

# *Sisonke: A Critical Appraisal of South Africa's Covid-19 Vaccine Trial*

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*When South Africa's Covid-19 pandemic emerged in March 2020, scientists mobilised quickly and effectively to parse and produce evidence to inform the state's response. South Africa became a site for numerous Covid-19 vaccine trials. While many publications in scientific journals have explored the effects of Covid-19 vaccinations, in South Africa and globally, the social aspects of the vaccination rollout remain underexplored, particularly concerning the scientists and medical officials who were responsible for vaccine development. This article analyses the insights and experiences of vaccine trial investigators and other healthcare workers in South Africa. The study is based on in-depth, qualitative interviews conducted with 16 trial investigators and participants in three provinces – the Western Cape, KwaZulu-Natal and Gauteng – as well as with recipients and providers of the vaccine. Sisonke, meaning 'together' in isiZulu, is one of the most ambitious public health endeavours yet pursued in South Africa. Initially targeting frontline healthcare workers and then a more broadly defined notion of 'healthcare worker', the vaccination trial brought almost half a million South Africans into a new 'experimental order', facilitated by a consortium of vaccine providers. Crucially, the Sisonke trial was conducted largely through the same healthcare system that provided public treatment for another pandemic of communicable disease: HIV. Collaborations built in the struggle against the HIV/AIDS pandemic provided a critical framework upon which partners built the response to the Covid-19 pandemic.*

**Keywords:** Covid-19 pandemic; vaccination; South Africa; Sisonke trial; healthcare workers; HIV; government failure; Electronic Vaccination Data System (EVDS)

## Introduction

On 15 March 2020, after a man who had flown back to South Africa from Italy tested positive for Covid-19, President Cyril Ramaphosa declared a national state of disaster. This included imposing severe travel restrictions and school closures, with devastating consequences for the approximately 10 million children who relied on school feeding programmes.<sup>1</sup> Undoubtedly, Covid-19 had a critical and momentous impact on South

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1 J. Seekings, 'Failure to Feed: State, Civil Society and Feeding Schemes in South Africa in the First Three Months of the Covid-19 Lockdown, March to June 2020', *Centre for Social Science Research Working Paper*

Africa. In 2022 official reports stated that South Africa had over 4 million confirmed cases.<sup>2</sup> Over 50,000 deaths were officially attributed to the disease, while data on excess deaths revealed much greater Covid-19-related mortality.<sup>3</sup>

When South Africa's Covid pandemic emerged in March 2020, scientists mobilised quickly and effectively to parse and produce evidence to inform the state's response. South African scientists foregrounded South Africa as a site for numerous Covid-19 vaccine trials: Janssen's ENSEMBLE trial using the Ad26.COV2.S vaccine; the Oxford/AstraZeneca ChAdOx1-s vaccine; Pfizer-BioNTech's trial of BNT162b2; and, lastly, Novovax's NVX-CoV2373. The South African government was similarly quick to establish and formalise a group of scientific advisors, named the Ministerial Advisory Committee (MAC), to marshal support for an empirical and effective public health response. Its functioning as an independent advisory body came under rapid scrutiny, as government failed to make public the contents of its advisories. The MAC was later reconstituted as several different bodies, including a specific vaccination committee – the 'vac-MAC' or 'vaccine Ministerial Advisory Committee'. These newly constituted MACs incorporated a broader array of constituents, but excluded scientists who were deemed insufficiently subordinate to the state due to their criticism of the government's response to the pandemic.<sup>4</sup> On being dropped from official forums to advise the government on its Covid-19 response, a group of frustrated scientists founded the Scientists' Collective, which sought to publicise and popularise the rapidly emerging evidence-based information on Covid-19, including its vaccination.<sup>5</sup>

South Africa's research infrastructure and experience of the dual epidemics of human immunodeficiency virus (HIV) and tuberculosis (TB) meant that the healthcare system, in partnership with numerous research and healthcare advocacy organisations, was able to conduct an early SARS-CoV-2 vaccination trial, the ENSEMBLE trial. This trial sought to test the efficacy and safety of a single dose of the Ad26.COV2.S, a vaccine manufactured by Johnson & Johnson (J&J), through a randomised, placebo-controlled trial. The ENSEMBLE trial was conducted in a myriad of countries, including South Africa.<sup>6</sup> The trial results, first reported in the *New England Journal of Medicine* in July 2021, showed that a single dose of Ad26.COV2.S was protective against symptomatic Covid-19 and asymptomatic SARS-CoV-2 infection, and was effective against severe-critical disease, including hospitalisation and death. Safety appeared to be similar to that in other Phase 3 trials of Covid-19 vaccines.

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No. 455 (Cape Town, University of Cape Town Centre for Social Science Research, 2020), available at <https://humanities.uct.ac.za/cssr/failure-feed-state-civil-society-and-feeding-schemes-south-africa-first-three-months-covid-19>, retrieved 6 April 2025.

2 National Institute for Communicable Diseases, 'National COVID-19 Daily Report', available at <https://www.nicd.ac.za/diseases-a-z-index/disease-index-COVID-19/surveillance-reports/national-COVID-19-daily-report>, retrieved 22 March 2022.

3 N. Natrass and J. Seekings, 'High Modernist Hubris and its Subversion in South Africa's Covid-19 Vaccination Roll-Out', *Journal of Southern African Studies*, 48, 5 (2022), p. 1.

4 S. Amod, 'Op-Ed: Health Minister caught between Politics and Medicine', *Spotlight*, 26 May 2020. Available at <https://www.spotlightnsp.co.za/2020/05/26/op-ed-health-minister-caught-between-politics-and-medicine>, retrieved 7 October 2023.

5 G. Gray, A. van der Heever, S.A. Madhi, J. McIntyre, B. Kana, W. Stevens, I. Sanne *et al.*, 'The Scientists' Collective 10-Point Proposal for Equitable and Timeous Access to COVID-19 Vaccine in South Africa', *South African Medical Journal*, 111, 2 (2021); The Scientists' Collective: M. Mendelson, S.A. Madhi, J. Nel, G. Gray, R. Osih and F. Venter, 'Op-Ed: The Incoherent and Illogical New Government Covid-19 Regulations are the Real State of Disaster', *Daily Maverick*, 22 March 2022, available at <https://www.dailymaverick.co.za/article/2022-03-22-the-incoherent-and-illogical-new-government-covid-19-regulations-are-the-real-state-of-disaster>, retrieved 3 April 2023.

6 J. Sadoff, G. Gray, A. Vandebosch, V. Cárdenas, G. Shukarev, B. Grinsztejn, P.A. Goepfert *et al.*, 'Final Analysis of Efficacy and Safety of Single-Dose Ad26.COV2.S', *New England Journal of Medicine*, 386, 9 (2022), pp. 847–60.

