



# BMJ Open Social ecological factors and medication treatment for opioid use disorder among justice-involved rural and urban persons: the Geographic variation in Addiction Treatment Experiences (GATE) longitudinal cohort study protocol

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## ABSTRACT

**Introduction** Three medications are Food and Drug Administration approved for the treatment of opioid use disorder (OUD); however, these medications are underused within prisons, which elevates the risk of relapse and overdose when persons with opioid use disorder (POUD) are released. Research is scant regarding the multilevel factors associated with POUDs' willingness to initiate medication treatment for opioid use disorder (MOUD) while in prison and their continued engagement in treatment after release. Furthermore, rural and urban populations have not been compared. The Geographic variation in Addiction Treatment Experiences (GATE) study seeks to identify multilevel factors (ie, individual, personal network, and structural factors) influencing prison-based extended-release injectable naltrexone (XR-NTX) and buprenorphine initiation and will examine predictors of postrelease MOUD use and adverse outcomes (ie, relapse, overdose, recidivism) among both rural and urban POUDs.

**Methods and analysis** This mixed methods study employs a social ecological framework. A prospective observational longitudinal cohort study is being conducted with 450 POUDs using survey and social network data collected in prison, immediately postrelease, 6 months postrelease and 12 months postrelease to identify multilevel rural-urban variation in key outcomes. In-depth qualitative interviews are being conducted with POUDs, prison-based treatment staff and social service clinicians. To maximise rigour and reproducibility, we employ a concurrent triangulation strategy, whereby qualitative and quantitative data contribute equally to the analysis and are used for cross-validation when examining scientific aims.

**Ethics and dissemination** The GATE study was reviewed and approved by the University of Kentucky's Institutional Review Board prior to implementation. Findings will be disseminated through presentations at scientific and professional association conferences, peer-reviewed journal publications and a summary aggregate report submitted to the Kentucky Department of Corrections.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study uses a mixed methods approach to explore the multilevel factors influencing medication treatment for opioid use disorder (MOUD) initiation and continuity of care for persons with opioid use disorder (POUD) in rural and urban settings following prison release.
- ⇒ Longitudinal survey data and social network data will be collected from POUDs at four time-points over a year.
- ⇒ Qualitative interviews will be conducted with both POUDs and clinicians.
- ⇒ Recruitment, enrolment and data collection adaptations due to COVID-19 will be addressed.
- ⇒ Limitations include data collection in only one state, potential limited uptake of MOUD, possible under-reporting of network ties and/or retention challenges.

## INTRODUCTION

Kentucky is an epicentre of the opioid epidemic with both urban and rural counties experiencing disproportionately high overdose rates and opioid-related health sequelae.<sup>1 2</sup> Injection drug use (IDU) is the predominant opioid administration route in Appalachia,<sup>3-7</sup> resulting in disproportionately elevated rates of acute hepatitis C virus (HCV),<sup>8</sup> HIV<sup>9</sup> and additional long-term health adversities (eg, cardiovascular disease, endocarditis, cancer).<sup>10 11</sup> Additionally, a recent White House report notes that the economic cost of the opioid epidemic is at a crisis level.<sup>12</sup> The epidemic has led to substantial increases in spending for healthcare and criminal justice (CJ), as well as significant

workforce loss and decreased potential earnings.<sup>13</sup> These consequences, in addition to the loss of human life, point to the vital importance of efforts to increase access to evidence-based treatment.

