Implementation of COVID-19 Testing Strategies in Community Health Centers

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I. BACKGROUND AND SIGNIFICANCE

a. Historical background

Stark disparities in COVID-19 incidence and mortality have emerged, with disproportionately more cases among Latinos and deaths among Blacks. Missing race data for almost half of COVID cases likely masks the full extent of the disparities. These patterns are not surprising- communities with high poverty rates, high population density, and crowded housing are at high risk. Many racial/ethnic minorities and low-income individuals are over-represented in essential jobs that increase exposure to the virus. Individuals experiencing housing insecurity and homelessness are another subset of the population with disproportionately high rates. The condition of homelessness creates the potential for rapid transmission of SARS-CoV-2. Programs focusing on individuals experiencing homelessness to date have focused on PCR testing, and the role of rapid COVID testing has not been systematically explored. Furthermore, testing efforts have focused on shelters rather than in-person outreach. Strikingly inequitable patterns of COVID disease burden highlight the urgent need for improved testing, more accessible testing, surveillance and monitoring, data transparency, and interventions that address the material circumstances in which people live and work.

The nation's CHCs provide care for 28 million patients, and their importance for serving vulnerable populations cannot be overstated. CHCs care for one in three people living in poverty, one in seven racial/ethnic minority individuals, and one in five individuals on Medicaid or who are uninsured[3]; 82% of CHC patients are uninsured or publicly insured, and over 90% are within 200% of federal poverty level (FPL). CHCs must address some of the most vexing problems impacting health equity, including social needs. CHCs provide higher quality care compared to national averages and have higher rates of patient satisfaction[4]. In the pandemic, CHCs have had a crucial role in using their infrastructure and trust to engage their communities and have been much more effective at gathering race/ethnicity data than states overall (missing data rates under 20%[5]).

b. Previous pre-clinical or clinical studies leading up to, and supporting the proposed research

Our research team has worked closely with MA CHCs for years, and in the context of our P50 developed a network of centers focused on health equity. We will leverage these strong relationships to increase COVID testing in 9 vulnerable communities with 6 community health center partnerships that have among the highest COVID cases in MA (mean positivity rates Mar-June: 17% - 36%). MA CHCs have been actively involved in testing and contact tracing. However, despite the rapid deployment of testing in the CHCs, there continue to be significant concerns about testing rates overall and access among vulnerable residents.

c. Rationale behind the proposed research, and potential benefits to patients and/or society

Barriers to testing including data sharing fears, possible lost wages if one tests positive, confusion about the need for continued testing in the prolonged epidemic and deepening social needs. These barriers have not yet been systematically addressed; doing so will be key to accelerating COVID testing in hot spot communities.

We will study the implementation of community-derived strategies for increasing COVID testing in 9 communities with among the highest COVID positivity rates in MA. This work will help us understand

how to increase testing among marginalized communities, that have been significantly affected by COVID.

The MGH specific supplemental work will be focused on developing, implementing and evaluating a community-partnered infrastructure that will increase access to COVID-testing among individuals experiencing homelessness, a marginalized community and those who experience housing insecurity.

II. SPECIFIC AIMS (Research Objectives)

a. Specify objectives and hypotheses to be tested in the research project

This project is part of a competitive revision that aims to accelerate COVID-19 testing in underserved populations. The overall aim is to accelerate COVID testing in 9 hotspot communities in MA, through 6 community health center (CHC)-community partnerships. These CHCs have 141,000 patients, and their communities have over 1.3M residents. The implementation of a*ccelerated testing efforts will be focused on CHC patients and community members who have significant social and medical vulnerabilities to COVID, including those living in congregate housing, people experiencing homelessness, those with substance use disorders, low wage essential workers, and those with limited English proficiency.* The partnership is well-integrated into the State's testing and contact tracing strategy and leverages those resources. We will support the CHC-community partnerships through a team of community health and infectious disease expertise with technical guidance on COVID testing. We have an established partnership with the Massachusetts League of Community Health Centers to support this community-engaged, equity-focused approach to implementation of COVID-19 testing strategies. This is a multi-project research center. The aim of the project proposed here is:

