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Bridging waitlist delays with interim buprenorphine treatment: Initial feasibility

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HIGHLIGHTS

- Despite the effectiveness of opioid maintenance, treatment waitlists persist.
- We developed an interim buprenorphine treatment (IBT) for waitlisted opioid abusers.
- IBT significantly reduced illicit opioid use, withdrawal and craving.
- IBT may reduce risks for patients and society during delays to treatment.

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ABSTRACT

Despite the effectiveness of agonist maintenance for opioid dependence, individuals can remain on waitlists for months, during which they are at significant risk for morbidity and mortality. Interim dosing, consisting of daily medication without counseling, can reduce these risks. In this pilot study, we examined the initial feasibility of a novel technology-assisted interim buprenorphine treatment for waitlisted opioid-dependent adults. Following buprenorphine induction during Week 1, participants (n = 10) visited the clinic at Weeks 2, 4, 6, 8, 10 and 12 to ingest their medication under staff observation, provide a urine specimen and receive their remaining doses via a computerized Med-O-Wheel Secure device. They also received daily monitoring via an Interactive Voice Response (IVR) platform, as well as random call-backs for urinalysis and medication adherence checks. The primary outcome was percent of participants negative for illicit opioids at each 2-week visit, with secondary outcomes of past-month drug use, adherence and acceptability. Participants achieved high levels of illicit opioid abstinence, with 90% abstinent at the Week 2 and 4 visits and 60% at Week 12. Significant reductions were observed in self-reported past-month illicit opioid use ($p < .001$), opioid withdrawal ($p < .001$), opioid craving ($p < .001$) and ASI Drug composite score ($p = .008$). Finally, adherence with buprenorphine administration (99%), daily IVR calls (97%) and random call-backs (82%) was high. Interim buprenorphine treatment shows promise for reducing patient and societal risks during delays to conventional treatment. A larger-scale, randomized clinical trial is underway to more rigorously examine the efficacy of this treatment approach.

1. Introduction

Opioid misuse and dependence are reaching epidemic proportions in the United States (US), resulting in overdoses, premature death, infectious disease and economic costs of $56 billion annually (Becker, Sullivan, Tetrault, Desai, & Fiellin, 2008; Birnbaum et al., 2011; Clausen, Waal, Thoresen, & Gossop, 2009; Hser, Hoffman, Grella, & Anglin, 2001; Jones, Mack, & Paulozzi, 2013; Paulozzi, 2012; SAMHSA, 2010; Shah, Lathrop, Reichard, & Landen, 2008; Wisniewski, Purdy, & Blondell, 2008). The problem is increasingly urgent in rural areas which often struggle with high rates of opioid misuse and a lack of available treatment options (Fortney & Booth, 2001; Lenardson & Gale, 2007; Rosenblum et al., 2011; Rounsaville & Kosten, 2000; Sigmon, 2014).

While opioid maintenance is the most efficacious treatment (Johnson et al., 2000; Mattick, Breen, Kimber, & Davoli, 2014; Stotts,

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Dodrill, & Kosten, 2009), demand for treatment can exceed available capacity (Friedmann, Lemon, Stein, & D'Aunno, 2003; Wenger & Rosenbaum, 1994). An alarming number of methadone clinics have waitlists, due in part to inadequate public funding, unfavorable zoning regulations and requirements for comprehensive care that increase their cost (Des Jarlais, Paone, Friedman, Peyser, & Newman, 1995; Fountain, Strang, Griffiths, Powis, & Gossop, 2000; Gryczynski, Schwartz, O'Grady, & Jaffe, 2009; Peles, Schreiber, Sason, & Adelson, 2012; Peles, Schreiber, & Adelson, 2013; Peterson et al., 2010). Many areas also lack office-based buprenorphine treatment capacity due to barriers to obtaining the special federal certification needed for prescribing buprenorphine, physicians' concerns about induction logistics, reimbursement challenges, potential for medication nonadherence or diversion, and challenges in delivering psychosocial services to patients (Barry et al., 2008; Becker & Fiellin, 2006; Kissin, McLeod, Sonnefeld, & Stanton, 2006; Netherland et al., 2009; Sigmon, 2015). Taken together, opioid-dependent individuals can remain on waitlists for months and are at significant risk for illicit drug use, criminal activity, infectious disease and mortality during this delay to treatment (Adamson & Sellman, 1998; Clausen et al., 2009; Cooper, 1989; Darke & Hall, 2003; Schwartz et al., 2009; Schwartz et al., 2009; Schwartz, Kelly, O'Grady, Gandhi, & Jaffe, 2011; Warner-Smith, Darke, Lynskey, & Hall, 2001; Wenger & Rosenbaum, 1994).

