Treatment Navigation for Opioid Use Disorders

Study Protocol

A113229 Banta-Green (FA130694) (WA State Innovation Initiative- Medication Assisted Treatment upon Release from Prison)

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Abstract

We will conduct a pilot randomized controlled trial (RCT) study. One hundred inmates with OUD releasing from WA State prisons to community corrections supervision in King County, WA will be enrolled (the county has a population of 2 million residents out of a state population of 7 million). Half of the subjects will receive treatment as usual, for instance outpatient drug counseling, and half will receive 6 months of intervention. The aims of this study are to determine: 1) whether study procedures can be implemented with fidelity, 2) whether offenders can be enrolled and maintained in the study, 3) which medications/treatment options subjects select and their experiences and satisfaction with the interventions, and 4) preliminary intervention effect size on outcomes of interest including recidivism, drug use, hospitalization, and treatment enrollment and retention.

Introduction

One-third of heroin users are incarcerated each year primarily due to criminal activity related to their drug use and "*policy changes and interventions are urgently needed to reduce the negative consequences of opioid relapse following re-entry"* (Fox et al., 2015). The number of heroin users and the number dying from opioid overdoses have increased significantly in recent years across the U.S. while pharmaceutical opioids remain a common pathway into heroin and a persistent overdose risk (Jones et al., 2015; Peavy et al., 2012).

The time shortly after release from prison is a period of greatly increased risk for fatal opioid overdose (Binswanger et al., 2013; Merrall et al., 2010). Opioid use disorder can be readily treated with medication assisted treatment (MAT) reducing criminal activity, recidivism, improving

functioning, decreasing mortality and transmission of infectious diseases like HIV and HCV, and substantially reducing costs (Clark et al., 2011; MacArthur et al., 2012; Nolan et al., 2014; Nordlund et al., 2004; Tkacz et al., 2014; Tsui et al., 2014; White et al., 2014). A major challenge in breaking the cycle of addiction and criminality and related morbidity and mortality is seamlessly getting people onto MAT as they leave incarceration. This is a matter of simultaneously building interest in treatment among newly released inmates and increasing and facilitating access to ongoing services.

Great interest in this topic has been expressed locally as indicated by the January 2016 release of Washington State's Interagency Opioid Workplan, co-authored by Drs. Banta-Green and Fotinos, collaborators on this project. A main strategy in the Workplan is to *"Optimize access to chemical dependency treatment services for offenders who have been released from prison into the community…"*[i]. Numerous challenges exist to providing effective services to releasing prison inmates with OUD, including: 1) identification of the population at risk, 2) inmates' often modest knowledge and misperceptions of MAT as well as limited motivation and self-efficacy for accessing treatment, 3) lack of continuity of care between the relatively protected prison environment and effective services in the community and 4) maintaining ongoing utilization of MAT to support recovery and reduced consequences related to opioid use.