1. **Create and implement a community-partnered infrastructure that will accelerate COVID-testing and contact tracing among underserved and vulnerable populations in nine "hotspot" communities as measured by change in testing rate and equity in testing (by race/ethnicity).** We will use a controlled interrupted time series design to evaluate the impact of enhanced outreach and capacity building on testing rates and contact tracing overall and on priority populations compared to a set of matched control clinics. The point-of-care COVID diagnostics will focus on the four MGH Health Center communities which fall in the aforementioned nine "hotspot" communities.

2. **Determine the impact of key implementation process strategies, such as tailored communication and outreach, on testing among LEP and other priority populations.** We will add tailored strategies based on barriers faced by priority populations within partner communities to the outreach and capacity building strategies in Aim1 and measure the impact of the tailored strategies using a stepped wedge design.

3. Develop, implement and evaluate a community-partnered infrastructure that will increase access to COVID-testing among individuals experiencing homelessness.

This project is part of a competitive revision that aims to accelerate COVID-19 testing in underserved populations. Building on the existing mobile COVID testing program, this sub study at MGH will organize a dyad team (one mobile team clinician and one community health worker). This team will conduct outreach in the neighborhoods of Chelsea, Everett, Revere, Lynn, and Boston that have a high rate of unsheltered individuals for four hours per week and offer rapid COVID testing to any undomiciled individuals encountered. This street outreach will use Boston Health Care for the Homeless Program's established street outreach methods. The dyad team will also co-locate in high foot-trafficked areas such as food pantries during a testing session to build trust through their collaboration with community-based organizations. The consistent team will establish rapport over time with the individuals, offer a small incentive for engagement and complete the Abbott BinaxNOW or Acon Laboratories FlowFlex, rapid antigen tests in real-time. Compared with real-time RT-PCR testing, the BinaxNOW antigen test had a sensitivity of 64.2% for specimens from symptomatic persons and 35.8% for specimens from asymptomatic persons, with near 100% specificity in specimens from both groups. The FlowFlex antigen test had a sensitivity of 93% for specimens from symptomatic persons and 92% for asymptomatic persons, with near 100% specificity in specimens from both groups.

The mobile team clinician will relay the result of the rapid test with appropriate counseling, on isolation or continued preventive measures. Simultaneously, a PCR test will also be offered to the patient and contact information will be secured to be able to relay the result of that test in 24 hours. If team is unable to reach individual by phone, team would try to locate the individual in the community to share instructions if positive. The result RN who is part of the mobile COVID testing van will relay the result of the PCR test. The mobile COVID Testing Van community health worker will follow up with any individual who tests positive on the rapid test and / or on the PCR COVID tests and offer connections and resources to social support services including an isolation facility. We will use an interrupted time series design to evaluate the impact of enhanced outreach and capacity building on testing rates and contact tracing overall and on priority populations compared to a set of matched control clinic.

III. SUBJECT SELECTION

a. Inclusion/exclusion criteria

We planned to use a controlled interrupted time series in the original design, comparing number of tests, its trend over time, and testing in respond to surges in covid infections, across the participating CHCs with matched comparison CHCs in MA for which data is available. But, an appropriate control time series was not found. The participating sites constitute one group; a set of matched CHCs that will conduct testing as usual constitute the second group.

Participants are patients at the partner CHCs or members of the local community. They could be approached for COVID testing anytime during the 2-year study period. We anticipate that the 6 CHC partnerships will test at least 76,300 community members during the study period. We estimate the MGH CHCs will test 18,000 community members through their clinic-based testing and a mobile testing van serving these communities. For the sub study at MGH, the inclusion criteria will be individuals experiencing homelessness or housing insecurity, as identified by service engagement.

b. Source of subjects and recruitment methods

We are studying the impact of the process of implementing a COVID testing expansion strategy in CHCs. We will not be enrolling individual participants receiving testing services.

