Injectable Extended-Release Buprenorphine in A Correctional Setting: Phase 2
IRB RESEARCH PROTOCOL – 10/9/23
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RESEARCH OBJECTIVES:

(1) To better understand the perceived benefits and risks associated with injectable buprenorphine ("Sublocade") in a correctional setting
(2) To better understand the facilitators and barriers of Medication for Addiction Treatment (MAT) programs in a correctional setting and if/how injectable buprenorphine can affect implementation
(3) To identify specific groups of individuals within a correctional setting that may benefit from injectable buprenorphine

Background

The opioid overdose epidemic continues to escalate,[1] further exacerbated by the Covid-19 pandemic,[2–5] and incarcerated individuals are a particularly vulnerable group for death. One-third of people with opioid use disorder (OUD) have encountered the criminal justice (CJ) system in the past year.[6–8] Upon release from prison, individuals have a 129 times greater risk of opioid overdose death than the general population.[9] **Nearly half of fatal opioid overdoses occur in people with CJ involvement.**[10]

When initiated in a correctional setting (i.e., a jail or prison), medications for OUD (MOUD), such as **buprenorphine, can significantly increase treatment engagement in the community and reduce mortality by 50%**.[11–15] Despite the robust evidence on MOUD effectiveness, <10% of incarcerated individuals with OUD receive medication.[16,17] Crucial individual- and structural-level barriers including stigma, diversion, resource needs for daily oversight, and cost, have constrained MOUD uptake in jails and prisons.[18–21]

Extended-release buprenorphine (XR-B), a novel MOUD modality, can address many barriers to implementation. XR-B is a monthly injectable MOUD that can decrease burden on correctional staff, reduce medication diversion, increase adherence, and offer individuals more time for linkage to post-release care in the community. XR-B has demonstrated efficacy in community settings[22] but **there is no published data on the feasibility, acceptability, and implementation of XR-B initiation in a correctional setting.**

This proposal seeks to fill this gap. The *overall research objective* of this work is to evaluate the initiation of XR-B in a correctional facility. The *central hypothesis* is that XR-B is a feasible, acceptable, and effective alternative to treatment-as-usual sublingual buprenorphine (SL-B).

Stigma, racial inequality, and mass incarceration decrease MOUD access to CJ-involved individuals compared to the general population.[16,23,24] To better understand this multi-level disparity, the proposed work will identify barriers and facilitators to MOUD treatment across multiple stakeholders in the carceral system. By understanding the experiences and needs of a marginalized population, and identifying concerns from other key stakeholders, this proposed work can enhance future uptake of lifesaving MOUD, provide data to inform future trials, and support patient-centered treatment considerations across all CJ facilities.

The Rhode Island Department of Corrections (RIDOC) is an ideal study site for this proposal. RIDOC was the first statewide CJ institution to create a comprehensive program for MOUD[25] and is one of few facilities to have familiarity with XR-B initiations in a small non-research sample.

Theoretical Goals

The proposed research offers a critical opportunity to leverage RIDOC institutional support and experience to assess implementation of XR-B initiation through an implementation science framework.

Purpose of Research Project
This proposed research seeks to identify multi-level barriers and facilitators to the implementation of XR-B. This study initiates a mixed-methods multi-level process evaluation that will explore perspectives from individual and organizational stakeholders before a planned clinical trial to measure the effectiveness of XR-B in a CJ setting (a future IRB application: Phase 3).

The proposed study will enhance the understanding of MOUD treatments in correctional settings especially during transition to the community. This will include interviews with incarcerated individuals with diagnosed opioid use disorder and organizational stakeholders (e.g., medical staff, Wardens, leadership) who are willing and able to participate in interviews and/or surveys to assess their views on MAT operations. All interviews are guided by a structured interview guide based on prior research and implementation frameworks, in collaboration with the COBRE on Opioids and Overdose Community Engaged Research Core.

