Expansion of testing, isolation, quarantine, e-health and telemonitoring strategies in socioeconomically vulnerable neighbourhoods at primary healthcare in the fight against COVID-19 in Brazil: a study protocol of a multisite testing intervention using a mixed method approach

Laio Magno, Thais Regis Aranha Rossi, Débora Castanheira, Thiago S Torres, Carina Carvalho dos Santos, Fabiane Soares, Valdílea G Veloso, Marcos Benedetti, Ines Dourado

ABSTRACT

Introduction The key tools for mitigating the impact of COVID-19 and reducing its transmission include testing, quarantine and isolation, as well as telemonitoring. Primary healthcare (PHC) can be essential in increasing access to these tools. Therefore, the primary objective of this study is to implement and expand an intervention consisting of COVID-19 testing, isolation, quarantine and telemonitoring (TQT) strategies and other prevention measures at PHC services in highly socioeconomically vulnerable neighbourhoods of Brazil.

Methods and analysis This study will implement and expand COVID-19 testing in PHC services in two large Brazilian capital cities: Salvador and Rio de Janeiro. Qualitative formative research was conducted to understand the testing context in the communities and at PCH services. The TOT strategy was structured in three subcomponents: (1) training and technical support for tailoring the work processes of health professional teams, (2) recruitment and demand creation strategies and (3) TQT. To evaluate this intervention, we will conduct an epidemiological study with two stages: (1) a cross-sectional sociobehavioural survey among individuals from these two communities covered by PHC services, presenting symptoms associated with COVID-19 or being a close contact of a patient with COVID-19, and (2) a cohort of those who tested positive, collecting clinical data.

Ethics and dissemination The WHO Ethics Research Committee (ERC) (#CERC.0128A and #CERC.0128B) and each city’s local ERC approved the study protocol (Salvador, ISC/UFBA: #53844121.4.1001.5030; and Rio de Janeiro, IN/Fiocruz: #53844121.4.3001.5240, ENSP/ Fiocruz: #53844121.4.3001.5240 and SMS/RJ #53844121.4.3002.5279). Findings will be published in scientific journals and presented at meetings. In addition, informative flyers and online campaigns will be developed to communicate study findings to participants, members of communities and key stakeholders.

INTRODUCTION

Brazil was severely affected by the COVID-19 pandemic, with a high registered number of cases and deaths. Nevertheless, vaccination coverage was expanded, reaching 82.0% and 6.0% of the Brazilian population with all recommended and partial doses, respectively (as of 22 March 2023).
Although improvements in vaccination coverage against SARS-CoV-2 have been observed, the emergence of new variants poses a risk to the escape of the immune response and the triggering of new pandemic peaks.\(^4\)\(^5\) In this context, testing and diagnosis are still insufficient\(^3\)\(^6\) mainly in areas with more significant socioeconomic disadvantages, such as low-income and middle-income countries. Low-income countries' investments in public health are often insufficient in these settings,\(^7\) leading to increases in the number of under-reported cases.\(^8\)\(^9\) For example, the prevalence of anti-S IgG antibodies for SARS-CoV-2 in an extremely socioeconomic vulnerable population in Rio de Janeiro and Salvador before vaccine implementation was higher than previous estimates for these cities, indicating the significant burden of COVID-19 in these communities.\(^10\)\(^11\) The unavailability of diagnostic tools is aggravated by the arrival of new SARS-CoV-2 variants, also contributing to under-reporting of cases.\(^8\)\(^9\)

The essential tools for mitigating the impact of COVID-19 and reducing its transmission include testing, isolation, quarantine, contact tracing and telemonitoring.\(^12\)\(^13\)\(^14\)\(^15\) Access to tools that facilitate early and accurate diagnosis of SARS-CoV-2 infection is essential for prevention and pandemic containment.\(^14\)\(^16\) It is critical to understanding the epidemiological context, informing case management and suppressing the transmission of the virus.\(^17\) One of the most effective measures for detecting and preventing new cases of COVID-19 in several countries is mass testing,\(^18\)\(^19\)\(^20\)\(^21\) as recommended by the World Health Organization (WHO).\(^22\) WHO has also highlighted the importance of strategies that can expand access to testing for COVID-19, for example, self-testing and rapid antigen test (RAT).\(^22\)\(^23\) In addition, the indication of case isolation and quarantine measures after contact with a person diagnosed with COVID-19 is crucial to reduce transmission when integrated with mass testing.\(^14\)\(^23\)

