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# Implementing expanded COVID-19 testing in Massachusetts community health centers through community partnerships: Protocol for an interrupted time series and stepped wedge study design

Gina R. Kruse<sup>a,b,\*</sup>, Leslie Pelton-Cairns<sup>c</sup>, Elsie M. Taveras<sup>b,d,e</sup>, Susan Dargon-Hart<sup>c</sup>, Daniel A. Gundersen<sup>f</sup>, Rebekka M. Lee<sup>g,h</sup>, Barbara E. Bierer<sup>b,h,i</sup>, Erica Lawlor<sup>b,h</sup>, Regina C. LaRocque<sup>b,j</sup>, Julia L. Marcus<sup>k</sup>, Madeline E. Davies<sup>d</sup>, Karen M. Emmons<sup>g,h</sup>, The RADx-MA Partnership<sup>1</sup>

<sup>b</sup> Harvard Medical School, Boston, MA 02114, USA

<sup>d</sup> Massachusetts General Hospital, Kraft Center for Community Health, Boston, MA 02114, USA

<sup>e</sup> Massachusetts General Hospital, Division of Academic Pediatrics, Boston, MA 02114, USA

<sup>f</sup> Dana Farber Cancer Institute, Division of Population Sciences, Boston, MA, USA

<sup>g</sup> Harvard T.H. Chan School of Public Health, Department of Social and Behavioral Sciences, Boston, MA, USA

<sup>h</sup> Harvard Catalyst | The Harvard Clinical and Translational Science Center, Boston, MA, USA

<sup>i</sup> Brigham and Women's Hospital, Boston, MA, USA

<sup>j</sup> Massachusetts General Hospital, Division of Infectious Diseases, Boston, MA 02114, USA

<sup>k</sup> Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

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## ABSTRACT

*Background:* Community Health Centers (CHCs) are a critical source of care for low-income and non-privately insured populations. During the pandemic, CHCs have leveraged their infrastructure and role as a trusted source of care to engage the communities they serve in COVID-19 testing.

*Methods*: To directly address the impact that COVID-19 has had on historically marginalized populations in Massachusetts, we designed a study of community-engaged COVID-19 testing expansion: (1) leveraging existing partnerships to accelerate COVID-19 testing and rapidly disseminate effective implementation strategies; (2) incorporating efforts to address key barriers to testing participation in communities at increased risk for COVID-19; (3) further developing partnerships between communities and CHCs to address testing access and disparities; (4) grounding the study in the development of a shared ethical framework for advancing equity in situations of scarcity; and (5) developing mechanisms for communication and science translation to support community outreach. We use a controlled interrupted time series design, comparing number of COVID-19 tests overall and among people identified as members of high-risk groups served by intervention CHCs compared with six matched control CHCs in Massachusetts, followed by a stepped wedge design to pilot test strategies for tailored outreach by CHCs.

*Conclusions*: Here, we describe a community-partnered strategy to accelerate COVID-19 testing in historically marginalized populations that provides ongoing resources to CHCs for addressing testing needs in their communities. The study aligns with principles of community-engaged research including shared leadership, adequate resources for community partners, and the flexibility to respond to changing needs over time.

\* Corresponding author at:16th Floor, 100 Cambridge Street, Boston, MA 02114, USA.

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<sup>&</sup>lt;sup>a</sup> Massachusetts General Hospital, Division of General Internal Medicine, Boston, MA 02114, USA

<sup>&</sup>lt;sup>c</sup> Massachusetts League of Community Health Centers, Boston, MA 02114, USA

E-mail address: gkruse@mgh.harvard.edu (G.R. Kruse).

<sup>&</sup>lt;sup>1</sup> RADx-MA Partners listed in Acknowledgements

# 1. Background

Predictable patterns of COVID-19 incidence, morbidity, and mortality have emerged worldwide during the COVID-19 pandemic. In the United States, COVID-19 infection rates have been higher among Black and Latino persons compared with white persons [1,2], with especially high risks of disease incidence and severity in subgroups experiencing poverty [3]. These inequitable patterns of COVID-19 disease burden have highlighted the urgent need for improved testing, surveillance and monitoring, data transparency, and tailoring of public health interventions to the circumstances in which people live and work, with particular attention to historically marginalized communities.

