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Use of a Decision Aid in Medication Initiation Among Patients with Opioid Use Disorder and HIV

Katrina Gateley
Yale Physician Associate Program, katrina.gateley@yale.edu

USE OF A DECISION AID IN MEDICATION INITIATION AMONG PATIENTS WITH OPIOID USE DISORDER AND HIV

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Katrina Gateley, PA-SIII
Class of 2023
Yale Physician Associate Program

Jaimie Meyer, MD, MS, FACP
Associate Professor
Yale School of Medicine

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ABSTRACT

Opioid use disorder refers to the maladaptive use of prescribed or illicit opioids. This condition can be treated using pharmacotherapy referred to as medications for opioid use disorder (MOUD), but they are underutilized. Opioid use disorder is more prevalent among people living with HIV (PLH), highlighting a target population for interventions to increase treatment. Patient decision aids have been successful in affecting decision-making in other populations. However, no decision aid for medication for opioid use disorder has been utilized among patients with comorbid HIV and OUD. In this randomized cluster trial, we will determine whether a patient decision aid affects decisional preference to initiate medication for opioid use disorder among patients with HIV and opioid use disorder who are receiving care at HIV clinics across Connecticut. This intervention will provide insight into whether decision aids could facilitate integrated treatment of OUD for PLH in HIV clinics.

CHAPTER 1: INTRODUCTION

1.1 Background

The U.S. opioid epidemic has gained national attention in recent years, generating various efforts to combat the use of opioids and to implement strategies to treat opioid use disorder (OUD). According to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders, OUD can be defined as "the maladaptive use of opioids, prescribed or illicit, resulting in two or more criteria that reflect impaired health or function over a 12-month period."[1] The Center for Disease Control (CDC) reports drug overdose deaths rose 30% from 2019 to 2020 and 15% from 2020 to 2021,[2] with the majority of these deaths attributed to opioids.[3]

Rapid rise in fatal opioid overdoses has resulted in increased attention to overdose prevention. Evidence-based prevention strategies for overdose include antidotes/reversal medications (naloxone) and the use of pharmacotherapy as a treatment for OUD, often referred to as Medication for Opioid Use Disorder (MOUD). These medications reduce withdrawal symptoms and opioid cravings while altering response to future drug opioid exposure.[4] Additionally, evidence demonstrates long-term use of MOUD can reduce overdose death risk from 66-80%.[5] MOUD include methadone, which has been used since the 1960s, and buprenorphine, which was approved by the United States FDA in 2002.[4] Methadone is a long-acting opioid agonist used for MOUD. It must initially be taken daily under the supervision of a practitioner at a specially-licensed facility, and may eventually be taken at home after a period of stability.[6] Buprenorphine, a partial opioid agonist, has a more favorable safety profile than methadone, as risks including euphoria or respiratory depression are weaker than those of full-opioid agonists.[6] Buprenorphine

can be dispensed by any provider with a DEA license, as the previously required 'X-waiver' was eliminated in 2023. Naltrexone is an additional option used for both alcohol use disorder (AUD) and OUD. It is available in a monthly injectable form and as a daily oral medication, and though it is not an opioid, it binds/blocks opioid receptors and reduces opioid cravings.[6]

A metanalysis of 19 cohort studies suggests that use of both methadone and buprenorphine for OUD contributes to a decrease in mortality rate among patients[7], and several other studies conclude that these medications, in addition to extended-release naltrexone, can facilitate recovery from OUD.[8] In a randomized controlled trial comparing a monthly injection of extended-release naltrexone to daily sublingual buprenorphine-naloxone, naltrexone was found to be more difficult to initiate in patients.[9] However, among patients successfully inducted with either medication, there was no significant difference in the primary outcome of opioid relapse-free survival over 24 weeks.[9] Existing data supporting the efficacy of various MOUD options demonstrates that medication choice should be tailored to each individual patient rather than centered on the idea that one medication is superior to others.

1.2 Statement of the Problem

Despite the availability of a valid treatment option for patients with OUD, the majority of people who could benefit from treatment are not receiving any. According to one study, less than 30% of people who needed OUD treatment received MOUD.[10] This public health issue has prompted researchers to examine barriers that may exist for patients or providers receiving and prescribing MOUD. One problem patients experience is limited access to treatment for OUD. As of 2016, only 36% of substance-use treatment

facilities offered outpatient MOUD.[11] Furthermore, only 6.1% of facilities offered all three medications listed above.[11] Patients are likely unaware of the options that exist for the treatment of OUD, especially if the facility they are connected with only presents them with one choice or requires inpatient treatment.

Another barrier related to MOUD is the need for daily dosing of most medications. Some patients may feel overwhelmed by taking a medication every day, especially if they are already on medications for other conditions. However, advances such as extended-release naltrexone (XR-NTX), a once-monthly buprenorphine injection called Sublocade, and an implantable buprenorphine product called Probuphine eliminate the need for daily dosing.[4] Brixadi, a weekly or monthly subcutaneous injectable form of buprenorphine available at lower doses than Sublocade, was approved by the FDA in May of 2023.[12] Though availability of these medications may be scarce, it is still important to educate patients on the options that do exist so they can make an informed decision about their care. These medications will likely become more widely available over time, so there is value in developing a framework for patient education and decision-making despite current limited availability. Further, providers may be more likely to prescribe these medications if they are familiar with them.

Integrating MOUD into other healthcare settings is an evidence-based strategy that has benefits for both patients and providers.[13,14] This may be targeted at primary care settings, or toward outpatient specialties. A target population for OUD screening is among PLH, as these two conditions are often co-occurring. One report stated that the HIV prevalence among people who inject drugs (PWID) in the U.S. was 16%.[15] PWID primarily inject opioids, making this a vulnerable population for both OUD and HIV.[16]

Another study indicated that illicit drug use among patients with HIV may be as high as 40%.[17] Data demonstrates that PLH are more likely to be prescribed opioids than the general population.[18] Though these prescriptions may be prescribed for medical reasons, including chronic pain, this increases the risk for development of substance misuse or OUD.[18] The overlap between patients who have OUD and PLH presents an opportunity to improve continuity of care, as it can be difficult to schedule and attend appointments in multiple locations and at different times.

A retrospective analysis conducted in Germany found that rates of comorbidity and economic burden were higher in PLH.[19] As comorbidities increase, and because care is often siloed, patients are forced to find time for multiple healthcare appointments at separate offices, increasing their care burden. The burden of having several appointments may be lessened by receiving care for treatment of OUD and HIV by a single provider. Combating OUD in the HIV population is also important for the prevention of Hepatitis C,[1] as 20-30% of PLH and 60-90% of people who use drugs (PWUD) are coinfected with HCV in the United States.[20]

A systematic review found that not only is integration of care for HIV and OUD possible, it is also viewed favorably by patients.[21] Patients likely feel more supported and understood by their provider if treatment is provided for their diagnoses of both HIV and OUD. Quantitatively, integrating care for these groups has been shown to increase the percent of patients on anti-retroviral therapy (ART) for HIV. Hassan et al. found that integrating ART into an opioid treatment program increased percentage of patients with HIV on medication by 28%.[22] Based on a systematic literature review published in 2012, the International Association for Physicians in AIDS Care (IAPAC) developed guidelines

for entry into and adherence to ART.[23] They recommend offering buprenorphine or methadone to patients who have HIV and OUD, as these medications improve ART adherence.[23] Opportunity to integrate care has recently been strengthened by the elimination of the X-waiver requirement for prescribing buprenorphine, allowing all health care providers with a DEA waiver to prescribe.[24]

1.3 Goals and Objectives

Future directions for OUD treatment should focus on patient-centered care (PCC). PCC includes the principles of holistic and individualized focus to care, shared decision-making, and enhanced therapeutic alliance.[25] A scoping review examining PCC for substance use disorder (SUD) concluded that, to increase shared decision-making (SDM) for SUD, more evidence is needed to illustrate its effectiveness in practice.[25] SDM has been defined as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options to achieve informed preferences."[26] Integrating SUD care into other healthcare settings such as HIV clinics is a critical step, but at a more individualized level, it is important to ensure that patients are presented with all options for MOUD and that they understand the implications of each medication. This practice supports patient autonomy, and helps foster a trusted patient-provider relationship.

