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The Effect of a Payer-Mandated Decrease in Buprenorphine Dose on Aberrant Drug Tests and Treatment Retention Among Patients with Opioid Dependence

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ABSTRACT

Background: The optimal dose for office-based buprenorphine therapy is not known. This study reports on the effect of a change in payer policy, in which the insurer of a subset of patients in an office-based practice imposed a maximum sublingual buprenorphine dose of 16 mg/day, thereby forcing those patients on higher daily doses to decrease their dose. This situation created conditions for a natural experiment, in which treatment outcomes for patients experiencing this dose decrease could be compared to patients with other insurance who were not challenged with a dose decrease.

Methods: Subjects were 297 patients with opioid use disorder in a primary care practice who were prescribed buprenorphine continuously for at least 3 months. Medical records were retrospectively reviewed for urine drug test results and treatment retention. Rates of aberrant urine drug tests were calculated in the period before the dose decrease and compared to rate after it with patients serving as their own controls. Comparison groups were formed from patients with the same insurance on buprenorphine doses of 16 mg/day or lower, patients with different insurance on 16 mg/day or lower, and patients with different insurance on greater than 16 mg/day. Rates of aberrant drug tests and treatment retention of patients on 16 mg/day or less of buprenorphine were compared to that of patients on higher daily doses.

Results: The rate of aberrant urine drug tests among patients who experienced a dose decrease rose from 27.5% to 34.2% ($p = 0.043$). No comparison group showed any significant change in aberrant drug test rates. Moreover, all groups who were prescribed buprenorphine doses greater than 16 mg/day displayed lower rates of aberrant urine drug tests than groups prescribed lower doses. Retention in treatment was also highest among those prescribed greater than 16 mg/day (100% vs. 86.8%, 90.1%, and 84.4% $p = 0.010$).

Discussion: An imposed buprenorphine dose decrease was associated with an increase in aberrant drug tests. Patients in a control group with higher buprenorphine doses had greater retention in treatment. These findings suggest that buprenorphine doses greater than 16 mg/day are more effective for some patients and that dose limits at this level or lower are harmful.

Opioid dependence is a leading cause of morbidity, early mortality and accidental death (Cdc.gov, 2015; Substance Abuse and Mental Health Services Administration, 2014). An estimated 1.9 million Americans met criteria for an opioid use disorder based on their use of prescription painkillers in the past year and 0.5 million met criteria for heroin use disorder (Substance Abuse and Mental Health Services Administration (SAMHSA), 2011). Opioid agonist treatment with methadone (Mattick, Breen, Kimber, & Davoli, 2009) or buprenorphine (Fudala, Bridge, Herbert, et al., 2003; Mattick, Breen, Kimber, & Davoli, 2014) has been shown to be the most effective treatment for opioid use disorders. Office-based treatment for opioid dependence with buprenorphine is now a decade old, and has greatly expanded the treatment for opioid use disorders.

Pharmacologically, buprenorphine is a high-affinity ligand with partial-agonist activity at the mu-opioid receptor and antagonist activity at the kappa-opioid receptor (Mauger, Fraser, & Gill, 2014). Its lack of full agonist effect is responsible for its high therapeutic ceiling, allowing for office-based treatment due to the decreased potential for respiratory suppression (Center for Substance Abuse Treatment, 2004). Early studies of buprenorphine allowed for doses of up to 32 mg/day. Current American Society of Addiction Medicine (ASAM) buprenorphine training recommends a target dose of 16 mg/day in most cases, with a maximum dose of 32 mg/day, but qualifying that as rarely necessary (ASAM).

Despite over 10 years of experience, the optimal dose of buprenorphine is still not known (Farmer, Lindsay, Williams, et al., 2015). While there is evidence that a sublingual dose of 8 mg/day is

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generally sufficient for controlling withdrawal symptoms (Correia, Walsh, Bigelow, & Strain, 2006; Soeffing & Rastegar, 2007), other evidence has suggested that higher daily doses of buprenorphine are associated with better treatment outcomes, including higher treatment retention (Fareed, Vayalapalli, Casarella, & Drexler, 2012). While underdosing of buprenorphine may cause craving and lead to illicit drug use (Petry & Bickel, 1999), the potential benefits of higher dosing may be partially offset by a greater risk of buprenorphine diversion. Buprenorphine diversion – giving or selling medication to others - is a documented phenomenon internationally and domestically (Yokell, Zaller, Green, & Rich, 2011), and may be increasing (Johanson, Arfken, di Menza, & Schuster, 2012). One study found friends and family to be an important source of buprenorphine for people who reported acquisition of diverted-buprenorphine (Lofwall & Havens, 2012). Thus, demonstration of an optimal buprenorphine dose could serve to balance the competing concerns of treatment retention and the minimization of diversion.

