RESEARCH PROTOCOL

Title of Project: Community-engaged Approaches to Testing in Community and Healthcare settings for Underserved Populations (CATCH-UP)

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Abstract

The pandemic caused by the novel coronavirus SARS-CoV-2 has resulted in substantial global morbidity and mortality including in Oklahoma and caused unprecedented interruptions in nearly all aspects of our lives. The population of the state of Oklahoma is at particular risk to SARS-CoV-2 due to its large rural population, strained healthcare system, and poor overall health. The Community-Engaged Approaches to Testing in Community and Healthcare Settings for Underserved Populations (CATCH-UP) program will involve both practice-based and community- based approaches to maximize the reach of the RADx-UP consortium, broaden the potential perspectives that could be captured, and compare the effectiveness of strategies. The interventions will be pragmatic to allow CATCH-UP to respond to changing attitudes, barriers, and environments as the pandemic progresses as well as expected technology developments to produce more effective viral testing that can provide rapid results to patients. We will assist 50 small primary care practices to implement guidelines-based testing and patient education about COVID-19 and risk mitigation strategies. Our community-based approach is designed to rapidly respond to community testing needs by deploying mobile testing sites that will provide operational support to increase the efficiency and the existing capacity for state-wide testing by Oklahoma's public health authorities. Together, we estimate that the CATCH-UP program will result in at least 105,000 SARS-CoV-2 tests performed during the first year of implementation. A comprehensive, ongoing evaluation will be performed to analyze patient and provider attitudes, barriers and facilitators of viral testing, identified health disparities caused by COVID-19, effectiveness of the intervention in both settings, and to allow robust collaboration with other RADx-UP consortium sites.

A. Specific Aims

The project's specific aims are:

1. Provide technical support to a minimum of 50 Oklahoma primary care practices to implement a person-centered approach to SARS-CoV-2 testing based on best available evidence and current guidelines. The implementation approach will include 1) development of implementation support resources for COVID-19 testing and risk mitigation strategies to meet the needs of vulnerable populations through continuous adaption to changing guidelines, testing protocols and availability, and information learned from our provider network and the broader RADx-UP community, 2) support practices to integrate tailored, guideline- based SARS-CoV-2 testing protocols and resources into their workflows through our proven methodologies of academic detailing from peer- physician experts, practice change facilitation through quality improvement implementation professionals, and health information technology support. Based on the average number of providers and daily caseload in rural Oklahoma practices we estimate this will result in approximately 60,000 viral tests performed in the first year.

2. Rapidly respond to community testing needs by deploying mobile testing units in community settings that will provide operational support to increase the efficiency and the existing capacity for statewide testing by Oklahoma's public health authorities. The model used by the Chickasaw Nation in deploying a high- efficiency community testing system will be combined with ongoing observation and analysis to identify facilitators and barriers to implementing community testing sites to accelerate convergence on effective and replicable methods to increase access and acceptance of testing. We will adapt to ongoing disease outbreaks and community needs, but anticipate that this aim will result in more than 250 testing events at sites throughout the state and 45,000 viral tests performed in the first year.

3. Conduct a comprehensive evaluation of the impact of the CATCH-UP program, collaborate closely with other RADx-UP projects in sharing data and adapting processes, and continuously communicate with our community partners to assess effectiveness and disseminate research findings. This evaluation will include measurement and dissemination of data related to 1) Provider-level Outcomes that include knowledge and attitudes of disease prevalence, clinical characteristics including typical and atypical symptoms and disease severity, testing importance and strategies, vaccination, importance and use of personal protective equipment, availability of testing and delays in return of results, and provider observations of patient attitudes and other reported barriers, 2) Care Process Outcomes such as testing, test positivity, and test refusal rates, influenza, pneumococcal, and zoster vaccination rates, 3) Community-level Outcomes that include the number of tests conducted by mobile testing units and the resulting test positivity rate, 4) Patient-level Outcomes such as knowledge and attitudes of disease prevalence, disease characteristics including severity and acute and chronic symptoms, risk perspective and preferences, importance and use of personal protective equipment, patient acceptance of various testing options, and facilitators and barriers to participating in testing and future vaccination programs, 5) Patient Factors such as demographics, social

determinants of health, and clinical characteristics that may be associated with COVID-19 morbidity and mortality disparities or reach of each testing modality, and 6) Qualitative Outcomes including perceptions of facilitators and barriers to testing and the utility, effectiveness, and generalizability of the program, explored through key informant interviews, exit interviews, and in-depth program implementation process observations.