A strategy for improving SDM in OUD is through the use of a patient decision aid. Patient decision aids are "evidenced-based tools designed to help patients make specific and deliberated choices among healthcare options."[27] These tools are meant to supplement counseling by healthcare providers, as they provide information about treatment options and their associated relevant outcomes.[28] Though patient decision aids

align with the principle of SDM, having a defined protocol to discuss options with patients will likely increase SDM practice and allow patients to further engage in conversation with their healthcare provider. A scoping review examining SDM in treatment for OUD concluded that providing adults with OUD treatment options/choices may improve outcomes such as substance use, retention in treatment, quality of life, arrest rates, and satisfaction with care.[29] Decision aids have shown promising results in other realms of medicine. One study concluded that the use of a decision aid for patients with obstructive sleep apnea (OSA) reduced decisional conflict, improved preparation for decision-making, and increased participants' OSA knowledge.[30] From a more focused perspective, another study found that the use of a decision aid for PrEP for women with SUD increased interest in and initiation of medication.[31]

The main goal for the proposed study is to determine the efficacy of a patient decision aid in initiating MOUD among patients living with HIV. Secondary goals include decreasing appointment burden for patients, increasing patient satisfaction, and improving SDM practices.

1.4 Hypothesis

By providing patients 18 years or older at an HIV clinic who have a concurrent diagnosis of OUD with a decision aid for MOUD, it is hypothesized that a higher proportion of patients will indicate decisional preference to initiate pharmacotherapy than those who are met with traditional SDM practices.

1.5 Definitions/Abbreviations

- Opioid Use Disorder (OUD): The maladaptive use of opioids, prescribed or illicit, resulting in two or more criteria that reflect impaired health or function over a 12-month period**.**
- Medications for Opioid Use Disorder (MOUD): Pharmacotherapy used to treat opioid use disorder with the goal of decreasing the use of opioids and mortality associated with their use.
- Patient Decision Aid: evidenced-based tools designed to help patients make specific and deliberated choices among healthcare options
- Antiretroviral Therapy (ART): Treatment of people infected with human immunodeficiency virus (HIV) using anti-HIV drugs.
- Pre-exposure Prophylaxis (PrEP): The use of antiviral medications to prevent the spread of HIV in people who have not yet been exposed to it.

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CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Introduction

The literature review for the present study was conducted with initial review in July 2022 and completion in July 2023 using PubMed, Cochrane and Scopus. In addition to the database search, bibliographies of relevant journals were utilized. A combination of the terms “Medication for Opioid Use Disorder”, “MOUD”, “Medication Assisted Treatment”, “MAT”, “Opioid Use Disorder”, “OUD”, “Patient Decision Aid”, “HIV”, and “Shared Decision Making” were used in primary searches. Articles were screened and analyzed for relevance to the proposed study. Though several articles focusing on some combination of these topics were identified, a gap exists related to patient decision aids for MOUD. Several articles were identified to support a focus on patients with HIV and OUD.

2.2 Review of Empirical Studies About the Relationship Being Studied

2.2.1 Integrated Care for HIV and Opioid Use Disorder

The integration of care for patients with HIV and OUD is a pressing opportunity to improve health outcomes and decrease healthcare burden for patients. These groups represent an important overlap in medicine, as PLH are more likely to have OUD than other populations, and PWID have an increased risk of HIV infection.[1,2] Additionally, evidence demonstrates that OUD can negatively impact HIV care and prognosis. In one study, researchers found that the risk of opportunistic infection was higher for people who actively used cocaine or heroin (OR 1.9, 95% CI: 1.4 to 2.9).[3] Another group concluded that current heroin use was associated with 53% lower CD4 lymphocyte counts.[4] A more recent study demonstrated that fentanyl can promote HIV replication in

vitro, highlighting a need for additional research toward optimizing treatment for PLH and OUD.[5] Despite evidence showing a positive impact of MOUD on ART uptake and adherence, patients report a lack of integrated care (i.e., siloed).[6-8] In a cross-sectional study surveying adults receiving care at HIV primary care sites, less than half of patients who reported substance use had discussed substance use issues with their providers, and less than a quarter were receiving substance use treatment.[9]

Recommendations to integrate treatment of HIV and OUD have been present for several years. An article published in the *Clinical Infectious Diseases* Journal in 2006 discussed the importance of bridging the fields of addiction medicine and infectious diseases with support from the Forum for Collaborative HIV Research, the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, and the Centers for Disease Control and Prevention.[10] Studies have explored options for integration of these fields, but opportunity for improvement remains, particularly in the primary care setting, as several models have been implemented in specialty care settings.[11]

A systematic review aimed to identify optimal strategies for integrating HIV and OUD screening and treatment.[12] Of the twenty-nine articles included in the review, only six were in HIV care settings. As part of the Buprenorphine HIV Evaluation and Support (BHIVES) Collaborative, a prospective study conducted by Fiellin et al. found that among patients with HIV and OUD taking buprenorphine/naloxone, illicit opioid use was 52% less likely for each quarter in MOUD treatment (OR 0.66, 95% CI: 0.61 to 0.72).[13] A similar study concluded that initiating buprenorphine/naloxone resulted in a higher likelihood of initiating or remaining on ART and improving CD4 counts over time.[14]

Patients with HIV and OUD who receive MOUD may also have improved health-related quality of life.[15] Two studies assessed the effect of nurse-led adjunctive counseling in addition to buprenorphine/naloxone on HIV-related and OUD-related outcomes, with neither finding significant effects.[16,17] Each of these studies illustrate the feasibility and potentially positive outcomes of integrating HIV and OUD care. They also highlight a gap in the literature, justifying the need for studies evaluating decision-making interventions to support MOUD engagement.

2.2.2 Shared Decision-Making and Opioid Use Disorder

Shared decision-making (SDM) is a concept backed by decades of literature and has proven to have positive effects on patient care. Dozens of randomized trials have demonstrated SDM is associated with knowledge gain by patients, more confidence in decisions, and more active patient involvement.[18] Elwyn et al. developed a three-step model for conducting SDM to provide clinicians with a practical guide for implementing the concept into their work. The steps include *choice talk,* in which patients are provided with reasonable available options, *option talk,* where more detailed information is provided about the options and *decision talk,* in which clinicians support the work of considering preferences and deciding what is best.[18] These tenants can be implemented into the treatment of OUD, as there are several MOUD options available with necessary details to be explained along with each medication choice.

Further research is necessary to determine effects of SDM on clinical outcomes for patients with substance use disorders. A scoping review examining the use of SDM for OUD suggests that more evidence is needed to determine its effects on health outcomes. Quantitative studies included in the review demonstrated that providing

patients with OUD treatment options or enabling involvement in decision-making may decrease substance use and improve retention in treatment, quality of life, arrest rates, and satisfaction with care.[19] However, the review concludes that evidence for SDM in OUD is lacking in breadth, depth, and quality. A systematic literature review examined patient preferences and SDM in the treatment of substance use disorders. Two studies included in the review examined patient preference for SDM, with both concluding that participants preferred to be actively involved with decisions surrounding their substance use disorder management.[20] The authors of the review articulated the heterogeneity of the studies was a limiting factor in making conclusions, and encouraged further research in the field. The proposed study will aim to expand on this evidence, demonstrating the effectiveness of a decision-aid at increasing initiation of MOUD.

