

California Bridge Program
Patient Outcomes Evaluation
Study Protocol (Main Study)

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This protocol was reviewed by the Public Health Institutional Review Board (IRB) and approved on 9/30/19.

California Bridge Program
Protocol

1. Description of Study Aim, Background and Design

Study aims

The Public Health Institute (PHI) has initiated the California Bridge Program (CA Bridge). CA Bridge is a health care service delivery program to increase access to evidence-based treatment for substance use disorders (SUDs). This program will take place in up to 60 sites in California from February 2019 to July 2020. Specifically, the program seeks to increase access to medication for opioid use disorder (MOUD) at sites where patients with opioid use disorder (OUD) receive much of their healthcare in urgent care, emergency departments (EDs), inpatient hospital wards, and hospital-based specialty clinics.

Data collection for this study will evaluate outcomes of CA Bridge using two data sources: one, the clinical data abstracted from the medical record and programmatic treatment record of CA Bridge participants; and a second, the “substudy,” which will collect in-depth sociodemographic, substance use, overdose history, treatment history, and infectious disease risk assessments at baseline, 7- and 30-days following baseline from a subset of participants at select locations. For the first data source, all patients will be approached for eligibility and consent to collect data regarding demographics, service provision and linkage to care as part of ongoing conduct of CA Bridge. The data are collected from the clinical documents already in use and no specific research surveys are to be administered. The primary aim of this study component to enhance CA Bridge program evaluation.

Substudy Only

The second component of the study, referred to as the ‘substudy,’ will involve additional participant recruitment at six CA Bridge sites that have shown early success with program implementation.¹ At these sites, participants will undergo a second round of eligibility screening and consent before entering into the substudy. Participation in the substudy is voluntary and decision to participate will in no way affect clinical care. In the substudy, participants will complete self-administered, structured research surveys and will be compensated for their time. The data collected in the substudy are for research purposes only. The data collected in the substudy will not be shared with the clinical care team in any way.

The aims of this study are:

AIM 1. To assess system-level impact of the CA Bridge program on treatment outcomes in participating CA Bridge sites. We will assess the number of patients with OUD that are initiating MOUD, the number that are linked to ongoing community-based care for OUD, and the number that are continuing community-based treatment at 1 month following the initiation of MOUD in the acute care hospital (ACH) setting.

AIM 2. To describe engagement in care outcomes at 7- and 30-days by baseline sociodemographic and substance use characteristics for all patients in CA Bridge. We will attempt to enroll all eligible patients participating in CA Bridge to collect basic patient level data that includes age, gender, race/ethnicity, insurance and housing status as part of our programmatic treatment record. Patients will be followed up at 7- and 30-days to determine engagement in care for OUD. Descriptive statistics will be provided by location and treatment setting.

AIM 3. To analyze treatment outcomes by a detailed set of sociodemographic and clinical characteristics for a select group (n~400) of patients provided services under CA Bridge. Substudy participants will have a detailed systematic evaluation at baseline, and 30-days after baseline, and a brief follow-up at 7-days. Data will be collected as part of a research program to determine links between factors related to successful engagement

¹References to the substudy in this protocol are not applicable to participation in the main study. Sections or paragraphs that are only relevant to the substudy are highlighted with a grey box and header throughout in order to facilitate interpretation for sites participating in the main study only. Other references to the substudy indicate information that only applies to sites participating in the substudy.

in care at 7- and 30-days after enrollment in CA Bridge. Secondary outcomes will include changes in substance use and HIV/hepatitis C related risk behavior at 30-days.

The evaluation of CA Bridge will enhance its capacity to inform larger efforts at the policy level, as well as contributing to clinical practice and informing standards of care in the treatment of OUD. Our ultimate aim in this undertaking is to improve care for patients with OUD and reduce the current unacceptably high rates of mortality and morbidity in the patient population. Information gathered from this study will be essential to identify patient-level factors that correspond with success in engaging MOUD and to help identify the type and intensity of services that could help CA Bridge patients stay in MOUD for the long-term.

Background

There is an alarming epidemic of opioid use disorder in the United States, with the rate of drug overdose deaths increasing by nearly 140% since 2000, largely due to overdose deaths involving opioids. Overdose deaths associated with the most commonly prescribed opioids for chronic pain relief increased dramatically from 2013 to 2014. (1,2)

The rate of increase for opioid-related ED visits was greater than that for opioid-related inpatient stays. This represented a 5.7 percent average annual growth rate. During this same time period, the rate of opioid-related ED visits increased 99.4 percent, from 89.1 per 100,000 population in 2005 to 177.7 per 100,000 population in 2014. This represented an 8.0 percent average annual growth rate. (3)

Opioids commonly prescribed to treat painful conditions have had a dramatic increase in the rate of misuse, addiction, overdose, and death. The increase in complications corresponds with a dramatic increase in the rate of opioid prescriptions that resulted from pressures placed on practitioners to avoid undertreatment of pain. (4)

Efforts to address this urgent public health crisis include increasing access to treatment of OUDs, particularly through the use of emergency rooms (ED) and acute care hospitals (ACH) that can serve as portals for access to expanded use of buprenorphine and methadone. (5-7) Naloxone is a competitive opioid antagonist that is used to reverse the adverse effects of opioid intoxication. It is increasingly being prescribed for emergent outpatient administration to prevent future overdose cases. (8,9)

The evidence suggests that ED and ACH-based delivery of MOUD has strongly positive outcomes, with some directions for future work to improve outcomes. In a randomized controlled trial assessing outcomes of care among 329 opioid-dependent patients treated in an ED, ED-initiated buprenorphine treatment vs brief intervention and referral significantly increased engagement in addiction treatment, reduced self-reported illicit opioid use, and decreased use of inpatient addiction treatment services. The strategy did not significantly decrease the rates of urine samples that tested positive for opioids or of HIV risk at 30 days following the ED visit. (10) In follow-up assessments at 2, 6, and 12 months, patients initiating buprenorphine treatment in the ED setting continued to have significantly higher rates of engagement with substance abuse treatment at 2 months following their ED treatment compared with patients receiving referrals or a brief intervention (74% versus 53% versus 47%). However, outcomes were comparable across treatment groups at 6- and 12-month follow-up, suggesting the need for long-term support to keep patients engaged in treatment over time. (11)

Description of the CA Bridge.

CA Bridge is building capacity for the initiation of evidence-based MOUD treatment in ACH settings in over 35 counties across California. This is achieved by promoting integrated systems of care by increasing care coordination service linkages and referral networks to community-based substance abuse treatment in local communities. Over the course of 17 months (February 2019 – July 2020) accelerated training and technical assistance for healthcare providers in the use of MOUD as a treatment modality to address the acute symptoms

of OUD in ACH settings will provide the foundation necessary to enhance and increase access to 24/7 treatment in every community in the state.

On behalf of CA Bridge, PHI has contracted with 31 sites to provide MOUD in ED/ACH. An additional 22 sites will be added by September, 2019. All 53 California Bridge sites are required to provide monthly aggregate de-identified data to PHI for the purpose of compliance and quality improvement.

Research Objectives

- To provide a system-level description of the impact of the CA Bridge program.** We will describe the impact of CA Bridge implementation facilitation and technical assistance combined with placing substance use navigators (SUNs) and trained buprenorphine providers in acute care hospitals (ACHs). Aggregated outcomes include the number of patients with OUD that are initiating MOUD, the number that are linked to ongoing community-based care for OUD, and the number that are continuing community-based treatment at 1 month following the initiation of MOUD in the ACH setting.
- To determine factors that describe success in linking to ongoing MOUD at 7 and 30 days after initial Bridge contact.** We will describe patient-level characteristics associated with CA Bridge outcomes. All patients will be approached for eligibility assessment and consent for the collection of demographic and relevant clinical data. Additionally, in the substudy we will analyze in-depth patient-level data collected at point of care and at short-term follow-up (day 7, day 30) evaluations of the key factors within diverse treatment settings that associate with the successful implementation of this innovative treatment model. Findings will describe factors that correspond with treatment entry and early retention success and that point to services necessary to ensure longer-term retention in medication treatment for opioid use disorder.

Design

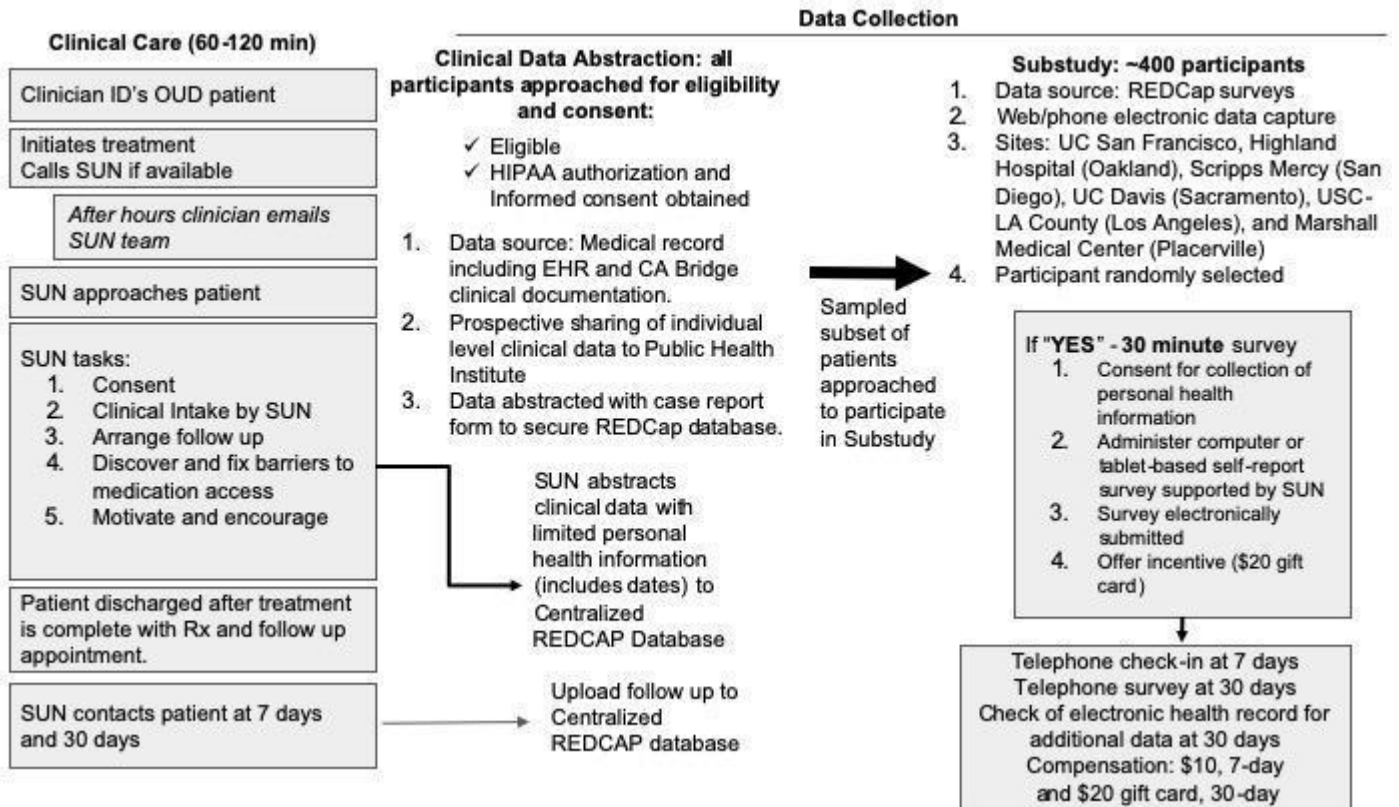


Figure 1. The CA Bridge (left column) provides clinical care in Emergency Rooms and Acute Care Hospitals across California. Data is collected (middle column) and uploaded a central, secure server comprising a limited data set to evaluate the CA Bridge. Each patient in the CA Bridge will be asked to provide informed consent to collect and store data. The substudy (right column) will collect

patient-level data from in-depth interviews from a subset of individuals at six CA Bridge sites (Highland, UC Davis, UCSF, USC-LA County, Scripps Mercy, and Marshall).