In late 2012, Priority Partners, a Medicaid managed care organization in Maryland (MMCO) announced that it would be restricting the maximum covered dose of buprenorphine to 16 mg/day. Patients on greater daily doses received a letter from the company in October 2012, as did their physicians, informing them of the impending dose decrease in January 2013. We decided to perform a retrospective analysis of the impact of this dose decrease on treatment outcomes for this cohort of patients in our practice, using other patients in the practice who were prescribed buprenorphine as comparison groups. We hypothesized that the dose decrease would lead to an increase in aberrant drug test rates and a decrease in treatment retention.

1. Methods

This study was conducted at the comprehensive care practice, a primary care practice on the campus of the Johns Hopkins Bayview Medical Center in Baltimore, Maryland, an academic hospital center. The practice and patient outcomes have been described previously (Soeffing, Martin, Fingerhood, Jasinski, & Rastegar, 2009). Briefly, it is staffed by five attending physicians who are certified to prescribe buprenorphine, three resident physicians who share a panel of patients, and a nurse practitioner. All of the practitioners provide primary care, with a concentration on caring for patients with substance use disorders and HIV infection. It is the policy of the practice that buprenorphine treatment is provided as part of primary care and buprenorphine is only prescribed to patients who also receive their primary care at this practice. There is no set protocol for dosing of buprenorphine or monitoring with drug testing and this left to the discretion of the treating practitioner. The practice has onsite case managers and a mental health counselor, but patients on buprenorphine are not required to use any additional onsite services and are referred to community resources for additional counseling, if needed.

Priority Partners is a local managed care organization, (MMCO) that covered 55% of the patients prescribed buprenorphine for opioid dependence within this practice during the study period. Most of those prescribed more than 16 mg/day had a decrease in dose in accordance with the new restriction, and urine drug testing was performed at periodic intervals, as per usual treatment practice.

Urine drug testing results for our entire practice from July 1, 2012 through April 30, 2013 were downloaded from LabCorp using the LabCorp Beacon platform. This set up created a 6 month pre-period and a 4 month post-period. The rationale for the April stop date was the incidental fact that our practice converted to a new electronic health record system at that time, ending the period during which LabCorp was our exclusive laboratory provider.

Names of all patients with urine drug testing were tabulated, and a query of the medical record to identify any patients who received at least one buprenorphine prescription was also performed. Paper charts and electronic medical records of physician notes were then reviewed in order to identify patients who were being prescribed buprenorphine during the study period. Records of patients who were maintained on buprenorphine were then reviewed in order to note the dose of buprenorphine, the patient's insurer, and any additional prescribed medications, including other opioids or benzodiazepines. Specific attention was paid to benzodiazepines to distinguish prescribed from illicit use. Using chart review and a list of affected patients provided by the MMCO, patients who were required to decrease their buprenorphine maintenance dose were identified. The date of the dose decrease was ascertained from records of the buprenorphine prescriptions as well as review of physician notes.

We included patients who were continuously in treatment from October 1, 2012 to December 31, 2012 and received no prescriptions for opioid pain medications during that period. Patients were then assigned to one of four groups. Group 1 was comprised of patients with MMCO insurance who had been on doses greater than 16 mg/day of buprenorphine, who then experienced a payer-mandated dose decrease to 16 mg/day. Group 2 was comprised of patients with the same MMCO insurance who had been stable on buprenorphine doses of 16 mg/day or less in the pre-period, and did not experience any change in dosing. Group 3 was comprised of patients with other

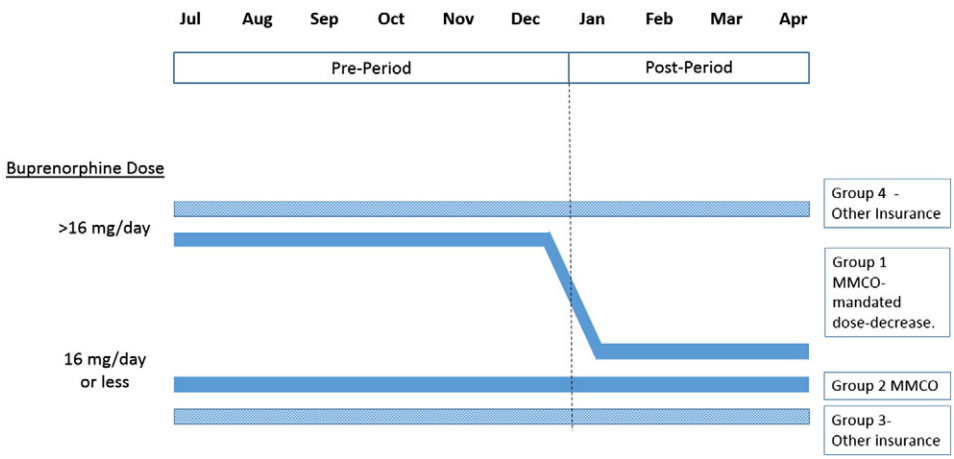

Fig. 1. A schematic representation of the study design.