

**SOCIAL NETWORK DIFFUSION OF COVID-19 PREVENTION FOR DIVERSE CRIMINAL
LEGAL INVOLVED COMMUNITIES**

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BACKGROUND

The “Social network diffusion of COVID-19 prevention for diverse Criminal Legal Involved Communities”, will implement a situation appropriate COVID-19 testing and vaccination social network diffusion intervention – C3. C3 builds upon RADx-UP Phase I lessons and successful social network prevention interventions developed previously by the research team.¹⁻³ COVID-19 prevention messaging can no longer be simplified to “everyone test and/or everyone vaccinate” as testing and vaccination personal decisions are *situation appropriate* and sensitive to prior histories (i.e., prior infection), local infection rates (i.e., low rates) and testing/vaccination availability. As COVID-19 prevention efforts have become more situation appropriate (i.e., test if exposed), people tend to focus on the messenger³³, and particularly those that are close to them. Those who are vaccine hesitant, for example, report that the top reason they would change their mind is if close friends or family were vaccinated⁴, a finding similar to other health behaviors.^{4,5,6} Personal connections and communications within existing personal network structures, such as families and friends represent the cornerstone to increase situation appropriate testing and overcoming COVID-19 vaccine hesitancy. Appropriate and timely messaging that local networks can utilize to make situation specific decisions (i.e., test if symptomatic) is urgently required for disenfranchised populations that do not want testing/vaccination, are concerned about safety or are not sure.

Social network driven diffusion of innovation interventions (Type 1 or popular opinion leader network interventions)⁸ utilize peer change agents who are trained as part of the intervention to motivate network members around behavior change and represents an approach that can rapidly move beyond individual-level behavioral change interventions.⁸ Our work and that of others suggests that biomedical innovation uptake can be driven by information and influence within personal networks that organically exist.^{1,2,4,5} Reaching vulnerable and disenfranchised populations can be straightforward as many community members often obtain and transmit information primarily through their informal social networks, especially their friends and family.^{9,10} By leveraging trusted voices and support systems that already exist within affected populations¹¹, network interventions embody more than a process of information diffusion and behavioral modeling via influential peers (i.e., the influence dimension); they also strengthen community connectedness¹², build community resilience¹³ and facilitate community-directed action¹⁴ (i.e., the empowerment dimension). We believe that these cascading network effects are key for facilitating longer-term community-level change.

C3 builds upon RADx-UP I, by using a network diffusion approach facilitated through motivational interviewing purposefully geared to mobilize one’s own organic social network to increase situation appropriate testing and vaccine uptake. Through this process we will maximize the primary benefit and impact of this type of intervention which also has the intended effect of increasing likelihood that *the messenger themselves will undergo the same behavior change* that they have been trained to promote.¹⁵⁻²⁰ We will leverage infrastructure developed in RADx-UP Phase I, which includes 4 high-impact sites across the Central US that are also the highest recruitment sites from Phase I: Baton Rouge LA, Little Rock AR, Indianapolis IN, and Chicago IL and engage individuals who have directly and/or indirectly interacted with law enforcement (ILE). We will utilize established engagement efforts already in place and continue to fully integrate communities in the strategic application of the intervention through our COVID-19 Community Advisory Board.

STUDY DESIGN

The scientific premise of C3 is to engage people who have been interacted with law enforcement in COVID-19 prevention (testing and/or vaccination) through social network mobilization combined with theory-driven COVID-19 prevention messaging delivered in an interactive group format. Eligible individuals will be enrolled into C3. Using a two-arm 1:1 randomized controlled trial design, 800 participants will be enrolled into either a: 1) COVID-19 prevention education arm (Education Arm) or, 2) a network mobilization change agent intervention (Motivational Arm); the latter is a Type I network intervention that includes specific training on mobilization of network members which we have adapted to COVID-19 from HIV prevention.^{2,3} Training occurs in a group-based setting of 8-10 enrolled participants facilitated by a community facilitator and Motivational Interviewing trained interventionist. At 30 days, a 15-20-minute phone booster communication session reinforces the intervention content. Information on the personal social network members of these participants will be collected during the study visit (estimated at $n \sim 2-4$ /participant, total $\sim 3,200$) using a network elicitation and collection approach prior to randomization as in previous work.^{1,2}

Primary outcomes are: 1) the number of study participants who undergo COVID-19 testing (situation appropriate) at 3 months; and 2) the number of study participants who receive at least one COVID-19 vaccine dose at 3 months. Secondary outcomes are the same as primary, except measured among people who are in the networks of primary participants (referred to as secondary subjects moving forward). Additional secondary outcomes include: COVID-19 testing and vaccination knowledge; intent to receive a COVID-19 test or vaccination, and intent to participate in a future vaccine trial. Additional analyses will begin to understand the complex relationships between testing and vaccine statuses and proclivity to test (and potentially obtain a vaccine booster) among both study participants and their network members. For example, do those who are vaccinated serve as more effective change agents? Are vaccinated persons more or less likely to test compared to unvaccinated persons? Are people with prior COVID infection less likely to get vaccinated than those without a known history of infection? We have leveraged the RADx-UP phase I infrastructure to adapt the intervention resulting in C3.