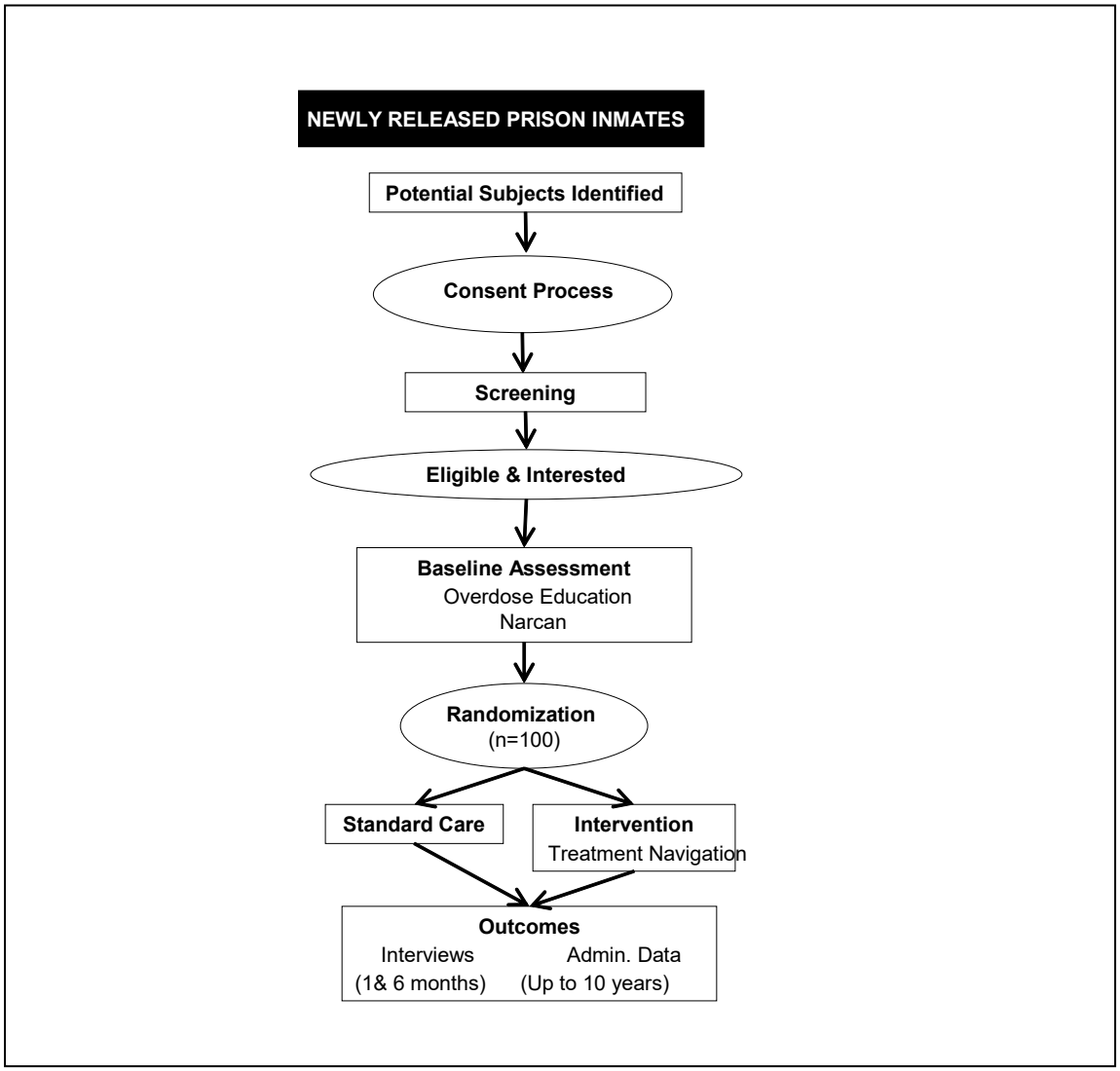
This innovation initiative, based on evidence-based practices, will develop, implement, and assess the feasibility of procedures to provide effective services for offenders with OUD releasing from WA DOC prisons. We will aim to facilitate linkage to ongoing MAT in the community following release from custody beginning with an initial intervention aimed to educate inmates so they can make informed decisions regarding medication options.

The Affordable Care Act (ACA) has markedly increased eligibility for health insurance coverage for releasing offenders, such that a very high proportion of offenders releasing from WA DOC prisons qualify for Medicaid coverage. Since 2014, WA DOC has launched an effort to enroll as many releasing offenders as possible into Medicaid coverage effective at the time of release resulting in a substantial majority of inmates obtaining Medicaid coverage. We are fortunate that WA HCA (Medicaid) has undertaken several initiatives to promote better integration of healthcare services including integrating medical, mental health, and substance use disorder treatment that should facilitate this study and support sustainability long term (see letter of support).

The crux of this innovation initiative is building motivation and self-efficacy for and ready access to adequate coordinated care for releasing offenders with OUD to initiate and maintain MAT. Given that MAT has the best evidence base for effective treatment of OUD, facilitating access to MAT (accompanied by psychosocial treatment as appropriate) will be the major thrust of the initiative. Our intention is to make appropriate treatment (buprenorphine, methadone, and long-acting-naltrexone) available, with the particular treatment approach selected on a case-by-case basis by the patient and medical provider. We will be working with community based partners who will be providing MAT including, but not limited to Dr. Tsui, co-investigator and Evergreen Treatment Services (see letter of support). These partners will be responsible for all medical and related care

including counseling as indicated, we will be coordinating with them and the study participants to facilitate care.

