Local IRB # 2206-001 **IRBNet #** 1865514

BUTLER HOSPITAL
INSTITUTIONAL REVIEW BOARD
PROTOCOL

1.) Project

Title of Project: Managed Care Updates of Subscriber Justice System Involvement for Suicide Prevention

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Other Investigator(s): _____

2.) Description of Study

A. Specific Aims

More than 10 million people pass through US jails each year. Suicide risk is especially high at jail release. Individuals are often arrested when they are out of care and experiencing worsening symptoms. Jail detention may disrupt existing care and provide additional stressors. However, high jail admission and discharge volumes (>10,000,000 per year), jail stays that only last a few days, and understaffing mean that most of the U.S.'s ~3,100 county and local jails do not have the capacity to coordinate care. Outside jail, many justice-involved individuals are supported by professionals in publicly funded systems, who are typically unaware that their client was in jail and may drop the client for missing appointments. The resulting lack of care or fragmented care leads to unnecessary cycling in and out of jail and suicide-related morbidity and mortality.

Better coordination of care between county jails and healthcare systems is widely acknowledged as crucial but difficult to achieve at scale. To address this problem, a large Medicaid managed care organization (MCO; CareSource) and a justice data vendor partnered to track county jail booking and release data for Ohio CareSource through an algorithm using publicly available data, generalizable to other healthcare/MCOs. The goal was to help CareSource ensure that subscribers were connected to needed community care following jail release and to minimize disruptions of any existing care due to jail detention. MCOs like CareSource are ideal organizations to help address system fragmentation because they span multiple behavioral health (BH) care systems (400 in Ohio alone) and multiple county jails (~88 in Ohio alone). In 2019, 43,000 (5.4%) of CareSource's 800,000 total adult subscribers in Ohio, including 2,306 pregnant women, spent time in jail. CareSource is exploring ways to ensure that these subscribers receive needed care.

This proposal involves two studies of evidence-based suicide prevention practices triggered by CareSource justice notifications, in a 2x2 factorial design. The **first study** will randomize CareSource's ~43,000 Ohio subscribers who pass through jails over 12 months to receive monthly Caring Contact letters sent by CareSource over a 6-month period or to Care as Usual. The **second study** (running simultaneously) will involve a subset of ~6,000 of the 43,000 subscribers passing through jail who were seen in one of 12 large BH agencies in the 6 months prior to jail detention. Using a stepped wedge design, the 12 agencies will be brought online over time, receiving (a) notifications of jail detentions/releases with instructions for re-engaging clients in services; and (b) training in the Safety Planning Intervention plus notification to use it when a subscriber with past *medically treated* suicide attempts (identified by CareSource through claims data) is released from jail.

Specifically, we plan to examine the following:

Aim 1: Evaluate the effectiveness of the implemented study interventions.

Hypothesis 1a: CareSource subscribers who receive CC letters during the 6-month period will have fewer claims related to suicide attempts than subscribers who did not receive CC letters.

Hypothesis 1b: Provider involvement in the reports, re-engagement, and training (RRT) intervention will be associated with a reduction in subscriber claims related to suicide attempts. Further, the addition of flags and recommendations to provide SPI for individuals with past 12 months claims data identified suicide attempts will further reduce suicide attempts.

Aim 2. Examine the number of outpatient behavioral health claims in the 6 months following the index jail release and number of calls to CMS line as mediators of the intervention/s effects on suicide attempts. Mediation will be revealed by the extent to which the intervention effect parameter estimates change with the addition of the putative mediator. We will use bootstrap methods to estimate 95% uncertainty intervals around the mediated effect.

Aim 3. Examine intervention cost-effectiveness and return on investment. We will examine costs (and savings) in future years for both the Caring Contacts and Reports, Re-engagement, and Training (RRT) components of the proposed study.

Aim 4. Identify and define implementation outcomes and processes to guide future implementation trials. In line with common implementation data elements and activities, we will conduct systems analysis and improvement (e.g., process mapping and cascade analysis), keep and analyze implementation documentation, and collect and analyze pilot implementation measures. This will allow us to: (1) optimize scalability and sustainability of the interventions, and (2) identify implementation strategies that maximize scalability and sustainability to inform future research.

B. Background

More than 10 million people are arrested and booked into jails each year in the U.S.[1] Half (40-50%) report lifetime suicide ideation or behavior, 13-20% have attempted suicide, and suicide is a leading cause of death in the months after jail release (18 times the general population).[2-6] Those who end up in jail are often from vulnerable groups among the highest risk for suicide, such as young males, persons with mental health and substance use disorders, socially disenfranchised, and those who have previously engaged in suicide behaviors.[7] Given that ~10% of all suicides with known causes in the U.S. occur in the context of a recent criminal or legal stressor (often arrest and jail detention)[8,9] targeting suicide risk after jail detention could have a noticeable impact on national suicide rates.

Individuals are most likely to be arrested when acutely ill (i.e., manic or psychotic), but arrest and jail detention often exacerbate symptoms of mental illness and destabilize medication and other treatment regimens.[10-12] Unfortunately, few of the ~3,100 U.S. jails have adequate staff to fully address health needs of individuals at risk for suicide, including basics like service linkage. Post-release outcomes are poor.[13-25] Among community mental health-affiliated individuals with serious mental illness, only one-third engage in an anticipated treatment service following jail release.[27] In fact, for many (45%), the next mental health treatment received was in jail.[26] Both health and jail providers want better linkage between systems to provide service continuity and reduce unnecessary morbidity and mortality.[10,27-34]

Most (95%) people who are arrested are booked into jail (>10 million per year). Unlike prison, jail stays are usually brief (median 36 days, mode 2 days[35]) and releases for pretrial detainees are typically unscheduled. High jail admissions and discharge volumes, short jail stays, and understaffing mean that many county jails do not have capacity to coordinate care between jails and outside health agencies.[13,15,36-43] Outside jail, many justice-involved individuals are supported by professionals within publicly funded systems, who themselves face resource restrictions, are often unaware that their client was in jail, and may drop the client for missing appointments. Coordination across ~3,100 jails and thousands of behavioral health (BH) agencies is a challenge.

