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Rapid Review of COVID-19 Mitigation Within a Clinical Trials Unit: The UZ- CTRC Experience

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Abstract: *Background and aim*: The University of Zimbabwe-Clinical Trials Research Centre (UZ-CTRC) continued to provide essential services while safeguarding the safety of study participants and research staff during the COVID-19 pandemic. A COVID-19 Infection Prevention and Control (IPC) Taskforce formed in March 2020 drafted the institutional IPC Standard Operating Procedures (SOP) to prevent, mitigate, and manage SARS-CoV-2 infections. Identifying staff infected with SARS-CoV-2, isolation of positive cases and promoting risk reduction measures were key strategies to prevent workplace transmission. The SOP included a routine self-completed risk assessment questionnaire for staff prior to entering Clinical Trials Unit (CTU) facilities each day in addition to the recommended non-pharmaceutical preventative measures. Staff reporting a risk factor of greater than zero were assessed by a clinician and offered real time COVID-19 testing. Details of confirmed cases were reported to the IPC Taskforce and documented in the CTU COVID-19 tracker by the Monitoring and Evaluation Department. COVID-19 vaccine uptake was reported weekly by each clinical research site from February 2021. *Methods*: We conducted a desk review of this operational information, from March 2020 to August 2021, which was recorded as de-identified data in the CTU COVID-19 Tracker from ten active sites and 247 research staff. Data was tabulated in Microsoft Excel and analyzed using Stata 15.0. Results: A total of 753 SARS-CoV-2 tests were conducted (560 PCR tests and 193 Rapid Antigen tests) on CTU staff. Fifty-three SARS-CoV-2 cases were identified; 1 (1.9%) from March-August 2020 (first wave), 15 (28.3%) from September 2020- February 2021 (second wave; 2 deaths) and 37 (69.8%) from March-August 2021 (third wave; 1 death). Vaccination uptake was 84.6% (209/247) among staff between February and August 2021. Of 37 confirmed cases occurring after vaccines became available, 27 (73%) were fully vaccinated, 4 (10.8%) had received 1 vaccine dose and 6 (16.2%) were not vaccinated. Close contact with a known case was reported by 23 (43.4%) of whom 11 (20.7%) was presumed associated with workplace contact, and 10 (18.9%) a family member. Association with positive cases was unknown in 30 (56.6%) cases. *Conclusion*: We observed a significant rate of breakthrough COVID-19 infections in our Research Unit in the background of 84.6% vaccine uptake. Clinical trial units should consider having mechanisms in place to identify, test and isolate SARS-CoV-2 cases among staff for containment, safety, and continuity of research activities. Our staff remained at risk of acquiring COVID-19 even after vaccination, therefore non-pharmaceutical COVID-19 preventative measures remain critical in preventing SARS-CoV-2 transmission.

Keywords: COVID-19, Workplace Infection Prevention and Control, Clinical Research Staff

1. Introduction

Coronavirus disease 2019 (COVID–19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection [1]. The first known case was identified in Wuhan, China, in December 2019 [2]. The World Health Organization (WHO) recognized SARS-CoV-2 as a public health concern and declared it a pandemic on March 11, 2020[3]. By the end of August 2021, there were an estimated 217 million SARS-CoV-2 cases, 4.5 million deaths and 200 million recoveries worldwide [4]. In Zimbabwe, a resource limited country with an estimated population of 15 million, there had been 126,000 SARS-CoV-2 cases, 4,419 COVID-19 deaths with a case fatality of 3.5% and 113,000 recoveries from the disease as of 31 August 2021 (5). As of 31 August 2021, 1,636,498 (10.9% of population) adults had received 2 doses of one of the vaccines in use and 2,582,705 (17.2% of population) had received at least one dose of vaccine [5].

SARS-CoV-2 infection is spread from an infected person's mouth or nose in small liquid droplets when they breathe, cough, sneeze, speak or sing. Direct transmission may occur via other body fluids and secretions, for example, feces, saliva, urine, semen, and tears. Indirect transmission may occur via fomites or surfaces present within the immediate environment of an infected patient [3]. Apart from vaccination, prevention measures are premised upon physical distancing (isolation; quarantine; restricted movement; physical spacing); physical barriers (personal protective equipment; masking) and removal (hand washing; fumigation; sanitization; disinfection).