B. Background and Significance

The pandemic caused by the novel coronavirus SARS-CoV-2 and the disease COVID-19 has resulted in substantial global morbidity and mortality, including in Oklahoma, and caused unprecedented interruptions in nearly all aspects of our lives. As would be expected in a viral pandemic, geographic and other characteristics of the populations contributed to an uneven distribution of cases with more densely populated states and urban centers bearing a large proportion of the early infections.[1-2] Both early case numbers and mortality rates demonstrated considerable disparities based on age and certain chronic illnesses (e.g., obesity, cardiovascular disease, pulmonary diseases, diabetes) [3-6] but also on other social determinants of health (e.g., economic insecurity, race, occupation, access to health care).[7-10]

As the pandemic progressed, we have seen the increasing expansion of infection rates in rural locales. This is particularly problematic due to the current state of rural healthcare, lack of robust public health infrastructure in rural locations, and the general health of the rural population. Even before this pandemic, rural healthcare providers[11] and hospitals have been under enormous stress that threatens care delivery in these regions, with Oklahoma expected to be particularly hard hit.[12] Rural providers and hospitals are often under-resourced, and the existing health disparities in rural America that exacerbate COVID-19 cases may further strain capacity in these settings.[13-14] Rural populations in general are medically underserved, older, and experience significant health disparities compared to urban communities, and these disparities are even more pronounced for racial and ethnic minorities in rural America.[15-16] Together, the relative scarcity of medical and public health resources and higher prevalence of risk factors that increase the severity of COVID-19 make rural populations highly vulnerable and subject to higher morbidity and mortality rates in the event of continuing and increasing outbreaks.

Based on these factors, the population of the state of Oklahoma is at particular risk to SARS-CoV-2 due to its large rural population, strained healthcare system, and poor overall health. In addition, the *per capita* rate of cases is currently rising higher than the U.S. average and risk mitigation strategies have been poorly received by the population. Oklahoma is a highly rural state with 1.4 million residents (34%) living in rural areas in 2019, more than twice the national average of 14%.[17-18] Of Oklahoma's 77 counties, 59 are designated as rural (*US Census, USDA*). High rates of poverty, tobacco use, obesity, and other health risk factors that are more prevalent among rural residents, often compounded by the additional distance required to access care

and an older population, contribute to the high incidence and mortality rates for a range of chronic conditions among this underserved population. Combating the spread of SARS-CoV-2 has proved extremely difficult in the United States due to a variety of well-publicized economic and sociological factors.[20-21] Certain biological characteristics of the infection, particularly the variable incubation period [22-23] and a high degree of spread by asymptomatic and presymptomatic individuals,[24-25] requires us to conceptualize a broader range of testing strategies than has been used previously in this country. We have observed the development of new tests at unprecedented speed, and of unproven sensitivity and specificity, with hundreds of new tests receiving an FDA EUA and major initiatives like RADx being launched.[26] To date, the majority of FDA-authorized tests are molecular (RT-PCR) based or serological and are authorized only in high- or medium-complexity CLIA/CAP-certified laboratories.

However, the most effective testing for SARS-CoV-2 infections requires high-quality Point-of-Care (POC) tests that can accurately and quickly provide results in patient-care or other community testing settings. We must overcome shortages in the testing capacity that have led to periods where individuals have been prioritized for testing based on certain factors (symptomatic requiring hospitalization, presence of fever, elderly, co- morbidities, known contact with confirmed infection) while others have been ignored (asymptomatic, pediatric, young adults, healthier populations). A comprehensive testing strategy will need to include testing in a wide variety of settings to maximize reach into high-risk populations. These can include community "pop-up" testing, primary care or healthcare facility testing (both symptomatic and screening patients prior to hospitalization or elective procedures), employment-based testing, and population-based random screening.

C. Preliminary Studies/Progress Report

The broad RADx-UP initiative aims to understand the factors associated with COVID-19 morbidity and mortality disparities and to lay the foundation to reduce disparities for underserved and vulnerable populations disproportionately affected by the pandemic through efforts to increase access and effectiveness of diagnostic methods. We believe that Oklahoma's IDeA-CTR, the Oklahoma Shared Clinical and Translational Resources (OSCTR), and its long-standing community-engaged research programs and partnerships are perfectly positioned to contribute to the knowledge base necessary to improve the effectiveness of interventions to increase testing in underserved and vulnerable populations. Our approach will leverage our experiences in designing and implementing evidence-based interventions in primary care settings, our partnerships with AI and Latino communities, our investments in the development of community- driven and responsive organizations developed primarily in rural counties, and the capacity and needs of Oklahoma's government testing and contact tracing infrastructure to develop, test, and evaluate a culturally- responsive SARS-CoV-2 testing intervention, collection of additional data on COVID-19 related health disparities, and identification of additional attitudes, facilitators, and barriers to testing and eventual vaccination.

We have designed an approach that allows us not only to collect essential information about community, provider, and patient-relevant impediments to viral testing but also to meet the critical need to increase testing in testing deserts in Oklahoma as rapidly as possible. We believe that a singular focus on one testing strategy will be ineffective in truly understanding the barriers to testing. No one strategy would be effective in reaching all of the population, due to issues such as lack of access to a primary care provider, lack of insurance, transportation, available time, or individual/community perceptions on testing itself (e.g., safety, necessity, availability, trust). Thus, we have chosen to develop the Community- engaged Approaches to Testing in Community and Healthcare settings for Underserved Populations (CATCH-UP) program with practice-based and community-based approaches to maximize the reach of the RADx-UP consortium, broaden the potential perspectives that could be captured, and compare the effectiveness of strategies. Rather than developing an inflexible practice-based intervention *a priori*, we believe that the ever-changing barriers, attitudes and conditions in the pandemic, as well as the development and deployment of more effective diagnostic technologies over the next few months, necessitate a pragmatic approach in which we initiate increased testing quickly while simultaneously collaborating with stakeholders and collecting participant survey data in real-time, which we believe will allow the intervention to evolve to changing needs, and provide rapid-cycle evaluation of effectiveness of these activities to provide timely feedback to our partners and other RADx-UP initiatives.

