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Protocol #: 22-0961

Project Title: In Hospital Extended-Release Naltrexone for Alcohol Use Disorder: A Mixed Methods Study

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I. **Hypotheses and Specific Aims**: This mixed methods study seeks to evaluate the administration of IM naltrexone versus oral naltrexone among hospitalized adults with DSM-5 diagnosis of alcohol use disorder (AUD) at the University of Colorado Hospital and examine the acceptability and feasibility of IM naltrexone administration and receipt among clinicians and patients with AUD.

Study Aim 1: Estimate the combined 30-day readmission rate plus 30-day emergency department encounter rate for patients who receive in-hospital IM naltrexone vs. oral naltrexone at hospital discharge.

Hypothesis 1: The combined 30-day readmission rate and 30-day emergency department encounter rate will be lower for patients who received in-hospital IM naltrexone compared to patients who receive oral naltrexone at hospital discharge.

Study Aim 2: Estimate the combined 90-day readmission rate plus 90-day emergency department encounter rate for patients who receive in-hospital IM naltrexone vs. oral naltrexone at hospital discharge.

Hypothesis 2: The combined 90-day readmission rate and 90-day emergency department encounter rate will be lower for patients who receive in-hospital IM naltrexone vs. oral naltrexone at hospital discharge.

Study Aim 3: Estimate the 30-to-60-day treatment linkage rate for patients who receive in-hospital IM naltrexone vs. oral naltrexone at hospital discharge.

Hypothesis 3: The 30-to-60-day treatment linkage rates will be higher for patients who receive in-hospital IM naltrexone compared to patients who receive oral naltrexone at hospital discharge.

Study Aim 4: Assess the feasibility, acceptability, and appropriateness of in-hospital administration of IM naltrexone for patients with AUD among hospital-based clinicians (n=15).

Hypothesis 4: Hospital-based clinicians will perceive that administration of IM naltrexone is feasible, acceptable, and appropriate for hospitalized patients with AUD.

Study Aim 5: Conduct interviews with hospitalized patients with AUD to identify key barriers to receipt of IM naltrexone (n=25).

Hypothesis 5: Key barriers and facilitators to IM naltrexone receipt include: feeling pre-contemplative or ambivalent vs. contemplative or concerned about alcohol use (Transtheoretical Mode/Stages of Change), self-efficacy about personal recovery, perceived benefit from treatment, and perceived access to treatment receipt (Health Belief Model).

II. Background and Significance

In the United States, 70.1% of the population aged 18 and older (about 173.3 million people) consumed alcohol in 2017, averaging approximately 3.6 gallons of pure alcohol per drinker per year, or about 2.1 standard U.S. drinks per day.[2,3] Alcohol use and high risk drinking, which often leads to alcohol use disorder (AUD), are significant contributors to the burden of disease in the United States.[4,5] From 2000 to 2015, rates of hospitalization related to alcohol consumption increased 51.4% among persons aged 12+ (from 62.5 to 94.6 per 100,000 population) and the number of such visits increased 76.3% (from 1,461,700 to 2,576,600).[6] Highly effective medications used to treat AUD, including naltrexone, decrease relapse to heavy drinking and total

alcohol consumption.[7] Unfortunately, the use of medication for AUD treatment is underutilized in the hospital setting, leaving a large gap in treatment for this vulnerable population.[8]

Strong evidence supports the use of naltrexone in the treatment of AUD to reduce alcohol relapse, to decrease the frequency and quantity of alcohol consumed, and to reduce alcohol cravings.[9-12] Naltrexone is a non-selective antagonist at the opioid receptor. Endogenous opioids are released in the brain following alcohol consumption.[3] It is thought that naltrexone blunts the pleasurable effects of alcohol by blocking endogenous opioids at the opioid receptor thereby reducing the rewarding effects of alcohol and alcohol-related cravings.[13,14] The target population for naltrexone is men and women who wish to reduce heavy drinking or maintain abstinence, do not have significant hepatic insufficiency, and who are not taking opioids. Past studies indicate that the medication is relatively safe with minimal side effects, typically described as nausea upon initiation and mild headaches.[15]