Community Health Centers (CHCs) are a critical source of medical care for persons of low-income and persons who are uninsured or underinsured. Federally qualified CHCs are federally mandated to serve all who seek services, regardless of ability to pay. At their inception, CHCs were designed to reduce health disparities that affect people who are uninsured, living in poverty, and racial and ethnic minoritized groups [4]. The nation's CHCs provide care for 28 million patients, including one in three people experiencing poverty, one in seven people from racial and ethnic minority groups, and one in five people who are on Medicaid or uninsured; 82% of CHC patients are uninsured or publicly insured, and over 90% are within 200% of the federal poverty level (FPL) [5,6]. CHCs are ideally positioned to address some of the most vexing problems impacting health equity, including COVID-19.

During the pandemic, CHCs have used their infrastructure, services, and role as a trusted source of information to engage the communities they serve. Their position in the community also means that CHCs are a powerful force in promoting health equity, social justice, community pride, and resilience. To meet the needs of their communities, by October 2020, 97% of CHCs across the US had implemented COVID-19 testing services [7]. We designed a study that aims to expand COVID-19 testing in collaboration with Massachusetts CHCs that serve populations highly impacted by the pandemic. To achieve this goal, we are building upon strong existing partnerships, developing an ethical framework to advance health equity, developing mechanisms for communication and science translation for community outreach, and using practice facilitation and technical assistance to accelerate COVID-19 testing and rapidly disseminate strategies found to be effective.

In this manuscript, we outline our protocol for an NIH-funded Rapid Acceleration of Diagnostics in Underserved Populations (RADx-UP) project [8]. We recognize that underserved is not a preferred term in inclusive communication here but use it in places to reference this funding mechanism. This project aims to implement expanded COVID-19 testing among CHCs in Massachusetts using a community-engaged approach (RADx-MA).

# 1.1. Overall approach

Our aim is to accelerate COVID-19 testing among CHC patients and community members who are medically underserved or historically marginalized, including those living in congregate housing, people experiencing homelessness, and low-wage essential workers. We support the CHC-community partnerships through: 1) a Testing Capacity and Innovation Team, which provides infectious disease expertise and technical guidance on COVID-19 testing; 2) a Community Communications Team that uses educational and communication design strategies to develop culturally and linguistically appropriate materials to support pandemic response outreach activities; and 3) a community-engaged, equity-focused approach to implementation supported by the Massachusetts League of Community Health Centers (MA League). The MA League is the Primary Care Association for health centers in Massachusetts. They support and assist with communication, workforce development, technical assistance and advocacy for health centers and the communities they serve. This collaborative design brings together MA League's expertise in implementation and quality improvement programs, community-engaged research principles, and the tools of implementation science applied through an equity lens to support CHCs.

Our main hypothesis is that strengthening CHC-community partnerships through equity-focused implementation efforts, involvement of local advisory groups, and community outreach communications will increase volume of COVID-19 testing in underserved populations. RADx-MA has three specific aims:

- 1. Create and implement a community-partnered infrastructure that will accelerate COVID-19 testing in six CHCs that serve nine communities.
- 2. Conduct a series of community-engaged pilot studies to address key barriers to testing through communications and outreach.
- 3. Create a Human Participant Research Unit (HPRU) to guide the partnership's work through an ethics and equity lens.

This two-year project started in September 2020. Here we present our research protocol, including our early experiences, challenges, and successes with the implementation of intervention activities.

# 2. Methods

This study aims to accelerate COVID-19 testing in communities that are highly affected by the pandemic through six CHC-community partnerships in Massachusetts. This includes five federally-qualified health centers and one group of CHCs licensed by an academic medical center that itself serves four communities [9]. The RADx-MA CHCs care for 141,000 patients, and their surrounding communities have over 1.3 million residents. The study is supported by our Implementation Science Center for Cancer Control Equity (ISCCCE, National Cancer Institute #5P50CA244433), a collaboration with the MA League. ISCCCE supports an implementation laboratory (iLab) of partnerships with Massachusetts CHCs to support community-engaged implementation science research. ISCCCE also partners with Azara Healthcare, creator of a population management platform, the Data Reporting and Visualization System (DRVS), that is used by CHCs across Massachusetts and nationally. DRVS enables rapid data aggregation and reporting, including the capture of COVID-related data across the different electronic health records in use by Massachusetts CHCs. The study was approved by the Mass General Brigham Institutional Review Board (Protocol #2020P003743) and registered in ClinicalTrials.gov (NCT04802187).

