Implementing SARS-CoV-2 antigen testing scale-up in Rwanda: retrospective analysis of national programme data and qualitative findings

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ABSTRACT

Objectives Reverse transcriptase PCR is the most sensitive test for SARS-CoV-2 diagnosis. However, the scale-up of these tests in low-income and middle-income countries (LMICs) has been limited due to infrastructure and cost. Antigen rapid diagnostic tests are an alternative option for diagnosing active infection that may allow for faster, easier, less expensive and more widespread testing. We compared the implementation of antigen and PCR testing programmes in Rwanda.

Design We retrospectively reviewed routinely collected PCR and antigen testing data for all reported tests conducted nationally. We administered semiquantitative surveys to healthcare workers (HCWs) involved in COVID-19 testing and care and clients receiving antigen testing.


Participants National SARS-CoV-2 testing data; 49 HCWs involved in COVID-19 testing and care; 145 clients receiving antigen testing.

Interventions None (retrospective analysis of programme data).

Primary and secondary outcome measures Test volumes, turnaround times, feasibility and acceptability of antigen testing.

Results Data from 906 204 antigen tests and 445 235 PCR tests were included. Antigen testing increased test availability and case identification compared with PCR and had a median results return time of 0 days (IQR: 0–0). In contrast, PCR testing time ranged from 1 to 18 days depending on the sample collection site/district. Both HCWs and clients indicated that antigen testing was feasible and acceptable. Some HCWs identified stockouts and limited healthcare staff as challenges.

Conclusions Antigen testing facilitated rapid expansion and decentralisation of SARS-CoV-2 testing across lower tier facilities in Rwanda, contributed to increased case identification, reduced test processing times, and was determined to be feasible and acceptable to clients and providers. Antigen testing will be an essential component of SARS-CoV-2 test and treat programmes in LMICs.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Analysis of a large national-level dataset with relatively detailed individual-level information and supporting qualitative feedback from providers and clients.

⇒ Analysis of real-world implementation data; not a controlled study comparing the two technologies so causality cannot be assumed.

⇒ Data collated from routine clinic data systems, and therefore, may be subject to some inaccuracies/incompleteness.

INTRODUCTION

Reverse transcriptase PCR is the most sensitive test to diagnose for SARS-CoV-2, the aetiological agent of COVID-19.1 Easily accessible SARS-CoV-2 testing and stringent mitigation strategies have been the cornerstone of public health interventions to limit the spread of the virus globally. However, there have been significant challenges to the scale-up of PCR tests including high test costs and centralised testing leading to long turnaround times to test results. This has been due to weak sample referral systems and limited numbers of skilled laboratory staff, especially in low-income and middle-income countries (LMICs).2 3 As a result, many LMICs limited testing to severely ill patients requiring hospitalisation and/or to high mobility ports of entry such as borders. The median turnaround time for PCR results is often greater than 48 hours and up to 7 days,4 further limiting the ability to effectively isolate, treat and contact trace in a timely fashion.

Detection of viral proteins through rapid lateral flow tests is an alternative option for diagnosing active infection that may allow
for faster, easier, less expensive and more widespread testing. Whereas PCR detects viral RNA, rapid lateral flow tests directly detect SARS-CoV-2 protein produced by the virus in respiratory secretions and can be used to diagnose COVID-19 cases within up to 7 days after the onset of symptoms. Test sensitivity is lower for antigen testing compared with PCR testing, particularly for asymptomatic patients, but most antigen tests are able to identify individuals with viral loads who are at risk of transmitting their infection. With increased access and more frequent antigen testing (given lower test processing time and costs), antigen testing has been hypothesised to be an important tool to contain the COVID-19 pandemic. Antigen tests are designed to be run at the point of care and have a 15–30 min turnaround time to results, which can enable individuals testing positive to quickly self-isolate to prevent further transmission and expedite clinical decision-making. The adoption of antigen testing can facilitate testing at primary care facilities as well as community sites, thereby increasing access to on-site testing compared with PCR. While some previous publications have highlighted the need for antigen-based and other assays to meet test demand in LMICs, there are limited data on the implementation of antigen testing as part of the overall COVID-19 pandemic response, particularly in LMICs.

Rwanda, an Eastern African country with a population of 12.95 million people, has made significant advances in healthcare and economic development over the last 20 years. The country has 1744 public health facilities of which 55 are hospitals, 510 health centres and 1179 health posts. Rwanda was quick to leverage existing infrastructure from Ebola preparedness efforts and developed a National COVID-19 Preparedness and Response Plan that included testing, contact tracing, community healthcare outreach, communication with the public, screening of travellers at ports of entry and plans for identification and assessing of hotspots. As of 4 January 2023, the country had recorded 133033 positive cases and 1468 deaths.