AIMS

Aim 1a. Test the efficacy (3-month situation appropriate testing or vaccination) of a network diffusion motivational intervention versus an educational intervention among: 1) primary study participants (primary outcome); and 2) secondary study subjects connected to primary participants (secondary outcome) using a randomized controlled trial design.

Aim 1b. Examine differential intervention effects by individual and network-level characteristics that may increase situation appropriate testing and/or vaccination uptake, such as age, prior COVID-19 infection, mental health status, historical trauma, early adopter status, COVID-19 prevention behaviors, government mistrust, network testing/vaccination and prior infection, and network density. We will also explore hypothesized individual and network level mechanisms through which the intervention works (e.g., increased knowledge, self-efficacy, trust).

STUDY SITES

The sample ($n=800$ primary participants and $n \sim 3,200$ secondary subjects ($\sim 2-4$ network members per participant)) will be spread across four jurisdictions: Baton Rouge, LA; Little Rock, AR; Chicago, IL and Indianapolis, IN.

Table 1: Breakdown of study sites

| Study Sites | Site Lead | Stakeholders | IRB of Record | Sample Size(n) |
|---|---------------|---|---------------------------|----------------|
| Chicago, IL University of Chicago | Schneider | Chicago Dept. of Public Health | University of Chicago IRB | 150 |
| Pulaski Cnty., AR University of Arkansas for Medical Sciences | Zaller, | Arkansas Dept of Health and Central Arkansas Housing Corporation (CAHC) | University of Chicago IRB | 250 |
| Baton Rouge, LA Capitol Area Reentry Program (CARP) | Brewer | Aspire Health Care | University of Chicago IRB | 250 |
| Indianapolis, IN Indiana University | Aalsma, Knopf | Inner Beauty, New B.O.Y., VOICES | Indiana University IRB | 150 |
| Northwestern University Evanston, IL | Pyra | NA | University of Chicago IRB | NA |
| NORC | Leslie Watson | All study sites. NORC will assist with site management and training, as well as study design and data analysis. | University of Chicago IRB | NA |

This multi-site study will be completed at four sites as shown in Table 1. Upon IRB approval, these sites will participate in research activities as listed in Appendix A, including recruitment, participant engagement and interviews. Study activities will be conducted by IRB approved study staff and faculty at the study center shown in Table 1, or in a private room at a community based organization, public library or school. If the study interaction takes place at these locations, study activities will be conducted by IRB approved study staff who will ensure that subjects have complete privacy.

University of Chicago will provide pre-programmed laptops to all study sites. These laptops have been programmed by the Research Computing Group within the Department of Public Health Sciences (leadership Phil Schumm) at the University of Chicago to ensure data protection and enable data transfer. All data collection will be conducted electronically via laptops and data will be uploaded into databases hosted by University of Chicago. These are similar procedures as have been developed with Schumm for NIDA's Methodology and Advanced Analytics Research Center (PI Schneider).

The University of Chicago BSD IRB will act as IRB of Record for Chicago, Arkansas, and Baton Rouge. Indiana University will utilize their own IRB due to their enrollment of juvenile CJJ populations.

METHODS

Aim: Test the efficacy (3-month situation appropriate testing or vaccination) of the Motivation Intervention versus the Education intervention among: 1) primary study participants (primary

outcome); and 2) secondary study subjects connected to primary participants (secondary outcome) using a randomized controlled trial design.

We hypothesize that primary study participants randomized to receive the Motivational intervention condition (tailored motivational messaging plus network diffusion in a group setting with 1-month booster communication) will be more likely to get tested and/or vaccinated within 3 months of the intervention as compared to COVID-19 Education condition alone (attention control). We also hypothesize that Motivational intervention will result in more secondary study subjects (network members of primary participants) will receive testing and/or vaccination within 3 months. Finally, we anticipate that there may be differential intervention effects across participant characteristics across study sites, by mental health, exposure to law enforcement, prior COVID-19 infection, testing frequency, age and network composition, and will explore these sub-group differences in the context of any power limitations.

RECRUITMENT OF STUDY PARTICIPANTS

We will enroll 800 study participants ages ≥ 18 years of age across all four sites. Study participants will be recruited by local research assistants (RAs) embedded within community settings that provide a number of in-person and remote social and care services, including community COVID-19 testing and vaccination. We will utilize several strategies that we have utilized previously.^{22,54-58}

Recruitment activities may include:

- In-person recruitment may be conducted at the study center (Table 1), during regular drop-in and community-based services, and events occurring at the study center and its outreach programs. This may include providing a study flyer or contact card so that a client can contact the study team directly about participation. A sign-up sheet may also be provided, where interested clients can provide their contact information if they wish to be contacted by the study team about the study.
- Flyers posted at study centers
- Social media postings
- Contacting individuals from previous studies who have indicated interest in being contacted for future work or from existing community programs.

All participants will be asked to sign a release of information so that the study team receives COVID-19 testing/vaccination results as part of existing COVID-19 testing and vaccine registries in the four locations.