Study Design



Eligibility Criteria

Inclusion criteria

1) Meets DSM-5 criteria for opioid use disorder (at least 2 criteria) or were receiving treatment for opioid use disorder in the 12 months prior to incarceration.
2) Released to community corrections, not currently incarcerated.
3) Able to understand and provide informed consent.
4) Has access to phone (voice or text) or email to communicate with research staff.

Exclusion criteria

1) Under age 18 or over age 70 at time of recruitment.
2) Currently enrolled in an opioid treatment program using medications.
3) Has not used opioids (prescription type or heroin) in the past 6 months prior to incarceration.
4) Unwilling to allow access to medical or drug treatment records, criminal history or criminal activity records.
5) Inability to communicate in English verbally.
6) Inability to provide adequate contact information to assist with follow-up.
7) Not planning on being in King County or reporting to community corrections in King County for 6 months.
8) Violent or overtly hostile/threatening towards research staff.
9) Entering 31 days or more controlled environment in the next 6 months.

Potential Subjects Identified

Recruitment, baseline interviews, and some follow-up interviews (if convenient for the subject) will take place in community corrections offices (CCOs) throughout King County. We will concentrate initially on offices in Seattle and South King County. Department of Corrections (DOC) will run weekly reports on inmates for upcoming releases to King County CCO facilities. DOC will notify CCO staff that a potential subject will be released to that facility. Once released, we will approach, recruit and enroll them during their first visit at the community corrections office and randomize to treatment as usual or intervention.

Obtain Informed Consent

Written informed consent will be obtained from all subjects who wish to participate in the study. Subjects will also be asked to complete HIPAA authorization agreements for treatment and medical records information and other secondary data sources.

Eligibility Screening

Subjects will be men or women aged 18-70 released from Washington State prisons to community corrections supervision in King county, meeting at least mild severity for Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) criteria for diagnosis for opioid use disorder (e.g.

opiate dependence).Subjects will be asked to complete an eligibility screening questionnaire. The items covered are general demographics, proximity to the research settings, drug use questions, and DSM 5 checklist.

Baseline Assessments

Eligible subjects will undergo baseline assessments and provide information on personal information and health:

1) Opioid Use and Treatment Experiences. This assessment captures opioid use, overdose history, past treatment and feelings about future treatment.

2) Education, Employment, Income and Housing: This assessment captures other demographic information related to subject's resources and social stability.

3) Overdose Risk Assessment: This assessment is used to determine the potential for future overdose based on prior overdose history, current drug use practices and social context for current drug use. This assessment is not standardized but is compiled from individual items of known risk factors for overdose.

4) World Health Organization Alcohol, Smoking and Substance Involvement Screening Test (WHO-ASSIST v.3). This is a multi-item tool to determine areas of substance use and misuse. This assessment battery screens for recent and lifetime use of a variety of substances, including illicit drugs, alcohol, pharmaceuticals and tobacco products.

5) EQ-5D-3L: This validated quality of life measure asks about problems in mobility, self-care, usual activities, pain and discomfort, anxiety and depression and overall health.

Locator information:

Subjects will be asked to provide a number of sources to ensure they can be contacted for follow-up visits. However, because we anticipate a number of subjects to have unstable housing, subjects may be enrolled if they provide at least one primary source of locator information.

Randomization

Subjects will be randomized to receive either standard of care or the study intervention. We will recruit equal numbers of subjects in the intervention and control arms of the study.

Follow-up Visits

Follow-up visits will occur at 1and 6 months after enrollment. Interviews will be by phone or in-person. Assessments given at the baseline interview will be repeated at each follow-up point. In

addition to the assessments subjects will be asked questions in the intervention arm about how well the treatment navigation process is working.

Secondary Data Sources

Secondary data on health care and drug treatment utilization will be obtained from Washington State (separate IRB action pending) using the following sources:

- Division of Behavioral Health and Recovery (DBHR) data for drug treatment admissions data (formerly TARGET) and King County Behavioral Health and Recovery Division
- The Comprehensive Hospital Abstract Reporting System (CHARS) for hospital admissions
- Criminal History data extracted from Administrative Office of the Courts (AOC) and Department of Corrections (DOC) by the Washington Institute for Public Policy (WSIPP)
- Emergency Department Information Exchange data for emergency department visits administered by Collective Medical Technologies.

