Human rights and legal implications

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Second wave

Background

At the peak of the worldwide second COVID-19 wave in February 2021, more than 105 million global cases have been reported, whilst more than 2.2 million of those cases resulted in death.

Pandemics are characterised by second and more waves, but an increase in transmission intensity was observed from October 2020 which may have been caused by increased social mixing precipitated by the premature, rapid and simultaneous (rather than step-wise) lifting of public health and social measures, especially considering the large number of people travelling across South Africa for their traditional summer school and work vacations taken over December. The lack of critical resources for infection prevention, such as masks and water, including the absence of a proactive public health system to detect cases, quarantine positive cases and support contacts to break chains of transmission also contributed to the swelling of the second wave.

Although some countries have since reported the stabilisation or even a decrease in COVID-19 cases, the reported figures seem questionable in view of severe limitations in testing capacity, or where a country's capacity for case investigation, contact tracing, and quarantine have been put under additional pressure, especially in low-resource countries, such as South Africa, or humanitarian settings. Persistent poor living conditions, including overcrowding, poor ventilation and limited access to water and sanitation further gave momentum to the second wave. The substantial disruption in health services across disciplines such as sexual, reproductive health services, and TB/HIV testing and treatment, coupled with a reluctance to attend healthcare facilities in fear of contracting COVID-19, have resulted in additional, albeit preventable deaths.

With the arrival of the first generation of safe and effective COVID-19 vaccines, the world faces a pivotal point in its history, which has been complicated by so-called vaccine nationalism, COVID-19 variants, and supply chain difficulties. Regardless of the findings of a study commissioned by the International Chamber of Commerce that concluded that "even with high vaccine coverage in high-income countries, restricted coverage elsewhere would cost high-income economies an additional US$ 2.4 trillion in 2021 alone", high income countries nonetheless circumvented the Access to COVID-

19 Tools (ACT)-Accelerator to make beneficial bilateral deals with vaccine manufacturers directly and at the expense of the most vulnerable around the world. Vaccine equity is not just a moral, strategic, or economic imperative, but simply a matter of survival. Vaccines will only eradicate the COVID-19 virus if everyone seems to have been vaccinated against the disease to prevent any transmission of the virus.

Although some laud heard immunity to be the evolutionary saviour of the pandemic, estimates of the threshold for SARS-CoV-2 may range from 10% to 70% and these models rely on very uncertain or speculative assumptions about how people interact in social networks. One of the unproven assumptions are that people who survive an infection will become immune but are the duration and effects of the immune response not understood yet, especially not from a longitudinally point of view. The ACT Accelerator, launched at the end of April 2020, is a global collaboration between governments, scientists, businesses, civil society, philanthropists, and global health organizations such as the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, the WHO, and the World Bank which aim to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. To further co-ordinate the fair and reasonable dispensing of vaccines globally the WHO published a *COVID-19 Strategic Preparedness and Response Plan for 2021* with guidelines that set out practical and coordinated actions that must be taken collectively on national, regional, and global level to overcome these challenges and steer the world out of this pandemic.

The emergence of different SARS-CoV-2 variants in Brazil, the UK, and South Africa, made it clear that the longer and more widely SARS-CoV-2 circulates, the more opportunities it will have to adapt, and the greater the threat to our ability to test, treat and vaccinate for COVID-19.