Naltrexone is available in two formulations, an oral pill and an intramuscular (IM) injection. Oral naltrexone has been approved to treat AUD since 1994 and is dosed 50 mg by mouth once daily.[11,16] IM naltrexone is a long-acting, FDA-approved formulation of naltrexone also used to treat AUD.[17] It is dosed 360 mg via IM injection once monthly.[16] Due to its injectable depot formulation, IM naltrexone maintains relatively constant plasma levels for weeks with a slow, timed release of the compound, in contrast to oral naltrexone, where plasma levels fluctuate over 24 hours.[18] IM naltrexone is associated with a reduction in drinking days and heavy drinking days per month compared with placebo. Reductions in alcohol use are greater, and more successful, with longer use of the medication over time. Treatment compliance is greater with IM naltrexone, compared to oral naltrexone.[19] Currently, only oral naltrexone is available to hospitalized adults with AUD at the University of Colorado Hospital. When patients are interested in taking this medication, oral naltrexone is typically prescribed by the Addiction Consultation Service (ACS) and dispensed from the Atrium Pharmacy for patient pick up following hospital discharge. IM naltrexone may be administered during outpatient clinic visits by providers and staff with experience and specialized training in the management of patients with AUD.

Previous work demonstrates a significant decrease in 30-day hospitalization and emergency department visits when patients with AUD were initiated on oral naltrexone during hospitalization (n=50).[20] If, or how, IM naltrexone affects rates 30-day all cause rehospitalization and emergency department encounters among people with AUD is unknown. It is also not known if administration of IM naltrexone during hospitalization improves continuation of care after discharge as there is a paucity of evidence testing this hypothesis. Recently, Dr. Calcaterra and key stakeholders within the pharmacy department at UCHealth have partnered to make IM naltrexone available to hospitalized patients with AUD. This mixed methods study seeks to assess outcomes related to the administration of IM naltrexone among hospitalized adults with AUD, to assess the feasibility, acceptability, and appropriateness of IM naltrexone administration during hospitalization, and to assess key barriers to IM naltrexone receipt among hospitalized adults with AUD.

III. Rationale: Both IM and oral naltrexone are used to treat AUD, but IM naltrexone costs much more. The question of efficacy to reduce health care utilization comes from IM naltrexone's long half-life (30 days) vs. 24 hours for oral naltrexone. Adherence to IM naltrexone (compared to oral naltrexone) is more easily achieved. Presumably, adherence is associated with efficacy. In one retrospective analysis based on claims data, Baser et al. found that use of an FDA-approved medication for alcohol dependence was associated with fewer admissions and lower total health care costs ($8,134 vs. $11,677) over 6 months following medication or non-medication alcohol treatment initiation.[21] Total costs were similar for IM naltrexone, oral naltrexone, and disulfiram, another FDA approved medication used to treat AUD. In Baser's study, the IM naltrexone group had significantly higher refill rates and greater median days of medication received, both good proxies for adherence.[21] A recent Swedish study of 125,556 patients with an International Classification of Diseases Code (ICD)-10 for AUD demonstrated that patients were less likely to have an alcohol-related hospitalization when they were prescribed naltrexone (HR = 0.89, 95% CI 0.81 – 0.97; p = 0.0260, naltrexone + acamprosate (HR = 0.74, 95% CI 0.61 – 0.89; p = 0.008), or naltrexone + disulfiram (HR = 0.76, 95% CI 0.60 – 0.96; p = 0.1).[22] These observational database studies suggest that the use of medications for AUD may reduce health care utilization. Whether or not similar outcomes would result from IM naltrexone administration during hospitalization is unknown.