Future efforts to expand on SDM should consider the importance of patient viewpoints. Patient perspectives were gathered in a study examining the initiation of MOUD in the emergency department.[21] Patients believed that both buprenorphine and methadone should be offered, that clinicians should understand the features of each option and appear nonjudgmental, and that though many patients may not be interested in MOUD, it should still be offered. Finally, they explained that treatment should be tailored to an individual's needs and circumstances. Another study explored psychosocial support during office-based buprenorphine treatment through patient focus groups. Patients valued care delivery models that were patient-centered, created a space for self-disclosure, and utilized coordinated team-based care.[22]

2.2.3 Utility of Patient Decision Aids for SDM

Decision aids have been established in the literature for decades, with the International Patient Decision Aid Standards concluding that these tools "should present information in a balanced manner, utilize a systematic development process, use scientific evidence that is cited and referenced, and use plain language."[23] A systematic review examining the use of decision aids for health treatment or screening decisions concluded that these tools increased patients' knowledge, accuracy of risk perceptions, and congruency between informed values and care choices compared to usual care.[24,25]

Patient decision aids have been used in both inpatient and outpatient settings, with several studies demonstrating efficacy in the primary care setting.[26] A randomized controlled trial was conducted in Spain to assess the effectiveness of a decision aid developed to promote colorectal cancer screening. Results showed decreased decisional conflict and increased knowledge. The absolute differences favoring the decision aid group in intention to undergo fecal occult blood test (10.5%) and colonoscopy (13.7%) were significant before correcting for attenuation.[27] Health screening decisions represent an important area of patient decision-making, and they have been assessed using patient decision aids in the literature. Reduction in prostate cancer screening was greater in an intervention group assigned to a decision aid than in the control group ($p = 0.047$), which may align with evidence supporting more conservative screening choices for the disease.[28] Another study concluded that a decision aid for breast cancer screening resulted in reduced decisional conflict for women considering screening ($p < 0.001$).[29] Changes in screening decisions were not statistically significant, though 19% of women represented this group.

Two studies with populations similar to that of the proposed study have shown promising results with the use of patient decision aids. Meyer et al. conducted a randomized preference trial using a patient decision aid for HIV pre-exposure prophylaxis (PrEP) for women with substance use disorders, 92% of whom had opioid use disorder. Women who opted to receive the decision aid had a higher interest in PrEP compared to those who received enhanced standard of care (89% vs 25%). They were also more likely to see a provider for PrEP during follow-up (15.7% vs 6.2%). Mooney et al. conducted a case-control study in which a patient decision aid for MOUD was pilot tested with patients entering OUD treatment. Though the sample size was not large enough to detect significant differences, more patients who used the decision aid started MOUD than matched controls (37% vs 11%).[23]

2.3 Review of Relevant Methodology

2.3.1 Patient Decision Aid Intervention and Control

Patient decision aids have been well established in the literature, though most have been operationalized in populations without HIV or OUD. A randomized controlled trial investigating the efficacy of a patient decision aid for treatment options for obstructive sleep apnea (OSA) found that patient decision aids promote patient-centered decision-making.[30] Outcomes were based on a decisional conflict scale, preparation for decision-making, and knowledge of OSA. Each of these categories were measured on a 0-100 scale, with 0 = low conflict and 100 = high conflict. The decision aid was delivered via a virtual web coach along with a patient workbook in which patients were able to explore treatment options, determine what mattered most to them in their treatment decisions, and reflect on their support in relation to their treatment decisions.

A randomized controlled trial used a patient decision aid to examine its effect on decisional conflict in women presenting for management of pelvic organ prolapse (POP). Women were randomized into either the standard counseling group or the standard counseling plus a decision aid group. Standard counseling was described as an average 30-minute appointment, in which surgical and nonsurgical options are discussed and pamphlets on POP are routinely reviewed. The decision aid defines POP, provides details on surgical and nonsurgical options for treatment, describes risks associated with surgery, discusses postoperative expectations, and includes testimonials from women who have chosen each option in the past.[31]

Using a randomized preference trial, Meyer et. al examined preference for and efficacy of a PrEP decision aid for women with substance use disorders.[32] The decision aid included potential pros and cons of using PrEP, its efficacy, cost, side effects, medication interactions, insurance coverage and need for disclosure to partners. For the control group in the study, women who preferred no further information on PrEP were provided with enhanced standard of care, which "involved providing a phone number and website for more information about HIV prevention and where PrEP could be accessed, without any additional personalized assessment or coaching."

Mooney et. al conducted a randomized controlled trial to study the use of a patient decision aid for MOUD in California. The aim of the study was to "develop and test a decision aid that assists individuals with OUD in making informed decisions about medication treatment at the time of initial clinical visit."[23] The first phase of the study was dedicated to development of the decision aid while the second phase examined the effect of the tool on medication uptake and adherence, as well as future events found in

death records and criminal justice encounters. The decision aid includes descriptions of OUD, consequences of untreated OUD, a description of medications approved for OUD and their formulations, evidence for positive outcomes of MOUD, patient values and myths surrounding MOUD and guidance on communicating with providers.[23] The control group for the study was constructed using clinical data sets from the same facility and treatment time period, matching based on primary substance of treatment, gender, race, ethnicity, age and treatment modality.

Guille et al. developed a decision-making tool for the treatment of perinatal opioid use disorder and assessed the tool's adherence to International Patient Decision Aid Standards through a cohort study.[33] Pregnant women with OUD engaged in shared decision-making with their healthcare provider through the use of the decision aid to decide whether to continue or taper their MOUD treatment during pregnancy. After their appointment, patients completed a survey to provide feedback about the decision aid. A secondary outcome was the choice to continue or taper their methadone or buprenorphine.

2.3.2 Cluster Randomization and the Use of Patient Decision Aids

Patient decision aids are sometimes tested in randomized cluster trials in an effort to avoid contamination. In a traditional randomized controlled trial, the intervention may be physically present across the entire study population, which creates the potential for members of the control arm to receive the intervention. In contrast, randomized cluster trials allow for entire clinics to be free of the intervention and are most acceptable when educational interventions such as decision aids are utilized.[34] In a cluster randomized trial using a decision aid for antidepressants in primary care, clinicians in the intervention

group were instructed to use the decision aid in conversations with patients, while clinicians in the control group did not have access to the decision aid.[35] Similarly, a decision aid for diabetes medication choice served as the intervention in a randomized cluster trial in Greece. Authors explained that this design was used in an effort to avoid contamination by preference of patient or clinician, and randomization was stratified by clinical practice.[36]

2.3.3 Potential Confounding Variables

One potential confounding variable for the proposed study is the level of health literacy among participants. Health literacy can be defined as "people's knowledge, motivation, and competences to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning healthcare, disease prevention and health promotion."[37] A systematic review assessing randomized controlled trials that used patient decision aids found that only 12% of studies addressed the needs of low health literacy groups, and that studies who used strategies to reduce cognitive demand resulted in greater knowledge improvements.[37] This was accounted for in both the Mooney et al. study using a patient decision aid for MOUD and the Meyer et al. study using a patient decision aid for PrEP, as the tools were written at an 8th grade reading level.[23,32]

Due to high prevalence in patients with OUD and/or HIV, another protentional confounder for the proposed study is the presence of psychiatric disorders.[38-40] Zhu et al. assessed psychiatric comorbidity and treatment outcomes in patients with OUD and found that groups with mental disorders had worse substance use outcomes and poorer psychosocial functioning. They also found that patients with major depressive disorder

(MDD) spent more time engaged with MOUD than patients without MDD.[38] Psychiatric disorders have been accounted for at baseline in other studies using patient decision aids. Using the electronic health record, Meyer et al. extracted bipolar disorder, anxiety disorder, post-traumatic stress disorder, and major depressive disorder.[32]

Additional variables measured at baseline will include past use of MOUD, polysubstance use, demographics, and past discrimination potentially related to race, gender, socioeconomic status, or other factors. MOUD retention/adherence has been well-documented as a barrier to OUD treatment.[41,42] Past use of MOUD or polysubstance use, which may include alcohol, stimulants, or hallucinogens, may affect choice to initiate pharmacotherapy or the desire to learn more about options. Using a nationally representative claims-based database, Morgan et al. found that patients who had another SUD in addition to OUD were more likely to receive MOUD.[42] An article analyzing racial and ethnic disparities in the use of MOUD found that the use of MOUD was less likely for Black and Hispanic patients in short-term settings, despite evidence that it may result in a more positive effect on OUD treatment outcomes than in white patients.[43] Finally, discrimination has been documented as a factor contributing to healthcare decisions. For example, Turan et al. found that perceived discrimination in healthcare settings was negatively associated with optical ART adherence.[44] For the proposed study, it will be important to consider discrimination, stigma, shame, and trust in providers when evaluating MOUD uptake.