The South African government had planned to roll out the AstraZeneca vaccination in 2021, and had procured a million doses of this vaccine. But on the cusp of its roll-out in February 2021, a groundbreaking study by South Africa's leading vaccinologist, Shabir Madhi, showed that this vaccine was ineffective in protecting against the Beta wave of the coronavirus, which was at the time the dominant strain of Covid-19 in South Africa.<sup>7</sup>

Pivoting, several national and non-governmental health bodies, public and private bodies, including the National Department of Health, the South African Medical Research Council, the Desmond Tutu Health Foundation, the Centre for the AIDS Programme of Research in South Africa (CAPRISA) and the pharmaceutical corporations Janssen and J&J came together to form a consortium which began the Sisonke trial in mid February 2021, using instead the J&J Ad26.COVS vaccine.<sup>8</sup> Sisonke allowed researchers to make the J&J vaccine rapidly available to healthcare workers.<sup>9</sup> The study aimed to vaccinate 500,000 healthcare workers ahead of the third wave of Covid-19 in 2021. It was implemented while waiting for the registration of the Ad26.COVS vaccine with the South African Health Products Regulatory Authority (SAHPRA). The Sisonke study was at first initiated in 18 hospital-based vaccination sites overseen by 16 clinical research sites. As the study expanded, 122 urban and rural vaccination sites were established across all nine of South Africa's provinces, overseen by 43 clinical research sites.<sup>10</sup> Between 17 February and 26 May 2021, the Sisonke study enrolled and vaccinated participants nationally at vaccination sites across South Africa.<sup>11</sup>

While scientific publications about clinical trials are legion, there is relatively little social science research that explores how populations are brought into new 'experimental orders' (conditions for enrolment and access to the vaccine) wrought by their participation in medical trials. Moreover, the international standardised ethics approvals that clinical trials must abide by often fail to account for local contexts and lived experiences, both of investigators as well as healthcare workers providing medical interventions. Since the early 1990s, there has been massive growth in the number of clinical trials conducted globally.<sup>12</sup> In the early 1990s alone, the number of clinical trial investigations conducting research on drugs in resource-scarce settings increased sixteenfold.<sup>13</sup> Medical research in Africa has been shaped intensely by a history of colonial subjugation, and the fact that medical research is often oblivious to its own origins and evolution makes it especially important to conduct historical research into clinical developments, including the roll-out of vaccines.<sup>14</sup>

Furthermore, the global evidence-base on Covid-19 has been rapidly populated by clinical studies and epidemiological models.<sup>15</sup> While humanities scholars and social

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7 S.A. Madhi, V. Baillie, C.L. Cutland, M. Voysey, A.L. Koen, L. Fairlie, S.D. Padayachee *et al.*, 'Efficacy of the ChAdOx1 nCoV-10 Covid-19 Vaccine against the B.1.351 Variant', *New England Journal of Medicine*, 384, 20 (2021), pp. 1885–98. These findings prompted the government to sell its procured vaccine stocks to other African countries. Tragically, however, the AstraZeneca vaccine was later shown to offer protection against serious illness and scientists have argued that it should therefore have been used in the South African public healthcare sector.

8 W. Preiser and T. Fish, 'Sisonke: Reaching Several Goals Together', *The Lancet*, 399, 1033 (2022), pp. 1095–7.

9 *Ibid.*

10 A.E. Goga, L.-G. Bekker, N. Garrett, S. Takuva, I. Sanne, J. Odhiambo, F. Mayat *et al.*, 'Sisonke Phase 3B Open-Label Study: Lessons Learnt for National and Global Vaccination Scale-Up during Epidemics', *South African Medical Journal*, 112, 5b (2021), 13486, p. 378.

11 Goga *et al.*, 'Sisonke Phase 3B Open-Label Study', p. 378.

12 A. Petryna, 'Ethical Variability: Drug Development and Globalizing Clinical Trials', *American Ethnologist*, 32, 2 (2005), p. 183.

13 *Ibid.*

14 P. Wenzel Geissler, 'Studying Trial Communities: Anthropological and Historical Inquiries into Ethos, Politics and Economy of Medical Research in Africa', in P. Wenzel Geissler and C. Molyneux (eds), *Evidence, Ethos and Experiment: The Anthropology and History of Medical Research in Africa* (New York, Berghahn Books, 2011), p. 1.

scientists have been researching and writing about the pandemic as it evolves,<sup>16</sup> age-old methodological cautions – including concerns about bioethics, combined with prohibitions against direct, in-person research under various lockdown regulations – have staggered and stymied much qualitative work on the pandemic. The result is that, while the medical and health scientific literature about Covid-19 in South Africa has flourished, there is comparatively little published research within the social sciences and the humanities about the many contentious components of the pandemic and the medical and political responses it evoked, including the creation of local, qualitative evidence.

This article seeks to address these gaps, exploring the Sisonke clinical trial in South Africa, which was established to provide Covid-19 vaccines to healthcare workers and, in further months, to those working more broadly within the healthcare sector. This study aims to contribute to the growing literature within the medical and health humanities that investigates the significance of pharmaceutical technologies, specifically in relation to Covid-19 vaccines, through investigating the experiences of healthcare workers and Sisonke trial investigators.<sup>17</sup> This article addresses parallels between Covid-19 and HIV in South Africa, and goes on to explore the architecture of the Covid-19 response, including through examining the Electronic Vaccination Data System (EVDS) and its use through the Sisonke trial.

This research had two components for data gathering over the course of six months: the first, a review of the academic and grey literature about Sisonke; and, second, interviews with (a) trial principal investigators (n = 7), and (b) healthcare workers (n = 10) who had worked as vaccinators and recipients of the vaccine (themselves healthcare workers according to trial stipulations, but encompassing a broader remit than ‘frontline’ healthcare workers dealing directly with Covid-19 patients). Pursuing a strategy of purposive sampling, I contacted Sisonke investigators and healthcare workers who were recipients of the vaccine to request and conduct interviews. Interviews, conducted both in person and online, were coded thematically and manually, with the results and findings presented here drawn from the analysis.<sup>18</sup> Interviews were conducted until thematic saturation was reached, ascertained through the coding of findings from interview transcripts.