IV. Preliminary Studies/Progress Report: The Addiction Consultation Service (ACS) at the University of Colorado Hospital is a weekday, hospital-based consultation service that provides medication-assisted

treatment for substance use disorder, including opioid, alcohol, and methamphetamine use disorder. The service manages complicated alcohol and benzodiazepine withdrawal, facilitates the emergency commitment process for people whose substance use is placing them in serious harm, provides harm reduction education, and directly enrolls patients with opioid use disorder into methadone or buprenorphine treatment programs. From July 2021 to March 2022, the ACS completed 1,244 encounters on 754 unique patients. Of these encounters, 79% were for alcohol use. Among patients with alcohol use, naltrexone or acamprosate were prescribed 318 times upon hospital discharge. Thus, the frequency of encounters for AUD and opportunities to initiate naltrexone in the hospital support an opportunity for robust study enrollment.[23] We examined 30-day hospital readmissions and 30-day emergency department encounters for patients cared for by general internal medicine and hospital medicine teams at the University of Colorado Hospital from July 2020 to June 2021. Of the approximately 12,500 patients discharged from a medical team over this time period, 19.1% had a 30-day readmission and 13.1% had a 30-day emergency department encounter at University of Colorado Hospital.

V. Research Methods

A. Outcome Measure(s) and Data Sources:

i. **Specific Aim 1:** Combined all-cause 30-day readmission rate + all cause 30-day emergency department encounter rate for patients who received IM vs. oral naltrexone

ii. **Specific Aim 2:** Combined all-cause 90-day readmission rate + all cause 90-day emergency department encounter rate for patients who received IM vs. oral naltrexone

iii. **Specific Aim 3:** 30-to-60-day addiction treatment encounter rate for patients who received IM vs. oral naltrexone defined as "documentation of ≥1 healthcare encounters with an associated ICD-code for AUD (F10.X) identified within 30-to-60-days following the index hospitalization"

   a. Data assessing SA 1 – 3 measures will be obtained from Health Data Compass at University of Colorado[26] which includes data obtained from the All Payer Claims Dataset (APCD)[27] and UCHealth related-encounters. Data will also be obtained from Denver Health (and a data use agreement will be completed between Denver Health and University of Colorado). Claims data will be obtained from Colorado All Payer Claims data.

iv. **Specific Aim 4:** *Feasibility, Acceptability, and Appropriateness provider measure:* We will conduct a survey of ACS attendings (n=10) on their perception of the intervention (IM naltrexone) and the process for administration of IM naltrexone

   a. We will use survey questions with Likert responses proven to be both valid and reliable measures of *acceptability* ("the intervention meets my approval", is "appealing", is "likable", is "welcomed") and *feasibility* ("intervention seems implementable", "is possible", "is doable", and "is easy to use)[24,25]

   b. We will disseminate the survey prior to study implementation and at the study endpoint, once all patients have been recruited

v. **Specific Aim 5:** Patient-reported barriers and facilitators to accepting or declining in-hospital IM naltrexone

Study Outcome Measures		**Data Source**
Quantitative: Healthcare Utilization		
Patient & encounter data	• SA1: 30-day hospitalization + 30-day ED encounter • SA2: 90-day hospitalization + 90-day ED encounter • SA 3: 30-to-60-day addiction treatment linkage	Health Data Compass at University of Colorado; Denver Health; All Payer Claims Data via CIVHC
Quantitative: Feasibility and Acceptability		
Clinicians	• SA4: Feasibility, acceptability, and appropriateness of in-hospital IM naltrexone administration	Pre/Post Survey, REDCap
Qualitative: Barriers to IM naltrexone receipt		
Patients	• SA5: Patient reported barriers/facilitators to IM naltrexone receipt	Key informant interviews

B. Description of Population to be Studied:

i. **Specific Aim 1 - Specific Aim 3:** This is a retrospective chart review of hospitalized patients who received IM naltrexone or oral naltrexone.

ii. **Specific Aim 4:** Physician and advanced practice provider participants who work on the ACS at the University of Colorado Hospital. There are no exclusion criteria for physician participants.

iii. **Specific Aim 5:** Hospitalized patients with AUD who were seen by the ACS and who were offered IM naltrexone.