IV. SUBJECT ENROLLMENT

a. Methods of enrollment, including procedures for patient registration and/or randomization
No individual patients will be enrolled.

CHCs will undergo randomization in the stepped wedge pilot with randomization of sites to one of three start time-points and the two CHCs randomly assigned to each start time-point we will randomly assign them to two alternative implementation strategies.

b. Procedures for obtaining informed consent (including timing of consent process)

Obtaining individual consent from thousands of individuals outreached as part of the testing expansion strategy implemented at the CHCs would not be feasible. The study poses no more than minimal risk given the protocols we have to minimize risks to confidentiality including de-identification of data before sharing it with the research data coordinating unit to remove or mask identifiers including both personal identifiers and membership in small and potentially eligible groups. Patient level data includes only data collected as part of routine care to understand who is reached with available testing services and how clinical services can be improved through linkage with social services or health education. The data elements are detailed below; briefly they include COVID test registration and results, electronic health record data, assessment of membership in priority populations including language, socioeconomic status and other social determinants of health, ease of accessing testing and vaccine beliefs.

c. Treatment assignment, and randomization (if applicable)
In the tailored implementation strategies (Aim 2 strategies for LEP and other priority groups) being tested with the stepped wedge design, CHCs will be randomly assigned to one of three implementation start months. Random order assignment will be determined by the evaluation team led by Dr. Dan Gundersen at DF/HCC.

In the MGH sub study focused on testing individuals experiencing homelessness, there will be no treatment assignment or randomization. Every individual who meets criteria of homelessness or housing insecurities will be offered a test.

For implementation evaluation purposes, the CHCs will collect a sample of data from test participants as part of their testing workflows to understand who is reached through implementation strategies. A minimum of 50 test participants or 5% of test participants per month will be randomly selected and invited to complete a survey. The randomization will vary by CHC with some CHCs randomly selecting days to collect additional data on test participants or a frameshift approach in which every N^{th} test participant is invited, depending on what aligns

with local workflows. This data is collected by CHC staff and linked with patient EHR data by the CHCs and de-identified before sharing with the project data coordinating center.

V. STUDY PROCEDURES

a. Study visits and parameters to be measured (e.g., laboratory tests, x-rays, and other testing)
Study procedures consist of engaging community health center and community partners in implementing a testing strategy to outreach underserved populations. Engagement will consist of meeting with the study implementation team to tailor the overall testing strategy to local workflows and populations, for example COVID-19 wastewater surveillance collected in Chelsea, Massachusetts, which is one of the "hotspot" communities, will be used to tailor the testing strategy in that particular community by directing the location of the mobile testing van to where there are signals of viral shedding from wastewater data. As another example, engaging different staff (CHWs versus medical assistants) depending on local staffing structures and delivering materials in the languages of the populations they serve. Specific activities will include coaching calls and training.

Recruitment plan for the MGH sub study focusing on individuals experiencing homelessness will include working with health promoters who already provide social services in the community to identify potential participants. Co-location with food pantries and near the Office of Veterans Affairs will further guide identification of participants. Target population will be individuals who are undomiciled at time of test. Coaching calls will not be done as part of the sub study.

Coaching calls: Coaching calls with the implementation research team on use of quality improvement tools (workplan development, audit and feedback methods, plan do study act [PDSA] cycles, process mapping, and workflow analysis) and data collection methods. Coaching will also support partnering with local community organizations to engage priority populations in testing. Calls will be monthly with and biweekly email communications at a minimum, with additional coaching based on CHC's needs.

