Utilization of digital tools to enhance COVID-19 and TB testing and linkage to care among Boda Boda riders in the Nairobi metropolis

Digital Tools for enhancement of COVID-19 and TB testing and linkage to care

JKUAT-DHARC

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by

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List of Abbreviations

Ag-RDT	Antigen based RDT
BAK	*Boda Boda* Safety Association of Kenya
BMI	body mass index
CHT Core	Community Health Toolkit Core Framework
CIF	Case Investigation Form
COVID-19	coronavirus disease 2019
DHARC	Digital Health Applied Research Centre
FIND	Foundation for Innovative New Diagnostics
HBIC	Home-Based Isolation and Care
ICF	informed Consent Form
IPC	infection prevention and control
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KenyaEMR	Kenya Electronic Medical Records
LabWare LIMS	LabWare Laboratory Information Management System
MoH-K	Ministry of Health Kenya
NCD	Noncommunicable disease
NHIF	National Hospital Insurance Fund
NPV	Negative Predictive Value
NTLD-P	National Tuberculosis Leprosy and Lung Disease Program
PI	Principal Investigator
PPV	Positive Predictive Value
RDT	rapid diagnostic test
RT-PCR	reverse transcription polymerase chain reaction
SARS-COV-2	severe acute respiratory syndrome coronavirus 2
SMS	Short Message Service
SSA	Sub Saharan Africa
TaT	turnaround time
TB	Tuberculosis
TTI	test, trace and isolate
UI	User Interface
VM	virtual machine
WHO	World Health Organization

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1 Introduction

1.1. Background and Rational

COVID-19 is an ongoing global pandemic caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) virus. The first human cases of COVID-19, were first reported by officials in Wuhan City, China, in December 2019, and since then, it has had an unprecedented impact on the health, economic, and social well-being of most populations. This pandemic has had an unprecedented impact on the health, economic, and social well-being of Kenyans. The first case in Kenya was confirmed on the 12th of March 2020, and to date, there have been over 343,000 cases with over 5,646 deaths. [1].

By the time this study commenced in September 2021, the number of cumulative COVID-19 tests undertaken nationally since the beginning of the pandemic stood at 1,815,766 [15]. Efforts to track the disease progress and public health impact of COVID-19 in Kenya largely depends on the ability to have effective screening and availability of diagnostic tests, calling for fast and equitable access to testing. The COVID-19 pandemic has added an additional burden to already overstretched health systems in Sub Saharan Africa (SSA), which, among other things, have been focused on the long-standing dual epidemics of TB and HIV [11].

Both TB and COVID-19 are respiratory infections and can present with similar symptoms although SARS-COV-2 being more infectious requires prompt deployment of public health and social measures with an emphasis on individual protection devices, as well as social distancing, whereas TB has a longer incubation period and a slower onset of disease. [8, 4]. COVID-19 and TB therefore present substantial infection prevention and control (IPC) challenges, requiring timely and rapid case detection. Both diseases can spread easily in conditions associated with poverty where social distancing is difficult to implement. Nonetheless, the well-established community outreach capabilities for contact tracing established for TB can be deployed to assist in contact tracing and monitoring COVID-19 cases in isolation [11, 8].

During the periods of June to July 2020, October and November 2020 and March and April 2021, Kenya recorded exponential increase in COVID-19 confirmed cases and deaths. Further, it has become evident that 98% of current cases of COVID-19 in Kenya are due to community transmission [2]. However, the existing capacities for testing have been unable to match the demand for testing. The country has to a great extent relied on the use of RT-PCR, which is expensive, available in few high-end laboratories, requires high level of skill and has a long turnaround time between sample collection and result communication. This has been a major barrier for testing especially, among the citizens (including *Boda Boda* riders) of low

[1] https://www.worldometers.info/coronavirus/country/kenya/

socio-economic status in the country.

Fast, efficient and timely testing is a vital prerequisite for early identification and reporting of COVID-19. Coupled with adequate contact tracing, isolation of cases and quarantine of contacts, testing is critical in breaking transmission chains and slowing down the spread of SARS-COV-2. However, the demand for COVID-19 testing in Kenya has been hampered by a perennial shortage of reagents, limited testing laboratories and insufficient requisite human resource. The average rate of testing in Kenya is about 4000 tests per day, against the World Health Organization (WHO) recommended rate of 7,000 tests per day. This implies that currently, there is a high chance we are not even meeting half of the required testing needs per capita. The testing levels up to date have given an overall positivity rate of about 11.5%. The current testing strategy targets administration of tests for only those who meet the case definition of a COVID-19 case as per the screening guidelines Recent approval of use of RDT as an additional test for SARS-COV-2 is anticipated to improve the ease of testing by introducing decentralized testing, while reducing the turn-around time and dependence on the highly trained human resource that is a requirement in RT-PCR based tests.

In addition, the use of the Antigen based RDT (Ag-RDT) test is expected to contribute significantly to overall COVID-19 testing capacity. It offers advantages which include a low requirement for specialized laboratories and highly skilled officers of health, shorter turnaround times and reduced costs, especially in situations in which RT-PCR testing capacity is limited. The use of rapid antigen tests is appropriate in high prevalence settings when a positive result is likely to indicate true infection. In addition, rapid antigen tests can help reduce further transmission through early detection and isolation of infectious cases, enabling a rapid start of contact tracing

Due to these features, antigen tests have the potential to catalyze decentralization of testing. However, expanding testing outside of health facilities also presents specific challenges, including around the management and transmission of data; both between the testing site and the central health system, and between the site and the patient. The latter is particularly challenging when dealing with mobile populations who may not reside near the testing site but need to be followed up if positive to ensure appropriate linkage to care and contact tracing. Digital tools can help to address these challenges, by establishing reliable patient databases with end-to-end data, automating transmission of data between different sections of the health system and patients, and remote monitoring or follow-up of patients. Digital tools can also offer clinical decision-making support to triage patients for testing.

Approaches to the diagnosis of both COVID-19 and TB are faced with similar barriers, for instance, lack of decentralized testing, and inadequate systems for contact tracing. There are missed opportunity to build synergies between the programs. Globally, TB diagnosis has declined during the pandemic due to various factors including de-prioritization and movement restrictions. Integrating case-finding for the two would lead to better health outcomes and more efficient use of health systems resources. Digital tools can facilitate this by integrating screening questions and data capture at the point of care and automating data transmission between TB program and sites offering decentralized testing. The study will demonstrate a model for delivering these services while also assessing prevalence of these diseases in the study population, and potential overlap. To further rationalize on resource utilization, testing facilities can be shared and TB laboratory staff could participate in COVID-19 diagnosis. TB laboratories are designed to work with a dangerous infectious disease and in general have

safety measurements in place to avoid infection by aerosol-generating activities [12].

Additionally, a number of digital tools have been deployed for COVID-19 management in Kenya, and have played a central role in the national response. However, a previous assessment by Jomo Kenyatta University of Agriculture and Technology (JKUAT) and Ministry of Health Kenya (MoH-K) highlighted fragmentation between these tools, which results in the lack of cohesive end-to-end data across the test, trace and isolate (TTI) cascade [7]. For screening, particularly, available digital tools were not being utilized to systematically capture data on symptoms and other risk factors, including the presence of possible indicators of other diseases such as TB.

The aim of this study was to enhance COVID-19 and TB diagnosis and linkage to care among the *Boda Boda* riders within the Nairobi Metropolis using rapid antigen testing and digital tools. The study would determine the average turnaround time for diagnosis when point-of-care tests are delivered to a highly mobile population, namely *Boda Boda* riders, supported by digital tools for screening, data capture, results return and follow-up. It would also measure costs incurred in the continuum of COVID-19 management using this decentralized testing model, and highlight opportunities to strengthen COVID-19 diagnosis and patient management within the Nairobi metropolis.

Integrating TB and COVID-19 diagnosis can help to overcome the decrease in registered TB cases. To date, the majority of digital interventions for TB focus on diagnostic tools and treatment adherence technologies, such as video-observed therapy and Short Message Service (SMS) and none on screening [9]. The COVID-19 pandemic has created an opportunity for case finding for both diseases at the same time. The integration of control programmes for HIV and TB have been successfully established and newly diagnosed TB patients are always tested for HIV before starting on TB treatment. The same integrated approach could be used for COVID-19 and TB. [3]

Boda Boda riders were selected for this study as they represent a population is considered critical in the transmission of both COVID-19 and TB. These persons consist mainly of low-wage males aged 22-45 years who earn about Kshs 200-500 per day and therefore can be considered to be of low socio-economic status [6]. As a result of this, they lack medical insurance and have limited access to healthcare. Majority of *Boda Boda* riders within the Nairobi Metropolis reside in informal settlements with poor hygiene and sanitation facilities.

The TB survey conducted in Kenya in 2016 indicated that the national TB prevalence was 558/100,000. The urban slums had the greatest burden of TB (760/100,000), nationally. In addition, the survey indicated that persons aged 25-34 years had the highest burden of TB for age with a prevalence of 716/100,000. Males had a higher prevalence rate of 809/100, 000 compared to females whose TB prevalence was 359/100,000 (Kenya TB survey, 2016). In addition, *Boda Boda* riders who are mainly male are highly mobile and interact with multiple clients daily, thereby compounding the risk of transmission for both COVID-19 and TB. Further, the *Boda Boda* transport sector has not been given the same priority for COVID-19 screening, testing and vaccination by MoH-K compared to persons in other sectors such as health, educations, security, and long distance truck drivers.

The high mobility by *Boda Boda* riders coupled with lack of infection prevention and control measures is a good recipe for nurturing ‘super-spreaders’ for COVID-19. It is therefore imper-

ative to create awareness and demand among the *Boda Boda* riders for COVID-19 and TB testing aimed at including this critical group in healthcare planning.

The study targeted this sector within the larger Nairobi Metropolis with the aim of creating awareness and demand for COVID-19 and TB testing among *Boda Boda* riders. This would further support the decentralized testing of COVID-19 and TB of the riders and provide an opportunity for digital follow-up for participants who test positive for COVID-19 and TB. This would enhance the COVID-19 management cascade and linkage to care among *Boda Boda* riders.

1.2. Study Objective and Outcomes

1.2.1. General objective

To use digital platforms to enhance COVID-19 and TB testing and linkage to care among *Boda Boda* riders in Nairobi metropolis.

1.2.2. Specific objectives

1. To create awareness and demand for COVID-19 and TB testing among *Boda Boda* riders using digital messaging
2. To use digital solutions (*Kenya COVID-19 Tracker app* Kenya Electronic Medical Records (KenyaEMR), *Jitenge system* LabWare Laboratory Information Management System (LabWare LIMS) and *TIBU*) in conjunction with RDTs (PANBIO™ COVID-19 Ag RAPID test device) to support decentralized COVID-19 and TB screening, testing, contact tracing and linkage to care of *Boda Boda* riders in the Nairobi metropolis.
3. To determine the COVID-19 and TB positivity and co-infection rates among the *Boda Boda* riders
4. To evaluate the accuracy /reliability of the RDT against the RT-PCR (gold standard).

The specific objectives were to be measured using the metrics in Table 1.1.

1.3. Technical Approach

1.3.1. Study Design

This was an intervention cohort study to demonstrate the use of digital platforms in enhancing COVID-19 and TB testing and linkage to care among *Boda Boda* riders in Nairobi metropolis.

1.3.2. Study Setting

This study was carried out in the Nairobi Metropolis. Figure 1.1 shows a map of the study site. The Nairobi Metropolis is divided into four sub regions and the city of Nairobi forms the core centre to this region in terms of, provision of goods and services, employment opportunities and a market of the goods from the rest of the region. On the other hand, the surrounding areas serve largely as dormitory corridors for the population working in the Nairobi City. The four regions which cover approximately 30,000 square kilometres and their population based on the 2019 National Population and Housing census are summarized in Table 1.2.

For purposes of the management of COVID-19, an area slightly smaller than the Nairobi metropolitan area was curved out and considered as the Nairobi Metropolis. They include Nairobi County, Kiambu County, Muranga County, Kajiado County and Machakos County. However, apart from Nairobi County, not all sub-counties or regions or towns found in the other 4 counties fall in Nairobi Metropolis. This geographical area is densely populated with a

Table 1.1: Metrics used to measure the objectives

Objective	Metric
To create awareness and demand for COVID-19 and TB testing among *Boda Boda* riders using digital messaging	(i) Proportion of riders who visited the testing site out of all those who received the messages.
To use digital solutions (*Kenya COVID-19 Tracker app*) in conjunction with RDTs (PANBIO™ COVID-19 Ag RAPID test device) to support decentralized COVID-19 and TB screening, testing, contact tracing and linkage to care of *Boda Boda* riders in the Nairobi metropolis.	(i) Proportion of participants successfully completing the screening form (ii) Number of suspect cases (per MoH-K criteria) for COVID-19 only (iii) Number of suspect cases for TB only (iv) Number of suspect cases for both COVID-19 and TB (v) Proportion of suspect cases tested for SARS-COV-2 (vi) Number of sputum samples collected and sent to lab (vii) Proportion of samples submitted for TB testing who had results recorded in the *Kenya COVID-19 Tracker app*. (viii) Proportion of samples submitted for TB testing who had results recorded in *TIBU* and reported back to the study team through the data transmission channel. (ix) Proportion of TB positive cases who are placed on follow-up by the TB national programme through the county co-ordinators.
To determine the COVID-19 and TB positivity and co-infection rates among the *Boda Boda* riders	(i) Proportion of individuals tested with RDTs who were positive for COVID-19. (ii) Proportion of individuals referred for TB testing who were positive (iii) Proportion of dual suspect cases who tested positive for both COVID-19 and TB.
To evaluate the accuracy /reliability of the RDT against the RT-PCR (gold standard)	(i) Sensitivity (ii) Specificity (iii) Predictive values (iv) Kappa statistics for level of agreement

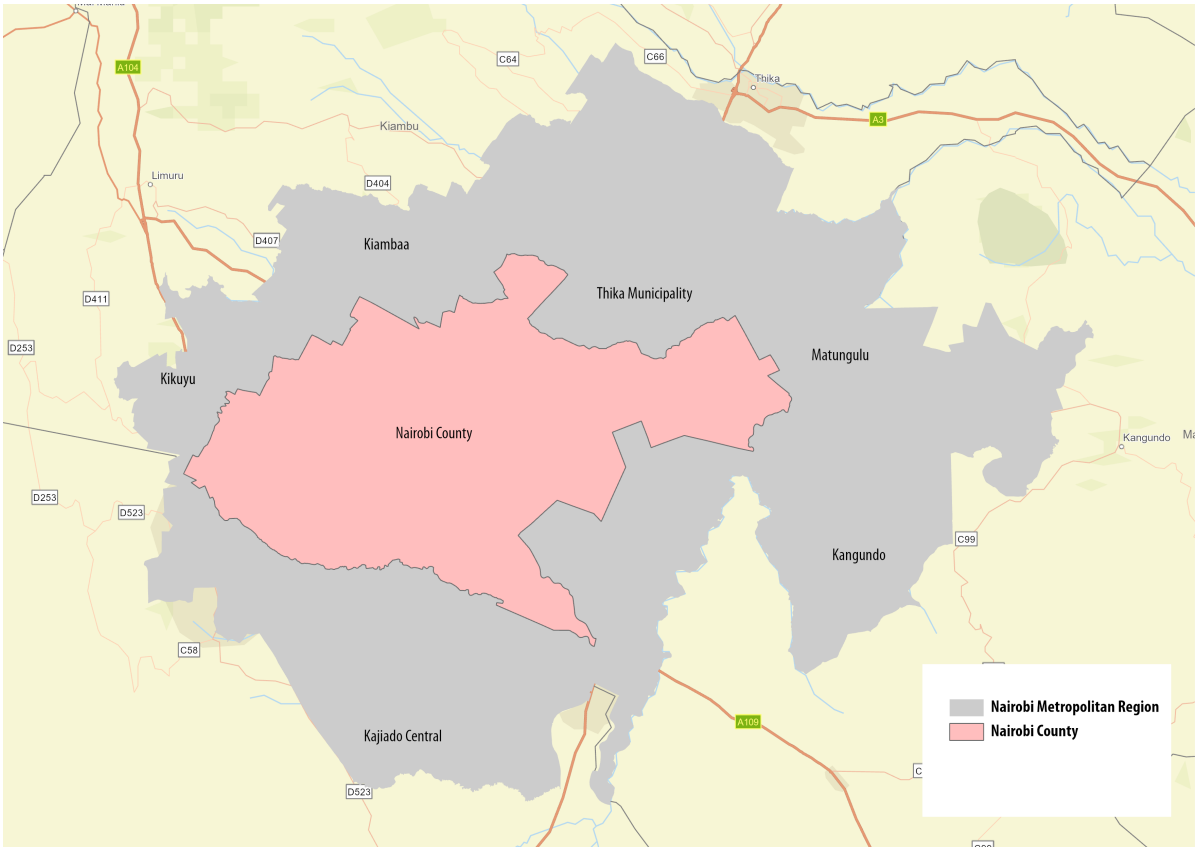


Figure 1.1: Map showing the Nairobi Metropolis

lot of inter-county movement of people and goods, as many workers in Nairobi County live in the surrounding counties.

1.3.3. Study Population

Given that the Nairobi metropolis is the largest urban centre and financial hub of Kenya, it has the largest number of registered *Boda Boda* riders due to the huge demand for this medium of transport. In addition, this region has the highest burden of COVID-19 in the country, and has been the most affected by all the prevailing COVID-19 waves. The *Boda Boda* riders' population found in the study area is as represented in Table 1.3.

Table 1.2: Total Population of Nairobi and the counties with towns and municipalities within the Nairobi Metropolis

Area	County	Area (km2)	Population	Cities/towns/municipalities in the Counties
Core Nairobi	Nairobi County	696	4,397,073	Nairobi
Northern Metro	Kiambu County	2,449.20	2,417,735	Kiambu, Thika, Limuru, Ruiru, Karuri, Kikuyu, Ruaka, Kahawa and Githunguri
Southern Metro	Kajiado County	21,292.70	1,107,296	Kajiado, Olkejuado, Bissil, Ngong, Kitengela, Kiserian, Ongata Rongai
Eastern Metro	Machakos County	5,952.90	1,421,932	Kangundo-Tala, Machakos, Athi River
Totals	**Nairobi Metro**	**30,390.80**	**9,344,036**	

Table 1.3: Total *Boda Boda* Population in the Nairobi Metropolis

County	Subcounties/ townships	Population	Number of Boda boda riders
Nairobi	Dagoretti North, Dagoretti South, Embakasi Central, Embakasi South, Embakasi North, Embakasi East, Embakasi West, Kamukunji, Kasarani, Kibra, Lang'ata, Makadara, Mathare, Roysambu, Ruaraka, Starehe, Westlands	**4,397,073**	**125,000**
Kiambu	Ruiru, Juja, Thika West, Kikuyu, Kabete, Kiambu, Kiambaa	**1,686,957**	**59,500**
Machakos	Athi River, Kangundo, Machakos, Matungulu	**752,579**	**26,000**
Kajiado	Ngong, Kiserian, Ongata Rongai, Ktengela	**517,069**	**21,000**

1.3.4. Inclusion and exclusion criteria

Inclusion criteria

(i) Registered *Boda Boda* riders operating within the Nairobi metropolis who presented themselves at testing sites.

(ii) *Boda Boda* riders who were willing to consent and provide sample

Exclusion criteria

(i) *Boda Boda* riders who had already been registered in the study.

(ii) *Boda Boda* riders who had been on TB treatment in the last 24 months.