Inclusion and Exclusion Criteria.

Inclusion Criteria:

- (1) ≥ 18 years of age
- (2) spend majority of their time in the metropolitan area or county where recruited
- (3) primary communication in English
- (4) previous direct or indirect exposure to law enforcement
- (5) has covid vaccination and applicable boosters (self-report, not required to show proof)

Exclusion Criteria:

- (1) inability to provide informed consent; and
- (2) active COVID-19 symptoms per CDC.⁵⁶

(3) Parolees currently living in a court ordered treatment center as part of parole and/or individuals otherwise meeting the definition of a prisoner

We include participants with prior COVID-19 vaccination (completed series) or recent COVID-19 infection in past 3 months given that they may be important change agents. We will remove the estimated numbers (n=160) who are vaccinated/recent infection from our primary analysis if there are no future vaccine boosters or new vaccines required (i.e., new variant). Candidate participants with COVID-19 symptoms will be referred for free testing at existing partners for each of the study sites.

Sex as a Biologic Variable. Both sexes and all genders will be included in this study with exploratory analyses to determine any differences in intervention effects.

STUDY VISIT PROCEDURES

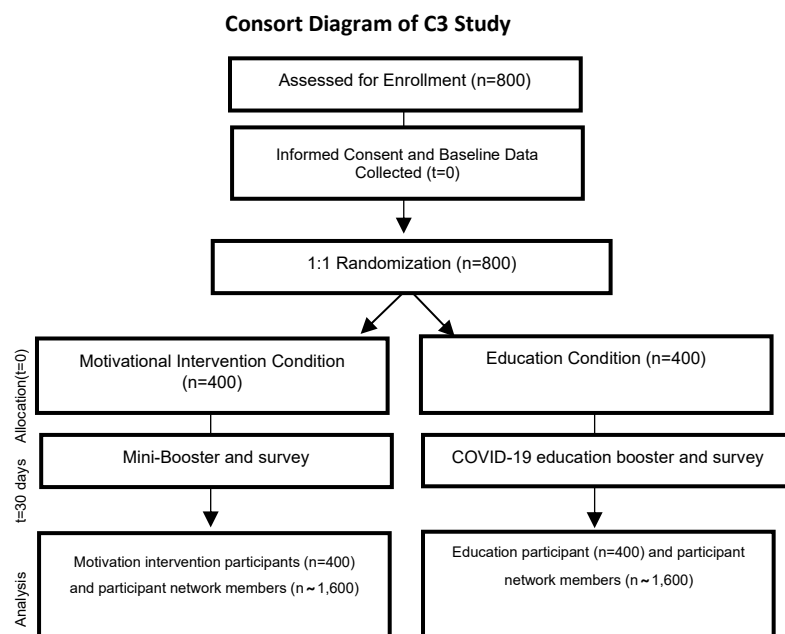
Study procedures include:

- 1) Informed consent, locator form
- 2) Baseline survey with network elicitation
- 3) Randomization
- 4) Motivational or Education intervention (approximately 3 hours)
- 5) Booster/Communication 30-day \pm 7 days phone follow-up
- 6) 3-month follow-up phone survey \pm 7 days to assess participant and network COVID-19 testing/vaccination history

Eligible candidate study participants will undergo written informed consent. Following consent, study participants will complete a survey (Baseline Assessment) includes variables of interest and the social network inventory. Randomization will occur following the survey, and participants will be assigned to one of two concurrent Motivational or Educational group-level sessions. Sessions will be held weekly, also with availability, in the evening or on weekends. Study staff will be notified of group allocation and bring study participants to the appropriate group session/intervention rooms.

Between 8-10 study participants will participate in each intervention room and the interventions (either Motivational or Educational) co-facilitated by both trained research staff and community members. Please note that community members will either be part of an IRB approved study site or will have an Individual Investigator Agreement with approved reliance on the University of Chicago IRB. All study sites have approved COVID-19 infection control plans for research participant studies and guidance updates will be continuously monitored by multi-PI Schneider. The entire study visit including group intervention will take 4-5 hours. All participants (irrespective of study arm) will receive referral information for COVID-19 testing/vaccination. The group sessions may be conducted in-person or virtually depending on changes in the COVID-19 response.

Informed Consent: Eligible participants will be asked to participate in written informed consent using either a paper consent or electronic consent. The following consent processes applies to both the study consent form and the release of information form.



In-person Consent Methods:

Paper Consent:

A study team will provide the subject with a copy of the study consent. The consent document will be reviewed and any questions regarding the study will be answered by the study team. If the subject agrees to participate in the study, they will be instructed to sign the consent form. Staff will also sign and the subject will be provided with a final signed copy. A signed copy will be stored by the study team.

Electronic Consent:

Consent may be obtained in-person electronically via RedCAP. Study staff can present the consent to the subject on the tablet or on paper depending upon subject preference. The consent document will be reviewed and any questions regarding the study will be answered by the study team. If the subject agrees to participate in the study, the subject will be instructed to sign the consent form via RedCAP e-consent signature. Staff will also sign the consent form and update the RedCAP link to provide the subject with a final, signed version of the consent form via email. The final signed consent document will be stored in RedCAP.

