COMMUNITY NETWORK DRIVEN COVID-19 TESTING AND VACCINATION AMONG MOST VULNERABLE POPULATIONS IN THE CENTRAL UNITED STATES (C3)

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BACKGROUND

Existing COVID-19 testing and prevention strategies are failing many communities in the United States.[1] COVID-19 testing uptake, social distancing, contact tracing, all face significant acceptability and implementation challenges among those most impacted in the US.[2] COVID-19 testing has had technical and diagnostic challenges since its inception; however, these challenges are overshadowed by significant implementation challenges. First, messaging of testing importance is complicated because of stigma related to subsequent social isolation, employment loss and potential illness and death.[3,4] Second, testing has been perceived by many community members to be futile. In C3 focus groups, participants have described that it is not safe to go out and seek testing without private transportation and further there is no reason to test as there is nothing that can be done (July 2020 C3 FGD, Chicago). Third, messages about the importance of testing are most often delivered by public health authorities. These messages (and the messenger) do not resonate with community who often are facing significant racism/stigma, lack resources to meet basic needs, and structural violence in the form of law and immigration enforcement.[5] Finally, community members who are disenfranchised from health insurance are concerned about costs of testing or that their data will be used by government. Because of these factors, community faces significant real and perceived barriers to testing.[2,5]

The distribution of COVID-19 vaccines faces similar challenges. Although COVID- 19 vaccine acceptance is slowly increasing across all demographic groups, vaccine confidence still lags behind in Black and Hispanic communities[50] First, structural violence, historical trauma, and sustained inequality largely shape medical mistrust in those who are experiencing health disparities[10]. Within the United States' context, the medical establishment has a long history of exploiting people of color - specifically black, Latinx, and Indigenous individuals - for the sake of purported medical advancement[51] . The case of Henrietta Lacks, the Tuskegee Studies, and the experiments of James Marion Sims upon Lucy, Betsy, and Anracha are just a few examples of the historical medical trauma exerted upon Black and African American individuals living within the United States[51]A strong predictor of intention to get vaccinated is confidence in vaccine safety and effectiveness[49] Second, there are concerns around vaccine side effects and concerns about getting COVID-19 from the vaccine [50] Finally, vaccine misinformation ranging from rumors to conspiracy theories is contributing to the mistrust around eth COVID-19 vaccines, making it challenging to build confidence around vaccines [52]

COVID-19 has disproportionately impacted disenfranchised communities.[6] Disenfranchisement is a status that results in distrust of public institutions and therefore individuals do not participate in services, resources, and benefits.[7,8] Disenfranchisement generates, maintains, and propagates vulnerability both directly and indirectly.[7,9]Poverty, limited opportunity for prevention or other health services and racism all contribute to the COVID-19 inequities that are similar in magnitude to other socially determined outcomes, such as kidney disease, violence and death due to AIDS.[10,11]Two key disenfranchised populations where significant COVID-19 transmission occurs is among criminal justice involved (ie. arrest, history of jail/prison, probation/parole) and low-income Latinx community members.6,[11,12,13,14] Both of these populations, and the overlap between them, have some of the highest rates of COVID-19 infection and death in the US.[13,15] These stark COVID-19 inequities are driven by several factors that the communities share.[15] First, both are often disenfranchised from employment, social services and health-care, all critical to supporting those impacted most by COVID-19. In addition, if employed, most are part of the essential low-wage workforce where transmission is high, and frequent outbreaks occur within multi-generational working households.[12,16,17] There often can be limited agency and self-determination in such contexts (ie. inability to self-isolate) which can be disempowering and thus requires interventions that are self-affirming. Finally both CJI and Latinx communities often have considerable distrust in institutions including public health[18] and lack access to accurate and contextually/linguistically appropriate COVID-19 information.[19,] Misinformation around testing and vaccination impedes efforts to effectively engage these communities.[10,20,50]Therefore, we utilize theory-driven self-affirming message framing

as well as misinformation correction in order to fully engage communities around COVID-19 testing and vaccination.[11,21-23]