CA Bridge Overview

CA Bridge provides technical assistance and implementation facilitation to support initiation of high-quality care for patients with OUD presenting at ED/ACH sites across California. The current standard of care for patients with OUD at ED and ACH is to identify and treat patients' acute medical needs and refer patients for ongoing outpatient treatment of their substance use disorder. The innovation of the CA Bridge is that patients with OUD are identified in the ED and/or ACH, and medication assisted treatment is initiated on-site. Treatment is initiated based on accepted treatment pathways and directed by the patient's clinical care team. The patient will then have a facilitated referral to outpatient treatment.

An integral component of the CA Bridge is the substance use navigator (SUN). The SUN is a care coordinator and patient advocate that improves access to MOUD. A SUN is embedded within an ED/ACH to assist patients to begin and remain in addiction treatment via motivation, resources, and encouragement. An essential link to the community, SUNs outreach to treatment partners and facilitate transitions from the acute care setting to outpatient treatment. They also provide a direct link to organizations and individuals seeking treatment. SUNs conduct initial brief assessments, introduce patients to MOUD programs and services, expedite appointments at MOUD-capable clinics, serve as the primary coach for their clients, and maintain ongoing contact with their panel. They also assist with access to other services such as financial counseling, primary care, mental health services, social services, and residential treatment facilities.

The SUN will be instrumental for data collection. The SUN will collect basic data relating to demographics, clinical variables and linkage to care (see next section for details) at the point of care visit, and at 7- and 30-day follow-ups from all participants. For the substudy, the SUN will provide electronic mediums (tablet or computer) for participant self-administered surveys, and then retrieve the device and ensure completion of survey, and proper upload of data. If, for any reason, a substudy participant is unable to use a tablet or computer for data collection, then the SUN would provide assistance. The SUN will also be tasked with providing compensation to the participants of the substudy.

Data Collection Overview

We aim to collect and analyze patient-level data documented in the CA Bridge sites' electronic health record (EHR) and CA Bridge clinical charts to describe and evaluate the patient-level impact of CA Bridge. The patient's decision to participate or not participate in the research activities for CA Bridge will not affect the patient's medical treatment. Patients who are participating in the CA Bridge will be asked to sign a Health Insurance Portability and Accountability Act (HIPAA) authorization and release of information forms and informed consent (see section 8 for detailed processes). There will be no monetary compensation for participation in CA Bridge. Data collected for CA Bridge is data typically collected within the workflow of clinical care. The data collected will include (see accompanying document for full description):

- 1) Locator information: Name, medical record number, date of birth, phone number, address, email, site of enrollment.
- 2) Demographics: Age (calculated from date of birth), gender, race/ethnicity, insurance, and housing status.
- 3) Basic substance use questionnaire: Use of oral non-medically prescribed opioids, inject opioids (i.e., heroin or fentanyl), methamphetamine, cocaine, crack cocaine, benzodiazepines, barbiturates, hallucinogens (i.e., LSD, psilocybin), cannabis.

- 4) Clinical: Presenting complaint, previous use of buprenorphine, participant identification, participant referral, treatment provided (buprenorphine or methadone), dose, medical and psychiatric comorbidities.
- 5) Linkage to care: Participant accepted referral, location of referral, date of appointment, contact at 7 and 30 days, engagement in treatment at 7 and 30 days.

Data is collected by SUNs during clinical intake. For eligible and consented participants, selected data is abstracted via paper case report forms then uploaded through REDCap. A unique identifier will be assigned to each individual. This unique identifier will be the only link between study related data and personal health information. Study related data will be uploaded by the SUN at each site via a standardized REDCap form without personal health information (except for dates and hospital of enrollment) to constitute a “limited data set.” All data will be collected and stored via REDCap on a secure server at UCLA. REDCap (Research Electronic Data Capture) is a secure, HIPAA compliant web-based application for quickly building and managing online surveys, data collection forms and databases. REDCap provides an audit trail for tracking data manipulation and user activity, as well as automated export procedures for seamless data downloads to Excel, PDF, and common statistical packages (SPSS, SAS, Stata R). All data will be stored on an encrypted, password-protected server to which only key personnel will have access. A data manager at the Public Health Institute and PI will be responsible to ensure data quality and completeness.

A Locator Form will be used to contact participants at approximately seven and 30-days. The Locator Form will contain personal health information (names, date of birth, medical record number, telephone number, physical address and email). Participants will be contacted via telephone. When a contact is not located via telephone, a letter or email (if available) will be sent to schedule a telephone call. The seven-day follow-up will be used to ascertain follow-up with an addiction medicine provider within approximately seven days. The 30-day follow-up will be used to ascertain other health related outcomes at approximately 30-days. Participants will be asked, as part of the informed consent, for permission to review data from their electronic medical record regarding their CA Bridge care episode and subsequent follow-up.

Descriptive analyses will be conducted to summarize patient characteristics and treatment patterns over time within each of the sites. Analyses will focus on the identification of disparities in program enrollment and retention by gender, age, and ethnicity of patients; or by special needs, such as homelessness, medical or psychiatric comorbidities, and substance use that may affect treatment outcomes and retention in community-based substance abuse treatment. Identifying distinct treatment patterns in the patient population will inform efforts to improve the quality of care and to better serve patients with OUD.

Substudy Only

Substudy Overview

The substudy will analyze detailed participant-level data in a subset of patients at selected CA Bridge sites. CA Bridge participants will be selected at UC San Francisco, Highland Hospital (Oakland), Scripps Mercy (San Diego), UC Davis (Sacramento), USC-LA County (Los Angeles), and Marshall Medical Center (Placerville). Clinical sites have been chosen due to current enrollment rates and diverse geographic representation in California. Again, if invited for participation, an individual’s agreement to participate in the substudy will not be necessary for receipt of services within CA Bridge. We will stratify selection of participants by clinical site and month to achieve representation over time and across sites. No more than 25 participants will be enrolled per site per month, and participants will be stratified by gender to include at least 40% women in our sample. Our goal enrollment for the substudy is up to 400 participants. Those individuals selected and willing to participate in the substudy will receive a second informed consent process (see section 8 for detailed processes).

After providing informed consent, substudy participants will respond to a self-administered survey instrument using REDCap delivered through a computer or a tablet. If issues with literacy or vision or difficulties working with computer equipment prevent a participant from self-administering the survey, SUNs will assist the

participant with the survey. Data will be entered by the participant at the initial visit and subsequent data will be entered by the SUN after reviewing the EHR and after communication with the participant by telephone at 7- and 30-days. The SUN will contact the participant via the telephone number the participant provided during the initial encounter. The SUN will confirm the expectation of privacy on both ends of the call. The SUN will state his/her capacity as research personnel in which they are making the call on behalf of the study.

Participants in the substudy will receive up to \$50 for completion of the survey. The breakdown of compensation will be as follows: \$20 for the point of care visit survey; \$10 for the seven-day follow-up; and, \$20 for the 30-day follow-up.

Questions in the substudy will be based on the National Institute of Drug Abuse (NIDA) harmonization initiative. Table 1 describes the survey domains at baseline, 7- and 30-days for both the entire CA Bridge and the substudy.

Table 1. Data collection instruments for CA Bridge study and substudy.

Data source		Day 0	Day 7	Day 30	
		In person	Phone call	Phone call	EHR
Written informed consent	All	X			
DSM-5 for OUD	Substudy	X			
Locator information form	All	X			
Basic demographics	All	X			
Clinical variables	All	X			
Linkage variables	All	X	X	X	
Written informed consent, additional	Substudy	X			
Socioeconomic variables	Substudy	X			
Detailed substance use assessment with TLFB	Substudy	X		X	
AUDIT-C for alcohol use	Substudy	X		X	
Psychiatric assessment	Substudy	X		X	
Depression assessment (PHQ9)	Substudy	X		X	
Anxiety assessment (GAD7)	Substudy	X		X	
Pain assessment (PEG)	Substudy	X		X	
Infectious diseases risk	Substudy	X		X	
Overdose and access to naloxone	Substudy	X		X	
Quality of life: EuroQol-5D	Substudy	X		X	
Crime and criminal justice	Substudy	X		X	
Treatment Effectiveness Assessment	Substudy	X		X	
Engagement in treatment	All		X	X	X
ED visits and hospitalizations	All		X	X	X
HIV/HCV/HBV testing	All			X	X
Urine drug screen	All				X
Total duration in minutes for participant interaction:	CA Bridge	15	5	5	
	Substudy	+30		+30	

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, 5th Edition; ED, emergency department; EHR, electronic health record; GAD-7, General

Review of the electronic health record (EHR)

At the baseline visit and 30 days after, the SUN will review the participant's EHR and extract data that includes: engagement in care; use of medication assisted therapies (buprenorphine, methadone or long-acting naltrexone); continued use of substances; testing and diagnosis status for infectious diseases (HIV, hepatitis B and C, skin and soft tissue infections, and blood stream infections); use of emergency room, urgent care services, and hospital admissions following CA Bridge episode.

2. Subject population

Individuals eligible for the CA Bridge study include all patients with opioid use disorder (OUD) who present to a CA Bridge site and receive care as part of the CA Bridge. Individuals eligible for the substudy will include CA Bridge participants enrolled at UC San Francisco, Highland Hospital (Oakland), Scripps Mercy (San Diego), UC Davis (Sacramento), USC-LA County (Los Angeles), and Marshall Medical Center (Placerville). All substudy participants will be adults 18 years or older, and will be from all race/ethnic backgrounds of persons seeking care for OUD in CA Bridge sites. Patients will be excluded if they fail to or cannot provide informed consent to participate in the CA Bridge or the substudy.

Vulnerable populations

Prisoners. As opioid use disorder disproportionately affects people involved with the criminal justice system and many of the CA Bridge sites provide medical care to prisoners, we expect to enroll a considerable number of individuals referred from local jails. As such, we request that this proposal be reviewed with at least one member who is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. Prisoners will be excluded from the substudy due to the difficulties and complexities of ascertaining follow-up and providing compensation.