The University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC) is a Clinical Trials Unit (CTU) which conducts high quality phase I – IV, HIV prevention and treatment clinical trials in Zimbabwe, in collaboration with the University of California, San Francisco (UCSF) and other partner institutions. The CTU has seven Clinical Research Sites, three located in Harare and four in Chitungwiza, two administrative offices and a central laboratory housed in one of the main referral hospitals, Parirenyatwa Group of Hospitals in Harare. The CTU employs 247 (66% female) clinical research and administration staff. An estimated 2,659 study participants {168 (6.3%) being men, 1,792 (67.3%) women and 699 (26.3%) infants and children below 18 years} in the period from March 2020 to August 2021. The study participants are enrolled in Phase 1 to 4 clinical trials focusing on HIV prevention, HIV treatment, TB disease and various comorbidities in HIV infected and uninfected, high-risk populations.

There is evidence that health care workers (HCW) are at a higher risk of acquiring SARS-CoV-2 infection, and can subsequently, expose patients and colleagues in the workplace [6]. The WHO decreed COVID-19 disease an occupational hazard to health workers and recommended modalities that can limit this risk [7]. There is a pool of evidence documenting the risk, effects, and statistics of SARS-CoV-2 infection in health workers within hospitals and clinics [8-10]. Health care workers in clinical research settings perform medical procedures on participants according to different study protocols and are in close contact with study participants and maybe at risk of acquiring SARS-CoV-2 infection while performing these procedures in addition to community risk.

COVID-19 pandemic has disrupted and affected clinical research activities due to health concerns about congregate settings and ongoing social distancing requirements [6]. The need to ensure uninterrupted treatment access, safety monitoring, safety and protection of trial participants and research staff became a primary concern [7]. Researchers and clinical research stakeholder including sponsors, sites and Institutional Review Boards put several measures in place that promote safety of research participants, continuity of research and data integrity.

In response to the COVID-19 pandemic and to mitigate COVID-related disruption of clinical research operations, the CTU Leadership constituted the COVID-19 Infection Prevention and Control (IPC) Taskforce in March 2020. Basing on the WHO, Centre for Disease Control (CDC) and Zimbabwe COVID-19 guidelines, the Taskforce developed Standard Operating Procedures (SOP) to establish processes and systems across the CTU to prevent, mitigate and manage the novel 2019 coronavirus disease. CTU employees and consultants, and study participants were trained and expected to follow the SOP. The SOP outlined non-pharmaceutical preventative measures and mandated completion of a routine self-completed risk assessment for staff and participants prior to entering CTU premises each day. All persons reporting a risk factor greater than zero were offered real time SARS-CoV-2 testing. It was anticipated that implementing the SOP and enforcing its use would prevent and control the spread of SARS-CoV-2 infection among all who work within and visit the CTU premises. The SOP was regularly updated to be in line with evolving WHO and national guidelines and recommendations.

We set out to report on the results of activities conducted to mitigate COVID-19 within the CTU including CTU research activity conducted within 18 months of implementing the CTU IPC SOP, cases of SARS-CoV-2 infections identified through implementing the IPC SOP measures, uptake of COVID-19 vaccination, and cases of breakthrough SARS-CoV-2 infections after vaccination among research staff. We also assessed cases of SARS-CoV-2 infection perceived to be attributable to the CTU work environment.

2. Methods

A desk review of the data that was gathered from implementing the COVID-19 IPC SOP including daily risk assessment and management of staff members working in the CTU was performed. As highlighted in figures 1 and 2, COVID-19 risk assessment and management involved:

1) Screening and identification of suspected COVID-19 cases though a daily screening tool and daily temperature checks.
2) Testing and isolation of suspected cases.
3) Isolation and reporting of confirmed cases according to local standard guidelines.
4) Tracing and testing of possible contacts within the CTU.
5) Follow up and rescreening of confirmed cases before resumption of duties.

The reported data was collected from CTU operations and systemically recorded and stored centrally in the CTU COVID-19 Weekly and Monthly Reports from March 2020 to August 2021.