Currently, there are three Food and Drug Administration (FDA)-approved medications for the treatment of opioid use disorder (MOUD): extended-release naltrexone (XR-NTX), buprenorphine and methadone. MOUD is underused in community<sup>14</sup> and CJ settings.<sup>15–17</sup> National data indicate <10% of persons with opioid use disorder (POUDs) receive treatment,<sup>18</sup> with only 37% receiving MOUD.<sup>19</sup> Over half of Kentucky counties do not have any MOUD providers.<sup>20</sup> Our prior research in rural Kentucky demonstrates limited access to treatment due to social, economic and geographical challenges.<sup>5 21–24</sup>

Justice-involved POUDs face additional barriers to accessing MOUD due to concerns among prison officials about potential diversion or misuse. The diversion potential of XR-NTX is limited as it is a long-acting injectable antagonist, making it more acceptable to CJ agencies than methadone or buprenorphine.<sup>15</sup> Consequently, XR-NTX is the only MOUD available in all Kentucky prisons. However, the Kentucky Department of Corrections (DOC) recently launched a buprenorphine pilot programme in three prisons. The Kentucky DOC's adoption of XR-NTX and piloting of buprenorphine offers a unique opportunity to explore MOUD initiation both in prison and on re-entry to rural and urban counties. Recent studies have noted that up to 50% of prisons offer at least one MOUD,<sup>25</sup> but the majority offer XR-NTX.<sup>26</sup> While more prisons are offering MOUD, little is known about social influences and MOUD initiation decision-making processes among people who are incarcerated.

POUDs re-entering rural areas from prison likely have less access to treatment relative to those in urban areas, but there is a lack of recent comparative rural-urban data measuring the magnitude of this gap after controlling for social network factors. Thus, there is a vital need for research comparing rural and urban POUDs seeking treatment, particularly after re-entry, and their use of MOUD and other treatment services to promote geographically targeted interventions.

## Objectives

This paper describes the Geographic variation in Addiction Treatment Experiences (GATE) study, which addresses the limited knowledge that currently exists on MOUD initiation in prison and treatment use on community re-entry in rural and urban areas. The study aims to: (1) identify the individual, interpersonal and structural factors associated with MOUD initiation in prison among rural versus urban POUDs and (2) examine the individual, interpersonal and structural factors predicting MOUD use, treatment use and adverse outcomes (ie, relapse, overdose, recidivism) in the community among re-entering rural, as compared with urban, POUDs over a 12-month period.

## Broad goals for the study

The convergence of ongoing dual epidemics—opioids and incarceration—in Kentucky results in high rates of opioid overdose and injection-related HCV. Retention in MOUD treatment leads to less criminal involvement,<sup>26</sup> but this evidence-based treatment is underused and often stigmatised. Few studies have examined the factors associated with prison-based MOUD initiation, and none have integrated social network analyses using a multilevel social ecological model. Importantly, this study will inform process improvement efforts for prison-based MOUD initiation and postrelease treatment retention, improve the re-entry planning process through applying network science findings and informing future interventions.

## Social ecological conceptual framework

Drug use is typically studied at the individual-level. However, contexts distal to the individual, including interpersonal relationships and structural factors,<sup>27–29</sup> are particularly important social influencers for POUDs in rural areas<sup>4</sup> and for those incarcerated.<sup>30</sup> The social environment in which a person operates greatly impacts treatment continuity and outcomes, especially in rural Appalachia where service availability and accessibility are limited.<sup>5</sup> Examining individual behaviour and decision-making in the context of network-level risk and protective factors is critical for understanding health outcomes and for developing targeted interventions and correctional policies. The GATE study uses a social ecological framework<sup>27 31</sup> (see figure 1), which posits that behavioural outcomes are influenced by: (1) individual, (2) interpersonal (also known as personal or egocentric social networks) and (3) structural factors.

## METHODS AND ANALYSIS

### Study design

The GATE study uses a mixed methods design including: (1) a longitudinal prospective cohort study of incarcerated POUDs in Kentucky and (2) a qualitative study of POUDs and DOC staff.