## 2.1. Conceptual model

Our work is guided by the Consolidated Framework for Implementation in Research (CFIR), adapted to incorporate an equity lens [10]. Equity focused constructs are incorporated at each CFIR domain: intervention characteristics, processes, individual characteristics, and inner and outer setting measures. The CFIR framework is paired with implementation outcomes, service outcomes, and client outcomes specified using Proctor's outcomes model [11]. The framework developed from CFIR and the Proctor model informs the CHC- and area-level data that we collect from the six RADx-MA CHCs (Fig. 1).

## 2.2. Sample

RADx-MA CHCs serve communities at increased risk for COVID-19 that were highly impacted by the initial surge in Massachusetts (late summer 2020). In June 2020, prior to the start of this project, the six CHCs were conducting between 150 and 500 tests per week with positivity rates of 17% to 36% (Table 1). The CHCs identified populations at increased risk of COVID-19 who faced barriers to testing in summer 2020, including essential workers, people with limited English proficiency, immigrant populations, people who are incarcerated or formerly incarcerated, people facing housing instability or homelessness, seniors in congregate housing, people with substance use disorders, and those in



Fig. 1. Health Equity Informed Implementation Factors\* (Consolidated Framework for Implementation Research). \*Italicized bullets indicate health equity factors and outcomes added.

multigenerational homes. The six RADx-MA CHCs were matched with six control CHCs for the main outcome analysis. Matched clinics were selected purposively to be similar with respect to volume of patients 18 years and older, percent of patient population in racial or ethnic minoritized groups, and COVID-19 testing volume.

#### 2.3. Study team organization

We used a multiple principal investigator model, wherein two researchers and the lead of MA League share project leadership responsibilities. We collaboratively designed a study team structure to support the CHCs as they roll out accelerated testing efforts. The study team structure (Fig. 2) situates the CHCs and their community partners, which include community-based organizations and local government, as the key focal points. The Implementation Laboratory (iLab) is our implementation research unit, supporting organizational capacitybuilding, knowledge transfer, and technical assistance in addition to financial resources. The iLab team, including representation from the MA League and the investigator team, serve as practice facilitators who work to build capacity and support implementation of testing services and community partnerships through regular meetings with each CHC team. The iLab was designed with a central role for the MA League to leverage both their experience with implementation in CHCs as well as their role in pandemic-related advocacy and coordination as the CHC primary care association for the state. To facilitate knowledge transfer and technical assistance, the iLab hosts an online learning community through the MA League for RADx-MA partner CHCs to compare approaches, share successes, and distribute resources. Technical assistance is also provided for DRVS and study data collection. Each of the six RADx-MA CHCs receives \$300,000 in year one and \$75,000 in year two to support implementation and evaluation of testing expansion and development of community-partnerships with more funding in year one due to funding mechanism requirements. The six matched control CHCs participate in a data sharing agreement and receive \$3000 to facilitate data sharing.

#### 2.4. Initial rapid needs assessment

To inform our initial approach, we conducted a rapid organizational needs assessment, combining secondary data on community-level COVID-19 rates with CHC-level data gathered by videoconference with leaders at each of our six partner CHCs prior to grant submission. This initial CHC data included a description of current testing volume and positivity rates, populations at increased risk for COVID-19, community partners, and testing infrastructure (Table 1). This step was essential to understand the scope of work and planning that was already happening in the CHCs around COVID-19 testing prior to the RADx-MA project.

#### 2.5. In-depth community needs assessment

An in-depth needs assessment was conducted concurrently with the initial testing expansion efforts at study start. The in-depth needs assessment engaged CHC staff, community-based organizations, and residents to identify testing barriers in the external community setting (economic stability, social environment, employer and municipal policies, reopening phase, local resources), inner organizational setting (competing demands, culture, linguistic services, staffing), individual barriers (knowledge/beliefs about testing, perceived risks, stigma), testing workflow characteristics (complexity, adaptability, accessibility, cost, source), and processes (integrating testing into existing services and treatment for those infected, adapting testing processes to community contexts, and engaging stakeholders). One-on-one interviews with stakeholders were conducted in interviewee's preferred language, transcribed and translated. Transcripts were analyzed using a rapid framework analysis [12], guided by CFIR [10], to identify common actionable themes around barriers to testing [13].