Pregnant women. Opioid use disorder affects pregnant women, and many women either use ED/ACH to receive medical care or are first diagnosed pregnant at one of these sites. The research procedures (i.e., surveys) are of minimal risk to all participants including pregnant women. The understanding of the impact of providing medical care for the treatment of OUD in pregnant women presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses. Participation in this study provides only minimal additional risk to pregnant women or their fetuses above routine clinical care.

Children. We will exclude minors from participation in the research activities of the CA Bridge.

Non-English speaking individuals. We will exclude individuals who cannot consent in English.

Decisionally impaired individuals. Opioid use disorder is common in patients with psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions that may cause a diminished capacity to understand the risks and benefits for participation in research and to autonomously provide informed consent. For individuals with co-existing mental health or organic disorder that affect their decisional capacity, we will seek consent from a guardian, health care proxy, or a legally authorized representative. We will inform the proxy that, where possible, s/he should base the decision on substituted judgment, reflecting the views that the subject expressed while decisionally capable. If the values of the subject are not known with respect to a proposed research study, we will ask the proxy to act in the best interest of the subject. If the individual with decisional impairment is capable of exercising some judgment concerning the nature of the research and participation in it, we will obtain the subject's assent in addition to the consent of his/her legally authorized representative.

Many individuals who present to the ED may be impaired due to drug or alcohol use and may not have the decisional capacity to provide consent. Acute intoxication is a contraindication to buprenorphine or methadone use, and patients clinically impaired as deemed by the treating provider, will be excluded from the study.

Inclusion criteria for the CA Bridge study:

- Adults, 18 years or older
- Clinically diagnosed with an opioid use disorder
- Receiving care for OUD in the CA Bridge Program
- Able to provide informed consent

Additional inclusion criteria for the substudy:

- Receiving care in the California Bridge Program at UC San Francisco, Highland Hospital (Oakland), Scripps Mercy (San Diego), UC Davis (Sacramento), USC-LA County (Los Angeles), or Marshall Medical Center (Placerville)

Exclusion criteria for the CA Bridge study:

- Decisionally impaired and no available proxy to consent
- Acutely intoxicated
- Younger than 18 years of age
- Unable to provide consent in English
- Presenting outside of normal business hours or SUN unavailable

Additional exclusion criteria for the substudy:

- Prisoners
- Fulfilled monthly and gender quotas at the enrollment site

3. Recruitment process

Potential participants will be identified by clinical and triage staff at CA Bridge sites. Clinical staff will alert SUNs of the availability of a potential participant as individuals in need of treatment for OUD. SUNs will approach potential participants at CA Bridge sites. Individuals interested in initiating treatment for their OUD at the CA Bridge sites will receive immediate treatment within the ED/ACH setting and linked to continuing care in an affiliated clinic, or in some cases, directly to community resources, such as a MOUD-capable Federally Qualified Health Center (FQHC) or opioid treatment program for continuing care of their OUD. The SUN will conduct a comprehensive needs assessment of the patient and work to identify appropriate services and resources in the community that the patient can be referred to for comprehensive care and “wrap around” services to support recovery from addiction. The SUN will inform CA Bridge patients of the study and evaluate their interest to participate. If an eligible patient is interested in participating, the SUN will initiate the informed consent process (see section 8 for details). An individual’s willingness to participate in the CA Bridge study will not affect their clinical management.

Substudy Only

Participants at the six CA Bridge substudy sites (UCSF, Highland, Marshall, UC Davis, Scripps Mercy, and USC-LA County) will also be informed about the possibility for enrollment into the substudy if monthly quotas for the site have not been fulfilled. If the eligible CA Bridge participant at one of these six sites is interested in enrolling in the substudy, the SUN will initiate the informed consent process (see section 8 for details). An individual’s willingness to participate in the substudy’s research activities will not affect their clinical management.

4. Procedures involving human subjects

The CA Bridge study will collect patient level-data from participants who decide to enroll in the study. Personal health information will be collected via paper case report forms. Data from paper case report forms will be subsequently uploaded by the SUN via a standardized REDCap form. Paper case report forms will be stored at CA Bridge sites in locked file cabinets. All electronic data will be stored on a secure, password protected, encrypted server at UCLA.

Personal health information will be collected on case report forms only after patients agree to participate in the study and sign the informed consent document. Personal health information will be collected from the participant and review of the electronic health record. Personal health information will then be used to ascertain outcome data at 7- and 30- days. Personal health information will include names, date of birth, date of services, medical record number, telephone number, address, and email necessary to reach the participant for follow-up evaluations. Only key personnel and SUNs will have access to personal health information on a need to know basis. SUNs will only have access to personal health information if they need to contact the patient for study related activities. Personal health information will be maintained during the entire course of the study. This will be kept to avoid duplicate enrollment of study participants. The REDCap database will not include: names; street addresses (other than town, city, state and zip code); telephone numbers; fax numbers; e-mail addresses; Social Security numbers; medical records numbers; health plan beneficiary numbers; account numbers; certificate license numbers; vehicle identifiers and serial numbers, including license plates; device identifiers and serial numbers; URLs; IP address numbers; biometric identifiers (including finger and voice prints); or full face photos (or comparable images). The REDCap database will contain dates such as admission, discharge, service, date of birth, date of death; city, state, five digit or more zip code; and ages in years, months or days or hours. The REDCap database will use unique participant identification numbers, with no links to personal health information contained in the Locator Form.

The Locator Form will be completed by each consented participant and will be kept confidential in the participant's records. Data collected on the Locator Form will be used to facilitate contact with the participant for the follow-up aspects of the project. Participants will be asked to provide locator information, including a residential street address, working telephone number, driver's license and social security numbers, as well as the addresses and phone number of individuals who may know of their whereabouts.

Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data known as REDCap (Research Electronic Data Capture). REDCap servers will be housed at UCLA and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines. REDCap has been disseminated for use locally at other institutions and currently supports over 1000 academic/non-profit consortium partners on six continents and over 100,000 research end-users (www.project-redcap.org).

Substudy Only

For the substudy, detailed surveys will be collected using self-administered questionnaires directly via REDCap on computers or tablets at the point of care visit. At 7- and 30-days, surveys will be administered via telephone call. Again, the REDCap dataset will only link back to the Locator Form containing personal health information through a unique identifier. The SUN will call the participant at a scheduled time. The SUN will ask survey questions over the phone and input the answers into a REDCap form. All substudy survey data will be uploaded to UCLA servers and no substudy data will be stored locally. In the rare case that there is no internet access, a paper version will be available as backup. Data from this paper version would be uploaded via REDCap, and the paper version stored in a locked cabinet and transferred to PHI.

There will be no research intervention as part of this research study. All interventions (i.e., receipt of medications, referrals) will be as part of routine clinical care and service provision. MOUD (specifically,

buprenorphine, buprenorphine/naloxone and methadone) are FDA-approved for the treatment of OUD. Individuals who decide against participation in the CA Bridge study or substudy will continue to receive clinical care and treatment for OUD per local clinical protocols. Personal health information for individuals who decline to participate in research activities will be collected for clinical services based on local protocols. For individuals who decline to participate, personal health information or other clinical data for these individuals will not be collected on case report forms or uploaded to central servers.

All research personnel (investigators, research assistants, SUNs) will have completed educational trainings in HIPAA and protection of human subjects. The SUNs will receive this training as part of their required curriculum in the CA Bridge. The CA Bridge study coordinator at PHI will ensure completion of mandated trainings by all staff personal and will collect training certificates. Training completion certificates will be held at PHI.

5. Assessment of benefits

There may be no direct participant benefit to participating in the CA Bridge research activities. Participants in the CA Bridge will not be compensated for their participation. Due to the length of the survey, participants in the substudy will be compensated for their time in answering the survey (see section 9). There may be an indirect benefit to patients, their families, and to communities as a whole, in the use of these data by the CA Bridge to inform quality improvement efforts to better meet the urgent needs of patients with OUD, plan future studies, and inform policy makers. Patients will be told that their decision to participate or not to participate in CA Bridge data collection and research activities will have absolutely no impact on the treatment that they receive at the CA Bridge sites.

6. Assessment of risks

There are no experimental interventions as part of the research activities of CA Bridge. The research activities include collection of data through surveys or via review of the electronic medical record. Due to this, we deem the CA Bridge to pose minimal physical risks to the subjects. However, there may be psychological, economic, employment related, legal, social, or reputational risk to the participant. Due to the highly stigmatized nature of opioid use disorder and its treatment, the biggest factor leading to risk in any or all of these domains is loss of confidentiality (below for a detailed description of safeguards to protect against loss of confidentiality). The other aspect to highlight is the psychological discomfort from completing the survey. If this were to occur SUNs will engage participants to resolve this discomfort and provide referrals to available psychological services at the clinical sites.

7. Confidentiality

The procedures to maintain the confidentiality of patient data at each of the CA Bridge sites will be strictly maintained, following the standard operating procedures for HIPAA compliance that govern protected patient health information within each of the Bridge ED/ACH sites that are participating in the CA Bridge. Within each site, SUNs will obtain a signed release of information form, HIPAA authorization, as well as informed consent to participate in research activities that include collection of personal health information, study related data and to be contacted for follow-up by the SUN. Personal health information will be collected on case report forms. A unique identifier will be created to link study data with personal health information. Study data will be collected on separate forms to any personal health information. Personal health information will be stored locally in locked filing cabinets. There will be no upload of personal health information (except for dates) to UCLA servers. Personal health information will only be used to subsequently contact the participant for follow-ups or to locate the participant in the local hospital's electronic health record.

Study related data will be abstracted from the treatment record (including the EHR) by the SUNs using case report forms on paper or through direct entry into REDCap. All study related data will be identified only by the

unique identifier assigned at study entry. The unique identifier will be a combination of three letters identifying the site, followed by a sequential number at each site. All study related data will be stored on UCLA servers when submitted through REDCap.

Substudy Only

For the substudy, data will be directly entered by the participant or with the assistance of the SUN to electronic forms created in REDCap. No personal health information will be uploaded. Data will be entered with use of tablets or local computers, however, no substudy data will be stored locally. SUNs will be required to retrieve the tablet after use. All tablets when not in use will be stored in locked storage cabinets in locked offices. Hospital computers may also be used to record data. If these will be used, SUNs will login with their unique username and password. After login-in, they will enter the REDCap form and enter the participant's unique identifier. After the participant finishes the survey, the SUN will logout of REDCap and the computer.

All data will be owned by PHI. Data sharing to outside investigators will be allowed only after prior review by the principal investigator and PHI staff. Only de-identified datasets will be provided to outside investigators. All dates and locations will be stripped from the data to make it fully de-identified. Research records, including case report forms and electronic databases, will be retained for 6 years after completion of study related activities. After this period all study related data will be destroyed.