In 2018, CareSource partnered with a justice alert company (which scans publicly available booking and release data and provides alerts when individuals are booked into or released from jail) to track jail booking/release data (from ~88 Ohio county jails) for Ohio CareSource members. The goal of the resulting Jail-Medicaid data project is to help CareSource be aware and follow up when one of its subscribers passes through jail. The linking system sits within CareSource and automatically crosswalks CareSource's subscriber list against booking and release data for all Ohio jails each day. Jail booking and release data are publicly available, alleviating privacy issues. In the past year, approximately 43,000 (5.4%) of CareSource's 800,000 total adult subscribers in Ohio spent time in jail. Of those who spent time in jail, 16% had a serious mental illness, 50% had a substance use disorder, 47% had chronic medical conditions, and 2,306 were pregnant. This Jail-Medicaid data linking system arose naturalistically to meet a clinical care demand. This system, facilitated by the national justice alert company, is generalizable to other payors/MCOs.

CareSource can track its subscribers across multiple BH agencies (400 in Ohio alone) and county jails (>80 in Ohio alone). Given jail detention is a marker for suicide risk, daily information to Medicaid MCOs about their subscribers' jail bookings/releases can serve as a catalyst for identification and preventative action (i.e., suicide prevention, treatment engagement).

The proposed project, developed in partnership with CareSource, tests the effectiveness and cost-effectiveness of using their Jail-Medicaid data system as a suicide prevention tool to: (1) identify jail releases (an indicator of person-level and temporal suicide risk); and (2) trigger suicide prevention activities. Evidence-based suicide prevention practices to be used were chosen in close collaboration with CareSource, who will be providing and/or funding them. Guiding principles in choosing interventions and study design included research evidence, scalability (to 43,000 Ohio subscribers passing through jail annually), and CareSource needs, constraints, and ongoing initiatives. Involving end-users intimately in study and intervention design, as we have done in this proposal, helps shorten the research-to-practice pipeline.[44]

C. Experimental Method

The following sections summarize the methods for the study components of Study 1 (Caring Contacts) and Study 2 (Reports, Re-engagement, and Training). Each section will be broken down into the following subsections:

1. Study 1 (Caring Contacts [CC])
    a. Focus Groups
        i. Provider focus groups
        ii. Subscriber focus groups
    b. CC letters
2. Study 2 (Reports, Re-engagement, and Training [RRT])
    a. RRT Intervention
    b. Provider meetings

For clarity, there are three types of groups that will be convened over the course of the study to gather information related to study-relevant topics:

- The first pertain to focus groups (including providers and CareSource subscribers) that will be used to (a) design and (b) provide feedback on revisions of the CC letter to be mailed by CareSource. These are referred to as focus groups in this protocol;
- The second are provider meetings where providers who have consented to participate in the RRT intervention will be asked to meet monthly with the Study PIs and CareSource to talk about their experiences, offer feedback, and help problem-solve challenges. These are referred to as provider meetings in this protocol; and
- The third will include stakeholders (e.g., individuals with lived jail experience, providers) will provide feedback on the intervention to improve scalability, sustainability, feasibility, acceptability, and appropriateness. The recruitment and processes for this third group will be part of the larger P50 Center's Methods Core and will be covered under the Center's IRB.

C1. Brief Description of Subjects

Study 1 (Caring Contacts)

Focus Groups: There will be up to 5 total focus groups: 2 involving CareSource providers (1 initial to design message; 1 for feedback/problem-solving) and up to 3 involving CareSource subscribers who have been in jail in the past year (1 initial to design message; up to 2 additional for feedback/problem-solving). Each of the focus groups may have up to 10 participants (up to 10 participants per focus group x up to 5 focus groups = ~50 potential focus group participants). All focus groups will be conducted virtually.

Provider Focus groups: Providers for the focus groups will be recruited from the 12 participating behavioral health (BH) agencies affiliated with CareSource. There will be up to 2 focus groups that involve providers with up to 10 providers participating in each focus group. The initial focus group will be aimed at developing the Caring Contacts messages for the mailings that will be sent by CareSource. An additional focus group may be conducted to provide feedback on the CC message and target problem-solving directed at the use of the CC letters during the study intervention.

Subscriber Focus groups: Focus groups also will be conducted that include CareSource subscribers (up to 3 total). Subscribers will be recruited through the use of flyers. Similar to the providers, there will be an initial focus group for subscribers that will focus on designing the CC message for the letters to be sent by CareSource and up to 2 additional for feedback and problem-solving.

Recruitment efforts will include posting flyers in BH agencies and posting flyers via Internet/social media. In addition, for subscribers, recruitment efforts may be made through contact with participants from previous studies who provided permission to be contacted for future research.

Caring Contacts Letters (participants = CareSource subscribers) ~43,000 Ohio CareSource subscribers (age 18+ years old) are released from jail annually. CareSource subscribers who passed through jail over 12 months will be randomized to receive either CC letters sent by CareSource or Care as Usual (CAU).

Study 2 (Reports, Re-engagement, and Training)

RRT Intervention: (participants = BH providers at CareSource Ohio-affiliated BH agencies) From each of the 12 participating BH agencies, 10 providers (for a total of 120 providers overall) will be recruited and consented to participate in the RRT Intervention. These providers potentially treat individuals that are part of the ~6,000 of the 43,000 subscribers passing through jail who have been seen at one of these 12 BH (i.e., mental health and/or substance use) agencies in the 6 months prior to their jail detention.