SUBJECT RECRUITMENT:
Recruitment Population.
Incarcerated individuals will be recruited across RIDOC facility during the required group sessions for treatment; this is consistent with previous NIH-funded studies at RIDOC.[20] The interviews will be described and participants will be able to sign up confidentially. Participants who are eligible for MOUD but decide not to pursue treatment will still be interviewed to provide better understanding of the key factors that drive program participation. These individuals can be recruited through routine clinical care by addiction medicine providers. Every precaution will be taken to ensure confidentiality and protection of all participants.
Organizational stakeholders (clinicians, Wardens, leadership and/or other staff) will be recruited through snowball sampling. I will individually approach leaders of each facility to recruit correctional individuals interested in participating and will also allow participants to confidentially sign up at administrative meetings related to Medication for Addiction Treatment (MAT).

Interview Sample Size. Each interview group (i.e., Incarcerated Individuals and Organizational Stakeholders) will recruit at least 6 - 12 individuals until analysis reflects saturation. Incarcerated persons will be stratified by on injectable treatment or not and so may have 18 - 24 interviewees total. In implementation science, this number of interviews per stakeholder group should ensure saturation based on previous literature.[26,27] All individuals will be over the age of 18. Diverse participants according to race, gender, age, type of MOUD, and facility of residence will purposively be recruited. Women make up 15% of incarcerated individuals at RIDOC and will be oversampled to include their important perspective. Individuals will receive renumeration in their commissary account, similar to previous RIDOC studies.[20]

Survey Sample Size. We hope to have ~12 surveys completed by organizational stakeholders during provider meetings, Medication for Addiction Treatment (MAT) meetings, or during research interviews with stakeholders. Surveys take under 5 minutes to complete. Additional compensation will not be offered. All survey data is anonymous.

Recruitment Process. For incarcerated individuals, a member of the research staff will approach group therapy sessions for individuals enrolled in the Medication for Addiction Treatment (MAT) program at the Rhode Island Department of Corrections. They will explain the study, the time requirement (60 - 90 minutes) and the compensation ($25) for interviews and offer the opportunity to confidentially sign up for the study. Addiction providers will also be able to sign up interested participants during routine clinical care.

Organizational stakeholders will be recruited through snowball sampling and/or administrative meetings. I will individually approach leaders of each facility to recruit correctional individuals interested in participating (in either survey completion and/or in-depth interviews) and will also allow participants to confidentially sign up at administrative meetings related to Medication for Addiction Treatment (MAT).

All recruitment and tracking will be captured through a HIPAA-secure server: REDCap.

Eligibility.

For incarcerated individuals, inclusion criteria:

- English speaking
- Over the age of 18
- Diagnosed with opioid use disorder

Exclusion Criteria:

- Diagnosed with "Severe, Persistent, Mental Illness (SPMI)"

  Rationale for Exclusion: *These individuals suffer from severe mental health disease and therefore warrant greater protection, have greater risk for coercion, and offer insights to severe co-diagnosis treatment that, while important, remain outside the scope of general MAT implementation*.

FOR ORGANIZATIONAL STAKEHOLDERS:

Inclusion Criteria:

- Employed or contracted by Rhode Island Department of Corrections (for organizational staff interviews) and involved with the Medication for Addiction Treatment (MAT) program

Exclusion Criteria:

- If not permitted by their organizational union to participate

Data Storage. All participant data will be kept confidential. Survey data will be anonymous. Qualitative interview data will be kept confidential. Audio will be collected on password-protected digital voice recorders. Audio files and transcripts will be identified by participant ID only. The participant's identification number will only be connected to the participant's name through a single encrypted password-protected master file kept on password-protected computers, accessible only to approved research staff. We will protect all other data files with passwords and lock any paperwork in cabinets. Transcripts will be the primary data source after audio is deleted. Audio files will be deleted on a monthly review basis after transcripts have been certified per methodology below. Survey data will be password protected in a secure REDCAP server and paper copies will be kept in a locked cabinet in a locked office with research staff access only. Surveys will be anonymous.

