

ANNEXARE A

A FRAMEWORK FOR RATIONAL COVID-19 VACCINE ALLOCATION IN SOUTH AFRICA

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Introduction

Efficacy results from the Phase 3 Covid-19 vaccine trials are becoming available and more are expected in late 2020 / early 2021 and beyond. To date five vaccine trials have reported preliminary efficacy data ranging from 62–95%. In addition, the data suggest that these vaccines have no significant adverse events attributed to them.

Assuming that one or more of these vaccines are approved by SAHPRA, it is unlikely that there will be sufficient vaccines available for use beyond specific high-risk groups in the country before the end of the second quarter of 2021 and even then it is likely that only limited quantities of vaccine will be available. Vaccine allocation will thus have to be based on a framework of prioritisation and need. The principles underpinning this framework emphasises an evidence based approach and an ethical and moral perspective, including an African indigenous values context.

The framework will serve as a guide and will have to be adapted as new scientific information becomes available e.g. information about specific characteristics of available vaccine/s, the benefit-risk assessment for different population sub-groups, the amount and pace of vaccine supply, the epidemiology at the time of vaccine introduction, clinical management, public health response, and economic and social impact of the pandemic.

African Indigenous Values and Voices in the Context of COVID-19 Vaccines

It is critical that African voices add not only to the debate but also to influencing the implementation of immunization equity. In particular, the vulnerable and disadvantaged in remote and rural areas and urban slums should not be left behind. Therefore, it is important to consider African indigenous values and draw from the principles of Ubuntu.

The importance of community is clearly indicated by Mbiti when he states “I am because we are, we are therefore I am.” (Mbiti J. Introduction to African religion and philosophy. Oxford/Portsmouth: Heinemann Educational Books. 1991.) In terms of the Nguni and Sotho/Tswana sayings, *umuntu ngumuntu ngabantu* and *motho ke motho ka batho*, a human being is a human being because of other human beings. Hence, one cannot function in isolation and independently participate in a community of other people. Inter-dependence and inter-relatedness is at the heart of these values. In the context of access to COVID-19 vaccines and also addressing vaccine hesitancy, this could translate to decision-making towards the greater good for all while protecting vulnerable individuals and groups from exploitation and other forms of harms and wrongs.

Ubuntu leads to an appreciation of the survival of the community as an important ethical consideration. Therefore, the Ubuntu standard, which reflects living in solidarity with other people and humanness that is grounded in social life, comprises the fundamental basis of an African approach towards ethics. This has particular bearing *inter alia* in the vaccines discussion and decision-making.

Mutually respectful discussion and dialogue in the community as seen with the indigenous African tradition of *lekgotla* could be likened to meaningful community engagement in vaccines discussions. Members of the community are to be given a chance to voice their opinion towards reaching a consensus and the decisions generated from the process would be socially and communally negotiated.

Framework for prioritization of fair allocation of COVID-19 vaccines

1. Fair Allocation guided by African indigenous values

a. Affirming the humanity of others: Allocation decisions must be for societal benefit and promote common good while respecting human dignity. Every person has equal dignity, worth, and value, hence allocation decisions must be non-discriminatory. Characteristics such as ethnicity, nationality, gender, sexual orientation, race and religion are not to play a role in allocation decisions. People are to be treated fairly and equally. Allocation decisions are to be impartial and in accordance with fair criteria.

b. Survival of the community: Allocation decisions are to be based on the best available evidence. In addition, essential service workers and those that contribute towards preventing and treating disease could be considered as essential for survival of the communities. Furthermore, those at greatest risk of severe illness and death could be included in priority groups. In this way, benefits will be maximized and the risks of severe morbidity and mortality caused by transmission due to SARS-CoV-2 reduced, and hence the community will survive.