1.3.5. Mapping of *Boda Boda* pick-up points and enrolment of participants

(i) All *Boda Boda* riders registered under *Boda Boda* Safety Association of Kenya (BAK) belong to a specific pick-up point. The study identified *Boda Boda* pick-up points within the participating sub-counties.

(ii) High volume (more than 20 members) *Boda Boda* pick-up points were then be identified, from where study participants were drawn.

(iii) After listing, messages crafted jointly by the study team and BAK officials were shared with the officials for onward transmission to their members. These messages were about free basic health check-up including screening for COVID-19 and TB, testing of COVID-19, TB, random blood sugar, and blood pressure will be sent to *Boda Boda* riders by their leaders via bulk SMS and WhatsApp through their telephones using the existing BAK communication networks.

(iv) In addition, sensitization flyers were circulated via WhatsApp and physically through the leadership at the pick-up points.

(v) Field officers were also sent to the respective pick-up points for further sensitization. This enabled the *Boda Boda* riders to get more details about the study.

(vi) Tents were pitched strategically to serve between 5 to 10 pick-up points.

1.3.6. Data Collection and Transmission

Data collection and transmission from screening and testing was through digital tools. The study used already existing tools by partnering with various system owners, and leveraging on existing technologies. Where some tools are deficient, other tools compensated and new input inform of additional development was considered where functionalities needed to be enhanced. Figure 1.2 shows the initial framework of data transfer that was envisaged between

the systems.

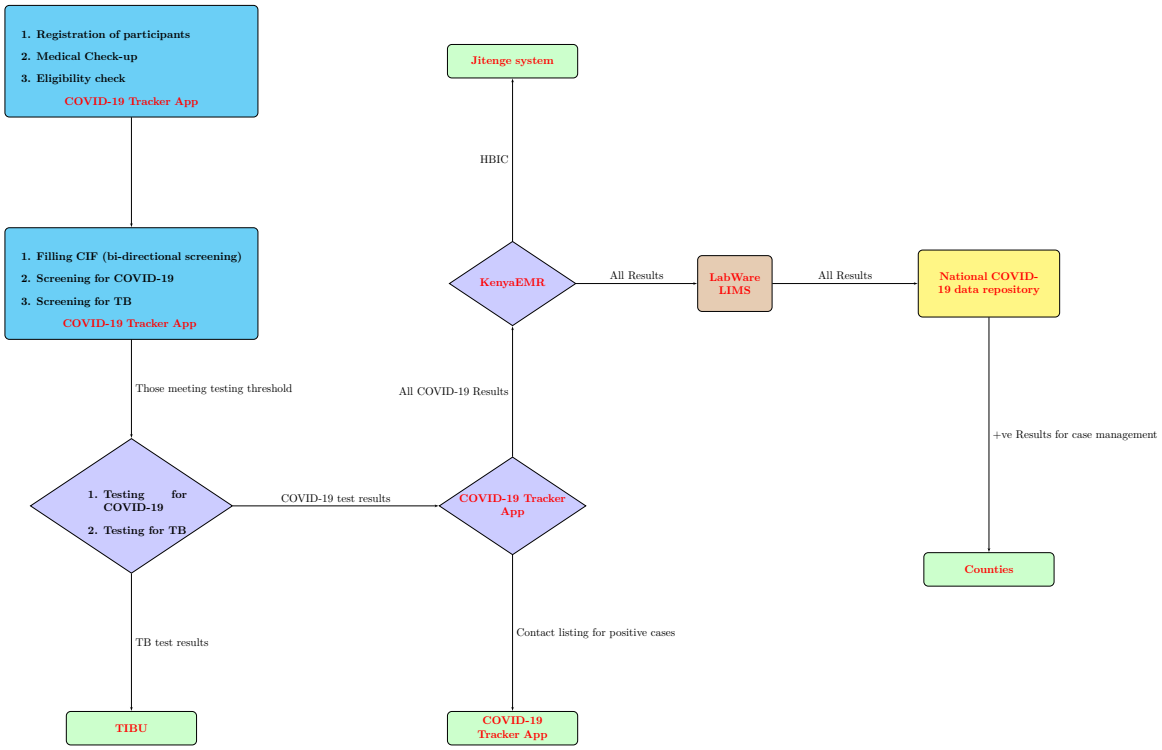


Figure 1.2: Data flow schematic diagram

The *Kenya COVID-19 Tracker app* provided the entry point for data collection. Registration of study participants was done on this system. After registration, the participants were screened for both COVID-19 and TB.

(i) For COVID-19 suspect cases, a Case Investigation Form (CIF) which is available on the *Kenya COVID-19 Tracker app* was completed. After this, samples were collected from the COVID-19 suspect cases for testing using both Ag-RDT and RT-PCR.

(ii) TB presumptive cases had their information transferred to the TB programme through the Countyb personnel from the TB programme that were involved in the study. Sputum samples were collected and sent to respective County GeneXpert centres for analysis.

A unique sample identifier was generated at this point by the *Kenya COVID-19 Tracker app* to facilitate onward processing. This unique identification was stored in the database and used for sample identification during analysis. All samples were identified through the unique identification system employed by the *Kenya COVID-19 Tracker app*. These unique identifiers were retained as information about the samples during analysis. The anonymized sample identifiers would have helped in the identification and follow-up of the samples across the different platforms, had this been possible.

RDTs was be conducted and results updated on the CIF in the *Kenya COVID-19 Tracker app*. A portion of these samples (about 25% based on the formula in Equation (1.2)) were tested a second time using RT-PCR. When updating COVID-19 results to the national database, the results from the RT-PCR tests were not forwarded to the national repository to avoid double count. In addition, after testing, the positive cases will be sent for case management. The symptomatic cases will be directed to health facilities for case management, and their data

was managed at health facility level.

For the participants who were identified as TB presumptive cases, the information was captured using data capture sheets provided by the county TB programme for onward management. After this samples will be collected for GeneXpert analysis. After GeneXpert analysis, the data was sent to the National Tuberculosis Leprosy and Lung Disease Program (NTLD-P) via *TIBU* an application that links all GeneXpert machines in the country to the NTLD-P. The TB positive cases had their contacts followed up as per the MoH-K guidelines for the TB management cascade. The study team was then able to access data for follow-up and analysis through the County TB coordinators who will be attached to the project.

1.3.7. Study procedures

Figure 1.3 summaries the study procedures explained below. It details the process from regis-

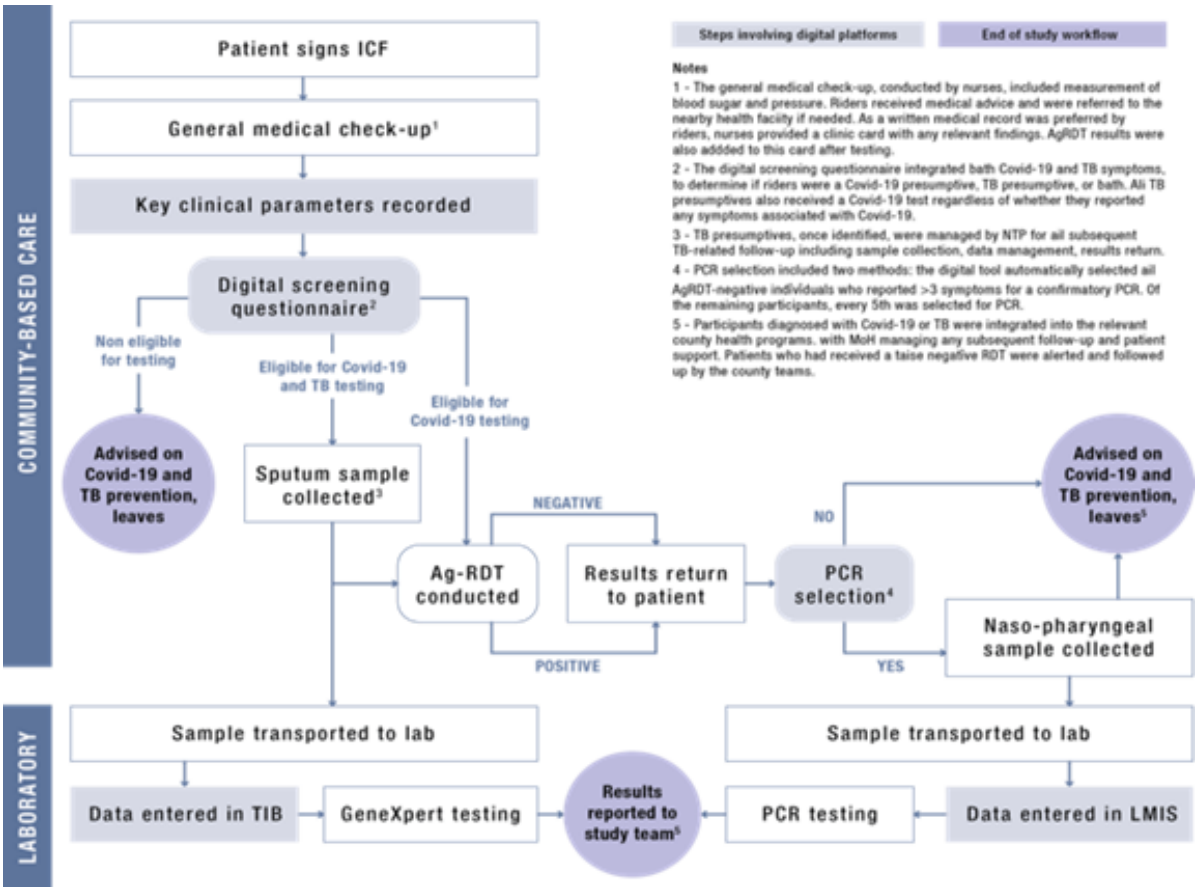


Figure 1.3: Registration, screening and testing flow diagram

tration of study participants all the way up to linkage to care. The procedures for use at various stages are also highlighted in pink. A detailed explanation is provided in the sections below.

Registration of participants and signing of ICF

Boda Boda riders who heeded the campaign calls and presented themselves to the testing sites were required to sign the informed Consent Form (ICF), after which they were registered using the *Kenya COVID-19 Tracker app* and then directed to move to the next desk for a free medical check-up.

Free Medical check-up
After registration, the participants got a free medical check-up. The check-up involved random blood sugar and blood pressure checks, and the participants also benefited from advice on care based on parameters observed from the medical check-up. At this point, all participants benefited from the free medical check-up, even if they were not eligible for the study.

After this, they progressed to the next step for eligibility check. At this point, based on the inclusion criteria, participants who meet the threshold were enrolled in the study. Those who did not satisfy the inclusion criteria were released to go home and reminded to observe COVID-19 and TB safety measures. Those enrolled into the study then proceeded to the screening desk.

Bi-directional COVID-19 and TB screening
All enrolled participants were taken through the digitized CIF which integrated a series of questions on symptoms or risk factors common to both COVID-19 and TB, including additional questions specific to each disease, in line with MoH-K guidelines. The screening questions are summarised in Table 1.4.

Table 1.4: Bi-directional COVID-19-TB screening questions

COVID-19	TB
Cough of any duration	
Fever or chills	
Chest Pain	
Shortness of breath or difficulty breathing	Drenching night sweats
Fatigue	Unintended weight loss
Muscle or body aches	Body mass index (BMI) less than 18.5
Headache	Recent contact with confirmed TB case
New loss of taste or smell	
Sore throat	
Congestion or runny nose	
Nausea or vomiting	
Diarrhoea	
Recent contact with confirmed COVID-19 case	

All those who reported risk factors common to COVID-19 and TB, as well as those who reported TB-specific risk factors (ie TB suspect cases), received both COVID-19 and TB testing.

Those who reported only COVID-19-specific risk factors, in the absence of any common OR any TB-specific risk factors, received antigen testing only.

For the purposes of analysis, we considered three broad patient populations that received testing:

1. “Yes” to any two green, regardless of grey or pink responses – TB suspect case AND COVID-19 suspect case $\rightarrow$ Ag-RDT + GeneXpert.

2. “Yes” to any pink, “yes” to any green, and “yes” to any grey —TB suspect case AND COVID-19 suspect case → Ag-RDT + GeneXpert.
3. “Yes” to any pink, and “yes” to any grey regardless of the responses for green —TB suspect case AND COVID-19 suspect case → Ag-RDT + GeneXpert.
4. “Yes” to any pink, “no” to all green and grey —TB suspect case ONLY → Ag-RDT + GeneXpert.
5. “Yes” to any pink, “yes” to any green, and “no” to all grey —TB suspect case ONLY → Ag-RDT + GeneXpert.
6. “Yes” to any grey, “no” to all green and pink —COVID-19 suspect case ONLY → Ag-RDT only.
7. “Yes” to any grey, “yes” to any green, and “no” to all pink —COVID-19 suspect case ONLY → Ag-RDT only.

The *Kenya COVID-19 Tracker app* was updated to include this screening algorithm.

Sample collection
All COVID-19 suspect and TB presumptive cases had samples collected from them at the point of care, for testing. Nasopharyngeal swabs were collected from all the *Boda Boda* riders who met the criteria for testing COVID-19, TB or both. Similarly, sputum samples were collected from the TB presumptive cases and those suspect for both. Those who did not meet the threshold for testing were released to go home and reminded to observe COVID-19 and TB safety measures. Sampling activities observed IPC requirements as recommended by MoH-K with strict adherence to the manufacturer’s SOP/ instructions for use.

Specimens for both COVID-19 and TB were stored in cool boxes with ice packs until they were analysed or transported to various laboratories for analysis. Nasopharyngeal swabs for COVID-19 RT-PCR and sputum samples for GeneXpert analysis were transported in the cool boxes to the respective laboratories using MoH-K designated riders

Testing for both COVID-19 and TB
All the samples collected for COVID-19 were tested using Ag-RDTs, and results captured in the *Kenya COVID-19 Tracker app*. In addition, 25% of these samples (670 samples from participants from Nairobi, 270 from Kiambu and 160 samples from Machakos and Kajiado) were also tested using RT-PCR. Of the 25%, 20% were sampled randomly from all the existing specimen, and 5% were sampled from the specimen with negative Ag-RDT results. Results from the RT-PCR were however not be sent to the national repository as these were used to test the accuracy and reliability of the Ag-RDTs.

Where RT-PCR results are discordant with the Ag-RDT results, particularly where a samples tested positive under RT-PCR when it had tested negative under the Ag-RDT, the RT-PCR results were sent to the national repository for inclusion in the national tally, the patient contacted and referred to care, and the primary contacts listed and handed over to the County COVID-19 surveillance teams for tracing and linkage to care.

Further, all samples collected for TB testing were sent to the County hospital laboratories for GeneXpert analysis. The results from these tests were communicated back to the study team through the respective TB County coordinators.

Case management
All *Boda Boda* riders who registered blood pressure measurements and random blood sugar levels outside the normal range were referred appropriately as guided by the county health facility staff who were part of the study. In addition, all COVID-19 positive cases were referred for management (either Home-Based Isolation and Care (HBIC) or hospitalization depending on their condition as assessed by the county health facility staff attached to the study).

All positive TB cases were handed over to the county TB coordinator for further management under the national TB programme.

Contact tracing
All COVID-19 positive cases were required to list their primary contacts (spouse / next of kin and contractual clients) on the *Kenya COVID-19 Tracker app*. The identified contacts were listed on the *Kenya COVID-19 Tracker app*. Data on all listed contacts was handed over to the County COVID-19 surveillance teams for tracing and linkage to care. Further, contact tracing for TB was done as coordinated by the County TB coordinators following the NTLD-P guidelines.

Accuracy and Reliability of Ag-RDT
The accuracy and reliability of the RDT was checked against the RT-PCR (gold standard) using the following metrics:

1. Sensitivity
2. Specificity
3. Predictive values
4. Kappa statistics for level of agreement

Use of digital tools in management of COVID-19 among *Boda Boda* riders
Digital tools were used in the end-to-end transmission of data during all the processes in this study.

1. Registration of participants and screening for eligibility for TB or COVID-19 testing, was done on the *Kenya COVID-19 Tracker app*.
2. Data from the RDTs was entered into the *Kenya COVID-19 Tracker app*.
3. All testing data was uploaded on the LabWare LIMS to be fed into the national daily tallies by county health officials.

1.3.8. Sample Size determination

The study area under consideration is made up of 32 sub-counties/ townships as shown in Table 1.3 with approximately 231,500 *Boda Boda* riders. A sample of *Boda Boda* riders from all these sub-counties were enrolled in the study. The samples required were calculated per sub-county using the formula in Equation (1.1), (see [16, 14, 5]), where the $\alpha = 0.05$ and $Z_{\alpha/2} = 1.96$, and the level of error $E = 5\%$. $p = 11.5\%$ and this was approximated using the national positivity rate considering all the tests that had been carried out so far in the country at the time (September 2021). This was considered since the precise positivity rates for all the sub-counties will be largely affected by the levels of testing which varies disproportionately across counties, with Nairobi county getting the lion's share of the tests.

$$
\begin{aligned}
n &= p(1-p)\left(\frac{Z_{\alpha/2}}{E}\right)^2 \\
&= 0.115(1-0.115) * \left(\frac{1.96}{0.05}\right)^2 \\
&= 156
\end{aligned}
\tag{1.1}
$$

Therefore a round figure of 160 samples was considered per sub-county yielding a total of **5,120** samples with Nairobi getting **2,720**, Kiambu getting **1,120**, and Kajiado and Machakos getting **640** each. After testing for COVID-19 using Ag-RDT, a sample from the collected specimen was tested using RT-PCR and these were later be used to test the reliability and accuracy of the Ag-RDTs. To achieve this level of testing, it was estimated that 50% of those screened would meet the suspect case criteria.

For RT-PCR, a sample of **1,260** specimens were considered with Nairobi taking **670**, Kiambu **270**, and Machakos and Kajiado getting **160** each. The 1,260 samples were obtained based on the formula in Equation (1.2) (1,144 boosted by 10%), and distributed based on the sub-counties considered for each county. These samples were picked based on a lottery method.

$$
\begin{aligned}
n \text{ based on sensitivity } &= \frac{(Z_{\alpha/2}+Z_{\beta})^2 \times S_N(1-S_N)}{L^2 \times \text{ Prevalence}}, \text{ and} \\
n \text{ based on specificity } &= \frac{(Z_{\alpha/2}+Z_{\beta})^2 \times S_P(1-S_P)}{L^2 \times (1- \text{ Prevalence})}
\end{aligned}
\tag{1.2}
$$

Where $S_N = 80\%$ is the anticipated sensitivity, $S_P = 80\%$ is the anticipated specificity, $\alpha = 0.05$ is the size of the critical region ($1-\alpha$ is the confidence level), $1-\beta = 0.8$ is the power of the test so that $Z_{\alpha/2} = 1.96$ and $Z_{\beta} = 0.845$. $L = 0.1$ is the absolute precision desired on either side (half-width of the detection level) of sensitivity or specificity and the prevalence has been taken as equal to the positivity of 11%.

For GeneXpert analysis, sputum samples will be collected from all the *Boda Boda* riders who turn out to be presumptive positive after the screening process.

1.4. Data Management Plan

To ensure confidentiality and anonymity of study subjects, data was extracted and de-identified and stored in specific password protected computers. Only persons related to this study were granted access to this data.

1.4.1. Quality assurance of data entry

All data collection from this study was captured digitally on systems that have already been tested and are currently in use by the MoH-K. In addition data collection was conducted by well trained staff to ensure enhanced data quality.

Any request to access data will have to be authorized by the Principal Investigators (PIs). For study purposes, data was downloaded from the *Kenya COVID-19 Tracker app*back-end once every week. Once downloaded by the JKUAT investigators, data was stored in the JKUAT server in password protected files and drives and was only be accessible to the study team

from JKUAT and FIND, the global alliance for diagnostics. The TB data was stored in the National TB repository. The TB positive case numbers from this study was shared with the study team by the County TB coordinators.

