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Timely Detection of SARS-CoV-2 in Limited Resource Settings: The Role of the Laboratory in Zimbabwe

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Abstract

The recommended approach for response to severe acute respiratory syndrome coronavirus 2, was to test to enable timely detection, isolation and contact tracing so as to reduce the rapid spread of the disease. This highlighted that the laboratory as one of the core capacities of the International Health Regulations and key technical area in the International Health Security was critical in curbing the spread of the virus. Zimbabwe embarked on testing for SARS-CoV-2 in February 2020 following the guidance and support from WHO leveraging the existing testing capacity. Testing was guided by a laboratory pillar which constituted members from different organizations partnering with the Ministry of Health and Child Care. SARS-CoV-2 testing expansion was based on a phased approach using a tiered system in which laboratory staff from lower tiers were seconded to test for coronavirus using RT-PCR with National Microbiology Reference Laboratory (NMRL) being the hub for centralized consolidation of all results. As the pandemic grew nationally, there was an increase in testing per day and reduction in turnaround time as five laboratories were fully capacitated to test using RT-PCR open platforms, thirty-three provincial and district laboratories to test using TB GeneXpert and 5 provincial laboratories to use Abbott platforms.

Keywords: pneumonia, detection, laboratory expansion, testing, partner coordination

1. Introduction

Coronavirus Disease 2019 (COVID-19) as it came to be known, was first reported as a novel pneumonia in Wuhan, China in December 2019 [1]. It was eventually shown to be caused by a coronavirus strain known as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [2]. This disease was

declared a Public Health Emergency of International Concern by the World Health Organization (WHO) on 30th January 2020 and eventually a pandemic on 11 March 2020. Africa experienced its first COVID-19 virus case on 14th February in Egypt [3]. This was an Italian citizen returning from Milan and had mild symptoms. South Africa a neighboring country to Zimbabwe had its first case confirmed on the 5th of March 2020 and this was also an Italian returning from Italy with mild symptoms identified on visiting a private general practitioner to consult for some symptoms [4]. Zimbabwe and other neighboring countries were at a high risk of importing cases and subsequent community spread of COVID-19 cases owing to the border trade activity with South Africa. SARS-CoV-2 presents differently among individuals in different population. The majority of cases in the African population present with asymptomatic to mild symptoms with few symptomatic cases [5]. People with severe forms of the disease mostly present with pneumonia and difficulty in breathing which may sometimes require mechanical ventilation [6]. SARS-CoV-2 infection is spread through contact and exposure to droplets and aerosols of viral particles from infected persons coughing, sneezing and talking [6, 7]. Therefore, the main prevention method for spread is by practicing hand hygiene through frequent hand washing with soap or alcohol based hand sanitizer [8, 9] and use of face masks as guided by WHO [10]. In order to control the rate of infection, it is important to put in place active disease surveillance for early identification, isolation and contact tracing [11, 12]. The detection of COVID-19 is largely based on the laboratory identification of SARS-CoV-2 virus [13, 14] hence the need to increase laboratory capacity for testing of suspected cases, in order to isolate cases and their contacts from the healthy population to reduce the spread.

The COVID -19 pandemic presented a huge demand on the laboratory compared to previous emergencies and at a time when most low-middle income countries were not well capacitated to respond to outbreaks/pandemics [14]. Laboratory being among the core capacities of the International Health Regulations, IHR (2005) plays a critical role in the timely response to emergencies [15]. Laboratory is a key technical area of International Health Security enabling countries and entities to detect infectious agents of human or animal origin, enhancing preparedness and response to infectious diseases of epidemic potential [16, 17]. Efficient diagnostic strategies and methods ensures timely detection of the virus [18].

Globally, SARS-COV-2 can be detected most reliably using Real-Time Polymerize Chain Reaction (RT- PCR), a highly sensitive molecular technique for viral nucleic acid detection using a number of different in-house as well as commercially available kits. Antigen and antibody based rapid diagnostic tests (RDTs) are less sensitive and also used as directed by testing strategies developed by the country's health regulatory authorities as recommended by WHO [19, 20].