Site Interviews: Prior to the start of the RRT Intervention, each participating site will be asked to provide information on their site's current procedures and practices including types of services the agency offers, level of services offered, how clients are typically screened for suicide risk, source(s) of funding for the organization, how clients are re-engaged in care, and other questions pertaining to the agency's existing support system(s).

Provider meetings: Approximately 10 BH providers from each of the 12 BH agencies who are participating in the RRT Intervention (N=120).

C2. Study Design

This trial tests effects of two suicide prevention interventions triggered by notification of subscribers' jail release through CareSource's Jail-Medicaid database in a 2x2 factorial design.

Study 1: Caring Contacts

Focus Groups

The first part of this study will involve designing the CC letter message. It is standard in CC interventions to collaborate with individuals with lived experience to tailor specific messages.[32,83] We will do this in the first 3 months of the project in collaboration with the Center's Methods Core, Consortium Partners, CareSource. This will involve conducting up to 5 separate focus groups with at least 2 groups of CareSource providers and 3 groups of CareSource subscribers (who went through jail in the past year) to ensure that messages are engaging to them following well-established procedures.[23,47]

Provider Focus Group (up to 10 providers per focus group with up to 2 focus groups [1 initial to design message; 1 additional for feedback/problem-solving]): Providers will be recruited from the 12 BH

agencies. We anticipate recruiting up to 10 providers to provide feedback during each of the focus groups. The initial provider focus group will be aimed at designing the CC message, while the follow-up focus group will target feedback and problem-solving directed at the use of the CC letters during the study intervention.

Subscriber Focus Groups (up to 10 subscribers per focus group with up to 3 focus groups [1 initial to design message; up to 2 additional for feedback/problem-solving]): Similar to providers, we anticipate recruiting up to 10 CareSource subscribers who have spent time in jail within the past year to participate in each of the focus groups (1 initial and up to 2 follow-up).

Recruitment efforts will include posting flyers in BH agencies and posting flyers via Internet/social media. In addition, for subscribers, recruitment efforts may be made through contact with participants from previous studies who provided permission to be contacted for future research.

Following the focus group, audio/video files recorded during the meeting will be downloaded onto secure servers at Butler and Michigan State University (MSU) and the recordings will be transcribed. Information provided by focus group members will be identified using a unique code for each participant instead of their names.

CC letters

Once the CC letter has been developed and received final approval by the Butler IRB and CareSource, subscribers who have been released from jail during the 12-month randomization period will be randomized on a 1:1 ratio to either receive the CC letter or CAU. All adult (age 18+ years) CareSource subscribers in Ohio who are released from jail over the 12-month randomization period will be included in Study 1. Letters will be mailed monthly for 6-months following notification of jail release. Randomization to CC or CAU will occur in a 1:1 ratio. The Methods Core (located at Michigan State University) will prepare the randomization schedule and provide it to CareSource. CareSource will incorporate it into their automated mailing system to trigger CC letters when an individual is released from jail and randomized to CC.

Following notification of jail release, CareSource will mail CC letters to subscribers randomized to CC (~21,500) monthly for 6 months after jail release. CC involves sending individuals at risk for suicide brief, non-demanding messages of care.[26,34,45,46] Messages: (1) include a simple expression of care or concern; (2) are non-demanding; and (3) include a reminder of available resources/ways to connect with care. CCs in this study will be addressed from and refer to CareSource's Care Management team via the care management service (CMS) line. This team, who works with individuals to arrange appointments with appropriate providers and other relevant resources (including crisis lines). Individuals who are re-arrested during the 6-month follow-up period will continue to receive letters, but will not be re-randomized.

Caring Contacts fidelity: CC letters sent, the dates they were sent, and any letters returned will be tracked using CareSource's automated mailing system. Since the mailing system is automated, it should involve minimal human error or noncompliance.

Study 2: Reports, re-engagement, and training (RRT)

RRT Intervention will involve 120 BH providers who provide services at 12 of the largest BH agencies in Ohio (10 providers per agency). These agencies serve ~6,000 of the 43,000 CareSource subscribers who passed through jail in the 6 months prior to detention. Providers who consent to participate in the RRT Intervention will receive: (a) notifications of jail release for their clients, (b) instructions for re-engaging these clients in services and training in suicide risk assessment to use at re-engagement; and (c) training in SPI plus notification to use SPI when a client with past suicide attempts is released from jail. Suicide attempts for this proposal will primarily refer to medically-treated (MT) suicide attempts (i.e., presented

to ED/hospital for treatment following a suicide attempt) as these are the only types of attempts we can identify through claims data.

Site Interviews: The primary contacts at each of the participating BH agencies will participate in the site interviews. These will be conducted virtually and will be recorded. Audio/video files recorded during the meeting will be downloaded onto secure servers at Butler and Michigan State University (MSU).

Provider meetings: BH providers who are participating in the RRT Intervention (N=120) will be asked to participate in monthly meetings with the Study PIs and CareSource to talk about their experiences, offer feedback, and help problem-solve challenges. These meetings will be held virtually. Additional personnel, including clinical directors, business managers, and other relevant staff may attend these meetings. These meetings are intended to provide an opportunity for the site to ask us questions, address concerns, work through challenges, etc. Because part of this study is focused on implementation, we will need to have formal review and ratings of the information provided in the meetings. CareSource will record the meetings and provide transcripts of the discussions for analysis. Due to the variation in staff attending the steering team meetings, verbal consent will be obtained prior to the start of each of these meetings. If verbal consent is not received, the meeting will not be recorded/transcribed.