Over two decades of research conducted by our team and other researchers have demonstrated that a healthcare research dissemination and implementation (D&I) extension system, similar to the agriculture- focused Extension Service, is effective at assisting primary care practices to translate research findings into practice.[27-30] The OSCTR and the EvidenceNOW: Healthy Hearts for Oklahoma project (H2O) (R18HS023919), provided the infrastructure support to build the Oklahoma Primary Healthcare Improvement Cooperative (OPHIC) to provide research and dissemination capacity for implementation of evidence-based best practices, quality improvement (QI) techniques and an array of care improvement resources in primary care practices across the state.[31] In H2O, we guided over 250 practices through improvements in patient care to reduce the risks of cardiovascular events by employing the OPHIC implementation support model that consists of Benchmarking and Feedback to track practice care quality, Academic Detailing (AD) by peer clinicians, Practice Facilitation by trained primary care Practice Facilitators (PFs), and Technology Assistance by health information technology advisors to enhance the optimal use of Electronic Health Records (EHRs). OPHIC has collected critical information on the abilities of practices to facilitate changes in their care activities by developing surveys that examine the effects of practice characteristics, practice member attitudes, and domains according to the Building Blocks of Primary Care (BBPC).[32] The success of the OPHIC model has led to new partnerships with Oklahoma state agencies including SAMHSA-funded development of Do No Harm (DNH) a new approach for helping primary care practices implement safer pain and opioid management that was tested with 60 primary care practices, a SAMHSA-funded project to develop and implement a practice- based approach to screening, brief intervention, and referral to treatment for substance abuse and depression, and a CDC-funded project to work with rural practices to improve diabetes care and continued monitoring for cardiovascular risk factors.

D. Research Design and Methods (What, When, How, Where)

Our project will design the initial implementation strategies based upon addressing obvious barriers and concerns of our community partners and patient/provider stakeholders identified at

the beginning of the project. Subjects for this research project will include primary care clinicians and their office staff. They will be interviewed and observed, and their performance will be evaluated. Each practice will be asked to complete one approximately 15-minute Practice Characteristics Assessment twice (at enrollment and at the end of the study).
Each clinician and office staff member will be asked to complete a 10-minute Provider Survey at baseline and quarterly thereafter. The Practice Characteristics Assessment and Provider Surveys will be delivered to practice staff via an email that includes a web-based REDCap survey link. Medical record data will be abstracted from each practice for performance feedback and outcome measure assessment using EHR registry reports. Each practice will receive support from academic detailers and practice facilitators and performance reports to improve their processes of care.

Patients will be involved in two ways, through completion of patient surveys and through retrospective abstraction of their medical record data for performance tracking and reporting. Patients offered SARS-CoV-2 testing (at either a participating primary practice or mobile testing unit) will be provided a flyer that includes both a QR code and URL to the Patient Survey in REDCap. This survey will be completed anonymously and set up to ensure that patients can only complete the survey one time.

Key Informant Interviews (KII) and Patient/Provider Surveys

KII will be conducted over Zoom at the beginning and end of the project, with community stakeholder, provider, and patient representatives to help inform the facilitators and barriers to be included in the Practice/Provider and Patient Surveys with a focus on identifying and capturing those encountered by underserved, vulnerable populations. Participants will be consented electronically via REDCap prior to conducting the interviews. Provider and Patient Surveys responses will also be monitored on a monthly basis and shared with the SAB and CAB to identify whether adaptations to our program are needed.
Practice/Provider Surveys will be delivered to practice staff via an email that includes a web-based REDCap survey link. When offered testing, patients will be given a flyer with a QR code and web-based link to complete the Patient Survey via REDCap. The survey link will be unique for each flyer to ensure that an individual can only complete the survey once.

Testing Capacity

The CATCH-UP project is designed to maximize the number of tests provided to vulnerable individuals by leveraging external testing capacity and funding to every extent possible. In Aim 1, we are assisting practices in guidelines-based testing of patients. At the initiation of the intervention, we anticipate that this will be accomplished through the existing laboratory testing relationships of the practice. However, as POC testing is vital to rapidly responding to the pandemic, we will assist practices to implement FDA authorized systems/tests of their choosing as they become widely available. The majority of test costs would be borne by the patients' insurance. However, we will provide additional test kits to practices to help ensure insurance-status is not a barrier for testing in vulnerable populations. We are providing additional remuneration to practices to assist them in acquiring personal protective equipment (PPE) and assistance in integrating EHR systems to allow reporting of results to patients and public health authorities for contact tracing and epidemiological studies. In Aim 2, we are acting as force-multipliers to increase the geographical distribution of testing sites to meet the existing capacity for laboratory testing, contact tracing, and patient return-of- results available from OSDH to offer greater availability in underserved regions of the state while allowing us collect data on the testing barriers and attitudes of individuals in a wide variety of settings. OSDH has committed to providing the test kits and laboratory analysis and has contracted with multiple academic and

commercial entities to ensure testing capacity is available for surveillance purposes. All OSDH testing protocols utilize FDA authorized tests, and as testing modes (NP, nasal, saliva) change over the course of the intervention, we will adapt to protocols prioritized and testing kits provided by OSDH.