2.3.4 Sample Size and Statistical Significance

The two studies with populations and designs most similar to the proposed study are the Mooney et al. patient decision aid for MOUD and the Meyer et al. patient decision

aid for PrEP.[23,32] Mooney et al. was a case-control study including 36 participants who received the intervention and 36 matched controls. Results indicated 37% of patients using the decision aid were started on MOUD compared to 11% of matched controls.[23] Meyer et al. included 164 participants, with 83 receiving the decision aid and 81 receiving enhanced standard of care. Of women who opted to receive the decision aid, 89% had an interest in PrEP, compared to 25% who received enhanced standard of care.[32]

For the proposed study, the difference in effect size was calculated for Mooney et al. and Meyer et al. and was averaged to estimate the sample size needed. A value of 18% will be used for the control group as it is the median between the controls of 11% and 25% in the above studies. A relative effect size for Mooney et al. was calculated by dividing the absolute effect size by the control effect size: (37% - 11%)/(11%) = 2.36. The same calculation was completed for Meyer et al.: (89% - 25%)/(25%) = 2.56. Using a rounded median of 2.4 for simplicity, we calculated a relative difference in effect of 18% x 2.4 = 43.2. Therefore, an estimated 18% of participants in the control group and 43% of patients in the intervention group will be expected to indicate preference to start MOUD, producing a sample size of 104 using an alpha value of 0.05 and a power of 0.8. With the use of a randomized cluster design, this sample size will be inflated to account for potential contamination and is discussed in Section 3.8 of the Study Methods section.

2.3.5 Primary and Statistical Analysis

The primary outcome for the proposed study is decisional preference for the initiation of MOUD. The pilot case-control study using a patient decision aid for MOUD by Mooney et al. aligns most closely with the proposed study in terms of outcomes.

There were several outcomes measured in the pilot test phase, one of which was MOUD induction. Though more participants who used the decision aid initiated MOUD, results were not statistically significant. Other outcomes included a Treatment Outcomes Profile, a 20-item instrument recording substance use and behaviors as well as social activity, a Treatment Knowledge Questionnaire evaluating knowledge before and after using the decision aid, a Treatment Needs Questionnaire assessing ideal level of treatment, a Barriers to Treatment Checklist, an MOUD Experiences and Expectations Questionnaire, and a Participant Evaluation Form capturing feasibility and acceptability of the decision aid.[23] For continuous variables, a Wilcoxon-Mann-Whitney test was used to compare treatment outcomes between cases and controls. For categorical variables, a Fisher's exact test was used.

When considering decisional preference for initiating a medication as the outcome, the randomized preference trial conducted by Meyer et al. aligns with the proposed study. The primary outcome in the study was opting for more information about PrEP. Paired t-tests were used to compare mean PrEP interest before and after the decision aid for participants who chose to use it. Additional outcomes included the efficacy of the decision aid examined using Likert scales to determine decisional preference as well as PrEP uptake, which was assessed at 3-, 6-, 9- and 12-month post-enrollment.[32] At baseline, answers to the Likert scales for decisional preference to use PrEP were analyzed continuously and categorized into three groups (no, unsure, and yes). Immediately after using the decision aid, responses to a 5-point Likert scale were assessed as an ordinal variable and dichotomized as likely versus unlikely.

A pilot randomized controlled trial conducted in an emergency department assessed the use of a collaborative care intervention for patients with OUD. Though comparisons did not achieve statistical significance, outcomes included days of opioid use over the past 30 days, number of days of illicit opioid use, and MOUD initiation. [45] Mixed effects regression models were used to determine changes in opioid use between intervention and control. MOUD initiation over three months was compared using a two-sample test of proportions.

A cross-sectional study analyzing the use of a prostate-specific antigen test decision aid used a primary outcome of preference shift, with participants who used the decision aid being more likely to change their preference to not have the PSA test.[46] Secondary outcomes included knowledge level and decisional conflict. Preference options included 'having the PSA test,' 'not having the PSA test,' or 'I am not sure,' and the McNemar test was used to determine whether preference shifted significantly. Knowledge level was assessed with a score from 0-5, which was recorded as a continuous variable. The pre- and post-knowledge scores were used in a paired t test to determine significant changes. Decisional conflict was also assessed before and after using the decision aid, with a paired t test used to compare differences.

2.3.6 Secondary Outcomes and Statistical Analysis

The main secondary outcome for the proposed study is the initiation of MOUD. Data describing this outcome is somewhat limited, with few studies exploring the rate of MOUD uptake among patients offered medication. A large proportion of the literature documents the need for increased use of MOUD and often discusses barriers to its initiation and retention, but these barriers may act as confounders in statistical analysis on

the use of MOUD. It is clear that the number of patients with OUD is increasing alongside opioid overdose deaths, and the utility of MOUD for decreasing mortality rates has been well established. For example, a cross-sectional study using the 2019 National Survey on Drug Use and Health in the U.S. found that 27.8% of people needing OUD treatment received it in the last year.[47] However, this data does not account for the distribution and access to substance use treatment facilities or primary care providers who prescribe buprenorphine. Though any licensed health care provider can prescribe extended-release naltrexone, no data is available to know how many patients with OUD are offered MOUD. Additionally, providers may not feel confident in diagnosing OUD and patients may choose not to disclose use of opioids when establishing care in a setting that may offer MOUD. There was insufficient data to inform power calculations on MOUD initiation as a primary outcome for the proposed study, making it a more appropriate secondary outcome.

One retrospective observational study aimed to identify predictors of MOUD use in an interdisciplinary primary care model.[48] Researchers used electronic health records of patients visiting one of two primary care clinics in the pacific northwest between 2015 and 2017 and recorded the number of patients with a diagnosis of OUD and the number of patients who had initiated MOUD. Logistic regression was performed with an MOUD order as the dependent variable and patient characteristics as dependent variables. This accounts for use of buprenorphine and extended-release naltrexone only, as these medications can be initiated in a primary care setting, whereas methadone requires distribution at a substance use treatment facility.

Another retrospective study published in 2020 investigated predictors of medication utilization for OUD among Medicaid-insured HIV patients in New York.[49] Researchers identified their population using New York State Medicaid claims data in 2014. Patient characteristics were assessed using chi-square tests to compare people imitating vs not initiating MOUD, and univariate and multivariate logistic regression analyses were performed to assess associations between MOUD utilization among people with OUD and HIV. This study differed from the study completed in the pacific northwest in that methadone was included as a MOUD.

We included patient satisfaction with shared decision-making as a secondary outcome, which is justified by the literature documenting a need for further research in this area, as discussed in Section 2.2.2. Other prior studies have included similar outcomes, as a study assessing the development of a decision aid for hidradenitis suppurativa included outcomes of whether the tool was helpful and if patients felt the decision was up to them.[50] Another study assessing a decision aid for smoking cessation included outcomes of communication satisfaction and overall patient satisfaction.[51]

2.4 Conclusion

Several studies have been published examining decision aids, the intersection of HIV and OUD, and the use of MOUD, but we did not identify any study examining the use of a patient decision aid for MOUD in patients with HIV and OUD. Patient decision aids have proven effective in other settings, and the literature demonstrates a need for increased SDM among the OUD population. The above evidence supports the design of the proposed study.