1.4.2. Data Ownership and Sharing Policy

All data collection will be on behalf of MoH-K who wholly own it and reserve the rights to share under the data protection act of 2019. However, under the existing partnerships with MoH-K, the study team will have access to data relevant to the work. This will be through the Digital Health Applied Research Centre (DHARC) server where the data will be reposited. Data sharing will be further governed by the FIND-JKUAT agreement.

1.4.3. Duration of the Study

The study was carried out over a six-month period in line the following timelines:

Table 1.5: Study Timelines

Activity	May 21	June 21	July 21	Aug 21	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22
Desktop Review	X	X									
Review and Compilation of study protocol	X	X	X								
Ethical Review			X								
National Entry				X							
County Entry				X							
Development of digital tools				X	X						
Development of training materials				X	X						
Sensitization Meetings					X						
Recruitment of participants and data collection (testing)					X	X	X	X	X	X	
Data Processing					X	X	X	X	X	X	
Data analysis						X	X	X	X	X	X
Development of manuscript										X	X
Final report										X	X

2

Data Analysis

2.1. Preliminary data preparation

For this study, all information was collected using the *Kenya COVID-19 Tracker app* in a digital format, except the COVID-19 RT-PCR results, and the TB results from GenXpert analysis. The COVID-19 RT-PCR results, and the TB results from GenXpert were also included in the main data-frame downloaded from the *Kenya COVID-19 Tracker app* for analysis.

Despite this, there were still some simple errors in specific data capture fields where validation checks failed. Most of the erroneous entries, which were less that 5% on the overall, were solved by logically correcting the clear mistakes, e.g temperature of 3.6 as opposed to 36, while the other very unclear observations like Sp02 of 16 were replaced using the mean of the Spo2 observations to make them meaningful. This approach was applied across the variables, on a case by case basis. Cases of wrong units were also corrected, for example, height was collected in centimetres and later used to compute BMI. However, in some instances the height was recorded in meters and this completely distorted the BMI which was a calculated field by the tool. For such cases, the correct conversions were done.

Observations from blood sugar and blood pressure measurements that that were anomalous were left in the category of abnormal observations (abnormal blood pressure, abnormal blood sugar) to avoid too much modification that would result in modification of very sensitive outcomes.

2.2. Metrics that could not be computed

At the onset, the study outlined the metrics in Table 1.1 to be used to measure the study objectives. However, due to some challenges in the workflow and in the field activities, some of these metrics could not be measured. The metrics that were not computed are listed and explained below.

Proportion of riders who visited the testing site out of all those who received the messages

Digital messaging was one of the ways intended for popularisation of the study for purposes of demand creation. The proportion of riders who visited the study site out of all those who received text messages about the study was to be computed. However, eventually, other modes of communication were used to reach out to the *Boda Boda* riders that it would not be accurate to attribute all the visits to digital messaging. The BAK chairmen and other local leaders were engaged in active mobilisation of participants. In addition, the sites received participants who were not necessarily *Boda Boda* riders, some were curious passers by, while

others accompanied the *Boda Boda* riders (mainly spouses) and they too were enrolled. For that reason, this particular metric was not computed.

The study engaged and recruited the top BAK leadership at the level of County Chairmen from the study Counties of Nairobi, Machakos, Kiambu and Kajiado. The Chairmen were responsible for the active mobilization of over 68,000, 20,000, 24,000 and 33,000 *Boda Boda* members, respectively. Their mobilization activities included face to face meetings with the Sub- County, Ward and *Boda Boda* "Stage" officials drawn from the regions where the *Boda Boda* riders were recruited. Further, the BAK County leadership reached out to their officials and members through various media such as SMS and Whatsapp and announcement and sensitization using a public address system. Mobilization of riders took place during the entire duration of the study. The lowest organizational unit for the *Boda Boda* riders is called a stage. Each stage has an average of 30 riders with 2 "stage" officials. We estimate that over 7,680 short text and Whatsapp messages were sent to the riders as a way of mobilization over the study period.

It is important to add that the methods used for demand creation were effective and the study was able to conduct a total of 4,946 (96.6%) out of the planned target of 5120 tests at the time of completing the field work by the end of February 2022.

Proportion of participants that received a digital result
In the study protocol, a key study metric was to link various systems, so that test results would be relayed by text messages to the participants. However, the study ran into some interoperability challenges, and eventually this wasn't possible. However given that the tests were rapid, the participants often waited for about 15 to 20 minutes for their test results and left the study site with their test results. Those tested using the COVID-19 RT-PCR and those who took TB tests all got their results using the usual County health department communication channels.

Median turnaround time for results return (RDT)
The median turnaround time (TaT) was not possible to compute since the testing platform wasn't digitally linked to the lab or the testing platforms, again due to lack of interoperability.

Proportion of COVID-19 positive cases eligible for Home-Based Isolation and Care (HBIC) who register on *Jitenge system*
No cases for HBIC were registered on the *Jitenge system* because there was no direct link between the *Kenya COVID-19 Tracker app* and *Jitenge system*. In addition, the cost for sending the text messages had not been factored into the budget.

Proportion of positive cases who provided contact information
Contract tracing was also a study metric, however, due to the complexity of the logistical requirements, this function was taken up by the County health department, together with the relevant government security organs, and hence this metric was also not computed.

2.3. Demographic Characteristics of the participants

2.3.1. Nationality, Level of Education and Marital status

A total of 5,663 *Boda Boda* riders from the four counties visited the study sites, out of which, 5,637 (99.5%) provided information about their nationalities. Only less than about 1% (61) of the participants who provided information about their nationalities were from the other East African countries. The rest were all Kenyan (Table 2.1).

Table 2.1: Nationality of participants

Nationality	Number	Percentage
Others	2	0.04%
Ethiopia	2	0.04%
Uganda	4	0.07%
Tanzania	8	0.14%
Burundi	19	0.34%
Rwanda	26	0.46%
Kenya	5576	98.92%
Total	5637	100.00%

Table 2.2: Levels of Education of participants

Level of Education completed	Number	Percentage
College/university/polytechnic	980	17.36%
secondary school education	2752	48.74%
Primary school education	1834	32.48%
none	68	1.20%
not willing to disclose	12	0.21%
Total	5646	100.00%

Of the 5,663 participants, 5,646 had some form of information on their levels of education collected. From this group, 17.36% had completed tertiary level of education, 48.74% had completed secondary level of education, and 32% had completed primary level. Only 1% reported that they had no formal education, while less than 1% declined to disclose their education status (Table 2.2).

Table 2.3: Marital Status of participants

Marital Status	Number	Percentage
cohabiting	38	0.67%
divorced	126	2.23%
married_monogamous	3977	70.30%
married_polygamous	373	6.59%
single	1113	19.67%
widowed	24	0.42%
not willing to disclose	6	0.11%
Total	5657	100.00%

5,657 of the 5,663 participants provided information about their marital status. Less than 1% were unwilling to disclose their marital status, less than 1% were widowed or cohabiting. About 2% were divorced and 19% were single. The rest (77%) were married, with 6.59% being in polygamous marriages, and 70.3% being in monogamous marriages (Table 2.3).

2.3.2. Gender, Age and County

As part of the registration process, some simple demographic characteristics were collected as summarised in Table 2.4. In as much as this study targeted *Boda Boda* riders, some of the riders requested to be tested together with their spouses, while other members of the

community, not necessarily *Boda Boda* riders also requested to undergo testing. There were a total of 5,498 (97.1%) male and 165 female participants, most of them aged between 25 and 44 years (61.2%). The ages of 692 (12.22%) participants were missing due to a problem with the age calculation feature in the tool. Overall, the average age among participants was 33.7 years. Most of the participants were from Nairobi County, and the fewest numbers were recorded in Kajiado county.

Table 2.4: Count of participants by age, gender and county

Gender/County	Below 24	25-34	35-44	45-54	55+	Missing	Total
Female	26	59	39	23	6	12	165
Kajiado		3	1				4
Kiambu	16	26	14	10	5	3	74
Machakos		5	2			1	8
Nairobi	10	25	22	13	1	8	79
Male	790	2143	1223	496	166	680	5498
Kajiado	28	112	66	28	8	3	245
Kiambu	154	455	281	109	29	210	1238
Machakos	104	259	137	58	21	234	813
Nairobi	504	1317	739	301	108	233	3202
Total	816	2202	1262	519	172	692	5663

2.3.3. NHIF Coverage

This study also sought to establish whether participants had medical cover with the National Hospital Insurance Fund (NHIF). At the height of the COVID-19 pandemic in the country, one of the greatest challenges with case management was the costs involved. NHIF covered some aspects of case management at various health facilities, and this study was keen to establish how the participants would benefit from NHIF coverage if they were found to be positive and symptomatic.

Table 2.5: Count of participants who have medical cover with NHIF

Age group	No NHIF	Have NHIF	Total	Percentage With NHIF
Below 24	624	192	816	23.53%
25-34	1294	908	2202	41.24%
35-44	599	663	1262	52.54%
45-54	252	267	519	51.45%
55+	81	91	172	52.91%
NA	401	291	692	42.05%
Grand Total	3251	2412	5663	42.59%

It was established that only 42.59% of the participants had NHIF cover, with 50% of them being above age 35 years. The lowest levels of NHIF coverage was among those participants below 24 years old (Table 2.5). By County of resident, the lowest numbers registered under NHIF were recorded in Nairobi County (39.87%) followed by Machakos County (42.02%). For Kiambu a total of 48.09% of the riders were registered under NHIF and Kajiado lead with 51.41%

NHIF registration. In all the counties, the group with least registration were those under 24 years old, and the highest registration was among the 55 years and above.

It was also noted that of the 45 COVID-19 Ag-RDT positive cases, only 24 (53.33%) were registered for NHIF cover, whereas of the 7 TB cases, only 2 (28.6%) had NHIF cover. For the RT-PCR COVID-19 positive cases, only 24 out of 47 (51.06%) had NHIF cover.

Table 2.6: Count of participants who have medical cover with NHIF by County of residence

County/ Age group	No NHIF	Have NHIF	Total	Percentage With NHIF
Kajiado	121	128	249	51.41%
Below 24	22	6	28	21.43%
25-34	59	56	115	48.70%
35-44	26	41	67	61.19%
45-54	9	19	28	67.86%
55+	3	5	8	62.50%
NA	2	1	3	33.33%
Kiambu	681	631	1312	48.09%
Below 24	127	43	170	25.29%
25-34	240	241	481	50.10%
35-44	130	165	295	55.93%
45-54	55	64	119	53.78%
55+	16	18	34	52.94%
NA	113	100	213	46.95%
Machakos	476	345	821	42.02%
Below 24	81	23	104	22.12%
25-34	154	110	264	41.67%
35-44	58	81	139	58.27%
45-54	31	27	58	46.55%
55+	8	13	21	61.90%
NA	144	91	235	38.72%
Nairobi	1973	1308	3281	39.87%
Below 24	394	120	514	23.35%
25-34	841	501	1342	37.33%
35-44	385	376	761	49.41%
45-54	157	157	314	50.00%
55+	54	55	109	50.46%
NA	142	99	241	41.08%
Total	3251	2412	5663	42.59%

2.4. Medical Characteristics of the participants

For demand creation, this study offered some simple investigations for free and depending on the parameters observed, the *Boda Boda* riders and any other participants were linked to care. After registration, measurement of random blood sugar, blood pressure, temperature, SPo2 and BMI were taken. The average BMI observed was 23.97, which falls within the normal range. In the STEPS Survey of 2015, 61% of respondents had normal weight BMIs ranging between 18-24.9 (STEPS Survey, 2015).

The average SPo2 in this study was 96.64% and the average temperature measurement

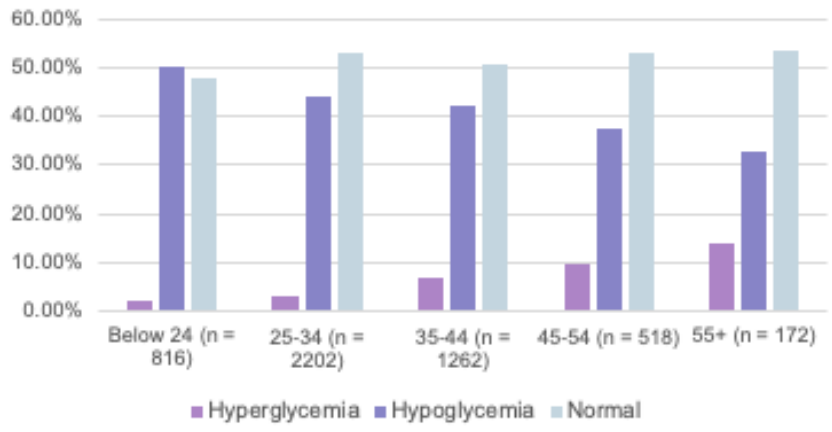
recorded was 36.5° Celsius. Out of 5,665 SPo2 measurements taken, 462 (8.15%) had an SPo2 below 95%.

Figure 2.1 and Tables 2.7, 2.8 and 2.9 show some of the parameters that were observed after the random blood sugar measurements. From Table 2.7, it can be noted that 51.6% of the participants had normal blood sugar levels (4-7.8 mmol/L), 5.17% of the participants had raised blood sugars (more than 7.8 mmol/L), which is slightly higher than the national diabetes prevalence of 4.56% (STEPS Survey, 2015). Our findings show that 43.2% have below normal sugar levels (below 4 mmol/L). This distribution seemed to be uniform across both gender, and across all the counties. There is not a lot of variation across the gender (even though there are disproportionately more males than females in the data-set). Overall 48.4% of the participants had abnormal blood sugar levels.

Table 2.7: RBS status of participants by gender and county

	Random Blood Sugar			
Gender/County	Hyperglycemia	Hypoglycemia	Normal blood sugar	Total
Female	11	60	94	165
Kajiado	1	3		4
Kiambu	6	22	46	74
Machakos		2	6	8
Nairobi	4	33	42	79
Male	282	2387	2827	5496
Kajiado	11	114	120	245
Kiambu	73	505	659	1237
Machakos	25	373	415	813
Nairobi	173	1395	1633	3201
Total	293	2447	2921	5661

Figure 2.1: Blood Sugar Measurements by Age



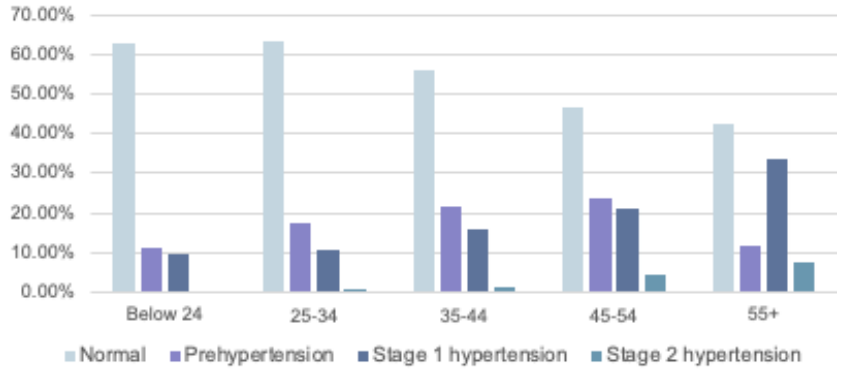
From Table 2.9, we note raising blood sugars as age advances, with the highest instances recorded among the 55+, with Kajiado having the highest at 37.5%. From the 2015 STEPS survey, 0.0% of those aged between 18-29 have diabetes, whereas 0.2% of those aged between 30-44 have diabetes.

Table 2.8: RBS status of participants by age and gender

Age/Gender	Hyperglycemia		Hypoglycemia		Normal blood sugar		Total
25-34	67	3.04%	973	44.19%	1162	52.77%	2202
Female	3	5.08%	25	42.37%	31	52.54%	59
Male	64	2.99%	948	44.24%	1131	52.78%	2143
35-44	86	6.81%	534	42.31%	642	50.87%	1262
Female	3	7.69%	12	30.77%	24	61.54%	39
Male	83	6.79%	522	42.68%	618	50.53%	1223
45-54	49	9.46%	195	37.64%	274	52.90%	518
Female	3	13.04%	7	30.43%	13	56.52%	23
Male	46	9.29%	188	37.98%	261	52.73%	495
55+	24	13.95%	56	32.56%	92	53.49%	172
Female	1	16.67%	1	16.67%	4	66.67%	6
Male	23	13.86%	55	33.13%	88	53.01%	166
Below 24	17	2.08%	410	50.25%	389	47.67%	816
Female		0.00%	11	42.31%	15	57.69%	26
Male	17	2.15%	399	50.51%	374	47.34%	790
Age missing	50	7.24%	279	40.38%	362	52.39%	691
Female	1	8.33%	4	33.33%	7	58.33%	12
Male	49	7.22%	275	40.50%	355	52.28%	679
Total	293	5.18%	2447	43.23%	2921	51.60%	5661

Figure 2.2 and Tables 2.10, 2.11 and 2.12 show various charts representing the blood pressure analysis based on the systolic and diastolic blood pressure measurements. The observations were classified as normal, prehypertension, stage 1 hypertension, stage 2 hypertension and CHECK. Those placed under the check category were either low or undefined based on the classification of the systolic and diastolic blood pressure measurements that did not fit within the prescribed interpretation chart (Figure 2.3).

Figure 2.2: Blood Pressure Measurements by Age



58.29% of the participants had normal blood pressure, 18.05% were prehypertensive, 14.53% were in stage 1 hypertension, and 1.32% were in stage 2 hypertension. 7.81% of the participants had either very low, or very high blood pressure (those in the CHECK category). Those in the CHECK category had figures that were anomalous, some of these could be attributed to data quality issues, hence this category. About 42% of participants (mostly male riders) had elevated blood pressure, higher (x1.5) than an estimate of national prevalence for hyperten-

Table 2.9: RBS status of participants by age and county

Age/County	Hyperglycemia		Hypoglycemia		Normal blood sugar		Total
25-34	67	3.04%	973	44.19%	1162	52.77%	2202
Kajiado	3	2.61%	56	48.70%	56	48.70%	115
Kiambu	21	4.37%	202	42.00%	258	53.64%	481
Machakos	7	2.65%	113	42.80%	144	54.55%	264
Nairobi	36	2.68%	602	44.86%	704	52.46%	1342
35-44	86	6.81%	534	42.31%	642	50.87%	1262
Kajiado	5	7.46%	27	40.30%	35	52.24%	67
Kiambu	16	5.42%	110	37.29%	169	57.29%	295
Machakos	1	0.72%	67	48.20%	71	51.08%	139
Nairobi	64	8.41%	330	43.36%	367	48.23%	761
45-54	49	9.46%	195	37.64%	274	52.90%	518
Kajiado	1	3.57%	12	42.86%	15	53.57%	28
Kiambu	14	11.86%	44	37.29%	60	50.85%	118
Machakos	1	1.72%	28	48.28%	29	50.00%	58
Nairobi	33	10.51%	111	35.35%	170	54.14%	314
55+	24	13.95%	56	32.56%	92	53.49%	172
Kajiado	3	37.50%	3	37.50%	2	25.00%	8
Kiambu	3	8.82%	6	17.65%	25	73.53%	34
Machakos	3	14.29%	7	33.33%	11	52.38%	21
Nairobi	15	13.76%	40	36.70%	54	49.54%	109
Below 24	17	2.08%	410	50.25%	389	47.67%	816
Kajiado		0.00%	17	60.71%	11	39.29%	28
Kiambu	8	4.71%	80	47.06%	82	48.24%	170
Machakos	2	1.92%	57	54.81%	45	43.27%	104
Nairobi	7	1.36%	256	49.81%	251	48.83%	514
Age Missing	50	7.24%	279	40.38%	362	52.39%	691
Kajiado		0.00%	2	66.67%	1	33.33%	3
Kiambu	17	7.98%	85	39.91%	111	52.11%	213
Machakos	11	4.68%	103	43.83%	121	51.49%	235
Nairobi	22	9.17%	89	37.08%	129	53.75%	240
Total	293	5.18%	2447	43.23%	2921	51.60%	5661

sion, estimated at 28.6% [13]- although data on this is scarce.The STEPS survey noted that 1.7%[0.6- 2.8] of men aged between 18-29 years, and 1.5%[0.4-2.6] of those aged between ages 30-44 years had raised blood pressure.