Study Outcomes: All study outcomes will be tracked through the use of claims data. These data include diagnosis, treatment, and billed and paid amounts. Data will be extracted using previously established algorithms for suicide and self-injury research developed by the Mental Health Research Network. This is not medical record data. We will not have access to the patient's health record. CareSource will extract data from their Jail-Medicaid database to examine billing and insurance claims submitted for visits associated with our study suicide-outcomes of interest (suicide attempts, all cause injury and poisoning, outpatient BH visits, calls to CMS line, suicide-related ED visits/hospitalizations, and returns to jail detention).

Training behavioral health providers: The 12 BH agencies who see the largest number of justice-involved CareSource subscribers (approx. 6,000 total annually) will be randomly assigned to four cohorts. All four cohorts will follow the same intervention protocols, but they will begin at Months 4, 6, 8, and 10 of the CC intervention, respectively. As BH agencies are assigned to the RRT condition, they will receive training in reaching out to and re-engaging clients who pass through the justice system, and training in suicide risk assessment (C-SSRS[28]) and response (SPI[29]).

Training will use Stanley and Brown's well-established methods for videoconference training. SPI and C-SSRS training take about 6 hours total. Prior to the training, individuals will be emailed the SPI manual used in a previous intervention trial (SPIRIT).[29,46] On the day of the training, information on the rationale for SPI, an overview of SPI, and the steps of SPI, with video clip demonstrations interspersed will be presented. We will provide an additional 30 minutes of training in reaching out to and re-engaging justice-involved individuals in BH care. After completing the online training and study of the written SPI manual, counselors will receive a 2.5 hour live training in SPI fidelity rating via webcam (i.e., it is live, but not in person). The group views and rates fidelity of SPI videos that vary in quality, and then discusses their answers. Drs. Stanley and Brown have found that practicing SPI fidelity assessment by critiquing SPI helped learners understand the SPI model and commit it to memory. C-SSRS training also includes video and live practice. These trainings will be recorded to ensure fidelity and consistency across the trainings. The audio/video files recorded during the meeting will be downloaded onto secure servers at Butler and Michigan State University (MSU).

Weekly reports: During the months BH agencies are assigned to the RRT intervention condition, they will receive weekly reports from CareSource with notifications of jail booking/release dates of any client seen by the agency in the 6 months prior to arrest. Reports will include instructions for how to reengage the client, and a reminder that the C-SSRS can be used for suicide risk assessment. Subscribers with any past (lifetime) suicide attempt documented in available claims data will be flagged for additional outreach and action, including SPI. These reports will be built into an existing, automated CareSource system that

sends jail booking/release data to BH agencies. This system is currently being piloted and refined by CareSource.

RRT Fidelity. We will be able to electronically track whether reports go out and whether they are timely/accurate. In addition, although we do not have a scalable way to track outreach attempts for 6,000 subscribers in Study 2, we will carefully document implementation processes and meet monthly with CareSource and intervention agencies, hear their experiences, offer feedback, and help problem-solve challenges. We will keep structured implementation process notes from these meetings for further analysis. Provider names will be included in the notes. All data from the implementation process feedback will be securely stored in REDCap. No names or identifiers will be used in any published works and will be accessible only to authorized research staff. Testing our service engagement mechanism will also help to elucidate steps in the causal chain (i.e., from the reports, to services provided, to suicide attempts).

Assignment to "intervention" and "control" conditions in the two studies is independent: participants may receive Intervention-Intervention, Intervention-Control, Control-Intervention, or Control-Control. Participants will be followed for 6 months following jail release using claims data.

C4. Data Analysis

Twelve months of historical (i.e., prior to arrest) and six months of prospective (i.e., after release) jail and Medicaid claims data will be extracted from CareSource's Jail-Medicaid database for each participating subscriber for all measures, including demographics, diagnoses, suicide attempts, service use, number of arrests, dates of jail bookings/releases, and days incarcerated. Each eligible subscriber will be followed for 6 months following the index release from jail using claims data. CareSource will provide a limited dataset to the P50 Center (at MSU) that will be de-identified and analyzed by Center statisticians. Because these statisticians are employed by Brown University, an IAA will be established with both MSU and Brown University.

For Aim 1, we will assess total number of subsequent attempts using the already-developed Mental Health Research Network (MHRN) algorithm for extracting MT suicide attempt information from claims data.[10-12,48-58] The main effectiveness analysis is planned as a comprehensive model (i.e., including all 43,000 subscribers) evaluating Study 1 and Study 2 intervention effects, which provides optimal power and the ability to test interactive effects of interventions. All analyses will covary baseline (i.e., past year) values of dependent variables, and will use days incarcerated in the 6 months after the index jail release as an offset. MT suicide attempts. The main analysis framework will be logistic regression with the cumulative risk of a claims-data-identified suicide attempts requiring medical treatment over six months post-release as the outcome. We will secondarily use a negative binomial model and a count outcome for the number of MT suicide attempts. Our models will include robust standard errors due to clustering at the agency level. We will adjust for study month, and include indicator variables reflecting: (1) Study 1 intervention condition (i.e., CC or CAU); (2) inclusion in Study 2; (3) Study 2 intervention condition (i.e., RRT or Control). The ***hypothesis that the Study 1 intervention (CC) reduces suicide attempts*** is evaluated with magnitude and significance of parameter estimate associated with random assignment to the Study 1 intervention. The ***hypothesis that the Study 2 intervention (RRT) reduces suicide attempts*** is tested with the parameter estimate associated with exposure to the level 2 intervention. ***The hypothesis that the addition of flags and recommendations to provide SPI*** for individuals with past 12 months claims data identified suicide attempts (one component of the Study 2 intervention) ***will further reduce suicide attempts*** will be tested through the interaction between past history of suicide attempt and being in the Study 2 intervention condition. Identical analyses will be conducted for the other outcomes (all count outcomes): all cause injury and poisoning, outpatient BH visits, calls to CMS line, suicide-related ED visits/hospitalizations, and returns to jail detention. ***Exploratory.*** We will evaluate the interaction of Study 1 and Study 2 interventions by including an interaction term of the two indicators. ***Moderators.*** We will test sex, race/ethnicity, past suicide attempt (y/n), past 6-month BH visit (y/n), past 12-month arrest (y/n), area Deprivation Index,[59-60] Mental Health Professional Shortage Area (HPSA)

