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Hard choices: Ethical challenges in phase 1 of COVID-19 vaccine roll-out in South Africa

K Moodley,¹ MB ChB, MFamMed, FCFP (SA), MPhil (Applied Ethics), Executive MBA, DPhil;
M Blockman,² MB ChB, BPharm, PG Dip Int Res Ethics, MMed; **D Pienaar,³** MB ChB, FCPHM (SA);
A J Hawkridge,⁴ MB ChB, FCPHM (SA); **J Meintjes,⁵** MB ChB, DOM, MMed (Occ Med);
M-A Davies,⁶ MB ChB, MMed, PhD, FCPHM (SA);
L London,⁷ MB ChB, MMed (PHM), MD, DOH, BSc Hons (Epidemiol)

¹ Centre for Medical Ethics and Law, Department of Medicine, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa

² Division of Clinical Pharmacology, Department of Medicine, Faculty of Health Sciences, University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa

³ Western Cape Department of Health, Cape Town, South Africa

⁴ Medical Services: Swartland Hospital, Malmesbury, South Africa

⁵ Academic Unit for Infection Prevention and Control, Division of Community Health, Faculty of Medicine and Health Sciences, Stellenbosch University and Tygerberg Hospital, Cape Town, South Africa

⁶ Centre for Infectious Disease Epidemiology and Research, School of Public Health and Family Medicine, University of Cape Town; and Health Impact Assessment Directorate, Western Cape Government: Health, Cape Town, South Africa

⁷ Division of Public Health Medicine, School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, South Africa

Corresponding author: K Moodley (km@sun.ac.za)

Access to COVID-19 vaccines has raised concerns globally. Despite calls for solidarity and social justice during the pandemic, vaccine nationalism, stockpiling of limited vaccine supplies by high-income countries and profit-driven strategies of global pharmaceutical manufacturers have brought into sharp focus global health inequities and the plight of low- and middle-income countries (LMICs) as they wait in line for restricted tranches of vaccines. Even in high-income countries that received vaccine supplies first, vaccine roll-out globally has been fraught with logistic and ethical challenges. South Africa (SA) is no exception. Flawed global institutional strategies for vaccine distribution and delivery have undermined public procurement platforms, leaving LMICs facing disproportionate shortages necessitating strict criteria for vaccine prioritisation. In anticipation of our first consignment of vaccines, deliberations around phase 1 roll-out were intense and contentious. Although the first phase focuses on healthcare personnel (HCP), the devil is in the detail. Navigating the granularity of prioritising different categories of risk in healthcare sectors in SA is complicated by definitions of risk in personal and occupational contexts. The inequitable public-private divide that characterises the SA health system adds another layer of complexity. Unlike other therapeutic or preventive interventions that are procured independently by the private health sector, COVID-19 vaccine procurement is currently limited to the SA government only, leaving HCP in the private sector dependent on central government allocation. Fair distribution among tertiary, secondary and primary levels of care is another consideration. Taking all these complexities into account, procedural and substantive ethical principles supporting a prioritisation approach are outlined. Within the constraints of suboptimal global health governance, LMICs must optimise progressive distribution of scarce vaccines to HCP at highest risk.

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As South Africa (SA) braced itself for a second wave of COVID-19 infections in December 2020, the desperate need for access to an efficacious vaccine was amplified. The emergence of a new variant of SARS-CoV-2 (501Y.V2) in the country since October 2020^[1] increased transmissibility by 50%,^[2,3] probably magnifying the second wave, during which there was a sharp increase in infections and hospitalisations. It was clear that an efficacious vaccine was necessary, but would low- and middle-income countries (LMICs) receive supplies sufficient to meet demand? This question raised global debate on how access to COVID-19 vaccines would be equitably distributed on a worldwide scale at a time when all countries required vaccines with simultaneous urgency to preserve life and minimise disease, protect health systems and reduce transmission.^[4-6]

Global justice and COVID-19 vaccine access

Unsurprisingly, inequality in access to COVID-19 vaccines has raised concerns globally. Despite calls for solidarity and social justice during the pandemic, vaccine nationalism and stockpiling of limited vaccine supplies by high-income countries (HICs) have brought into sharp focus global health inequities and the plight of LMICs as they wait in line for small tranches of vaccines. HICs have bought up or are busy buying up vaccine stocks in advance.^[7] Data suggest that some HICs have purchased more than four times the quantity of vaccine doses that have been secured by the COVAX facility,^[8] which is jointly hosted by the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations and the Global Alliance for