We have also budgeted to allow for limited serology and POC testing at community sites in Aim 2 to allow for in-depth analyses of how different testing strategies may impact patient choices/attitudes about SARS-CoV-2 testing. We have already performed extensive serology testing utilizing FDA-EUA authorized Lateral Flow Assays (LFA) combined with confirmation on the Abbott Architect platform and have access to adequate supplies to support this study.

We anticipate that approximately 5,000 individuals will participate in the limited serology study through the community-based testing sites for the CATCH- UP program. Individuals 13 years of age or older are eligible to participate.

Given the minimal risk of the study and because study participants will already be at the site to participate in community viral testing, we will not provide compensation to the individuals for participation in the study.

Consortium Data Reporting Unit

OSCTR and OPHIC have the experience and capability to collaborate with other RADx-UP grantees to share effective implementation strategies and for reporting of protocols, survey results, testing data, referral data, demographics, and other required documentation to the RADx-UP Coordinating and Data Collection Center (CDCC). As described in Aim 3, we will collaborate closely with the CDCC to share our evaluation efforts, modify data collection plans to align with the national effort, and report data at intervals set by the CDCC.

Practice-based SARS-CoV-2 Testing Strategy

The goal is to provide technical support to Oklahoma primary care practices to help them implement a culturally-responsive approach to SARS-CoV-2 testing based on best available evidence and current guidelines. The approach will include development of implementation support resources for testing and risk mitigation strategies to meet the needs of vulnerable populations. We are instituting a pragmatic approach that allows continuous adaption to changing guidelines, testing protocols and availability, and information learned from our provider network and the broader RADx-UP community. We will assist practices to integrate tailored SARS-CoV-2 testing protocols and resources into their workflows through our proven methodologies of academic detailing from peer- physician experts, practice change facilitation through QI implementation professionals, and health information technology support.

Scope of testing

The practice-based testing strategy in CATCH-UP aims to assist practices to increase their ability to test patients, either through existing laboratory relationships, public health authority testing, or POC diagnostics implemented at the practice. Each individual offered a SARS-CoV-2 test will be provided a flyer with a description of the initiative and a unique link to the REDCap survey. We will adapt to ongoing disease outbreaks and community needs and focus heavily on rural primary care practices. Based on the average number of providers in rural practices and daily case loads, we anticipate that this aim will result in approximately 60,000 viral tests performed in the first year of implementation.

SARS-CoV-2 Testing Implementation Design

The nature of this pandemic has necessitated a rapid increase in testing to control the spread of the disease. Our goal is to develop a pragmatic approach that will focus on increasing evidence-based testing that is responsive to changing CDC guidelines, to assist practices in implementation of high-quality POC diagnostic tests emerging from commercial enterprises, the RADx- Advanced Technology Platforms, and/or the Point-of- Care Technology Research Network, and to collect essential data on attitudes, facilitators, and barriers to COVID-19 testing. This approach allows us to change the approach as necessary to adapt to findings from our own study and other RADx-UP projects and to design a more extensive implementation study for the proposed second phase of RADx-UP. The practice-based implementation in CATCH-UP will focus on reducing missed opportunities for testing. We will provide academic detailing at the beginning of our intervention using updated COVID-19 information in order to impact knowledge, attitudes, and skills with evidence-based sources, recognizing that some clinicians may still have beliefs that COVID's impact is "not concerning." While some clinicians with such a perspective may decline to participate, others may still be interested in providing increased testing services for their clients. In such a case, the practice's and their patients' perspectives may be extremely important for designing truly rigorous, adaptive approaches to testing.

Our baseline implementation approach includes assisting the practice to implement risk mitigation strategies, such as employee health checks, hazard assessment, training in use of routine PPE, such as masks and face shields for office work, social distancing, and increased ventilation. We will assist the practice to develop clinician scripts that explain testing protocols, ramifications of testing, patient instructions on self- care and quarantine, and symptoms that indicate an infection or worsening conditions. We will aid them in implementing initial patient *screening* by the office staff with standardized questions, with positive screens presented to the clinician for further direction on guideline-based testing. Patients calling or presenting to the primary care office with *signs and symptoms* of COVID-19 will be offered testing in their automobile. Staff will be taught to perform nasal swab testing dressed in full PPE for acute infection.

Other categories of patients who will be tested *within* the primary care office include asymptomatic individuals with recent known or suspected exposure OR without known or suspected exposure but working in high risk settings (*e.g*. healthcare), as recommended by the CDC. We will assist the practice to develop a registry of patients who are most vulnerable to serious morbidity and mortality based on demographics or existing co-morbidities. This will allow the clinicians to ensure they address risk mitigation strategies with patients, including routine vaccination for influenza, pneumococcus, and shingles, PPE use in public settings, and importance of monitoring for common symptoms that might indicate severe or worsening COVID-19 conditions.