Training: Training topics include workflow analysis methods, COVID epidemiology, testing technology, local/state testing policies, disparities, stigma and discrimination, and cultural competency. Trainings will be delivered in meetings with the study implementation team and via listserv which includes participating CHCs.

b. Drugs to be used (dose, method, schedule of administration, dose modifications, toxicities), include Toxicity Grading Scale (if applicable)
None

c. Devices to be used
Testing will be done with normal CHC testing workflows with the addition of testing capacity made available by the Broad Institute for RADx-UP recipients, and rapid antigen testing made available from the state, the Abbott BinaxNOW and Acon Laboratories FlowFlex antigen tests. The Broad Institute is making available a self-administered anterior nares PCR testing option for RADx-UP awardees.

d. **Procedures/surgical interventions, etc.**
None

e. **Data to be collected and when the data is to be collected**
Data is collected using two clinical/population health systems: 1) the Data Reporting and Visualization System (DRVS) which works with federally qualified health centers, it maps data elements from EHRs to the DRVS for reporting purposes and population health, and 2) MGH CHC data will be collected as part of routine care in the testing process at the Chelsea CHC testing site and the MGH mobile testing van serving the MGH CHC communities via Epic reports and RPDR. As part of the implementation efforts, CHCs will also collect data among test participants that is intended to supplement EHR data as part of routine care such as testing accessibility and social determinants of health, data intended to improve the quality and equity of testing services offered. The method of data collection may vary between CHCs depending on their testing workflows. The methods will include paper survey, phone call or online tools (e.g. REDCap survey or Google docs) depending on the CHCs data management and security practices, at time of testing. The MGH mobile testing van will collect data via Microsoft Teams. All CHCs will collect this supplemental data from a sample of test participants (minimum of 5% of monthly test participants or 50 test participants per month). Sites doing this data collection will offer an incentive for completing the survey for the additional time spent by patients outside of the test site activities. The incentive will be a $25 gift card. Gift cards will be available on-site at the CHCs for the patients to pick up or sent by mail.

This supplemental data will be linked with patients' EHR data internally by each CHC or by the Mass League of Community Health Centers based on established data sharing practices. All data will be deidentified before sharing with the research center data coordinating unit. The data elements include: demographics (age, gender, race, ethnicity, sexual orientation, preferred language), socioeconomic status (insurance, educational level, zip code), symptoms (fever, cough, dyspnea, fatigue, sore throat, headache, myalgia, new loss of taste or smell, runny nose or nasal congestion, nausea, vomiting, diarrhea, rash), job status (employed/unemployed) and job characteristics (essential worker), household characteristics (number of people living in the home), social needs (housing instability, food insecurity), disability status, existing primary care site, personal impacts of COVID, ease of testing access, COVID vaccine beliefs, COVID vaccine status, vaccine type, and vaccine date (MGH dates masked before sharing). Medical history and comorbidities that alter COVID-19 risk (chronic kidney disease, chronic lung disease, on immunocompromising medications, obesity [BMI>30], heart disease, CD4 count < 200, sickle cell disease, type 2 diabetes, smoking status) and details of COVID tests (test type [PCR vs. antigen], Ct values for PCR testing, time to return of results, test result) will also be collected the CHC data reporting systems for those who are CHC patients.

Under a data use agreement, we will also obtain data from the Center of Complex Interventions, a non-profit organization that performs COVID-19 wastewater surveillance in one of the "hotspot" communities being targeted in our testing efforts. Data will be analyzed internally at MGH and will not be shared with the data coordinating center at Dana Farber. Data will be sent to us using a secure file transfer service. It will include geographical information about the location of wastewater sampling sites, which are smaller than a state but larger than a specific address. Data will also include wastewater analysis reports, which include the raw concentration

of SARS-CoV-2 virus in the samples (copies of virus/ml) and the normalized concentration of the virus in samples. The partnering CHCs will also participate in monthly individualized implementation facilitation support. These calls will be recorded, and qualitative field notes will be collected for each meeting and stored in REDCap.

VI. BIOSTATISTICAL ANALYSIS

a. Specific data variables being collected for the study (e.g., data collection sheets).