Criminal justice involved populations include diverse non-incarcerated people with history of arrest/jail/ prison, community supervision (probation/ parole), mandated drug court attendance and are susceptible to distrust in public health institutions. One in five American adults has had justice exposure including arrest, incarceration, being on supervision, and/or being subjected to a number of liberty restrictions including the right to vote, right to live with family members, and employment limitations.[24] CJI populations' differential experiences with justice systems, and other social institutions like child welfare and Medicaid, impact willingness to engage in testing. In NIDA's first JCOIN data product developed by the C3 team we used NORC's AmeriSpeak Panel,[25] a probability-based panel of about 35K households designed to be representative of the US to examine COVID-19 among CJI people. We found that respondents with a history of CJI are 18x more likely to have a household member pass away from COVID (9% to 0.5%) than those without such history. Those respondents with a history of CJI are also less likely to be able to follow important preventative health measures recommended for COVID-19 (e.g., wearing a mask, social distancing). Complicating these relationships are that CJI individuals are more likely to have higher rates of legal cynicism and perception of procedural misjustice which affect trust in social institutions. Legal cynicism often translates into anti-authority attitudes that affect willingness to engage in health or self-care activities, and given the higher rates of substance use, mental health, and infectious diseases among CJI populations, [26,27] COVID-19 testing and vaccination promotion messaging must be tailored to address the justice experience, distrust of justice agencies, and self-efficacy.

Low-income Latinx people (250% at or below FPL) have some of the highest rates of COVID-19 in the US and require testing interventions that address unique cultural factors and engage familial support systems. Latinx and Hispanic people (hereafter Latinx) include a diverse set of communities and several intersectional factors: country of origin, duration of time in US, and documented status. Nearly 25% of Latinx people are employed in essential service industries [28] (e.g., food service, factory processing) and are exposed to a greater likelihood of contracting COVID while working.[29] Additional barriers to consider for non-citizens are that they are more likely to experience barriers to social distancing due to household size,[30] and few roles in the low-wage, essential workforce have the option to work fully or even partially remotely. Latinx are also more likely to have three generations reside in a household,[31] which requires different approaches to promote public health messages for testing and preventing the spread of COVID-19 within a household. Latinx who are undocumented or who are in mixed-status households are more likely to be uninsured and less likely to access and utilize healthcare services[32] including COVID-19 testing. The existence of multi-generational and other mixed-status households are examples of the collectivistic culture that places a prominent role on familismo, which is an important protective factor for an individual's well-being. [33,34] Family network based approaches that integrate household members play a critical role in promoting well-being for oneself as well as others.[35] The social network strategy is an example of a testing approach that can leverage existing family network structures to promote and engage even the most marginalized communities in testing and vaccination.

The Social Network Strategy (SNS) was developed for HIV and is adapted to accelerate COVID-19 testing to identify networks most at risk. Social network interventions are recognized as highly potent testing interventions that move beyond individual-level "risk"[36] which are key to COVID-19 elimination efforts. Network mobilization/induction is a Type III intervention strategy that stimulates peer-to-peer interaction to create behavioral diffusion through existing social pathways among network members.[37] This Type III intervention [37] represents a class of network interventions that have been found to be effective in HIV prevention (i.e., CDC's EBI—Social Network Strategy). [38] Past research has shown that individuals who are members of the same social network are more likely to have similar HIV risk potential.[39] SNS identifies HIV positive individuals and/or individuals at risk for acquiring HIV and motivates them to recruit persons from their social network for testing and provides modest compensation for referrals. In so doing, the reach of the testing program increases as does the volume of people tested. In a recent study conducted by members of C3,[40] the social network strategy (SNS)

was superior in HIV case identification when compared to standard testing approaches, such as those in health care settings (i.e. emergency department) or contact tracing. These findings are not surprising given that social network theory, such as homophily (i.e. birds of a feather) [41] suggest that subsequent waves of referred network members will resemble an index client's attributes.