#### Table 1

Pre-implementation test volume, positivity, and initial Rapid Needs Assessment findings.

CHC	Number of tests/ week*	Community positivity % **	Populations at increased risk for COVID-19	Specific testing barriers to be addressed Employment challenges, fear of visiting CHC, transportations				
А	150	17%	People with limited English proficiency (LEP)§, low wage essential workers					
В	350	25%	Immigrants, LEP, Latino business community, formerly incarcerated residents, homeless populations	Employment challenges, transportation, ability to quarantine, NP swab acceptability, testing hours				
C.	425	36%	Immigrants, LEP, low wage essential workers, senior housing	Transportation, accessibility (testing hours and geographic proximity), fear of visiting testing facilities in high prevalence communities				
D	500	26%	Immigrants, LEP, low wage essential workers, people with substance use disorders	Fears about cost and privacy, documentation, stigma, limited sick pay/time, transportation				
Е	200	17%	Immigrants and refugees, LEP, low wage essential workers, multi-generational homes	Employment challenges, transportation, unclear COVID-19 messaging, collective norms in religious communities, fear of being sick				
F	200	19%	Immigrants and refugees, LEP, low wage essential workers, multi-generational homes, homeless populations	Fear of visiting CHC, stigma, unclear COVID-19 messaging, transportation				

\* Month of June 2020; \*\* March – June 30, 2020; § Languages served by the six CHCs include Spanish, Vietnamese, Cape Verdean Creole, Khmer, Arabic. The academic medical center affiliated CHC testing site serves four communities, their positivity data is shown for the community in which the testing site is located. Abbreviations: CHC = community health center, LEP = limited English proficiency, NP = nasopharyngeal.

## 2.6. Community-partnered infrastructure

The community-partnered infrastructure design decisions were informed by the needs assessments, known predictors of COVID-19 testing access [14,15], and the populations at increased risk for COVID-19 who were known by the CHCs to have limited access to testing. For the selection of community partners, the CHCs were asked to consider which community-based organizations could best help them to address local barriers to testing. The organizations the CHCs initially selected to partner with for the study included faith-based organizations, food banks, shelters, YMCA/YWCA, transit and housing authorities, local health departments, immigration and refugee services, and groups supporting essential workers.

## 2.7. Testing acceleration plans

Each CHC was asked to implement expanded testing services, both on-site and off-site. On-site activities included expanded hours, walk-up testing services, expanded testing throughput, and enhanced services to overcome testing barriers, such as provision of resources to address social determinants of health or meet educational needs. Off-site activities included mobile or pop-up testing services with community partners or community outreach to encourage uptake of on-site testing services. These on- and off-site activities were designed to be flexible during the study to accommodate the shifting pandemic circumstances. To facilitate the optimal integration of each CHC's testing acceleration plan



Fig. 2. Organizational structure of the study team.

within the CHC-community partnership, the iLab team provided facilitation including workplan development, local technical assistance, linkage to resources and expertise for testing technology or community partnerships, and peer learning through calls with all six CHCs to compare workflows and share successes. The peer learning and individual CHC coaching calls were monthly in the first year and are quarterly in the second year. Coaching involves review of number of tests completed using the DRVS reporting capabilities to track the impact of implementation strategies.

## 2.8. Advisory groups

Two advisory group structures were developed to guide local and center-wide efforts: local community advisory groups (LCAGs) and a center-wide community advisory board (CWCAB). Each CHC developed an LCAG with representatives from their specific priority populations and the CHC. The LCAGs include a minimum of two patient representatives. Other members vary by CHC and include local board of health representatives and community organizations serving populations at increased risk for COVID-19 to support testing outreach. The governance structure for the LCAGs is designed to be flexible to fit existing structures and community needs. The LCAGs met monthly throughout the first year and are encouraged to adjust the meeting frequency in year two to match ongoing community needs. Two representatives from each LCAG participate in a Center-Wide Community Advisory Board (CWCAB) that meets quarterly. The CWCAB also includes members with statewide perspectives and resources (e.g., public health officials, representatives of community health workers, immigrant, and refugee advocacy groups).