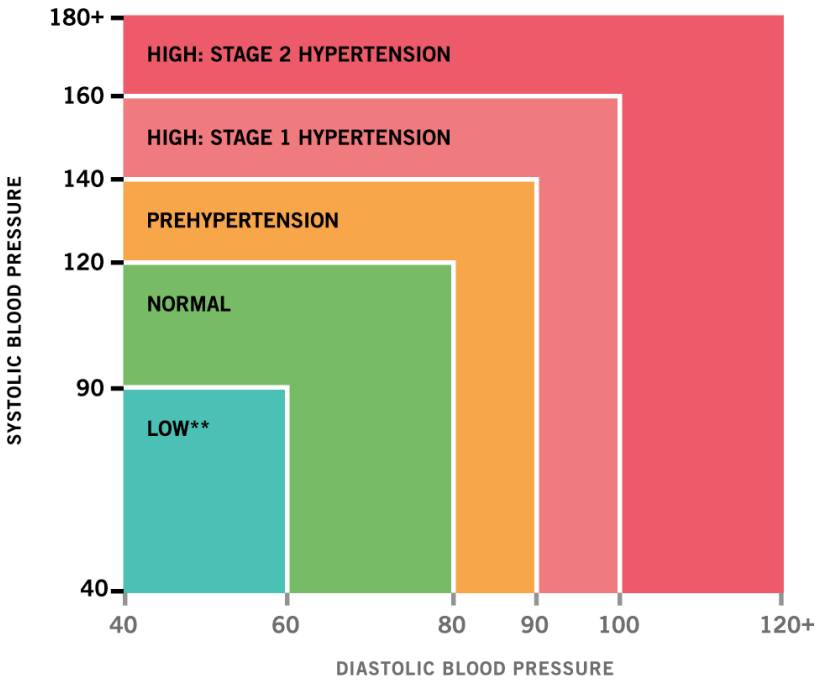


Figure 2.3: BP range chart

Table 2.10: BP status of participants by gender and county

Gender/County	Normal		Prehypertension		Stage 1 hypertension		Stage 2 hypertension		CHECK		Total
Female	99	60.00%	22	13.33%	27	16.36%	2	1.21%	15	9.09%	165
Kajiado	1	25.00%	2	50.00%		0.00%		0.00%	1	25.00%	4
Kiambu	50	67.57%	9	12.16%	10	13.51%	1	1.35%	4	5.41%	74
Machakos	5	62.50%	1	12.50%	2	25.00%		0.00%		0.00%	8
Nairobi	43	54.43%	10	12.66%	15	18.99%	1	1.27%	10	12.66%	79
Male	3202	58.24%	1000	18.19%	796	14.48%	73	1.33%	427	7.77%	5498
Kajiado	127	51.84%	55	22.45%	50	20.41%	3	1.22%	10	4.08%	245
Kiambu	738	59.61%	262	21.16%	154	12.44%	10	0.81%	74	5.98%	1238
Machakos	414	50.92%	151	18.57%	184	22.63%	13	1.60%	51	6.27%	813
Nairobi	1923	60.06%	532	16.61%	408	12.74%	47	1.47%	292	9.12%	3202
Total	3301	58.29%	1022	18.05%	823	14.53%	75	1.32%	442	7.81%	5663

Table 2.11: BP status of participants by age and county

Age/County	Normal		Prehypertension		Stage 1 hypertension		Stage 2 hypertension		CHECK		Total
25-34	1396	63.40%	384	17.44%	232	10.54%	8	0.36%	182	8.27%	2202
Kajiado	62	53.91%	26	22.61%	18	15.65%	2	1.74%	7	6.09%	115
Kiambu	305	63.41%	105	21.83%	38	7.90%	1	0.21%	32	6.65%	481
Machakos	132	50.00%	51	19.32%	66	25.00%		0.00%	15	5.68%	264
Nairobi	897	66.84%	202	15.05%	110	8.20%	5	0.37%	128	9.54%	1342
35-44	707	56.02%	272	21.55%	203	16.09%	16	1.27%	64	5.07%	1262
Kajiado	36	53.73%	15	22.39%	13	19.40%		0.00%	3	4.48%	67
Kiambu	169	57.29%	77	26.10%	33	11.19%	3	1.02%	13	4.41%	295
Machakos	76	54.68%	26	18.71%	28	20.14%	5	3.60%	4	2.88%	139
Nairobi	426	55.98%	154	20.24%	129	16.95%	8	1.05%	44	5.78%	761
45-54	243	46.82%	122	23.51%	109	21.00%	24	4.62%	21	4.05%	519
Kajiado	12	42.86%	8	28.57%	7	25.00%	1	3.57%		0.00%	28
Kiambu	56	47.06%	27	22.69%	28	23.53%	4	3.36%	4	3.36%	119
Machakos	20	34.48%	21	36.21%	15	25.86%	1	1.72%	1	1.72%	58
Nairobi	155	49.36%	66	21.02%	59	18.79%	18	5.73%	16	5.10%	314
55+	73	42.44%	20	11.63%	58	33.72%	13	7.56%	8	4.65%	172
Kajiado	3	37.50%		0.00%	5	62.50%		0.00%		0.00%	8
Kiambu	17	50.00%	2	5.88%	11	32.35%	2	5.88%	2	5.88%	34
Machakos	6	28.57%	3	14.29%	12	57.14%		0.00%		0.00%	21
Nairobi	47	43.12%	15	13.76%	30	27.52%	11	10.09%	6	5.50%	109
Below 24	514	62.99%	93	11.40%	77	9.44%		0.00%	132	16.18%	816
Kajiado	13	46.43%	8	28.57%	6	21.43%		0.00%	1	3.57%	28
Kiambu	119	70.00%	17	10.00%	16	9.41%		0.00%	18	10.59%	170
Machakos	66	63.46%	7	6.73%	12	11.54%		0.00%	19	18.27%	104
Nairobi	316	61.48%	61	11.87%	43	8.37%		0.00%	94	18.29%	514
Age Missing	368	53.18%	131	18.93%	144	20.81%	14	2.02%	35	5.06%	692
Kajiado	2	66.67%		0.00%	1	33.33%		0.00%		0.00%	3
Kiambu	122	57.28%	43	20.19%	38	17.84%	1	0.47%	9	4.23%	213
Machakos	119	50.64%	44	18.72%	53	22.55%	7	2.98%	12	5.11%	235
Nairobi	125	51.87%	44	18.26%	52	21.58%	6	2.49%	14	5.81%	241
Total	3301	58.29%	1022	18.05%	823	14.53%	75	1.32%	442	7.81%	5663

Table 2.12: BP status of participants by age and county

Age/ Gender	Normal		Prehypertension		Stage 1 hypertension		Stage 2 hypertension		CHECK		Total
25-34	1396	63.40%	384	17.44%	232	10.54%	8	0.36%	182	8.27%	2202
female	42	71.19%	7	11.86%	4	6.78%		0.00%	6	10.17%	59
male	1354	63.18%	377	17.59%	228	10.64%	8	0.37%	176	8.21%	2143
35-44	707	56.02%	272	21.55%	203	16.09%	16	1.27%	64	5.07%	1262
female	17	43.59%	6	15.38%	12	30.77%	1	2.56%	3	7.69%	39
male	690	56.42%	266	21.75%	191	15.62%	15	1.23%	61	4.99%	1223
45-54	243	46.82%	122	23.51%	109	21.00%	24	4.62%	21	4.05%	519
female	9	39.13%	6	26.09%	7	30.43%	1	4.35%		0.00%	23
male	234	47.18%	116	23.39%	102	20.56%	23	4.64%	21	4.23%	496
55+	73	42.44%	20	11.63%	58	33.72%	13	7.56%	8	4.65%	172
female	3	50.00%		0.00%	2	33.33%		0.00%	1	16.67%	6
male	70	42.17%	20	12.05%	56	33.73%	13	7.83%	7	4.22%	166
Below 24	514	62.99%	93	11.40%	77	9.44%		0.00%	132	16.18%	816
female	22	84.62%	1	3.85%		0.00%		0.00%	3	11.54%	26
male	492	62.28%	92	11.65%	77	9.75%		0.00%	129	16.33%	790
Age Missing	368	53.18%	131	18.93%	144	20.81%	14	2.02%	35	5.06%	692
female	6	50.00%	2	16.67%	2	16.67%		0.00%	2	16.67%	12
male	362	53.24%	129	18.97%	142	20.88%	14	2.06%	33	4.85%	680
Total	3301	58.29%	1022	18.05%	823	14.53%	75	1.32%	442	7.81%	5663

2.4.1. Relationship between NCD related medical Characteristics and infection status

The study went on to check if there was any relative risk of COVID-19 infection attributable to the Noncommunicable disease (NCD) variables observed during the medical examinations offered to the participants. For this, odds ratios for COVID-19 positivity by RT-PCR in participants with abnormal blood sugar or abnormal blood pressure were calculated as per the contingency tables shown below.

Table 2.13: COVID-19 positivity by blood sugar contingency table

COVID-19/ RBS	Abnormal BS	Normal BS	Total
Positive	17	30	47
Negative	485	488	973
Total	502	518	1020

OR	0.57
Upper CI	1.05
Lower CI	0.31

According to Table 2.13, and from the odds ratio, there is a lower likelihood of contracting COVID-19 given that abnormal blood sugar has been observed. From the confidence interval, the odds ratio is not statistically significant.

Table 2.14: COVID-19 positivity by blood pressure contingency table

COVID-19/ BP	Abnormal BP	Normal BP	Total
Positive	21	26	47
Negative	418	556	974
Total	439	582	1021

OR	1.07
Upper CI	1.94
Lower CI	0.60

According Table 2.14, and from the odds ratio, there is no association between COVID-19 positivity and blood pressure. From the confidence interval, the odds ratio is not statistically significant.

2.4.2. Relationship between SPo2 and infection status

The study also explored the relationship between SPo2 and COVID-19 or TB infection status. Table 2.15 shows the proportions of COVID-19 positive cases who had abnormal SPo2, 12.77% of the positive cases had abnormal SPo2 (below 94%).

Table 2.15: COVID-19 positivity by SPo2 contingency table

SPo2	Negative	Positive	Total	% Positive
Abnormal	109	6	115	12.77%
Normal	865	41	906	87.23%
Total	974	47	1021	

Similarly, Table 2.16 shows the proportions of TB positive cases who registered abnormal SPo2. For TB, 28.57% of the positive cases recorded abnormal SPo2.

Table 2.16: TB positivity by SPo2 contingency table

SPo2	Negative	Positive	Total	% Positive
Abnormal	33	2	35	28.57%
Normal	315	5	320	71.43%
Total	348	7	355	

2.5. COVID-19 and TB screening and testing

The screening questions used were as in Table 1.4. Out of the 5,663 participants who visited the sites, 719 (12.7%) did not meet the testing criteria and so only 4,946 were screened, out of which 40 responded no to all questions and the remaining 4916 gave varied responses. Figure 2.4 shows the percentages of responses to specific screening questions, for those who responded to various questions.

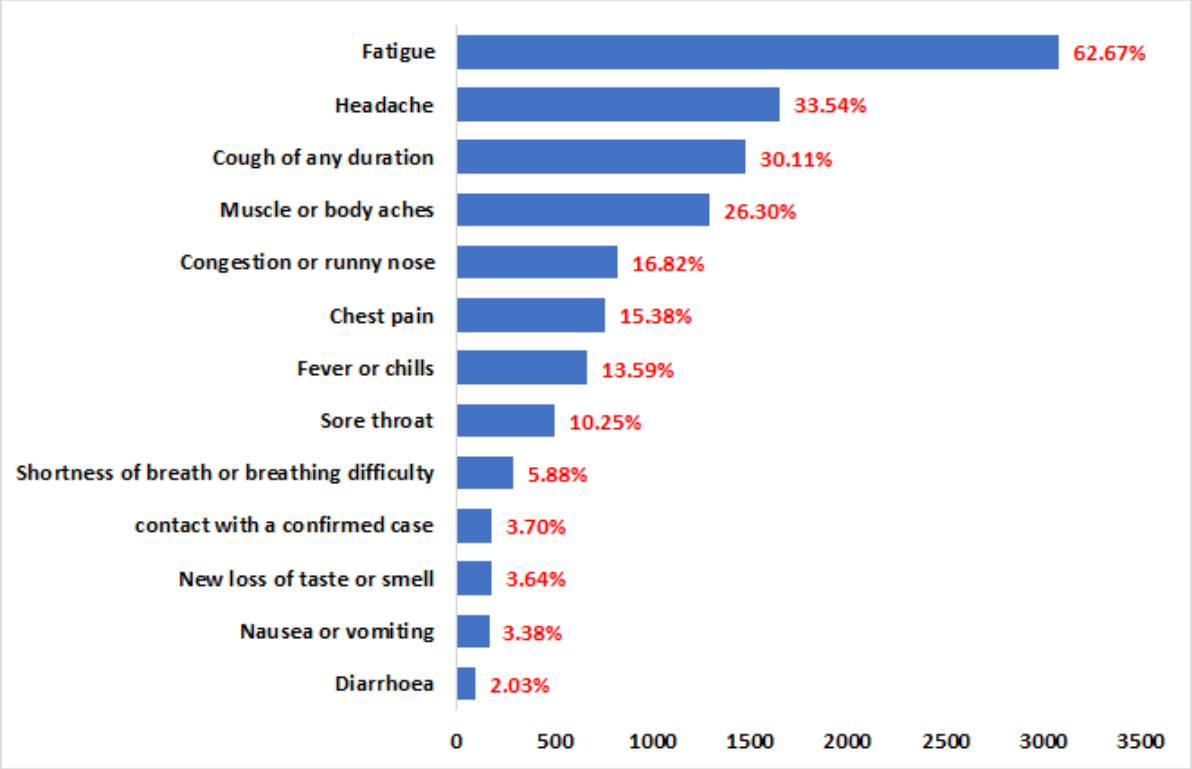


Figure 2.4: Count of responses to specific screening questions

These are just the responses given regardless of the final outcome of the test. Most of them (62.67%) had fatigue, 33.54% also had headaches. 30% of the respondents had coughs, 26.30% muscular aches. Diarrhoea, nausea and vomiting, new loss of taste and smell, contact with an infected case and shortness of breath featured the least.

However, respiratory symptoms combined (cough of any duration, congestion or runny nose, chest pain, sore throat and shortness of breath or breathing difficulty) accounted for 51.71% of the symptoms (Figure 2.5).

2.5.1. Symptoms exhibited by those who tested positive for COVID-19

Of the 45 cases who tested positive for COVID-19 based on the Ag-RDT, the most common symptoms were respiratory symptoms and fatigue (both at 68.89%) followed by headache

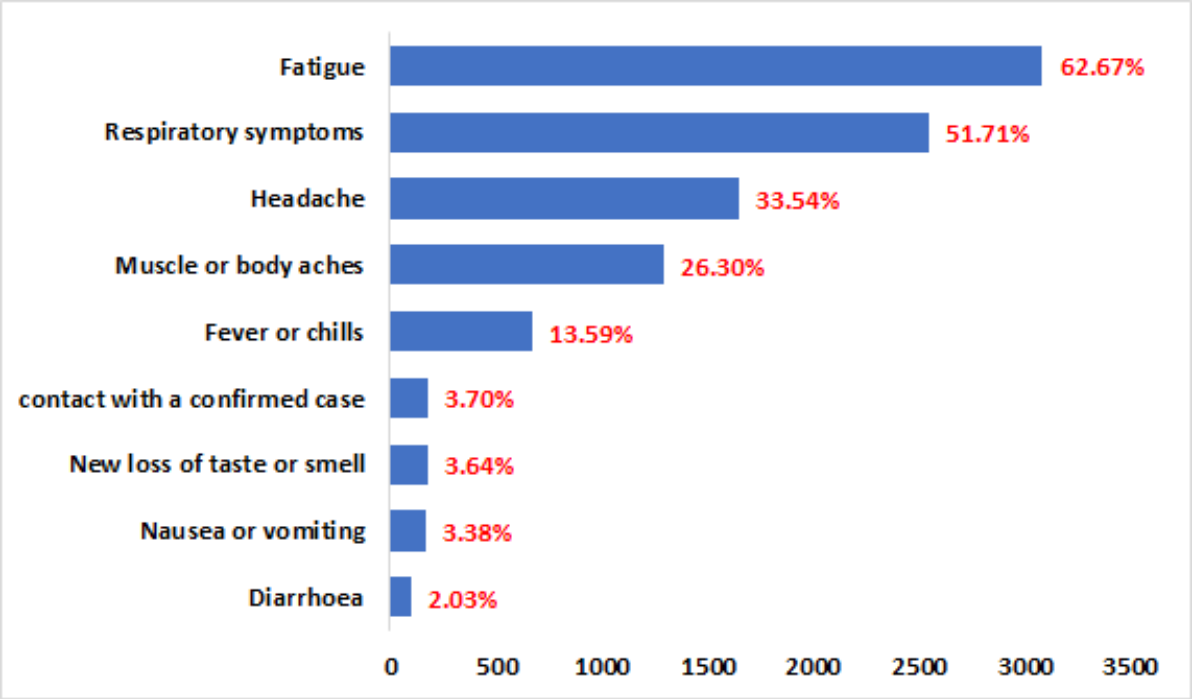


Figure 2.5: Count of responses to specific screening questions, with respiratory symptoms combined

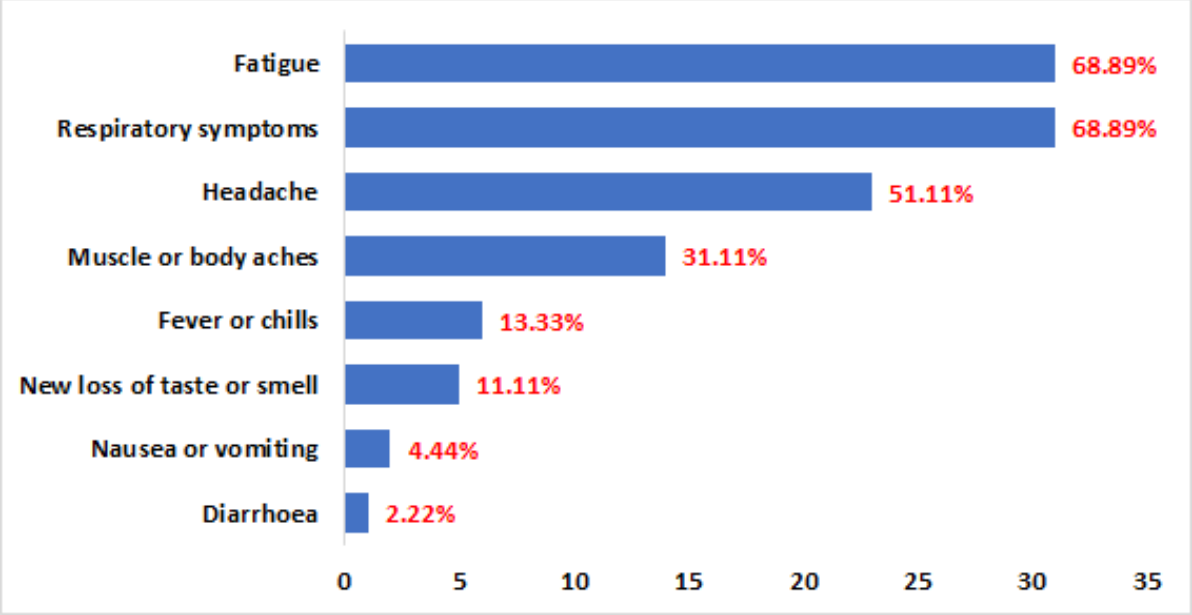


Figure 2.6: Count of responses from COVID-19 Ag-RDT positive cases

(51.11%) and then muscle or body aches (31.11%). The least observed symptom was diarrhoea (2.22%), followed by nausea and vomiting (4.44%) (Figure 2.6).