OPHIC evidence-based dissemination and implementation support strategy

OPHIC will use an evidence-based, multi-component approach to accelerate implementation of SARS-CoV-2 testing in primary care practices. Our rigorous and well-tested implementation approach incorporates specific components of the Solberg-Mold Model of Practice Change into the well-accepted Consolidated Framework for Implementation Research (CFIR).[34] We are not testing component implementation-effect relationships since these have already been established.[31] The components of the OPHIC D&I model employed will be:

Performance Feedback and Benchmarking will be supported by a robust data infrastructure that will collect practice characteristic and practice member surveys, performance measures, and facilitation support records using a REDCap survey manager. Data from surveys and measures will be analyzed to populate practice performance dashboards used by PFs to provide quarterly

feedback. These stimulate data-based improvement in the practice and to permit practices to identify high performing practices to emulate. These same data will be assembled and analyzed by the OPHIC internal evaluation team for CDCC reporting.

Practice Assessments and Provider Surveys: Participating practices will complete or update an assessment of practice characteristics such as ownership, specialty mix, size, structure, patient volume, patient demographics, technology infrastructure, and financial status. The practice clinicians and staff will complete a quarterly survey assessing the practice atmosphere, and provider and patient attitudes about the SARS-CoV-2 pandemic, current testing and risk mitigation strategies, and vaccination strategies.

Academic Detailing: During one or more virtual visits, peer clinicians will conduct a conversation with the clinicians and staff regarding the importance of CDC guidelines for testing and to answer additional questions the practice may have about mitigation strategies. We will provide graphical discussion aids that summarize the evidence and best practices for testing that can be rapidly modified as information evolves. During the peer coaching conversation, ADs will help practices perform a self-assessment of current testing performance and help the practice prioritize the components they choose to begin implementing.

Practice Facilitation: PF support will begin with an intensive phase of half-day in-practice or virtual visits weekly for 3 months and follow with a maintenance phase of monthly visits for 6 months or more frequently if new POC technologies are deployed. Using a suggested support plan for each visit, the PF will help the practice form a QI team and engage clinical leadership in implementing the CATCH-UP testing protocol. The PF will document the support plan, support provided, and the outcome achieved by the practice in the OPHIC Electronic Practice Record (EPR), a system we developed to document all interactions with a practice, goals and accomplishments for facilitation encounters, and plans for the next contact. The structured notes in the EPR will guide facilitation planning indicating the anticipated services that will be provided during a visit as well as what happened during the visit and the practice's responsiveness and engagement in the improvement activity. EPR notes permit other PFs to fill in without interrupting the support plan and provides a record for analysis needed to improve the facilitation process itself.

Information Technology Support:

The PF, with the assistance of Oklahoma Foundation for Medical Quality (OFMQ) will help maximize the EHR's documentation and reporting capacity to capture testing process data. They will train clinicians and staff in the proper use of the EHR and introduce tools such as a care management registry to assure a seamless incorporation of SARS-CoV-2 testing into the existing workflow (including the use of POC technologies when implemented), consistent documentation, performance measure reporting needed to stimulate and track data- based improvement, and integration into the OSDH data reporting system for surveillance and contact tracing.

In addition, OFMQ collaborators will provide support for chart abstraction protocols, development of novel measures, quality control, and training of OPHIC PFs. They will provide technical advisors for both practice-based and community- based testing to participate in the generation of performance measures, assist with EHR data extraction and integration of POC diagnostic equipment, and visit practices as needed to facilitate more effective EHR use.

Virtual Learning Community is created by clinician and staff engagement in RPR Exchange.[33] The RPR Exchange creates a learning community by providing: (1) e-mail or text messages

notifying clinicians of relevant information filtered according to their preset preferences; (2) a searchable internet database of all disseminated information; (3) an electronic process that facilitates participant interactions and project development; (4) a process for clinicians' electronic communication of clinical observations, questions, suggestions, and requests to the academic team; (5) a listserv on which clinicians and academicians routinely discuss current hot topics and ask for advice. It will support this project by posting and disseminating COVID- 19 relevant meta-analyses, reviews, guidelines, clinical research results, clinical decision aids, practice management summaries, best local practices, training materials, and patient education materials.

Community-based SARS-CoV-2 Testing Strategy

Our goal is to rapidly respond to community testing needs by deploying mobile testing units in community settings that will provide operational support to increase the efficiency and the existing capacity for state-wide testing by Oklahoma's public health authorities and to allow us to collect essential information about attitudes, barriers, and facilitators through survey collection from tested sites. This strategy will allow us to act as a much-needed force multiplier for efforts by our state health authorities to provide free SARS-CoV-2 testing, tracing contacts to limit the spread of the disease, and better understand the epidemiology within regions of the state. This will be accomplished by leveraging our existing relationships and the experiences of the OSCTR's community partners to refine and tailor existing guidelines and protocols for SARS-CoV-2 testing in community settings to meet the needs of vulnerable populations, particularly in rural, underserved areas. The community-based approach in CATCH-UP will be an inclusive, state-wide approach to aid community testing for SARS-CoV-2.

Communication and Organization

The CPP will use an established structure of meetings to launch efforts with both virtual and in-person capabilities for participation that CHIOs have utilized with great success and sustainability. Communication platforms managed by the CHIOs represent individuals from all 77 Oklahoma counties with over 3,000 community-based organizations receiving information. Communities will have multiple pathways to request and deploy stationary and mobile testing events to support COVID-19 testing including scheduled events at the county level, requests by individual employers for workplace testing events (including public schools and private businesses), and specific requests by the public health authorities to address urgent hotspots or existing testing deserts. These requests can come directly to the CATCH-UP leadership or CEO Core, to CHIO organizations in their localities, or through existing community partners such as the LCDA and SPTHB, or new partnerships developed as a result of this initiative.

