**Cover Page**

**Study Title**

**"Implementation of a Shared Decision-Making Aid for Reducing Stigma against Drug Use and HIV Harm Reduction in a Rural Setting"**

Identifiers: NCT05352412

Unique Protocol ID: 202107155

Date: March 25, 2022

**Study Protocol**

**Project Title:**

Implementation of a Shared Decision-Making Aid for Reducing Stigma against Drug Use and Harm Reduction in a Rural Setting

**Select how you plan to obtain consent:**

- Let er or information sheet with no signature
- Script for use either in person or over the phone with no signature

**Summary:**

Patients who inject drugs are at high risk for invasive bacterial and fungal infections related to contaminated needles. These patients should be treated with a combination of antibiotics and addiction treatment. Our team has demonstrated that medications for opioid use disorder (MOUDS; e.g., methadone, suboxone), improve patient outcomes. However, there is substantial stigma associated with these medications. Both patients and healthcare providers view them as drugs for "addicts." The goal of this proposal is to determine if a shared decision aid to help patients select the most appropriate MOUD will reduce internal stigma by the patient (reluctance to start on MOUDs) and stigma from the healthcare provider to offer a prescription for MOUDs. We propose to use serial stigma survey assessments before, directly after, and weeks after use of the tool.

**Specify your research question(s), study aims or hypotheses:**

We hypothesize that the use of the tool will reduce healthcare and patient stigma about use of MOUDs.

**Background and significance and/or Preliminary studies related to this project:**

In the past decade, the US opioid crisis has emerged as a leading cause of death among adults. It has also led to an increase in invasive bacterial and fungal infections; and HIV and HCV outbreaks in multiple regions. Rural communities have had an especially disproportionate burden from the impact of opioid use disorder (OUD). Treatment of OUD with pharmacotherapy is one of the most effective strategies for reducing OUD related mortality and morbidity. But while there has been increasing will for expanding pharmacotherapy, stigma – from community, providers and patients—remains a significant barrier to uptake pharmacotherapy and harm reduction. The approach to substance use has historically favored abstinence strategies that are often without evidence, influenced by punitive, stigmatizing framework. This stigma may be even more prevalent in rural communities. To date there have been very few effective interventions to address inter- and intrapersonal stigma, and none with sustained effectiveness.

**Describe EACH of your participant populations**

We will have 2 patient populations.

1) Healthcare providers.

Inclusion criteria:

-physician, nurse practitioner, or physician assistant with a DEA X waiver to prescribe MOUDs

-provides care to patients at Barnes-Jewish Hospital

-must be able to complete electronic survey writ en in English

2) Patient inclusion criteria

-patient from a rural community currently admit ed or recently admit ed to Barnes-Jewish Hospital

-Admission must be for an infection associated with intravenous drug use

-Patient must be willing to speak with healthcare provider about MOUDs

-patient must be over 18 years old

-must be able to complete electronic survey writ en in English

**Describe where the consent discussion will occur (check all that apply):**

- Private room or area
- By phone

**Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):**

- As much time as they desire to consider enrolling in the study, including:

**An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate**

- Sufficient time to have all of their questions answered

### Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

Study population: We will have 2 study populations. Patients who receive MOUDs and healthcare providers who prescribe MOUDs. These populations will be randomized to either receipt or no receipt of the shared decision tool.

Recruitment: We will send an email to healthcare providers who prescribe MOUDs in the hospital. This will likely include addiction medicine services, internists, emergency medicine providers, psychiatrists, and infectious diseases physicians. We will send the email to people in these divisions. We will also notify staff in the Washington University Bridge to Health Program via email. These individuals include a case manager and 2 health coaches who care for persons who inject drugs as part of a quality improvement project. If these individuals identify a suitable candidate, they will contact our study coordinator or the PI that it is acceptable to approach the healthcare provider and/or patient for study recruitment. The study coordinator will discuss the study either in person or over the phone with the healthcare provider and in person with the patient. The study coordinator will discuss the risks and benefits of enrolling in the study and consent the patient.

Time to consider participation: patients and healthcare providers will have as much time as they need to consider participation. However, ideally, they should start this intervention prior to initiating a MOUD in the hospital.

Minimize coercion: our study coordinator is a trained staff therapist who will inform the participant that the study is completely voluntary and participation will not impact clinical care.

**Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.**

This decision aid is a web-based survey that is presented on a tablet. It includes five sections: (D1) Provide an overview of both the disease and treatment. (D2) Assess the patient's eligibility for pharmacotherapy. (D3) Compare the current medication options (methadone, buprenorphine, and long-acting naltrexone), examining demand characteristics, such as side effects, route of administration, and cost. (D4) Describe expectations for treatment duration and effects if the medication is self-discontinued. (D5) Complete a brief values clarification exercise.

After Alpha and beta testing are completed in Aim 1 of this project: After the patient meets with a member of the Bridge To Health team, they will be referred to a member of the research team. The research team member will approach the patient and their provider of medication-assisted treatment once the patient has been stabilized to determine the patient's interest in treatment for their opioid use disorder, but prior to discharge from the hospital. This will usually occur within 2 weeks of the patient being discharged from the hospital. If a patient is interested in participating, consent will be obtained from the patient and their healthcare provider will be approached for consent as well. Once consent from both parties, patient and provider, is obtained the patient will be randomized to either receive the shared decision aid or standard of care. If randomized to receive the shared decision aid, the patient and provider will take the survey on separate devices but at the same time. The decision aid survey integrates a values clarification exercise and summarizes patient concerns/preferences to guide shared decision-making with clinicians. We will measure stigma and other outcomes prior to discharge, 2 weeks post-discharge, and 3 months post-discharge to assess the feasibility and preliminary effectiveness of the decision aid. If the patient is not randomized to receive the decision aid tool, they will complete the survey and receive standard of care. We will measure stigma and other outcomes prior to discharge, 2 weeks post-discharge, and 3 months post-discharge to assess the feasibility and preliminary effectiveness of standard of care.

We will implement a method to create a unique patient ID code to link participant data and information to rather than their name, and that the study team will not collect or record any identifiable health information in order to protect participants' confidentiality

**What have you done to minimize any risks?**

- Adverse event monitoring

**What are the potential benefits related to this project for:**

The patient will have more input on what type of MOUD they will receive. This might increase adherence.

The tool may help reduce stigma and improve long-term MOUD acceptance, which will reduce overdose rates among persons who inject drugs.

**Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.**

We will use likert scale questions to assess stigma immediately before and after the survey. We will also measure long-term stigma changes compared to baseline at 2 weeks and 3 months. These results will be compared to the baseline testing results in a paired manner. We will use non-parametric tests to evaluate for statistical significance. We will also compare overall response rates between those who did vs. did not receive the clinical decision tool.

**Provide the rationale or power analysis to support the number of participants proposed to complete this study.**

This is a pilot study. No power analyses needed.

**Participants**

18 years old. No age limit. We will not recruit non-English speaking people. Must have diagnosis of opioid use disorder and come from a rural location.

**Sites:**

Barnes-Jewish Hospital

**Privacy and Confidentiality:**

Only minimum necessary information to be collected. Recruit in a private setting when possible. Materials will be stored in a secured environment and team members will be the only ones with access.