Vaccines Initiative to support access for LMICs.^[9-11] In fact, countries such as Canada and the UK, and others, have secured vaccine doses in numbers that are up to five times more than their populations, when most LMICs have not yet secured any vaccines, an inequity the WHO Director-General, Dr Tedros Ghebreyesus, has described as 'a catastrophic moral failure'.^[12] This situation has prompted a call for HICs to release excess vaccine for use in LMICs desperate to acquire vaccine.^[13]

In addition to vaccine supplies via the COVAX facility^[8] and the African Union, SA was able to source an initial supply of the AstraZeneca-Oxford vaccine under the tradename Covishield, from the Serum Institute of India. By the end of January 2021, 1 million doses of the vaccine had arrived, at a cost of USD5.25 per dose, more than double the USD2.16 per dose paid by European Union countries.^[14] Disappointingly, SA was unable to secure a fair pricing agreement despite hosting a clinical trial of the AstraZeneca vaccine, violating the principles of post-trial access for communities and benefit sharing in research, and raising queries around researcher responsibilities and reviews by research ethics committees.^[15] Notably, the lack of transparency in bilateral agreements has meant that national governments have not been able to negotiate the fairest deals in accessing vaccine for their populations, which has undermined the global solidarity needed between countries to ensure an equitable distribution of vaccine.

However, the results of the local arm of the study raised concerns that the AstraZeneca vaccine would not protect against the 501Y.V2 variant. Given that participation was limited to young adults, generalisability was limited, as results could only be extrapolated to the lack of prevention of mild and moderate disease and not to prevention of severe disease.^[16] Subsequently, the Johnson & Johnson COVID-19 vaccine was adopted for roll-out in the form of a phase 3B 'implementation trial'. As it is an open-label trial, all participants are offered an active vaccine.

Global distribution of vaccines

From an ethics perspective, conceptual attempts at global distribution have been proposed, most notably the 'Fair Priority Model' that describes three fundamental values – benefit and minimising harm, prioritising the disadvantaged, and equal moral concern.^[17] An early WHO approach recommended that countries receive doses in proportion to between 3% and 20% of their populations.^[17,18] This type of distribution could be challenging if population age and risk are taken into account. Proportionality may also be considered in relation to burden of COVID-19 disease, raising the ethical challenge of allocating more vaccine to countries that have managed the pandemic poorly than to those that have implemented strong public health containment measures.^[17] National burden of all-cause disease is, however, another consideration. SA has a high burden of diseases that increase the risk of developing severe COVID-19 infection, including tuberculosis, HIV and non-communicable diseases.^[19] This disease burden should be considered in global vaccine distribution strategies based on proportionality.

At a national level, given that global demand will outstrip supply, many countries have opted for a phased distribution of efficacious vaccines.

Incremental vaccine distribution: A phased approach

Global inequality in the governance of vaccine availability has created conditions that present LMICs with thankless choices regarding prioritisation. Firstly, vaccine producers have not played ball with

enabling technology transfer but kept their intellectual property tightly under their control, as shown by their unwillingness to support the WHO COVID-19 Technology Access Pool.^[20,21] Had this been handled differently from the start, we would not be reliant on merely a few producers, and though we would probably still have had to ration vaccine, the extent of rationing would probably be neither as brutal or as chaotic.

Secondly, we are waiting in a vaccine procurement queue determined by power and money, shrouded in secrecy and in circumstances beyond the control of most LMICs. The Johnson & Johnson vaccine is slated to arrive in tranches of 80 000 doses every 2 weeks, which means that SA has not yet secured sufficient doses for all its health personnel. As a result, we are faced with deciding which health personnel go to the back of the first queue without being sure if we will ever get to the end of that queue in phase 1.

Thirdly, while SA has managed to extract some vaccine for itself, what of other less wealthy and less politically influential countries in Africa, for which vaccination looms as a distant likelihood only in 2022 or 2023?^[22] That is a reflection of the weakness of global institutions for vaccine access. This global inequality has given SA limited options (and other African countries even fewer options) within which we have to prioritise. In considering the ethical choices for incremental vaccine distribution, we therefore need to constantly locate these difficult choices in a political context of global inequality rather than solely in wrong decisions by LMIC policy makers, governments, health services or ethicists.