Scope of Testing

CATCH-UP aims to complete more than 250 testing events across Oklahoma, including 88 small events of 25-50 tests, 66 medium events of 51-100 tests, 44 large events of 100-200 tests, 33 x-large events of 200-500 tests, and 22 community-level events of > 500 tests. Each tested individual will be provided a flyer with a description of the initiative and a link to a REDCap survey described above. Mobile testing support will be facilitated by the SPTHB and Oklahoma Caring Foundation through the use of their Caring Vans. The combined fleet of 12 vans will be deployed to support CHIOs and communities in event organizing, event management, staffing support, and further addressing community-level needs. Partners from each of the organizing CHIOs will further identify and recruit community-based organizations to support addressing social determinants of health needs identified during the testing projects, including food insecurity, medication assistance, and utility vouchers. We will adapt to ongoing disease outbreaks and community needs, but anticipate that this aim will result in a minimum of 45,000 viral tests

performed in the first year of implementation. We also anticipate that early demonstrated successes will allow us to leverage other state or philanthropic funding to increase the number of testing sites and events. At selected events, we will also explore the feasibility of POC diagnostics for future CATCH-UP events as well as collaborate with OMRF to provide limited serologic testing. Both of these facilitate further understanding of how different testing strategies may impact participant attitudes towards COVID-19 and identify additional socioeconomic facilitators and barriers to testing (such as the role of wait time for both testing and return of results).

Supporting the CPP

General testing supplies and laboratory analysis will be provided by the OSDH as part of their existing program for community-based testing and supplemented as described by this project. OSCTR partners and CHIOs will be incentivized and supported to organize testing events in the same manner we have done in other projects. At the initiation of the project, each certified CHIO or OSCTR partner will be provided start-up funds to initiate the program, assist in identifying community barriers and facilitators, and secure community testing sites. For each testing event completed, we will provide additional innovation funding to support the community partner for use in evidence-based activities targeted at addressing COVID-19 related health disparities and social determinants of health. Funding will also be provided to partners to staff and supply events based on the anticipated size. We will leverage the existing process PHIO has for its Community Development Fund for local, evidence- based health improvement activities. Activities will be monitored and reported quarterly as a component of our dissemination activities to our community partners and the CDCC, and broader RADx-UP consortium

Program Evaluation and Dissemination

We will collaborate closely with other RADx-UP projects to share data and adapt processes and continuously communicate with our community partners to assess effectiveness and disseminate research findings. Quantitative approaches will include measurements of provider-level, care process, community-level, and patient-level outcomes. Qualitative approaches will include capturing information via semi-structured interviews, exit surveys, and in-depth program implementation process observations. The goals of the evaluation are to: (1) identify community facilitators and barriers to testing; (2) monitor ethical and social implications of testing; (3) measure the fidelity of the practice implementation support strategy; (4) determine the effectiveness, acceptability, and reach of the implementation support model for disseminating and helping practices to implement SARS-CoV-2 testing protocols; and (5) determine the effectiveness of different testing modalities.

E. Chart Review

1. For those practices that cannot generate performance measure data from the EHR, we will provide a chart abstraction protocol for obtaining performance measures through manual chart abstraction of the practice EHR.
2. More specifically, we will be collecting structured data needed for calculating performance measure from automated measure reports built into the EHR, or where these are not available, but developing a Registry Report to collect the data needed to calculate the performance measures.
3. Only aggregated performance measure data (therefore, deidentified) will be entered into REDCap.

4. Entry of data into REDCap will have user controls and logged access.
5. At the end of the Project, the data will be stored for potential future analysis for 10 years.

F. Biospecimens

No specimens will be obtained from participants except for the limited serology studies performed with our collaborators at the Oklahoma Medical Research Foundation, and only for those with positive POC test results to allow confirmation on other platforms. Participants in the limited serology study will be fully consented to participate in the research study. For all other participants, the only research material will be the data obtained by surveys, direct observation, key informant interviews, and medical record abstraction. Abstractions will be conducted at the practices.

G. Banking/Repository/Database

Information pertaining to COVID-19 screening, testing, and treatment will become part of the practice's standard medical record and will not be available to third parties other than the study team under OUHSC IRB protocol. Information from medical record abstractions will be immediately de-identified and coded on site by a trained abstractor. De-identification of patient records means that all patient identifiers listed in HIPAA regulations including, but not limited to, name, date of birth, social security number, medical record number, insurance identifiers, address, zip code, phone number, and email address will be removed so that research data cannot be linked directly to individual patient records without participant codes. Each participating practice, clinician, and patient will be assigned a code number matched to an identifier. A list that links the code number with the patient's name and medical record number will be kept in a secure location by the data analytics team.