## Living and Working through Covid-19

The devastating effects of the Covid-19 pandemic were strikingly apparent among patient-facing healthcare workers. As one nurse described, ‘[i]n 35 years I’ve never seen 4 to 8 people die in a 48-hour shift. It was horrendous. I’ve never seen anything like it. So we were grateful for the opportunity to be vaccinated and at least to have that courage’.<sup>19</sup> This healthcare worker went on to provide Covid-19 vaccines to her own patients, explaining:

Seeing what we saw in the Covid waves, I just wanted to vaccinate as many people as possible. And luckily, the people who came to the vaccination stations, they wanted to be vaccinated.  
 15 D. Chiriboga, J. Garay, P. Buss, R. Sáenz Madrigal and L.C. Rispel, ‘Health Inequity during the COVID-19 Pandemic: A Cry for Ethical Global Leadership’, *The Lancet*, 395, 10238 (2020), available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31145-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31145-4/fulltext), retrieved 4 April 2025.

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16 H. Phillips, ‘More Eyes on COVID-19: Perspectives from History: The Need for History in a Time of Plague’, *South African Journal of Science*, 116, 7/8 (2020), <https://doi.org/10.17159/sajs.2020/8495>; C. Tsampiras, ‘Pandemics Act on Social Fault Lines: Lessons for COVID-19 from HIV and AIDS’, *The Conversation*, 23 March 2020, available at <https://theconversation.com/pandemics-act-on-social-fault-lines-lessons-for-covid-19-from-hiv-and-aids-134251>, retrieved 6 April 2025.

17 This study received ethical permissions from the University of Pretoria Humanities Faculty’s Research Ethics Committee under protocol no. HUM038/0622.

18 Where the author and the research participants were in the same location, interviews were conducted in person. Where the locations were different, interviews were conducted online.

19 Interview with PQ, Pretoria, 1 September 2022.

there. So it was a very uplifting experience for me after the badness of Covid. I felt like every jab that you gave, you are just giving someone a chance ... So for me psychologically that was a very uplifting, positive experience.<sup>20</sup>

Not all participants in this study were able to access the vaccination on their first attendance at a healthcare facility. The frustration created by the lack of access to vaccines was acute, particularly for healthcare workers who were treating Covid-19 patients directly in their emergency wards. One doctor recounted:

I was seeing Covid patients every day. At that time, we had all heard about Sisonke, and the first place to have people [get the vaccine] was at Bara[Chris Hani Baragwanath Hospital]. The first day that I went ... they ran out of vaccine. I cried, because I was so desperate. I waited there for about four hours, and I was able to come back the next day. I got the injection and there was just a sense of relief. There were a few of us that were there, there was camaraderie, and there was quite a lot of desperation.<sup>21</sup>

This doctor had already had Covid-19 'officially' three times, that is, confirmed by a polymerase chain reaction (PCR) test. She explained how she 'got quite ill and was sick for probably a week. I was breathless, on oxygen. There were no hospital beds. I remember scrawling a will at 3.30 a.m. one day'. This healthcare worker recounted how the motto of 'Doctor, heal thyself' had been challenged by the pandemic. She stated: '[i]t's nothing. You're a human being like everyone else when you're in it'.<sup>22</sup>

The dire shortages of equipment to treat Covid-19, including the supply of oxygen in healthcare facilities, was emphasised as one of the key challenges in the pandemic response. As one principal investigator stated:

This province [the Western Cape] nearly ran out of oxygen on the 1 January 2021. To describe it as a wave would not do it justice. It was more like a tsunami. And all of the hospitals within the coastal regions of South Africa were completely overwhelmed with severe cases, with people who were dying. The death rates were incredibly high, and healthcare workers were exhausted.<sup>23</sup>

South Africa had suffered terribly from the results of the first wave of Covid-19. In January 2023 the government stated its aim to vaccinate over 40 million people, which was radically ambitious considering the country's crumbling and already overburdened health infrastructure.<sup>24</sup> The same investigator described how healthcare services 'had really been beached' during the first two waves of the pandemic, which peaked in July 2020 and January 2021.<sup>25</sup> Speaking of the high rate of mortality among healthcare workers prior to the onset of the Sisonke trial, they explained that:

What Covid did repeatedly was challenge the limits of the human imagination. We couldn't process the images that we were seeing, the data that we were receiving, the pace at which it was spreading. We actually couldn't process that. So it really challenged our imagination, in terms of how we responded. A lot of how we responded was a failure of the imagination.<sup>26</sup>

The notion that Covid-19 challenged the boundaries of knowledge and experience was voiced by another participant and Sisonke trial investigator. As they explained:

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20 *Ibid.*

21 Interview with MN, Gauteng, 22 September 2022.

22 *Ibid.*

23 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

24 Goga *et al.*, 'Sisonke Phase 3B Open-Label Study', p. 375.

25 Interview with AB, 31 January 2023.

26 *Ibid.*

It was almost like you were taken and hurtled through a black hole... where you didn't know quite what was happening... And everyone trying to lean on the best public health information and experience they had from the past, but not quite knowing surely whether this was really what's needed in this situation. You had the experience of other pandemics or other epidemics, and you were using that to try and deal with Covid.<sup>27</sup>

Covid-19 stretched the boundaries of what it meant to be human, particularly in the view and experience of healthcare workers who were treating patients. The private health sector experienced the same logistical challenges that perennially confront the public health sector, such as a lack of beds for severely ill patients. As one nurse working for a private sector hospital explained:

The trauma that we experienced, it was really harsh. It was a harsh, cruel pandemic, it was a cruel period. It's a nightmare... The patients just kept coming. So you'd have to transfer your patients out, or keep them in casualty instead of in ICU [Intensive Care Unit] because ICU had no more beds. And ward beds were being converted into ICU beds. And every hospital was doing that in order to cope. So you'd have to make a plan, push in an extra bed, push in an extra stretcher. One hospital had a tent. Another hospital had emptied out their parking basement and created beds and stretchers there. That's how we all coped... We don't want to do that ever again. It is inhumane.<sup>28</sup>

The inability of patients' families to visit their sick and dying loved ones was emphasised as a particular cruelty of the Covid-19 pandemic. Hospital beds, oxygen and ventilators were all in desperately short supply. Regarding the lack of beds, one nurse recounted how

ambulances were driving around with patients trying to find beds, because there were no beds. So this ambulance guy phoned and said, 'Matron, help us'. I said to him, 'just give me five minutes'. But there wasn't enough time, and the patient passed. That's how it was. Horrible. The sense of reverence that a nurse feels at the side of a patient dying, that reverence was ripped out of our lives.<sup>29</sup>

It was within this context of high demand for Covid vaccination, scarcity of healthcare resources including staff and equipment and high rates of Covid-19 mortality and morbidity that the Sisonke study was designed and implemented.

### **'That's the resilience': The Sisonke Partnership**

The post-apartheid South African state has pursued a number of large-scale health interventions. Principal among these has been the government's HIV testing campaign in 2010–11, in which over 20 million tests were conducted.<sup>30</sup> Essentially, all patients presenting at public healthcare clinics were given an HIV test, prior to any further access to care and treatment. Many of those who tested positive were initiated onto antiretroviral treatment (ART) the same day. South Africa's ART programme for people living with HIV is the largest ART programme the world over and it proves that advanced tertiary healthcare can be made available for the public with the right training and oversight.<sup>31</sup> Sisonke is

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27 Interview with GH, Pretoria, 26 August 2022.