The study will also be approved by the Medical Research Advisory Group (MRAG) at the Rhode Island Department of Corrections (RIDOC). All research will be conducted in a manner consistent with the highest ethical standards using these multiple oversight groups as well as collaboration with the COBRE for Opioids and Overdose Community Advisory Board and in line with previous NIH-supported research conducted at the RIDOC.

METHOD AND PROCEDURES:

In-depth Interviews (IDI). Interviews (60-90 min) will be scheduled with stakeholders and guided by well-established qualitative methodology practices in implementation research.[28] Interviews will be audio-recorded and transcribed verbatim. A debriefing template[29(p30)] will be used after every interview to assess process issues, evaluate data quality, and consider

saturation. Interviews will continue until data analysis reflects saturation. All participants will receive $25 reimbursement for their time via electronic gift-card or commissary deposit, as has been done in previous studies approved by the IRB and the RIDOC.

Surveys. The NIH JCOIN has developed standardized measures implemented across multiple correctional facilities to harmonize data. Measures used in this study will include: Organizational Readiness for Implementing Change (ORIC), Staff Attitudes Toward MOUD (SATM), and Implementation Outcome Measures. These are NIH-endorsed survey measures. Each survey is very short (under 15 Likert-style questions each). Enrollment of 20 stakeholders or more should be very feasible based on similar studies with similar participation at the RIDOC.[20,30] All survey data will be anonymous and on paper. A member of the research team will input data into a secure server using REDCap, original paper documents will be locked in the office of the PI.

Risks. This study will have minimal risk, described below.
Study Site: Rhode Island Department of Corrections.
Study Start Date. Within 1 month of IRB and MRAG approval.
Study End Date: Upon saturation (anticipated within 3 – 6 months).

Interview Guide. An open-ended interview guide has been developed based on existing literature[31–33] and with input from the COBRE Community Engagement Research Core. *The core qualitative research question* will be: What are the barriers and facilitators to successful uptake of XR-B? As common practice in implementation research, the interviews will be shaped by a conceptual framework,[28] in this case, iPARIHS. A preliminary interview guide is attached though will be revised in an iterative process based on emerging themes. As described in the guide, questions will not be verbatim but ensure all content areas are discussed. Interviews with patients will have greater emphasis on Recipient and Innovation domains, while interviews with other stakeholders will focus on Context and Facilitation domains.

Surveys. Copies of (1) Organizational Readiness for Implementing Change (ORIC), (2) Staff Attitudes Toward MOUD (SATM), and (3) Implementation Outcome Measures are attached. Paper forms will be completed by organizational stakeholders (without name or other PHI) and will be entered into REDCap secure software to record results. Original copies of survey sheets will be locked in the PI's office.

<u>This research will not affect standard treatment or routine care in any way.</u>

Data Collection and Analysis. Audio interviews will be transcribed and then coded in nVivo software. Transcription and analysis will be iterative; initial findings may influence the interview guide and future questions asked. Using NVivo, a directed content analysis[34] will identify key themes in structured interviews. Interviews will be discussed by the research team including qualitative research mentors to achieve consensus in the coding framework. All interviews will be double coded by myself and a trained research assistant. Analysis will be guided by the Applied Thematic Approach[29] to identify barriers and facilitators for XR-B initiation at individual, and organizational levels. Themes will be coded and compiled in a codebook which will include iPARIHS domains *a priori* and other codes that emerge from the data.

Costs to Subjects. There are no costs to subjects for participations. This research will not affect standard treatment or routine care in any way. There are no risks above minimal risk as detailed below.

Subject Compensation. Upon completion of the interview, all participants will receive $25 reimbursement for their time via electronic gift-card or commissary deposit, as has been done in previous studies approved by the IRB and the RIDOC. The compensation will be consistent with previous amounts (i.e. $25) that have not been found to be assocaited with coersion but that adequately compensate individuals for their time. If staff are unable or unwilling to receive $25, we will offer to donate the $25 to a charity of their choice and provide them with receipt.