## 2.9. Testing Capacity and Innovation Team (TCIT)

A Testing Capacity and Innovation Team (TCIT) provides infectious disease expertise, expert technical guidance, and ongoing support to the CHCs for expansion of community-based testing and identification of strategies to overcome testing barriers. The CHC's testing goals include COVID-19 testing in symptomatic and exposed individuals and 'surveillance-like' outreach testing in high-risk groups. TCIT provides ongoing expertise to identify emerging FDA-authorized/approved testing platforms to support testing expansion and ready access to infectious disease expertise.

# 2.10. The community communications team

Table 2

In partnership with CHCs, throughout the first year of the project, the Community Communications Team (CCT) developed communication materials to address the barriers identified in the needs assessments and by the LCAGs, translated relevant findings to the community, and created a collection of accessible resources in multiple languages. The CCT developed and maintained a network of translators to produce materials in English, Spanish, Portuguese, Haitian Creole, Vietnamese, and Arabic. The CCT aimed to identify the intersection among: (1) scientific findings; (2) the context in which community residents work and live; and (3) needs and barriers to testing as identified by community partners. From that intersection, the team extrapolates appropriate messaging to develop a series of relatable communication materials. The team identifies key learning outcomes and critical knowledge to incentivize testing, prevention, and mitigation. Using the Understanding by Design Framework [17], materials are designed by working backwards from the desired outcomes, beginning with a deeper understanding of the audience and specifying measurable goals. The CCT integrates feedback from community partners and end-users to maintain the currency of materials. The team used open-source materials from public health entities and others to speed material development. Materials are created in multiple formats to meet local needs (e.g., fliers, social media). In addition to creating materials in multiple languages, the CCT seeks input from the CHCs, LCAGs, and a team of translators on cultural appropriateness. Diverse levels of education are accommodated by use of visual content (e.g., digital flyers). While many of the individual gaps in knowledge address 'what people need to know,' barriers to testing as identified in the external community setting (e.g., economic stability, social environment, employer/municipal policies, reopening phase) and inner organizational setting (e.g., competing demands, networks/ communication, culture, linguistic services, staff capacity) also inform the design of these tools. Communication strategies used in the first year of the project are being evaluated by measuring information conveyed to the community, role of communication tools in support of each CHC network, and the intended behavior change. Specific metrics for this evaluation include number of people accessing the tools, health literacy review, web accessibility standards, scores using CDC Clear Communication Index [18], communication source (distributed by CHC or community partners), and CHC-reported assessment of communication tools and COVID-related community outreach.

#### 2.11. Human Participant Research Unit (HPRU)

Per the funding mechanism RFA, a Human Participant Research Unit was designed to guide and monitor the RADx-MA partnership's work through an ethics and equity lens. The HPRU supported community partners to (1) develop an ethics and equity framework building on several sources, including the 2016 World Health Organization guideline for managing ethical issues in infectious disease outbreaks [19], eco-social theory, the impact of social determinants of health [20,21], and life course frameworks [22], and (2) serve as a resource to CHCs if and when they face ethical or equity challenges in testing implementation. The HPRU gathers community stakeholder input through interactions with the LCAGs. The HPRU aims to help translate theoretical concepts into practice-based principles to contextualize the implications of their real-life application.

## 2.12. Community-engaged pilot studies of community outreach strategies

Following implementation of the testing acceleration strategies, CHC-community partnerships implemented outreach strategies to support testing in populations at increased risk for COVID-19. Outreach strategies were developed using an exploratory sequential mixed methods approach [23]. With this approach, qualitative data collected from in-depth needs assessment informed outreach communications that would be tested in a stepped-wedge design. The outreach activities included tailored communications aimed to address barriers to testing highlighted in the in-depth needs assessment. Using a stepped-wedge design, our six CHCs were randomly assigned to one of three implementation steps, with two CHCs per step. The step intervals were set every two weeks (Table 2). With each step, CHCs were asked to identify up to two communication goals, informed by the qualitative needs assessment and LCAG input, to incorporate into their outreach strategy. Each site then worked with the iLab and the CCT in consultation with the TCIT to create communications materials along with a strategy involving community partners in the dissemination of materials.

## 2.13. Statistical power and sample size

For the overall primary outcome of number of COVID-19 tests, we used a controlled interrupted time series design, comparing the aggregated number of tests across the RADx-MA intervention CHCs with six matched control CHCs in Massachusetts that also use the DRVS system.