In the event of a subject death during the study we will request information on cause of death from the King County Medical Examiner's Office or Vital Records from Washington Department of Health. If we are unable to locate a subject during the course of the study or at final follow-up we will utilize the King County Jail Inmate Look-up Service. At no time will subjects be contacted or study procedures attempted while the subject is incarcerated.

Intervention Description

Subjects in the intervention arm will additionally begin a discussion with the interventionist about whether they are interested in treatment and medication choices for opioid use disorders. The interventionist, called a Treatment Navigator, will use a decision tool based on the SAMSHA guide to medication assisted treatment in order to help make an informed decision about treatment choices. A treatment decision may be made during the baseline visit or at some later visit. Once a decision is reached, the Treatment Navigator will meet with the subject periodically to assist with entering treatment and help with locating other social services as needed within the community. The meetings are neither structured nor scripted and the subjects will determine the agenda based on their areas of concern. The Treatment Navigator will, however, emphasize getting into treatment as quickly as possible once a decision is made. The Treatment Navigator and the subject will determine the schedule of meetings and will continue throughout the 6 month study period, with more visits anticipated at the start of participation, and fewer visits anticipated at the end. See Appendix A for the Treatment Decision Making Guide.

Study Medication

The medication, naloxone, is being used for an indicated condition, opioid overdose. The specific formulation of Naloxone we will use is Narcan® nasal spray, 4mg naloxone hydrochloride from ADAPT Pharma.

At usual doses, naloxone is relatively free of adverse effects. Because the duration of action of naloxone may be shorter than that of the narcotic being reversed, patients being treated for opioid intoxication with symptoms of respiratory depression should be closely monitored as additional doses of naloxone may be required.

Administration of naloxone to opioid-dependent patients may provoke an acute withdrawal syndrome (including body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure). Withdrawal reaction are not life threatening. Agitation and paresthesia have been infrequently reported with the postoperative use of naloxone hydrochloride injection.

Hypersensitivity reactions, such as allergic reactions, are theoretically possible, but have never been documented with naloxone. We will ask about allergic reactions to naloxone during the baseline interview and at each of the three follow up interviews. Any allergic reactions will be reported to the University of Washington's human subjects division.

Subjects will be educated about withdrawal reactions. The overdose intervention training and all education materials will clearly and strongly encourage calling 911 during any suspected overdoses. Emergency medical services are well equipped to handle any withdrawal reactions.

Regulatory Compliance and Safety

Regulatory binder

The regulatory files should contain all required documents, study-specific documents, and all important communications. Regulatory files will be checked for compliance prior to study initiation, throughout the study, as well as at study closure.

Study documentation includes all case report forms, data collection forms, workbooks, source documents, monitoring logs and appointment schedules, sponsor-investigator correspondence, and signed protocol and amendments, or Institutional Review Board correspondence and approved current and previous consent forms and signed participant consent forms.

Source documents include all reports and records necessary for the evaluation and reconstruction of the clinical research study. The original recording of an observation should be retained as the source document. Because direct data entry through the REDCap electronic data capture system will be employed relatively few source documents are anticipated for the collection of primary data.

Data Safety Monitoring Oversight Committee

The Data Safety Monitoring Oversight Committee will have 2-4 representatives who have clinical and research expertise relevant to the study. They are not directly involved in study procedures. They will meet during the period of study planning, one month and 4 months after the study is initiated. The committee will receive reports on the progress of the study prior to the meeting, including the number and characteristics of subjects and those who declined to participate. Any serious adverse events (SAE) will be discussed with the committee to determine if the risks of SAE could be modified by any changes in study procedures. Other reports will be provided as the committee requests. Committee membership will be determined prior to study initiation.

Drug accountability

Study medication will be ordered and prescribed by Kelly-Ross Pharmacy in Seattle. Upon receipt, the investigator is responsible for taking inventory of the investigational agent. A record of this inventory will be kept and usage will be documented. Any unused or expired investigational agent shall be accounted for.