28 *Ibid.*

29 *Ibid.*

30 B. Maughan-Brown, N. Lloyd, J. Bor and A.S. Venkataramani, 'Changes in Self-Reported HIV Testing during South Africa's 2010/2011 National Testing Campaign: Gains and Shortfalls', *Journal of the International AIDS Society*, 19, 1 (2016), no. 20658.

31 A. Moosa, T.N. Gengiah, L. Lewis and K. Naidoo, 'Long-Term Adherence to Antiretroviral Therapy in a South African Adult Patient Cohort: A Retrospective Study', *BMC Infectious Diseases*, 19, 775 (2019), <https://doi.org/10.1186/s12879-019-4410-8>.

among the largest and most significant healthcare interventions yet provided in contemporary South Africa. Sisonke trial investigators foregrounded the remarkable nature of the trial, citing the speed with which the protocol was written (48 hours) and the hard work that the trial itself required.<sup>32</sup> In fact, for many, the trial was a means of providing rapid access to Covid-19 vaccination in the absence of government provision, with the research conducted as secondary to this primary intent.<sup>33</sup>

Sisonke was built upon the ENSEMBLE trial, which had established the efficacy and safety of a single dose of the J&J Covid vaccine.<sup>34</sup> The endpoints for this study were severe-critical coronavirus disease, hospitalisation and death; however, the ENSEMBLE study was a double-blinded, randomised, placebo-controlled trial, whereas Sisonke was essentially an implementation study in which all participants received a live vaccine. As one trial investigator explained,

We did it on the back of ENSEMBLE. So we used the 30-odd sites that had taken part in ENSEMBLE and we literally said to them, '[o]kay, you guys are going to run this baby', and everybody was very supportive. It was an incredible moment of solidarity ... And that's our country for you, that's the resilience.<sup>35</sup>

This positive framing of the trial as a remarkable achievement for democratic South Africa is reminiscent of 'rainbowism', the ideology that celebrates positive aspects of post-apartheid South Africa, foregrounding the utopian ideals of equity and unity in diversity. The same lead investigator spoke of the life-saving outcomes of the Sisonke trial: '[w]e saved healthcare workers' lives, we saved healthcare workers' stress levels, and we did it in as painless a way as we could'.<sup>36</sup> This was echoed by another clinician: 'Sisonke 1 was a lifesaver. The trial did things that our own government should have done. Our own government should have vaccinated healthcare workers and frontline people. But the trial was able to do that, so I'll always be grateful for that'.<sup>37</sup> Another HIV clinician stated: '[w]e got a whole lot of healthcare workers vaccinated and didn't see a major safety signal, so we did a good thing'.<sup>38</sup>

The first ethical approval for the study was provided by SAHPRA, and subsequently by all health research ethics committees associated with the sites through which Sisonke was being conducted.<sup>39</sup> Numerous investigators worked with health authorities who were aligned with the state, and Sisonke had sought and procured the approval of the South African Department of Health through direct interactions with the Minister of Health, Zweli Mkhize. The unity of purpose and the agility of trial investigators emphasised Sisonke's successes. As one trial investigator described:

It was intense. It was a group of us who were key stakeholders ... and then a core group of interested people. We wrote the protocol literally getting up early in the morning, talking to each other, talking to each other at night. I think for those three months we literally spoke to each other three or four times a day. We woke up and had our first meeting at 7 a.m. in the

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32 Interview with KL, Cape Town, 4 October 2022; interview with LM, author in Cape Town, participant in KwaZulu-Natal, 7 November 2022.

33 Interview with LM, 17 November 2022, author in Cape Town, participant in Durban.

34 Sadoff *et al.*, 'Final Analysis'.

35 Interview with AG, Pretoria, 4 October 2022.

36 *Ibid.*

37 Interview with MN, Johannesburg, 22 September 2022.

38 Interview with DE, Johannesburg, 6 September 2022.

39 L.-G. Bekker, N. Garrett, A. Goga, L. Fairall, T. Reddy, N. Yende-Zuma, R. Kassanjee *et al.*, 'Effectiveness of the Ad26.COV2.S Vaccine in Health-Care Workers in South Africa (The Sisonke Study): Results from a Single-Arm, Open-Label, Phase 3B, Implementation Study', *The Lancet*, 399, 10330 (2022), pp. 1141–53, p. 1143.

morning ... Often at seven o'clock, eight o'clock at night, we were on Zoom calls to the SAHPRA leadership. So everyone got the message that this needed to happen quickly.<sup>40</sup>

Patient-facing, frontline healthcare workers were the initial target group for the Sisonke trial. For the first two-and-a-half months of the study, frontline healthcare workers who were actively consulting with and treating patients on emergency wards were prioritised for study enrolment and vaccination. This remit was expanded from 11 May 2021, after which the definition of healthcare workers was broadened to 'non-patient-facing healthcare workers, support and administrative staff, staff at multilateral health agencies, laboratory staff, health research staff, community health workers, staff working in care homes, funeral workers and registered traditional health practitioners'.<sup>41</sup> This definition of a healthcare worker was sufficiently expansive to open up the trial to essentially everyone who worked within the broader remit of 'health'. Within this expanded remit, the president and the deputy president of South Africa received their vaccination on the first day of the Sisonke roll-out. Controversially, South African athletes who were competing in the Olympic Games also received the vaccine through the Sisonke trial, although they could in no way be construed as healthcare workers.<sup>42</sup> This led to disgruntlement among members of the public who were desperate for a vaccine but could not show beyond any stretch of the imagination that they were healthcare workers.

Trial participants had to register on the EVDS, consent to participate in the study after viewing an online consent form, and answer six questions to ensure their understanding of the trial. Thereafter, participants were given a screening appointment at a vaccine site which also served as the date of their vaccination. The online registration process was onerous, but tech-savvy people soon found the loopholes in the system that would enable them to get the vaccine, particularly through using a separate passport to their South African passports. As one participant described, strategies for circumventing the trial's enrolment criteria were widely and popularly disseminated, particularly on the social media platform WhatsApp, including by a Sisonke trial investigator.