The COVID-19 pandemic brought in a new dimension to international health security bringing new dimensions of solidarity [21] and selfishness in certain situations. These issues were more marked in the laboratory side of the preparedness and response efforts. First, to develop COVID-19 diagnostic testing, there was a need to share the viral material in line with the pandemic influenza preparedness plan [22] as well as the Nagoya Protocol [23]. This was done, according to WHO. Secondly, the development and distribution of diagnostics brought in a crunch with countries with capacity for development of these resources prioritizing themselves to the detriment of poorer countries with less capacity. This would then be improved with a solidarity movement spearheaded by WHO, which pooled organizations and entities involved in the response for centralized procurement and allocation of resources to countries in need. This saw the development of the online platform, COVID-19 supply portal [24] where countries could layout their requirements and have allocations from the global level according to their need and availability.

Like most of the Low to middle-income countries (LMIC), Zimbabwe started testing for SARS-COV-2 in February 2020 without a clear strategy for testing with support from WHO and Africa CDC. At this point, there was one laboratory staff at National Microbiology Reference Laboratory (NMRL) trained at NICD in South Africa (facilitated by Africa CDC) on testing for COVID-19 with only 5 tests being done a day. The available capacity for influenza surveillance in terms of staff and HIV surveillance in terms of equipment and laboratory consumables became the initial basis for COVID-19 testing. The first case of SARS-COV-2 was detected in Zimbabwe on 20th of March 2020 where a male traveler of 38 years of age traveling from UK to Victoria Falls, had mild symptoms and tested positive for SARS-COV-2. At this time, there was a great need to establish a strategy to expand testing to meet the country's needs before cases increased [25]. The speed at which WHO developed guidance document on the onset of the pandemic provided an opportunity for countries including Zimbabwe to ride on to develop their country testing strategies.

In this report, we showcase Zimbabwe's hands on experience in scaling up testing for COVID-19 using RT-PCR since the start of the response in February 2020 following a step by step tier-based approach and highlighting the major challenges identified along the process and key lessons learned from this experience.

2. Methodology

Zimbabwe employed a multisectoral approach through setting up dedicated expert committees to cover specific areas of the response based on the WHO guidelines on COVD-19 response preparedness [20]. In addition, a literature review of the available evidence was also done to understand the role of the laboratory in emergencies particularly of infectious diseases and how other countries have responded to the need to scale up laboratory capacity in order to meet the country needs in emergencies and outside emergencies [14, 26]. An operational plan was developed as well as guidelines and procedures for implementation. Coordination led by the MoHCC involved daily updates at the beginning reducing their frequency as implementation progressed. There were also weekly national coordination meetings for the national taskforce who reported to the inter-ministerial committee, cabinet and ultimately the presidium.

2.1 Expansion of laboratory testing

One of the Joint External Evaluation (JEE) focus areas in the laboratory technical area is the presence of an effective national diagnostic network [17]. Zimbabwe set out to scale up laboratory capacity to test for SARS-CoV-2 leveraging existing capacity from other programs like influenza, HIV and TB. This expansion was spearheaded by the laboratory pillar in a stepwise manner as explained in the following sections.

2.1.1 The laboratory pillar structure establishment

The journey in the COVID-19 laboratory response in Zimbabwe began with establishing of the Laboratory Pillar members mandated to support scale up of COVID-19 testing through developing a testing strategy and supporting its implementation. The laboratory pillar was one of the Zimbabwe modified Incident Management System (IMS) guided by WHO Emergency Response Framework (ERF) [27] in which the Laboratory was one of the pillars in addition to surveillance, case management and continuity of essential services, Infection