Adverse event reporting

The risks expected from trials employing behavioral interventions are presumed minimal and the medication being prescribed for possible future use is designed to be used to prevent a fatal overdose with side effects being rare. However, given the nature of ongoing drug and/or medication use the population studied in this trial is possibly at risk for an overdose. Adverse events (AEs) will be categorized as serious or non-serious, as related or not related to the study, and as expected or unexpected. An AE is defined as any reaction, side effect, or untoward event that occurs during the course of the clinical trial. Stable chronic conditions, such as substance abuse, which are present prior to clinical trial entry and do not worsen, are not considered AEs. Common, minor ailments and complaints will be excluded from any type of documentation. These may include: colds, flu's, cuts, scrapes, coughs, headaches, stomach complaints, and general fatigue.

Serious adverse events (SAEs) are defined as any fatal event, any immediately life threatening event, any permanent or substantially disabling event, any event that requires or prolongs inpatient hospitalization, congenital anomaly or birth defect, or any event requiring intervention to prevent any of the previously listed serious events. Hospital visits that do not result in admittance are not considered SAE's (e.g. emergency room visit for a non- study-related injury that does not result in admittance). Normal childbirth and pre-planned elective procedures are not considered SAEs. AE/SAE's will be elicited by interventionists/research interviewers at each assessment visit by asking the participants if they have noticed any new problems or existing problems that have gotten worse (using the Adverse Events Worksheet).

Disclosure of an AE/SAE may also occur in an unsolicited manner to a research or clinical staff member. The interviewers should be focused on gathering data to aid in determining study relatedness. Study-relatedness will be determined by the interviewers in consultation with one of

the investigators. All AEs and SAEs will be recorded in the AE/SAE log and entered into the secured project database. AEs that are not study related do not require any further paperwork documentation besides the AE Log. In this study, potential AEs that may be related to the study would be an increase in emotional distress in relation to discussion of past or current drug use behaviors *or side effects of naloxone.*

University of Washington Adverse Events reporting requirements

The term adverse event is generally used to refer to any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research although, on occasion, they can occur in the context of social and behavioral research.

Unanticipated problems, in general, include any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The adverse event report form is to be used to report an adverse event where there is a reasonable probability that the event was attributable to a study procedure. The UW IRB defines reasonable probability as "more likely than not" - that is, there is a greater than 50% likelihood of the event having been caused or partially caused by the research or arising from the circumstances of the research.

Per HSD policy the form is required to be submitted as soon as possible but no later than 10 business days after becoming aware of the event.

Data security

Data will be uploaded to ADAI servers weekly. Only authorized individuals are permitted access to the project database. Data are backed up nightly so there is minimal risk of data loss. Any edits to previously saved data are fully tracked in an electronic audit table and include the date/time stamp

and user ID of the person making the edit. Ongoing data monitoring will be the responsibility of the research coordinator.

Confidentiality

We will obtain a federal Certificate of Confidentiality (CoC), protecting participants against disclosure of sensitive information (e.g., drug use). The Department of Health and Human Services (HHS) office that issues the CoC will be advised of any changes in the CoC application information.

Participant records will be kept confidential by the use of study codes for identifying participants on data collection forms, secure separate storage of any documents that have participant identifiers, and secure computing procedures for entering and transferring electronic data.

Study monitoring

The monitoring of study records will be conducted on a regular basis by the research coordinator. The purpose of these visits is to encourage and assess regulatory compliance and to document the integrity of the trial progress. Monitoring activity will assure that submitted data are accurate and in agreement with source documentation and will also review regulatory/essential documents such as correspondence with the IRB. Areas of particular concern will be participant informed consent, protocol adherence, safety monitoring, IRB reviews and approvals, regulatory documents, participant records, study drug accountability, and principal investigator supervision and involvement in the trial. The research coordinator will ensure that staff are trained and able to conduct the protocol appropriately and that study procedures are properly followed. If additional training of study personnel is needed, project staff will undertake or arrange for that training.

Data monitoring

Study data will be entered by interventionists directly into password protected, study specific laptop computers. Data will be captured using the REDCap electronic data capture system which uses a secure connection to local REDCap servers located at ITHS. Only authorized users will be allowed access to the data entry system and no identifiable data will be entered into REDCap. Research staff will use password protected UW works for data entry.