A Certificate of Confidentiality will be obtained from the National Institutes of Health (42 CFR Part 2a) to ensure that we will not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify participants of the proposed research activities in the CA Bridge. Details are available at: <https://grants.nih.gov/policy/humansubjects/coc.htm>.

There will be no disclosure of data to outside agencies including law enforcement. The only instances when we may disclose information consistent with local laws are if 1) the participant poses imminent physical harm to him/herself or others; if the participant poses immediate mental or emotional injury to him/herself; if the research team learns that a child has been, or may be, abused or neglected; or if the researcher team learn that an elderly or disabled person has been, or is being, abused, neglected, or exploited.

No publication or presentations resulting from this study will lead to identification of individual human subjects. All results will be reported in aggregate.

8. Informed consent/assent process and documentation

Each of the CA Bridge sites are governed by the standard operating procedures to ensure HIPAA compliance and protection of patient health information at their respective institutions. This includes obtaining patient consent for release of information to other service providers, and consent to be contacted in the future. Additionally, every patient the decides to participate in the CA Bridge research activities will be asked to sign an informed consent document (attached). SUNs will go over informed consent materials with the participants. If the participant decides to participate, the SUN will request that the individual sign the informed consent document. Only after signing of the informed consent document, will study related activities and collection of personal health information on case report forms will initiate. Again, potential participants will be told that their decision to participate or not to participate in the CA Bridge study will have absolutely no impact on the treatment that they receive through at the clinical site.

Substudy Only

For participants who are selected for participation in the substudy, a second informed consent will be presented and reviewed. SUNs will delineate the fact that consent is being sought for research and that participation is voluntary; the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; the reasonably foreseeable risks or discomforts to the prospective subject; the benefits to the prospective subject or to others that may reasonably be expected from the research;

and appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject. For purpose of this research, biospecimens will not be collected.

9. Financial issues

Participants will not be compensated for their participation in the CA Bridge study but will be compensated for their participation in the substudy. Compensation will be in the form of gift cards to local shops in each sites area. The gift cards will be stored on site at the five substudy sites. Compensation will be \$20, \$10, \$20 for the point of care visit, seven day, and 30-day follow-up, respectively. At the point of care visit, gift cards will be provided after completion of the survey in person. For the follow-up visits, gift cards will either mailed, delivered electronically (email) or could be picked up at the site, based on participant preference. The participant's decision to sign a release of personal health information, HIPAA authorization and informed consent is completely voluntary and will have no impact on the treatment or care that patients receive in the CA Bridge.

10. Written materials

- *Appendix 1: CA Bridge Flyer*
- *Appendix 2: CA Bridge Locator Form for collection of personal health information*
- *Appendix 3: CA Bridge basic questionnaire*
- *Appendix 4: Substudy questionnaire*

11. Qualifications of principal investigator

Dr. Andrew A Herring graduated from Harvard Medical School and completed his residency in emergency medicine at Highland Hospital—Alameda Health System in Oakland, CA where he continues as an attending emergency physician and Associate Director of Research. Dr. Herring's current research focuses on emergency department treatment of opioid use disorders and pain management. He is an active researcher within the NIDA Clinical Trials Network and lead investigator of NIDA CTN-0069-A-1 and a co-investigator on NIDA CTN 0099 (ED-INNOVATE). Dr. Herring is the Principal Investigator of the CA Bridge. Dr. Herring is an Assistant Clinical Professor at the University of California, San Francisco and conducted health policy research as a Fulbright Scholar in Central America. Dr. Herring is board-certified in Emergency Medicine, Addiction Medicine, and Pain Medicine.

References

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6. Herring AA, Perrone J, Nelson LS. Managing Opioid Withdrawal in the Emergency Department With Buprenorphine. *Annals of Emergency Medicine*. 2019 May 1;73(5):481–7.
7. Houry DE, Haegerich TM, Vivolo-Kantor A. Opportunities for Prevention and Intervention of Opioid Overdose in the Emergency Department. *Annals of Emergency Medicine*. 2018 Jun 1;71(6):688–90.
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9. Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic. *New England Journal of Medicine*. 2014 May 29;370(22):2063–6.
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11. D'Onofrio G, Chawarski MC, O'Connor PG, Pantalon MV, Busch SH, Owens PH, et al. Emergency Department-Initiated Buprenorphine for Opioid Dependence with Continuation in Primary Care: Outcomes During and After Intervention. *J Gen Intern Med*. 2017 Jun;32(6):660–6.

California Bridge Program:
Clinical Intake form

CA BRIDGE PHI

Codebook ▾

Data Dictionary Codebook

07/22/2019 12:38am

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)								
Instrument: Bridge Hgh (bridge_hgh)											
1	study_id	(A.1) BRIDGE ID	text								
2	last_name	(B.1) Last Name	text								
3	first_name	(B.2) First Name	text								
4	mrn	(B.3) MRN	text								
5	dob	(B.4) Date of birth <i>mm/dd/yyyy</i>	text (date_mdy)								
6	age	(B.5) Age, years <i>calculated from dob</i>	calc Calculation: rounddown(datediff("today", [dob], "y", "mdy"), 0)								
7	gender	(B.8) Gender	radio <table border="1"> <tr><td>1</td><td>Male</td></tr> <tr><td>2</td><td>Female</td></tr> <tr><td>3</td><td>Transgender</td></tr> <tr><td>4</td><td>Gender non-binary</td></tr> </table>	1	Male	2	Female	3	Transgender	4	Gender non-binary
1	Male										
2	Female										
3	Transgender										
4	Gender non-binary										
8	preg Show the field ONLY if: [gender] = '2'	Is the patient pregnant? <i>mm/dd/yyyy</i>	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
9	primary_phone	(B.6) Primary Phone Number	text								
10	primary_phone_2	(B.6a) Secondary Phone Number	text								
11	date_intake	(B.7) Date intake <i>mm/dd/yyyy</i>	text (date_mdy)								

	12	race_ethn	(B.9) Race/Ethnicity	<table border="1"> <tr><td colspan="2">radio</td></tr> <tr><td>1</td><td>white non-hispanic</td></tr> <tr><td>2</td><td>Hispanic/Latino</td></tr> <tr><td>3</td><td>Black or African American</td></tr> <tr><td>4</td><td>Native American or American Indian</td></tr> <tr><td>5</td><td>Asian Pacific Islander</td></tr> <tr><td>6</td><td>Other/Mixed</td></tr> </table>	radio		1	white non-hispanic	2	Hispanic/Latino	3	Black or African American	4	Native American or American Indian	5	Asian Pacific Islander	6	Other/Mixed				
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	13	insurance	(B.10) Insurance	<table border="1"> <tr><td colspan="2">radio</td></tr> <tr><td>0</td><td>Private</td></tr> <tr><td>1</td><td>Medi-Cal</td></tr> <tr><td>2</td><td>Medicare</td></tr> <tr><td>3</td><td>Military (ie Tricare, VA)</td></tr> <tr><td>4</td><td>Indian Health Service</td></tr> <tr><td>5</td><td>County based (Alameda Alliance, Healthy SF)</td></tr> <tr><td>6</td><td>No Insurance</td></tr> <tr><td>7</td><td>Unknown</td></tr> </table>	radio		0	Private	1	Medi-Cal	2	Medicare	3	Military (ie Tricare, VA)	4	Indian Health Service	5	County based (Alameda Alliance, Healthy SF)	6	No Insurance	7	Unknown
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	14	housing	(B.11) Housing status	<table border="1"> <tr><td colspan="2">radio</td></tr> <tr><td>0</td><td>Stably housed (own or rent house or apartment, share housing, etc)</td></tr> <tr><td>1</td><td>Marginally housed (including couch surfing)</td></tr> <tr><td>2</td><td>Shelter</td></tr> <tr><td>3</td><td>Street or vehicle</td></tr> <tr><td>4</td><td>Sobering center (short term, e.g. Cherry Hill)</td></tr> <tr><td>5</td><td>Sober living facility/halfway house (Teen Challenge, Orchid House, etc)</td></tr> <tr><td>6</td><td>Other</td></tr> <tr><td>7</td><td>Unknown</td></tr> </table>	radio		0	Stably housed (own or rent house or apartment, share housing, etc)	1	Marginally housed (including couch surfing)	2	Shelter	3	Street or vehicle	4	Sobering center (short term, e.g. Cherry Hill)	5	Sober living facility/halfway house (Teen Challenge, Orchid House, etc)	6	Other	7	Unknown
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7	Unknown																					

15	pres_comps	(B.12) presenting complaints <i>Check all that apply</i>	checkbox <table border="1" data-bbox="1047 121 1523 1339"> <tr> <td>1</td> <td>pres_comps__1</td> <td>Opioid withdrawal</td> </tr> <tr> <td>2</td> <td>pres_comps__2</td> <td>Overdose</td> </tr> <tr> <td>3</td> <td>pres_comps__3</td> <td>Seeking detox or addiction treatment (MOUD)</td> </tr> <tr> <td>4</td> <td>pres_comps__4</td> <td>Opioid related infection (e.g. abscess, endocarditis)</td> </tr> <tr> <td>5</td> <td>pres_comps__5</td> <td>Seeking opioid pain medications</td> </tr> <tr> <td>6</td> <td>pres_comps__6</td> <td>Alcohol use disorder</td> </tr> <tr> <td>7</td> <td>pres_comps__7</td> <td>Stimulant use disorder</td> </tr> <tr> <td>8</td> <td>pres_comps__8</td> <td>SSTI (abscess, cellulitis)</td> </tr> <tr> <td>9</td> <td>pres_comps__9</td> <td>Non-opioid related ED visit or hospitalization (appendicitis, trauma stroke, etc)</td> </tr> <tr> <td>10</td> <td>pres_comps__10</td> <td>Other</td> </tr> <tr> <td>14</td> <td>pres_comps__14</td> <td>Unknown</td> </tr> </table>	1	pres_comps__1	Opioid withdrawal	2	pres_comps__2	Overdose	3	pres_comps__3	Seeking detox or addiction treatment (MOUD)	4	pres_comps__4	Opioid related infection (e.g. abscess, endocarditis)	5	pres_comps__5	Seeking opioid pain medications	6	pres_comps__6	Alcohol use disorder	7	pres_comps__7	Stimulant use disorder	8	pres_comps__8	SSTI (abscess, cellulitis)	9	pres_comps__9	Non-opioid related ED visit or hospitalization (appendicitis, trauma stroke, etc)	10	pres_comps__10	Other	14	pres_comps__14	Unknown
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10	pres_comps__10	Other																																		
14	pres_comps__14	Unknown																																		
16	pt_id_by	Section Header: <i>Section C: Intake</i> (C.1) Who initially identified patient with OUD <i>patients not identified by a clinician are considered identified by SUN</i>	radio <table border="1" data-bbox="1047 1398 1323 1556"> <tr> <td>1</td> <td>ED clinician</td> </tr> <tr> <td>2</td> <td>Inpatient Clinician</td> </tr> <tr> <td>3</td> <td>SUN</td> </tr> </table>	1	ED clinician	2	Inpatient Clinician	3	SUN																											
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17	referral_date	(C.2) Date First Referral <i>mm/dd/yyyy</i>	text (date_mdy)																																	
18	sun_contacted	(C.3) SUN In-Person Contact	radio <table border="1" data-bbox="1047 1698 1523 1940"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>2</td> <td>No</td> </tr> <tr> <td>3</td> <td>N/A after hours referral</td> </tr> <tr> <td>4</td> <td>Eloped / discharged prior to SUN contact</td> </tr> </table>	1	Yes	2	No	3	N/A after hours referral	4	Eloped / discharged prior to SUN contact																									
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19	mode_referral Show the field ONLY if: [pt_id_by] = '1'	ED Referral method	radio 0 In person consult/warm handoff 1 After hours referral via email/amion/EHR 2 Other
20	inpt_referral Show the field ONLY if: [pt_id_by] = '2'	Inpatient referral source	radio 0 Medicine 1 General Surgery 2 Ortho 3 Other
21	opioid_fav	(C.4) What is their current primary opioid ?	radio 1 heroin 2 pain pills from the street 3 pain pills from a doctor 4 fentanyl from the street 5 opium 6 other
22	opioid_fav_2	(C.5) How do they typically take their opioid?	radio 1 swallow it 2 Snort it 3 smoke it 4 inject it with a needle 5 other
23	idu	(C.6.) Has the patient ever used a needle to inject any drug?	yesno 1 Yes 0 No