Participants described their experiences of getting vaccinated as a part of Sisonke in ways that were reminiscent of South Africa's first democratic election, particularly in terms of the characterisation of long lines snaking towards the rooms in which people were getting vaccinated. Long queues characterised vaccine access in many healthcare sites. Additionally, once a clinic had reached its peak provision for the day, people were turned away from vaccine sites and told to return in the following days. In some instances, vaccine access was procured through strategic leveraging of informal networks. As one participant recounted:

It was like a mob scene. People were queueing in two directions, and there was a crowd at the front. The police were trying to do crowd control ... It was wild. It was bedlam. There was shouting and screaming and pushing and shoving and everyone was just desperate to get vaccinated, because there was no other option for vaccination available.<sup>43</sup>

This participant explained that she had only been able to access the vaccine at a hospital in Durban because a former colleague of hers was working 'inside' and 'was on the vaccination team'. Large public hospitals became essential nodes of vaccine access, in some instances providing thousands of vaccinations on a single day. The same participant recounted how she queued for five hours at a hospital in Durban and was deeply frustrated

40 Interview with KL, Pretoria, 4 October 2022.

41 Goga *et al.*, 'Sisonke Phase 3B Open-Label Study', p. 378.

42 T. Kahn, 'Activists Go to Court to Scrutinise Vaccine Advice to Government', *Business Day*, Johannesburg, 7 April 2022, available at <https://www.businesslive.co.za/bd/national/health/2022-04-07-activists-go-to-court-to-scrutinise-vaccine-advice-to-government>, retrieved 6 April 2024.

43 Interview with JK, author in Cape Town, participant in Durban, 14 February 2023.

as she witnessed government employees being ushered to the front of the queue ahead of others. She explained, 'I had the legitimate SMS [text message], I was where I was supposed to be. I was enrolled. And nevertheless there were people who were being let in who were from, like, the Department of Public Works, people who clearly had no connection to health'. Public demand for the vaccine remained extremely high throughout the course of the Sisonke trial. As one investigator recounted, '[t]owards the end... it was so popular that almost on the last day there was a bit of a stampede... people really came out, we had a kilometre-long queue to get into [the healthcare facility]'.<sup>44</sup>

Sisonke had the effect of strengthening operations at healthcare facilities, as pharmacists and pharmacy assistants were trained in dispensing the vaccine to healthcare workers who then 'drew down' the vaccine, essentially extracting the liquid from vials into syringes and injecting it into patient's arms. In many places, training of healthcare workers in dispensing the vaccine took the form of 'see one, do one, teach one',<sup>45</sup> with those who had received training directly from trial investigators in turn training their own colleagues on how to dispense and provide the vaccine.

The partnership of Sisonke with CAPRISA in KwaZulu-Natal, for example, leveraged the experience that healthcare workers had developed in providing HIV testing and counselling and the provision of ART to people living with HIV, with the support of large bilateral agencies, principally the US President's Emergency Plan for AIDS Relief (PEPFAR). In partnership with healthcare provision and research organisations, such as CAPRISA in KwaZulu-Natal and the Desmond Tutu Health Foundation in the Western Cape, PEPFAR staff have amassed copious experience of operationalising healthcare programmes in clinics across South Africa, including in resource-scarce contexts. Their inclusion in Sisonke served to capitalise on their experience of the logistics of healthcare in such resource-scarce settings, and this was particularly important for Sisonke in KwaZulu-Natal and the Northern and Eastern Capes, where healthcare settings lack the equipment and the staff of the healthcare systems in the Western Cape and Gauteng.

## **Parallels between Covid-19 and HIV in South Africa**

Sisonke was constituted by an array of researchers, all of whom had collaborated indirectly, if not directly, on HIV research and clinical trials. Scientists working on the Covid vaccine trials were grouped into 'gold', 'silver' and 'bronze' categories, encompassing their roles and professional commitments in the trial. During the course of the trial, 7 a.m. Zoom calls were followed up with numerous calls throughout the day, with daily debriefings taking place often late into the night. The Sisonke consortium built on similar collaborations, such as those between CAPRISA, the Desmond Tutu Health Foundation and PEPFAR, which had been conducting clinical trials focused on HIV for well over a decade and which also had copious experience of implementing new healthcare initiatives within public healthcare facilities spanning large tertiary hospitals to small community-based clinics. The collaborative nature of Sisonke (meaning 'together' in isiZulu) is demonstrated by its title. The efficacy and safety of Sisonke is popularly understood as another medical trial, like the ENSEMBLE trial, although it was in fact a Phase 3B implementation study,<sup>46</sup> focusing more

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44 Interview with LM, author in Cape Town, participant in Durban, 17 November 2022.

45 Interview with KL, Cape Town, 4 October 2022.

46 Phase 3 clinical trials compare the safety and effectiveness of one treatment against another current treatment.

on the operational and health systems aspects of Covid-19 vaccination as well as the safety of the vaccine.<sup>47</sup>

A number of participants described the similarities between HIV and Covid-19, with the latter seeming like a concentrated and ‘sped-up’ version of the HIV pandemic. As MN, an HIV clinician, explained, ‘Covid-19 was like HIV fast-forward’.<sup>48</sup> The same trope was used by a doctor in Cape Town, who described Covid-19 as ‘almost like AIDS on steroids, AIDS fast-forward’.<sup>49</sup> The medical response to Covid-19 was led by clinicians and scientists whose careers had focused on the HIV epidemic, including the development of ART. The first head of the Ministerial Advisory Committee was Salim Abdool Karim, the erstwhile head of CAPRISA. AB, one of the trial investigators for Sisonke, spoke of how ‘AIDS veterans’ had led the Covid medical response and described how the Sisonke trial was not dissimilar to antiretroviral trials. In particular because of its effects on mortality and morbidity in South Africa, HIV has shaped how many healthcare workers have accrued experience, working within the context of an epidemic of communicable disease.<sup>50</sup>

Most research participants framed the comparison between the HIV and Covid-19 responses as a positive reflection of research capacity, resilience and ingenuity among doctors and scientists working within the public health domain. One trial investigator explained how Right to Care, a PEPFAR-funded non-governmental organisation that works with healthcare workers to support the provision of ART to people living with HIV, stepped in to support the Eastern Cape Department of Health, which struggled to provide the Covid-19 vaccine within the Sisonke trial, due to weak healthcare systems and a lack of infrastructure and staff. Aside from supporting the operationalisation of the Covid-19 vaccine, HIV activists also promoted the uptake of the Covid-19 vaccine, running community access drives and working alongside the police during the first and most stringent lockdown to ‘try and temper the police’s violent response’.<sup>51</sup> A trial investigator explained the collaboration behind the Sisonke trial in relation to her copious experience of the AIDS pandemic, from the era prior to the national roll-out of ART in 2005, in which activists and medics had collaborated to fight for access to life-saving treatment, beginning with drugs for the prevention of mother-to-child transmission. This Sisonke trial investigator explained how collaborations forged through AIDS activism were also fundamental in the Sisonke collaboration:

We have lived through the time when we saw HIV when nothing was being done about it. And I think nobody wanted a repeat of that. I think that’s why people came together as quickly with such purpose as they did, because nobody wanted a repeat of the thousands or millions of people dying from a disease that could be mitigated... we fed off the memory of loss that would result if we did nothing. And then we fed off that experience that collaborations move mountains. Because even in the whole HIV era, where we had AIDS denialism... we say people getting together can move mountains. And so that’s what we did. It was groups of people getting together to advocate for, firstly, perhaps a change in the vaccine strategy. Secondly, to say, well, let’s pivot from an AstraZeneca roll-out to a J&J roll-out. And let’s do that in two weeks, so that nobody dies... I think it was the memory of the past and the experience of the past that resulted in such action.<sup>52</sup>

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47 Preiser and Fish, ‘Sisonke’.