STUDY DESIGN

The scientific premise of C3 is to engage disenfranchised people in COVID-19 testing and vaccination referral through social network referral combined with theory-driven COVID-19 prevention messaging. Eligible CJI and Latinx clients (and the overlap between the two) will be enrolled into C3.

Using a two-arm randomized controlled trial design, participants will be enrolled into the SNS arm (involves social networking referrals only) or the SNS+messaging arm. The latter includes affirmation/misinformation correction messaging (discussion tools and coaching). SNS and SNS+messaging arms will both include an initial group of index study participants who will refer their network members into the study and the process will repeat itself one more time for a total of 3 waves.

A total of 2400 participants will be enrolled (estimated n=300 index seeds and n=2100 1st and 2nd degree network referrals) across sites in the Central US: Dallas County, TX (n=600); East Baton Rouge, LA (n=200); Pulaski County, AR. (n=200); Marion County, IN (n=200); Porter County, IN (n=200); and Cook County, IL (n=800).

AIMS

This study aims to evaluate the implementation of a combination Social Network testing Strategy (SNS) with COVID-19 prevention messages (SNS+) to engage disenfranchised populations such as criminal justice involved (CJI) and low-income Hispanic/Latinx (hereafter Hispanic) community members in COVID-19 testing, prevention strategies and vaccination across eight sites in the Central United States. Accordingly, the SNS+ team aims to:

Table 1: Breakdown of study sites

Study Sites	Site PI	IRB of Record	Stakeholders	Key Community Populations	Sample Size(n)	Scholarly Contribution
University of Chicago South Cook Cnty., IL	John Schneider	University of Chicago IRB	Illinois Dept. of Public Health Cook County Jail	Black CJI	350	Network science, COVID-19 testing
Howard Brown Health West Cook Cnty., IL	Aniruddha Hazra	University of Chicago IRB	Chicago Dept. of Public Health	Latinx	500	LGBTQ, COVID-19 testing implementation
Project Vida West Cook Cnty., IL	Aniruddha Hazra	NA - HBH study location only	Chicago Dept of Public Health	Latinx	Shared sample size with HBH	LGBTQ, COVID-19 testing implementation, harm reduction services
TCAP, Inc. Jackson Cnty., IL	Mai Pho	University of Chicago IRB	Jackson County. Health Dept. Jackson County. Jail	Rural, CJI, substance users	200	Rural Health
Indiana University Marion Cnty., IN	Matthew Aalsma,	Indiana University IRB	Indianapolis Juvenile Correction Facility Marion Superior Court	Juvenile CJI	200	Law, ethics
Indiana University Porter Cnty., IN	Matthew Aalsma	Indiana University IRB	Indiana Dept. of Public Health	Juvenile CJI	100	Adolescent health

University of Arkansas for Medical Sciences Pulaski Cnty., AR	Nickolas Zaller	University of Chicago IRB	Arkansas Dept of Health and Central AR Community Correction Center	CJI	200	Criminology, faith-based engagement
Better Community Development (BCD) Little Rock, AR	Nickolas Zaller	University of Chicago IRB	Pulaski County Health Unit Central AR community Correction Center	CJI	Shared sample size with UAMS	CJI, substance use recovery program, faith-based engagement
Capitol Area Reentry Program (CARP) Baton Rouge, LA	Russell Brewer	University of Chicago IRB	Orleans Health Dept.	CJI, substance users	250	Implementation science
University of Texas SW Dallas Cnty., TX	Kavita Bhavan	University of Chicago IRB	Parkland Hospital	Latinx	600	Predictive analytics, vulnerability index, COVID-19 testing
San Jose State University Santa Clara Cnty, CA	Moctezuma Garcia	University of Chicago IRB	NA	Latinx	NA	Health Inequities, Intersectionality, and Infectious Diseases
GMU Fairfax, VA	Faye Taxman	University of Chicago IRB	NA	NA	NA	Health Inequities, Intersectionality, and Infectious Diseases
NORC	Leslie Watson	University of Chicago IRB	NA	All	NA	Study design and planning, Site management and training, Data analysis

Test intervention efficacy (numbers tested - COVID-19 test results will be collected as part of study data; numbers vaccinated – COVID-19 vaccine records will be collected as part of the study) and community factors that may moderate efficacy. Secondary analysis to compare numbers tested in SNS strategies and COVID-19 contact and determine whether COVID-19 status within social networks impacts the referral process.