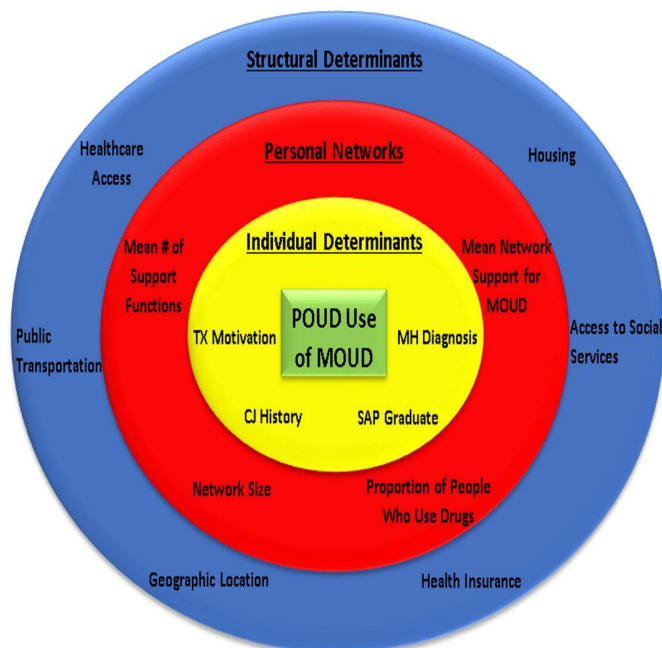
### Patient and public involvement

Patients and/or the public were not involved in the design, conduct, or dissemination plans of the GATE study.

### Longitudinal prospective cohort study

#### Participants

Participants for the longitudinal cohort study (n=450) are over the age of 18 years and currently incarcerated within one of the 10 Kentucky prisons that offer XR-NTX, 3 of which also offer buprenorphine. Eligibility criteria include: having a history of OUD based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria, enrolment in a Kentucky DOC prison substance abuse programme (SAP) and having a projected county of release to one of 54 Kentucky Appalachian counties,<sup>32</sup>



**Figure 1** The social ecological model (individual, personal network and structural determinants) of medication treatment for opioid use disorder among justice-involved people. CJ, criminal justice; MOUD, medication treatment for opioid use disorder; POUD, persons with opioid use disorder; SAP, substance abuse programme; MH, mental health; TX, treatment.

Jefferson county (including Louisville) or Fayette county (including Lexington).

### Recruitment

A DOC liaison provides a monthly list of people who are incarcerated that participated in SAP and are within 60 days of either being paroled or serving out their sentences. Potential participants are provided a recruitment letter to attend an information session. The letter states that information session attendance, the screening process and GATE study participation are voluntary. At the information session, individuals are screened for eligibility and provide written informed consent prior to enrolment.

### Longitudinal data collection

Survey data are collected at baseline, immediately post-release, 6 months postrelease and 12 months postrelease. Research Electronic Data Capture (REDCap)<sup>33–34</sup> surveys are used for questions regarding individual (eg, sociodemographics, criminal history, physical and psychiatric comorbidities, treatment motivation and treatment utilisation) and structural (prison treatment barriers, housing, employment, rurality) domains of the social ecological model.<sup>27–31</sup> Participants complete a social network inventory using Network Canvas<sup>35</sup> software to assess the interpersonal domain (eg, network size, density, turnover, sociodemographic composition, relationships, support functions, attitudinal context). Participants complete a locator form at all time-points,

documenting contact information for the participant (eg, phone number, address, email, social media) and collateral contacts. Participants receive US\$5 for screening (regardless of eligibility status) and US\$30 per survey. They also receive US\$10 for check-ins within the month after release, at 3 months postrelease and at 9 months postrelease to update the locator information. A US\$20 study completion bonus is provided for completing all surveys, resulting in total possible incentives of US\$175.

### Retention

Two tiers of evidence-based methods drawing on our prior projects are employed to track and retain participants. Tier 1 focuses on the participant and includes same day screening, enrolment and scheduled baseline data collection in prison. Check-ins after prison release with a monetary incentive are used to update participant locator information. Evening and weekend appointments provide flexibility in scheduling for survey completion. Personalised notes (eg, birthday and seasonal postcards) are used in addition to participant internet searches and home visits. Tier 2 strategies focus on the organisation and include retention-specific training/workshops for GATE staff as well as establishing a presence in the rural and urban communities through study branding and social media (ie, GATE study Facebook page).<sup>36</sup> Additional tracking strategies include: (1) courthouse record searches, (2) online internet searches for addresses (eg, Truthfinder, Whitepages), (3) VINELink (Victim Information and Notification Everyday) searches, which provide real-time information regarding the custody status of all registered offenders in Kentucky and (4) Kentucky Online Offender Look-up searches via this online data portal managed by the Kentucky DOC. While CJ populations can be hard to retain, our study team has successfully used these strategies to limit attrition<sup>36–38</sup>; and thus, we expect at least 80% retention.