24	<p>idu_complication</p> <p>Show the field ONLY if: [idu] = '1'</p>	<p>(C.7) Has the patient ever had any of the following complications from injecting drugs?</p>	<p>checkbox</p> <table border="1"> <tr> <td>1</td> <td>idu_complication__1</td> <td>skin abscess or infection</td> </tr> <tr> <td>2</td> <td>idu_complication__2</td> <td>spinal abscess</td> </tr> <tr> <td>3</td> <td>idu_complication__3</td> <td>bone infection (osteomyelitis)</td> </tr> <tr> <td>4</td> <td>idu_complication__4</td> <td>blood infection</td> </tr> <tr> <td>5</td> <td>idu_complication__5</td> <td>infection in the heart (endocarditis)</td> </tr> <tr> <td>6</td> <td>idu_complication__6</td> <td>infection in the brain (meningitis)</td> </tr> </table>	1	idu_complication__1	skin abscess or infection	2	idu_complication__2	spinal abscess	3	idu_complication__3	bone infection (osteomyelitis)	4	idu_complication__4	blood infection	5	idu_complication__5	infection in the heart (endocarditis)	6	idu_complication__6	infection in the brain (meningitis)
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25	<p>opioid_type_frst</p>	<p>(C.8.) What was the first opioid they EVER tried?</p>	<p>radio</p> <table border="1"> <tr> <td>1</td> <td>heroin</td> </tr> <tr> <td>2</td> <td>pain pills from the street</td> </tr> <tr> <td>3</td> <td>pain pills from a doctor</td> </tr> <tr> <td>4</td> <td>fentanyl from the street</td> </tr> <tr> <td>5</td> <td>opium</td> </tr> <tr> <td>6</td> <td>other</td> </tr> </table>	1	heroin	2	pain pills from the street	3	pain pills from a doctor	4	fentanyl from the street	5	opium	6	other						
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26	<p>frst_opioid</p>	<p>(C.9) How old were they when they tried any opioid for the first time? (include prescribed opioids)</p>	<p>radio</p> <table border="1"> <tr> <td>1</td> <td>Child (00-14 years)</td> </tr> <tr> <td>2</td> <td>Youth (15-18 years)</td> </tr> <tr> <td>3</td> <td>Young Adult (19-24 years)</td> </tr> <tr> <td>4</td> <td>Adult (25-64 years)</td> </tr> <tr> <td>5</td> <td>Senior (65 years and over)</td> </tr> </table>	1	Child (00-14 years)	2	Youth (15-18 years)	3	Young Adult (19-24 years)	4	Adult (25-64 years)	5	Senior (65 years and over)								
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27	<p>od</p>	<p>(C.10) Have they ever overdosed?</p>	<p>yesno</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
28	<p>times_od</p> <p>Show the field ONLY if: [od] = '1'</p>	<p>How many times ?</p>	<p>text (integer, Min: 1, Max: 100)</p>																		
29	<p>last_od</p> <p>Show the field ONLY if: [od] = '1'</p>	<p>When was the last time the patient OD?</p>	<p>checkbox</p>																		

30	other_sud	(C.11) Do they report or is there documentation of any other substance use?	checkbox <table border="1"> <tr> <td data-bbox="1040 121 1084 212">1</td> <td data-bbox="1084 121 1279 212">other_sud__1</td> <td data-bbox="1279 121 1526 212">opioid use disorder</td> </tr> <tr> <td data-bbox="1040 212 1084 302">2</td> <td data-bbox="1084 212 1279 302">other_sud__2</td> <td data-bbox="1279 212 1526 302">alcohol use disorder</td> </tr> <tr> <td data-bbox="1040 302 1084 392">3</td> <td data-bbox="1084 302 1279 392">other_sud__3</td> <td data-bbox="1279 302 1526 392">methamphetamine use disorder</td> </tr> <tr> <td data-bbox="1040 392 1084 483">4</td> <td data-bbox="1084 392 1279 483">other_sud__4</td> <td data-bbox="1279 392 1526 483">cocaine/crack use disorder</td> </tr> <tr> <td data-bbox="1040 483 1084 527">5</td> <td data-bbox="1084 483 1279 527">other_sud__5</td> <td data-bbox="1279 483 1526 527">benzo use disorder</td> </tr> <tr> <td data-bbox="1040 527 1084 581">6</td> <td data-bbox="1084 527 1279 581">other_sud__6</td> <td data-bbox="1279 527 1526 581">other use disorder</td> </tr> </table>	1	other_sud__1	opioid use disorder	2	other_sud__2	alcohol use disorder	3	other_sud__3	methamphetamine use disorder	4	other_sud__4	cocaine/crack use disorder	5	other_sud__5	benzo use disorder	6	other_sud__6	other use disorder
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31	bup_given	(C.12) Buprenorphine given at initial encounter	radio <table border="1"> <tr> <td data-bbox="1040 640 1084 688">1</td> <td data-bbox="1084 640 1526 688">Yes ED</td> </tr> <tr> <td data-bbox="1040 688 1084 743">2</td> <td data-bbox="1084 688 1526 743">Yes Inpatient</td> </tr> <tr> <td data-bbox="1040 743 1084 798">3</td> <td data-bbox="1084 743 1526 798">Yes ED and Inpatient</td> </tr> <tr> <td data-bbox="1040 798 1084 852">4</td> <td data-bbox="1084 798 1526 852">Not Given</td> </tr> <tr> <td data-bbox="1040 852 1084 942">5</td> <td data-bbox="1084 852 1526 942">N/A - seen as walk-in directly in clinic</td> </tr> </table>	1	Yes ED	2	Yes Inpatient	3	Yes ED and Inpatient	4	Not Given	5	N/A - seen as walk-in directly in clinic								
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32	not_given_reason Show the field ONLY if: [bup_given] = '4'	Reason Bup Not Given	radio <table border="1"> <tr> <td data-bbox="1040 997 1084 1087">0</td> <td data-bbox="1084 997 1526 1087">Opioids on board- not in withdrawal</td> </tr> <tr> <td data-bbox="1040 1087 1084 1142">1</td> <td data-bbox="1084 1087 1526 1142">Patient Declined</td> </tr> <tr> <td data-bbox="1040 1142 1084 1197">2</td> <td data-bbox="1084 1142 1526 1197">Clinician Declined</td> </tr> <tr> <td data-bbox="1040 1197 1084 1287">3</td> <td data-bbox="1084 1197 1526 1287">Ineligible-intoxicated or altered mental status</td> </tr> <tr> <td data-bbox="1040 1287 1084 1341">4</td> <td data-bbox="1084 1287 1526 1341">Ineligible-recent methadone</td> </tr> <tr> <td data-bbox="1040 1341 1084 1396">5</td> <td data-bbox="1084 1341 1526 1396">Ineligible-acute pain</td> </tr> <tr> <td data-bbox="1040 1396 1084 1451">6</td> <td data-bbox="1084 1396 1526 1451">Ineligible-acute illness</td> </tr> <tr> <td data-bbox="1040 1451 1084 1505">7</td> <td data-bbox="1084 1451 1526 1505">Ineligible-other</td> </tr> <tr> <td data-bbox="1040 1505 1084 1547">8</td> <td data-bbox="1084 1505 1526 1547">unknown</td> </tr> </table>	0	Opioids on board- not in withdrawal	1	Patient Declined	2	Clinician Declined	3	Ineligible-intoxicated or altered mental status	4	Ineligible-recent methadone	5	Ineligible-acute pain	6	Ineligible-acute illness	7	Ineligible-other	8	unknown
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7	Ineligible-other																				
8	unknown																				

33	<p>bup_dose</p> <p>Show the field ONLY if: [bup_given] = '1' or [bup_given] = '3'</p>	<p>Total Bup Dose in ED (round up and chose the closest amount)</p>	<p>radio</p> <table border="1" data-bbox="1047 121 1167 653"> <tr><td>1</td><td>2</td></tr> <tr><td>2</td><td>4</td></tr> <tr><td>3</td><td>6</td></tr> <tr><td>4</td><td>8</td></tr> <tr><td>5</td><td>12</td></tr> <tr><td>6</td><td>16</td></tr> <tr><td>7</td><td>20</td></tr> <tr><td>8</td><td>24</td></tr> <tr><td>9</td><td>32</td></tr> <tr><td>10</td><td>>32</td></tr> </table> <p>Custom alignment: RH</p>	1	2	2	4	3	6	4	8	5	12	6	16	7	20	8	24	9	32	10	>32
1	2																						
2	4																						
3	6																						
4	8																						
5	12																						
6	16																						
7	20																						
8	24																						
9	32																						
10	>32																						
34	<p>ed_discharge_rx</p>	<p>(C.14) Bup Rx written?</p>	<p>radio</p> <table border="1" data-bbox="1047 779 1523 1346"> <tr><td>1</td><td>Yes-at ED discharge</td></tr> <tr><td>2</td><td>Yes-at Inpatient discharge</td></tr> <tr><td>3</td><td>No - Patient has next day followup with an outpatient prescriber and does not want/need rx</td></tr> <tr><td>5</td><td>No - Plan for patient to return to ED next day for repeat dose</td></tr> <tr><td>6</td><td>No - Longer acting (higher) dose administered in ED</td></tr> <tr><td>7</td><td>No - Patient declined</td></tr> <tr><td>8</td><td>No - Clinician declined</td></tr> <tr><td>9</td><td>No - Other reason</td></tr> </table>	1	Yes-at ED discharge	2	Yes-at Inpatient discharge	3	No - Patient has next day followup with an outpatient prescriber and does not want/need rx	5	No - Plan for patient to return to ED next day for repeat dose	6	No - Longer acting (higher) dose administered in ED	7	No - Patient declined	8	No - Clinician declined	9	No - Other reason				
1	Yes-at ED discharge																						
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6	No - Longer acting (higher) dose administered in ED																						
7	No - Patient declined																						
8	No - Clinician declined																						
9	No - Other reason																						
35	<p>rx_until_appt</p> <p>Show the field ONLY if: [ed_discharge_rx] = '1'</p>	<p>How many days was the BUP Script written for?</p>	<p>slider</p> <p>Slider labels: <3, 3-7, >7</p> <p>Custom alignment: RH</p>																				
36	<p>methadone_given</p> <p>Show the field ONLY if: [bup_given] = '4'</p>	<p>(C.13) Methadone given initial encounter</p>	<p>radio</p> <table border="1" data-bbox="1047 1619 1360 1829"> <tr><td>1</td><td>Yes- ED</td></tr> <tr><td>2</td><td>Yes- Inpatient</td></tr> <tr><td>3</td><td>Yes- ED and Inpatient</td></tr> <tr><td>4</td><td>Not Given</td></tr> </table>	1	Yes- ED	2	Yes- Inpatient	3	Yes- ED and Inpatient	4	Not Given												
1	Yes- ED																						
2	Yes- Inpatient																						
3	Yes- ED and Inpatient																						
4	Not Given																						