score,[61-62] and per capita incarceration (by zip code) as moderators of intervention effects on suicide attempts, using p<.01.

Aim 2 will be analyzed by examining the number of outpatient BH claims in the 6 months following the index jail release and number of calls to the CMS line as mediators of the intervention/s effects on suicide attempts by adding this variable to our effectiveness model. Mediation is revealed by the extent to which the intervention effect parameter estimates change with the addition of the putative mediator. We will use bootstrap methods to estimate 95% uncertainty intervals around the mediated effect.

For Aim 3, our grants accounting will capture the costs of the CC mailings. Treatment received as part of the intervention and CAU conditions (including outpatient, inpatient, and ED mental health and suicide-related medical care visits) will be tracked using claims data. Costs of CAU will be computed as CareSource payments plus co-pay and deductibles. We will add training costs for providers but exclude other research costs that would not be incurred if RRT was standard care. The primary cost-effectiveness (CE) measure, computed from a societal perspective for each intervention arm, will be the program cost divided by the sum of suicide attempts prevented. We also will assess the net cost of the program from a MCO perspective. That measure will exclude patient payments from costs.

Costs (and savings) in future years will be discounted to present value in the year of jail release using the 3% discount rate recommended by the Second Panel on Cost-Effectiveness in Health and Medicine.[63] We will bootstrap the 95% uncertainty interval around the CE ratio. Analyses from the MCO perspective will compute the change in claims costs by running a generalized linear model (GLM) with gamma, inverse Gaussian, or Poisson variance based on data distribution, the log link function, and robust standard errors.[64] We will use a 2-part GLM unless less than 5% of patients have zero costs. Independent variables will include treatments received, demographics, Elixhauser co-morbidities,[65] and days of MCO coverage after jail discharge. We also will track the MCO separation rate post-discharge by group.

Using the IHI Framework for Going to Full Scale,[66-67] this project will focus on sustainability and scalability. We will assess, maximize, and optimize intervention: (1) scalability (per the Intervention Scalability Assessment Tool[68]); (2) sustainability (per the Program Sustainability Assessment Tool[69-70]) (3) feasibility, acceptability, and appropriateness to providers and systems (per the Acceptability of Intervention Measure,[71] Intervention Appropriateness Measure,[71] and Feasibility of Intervention Measure[71]); and (4) actual and recommended implementation strategies (via process mapping and implementation process/case notes).

Statistical power. ***Assumptions.*** We conducted a simulation study, allowing for variability in release dates, numbers eligible, and introducing a small intra-cluster correlation (ICC = .01). We assumed 43,000 eligible subscribers for Study 1, with 50% randomly assigned to CC. Based on last year's data, we assumed 6,000 eligible subscribers for Study 2. We expect that ~10% of the 6,000 (n~600) will have past suicide attempt identifiable through CareSource claims data. We assumed a six-month risk of suicide attempt 0.05, but past 12-month claims data-identified suicide attempt increases this risk (i.e., .034 in absence of past-year suicide attempt, 0.204 with a past-year suicide attempt, odd ratio (OR) = 5), similar to SPIRIT. ***Results****.* We ran the simulation model 2001 times. Significance was assessed using a two-tailed type-I error level of 5%. Caring Contacts. We will have 85.6% power to detect an effect equivalent to an OR of 0.89. CC has been found to have much stronger effects that this in previous studies[22] suggesting that we are adequately powered for CC. RRT. If we assume an intervention effect for Study 2 of 0.87 OR, we will have 88.3% power to detect this effect. For subscribers with a past year suicide attempt within Study 2 (who will be flagged to receive SPI), we will have 96.4% power to detect an OR of 0.63 (the OR detected for SPI in our previous trial, SPIRIT).[46] Having superadequate power for this test offsets concerns about providers potentially not providing SPI as instructed in this large, real-world study.

D. Material Inducements

Study 1

Provider focus groups: No material inducements will be provided for BH providers who engage in the focus groups. Providers will complete study-related procedures during work time and are typically not able to accept material inducements.

Subscriber focus groups: Subscribers who participate in a focus group will be compensated $50.

CC letters: No patients will be followed prospectively through any direct means of engagement, so no material inducements will be provided to study participants.

Study 2

RRT Intervention: Providers will be offered the opportunity to earn continuing education credits following completion of the required study trainings.

Site interviews and Provider meetings: No material inducements will be provided for involvement in the site interviews or provider meetings. As noted above, providers will complete study-related procedures during work time and are typically not able to accept material inducements.

E. Training of Research Personnel

All research personnel will receive training in research ethics. Research personnel will complete the Collaborative Institutional Training Initiative (CITI Program) on Human Subjects Research.

3) Human Subjects

A. Subject Population

Human subjects in this study include (1) Focus group participants (BH providers and CareSource subscribers), (2) BH providers participating in the RRT Intervention, and (3) the ~43,000 Ohio CareSource subscribers who pass through jails over 12 months. However, because our research will only use de-identified claims data from the individuals in #3, their involvement does not meet criteria for human subjects research and they are not considered participants in this study, even though they may be randomized to receive an intervention intended to reduce suicide outcomes. All participants will be 18 years of age or older.