A similar scenario was witnessed in the cases of those positive based on the RT-PCR (Figure 2.7). Even for these, fatigue was at the top (59.57%), followed by respiratory symptoms (55.32%) headache (40%) and muscle and body aches (38.3%). The least reported symptom was still diarrhoea (2.13%) (Figure 2.7).

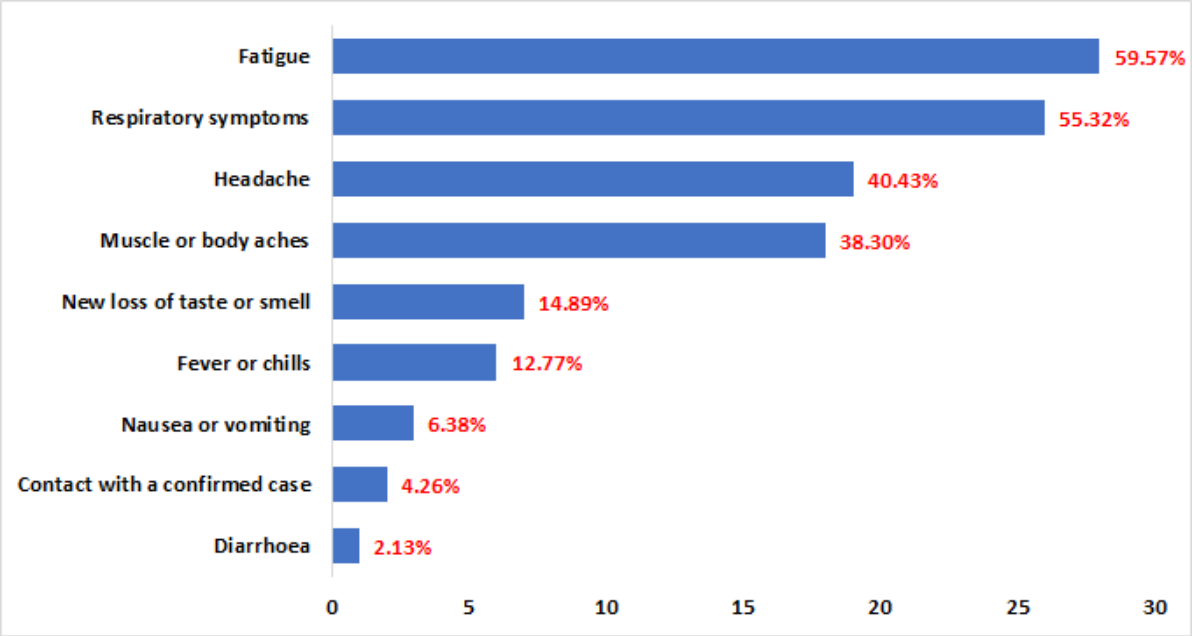


Figure 2.7: Count of responses from COVID-19 RT-PCR positive cases

2.5.2. Symptoms exhibited by those who tested positive for TB

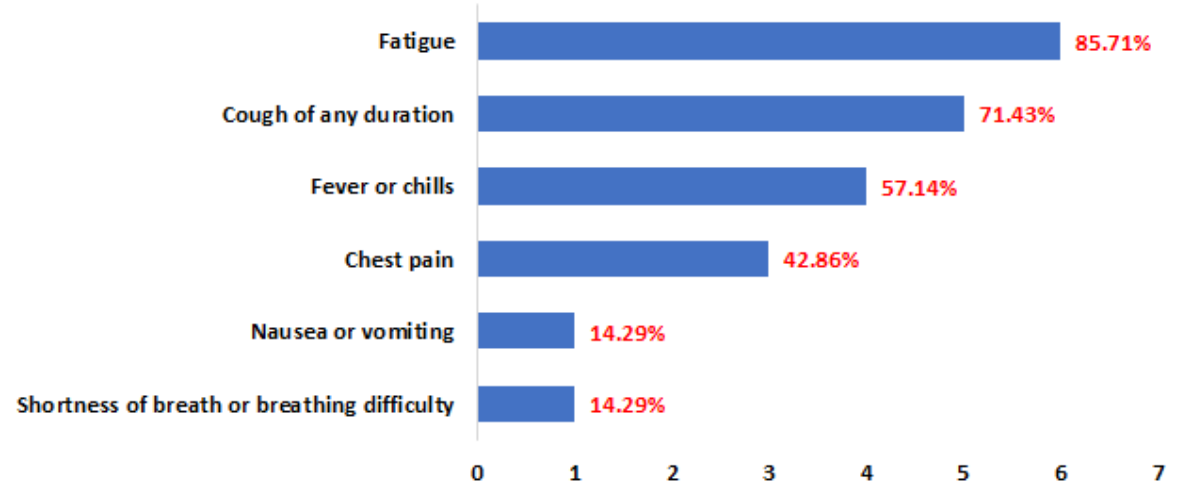


Figure 2.8: Count of responses from TB test positive cases

Based on all the symptoms (both COVID-19 and TB specific symptoms), fatigue was mostly experienced (85.7%), followed by cough of any duration (71.43%), fever and chills (57.14%), and lastly nausea or vomiting and shortness of breath or breathing difficulty both at 14.29% (Figure 2.8).

Collapsing the respiratory symptoms gives the distribution in Figure 2.9, with respiratory symptoms still accounting for 71.43% after fatigue (85.71%). However, among the symptoms considered here, the TB specific symptoms are cough of any duration, fever or chills and chest pain. The remaining ones are COVID-19 specific.

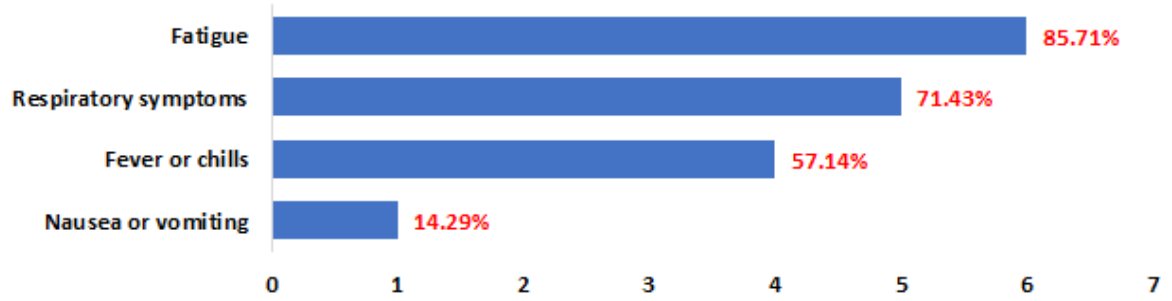


Figure 2.9: Count/ Proportion of symptoms from TB test positive cases with respiratory symptoms combined

Since no TB case was screened by any of the TB only symptoms, it implies that all the TB cases were screened via the bi-directional section of the screening tool. Classification of these TB specific symptoms gives the results in Figure 2.10

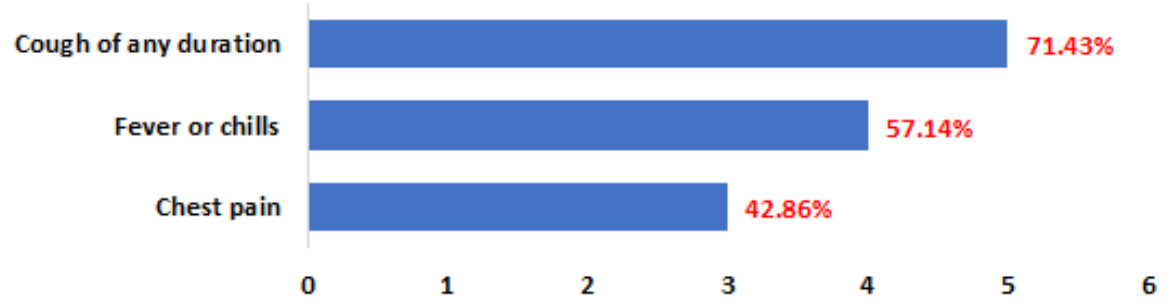


Figure 2.10: Count/ Proportion of symptoms by bi-directional screening from TB test positive cases

For TB, cough of any duration was the most important symptom (71.43%), followed by fever and chills (57.14%) and lastly chest pain (42.86%).

2.6. Positivity and co-infection rates of COVID-19 and TB

2.6.1. COVID-19 positivity rates

This study targeted a total of 5,120 tests using a Ag-RDT. In addition, 25% of these tests would also be tested using RT-PCR as a gold standard. Of these 25%, 20% were to be selected at random, and an additional 5% were to be selected based on a test turning negative despite a high perceived risk level. For the randomly selected test, every 5^{th} sample was used for both the Ag-RDT and the RT-PCR test, and this selection was programmed on the *Kenya COVID-19 Tracker app*. For risk profiling, the number of symptoms was considered, and any participant who exhibited 4 or more symptoms was profiled as having a high risk and these samples further tested using the RT-PCR.

Unfortunately, picking the 5% to test based on a negative result became a challenge since in the beginning, before the workflow was adjusted, this required collecting two different samples. The workflow was then adjusted to flag out any high-risk participant and test the sample using both Ag-RDT and RT-PCR. Figure 2.11 shows the number of persons who were tested for COVID-19 per County using Ag-RDT, and those tested by RT-PCR out of those tested by Ag-RDT.

Out of the 5,663 participants who visited the study sites, 4,946 were eligible for testing based on our eligibility criteria. 717 (48 female and 669 male) did not meet the testing threshold (Table 2.18). Of these 4946, a total of 1,023 (20.6%) were further tested using RT-PCR, out of which 859 (17.4%) were randomly selected and 163 (3.3%) were perceived to have a high likelihood of turning positive (See Table 2.17). Figure 2.11 shows the distribution of test by County.

Table 2.17: Breakdown of PCR outcomes by sample selection method

Sample selection	Negative		Positive		Total
Random selection	825	96.04%	34	3.96%	859
High risk profile	149	91.98%	13	8.02%	162
Total	974	95.40%	47	4.60%	1021

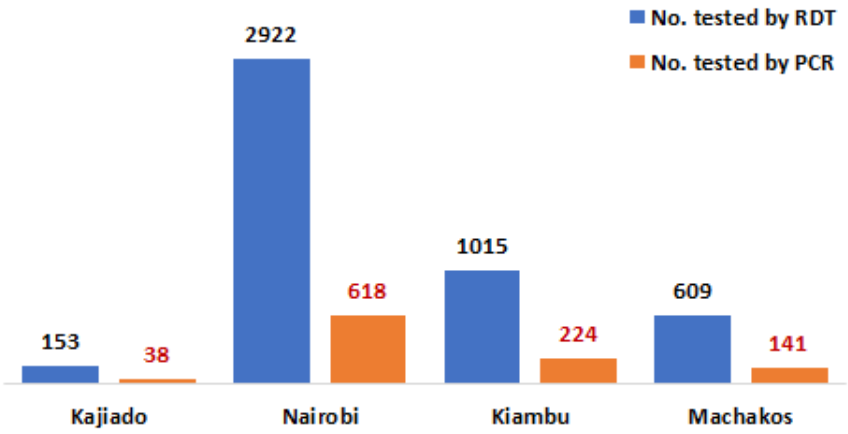


Figure 2.11: Number of people tested for COVID-19 per County

Positivity and co-infection rates were computed for COVID-19 and TB, among individuals tested during the project.

Table 2.18: Distribution of Ag-RDT by Gender

	Gender Distibution		
Ag-RDT result	Female	Male	Total
Decline		1	1
Inconclusive	4	101	105
Negative	110	4544	4654
Pending	1	140	141
Positive	2	43	45
Total	117	4829	4946

From Table 2.18, we notice that 1 participant declined to take the test after consenting, citing fears of discomfort from the nasopharyngeal swab procedure. A total of 246 tests (141+105) appear as pending or inconclusive, and this was attributed to a shortcoming in the data collection and transmission workflow. The pending/ inconclusive category was a place holder in the data collection tools to allow data clerks to attend to the next participant as they awaited test

results from already registered and tested persons. The 246 therefore arose because the data clerks forgot to update the results after obtaining them. Those considered for computations related to positivity rates were therefore only 4699 cases (Table 2.19).

Table 2.19: Distribution of Ag-RDT by Gender

	Gender		
Ag-RDT Result	**Female**	**Male**	**Total**
Negative	**110**	**4544**	**4654**
Positive	**2**	**43**	**45**
Total	**112**	**4587**	**4699**

Table 2.20: Distribution of COVID-19 Ag-RDT test results by Age Category

RDT test results	Below 24	25-34	35-44	45-54	55+	Age mising	Total
Negative	672	1813	1067	430	143	529	4654
Positive	4	20	5	4	1	11	45
% of positives	0.59%	1.09%	0.47%	0.92%	0.69%	2.04%	0.96%
Total	676	1833	1072	434	144	540	4699

Tables 2.19 and 2.20 show only the valid Ag-RDT positive and negative results from the study. Apart from the unclear category where age was missing, the highest positivity was observed among 25-35 year olds, followed by 35-44 year olds. these are the two age bands with the highest number of *Boda Boda* riders registered in the study, and even nationally. From Table 2.20, we now notice higher positivity among those in the 45-54 age category, although a lot of information is still lost among the category with missing age data (12% positivity).

We note that the positivity rate for COVID-19 based on the Ag-RDT was less than 1% (0.96%) although positivity by county varied because of the different waves experienced during the study. Enrolment of study participants begun in October 2021, and closed during the second week of January 2022. It is during December 2021 that the Omicron wave had hit the country. Enrolment in Machakos was from the third week of October to the last week of December 2021 and included the peak of the Omicron wave, Whilst enrolment in Kajiado County begun during the first week of November 2022 and ended in the second week of December 2021. In Kiambu and Nairobi Counties, enrolment begun during the second and third weeks of January 2022 respectively, by which time the positivity rate had decreased to about 1%. This explains why the positivity rate for Machakos. County appears higher than the other counties. (See Figure 2.12)

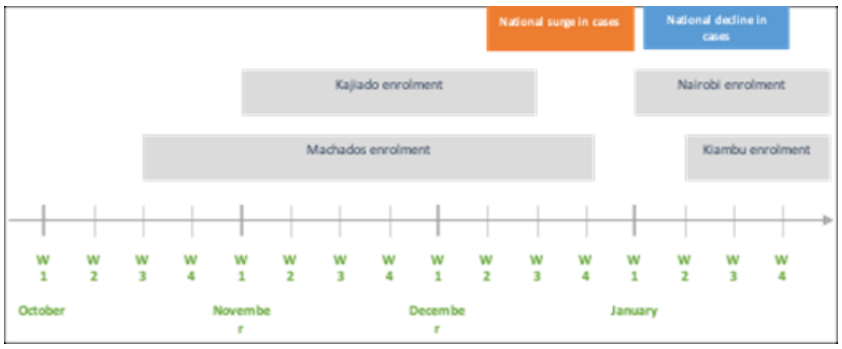


Figure 2.12: Data collection timelines in different counties

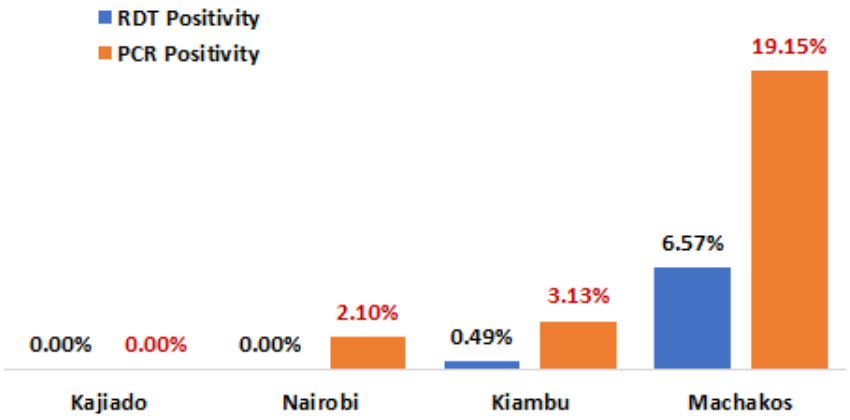


Figure 2.13: COVID-19 positivity rate per County as per the study

Figure 2.13 shows positivity rates by County. Positivity was highest in Machakos County and lowest in Kajiado County. Table 2.21 shows the results obtained from the sample that were sent for RT-PCR testing. A total of 1,022 RT-PCR tests were conducted, out of which, 1 was inconclusive, and 47 (no female) turned positive, resulting in a positivity rate of 4.6% (Table 2.22). During the study period when data collection was in Machakos, the positivity rate specific to the County was 19.15%.

Table 2.21: Distribution of PCR tests by Gender

	Gender		
PCR test Results	Female	Male	Total
Inconclusive		1	1
Negative	27	947	974
Positive		47	47
Total	27	995	1022

Table 2.22: Positivity of PCR tests by County

County	Inconclusive	Negative	Positive	Total	Positivity
Kajiado		38		38	0.00%
Kiambu	1	217	7	225	3.11%
Machakos		114	27	141	19.15%
Nairobi		605	13	618	2.10%
Total	1	974	47	1022	4.60%

Table 2.23: Distribution of COVID-19 PCR test results by Age Category

PCR test results	Below 24	25-34	35-44	45-54	55+	Age missing	Total
Negative	159	362	228	88	27	110	974
Positive	1	19	5	6	1	15	47
% of positives	0.63%	4.99%	2.15%	6.38%	3.57%	12.00%	4.60%
Total	160	381	233	94	28	125	1021

2.6.2. TB positivity rates

As per Table 2.24, a total of 372 sputum samples were collected for GeneXpert analysis. 355 samples gave a valid result, and, out of this, a total of 7 samples turned positive, which translates to a prevalence rate of 1,972/100,000, with a 95% confidence interval of 525/100,000 to 3418/100,000. The TB prevalence observed in the study is higher than national levels– Kenya has an estimated TB prevalence of 558/100,000–although wide confidence intervals were noted due to the small sample size.