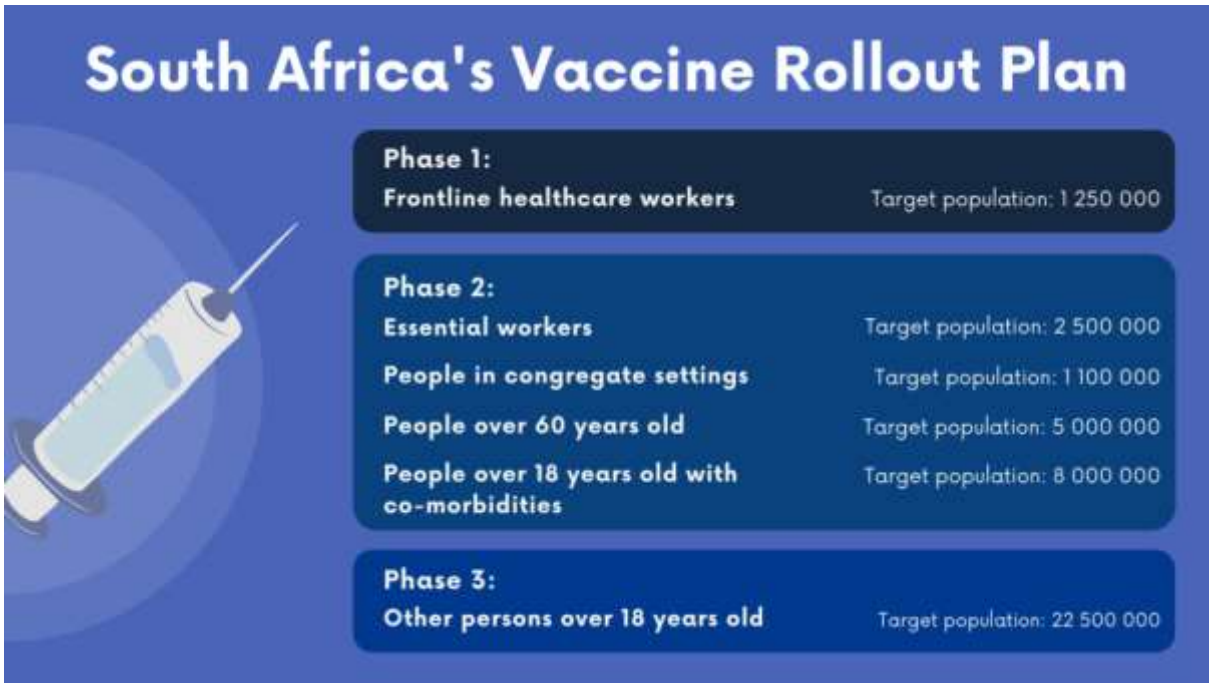
Leadership and co-operation

Vaccine procurement

Since 2020 the South African government, the National Department of Health and the Ministerial Advisory Committee had discussions with potential vaccine suppliers, including Pfizer, AstraZeneca, Johnson and Johnson, Moderna, Cipla, and vaccine producers in China and Russia, whilst the COVAX facility has focused mainly on vaccines that are suitable for developing nations with limited or non-existing ultra-cold storage facilities. The Biovac Institute, a South African company co-owned by the government and private sector started negotiations for the possible local manufacturing of up to 30 million doses of COVID-19 vaccines per year, depending on the required technology.

The South African vaccine rollout will be managed by a national vaccine co-ordinating committee established at the NDOH which will include an expanded Programme for Immunisation (EPI), Communicable Disease Cluster (CDC), Medicines Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and Evaluation. Provincial co-ordinating committees will be appointed by HODs and will provinces have to establish structures at district level to manage the mass rollout. The private health sector co-ordinating committee will include medical schemes, private hospital associations, pharmacies groups, general practitioners, specialist associations, nursing associations, allied health professions associations, logistics providers, pharmaceutical manufacturers, employers, labour unions, and other business associations.

Government's criteria for vaccine selection consisted of 6 key considerations, being availability; safety, efficacy and quality as determined by SAHPRA; ease of use and number of doses required; stability during storage and distribution; supply and sustainability; and costs. The South African rollout plan was planned to happen incrementally in accordance with the below 3 phases and people qualifying for each phase:



Vaccine rollout

Despite the early availability of the Pfizer and AstraZeneca vaccines, an analysis of the B.1.351 coronavirus variant first identified in South Africa in mid-November 2020, found that that the two-dose regimen of the ChAdOx1 nCoV-19 vaccine provides minimal protection against mild-moderate COVID-19 infection, but had high efficacy against the original coronavirus non-B.1.351 variants in South Africa. The AstraZeneca vaccines that arrived in South Africa early in February 2021 could subsequently not be used and the government was obliged to procure the Johnson and Johnson vaccines on an urgent basis.

South Africa secured 500 000 doses of the single dose Johnson & Johnson vaccine, which protects against severe COVID-19, including the South African variants, for use in its Sisonke ('Together') programme. An initial 80 000 doses could be administered to frontline healthcare workers in March 2021, who are 3-4 times more likely to contract COVID- 19 than the general population. Until the start of the Sisonke program approximately 40,000 South African health workers have contracted COVID-19, 6,473 have been hospitalised and 663 have died.