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CHAPTER 3: STUDY METHODS

3.1 Study Design

The proposed study will be a cluster by clinic randomized trial designed to assess the effect of a patient decision aid on decisional preference for MOUD initiation among patients 18 years or older with HIV and OUD.

3.1.1 Design of the Intervention

The patient decision aid will be developed via an interactive web-based system that is tailored based on responses. Patients will be directed to different pages with text, images, and videos discussing each MOUD option. For example, a question may ask "Are you interested in receiving a monthly injection to treat OUD?" Patients who answer 'yes' will be provided options to learn about Sublocade, a monthly buprenorphine injection, or Naltrexone, a monthly injection approved for both OUD and Alcohol Use Disorder. The web system will be modeled based on the chart form of the decision aid (APPENDIX B) adapted from the *American Family Physician* Journal with additional information provided via the Substance Abuse and Mental Health Services Administration (SAMHSA).[1,2] This form of the decision aid consists of a table using patient-centered language to convey options for MOUD and will be provided for patients to take home after their appointment. The chart form of the decision aid is written at an 8th grade reading level.[3] It includes each of the three medications available for MOUD: methadone, buprenorphine, and naltrexone, as well as the formulations available for each medication, where and how the medications can be obtained, benefits of the medications, and associated adverse effects. The tool also includes the definition of OUD and risks

associated with OUD. As a key part of a patient-centered decision aid, the tool also includes the option of choosing not to initiate MOUD.

3.2 Study Population and Sampling

The study population will include patients 18 years or older with a diagnosis of HIV and OUD receiving HIV care in the state of Connecticut. Ryan White HIV/AIDS clinics were identified using the Health Resources and Services Administration (HRSA) data warehouse, specifically via the "Find a Ryan White HIV/AIDS Program Medical Provider" tool.[4] Twenty total clinics are located in the state of Connecticut and will be included in the study. We will recruit study participants from the pool of patients receiving HIV care at these locations. Patients will be eligible for the study if they have a concurrent existing or new diagnosis of OUD.

3.3 Subject Protection and Confidentiality

The proposed study will be presented to the institutional review board (IRB) at Yale University to obtain approval. Informed consent will be obtained in accordance with the Yale School of Medicine Human Investigation Committee Informed Consent Checklist. A copy of the informed consent form (APPENDIX A), decision aid (APPENDIX B), pre-appointment survey (APPENDIX C) and post-appointment survey (APPENDIX D) will be provided for review. Medical information will be accessed via the electronic health record used at each clinic. All members of the research team will be named in the proposal and will have updated Health Insurance Portability and Accountability Act (HIPAA) and Human Subjects Protection training.

Confidentiality will be maintained throughout the study. Once extracted, data will be stored using a secure web application called REDCap and will only be accessible to

the research team via password. Upon data analysis, participants will be assigned a unique number identifier.

3.4 Recruitment and Eligibility Screening

Participants will be recruited across 20 Ryan White HIV/AIDS clinics across the state of Connecticut. Per standard clinical care guidelines, substance use screening should be performed at least annually and more often for patients who are being seen for falls, altered mental status, or other signs of impairment. In this study, all patients will be handed an iPad in the waiting room by the front desk or medical assistant as part of their check-in procedure. Patients will first be asked whether they are receiving HIV care at the clinic. Patients who answer 'yes' will then complete the screener titled *NIDA Modified ASSIST Q2: Screening for Substance Use*.[5] Patients who screen positive will receive the Rapid Opioid Dependence Screen (RODS).[6] If RODS positive for OUD, they will be asked if they are interested in participating in the study. If they indicate interest, they will then be prompted with the electronic IRB-approved informed consent form and a release of information. A phone number will be provided to research assistants if additional guidance is necessary. Patients who do not have a chart diagnosis of OUD will be excluded from the study.

Inclusion Criteria
18 years or older Diagnosis of HIV Diagnosis of OUD English or Spanish-speaking

Exclusion Criteria
Unable or unwilling to provide written informed consent Currently on MOUD

Figure 1. Inclusion and Exclusion Criteria

3.5 Assignment of the Intervention

The proposed study will use cluster randomization in an effort to prevent contamination within clinics. Sites included in the study will be randomized 1:1 into intervention and control groups via a computer program. This will be completed by a research assistant, who will inform the clinics of their assigned group and distribute iPads equipped with the decision aid software to intervention groups and iPads not equipped with the decision aid software to control groups.

3.6 Study Variables and Measures

Intervention: The intervention for the proposed study is the use of a web-based, interactive patient decision aid for medication for opioid use disorder. The decision aid consists of information about the diagnosis of OUD and MOUD treatment options. Participants will navigate the decision aid alongside their healthcare provider (MD, PA, or NP) using an iPad provided at the time of their appointment. Providers will answer questions patients may have about their options.

Control: The control group for this study will be a standard of care model. Participants at control clinics will be provided with iPads as they check in to their appointment and will answer identical questions to participants at intervention clinics to gather baseline characteristics and decisional preference before the appointment. Providers will be instructed to discuss MOUD in the manner they typically would during the appointment, providing information about options in a conversation with the patient. Providers will not receive specialized training to distinguish the control from the intervention groups. At the end of the appointment, participants will complete the same form as the intervention

group that indicates preference for MOUD initiation, patient satisfaction, and whether MOUD was discussed during the appointment.

Primary and Secondary Outcomes: The primary outcome for the proposed study will be decisional preference for starting MOUD at the end of the appointment in the intervention versus control group. This will be measured via the forms completed at the end of the appointment asking the question "Are you interested in starting medication for the treatment of opioid use disorder?" The answer 'yes' will indicate a preference for starting MOUD. Secondary outcomes will include the initiation of MOUD, which will be obtained via medical record reviews. This will be defined as an addition of a medication containing methadone, buprenorphine, or naltrexone products (specifically extended-release) to the patient chart within 6 months of the original appointment. Data points will include the date MOUD was prescribed, the dose prescribed, and which medication is prescribed. Additional secondary outcomes will include whether the topic of MOUD was discussed at the appointment and patient satisfaction regarding shared decision-making. Data will be obtained via a survey included on the form distributed at the conclusion of the appointment.

Baseline Variables: Providers at each clinic will be surveyed prior to the start of the study. Provider baseline variables will include age, gender, race, ethnicity, years in practice, and self-rated knowledge of MOUD. Patient baseline variables collected via the EHR will include age, gender, race, ethnicity, time elapsed since diagnosis of OUD, presence of concurrent psychiatric diagnosis, and presence of an additional substance use disorder. Patient baseline variables obtained through a form completed at the beginning

of the appointment will include health literacy level, past use of MOUD, and estimated level of discrimination experienced by the participant.

3.7 Data Collection

Data for the proposed study will be obtained via surveys completed on iPads and via HER record review with a signed release of information. Surveys will be conducted via REDCap with data managed by Yale and synced to the cloud, so no data will be stored on the iPad itself. Prior to the start of the appointment, iPads will be provided to all patients in the waiting room. As described in section *3.4 Recruitment*, patients who complete the informed consent form will then be prompted to complete a health literacy assessment obtained from the Agency for Healthcare Research and Quality. The tool used is titled "Short Assessment of Health Literacy" and will be provided in English or Spanish as the patient prefers.[7] It will also include a tool titled "The Everyday Discrimination Scale," borrowed from the Journal of Health Psychology and developed by Harvard Professor David R. Williams.[8] Patients will also be asked whether they have used MOUD in the past. Finally, the form will include the question "Are you interested in starting medication for the treatment of opioid use disorder?" with a 'yes' or 'no' answer, followed by 'if no, why not?'.

At the end of the appointment, patients will complete another form that asks the same question, "Are you interested in starting medication for the treatment of opioid use disorder?" with a yes or no answer, serving as the primary outcome measure. The yes or no answer will be followed by the questions 'If yes, what information was most important in helping you decide? Why?' and 'If no, why not?' This form will also include a survey to assess patient satisfaction, perception of shared decision-making, and whether

MOUD was discussed at the appointment. For the secondary outcome of initiation of MOUD, the EHR will be screened to determine whether any pharmacotherapy for MOUD has been added to the patient medication list 6 months after the baseline appointment.