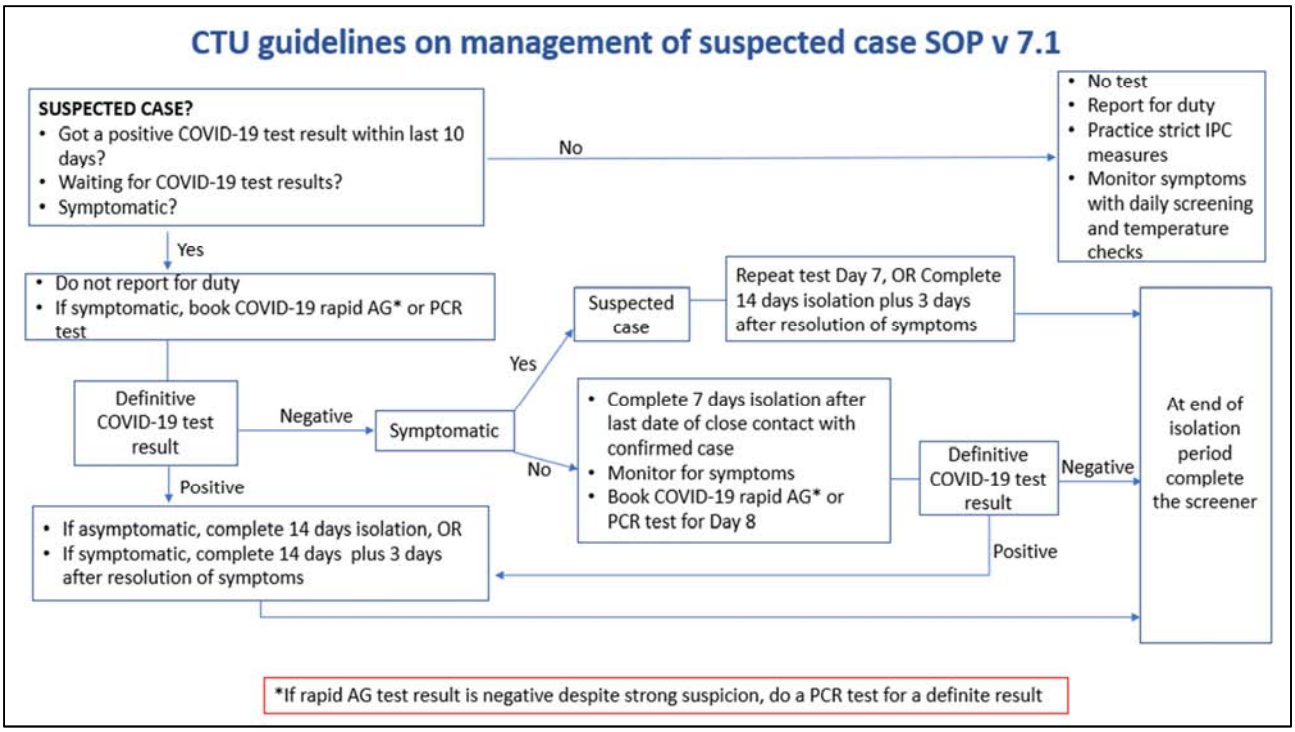

Figure 1. *CTU guidelines on management of suspected cases (Source: UZ-CTRC IPC SOP version 7.1 dated 17 August 2021).*