STUDY SITES

This multi-site study will be completed at eight 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. In-person 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 public library or school. If the study interaction takes place in a public library or school, study activities will be conducted by IRB approved study staff who will ensure that subjects have complete privacy including that the room has a door and there are no other people present except for the subject and the study staff member, unless the Messaging Intervention (described below, number 4 under Study Visit Procedures) is being delivered, which can occur as a small group of consented subjects.

University of Chicago will provide pre-programmed tablets to all study sites. These tablets 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 tablets 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 all sites, except Indiana University (due to their enrollment of juvenile CJI populations) who will use their own institutional IRB.

METHODS

AIM: Test intervention efficacy (numbers tested – COVID-19 test results will be collected as study data; numbers vaccinated – COVID-19 vaccine records will be collected as part of the study) and community factors that may moderate efficacy. Secondary analysis to compare numbers tested in SNS strategies and COVID-19 contact and determine whether COVID-19 status within social networks impacts the referral process.

We hypothesize that participants randomized to receive SNS+ (SNS+COVID-19 messaging) will be more likely to have their network members successfully tested and vaccinated (study participants will be given COVID-19 vaccine information and contact information to vaccination sites in their community. Vaccination will depend on the network members' tier/health department eligibility for vaccination). We also hypothesize that both SNS and SNS+ will generate more people tested per index as compared to COVID-19 contact tracing. Finally, we anticipate that there may be differential intervention effects across sites, by CJI status, prior COVID-19 testing history, race/ethnicity, and network composition, and will formally evaluate these differences as part of analyses.

Recruitment of Index and Network Member study participants.

We will enroll index seeds (12% of sample) ages 18 and over who are CJI or low-income Latinx across eight collaborative sites. Index clients and their social network referrals will be recruited by local Research Assistants (RAs) embedded within community-based agencies and community health care settings that provide a number of in person and remote social and care services, including community COVID-19 testing.

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.

Subjects will also be recruited through other study participants through compensated referral. Each study participant will be given a referral code that will be used for identification purpose. The study participants will distribute flyer and the referral code to people who are eligible for the study. People who are eligible and provide the referral code can be enrolled in the study. Participants will also be recruited from participants in other studies who have agreed to be contacted for future studies.

A two-step referral process will be utilized whereby index seeds will refer 308 first- and second-degree social network members (88% of sample). So indexes will refer network members (1st degree) and then those network members will refer one more round (2nd degree). Index seeds will meet the eligibility for index community members while the first and second-degree network members will meet the social network member eligibility (see inclusion and exclusion criteria below). Based upon previous experiences with SNS recruitment, we expect on average two social network members to be referred per study participant.

Each study participant will be given a referral code that will be used for identification purposes. The study participants will distribute the referral code to their network members who are eligible for the study. People who

are eligible and provide the referral code can be enrolled in the study. Network members will also have the option to bring others into the study visit with them or link them to the RA at a study site that is recruiting for this study.

Site specific details are listed in Appendix A, including recruitment plans, consent activities and overall study conduct for each site.

Inclusion and exclusion criteria

Index community members will be:
(1) 18 years or older;
(2) spend majority of their time in the metropolitan area or county where recruited;
(3) have access to a phone for 21-day follow-up call; and
(4) primary communication in English or Spanish (based on site chart above) AND at least one of the following:
(i) ever had CJI (operationalized as any jail, prison, arrest, parole (completed), probation, drug court);
(ii) ever had negative interaction with police or law enforcement that did not lead to an arrest or jail/prison time (operationalized as ever stopped, searched, physically or verbally abused, or had another negative interaction with police or law enforcement);
(iii) ever witnessed a negative interaction with police or law enforcement (operationalized as ever witnessed another person being stopped, searched, or physically or verbally abused by police or law enforcement);
(iv) lower-income Latinx (operationalized as at or below 250% of FPL).