### Study exposures and outcomes

The primary outcome for aim 1 is MOUD initiation, which is assessed by asking participants at baseline if they initiated XR-NTX or buprenorphine while incarcerated (1=yes; 0=no). Aim 1 will also examine prison-based XR-NTX and buprenorphine initiation separately. The outcomes for aim 2 are numerous due to the longitudinal observational cohort study design. Broadly, aim 2 outcomes include MOUD use, other treatment utilisation and adverse outcomes (ie, relapse, overdose, recidivism) postrelease. For example, use of XR-NTX, buprenorphine and methadone are assessed by asking participants if they have used each of these three types of medication in the past 6 months (1=yes; 0=no), the number of injections for XR-NTX and buprenorphine and the number of days of sublingual buprenorphine use and methadone use in the past 6 months. Overdose is operationalised as the number of times overdosed in the past 6 months and asked at both follow-up surveys. There are numerous approaches to measuring other treatment utilisation (eg, enrolment

in outpatient treatment, number of days in treatment, etc) and recidivism (eg, any arrest, number of days in jail/prison) in the past 6 months, which are measured at each follow-up using questions from the National Health Interview Survey<sup>39</sup> and the Global Appraisal of Individual Needs-Initial.<sup>40</sup> Return to substance use is measured using the NIDA-Modified Assist<sup>41 42</sup> and can be operationalised based on any drug use and frequency of drug use for each class of drug.

### Changes due to the COVID-19 pandemic

Due to COVID-19 and related research restrictions by Kentucky DOC, recruitment and retention efforts required adjustment. In May 2021, a passive virtual recruitment method was implemented and the eligibility criteria was expanded to include individuals released to any Kentucky county. For passive recruitment, GATE staff mail personalised screening packets to individuals who participated in SAP and were within 60 days of being paroled or serving out their sentences. A return envelope is included for returning forms by mail, but individuals can also call study staff using a toll-free study phone number to complete screening. A waiver of documentation of informed consent is used for screening because potential participants are asked to provide locator information that staff use to follow-up postrelease for baseline survey completion. The baseline and postrelease surveys are completed within 3 months of the participants' release dates collecting retrospective data. All follow-up data collection time-points are anchored to the release date. Beginning in March 2022, the GATE study resumed in-person or direct virtual recruitment inside of prisons, when feasible.

### Qualitative data collection

The GATE study includes in-depth guided qualitative interviews with three groups of participants: (1) key stakeholders of prison-based SAPs, including administrators (n=10), clinicians (n=27) and mentors (ie, a person who is incarcerated and is a SAP graduate, but has remained in SAP to help others until released) (n=10); (2) social service clinicians (SSCs) who are DOC employees providing intensive and/or therapeutic social work services, including treatment referrals, to individuals on community supervision (n=29) and (3) POUDs (n=40).

All administrators and clinicians of prison-based SAPs in Kentucky offering XR-NTX/buprenorphine and all SSCs in GATE counties are invited to participate in a one-time qualitative interview. SAP administrators are asked to provide a list of SAP mentors within their prison and one mentor per prison is randomly selected to participate in the qualitative interview. SAP administrators and clinicians are asked to describe the following: their professional background, how SAP operates and their training on MOUD. To gain diverse perspectives, SAP administrators, clinicians and mentors are asked questions about their views on the three FDA-approved MOUDs, how SAP clients are educated on MOUD, social ecological factors

influencing the initiation of MOUD, how these factors vary geographically and potential strategies to improve prison delivery of MOUD and continuity of care. The SSCs are asked to describe the case management process for their most recent clients who initiated MOUD in prison, including those who did and did not continue MOUD after release, as well as suggestions for improving MOUD treatment.