Rwanda’s response to COVID-19 has leveraged innovative interventions to limit the spread of the infection, including PCR pool testing to maximise capacity, providing testing and isolation of positive cases in treatment centres at no cost and communication strategies using social media and national toll-free numbers. Testing was initially restricted to 11 public health PCR laboratories; PCR testing was available starting in May 2020. As part of the strategy to make testing capacity available to all districts at the health centre level in response to community transmission, in November 2020 the Rwandan Ministry of Health introduced antigen testing. In this study, we aim to assess the implementation of an antigen testing programme in Rwanda between 1 November 2020 and 31 July 2021, including testing volume, geographical access and feasibility and acceptability of testing as assessed through surveys conducted with healthcare workers (HCWs) and clients.

METHODS

SARS-CoV-2 testing implementation in Rwanda

Starting from May 2020, 11 public health laboratories in Rwanda were conducting PCR testing. Across the study period, overall, there were 1086 sites offering PCR sample collection and/or antigen sample collection/testing. PCR sample collection was offered across 597 sites (301 clinics, 43 hospitals, 183 community testing sites, 42 port of entry sites and 28 other types of sites) and antigen testing was offered across 1039 sites (581 clinics, 49 hospitals, 397 community testing sites, 41 port of entry sites and 31 other types of sites). PCR samples were collected at sample collection sites and transported to PCR hubs for processing. In contrast, antigen tests were processed and results reported at the sample collection site. The antigen tests used included Abbott PanBio COVID-19 Ag (Chicago, USA), Excalibur Rapid SARS-CoV-2 Antigen Test (UK) and SD Biosensor STANDARD Q COVID-19 Ag Test (South Korea).

Per national guidelines, both PCR and antigen testing were used for symptomatic individuals, as well as HCWs, contact tracing in private and public facilities, outbreak settings and at schools, land borders, prisons and refugee camps. In addition, periodic random testing was conducted at community sites 1–2 days per month, including at markets, schools, prisons, churches, car parks and at borders for truck drivers. A negative test was required for interdistrict travel and tourism during periods of high transmission and tighter COVID-19 regulations.

When both technologies were available, antigen testing transitioned to become the primary testing technology in public facilities and at community sites and was available free of charge for symptomatic individuals or contacts of cases. PCR testing became primarily used for travellers who paid for testing services or those who were asymptomatic and chose to test for other reasons; the cost was approximately US$30–US$60. At private facilities, the cost for antigen testing was approximately US$5.

The testing algorithm was as follows: for high-risk groups including symptomatic HCWs and contacts of cases who tested negative, a repeat test was recommended after 3 days. Antigen testing and PCR testing were not generally conducted in parallel or sequentially on the same individuals, unless an individual who tested negative with an antigen test chose to pay for a PCR test out-of-pocket.

Rapid roll-out of Rwanda’s antigen testing programme was achieved through a training of trainers model. In December 2020, one laboratory technician from each public hospital was trained by the National Reference Laboratory staff. These trained individuals then rapidly trained laboratory technicians at each of their reporting health centres. All health centres (both public and private) were trained on antigen testing within a 2-week period to respond to the emerging COVID-19 transmission wave at that time. Materials from the African Society for Laboratory Medicine were used for training, and quality assurance was provided through routine
supervision and monitoring efforts. Supervision visits were made quarterly by National Reference Laboratory staff to a subset of facilities.

Analysis of national testing data
National data were extracted from Rwanda’s Health Management Information System on PCR and antigen tests conducted between November 2020 and July 2021. Data included client’s age, gender, site type, test type, reason for testing, test result and dates of sample collection and PCR test processing in the laboratory. Objectives of this analysis included to describe antigen testing scale-up over time in comparison with PCR, assess the extent to which antigen testing has been used to implement testing for SARS-CoV-2 within the overall testing landscape in Rwanda, understand how antigen testing influenced overall test access, case identification and equity across geographies and client characteristics and compare time from sample collection to testing with PCR. Descriptive statistics were used for the analysis (percentages and medians with IQRs). To compare categorical characteristics of those tested using antigen testing versus PCR, we used χ² tests adjusted for clustering by test site. For test processing times, a continuous variable, Somers’ D tests were used adjusting for facility clustering. Stata/SE V.15 was used for data analysis. A p-value<0.05 was considered to be statistically significant.