As part of routine care in the testing process, CHCs will collect demographics (age, gender, race, ethnicity, sexual orientation, preferred language), symptoms (fever, cough, dyspnea, fatigue, sore throat, headache, myalgia, new loss of taste or smell, runny nose or nasal congestion, nausea, vomiting, diarrhea, rash), socioeconomic status (insurance, educational level, zip code), job status (employed/unemployed) and job characteristics (essential worker/non-essential worker), household characteristics (number of people living in the home,), social needs (housing instability, food insecurity), existing primary care site, ease of accessing testing, disability status, personal impacts of COVID,COVID vaccine acceptance, COVID vaccine status, vaccine type, and vaccine date (MGH dates masked before sharing). In Chelsea, Massachusetts where COVID-19 wastewater surveillance data is being used to direct mobiles testing efforts, individual addresses will be collected for the purpose of determining which wastewater sampling site (i.e. "sewershed" area) they fall into. Individual addresses will be analyzed at MGH and this data will not be shared with the data coordinating center at Dana Farber. Medical history and comorbidities that alter COVID-19 risk (chronic kidney disease, chronic lung disease, on immunocompromising medications, obesity [BMI>30], heart disease, CD4 count < 200, sickle cell disease, type 2 diabetes, smoking status, immunocompromised condition, autoimmune disease, hypertension, cancer, abdominal pain) will be collected in the CHC data reporting systems for those who are CHC patients.

An additional analysis will be conducted of patients that were tested for COVID-19 at MGH Chelsea between November 2020 and March 2021 to understand how COVID-related risk factors (obesity and smoking status) may vary by race, gender, ethnicity and language. This analysis will utilize the same dataset listed above; no other data variables will be included.

The following data elements will be collected at each CHC as part of routine care to supplement EHR data. At MGH CHCs this is collected using an online REDCap survey or paper version of the REDCap survey. The paper REDCap survey will be entered into REDCap by a member of the research team. Federally qualified CHCs will use data collection methods (paper survey, online survey, phone) consistent with their usual care workflows for patient data collection aiming to improve clinical processes and understand the reach of services offered:

- Do you speak a language other than English at home? What languages?
- What is the highest level of education you have achieved outside or in the US?
- Including you, how many people live in your household?
- Are you currently living in transitional housing, staying in a shelter, or experiencing homelessness?

- Have you, or has anyone in your household experienced a loss of employment income since the start of the COVID-19 pandemic (March 2020)?
- Are you considered an essential worker? An essential worker is someone who was required to go to work even when stay at home orders were in place.
- Do you have a disability that interferes with your ability to carry out daily activities? Examples of daily activities include walking, climbing stairs, shopping, balancing a checkbook, bathing or dressing.
- It is easy to get tested for COVID-19.
- How likely are you to get an approved COVID-19 vaccine when it becomes available.
- Why would you get a COVID-19 vaccine?
- Why would you NOT get a COVID-19 vaccine?

Specific data to be collected through the individualized implementation support meetings with CHC staff will include details of their expanded testing strategy, populations reached, successes, challenges, how they are addressing equity and ways the implementation research team can support their site.

The data collected for the MGH sub study will not be shared with data coordinating center at Dana Farber.

b. Study endpoints

The primary outcome will be total number of daily and weekly tests. Secondary outcomes will include time to return of results, number of positive tests, completion of contact tracing, number of hospitalizations, intensive care admissions, and deaths. We will examine outcomes related to key socio-demographic and clinical covariates.

VII. RISKS AND DISCOMFORTS (Stratify by common and uncommon)

The only foreseeable risk would be loss of confidentiality. Individual addresses will be used for internal analysis at MGH for the purpose of mapping them to ”sewershed” areas where COVID-19 wastewater surveillance is conducted. However, no identifiers will be shared, and thus this is not a risk that will be associated with the research.