For the POUD qualitative interviews, longitudinal cohort participants are categorised into four groups using baseline responses regarding MOUD initiation (yes/no) in prison and geography (rural/urban). The first 10 participants from each of the 4 groups are invited to participate in a qualitative interview at the 6-month postrelease time-point (n=40). Interviews with POUDs explore the following domains: treatment motivation; knowledge, acceptability and experience related to XR-NTX/buprenorphine; multilevel barriers/facilitators of XR-NTX/buprenorphine use prerelease/postrelease and suggestions for future XR-NTX/buprenorphine interventions components.

Interviews are similar to structured conversations in which the interviewer poses open-ended questions to prompt and guide the participant's response.<sup>43</sup> This approach is useful when addressing sensitive topics such as drug use, treatment motivation and barriers to MOUD use.<sup>44</sup> All interviews are conducted in person, via phone, or virtually via Zoom, digitally recorded and transcribed. Brief field notes are taken during the interview to document observed participant behaviour and contextual aspects of the interview. Field notes are expanded directly after the completion of the interview to avoid participant distraction. Interviews last approximately 60–90 min. DOC staff are not allowed to receive monetary incentives, so a small gift (<US\$10) is provided as a token of appreciation. Mentors and POUDs receive US\$35 for the qualitative interview.

### Analytic plan

#### Longitudinal cohort analyses

The GATE study's longitudinal cohort design, which includes numerous measures at the individual, interpersonal and structural level, allows for examination of an array of research questions using descriptive, bivariate and multivariate approaches. Several sample hypotheses are offered for aims 1 and 2 and will be developed into papers for submission to peer-reviewed journals:

- ▶ Aim 1, *H1*: network treatment knowledge and support for POUDs will be positively related to XR-NTX initiation in prison. *H1a*: these relationships will be stronger for urban versus rural POUDs (ie, moderated by geographic location).
- ▶ Aim 1, *H2*: effective XR-NTX education in SAP (ie, structural factor) will positively influence XR-NTX initiation in prison.
- ▶ Aim 2, *H3*: initiating XR-NTX in prison will positively predict postrelease XR-NTX use. *H3a*: this

relationship will be stronger for urban versus rural POUDs (ie, moderated by geographic location).

- ▶ Aim 2, *H4*: network characteristics (eg, small, kin-centred, densely knit networks, avoidance of negative ties or people they used drugs with and a high degree of support for buprenorphine) and structural factors (eg, prerelease Medicaid enrolment) will increase buprenorphine use over time after release.
- ▶ Aim 2, *H5*: MOUD use will mediate the relationship between multilevel factors and adverse outcomes.

To ensure scientific rigour, data preparation includes determining distributional assumptions for variables, calculating transformations, collapsing categories when necessary and reviewing data for anomalies and inconsistencies. Unadjusted bivariate analyses (eg, rural-urban or male-female differences) will be conducted prior to multivariate modelling using contingency tables for categorical variables and summary statistics (eg, mean, median, IQR, min-max) for continuous variables. Missing data will be examined to assess whether it is missing at random given the observed variables. Multiple imputation will be used to create 30 or more complete datasets. Markov Chain Monte Carlo sampling will be used to allow for arbitrary (ie, non-monotone) data missing at random, and the covariate set used for multiple imputation will include variables in the standard data analysis as well as additional observed variables assumed to be related to the missing data mechanism. Standard full data analyses will be conducted on the imputed datasets and combined using Rubin's method.<sup>45</sup>