Data completion will be verified when study interviews are completed. Baseline data and study arm assignment will be captured by secure data servers at ITHS as data are collected in REDCap. Data will be managed by the principal investigator and research coordinator, who will access study data from desktop computers connected via local area network to computer servers that are in a locked room in a locked office suite at the Alcohol and Drug Abuse Institute (ADAI). Similarly, follow-up interview data will be entered directly into password protected, study specific laptop computers using REDCap, with data uploaded to servers at ADAI weekly.

Health services and cost data will be obtained, cleaned and made into analytic data sets by Dr. Sears. Data will be transferred securely and stored on ADAI servers which are backed up nightly. The research coordinator will be responsible for the integrity of all study data and will prepare

regular reports for the 3-person data and safety monitoring oversight committee which will review any adverse events as well as monitor study progress to ensure that study results are scientifically valid.

The research coordinator for the study will conduct software programming and data management activities. Data will be stored on computer servers at ADAI that are fully HIPAA-compliant in accordance with the University of Washington School of Medicine. The senior computer specialist at ADAI maintains nightly tape backups and active disaster recovery protection and procedures. The research coordinator will develop data collection forms used by research staff. These forms will also have a companion data dictionary which comprehensively defines each data element. The data dictionary specifies missing, illogical, out of range, and inconsistent value checks for each data element, in addition to logic checks and assists the project data analysis.

Intervention fidelity monitoring

The primary threat to the integrity of the intervention is that the intervention may not be delivered as intended. This potential problem is minimized because the intervention is highly structured and intervention fidelity will be regularly monitored by co-investigators who will monitor audio recordings of intervention sessions after the interventionist has initially been approved to conduct interventions without supervision.

Data Analysis Plan

Analyses will allow us to evaluate the aims of this study: 1) whether study procedures can be implemented with fidelity, 2) whether offenders can be enrolled and maintained in the study, 3) which medications/treatment options subjects select and their experiences and satisfaction with the interventions and 4) preliminary intervention effect size on outcomes of interest including recidivism, drug use, hospitalization, and treatment enrollment and retention. The number of subjects is not intended to be adequate to test the impact of the intervention, but rather to provide sufficient numbers of subjects to assess the feasibility of both research study procedures and intervention components.

The number and proportion of subjects retained at each step of the study will be documented and reported in a CONSRT diagram similar to the one in the Appendix for our current RCT. Baseline characteristics will be compared for each study arm to ensure randomization was properly implemented. Bi-variate test statistics of differences in outcomes of interest will be compared by study arm and reported for all outcomes. Study analyses will begin *prior* to study completion due to the fact that this is a pilot-feasibility trial and data will be used to determine if a full randomized trial is appropriate and what modifications to the study design are needed, this is different than procedures for a full RCT where analyses would await and complete, closed dataset. Data will be used to determine the possible treatment effect sizes which will allow sample size estimates to be calculated for a future full scale randomized controlled trial.

Equitable access to care and outcomes will be examined (Beletsky et al., 2015) by comparing the characteristics of the eligible pool of offenders with those screened, enrolled, and maintained throughout the study.

Appendix A: Treatment Decision Making Aid: Semi-Structured Intervention Guide

Helping you decide what works best for you

Treatment Decision Making

Introduction

I'd like to share with you some information about treatment options and support you in making a decision about what types of treatments you would like to try. This will involve:

1. describing what opiate use disorder is
2. compare treatment options
3. asking you some questions about your preferences for treatment
4. providing you feedback about the tradeoffs, pluses and minuses, of treatment options you are interested in
5. if you are interested in treatment we'll work on a plan to get you started including finding a treatment provider if you are interested in a medication

After today, I will continue to be available to work with you for six months to talk through how treatment is going, if you'd like to try a different type of treatment, and help you get back on treatment if you stop.