Remote Consent Methods:

Written consent signature using paper mail:

If the subject agrees to participate in the study, a paper consent will be mailed to the subject. The subject will be instructed to contact the study team once it is received. The consent will then be discussed in full over the phone and any questions will be answered. If the subject wishes to participate, he/she will sign the consent, then send back to the study team via direct mail. After the signed consent form is received, staff will also sign the consent form and send the subject a final, signed version via direct mail. A signed copy will be stored by the study team.

Electronic Consent Remote using RedCAP:

Remote consent would be conducted via telephone or video call (with preference being video call whenever possible) using a link through REDCap. A link to the consent in RedCAP will be sent to the subject via text and/or email. The study staff will discuss the consent form with the subject, and any questions regarding the study will be answered by the study team. The subject's identity will be verified as described below. If the subject agrees to participate in the study, he/she will be instructed to sign the consent form via RedCAP e-consent signature. Staff will also sign the consent form and update the RedCAP link in order to provide the subject with a final, signed version of the consent form. The final signed consent document will be stored in RedCAP.

The study team will do due diligence to verify the subject's identity before beginning the consent process. Traditional means of verifying subject identity may be challenging in this subject population. Most will not be patients with local medical records to reference, some will not have formal state IDs, some may not have permanent residence, etc. Strict enforcement of state ID could disenfranchise those who may well be the most important group to reach and the very population that needs to be studied. Subject identity will be verified using the following methods, in the following order of requirement:

- 1) Visually display a driver's license or state ID
- 2) Visually display an alternative photo ID (employee ID, school ID, etc) in combination with a piece of mail displaying the subject's name.
- 3) Visually display an alternative photo ID (employee ID, school ID, etc) alone

- 4) Visually display one of the following pieces of mail with subject's name and address: utility bill, cellphone bill, correspondence from the secretary of state or other government organization
- 5) Visually displaying any piece of mail listing the subject's name and address
- 6) Asking the subject to verbally state their name

Baseline Surveys:

The Locator Form and Baseline Assessment is completed at the time of enrollment. These are completed electronically and may be done in person using a study laptop or remotely via telephone or video call.

Randomization. Study participants will be randomized to receive the Education or Motivational intervention at a 1:1 ratio. Randomization will be performed at the participant level, meaning that in general, participants within a site will be assigned to different groups. Randomization will be stratified by site as well as by key participant characteristics such as prior infection/vaccination, to ensure balance. Random assignments will be provided via a web-based API, with the touchpads programmed to retrieve an assignment at the appropriate time and deliver message to staff so they can direct the participant to the appropriate room.

C3 Intervention: COVID-19 Testing and Vaccination Network Intervention Condition. Study participants randomized to the Motivational Intervention will receive the intervention using a social network diffusion approach. The Motivational intervention will be based upon a previous workshop divided into four learning and practice modules (Table 2 below).

Table 2. Motivation Intervention

C3 Intervention Components adapted from RADx-UP Phase I and PrEPChicago.

| Strategy | Content | Duration | Intervention Strategy Source(s) |
|--|---|-----------------|--|
| Fact or Myth session with sub-group role-play | COVID-19 prevention Fact or Myth session 1) different types of tests and vaccines; 2) technology, clinical development and effectiveness; 3) vaccine dosing administration and relationship to prior COVID-19 infection; 4) potential side-effects; and 5) how to access it. | 45 minutes | PrEPChicago/RADx-UP Phase I |
| Situation Appropriate COVID-19 Prevention | Knowing the network member's COVID-19 history (ie. prior infection, recent exposure). Discussion of indications for testing (ie. COVID-19 symptoms, known exposure) and vaccination post-infection. Testimonials around misinformation, correction and discussion. | 45 minutes | RADx-UP Phase I |
| Empowering Appropriate COVID-19 Prevention | Reasons for vaccination and group-selected topics of discussion (1) prompting individuals to generate and verbalize their own reasons for testing and vaccination and (2) allowing individuals to choose testing and vaccination topics most relevant | 30 minutes | Project Voice/RADx-UP Phase I |
| Network engagement and Motivational Interviewing | Effective Delivery of Information and MI strategy discussion (1) how the conversation will be raised, (2) how potential barriers to testing and vaccination will be addressed, (3) how network members can be assisted to make a visit to a COVID-19 services site, and (4) what sort of follow-up is required to motivate network members who have yet to be tested/vaccinated after earlier conversations. | 60 minutes | PrEPChicago/RADx-UP Phase I |

The first module introduces COVID-19 prevention (testing and vaccination) in an interactive *Fact or Myth* activity that will provide an overview for understanding the implications of COVID-19 tailored to the specific audience.

The second module builds upon RADx-UP Phase I to provide situation-appropriate recommendations given the diversity of COVID-19 spaces network members find themselves in (previously infected, congregate setting, recently exposed etc.). This module also utilizes video testimonials developed in RADx-UP Phase I that feature community members with lived testing and vaccination experiences. The videos will be viewed in a group setting using a large computer or TV monitor. A list of videos will be provided with descriptive information about the factual content they present. Content will be updated in real time as testing/vaccination recommendations change, and these changes will also be matched to outcome assessment.