c. Social Solidarity: Allocation decisions are to take into consideration the bonds unifying communities, interdependence, attachment to or interest in others and their concerns and the significant social, economic and personal disruptions and hardships experienced. During pandemics inequities may increase among those who are already socially vulnerable and/or new vulnerabilities may emerge for the first time among certain communities or individuals

d. Meaningful community engagement: Allocation decisions must be trusted and leaders at all levels must be at the forefront of communication to their constituencies. Community engagement allows for authenticity, trust, and ownership of the allocation decisions. Community involvement will be required for both allocation decision-making and addressing vaccine hesitancy. Faced with the challenge of maintaining public trust while simultaneously stemming the pandemic through various control measures, decision-makers need to be trustworthy by ensuring early engagement with stakeholders and that decision-making processes are ethical, transparent and actively communicated. For this, integrity, which reflects the need to act with honesty, reliability, and fairness, and a willingness to be held accountable to explain one's actions, is critical.

The framework proposed for SA is also in accordance with the principles articulated by the WHO SAGE (https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1)

- Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.
- Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration
- Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic
- Honour obligations of reciprocity to those individuals and groups within the country who bear substantial additional risks and burdens of COVID-19 response for the benefit of society
- Make decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties

2. Identification of risk groups

The allocation of vaccines to recipients will be guided by the principles outlined above and will be dependent on several factors including the efficacy of a vaccine for a specific population and on the doses available. It is unlikely that vaccines will be available to all who require them, and some sort of prioritization system will have to be applied.

Based on the principles of affirming the humanity of others, survival of the community and social solidarity and through meaningful community engagement, prioritization should be to those:

- (a) in roles considered to be essential for societal functioning;
- (b) most at risk of infection and serious outcomes, for example, those in overcrowded living arrangements, multigenerational homes, with comorbid conditions; and
- (c) most at risk of transmitting SARS-CoV-2 to others.

Individuals in the roles considered to be essential for societal functioning include those whose absence from their societal roles or work puts others and the society at risk of loss of needed goods and services should they become infected (e.g., doctors, nurses, other health care providers, first responders, workers employed in the food supply system, transportation workers, teachers, etc.).

Those most at risk of serious outcomes and most at risk of transmitting the virus would not only benefit for themselves, but if vaccinated – would prevent the health system and other essential services from becoming overwhelmed.

A phased approach is therefore recommended when limited supplies of vaccines become available. Prioritization of groups and individual groups will be developed.

- *Health Care workers*
Health professionals and general health workers at high risk of infection, care home workers and traditional healers
- *Persons with co-morbidities and at risk for morbidity and mortality*
These include persons 60 years and older, persons living with HIV, tuberculosis, diabetics, chronic lung disease, cardiovascular disease, renal disease, obesity etc
- *Persons in congregate or overcrowded settings*
This includes persons in prison, detention centres, shelters and care homes. In addition, people working in the hospitality and tourism industry, and educational institutions are also at risk.
- *Essential workers*
This group includes police officers, miners and workers in the security, retail food, funeral, banking and essential municipal and home affairs, border control and port health services.

Note that the safety and efficacy of vaccines in children and pregnant women are not known and will probably be the subject of future trials and thus the framework will be revised if necessary.

The only published peer reviewed data are from the Western Cape Province (Boulle et al; *Clinical Infectious diseases* 2020) <<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1198/5899044>>

In this population cohort of 3.5 million public sector patients in South Africa, increased COVID-19 mortality (n=625) was associated with HIV, previous and current tuberculosis as well as older age, male

sex, diabetes, hypertension and chronic kidney disease. Such data as well as other data from South Africa will be used to determine the priority groups for the country. The details of this step will be provided later with the list of groups in order of priority pending the availability of vaccine doses e.g. 3, 10 or 20% of the total SA population and at varying levels of vaccine acceptance and vaccine efficacy. In addition, the stage of the epidemic will also influence how vaccines will be prioritized e.g ongoing national community transmission, sporadic cases or clusters of cases, no cases. A draft of such a proposal for allocation is appended below.