37	m_not_given_reason Show the field ONLY if: [methadone_given] = '4'	Reason methadone not given	radio <table border="1"> <tr><td>0</td><td>Started on bus</td></tr> <tr><td>1</td><td>Patient Declined</td></tr> <tr><td>2</td><td>Clinician Declined</td></tr> <tr><td>3</td><td>Ineligible-intoxicated or altered mental status</td></tr> <tr><td>5</td><td>Ineligible-acute illness</td></tr> <tr><td>6</td><td>Ineligible-other</td></tr> <tr><td>7</td><td>Unknown</td></tr> </table>	0	Started on bus	1	Patient Declined	2	Clinician Declined	3	Ineligible-intoxicated or altered mental status	5	Ineligible-acute illness	6	Ineligible-other	7	Unknown
0	Started on bus																
1	Patient Declined																
2	Clinician Declined																
3	Ineligible-intoxicated or altered mental status																
5	Ineligible-acute illness																
6	Ineligible-other																
7	Unknown																
38	methadone_dose Show the field ONLY if: [methadone_given] = '1' or [methadone_giv en] = '3'	First Methadone Dose in Mg.	text (integer, Min: 0, Max: 200)														
39	referral_acc	Section Header: <i>SECTION D: Linkage to care</i> (D.1) Patient accepted referral	radio <table border="1"> <tr><td>1</td><td>Accepted</td></tr> <tr><td>2</td><td>Declined</td></tr> <tr><td>3</td><td>N/A - Already accessing outpatient MOUD treatment</td></tr> <tr><td>4</td><td>N/A - Incarcerated</td></tr> <tr><td>5</td><td>N/A - Leaving region</td></tr> <tr><td>6</td><td>N/A - Other reason not referred</td></tr> </table>	1	Accepted	2	Declined	3	N/A - Already accessing outpatient MOUD treatment	4	N/A - Incarcerated	5	N/A - Leaving region	6	N/A - Other reason not referred		
1	Accepted																
2	Declined																
3	N/A - Already accessing outpatient MOUD treatment																
4	N/A - Incarcerated																
5	N/A - Leaving region																
6	N/A - Other reason not referred																
40	not_referred_other Show the field ONLY if: [referral_acc] = '6'	Other reason not referred	text														
41	app_72hr Show the field ONLY if: [referral_acc] = '1'	Appointment available within 72 hours	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> </table>	0	No	1	Yes										
0	No																
1	Yes																
42	referral_location_2 Show the field ONLY if: [referral_acc] = '1'	(D.2) Where are they going to follow up for ongoing MAT?	text														
43	referral_location Show the field ONLY if: [referral_acc] = '1'	What type of program or clinic is it?	radio <table border="1"> <tr><td>1</td><td>Dedicated "Bridge Clinic"</td></tr> <tr><td>2</td><td>Primary care</td></tr> <tr><td>3</td><td>OTP or "Methadone Clinic"</td></tr> <tr><td>4</td><td>Other</td></tr> </table>	1	Dedicated "Bridge Clinic"	2	Primary care	3	OTP or "Methadone Clinic"	4	Other						
1	Dedicated "Bridge Clinic"																
2	Primary care																
3	OTP or "Methadone Clinic"																
4	Other																

44	referral_location_othe r Show the field ONLY if: [referral_location] = '4'	Other Referral Location	text										
45	app_date Show the field ONLY if: [referral_acc] = '1'	Follow up appointment date:	text (date_mdy)										
46	contacted_10d	(D.4) Pt successfully contacted by SUN within 10 days of discharge from ED/Inpatient?	radio <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>2</td><td>Attempted - unable to contact</td></tr> <tr><td>3</td><td>No contact info available</td></tr> <tr><td>4</td><td>Not attempted</td></tr> <tr><td>5</td><td>N/A - Not referred</td></tr> </table>	1	Yes	2	Attempted - unable to contact	3	No contact info available	4	Not attempted	5	N/A - Not referred
1	Yes												
2	Attempted - unable to contact												
3	No contact info available												
4	Not attempted												
5	N/A - Not referred												
47	fu_attended Show the field ONLY if: [contacted_10d] = '1'	Did they attended a follow up appointment after ED discharge in the first 10 days?	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> <tr><td>2</td><td>Unknown</td></tr> <tr><td>3</td><td>N/A - Not referred</td></tr> </table>	0	No	1	Yes	2	Unknown	3	N/A - Not referred		
0	No												
1	Yes												
2	Unknown												
3	N/A - Not referred												
48	fu_within_30d Show the field ONLY if: [fu_attended] = '1'	Patient attended follow up appt within 30 days after discharge from Hospital/ED?	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> <tr><td>2</td><td>Unknown</td></tr> <tr><td>3</td><td>N/A - Not referred</td></tr> </table>	0	No	1	Yes	2	Unknown	3	N/A - Not referred		
0	No												
1	Yes												
2	Unknown												
3	N/A - Not referred												
49	past_bup	Section Header: <i>SECTION E: Prior MAT</i> (E.1) Has the patient ever tried BUP before?	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> </table>	0	No	1	Yes						
0	No												
1	Yes												
50	past_bup_source Show the field ONLY if: [past_bup] = '1'	The first time they tried BUP, where did they get the BUP from?	radio <table border="1"> <tr><td>0</td><td>Prescribed</td></tr> <tr><td>1</td><td>Street (illicit)</td></tr> </table>	0	Prescribed	1	Street (illicit)						
0	Prescribed												
1	Street (illicit)												
51	past_bup_source_2 Show the field ONLY if: [past_bup_source] = '0'	Have they ever got bup from the street or a friend?	yesno <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No						
1	Yes												
0	No												

52	past_bup_source_3 Show the field ONLY if: [past_bup_source] = '1'	Have they ever been prescribed BUP?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
53	past_methadone	(E.2) Has the patient ever tired methadone?	radio <table border="1"> <tr> <td>1</td> <td>prescribed</td> </tr> <tr> <td>2</td> <td>from the street (illicit)</td> </tr> </table>	1	prescribed	2	from the street (illicit)														
1	prescribed																				
2	from the street (illicit)																				
54	mh_5150	Section Header: <i>SECTION F: Mental Health</i> (F.1) Was the patient brought to the Hospital for psychiatric evaluation? (e.g on a 5150 hold)	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
55	selfharm Show the field ONLY if: [mh_5150] = '1'	Is the 5150 for concern for self harm?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
56	suicide	(F.2) Does the patient report or is their documentation of ever attempting suicide ?	checkbox																		
57	mh_dx	(F.3) Does the patient report or is there documentation of a Mental Health Disorder? <i>mm/dd/yyyy</i>	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
58	psych_dx Show the field ONLY if: [mh_dx] = '1'	What psychiatric diagnoses are reported or documented?	checkbox <table border="1"> <tr> <td>1</td> <td>psych_dx__1</td> <td>depression</td> </tr> <tr> <td>2</td> <td>psych_dx__2</td> <td>anxiety</td> </tr> <tr> <td>3</td> <td>psych_dx__3</td> <td>schizophrenia</td> </tr> <tr> <td>4</td> <td>psych_dx__4</td> <td>Bipolar</td> </tr> <tr> <td>5</td> <td>psych_dx__5</td> <td>PTSD</td> </tr> <tr> <td>6</td> <td>psych_dx__6</td> <td>Other</td> </tr> </table>	1	psych_dx__1	depression	2	psych_dx__2	anxiety	3	psych_dx__3	schizophrenia	4	psych_dx__4	Bipolar	5	psych_dx__5	PTSD	6	psych_dx__6	Other
1	psych_dx__1	depression																			
2	psych_dx__2	anxiety																			
3	psych_dx__3	schizophrenia																			
4	psych_dx__4	Bipolar																			
5	psych_dx__5	PTSD																			
6	psych_dx__6	Other																			
59	dx_hiv	Section Header: <i>Section G: Use related infections</i> (E.6) Does the patient report or is there documentation HIV?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
60	hiv_screen Show the field ONLY if: [hiv] = '1'	Was the patient screened for HIV?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				
61	dx_hiv_2	(E.7) Does the patient report or is there documentation Hepatitis C?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No														
1	Yes																				
0	No																				

62	hcv_screen Show the field ONLY if: [hcv] = '0'	Was the patient screened for HEP C? <i>Include all meds</i>	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No		
1	Yes								
0	No								
63	prev_ed	Section Header: <i>Section G: Healthcare Utilization</i> (G.1) How many ED Visits has the patient had in the last 12 months?	text (integer, Min: 0, Max: 100)						
64	prev_ed_2 Show the field ONLY if: [prev_ed] >= 1	How many times were they hospitalized?	text (integer, Min: 0, Max: 100)						
65	bridge_hgh_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr> <td>0</td> <td>Incomplete</td> </tr> <tr> <td>1</td> <td>Unverified</td> </tr> <tr> <td>2</td> <td>Complete</td> </tr> </table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

California Bridge Program:
Retention messages

Messages

(Phone contact, email, follow-up letters, etc.)

These messages will be used for retention and communication purposes for contacting participants for follow-up visits.

Message 1:

Hi _____,
(Participant name)

We just wanted to remind you that your follow-up appointment is on _____ (list date and time). We look forward to talking to you then!

Let us know if you have conflicts with your schedule and we can work with you.

Please call us at xxx-xxx-xxxx to let us know how you are and if you are able to talk to us on _____ (date/time for follow-up appointment). (Optional - **You can also call our study cell phone xxx-xxx-xxxx.**)

(Optional on all messages – pick as needed) We hope you are doing well. If you are having any issues with scheduling, please let us know, and we can work with you to see if we can help make things easier. It's important that we evaluate your health and safety. We'd love to hear from you. Remember, you are a valuable member of this study!