C. Study Design and Research Methods:

i. **Study Design:** This is a mixed methods study that involves a retrospective chart review covering a 12-month period from time that IM naltrexone becomes available at UCH, approximately 6/2022 to 5/2023, a pre/post survey, and qualitative interviews.

ii. **Study Site:** SA1 to SA3 involves a retrospective chart review of hospitalized patients at University of Colorado Hospital and Denver Health (approx. 6/2022 to 5/2023). SA4 involves qualitative interviews which will be conducted at the University of Colorado Hospital (UCH) in patient rooms during their hospitalization (recruitment from 6/2022 to 5/2023, unless thematic saturation is reached before this end date); SA5 involves online surveys (6/2022 to 5/2023).

iii. **Study team members** will include research coordinators with the Division of Hospital Medicine, and Dr. Calcaterra, the study PI and the Denver Health Site PI, Dr. Dale Terasaki. The study PI has a potential treatment relationship with all subjects as the Director of the ACS.

iv. **Recruitment and Consent:**

a. **SA1-3:** Involves the use of data obtained during routine patient care. No patients will be recruited for these aims (see Table 1 for variables)

b. **SA4:** Surveys to assess physician's perceived feasibility and acceptability of the study and intervention will be sent out prior to the study implementation and at study completion (Table 2). The survey will be sent to all physicians and advanced practice providers who attend on the ACS using their email addresses (and the ACS list serve created by Dr. Calcaterra, study PI) (n=15). Surveys will be created and disseminated in REDCap and will be sent out in three waves to improve response rate. The survey will include a description of the research study, the purpose of the study, the possible risks involved with completing the survey, and PI contact information (post card consent). It will also include a line stating that "by completing the survey, the physician is agreeing to participate in the research study to assess provider's perceived feasibility and acceptability of the study and intervention". The survey will also include sections where ACS attending physicians can type in their thoughts and perceptions of the intervention, their perception/likelihood that they would administer the IM naltrexone, and where they can offer recommendations for study improvements. Each person completing the survey will receive a $20 gift card from Amazon.

c. **SA5:** The ACS attending physicians and/or advanced practice providers attending on the ACS service provide routine addiction medicine focused medical care, including history taking, performing a physical exam, reviewing laboratory values, and a discussion of the assessment and plan. If the patient meets criteria for AUD, the ACS attending will offer IM naltrexone or oral naltrexone, depending on the patient's preference, as medication-assisted treatment for alcohol use disorder (no deviation from routine medical care). After the patient accepts or declines IM or oral naltrexone, the ACS attending will inform the patient about the opportunity to participate in a research study to hear from them about why they accepted or declined IM naltrexone for the treatment of their AUD. If the patient is interested in learning more about the study or in study enrollment, the ACS team member will reach to the study team members (Ciii above). The study team member(s) will meet with the patient in their hospital room and will provide the patient with a brief description of the qualitative study to include the following: 1) the details of the nature and purpose of the research; 2) the expected duration of study participation (approximately 45 minutes of in-person interviewing

and a 15 minute phone interview at 30 days post-hospitalization); 3) a statement that study participation is voluntary; 4) probable risks and benefits associated with study participation; 5) information about procedures adopted for ensuring data protection / confidentiality / privacy; 6) reference contacts for any further answers to pertinent questions about the research and the subject's rights and in case of any research related injury to the subject; and 7) a statement offering the subject the opportunity to withdraw at any time from the research without consequences.[30] The study team member will review the consent form with each patient. The patient will provide verbal consent or will verbally decline study participation at this time. If the patient choses to participate, the interview will begin with permission to turn on the tape recorder. For Spanish speaking patients, the study team member will use the interpreter services provided by University of Colorado Hospital. If the patient consents to study enrollment, the study team member will use the interpreter services to inquire about demographic data and patient characteristics listed in Table 3. Some of the data will be obtained via a medical record chart review, i.e., medical record number, age, gender, race/ethnicity, and insurance status. Other data will be obtained directly from the patients. Finally, we will use the key informant guide (attached) to conduct key informant interviews, also using the University of Colorado Hospital interpreter services. Each key informant will receive a $50 gift card to King Soopers. We will complete interviews until thematic saturation is reached, approximately 25 to 40 interviews. Thirty days after completing the key informant interview with each patient, the study team member will make a follow-up phone call to inquire about subsequent alcohol use and health care access. Table 3 also includes follow-up questions and data sources. The study team member will make 5 attempts to reach the person in the follow up period by telephone.