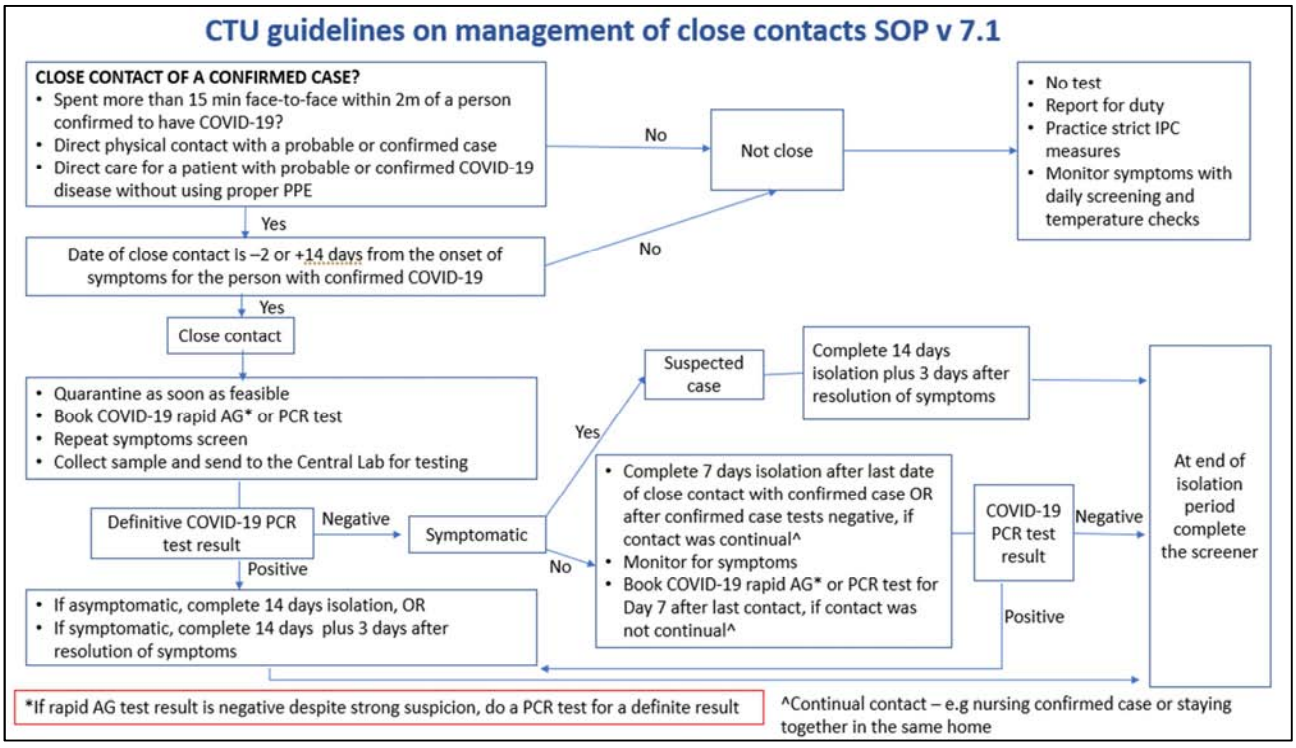

Figure 2. *CTU guidelines on management of close contacts (Source: UZ-CTRC IPC SOP version 7.1 dated 17 August 2021).*

2.1. IPC SOP: Daily Screening Tool

In addition to the recommended non-pharmaceutical preventative measures involving provision of personal protective equipment (PPE), handwash stations and alcohol-based hand rub (sanitizers) at each CTU facility, physical and social distancing, the SOP included a routine self-completed risk assessment for staff and participants prior to entering CTU premises each day. The tool could be completed electronically with a paper-based option. Questions covered on the daily screening tool included COVID-19 symptoms, recent close contact with a suspected/confirmed case, and exposure to higher risk situations (such as funerals or other social gatherings). All persons reporting a risk factor of greater than zero were further assessed by a clinician and referred for real time SARS-CoV-2 Polymerase Chain Reaction (PCR) or Rapid Antigen testing.

2.2. COVID-19 Testing

The CTU offered COVID-19 real-time PCR and COVID-19 Rapid Antigen testing to eligible staff members. COVID-19 PCR was performed using a validated, Atila Biosystems PCR platform. Performance characteristics for the Diagreat rapid antigen kit were validated by the National Microbiology Reference Laboratory (NMRL) on behalf of the country's Ministry of Health and Child Care (MoHCC) prior to use.

2.2.1. Sample Collection and Transportation

Sample collection was done at each of the 7 clinical sites within the CTU (Harare Family Care, Zengeza, Seke South, Seke North, St Mary's, Milton Park and Spilhaus). Sample types were nasopharyngeal or oropharyngeal swabs and were individually packaged.

2.2.2. Sample Processing

Upon receipt in the Molecular Department of the CTU Central Laboratory, the samples were processed per manufacturer recommended procedures. SARS-CoV-2 PCR test was performed using a validated assay, iAMP SARS-CoV-2 detection (Atila Biosystems, 740 Sierra Vista Ave, Suite E Mountain View, CA, 94043). iAMP COVID-19 Detection kit is a multiplexed, real-time fluorescent RT-isothermal assay based on Atila's proprietary isothermal amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal/oropharyngeal swabs or bronchoalveolar lavage (BAL) from individuals with suspected SARS-CoV-2 infection.

SARS-CoV-2 Rapid antigen testing was performed using Diagreat 2019-nCoV antigen rapid test kit (Beijing Diagreat Biotechnologies Co., Ltd, Room 301-303, 310-312, No.1 Building, No. 5 Jiachuang Road, Tongzhou District, 101111 Beijing, China). The Diagreat 2019-nCoV antigen rapid test kit is a colloidal gold assay in which the SARS-CoV-2 antigen in the sample combines with colloidal gold-labelled COVID-19 N protein antibody to form a colloidal gold-antigen-antibody complex. This complex is then chromatographed along a nitrocellulose membrane to the detection area, binds to the pre-coated N protein monoclonal antibody, and forms a purple line, indicating positivity.

2.2.3. Quality Control and Laboratory Results

Positive and negative controls were included in every batch of samples tested on the Atila Biosystems PCR assay and the test was considered valid only if the controls were acceptable. For the rapid antigen test, the quality control antibody-labelled colloidal gold particles are chromatographed to the quality control area on the cassette and combined with the precoated anti-quality control antibody to form a purple line indicating that the test is effective. Results were reported as displayed by the Atila machine or the rapid antigen cassette. The sample worksheet was reviewed by a competent person. Results were then entered into Laboratory Information System (LIS) and automatically printed at the original Clinical Research Site's (CRS) point of sample collection. All positive results were communicated to the testing CRS and IPC taskforce along with national response team for further management within a turnaround time of 24 hours.