The safety and efficacy of the Johnson and Johnson vaccine was tested in the international ENSEMBLE study which was conducted across Latin America, USA, and South Africa with more than 43 000 participants between October 2020 and February 2021. In this study the vaccine proved to be 72% efficacious in preventing infection in the US; 57% efficacious in South Africa, and 85% effective overall in preventing severe infection and included participants exposed to the 501.V2 variant, suffering from

co-morbidities such as diabetes, HIV/AIDS, and participants above the age of 60. The South African part of the trial showed that while the Johnson and Johnson vaccine is not going to prevent mild symptoms, it provides 57% protection against moderate-severe disease, 85% protection against severe disease and 100% protection against death, whereas the Oxford-AstraZeneca vaccine provided only 27% protection against mild to moderate COVID-19 caused by the new 501Y.V2 variant. Although the governmental procurement criteria will not be applicable to all available vaccines, the Johnson and Johnson vaccine fits these criteria quite well as it is given in a single dose, has a long shelf life of 2 years at -20 degrees Celsius and can be safely stored in a domestic fridge for 1 month which makes it ideal for rollout in warmer countries like South Africa.

To finally be registered as a commercial medicine by SAHPRA, Johnson had a so-called "rolling" application with SAHPRA to allow the determination of the long-term effects of the Johnson and Johnson vaccine, whilst being rolled out under *The Sisonke Open Label Program,* since the safety and efficacy of this vaccine have already been proven. According to Professor Glenda Gray, president of the SA Medical Research Council (SAMRC) and the principal investigator of the Ensemble study in South Africa, SAHPRA was only likely to decide on an emergency use license for the vaccine in late March or April. The Sisonke Program allows government to make this vaccine immediately available to healthcare workers, whilst SAHPRA process the full licencing of the vaccine. It is important to note that the current Sisonke Program is indeed a clinical trial, which does not mean that the vaccine is not safe and efficient, but that the vaccine merely await licencing processing by SAHPRA. The Sisonke Open Label Program is thus described as an "open label, single-arm Phase 3b vaccine implementation study of the investigational single-dose Janssen COVID-19 vaccine candidate [that] aims to monitor the effectiveness of the investigational single-dose Janssen vaccine candidate at preventing severe COVID-19, hospitalizations and deaths among healthcare workers as compared to the general unvaccinated population in South Africa" and is co-hosted by the SAMRC and the Department of Health.

The 1 million doses of AstraZeneca vaccine which South Africa previously procured, but which cannot be successfully used will now be made available to the African Union for distribution to countries who do not suffer from the B.1351 variant, against which the AstraZeneca vaccine does not provide immunisation on recommendation of the African Centers For Disease Control. Although there were concern about the safety of the Astra-Zeneca vaccines, these vaccines have been cleared from all concerns and confirmed to be safe, resulting in vaccinations with these vaccines to be continued.

South Africa has already bought 20 million doses of vaccines directly from Pfizer which are expected during the second half of 2021. Meanwhile, 117 000 doses of the Pfizer vaccine has been allocated to South Africa by COVAX according to its interim distribution forecast, which doses are expected within a month or two and can then be administered in terms of an emergency use license, granted by the WHO. South Africa has been the hardest hit country on the African continent, accounting for over 55% of cases and an accumulated caseload of almost 1.5 million.

Regulatory matters

The Medicines and Related Substances Act 101 of 1965 provides for vaccines to be safe and effective before it may be registered and commercially administered. However, to enable expedited regulatory approvals of safe vaccines, SAHPRA put the following measures in place:

- agreements with EMA, USFDA, MHRA, and TGA to use their assessment reports to rely upon when determining reduce timelines in the evaluation process;
- SAHPRA has adopted a priority review approach for all COVID-19 vaccine applications since the onset of the pandemic to allow for expedited reviews of specifically COVID-19 vaccine registration applications;
- flexibility in relation to labelling and packaging requirements effected in terms of section 36 of the Medicines Act which deals with the exemption of medicines by the Minister of Health from certain requirements of the Medicines Act for specific labelling and packaging requirements;
- authorisation of rolling applications in terms of Section 21 of the Medicines Act where manufacturers have not yet, or not submitted completed dossiers to SAHPRA, although the NDoH has encouraged vaccine manufacturers to nonetheless submit substantive dossiers to SAHPRA.