At the point-of-testing, data will be collected by CHCs. This data will include information about social determinants of health, and this may cause psychosocial distress in some participants. Capacity building activities will include supporting testing staff to identify distress and link patients with appropriate clinical follow-up by CHC providers.

a. Complications of surgical and non-surgical procedures, etc. None
b. Drug side effects and toxicities None
c. Device complications/malfunctions None
d. Psychosocial (non-medical) risks
e. Radiation Risks (statement provided by Radiation Safety Committee) None

VIII. POTENTIAL BENEFITS

a. Potential benefits to participating individuals

It is hoped that the co-designed testing expansion strategy will increase the accessibility and acceptability of SARS-CoV-2 testing among underserved populations. Expanded testing may have benefits to individuals within those communities in stopping the spread of SARS-CoV-2.

b. Potential benefits to society (e.g., increased understanding of disease process, etc.)

Potential benefits to society included an increased understanding of testing strategies in vulnerable and underserved communities with high incidence and low-test rates. Expanding testing will lead to stopping the spread of SARS-CoV-2.

IX. MONITORING AND QUALITY ASSURANCE

a. Independent monitoring of source data

The PI (Taveras) will monitor data integrity and adherence to the protocol. All staff will be trained in study procedures prior to working on the study. Completeness of the data from the CHCs data reporting systems will be monitored monthly as described above.

b. Safety monitoring (e.g., Data Safety Monitoring Board, etc.)

The Implementation Science Center for Cancer Control Equity (ISCCCE) has partnered with the develop of the Data Reporting and Visualization System (DRVS) used by all of the federally qualified health centers in the project and has established data sharing procedures through a Service Agreement with the centers data coordinating center led by Dan Gundersen at DFCI/HCC (Harvard IRB2-0988). The DRVS system has detailed data on all who were tested by all 52 CHCs in MA since March. We will combine data from DRVS on the five partner FQHCs, six control CHCs, and the MGH CHCs (Chelsea, Charlestown, Everett and Revere) that will similarly de-identified before sharing with the data coordinating center at DFCI/HCC. Data fields are described above and will include demographics, COVID test ordered, the test result, COVID symptoms, vitals, comorbid conditions, ease of testing, impacts of COVID, vaccine beliefs, and social needs. For non-patients who are tested by the CHC, at a minimum CHCs collect demographics, tests ordered, results, and symptoms. The MGH mobile testing van will collect the data fields mentioned above via Microsoft Teams. We have developed a rigorous data extraction and management protocol as part of the ISCCCE center and will adapt it to accommodate additional data being collected as part of this project. MGH investigators will support data extraction and safety from our institutional data systems and will de-identify the data before sharing with the data coordinating unit. The Mass League of Community Health Centers will work with the DRVS and the FQHCs to ensure data quality and safety per their internal procedures and regulations and will de-identify the data before sharing with the data coordinating unit. We will produce summary statistics to inspect for unexpected values and data completeness from both MGH and DRVS data each month. The data coordinating center will then clean the data and merge with existing organizational level data on the CHC organizational characteristics to produce an analytic file.

As part of the data de-identification, dates will be masked with a date shift. The shift will be different for the MGH data and the DRVS data from the federally qualified data. The date shift will be shared with the data coordinating center lead, Dr. Gundersen at DF/HCC, to enable comparison in the time series analysis. In this way neither MGH or DRVS will have access to each other's dates. This masking process will be detailed in data use agreements between MGH and the data coordinating center at DF/HCC and between DRVS and the data coordinating center and DF/HCC.

Study staff will maintain a regulatory binder. At each study team meeting we will discuss any data or safety issues that have arisen, and a culture of openness about such concerns will be created. We will submit any study protocol changes to the IRB in real time and assure that approval is received before changes are implemented.

c. Outcomes monitoring

The grant funding this project requires a Human Participant Research Unit (HPRU), which includes a team of ethicists who will pay particularly attention to equity issues in monitoring study outcomes and review all aggregate monitoring data and provide recommendations for addressing any concerns that are identified.

d. Adverse event reporting guidelines

We do not anticipate any adverse events. However, these will be appropriately monitored and reported as required. If there appear to be concerns that we do not anticipate, we will work with the IRB to develop appropriate mitigating strategies.

X. REFERENCES

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