Message 2:

Hi _____,
(Participant name)

We have not heard from you since your last contact with us on _____ (date of last contact). We tried to contact you by _____, _____, and _____ (list ways of communication) and did not hear back. We really want to see or hear from you. We hope everything is okay.

Please call us at xxx-xxx-xxxx to let us know how you are and we can talk to you briefly about the study. (Optional - **You can also call our study cell phone xxx-xxx-xxxx.**)

(Optional on all messages – pick as needed) We hope you are doing well. If you are having any issues with scheduling, please let us know, and we can work with you to see if we can help make things easier. It's important that we evaluate your health and safety. We'd love to hear from you. Remember, you are a valuable member of this study!

We hope to hear from you soon.

Thanks,

Staff Name (s)
Contact number
Contact email

Message 3:

Hi _____,
(Participant name)

You missed talking to you on _____ (date of missed appointment (s)). We just wanted to remind you that your participation in the study is very important to us. Please let us know if your (work, home, treatment, legal/court, or family) schedule is making it hard for you to keep your research appointments. We will do our best to work around your schedule and complete your visit.

Let us know what time and day works for you (days and times).

Please call us at xxx-xxx-xxxx to let us know how you are and if you can talk to us. (Optional - **You can also call our study cell phone xxx-xxx-xxxx.**)

(Optional on all messages– pick as needed) We hope you are doing well. If you are having any issues with scheduling, please let us know, and we can work with you to see if we can help make things easier. It's important that we evaluate your health and safety. We'd love to hear from you. Remember, you are a valuable member of this study!

Hope to see you soon,

Thank you!

Staff Name (s)
Contact number
Contact email

California Bridge Program:
Screening Script

SCREENING SCRIPT

Site Staff Instructions: Before you begin the screening, you will need to convey the following information to the potential participant (feel free to use your own words, but make sure all points are addressed and the meaning is unchanged).

Introduction

Hello. Thank you for talking to me regarding our research study. We are looking for adults who are using opioids and are seeking treatment who are interested in participating in a research study.

If yes:

Would you like to hear about our study?

If yes:

The purpose of this study is to evaluate emergency room and hospital treatments of patients with opioid use disorder. We want to understand how often patients who receive addiction medicine follow-up with providers at 7 and 30 day intervals. We want to understand what factors contribute to patients starting and staying in treatment, and what treatment services are most helpful to people with opioid use disorder.

If you are determined to be a good match for the study, we will ask you to provide personal health information and answer basic questions regarding your demographics, substance use, and clinical symptoms. We will attempt to contact you in 7 and 30 days after today's visit.

Your participation in this research study is voluntary and your decision to participate or not to participate in the research study will absolutely have no impact on the treatment you receive through the California Bridge Program.

Are you interested in participating in our study?

Yes No

If YES (ELIGIBLE):

Thank you for your willingness to answer our questions. I'd like to explain the study to you in more detail and, if you are still interested, they will obtain your written permission to begin the study screening process. Completing this process will in no way require you to participate in this study. You may choose not to participate or change your mind about participation at any time.

If NO (INELIGIBLE): (Indicate reason)

Not interested in study

Not eligible

Other, specify _____

Thank you for your willingness to answer our questions.

Closing

Do you have any questions about this research?

I am going to give you a couple of telephone numbers to call if you have any questions later. Do you have a pen?

If you have questions about the research screening you may email Dr. Andrew Herring at Andrew.a.herring@gmail.com.

If you have any questions about your rights as a research subject, please call the Public Health Institutional Review Board at (510) 285-5500.

California Bridge Program:
Substudy survey forms

Socioeconomic status

1. Religious preference

1[] Protestant

2[] Catholic

3[] Jewish

4[] Islamic

5[] Other

6[] None

2. *Have you been in a controlled environment in the past 30 days?*

1[] No - Go to Q4

2[] Jail

3[] Alcohol or Drug Treatment

4[] Medical Treatment

5[] Psychiatric Treatment

6[] Other _____

3. *How many days?* |__|__|

4. Do you have a profession, trade, or skill?

0[] No 1[] Yes _____ Specify

5. *Do you have a valid driver's license?*

0[] No 1[] Yes

6. *Do you have an automobile available for use? (Answer No if no valid driver's license.)*

0[] No 1[] Yes

How long was your longest full-time job?

|_|_|_|_|

YRS MOS

7. **Usual (or last) occupation.*

_____ (Specify in detail)

8. *Does someone contribute to your support in any way?*

0[]No 1[]Yes

9. Usual employment pattern, past 3 years.

1[]full time (40 hrs/wk)

2[]part time (reg. Hrs)

3[]part time (irreg, daywork)

4[]student

5[]service

6[]retired/disability

7[]unemployed

8[]in controlled environment

10. *How many days were you paid for working in the past 30? (include "under the table" work"*

11. *How much money did you receive from the following sources in the past 30 days?*

Employment (net income) |_|_|_|_|_|

Unemployment compensation |_|_|_|_|_|

DPA |_|_|_|_|_|

Pension, benefits or Social Security |_|_|_|_|_|

Mate, family or friends (Money for personal expenses.) |_|_|_|_|_|

Illegal |_|_|_|_|_|

12. How many people depend on you for the majority of their food, shelter, etc.? []

13. How many days have you experienced employment problems in the past 30? []

FAMILY/SOCIAL RELATIONSHIPS

14. Marital Status |__|

1-Married

2-Remarried

3-Widowed

4-Separated

5-Divorced

6-Never Married

15. How long have you been in this marital status? (*If never married, since age 18*).

|__|__| |__|__|

YRS MOS

16. *Usual living arrangements (past month.) |__|

1-With sexual partner and children

2-With sexual partner alone

3-With children alone

4-With parents

5-With family

6-With friends

7-Alone

8-Controlled environment

9-No stable arrangements

17. How long have you lived in these arrangements. *(If with parents or family, since age 18).*

|_|_|_| |_|_|_|

YRS MOS

18. Do you live with anyone who: 0 = No, 1 = Yes

a. Has a current alcohol problem? []

b. Uses non-prescribed drugs? []

19. With whom do you spend most of your free time: []

1-Family

2-Friends

3-Alone

20. How many close friends do you have? |_|_|

Direction for 21: Place "0" in relative category where the answer is clearly no for all relatives in the category; "1" where the answer is clearly yes for any relative within the category; "X" where the answer is uncertain or "I don't know" and "N" where there never was a relative from that category.

Would you say you have had close, long lasting, personal relationships with any of the following people in your life:

- Mother []
- Father []
- Brothers/Sisters []
- Sexual Partner/Spouse []
- Children []
- Friends []

Have you had significant periods in which you have experienced serious problems getting along with:

0 = No 1 = Yes

	PAST 30 DAYS	IN YOUR LIFE
22. <i>Mother</i>	[]	[]
23. <i>Father</i>	[]	[]
24. <i>Brothers/Sisters</i>	[]	[]
25. <i>Sexual partner/spouse</i>	[]	[]
26. <i>Children</i>	[]	[]
27. <i>Other significant family</i>	[]	[]
28. <i>Close friends</i>	[]	[]
29. <i>Neighbors</i>	[]	[]
30. <i>Co-Workers</i>	[]	[]

Did any of these people (Questions 22-30) abuse you:

0 = No, 1 = Yes

	PAST 30 DAYS	IN YOUR LIFE
31. Emotionally (make you feel bad through harsh words)?	[]	[]
32. Physically (cause you physical harm)?	[]	[]
33. Sexually (force sexual advances or sexual acts)?	[]	[]

How many days in the past 30 have you had serious conflicts:

34. *With your family?* |_|_|

35. *With other people? (excluding family)* |_|_|

Source: Addiction Severity Index

NIDA Clinical Trials Network

Timeline Followback (TFB) Method Assessment

Instructions

Complete questions on the form each day for 7 days or as directed by clinical personnel.

TFB Week Start Date: (mm/dd/yyyy) --/--/----

Day

Sunday

Wednesday

Saturday

Monday

Thursday

Tuesday

Friday

Date: (mm/dd/yyyy) --/--/----

1. **Have any illicit substances or alcohol been used on this day?**

No

Yes

2. **Alcohol - number of standard drinks (xx):** --

3. **Cannabinoids/ Marijuana**

No

Yes

4. **Cocaine**

No

Yes

5. **Crack**

No

Yes

6. **Amphetamine-type stimulants**

No

Yes

7. **Opioid analgesics, including methadone**

No

Yes

8. **Heroin**

No

Yes

NIDA Clinical Trials Network

Timeline Followback (TFB) Method Assessment

9. **Hallucinogens, including MDMA/ecstasy**

No

Yes

10. **Sedatives and hypnotics, excluding Benzodiazepine**

No

Yes

11. **Benzodiazepines**

No

Yes

12. **Inhalants**

No

Yes

Other Drugs

13. **Other drug, specify** (enter name - 1): ____

No

Yes

14. **Other drug, specify** (enter name - 2): ____

No

Yes

Comments:

Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]

1. How often do you have a drink containing alcohol?

- Never Monthly or less 2-4 times a month 2-3 times a week
 4 or more times a week

2. How many standard drinks containing alcohol do you have on a typical day?

- 1 or 2 3 or 4 5 or 6 7 to 9
 10 or more

3. How often do you have 6 or more drinks on 1 occasion?

- Never Less than monthly Monthly Weekly
 Daily or almost daily

4. Total score [AUDIT-C]

The Alcohol Use Disorders Identification Test C (AUDIT-C) is scored on a scale of 0-12 where the higher the score, the more likely the patient's drinking is hazardous. A score of 4 or more for men and 3 or more for women is considered positive for hazardous drinking or active alcohol use disorders. If the points are all from Question 1 alone where 2 and 3 are 0, it is likely the patient is drinking below recommended limits. The care provider may review the patients alcohol intake over that past few months to confirm accuracy. [PMID: 12695273]

 {score}

PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problems?

1. **In a hospital* |__|__|

2. **As an outpatient, or private practice, patient* |__|__|

3. *Do you receive a pension for a psychiatric disability?* 0 = No, 1 = Yes []

Have you had a significant period (that was not a direct result of drug/alcohol use), in which you have: 0 = No, 1 = Yes

	PAST 30 DAYS	IN YOUR LIFE
4. <i>Experienced serious depression</i>	[]	[]
5. <i>Experienced serious anxiety or tension</i>	[]	[]
6. <i>Experienced hallucinations</i>	[]	[]
7. <i>Experienced trouble understanding, concentrating, or remembering</i>	[]	[]
8. <i>Experienced trouble controlling violent behavior</i>	[]	[]
9. <i>Experienced serious thoughts of suicide</i>	[]	[]
10. <i>Attempted suicide</i>	[]	[]
11. <i>Been prescribed medication for any psychological emotional problem</i>	[]	[]

12. *How many days in the past 30 have you experienced these psychological or emotional problems?* |__|__|

Source: Addiction Severity Index

NIDA Clinical Trials Network

Patient Health Questionnaire-9 (PHQ-9)

Instructions:

Please respond to each question.