prevention and control, Risk Communication and Community Engagement, Logistics and Points of Entry. MoHCC and partners conducted a rapid assessment of the available capacity in country, leveraging existing investments in different programs and established a diagnostic network and infrastructure for COVID-19 testing. The Laboratory Pillar was led by the Directorate of Laboratory services (DLS) under the MoHCC and constituted of partners including United States Centers of Disease Control and Prevention (US. CDC), World Health Organization (WHO), Clinton Health Access Initiative (CHAI), African Society of Laboratory Medicine (ASLM), the leadership from the COVID-19 testing laboratories including the National Reference laboratories (NMRL) and institutions providing testing services on behalf of the MoHCC. With the pillar in place, a testing strategy, following the WHO guidance and recommendations for laboratory testing [20] was developed to guide the scale up process. The strategy employed a tier-based approach for expansion which activated higher tier laboratories followed by provincial then district. The pillar members were involved in the planning of this expansion which involved identifying through assessment and listing the laboratories with available capacity for COVID-19 molecular testing, drafting budgets and partner commitment to support in particular areas of the response.

2.1.2 The scale-up of testing: the tier-based system

In March, when the first case was detected, minimal testing was being done by the National Microbiology Reference Laboratory (NMRL) only with a few staff trained to perform testing for COVID-19 virus using RT-PCR. Tier-1 of the expansion involved assessment of the NMRL and training of extra staff who would support to test for COVID-19 virus using RT-PCR and further train other staff during the expansion process. After successful implementation of tier-1, tier-2 was initiated as shown in the scale up plan in **Figure 1**. This involved training of more laboratory cadres and capacitating five more national level laboratories to test for COVID-19 virus using RT-PCR on open PCR platforms to support the tier-1 laboratory. The cadres trained in tier-2 were from the laboratories listed during the initial planning process. The laboratories included tertiary, research and training laboratories namely, National Tuberculosis Reference Laboratory (NTBRL), National Virology Reference Laboratory (NVRL), African institute of Biomedical Research (AiBST), Biomedical Research Training Institute (BRTI) and University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC). The inclusion criterion was based on presence of existing testing capacity based on availability of RT-PCR equipment and resources as well as staff experienced in RT-PCR. This process took a total of 3 months to complete full rollout of tier-2 testing.

Leveraging existing TB GeneXpert platforms in the different provinces, university Bio-labs and Mobile trucks, tier-3 was implemented through capacitating thirty-three provincial and district laboratories to test for COVID-19 and 5 provincial laboratories to test using the Abbott platforms.

With the country experiencing a high influx of returnees from South Africa, there was increased risk of local transmission. This heightened the need for a robust surveillance strategy to minimize transmission. The country projected to test 33 000 tests in the month of April which target was not reached as planned. This saw the laboratory encouraging support from private laboratories which also joined forces increasing testing capacity. In this line, Lancet and CIMAS laboratories joined in supporting to test for SARS-CoV-2 using RT-PCR to complement government efforts to test for SARS-COV-2.
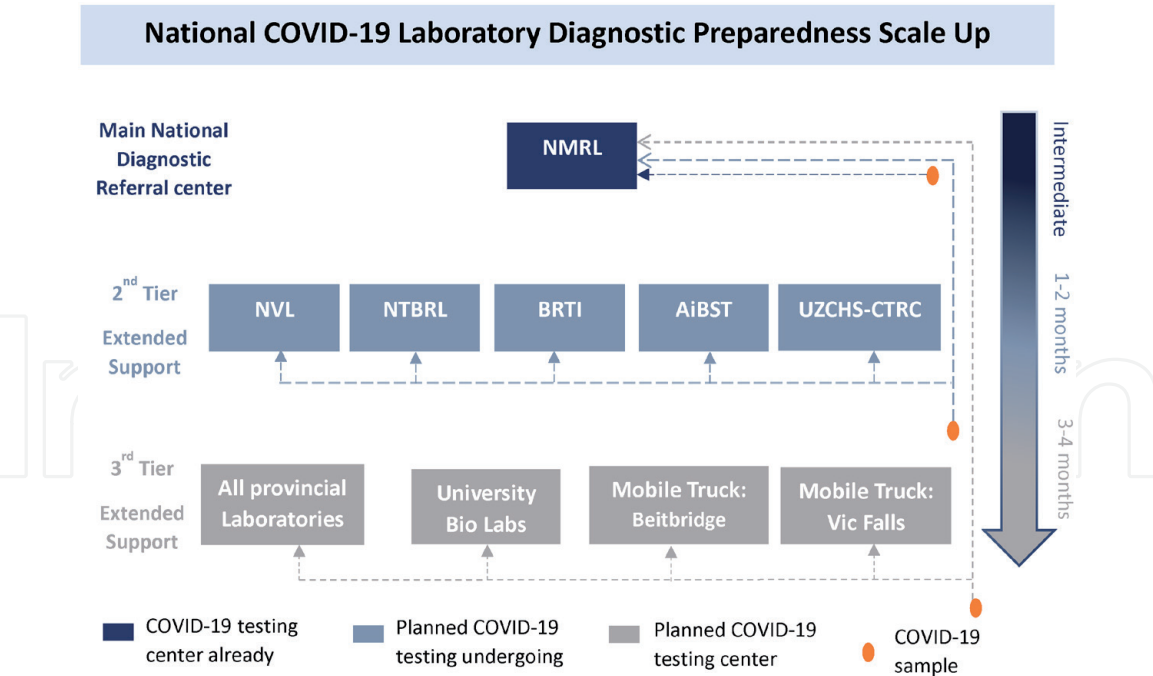
Figure 1.
National COVID-19 Laboratory Diagnostic Preparedness Scale Up plan. Tier 1; NMRL initially carried out all the testing, tier 2; expanded laboratory testing to National Virology Reference Laboratory (NVRL), Biomedical Research and Training Institute (BRTI), National Tuberculosis Reference Laboratory (NTBRL), African Institute of Biomedical Science and Technology (AiBST) and UZ Clinical Trials Research Centre, tier 3; capacitation of all provincial laboratories, University Biolabs and mobile trucks to test using GeneXpert.