Conclusion

The scientific community leads the fight against the COVID-91 pandemic through collaboration, urgency, and commitment. They rose to the challenge of developing vaccines, diagnostics and therapeutics and these achievements must now be matched and followed up with commitment from the global community to ensure that these new technologies are distributed fairly, equitably, and affordably to where they are needed most.

Within the framework of the WHO's *COVID-19 Strategic Preparedness and Response Plan for 2021* all countries, including South Africa must conduct a substantive gender, equity, and inclusion analysis, in

line with its existing constitutional human rights framework to properly inform programs and implemented into operations from the outset, including assessment, design, planning and implementation. This will only be established through the meaningful participation, collaboration, and consultation with the South African population, including sub-populations that are experiencing poverty and social exclusion, frontline workers and those facing vulnerabilities, discrimination, and additional barriers to access needs with the view of connecting these needs with other services such as safety and care, therapeutics, and vaccines.

COVID-19 will not be the last health threat or emergency. May it serve as a stark reminder that the costs of effective preparedness are dwarfed by the costs of a failure to prepare. South Africa now has the benefit of hindsight to learn and build from towards a more resilient future of emergency preparedness through healthy governance.

Up to date of this report South Africa managed to vaccinate 83 570 healthcare workers with the Johnson and Johnson vaccine.

> "*The coronavirus pandemic has illuminated the critical role of socio-economic rights in securing a dignified life for all and in countering social and economic inequalities. There is a silver lining to this dark cloud. It is the hope that the short-term efforts we now make to protect these rights in a crisis will translate into long-term public and private resource mobilisation for securing accessible, affordable and quality public goods and services for all*"
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Key lessons and challenges

- The management of epidemiology is uncertain due to a lack of data and may further be complicated by variable public health responses and emerging variants but must South African continue to suppress transmission using available tools.
- Health care systems and workers are still under extreme pressure and often lack sufficient capacity, capabilities, financial resources, and access to vital supplies. South Africa must build resilient healthcare systems, not only to mitigate the impact of COVID-19, but also to ensure continuance of essential healthcare services and readiness for future health emergencies.

- Surveillance systems are straining under the high volume of infection, cases, and cluster investigations, contact tracing and supported quarantine of contacts. The capacity of these systems must be enlarged to ensure sufficient testing.
- Communities have fragmented and individuals feel isolated due to the erosion of social cohesion, limited access to education, and reduced income and security. Lock down regulations and other social measures designed to limit transmission, a reduction in earnings or earning capacity and other movement restrictions have contributed to significantly reduced utilisation of healthcare services, especially in reproduction and TB contexts.
- Public health and social measures to control COVID-19 had and are still having considerable social and economic costs and must be approached on a proportional risk-basis which is regularly reviewed with due consideration of public health intelligence and the socioeconomic costs of participation.
- Global, regional, and national supply chains have been disrupted and were often unable to meet demand, with several implications for surveillance, infection prevention and control, case management, and the maintenance of essential health services.
- The info-demic of misinformation continue to shape perceptions and undermine the application of an evidence-based responses and individual risk-reducing behaviours.
- Comprehensive preparedness and emergency response systems to especially health emergencies remain underinvested in many countries. The costs of effective preparedness are dwarfed by the costs of a failure to prepare.
- Science has delivered explanations, evidence-based guidance, and vaccines. Although production of these tools is being scaled up for equitable delivery, demand and utilisation remain suboptimal, and equity is under threat.

Strategic objectives

- Suppress transmission through the implementation of effective and evidence-based infection prevention and control measures such as testing, tracing, quarantine of contacts, isolation of probable and confirmed cases, measures to protect high-risk groups and vaccination.
- Reduce exposure by enabling communities to adopt risk-reducing behaviours and practice infection prevention and control, including avoiding crowds, social distance, hand hygiene, masks, and improved indoor ventilation.
- Counter misinformation and disinformation by managing the info-demic through communication, engagement and enriching the information eco-system online and offline through high-quality health guidance that is accessible and appropriate to every community.

- Ensuring vaccine deployment readiness in all countries and all populations, by communicating, implementing, and monitoring COVID-19 vaccination campaigns.
- Reduce mortality and morbidity by ensuring early diagnosis and that health systems can surge to maintain and meet the increasing demand for care
- Accelerate equitable access to COVID-19 vaccines, including diagnostics and therapeutics.

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