Three major vaccine allocation frameworks that include national allocation criteria merit noting – the WHO Strategic Advisory Group of Experts,^[23] the National Academies of Science Engineering and Medicine^[24] approach and the Centres for Disease Control guideline.^[25]

All guidelines underscore the moral legitimacy of priority-setting in the context of this pandemic by including principles relating to procedural justice.^[26] A fair process for allocating scarce resources requires decision-making that is: (i) transparent in how allocation is made and what prioritisation criteria are used; (ii) inclusive of affected stakeholders; (iii) consistent in how it treats persons in the same category; and (iv) accountable to the public.

The National Academies framework is comprehensive. Central to the framework are important substantive aspects based on the risk of acquiring and transmitting infection, prevention of morbidity and mortality, and negative societal impact. A stakeholder engagement process is highlighted and the uncertainty regarding efficacy and safety of COVID-19 vaccines in children, pregnant women, older adults and those who have had natural infection with COVID-19 is flagged. Solidarity and social responsibility are embraced, where countries with vaccine manufacturing capability are expected to provide for their own citizens first, but also allocate a proportion of the supply to other countries.^[24] Uncertainty related to vaccine efficacy and the emergence of new variants could be added to their list.^[27]

All prioritisation frameworks include HCP in phase 1, which reflects global consensus that HCP ought to be first in line to receive the vaccine. This choice rests on multiple premises. Firstly, this group is at increased occupational risk owing to exposure to high viral loads from the volume of patients presenting for treatment during the pandemic. Globally, many HCP have been infected, have died or have survived with physical or psychological sequelae.^[28,29] Given the pre-existing HCP shortage in LMICs, countries such as SA cannot afford to lose any more health staff without risking serious compromise to quality of care in health facilities. By protecting HCP, the health system is indirectly protected. HCP have instrumental value that is both retrospective (based on the patient lives already saved, and

prevention and treatment of illness) and prospective (based on potential lives saved and illness prevented and treated in the future).

It may be argued that many HCP are just doing their jobs, which carry inherent risk, which therefore should attract no additional entitlement to preferential treatment. However, this risk was significantly elevated during the pandemic, and many went beyond their scope of duty by working outside their usual disciplines, working longer hours and sacrificing leave and other benefits, among others. Some returned from retirement, assisting in casualty departments and doing ward rounds in hospitals. On a personal level, some also made sacrifices that transcended regular personal compromises to family time, such as living separately and minimising contact to protect their families due to unanticipated elevated occupational risk. These factors justify priority access to vaccines based on reciprocal obligation, as reciprocity in this context requires protection of those who 'bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others'.^[23]

Likewise, the SA approach^[30] includes a broad framework with three phases (Table 1).

Unique to the SA framework is the inclusion of traditional healers in phase 1. In the SA context, ~60% of the population consult traditional healers before approaching the allopathic health system. There are ~200 000 traditional healers in the country.^[31] It is assumed that those who are registered with the Department of Health (DoH) in terms of the Traditional Health Practitioners Act 2007 (No. 22 of 2007) will be included in the phase 1 roll-out. During the pandemic the DoH issued guidelines for traditional practitioners to assist them with pandemic prevention measures and to promote community education.^[32]

Broad frameworks are often a point of departure in vaccine prioritisation. Phase 1, however, requires further attention with regard to the granularity inherent at several levels.

Ethical considerations in phase 1 vaccine allocation

Fairness in public-private sector allocation

Given the dual healthcare system in SA, phase 1 guidance specifies that both public and private health sectors must be included. Ideally, both sectors ought to be covered completely, based on the number of HCP at risk, especially because the private sector was not at liberty to procure vaccine supplies. However, when supplies are scarce, how should limited vaccines be fairly distributed between these two health sectors?

As a point of departure, one needs to decide whether the prioritisation approach is based on protecting HCP or preserving health systems. If preservation of the latter is the primary goal, a decision must be taken on whether the different health systems are being preserved for the acute COVID-19 wave or for their general health functions. The latter option would justify using dependent populations as a more appropriate metric. Pre-pandemic data indicated that ~20% of the SA population receives healthcare in the private sector, while the public health sector attends to ~80% of the population.^[33] Short- to medium-term preservation of health systems for COVID-19 would, however, only consider the number

of patients treated in each sector for COVID-19. During the peak of the pandemic waves, both healthcare sectors were overwhelmed, especially during the second wave, with patients being cross-referred when necessary.^[34] However, while both sectors used standardised guidelines for intensive care unit (ICU) admission, length of stay differed, with the private sector able to accommodate critical care patients for longer due to more critical care beds being available. However, outpatients also need to be taken into account. Also, many patients who usually use the public health sector were paying to receive treatment for COVID-19 and other diseases in the private sector via general practices.