The third module will ensure participants actively engage with COVID-19 prevention information and content. We will facilitate an empowerment process that will direct participants to choose testing and/or vaccination topics that they would like to consider (e.g., prevent health risks, protect others from infection, vaccine safety, future regret) and then prompt them to generate and verbalize their own reasons for testing/vaccination based on those topics.

The fourth module aims to develop the social network motivation strategy which will be reinforced by interventionists who have completed motivational interviewing training. Through role-playing scenarios, participants will rehearse conversational strategies for addressing some of these personal barriers and develop their ability to deliver information in effective and productive ways. Walkthrough and scenario play will be strategies to assist with planning regarding: 1) how the conversation will be raised; 2) how potential barriers to testing/vaccination will be addressed; 3) how network members can be assisted to make a testing/vaccine site visit; and 4) what sort of follow-up is required to motivate network members who have yet to engage in COVID-19 prevention after earlier conversations. This strategy develops participants' communication skills in order to increase their effectiveness as COVID-19 testing/vaccine change agents.⁶²

COVID-19 Prevention Education Intervention.

The Education condition will include COVID-19 prevention messaging and an interactive activity reinforcing the messages. RADx-UP Phase I testimonial video messages were developed based on previous focus group data, featuring community advocates recruited from those focus groups and have undergone adaptation and have been vetted by the COVID-19 CAB. Testimonial videos will be played including those that describe the testing experience and their motivations for testing. This approach combines self-affirmation with misinformation correction to take advantage of the ability to promote adaptive COVID-19 prevention behaviors. The self-affirmation activity will always precede the presentation of the testimonial videos as leading with misinformation correction can be construed by some as a threat to one's self-adequacy. An active control group, as opposed to clinic standard of care (i.e., provision of limited COVID-19 information and/or materials) was selected for C3 for several reasons. First, provision of standard of care would not control for the attention that study participants will receive from study staff as well as the time to deliver the intervention (both Motivational and Education conditions will take 4 hours). In addition, there is an ethical mandate to provide the best tailored control available in the context of ongoing COVID-19 morbidity and mortality. Finally, community feedback and CAB input clearly delineates the requirement that community members are receiving meaningful education and COVID-19 prevention engagement activities as part of this research and not "substandard care".

Mini-Booster Communication Session at 30-day follow-up

Additional contact with project staff following initial interventions is an important component of sustained behavior change and study engagement. For this reason, staff trainers will maintain contact with participants after the initial training through a telephone check-in referred to as a "mini-booster", which

the C3 team has utilized successfully in previous work.¹⁻³ A staff member will conduct the mini-booster with each participant, lasting 10-20 minutes.

Each mini-booster consists of four components: 1) collecting information about specific network members that the participant has engaged with about testing/vaccination (both Education/Motivational arm); 2) devising personalized conversational strategies for approaching these network members (C3); 3) troubleshooting communication barriers (C3); and 4) setting personal outreach goals (C3). The Education condition will also have a 30-day follow-up conversation and review of any questions that may come up. Measurement of testing/vaccine barriers for participants and participants' report on network members will be collected during the booster session for both Motivational and Education conditions. The same staff member who provided the initial intervention will conduct the booster with a given participant in order to continue rapport building.

Subject Compensation. Compensation will be provided for study participation- up to \$200 will be provided for study participation and all participants will receive snacks/refreshments during the Education and Motivational arm sessions. Compensation will be provided as follows:

- 1) \$150 will be provided for completing the first study interaction (i.e., consent, ROI, Education or Motivation group session, baseline survey and short locator form);
- 2) \$25 for completing the second study interaction (i.e., short phone booster session and second survey 30 days later); and
- 3) \$25 for completing the third study interaction (i.e., final survey 90 days post enrollment).

Payments will be in cash, gift cards or e-payments such as CashApp, PayPal or Venmo.

Staff Training and Fidelity. Site teams consisting of existing research staff and community facilitators will deliver the study conditions. Separate staff will deliver the Educational and Motivational intervention group sessions (described below). Site teams will undergo two full day training sessions that include study procedures and group session activities. All research and community facilitators will undergo initial motivational interviewer training with a certified MINT trainer on core motivational interviewing (MI) principals and then monthly follow-up sessions providing clear and objective feedback. In addition, research staff will be trained to have capacity to support multiple participants simultaneously in the self-administered portion of the study visit: clarifying any survey items, troubleshooting any technology/data collection issues, and transitioning to interviewer administered for people with limited literacy. Fidelity to Educational and Motivational intervention conditions will be evaluated using a self-monitoring fidelity check-list for interventionists. A sample of 10% of the sessions will be recorded (video and/or audio) for quality improvement purposes and reviewed by project managers/PIs. These recordings may be shared amongst the respective site-specific study team, but will not be shared outside of the subject's study site). Subjects will be asked whether they are willing to have the session recorded and can indicate yes or no on the study consent form.