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Give answers as 0 to 3, using this scale:

0=Not at all; 1=Several days; 2=More than half the days; 3=Nearly every day

1. **Little interest or pleasure in doing things**

0 1 2 3

2. **Feeling down, depressed, or hopeless**

0 1 2 3

3. **Trouble falling or staying asleep, or sleeping too much**

0 1 2 3

4. **Feeling tired or having little energy**

0 1 2 3

5. **Poor appetite or overeating**

0 1 2 3

6. **Feeling bad about yourself - or that you are a failure or have let yourself or your family down**

0 1 2 3

7. **Trouble concentrating on things, such as reading the newspaper or watching television**

0 1 2 3

8. **Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual**

0 1 2 3

NIDA Clinical Trials Network

Patient Health Questionnaire-9 (PHQ-9)

9. Thoughts that you would be better off dead or of hurting yourself in some way

0

1

2

3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Give answers using this scale:

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

Instructions

Clinic personnel will follow standard scoring to calculate score based on responses.

Total score:

--

Generalized Anxiety Disorder (GAD-7)

1. Over the last 2 weeks, how often have you been bothered by the following problems? Feeling nervous, anxious or on edge

No instructions available

- not at all Several days More than half the days Nearly every day

2. Over the last 2 weeks, how often have you been bothered by the following problems? Not being able to stop or control worrying

No instructions available

- not at all Several days More than half the days Nearly every day

3. Over the last 2 weeks, how often have you been bothered by the following problems? Worrying too much about different things

No instructions available

- not at all Several days More than half the days Nearly every day

4. Over the last 2 weeks, how often have you been bothered by the following problems? Trouble relaxing

No instructions available

- not at all Several days More than half the days Nearly every day

5. Over the last 2 weeks, how often have you been bothered by the following problems? Being so restless that it is hard to sit still

No instructions available

- not at all Several days More than half the days Nearly every day

6. Over the last 2 weeks, how often have you been bothered by the following problems? Becoming easily annoyed or irritable

No instructions available

- not at all Several days More than half the days Nearly every day

7. Over the last 2 weeks, how often have you been bothered by the following problems? Feeling afraid as if something awful might happen

No instructions available

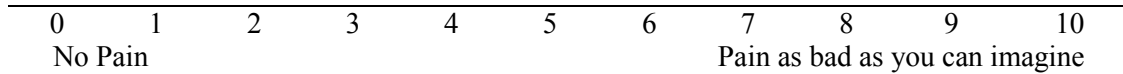
- not at all Several days More than half the days Nearly every day

8. Total score for the GAD-7

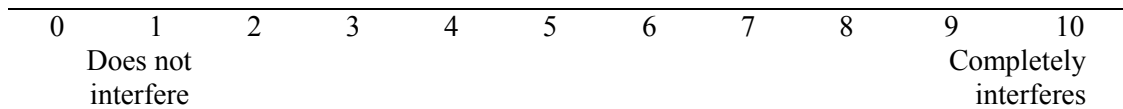
No instructions available

PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)

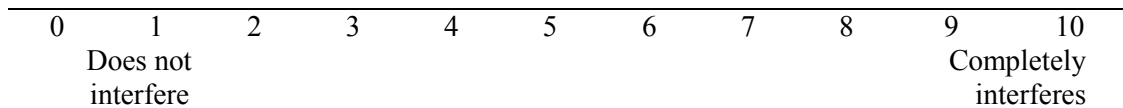
1. What number best describes your pain on average in the past week?



2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?



3. What number best describes how, during the past week, pain has interfered with your general activity?



Computing the PEG Score.

Add the responses to the three questions, then divide by three to get a mean score (out of 10) on overall impact of points.

Using the PEG Score.

The score is best used to track an individual's changes over time. The initiation of therapy should result in the individual's score decreasing over time.

Source.

Krebs, E. E., Lorenz, K. A., Bair, M. J., Damush, T. M., Wu, J., Sutherland, J. M., Asch S, Kroenke, K. (2009). Development and Initial Validation of the PEG, a Three-item Scale Assessing Pain Intensity and Interference. *Journal of General Internal Medicine*, 24(6), 733–738. <http://doi.org/10.1007/s11606-009-0981-1>

Infectious diseases risk questionnaire

Have you ever in your life injected any drug? By injected we mean shot up.

No Yes

Have you injected drugs in the last month?

No Yes

In the past month, how often have you injected any drugs?

Never Once in the month At least once weekly At least once daily

If daily, how many times do you inject drugs in a day?

____ months

Where did you get your needles during the past month? (choose all that apply):

- From a patient who is diabetic or has some other illness
- Drugstore or pharmacy
- Shooting gallery or other place where users go to shoot up
- Needle Exchange Program
- Emergency room, the hospital or a doctor's office
- Online or the internet
- Other _____

Have you reused needles in the past month?

No Yes

If you have cleaned your needles and works in the past month, how did you clean them? (Choose all that apply)

- Soap and water or water only
- Alcohol
- Bleach
- Boiling water
- I did not clean my needles in the last month
- Other _____

Have you shared needles in the past month?

No Yes

In the past month, how often have you shared a needle with someone?

Never Once in the month At least once weekly At least once daily

Have you shared equipment like rinse water, cooker, cotton or syringe in the past month?

No

Yes

HIV

Have you ever been tested for HIV?

No

Yes

When were you tested for HIV? (how long ago)

|_|_| months

What was the result of your last HIV test?

Negative.

Positive

Don't remember

If HIV positive

Do you have a provider (MD or NP or PA) who provides care for HIV?

No

Yes

Are you on antiretroviral medications to treat your HIV?

No

Yes

What was your last CD4 count

|_|_|_| number of cells

Was your last viral load undetectable?

No

Yes

HCV

Have you ever been tested for hepatitis C (HCV)?

No

Yes

When were you tested for hepatitis C (HCV)? (how long ago)

|_|_| months

What was the result of your last hepatitis C (HCV) test?

Negative.

Positive

Don't remember

If known HCV positive

Have you ever been treated for hepatitis C (HCV)?

No

Yes

HBV

Have you ever been tested for hepatitis B (HBV)?

No

Yes

When were you tested for hepatitis B (HBV)?

Overdose and Naloxone access

1. Have you ever overdosed on heroin or other opiates like morphine, methadone, or oxycontin?

No

Yes

2. If yes, in the last 30 days, how many times have you overdosed on heroin or other opiates?

Please write number of times: _____

3. Have you ever been provided with naloxone to take home and use in case you or someone else overdoses?

No

Yes

4. If yes, did you get any training in how to use the naloxone?

No

Yes

5. Where did you receive your naloxone kit?

___ Emergency room

___ Needle exchange

___ Methadone clinic

___ Pharmacy

___ Friend or family member

___ Other: _____

6. Do you know that in the state of California there is a state law that anyone can receive a naloxone kit without a prescription at a pharmacy?

No

Yes

7. Have you ever used naloxone to reverse somebody's overdose?

No

Yes

|_|_| months

What was the result of your last hepatitis B (HBV) test?

No

Yes

If known HBV positive

Have you ever been treated for hepatitis B (HBV)?

No

Yes

HAV

Have you ever been diagnosed with Hepatitis A?

No

Yes

If no, have you ever been vaccinated for hepatitis A?

No

Yes

If vaccinated, when were you vaccinated for hepatitis A?

|_|_| months

Bacterial infections

Have you ever been diagnosed with a skin infection like an abscess or cellulitis?

No

Yes

When was the last time you were diagnosed with a skin infection?

Have you ever been diagnosed with an infection of your blood stream for example bacteremia or endocarditis (heart valves)?

No

Yes

When was the last time you were diagnosed with a blood stream infection?

|_|_| months

Do you know what kind of bacteria? (ie., staph, strep)

|_|_| months

Have you ever been diagnosed with tuberculosis?

No

Yes

Have you ever been diagnosed with wound botulism?

No

Yes

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No

Yes

7. Have you ever used naloxone to reverse somebody's overdose?

No

Yes



Health Questionnaire

English version for the UK

Sample

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

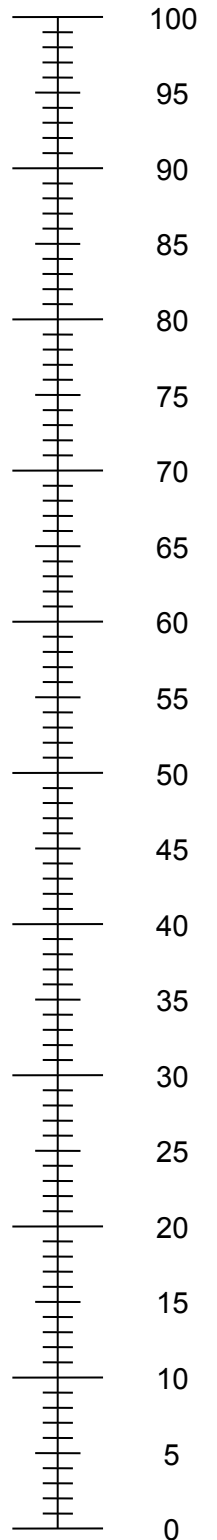
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Criminal Justice

1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)

No

Yes

2. Are you on probation or parole?

No

Yes

3. *How many months were you incarcerated in your life?

|_|_| months

4. How long was your last incarceration?

|_|_| months

5. Are you presently awaiting charges, trial or sentence?

No

Yes

6. How many days in the past 30 were you detained or incarcerated?

|_|_|

7. How many days in the past 30 have you engaged in illegal activities for profit?

|_|_|

8. How serious do you feel your present legal problems are? (Exclude civil problems)

|_| On a scale from 1 to 100

30-day follow-up

Please express the extent of changes for the better from your involvement in the program to this point in four areas: substance use, health, lifestyle, and community. For each area, think about how things have become better and circle the results on the scale below: the better, the higher the number – from 1 (not better at all) to 10 (very much better).

Substance use: How are you doing with drug and alcohol use? Consider the frequency and amount of use, money spent on drugs, amount of drug craving, time spent being loaded, being sick, in trouble and in other drug-using activities, etc.

None or not much					Better				Much better	
1	2	3	4	5	6	7	8	9	10	

Health: Has your health improved? In what way and how much? Think about your physical and mental health: Are you eating and sleeping properly, exercising, taking care of health problems or dental problems, feeling better about yourself, etc?

None or not much					Better				Much better	
1	2	3	4	5	6	7	8	9	10	

Lifestyle: How much better are you in taking care of personal responsibilities? Think about your living conditions, family situation, employment, relationships: Are you paying your bills? Following through with your personal or professional commitments?

None or not much					Better				Much better	
1	2	3	4	5	6	7	8	9	10	

Community: Are you a better member of the community? Think about things like obeying laws and meeting your responsibilities to society: Do your actions have positive or negative impacts on other people?

None or not much					Better				Much better	
1	2	3	4	5	6	7	8	9	10	