CHC	Comparison Strategy	Baseline Months 0 to -2	Months												
			1	2	3	4	5	6	7	1	8	9	10	11	12
I.1	RADx-MA														
C.1	Control														
1.2	RADx-MA														
C.2	Control														
1.3	RADx-MA														
C.3	Control														
1.4	RADx-MA														
C.4	Control														
1.5	RADx-MA														
C.5	Control														
1.6	RADx-MA														
C.6	Control														
	I RADx-MA testing d wedge site-spe								site I	begin	ning	outre	ach ac	tivities	every

Overall RADx-MA testing acceleration strategy roll out begins in month 4. Stepped wedge site-specific tailored outreach begins mid-month 7 with a new site beginning outreach activities every 2 weeks. We conducted a simulation study (1000 simulated data sets) to estimate power to detect a 3.5% acceleration in weekly testing (or roughly 0. 5% acceleration of daily testing) at  $\alpha = 0.05$  threshold. Population parameters were determined based on a preliminary analysis of a testing time series from 4 CHCs with available testing data between May 1 and July 11, 2000 (when testing was more widely available in Massachusetts). We observed an average of 212 tests per day, a flat time-trend, and no significant autocorrelation after adjusting for seasonality related to the day of the week. Further, we assumed 518 days in the time series (for a total of 1036 across both intervention and control CHCs) with an equal number of days pre- to post-implementation, no difference between intervention and control CHCs during the pre-implementation time series and a 5% difference in the post-implementation intercept. Based on these assumptions we estimated greater than 90% power to detect 3.5% weekly acceleration in testing (~0.5% daily).

## 2.14. Data analysis and management plan

The DRVS platform used by CHCs and an enterprise data registry used by the academic medical center affiliated CHCs provide detailed data on test participants, including demographics, the type of COVID-19 test ordered, test result, documented COVID-19 symptoms, vitals, comorbid conditions, and social needs. For people who are tested by CHCs but are not their patients, at a minimum CHCs collect demographics, tests ordered, and results. As required by the RADx-UP funding mechanism, CHCs were asked to collect a core set of common data elements that gathered specific information related to testing from a random sample of individual test participants. All other data are collected and examined at the CHC level. We implemented a rigorous data extraction, de-identification, and management protocol to ensure data quality and safety.

For our planned analysis of the primary outcome, we will compare improvement in the COVID-19 testing rate overall and within population groups at increased risk for COVID-19, and characterize major contextual events (e.g., transition to subsequent phases of re-opening or closure; initiation of the Massachusetts contact tracing program; citylevel case counts) as well as the implementation of the planned testing acceleration strategies. We will describe the time series of testing in the intervention and control CHCs individually and in aggregate. Estimation will be done via generalized linear time series model for number of tests per day. Tests per day will be modeled as a function of time (in day units), a dummy variable for pre- vs. post-intervention period, a dummy variable for whether the CHC is an intervention or control clinic, and two- and three-way interaction terms for time, pre- vs. post-intervention dummy, and intervention versus control dummy. The coefficient for the three-way interaction is interpreted as the acceleration in the testing trend for intervention relative to control CHCs. The model will control for day of week to account for day-of-week seasonality.

In our stepped-wedge cluster randomized pilot implementation study we will estimate the impact of strategies for tailored outreach by fitting a generalized linear mixed effects model, where testing is modeled as a function of time (to control for secular trend), an indicator for whether the data are from an intervention or baseline step, a random intercept for CHC to control for clustering of patients within CHCs, and a set of clinic- and patient-level covariates, including inner and outer setting data (Fig. 1) for CHCs, and patient clinical and demographic data. Estimates will be presented with 95% confidence intervals with practical recommendations at different effect sizes within the range of the estimated confidence interval discussed.

# 2.15. Dissemination plan

By design, we have several mechanisms for disseminating information about successes with reducing barriers to testing. First, within the project, the iLab team is well-positioned to share experiences related to common issues between the six CHCs through their online learning community for RADx-MA partner CHCs. The MA League also leads regular meetings with all Massachusetts CHCs on COVID-19 services. These meetings provide an opportunity for real-time dissemination and sharing of strategies to respond to rapidly changing state regulations and resources. Communications materials are also available on the ISCCCE website (https://www.hsph.harvard.edu/isccce/rapid-acceleration-of-d iagnostics-underserved-populations-radx-up/).