3.8 Sample Size Calculation

The primary outcome for this study will be assessed as a dichotomous variable through a chi-square analysis. Based on a two-tailed hypothesis with a power of 80% and a confidence interval of 95% (alpha=0.05), a sample size of 104 was calculated using the sample size calculator from Clincalc.com (See APPENDIX F). Because the study will use cluster randomization, the following equation was used to determine the level of inflation needed for the sample size: VIF = 1 + (m-1)*ICC, where *VIF* is the variance inflation factor, *m* is the average number of patients seen at each clinic, and *ICC* is the interclass correlation. An ICC of 0.05 will be used based on previous statistical analyses in studies testing the use of a decision aid on treatment choice outcomes. [9,10]

According to the Ryan White HIV/AIDS Program Annual Client Level Data Report, Connecticut served 4,671 patients with HIV in 2021.[4] Though individual clinic data is not available, there are 20 total clinics across the state. A rough estimate of 4,671 total patients divided by 20 clinics is equal to 231.05 patients per clinic. Three studies were identified to estimate the prevalence of OUD among patients with HIV. Values included those of Tsui et al. at 1.6%, Morford et al. at 1.1-6.3%, and Hartzler at 4%.[11-13] These values were used to determine an average of 3.1%. Further, Tsui et al. reports 16% of patients with HIV and OUD are currently on MOUD. Using this value, 2.6% of patients with HIV will be estimated to have a concurrent diagnosis of OUD with no

current prescription for MOUD. Using this data, 231.05 x 0.026 = 6.02. Using an *m* of 6.02, a VIF of 1.25 was calculated. Multiplying this by the original sample size of 104, a sample size of 130 patients will be needed for the proposed study.

This is likely a conservative sample size estimation, as evidence demonstrates that OUD is often underdiagnosed. Williams et al. compared the prevalence of substance use disorders among patients who completed a telephone survey to those documented in the EHR and found that survey-based prevalence rates of each disorder exceeded the diagnosis rates in every demographic subgroup.[14] Probable underdiagnosis of OUD strengthens the feasibility of the study, as more patients than estimated may screen positive and increase the available sample size.

3.9 Analysis

As discussed in section *3.6 Study Variables and Measures*, provider baseline frequencies (*Table 1*) and patient baseline frequencies (*Table 2*) will first be assessed in the overall sample. The treatment and control arms will then be compared using chi-squared tests to compare proportions and independent t-tests to compare means. Chi-squared tests will also be used to compare proportions of participants indicating decisional preference to initiate MOUD via a 'yes' answer before appointments between each treatment arm. We will calculate a change in decisional preference (% going from 'no' pre-visit to 'yes' post-visit). We will then compare changes in decisional preference by randomization arm (*Table 3*).

The secondary outcome of MOUD initiation will be operationalized as starting or not starting pharmacotherapy within 6 months of the appointment. We will compare proportions initiating MOUD in the intervention versus control group using chi-squared

tests to evaluate for statistical significance. The secondary outcomes of patient satisfaction, perception of shared decision making, and whether MOUD was discussed will be assessed using a Likert scale model and a student's t-test to compare means between the control group and the intervention group. After assessing bivariate associations between baseline variables and the primary outcome using logistic regression, variables significant at $p < 0.05$ will be included in a multivariate regression. Finally, among the intervention group, the proportion of participants who indicate decisional preference to start MOUD before the appointment will be compared to the proportion indicating decisional preference to start MOUD after the appointment using a chi-squared test.

Table 1. Provider Baseline Characteristics

Characteristic	**Decision Aid**	**Standard of Care**	**Statistical Test**
Age	Mean (SD)	Mean (SD)	Student's t-test
Gender Female Male Other (Non-binary, trans, etc)	 N(%) N(%) N(%)	 N(%) N(%) N(%)	Chi-square test
Race White Black Other	 N(%) N(%) N(%)	 N(%) N(%) N(%)	Chi-square test
Ethnicity Hispanic Non-Hispanic	 N(%) N(%)	 N(%) N(%)	Chi-square test
Years in Practice	Mean (SD)	Mean (SD)	Student's t-test
Knowledge of MOUD	Median (IQR)	Median (IQR)	Mann-Whitney U Test

Table 2. Patient Baseline Characteristics

Characteristic	Decision Aid	Standard of Care	Statistical Test
Decisional Preference for MOUD			Chi-square test
Yes	N(%)	N(%)	
No	N(%)	N(%)	
Age	Mean (SD)	Mean (SD)	Student's t-test
Gender			Chi-square test
Female	N(%)	N(%)	
Male	N(%)	N(%)	
Other (Non-binary, trans, etc)	N(%)	N(%)	
Race			Chi-square test
White	N(%)	N(%)	
Black	N(%)	N(%)	
Other	N(%)	N(%)	
Ethnicity			Chi-square test
Hispanic	N(%)	N(%)	
Non-Hispanic	N(%)	N(%)	
Prior use of MOUD in lifetime	N(%)	N(%)	Chi-square test
Presence of Psychiatric Diagnosis	N(%)	N(%)	Chi-square test
Mood Disorders			
Psychotic Disorders			
Personality Disorders			
Presence of another SUD	N(%)	N(%)	Chi-square test
Alcohol use disorder			
Benzodiazepine use disorder			
Stimulant Use Disorder			
Other			
Time elapsed since diagnosis of OUD	Median (IQR)	Median (IQR)	Mann-Whitney U Test
Health Literacy Score	Mean (SD)	Mean (SD)	Student's t-test
Everyday Discrimination Scale	Mean (SD)	Mean (SD)	Student's t-test

Table 3. Outcome Comparisons in Intervention vs Control Arm

Outcome	Intervention Arm	Control Arm	Statistical Test
'Yes' to starting MOUD Before appointment After appointment	N(%)	N(%)	Chi-square test
% changing from 'No' before appointment to 'Yes' after appointment'	N(%)	N(%)	Chi-square test
MOUD initiation within 6 months	N(%)	N(%)	Chi-square test
Satisfaction	Mean (SD)	Mean (SD)	Student's t-test
Shared Decision-Making	Mean (SD)	Mean (SD)	Student's t-test

3.10 Timeline and Resources

The proposed study will take place over the span of two years. It will begin with a rolling recruitment period of 18 months, in order to ensure the secondary outcome of initiation of MOUD at a 6-month time period can be accurately assessed.

3.11 Methodology Considerations

3.11.1 Blinding

Due to the nature of the study, blinding of the intervention to participants and clinicians involved will not be possible, as they will receive and distribute the decision aid. However, research assistants involved in data collection via the forms obtained from participants will be blinded to which group received the intervention.

3.11.2 Missing Data

We do not anticipate significant missing patient-level for the pre-post intervention evaluation as all data is being collected in a single clinic visit. To circumvent the issue of potential missing data with self-reported 6-month outcomes of MOUD initiation, we are collecting data from the EHR. There may be missing data if a patient obtains MOUD from a clinic that does not use the EHR, so we will assume missing = failure.

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CHAPTER 4: CONCLUSION

4.1 Advantages and Disadvantages

This will be the first study to assess the efficacy of a patient decision aid for MOUD in a population with HIV and OUD. Using evidence that supports integrated care for these groups, we will target the specific public health need for increased use of MOUD to treat OUD. It may facilitate shared decision making both by increasing provider familiarity with treatment and by providing patients with the ability to learn about their options. Mooney et al. was the only study identified to use a patient decision aid for MOUD, but it was utilized in a pilot case-control setting and was not able to report statistical significance with the available sample size. This study will aim to build upon this evidence in a specific and vulnerable population of PLH and OUD.

