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Extended-Release Naltrexone: A Qualitative Analysis of Barriers to Routine Use

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ABSTRACT

The Medication Research Partnership (a national health plan and nine addiction treatment centers contracted with the health plan) sought to facilitate the adoption of pharmacotherapy for alcohol and opioid use disorders. Qualitative analysis of interviews with treatment center change leaders, individuals working for the manufacturer and its technical assistance contractor, and health plan managers extracted details on the processes used to order, store, bill for, and administer extended-release naltrexone. Qualitative themes were categorized using domains from the Consolidated Framework for Implementation Research (intervention characteristics, outer setting, inner setting, and provider characteristics).

Characteristics of XR-NTX that inhibited use included the complexity of ordering and using the medication; cost was also a barrier. Outer setting barriers reflected patient needs and external health plan policies on formulary coverage, benefit management, and reimbursement. Program structures, the lack of physician linkages, a culture resistant to the use of medication, and unease with change were inner setting elements that limited use of XR-NTX. Patient stereotypes and a lack of knowledge about XR-NTX affected practitioner willingness to treat patients and prescribe XR-NTX. The Consolidated Framework for Implementation Research provided a useful lens to understand and interpret the processes affecting access to XR-NTX.

1. Introduction

The Food and Drug Administration (FDA) approved extended-release naltrexone (XR-NTX; Vivitrol®) (an injectable opioid antagonist released over 28 days) for treatment of alcohol dependence (in 2006) and to prevent opioid relapse (in 2010). Oral naltrexone is efficacious (O'Malley et al., 1992; Volpicelli, Alterman, Hayashida, & O'Brien, 1992), and effective when compared to acamprosate (Anton et al., 2006). Studies document the efficacy and tolerability of the extended-release formulation in clinical trials (Garbutt et al., 2005; Lapham, Forman, Alexander, Illeperuma, & Bohn, 2009), effectiveness in primary care for treatment of alcohol dependence (Lee et al., 2010) and use with drunken driving offenders (Finigan, Perkins, Zold-Kilbourn, Parks, & Stringer, 2011).

Routine use in clinical practice for alcohol and opioid dependence, however, remains uncommon; a 2007/2008 survey of addiction treatment centers reported that 16% used XR-NTX for some patients (Abraham & Roman, 2010). The 2013 National Survey of Substance Abuse Treatment Services, however, suggests few patients are on the medication; of more than 1.2 million patients in care on March 31, 2013, less than 1% ($n = 3{,}781$) received XR-NTX (SAMHSA, 2014). Use for treatment of opioid dependence, moreover, remains stunted despite a randomized placebo controlled trial that demonstrated enhanced opioid abstinence and reduced craving (Krupitsky et al., 2011). In view of the empirical evidence of efficacy and effectiveness, the slow adoption of XR-NTX is disappointing and requires careful assessment of the barriers to routine use.

1.1. Medication research partnership

Nine addiction treatment centers, a health plan they contract with, and investigators collaborated in the Medication Research Partnership to integrate pharmacotherapies into routine care for alcohol and opioid use disorders. Eight programs were specialty addiction treatment centers providing detoxification and residential rehabilitation and one program provided intensive outpatient and outpatient treatment. When the study began, participating programs routinely used methadone or

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buprenorphine ($n = 8$ sites) to facilitate opioid withdrawal (but not as long-term opioid agonist therapy). There was limited use of opioid antagonists primarily for alcohol dependence if patients requested oral naltrexone (5 sites) or XR-NTX (4 sites).

The study sites reported that the approval, ordering, and induction processes for XR-NTX provided unexpected challenges and required development of internal processes and infrastructure to support prior authorization, ordering, receipt and delivery of the medication. To better understand the complexities, we interviewed providers, prescribers, health plan managers and pharmaceutical representatives. Studies on the adoption of medication for the treatment of alcohol and drug use disorder have examined the association of counselor education (Fitzgerald & McCarty, 2009; Fuller, Rieckmann, McCarty, Smith, & Levine, 2005), counselor and client attitudes (Rieckmann, Daley, Fuller, Thomas, & McCarty, 2007), organizational characteristics (Knudsen, Abraham, & Roman, 2011; Knudsen, Ducharme, & Roman, 2006)) and financing (Knudsen & Roman, 2012) with use of medications but there is little work on features of the medication and payer systems that can inhibit use.

2. Methods

The Medication Research Partnership tested organizational change strategies to promote enhanced patient access to medications that can support recovery from alcohol and opioid dependence. Because the health plan's headquarters were in the Delaware Valley, the participating providers were drawn from nearby states (Delaware, Maryland, and Pennsylvania). Participating addiction treatment center staff and health plan personnel completed training in organizational change using the NIATx model (Gustafson et al., 2011; McCarty et al., 2007) and received coaching on organizational change, topical webinars, and presentations on the use of medications at four learning sessions.