v. **Education and Training:** Prior to study implementation, Dr. Calcaterra will inform the ACS physician and advance practice providers about the study to ensure their agreement to inform the patients about the opportunity to participate in the study. This will occur at one of our monthly ACS team meetings and will be followed up with an email to the ACS email listserv. If an ACS attending does not wish to participate in the study, we will not involve them further and the patients they care for will not be considered for study participation. Dr. Calcaterra will be available by phone, in person, or by email to answer any questions which may arise during the study period as well. All study team members have Dr. Calcaterra's cell phone number.

vi. **Spanish Speakers:** For Spanish speaking patients, the study team members will use the Spanish interpreting service available to all hospitalized patients at University of Colorado Hospital. This will include for consenting participants for enrollment, obtaining demographic data, and for conducting key informant interviews.

D. Measures / Data Collection:

a. SA1-SA3: Demographic data will be obtained from the electronic medical record via Health Data Compass at University of Colorado and the Denver Health Data Warehouse at Denver Health. Data will include information on age, gender, race, ethnicity, and insurance status. Data regarding comorbid conditions (Charlson Comorbidity Index),[32] past 3-year history of substance use disorder as documented by an International Classification Diagnosis code (ICD-10) clinical modification (CM) (see Appendix 1 relevant ICD codes) and number of healthcare encounters to a medical emergency department, a psychiatric emergency department, an inpatient hospitalization, primary care, or subspeciality care will be obtained from electronic medical records via Epic chart review or via Health Data Compass.

a. **SA4:** Data will be collected and stored in REDCap. Table 1 lists questions included in survey.

b. **SA5:** Before the interview begins, we will ask for the patient's phone number they would like to be contacted at for the 15 minute follow-up phone interview at 30 days post hospitalization. We will begin each interview with broad questions to encourage participants to describe their personal experience with hospitalizations related to alcohol, their perceived disease severity,

and their experiences with treatment for AUD. Examples of "warm up" questions include: "Can you tell me why you were hospitalized?" and then we will move onto questions about the hospitalization, "Do you recall meeting with the addiction medicine team while hospitalized?", "What was helpful about those meetings with respect to your alcohol use?" and "Have you ever taken medication to reduce alcohol use before?" We will elicit open-ended feedback regarding their perception of taking medications for AUD (see interview guide attached). Fifteen-minute follow-up interviews will take place at 30 days post hospitalization via phone call in which the study team will inquire about subsequent alcohol use and health care access.

E. Data Analysis Plan:

a. **SA1-SA3:** Participant's characteristics and baseline clinical data will be tabulated, and differences between IM vs. oral naltrexone groups will be assessed using a Chi-Squared or Fisher's Exact Test for categorical variables and t-tests or Wilcoxon rank-sum tests for continuous variables. We will assess 30-day all cause hospitalization rates + 30-day emergency department encounter rates by IM vs. oral naltrexone groups, and 30 to 60-day post discharge linkage rates by IM vs. oral naltrexone groups, 90-day all cause hospitalization rates + 90-day emergency department encounter rates by IM vs. oral naltrexone groups, and 30 to 60-day post discharge linkage rates by IM vs. oral naltrexone groups. If we have sufficient power, we will conduct a multiple logistic regression to assess for differences in 30-day, 90-day readmission and 30 to 60-day treatment linkage between each group (IM vs. oral naltrexone) (see Table 1).

b. **SA4:** Data will be descriptive in nature only to assess how ACS physicians and advanced practice providers perceived administration of IM naltrexone before and after the it became available at University of Colorado Hospital.