Social network referrals will be:
(1) linked to the index as a "friend, family, coworker or someone you spend time with on a regular basis";
(2) visit within two weeks of index visit;
(3) 18 years or older;
(4) spend the majority of their time in the metropolitan area or county where recruited;
(5) have access to a phone for 21-day follow-up call; and
(6) primary communication in English or Spanish (based on site chart above).

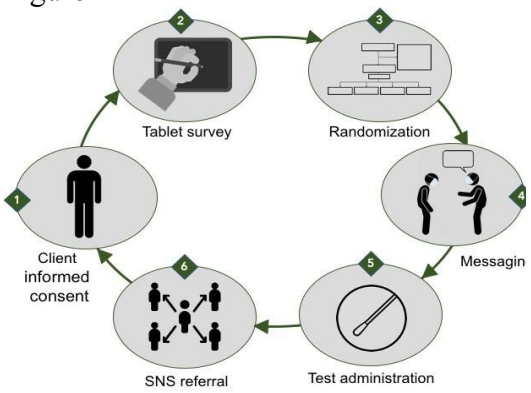
Exclusion criteria include:
(1) inability to provide informed consent; and
(2) active COVID-19 symptoms per CDC. Participants with COVID-19 symptoms will be referred for free testing at existing partners for each of the study sites.
(3) currently on parole

Study Visit Procedures

All study participants (index and referral) will go through the following study procedures (Figure 4) include:

- Informed consent;
- Day 1 survey;
- Randomization;
- Messaging intervention (for SNS+ only);
- COVID-19 testing
- Social Network referral
- Day 21 Follow-up

Figure 4



1. 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.

   Paper Consent in-person:
   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. The subject will be provided with a final signed copy. A signed copy will be stored by the study team.

   Electronic Consent in-person:
   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.

   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 to the consent in RedCAP will be sent to the subject via text and/oremail. 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

2. Day 1 Survey. Following consent, study participants will complete an electronic survey that includes social network inventory. Identifying information of social network members (first name and last initial and cross streets/zipcode/neigborhood) is collected through self-report for the purposes of connecting social networks of study subjects. Day 1 Survey is found in Appendix B. This will survey will be completed on the day of recruitment and will take 60 minutes. The RA can interview participants who have difficulty self-administering the survey.

3. Randomization. Will occur following the survey, and participants in the SNS+messaging arm will receive the messaging intervention (discussion tools and coaching). Study participants will be randomized to receive no messaging (i.e., SNS only) or SNS+messaging with equal probability. Randomization will be performed at the participant level, meaning that in general, participants within a recruitment cluster will be assigned to different groups. Random assignments will be provided by the University of Chicago via a web-based API, with the touchpads programmed to retrieve an assignment at the appropriate time and deliver the messaging (or not), as appropriate.

   Indexes and first-degree referrals will be randomized as described above. Second-degree referrals will also be randomized, however, we will not ask for additional SNS referrals from them if the study sample size has been reached.

4. Messaging Intervention. Study staff will be notified of group allocation and provide the in-person message reinforcement and will address questions related to messaging.
   a. *C3 Study Conditions*. Trained community engagement coordinators (CEC) that exist across C3 sites will deliver the study conditions. The CECs will 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. CECs will provide the appropriate scripted messaging strategy based upon condition assignment (see conditions below) and will follow with describing and motivating the SNS network referral process.
   b. *SNS Study Condition*. Study participants in the SNS condition will receive the SNS intervention training which will take about 30 minutes. This will occur towards the end of the study visit when CEC staff describe the SNS, construct a plan for successfully referring network members into the study, and discuss compensation for the recruitment efforts. CECs will specifically discuss network members of interest: "friend, family, coworker or someone you spend time with on a regular basis". 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 will be addressed, (3) how the screening by phone or web survey will be conducted, (4) what information about the study will be shared. Information from the client providing referrals will be kept confidential. Participants will be compensated $20 per successful test completed per network member and up to six referrals, consistent with our previous work.[42]
   c. *SNS+Messaging Condition.* The SNS+ condition will include everything described in the SNS condition above. In addition, a scripted message (Appendix C) in the participant's preferred language

will be deployed via the tablet in written or audio format. Training for this additional messaging will take about 15 minutes.