Transcribed telephone interviews with the change leaders from each study site ($n = 39$), notes from coaching calls and site visits ($n = 75$) and program reports during learning sessions ($n = 23$) were reviewed to extract implementation barriers related to XR-NTX. We also interviewed health plan managers ($n = 3$) and representatives from the pharmaceutical company and its technical assistance contractor ($n = 3$) to confirm processes for ordering and using XR-NTX. Institutional Review Boards at Oregon Health & Science University, University of California, San Francisco, and University of Wisconsin reviewed and approved the study; Treatment Research Institute deferred to the Oregon Health & Science University review.

2.1. Implementation support

2.1.1. Learning sessions

Four learning sessions provided an arena for training and cross-collaboration among sites and with the national health plan. The first learning session (October 2011), conducted prior to the initiation of change cycles, oriented sites to the project, process improvement strategies, walkthroughs, rapid cycle change projects, and provided tools for tracking action plans and monitoring change. Sites also completed a questionnaire on the services available at the study site and prior experience with medication. In the second learning session (May 2012), conducted after completion of the first 6-month change cycle, physicians with addiction medicine expertise provided training on the use of medications for alcohol and drug use disorders. Additional presentations addressed strategies for reducing staff resistance and summarized the business case. Participants received copies of papers describing cost–benefits of using pharmacotherapy for treatment of alcohol and opioid dependence. Sites made brief presentations outlining their initial change cycles and plans for the next change cycle. The third Learning Session (December 2012), conducted at the end of the second change cycle, emphasized site presentations and also provided guidance on building partnerships with primary care and sustaining change. The fourth learning session (June 2013), conducted following completion of the third and final change cycle, focused on site presentations and sustainability plans. The learning sessions provided a forum for sites to share their successes and failures and plans for sustaining their successes.

2.1.2. Change teams

Prior to the initial learning session, sites selected an administrator or clinician as a change leader and formed a change team of staff in key positions (e.g., clinic director, chief medical officer, lead counselor, lead nurse) to assist in increasing use of addiction medications. Teams ranged in size from two to five, and met weekly at the beginning of a change cycle. Teams developed and tested organizational changes to support increased use of medications during each 6-month change cycle; based on results, they adopted, adapted, or abandoned changes. Change teams determined the method, frequency, and extent to which they promoted the use of medications to agency staff and leadership. Organizational change coaches familiar with the substance abuse field supported change leaders with ongoing assistance through monthly conference calls and a site visit during the second change cycle.

2.2. Interviews

Qualitative interviews were scheduled every 7 to 9 months; change leaders at four sites completed five of five scheduled interviews, four change leaders completed four interviews and one change leader completed three interviews. The interviews provided qualitative data about site experiences with organizational change and the use of medications. The semi-structured interviews inquired about system changes supporting the integration of medication into addiction treatment, and financial, administrative, and technical barriers to the use of the medication and its sustainability. Interviews were conducted with the change leader at each site to maximize comparability across time. To minimize participation burdens, we did not interview other members of the change teams. Interviews were digitally recorded and professionally transcribed.

Change leader interviews conducted prior to the first learning session served as a reference point for agency culture and treatment philosophy prior to receiving implementation support from the Medication Research Partnership. During the 21 month period of change implementation (three 6-month change cycles plus 1 month to organize and attend learning sessions at the end of each change cycle), interviews focused on internal and external barriers to integrating medication into treatment and the strategies utilized to make policy and process changes. In the sustainability period (24 months following the end of the third change cycle) change leader interviews probed internal change processes, involvement of leadership and staff, relationships with the commercial health plan, and strategies to initiate, test, and sustain changes to support use of medications. Overall, the interviews captured transitions in staff and leadership attitudes, level of internal support for changes, the decision-making process, barriers to the use of medication, and the sustainability process to promote continued use of medications.

2.3. Qualitative analysis

Interview transcripts were coded using Atlas-ti 7.0 software. Standard methods for qualitative analysis were used with a focus on constant comparison to explore similarities and differences across sites (Glaser & Strauss, 1967). Analysis and data collection were conducted simultaneously. Four members of the research team coded transcripts that were not from interviews they conducted to allow a wider view of the change challenges and strategies. Coders developed a common coding scheme deductively based on themes from interview guides and inductively from themes repeatedly mentioned during interviews and presentations. The analysts returned to the interview data to confirm and clarify specific themes, collapse similar themes and expand divergent themes. Transcripts were evenly divided among the analysts. Analysts coded the