Table 2.24: Distribution of TB tests by Gender

TB test results	Female	Male	Total
Bloody Sputum		1	1
Inadequate Sample		6	6
Inappropriate Sample		9	9
Invalid		1	1
Negative	6	342	348
Positive		7	7
Total	6	366	372

Table 2.25: Distribution of TB positivity rates in percentage by County

County	Negative	Positive	Total	Positivity
Kajiado	18	1	19	5.26%
Kiambu	74	3	77	3.90%
Machakos	9		9	0.00%
Nairobi	247	3	250	1.20%
Total	348	7	355	1.97%

Table 2.26: Distribution of TB test results by Age Category

TB test results	Below 24	25-34	35-44	45-54	55+	Age missing	Total
Negative	45	137	90	46	8	22	348
Positive		3	4				7
% of positives	0.00%	2.14%	4.26%	0.00%	0.00%	0.00%	1.97%
Total	45	140	94	46	8	22	355

From Table 2.26, it is observed that the highest positivity is also in 25-44 year olds. These age positivity related findings are similar to thoe of COVID-19 test results. There were zero co-infection cases between COVID-19 and TB observed during the study. This was true for all samples tested for COVID-19 using either the Ag-RDT or the RT-PCR tests. However, apart from the cough, fever and chest pains experienced by these cases, they also had cases of fatigue, a symptom that was most common among the COVID-19 positive cases.

2.7. RDT test accuracy / reliability

One of the aims of this study was to test the accuracy or reliability of the COVID-19 Ag-RDT (the index test) using the RT-PCR as a gold standard or a reference test [1]. 1021 samples that were tested tested using the Ag-RDT were also tested using RT-PCR. The outcomes of the two tests were then be compared in order to evaluate the accuracy of the index test (Ag-RDT).

Figure 2.14: Distribution of Ag-RDT results tests by TB test result

Ag-RDT	TB Test: Negative	Positive	Total
Inconclusive	4		4
Negative	320	7	327
Pending	12		12
Positive	2		2
Total	338	7	345

Figure 2.15: Distribution of COVID-19 PCR results tests by TB test result

PCR	TB Test: Negative	Positive	Total
Inconclusive	1		1
Negative	63	2	65
Positive	3		3
Total	67	2	69

Those who tested positive for COVID-19 by the reference test (RT-PCR) were considered as cases, whereas those who tested negative were considered as the controls. Diagnostic accuracy was then represented by two measures, sensitivity and specificity. Sensitivity refers to the probability of a person with COVID-19 having a positive result (true positive proportion), whereas specificity is the probability of a person without COVID-19 having a negative result (true negative proportion). They were calculated as shown in Equation (2.1) and presented in a 2×2 table.

$$\begin{aligned} \text{Sensitivity} &= \frac{\text{True positives}}{\text{True Positives} + \text{False Negatives}} \\ \text{Specificity} &= \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Positives}}. \end{aligned} \tag{2.1}$$

To calculate the 95% confidence interval for sensitivity, we used the formula

$$95\% \text{ confidence interval = sensitivity } \pm 1.96 \text{ (SE of sensitivity)}$$

where SE (standard error) of sensitivity is given by $SE_{sen} = \sqrt{\frac{sen(1-sen)}{n_{sen}}}$

similarly, to calculate the 95% confidence interval for specificity, we used the formula

$$95\% \text{ confidence interval = specificity } \pm 1.96 \text{ (SE of specificity)}$$

where SE (standard error) of specificity is given by $SE_{spec} = \sqrt{\frac{spec(1-spec)}{n_{spec}}}$

We also calculated the Positive Predictive Value (PPV) which is the probability that a patient has COVID-19 given that the test results are positive, and the Negative Predictive Value (NPV)

which is the probability that a patient does not have the disease given that the test results are indeed negative. These were calculated as shown in Equation (2.2)

$$\begin{aligned} \text{PPV} &= \frac{\text{True positives}}{\text{True Positives} + \text{False Positives}} \\ \text{NPV} &= \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Negatives}}. \end{aligned} \tag{2.2}$$

To calculate the 95% confidence interval for PPV, we used the formula

$$95\% \text{ confidence interval = PPV } \pm 1.96 \text{ (SE of PPV)}$$

where SE (standard error) of PPV is given by $SE_{ppv} = \sqrt{\frac{ppv(1-ppv)}{n_{ppv}}}$

similarly, to calculate the 95% confidence interval for NPV, we used the formula

$$95\% \text{ confidence interval = NPV } \pm 1.96 \text{ (SE of NPV)}$$

where SE (standard error) of NPV is given by $SE_{npv} = \sqrt{\frac{npv(1-npv)}{n_{npc}}}$

Table 2.27 shows the comparison of the test results as per the RT-PCR and the Ag-RDT, and below, the sensitivity, specificity, PPV and NPV have been calculated.

Table 2.27: Cross tabulation for sensitivity and specificity (All counties combined)

		PCR (Gold Standard)		
		Negative	**Positive**	**Total**
Ag-RDT	**Negative**	**856**	**31**	**887**
	Positive	**14**	**12**	**26**
	Total	**870**	**43**	**913**

Table 2.28: An excerpt of the data containing CT values for False Negatives

RDT test	PCR Test	CT Value(ORF-1ab)	CT Value(N-GENE)
Negative	Positive	36.88	38.88
Negative	Positive	34.25	35.27
Negative	Positive	31.94	30.84
Negative	Positive	29.01	30.04
Negative	Positive	31.47	31.45
Negative	Positive	30.21	32.47
Negative	Positive	36.99	38.44

$$\text{Sensitivity} = \frac{TP}{TP+FN} * 100 = \frac{12}{12+31} * 100 = 27.91\% \text{ with 95\% C.I as [14.67\%, 41.15\%]}$$

$$\text{SE of sensitivity} = \sqrt{\frac{0.2791(1-0.2791)}{43}} = 0.06754488$$

$$\text{Specificity} = \frac{TN}{TN+FP} * 100 = \frac{856}{856+14} * 100 = 98.39\% \text{ with 95\% C.I as [97.55\%, 99.23\%]}$$

$$\text{SE of specificity} = \sqrt{\frac{0.9839(1-0.9839)}{870}} = 0.00426706$$

$$\text{PPV (Precision)} = \frac{TP}{TP+FP} * 100 = \frac{12}{12+14} * 100 = 46.15\% \text{ with 95\% C.I as [26.99\%, 65.31\%]}$$

$$\text{SE of PPV} = \sqrt{\frac{0.4615(1-0.4615)}{26}} = 0.09776694$$

$$\text{NPV} = \frac{TN}{TN+FN} * 100 = \frac{856}{856+31} * 100 = 96.51\% \text{ with 95\% C.I as [95.3\%, 97.72\%]}$$

$$\text{SE of NPV} = \sqrt{\frac{0.9651(1-0.9651)}{887}} = 0.006162218$$

Based on these, the test had a sensitivity of 27.91% and a specificity of 98.39%. The PPV was 46.15% and the NPV was 93.24%. These statistics could have been influenced by the fact that the larger part of the study took place in January 2022 (during registration in Nairobi and Kiambu Counties) when COVID-19 cases had significantly decreased in the country. During this time, the study only found 5 positive cases from Kiambu County, and none from Nairobi County using Ag-RDT.

In addition, in some instances, CT values from the RT-PCR were also collected. Out of the 47 RT-PCR positive results, 8 (17%) had the CT values available for analysis, as these are not routinely recorded. These values ranged from 29.01 to 36.99. Unfortunately, of the 12 true positives (Table 2.27), no CT values were registered. Table 2.28 is an excerpt of the testing data containing the CT values for the false negatives. Some of these CT values are useful in further explaining the sensitivity and specificity of the Ag-RDT. Of the 31 false positives, 7 (22.58%) had CT values as shown in Table 2.28, majority of which were over 30. Higher CT values are associated with lower viral loads, and lower sensitivity of the Ag-RDTs.

Another key factor to consider is the disease prevalence during the larger phase of the study which involved enrolment in Nairobi and Kiambu Counties. This could have also affected the sensitivity of the Ag-RDT, since the levels of the disease in the population was really low at the time.

Figure 2.16 shows the symptom profile for the false negatives (the 31 cases in Table 2.27). Figure 2.17 shows the symptom profile for the true positives (the 12 cases in Table 2.27). In order to check the influence of the prevalence in January 2022, these statistics were recalculated using data from Machakos county which was registered during the peak of the Omicron variant wave in the country and Table 2.29 summarises the results.

With this the sensitivity recorded was 46.15%, specificity of 87%, PPV was 48% and NPV was 86.14%. Similar statistics were computed for both Kiambu and Machakos counties combined and the results were as shown in Table 2.30. Here the sensitivity was 37.5%, specificity was 95.17%, PPV was 46.15% and NPV was 93.24%.

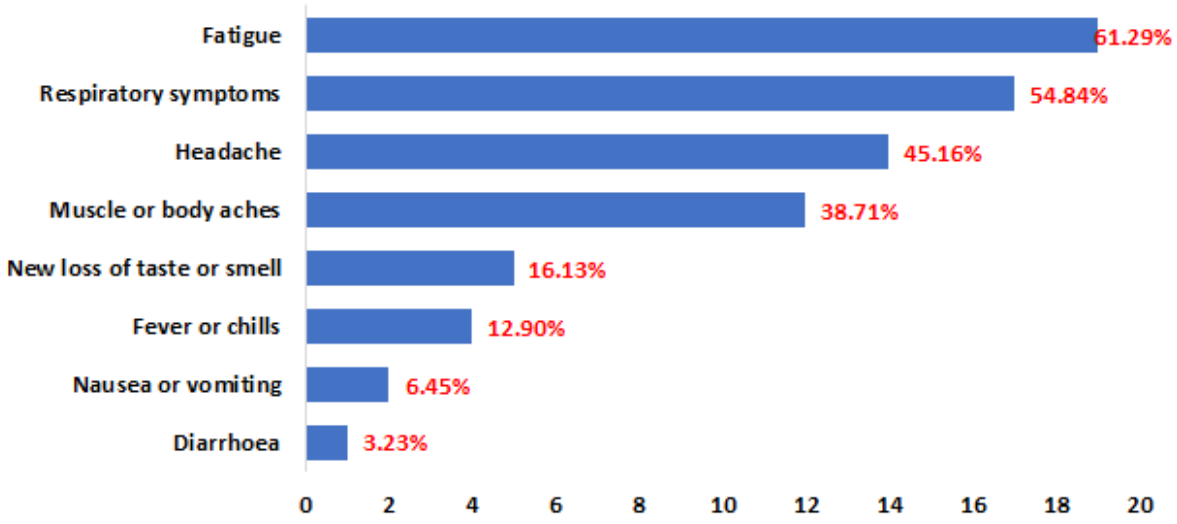


Figure 2.16: Symptom profile for the false negative cases

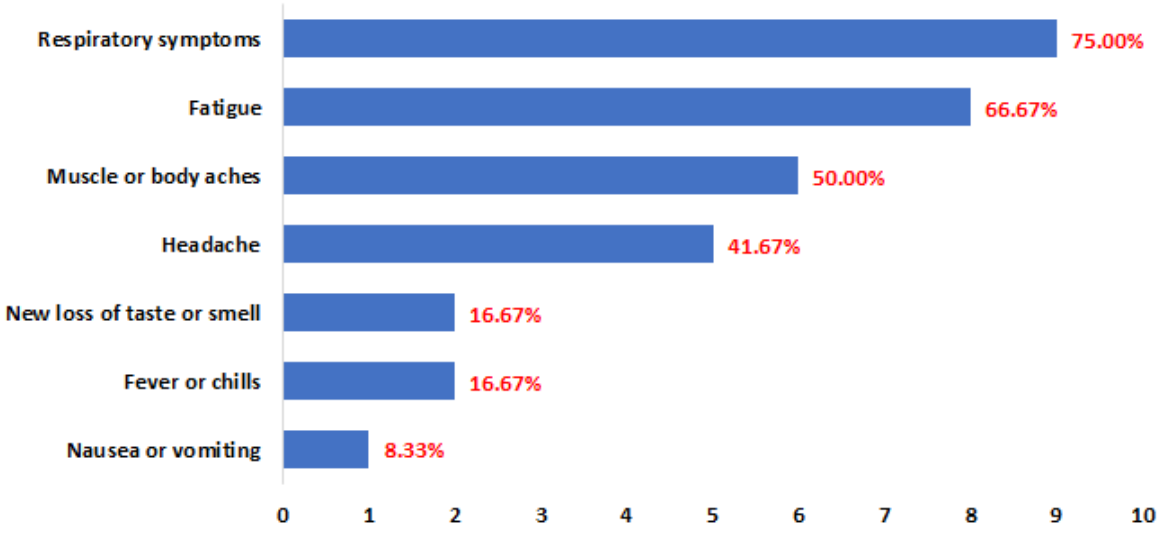


Figure 2.17: Symptom profile of the true positive cases

Table 2.29: Cross tabulation for sensitivity and specificity (Machakos county)

		PCR	
	Negative	**Positive**	**Total**
AG-RDT			
Negative	**87**	**14**	**101**
Positive	**13**	**12**	**25**
Total	**100**	**26**	**126**

Sensitivity = $\frac{TP}{TP+FN} * 100 = \frac{12}{12+14} * 100 = 46.15\%$ with 95% C.I as [26.99%, 65.31%]

Specificity = $\frac{TN}{TN+FP} * 100 = \frac{87}{87+13} * 100 = 87\%$ with 95% C.I as [80.41%, 93.59%]

PPV = $\frac{TP}{TP+FP} * 100 = \frac{12}{12+13} * 100 = 48\%$ with 95% C.I as [28.42%, 67.58%]

NPV = $\frac{TN}{TN+FN} * 100 = \frac{87}{87+14} * 100 = 86.14\%$ with 95% C.I as [79.4%, 92.88%]

Table 2.30: Cross tabulation for sensitivity and specificity (Machakos and Kiambu counties)

		PCR	
	Negative	**Positive**	**Total**
AG-RDT			
Negative	**276**	**20**	**296**
Positive	**14**	**12**	**26**
Total	**290**	**32**	**322**

Sensitivity = $\frac{TP}{TP+FN} * 100 = \frac{12}{12+24} * 100 = 37.5\%$

Specificity = $\frac{TN}{TN+FP} * 100 = \frac{276}{276+14} * 100 = 95.17\%$

PPV = $\frac{TP}{TP+FP} * 100 = \frac{12}{12+114} * 100 = 46.15\%$

NPV = $\frac{TN}{TN+FN} * 100 = \frac{276}{276+20} * 100 = 93.24\%$

The Kappa statistics were also be calculated so that from the p-value established the level of agreement of the two tests. Analysis was carried out using MS-Excel and R. The output was presented in summary tables and charts.

3

Kenya COVID-19 tracker app

3.1. Introduction

We customized an existing application; *Kenya COVID-19 Tracker app* [10], built on the Community Health Toolkit Core Framework (CHT Core)[1] consisting of a number of open source technologies, for this study. The CHT Core client-interface is multichannel, however for the purpose of the project, the browser and smartphone User Interface (UI) was adapted with details described in Section 3.2. We had a local server instance on the backend, and a mobile app on the front end, through which data was collected and synchronized to the server. The synchronisation was configured to initialise in the evening to prevent disruption of server services. We used the following modules from the CHT Core architecture shown in Figure 3.1. CouchDB[2] backend with the associated configuration files, browser applications through which the medic portal could be accessed, and targets for showing analytics on the dashboard.

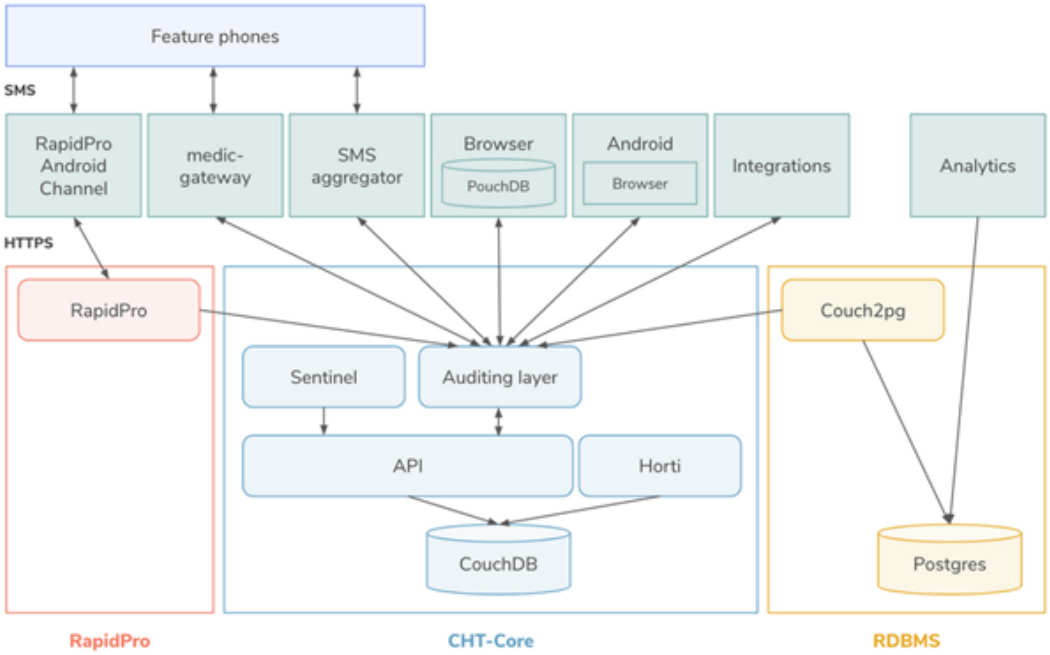


Figure 3.1: Architecture of CHT Instances

[1] https://docs.communityhealthtoolkit.org/core/
[2] https://couchdb.apache.org/

3.2. Customization and Configuration

3.2.1. Customizing the Forms

The existing contact registration forms and case investigation forms from the *Kenya COVID-19 Tracker app* were customized for this study. The screening questions were also added according to the protocol. The revised XLS Forms for both contact tracing and case investigation were tested to confirm the screening algorithm works, before uploading the forms onto the server.

3.2.2. Local Environment Setup

A virtual machine (VM) was prepared from our local server to host the configuration files running on the Linux operating system called Ubuntu 20.04, and installed the following software's as required: nodejs version 12, npm, git, docker and docker-compose. We followed the installation steps in the online documentation[3] and installed the core framework and cht-conf. We installed a valid TLS certificate mapped to our VM IP address. Finally targets were configured for the overall national office and the four project counties.