c. **SA5:** In-person key informant interviews will be recorded on multiple digital recorders, transcribed, and loaded into ATLAS.ti qualitative software.[35] Dr. Calcaterra (PI) will develop an initial code list based on the interview guide and conceptual framework (health belief model and stages of change model). Codes will be applied to the data; a trained research assistant with qualitative experience and I will analyze each transcript. Discrepancies will be resolved by discussing with study team to reach a consensus. We will add additional codes based on emergent findings. We will use the constant comparative analytic method[36] to identify themes in key informant interview data related to (1) barriers to receipt of IM naltrexone, and (2) alcohol use goals. The team will meet after every two focus group sessions and after interviews have been coded to ensure iterative content development. When new codes or categories emerge from the data, including unanticipated information relevant to our study, we will include these in our interview guide for subsequent focus group sessions or key informant interviews. I will segment data across provider type and patients to identify universal barriers (versus hospital type) with a goal to develop an acceptable intervention across many hospital types (Aim 2).Thirty-day follow-up phone interview data may be descriptively compared to other data collected and will serve as supplemental patient experience data.

F. Data Collection Tools: Survey and 30-day follow-up interview data will be entered data directly into REDCap We will also obtain data from the EHR via Health Data Compass and will conduct a manual chart review of patient encounters outside of UCHealth hospitals by reviewing data available in Epic for follow up hospitalizations or emergency department encounters. We will review data available in COHRIO, a health information exchange, which includes patient level information on health care encounters https://www.corhio.org. Key informant in-person interview data will be recorded on audio handheld devices, those files will be uploaded to a secure server where a transcriptionist will transcript the audio recordings, after which time the audio recordings will be deleted. No personal identifying information will be included in the audio recording or transcripts.

VI. Potential Scientific Problems: We are limited in capturing data on hospital readmissions, emergency department encounters, and linkage to follow-up appointments to data available in Health Data Compass, in Epic or COHRIO. The latter data sources will be reviewed manually by the study PI. An electronic

review of insurance claims data available through Center for Improving Value in Health Care (CIVHC) would be ideal to capture all patient encounter data where an insurance claim was submitted, but obtaining these data is cost prohibitive. Due to this limitation, we will likely underestimate the risk of hospital readmission, subsequent emergency department encounter, and will underestimate care linkage post discharge. The in-person and 30-day follow-up key informant interviews that will be completed present low risks to participants from a physical, psychological, and legal perspective. We will take every effort to mitigate any potential breach of confidentiality through ensuring secure storage of study materials, adequate training of study personnel in human subjects research, and removal of identifiers from study materials. All paper files will be stored in a secured cabinet on the University of Colorado Anschutz Medical Campus.

VII. Justification and Feasibility: This study will identify barriers and facilitators to administration and accept IM naltrexone among hospitalized adults with AUD, as well as outcomes related to re-hospitalization, emergency department encounters, and treatment linkage. The PI on this study is the Director of the Addiction Medicine Consultation service and will be able to identify patients eligible for study enrollment at UCH if physicians and APPs on the ACS do not actively recruit participants.

VIII. Summarize Knowledge to be Gained: Knowledge gained from completion of this study will allow us to determine whether administration of IM naltrexone in the hospital setting is feasible and acceptable to clinicians, if patients accept IM naltrexone, and if IM naltrexone improves outcomes (if study N permits appropriate data analysis to assess any association between IM naltrexone and outcome measures noted above).

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Table 1. Patient Characteristics and Outcomes (SA1-3)		
	IM naltrexone	Oral Naltrexone
Age in years (mean, SD)		
Gender (n, %)		
Male		
Female		
Race (n, %)		
White		
Black or African American		
American Indian / Alaskan Native		
Asian Native Hawaiian / Pacific Islander		
Other / Declined		
Ethnicity (n, %)		
Non-Hispanic		
Hispanic		
Declined		
Substances regularly used (n, %)		
Stimulant		
Opioid		
Alcohol		
Cannabis		
Methamphetamine		
Nicotine/Tobacco		
Psychiatric comorbidity		
Schizophrenia		
Bipolar disorder		
Anxiety disorder		
Depression		
Personality disorder		
Alcohol related diagnoses		
Alcoholic liver disease		
Alcoholic gastritis		
Alcoholic cardiomyopathy		
Toxic effect of alcohol		
Alcohol use complicating pregnancy		
Alcoholic polyneuropathy		
Alcoholic myopathy		
Alcohol induced pancreatitis		
Secondary esophageal varices		
Past year emergency department encounter, or hospitalization related to alcohol use (Yes/No) (n, %)		
Past receipt of any (n, %) (Yes/No)		
Oral naltrexone		
IM naltrexone (Vivitrol)		
Acamprosate (Campral)		
Disulfiram (Antabuse)		
30-day ED encounter (n, %)		
30-day Hospitalization (n, %)		
90-day ED encounter (n, %)		
90-day hospitalization (n, %)		
30-60 day clinic follow up (yes/no) (n,%)		