However, COVID-19 tests have not been widely accessible, especially in lower socioeconomic status communities, which calls attention to the inequalities in access to testing.\(^24\) Moreover, studies show that long waits for test results are also barriers to testing.\(^25\) These barriers can be coupled with the difficulty of paying the price to purchase the tests, as observed in two studies.\(^26\)\(^27\) This context highlights the importance of providing accessible and affordable testing and clear communication with people diagnosed with COVID-19 about the importance of isolation. In addition, studies suggest policymakers and healthcare providers should work with community-based organisations to provide and scale up COVID-19 testing and healthcare in the most vulnerable communities.\(^25\)

The response to other epidemics has demonstrated the importance of bringing testing closer to people and communities to increase early diagnosis and rapid linkage to healthcare (eg, HIV/AIDS and tuberculosis).\(^28\)\(^29\)\(^30\) Furthermore, implementing digital health strategies in primary healthcare (PHC) demonstrably improves COVID-19 care.\(^31\) PHC can be essential in expanding and bringing testing closer to people worldwide.\(^31\) Particularly in Brazil, as PHC is the preferred gateway to Brazilian National Health System (in Portuguese: Sistema Único de Saúde (SUS)), and it is established in the country’s most remote areas.\(^32\) Moreover, the model of PHC in Brazil may play an essential role in the expansion of testing as it is composed of community-based health agents (CBHAs) who are in close contact with the communities\(^33\) and health professionals already trained in providing other rapid tests (ie, HIV, syphilis and viral hepatitis)\(^34\) and vaccination (including COVID-19).\(^35\)

The primary objective of this study is to implement and expand testing, isolation, quarantine, e-health and telemonitoring strategies, and to prevent COVID-19 at PHC services of socioeconomically vulnerable neighbourhoods in two large Brazilian capital cities. The secondary objectives are as follows:

- To identify barriers and facilitators to expand RAT and map non-governmental organisations and community-based organisations to inform the testing, isolation and quarantine intervention implementation and demand creation for COVID-19 testing.
- To identify people currently unvaccinated against SARS-CoV-2 and facilitate access to COVID-19 vaccines for those who are not fully vaccinated and those who need additional booster doses.
- To evaluate knowledge, attitudes and practices of COVID-19 prevention measures.
- To follow up the clinical course of infection among those who tested positive for COVID-19 during the intervention strategy by telemonitoring strategies.
- To analyse the demand creation strategies to reach and enrol individuals in testing, quarantine and telemonitoring strategies.
- To monitor the emergence of variants and subvariants of SARS-CoV-2.

**METHODS AND ANALYSIS**

**Study design and population**

This is an epidemiological study with two designs: cross-sectional and cohort. The cross-sectional component will evaluate outcomes related to testing, isolation, quarantine and telemonitoring (TQT) intervention (ie, acceptability, uptake and coverage of community testing, and detected cases, etc.), knowledge, attitudes and practices for COVID-19 prevention, evaluation of the vaccination status of study population, and acceptability of COVID-19 self-testing. Individuals aged 12 years or older will be invited to respond a structured questionnaire, and children under 12 years will have their questions answered by parents or guardians. The cohort component will be composed of individuals who tested positive for COVID-19 and are followed up for disease progression verification. These individuals will be telemonitored by PHC health professionals using telephone contact or text messages sent by cell phone applications. Those with comorbidities will be contacted every 24 hours, and those without comorbidities will be contacted every 48 hours.
Follow-ups will be conducted until the end of isolation or quarantine.

This study will evaluate the primary intervention, named ‘TQT strategy in PHC’ (figure 1). The TQT intervention started in May 2022 and has been conducted in PHC units in the Cabula-Beirú Sanitary District in Salvador (Bahia state, Northeast Brazil) and the Manguinhos neighbourhood in Rio de Janeiro (Rio de Janeiro state, Southeast Brazil). Individuals aged 12 years or older from these two communities covered by PHC services and who present symptoms associated with COVID-19 that appeared between 3 days and 7 days after onset, or having close contact with a confirmed case of COVID-19 (if asymptomatic between 5 and 7 days after the last contact) are eligible to participate in this study.