## 2.16. Challenges

We have encountered a few key challenges and learnings through our first year of this two-year project. One challenge has been the speed at which communication resources are needed for pandemic response. For some communication materials, it worked well for the Communications Team and CHC teams to coordinate, iterate, and translate materials. At other times, the materials were needed more quickly than this iterative process could support, and in these cases the CHCs often produced materials internally, using their usual methods rather than those used by the Communications Team. Second, it has been challenging to keep attention and resources focused on COVID-19 testing as the pandemic circumstances continue to shift, particularly during phases where a substantial proportion of CHC resources were being directed toward vaccine outreach and delivery. For example, CHCs described LCAGs where members emphasized vaccine access over testing. CHCs were coached to be flexible to allow LCAGs to discuss other key pandemic response issues, but to maintain focus on testing needs in the community to align with the aims of the grant. Third, extensive CHC staffing constraints have been limiting throughout the project. This particularly impacted the proposed activities of the HPRU in that planned additional meetings with the CHCs increased burden and expectations on staff who were already burdened with care responsibilities. The data sharing and transfer processes also meant that data were available for analysis by the HPRU only late after initiation of testing paradigms. As a result, HPRU relied on interactions with LCAGs to learn about ethical issues and health equity in testing expansion. All data collection activities have had to be streamlined and flexible enough to accommodate the unique workflows at each CHC. Collection of patient-level data has been particularly challenging from the perspective of CHC burden. To illustrate this, CHCs were supported to gather additional data to assess reach among their priority populations using whatever methods produced the least burden on their staff, whether in-person at time of testing or by telephone after the testing encounter. However, when testing volumes were high the workflows were challenged to accommodate additional data collection.

#### 3. Conclusions

We have designed a community-partnered strategy to accelerate COVID-19 testing among historically marginalized populations. We have set up mechanisms that provide active and on-going resources to the CHCs for addressing testing challenges with populations at increased risk for COVID-19, all designed following an in-depth needs assessment with CHC clinical teams, community partner organizations, and community residents. A key part of our study design is provision of adequate resources to the CHCs to facilitate their outreach activities, as well as flexibility in responding to the various demands of the pandemic over time. This work will produce needed information on the value of community-centered interventions in the equitable expansion of COVID-19 testing.

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#### Data statement

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#### Disclosures

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# **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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#### References

- [1] K. Mackey, C.K. Ayers, K.K. Kondo, S. Saha, S.M. Advani, S. Young, H. Spencer, M. Rusek, J. Anderson, S. Veazie, et al., Racial and ethnic disparities in covid-19related infections, hospitalizations, and deaths: a systematic review, Ann. Intern. Med. 174 (2021) 362–373, https://doi.org/10.7326/M20-6306. https://www. ncbi.nlm.nih.gov/pubmed/33253040.
- [2] C.P. Gross, U.R. Essien, S. Pasha, J.R. Gross, S.Y. Wang, M. Nunez-Smith, Racial and ethnic disparities in population-level covid-19 mortality, J. Gen. Intern. Med. 35 (2020) 3097–3099, https://doi.org/10.1007/s11606-020-06081-w. https:// www.ncbi.nlm.nih.gov/pubmed/32754782.
- [3] S. Magesh, D. John, W.T. Li, Y. Li, A. Mattingly-App, S. Jain, E.Y. Chang, W. M. Ongkeko, Disparities in covid-19 outcomes by race, ethnicity, and socioeconomic status: a systematic-review and meta-analysis, JAMA Netw. Open 4

(2021), e2134147, https://doi.org/10.1001/jamanetworkopen.2021.34147. https://www.ncbi.nlm.nih.gov/pubmed/34762110.