Table 2. ACS Attending Physician and Advanced Practice Provider Survey Questions (SA4)*

Acceptability Intervention Measure
1. Provision of both IM naltrexone and oral naltrexone in the hospital setting meets my approval. 2. Provision of both IM naltrexone and oral naltrexone is appealing to me. 3. I like offering patients IM naltrexone if they are interested in receiving this medication. 4. I welcome the use of IM naltrexone. 5. I feel it is within my scope of practice to perform the IM naltrexone injection during hospitalization. 6. I feel I can make the time to perform the IM naltrexone injection during hospitalization. 7. I prefer to not offer IM naltrexone to patients during hospitalization 8. Enter additional feedback here.
Feasibility Intervention Measure
1. Offering IM naltrexone to hospitalized patients cared for by the addiction consultation service seems implementable. 2. Offering IM naltrexone to hospitalized patients cared for by the addiction consultation service seems possible. 3. Offering IM naltrexone to hospitalized patients cared for by the addiction consultation service seems doable. 4. Offering IM naltrexone to hospitalized patients cared for by the addiction consultation service seems easy to use. 5. Enter additional feedback here.
Appropriateness Intervention Measures
1. Offering IM naltrexone seems fitting as treatment for alcohol use disorder by the addiction consultation service. 2. Offering IM naltrexone seems suitable as treatment for alcohol use disorder by the addiction consultation service. 3. Offering IM naltrexone seems applicable as treatment for alcohol use disorder by the addiction consultation service. 4. Offering IM naltrexone seems like a good match for patients care for on the addiction consultation service. 5. It is appropriate that MDs, Pas, and NPs should administer the IM naltrexone injection when they are working on the addiction consultation service.

*to be administered prior to study implementation and at study end point via REDCap

Table 3. Qualitative Interviews with Patients, Demographic and Patient Characteristics and Data Source	
Baseline Interview Data	**Data Source**
Participant ID	Medical record
Patient MRN	Medical record
Today's date and year	NA
Patient's birth date and year	Medical record
Patient's reported gender	Medical record
Patient's reported race, ethnicity	Medical record
Patient's health insurance	Medical record
Patient received Vivitrol? Yes No	Medical record
Patient phone call	Patient reported
Self-reported substance use and type	Patient reported
Heroin or fentanyl	Patient reported
Methamphetamine	Patient reported
Cocaine	Patient reported
Tobacco/Nicotine, i.e., vaping	Patient reported
Marijuana/Cannabis	Patient reported
Opioid pills, not prescribed	Patient reported
Other	Patient reported
Have you ever been told you have any of the following psychiatric illnesses?	Patient reported
Depression	Patient reported
Anxiety	Patient reported
Bipolar	Patient reported
Schizophrenia	Patient reported
Other	Patient reported
Past year emergency department visits or hospitalizations due to alcohol?	Patient reported
Past alcohol withdrawal seizures?	Patient reported
On average, how many regular size alcohol drinks do you have each day?	Patient reported
Over the last 30 days, how many days were you intoxicated from alcohol?	Patient reported
If you do not drink for a day, do you develop anxiety, nausea, shakes, or become irritable?	Patient reported
Where do you currently live?	Patient reported
House / Apartment / Condominium Stay with friends Unhoused / Outside / Streets Shelter	Patient reported
Have you ever received treatment for alcohol use disorder?	Patient reported
If yes, what treatment?	Patient reported
Residential Outpatient support in a group setting Outpatient support in a one-on-one counseling session Work for treatment program Other	Patient reported
Have you ever taken medications to help with your drinking?	Patient reported
If yes, what medications?	Patient reported
Oral naltrexone	Patient reported
Vivitrol	Patient reported
Acamprosate or Campral	Patient reported
Gabapentin	Patient reported
Other	Patient reported