Note, identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

H. Inclusion / Exclusion Criteria

Inclusion Criteria:

Practices

1. Primary care practices located in Oklahoma.
2. Priority to practices serving a majority of patients that are underserved or vulnerable populations (rural, minority, elderly).
3. Practices routinely using a certified electronic health record (EHR) will be eligible to participate, as practices that are still using paper records are either planning to close due to clinician retirement or will likely be implementing an EHR during the project, which would compromise their ability to participate.
4. Practice-wide participation will be encouraged, but participation of all members within a practice (both clinicians and staff members) will not be required. The minimum acceptable level of participation will be one clinician and nurse/medical assistant dyad plus anyone else who would have to be involved to make changes in the processes of care (e.g. clinic manager) for that unit of care.
5. Clinicians and staff members 18 years of age and older at the time of enrollment (consent).

Patient Survey Participants

1. Patients (or caregivers of patients) who are seen in eligible practices or community testing sites and received a recommendation for the patient to receive a SARS-CoV-2 diagnostic test.
2. Patients (or their caregivers) who are 18 or older.

Exclusion Criteria:

Practices

1. Practices that are uninterested in reducing missed opportunities for guidelines-based testing for SARS-CoV-2
2. Solo practices with a clinician planning to retire within 12 months of enrollment will not be eligible for participation.
3. Practices likely to experience ownership change in the next 12 months will not be eligible for participation.

Patient Survey Participants

1. Patients unable to complete the consent process or survey instruments in English.
2. Patients or caregivers of patients who are under the age of 18.

Early Termination Criteria:

1. ***Practices:*** Deny access to data needed to calculate performance measures. Decline to participate with Academic Detailers or Practice Facilitators in the practice change interventions.
2. ***Clinicians:*** Inability to participate with the external support provided to the practice. Terminates relationship with the practice.
3. ***Staff:*** Terminates employment with the practice.
4. ***Patients:*** Decline to participate. No longer with the primary care practices enrolled in the CATCH-UP Project.

I. Gender/Minority/Pediatric Inclusion for Research

No clinicians or staff members will be excluded from participation based on gender, ethnicity, race, or socioeconomic status. . For the Provider and Practice Surveys, no provisions for including non-English speakers or those with limited fluency in English have been made due to the resources needed to develop multilingual materials and processes. Women clinicians and staff members may be pregnant, planning pregnancy, or breastfeeding during the course of this study and therefore will be eligible to participate.

No patients will be excluded from this study due to gender, ethnicity, race, or socioeconomic status. The study design involves targeting practices and communities that tend to be more rural or primarily serve underrepresented populations.

English-language only status would not be a limitation to being tested as part of this study. While there are limitations to the generation of surveys in other languages, every provision possible will be made to include Spanish-language materials and surveys to ensure the ability of Spanish-only speakers to participate in this study.

J. Recruitment and Enrollment

We will enroll 50 practices, which is approximately 3% of the primary care practices in Oklahoma. Practices will be defined as clinician-staff units that work together to deliver care to a population of patients. These care units may be a 'pod' or 'clinic' within a larger heath system with multiple practices located at the same street address of a medical building. The practice, or microsystem, has the responsibility and capacity to implement Quality Improvement (QI) interventions with or without corporate or larger group assistance. We will prioritize small- and medium-size primary care practices (<10 clinicians) to participate in this project. A practice facilitator (PF) will contact interested practices to screen for eligibility and arrange a date for enrollment, if applicable. During in-person enrollment, participating clinicians and office staff will receive additional information and be able to ask questions and express concerns about the project. Those still interested will sign an informed consent document and a lead clinician and participating staff will complete baseline surveys.

Patients undergoing SARS-CoV-2 testing will be given a card/flyer with information about participating in surveys about attitudes towards COVID-19 and barriers and facilitators of testing. Consent for low-risk survey participation will occur through a REDCap form. We do not plan repeated survey measures and thus retention is not applicable.

K. Risks and Benefits

Our study focuses on the translation of evidence-based guidelines into practice. The major risk to the clinicians and office staff is loss of productivity and income. It will take some time to complete enrollment forms and questionnaires and help the practice facilitators and medical record abstractors access the performance data. In addition, the level of clinician and practice performance will be known to the research team, which if below average, might make practices' staff feel uncomfortable. The risks to patients are minimal. They involve risks associated with abstraction of their records (confidentiality) and temporary disruptions in services associated with efforts to improve care processes. There may also be concerns of loss of confidentiality when completing the Patient Surveys.

For those participating in the limited serology study, it remains a minimal risk study, where possible risks associated with blood draws include: occasional slight discomfort associated with blood drawing and occasional hematoma (bruise) or infection at the blood drawing site. Rarely, a participant may experience fainting or dizziness.

Human Subjects Protection Training

All investigators and staff involved in this Project have undergone human subjects' protection training as specified by their individual organizations.

IRB Review and Oversight

The conduct of the Project will be periodically reviewed and overseen by the appropriate IRBs to ensure that human subjects are being adequately protected.

Quality Improvement Components – *Benefits for the Practice*

1. Feedback on performance at baseline and throughout the intervention period.
2. Benchmarking comparisons of performance to other clinicians/practices in the project.
3. Updates on latest evidence and guidelines.
4. Clinical Decision Support Tools (e.g. algorithms, one-pagers, summaries).