For the Focus groups in Study 1 (Caring Contacts), there will be up to 5 total focus groups: 2 with CareSource providers and up to 3 with CareSource subscribers who have spent time in jail. Each of the focus groups may have up to 10 participants (up to 10 participants per focus group x up to 5 focus groups = ~50 potential focus group participants).

We plan to randomize approximately 43,000 Ohio CareSource subscribers who pass through jails over 12 months to receive either Caring Contact letters sent by CareSource or Care as Usual. In Study 2, we will include a subset of those subscribers (approximately 6,000) who have also been see at one of the 12 largest behavioral health agencies in Ohio in the 6 months prior to their jail detention.

For Study 2, we anticipate engaging at least 120 providers (~10 from each of the 12 participating behavioral health agencies). The study intervention will take place in Hamilton, Franklin, and Cuyahoga Counties in Ohio, with remote meetings between providers and investigators at Butler Hospital and MSU for training and implementation process supervision. Detailed implementation process notes will be generated from discussions between researchers and providers at the monthly meetings to characterize study implementation, offer feedback, and help problem-solve challenges.

Three sources of data will thus be used in this study: (1) input from focus group members, (2) implementation process notes and feedback from providers, and (3) claims data from subscriber recipients of the intervention or care as usual (CAU).

Per OHRP, this study does not constitute research on a vulnerable population (i.e., prisoners) for the following reasons:

1) The study activities include no interactions or interventions with incarcerated individuals through which their information is collected for research. Although the program may inspire

providers to communicate with prison populations in new ways consistent with known best practices, this would not be a research interaction or intervention through which information is obtained.

2) The study activities include no plans to obtain the private, identifiable information about any individual while incarcerated, or even to use such information for the research. While some information about the individuals' incarceration will be used, this is limited to publicly available information only.

Outcome analysis. Suicide attempts as well as service utilization outcomes will be assessed using CareSource's Jail-Medicaid data, which includes Medicaid claims, information on jail booking and release, and other data. As in our past and current studies, this will not be human subjects data because the dataset will not contain personal identifiable information. CareSource will prepare a deidentified dataset that will be made available to authorized research staff through the secure MSU server. Although dates are included in the claims data, all dates relating to the patient, including date of birth, visit dates, dates of labs performed, will be randomly shifted to a fabricated set of dates by CareSource prior to being sent to the research staff. For instance, if a patient's actual visit date was 10/15/2020, CareSource will generate a random date (e.g., 01/30/2001). This will allow us to calculate date and time ranges without using actual patient identifiers.

B. Recruitment and Consent Procedures

Study 1 (Caring Contacts)

Focus Groups:

Provider Focus Groups: Providers will be recruited from the 12 BH agencies via flyers posted in the agencies and on the Internet/social media (e.g., Facebook, LinkedIn). We anticipate recruiting up to 10 providers to provide feedback during each of the focus groups. The initial focus group will be aimed at designing the CC message, while the follow-up focus group will target feedback and problem-solving directed at the use of the CC letters during the study intervention.

Subscriber Focus Groups: Subscribers will be recruited through methods including the use of flyers posted in BH agencies frequented by CareSource subscribers, posting flyers on the Internet/social media, and outreach to participants from a previous study who have given permission to be contacted for future research. Similar to providers, we anticipate recruiting up to 10 subscribers to participate in each of the focus groups (1 initial; up to 2 follow-up).

CC Letters:

After development of the CC letter through stakeholder input in the initial focus groups, CareSource subscribers randomized to the CC group will be mailed CC letters by CareSource. Because this study involves the use of retrospective claims data, individual patients will not be consented for participation. Due to the retrospective nature of the data and the large population, written or verbal consent is not feasible.

Study 2 (Reports, Re-engagement, and Training)

RRT Intervention: Behavioral health providers at the participating agencies will be contacted by Drs. Arias (Butler) and Sperber (CareSource) and provided with information about the study. If the provider is willing to participate in the study, they will be emailed a link to review and sign the informed consent in REDCap.

Site Interviews: Primary contacts at the participating agencies will be contacted by Dr. Arias (Butler) or her RA and provided with information about the interview. If the provider is willing to participate in the study, they will be emailed a link to review and sign the informed consent in REDCap.

Provider meetings: Providers participating in the RRT Intervention will consent to engaging in monthly meetings as part of the RRT Intervention consent procedure.

C. Potential Risks

Study 1 (Caring Contacts)

Focus Groups:

The main risks associated with focus groups are related to lack of privacy and potential loss of confidentiality. Because focus groups involve multiple people together in an open discussion format, other participants in the group will be aware that the individual participated in the focus group and will be able to hear their input. Focus group participants will be asked to respect the confidentiality of other focus group members by not talking about any content discussed during the meeting, but we have stated in the informed consent that this cannot be guaranteed. No focus group participants will be personally identified in any reports or publications that may result from this study.

CC Letters:

The main risk for subjects randomized to the intervention or control is loss of confidentiality. No patients will be followed prospectively through any direct means of engagement. Caring Contact letters will not contain any information about arrest. However, if the subscriber calls the phone number provided by CareSource and asks why he/she received the letter, the care managers will say that they received word of the subscriber's arrest and wanted to check in with him/her and offer resources and services. Regardless of the source, all data associated with this project will be stored on servers that adhere to or exceed HIPAA principles and protected using the same protections associated with clinical data. There is only one notable risk in the proposal research study: (1) a breach of confidentiality. Although every effort will be made to minimize this risk, it is possible that a breach of confidentiality (e.g., answers to questions about post-jail release and suicidal thoughts and behaviors) could affect a subject's reputation.