2.3. SARS-CoV-2 Results Management

The clinician who collected specimens at each CRS was responsible for relaying the SARS-CoV-2 test results to the concerned staff member and compiling a case report for submission to the IPC Taskforce as necessary. CTU and household contacts of positive cases were identified and SARS-CoV-2 testing offered to all CTU contacts. All household contacts were managed per national guidelines by the National COVID-19 response team. Detailed reports of confirmed cases were reported to the IPC Taskforce and documented on the central CTU COVID-19 tracker as deidentified data. Clinical management was done per national guidelines. Psychological counselling and support for staff were offered by qualified psychologists through the CTU's Medical Aid Fund.

2.4. COVID-19 Vaccination

As COVID-19 vaccination became available in Zimbabwe from end of February 2021, the sites reported weekly staff vaccination data to the IPC taskforce. This information was recorded in the CTU COVID-19 central tracker as part of CTU operational data. Vaccines approved for use and available in Zimbabwe as of 31 August 2021 were Sinopharm, Sinovac, Sputnik V, and Covaxin.

2.5. Data Analysis

A desk review was performed on the CTU COVID-19 central tracker data to report CTU activity over the period, identified SARS-CoV-2 infections, uptake of COVID-19 vaccination, and breakthrough SARS-CoV-2 infections after vaccination among research staff after 18 months of implementing key COVID-19 mitigation strategies. The data

was reviewed to establish SARS-CoV-2 infection possibly attributable to work environment and the formation of work clusters.

The number of participant visits conducted during the period under review were summed up, tabulated, and graphed using Microsoft Excel while COVID-19 infection results were analyzed using Stata 15.0 and tabulated in Excel. SARS-CoV-2 positive cases after vaccine availability were aggregated by vaccination status. Full vaccination was defined as ≥14 days after receiving 2 vaccine doses for a 2-dose vaccine regimen. According to CDC, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses of an approved vaccine [11]. Partial vaccination was defined as receiving one of two vaccine doses for a two-dose vaccine schedule and unvaccinated defined as receiving nil vaccine doses after vaccine availability in February 2021. The length of time from full vaccination to collection of a sample resulting in a positive SARS-CoV-2 test was factored as exposure period.

All positive cases were requested to provide a perceived or suspected infection contact and this attribution was documented in the CTU COVID-19 central tracker. This self-reported infectious contact attribution was reviewed and reported as given in the tracker. Results were teased into local high community transmission periods (waves).

3. Results

The CTU conducted 8,442 study participant visits between 31 March and 31 December 2020, and 7,215 visits between 01 January through to 31 August 2021 across the 7 CRSs (Figure 3).

Figure 3. *CTU Study visits conducted during COVID-19 pandemic (Source: UZ-CTRC CRS Weekly reports).*

Between March 2020 and August 2021, 753 SARS-CoV-2 tests were conducted among CTU staff, 560 PCR tests and 193 Rapid Antigen tests. Of the 247 staff members within the CTU, 53 (21.5%) tested positive for SARS-CoV-2 infection, 1 (0.4%) between March and August 2020 (first wave), 15 (6.1%) from September 2020 to February 2021 (second wave; 2 deaths) and 37 (15%) from March to August 2021 (third wave; 1 death). These findings are summarized in Table 1 and Table 2. Association with positive cases was unknown in 30 (56.6%) cases. Close contact with a known case was reported by 23 (43.4%) of whom 11 (20.8%) were an infected workmate, and 10 (18.9%) a family member. One infection was attributed to visiting a hospital for a dental procedure and one to attending a funeral. Sixteen (30.2%) of the cases occurred during the first and second waves of the pandemic, when vaccines were not available.

Table 1. *COVID-19 Test Results.*

Reporting Period	Rapid Antibody Tests			Rapid Antigen Tests			PCR Tests		
	Total	Negative	Positive	Total	Negative	Positive	Total	Negative	Positive
March 20 to August 20	119	115	4	0	0	0	216	215	1
September 20 to February 21	76	74	2	7	6	1	275	261	14
March 21 to May 21	0	0	0	2	2	0	36	36	0
June 21 to August 21	0	0	0	184	154	30	33	26	7
TOTAL	195	189	6	193	162	31	560	538	22

Vaccination uptake was 84.6% (209 out of 247) among staff between end February and August 2021 when vaccines became available. Thirty-seven (37) SARS-CoV-2 cases were recorded after vaccines availability, 6 (16.2%) of these were not vaccinated, 4 (10.8%) had received one vaccine dose and 27 (73%) had received 2 vaccine doses before infection.