2.1.3 Managing human resources

With the increase in samples being tested a day, it was pertinent to organize the flow of work to meet the workload demand. To do this, a two-shift duty system was introduced at every testing laboratory to increase daily throughput and reduce staff burnout. This extra shift system also involved separation of staff into cohorts such that in case of infection, quarantine and isolation procedures could be implemented without bringing the laboratories to a complete standstill. Additionally, locum staff were also hired in select laboratories to maintain adequate human resource for laboratory operations.

2.1.4 Quality assurance

Implementation of a new testing method for SARS-CoV-2 and use of a wide range of equipment, reagents, kits and consumables meant that a robust quality management system needed to be in place. The Laboratory services leveraged existing Quality Management Systems (QMS) to ensure key quality system essentials were adapted for the new testing requirements. Given that at least 7 laboratories had ISO 15189 accreditation, this process moved smoothly. Safety trainings were implemented together with waste management activities related to Guanidine thiocyanate (GITC) waste produced during RT-PCR testing using Abbott and GeneXpert machines. In addition, thirty-two laboratories were enrolled for external quality assurance Proficiency Testing (PT) program with Thistle, a South African PT provider as an external means to objectively check and ensure reliable results are being produced.

2.1.5 Data management

A robust data management system is key in the response to enable timely identification of at-risk populations, timely contact tracing and resource mobilization

and response optimization [28]. With the increasing testing, there was a growing need for streamlining data management and flow to efficiently manage and report data. To achieve this, we leveraged on the HIV CDC-PEPFAR supported Laboratory Information Management System (LIMS) by introducing the COVID-19 module and training laboratory data staff for data entry. Fifteen testing laboratories were added on the LIMS allowing timely relay of results to requesting sites. To further reduce the data linked TAT, instant messaging system was added to the LIMS for automatic patient notification as soon as the results were released and published by the testing laboratory.

2.1.6 Resource mobilization

The beginning of the response was mostly supported through donations of testing kits and supplies from China Embassy, Jack Ma foundation, Africa CDC, World Health Organization (WHO), Clinton Health Access Initiative (CHAI), USAID and many other well-wishers. The laboratory pillar members also developed a budget projection that specified the test expansion requirements and partners in the pillar committed to specific items on the budget, making the process easier. Procurement requests were made through the WHO global procurement platform [22] which was established as a hub for laboratory to support the LMIC countries in procuring these resources with assured equitable distribution.

