



Welcome to the VIP Initiative

August 2018

An IDEAS2 –VISN 19 Service and Research Collaborative

## SITE VISIT



Dr. Adam Gordon visited the Spokane Veterans Affairs to expand medication addiction treatment to veterans by providing a 4-hour face to face X-waiver training as well as a discussion on “Difficult Cases” with the Spokane VA providers. The training covers medications to manage patients with addiction involving opioids , teaches how to overcome barriers and explains to providers how to use medications appropriately.

Under the [Drug Addiction Treatment Act of 2000 \(DATA 2000\)](#), physicians are required to complete training to qualify for a waiver to prescribe and dispense buprenorphine. The on-site training covers legislation, pharmacology, safety, patient assessment, and more.

## MEDICATION-ASSISTED ADDICTION TREATMENT IN THE NEWS

### *Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial.*

Joshua D Lee, MD, Edward V Nunes Jr, MD, Patricia Novo, MPH, Ken Bachrach, PhD, Genie L Bailey, MD, Snehal Bhatt, MD, Sarah Farkas, MA, Marc Fishman, MD, Phoebe Gauthier, MPH, Candace C Hodgkins, PhD, Jacquie King, MS, Robert Lindblad, MD, David Liu, MD, Abigail G Matthews, PhD, Jeanine May, PhD, K Michelle Peavy, PhD, Stephen Ross, MD, Dagmar Salazar, MS, Paul Schkolnik, PhD, Dikla Shmueli-Blumberg, PhD, Don Stablein, PhD, Geetha Subramaniam, MD, and John Rotrosen, MD.

The study extended-release naltrexone (XR-NTX), an opioid antagonist, and sublingual buprenorphine-naloxone (BUP-NX), a partial opioid agonist, are pharmacologically and conceptually distinct interventions to prevent opioid relapse. The authors aimed to estimate the difference in opioid relapse-free survival between XR-NTX and BUP-NX.

It is an open-label, randomised controlled, comparative effectiveness trial at eight US community-based inpatient services and followed up participants as outpatients. Participants were 18 years or older, had Diagnostic and Statistical Manual of Mental Disorders-5 opioid use disorder, and had used non-prescribed opioids in the past 30 days. The researchers stratified participants by treatment site and opioid use severity and used a web-based permuted block design with random equally weighted block sizes of four and six for randomisation (1:1) to receive XR-NTX or BUP-NX .

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5806119/pdf/nihms929299.pdf#page=1>

## UPDATES IN RESEARCH

Sarah E. Wakeman, Michael L. Barnett. **Primary Care and the Opioid-Overdose Crisis - Buprenorphine Myths and Realities.** New England Journal of Medicine, 2018; 379 (1): 1 DOI: 10.1056/NEJMp1802741.

<https://www.nejm.org/doi/full/10.1056/NEJMp1802741>

**Expanding primary care buprenorphine treatment could curb opioid overdose crisis.** Massachusetts General Hospital. "Expanding primary care buprenorphine treatment could curb opioid overdose crisis." ScienceDaily. ScienceDaily, 4 July 2018. <[www.sciencedaily.com/releases/2018/07/180704174955.htm](http://www.sciencedaily.com/releases/2018/07/180704174955.htm)>.Physicians write that expanding the availability of medication treatment for opioid use disorder in primary care settings would be a major step toward reducing overdose deaths. <http://www.sciencecodex.com/expanding-primary-care-buprenorphine-treatment-could-curb-opioid-overdose-crisis-621705>



## Office of Health and Constituent Affairs

### Food and Drug Administration

### U.S. Department of Health and Human Services

Because of your interest in opioids, the Office of Health & Constituent Affairs wanted to share several recent announcements. Addressing opioid addiction is one of the FDA's highest priorities and supports the [U.S. Department of Health and Human Services' 5-Point Strategy To Combat the Opioid Crisis](#). The FDA remains committed to addressing the national crisis of opioid addiction on all fronts, with a significant focus on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies and opioids more resistant to abuse and misuse; and taking action against those who contribute to the illegal importation and sale of opioids. The agency will also continue to evaluate how opioids currently on the market are used, in both medical and illicit settings, and take regulatory action where needed.

- **FDA takes action against 53 websites marketing unapproved opioids as part of a comprehensive effort to target illegal online sales:** FDA announced that it has warned nine online networks, operating a total of 53 websites, that they must stop illegally marketing potentially dangerous, unapproved and misbranded versions of opioid medications, including tramadol and oxycodone. Patients who buy prescription medicines from illegal online pharmacies may be putting their health at risk because the products, while being marketed as authentic, may be counterfeit, contaminated, expired, or otherwise unsafe. [More information](#)
- **FDA approves first generic versions of Suboxone sublingual film:** FDA approved the first generic versions of Suboxone (buprenorphine and naloxone) sublingual film (applied under the tongue) for the treatment of opioid dependence. Mylan Technologies Inc. and Dr. Reddy's Laboratories SA received approval to market buprenorphine and naloxone sublingual film in multiple strengths. Buprenorphine and naloxone sublingual film should be used as part of a complete treatment plan that includes counseling and psychosocial support. "The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure these medicines are accessible to the patients who need them. That includes promoting the development of better drugs, and also facilitating market entry of generic versions of approved drugs to help ensure broader access," said FDA Commissioner Scott Gottlieb, M.D. [More information](#)