SARS-CoV-2 attack rates were 26.3% and 12.9% in the unvaccinated/partially vaccinated and in the fully vaccinated individuals respectively. Of the 209 vaccinated staff 154 (73.7%) had received the Sinopharm COVID-19 vaccine, 54(25.8%) had received the Sinovac COVID-19 vaccine and 1(0.5%) had received the Covaxin COVID-19 vaccine. Among 27 individuals testing positive for SARS-CoV-2 infection post full vaccination, 24 (88.9%) had received Sinopharm vaccine and 3 (11.1%) Sinovac vaccine. Among the 4 partially vaccinated individuals who tested positive for SARS-CoV-2 infection, 2 (50%) had received the Sinopharm vaccine and 2 (50%) had received the Sinovac vaccine. Among the 27 fully vaccinated individuals who acquired SARS-CoV-2 infection, 2 (7.4%) acquired the infection within 30 days of being vaccinated; 5 (18.5%) within 31-60 days; 13 (48.1%) within 61-90 days; and 7 (26%) within 91-120 days. Average time to positive SARS-CoV-2 test post full vaccination was 71.3 days (SD 24) with a range of 2 days and 103 days (median 70 days, IQR 60-92days).

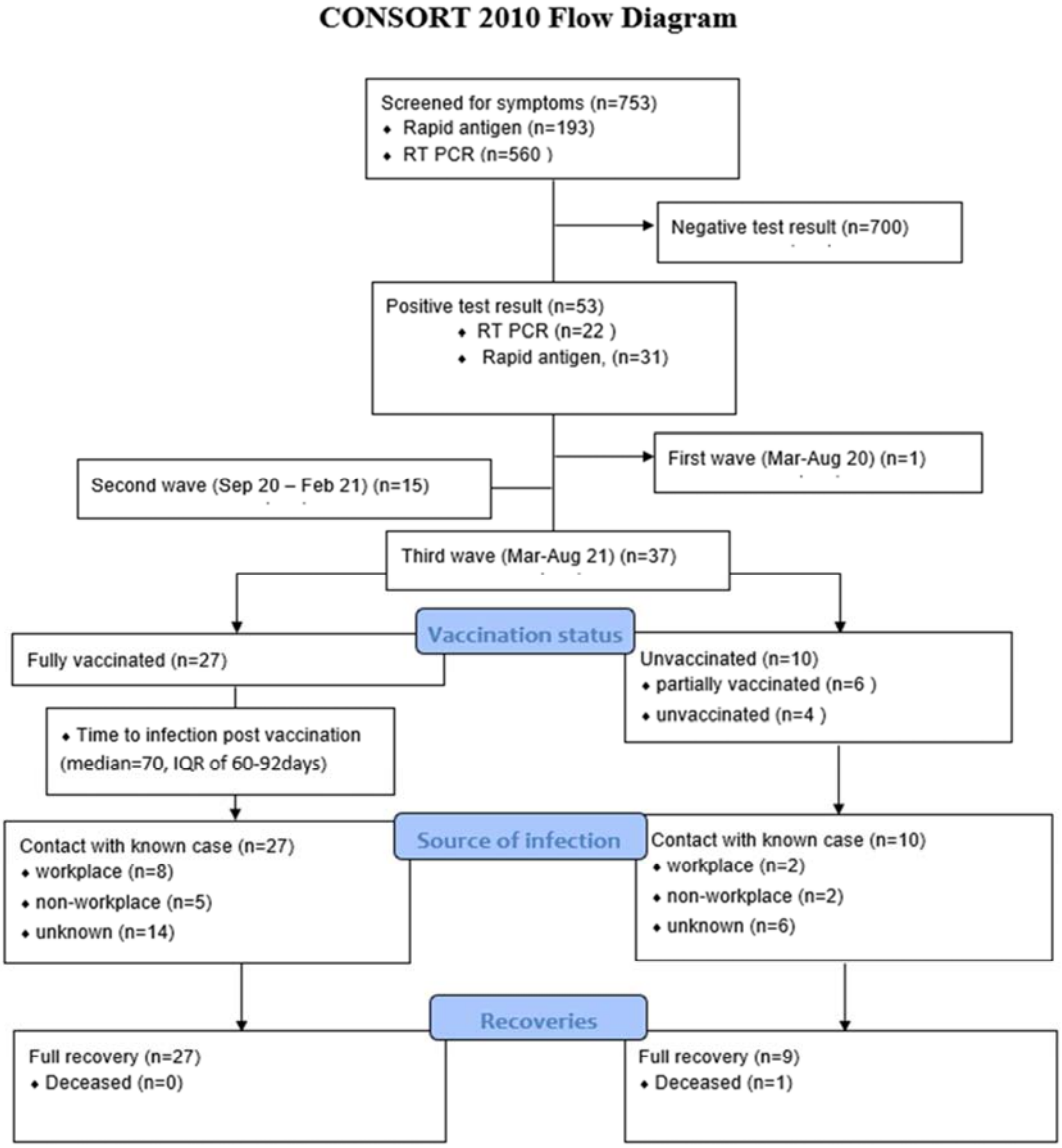

Figure 4. *Consort Diagram of COVID-19 infection.*

Table 2. *Positive Case detail by vaccination status.*

		Unvaccinated (pre-vaccines)	Unvaccinated (post-vaccines)	Fully vaccinated	Total
n		16	10	27	53
Age-	Mean (SD)	44.5 (11.3)	39.3 (9.8)	46.3 (8.3)	44.5 (9.8)
	min	29	28	34	28
	max	67	62	63	67
Gender	Male, n (%)	5 (36)	4 (29)	5 (36)	14 (26)
	Female, n (%)	11 (28)	6 (15)	22 (56)	39 (74)
Possible contact	Workplace, n (%)	1 (9)	2 (18)	8 (73)	11 (21)

		Unvaccinated (pre-vaccines)	Unvaccinated (post-vaccines)	Fully vaccinated	Total
	Non-workplace, n (%)	5 (42)	2 (17)	5 (42)	12 (23)
	Unknown, n (%)	10 (33)	6 (20)	14 (47)	30 (57)
Place of residence	Chitungwiza, n (%)	1 (13)	0 (0)	7 (88)	8 (15)
	Harare, n (%)	14 (35)	8 (20)	18 (45)	40 (75)
	Norton, n (%)	0 (0)	0 (0)	1 (100)	1 (2)
	Ruwa, n (%)	1 (33)	1 (33)	1 (33)	3 (6)
	Domboshawa (%)	0 (0)	1 (100)	0 (0)	1 (2)