d. *Quality Monitoring* - A sample (5%) of the trainings will be recorded (video and/or audio) for quality improvement purposes. These recordings may be shared amongst the respective sites-specific study team (not 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.

5. COVID-19 Testing. All study participants, irrespective of symptoms, will be tested for COVID-19. Based on routine practices of the site, testing will be either administered by a clinical professional or conducted through self-administration according to CDC guidelines (Appendix I). Testing procedures will follow existing SOPs utilized at each site, utilizing FDA-approved tests. COVID testing at these sites is covered by public health programs for each site.

   Test result provision will be provided by the testing/clinical team. All subjects will be provided with the CDC's information page "What Your Test Results Mean" (Appendix J).

6. COVID-19 Vaccination: All subjects will be provided with the link to CDC's COVID-19 vaccine information page "Key Things You Need To Know About COVID-19 Vaccines" (Appendix K) and a link to CDC's "Vaccines for COVID-19" page available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html. Access to vaccines will follow routine practices and will depend on a participants' tier/health department eligibility to get the vaccine as well as vaccine availability. Contact information for vaccination sites and any referrals will be given according to the normal practices at each site.

   All participants will be asked sign release of information forms for study team members to obtain test results and vaccination records. Vaccination records will also be collected through participant self-report (participants can show study staff their vaccination card). COVID test results and vaccine records will be collected as part of study data and will be needed to determine the effectiveness of the intervention.

7. Social Network Referral – Network referrals will be conducted as outlined above (See SNS Study condition). A study information card (Appendix D) will be given to all enrolled subjects to share with their network referrals. The information card contains information about the study and study team contact information. Linkages between study participants are collected through a code/code word process that our team has used in previous network referral studies.

8. Day 21 Assessment - Study participants will be contacted 21 days following the initial study visit via phone or Zoom, depending upon client preference. Data will be captured electronically by the research coordinator using a study tablet. This interview also includes social network inventory (identifying information: first name, last initial, cross streets/zipcode/neighborhood) for the purposes of connecting social networks of study subjects. Day 21 Interview is found in Appendix E. The 21day follow-up (Day 21 Interview) has two purposes:
   (1) administering perceived message effectiveness surveys and post-intervention COVID-19 knowledge assessment; COVID vaccine information and (2) check-in on network member referral (Appendix D).

Subject Compensation. Compensation will be provided for study participation - $50 after the first visit and $20 after the 21-day follow-up. Participants will be provided a $20 incentive for each network referrals initiated (up to six referrals, up to $120 for referrals). Payments will be in cash, gift cards or e-payments such as CashApp, PayPal or Venmo.

C3 Study Conditions. Trained community engagement coordinators (CEC) that exist across C3 sites will deliver the study conditions. The CECs will 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. CECs will provide the appropriate scripted messaging strategy based upon condition assignment (see conditions above) and will follow with describing and motivating the SNS network referral process.

Primary Outcomes. We focus on two primary outcomes:
(1) Total number of tests among network members referred for COVID testing (network tested) - Network tested is measured at the participant level by the number of network members that are tested through the SNS
(2) proportion of network members tested (tested proportion).
(3) Total number of vaccinations among study participants given COVID vaccine information (number vaccinated) - Number vaccinated is measured at the participant level by the number of study participants that are vaccinated through the SNS.

Other Important Variables: Age, race, ethnicity, gender, sex at birth, and CJI history; as well as COVID-19 knowledge, testing history, infection history, substance use history, beliefs around mask efficacy, treatment/prevention history, vaccine knowledge/attitudes, prior contact by contact tracer, experiences of racism, housing status, food insecurity, employment, experience of violence, workplace resources, PPE availability, and known COVID-19 contact.