**TQT strategy**

The TQT strategy was structured in three subcomponents: (1) training and technical support for tailoring the work processes of health professional teams, (2) strategies of recruitment and demand creation, and (3) TQT. The summary of study procedures is in table 1.

**Training and technical support**

In collaboration with the local health authorities in each city, the research team will develop training for the PHC staff. First, health professionals, municipal health managers and CBHA from PHC units will be trained in Salvador and Rio de Janeiro through virtual and/or face-to-face workshops. In addition, the digital platform developed by the project will incorporate a self-training module to clarify questions and concerns related to clinical conduct and research protocols (online supplemental appendix 3).
Demand creation

Trained research teams, CBHA and health professionals from PHC will develop strategies to create demand. These strategies include (1) internet and online social networks (figure 2), (2) community radio and podcasts, (3) CBHA recruitment, (4) school health programme, (5) mobilisation of religious institutions and (6) mobilisation of civil society organisations. In addition, posters and informative flyers will be distributed during meetings (online supplemental appendix 4).

The residents of these areas will be invited to participate in the intervention, and the testing criteria will be explained. CBHA will identify (ie, active demand) the individuals and families eligible for testing, and according to consent, the testing will be carried out in the households covered by PHC. In addition to households, testing will also be carried out in schools, churches and neighbourhood associations. People eligible to test can also go directly to PHC units (ie, passive demand).

Testing, isolation, quarantine and telemonitoring

Through demand creation and recruitment strategies, an active search will be conducted for suspected cases of SARS-CoV-2 infection with positive RAT and respiratory symptoms and household and community contacts of positive cases. This RAT will be performed using nasal swab samples collected in healthcare services or at the patient’s home by trained healthcare professionals from PHC or by health professionals trained by the project research team.
Children and adolescents under 18 years of age will have swabs collected only with the authorisation of their parents or guardians. After testing, the participants will answer a sociobehavioural questionnaire while waiting for the result. If positive, the health professional will provide guidance and isolation recommendations according to local protocols, investigate contacts and record the information on the virtual monitoring platform. The professionals indicated 10 days of isolation after the onset of the symptoms (the time to be adopted in this study will follow the protocols adopted by each municipality). If negative, the patient will receive instructions for SARS-CoV-2 infection prevention.

Participants with a positive RAT will have a nasopharyngeal swab sample collected simultaneously for confirmation by a real-time polymerase chain reaction (RT-qPCR) test that will be performed in a specialised laboratory. The PCR results will be available to participants through the study homepage or cell phone app, requiring a login and password. Participants who are illiterate, computer illiterate, and do not have electronic devices or internet access will be able to obtain their results printed at the health services participating in the study. The test result will be explained to the participant by the health providers in the PHC units.

People with COVID-19 testing recommendations are those symptomatic or their contacts (ie, symptomatic or asymptomatic). Definitions of suspected cases, confirmed cases and contacts will follow the WHO and Brazilian Ministry of Health (MoH) criteria. In addition, all patients with a positive diagnosis will be provided with masks to help with isolation at home.

All suspected and confirmed cases of COVID-19 (ie, based on RAT and RT-qPCR findings) will be reported to the Brazilian Epidemiological Surveillance System of the MoH.

All TQT testing strategies are being agreed on with the staff of the municipal health department, coordination of PHC and the health districts of the municipalities. Thus, carrying out TQT strategy is integrated into the government guidelines.

Health professionals from the PHC units will prospectively telemonitor individuals with positive RAT and their contacts. In addition, these professionals will contact participants to monitor disease evolution through a specific form (online supplemental appendix 2). Those individuals with comorbidities will be followed up every 24 hours, while those who do not will be followed up every 48 hours. Participants with no electronic equipment or internet access will be monitored face-to-face in the territories.

Participants will be referred for the standard of care at SUS services according to the disease severity (ie, mild, moderate and severe cases) by PHC professionals. People with a worsening clinical situation will be referred to emergency or specialised care. In addition, PHC professionals may receive counter-referrals. All individuals diagnosed with COVID-19 will be classified according to the outcome of the case:

- Recovery: persons who remain asymptomatic for 90 days at the end of quarantine.
- Reinfection: persons who become infected again with SARS-CoV-2 after recovering.
- Death: clinical diagnosis of SARS-CoV-2 followed by death.