Primary Outcomes. Two primary outcomes will be assessed at the level of the participant: the probability of receiving at least one 1) test and 2) vaccination dose within 3 months of baseline. Outcomes will be ascertained specifically by testing/vaccine registry data held by city and state held vaccine registries (Letters, Huang, Arwady, Zohoori). Study participants will sign release of information forms, as in RADx-UP Phase I, in order for study staff to obtain 3-month testing/vaccination disposition statuses. Covid testing/vaccination status may also be provided by subject showing a copy of their covid testing result and/or vaccination information. This may be provided in person, shown during a video call, emailed or texted as a picture. Finally, study staff will reach out to all study participants (N=800) at 3 months following baseline to collect information on testing and vaccination uptake among study participants and barriers and facilitators for both network members and study participants. During

this assessment, information on situation appropriate testing will be collected to better understand the circumstances and context of testing. At the time of this writing, situation appropriate testing includes testing if symptomatic, if exposed to someone with COVID-19 infection and if entering a congregate living setting. Only participants reporting symptoms, exposure, and/or congregate housing will be included in the primary testing outcome analysis; post-hoc analysis will include all participants tested irrespective of the situation/context.

Secondary Outcome. Two secondary outcomes will be assessed at the level of the secondary subjects (network member connected to primary participant): the probability of receiving at least one 1) test and 2) vaccination dose within 3 months of baseline. Network member information, including identifying information will be collected during the baseline assessment through specialized network canvas software (described above). The secondary outcome will be determined based upon self-report from participants during the 30 and 90-day follow-up surveys. Note that this information is collected based asking the study subject whether the social network contact underwent these activities and not from contact with or medical record data collection of the social network member. Analyses for our secondary outcome will account for variability in network size across individuals.

Other Variables for Analysis. Additional variables for analysis will be obtained from the JCOIN Community Measures database that is stored in the JCOIN Data Core and which the PIs have access.^{69,70} These measures have been collected from other validated scales and items and include items from the Phenx toolkit⁶⁴ including vaccine hesitancy. Measures to be included in analyses include the following: age, race, ethnicity, gender, sex at birth, mental health (e.g., PHQ-9), symptoms of anxiety/depression, and CLI history; as well as COVID-19 knowledge, testing history, infection/treatment history, access to medical care, substance use history, prevention behaviors, attitudes/beliefs about prevention efficacy, vaccine knowledge/attitudes and vaccination practices (e.g., flu vaccination), medical mistrust, perceptions about COVID-19 risk and severity, prior contact by contact tracer, experiences of racism, fears about immigration status, housing status and household composition, food insecurity, employment/occupation, mobility, experience of violence, workplace resources, PPE availability, and known COVID-19 contact. Social network size, density, social control, influence and trust will be from the Community Measures database and collection will be facilitated by NC.⁶³

Primary and Secondary Outcome Analysis. Two sets of analyses will be performed. The first will focus on testing and vaccination among participants and the second will focus on testing and vaccination among the networks of participants. Testing and vaccination will be analyzed as separate outcomes throughout. The primary outcome analysis will compare the probability of testing and the probability of vaccination among participants assigned to Educational vs. Motivational intervention. Secondary analyses will compare the total number of network members tested and vaccinated and the probability of testing/ vaccination among network members of participants assigned to Educational vs. Motivational intervention (Aim 1). All analyses will use generalized linear models with link functions based on the distribution of the outcome (logistic or log binomial for binary outcomes; negative binomial regression for count outcomes) and random effects as appropriate to account for clustering of network members within participants. The initial analysis will include an indicator for intervention assignment as the only independent variable and will not adjust for covariates since the randomization should ensure comparability between the groups on measured and unmeasured confounders, though group characteristics at baseline will be inspected visually for imbalances (Aim 1a). We will then incorporate participant (e.g., mental health, early adopter status) and network level (e.g., network thresholds, density) covariates to improve the precision of the estimates and to identify sociodemographic and network characteristics associated with differences in testing and vaccination yield. In addition, we will explore interactions between intervention group (Education vs. Motivational intervention) and participant characteristics to determine whether the intervention is more effective in certain groups than

others (Aim 1b). Because we will likely have limited power to detect small to medium sized interaction effects in subgroup analyses, we will consider these analyses exploratory, with the goal of generating insights to guide future work. Partial pooling within a Bayesian estimation framework⁷¹ will be used to avoid bias and address the issue of multiple comparisons when testing interactions. We will also include an indicator for time trends to control for potential changes in testing recommendations, vaccine availability, infection rates, or other factors that could impact testing and vaccination outcomes over the study. The small number of sites precludes inclusion of a site-level random effect so site will be included as a fixed effect to account for between site differences in participant characteristics and local epidemic trends. The clustered version of the robust (i.e., sandwich) variance estimator will be used in all analyses to ensure correct inference even in the presence of other sources of within-cluster correlation in the data not captured in the model.⁷² For the participant outcomes, the probability of testing and vaccination (binary outcomes) will be modeled using logistic or log binomial regression based on model fit and consistency with model assumptions. The total number of tested/vaccinated network members will be modeled using negative binomial regression with total network size as an offset to account for differences among participants in the number of named network members.⁷³ A second analysis will treat each network member as an observation (tested/vaccinated or not) and will model the likelihood that network members are tested/vaccinated using logistic regression with random effects at the level of the study participant. We will also include a fixed effect for site. This approach will also allow us to examine whether characteristics of the network members (e.g., trust, social influence and social control within a dyad) are associated with probability of testing/vaccination.