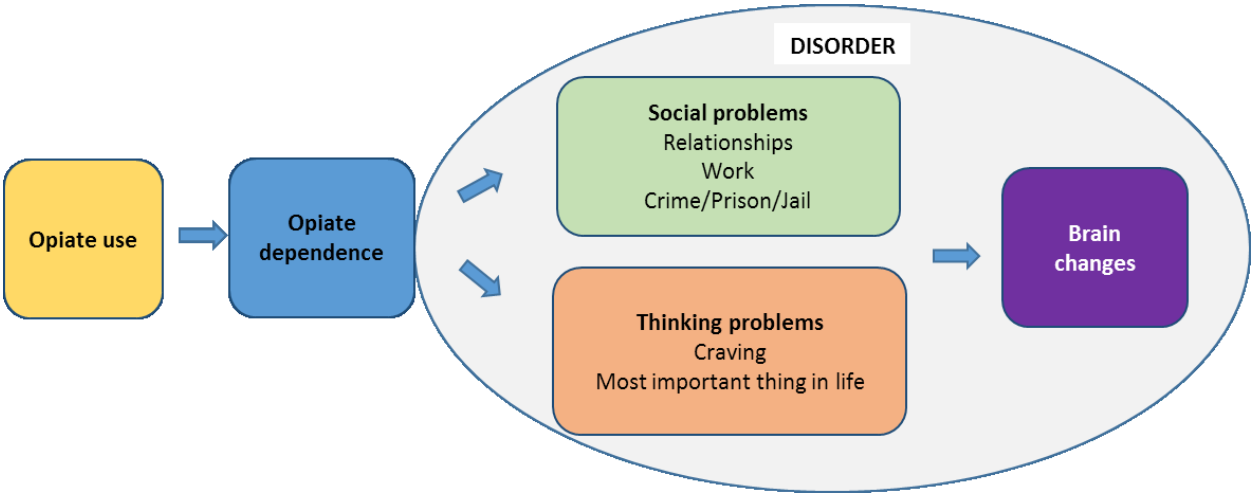
Treating opiate use disorder is like treating other health conditions. Often different treatments need to be tried until the one that works best if found.

1. What is opiate use disorder?

To understand opiate use disorder, it is helpful to look at the difference between physical dependence on opiates and opiate use disorder:

Opiate dependence: A physical condition in which the body gets used to the amount of opiates taken. This happens whether a person take pain pills like Vicodin, Percocet or OxyContin or heroin. The body adapts by needing more opiates to feel the same effect (tolerance) and feeling terrible (withdrawal) when opiates are reduced or removed. This is normal and happens to anyone who takes opiates for awhile.

Opiate use disorder is the current medical term used to describe what has been commonly known as addiction. Opiate use disorder involves being 1) physically dependent on opiates as well as negative impacts on a 2) person's thinking, and 3) relationships and ability to function. Opiate use disorder is considered to be a chronic, relapsing medical condition, meaning it lasts a long time and can keep coming back, much like diabetes and high blood pressure. It can also be managed very well with medication and supportive services. A person can be on treatment medications and be in recovery.



Why might opiate use disorder be relevant to you?

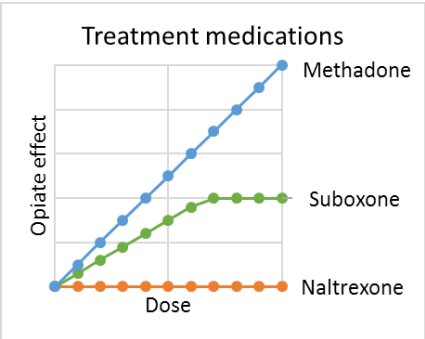
People releasing from prison or jail are at very high risk for using opiates again as well as fatal overdose. If not treated opiate use disorder can cause great physical, social and psychological harm- both to the person with the disorder and others in their life. People with opiate use disorder are at increased risk for HIV, hepatitis, other serious health problems, and dying from an overdose.

2.What are treatments for opiate use disorder?

Three types of treatments may be combined, or you may choose to do nothing at this point.

- **Watchful waiting**, do nothing right now, but observe how you are feeling and what you are doing. Notice if you are having cravings or start using opiates or other drugs or alcohol.

