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Research Paper

A qualitative study comparing physician-reported barriers to treating addiction using buprenorphine and extended-release naltrexone in U.S. office-based practices

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ABSTRACT

Aim: Our aim was to compare physician-reported barriers to sublingual buprenorphine (BUP) and extended-release naltrexone (XR-NLT) prescribing in U.S. office-based practices, and to identify potential policies for minimizing these barriers. Only one previous qualitative study has examined physician-reported barriers to prescribing XR-NLT and no qualitative study has compared physician-reported barriers between the two medications.
Methods: Researchers conducted individual semi-structured and in-depth interviews with 20 licensed physicians in four U.S. states between January 2016 and May 2017. Interview questions included general barriers to addiction treatment in office-based settings, barriers specific to BUP and XR-NLT prescribing, and potential government policies to decrease barriers. Researchers conducted thematic analysis of transcribed interviews. They developed and pilot tested a coding template based on a sample of transcripts, independently coded transcripts in Dedoose software, conducted consensus coding to eliminate coding discrepancies, and then assessed data for themes using research questions as a guide.
Results: General barriers to office-based OUD treatment included limited physician education, limited insurance reimbursement, stigma, and perceptions of "difficult" patients. Barriers specific to BUP prescribing included regulatory restrictions, liability fears, and restrictions imposed by the criminal justice system. Barriers specific to XR-NLT prescribing included limited access to medically-supervised opioid detoxification, lack of awareness of the medication, and patient fears or disinterest. Participants without experience prescribing either medication emphasized barriers to treating OUD in general. Participants with experience prescribing BUP and/or XR-NLT described barriers to treating OUD in general as well as barriers specific to each medication. Policy makers should increase access to addiction medicine education, mandate insurance coverage of both medications and inpatient detoxification, prohibit excessive insurance prior authorization requirements, increase insurance reimbursement for behavioral healthcare, and incentivize interdisciplinary collaboration.
Conclusions: While overlap exists, some barriers to BUP prescribing differ from barriers to XR-NLT prescribing.

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Introduction

Rates of opioid-related overdose death quadrupled in the U.S. between 2000 and 2015, from 8409 deaths in 2000 to 33,091 in 2015 (Dowell et al., 2017). Rates of opioid misuse doubled in the U. S. between 2002 and 2013, from 1.8% of the adult population reporting opioid misuse in 2000 to 4.1% in 2013 (NIAAA, 2016). An estimated 0.9% of the U.S. adult population (or 2.1 million adults) reported symptoms of opioid use disorder ("OUD") in 2013 (NIAAA, 2016). Unfortunately, fewer than 20% of individuals with OUD receive treatment, and the percentage of individuals receiving treatment has not significantly increased since 2004 (Saloner & Karthikeyan, 2015). Most treatment in the U.S. occurs through self-help groups, with only 35% of treatment occurring in office-based settings, such as physician or therapist offices (Saloner & Karthikeyan, 2015). Use of medication-assisted treatment (MAT) for OUD remains low, even though MAT is more effective for OUD than behavioral treatment alone (Nielsen et al., 2016). Expanding office-based physician involvement in OUD treatment is a key way

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to increase MAT access (Arfken, Johanson, di Menza, & Schuster, 2010).

Three forms of MAT for OUD are available in the U.S.: buprenorphine, naltrexone and methadone, with only buprenorphine and naltrexone available in office-based settings (Korthuis et al., 2017). Methadone and buprenorphine are extensively regulated by the federal government, resulting in minimal state variation in prescribing rules. Methadone for OUD may only be prescribed and dispensed in Opioid Treatment Programs (OTPs), also referred to as "methadone clinics," which are highly regulated settings typically requiring daily visits. Methadone is not prescribed within office-based practices or dispensed within community pharmacies. Sublingual buprenorphine may be prescribed in office-based settings by prescribers with a waiver from the Substance Abuse & Mental Health Services Administration ("SAMHSA waiver"), retrieved from community pharmacies (typically monthly), and taken at home daily (SAMHSA, 2017). A six month implantable version of buprenorphine, and a monthly injectable extended-release version of buprenorphine, approved by the U.S. Food and Drug Administration ("FDA") in 2016 and 2017 respectively, may be prescribed and administered by a provider in office-based settings with both a SAMHSA waiver and Risk Evaluation and Mitigation Strategy certification (Braeburn, Inc., 2017; Indivior Inc., 2017), approved in mid-2016 by the U.S. Food and Drug Administration ("FDA"), may be prescribed and surgically implanted in office-based settings every six months by a prescriber with both a SAMHSA waiver and Risk Evaluation and Mitigation Strategy certification. Naltrexone is subject to fewer federal regulations than methadone or buprenorphine because it is not a controlled substance. Every state allows any physician with a medical license to prescribe naltrexone, resulting in minimal state variation in prescribing rules. Oral naltrexone is prescribed in office-based settings, retrieved from community pharmacies (typically monthly), and taken at home daily. Extended-release naltrexone is prescribed and administered in office-based settings monthly via depot injection (Arfken et al., 2010; Braeburn, Inc., 2017; Korthuis et al., 2017). Given that buprenorphine and naltrexone treatment do not require daily visits to an OTP but rather monthly office visits, they are potentially more accessible than methadone. Furthermore, since buprenorphine and naltrexone may be prescribed in primary care practices and other facilities not visibly associated with substance use disorder, patients may feel less stigma when seeking these medications. Oral naltrexone is significantly less effective than sublingual buprenorphine or extended-release naltrexone, due to poor patient retention (Nielsen et al., 2016). Given their recent FDA approvals, few studies exist of implantable or injectable extended-release naltrexone's efficacy; they each also require stabilization on sublingual buprenorphine prior to administration. (FDA, 2017; Indivior Inc., 2017), few studies exist of implantable buprenorphine's efficacy; it also requires stabilization on sublingual buprenorphine for three months prior to implantation (FDA, 2017). Therefore, the remainder of this paper focuses exclusively on sublingual buprenorphine and extended-release naltrexone prescribing in U.S. office-based settings.