The nature of the intervention prevents blinding in the proposed study, which could affect providers standard of care conversations. Knowing that the intervention group has a tool to educate patients on MOUD could prompt them to increase their own knowledge or unconsciously emphasize it during patient appointments. Further, standard of care cannot be fully controlled in this study. Providers will be encouraged to use guidelines for discussing MOUD, but personal styles will vary. The geographical setting of the study could also prevent generalizability, as prevalence of OUD may differ across regions.[1]

4.2 Clinical and/or Public Health Significance

The proposed study has several implications for both clinical practice and the public health realm. OUD will likely continue to be a public health threat in the U.S.: the number of deaths due to drug overdose in the previous 12-month period has remained

above 100,000 since May of 2021 (data up to July 2022).[2] Because OUD increases HIV risk, OUD and HIV are often concurrent and overlapping epidemics. Efforts to combat these conditions are visible at government levels. In 2017, the opioid crisis was declared a public health emergency, and in 2018, the National Institutes of Health (NIH) launched the *Helping to End Addiction Long-term Initiative (HEAL)* to support solutions to the opioid crisis.[3] *HEAL* has the potential to facilitate increased uptake of MOUD via patient education and shared decision-making. A plan announced in 2019 titled *Ending the HIV Epidemic in the U.S. (EHE)* aims to end the HIV epidemic in the United States by 2030.[4] HIV prevention is one pillar of the *EHE* plan, and MOUD is HIV prevention. For the proposed study, if the decision aid is found to be effective at increasing decision to initiate MOUD, it could be incorporated into the clinics and the EHR. The decision aid could also be considered for use in HIV prevention settings.

The proposed project has specific implications for Advanced Practice Providers (APPs). Physician assistants and nurse practitioners were granted the ability to prescribe buprenorphine in 2016 via the Comprehensive Addiction and Recovery Act. Buprenorphine has become a more popular choice for OUD treatment, as it can be prescribed in a primary care setting and taken at home, whereas methadone must be administered in person at specific designated addiction medicine clinics. It is important to recognize patients with OUD in any setting and be informed on treatment options. As of 2019, 18.6% of PAs worked in primary care, which is an important venue for diagnosing and treating OUD.[5] As the opioid crisis remains a top public health issue in this country, PAs will likely find more expansive career opportunities in addiction medicine, which highlights the need for increased evidence related to SDM in OUD.

As the U.S. healthcare system continues to become more specialized, the health care provider shortage becomes more evident. According to a 2020 report from the American Association of Medical Colleges, a total physician shortage of 54,100-139,000 is projected by 2033.[6] Though APPs can help to lessen this burden, Health Professional Shortage Areas (HPSAs) remain an area of concern. Opioid overdose deaths have remained higher in rural areas, and there are fewer treatment programs in these areas.[7] By integrating care for HIV and OUD, patients can receive both primary and specialty care in the same setting, which has promoted patient satisfaction and positive health outcomes, as discussed in the previous sections. Additionally, the proposed study has the potential to promote patient-centered shared decision making between providers and patients, particularly in in a population of PLH and OUD who often experience stigma and discrimination in healthcare settings. After completing in-depth interviews with patients who have HIV and OUD, Nguyen Thu et al. found that provider stigma was a problem for patients, with an entrenched provider belief that substance use results in a decreased level of morality.[8] If providers can use the decision aid to become more knowledgeable about OUD treatment options, they may have the ability to improve their unconscious bias and aid in the efforts to combat the HIV and OUD epidemics.

4.3 References

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APPENDIX A: Informed Consent Form

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE

RYAN WHITE HIV/AIDS CLINICS OF CONNECTICUT

Study Title: USE OF A DECISION AID IN MEDICATION INITIATION AMONG PATIENTS WITH OPIOID USE DISORDER AND HIV

Principal Investigator: Katrina Gateley, PA-SII

Funding Source: Yale University School of Medicine Physician Associate Program

Invitation to Participate and Description of Project

Suggested Text:

You are invited to participate in a research study designed to assess the use of a patient decision aid for Medications for Opioid Use Disorder (MOUD) in initiating treatment for Opioid Use Disorder (OUD) among patients with HIV and OUD. You have been asked to participate because you have a diagnosis of HIV and OUD and are not currently taking MOUD. Twenty clinics and approximately 130 people will be participating in the study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, the clinic you attend for your HIV care will be randomly assigned to either discuss MOUD using a patient decision aid or discuss MOUD in a traditional shared-decision making manner during your appointment. The patient decision aid consists of a chart describing options for MOUD and things to consider when choosing a medication.

You will be asked to complete a pre-appointment survey to collect baseline characteristics of study participants. You will also be asked to complete a post-appointment survey to assess feelings about MOUD and your satisfaction with the appointment. To determine whether you have initiated MOUD at a time after your appointment, your electronic health record will be checked 6 months later.

Risks and Inconveniences

There are no physical risks associated with this study. However, some questions may be personal there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential.

Benefits

The results of this study may help to improve the approach to treating patients with OUD, particularly among those who have a concurrent diagnosis of HIV. They may also contribute to literature about patient decision aids.

Economic Considerations

Though there is no compensation available for participants of the study, there are no expected costs to participating. You will be responsible for any previously established co-pays or medical costs at your appointment.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. Entrance and exit forms will be kept in a locked room and will be collected at monthly intervals. After data is entered by research assistants, it will be assigned a unique number identifier and documents will be immediately shredded. Your information will be protected by using a secure, password-protected web application for data collection. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. The researchers may withdraw you from participating in the research if either the pre- or post-appointment survey is not completed. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own health care providers or with your Ryan White Clinic.

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____

Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator *[cite name and full telephone number]*.
If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

APPENDIX B: Decision Aid

What is opioid use disorder?

A pattern of opioid use that may cause problems in your life, in many different ways. This may mean that you really want to stop using opioids, but you haven't been able to do so by yourself. You may be taking more opioids than you used to, or for a longer amount of time than you wanted to.

Opioid use disorder can affect people in different ways. You can talk with your health care provider about the diagnosis.

What is the recommended treatment for opioid use disorder?

There are medications that can help treat opioid use disorder. These can help you enter recovery, where you no longer use opioids. They can also lower cravings and withdrawal symptoms. Some of them can lower your chances of overdose or death if you continue using opioids.

Things to Think About	**Methadone**	**Buprenorphine**	**Naltrexone**	**Choosing not to take a medication**
How do I take the medication?	By mouth in liquid form, every day at an opioid treatment clinic	Many choices: your insurance may not cover all of them -By mouth: as a tablet or a film that dissolves under the tongue, once a day -As an injection/shot, given once per month -As an injection/shot given under the skin at home once per week	As an injection/ shot, given once a month in a primary care office like this one	As with any choice about your health, you can choose not to take a medication for opioid use disorder. You can change your mind at any time by talking to your healthcare provider.

		-As an implant that is placed under the skin and stays for 6 months		
Where can I get it?	You can get methadone at an opioid treatment program. Your health care provider can help you set up an appointment. In CT, many methadone providers are open access.	You can get buprenorphine at a primary care clinic, like this one.	You can get naltrexone at a primary care clinic, like this one. You can ask your health care provider for more information.	
How often do I need to be seen by the person prescribing my medication?	When you first start taking methadone, you will have to be seen at the clinic every day.	When you first start taking buprenorphine, you might have to be seen one to two times per week. After a couple of weeks, most people can be seen once a month, taking the medication at home.	You can be seen once a month when taking Naltrexone, when you get your injection.	
Why should I think about taking this medication?	In patients with opioid use disorder, methadone has been proven to lower the number of deaths, the amount of opioid use, and the amount of HIV transmission.	At high doses, patients have been shown to stay on buprenorphine at the same rate of patients on methadone. It also lowers the number of deaths and amount of opioid use.	This medication has higher dropout rates than methadone or buprenorphine, but it may be the best choice if you also have an alcohol use disorder, as it can treat both conditions.	