3. Programmatic implications

Standard operating procedures are currently being developed to ensure that the vaccine rollout programme is effectively managed and implemented. These include:

- a. **Development of vaccine guidelines:** This needs to be completed for each vaccine and provide guidance around eligibility, application, dosage and storage.
- b. **Vaccine supply management:** This includes the ordering and distribution of and the safe storage and handling of vaccines to maintain potency.
- c. **Health care worker training:** Staff will be trained on how to counsel recipients on the benefits and risks of the vaccines and delivery of the vaccines.
- d. **Adverse events following immunization surveillance:** This is a standard component of the current national Expanded programme on Immunization (EPI) and is being adapted for COVID-19 vaccine rollout as well. In addition, SAHPRA might specify certain pharmacovigilance requirements for specific vaccines.
- e. **Monitoring and evaluation (M&E):** The EPI M&E tools currently in use is being adapted for the COVID-19 vaccine rollout. This should include registration and tracing mechanisms, especially in the event of the requirement for more than one dose per person.
- f. **Development of vaccination certification tools:** This should be aligned to International Health Regulations (2005) if there are any requirements. These can be paper-based or electronic.
- g. **Development of a strategy to reach identified target groups:** As the target groups vary in terms of where they are located strategies on how to reach them needs to be identified.

4. Communication and social mobilisation

There is an urgent need to put in place a multi-sectoral communications strategy to support the work of government and civil society to ensure that the investment made into COVID-19 related scientific research including vaccine research and the eventual rollout is not jeopardized but protected through the provision of scientifically sound, evidence-based communications and a critical mass of community support.

The development of a Covid-19 vaccine communication strategy should be a joint effort created by government agencies and civil society and will ensure that all stakeholders have clear guidelines within which to communicate scientifically sound, evidence-based messages to the public. The strategy should take into account global research, whilst articulating where appropriate the need for South African research to explore the national context.

The issues around science denialism, anti-vax sentiments and vaccine hesitancy in South Africa should be addressed through an understanding of the main drivers of the hesitancy and the development of effective local responses.

The COVID-19 vaccine communication strategy should be informed by the communication strategies developed for other South African Health programmes (HIV, TB, Diabetes, etc), but it is of importance that the impact of the COVID-19 pandemic on the national psyche should also be taken into account. Engagement with representatives of community and professional groups affected by the COVID pandemic will be essential.

The communication strategy should include the use of online social media platforms (WhatsApp, Facebook, Twitter, etc), as well as traditional media (print, community, radio etc.) as critical platforms for engagements, and should take into account the needs of different target audiences.

Draft proposal for the distribution of vaccines to priority groups given a 3, 10 or 20% vaccine allocation based on population of 60m with a 60 or 70% vaccine coverage / acceptance rate per group.

Priority group	Number	70% accept vaccination Option A	60% accept vaccination Option B	Proportion in groups that will be covered with available doses. Option A refers to 70% vaccine acceptance and Option B refers to 60% vaccine acceptance rate						
				3% - 1.8m Option A	3% - 1.8m Option B	10% - 6m(a) Option A	10% - 6m(b) Option B	10% - 6m (a) Option A	10% - 6m (b) Option B	20% - 12m Option A or B
		N	N							
Health workers	1 250 000	870 000	750 000	100%	100%	100%	100%	100%	100%	100%**
Essential workers	2 500 000	1 750 000	1 500 000	57 %	70%					
Persons in congregate settings	1 100 000	770 000	660 000							
Subtotal	4 850 000	3 395 000	2 910 000							
At risk population										
60 yrs and older	5 000 000	3 500 000	3 000 000			75%	100%	29%	40%	
Co-morbidity*	8 000 000	5 600 000	4 800 000							
Sub total	13 000 000	9 100 0000	7 800 000							
Total	17 850 000	12 495 000	10 710 000							

*Co-morbidity numbers are estimate given that many in the other groups (especially the over 60 year olds) will also have co-morbidities.

** The 20% vaccine allocation option here will allow for an additional 1.3m persons to be vaccinated if vaccine coverage is only 60%