2.2 Data analysis

The outcomes of this response were measured through the increase in number of testing laboratories which was linked to the number of samples tested per day. The changes in sample testing per day was analyzed using R 3.62 software.

3. Results

Through this response, Zimbabwe had an opportunity to strengthen systems regarding partner coordination, staff capacitation, resource mobilization, data management and laboratory testing output during this critical time. This response created and encouraged lasting coordination among the different partners on the laboratory pillar enabling a quick and successful scale up of testing. This coordinated approach enabled capacitation of staff to test for SARS-CoV-2 while observing the necessary biosafety measures and quality assurance. Besides the increased knowledge in using a wide range of testing platforms, a number of scientists gained the skills which can be used in other instances where testing is required. Data management platforms have been put in place and these have strengthened the data handling and dissemination system. Resource mobilization was enhanced through the response and timely stock replenishment measures put in place. Stock projections were developed and monitored strictly to avoid stock-outs using a stock availability tracing tool. In addition, the WHO global platform [24] was established to support procurement of COVID-19 commodities in an equitable way. This greatly reduced the delays in procurement and ensured timely and equitable supply of the required resources through a hub. In this line, over a period of 5 months, more than thirty-three laboratories could perform molecular testing for COVID-19 using available PCR platforms, capacity that can be used in case of any other emergency that requires extensive molecular testing. With this expansion, testing increased from five samples a day to more than 1000 samples a day over six months. As a result of this collaborative effort, the target of testing 1000 samples per day was surpassed
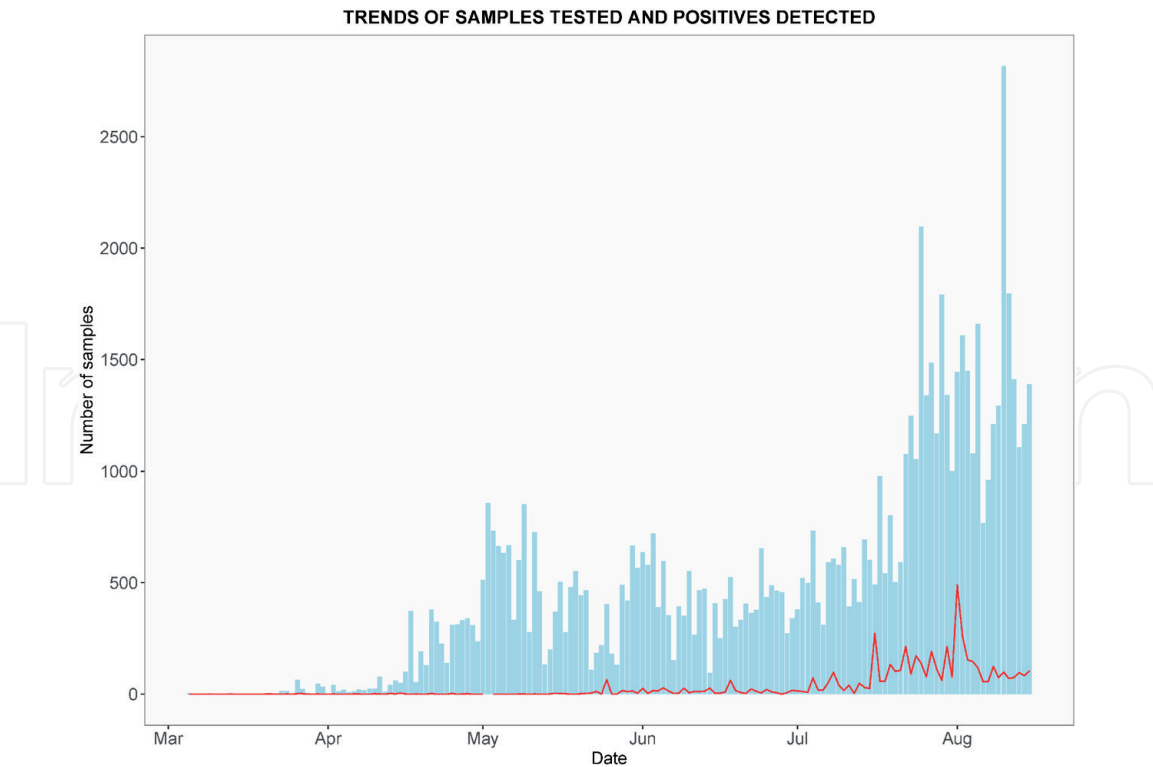
Figure 2.
Trends of samples tested and positives detected. Testing started in early March with one laboratory performing PCR testing. There was a marked increase in testing from April owing to the capacitation of five other labs to support the main reference laboratory to test using PCR. There were fluctuations owing to stock depletion due to the global challenge of timely delivery of reagents. Provincial laboratories were further capacitated to test using GeneXpert which further boosted the testing hence increasing the number of samples tested per day by early August.