3.2.3. App Deployment and Use

We developed the project hierarchy as shown in Figure 3.2. All the accounts were created and tested before the pilot study. After pilot testing, the app was rolled out to the field, data was collected and targets on the dashboard were updated for the overall project and the four counties as shown in Figure 3.3. We downloaded the Android Medic app container from play store and configured with the URL of the server

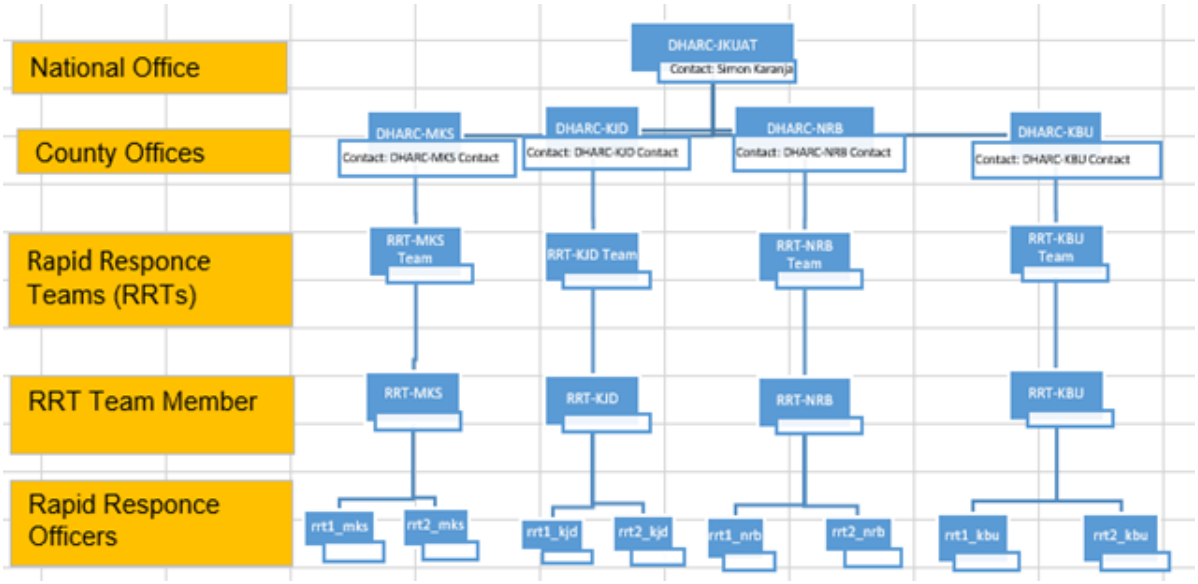


Figure 3.2: Customised app hierarchy

3.3. Challenges and work in progress

3.3.1. Customization challenges

Developing the local sever instance was time consuming due to adequacy of online documentation. Through the online CHT Core community, we shared the screenshots of the errors we received during configuration, and the community assisted in ensuring that our instance was

[3] https://docs.communityhealthtoolkit.org/core/guides/

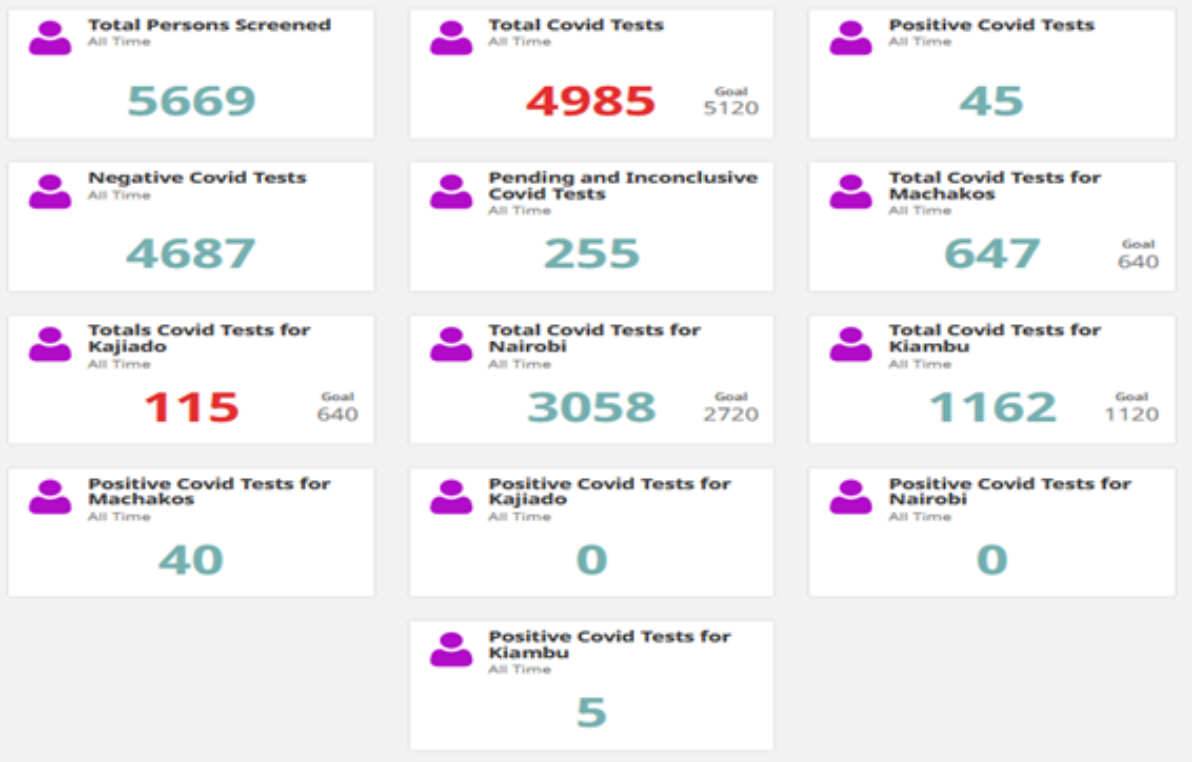


Figure 3.3: Target Analytics

up and running. Feedback from the community members are sometimes delayed due to the large volume of requests and limited bandwidth of members.

3.3.2. Slow Speed while loading the app

As data collection was progressing and the number of documents increased, we experienced in slow speeds in the Samsung A7 devices, which delayed the data collection process. Troubleshooting was done to determine the cause of delay; we found that both device internal memory and RAM were not full as shown in the Figure 3.4, thus we ruled out device resources being exhausted. We revised the hierarchy with a team from Medic and removed any redundant contact_types, but the challenge persisted. After sharing this with the community, no clear solution was given, but it was suggested we implement purging under very careful testing before implementation to avoid losing data. We are still exploring this with developers from Medic mobile to improve speed of loading.

3.3.3. Client-side Purging

We noted as the number of documents grew, it took time to load documents on the tablets, thus we wanted to implement a purging rule that deletes documents at the end of every week at Friday at 6 pm. The online documentation on purging wasn't sufficient, and community members didn't provide feedback on how to implement the same. We will review with the team from Medic mobile and implement the same on our test server

3.3.4. Number of documents (Max 10,000)

As the data collection progressed, slowly due to slow speeds in loading the application, an error appeared on the screen indicating that the maximum number of documents (10,000) were reached, with a warning message asking if one still wishes to proceed. We are exploring

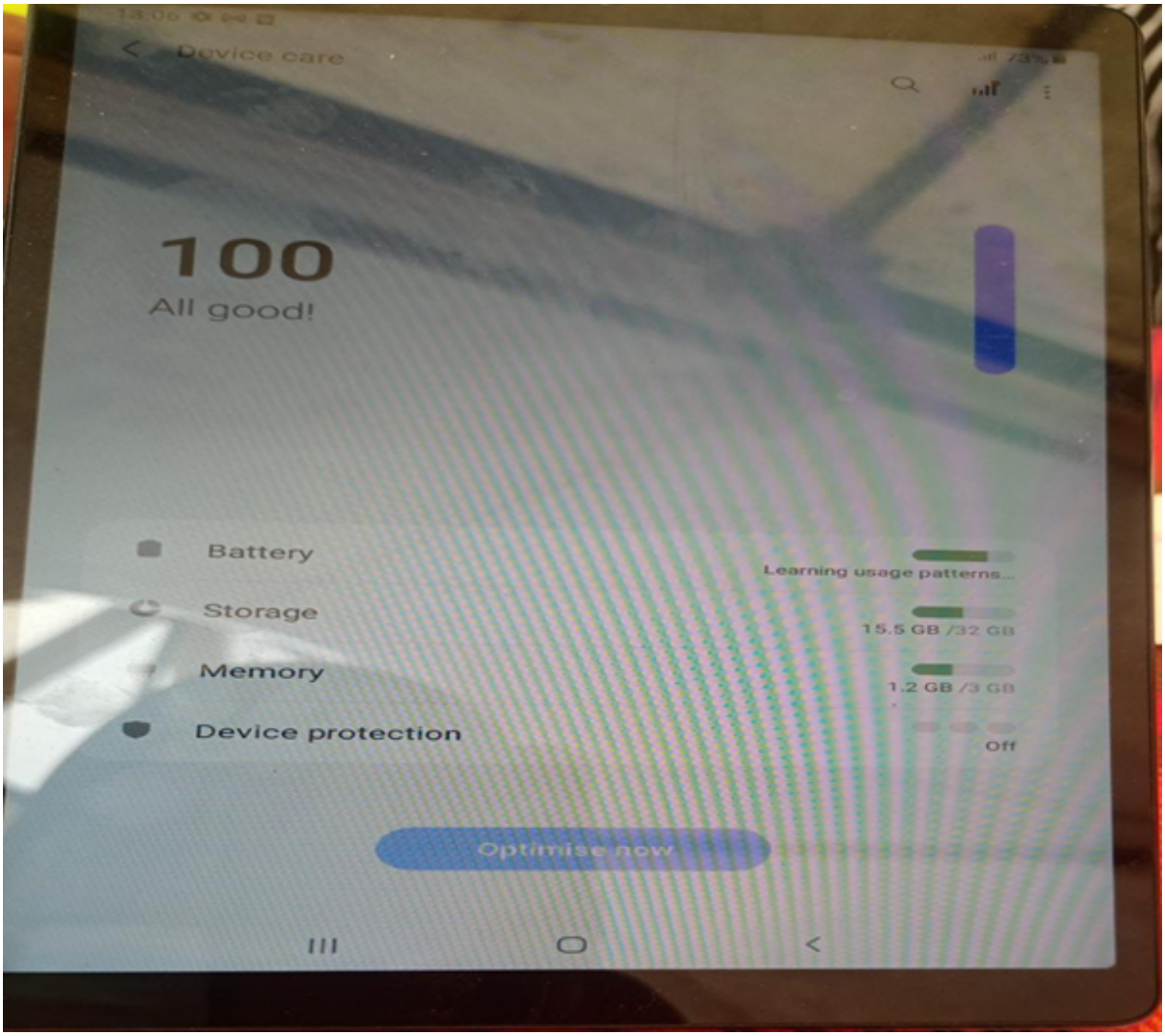


Figure 3.4: Samsung A7 resource usage status

the purging rules as a possible solution to this challenge.

3.3.5. CouchDB to Postgres

From Figure 3.1, we have couch2p API for creating read-only replicas of data from CHT applica- tions, using PostgreSQL. Configuring the API to pull data from couchDB to PostgreSQL was challenging, following the online documentation for three (3) weeks has not worked to have data in a relational database, which makes it easier to manipulate. We have shared this in the community and the feedback given is that efforts are underway to streamline the docker compose file used for cht-couch2pg. We need to access client registration data, which at the moment can't be downloaded from the medic portal, thus the need to have the whole database replicated to PostgreSQL

3.3.6. App-specific learnings:

1. JKUAT with support of Foundation for Innovative New Diagnostics (FIND), Medic mobile team & community, had to customize *Kenya COVID-19 Tracker app*to meet project needs.
2. TheCHT Core is a robust platform, for this study the major component adapted was

the registration and case investigative form. Adaptations included addition of fields at the steps of registration, symptom screening and testing. The dashboard which had not been used previously was also activated to generate aggregates and monitor study progress remotely.

3. Given the extensive adjustments to the forms, pulling these new data fields into the dashboard was challenging. Once that link was established, there was some concern about making further changes to the forms during implementation, in case this disrupted the back-end. This has implications for how rapidly the tool can be adapted if being used in community settings where various modifications may be required. However, it was later confirmed that the fields could be updated with no risk to previous records. This is promising for use of the tool in other community settings where adaptation may be required to inform more agile response to the context.
4. Experience suggests that the app is useful for community-based testing, but would require a number of modifications from its original form, and more extensive piloting of the modified versions is needed. For future projects, a more streamlined tool would improve both the case management as well as data consolidation and analysis on the back-end: this study was a first-time experience so some of these lessons were learnt during implementation.
5. Medic encouraged peer to peer learning and linked JKUAT with other peers to support the process. CHT community was very helpful with resolving issues that came up during implementation; however this is a small community so response time to queries was slow. It would be good to expand this community for faster turnaround times. Teams will also collaborate on a blog post about the experience.
6. Hierarchy was interfering with performance of app
7. Waiting period for test results had implications for workflow, as sometimes another entry needed to begin during that period. Data clerk would have to close the record and go back to update it later; if this was not done it generated an error.
8. As the number of documents increased, device performance decreased; there's a need to delete records on the client side periodically. The reason for slow-down of devices has not yet been established, because current number of records is smaller than maximum number (10,000). Medic will investigate.
9. The monotonic counter was used to generate unique sample identification numbers, as a concatenation between the RRT id and the monotonic counter. However, there are several instances where the counter failed and hence a unique sample ID was not assigned.

3.3.7. Overall data management and flow:

1. Initially, project had envisioned integration of the community-data system with national data systems e.g. EMR. In practice, it was found that counties had different ways of handling covid-19 data (for example, some were only focused on positives). To align with the local processes, JKUAT testing data was sent directly to each county and included in their numbers, which were then transmitted to national level.
2. TIBU was not able to communicate with CHT: at national level the NTP had committed to this , but faced barriers when it came to implementing the technical changes. Integration of these systems would be a longer process that also requires lobbying.
3. Integration and interoperability are recurring issues in DH work in Kenya, which also emerged during the assessment conducted last year: what practical steps can help to circumvent this especially if looking to coordinate expanded testing at community level?

4. Data completeness; at the time of the call, majority of records (>95% as estimated by JKUAT) were complete. The incomplete records were due to:

   (a) Challenges with data syncing from some sites; JKUAT was following up on this.
   (b) Challenges with integration of registration form: some of this data also included in CIF but key indicators like NCD outcomes are not yet in the consolidated data frame. This data was however captured on the front end and is available in all the devices. JKUAT team was able to integrate all records successfully.

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A

Study protocol synopsis

Utilization of digital tools to enhance coronavirus disease 2019 (COVID-19) and Tuberculosis (TB) testing and linkage to care among *Boda Boda* riders in the Nairobi metropolis

STUDY PROTOCOL

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Investigator Signature Page

Utilization of digital tools to enhance COVID-19 and TB testing and linkage to care among *Boda Boda* riders in the Nairobi metropolis.

`I, the undersigned, am responsible for the conduct of the trial at this site and affirm that:`

- I agree to personally conduct or supervise the study.
- I have read the protocol and agree that it contains all necessary details for carrying out the study as described. I will conduct this protocol as outlined therein, as per any approved protocol amendments, as per International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use) (ICH) Good Clinical Practices (GCPs) and all applicable Regulatory Authority requirements and national laws.
- I will not deviate from the protocol without prior written permission from the Sponsor and prior review and written approval from the Institutional Review Board or Ethics Committee, and Regulatory Authority, except where necessary to prevent immediate danger to the participant.
- I have read and understand the information in the relevant Summary of Product Characteristics, and I am familiar with the Investigational Products (IPs); I also understand the device use, including its potential risks.
- I agree to inform all participants that the IPs are being used for investigational purposes and I will ensure that the requirements related to obtaining informed consent are in accordance with ICH Guidelines for GCPs Section 4.8 and local requirements.
- I agree to report adverse events that occur in the course of the study to the Sponsor, to maintain adequate and accurate records and make those records available, in accordance with ICH Guidelines for GCPs Section 4.11 and local requirements. I agree to promptly report to the Ethics Committee (EC) all changes in the research activity and all unanticipated problems involving risk to the participants.
- I have sufficient time to properly conduct and complete the trial within the agreed trial period, and I will ensure that any qualified staff at my site(s) who are involved in the trial conduct are adequately trained regarding the IPs, the protocol and their responsibilities for the foreseen duration of the trial to conduct the trial properly and safely. If I delegate any of my trial activities, I will provide the Sponsor with a Delegation of Activities Form. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
- I understand that the study may be terminated, or enrolment suspended at any time by the Sponsor, with or without cause, or by me if it becomes necessary to protect the best interest of the participants.

Prof. Simon Karanja

10th January 2022
Date

Partners Involved in the Project

1 Jomo Kenyatta University of Agriculture and Technology (JKUAT)

Jomo Kenyatta University of Agriculture and Technology (JKUAT) is a public university established in 1981 as a Middle Level College and as an institution of higher learning in Kenya under the Universities Act of 2012 and the JKUAT Charter, 2013. Its mission is to offer accessible quality training, research, innovation and entrepreneurship in order to produce leaders in various fields, among them Health Sciences and Technology, to suit the needs of a dynamic world. JKUAT has research interests in COVID-19 epidemiology in Kenya, development of eHealth solutions, HIV/AIDS, data science and Big-data analytics; and its researchers are part of the Presidential Advisory Committee on COVID-19 and the National COVID-19 Technical Modelling Team. This proposed work will be administered through JKUAT Enterprises Ltd (JKUATES), a private limited company that is 100% owned by JKUAT. The mission of JKUATES is to train, produce and consult in innovative emerging technologies using highly qualified human resources for improved performance of public, private and non-governmental organizations.

Contact person:	Prof Simon Karanja
Address:	School of Public Health, JKUAT
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	Nairobi, Kenya
	Email: skaranja@jkuat.ac.ke

2 Ministry of Health

The Ministry of Health Kenya (MoH-K), has a mission of building a progressive, responsive and sustainable health care system for accelerated attainment of the highest standard of health to all Kenyans. Its vision is to ensure a healthy, productive and globally competitive nation. To undertake this work, the MoH-K has various departments among them, the department of Monitoring and Evaluation and Health Informatics where healthcare-related data is managed. At the onset of the COVID-19 pandemic, the department reached out to partners and public institutions such as JKUAT for technical support in the development and roll-out of end-to-end digital solutions for the management of the disease. In addition, JKUAT and University of Nairobi (UoN) were identified as the main teams for COVID-19 modelling consortium, a task that they have, and continue to undertake diligently. In the management of COVID-19, MoH-K in collaboration with various partners have deployed several digital tools at various points of the COVID-19 management cascade. Several of these tools have demonstrated the possibility of their scale-up not only to cover COVID-19 management national but also other programmatic diseases in MoH-K. In this regard, the MoH-K is ready to partner with institutions that can deliver on the aforementioned mandate.

Contact person:	Dr. Denver Mariga Kamau
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	Ministry of Health, Kenya
	P.O. Box 30016-00100
	Nairobi, Kenya
	Email: dmariga15@gmail.com; Tel +254720426183

3 Foundation for Innovative New Diagnostics (FIND) (Sponsor)

Foundation for Innovative New Diagnostics (FIND) is a global non-profit organization driving innovation in the development and delivery of diagnostics to combat major diseases. In the

wake of the COVID-19 pandemic, FIND and The Global Fund to Fight AIDS, Tuberculosis and Malaria are co-conveners of the Diagnostics Pillar of the global Access to COVID-19 Tools (ACT)-Accelerator partnership, launched by World Health Organization (WHO) and partners. Together with partners around the world, FIND is monitoring the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) diagnostic pipeline, conducting independent evaluations of molecular tests and immunoassays, and collating and centralizing performance data on commercially available in vitro diagnostic tests. FIND is also supporting research to inform the use of digital tools in generating end-to-end data that strengthens testing strategies using current and future diagnostic technologies. FIND has successfully partnered with JKUAT and MoH-K on the project "Assessing the use of digital tools to strengthen COVID-19 screening, testing, contact tracing and patient management in Kenya in 2 counties, Machakos and Mombasa" from October 2020 to April 2021.

