that the OIG could find a particular CM program that was designed to be compliant with the OIG Final Rule out-of-compliance and therefore illegal. In this sense, there is still a barrier to overcome with respect to federal payments for CM services.

Overall, the OIG Final Rule provides hope for the dissemination of CM services relative to the situation prior to the ruling, but does not completely free individuals or organizations interested in implementing CM services from legal burden or the threat of legal sanction. It is in this context that the previously mentioned ONDCP priorities related to CM are a great source of optimism that CM will be available to Medicaid recipients going forward. This optimism is strengthened by recent developments in California. The California Assembly and Senate both passed State Bill 110 with unanimous bipartisan support (California State Senate District 11, 2021). This bill was designed to allow Medi-Cal, the State’s Medicaid program, to offer CM services broadly. Unfortunately, California Governor Gavin Newsome vetoed

the bill pending the results of a previously approved pilot program of CM in Medi-Cal that will conclude in March 2024 (Newsome, 2021). Despite this setback, it is clear that governmental officials and payers all over the country are in support of CM, and that it is likely a matter of time before remaining barriers related to cost are overcome.²

The Referral Barrier

Even after the cost barrier to CM is finally overcome, there will still be one remaining barrier that could slow its dissemination. In particular, adopting any new technology, procedure, or service in substance use disorder care requires changing the behavior of providers. To be clear, it is not initial uptake or acceptance that is at issue. If a behavioral health service is to have an impact, providers must actively refer their patients to it and ideally assist patient enrollment with a warm handoff. Better still is a “collaborative care” arrangement, in which primary care providers and specialty treatment providers share resources and expertise to provide effective, efficient, and timely care (Kates et al., 2019). Office-based opioid treatment has been a context for the development of a successful collaborative care model in which the responsibility for ongoing monitoring of buprenorphine patients was shifted from prescribers to collaborating community health centers (Alford et al., 2011). In one system, this increased the number of waived (i.e., able to prescribe buprenorphine) physicians from 24 to 114 within 3 years (LaBelle et al., 2016).

Active referral and collaborative care are strong forces for dissemination that could greatly enhance patient access to CM services. However, these activities require effort on the part of providers, and there is no cultural or systemic inertia to support the integration of these practices into their regular routines. This effort-and-inertia obstacle has obstructed buprenorphine prescribing as well, despite massive government effort at education and training. For example, in the United States, physicians are required to complete specialized training to be legally eligible to prescribe buprenorphine for the treatment of opioid use disorder. Providing \$750 incentive payments directly to physicians to undergo the training succeeded in getting 89% of eligible physicians to complete the training, but only increased prescribing over the next 5 months from 0.5% to 16% of OUD-related encounters (Foster et al., 2020).

² In addition to adoption by Medi-Cal, positive signs of broad support for CM include adoption of Prescription Digital Therapeutics that include CM by MassHealth (Massachusetts’ Medicaid program), and ongoing Medicaid pilot programs in other states such as Vermont, as well as State Bill S7543 under consideration in the New York State Senate’s 2021–2022 session. Review of press releases posted to the websites of companies that provide CM services (e.g., Affect Therapeutics, DynamiCare Health, Pear Therapeutics) illustrates that these companies have been increasingly successful in securing direct service contracts from payers such as Blue Cross Blue Shield and Aetna, among others. This recent increase in support adds to prior key dissemination victories such as inclusion of CM in NIDA Clinical Trials Network studies (e.g., Peirce et al., 2006) and nationwide adoption of CM by the U.S. Department of Veterans Affairs (Petry et al., 2014).

Substance use disorder treatment typically does not involve any system under which payment for services is contingent on any given outcome, nor is strict adherence to data-based decision-making required for reimbursement. As a result, there is no systemic motivation for adopting more effective methods. Given that the health-care system is not a strong source of motivation for adopting new more effective approaches, the motivation to change must be supplied by the new service itself. As CM illustrates, financial incentives are among the most potent and efficient sources of motivation for producing behavior change. Given extensive evidence that reinforcers change behavior in patients, the same effect is likely for provider behavior as well, and as such represents a key pathway to widespread dissemination of CM.