Despite physicians' ability to prescribe sublingual buprenorphine and extended-release naltrexone in office-based settings, few physicians prescribe these medications. For example, Rosenblatt et al. found that 46% of counties lacked a physician with a SAMHSA waiver (required for buprenorphine prescribing), with only 3% of all primary care physicians having a SAMHSA waiver (Rosenblatt, Holly, Andrilla, Catlin, & Larson, 2015). A 2013 National Survey of Substance Abuse Treatment Services found that less than 1% of patients seeking OUD treatment received extended-release naltrexone (SAMHSA, 2013). The purpose of our study is to compare physician reported barriers to prescribing sublingual buprenorphine and extended-release naltrexone in U.S. office-based settings and to identify potential policies for decreasing these barriers. Policymakers need information about comparative barriers, because policies designed to minimize barriers to prescribing sublingual buprenorphine may not necessarily minimize barriers to prescribing extended-release naltrexone and vice versa.

Existing qualitative and quantitative studies have found the following barriers to U.S. office-based sublingual buprenorphine prescribing. Physician-level barriers include lack of patient and physician interest (Barry et al., 2009; Gordon et al., 2011; Walley et al., 2008), lack of physician expertise and education (Barry et al., 2009; DeFlavio, Rolin, Nordstrom, & Kazal, 2015 Gordon et al., 2011; McMurphy et al., 2006), concern about patient costs (Barry et al., 2009), confidentiality concerns (Barry et al., 2009), limited physician time and resources (Barry et al., 2009; DeFlavio et al., 2015; Kermack, Flannery, Tofighi, McNeely, & Lee, 2017; McMurphy et al., 2006), discomfort treating comorbid psychiatric conditions (Kermack et al., 2017), concern about abuse or diversion (Turner, Laine, Lin, & Lynch, 2005), and stigma towards patients with OUD (Gordon et al., 2011; McMurphy et al., 2006). Bureaucratic barriers include cumbersome regulations (DeFlavio et al., 2015), lack of institutional support (Walley et al., 2008), lack of collaboration with mental health providers (Barry et al., 2009; Kissin, McLeod, Sonnefeld, & Stanton, 2006; Netherland et al., 2009), and insurance barriers (Barry et al. 2009; Kermack et al., 2017; McMurphy et al., 2006). Each of these barriers has also been reported in Western, Central and Eastern European nations (Fraeyman, Symons, Royen, Hal, & Peremans, 2016; Schulte et al., 2013; Vranken et al., 2017), despite different regulatory structures and health insurance systems.

Only one study has examined physician-reported barriers to prescribing extended-release naltrexone for OUD in U.S. office-based settings (Alanis-Hirsch et al., 2016). The study interviewed "change leaders" at specialized addiction treatment centers, not necessarily physicians, limiting results' applicability to office-based non-specialist physicians (e.g. primary care physicians). The study found the following barriers to prescribing extended-release naltrexone: a relatively complex process of ordering and injecting the medication (i.e. ordering from specialty pharmacies, refrigeration, medication mixing, and injection administration); medication cost; inadequate insurance coverage; patient detoxification requirements; lack of insurance coverage for medically-supervised detoxification; health insurance requiring physicians to "buy and bill" for the medication; abstinence-only treatment orientation; inadequate staffing; and limited physician education (Alanis-Hirsch et al., 2016). No qualitative study has assessed barriers to prescribing extended-release naltrexone in office-based settings in Europe, despite regulatory approval in Europe and Russia (Krupitsky, Zvartau, & Woody, 2010). However, extended-release naltrexone may have greater acceptability in Russia where buprenorphine and methadone for OUD are illegal (Krupitsky et al., 2010).

To our knowledge, our study is the first to use qualitative methods, specifically in-depth and semi-structured interviews, to compare physician-reported barriers to prescribing sublingual buprenorphine and extended-release naltrexone in U.S. office-based practices. We use a qualitative approach given the lack of existing data on barriers specific to extended-release naltrexone prescribing. Open-ended questions are more appropriate than closed-ended questions with preselected response options when significant uncertainty exists about a phenomenon (Sofaer, 1999). Qualitative methods are also particularly appropriate for describing complex settings and interactions in health services, especially treatment of stigmatized disorders (Sofaer, 1999). While acknowledging the importance of mental health therapy in OUD treatment,

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