Telemonitoring: digital health support tools

PHC professionals have been conducting manual monitoring of COVID-19-positive cases. The TQT project will include the development of a digital health platform (e-health) to optimise their work, accelerating the report of suspected or confirmed cases to the MoH, and planning healthcare based on collected data. This platform will feature distinct interfaces for health workers (eg, analysis of the distribution of positive cases, contacts and deaths by geographical area of the territory covered by the PHC team, monitoring management and access to test results) and community residents (eg, test results, vaccination monitoring, and contacts with the PHC centres, videos and educational messages).

The platform will also include a chatbot for information about COVID-19, testing and linkage to care to streamline contact with PHC centres. The platform will be available on computers, mobile phones and tablets. Furthermore, the digital health platform will provide a real-time dashboard for each health centre and central surveillance management of the intervention. The real-time dashboard may also help to improve the monitoring of other health conditions (eg, dengue, chikungunya and other infectious diseases). The digital health platform was discussed with the municipal health department in each city. Professionals from the health information centres of these municipal health secretariats will integrate working groups to implement the platform.

Laboratory details

Diagnosis by antigen tests

Nasal swabs will be collected from both nostrils, and the results will be interpreted by a health professional, following the test manufacturer’s instructions. Immediately after collection, the swab will be immersed in a tube containing an appropriate amount of buffer to inactivate the SARS-CoV-2 virus and elute the nucleoprotein antigen from the swab mesh.

RT-qPCR diagnosis

PHC professionals will collect nasopharyngeal swab samples. The swabs will be placed in a tube containing 1.5 mL of RNA shield medium. This medium will inactivate the virus and allow samples to be transported at room temperature until the genetic material (RNA) is extracted. The samples will be separated into two aliquots of 500 µL in cryotubes.

An aliquot of approximately 200 µL will be separated for RNA extraction. The viral genetic material (RNA) extraction will be performed using the Maxwell16 Viral Total Nucleic Acid Purification System (Promega).
RT-qPCR reactions will be performed using the Allplex SARS-CoV-2 kit (Seegene) according to the manufacturer’s instructions.

**Expected number of tests**

Although it is not possible to accurately estimate a disease incidence rate at the start of the intervention, considering the total number of tests (antigen and RT-qPCR) carried out in Salvador and Rio de Janeiro, we intend to increase by 10% the number of COVID-19 tests, comparing with the prior 6 months of study initiation in each site. Therefore, we planned to perform 12 000 RT-qPCRs for confirmation of positive cases. In addition, a total of 300 genetic sequencing tests for specific variants monitoring will be conducted. The tests acquired by this project will be distributed to the units based on a study of the geographical location and analysis of the weekly number of tests to be performed. One participant may be tested more than once.

**Salvador**

Considering the population of the Cabula-Beirú Sanitary District, which has >400,000 inhabitants, the sample was calculated for a RAT coverage of approximately 15% of the population of this territory (ie, 60,000 individuals) with an increase of 30% for the repetition of tests in case of reinfection throughout the intervention (ie, 18,000 tests), totalling 78,000 RATs.

**Rio de Janeiro**

Considering the population of Manguinhos, which has >37,000 inhabitants, the sample was calculated for a RAT coverage of approximately 20% of the population of this territory (7400 individuals), with an increase of 30% for the repetition of tests in case of reinfection throughout the intervention (2220 tests), totalling 9620 RAT tests.

**Instruments**

A structured sociobehavioural questionnaire (online supplemental appendix 1) will be applied individually during the RAT by health professionals and CBHÁ trained in survey research.

Cross-sectional data will be collected on (1) sociodemographics (ie, gender and race/skin colour) and housing (ie, number of people and number of rooms in the household); (2) history of comorbidities; (3) access to and use of health services; (4) history of infection and previous COVID-19 testing; (5) history of vaccination (ie, complete or incomplete COVID-19 vaccination schedule and vaccination hesitation); (6) behaviours, attitudes and practices of COVID-19 prevention (ie, adherence to non-pharmacological strategies for prevention—masks, social distancing and quarantine, self-medication for infection prevention and sources of information about the disease), and self-perception of severity and risk of infection; and (7) acceptability, feasibility and use of COVID-19 RAT. All participants tested will take this questionnaire.