Surveys with HCWs and patients
A sample of HCWs involved in administering antigen testing and/or care of COVID-19 patients and a sample of patients receiving antigen testing were surveyed about their experiences. Written informed consent was required to participate. These surveys were conducted from March to August 2021 at a sample of 10 urban, 3 semiurban and 7 rural public sites offering antigen testing. Four sites were selected within each province for participation, covering 19 of Rwanda’s 30 districts. Nineteen sites were health facilities and one site was a border testing site. Sites were selected purposively using heterogeneity sampling to achieve a diverse sample representing a wide array of situations and contexts.

For the staff surveys, all clinic or laboratory HCWs involved in antigen testing and/or clinical management of COVID-19 within selected sites were invited to participate. For client surveys, staff at these sites recruited 5–15 clients ages 15+ years receiving antigen testing to complete questionnaires, with a goal to include a diverse participant sample that had a variety of reasons for seeking testing at the facility (symptomatic vs requirement to access other services), and with both positive and negative results. Ultimately, 49 HCWs and 145 clients were surveyed.

Semistructured questionnaires were administered verbally by a trained interviewer and responses were recorded electronically. Sample sizes were determined based on logistical constraints and estimates of numbers needed to achieve theoretical saturation. Questions included how antigen testing was implemented in practice at the facility, feasibility and acceptability of antigen testing, and whether there had been challenges or were recommendations for programme improvement. Descriptive statistics were used for quantitative data from surveys. Qualitative responses were reviewed and key themes and quotations were extracted.

RESULTS
Antigen testing scale-up started in December 2020, when it accounted for 23% of total test volume, compared with 88% of volume in July 2021 (figure 1). Cumulatively across 9 months, 906 204 antigen tests and 445 235 PCR tests were conducted (table 1 and figure 1). Antigen testing also contributed to higher case identification (100 705, compared with 10 806 cases on PCR) given that

![Figure 1](https://example.com/figure1.png)  
**Figure 1** National public sector volumes of PCR and antigen (Ag) tests and per cent positivity, by month.
larger volumes of people screened with antigen testing and antigen testing was more frequently used for symptomatic clients and contact tracing. Eighty-four per cent of antigen testing was conducted in adults 20–59 years compared with 87% with PCR. There were no significant differences in the type of testing by age group (p=0.30). We observed gender disparities, with only 31.6% of PCR tests in females compared with 44.5% with antigen testing (p<0.001). In November 2021, when antigen testing was not scaled up, only 28% of all tests (PCR and antigen) were conducted for females compared with 49% of all tests conducted in July 2021 (data not shown). This
disparity in testing by gender held true when we stratified data by site type and despite positivity rates being equivalent or slightly higher in women within strata (data not shown).

Test type differed significantly by test reason (p=0.04). The majority of PCR tests were conducted in the general population (64.6%); 9.4% were travellers; 3.8% were symptomatic; 0.1% were contacts of confirmed cases and 21.3% of records had no reason for the test. For antigen testing, 81.3% were conducted in the general population, followed by 10.4% in symptomatic individuals, 2.5% conducted at events, 2.2% contacts of confirmed cases and 2.2% in the workplace. Antigen testing was not conducted among international airport travellers.

The proportion testing positive for antigen testing was 11.1% compared with 2.4% for PCR (p<0.001), indicative of the fact that antigen testing was more widely available across districts and was used as a primary test for symptomatic clients and contact tracing. Even though the general population had the lowest positivity rate (5.4%) with antigen testing, this group accounted for 54% (n=60 350) of total cases. PCR test volumes remained relatively consistent by month from November 2020 to July 2021, whereas antigen testing increased over time (figure 1).

Figure 2 shows weekly testing rates by district in November 2020 when SARS-CoV-2 testing was predominately available by PCR, compared with July 2021, after implementation of antigen testing. The testing rate was <1 test/1000/week in 25 out of 30 districts in Rwanda in November 2020. At this time, the highest test rates were observed in Kigali (the capital), Karongi (a major tourist destination) and Kirehe (on the border with Tanzania). After implementation and scale-up of antigen testing in July 2021, all districts’ testing rates exceeded 1 test/1000/week and in 11 out of the 30 districts, rates exceeded 7 tests/1000/week. At this time, Kigali averaged 21 tests/1000/week and Karongi averaged 40 tests/1000/week.