We will calculate the proportion of rural and urban POUDs who initiate XR-NTX/buprenorphine in prison, as well as create subnetwork measures (ie, support networks and drug networks) and complete egocentric network measures. Independent variables measuring the *structure* of personal networks will include network size, density (ie, proportion of network members that interact with each other), turnover-in (ie, number of new members entering network) and turnover-out (ie, number leaving network).<sup>46 47</sup> Network *composition* will be evaluated using proportions for each category, such as relationship type (eg, proportion of network members who are friends, family), gender (proportion women), incarceration status (proportion currently/previous incarcerated) and drug use status (proportion actively using). Measures of network *function* will include the mean number of different types of support functions provided by the network as well as mean relationship closeness and duration. Multiplexity will be measured using a count of different subnetworks to which network members belong (eg, per cent overlap in drug and support networks). The attitudinal *content* of networks is measured using the support for drug use, treatment, XR-NTX and buprenorphine among network members. Differences between rural and urban POUDs will be explored once these variables are calculated. Some of these network measures allow for the examination of social influence on the POUDs behaviour, wherein POUDs may be more likely to

use MOUD if they have a personal network comprising a high proportion of others in recovery who have favourable attitudes towards MOUD. These social network measures can be included as independent variables in the analyses along with traditional individual-level and structural-level variables, including geographic location.

For aim 1, logistic, linear and negative binomial regression models will be used to examine dichotomous, continuous and count dependent variables, respectively. For example, in aim 1 for *H1*, we will specify a logistic regression model that includes individual (eg, age, gender, education, treatment motivation, degree of good time credit influence) and personal network (eg, network size, mean network treatment knowledge, mean number of supportive functions, mean network support for MOUD) factors that are significant correlates of MOUD initiation while a person is incarcerated. Geographic location (eg, rural vs urban) will be examined as a moderator of this relationship.

While aim 1 examines correlates of the initiation of MOUD in prison, aim 2 includes several dependent variables (ie, MOUD use, treatment use, return to use, overdose and recidivism), which may be operationalised in a variety of ways. To examine aim 2, we will use random-coefficient logistic, linear and negative binomial regression which adjust for the dependency inherent in longitudinal data, where a given person contributes multiple (often correlated) observations. Random coefficient models permit multilevel analysis with interactions between levels, where appropriate. For example, to analyse *H4* in aim 2 with the number of days of buprenorphine use in the community as our dependent variable, we will specify a random effects negative binomial regression model with time-invariant factors, such as age, gender, prerelease Medicaid enrolment, prison-based XR-NTX initiation and geography (rural/urban) at level 2. Time-variant factors, including network characteristics such as network size, proportion of the network that is family, proportion of the network that used drugs with ego, density and mean network support for buprenorphine, will be entered into the model at level 1.

### Sample size calculations

Adequately powering the GATE study provides an element of rigour to ensure scientific validity. Aim 1 uses logistic regression to model MOUD use ( $1 = \text{XR-NTX/buprenorphine use}$ ;  $0 = \text{no MOUD use}$ ). Using Cohen's formula,<sup>48</sup>  $N = (L/R_a / 1 - R_{all}) + p + 1$ , where  $L = 8$  if  $\beta = 0.80$  and  $\alpha = 0.05$ , if we conservatively set  $R_{all}$  to 0.2 in a model with 10 explanatory variables ( $p = 10$ ) and set  $R_a = 0.05$ , the sample size necessary to be able to detect significant differences at the  $\alpha = 0.05$  level and power of 80% is 211. Multilevel regression is proposed for aim 2. As an illustrative example aligning with *H4*, when the sample size is 100 participants, the multiple linear regression test of  $\alpha = 0.05$  for 10 normally distributed covariates will have 90% power to detect an  $R^2$  of 0.19. However, we are assuming participants are clustered non-randomly into networks. To account for



clustering, we must estimate a design effect. The formula is:  $N_{\text{multilevel}} = N_{\text{single-level}} \times (1 + (\text{cluster size} - 1) \times \rho)$ , where the cluster size equals the hypothesised network size for each participant and  $\rho$  is the intraclass correlation (ICC). In prior studies of health and drug networks,<sup>49–51</sup> we estimate the average network size to be 13. An ICC of 0.24 is described as substantial in a personal drug network.<sup>49</sup> As an example, using an estimate of 13 network members per participant and an ICC of 0.24, we multiply our initial estimate of 100 by  $(1 + (13 - 1) \times 0.24) = 388$  to determine that a sample size of 450 participants is sufficient.