In addition, longitudinal clinical data will be collected by health professionals from PHC using a telemonitoring form (online supplemental appendix 2) for those who tested positive, encompassing the following: (1) patient’s clinical history (ie, medication use, symptoms, seeking healthcare seeking behaviour and depressive symptoms); (2) clinical conduct of health professionals; (3) case outcome (ie, mild, moderate, severe or death); (4) isolation and quarantine measures and prevention, and (5) search for contacts.

**Data and statistical analysis**

Epidemiological surveillance indicators will be estimated based on the cross-sectional data and results of the RAT and RT-qPCR tests for SARS-CoV-2. In addition, information on the reference population of the study neighbours will be estimated based on the official data from the Brazilian Institute of Geography and Statistics (in Portuguese: Instituto Brasileiro de Geografia e Estatística). We will conduct a descriptive analysis of the sociodemographic and behavioural characteristics of the population tested for COVID-19 and other indicators (table 2).

**ETHICS AND DISSEMINATION**

This study will be conducted according to guidelines from the Brazilian Research Ethics Commission Resolution (numbers 466/2012 and 510/2016). The protocol was approved by the research ethics committees of the WHO (protocol identification: numbers CERC.0128A and CERC.0128B) and the local Brazilian Institutional Review Boards at each site (protocol identification in Salvador, ISC/UFBA: number 53844121.4.1001.5030; and Rio de Janeiro, INI/Fiocruz: number 53844121.4.3001.5240, ENSP/Fiocruz: number 53844121.4.3001.5240, and SMS/RJ: number 53844121.4.3002.5279). Written informed consent (WIC) will be obtained from all participants aged 18 years or older. Children and adolescents under 18 years old will participate in this intervention only with the authorisation of their parents or guardians. Children under 12 years old will have only swabs collected, and parents or guardians will answer the research questionnaire. Adolescents aged 12–17 will have swabs collected and will answer the research questionnaire.

All individuals invited to participate will receive a verbal explanation of the study, its goals and its methods. They can clarify questions and can be invited to sign the WIC forms. These forms describe the research objectives, the potential risks and benefits of participating, and their voluntary nature. They also cover the use of the data obtained from the collection of swabs and the results of laboratory tests.

**DISCUSSION**

Our study proposed an intervention for mass testing and monitoring of cases of COVID-19 aiming to facilitate the COVID-19 pandemic control. Our results will be very valuable for preparing and building responses for future pandemics. However, some limitations may be
for those with mild disease. PHC is fundamental for isolation and quarantine strategies. PHC is closer to communities and has greater decentralisation and democratisation of COVID-19, particularly as the COVID-19 testing strategy can incorporate health-related measures such as the COVID-19 testing strategy, to support the control of the virus dissemination. Furthermore, PHC can articulate individual care using a community approach based on comprehensive healthcare strategies.

The SARS-CoV-2 virus may continue to circulate in the population for many years. Therefore, the incorporation of new technology-based interventions (eg, telehealth) and testing on a population scale can identify outbreaks early and quickly contain their spread with contact tracing and isolation. Furthermore, genomic surveillance monitors new variants and subvariants. COVID-19 testing can be incorporated into health and community services as well as in prisons, schools and universities, among other venues that involve agglomerations of people. The mass testing will be based on the RAT integrated into the PHC. The surveillance strategies are expected to reduce potential to incorporate health-related measures, such as the COVID-19 testing strategy, to support the control of the virus dissemination. Furthermore, PHC can articulate individual care using a community approach based on comprehensive healthcare strategies.

Despite these limitations, our study has the potential to show that PHC can become the central locus for the decentralisation and democratisation of COVID-19 mass testing in highly socioeconomically vulnerable Brazilian neighbourhoods. Moreover, our study will provide active search contacts of cases of COVID-19, provide and monitor isolation and quarantine strategies as well as primary care for those with mild disease. PHC is fundamental for a sustainable, equitable and competent health system. PHC deals with the most frequent community health problems and challenges and is the most effective healthcare model. PHC is closer to communities and has greater potential to incorporate health-related measures, such as the COVID-19 testing strategy, to support the control of the virus dissemination. Furthermore, PHC can articulate individual care using a community approach based on comprehensive healthcare strategies.