Median time from sample collection to test processing was significantly faster for antigen testing compared with PCR testing, 0 days (IQR: 0–0) and 1 day (IQR: 0–1), respectively. However, PCR testing turnaround time varied by district, with median time ranging from 1 day in Gasabo, Kicukiro, Nyarugenge (all Kigali City), and Nyamasheke districts (IQR: 0–1) to 12 days in Nyanza district (IQR: 8–18) (figure 3).

**HCW surveys**

Forty-nine HCWs were surveyed, of whom 69% were laboratory technicians, 18% were nurses and 12% had other roles at the facility (table 2). Eighty-eight per cent of those interviewed reported conducting antigen testing at their facility. Ninety-eight per cent reported that most clients waited <1 hour for antigen test results at their facility and 100% reported that the number of clients receiving SARS-CoV-2 tests had increased with antigen testing. One hundred per cent reported that after the roll-out of antigen testing, clients were receiving their results...
faster and being isolated or treated more quickly. No HCWs reported other facility staff expressing concerns about trusting antigen test results. The survey also identified challenges with implementation, including 31% of respondents reporting antigen test kit stockouts in the previous month, with 15 of 15 respondents reporting that stockouts lasted less than 7 days. Eight per cent of HCWs noted that some clients expressed concerns trusting antigen test results. In addition, 27% of HCWs surveyed noted that some clients should have received antigen testing but did not; the specific reasons for this were not collected, but some respondents noted that insufficient staff were trained for testing, in particular for mass testing campaigns, and others commented on the hesitancy of some clients. Providers noted that some clients were distrustful of positive results when asymptomatic. In addition, some staff noted power/internet connectivity issues affecting their ability to enter COVID-19 testing information into the electronic patient record management system.

Client surveys

A total of 145 clients participated in survey. Sixty-one per cent were female and the median age was 37 years (IQR: 27–47) (table 2). Thirty-seven per cent of respondents reported accessing testing services because they were symptomatic. Ninety-four per cent reported receiving their test results within an hour and 100% received results within 2 hours. Ninety-nine per cent found the antigen testing experience acceptable and 97% stated that they trusted the results. Some clients noted discomfort or pain with the nasopharyngeal swab sample collection and highlighted a need for an easier sample collection procedure. Suggestions for improvement of the antigen testing programme included increasing the number of staff available to provide testing (some clients reported long queues for testing) and minimising stockouts.

DISCUSSION

This analysis documents a first report on SARS-CoV-2 antigen testing scale-up in an LMIC, Rwanda. With antigen testing, there was dramatic expansion of the number of sites offering COVID-19 testing, diversified test access to low tier facilities and community sites, and improved geographical distribution of sites offering point of care testing, with a corresponding increase in the total volume of tests conducted. With a relatively small number of laboratories able to provide PCR testing across the country, antigen testing was able to augment total national test coverage and to provide same-day test results. Antigen testing made up 67% of overall testing volumes over the study period while identifying >90% of all cases. Unlike antigen testing, which was accessible at health centres and community settings, PCR testing was predominantly available at ports of entry such as airports, for screening of tourists at hotels, and at 10 hospitals activated for COVID-19 testing. In addition, antigen testing was more widely available compared with PCR during the beginning of the COVID-19 case surge in June 2021.

This analysis has a number of limitations. First, this was an analysis of real-world implementation data; it was not a controlled study with a head-to-head comparison of the
two technologies. Therefore, causality cannot be assumed when making comparisons between groups who received PCR vs antigen testing. Data were collated from routine clinic data systems, and therefore, may be subject to some inaccuracies/incompleteness. While policies are in place to ensure reporting of all test results, there is a possibility that some testing occurred outside of what is contained in the national public health dataset in Rwanda. The surveys with providers and clients were not a nationally representative sample. However, this analysis of a large national-level dataset with relatively detailed individual-level...
information and supporting qualitative feedback from providers and clients helps to understand how antigen testing fits into the overall picture of SARS-CoV-2 testing in Rwanda.

We observed high variability in turnaround times to test results for PCR, with relatively rapid processing in districts that had a PCR laboratory or were near a laboratory (median time from sample collection was same-day in all districts that had working labs for the duration of the study and 13 of the remaining 22 districts that did not have laboratories. However, in other districts, median time from sample collection to running the tests on the instruments was as high as 12 days, although results were made available by SMS once processed. Delayed sample processing and result delivery reduces the clinical utility of testing; mathematical modelling has indicated that when clients wait >2 days for results and a low proportion of individuals and their contacts quarantine, testing is likely to have minimal impact on reducing transmission.13 Furthermore, with emergence of more infectious variants such as Delta and Omicron, which are believed to have a considerably shorter generation time compared with Alpha variants,19 the turnaround time to test results may need to be significantly shorter in order to impact transmission. In response to more transmissible variants, a successful mitigation strategy may require same-day test and treat with antigen testing.