Study 2 : Reports, re-engagement, and training (RRT)

The main risk associated with Study 2 relates to personal difficulties or inconveniences a BH provider may experience during training and delivery of the intervention. Since these activities are within the scope already practiced by the providers, these are considered minor. There is a risk that BH providers will feel coerced to participate since they are agents of CareSource organization, and some of the CareSource leaders are co-investigators.

D. Protection of the Subject

D1. Measures to Minimize Potential Risks

Recruitment and Informed Consent.

Study 1 (Caring Contacts)

All focus group participants will complete an informed consent prior to study involvement. Information provided by focus group members will be identified using a unique code for each participant instead of their names. In addition, to mail checks to the CareSource subscribers who participate in a focus group, we will collect their mailing address for payment purposes. All information will be treated as confidential material and will be available only to authorized research staff. In addition, the University research servers maintain secure environments for storing and processing clinical data that adhere to or exceed HIPAA principles.

CC Letters:

Because this study involves existing patient records within a managed care organization, individual patients will not be consented for participation. Due to the retrospective nature of the data and the large population, written or verbal consent is not feasible. Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All research personnel will receive training in research ethics. All information will be treated as confidential material and will be available only to authorized research staff. CareSource will provide the P50 Center (at MSU) with a limited datafile that will be de-identified by P50 Center (Brown University-based) statisticians. Any results reported with the project will be reported in aggregate.

Study 2 (Reports, Re-engagement, and Training)
Participating providers will complete an informed consent process prior to study involvement; this process will make them aware that they are not required to participate as a condition of employment and that they may use regular work hours to complete training and attend meetings with the researchers.

For Study 1 Focus Group members and Study 2 Providers, any participant may withdraw from the study at any time by notifying the investigators that they would like to withdraw. The informed consent form will state that, unless they specify otherwise, any data that has been collected may be used for the planned analyses.

All research staff will be certified in human subjects education by their respective institutions before having contact with human subjects.

D2. Measures to Ensure Confidentiality
Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All research personnel will receive training in research ethics. All information will be treated as confidential material and will be available only to authorized research staff. All paper-based materials, if applicable, will be kept in locked files. In addition, the University research servers maintain secure environments for storing and processing clinical data that adhere to or exceed HIPAA principles. Therefore, we anticipate the proposed data collection and analysis procedures will pose minimal risk. Only authorized members of the research team will have access to the data. CareSource will provide the P50 Center (at MSU) with a limited datafile that will be de-identified by P50 Center (Brown University-based) statisticians. The Internal Privacy Department at CareSource will review and approve all data de-identification procedures to ensure compliance with the Safe Harbor Method as well as all internal agency protocols prior to the release of any deidentified data for research purposes. Any results reported with the project will be reported in aggregate. Additional data management and security steps are included in the Data Safety and Monitoring Plan.

D3. Data Safety Monitoring Plan
The study investigators will be responsible for implementing and maintaining quality assurance and quality control systems for this study. Written standard operating procedures will be used to guide the research. The PIs (Drs. Arias and Johnson) and research staff at their institutions will meet weekly to review study progress, including recruitment, procedures, and unanticipated problems. The protocol will be reviewed and approved by the investigators' IRBs prior to study start. All protocols and procedures will be reviewed with participants (i.e., focus group, providers) prior to study involvement.

Unanticipated problems related to participation in the study will be reported to the PIs or delegated research staff for the duration of the study. The PIs will have the front-line responsibility for identifying potential unanticipated problems experienced by study participants, adjusting the study procedures accordingly, and reporting the experience.

> For focus groups/implementation process notes (for which we have identifiable data), the PIs will ensure that information on any adverse effects on provider participants are reported to the IRB/DSMB. If any unanticipated problems are detected, these will be submitted to the respective IRBs and DSMB within 72 hours. The Principal Investigators will be responsible for tracking these reports and relaying them as required to their IRBs.
>
> For Caring Contacts and RRT, CareSource will provide a limited datafile to P50 Center statisticians who will generate a de-identified analytic dataset with aggregated, clinic-level data that will be used by the study team to analyze study findings. Similar to studies conducted in the Mental Health

Research Network, service connection and suicide-related outcomes for these 43,000 individuals are evaluated through claims data. Standard reporting and monitoring "adverse events" as typically defined (i.e., patient death, hospitalization, etc.) in real time is not possible because: (1) claims data lag, and (2) data are aggregated and de-identified. However:

1. All study interventions are either standard of care (reach out to individuals after jail release to see if they need additional mental health or substance use treatment) and we are providing a systematized way to do it (through Caring Contacts or weekly reports to agencies) or are considered suicide prevention best practices (assessment with the C-SSRS and intervention with SPI, the only evidence-based suicide prevention intervention for the target population). Therefore, it seems appropriate to evaluate aggregate outcomes of these system-level efforts to use evidence-based practices.

2. Study interventions take place over 12 months. Because of the lag in claims data (~3 months) and the need to de-identify and integrate datasets to be sent to the PIs, it is not possible for us to have real-time access to the data. However, we will take two steps to provide safety information to the DSMB in a timely way:
    a. We will have the Data and Safety Monitoring Board (DSMB) review the study prior to the start of the study, and then review extant safety data at 6, 9, and 12 months after the start of the study.
    b. CareSource estimates that about half of their claims are submitted within 30 days of the service date. Adding time to clean and de-identify the data, run the MHRN algorithm on the data, and prepare the DSMB report, we estimate that about half of claims data will be available for safety review within 60 days of the service date. Therefore, at Month 6, the DSMB will have all the cases from Months 1-3, and half of the cases from Month 4 for review. At Month 9, the DSMB will have all the cases from Months 1-6 and half of the cases from Month 7 for review. At Month 12, the DSMB will have all the cases from Months 1-9, and half the cases from Month 10 for review. Then, the DSMB will have a closeout meeting when all study data are available.