- [4] E.Y. Adashi, H.J. Geiger, M.D. Fine, Health care reform and primary care—the growing importance of the community health center, N. Engl. J. Med. 362 (2010) 2047–2050, https://doi.org/10.1056/NEJMp1003729. https://www.ncbi.nlm.nih. gov/pubmed/20427777.
- [5] National Association of Community Health Centers, America's health centers: 2021 snapshot, National Association of Community Health Centers, 2021. https://www. nachc.org/research-and-data/research-fact-sheets-and-infographics/americas-hea lth-centers-2021-snapshot/.
- [6] National Association of Community Health Centers, Community Health Center Chartbook 2021, National Association of Community Health Centers, 2021. http s://www.nachc.org/wp-content/uploads/2021/04/Chartbook-Final-2021.pdf.
- [7] National Association of Community Health Centers, Infographics: National Findings on Health Centers' Response to covid-19, National Association of Community Health Centers, 2021. https://www.nachc.org/research-and-data/re search-fact-sheets-and-infographics/infographics-national-findings-on-health-centers-response-to-covid-19/.
- [8] RADx-UP. https://radx-up.org/, 2021.
- [9] HRSA. https://bphc.hrsa.gov/programopportunities/lookalike/index.html, 2021.
- [10] L.J. Damschroder, D.C. Aron, R.E. Keith, S.R. Kirsh, J.A. Alexander, J.C. Lowery, Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science, Implement. Sci. 4 (2009) 50, https://doi.org/10.1186/1748-5908-4-50. https://www.ncbi.nlm.nih. gov/pubmed/19664226.
- [11] E. Proctor, H. Silmere, R. Raghavan, P. Hovmand, G. Aarons, A. Bunger, R. Griffey, M. Hensley, Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda, Admin. Pol. Ment. Health 38 (2011) 65–76, https://doi.org/10.1007/s10488-010-0319-7. https://www.ncbi. nlm.nih.gov/pubmed/20957426.
- [12] N.M. Deterding, M.C. Waters, Flexible coding of in-depth interviews: a twenty-firstcentury approach, Sociol. Methods Res. 50 (2021) 708–739, https://doi.org/ 10.1177/0049124118799377. https://journals.sagepub.com/doi/abs/10.1177/ 0049124118799377.
- [13] R.M. Lee, V.L. Handunge, S.L. Augenbraun, H. Nguyen, C.H. Torres, A. Ruiz, K. M. Emmons, R.A.-M.R. Partnership, Addressing covid-19 testing inequities among underserved populations in Massachusetts: a rapid qualitative exploration of health center staff, partner, and resident perceptions, Front. Public Health 10 (2022), 838544, https://doi.org/10.3389/fpubh.2022.838544. https://www.ncbi.nlm.nih.gov/pubmed/35400042.
- [14] K. Brandt, V. Goel, C. Keeler, G.J. Bell, A.E. Aiello, G. Corbie-Smith, E. Wilson, A. Fleischauer, M. Emch, R.M. Boyce, Sars-cov-2 testing in North Carolina: racial, ethnic, and geographic disparities, Health Place 69 (2021), 102576, https://doi. org/10.1016/j.healthplace.2021.102576. https://www.ncbi.nlm.nih.gov/pubmed /33915376.
- [15] M.E. Jimenez, Z. Rivera-Nunez, B.F. Crabtree, D. Hill, M.B. Pellerano, D. Devance, M. Macenat, D. Lima, E. Martinez Alcaraz, J.M. Ferrante, et al., Black and latinx community perspectives on covid-19 mitigation behaviors, testing, and vaccines, JAMA Netw. Open 4 (2021), e2117074, https://doi.org/10.1001/ jamanetworkopen.2021.17074, https://www.ncbi.nlm.nih.gov/pubmed /34264327.
- [17] G. Wiggins, J. McTighe, Understanding by Design. Expanded, 2nd edition, Association for Supervision & Curriculum Development, 2005.
- [18] Centers for Disease Control and Prevention, Cdc clear communication index. https://www.cdc.gov/ccindex/index.html, 2021.
- [19] World Health Organization, Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. https://apps.who.int/iris/bitstream/handle/10665/250580/ 9789241549837-eng.pdf?sequence=1&isAllowed=y, 2016.
- [20] R. Bell, S. Taylor, M. Marmot, Global health governance: commission on social determinants of health and the imperative for change, J Law Med Ethics 38 (2010) 470–485, https://doi.org/10.1111/j.1748-720X.2010.00506.x. https://www.ncbi. nlm.nih.gov/pubmed/20880235.
- [21] S. Venkatapuram, M. Marmot, Epidemiology and social justice in light of social determinants of health research, Bioethics 23 (2009) 79–89, https://doi.org/ 10.1111/j.1467-8519.2008.00714.x.
- [22] N. Halfon, M. Hochstein, Life course health development: an integrated framework for developing health, policy, and research, Milbank Q 80 (2002) 433–479, iii.
- [23] J.W. Creswell, V.L. Plano Clark, Designing and Conducting Mixed Methods Research, 2nd, SAGE Publications, Los Angeles, 2011.