48 Interview with MN, Johannesburg, 22 September 2022.

49 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

50 R. Hodes and R. Morrell, ‘Incursions from the Epicentre: Southern Theory, Social Science, and the Global HIV Research Domain’, *African Journal of AIDS Research*, 17, 1 (2018), pp. 22–31, <https://doi.org/10.2989/16085906.2017.1377267>.

51 Interview with JK, author in Cape Town, participant in Durban, 14 February 2023.

52 Interview with CD, Pretoria, 8 November 2022.

Some interviewees noted the distinction in government responses to the pandemic, contrasting Thabo Mbeki's AIDS denialism and protracted opposition to HIV treatment with Ramaphosa's rapid public response to Covid-19. Ramaphosa continuously engaged with the South African public through a series of televised addresses, intimately nicknamed 'family meetings'. However, the weaknesses of government's response was also framed in parallel to the weaknesses of the HIV response. As one HIV clinician explained:

There were so many mistakes made, again and again. And no one is going to be held accountable. They were mistakes that were foreseeable, and it was a combination of arrogance from government and arrogance from the private sector. I remember sitting in those [MAC] meetings and saying, '[t]his is the most ambitious public health programme that has been rolled out since the HIV testing programme in 2010, and none of you know how to do this... There were no lessons from the male circumcision programme, no lessons from the PrEP [Pre-Exposure Prophylaxis] programmes, no lessons from the HIV-testing programmes.'<sup>53</sup>

For this clinician, the failure of the state to learn from its own programmes, supported by widescale bilateral collaborations, was especially galling in the public Covid-19 response.

The central critique of government in relation to Covid-19 was its failure to provide public access to vaccinations, as well as to create demand for vaccines among the general population. Sisonke offered targeted campaigns for vaccination through the EVDS, essentially an online programme that could be accessed on a smart phone and through a series of digital 'cards' created by the Knowledge Translation Unit at the University of Cape Town and disseminated on WhatsApp. Between 17 February and 17 May 2021, Sisonke vaccinated 477,102 people broadly defined as healthcare workers.<sup>54</sup> Patient-facing and frontline healthcare workers were prioritised up until 11 May 2021, after which the participation criteria were broadened to include non-patient facing healthcare workers, support staff and administrative staff, together with community healthcare workers, staff in care homes, and funeral workers. The aim was to take a broad systems approach to vaccinating, on the basis that the healthcare system in its entirety had to support the vaccination programme, including workers such as porters and cleaners. As mentioned by one of the Sisonke trial investigators, a porter was the first healthcare worker to die of Covid-19 at Groote Schuur Hospital in Cape Town, where he had probably been infected iatrogenically by moving patients through wards. It was not only nurses and doctors who were at increased risk of Covid-transmission, and it was not only nurses and doctors who stood to benefit from vaccination.

## **The Electronic Vaccination Data System (EVDS)**

Healthcare experts have long been advocating for the implementation of a system of unique patient identification that could serve as a healthcare data repository for all individuals at all healthcare facilities. While such a system exists for patients in the Western Cape, the national implementation of a unique patient identifier remains piecemeal, resulting in massive duplication of patient records across healthcare sites, as well as limited insights into a patient's medical history.<sup>55</sup> In order to qualify for vaccination with Sisonke, healthcare workers across South Africa aged 18 years and older had to register for vaccination on the

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<sup>53</sup> Interview with DE, Johannesburg, 6 September 2022.

<sup>54</sup> Bekker *et al.*, 'Effectiveness of the Ad26.COV2.S Vaccine', p. 1141.

<sup>55</sup> K. Govender, L. Long and J. Miot, 'Progress towards Unique Patient Identification and Case-Based Surveillance within the Southern African Development Community', *Health Informatics Journal*, 29, 1 (2023), <https://journals.sagepub.com/doi/10.1177/14604582221139058>.

national online EVDS.<sup>56</sup> Participants were then asked to give electronic informed consent to participate in the study. The digital divide – the gap between demographic groups and regions that have access to the internet and are able to communicate digitally – was particularly stark in the workings of the EVDS, with older and rural people struggling to access and work the system. Moreover, the EVDS was employed not solely as a means of facilitating access to Covid-19 vaccination, but also as an instrument to expand state control over healthcare to start implementing the controversial National Health Insurance programme.<sup>57</sup> As one Sisonke trial investigator stated, '[t]his was National Health Insurance dressed up as the EVDS'.<sup>58</sup> The EVDS enabled the state to extend patient registration into the private sector, a long-standing goal of authorities in support of the National Health Insurance scheme.

The EVDS was not essential to the roll-out of the Covid-19 vaccine. Population-scale provision of vaccinations had long been conducted without prior registration or centrally allocated vaccination appointments, particularly among children.<sup>59</sup> Moreover, the EVDS denied vaccine appointments to those who were not frontline healthcare workers, with one of Sisonke's principal investigators sending out messages through its Whatsapp networks giving instructions to users of the EVDS on how to evade restrictions that blocked entry into the trial. As this principal investigator explained:

There was this one mistaken screen... So eventually I just gave up on trying to solve the EVDS, and just did the workaround on how to get into the trial. I just did a series of cards which basically said, 'when you go to this page where it asks you whether you are an official healthcare worker', say that you are, even if you're not. I screenshotted it and that went viral, completely viral. Like, the workaround on the EVDS. So I had to sort this out with the EVDS, repeatedly, to say, '[y]ou do realise there's a programming issue'. It was just going absolutely nowhere and the number of days that we had to get those vaccines out was reducing.<sup>60</sup>

Conversely, the EVDS was praised highly by other participants in this study. As another trial investigator explained:

It was an amazing system. It worked. It allows documentation of vaccination across the whole country. So it really was a fantastic system. It didn't crash. If we were not using it, it was because tablets were not available, or wifi was not available, but it didn't crash. And the people who worked on the EVDS were very amenable... listening to what the requirements were, they very quickly amended it... And then we had to add on the whole consent procedure, because it was a study. So they were very agile in helping to make all those changes. So it was a brilliant system, and the collaboration was just fantastic. Never before have I seen people come together like that and work, work 24/7 to make something happen in two weeks.<sup>61</sup>

Generally, however, damning critiques were levelled against the EVDS and its private developer, a corporation named Mezzanine Ware. Its complexity was regarded as a weakness, foreclosing access to the vaccine rather than promoting it. As the trial investigator who had created the 'EVDS workaround' stated, '[t]his was the National Health Insurance

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56 Bekker *et al.*, 'Effectiveness of the Ad26.COV2.S Vaccine', p. 1142.