in August and this exceeded the monthly projected target of 33,000 tests to 35,816 tests that month. The number of positive samples detected also increased with increase in testing as shown in **Figure 2**. There were notable fluctuations in testing as seen in **Figure 2** and these were due to intermittent stock outs which were due to the strain on the global supply that led to late delivery of commodities.

4. Discussion

The escalated and smooth scaling up of testing was made possible by leveraging existing capacity from other programs like Influenza Surveillance, HIV and TB work [29, 30]. The role of network optimsation exercises that had been done prior to the pandemic better placed the country to respond. The knowledge of locations and existing capacities and sample transport networks that had been mapped supported decision making in terms of activating new testing sites. However, like other countries, repurposing of testing laboratory facilities and consumables in Zimbabwe affected the HIV and TB programmes both in terms of human resources and consumables being repossessed for COVID-19 testing [31]. In addition, it was initially difficult to maintain quality management system for COVID-19 testing since everything operated as an emergency. At that time, there had not been proper planning and projecting of resources whether human resource or consumables which interfered with the processes. Partner coordination ensured the development of inter laboratory comparison panels and support sourcing of external quality assessment panels. Another challenge arose from the dependence on imports through external suppliers of all consumables which affected testing as supply chain

portals were overloaded with orders and could not meet the demand. Furthermore, competing with high income countries on these platforms to access *in vitro* diagnostics limited the projected rate of testing expansion. As a result like many other African countries [32], Zimbabwe faced a shortage in essential supply for use like GeneXpert supplies, PPE, molecular testing consumables and sample collecting kits which highly affected the testing capacity for over two months. Staff remuneration and motivation was also a setback throughout the participating pillars. In addition, some laboratory staff got infected in the course of the response which affected the work output and duty roster.

5. Conclusions

The laboratory is a key capacity area in International Health Security. Capacities to enable population access to testing of priority pathogens is key in enabling countries to respond to global health threats. More so the ability and agility of countries in finding solutions to respond to diagnostic needs of emerging novel infectious agents leveraging available capacities is a very important requirement in International Health Security. Collaboration of global and local stakeholders in responding to public health emergencies is key and this should be underpinned by a coordinated approach in addressing present and future challenges. This approach was key to successful implementation of processes to reduce the impact of COVID-19 pandemic in Zimbabwe. Working together with partners along with the country's Ministry of Health and Child Care made the process of expansion of testing easy as this facilitated leveraging off existing government and private infrastructure. Strengthening of laboratory systems is crucial in the timely detection of SARS-COV-2 virus and limiting its spread. It is also important to note that during emergencies, the population's need for other non-emergency laboratory tests remains important and should also be equally planned for in order to avoid unnecessary interruption of other lifesaving interventions.

- United Nations Children's Fund (UNICEF)

- United Nations Development Program (UNDP)

- US Center for Disease Control (CDC)

- World Bank

- World Health Organization (WHO)

Conflict of interest

There is no known conflict of interest.

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