BENEFITS:
Data received from this study could positively impact future medical services to participants in a way that is equal to others that suffer from similar medical problems.

For organizational stakeholders, it may provide a more streamlined approach to deliver medications and reduce diversion or other security risks.

RISKS TO SUBJECTS:
The risks are minimal and those assocaited with other qualitative studies, namely: emotional distress and breach of confidentiality. Both of these risks will be minimized in as many ways as possible to ensure the participants are emotionally supported, can stop the intervew at any time, and feel no pressure to give specific answers or talk about topics they'd prefer to omit. Confidentiality will be maintained through encryption, password-protection, and limited only-when-needed use of any identifiable data and by as few research staff as possible to maintain research operations.

INFORMED CONSENT if applicable:
Informed consent will be obtained at the time of the interview. All participants will be asked to sign an informed consent document and will be offered a copy of this form. The Informed Consent form will be written at a level the subjects will understand, at an elementary-school reading level as per RIDOC guidelines. The person obtaining consent will provide the participant the opportunity to ask any questions related to the study before the participant signs any consent form.

CONFIDENTIALITY OF DATA:
All participant data will be kept confidential. Survey data will be anonymous. Qualitative interview data will be kept confidential. Audio files and transcripts will be identified by participant ID only. The participant's identification number will only be connected to the participant's name through a single encrypted password-protected master file kept on password-protected computers, accessible only to approved research staff. We will protect all other data files with passwords and lock any paperwork in cabinets.

All digital recordings will be uploaded to the HIPAA-compliant nVivo AI transcription service within 24 hours of recording. Transcripts will be cleaned by a member of the research team and all PHI will be redacted from the transcriptions within 1 week of transcription. The PI will then certify each transcript as complete, at which time the original audio files will be deleted within 2 weeks.

The study will also be approved by the Medical Research Advisory Group (MRAG) at the Rhode Island Department of Corrections (RIDOC). All research will be conducted in a manner consistent with the highest ethical standards using these multiple oversight groups as well as collaboration with the COBRE for Opioids and Overdose Community Advisory Board and in line with previous NIH-supported research conducted at the RIDOC.

No data will be published that could allow for a reader to track responses back to an individual.

Survey data will be entered into REDCap. Thus, the Lifespan Hospital System will be used as the central location for data management. Vanderbilt University, with collaboration from a consortium of institutional partners, developed a software package for electronic collection and management of research and clinical trial data known as REDCap (Research Electronic Data Capture). The REDCap system provides secure, web-based applications that can be used for various types of research and operational support purposes, as well as provide an intuitive interface for users to enter data with real-time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails for reporting, monitoring, and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap servers are housed in a local data center at Lifespan, 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 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users (www.project-redcap.org). During the study, real-time data transmissions from the study site computers to the centrally housed server will be encrypted using SSL and public key encryption technology. All information will only reference a participant identification number. The participant's identification number will only be connected to the participant's name through a single master file kept on password-protected computers, accessible only to research staff at each study site. We will protect all other data files with passwords and lock any paperwork in cabinets in the PI's office.

The interview will contain sensitive questions about community drug use and medication diversion while incarcerated. As this is an NIH-funded study, there will be an automatic Certificate of Confidentiality applied. Per the NIH website, **"Information protected by a CoC is immune from the legal process and is not admissible as evidence (unless participant consents to this disclosure)."** This information will be shared with the participant. Topics of mandatory reporting (i.e., elder abuse, child abuse, suicidality, sexual contact as protected by the Prison Rape Elimination Act (PREA)) will be discussed and the participant will be informed that this information, if discovered, will be reported to the Warden of the facility. The research staff member will follow all mandatory reporting policies. A statement will be made that confidentiality must be broken if information revealed is considered a threat to self, facility, and/or community corrections security. A statement will be made that parole boards will not consider a prisoner's participation in the research in making decisions regarding parole. The mailing address for the PI and Lifespan HRPP will be included.