Analytic overview. Two types of analyses will be performed.
The first will focus on the likelihood that a participant's network members are referred for testing. This will be modeled using logistic regression, with each network member treated as an observation (tested versus not). A three-level hierarchical model will be used, with random effects at the level of the study participant (level two) and the recruitment cluster (level three, all participants referred by the same index participant).[43] We shall also consider adding site as a fourth level to permit us to estimate between-site variability both in the outcomes and in the effectiveness of the interventions.

The second analysis will focus on the total number of individuals referred by a participant for testing, including both network members and additional referrals not initially named as part of the participant's network. The total number of referrals will be modeled using negative binomial regression.[44] A random effect at the level of the recruitment cluster will again be included to capture potential within-cluster correlation in the number of referrals. To ensure correct inferences even in cases where our models do not fully capture the within-cluster correlation in the data, we shall use the clustered version of the robust (i.e., sandwich) variance estimator throughout.[45]

Primary outcome analysis (overall comparison of SNS vs. SNS + messaging). The primary outcome analysis will compare the likelihood of testing among network members and the total number of referrals tested between those assigned to SNS and those assigned to SNS plus messaging. Our initial analysis will not adjust for covariates, relying instead on the randomization to justify the comparison. We shall then incorporate covariates—measured at both the level of the network member (e.g., member characteristics and the nature of the relationship to the participant) and of the participant—to improve the precision of our estimates and to identify demographic and social characteristics associated with differences in referral yield. In addition, we shall consider interactions between intervention group (SNS vs. SNS + messaging) and participant characteristics to determine whether messaging is more effective in certain groups than others. Since we shall consider several possible interactions, we shall use partial pooling within a Bayesian estimation framework [46] to avoid bias and address the issue of multiple comparisons.

We will compare the probability of participants being vaccinated in the SNS vs. SNS + messaging arm using logistic regression with each participant treated as an observation (vaccinated vs. not). This will be modeled with a three-level hierarchical model with random effects at the level of the recruitment cluster and study site. We will also consider adjustments for time trends in vaccine availability and participant eligibility.

Secondary outcome analyses: We shall use negative binomial regression to compare the average number of referrals tested per index client between those recruited to C3 and assigned to the SNS condition and a comparison group of clients at the same sites receiving standard contact tracing only. This analysis will be performed first using only those contact tracing clients who visited the sites on a day randomized to no C3 recruitment, since these individuals should, on average, be similar to those recruited into the study. A subsequent analysis will be performed using a larger set of non-study clients to increase precision; this will use covariates capturing demographic and other client characteristics to adjust for potential differences between the C3 SNS group and the non-study comparison group. Analyses will use generalized linear mixed models similar to those described above, as appropriate.

Power calculations: In order to estimate our power, we performed the following simulation. We assumed that index participants generate network members according to a negative binomial distribution with mean 4 and SD 2.8 (to match the study design, networks larger than 6 were truncated). Each network member comes in for testing with a probability determined by the group to which they are assigned, and we conservatively assume intraclass correlations of 0.46 within a participant's network and 0.37 within a recruitment cluster. If we assume that the overall likelihood of testing among network members is 0.44 among the SNS group and 0.52 among the SNS plus messaging group, then an overall sample size of 2,400 participants will provide approximately 87% power to detect the difference at the 0.05 level (twosided). We shall have approximately 80% power to detect an interaction between the intervention and a binary participant characteristic (Groups A and B) such that the overall probability of testing for those receiving SNS only (both A and B) is 0.44, the probability of testing for those in Group A receiving SNS plus messaging is 0.50, and the probability of testing for those in Group B receiving SNS plus messaging is 0.63 (i.e., messaging is more effective among Group B).