Time to infection	0 days, n (%)	0 (0)	9 (90)	1 (10)	10 (19)
	1-30 days, n (%)	0 (0)	0 (0)	2 (100)	2 (4)
	31-60 days, n (%)	0 (0)	0 (0)	5 (100)	5 (9)
	61-90 days, n (%)	0 (0)	0 (0)	13 (100)	13 (25)
	91-120 days, n (%)	0 (0)	0 (0)	7 (100)	7 (13)
	None, n (%)	16 (100)	0 (0)	0 (0)	16 (30)
	Mean, days (sd)	-	-	71 (24)	71 (24)
	Median, days (IQR)	-	-	70 (60-92)	70 (60-92)
	Min, days	-	-	2	2
	Max, days	-	-	103	103
Recovery	Recovered, n (%)	14 (28)	9 (18)	27 (54)	50 (94)
	Deceased, n (%)	2 (67)	1 (33)	0 (0)	3 (6)

Four work clusters were identified, and the average size of a cluster was 3 (mode 3; median 3) with the largest cluster involving 4 cases. During each community transmission wave, no site had more than 4 staff members in isolation at any point in time. The smallest site comprised of 20 staff while the largest had a staff complement of 35. A total of 93 SARS-CoV-2 tests were conducted due to a work contact. From the 93 tests, 13 SARS-CoV-2 cases were identified and 12 of these were perceived to be attributed to the work environment.

4. Discussion

Unlike non-essential services where the staff compliment attending work in-person was reduced to as low as 10% in government offices in Zimbabwe [12], our CTU continued with research activities as recommended by Ministry of Health and local Institutional Review Boards. Approximately 90% of scheduled visits occurred during study period as seen by high number of participants who attended to visits across the 7 CRSs (Figure 3). The CTU instituted the WHO recommended COVID-19 preventive measures [13] and data accumulated from first through third wave shows evidence of exposure to SARS-CoV-2 infection resulting in 3 fatalities (2 unvaccinated and 1 partially vaccinated) within the Unit. We observed that the highest infection rate of 15% (37/247) occurred during the third wave, during which the predominantly circulating SARS-CoV-2 variant was the Delta variant [12].