#### Analytic plan for the qualitative interview data

The qualitative interview data will be analysed using a general inductive approach guided by the social ecological framework. Preliminary codebooks (version I) will be developed after the first three transcripts from each group with which qualitative interviews are conducted. The coding scheme will be tested by first selecting at least 50 text segments from each transcript. Two separate coders will code the text segments, compare coding and discuss and resolve areas of concordance/discordance, then code another 20 text segments, and percentage agreement will be calculated. Transcripts will be coded with open codes first to identify broad themes or patterns. Following open coding and broad thematic analysis, transcripts will be coded with axial codes or more interpretive codes that will be used to identify core concepts. In addition, memos and theory notes will be generated throughout the analysis, providing a rich source of theoretical data and an intellectual history of the development of concepts. After initial coding of the data, staff will summarise and organise the resulting data in NVivo 11.<sup>52</sup> Each theme and subtheme will be assigned a code, and the codes will be compiled in a codebook (version II).

#### Timeline

Recruitment for the longitudinal cohort was planned for spring 2020 to fall 2022 with follow-up data collection completed by December 2023; however, the timeline has been delayed 1 year due to COVID-19. Aim 1 analysis will take place in 2023–2024 while aim 2 analysis will take place in 2023–2025. Dissemination of study findings will take place in 2022–2025.

#### ETHICS AND DISSEMINATION

Research procedures for the GATE study were reviewed and approved by the University of Kentucky's Institutional Review Board (IRB). As this protocol included people who are incarcerated, the IRB review panel includes a 'prisoner' or 'prisoner representative', which is a person with an appropriate background or expertise related to working with people who are involuntarily confined/detained in a correctional institution. The protocol was also reviewed and approved by the Kentucky DOC's Office of Research and Legislative Services prior to implementation. No identifiable individual-level data will be shared

with the Kentucky DOC and participants are protected by a federal Certificate of Confidentiality.

To protect confidentiality, each participant is assigned a unique ID number which will be used in place of identifying information in the dataset. Only one secure password-protected file on a password-protected computer/server will contain participant names and corresponding ID numbers. REDCap and Network Canvas are secure, web-based applications designed exclusively to support data capture for research studies. Data collected using these applications are securely kept on university servers and encrypted during transmission. Qualitative data will be stored in a de-identified format only accessed using password protections on the university server. All GATE staff attended an intensive training covering human subjects protection, including issues that could arise during data collection with justice-involved and POUD populations.

Findings will be disseminated via presentations at both scientific and relevant professional conferences. Results will be submitted for publication in peer-reviewed journals. A final report will be shared with Kentucky DOC in an effort to progress delivery of the MOUD protocol in prisons, improve re-entry planning and inform clinical practices of SSCs assisting POUDs during their transition back to low-resourced rural and urban counties.

#### Data statement

A de-identified dataset and data dictionaries will be available by request within 6 months of the GATE study end date.

#### Methodological limits and concerns

The GATE study is not without limitations. The number of POUDs who initiate XR-NTX/buprenorphine in prison may be insufficient for estimating multivariate models of this outcome in aim 1; however, DOC data indicate that 19.7% of POUDs initiated XR-NTX in the inaugural year, so we expect at least 90 participants will have initiated XR-NTX. Within any network study, there is concern about the under-reporting of network ties; however, we will use procedures from established network studies and assure participants of confidentiality. Study findings may not generalise to rural or urban POUDs in other states but will fill gaps in the literature on personal networks and the use of MOUD during the high-risk re-entry timeframe. COVID-19 restrictions may negatively impact data collection and retention; however, we have a proven record of study retention for justice-involved populations and will take additional efforts (eg, extra staff and/or increased incentives) if our retention rate is below the projection of 80% during our first year of follow-up. Despite these limitations, the GATE study will contribute to identifying facilitating factors and barriers to MOUD initiation and continuity of care for rural and urban CJ-involved populations during the high-risk re-entry period.

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