One effort to reduce these risks has been to offer interim methadone treatment (IMT), in which methadone clinics can provide medication without accompanying psychosocial services on a temporary basis when only a waiting list would be otherwise available (Federal Register, 1993; IOM, 1995). IMT has been consistently demonstrated to reduce drug use, drug-related risk behaviors and criminal activity among patients awaiting entry into comprehensive treatment (Gruber, Delucchi, Kielstein, & Batki, 2008; Schwartz et al., 2006; Schwartz, Jaffe, Highfield, Callaman, & O'Grady, 2007; Schwartz et al., 2008; Schwartz et al., 2009; Schwartz et al., 2011; Schwartz et al., 2011; Yancovitz et al., 1991). However, methadone treatment in the US is limited to licensed specialty clinics, it requires daily visits during the first few months of treatment and the medication poses considerable risk of overdose death if ingested by non-tolerant individuals (Luty, O'Gara, & Sessay, 2005). Further, federal IMT regulations mandate that patients ingest all doses under direct observation, requiring daily clinic visits (IOM, 1995). They also limit its duration to 120 days, with clinics required to discharge patients at that time if a slot has not become available. Despite successful efforts in Baltimore to bring IMT to scale (Schwartz et al., 2009a), few other localities have used this approach. Taken together, these features have constrained the ability of IMT to treat opioid users while they await entry into standard opioid treatment.

We have been developing a novel interim opioid treatment to bridge delays in treatment access while surmounting the above barriers. Our intervention consists of four components, each selected to support delivery of an efficacious pharmacotherapy to waitlisted opioid-dependent adults while reducing the risk of medication nonadherence and diversion. First, we chose buprenorphine as the interim dosing medication because its pharmacological profile is associated with reduced abuse liability and overdose risk (Bickel & Amass, 1995; Johnson, Strain, & Amass, 2003; Walsh, Preston, Stitzer, Cone, & Bigelow, 1994; Walsh, Preston, Bigelow, & Stitzer, 1995). Buprenorphine is also available without the rigid regulatory regulations, daily observation of dosing and 120-day limit required for interim methadone. Second, we are using a computerized device to facilitate mobile buprenorphine dispensing while reducing risk of nonadherence or diversion. While pill bottles with Medication Event Monitoring System caps (MEMS; Aprex Corporation, Fremont, CA) have been used for years, they have substantive limitations. Patients can access all of their doses each time they open the bottle, and the cap only records a time-date stamp for each opening rather than the amount of medication removed. For the present study, we used the Med-O-Wheel Secure device (Addoz, Forssa, Finland), a portable, disc-shaped device which can hold several weeks' worth of doses with each dose stored in a separate cell and only available during a predetermined 3-hour window. The Med-O-Wheel also includes locks and alarms to prevent tampering and access to tablets outside the preset time window. Third, we developed a mobile health (*m*Health) platform for monitoring patients on a daily basis. *m*Health applications hold significant potential for permitting delivery of monitoring, education and treatment beyond the confines of the medical office (Boyer, Smelson, Fletcher, Ziedonis, & Picard, 2010). Particularly promising are those that provide customized content or monitoring via phone, as phone-based systems offer advantages of low cost, consistent delivery, expanded access, 24-hour availability, privacy and convenience (Crawford et al., 2005; Helzer et al., 2008; Kim, Bracha, & Tipnis, 2007; Moore et al., 2013; Rose et al., 2010; Rose et al., 2010; Stacy, Schwartz, Ershoff, & Shreve, 2009). Our *m*Health system uses an Interactive Voice Response (IVR) platform to deliver automated calls to participants nightly to assess their drug use, withdrawal and craving. Finally, while biochemical verification via urine drug testing is the most objective method for evaluating recent drug use (Chermack et al., 2000; Fendrich, Johnson, Wislar, Hubbell, & Spiehler, 2004; Kilpatrick, Howlett, Sedgwick, & Ghodse, 2000; Preston, Silverman, Schuster, & Cone, 1997; Wish, Hoffman, & Nemes, 1997), frequent visits are incompatible with resource-constrained settings and with rural areas where daily travel to treatment is challenging. We developed a random sampling approach whereby patients are contacted at random times via IVR and instructed to return to the clinic for urinalysis. Random sampling increases the effectiveness of urine monitoring, as patients remain unaware of when the next screen will be requested, reducing the possibility that they can tailor drug use to subvert monitoring (Harford & Kleber, 1978; Manno, 1986). At each random callback, participants also must present their device for inspection by staff to ensure there is no indication of tampering, nonadherence or diversion.

In this 12-week pilot study, we sought to evaluate the initial feasibility of this novel interim buprenorphine treatment (IBT) in reducing illicit opioid use and drug-related risk behavior among opioid-dependent individuals awaiting entry into agonist maintenance. Our aim was to pilot the intervention in a small sample of waitlisted opioid abusers and identify any procedural adjustments indicated to be necessary prior to proceeding with a larger-scale randomized trial.

2. Methods

2.1. Participants

Opioid-dependent adults were recruited via flyers posted throughout the community and distributed to local opioid treatment providers. Eligible participants had to be ≥18 years old, in good health, meet DSM-V criteria for opioid use disorder, provide an opioid-positive urine specimen and be currently waitlisted with an opioid treatment program (OTP) or office-based buprenorphine provider. Those with a significant psychiatric or medical illness that could interfere with participation were excluded, as well as those who were pregnant or nursing. Individuals dependent on sedative-hypnotics were also excluded, due to the medical risks and notably low success rates with sedative-dependent opioid abusers (Stitzer & Chutuape, 1999). The study was approved by the University of Vermont Institutional Review Board and participants provided written informed consent prior to participating. All 10 individuals who were screened, deemed eligible and offered the study agreed to participate.

2.2. Study design

Participants completed buprenorphine induction during Week 1 (or longer if required), during which they attended the clinic daily. Thereafter, they visited the clinic at Weeks 2, 4, 6, 8, 10 and 12 to ingest their