Power Calculations. Statistical power for Aim 1 was computed across a range of plausible effect sizes and outcome prevalence estimates. Power was estimated conservatively, assuming that of the 800 total participants and their network members, 10% would meet the current CDC recommended criteria for testing (recent exposure, symptoms, or congregate housing) and thus the sample size for the primary testing outcome was estimated at N=80 eligible participants. We assumed that 30% would previously have been fully vaccinated or infected with COVID-19 in the past 6 months, resulting in an analytic sample size for vaccination outcomes of N=560 participants and their network members. Power may change depending on the evolution of the pandemic (e.g., changes in infection rates, prevalence of variants, and/or local public health guidance regarding testing and booster vaccine recommendations), and will be higher with broader testing eligibility, higher outcome prevalence, and for analyses treating each network member as a separate observation. For each outcome, we computed minimum detectable effect sizes given estimated rates of testing and vaccination in the control group. We estimated 3-month testing rates among those eligible for testing of 10% in the control group. Based on our ongoing influenza vaccination work, as a starting point for calculations we estimated 3-month vaccination rates among study participants and their network members of approximately 30%. All calculations were conducted in Stata/SE version 15.1 with alpha=0.05, two-sided tests, and a 2:1 ratio of randomization to the intervention vs. control group. For participant testing (primary outcome 1), with a sample size of 80 eligible participants and control group testing prevalence of 10%, we would have 80% power to detect differences of 28 percentage points or more (proportion tested in the intervention group $\geq 38\%$). For participant vaccination (primary outcome 2), with a sample size of 560 and vaccination prevalence of 30% in the control group, we would have 80% power to detect differences of ≥ 12 percentage points (proportion vaccinated in the intervention group $\geq 42\%$). For evaluating interaction effects (Aim 1b), with a sample size of 560 we would have $>80\%$ power to detect an interaction between intervention assignment and an evenly distributed binary covariate (50% in group A and 50% in group B) when vaccination prevalence in the control group is 30% and the intervention increases vaccination to 40% in group A and 69% in group B (e.g., the intervention is more effective in group B). For the participant testing outcome, we will have limited power to detect interaction effects except those of very large magnitude, but will explore differences in testing across

subgroups to guide future work. For the network outcomes (secondary outcome 1&2), we assume that the number of network members tested/vaccinated follows a negative binomial distribution with an over dispersion parameter equal to 2 to reflect variability among participants in terms of testing and vaccination referrals. For network testing, with a sample size of 800 participants (with an average of 2-3 named network members per participant), we would have $\geq 80\%$ power to test the null hypothesis of no difference between groups if the mean number of tested network members per participant is 0.12 in the control group and 0.25 in the intervention group (i.e., the intervention increases the proportion of participants with any network members tested from 10% to 18% and the proportion with >2 network members tested from 0.2% to 1.3%). For network vaccination, with a sample size of 560, we would have $>80\%$ power to test the null hypothesis of no difference between groups if the mean number of vaccinated network members per participant is 0.51 in the control and 0.92 in the intervention group, which reflects a scenario where the intervention increases the proportion of participants with any network members vaccinated from 30% to 41% and the proportion with more than 2 network members vaccinated from 5.1% to 12.1%. Thus, we will have sufficient power to detect effect sizes consistent with our previous work.

Attrition and missing data. All participants enrolled in the study will be included in our analyses; since the primary outcome will be measured based on testing/vaccine registry data we are confident that there will be limited missing data given that this type of registry has considerable resources to support it and is required for the EUA status. As an additional precaution, all participants will be interviewed to assess for testing/vaccination status among themselves and network members at 3 months. Thus, we anticipate very little missing outcome data. Any missing data will be addressed using multiple imputation⁷⁴ or by using a fully Bayesian approach to estimate the model⁷⁵ (in which missing data are essentially treated as additional unknown parameters).

POTENTIAL RISKS AND BENEFITS TO SUBJECTS

In general, protection against risk to participants will be accomplished through thorough training of research staff; careful orientation of potential participants as to the nature, risk, and benefits of the research; strict adherence to study protocols; and regular surveillance for adverse events. Additionally, this study will receive an NIH Certificate of Confidentiality to further protect information shared.

- The following steps will be taken to protect the confidentiality of all data generated and collected throughout the course of the study:
- Data access will be limited to a specified group of programmers and researchers identified as study personnel. An audit trail will be maintained to track all user-access to the data.
- All study investigators and research team personnel will be trained in the importance of confidentiality and trained to follow all rules related to handling confidential data.
- All data sets resulting from this study will be kept exclusively in the BSD CRI system at the University of Chicago, access to which requires administrative approval and password. The internal server is encrypted at the storage, backup, and sharing levels, thereby maximizing protections against breaches of confidentiality.
- The research team will not be permitted to copy the raw data or to transmit the raw data other than through a secure server connection.
- Results of the study will be reported only in the aggregate and without other identifiable data, with attention to issues of statistical disclosure.