Among the 53 cases with confirmed COVID-19 infection, we observed 94% recoveries (14/16 unvaccinated, 27/27 fully vaccinated and 9/10 partially/unvaccinated [after vaccine availability]). All positive cases were isolated from the workplace for at least 14 days and had to test PCR negative before resumption of duty. Breakthrough infections were recorded, despite full vaccination for COVID-19 in 73% of the positive cases after vaccine availability. With an estimated prevalence of SARS-CoV-2 infection from health care workers' samples of 11% from other studies, (6) the CTU had a higher prevalence of 21.4% over a 12-month period, which is almost double that observed in other studies. In a study of vaccine effectiveness among health care workers given the Pfizer BNT162b2 vaccine with the Alpha (B1.1.7) variant in circulation, 98.9% of first dose vaccine recipients were not infected 21 days post vaccination [14]. Our cohort revealed more infections (9%) post first dose vaccine receipt under predominantly Delta variant which was in circulation [12].

We did not have access to blood samples to perform immunological test to measure antibody titers that would inform us of the response to natural infection compared to vaccine induced response and effect of waning immunity on the vaccinated members of staff.

We also observed that among the breakthrough infections, the average time to positive SARS-CoV-2 test post full vaccination was 71.3 days (SD 24) with a range of 2 to 103 days (median 70 days, IQR (60-92)). Breakthrough infection after vaccination in health workers has also been reported in health workers in other settings [15, 16]. The evidence of waning immunity after vaccination [17-19] and breakthrough infections after vaccination point towards possible benefit of a booster dose following vaccination. Additionally, there is the possibility that continued protection may be temporarily achieved through a booster dose after full vaccination [20].

In the CTU, daily risk assessment and management was instituted and led to testing and timeous isolation of staff with suspected or confirmed SARS-CoV-2 infection. As study activities continued at almost similar levels despite the varying levels of lockdown, isolation of infected individuals mitigated spread of SARS-CoV-2 infection to colleagues and participants at the clinical research sites. There was no identified work cluster greater than 4 individuals including the index case. In all waves of community transmission, no site had more than 4 staff members (20% for smallest site of 20 staff) in isolation at any point in time allowing continuity of CTU business. The daily risk assessment facilitated testing staff following close contact with a SARS-CoV-2 infected or suspected individual in the household, work or community including those who reported recently attending large gatherings like funerals and religious events. This inclusivity

was also key to controlling workplace transmission.

Identification and management of work clusters helped to control the spread of SARS-CoV-2 in the workplace. Clinical trial units among other health care centers, should consider having mechanisms in place to identify, test and isolate SARS-CoV-2 cases among staff for containment, safety, and continuity of research activities. For the UZ-CTRC, implementing the IPC SOP including, daily risk assessment, COVID-19 testing for those who reported risk resulted in continued functional operation of research subunits during the COVID-19 pandemic. Evaluating routinely collected data of the circumstances of each confirmed infection helped in identifying areas for improvement and risk mitigation.

There were, however, several limitations to this study. Data on staff tested outside our Central Laboratory was typically not reported to the IPC and not documented in the CTU COVID-19 central tracker. Staff may have accessed COVID-19 testing outside the institution during absence or leave from work, hence more cases could have occurred in the CTU but not documented. The data collected during daily risk assessment was not designed to adequately track possible contact, hence attribution of unknown source could also be linked with some workplace contact. Fidelity of use of PPE provided and strict follow up on adherence to measures in the IPC SOP were also not tracked in the daily risk assessment.

5. Conclusion

The UZ-CTRC managed to continue conducting essential clinical research activities throughout all 3 waves of SARS-CoV-2 community transmission, by implementing a rigorous case identification and isolation to minimize further spread in the CTU. This also limited the number of SARS-Cov-2 cases to 53 during the period with a maximum of 4 cases per cluster. Clinical trial units should consider having mechanisms in place to identify, test and isolate SARS-CoV-2 cases among staff for containment, safety, and continuity of research activities. Daily risk assessment promoted timeous isolation of staff with SARS-CoV-2 infection thereby limiting workplace transmission and ensuring continued research activities. Our staff remained at risk of acquiring COVID-19 even after a high vaccine uptake of (84.6%), therefore non-pharmaceutical COVID-19 preventative measures remain critical in preventing SARS-CoV-2 transmission.

Ethical Considerations

This study did not meet requirements for Ethics approval per local Medical Research Council of Zimbabwe guidelines as it is a review of routine operational de-identified programmatic data. Anonymity was maintained through use of staff codes generated at site level and all testing and data reporting to central tracker was coded.

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