Incentivized Collaborative Care

Here I propose one potential way to surmount the referral barrier. The proposed method combines incentivizing providers with a form of service delivery known as collaborative care. Because combining provider incentives and collaborative care is somewhat novel, a description of the two respective parts is necessary.

Providing incentives to providers based on the quality of their performance is a well-worn strategy for improving the quality of care (Eijkenaar et al., 2013; Fairbrother et al., 1999). Under these plans, measurable provider behaviors or patient outcomes are identified, and financial incentives are delivered to the providers contingent upon achieving quantified benchmarks. When incentive systems are built on empirically derived best practices (Meredith et al., 2014; Ogundeji et al., 2016; Rosenthal et al., 2004), and appropriate theoretical and conceptual foundations (Baer et al., 1987; Emanuel et al., 2016; Van Herck et al., 2010), they can produce outstanding results. In fact, such programs have resulted in reduced emergency department visits when directed at primary care providers (Li et al., 2019), reduced all-cause mortality in Type-2 diabetes mellitus patients (Kung et al., 2020), and improved outcomes in behavioral health care (Stewart et al., 2017), including in outpatient substance use disorder clinics in particular (Vandrey et al., 2011).

Another way to improve the quality of care is to foster collaboration between allied professionals who are providing care to the same patient. Under this collaborative care approach, primary care providers and specialty treatment providers share resources and expertise to provide effective, efficient, and timely care (Kates et al., 2019). The specific behaviors involved in a given instance must be agreed upon by the providers who are involved. For example, a primary care prescriber could inform mental health-care providers of changes in the medications that a patient is prescribed. The mental health-care providers can then monitor changes in patient status and report any changes back to the primary care provider, who can thus adjust prescriptions as necessary. In this way, adjustments to a medication regimen are made in a timely fashion based on more complete data than would otherwise be available to a primary care provider.

As primary care providers become a more common point of entry to specialty substance use disorder care, the utility of a collaborative care approach is becoming more apparent (Pace & Uebelacker, 2018). To reiterate, office-based opioid

treatment has been a context for successful collaborative care (Alford et al., 2011; LaBelle et al., 2016). It is important to note that incentives have been identified as critical to the further dissemination and maintenance of collaborative care to support behavioral health (Ramanuj et al., 2019).

There is some precedent for incentivizing collaborative care. The government of Australia successfully implemented a program involving incentives for families and incentives for physicians to increase uptake of childhood immunizations (Bond et al., 2002). The program began in 1997, when the immunization coverage rate was 53%, and was credited with large and sustained increases in immunization coverage to 90% as of 2012 (Ward et al., 2013). In addition, there is one controlled study in which incentives were provided to physicians and patients for reductions in patients' low-density lipoprotein cholesterol levels. Shared incentives outperformed incentives to either physicians or patients alone, and overall impact of the intervention was significant but moderate (Asch et al., 2015). It is worth noting that in this study, incentives were based on outcomes measured once every 3 months, rather than behaviors measured frequently as in typical successful CM programs.

Although there is some precedent for incentivized collaborative care as a means of promoting the dissemination of effective practice, the use of incentives as a means of promoting uptake of CM has only been rarely suggested (Carroll et al., 2011; Miller et al., 2006), and never tried. This is perhaps a curious state of affairs, given that this research community has extensive direct experience with the profound effects that incentives can produce in people with substance use disorders. Thus, incentivized collaborative care models are a high priority for future research related to the dissemination of CM. It will be important for such models to comply with the OIG Final Rule as described above. There are likely many ways to implement incentivized collaborative care in the context of contingency management. However, one key aspect of any such program would be data sharing. Smartphone-based contingency management involves the measurement of many relevant behaviors, such as patterns of drug use and specific drugs used, medication adherence, attendance at counseling and other programs related to supporting recovery, and earning and spending incentives, among others. Financial incentives for providers could be made contingent upon reviewing this data and completing a form that facilitates clinical consideration of the data. In this way, the providers are compensated for the extra time required for enhanced data-based clinical decision making. However, these incentives could produce important secondary outcomes, because the prerequisites for accessing them include accepting patients who have an opioid use disorder and referring these patients to CM services. Thus, the incentivized collaborative care program could directly reinforce enhanced clinical decision making, while indirectly reinforcing (1) provision of care to a marginalized population and (2) referring this population to an underused but highly effective psychosocial adjunct to medication assisted treatment (i.e., CM).