Given the lack of accurate data on actual numbers of patients treated in the private and public sectors during the pandemic and the lack of equivalence of clinical decision-making given differences in resources available, decision-making around fair rationing of suboptimal vaccine doses between the health sectors is compromised. Therefore, if the underlying rationale in prioritisation is based on protecting HCP and not necessarily health systems, using the number of HCP across both sectors is a reasonable alternative metric that could be used.

Prioritisation based on occupational and personal risk

In addition to the private-public distribution dilemma, occupational risk would justify further prioritisation across all health sectors. Occupational risk would include a spectrum of exposure ranging from extremely high-risk roles (such as performing aerosol-generating procedures, working in critical care environments, having direct contact with high volumes of COVID-19-positive patients for prolonged periods in COVID-19-specific wards, and testing for COVID-19) to high- to moderate-risk roles (such as screening in outpatient departments and general practice, working in the hospital laundry or mortuary, and cleaning) and lower-risk work with no direct patient contact (such as provision of support/administrative services).

Similar to other countries, SA has further stratified occupational risk as follows:

- Category 1a. Those conducting aerosol-generating procedures, e.g. intubation, ventilation, taking COVID-19 specimens
- Category 1b. Those in direct contact with known or suspected COVID-19 patients
- Category 1c. Those in contact with patients (not known/suspected to have COVID-19)
- Category 2. Those not in contact with patients.

This substratification of occupational risk is important. However, when vaccine supplies are extremely limited, personal risk ought to be considered as well.

Key to fair allocation, especially when not all can receive a vaccine in phase 1 of prioritisation frameworks, would be an objective measure of personal and occupational risk within healthcare environments and institutions. Personal risk factors would include age, comorbidities, previous COVID-19 infection and risk to family. Previous COVID-19 infection has become contentious, given the emergence of variants and uncertainty about the duration and quality

Table 1. Phased vaccine rollout plan in South Africa

Phase 1	Frontline healthcare personnel in the public and private health sectors, home care workers and traditional healers
Phase 2	Essential workers (teachers, police, military); those in congregate settings (elderly care homes, shelters and prisons); adults aged >60 years; and those aged >18 years with comorbidities
Phase 3	All other adults aged >18 years not included in phases 1 and 2

of immune protection after natural infection. Given some degree of anticipated post-infection immunity, in situations of extreme vaccine scarcity it is preferable to delay vaccination of those HCP who have had a recent infection (for example, within 2 - 3 weeks of vaccine roll-out). These HCP would be eligible for vaccination later when further vaccine supply becomes available, thereby preserving earliest vaccination for those HCP who could benefit the most.

Contextualised COVID-19 vaccine allocation approaches for HCP (phase 1)

Allocation approach 1

In an ideal setting, a combination of personal and occupational risk factors could be built into an algorithm or matrix (vulnerability v. risk) and administered on a digital platform for all HCP to score themselves. Non-digital scoring is also possible. These scores could assist in prioritising those at highest risk for early vaccine allocation across primary, secondary and tertiary levels of care in the public and private healthcare sectors. Appointments for vaccination could be based on prioritising HCP with the highest scores. This approach may have the indirect benefit of staggering vaccination in specific environments to prevent interruption in healthcare provision in the event of post-vaccine side-effects.

Allocation approach 2

In countries or settings where individual scoring on digital or non-digital platforms is not feasible, a different approach to vaccine allocation may be necessary. In such contexts, one could move from individual risk assessment to environmental risk assessment. Using this approach, environments classified as high risk would result in all personnel working there being eligible for early vaccination. For example, all personnel in ICUs, high-care units, COVID-19 wards, emergency/casualty/outpatient units or emergency response services, testing facilities, vaccinating teams and other high-risk environments in hospitals and clinics would be prioritised. This approach would apply across public and private health settings and could logically be relatively easy to implement. As further vaccine supplies become available, other environments would be progressively included. This approach would favour hospital-based tertiary healthcare in the early stages of vaccine roll-out, which raises questions of equity.

Allocation approach 3

Yet another approach could include allocation to specific categories of HCP based on occupational role, with preference in each category given to patient-facing staff. Such an approach could start with emergency services (including ambulance staff) and progress to nurses, then doctors, or vice versa, depending on risk in different contexts.^[29] Other patient-facing health professionals could then be incrementally included. In some contexts, nurses were found to be at higher risk of contracting infection, while doctors were at higher risk of death.^[29] Based on numbers supplied by institutions, vaccine doses would be dispatched to specific institutions.