What side effects could it cause?	You may feel sleepy or groggy and constipated. Methadone may affect some of your hormones or your heart rhythm, but these can be monitored. Overdose can happen at high doses or if it is used with other drugs.	You may have a headache or an upset stomach. You may feel constipated, and some patients may have trouble sleeping.	You may have redness or swelling where your injection is given. You may have headaches, feel depressed, or have trouble sleeping. It may affect your liver enzymes, which can be monitored. Your tolerance to opioids will go down, which may make the risk of overdose higher if you start using opioids again.	
Do I need to be in withdrawal?	No, you can start taking methadone without being in withdrawal.	A short period of withdrawal is required to start taking buprenorphine. This usually means not using opioids for 8 to 48 hours before starting the medication.	Yes, you must fully withdrawal from opioids before starting Naltrexone. This means not using opioids for 7 to 14 days before starting the medication.	

*adapted from Table 2[29]

APPENDIX C: **Pre-Appointment Survey**

Please complete the table by marking an 'x' in each row next to the word that is most similar to the word in the first column. If you don't know the answer, please mark "I don't know."

Stem	**Which word is most similar to the stem word?**		
1. kidney	__ urine	__ fever	__ don't know
2. occupation	__ work	__ education	__ don't know
3. medication	__ instrument	__ treatment	__ don't know
4. nutrition	__ healthy	__ soda	__ don't know
5. miscarriage	__ loss	__ marriage	__ don't know
6. infection	__ plant	__ virus	__ don't know
7. alcoholism	__ addiction	__ recreation	__ don't know
8. pregnancy	__ birth	__ childhood	__ don't know
9. seizure	__ dizzy	__ calm	__ don't know
10. dose	__ sleep	__ amount	__ don't know
11. hormones	__ growth	__ harmony	__ don't know
12. abnormal	__ different	__ similar	__ don't know
13. directed	__ instruction	__ decision	__ don't know
14. nerves	__ bored	__ anxiety	__ don't know
15. constipation	__ blocked	__ loose	__ don't know
16. diagnosis	__ evaluation	__ recovery	__ don't know

17. hemorrhoids	__ veins	__ heart	__ don't know
18. syphilis	__ contraception	__ condom	__ don't know

Please mark an 'x' next to your response to each of the following questions.

In your day-to-day life, how often do any of the following things happen to you?

1. **You are treated with less courtesy than other people are.**

   __ Almost everyday
   __ At least once a week
   __ A few times a month
   __ A few times a year
   __ Less than once a year
   __ Never

2. **You are treated with less respect than other people are.**

   __ Almost everyday
   __ At least once a week
   __ A few times a month
   __ A few times a year
   __ Less than once a year
   __ Never

3. **You receive poorer service than other people at restaurants or stores.**

   __ Almost everyday
   __ At least once a week
   __ A few times a month
   __ A few times a year
   __ Less than once a year
   __ Never

4. **People act as if you are not smart.**

   __ Almost everyday
   __ At least once a week
   __ A few times a month
   __ A few times a year
   __ Less than once a year
   __ Never

5. **People act as if they are afraid of you.**

__ Almost everyday
__ At least once a week
__ A few times a month
__ A few times a year
__ Less than once a year
__ Never

6. **People act as if they think you are dishonest.**

__ Almost everyday
__ At least once a week
__ A few times a month
__ A few times a year
__ Less than once a year
__ Never

7. **People act as if they're better than you are.**

__ Almost everyday
__ At least once a week
__ A few times a month
__ A few times a year
__ Less than once a year
__ Never

8. **You are called names or insulted.**

__ Almost everyday
__ At least once a week
__ A few times a month
__ A few times a year
__ Less than once a year
__ Never

9. **You are threatened or harassed.**

__ Almost everyday
__ At least once a week
__ A few times a month
__ A few times a year
__ Less than once a year
__ Never

Please answer the following questions regarding medications for opioid use disorder.

1. **Have you ever been prescribed a medication for opioid use disorder? If yes, which medication? Select all that apply.**

   __ I have never been prescribed a medication for opioid use disorder

   __ I have been prescribed methadone (Methadose/Dolophine) in the past

   __ I have been prescribed buprenorphine (Suboxone) in the past

   __ I have been prescribed naltrexone (Vivitrol) in the past

2. **If you have been prescribed a medication for opioid use disorder in the past, how long has it been since you last took the medication?**

   __ I have never been prescribed a medication for opioid use disorder

   __ less than 1 month

   __ between 1 and 6 months

   __ longer than 6 months

   __ longer than 1 year

   __ longer than 5 years

3. **Are you interested in starting medication for the treatment of opioid use disorder now?**

   __ Yes

   __ No

   If 'No', why not?

   _____

APPENDIX D: Post-Appointment Survey

1. **Are you interested in starting medication for the treatment of opioid use disorder now?**

   __ Yes

   If 'Yes', what information was most important in helping you decide?

   Which medication would you likely select? Why?

   _____

   __ No

   If 'No', why not?

   _____

2. **On a scale of 1-5, with 5 being the most-satisfied, how satisfied were you with the information you were provided about MOUD during your appointment today?**

   __1

   __2

   __ 3

   __ 4

   __ 5

3. **On a scale of 1-5, with 5 being the best, how did your conversation about MOUD support a shared decision-making process between you and your provider? In other words, did you feel well-informed about your medication options and feel you helped make a decision about your care?**

   __1

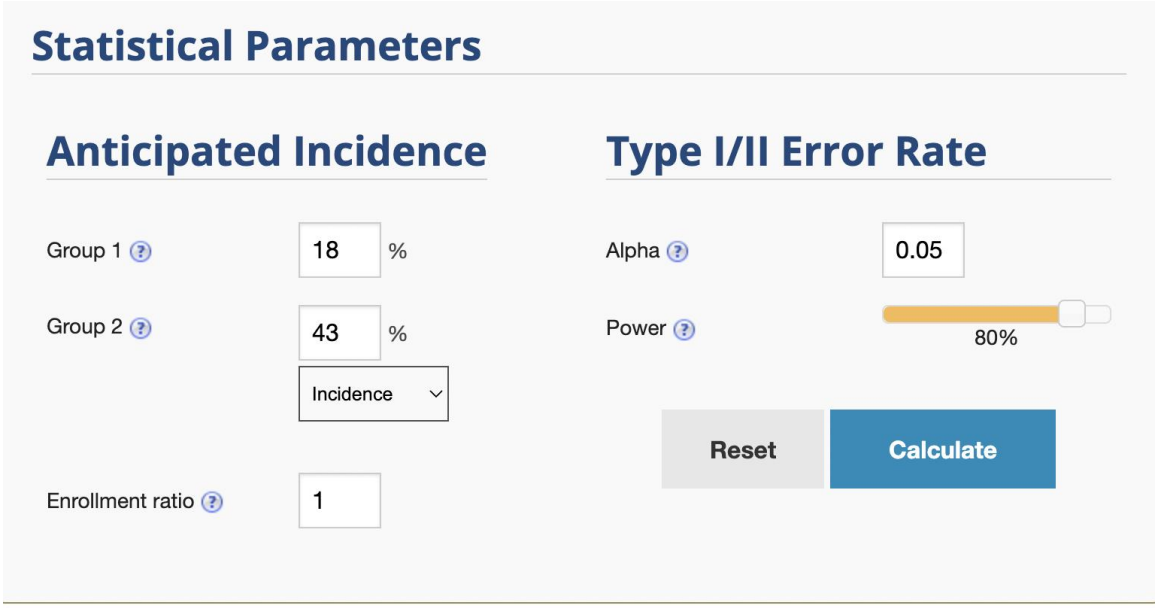
   __2

   __ 3

   __ 4

   __ 5

APPENDIX E: Sample Size Calculation



RESULTS

Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	52
Group 2	52
Total	**104**

Study Parameters	
Incidence, group 1	18%
Incidence, group 2	43%
Alpha	0.05
Beta	0.2
Power	0.8

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