A Special Policy Consideration for Smartphone-Based Contingency Management

As described above, the smartphone-based approach to CM obviates most dissemination barriers. However, it also requires consideration of a federal policy that is not relevant to CM when implemented directly by clinicians. In particular, the Food and Drug Administration (FDA, 2019) produced the “Policy for Device Software Functions and Mobile Medical Applications.” Under this policy, organizations that develop mobile medical applications could be required to seek FDA approval prior to bringing their product to market. Any mobile medical application that has obtained FDA approval is known as a Prescription Digital Therapeutic. In the case of CM services delivered via smartphone, requiring Prescription Digital Therapeutic status could stand as an enormous barrier, because obtaining FDA approval is expensive and time-consuming. Thus, if FDA approval were an absolute requirement, then only well-established behavioral health services companies with substantial resources would be in a position to deliver smartphone-based CM services. This would limit the ability of smaller service providers to enter the CM services market, and reduce diversity in CM service delivery models available to consumers. It could also hinder the adoption of any given service because a prescription would be required to access it. Thus, only people who are qualified to write prescriptions for the care of opioid use disorder would be able to refer patients to the Prescription Digital Therapeutic.

Fortunately, it does not appear that smartphone-based CM services will be required to obtain FDA approval. This is because the FDA has determined that some mobile applications are of sufficiently low risk that they do not require approval (FDA, 2019). In particular, devices that remind or prompt patients to engage in particular activities are exempted. Likewise, devices designed to help a patient communicate with a provider regarding their health by capturing an image for the provider are also exempted. Lastly, functions that provide access to information about treatment are exempted. Because these are the three primary functions of any smartphone-based CM intervention (e.g., an app would provide a reminder regarding a required activity, allow for a selfie-video to be recorded showing the activity, and then provide information regarding the contingencies and earnings that can be and have been delivered), it appears that FDA approval for smartphone CM is optional rather than required. Companies that have brought CM services to market to date have followed different pathways as per FDA approval, presumably due to the specifics of their own commercialization plans and business strategies in relation to the various costs and benefits of obtaining such approval. Thus, it appears that the current state of FDA policy is favorable for the dissemination of smartphone-based CM.

Conclusion

The decades of work by researchers and allied professionals that has been dedicated to the development and dissemination of contingency management intervention appears to be paying off. Current technology facilitates the delivery of high-fidelity

contingency management intervention that surmounts most traditional barriers. Contingency management services for substance use disorder have never been more widely available because there are now a variety of providers who offer smartphone-based CM services with national reach. In addition, the policy environment has never been more favorable. Interest in supporting these services is clear and rollout of payment for CM services by Medicaid and private insurers has begun. There is every reason to be optimistic that contingency management will be a regular part of care for people with substance use disorder throughout the United States within 10 years. If this comes to pass it will stand as one of the greatest accomplishments of behavior analysis. However, it should be recognized that such a victory would not be possible without gargantuan efforts of researchers and clinicians in other domains, including other behavioral sciences, medicine, and public health.

Funding This research was supported by grants R41DA049390 and R44DA055396 from the National Institute on Drug Abuse.

Declarations

Conflicts of Interest The author has served as a research consultant for DynamiCare Health, Inc. This company provides contingency management services for people with substance use disorders.

Research Involving Human Participants and/or Animals This research is a review and did not involve human participants or animals.

Informed Consent Because no human participants were involved in this study no informed consent was required.

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