57 Nattrass and Seekings, 'High Modernist Hubris', p. 5.

58 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

59 N. Dwandwe, C.A. Nnaji and C.S. Wiysonge, 'The Magnitude and Determinants of Missed Opportunities for Childhood Vaccination in South Africa', *Vaccines*, 8, 4 (2020), p. 705, <https://doi.org/10.3390/vaccines8040705>; Nattrass and Seekings, 'High Modernist Hubris', p. 9.

60 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

61 Interview with OP, Pretoria, 10 November 2022.

dressed up as the EVDS. This is classic South Africa, isn't it? We're going to have the Rolls-Royce model, we can't just be satisfied with a low-tech, practical solution'.<sup>62</sup>

While trial investigators themselves were unable to solve some of the problems that the EVDS created, such as the necessity of being a patient-facing healthcare worker in order to enrol, this was attributed by some as part of working in the midst of a pandemic. As one trial investigator stated, '[i]t was an amazing sense of building the ship while you sailed. But that's the nature of a pandemic. You can't wait until everything is perfect because the pandemic doesn't wait for you'.<sup>63</sup> Other research participants were extremely damning of the EVDS, describing how it prohibited rather than facilitated access to Covid-19 vaccination. One clinician recounted:

I think it was absolutely outrageous that you roll out an electronic system during a catastrophic pandemic, in a middle-income population that has never used something like this. And it was a complete mess. The numbers of problems, there were so many complaints of people not being to access [the vaccine], that things didn't work, and just excuse after excuse after excuse ... This country has never used an EVDS, and now we can roll it out and it's an urgent, urgent vaccination programme ... For the vast majority of people, when you are trying to vaccinate people as quickly as possible, the stories of people being turned away because the EVDS was not working, that's why we are sitting here with this mess, sitting with an under-vaccinated population. The EVDS was a complete catastrophe.<sup>64</sup>

The EVDS as a system of digital registration, and a prospective means of enrolling people within both the public and private systems into the National Health Insurance scheme, has been heavily critiqued. But whereas digital enrolment is not required for other vaccination programmes in South Africa, including childhood vaccinations, some research participants argued that the only way the trial could have enrolled and tracked participants was through a digital repository like the EVDS.

### **'Wrong and illegal': Opposition to the Pfizer Booster**

The primary goal of the Sisonke 1 study was to prevent Covid-related mortality and morbidity through a single dose of J&J's Ad26.COV2.S vaccine. The trial's protection of participants against severe disease and death was remarked upon by all participants in this study. The critical role of collaboration and partnership was also foregrounded, and government support for the trial was highlighted. As distinct from the AIDS epidemic, in which healthcare workers and activists struggled against the state for access to essential medicines, the Sisonke trial was characterised by a unity of purpose, with substantial support from state health authorities. One principal investigator described the leading role of Zweli Mkhize, whose work as the Minister of Health was later mired in a corruption scandal over kickbacks that Mkhize had received as a part of the government's Covid-19 communication campaign.<sup>65</sup> The scandal erupted in February 2021, just as the Sisonke trial was starting. Mkhize was ultimately replaced as the Minister of Health, but at the onset of the Sisonke trial he was still leading the Department of Health. His support for the Sisonke trial was resounding, in large part perhaps because the state had failed to procure a vaccine for public

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62 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

63 Interview with KL, Cape Town, 4 October 2022.

64 Interview with DE, Johannesburg, 6 September 2022.

65 P-L. Myburgh, 'Lest We Forget: Digital Vibes Two Years On – Zweli Mkhize & Co Still Free, Probe "Ongoing"', *Daily Maverick*, 26 February 2023, available at <https://www.dailymaverick.co.za/article/2023-02-26-lest-we-forget-digital-vibes-two-years-on-zweli-mkhize-co-still-free-probe-ongoing>, retrieved 1 April 2023.

access, and epidemiological models showed that a third wave of Covid-19 was imminent. As this principal investigator explained:

I think it was research machinery working at its best. Well-oiled and everybody swimming in the same direction. This is probably the key difference if you take the clock back to 2000 in this country. I've often said, it's hard enough fighting the virus, but where you've got to fight the machinery and the administration as well, that's exhausting. And we did not have that. We were fighting a virus with one focus and one mission and everybody swimming in one direction. Having the president receive the vaccine, he was leading the charge.<sup>66</sup>

Vaccinating the president was in fact a controversial component of the Sisonke trial, as he was not a healthcare worker. As with the elite athletes who were vaccinated before leaving for the Tokyo Olympics, the Sisonke trial attracted criticism for providing vaccination to non-healthcare workers. But this subsided as the trial progressed, and as the expanded remit of participants encompassed a broad definition of healthcare worker to include support and administrative staff, as described above.

Sisonke 1 was followed by another study, Sisonke 2, which aimed to provide a second, booster dose of the same vaccination to healthcare workers enrolled in Sisonke 1. It began on 10 November 2021. The strongest criticism levelled against Sisonke 2 was its exclusion of the Pfizer vaccination for heterologous boosting, that is, providing participants with access to the Pfizer vaccination to strengthen the immune system's protection against Covid-19. Typically, heterologous boosting involves combining an adenovirus vaccine, such as J&J's vaccine that was used in the Sisonke trial, with an mRNA vaccine such as the Pfizer and Moderna Covid-19 vaccines. As the Sisonke 1 trial was under way, studies began to show that heterologous boosting, that is, the use of multiple vaccinations to protect participants against Covid-19-related morbidity and mortality, was of significant health benefit.<sup>67</sup> By 2022, it was widely accepted that heterologous boosting helped to strengthen waning immunity against new strains of Covid-19 and expanded immunity against new 'variants of concern'.<sup>68</sup> Many participants in the Sisonke 1 trial sought to boost their immunity against Covid-19 through heterologous boosting, particularly through accessing the Pfizer mRNA vaccine, which was procured by the Department of Health in May 2021 and made widely available in the public and private health sectors.<sup>69</sup>

However, trial investigators had not foreseen that participants might seek heterologous boosting, and this threatened to confound the Sisonke 2 study. Participants in this study were extremely critical of the Sisonke trial because of its prohibition against heterologous vaccination. Notably, the veneer of legality was invoked by both proponents and opponents of heterologous boosting in Sisonke 1. One principal investigator described it vociferously as 'wrong and illegal',<sup>70</sup> while another participant described the inability of the Sisonke trial

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66 Interview with KL, Cape Town, 4 October 2022.