Analyzed participant data will be stripped of personal information by CareSource, and will be identified in the project only by numerical codes. Links between these codes and personal identifiable information (e.g. names) will only exist in the CareSource database (which will not be accessible by research staff). The collected data will be stored on secure servers at Butler and MSU, which are consistently used for data hosting needs. The outcomes of interest will include suicide attempts, engagement with outpatient mental health and substance use services, and returns to jail detention. We will report pre-post intervention changes in the outcomes, both unadjusted, and adjusted for participant characteristics

Most data collected during the study timeframe will be entered into an online data management system (REDCap). Data will be stored on backed up, password protected servers. Within each computer system, only those users authorized to access the data for a given study are able to do so.

Data from focus groups and provider meetings will also be shared with the DSMB. Since no adverse effects are anticipated from these participant groups, any significant negative feedback from these participants will be shared with the DSMB.

Data and Safety Monitoring Board (DSMB)

This project will utilize the central Center DSMB. Our analysis plan will be reviewed and approved formally by the DSMB prior to the start of the study.

E. <u>Potential Benefits</u>

There are no direct benefits from participation in this study, but there are potential benefits.
<u>Participating providers</u> will have the opportunity to be trained in how to address suicide risk assessment

and safety planning, and may be better able to serve the justice-involved population with whom they work.

Individuals passing through jail may benefit from having providers who are more attuned to and better able to meet their needs, which may improve both treatment outcomes and continuity of behavioral health care.

F. Risk-Benefit Ratio

Lack of data sharing is a main reason coordinating health care and jail reentry services has seemed insurmountable. CareSource's Jail-Medicaid data project has bridged this gap to provide an ongoing picture of the justice-involvement of their Medicaid population, making systematic outreach and suicide prevention possible. Further, few previous studies have engaged MCOs in suicide prevention efforts in any capacity. MCOs are an important and innovative suicide prevention partner. Health insurance providers and MCOs have unique access to statewide or even nationwide data on patients at risk for suicide. Actively involving these organizations in suicide prevention can address system fragmentation and result in both improved outcomes and cost-savings. The proposed study will be the first to (1) evaluate CC for individuals released from jail, and (2) evaluate MCO-provided flags for BH re-engagement and suicide prevention services for recently released individuals, a large population that contributes significantly to U.S. suicide rates. The potential benefits outweigh the potential risks. Further, potential risks will be mitigated by ensuring measures to protect participant confidentiality and appropriate data collection and storage.

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5) CRITERIA FOR WAIVER OF AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION (PHI)

5A. Does the requested use of PHI involve more than minimal risk to privacy?
☐ **YES** ***[if " YES," project is not eligible for PHI Waiver]*** ☒ **NO** ***[if "NO," address 1-3 below]***

1. **Plan to Protect Patient Identifiers from Improper Use and Disclosure:**
All paper-based materials, if applicable, will be kept in locked files. In addition, Butler Hospital and Michigan State University (MSU) research servers maintain secure environments for storing and processing clinical data that adhere to or exceed HIPAA principles. Therefore, we anticipate the proposed data collection and analysis procedures will pose minimal risk. Only authorized members of the research team will have access to the data. A CareSource will provide the P50 Center (at MSU) with a limited datafile that will be de-identified by P50 Center (Brown University-based) statisticians. The Internal Privacy Department at CareSource will review and approve all data de-identification procedures to ensure compliance with the Safe Harbor Method as well as all internal agency protocols prior to the release of any deidentified data for research purposes. Any results reported with the project will be reported in aggregate.

2. **Plan to Destroy Identifiers or Justification for Retaining Identifiers:**
The relevant PHI for this waiver is the claims data that will be access and extracted by CareSource. For the CC letters and claims data extraction, all patient identifiers will be maintained by CareSource until all data collection and quality assurance procedures are completed. Once all study-relevant tasks are completed, identifiers will be deleted.

3. **Assurances that the PHI will not be Re-used or Disclosed:**
Data collected during this study will be accessed by study-relevant research personnel only. No unauthorized use of the data will be allowed for any reason and no PHI will be re-used or disclosed.

5B. Could the research be practicably conducted without a waiver? ☐ **YES** ☒ **NO**
5C. Could the research be practicably conducted without access to and use of the PHI? ☐ **YES** ☒ **NO**
5D. PHI is only needed for activities preparatory to research ☐**YES** ☒**NO**

6) DESCRIPTION OF PHI TO BE COLLECTED UNDER WAIVER

No PHI will be collected for the CC letters and assessment of study outcomes via claims data. Authorized CareSource study staff will access subscriber claims data that have been randomly selected for study inclusion. CareSource will have access to the subscriber claims data, but none of the data exported for analysis and shared with study staff outside of CareSource will contain PHI.

7) ADVERTISEMENTS

Flyers will be used for provider and subscriber recruitment to participate in the focus groups. For the RRT intervention, interested BH agencies have already been identified by CareSource. Information about the study will be provided to the agencies prior to contacting providers about study participation.

8) INFORMED CONSENT FORM (ICF), ASSENT OF MINOR & PARENTAL PERMISSION FORM

✓Consent form(s) are attached. Indicate number of consent(s): 3

Identify each consent: BH_provider_ICF (to consent the behavioral health providers); Focus_Provider_ICF (for providers in focus groups); Focus_Subscriber_ICF (for non-provider participants in focus groups).