Protection of privacy. All study procedures will be performed in quiet, private spaces to ensure confidentiality. If covid test results and/or vaccine status is communicated via email or text picture using a cell phone, this communication would occur with the subject's site study personnel only. The testing/vaccination data would be recorded and the email/text picture would be deleted. The images

are not retained or shared.

Protection against psychological discomfort. Survey questions may touch on potentially sensitive topics. Participants will be informed of this possibility through assent/consent procedures and they will be reminded that they may skip questions or discontinue participation altogether. If a participant expresses distress directly to the research team, they will be provided the name and contact information of several licensed behavioral health providers on our research team and other local resources as needed.

Protection against testing risks. Testing Procedures and Infection Control Measures. All COVID-19 testing procedures will take place according to SOPs at each of the participating partnering health departments and clinics. These procedures ensure that appropriate infection control measures, a COVID-19 screener (Appendix C), counseling, including quarantine and isolation procedures, masking and results disclosures are provided in accordance to the current standard of care and CDC guidelines. Monetary, food, other tangible supports, and/or linkage to further medical evaluation and will be provided for individuals who test positive and require resources to adhere to quarantine and social distancing requirements. Performance of surveys and interviews will abide by social distancing guidelines.

Benefits: The potential benefits of this research far outweighs the risks. For individual participants, benefits include COVID-19 testing/vaccination information and reduced likelihood of COVID-19 severe complications and hospitalizations, with provision of financial and other tangible resources for quarantine and isolation as well as linkage to medical care if necessary. Possible risks (i.e. discomfort answering questions, potential confidentiality breaches, stigma) are outweighed by the new knowledge gained as described above and the direct clinical benefits and supportive services to participants.

DATA STORAGE AND SHARING

We will take several steps to ensure the security of the identifiers and data collected for this study. All data will be collected using dedicated laptops purchased by the project and configured and certified by BSDIS to meet their requirements for portable computers (e.g., timed log-out, whole-disk encryption, use of BigFix and antivirus software, etc.). Data will be entered into REDCap (web-based application hosted by the CRI at the University of Chicago). This data will be maintained on a HIPAA compliant, secure server hosted at the University of Chicago.

The identifiers of social network members (first name and last initial only) will be uploaded and stored in a separate, dedicated file share held on a secure, HIPAA compliant server at the University of Chicago, accessible only by the data analyst team who will be located at the University of Chicago and NORC. Social network identifiers will not be shared outside of the data analyst team and will not be accessible to the wider study team. The data analyst team will monitor the incoming files to ensure confidentiality. Social network identifiers are used to analyze whether the study interventions affect the study subject and their social network members' likelihood of becoming vaccinated and/or testing for COVID (based on the study subject's survey response). Once this analysis has been completed, all files containing network member identifiers will be destroyed.

Upon study termination, participant identifiers will be removed from the study dataset. All recordings of study trainings will be destroyed upon study termination. The de-identified study data may be maintained indefinitely at the University of Chicago.

UAMS will destroy any raw data received from Arkansas Department of Health upon study completion.

Data Transfer:

Before any data transfer, the University of Chicago will encrypt the data both at rest and in transit to provide a high level of security of sending and receiving file transfers. The encrypted data products will be securely uploaded to a server using a cyberinfrastructure service such as Globus (<https://www.globus.org/>) via the Biological Science Division Information Services (BSDIS). This will ensure high security features that meet authentication and authorization standards for sensitive data containing protected health information. Additionally, data management and transferring services for personally identifiable data will be with a High Assurance or HIPAA BAA subscription. If an institution is responsible to provide data (incoming), they will be responsible for encryption.

Northwestern University

Northwestern (NWU) will assist with data analysis for the planned qualitative interviews and survey data. NWU will receive text transcripts from interviews as well as survey data for analysis. These data may contain dates and zip codes but will not contain any other identifying information (such as names). Shared data will be linked to the subject's unique ID number, but the key will be kept by the University of Chicago team and not shared.

NIH and DCRI

The Duke Clinical Research Institute (DCRI) has been chosen by the National Institute of Health (NIH) to serve as the data coordinating center for all of the RADx-UP study centers (note, outside of our multi-center studies, there are other institutions who have received funding from the NIH to conduct related research under the RADx funding initiative). A limited study data set (includes zip codes and dates) will be shared with DCRI to link area level data sets and to add context to the socioeconomic, environmental, and public health outcomes in larger data sets. DCRI will maintain a database that can be shared with RADx-UP consortium members (those who are conducting the RADx-UP studies) for future research. The consortium database will include zip codes and dates and will be maintained by DCRI indefinitely. RADx-UP consortium members will be required to apply to use this dataset. All data shared for future research in this manner would be de-identified and could be used indefinitely.

DCRI will also transfer a de-identified study data set to the NIH for purposes for future research in keeping with the NIH's policy. All data shared for future research in this manner would be de-identified and could be used indefinitely.

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