Contact person:	Rigveda Kadam
Address:	Campus Biotech
	Chemin des Mines 9
	`rigveda.kadam@finddx.org`

4 Tools to be used

1. *Kenya COVID-19 Tracker app*by Medic Mobile
2. Kenya Electronic Medical Records (KenyaEMR) by Kenya Health Management Information Systems (KHMIS)
3. *Jitenge system* by mHealth (already handed over to MoH-K officially).
4. LabWare Laboratory Information Management System (LabWare LIMS) belonging to National Public Health Laboratories (NPHL)
5. *TIBU* belonging to National Tuberculosis Leprosy and Lung Disease Program (NTLD-P)

5 Protocol Synopsis

Long Title:	Utilization of digital tools to enhance COVID-19 and TB testing and linkage to care among *Boda Boda* riders in the Nairobi metropolis
Short Title:	Digital tools for the enhancement of COVID-19 and TB testing and linkage to care
Protocol date	February 26, 2022
Background & rationale	COVID-19 is an ongoing global pandemic caused by the novel SARS-COV-2. This pandemic has had an unprecedented impact on the health, economic, and social well-being of Kenyans. As of 19th September 2021, 246,296 positive cases and 4,980 deaths had been reported. Efforts to track the disease progress and the public health impact of COVID-19 largely depends on the ability to have effective screening, availability of fast and equitable access to diagnostic testing and a rapid turnaround in communication of test results to suspect cases. The pandemic has added an additional burden and challenges in the management of long-standing epidemics of TB and Human Immunodeficiency Virus (HIV). It is estimated that over 98% of current cases of COVID-19 in Kenya are due to community transmission. However, the existing capacities for testing have been unable to match the demand for testing. The country has to a great extent relied on the use of reverse transcription polymerase chain reaction (RT-PCR), which is expensive, available in few high-end laboratories, requires high level of skill and has a long turnaround time between sample collection and result communication. *Boda Boda* taxi riders, a highly mobile group that transports passengers on motorbikes from one location to another have not been prioritized for either testing or vaccination. They however represent a population considered critical in the transmission of both COVID-19 and TB. These persons consist mainly of low-wage males aged 22-45 years. They lack medical insurance and have limited access to healthcare. Majority of *Boda Boda* riders within the Nairobi Metropolis reside in informal settlements with poor hygiene and sanitation facilities. The TB survey conducted in Kenya in 2016 indicated that the urban slums had the greatest burden of TB (760/100,000), nationally. The survey further indicated that persons aged 25-34 years had the highest burden of TB with a prevalence of 716/100,000. The high mobility by *Boda Boda* riders coupled with lack of infection prevention and control (IPC) measures is a good recipe for nurturing 'super-spreaders' for COVID-19. It is therefore imperative to create awareness and demand among the *Boda Boda* riders for COVID-19 and TB testing aimed at including this critical group in healthcare planning. The demand for COVID-19 testing in Kenya has been hampered by a perennial shortage of reagents, limited testing laboratories and insufficient requisite human resource. Recent approval of use of Ag-RDT as an additional test for SARS-COV-2 is anticipated to improve the ease of testing by decentralizing testing, reducing the turn-around time and dependence on the highly trained human resource that are requirement in RT-PCR based tests. This approach is expected to contribute significantly to the overall COVID-19 testing capacity.

	Current published data suggests that globally, TB diagnosis has declined during the pandemic due to various factors including de-prioritization and movement restrictions. Studies suggest that presence or history of TB increases the risk of SARS-COV-2 infection, TB co-infection increases the risk of severe COVID-19 disease, and TB/SARS-COV-2 co-infection is associated with rapid and severe symptom development and disease progression with poor outcomes for both diseases[13]. Integrating case-finding for COVID-19 and TB would potentially help to overcome the decrease in registered TB cases, better health outcomes and more efficient use of health systems resources. The aim of this study is to use digital platforms to enhance COVID-19 and TB testing and linkage to care among the *Boda Boda* riders within the Nairobi Metropolis. The study will use Ag-RDTs to test for COVID-19, and leverage on MoH-K through NTLD-P systems for TB testing. Digital tools that have already been deployed for management of both COVID-19 and TB will be used in the study to ensure end-to-end transmission of data for decision making.
Study Objective	To use digital platforms to enhance COVID-19 and TB testing and linkage to care among *Boda Boda* riders in Nairobi metropolis.
Study Design	This will be an intervention cohort study to demonstrate the use of digital platforms in enhancing COVID-19 and TB testing and linkage to care among *Boda Boda* riders in Nairobi metropolis.
Outcome Measures	**Study outcomes:** (a) To create awareness and demand for COVID-19 testing among *Boda Boda* riders using digital messaging (b) To use a digital solution in conjunction with RDTs to support decentralized COVID-19 and TB testing of *Boda Boda* riders specifically to (i) Conduct screenings, using a digital algorithm built into the tool, to identify suspect cases; (ii) To conduct RDT testing for all suspect cases identified through the digital algorithm; (iii) To conduct sample collection for all TB suspect cases and link them to testing and track outcomes using the digital tools (iv) Provide a quick turnaround of testing results to patients; (c) To provide digital follow-up for participants who test positive: (d) To register, contacts and hand over to County COVID-19 surveillance teams for tracing. (e) To determine the COVID-19 and TB positivity rates among individuals tested during the project. (f) To evaluate RDT accuracy / reliability
Study sites/setting	This study will be carried out in the Nairobi metropolitan area as defined during cessation of travel as a COVID-19 management intervention. This area includes Nairobi county and bordering centres from, Kiambu, Machakos, Kajiado counties. These centres have a lot of interaction with Nairobi county, and provide residences for many workers in Nairobi county. The study area has a total population of 9,344,036.

Sample Size	Based on the assumption that 50% of individuals screened for COVID-19 and 10% of those screened for TB will meet the criteria for testing. A total of **5120** COVID-19 Ag-RDTs will be carried out (**2,720** from Nairobi, 1120 from Kiambu, and **640** each from Machakos and Kajiado). For RT-PCR a sample of **670** specimens will be considered from Nairobi, **270** from Kiambu and **160** each from Machakos and Kajiado. For TB testing, a total of 1,000 tests will be carried out in the following proportions, **540** for Nairobi, **224** for Kiambu, and **118** each for both Machakos and Kajiado Counties.
Data Collection & Management	Registration of study participants will be carried out on the *Kenya COVID-19 Tracker app*. Data on screening for both COVID-19 and TB will be collected through the *Kenya COVID-19 Tracker app*. Specimen for testing will be collected from enrolled *Boda Boda* riders. The samples for COVID-19 testing (Nasal swabs) will be analysed using Ag-RDT and a small sample (25%) using RT-PCR. Sputum samples will be tested for TB at the respective County GeneXpert centres. COVID-19 testing data will be transmitted from the *Kenya COVID-19 Tracker app* through the KenyaEMR to the LabWare LIMS and finally published on the national dashboard. Data on follow-up of contacts and cases enrolled for Home-Based Isolation and Care (HBIC) will be accessed via the existing *Jitenge system*. The study team will obtain data from respective platforms using access rights granted by MoH-K. After analysis, data collated by the study team will then be archived in the Digital Health Applied Research Centre (DHARC) server. The DHARC is a centre of JKUAT approved by MoH-K to host MoH-K data and applications.
Study Duration	May 2021 – March 2022
Investigating Institution	Jomo Kenyatta University of Agriculture and Technology (JKUAT)
Partners	▪ Ministry of Health Kenya (MoH-K) ▪ County Health Management Teams (CHMTs) in the 4 Counties within the Nairobi Metropolis (Nairobi, Kiambu, Machakos, Kajiado) ▪ Foundation for Innovative New Diagnostics (FIND)
Demand Creation	Participants will be encouraged to participate in the study through campaigns led by *Boda Boda* Safety Association of Kenya (BAK)leaders. Messages will be sent digitally via bulk SMSs, WhatsApp, and through addresses by field officers and *Boda Boda* leaders. Some of the campaign messages will include (i) Free medical check-ups (Blood pressure, random blood sugar) (ii) Linkage to care (iii) Sensitization seminars by National Social Security Fund (NSSF) and National Hospital Insurance Fund (NHIF) (iv) NHIF registration and part (3 months) subscription for positive cases.

Appendices

A Consent Form

CONSENT FORM – ENGLISH

Title: Utilization of digital tools to enhance C0vid 19 and TB Testing and Linkage to care among Boda Boda riders in the Nairobi Metropolis

Participant Information

We are researchers from Jomo Kenyatta University of Agriculture and Technology, Kenya Medical Research Institute (KEMRI), Ministry of Health Kenya (MoH-K), and Foundation for Innovative New Diagnostics (FIND), and we are doing research on end-to-end management of COVID-19 among Boda Boda riders in the Nairobi metropolitan area. In this study, we want to enhance the end-to-end management of COVID-19 among Boda Boda riders using Ag-RDTs and digital tools for complete data transmission. This study will include 5120 COVID-19 antigen rapid diagnostic tests (Ag-RDTs) (2,720 from Nairobi, 1120 from Kiambu, and 640 each from Machakos and Kajiado). For RT-PCR a sample of 670 specimens will be considered from Nairobi, 270 from Kiambu and 160 each from Machakos and Kajiado.

What are the aims of the study?

The Boda Boda (a person who rides or operates a motorcycle to offer transportation services) motorcycle transport is a major part of the Kenyan economy and a source of employment and livelihood for many, especially the thousands of unemployed youth. Hundreds of thousands of Kenyans use Boda Boda daily as an affordable, reliable, convenient and readily available mode of transport in both urban and rural settings in Kenya.

The Boda Boda riders are highly mobile and come into close contact with numerous individuals in the course of their work. Therefore, this makes them a “neglected", high risk group with regard to the spread of COVID-19 within communities that have been reported to not fully observe the directive of carrying only one passenger and wearing face masks. Moreover, there is lack of evidence on the rates of airborne infectious diseases in this population, despite the aforementioned risks and their potential to contribute to transmission.

We want to enhance COVID-19 management and linkage to care among the Boda Boda riders within the Nairobi Metropolis using digital tools, with an opportunity to integrate COVID-19 and Tuberculosis (TB) screening/testing.

According to the National Transport and Safety Authority (NTSA) there were 1,393,390 registered motorcycles in Kenya as of February, 2018. However, the exact number of motorcycles operating as Boda Boda in the country is not known since a number may be operating without formal registration and hence their existence is not documented.

We want to determine the average turnaround time and costs incurred in the continuum of COVID-19 management.

What are the benefits of the study?

You will receive free medical check-ups (Blood pressure, random blood sugar, TB screening), linkage to care for the positive cases, registration by BAK for those not registered so that they benefit from the insurance packages given by BAK and NHIF registration and part (2 months) subscription for positive cases. These will be provided at no cost to you.

What are the risks of the study?

All personnel who will perform medical examinations and treatment will be qualified and well experienced: this people will be medical doctors, nurses and technicians who are used to do this type of work. All methods applied within the study are routinely used in the field, the laboratories and the hospitals and therefore do not place any risk for you. The participation includes minor risks of bruise at the site of blood withdrawal on the skin, and pain/discomfort during the blood draw.

Who is funding the study?

The study is being funded by the Foundation for Innovative New Diagnostics (FIND), a global non-profit organization driving innovation in the development and delivery of diagnostics to combat major diseases.

Can I withdraw from the study?

Your participation in the study is entirely voluntary and free of charge. You are free to withdraw from the study at any time you wish, without giving reasons and without consequences. If you decide to withdraw from the study, your research data will be removed from all our platforms and will not be included in the analysis.

What is going to happen with the information (data)?

All collected data and information during the study will be treated confidentially and will only be used for scientific purposes. Your identity will not be disclosed when our findings will be communicated, including publication of the data in the scientific literature. At any time during the study you can demand to see your data.

Consent form

- Please read this consent form carefully or get it read and explained to you.
- If there are any terms that you do not understand, please ask.

Title of the study: Utilization of digital tools to enhance COVID-19 and TB testing and linkage to care among Boda Boda riders in the Nairobi metropolis

Place of conduction: Nairobi: Kiambu: Machakos: Kajiado

Study participant:

Name and Surname:_____

Date of birth: _____

I participate in this study on a voluntary basis and can withdraw from the study at any time without giving reasons and without any negative consequences.

I have been informed orally and in writing about the aims and the procedures of the study, the advantages and disadvantages as well as potential risks.

I have read or get it read out the written information for the volunteers. My questions related to the study participation have been answered satisfactorily. I have been given a copy of the information for the volunteers and the consent form and also agree to the collection, shipment, storage and use of samples (Nasopharyngeal swabs for Covid 19 and sputum for TB) as per the MoH guidelines.

I was given sufficient time to decide about participating in the study.

With my signature or thumbprint, I certify that I fulfil the requirements for the study participation mentioned in the information for the volunteers.

I agree that the responsible investigators and/or the members of the ethical committee have access to the original data under strict confidentiality.

I am aware that during the study I have to comply with the requirements and limitations described in the information for the volunteers.

_____	_____	_____
Place	Date	Signature or thumbprint of the participant

Confirmation by the study staff conducting consent discussion:

I hereby confirm that I have explained aims, objectives and meaning of this study to the study participant's caregiver.

I guarantee that applicable laws in relation to the conduction of this study will be followed by the study team at all times. Would any new information become available during the study, which could influence the decision of participating to the study by the study participants, I will inform them as soon as possible.

_____	_____
Name of Research Participant (please print)	Date
_____	_____
Signature of Participant	Time
_____	_____
Name of witness	Date

(Required only if participant is illiterate)

_____	_____
Signature of witness	Time

Confidentiality

The researchers will safeguard any information obtained during this study and make every effort to keep it confidential. Your name will not appear on the research forms or any of the reports. A separate list which connects your name to the study number will be kept and used to find you when the study is finished. Only information about the entire group that participated will be reported. No information about you, or information that connects you to the study, will be given to anyone without your wish and you written permission.

All information collected on you during the study will be recorded and will only be available to the research team at Jomo Kenyatta University in Kenya, Kenya Medical Research Institute (KEMRI), Ministry of Health Kenya (MoH-K), and Foundation for Innovative New Diagnostics (FIND). It will be kept confidential to the extent permitted by law.

Contact details of researchers – for further information / reporting of study related adverse

events:

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B Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

Title: Utilization of digital tools to enhance C0vid 19 and TB Testing and Linkage to care among boda boda riders in the Nairobi Metropolis

Local Principal Investigator:

As a member of this research team I understand that I may have access to confidential information about study sites and participants. By signing this statement, I am indicating my understanding of my responsibilities to maintain confidentiality and agree to the following:

- I understand that names and any other identifying information about study sites and participants are completely confidential.
- I agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained in the course of this research project that could identify the persons who participated in the study.
- I understand that all information about study sites or participants obtained or accessed by me in the course of my work is confidential. I agree not to divulge or otherwise make known to unauthorized persons any of this information, unless specifically authorized to do so by approved protocol or by the local principal investigator acting in response to applicable law or court order, or public health or clinical need.
- I understand that I am not to read information about study sites or participants, or any other confidential documents, nor ask questions of study participants for my own personal information but only to the extent and for the purpose of performing my assigned duties on this research project.
- I agree to notify the local principal investigator immediately should I become aware of an actual breach of confidentiality or a situation which could potentially result in a breach, whether this be on my part or on the part of another person.

_____	_____	_____
Signature	Date	Printed name
_____	_____	_____
Signature of local principal investigator	Date	Printed name

C Systems to be used

The individual systems used in this integrated system are discussed below.

C.1 Kenya COVID-19 Tracker App.

The *Kenya COVID-19 Tracker app* is deployment of the Community Health Toolkit Core Framework (CHT Core) Framework by Medic mobile, under the MoH-K guidelines. Community Health Toolkit Core Framework (CHT Core)[1] is an Open source application released under a free and open source license approved by the Open Source Initiative, specifically, under the Affero General Public License (AGPL) 3.0 [2]. It provides a collection of open source technologies and open access design, technical, and implementer resources that help in building and deploying digital tools for community health. Medic Mobile serves as the technical lead and a core contributor to the CHT Core.

The CHT Core is a global public good that is highly configurable to meet emerging program needs. There are open access documentation[3] on how to design, adapt or extend CHT Core, and deploy to support such a need. Medic Mobile also provides custom capacity building sessions for such needs. There is also an active community around the CHT Core that can readily provide technical support post deployment. For COVID-19 response in the Kenya, the CHT Core deployment was christened *Kenya COVID-19 Tracker app*.

C.2 TIBU

TIBU is a swahili word denoting "to medically treat". *TIBU* is a digital solution dedicated to digitizing sustainable lung health reporting and routine surveillance. It integrates a majority of program areas. It's an android based application running on handheld devices and stores data online which is accessible via the internet. Currently, *TIBU* is being used by over 350 county and sub-county coordinators country. With *TIBU*, NTLD-P has been able to digitize TB and drug-resistant TB Registers, Isoniazid Preventive Therapy registers, Geographic Information System reports and TB Heat Maps, Leprosy Registers, supervision checklist, Expense sheets as well as Payment Requests.[4].

C.3 Kenya Electronic Medical Records System (KenyaEMR)

The KenyaEMR is a tailored distribution of Open Medical Record System (OpenMRS) which meets the requirements laid out in the Kenya MoH-K document: 2011 Kenya Electronic Medical Records (EMR) Standards and Guidelines. KenyaEMR was originally developed by I-TECH and Washington State University and is currently supported by Palladium Group through KHMIS Project. The system has been deployed to over 800 health facilities in Kenya, in 44 out of the 47 counties, and supported by 38 Service Delivery Partners (SDPs). KenyaEMR was used for case management at Health Facility (HF) level. A facility web-based system based on the OpenMRS system. KenyaEMR shares confirmed cases and their contacts with Kenya *Kenya COVID-19 Tracker app*, the system also pushes lab requests to the Laboratory Management Information System (LMIS) and receives lab results from LMIS. It also has a quarantine management module which is used for managing data for individuals in quarantine.

[1] https://communityhealthtoolkit.org/tools
[2] https://github.com/medic/cht-core/blob/master/LICENSE
[3] https://communityhealthtoolkit.org/tools
[4] https://www.nltp.co.ke/2016/05/26/the-tibu-initiative

C.4 Laboratory Information Management system

According to the MoH-K guidelines for submission of COVID-19 testing data to the national data compilation centre, released on the 12th of June 2020, all laboratories were supposed to submit all test results to the NPHL repository daily by 6.00am daily. This online transmission of test data was through the LabWare LabWare LIMS. Initially, there were very few labs for COVID-19 testing, other than KEMRI. Consequently, results were being released mainly in Nairobi, at the national data compilation centre using summaries.

LabWare LabWare LIMS is a highly adaptable, flexible, configurable, compliant, easy to implement and easy to use software. It provides lots of functionalities to automate the lab process and thereby increase the efficiency and productivity of the lab. It provides very robust reporting functionalities. It is a proprietary software, with freedom to customize depending on user needs. The software was already in use for other lab functionalities, and was customized to manage COVID-19 data.

C.5 Jitenge mobile application and USSD platform

Jitenge, a Swahili word for self-isolate, is an innovation of mHealth Kenya developed to support the Government in the fight against COVID-19 in Kenya. The *Jitenge system* was developed as a module of the Emergency Alert and Reporting System (EARS) used by the MoH-K's PHEOC to respond to infectious diseases. *Jitenge system* is available as an Android Mobile Application - *Jitenge system* MoH-K, a USSD session - ***299#**, and an interactive web-based platform that supports a dynamic dashboard.

For management of COVID-19 in the country, the system is being used to manage and monitor; (i) Home based care management, (ii) Self-quarantine for contacts, (iii) Post-isolation follow-up, and (iv) Monitoring of long-distance truck drivers. *Jitenge system* allows users to either self-register or are registered by various MoH-K officials at the quarantine initiation point for home quarantine, at the quarantine facilities, and of the point of entries by port health officials. Registered users will then receive daily reminders and prompts to report on their health status including symptoms or any other information. The system supports contacts who have been put into quarantine or are in self-isolation to self-monitor themselves and report through an android app and USSD platform.

C.6 EID/VL NASCOP Lab Management Information System

This is the Early Infant Diagnosis (EID) and Viral Load (VL) LMIS managed by the National AIDS/STD Control Programme (NASCOP), supported by United States Agency for International Development (USAID). The system was adopted for the collection of laboratory data related to COVID-19 in both Mombasa and Machakos counties.

D Entry Strategy

D.1 sensitization meetings

In order to obtain concurrence and participation in the project activities, sensitization meetings will be held with the following stakeholders

(i) Ministry of Health at National and County Levels. The composition of the meetings will include: Ministry of Healths PHEOC team, Directors of Health at the National and County level and CHMTs.