Clients and providers were overwhelmingly positive about their experiences with and perceptions of antigen testing. All HCWs surveyed reported that antigen testing led to faster clinical action, and 99% of clients found the antigen testing experience acceptable. Challenges included intermittent test kit stockouts and a small percentage of clients (<10%) expressing concern about antigen test accuracy. Suggestions for test programme improvement included augmenting the number of staff providing testing services and shifting to nasal swabs for testing to reduce the discomfort associated with nasopharyngeal sampling. Only nasopharyngeal samples were collected during the study period; however, the country began shifting to nasal samples for antigen tests in the second half of 2021 resulting in availability of a preferred, less invasive sample type.19 While self-testing currently is not widely available in Africa,20 in the future, self-testing may help to increase SARS-CoV-2 test availability and accessibility. The WHO released interim guidance in March 2022 advocating for SARS-CoV-2 antigen self-testing in addition to facility-based testing (strong recommendation, low to moderate certainty evidence).21 In addition, as countries are moving from pandemic to control strategies for COVID-19, it is recommended that antigen testing is integrated into routine services within health facilities to allow testing across multiple entry points.

We also observed in this analysis that men were more likely than women to be tested when PCR testing was predominantly available. The difference in test access was true even if we limited the analysis to hospitals and clinics. This discrepancy is not surprising at certain types of targeted screening sites such as those for truck and motorcycle drivers, where the population was predominately male due to gender differences in occupation, but was unexpected at the health facility level. Implementation of antigen testing did lead to narrowing of this gap. Test costs at private sites and ability to pay could have contributed to this gender discrepancy. A concerted effort should be made to ensure that the gender gap closes as SARS-CoV-2 test and treat programmes are rolled out.

In conclusion, national-level data from Rwanda indicate that the implementation of antigen testing facilitated a dramatic expansion of SARS-CoV-2 testing volumes, decentralised testing across lower tier facilities and in the community, contributed to an increase in case identification, allowed for more equitable coverage geographically and by gender, and reduced test processing times. HCWs and clients found antigen tests to be feasible and acceptable. Despite its lower sensitivity compared with PCR testing, with its low cost, fast processing times, and lack of infrastructure needs, antigen testing will be a critical part of SARS-CoV-2 test and treat strategies in LMIC.

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Acknowledgements We acknowledge the support of Edouard Ntagwabira, Yvan Butera, Enatha Mukantwari, Maria Artesi, Jeanne d’arc Umuringa, Oneshpore Malyambere, Elfa Larissa Ndoricimiyaye, Esperance Umuramarungu, Alice Kabanda, Marylin Milumbu Murindahabi, Patrick Tuyisinge, Misbah Gashegu, Reuben Sindayiheba, Jacob Souopgui, Tharcisse Mpunga, Daniel Ngamije, Leon Mutesa, Nadine Rujeni, Claude Mambo Muvunyi, Alida Ngwije, Brenda Kateera, and Sidonie Uwimpuhwe.

Contributors RR conceived of the study, contributed to the design of the study and reviewed and approved the final draft of the manuscript. CB contributed to the design of the study, wrote the first draft of the manuscript, coordinated manuscript reviews, and reviewed and approved the final draft of the manuscript. JI contributed to the design of the study, conducted the data analysis, critically revised the manuscript, and reviewed and approved the final draft of the manuscript. NaB coordinated implementation and reviewed and approved the final draft of the manuscript. NoB conceived of the study, contributed to the design of the study and reviewed and approved the final draft of the manuscript. OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript. AK and OD assisted with implementation, critically reviewed the manuscript, and reviewed and approved the final draft of the manuscript.

Funding This analysis was funded through generous support from the ELMA Foundation.

Disclaimer The funder had no role in the study.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval IRB approval for this study was granted through the Rwanda National Ethics Committee (FWA Assurance No. 00001973 IRB 00001497 of IORG000110 Approval Notice: No. 742/RNEC/2021). Participants gave informed consent to participate in the survey questionnaires.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. Data are owned by the Government of Rwanda and are not publicly available. The study protocol and informed consent tools are available through the corresponding author.

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