5. Insights from and opportunities to interact with high performing clinicians/practices.
6. Access to increased testing for their own staff and patient population.
7. A Practice Facilitator to assist with workflow redesign and quality improvement efforts.
8. Assistance developing and implementing electronically-generated quality reports in practice workflow.
9. Opportunities to contribute to communitywide healthcare improvement initiatives.

Quality Improvement Components: *Benefits for Patients*

1. Improved access to decision support resources for COVID-19 screening, testing, and treatment.
2. Potentially better health outcomes.
3. Increased participation in decision-making regarding their health.

Project Evaluation (Research Component) Benefits

1. If the project is successful, it will improve the probability of future funding for similar types of assistance in the future.
2. Development of electronic data capture and reporting in EHRs will help clinicians/practices and health systems with continuous quality improvement.

L. Multiple Sites

Not applicable.

M. Statistical Methods

Descriptive statistics and qualitative summaries will be reported to summarize implementation process measures (type, dose, frequency, and sequencing of provided support strategies) and the facilitators and barriers of implementation.
We will calculate descriptive statistics for all Aim 1 measures and will perform formal hypothesis testing to compare pre- versus post-implementation provider- level, care process, and patient-level outcomes at the patient and practice levels. In addition to this pre-post analysis, trends in testing rates will be explored. A mixed effects linear regression model will be fit to explore changes in testing rates over time relative to the control period (0 months on intervention), accounting for correlation among repeated measures on the same practice and among practices nested within PFs will be accounted for using random effects.[38]

Descriptive statistics and qualitative summaries will be reported to summarize the facilitators and barriers to implementation. We will calculate descriptive statistics for all Aim 2 measures. County-wide initiatives to amplify community- based testing that are initiated by CHIOs will be descriptively summarized as a function of county, region, and time period. Patient Survey data and program implementation process observations will be used to understand the influence of internal and external contextual factors on the success of community-based testing events. For qualitative data analyses, we will use software-assisted (NVIVO v12) content analytic techniques. Key informant interviews will be transcribed and evaluated by at least two independent coders. Initial codes will be compared across evaluators and emergent thematic categories will be argued to consensus and graphically represented for a better understanding of their meaning and relationships. Although much of the interviews will be guided by a solid understanding of well-known facilitators and barriers to testing, we will be intentionally open to new or unexpected qualitative findings. A subset of the transcripts (10%) will be chosen at random and coded by another researcher to achieve an inter-rater reliability kappa of at least 90%.[39-40] Disagreements on codes will be resolved by discussion. We will take steps to minimize

potential bias[41] including conducting regular debriefs with members of the evaluation team. To better understand perceptions of the utility, effectiveness, and generalizability of the CATCH-UP program, detailed PF implementation notes will be summarized and analyzed according to the domains of the program model.

N. Data and Safety Monitoring Plan

Please note that confidentiality of the data in this Project will be safeguarded in accordance with the General Policy for Security and Access of University of Oklahoma School of Community Medicine. OU IT has implemented mechanisms to protect the privacy and security of all university data. OU-Tulsa's computer network, file servers, and network storage arrays are secured through role-based access control restricting users' access based upon their roles and responsibilities to prevent unauthorized access. Servers and network storage arrays are also physically and virtually secured and routinely monitored and backed up. University work-stations and terminals are secured by requiring domain membership and user authentication by logging in with a unique user ID and password for access, and log off or lock-down their station if the individual is absent/idle for more than 10 minutes. Passwords must comply with OUHSC Password Security policy and procedures.

O. Data Sharing

We are confident that we can most effectively disseminate the methods, products, and results of this initiative within Oklahoma and nationally. This will occur through both formal and informal mechanisms. We commit to a rigorous collaboration with other RADx-UP sites through our Consortium Data Reporting Unit in order to ensure our interim findings are disseminated rapidly to benefit other projects. We agree to review and provide timely feedback to NIH staff regarding materials they produce about this project. We will also provide high- level quarterly reports on the progress of our project and program to NIH and CDCC, and we will share any products we develop (e.g. results, publications, tools, etc.) for inclusion in NIH initiative descriptions. Finally, we agree to share our methods, results, and products with NIH, and other awardees and make our data available through a Data Use Agreement with other interested researchers.

While meeting the formal definition of a clinical trial, it is a Dissemination and Implementation Research study to assist primary care practices to effectively implement established guidelines and best practices. The project PI and the Regulatory Coordinator will submit the study to ClinicalTrials.gov to determine if the study should be listed to meet Federal requirements. In the event this study will be required to be registered, we will complete registry prior to enrolling the first participating practice. Once a record is established, the PI and the leadership team will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. The PI and the leadership team will be responsible for aggregate results reporting at the conclusion of the project and AE reporting. All reporting and submission of results will occur within the timeframes in the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Note, informed consent documents for this study will include a specific statement relating to posting of this trials information and results at ClinicalTrials.gov.

P. Confidentiality

Efforts will be made to keep practice, clinician, and staff personal information confidential. Participants will not be identifiable by name or description in any reports or publications about this Project. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Data will be stored for a minimum of 10 years. No one outside of the research team will have access to the Project data. Survey data and performance measurement data will be entered into REDcap. Paper copies of surveys and signed consent forms will be stored in a research storage room in the OU-Tulsa Schusterman building behind two locks, a locked office door and a locked drawer.

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