1. **Social support** such as organized groups like narcotics anonymous or smart recovery. Joining another social support group run by peers for other things impacting your life like chronic pain.
2. **Professional counseling**. Getting one on one counseling from a social worker, therapist, or chemical dependency professional.
3. **Treatment medications** including methadone, buprenorphine/Suboxone, or long-acting-naltrexone/Vivitrol.
    - **Methadone** is an opiate medication that lasts approximately 24 hours and that is taken by mouth. It is dispensed at a methadone clinic (also called an opiate treatment program). At these programs most days you will be observed while you take your dose. You will also have regular urine drug testing as well as counseling. Methadone is a full opiate meaning that the more you take the more you will feel it.
    - **Buprenorphine** is an opiate medication that you take orally that lasts approximately 24 hours. It has a partial opiate effect. You can get is at different settings. A common brand name is **Suboxone.**
        - You could get it at an opiate treatment program where most days you will be observed while you take your dose. You will also have regular urine drug testing as well as counseling.
        - You could get it prescribed to you by a doctor and pick it up at a pharmacy. Typically you would start with a prescription for a few days, then you might get weekly prescriptions for a while, and eventually you could get a 30 day prescription. Most will do some urine drug testing and some also include counseling supports as part of their care.
    - **Naltrexone** is an opiate blocker. It is typically given as a shot/injection that lasts 30 days and this form of the drug is called **Vivitrol**. It is not an opiate. It has to be prescribed by a medical provider who may offer other services as well including counseling and may require urine drug testing.



What is the evidence for the medications?

Methadone and buprenorphine have been shown to cut peoples' chances of dying by 50%. They have been very well studied and are very effective when taken as directed, they are opiate medications.

Naltrexone is a newer medication and we don't have good data on how it impacts the risk for fatal overdoses; however it is protective against overdose during the 30 days the medication is active in the body. After it wears off a person's overdose risk if very high because the body has a lower tolerance to opiates.

While some people with opiate use disorders are able to abstain from problem opiate use on their own or by entering a treatment program that does not include treatment medications, the scientific data overwhelmingly supports medications as the most effective way of avoiding relapse and supporting long term recovery for most people.

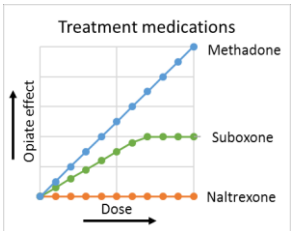
3. Which treatment is right for me?

It is important that a person with opiate use disorder understand the pros and cons of different treatment options, including the role of medications.

**** Now I'm going to ask you a few questions about what you prefer related to treatment.

4. Compare Options

The right choice for people may change over time. This decision aid aims to help you make the right choice for right now, but you may want to change their mind as your use, cravings, or life changes. The ultimate decision about what treatment options you will be able to use, and exactly how, will be made between you and the treatment providers. What options are you interested in?

	Watchful waiting	Social support	Counseling	Vivitrol Naltrexone	Methadone	Suboxone Buprenorphine
How will I feel 				Blocks opiates. May not feel anything.	Helps with cravings & withdrawal	Helps with cravings & withdrawal
How I will take it				Injection	Mouth	Mouth
Overdose risk	↑↑	↑↑	↑↑	↓	↓↓	↓↓
How often I have to go to clinic/pharmacy				Monthly	6x week OTP	6x week OTP ~Weekly @ pharmacy
How often do I take it				Monthly	Daily	Daily
Convenience Transportation Time						
Cost/Medicaid?						
Housing Relationships Supportive of choice?						

5. **Make a decision**

What treatment options sound good for you?

Let's make a plan to help you get you started.

Beletsky, L., Lasalle, L., Newman, M., Tochka, A., 2015. Prisoners ' Rights in the Modern Era Individuals Newly Released from Incarceration 7.

Binswanger, I.A., Blatchford, P.J., Mueller, S.R., Stern, M.F., 2013. Mortality after prison release: opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. Ann. Intern. Med. 159, 592–600. doi:10.7326/0003-4819-159-9-201311050-00005

Clark, R.E., Samnaliev, M., Baxter, J.D., Leung, G.Y., 2011. The Evidence Doesn't Justify Steps By State Medicaid Programs To Restrict Opioid Addiction Treatment With Buprenorphine. Health Aff. 30, 1425–1433. doi:10.1377/hlthaff.2010.0532

Fox, A.D., Maradiaga, J., Weiss, L., Sanchez, J., Starrels, J.L., Cunningham, C.O., 2015. Release from incarceration, relapse to opioid use and the potential for buprenorphine maintenance treatment: a qualitative study of the perceptions of former inmates with opioid use disorder. Addict. Sci. Clin. Pract. 10, 2. doi:10.1186/s13722-014-0023-0

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