# Improving Outcomes of Opioid Addicted Prisoners with Extended Release Injectable Naltrexone Before Reentry

A new re-entry project focused upon opiate addicts has been made available to PPS. This project is a collaboration between PPS, NorthEast Treatment & the University of Pennsylvania with Dr George Woody as the Principal Investigator and support from a new funding source PCORI.

Patient-Centered Outcomes Research Institute (PCORI), an independent nonprofit, nongovernmental organization located in Washington, DC, was authorized by Congress in 2010. The PCORI mandate is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions. Specifically, PCORI funds comparative clinical effectiveness research, or CER, as well as support work that will improve the methods used to conduct such studies.

True Opiate addiction results in part from significant changes to the addict's brain chemistry. Opiate addiction is a chronic re-occurring (relapsing) condition which frustrates not only the addict but all that are involved. A strong relapse factor in the opiate brain disease is protracted withdrawal symptoms (PAWS). People in recovery from heroin dependence show deficits in executive control functions that may persist for months beyond the period of acute withdrawal.

For the true opiate addict, medication is most times essential which is available via MAT (medication assisted treatment).

Currently, the Federal Government has only 3 approved medications to treat opiate addiction; Methadone, Buprenorphine (Suboxone, Subutex) and Naltrexone (ReVia, Vivitrol).

The new project will use VIVITROL® (naltrexone for extended-release injectable suspension). Vivitrol is a non-addictive medication that will block the effects of any narcotic (opiate) medicines. It effectively combats opiate cravings, lasts for approximately one month per injection and causes no further withdrawal symptoms. Most importantly, if someone were to use an opiate while on Vivitrol, they would feel no effect. Knowing the option of getting high is not available allows a person in early recovery the time and emotional energy to focus on developing an effective recovery program.

The new project will study the success of the Subjects re-entry as well as the related social and other ramifications.

Study candidates must be voluntary with a designated release date so the medication can be initiated.

## Project Summary

In 2014 PCORI, the FDA, CDC, ONDCP, and NIDA identified opioid abuse as a national problem. Jails and prisons, which serve as collection points for persons with these problems, typically provide detoxification, substance abuse education, counseling, support groups, and referral to treatment at reentry but rarely provide addiction treatment medication, and relapse is common. This situation differs from HIV, diabetes, and other disorders for which medication is prescribed in prison and at reentry for transition to continuing care. Methadone and buprenorphine are the most well-known treatment medications for opioid abuse, but few correctional facilities use them because they are narcotics and can be abused. Naltrexone is different—it is an antagonist with no abuse liability, is not sold or diverted, and does not cause withdrawal. An extended release injectable formulation (XR-NTX; Vivitrol®) blocks opioids for 30 days, and a dose before reentry will prevent relapse in the following weeks—thus giving the ex-prisoner "protected time" that is likely to reduce relapse and increase treatment participation. Conversations, a survey, and a focus group with ex-prisoners have shown that many of them are interested in trying it.

Only one controlled study has been performed comparing XR-NTX before reentry with usual treatment. It was a pilot study in which 33 consenting prisoners were randomized to XR-NTX before reentry or usual treatment; 6 of 16 (38 percent) XR-NTX patients relapsed within 2 months versus 15 of 17 (88 percent) in usual treatment. We propose to follow up these findings in a collaboration with the Philadelphia Prison System (PPS) and NET Steps, a local program that provides addiction treatment in the PPS (NET@PPS) and that has worked with the Penn PI and staff. The design is to identify detoxified, consenting, opioid-addicted prisoners who are interested in XR-NTX. The first 200 individuals who meet study admission criteria will be randomized to receive XR-NTX before reentry with follow-up XR-NTX at NET Steps after reentry, or told to report to NET Steps after reentry for their first dose. Three additional XR-NTX doses will be offered, and prisoners who later change their minds will be eligible for other treatments but encouraged to complete all follow-ups. All participants will receive drug counseling and have a patient benefits manager to help restore benefits lost during incarceration. Urine drug tests will be performed weekly, and brief assessments will be conducted at months 1, 2, and 4, with more detailed assessments at months 3 and 6. PPS records will document arrests and incarcerations.

The primary aim is proportion not relapsed by month 3. Secondary aims include quality of life; others are described in the protocol, as are dissemination plans. The long-term objective is to identify an intervention that correctional facilities will use and that prisoners will accept to improve their health and reduce the population burden of untreated opioid addiction.