Were any of these medications helpful?	Patient reported
Follow Up Interview Data	**Data Source**
Participant ID	Medical record
Patient MRN	Medical record
Medication received at discharge or during hospitalization. Vivitrol Naltrexone oral Acamprosate	Medical record
Today's date and year	NA
Since you were discharged from the hospital, have you been back to the emergency department or hospital for alcohol-related problems?	Patient reported
Since we last talked, did you follow up with a medical provider to get help for alcohol use?	Patient reported
Since we last talked, have you been taking oral medication for alcohol use, i.e, naltrexone or acamprosate?	Patient reported
Why or why not?	Patient reported
If yes, what did you like about it?	Patient reported
Since we last talked, did you follow up with a medical provider to receive a Vivitrol injection, the medication used to reduce cravings to alcohol?	Patient reported
Over the last 30 days, how many regular size alcoholic drinks do you have each day?	Patient reported
Do you think that is a different amount compared to the 30 days prior to your last hospitalization? If so, how?	Patient reported
I am drinking more alcohol I am drinking less alcohol I am trying to cut back I am not trying to cut back.	Patient reported
If you took any medication for alcohol use, do you think that affected how much alcohol you drank over the past 30 days?	Patient reported
Over the last 30 days, how many were you intoxicated from alcohol?	Patient reported

Appendix ICD 10 Codes

Category	Diagnosis	ICD 10
Alcohol Related Medical Diagnoses		
Alcoholic liver disease	Alcoholic liver disease, alcoholic fatty liver, alcoholic hepatitis, alcoholic fibrosis, alcoholic hepatic failure	K70
Alcoholic gastritis	Alcoholic gastritis	K29.2
Alcoholic cardiomyopathy	Alcoholic cardiomyopathy	I42.6
Toxic effect of alcohol	Toxic effect of alcohol	T51.9; T51.8
Alcohol use complicating pregnancy	Alcohol use complicating pregnancy	99.3
Alcoholic polyneuropathy	Alcoholic polyneuropathy	G62.1
Alcoholic myopathy	Alcoholic myopathy	G72.1
Alcohol induced pancreatitis	Alcohol induced pancreatitis	K86.0, K85.2
Secondary esophageal varices	Secondary esophageal varices	I85.1
Other Medical Diagnoses		
Renal Dialysis	Dependence of renal dialysis	Z99.2
HIV	HIV/AIDS	B20
Renal Diseases	Renal Diseases	N00-N08, N10-N16, N17-N19,
Diabetes	Diabetes Mellitus	E08-E13
Respiratory Diseases	Respiratory Diseases	J00-J99
CV Diseases	Cerebrovascular Diseases	I60-I69
Heart Diseases	Heart Diseases	I20-I25, I26-I28
Hypertensive Diseases	Hypertensive Diseases	I10-I16
Neoplasm	Neoplasm (includes malignant, carcinoma in situ, neoplasm of uncertain behavior, neoplasm of unspecified nature	C00-C96, D00-D489, D3A
Psychiatric Diagnoses		
Schizophrenia	Schizophrenia	F20-F25
Bipolar disorder	Bipolar disorder	F30, F31, F34
Anxiety disorder	Anxiety disorder	F4-F48
Depression	Depression	F32, F33, F39
Personality disorder	Personality disorder	F60-F69
Substance-Related Diagnoses		
Stimulant	Stimulant (Cocaine and Amphetamine)	F14, F15
Opioid	Opioid Use Disorder	F11
Alcohol	Alcohol	F10
Cannabis	Cannabis	F12
Methamphetamine	Methamphetamine	
Nicotine/Tobacco	Nicotine/Tobacco	