Table 2  Summary of study indicators

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing and prevention of COVID-19</td>
<td>Tests applied per health unit and site</td>
<td>Number of tests applied by the total number covered divided by each PHC unit and neighbourhood</td>
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<tr>
<td></td>
<td>Positivity rate</td>
<td>Number of cases of COVID-19 divided by the total number of tests applied (according to health unit and neighbourhood)</td>
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<tr>
<td></td>
<td>Refusal of testing</td>
<td>Number of people with symptoms or that are close contacts who refused testing divided by the total number of people with symptoms or that are close contacts</td>
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<tr>
<td></td>
<td>COVID-19 testing uptake</td>
<td>Proportion of people tested divided by the total people with symptoms or that are close contacts</td>
</tr>
<tr>
<td></td>
<td>COVID-19 incidence rate in neighbourhoods</td>
<td>Number of new cases of COVID-19, registered weekly, divided by the total population of the neighbourhoods</td>
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<tr>
<td></td>
<td>Death rate due to COVID-19 in the neighbourhod</td>
<td>Number of deaths due to COVID-19 divided by the total population of the neighbourhoods</td>
</tr>
<tr>
<td></td>
<td>Proportion of people fully vaccinated</td>
<td>Number of people fully vaccinated divided by the total number of people in the study</td>
</tr>
<tr>
<td>Demand creation and recruitment strategies</td>
<td>Proportion of tests applied</td>
<td>Number of tests applied divided by the total number of populations per PHC unit and neighbourhood</td>
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<tr>
<td></td>
<td>Proportion of cases of COVID-19 identified</td>
<td>Number of cases of COVID-19 divided by the total number of tests applied by PHC health unit and neighbourhood</td>
</tr>
<tr>
<td>Linkage strategies</td>
<td>Proportion of mild, moderate and severe cases of COVID-19</td>
<td>Number of mild, moderate and severe cases of COVID-19 divided by the total number of tests applied by each health unit and neighbourhood</td>
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<tr>
<td></td>
<td>Proportion of quarantine adherence</td>
<td>Proportion of cases of COVID-19 that underwent complete quarantine divided by the total number of positive cases (Quarantine adherence will be measured by the telemonitoring questionnaire through to the patient self-report.)</td>
</tr>
<tr>
<td></td>
<td>Proportion of moderate and severe cases of COVID-19</td>
<td>Cases referred to hospital care units and/or specialised care divided by the total number of cases monitored in PHC by each health unit and neighbourhood</td>
</tr>
<tr>
<td></td>
<td>Conditions for compliance with quarantine or isolation</td>
<td>Proportion of people positive in the test and who declared that they were able to comply with the quarantine or isolation divided by the total number of positive cases</td>
</tr>
<tr>
<td></td>
<td>COVID-19 fatality rate</td>
<td>Number of deaths due to COVID-19 by the total number of cases identified divided by each PHC unit and neighbourhood</td>
</tr>
<tr>
<td></td>
<td>Proportion of cases of COVID-19 monitored</td>
<td>Number of cases of COVID-19 monitored by PHC teams by the total number of cases stratified by mild, moderate and severe cases divided by each health unit and neighbourhood</td>
</tr>
</tbody>
</table>

PHC, primary healthcare.
under-reporting of cases in areas characterised by socio-structural vulnerabilities. These strategies are expected to be expanded in other Brazilian municipalities, contributing to the local and national responses to the COVID-19 pandemic by reducing cases and severe forms of the disease and preventing health system overload.

The study will facilitate access to the COVID-19 vaccines by identifying unvaccinated people while recruiting participants and referring them for vaccination at PHC within the SUS. Moreover, contact tracing and tele-monitoring are gaps in the work process in Brazilian municipalities. The TQT intervention will expand the population’s access to COVID-19 testing in the PHC services. Testing services will be expanded to units that provide limited tests and deployed to PHC units that have not yet performed testing. Finally, this intervention will help strengthen public health surveillance.

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