All persons who will be conducting evaluative research are informed of, and agree in writing to conform to, all applicable RIDOC policies including, but not limited to, those pertaining to the confidentiality of information obtained per the RIDOC Confidentiality Pledge.

DATA SAFETY AND MONITORING PLAN:
Though all participants will face no more than minimal risk, the inclusion of a vulnerable population (prisoners) and setting warrant additional assurances regarding a data safety and monitoring plan. In addition to the privacy considerations of participants, confidentiality considerations of participant data, and assurances of appropriate informed consent as above, additional safety and monitoring will include:

<u>Monitoring the safety of the participants</u>
The recruitment and interview of incarcerated can occur during routine clinical times, namely during group sessions or meeting with clinicians. Therefore, if any safety risk arises, the clinical

staff will be alerted immediately. Moreover, this recruitment setting provided additional privacy considerations within a healthcare setting. The research assistant (RA) will be trained specifically to work with this study population. While organizational stakeholders face less vulnerability to data, similar protections will be offered to protect their privacy and consideration during the recruitment and interview process.

All research staff members will receive training related to DOC policies on the Prison Rape Elimination Act and mandatory reporting. Study staff will receive training on maintaining a calm, empathic demeanor while speaking to study participants. Study staff will immediately notify the PI for any information that may require mandatory reporting and the PI will provide a report to an appropriate contact at the Department of Corrections (i.e., Special Investigations Unit) if the material disclosed does require reporting. Instances requiring mandatory reporting (i.e., PREA allegations, threats to staff or other individual) will be explicitly disclosed during the informed consent process. The PI will be available to the RA by phone and email at all times. All instances of possible will be discussed in weekly supervision and/or team meetings with PI and study staff.

Monitoring the safety of the researchers

It is possible that the physical safety of the PI and facilitators could be threatened through direct implementation of the study (e.g., a participant becomes agitated and assaults a researcher). To help prevent and/or respond to such occurrences, security will be always in ear shot for assistance though not present in the room to compromise participant privacy. Such events are unlikely to occur, but in the case that they do, the event will be reported to the PI immediately. If RA is injured as a result of such an event, they will seek care, as warranted, by hospital employee health services.

Maintaining the confidentiality and integrity of the data

Data will be confidentially maintained under the stringent guidelines as specified in the Protection of Human Subjects section**.** Rhode Island Hospital will maintain locked files, stored off-site, and permit access only to authorized individuals. Only authorized research staff will have any access to these records. See above for additional data safety considerations.

Receiving/eliciting reports of adverse events from the RA

Any adverse events that are observed and/or reported during this study will be reported immediately to the PI. The PI will receive these reports on an event-by-event basis and discuss with the research team. They will also be elicited in an open-ended manner through regular informal contact between the PI and the RAs. All adverse events will be reported in writing to the IRB within one week. All serious adverse events (SAE) will be reported to the IRB immediately by telephone and by written report within 24 hours of our receipt of information regarding the event. All SAEs will be reported to NIH within 48 hrs. At any time during the study period, if significant mental health concerns are reported, the participant will be referred to appropriate resources through the Department of Corrections Healthcare Services Unit.

IRB oversight

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB Human Subjects Protection Guidelines, independently or in conjunction with recommendations made by the IRB during the annual reporting cycle or following a special/emergency IRB session.

MRAG oversight

The Rhode Island Department of Corrections' Medical Research Advisory Group (MRAG) will provide additional review and approval of study logistics and approach to ensure privacy, confidentiality, and feasibility within the correctional setting. Any adverse events will be reported to the MRAG group in addition to the IRB as above.

Attachments include:

- Informed Consent Form
- JCOIN Survey Measures: SATM, ORIC, Implementation Outcomes Measures
- Interview Guide for Incarcerated Persons
- Interview Guide for Correctional Stakeholders

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