67 A.M. Borobia, A.J. Carcas, M. Pérez-Olmeda, L. Castaño, M. Jesús Bertran, J. García-Pérez, M. Campins *et al.*, 'Immunogenicity and Reactogenicity of BNT162b2 Booster in ChAdOx1-S-Primed Participants (CombiVacS): A Multicentre, Open-Label, Randomised, Controlled, Phase 2 Trial', *The Lancet*, 398, 10295 (2021), pp. 121–30.

68 R.L. Atmar, K.E. Lyke, M.E. Deming, L.A. Jackson, A.R. Branche, H.M. El Sahly, C.A. Rostad *et al.*, 'Homologous and Heterologous Covid-19 Booster Vaccinations', *New England Journal of Medicine*, 386, 11 (2022); pp. 1046–57, <https://www.nejm.org/doi/full/10.1056/NEJMoa2116414>; A. Jara, E.A. Undurraga, J.R. Zubizarreta, C. González, A. Pizarro, J. Acevedo, K. Leo *et al.*, 'Effectiveness of Homologous and Heterologous Booster Doses for an Inactivated SARS-CoV-2 Vaccine: A Large-Scale Prospective Cohort Study', *The Lancet: Global Health*, 10, 6 (2022), e798–e806, <https://pubmed.ncbi.nlm.nih.gov/35472300/>.

69 South African Department of Health, 'Minister Zweli Mkhize on the Arrival of Pfizer and Johnson & Johnson Coronavirus COVID-19 Vaccine', 2 May 2021, available at <https://www.gov.za/speeches/minister-zweli-mkhize-arrival-pfizer-and-johnson-johnson-coronavirus-covid-19-vaccine-2-may>, retrieved 1 April 2023.

to provide access to the Pfizer vaccine as ‘criminal and completely wrong’. Numerous participants related their pursuit of an ‘undocumented boost’, using alternative identity documents to those provided for inclusion in the Sisonke 1 study to access the Pfizer vaccine. As one healthcare worker explained, ‘[a] lot of healthcare workers had secured their own Pfizers by hook or by crook, so I think that was probably a weakness ... because by then a lot of people already had had a booster that was not necessarily on the label or on record’.<sup>71</sup> Another healthcare worker explained, ‘[p]eople were worried, they panicked. They didn’t quite trust the Sisonke leads, and people from overseas were saying that heterologous boosting is the most effective means of protection, so let’s do it even though it’s not permitted with the trial’.<sup>72</sup> The Sisonke 2 study, which sought to boost participants with a second dose of Ad26.COVS vaccine, was controversial precisely because it precluded access to mRNA vaccination, which an increasing international evidence base found to be more effective against Covid-19 morbidity and mortality than a single vaccination with J&J.

## **Conclusion**

Due to the study’s framing as pragmatic and as close to real-world vaccination roll-out as possible, Sisonke has been described as a part of the national roll-out of South Africa’s Covid-19 vaccines. It was in fact a discrete research study and not a formal part of national, public healthcare provision. The misrepresentation of the study as part of the public roll-out is disingenuous, providing cover for the state’s own failures to procure and dispense Covid-19 vaccines in time before the third wave of Covid-19 swelled the ranks of those who were extremely ill. It was only after the conclusion of the Sisonke trial, which rolled out vaccines to almost half a million people, that the national roll-out of the Covid-19 vaccine commenced. The state later co-opted the trial as ‘Phase 1’ of its vaccination roll-out.<sup>73</sup>

Ironically, the trial eased the pressure on government to provide its own vaccine roll-out, targeting healthcare workers who were among the most vulnerable to Covid-19 infection. Moreover, the trial inadvertently gave a public message that Covid-19 vaccines were experimental rather than safe, routine and widely accepted. One result of this has been widespread vaccine hesitancy, with many South Africans choosing not to get vaccinated as a part of the national vaccine roll-out.

The Sisonke trial was one of the largest and most ambitious healthcare programmes ever embarked upon in South Africa and indeed globally. The trial leveraged the knowledge and experience gained over the course of previous illnesses, including the HIV epidemic, to provide a life-saving intervention, the Ad26.COVS Covid-19 vaccine, to almost half a million South Africans. The trial brought these South Africans into a new experimental order facilitated by a consortium of vaccine providers. The Sisonke trial preceded the national, public roll-out of Covid-19 vaccine, filling the vacuum caused by the government’s failure to procure and dispense Covid-19 vaccines for healthcare workers prior to May 2021. Collaborations built in the struggle against the HIV/AIDS pandemic provided a critical framework upon which partners built the response to the Covid-19 pandemic.

Frontline, patient-facing healthcare workers were the first to be vaccinated, due to their vulnerability to Covid-19 infection and to their high rates of mortality within the first two waves of the pandemic in South Africa. Within the expanded remit of the Sisonke study, 70 Interview with KL, Cape Town, 4 October 2022; interview with IJ, author in Johannesburg, participant in Cape Town, 9 August 2022.

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71 Interview with OP, Pretoria, 10 November 2022.

72 Interview with AB, author in Pretoria, participant in Cape Town, 31 January 2023.

73 Natrass and Seekings, ‘High Modernist Hubris’, p. 16.

thousands of people who worked within healthcare more broadly were also able to be vaccinated against Covid-19. It is likely that the Sisonke trial saved the lives of thousands of people, although epidemiological models of its efficacy against morbidity and mortality were not yet available at the time of print.

The Sisonke study was not without its controversies. The EVDS proved challenging for many, with the digital divide precluding enrolment into Sisonke for poor and rural South Africans. Yet people still managed to work their way around the EVDS and to get vaccinated against Covid-19. The vaccination of non-healthcare workers, including athletes attending the Olympic Games, was chief among the trials criticisms, as was the prohibition in Sisonke 2 against heterologous boosting. Building on the success of South Africa's HIV treatment roll-out, the experiences of healthcare workers proved invaluable in providing the Covid-19 vaccine.

The vaccine roll-out was not as smooth as seems evident in its well-packaged publications. Long queues and a mob-like atmosphere characterised the provision of the vaccine in some places, specifically within more poorly resourced healthcare facilities. Overwhelmingly, however, the trial was regarded as an astonishing success: testament to what could be achieved in South Africa when solidarity and collaboration underpinned people's actions.

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