Attrition and missing data: All participants enrolled in the study will be included in our analyses; since the primary outcomes will be measured based on referrals coming in to get tested which does not require additional participation by the participant, we anticipate very little missing outcome data (referrals who come in for testing and decline to identify the person who referred them will not be counted). Any missing data will be addressed using multiple imputation [47] or by using a fully Bayesian approach to estimate the model[48] (in which missing data are essentially treated as additional unknown parameters).

POTENTIAL RISKS AND BENEFITS TO SUBJECTS

Study Risks. Interviewed subjects will be exposed to minimal risk: loss of confidentiality and discomfort from the questionnaire. Subjects will be told they do not need to answer any questions that make them uncomfortable. Linkages between study participants are collected through a code/code word process that our team has used in previous network referral studies. All survey data will be collected using a tablet and linked through the subject's study code instead of name. Tablets will be encrypted and data will be password-protected and HIPAA compliant. At all sites, COVID infection control procedures will be in place. These will include a COVID symptom screener (Appendix F), temperature checks, mask-wearing requirement and at least six feet apart during in-person interactions.

Benefits: The primary potential benefits of this research will accrue to participants of this study and their networks. Participants will be linked to COVID-19 testing and treatment services as needed. The results of this study may lead to future interventions which can support COVID-19 prevention messaging, linkage to testing and treatment services for disenfranchised populations.

DATA STORAGE AND SHARING

We shall take several steps to ensure the security of the identifiers and data collected for this study. First, 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 two applications: REDCap (web-based application hosted by the CRI at the University of Chicago) and Network Canvas (developed at Northwestern University, and running locally on the laptop). The social network data, including identifiers for social network members, will be entered into Network Canvas, which has been specially designed for collection of such data. Following an interview, the data will be exported from Network Canvas and the network member identifiers will be split off and placed in a separate file which will then be strongly encrypted using RSA via the software GnuPG (an implementation of the the OpenPGP standard as defined by RFC4880). This operation will be performed programmatically, using a custom utility installed on the laptop. After verification of the encrypted file, the unencrypted file will be deleted.

Before any data transfer, the University of Chicago will encrypt the data both at rest and in transit via a Shared File Transfer protocol (SFTP) to provide a high level of security of sending and receiving file transfers. The encrypted data products will be securely uploaded to a SFTP server using a cyberinfrastructure service such as Globus (https://www.globus.org/) via the Biological Science Division Information Services (BSDIS). Using a STFP 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. Thus, the network member identifiers will be encrypted both *in transit* and *at rest*.

The identifiers of network members will be firewalled from all other data in two ways. First, they will be uploaded and stored in a separate, dedicated fileshare. Second and more importantly, an honest broker within the University of Chicago Biostatistics Laboratory will hold the encryption key for the identifiers. Only this individual will be able to decrypt the files containing the identifiers (i.e., our protocol achieves end-to-end encryption between the laptop in the field and the honest broker). He or she will monitor the incoming files to ensure that the system is working properly, but the files will continue to be stored in encrypted format. The honest broker will not be a member of the research team, and will not have access to any of the other data collected by the project.

Finally, the honest broker will provide study subject and network member location identifiers to one or more data analysts who will perform the network matching and geocoding needed to generate files for analysis. This analyst (or analysts) will be located at the University of Chicago (e.g., CCHE, the Biostatistics Lab, the Center for Spatial Data Science, or Argonne), and his or her only role on the project will be to perform the network matching and geocoding. Once this operation has been completed and the results have undergone QC, the original files containing network member identifiers will be destroyed by both the analyst(s) and the honest broker. All network matching and geocoding will take place on a secure compute server maintained by the Research Computing Group in the Department of Public Health Sciences. This is the only location where the raw files will be decrypted.

After study termination, the de-identified study data may be maintained for up to 10 years at the University of Chicago. All recordings of study trainings will be destroyed upon study termination.

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

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. Coded data for all sites participating in our RADx-UP C3 study will flow from University of Chicago to DCRI for storage and sharing

purposes for future COVID 19 research as directed by the NIH (in keeping with the NIH's policy). All data shared in this manner would be deidentified and could be used indefinitely.

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