Irrespective of which approach is used, a further consideration at the outset requires a plan regarding protecting vaccinating teams, who would require priority immunisation so that they can proceed with vaccination at scale. In some contexts, this may include senior health science students who have been trained to administer vaccines.

Avoiding or minimising vaccine wastage

Important in such an approach would be avoidance of vaccine wastage as an ethical imperative under conditions of vaccine scarcity.

This implies that a vaccine allocation approach ought to start by identifying the number of those who will decline vaccination, for whatever reasons, and procuring only sufficient supplies for those who will accept vaccines. Once vaccines are received at vaccinator sites, it is important to ensure adherence to specific protocols to avoid vaccine wastage. Given that many of the COVID-19 vaccines will be distributed in multidose vials, a level of flexibility may be required at vaccinator sites to avoid wastage. Where vaccines are at risk of expiring or cold-chain disruption, it would be prudent to ensure that vaccine doses are administered to those willing to accept vaccination rather than discarding valuable doses.

Vaccine acceptance among HCP

SA has had a history of reasonable childhood immunisation coverage, reaching ~82% prior to the pandemic.^[35] However, a recent Ipsos survey commissioned by the World Economic Forum has demonstrated that only 64% of South Africans would accept a COVID-19 vaccine.^[34] While the validity of generalising these findings is unclear, vaccine hesitancy is growing in prominence in Africa.^[36] Globally, vaccine acceptance rates among HCP have been estimated to be ~70 - 80%,^[37] while estimates in SA are ~67%.^[38] Vaccine acceptance is dynamic and context-specific and is likely to evolve as vaccine roll-out progresses. Health workers, in particular, are regarded as role models for improving population uptake.

Mandatory vaccination in health environments

Currently, given the fact that vaccine access is part of an implementation trial, participation remains completely voluntary. Even if the Johnson & Johnson vaccine is registered under section 21 regulations (equivalent to Emergency Use Authorisation in other countries) and non-research-related roll-out commences, participation will still be voluntary. Mandatory vaccination will only be an option when a COVID-19 vaccine has full registration with the South African Health Products Regulatory Authority.

Given that HCP could decline COVID-19 vaccination for a number of reasons, there would be implications in the healthcare setting both for patients and staff. Ethical and professional obligations highlight patient safety, which is fundamental to the foundational principle of healthcare ethics: first do no harm or *primum non nocere*. Likewise, reducing risk to colleagues in the healthcare environment would be regarded as an ethical and legal obligation. The SA Constitution (1996) in section 23 indicates that 'Everyone has a right to fair labour practices'.^[39] This includes employers and employees. Consequently, employers would need to institute policies to ensure a safe working environment for all. Although the preferable approach would include encouragement and counselling of all staff regarding the benefits of vaccination, there would be legal and human rights considerations that must be taken into account in the context of public interest, the Disaster Management Act (No. 57 of 2002)^[40] and the National Health Act (No. 61 of 2003).^[41] Competing entitlements in the Bill of Rights can be resolved through appropriate application of section 36 of the Constitution that provides for conditions under which limitation of rights in the interests of the public good may occur.

Conclusions

Widespread inadequacies in global health governance have contributed to disproportionate vaccine distribution, forcing LMICs, including SA, to make difficult prioritisation decisions. Prioritising allocation of extremely limited vaccine supplies raises all the quintessential challenges of distributive justice. A legitimate COVID-19 vaccine

prioritisation plan must be built on fundamental ethical principles. In SA, justice in phase 1 distribution requires that all health personnel at risk in the public and private sectors, delivering care at primary, secondary and tertiary levels, are treated fairly and consistently. Operational and ethical challenges are inextricably intertwined, and in LMICs, compelling arguments exist for contextualising prioritisation approaches. Given the high emotions, concerns and anxieties seen during and after the second wave of COVID-19 in SA, prioritisation is necessary but raises the risk of divisions and mistrust at multiple levels – within the healthcare community in general as well as in the public and private health sectors. In the context of extreme vaccine scarcity, transparent, rational allocation approaches are important to legitimise phase 1 roll-out and improve vaccine uptake. Ultimately, reforms in global health governance are urgently needed to improve vaccine access in LMICs.

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