

Access to COVID-19 vaccines in South Africa



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Disclaimer

- I am a member of the South African Ministerial Advisory Committee (MAXC) on COVID-19, the National Essential Medicines List Committee (NEMLC), the NEMLC COVID-19 sub-committee, and the NDOH/NICD COVID-19 Clinical Guidelines Committee.
- I chair the South African Health Products Regulatory Authority (SAHPRA) Names and Scheduling advisory committee and serve on the Legal advisory committee and Pharmacovigilance advisory committee.
- I am speaking here as an independent academic, and not on behalf of the MAC, NEMLC, NDOH or SAHPRA.



Outline

- The COVID-19 pandemic in South Africa
- Emergence of a new variant of concern (called either 501Y.V2 or B.1.351)
- Excess deaths
- Vaccine procurement options
- Local vaccine efficacy data
- A national plan – why first an implementation study, then a rollout?

https://sacoronavirus.co.za/

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COVID-19
Online Resource & News Portal
SAcoronavirus.co.za



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COVID Alert SA app



9,986,203

Tests Conducted



1,551,964

Positive Cases Identified



1,477,363

Recoveries



52,987

Deaths

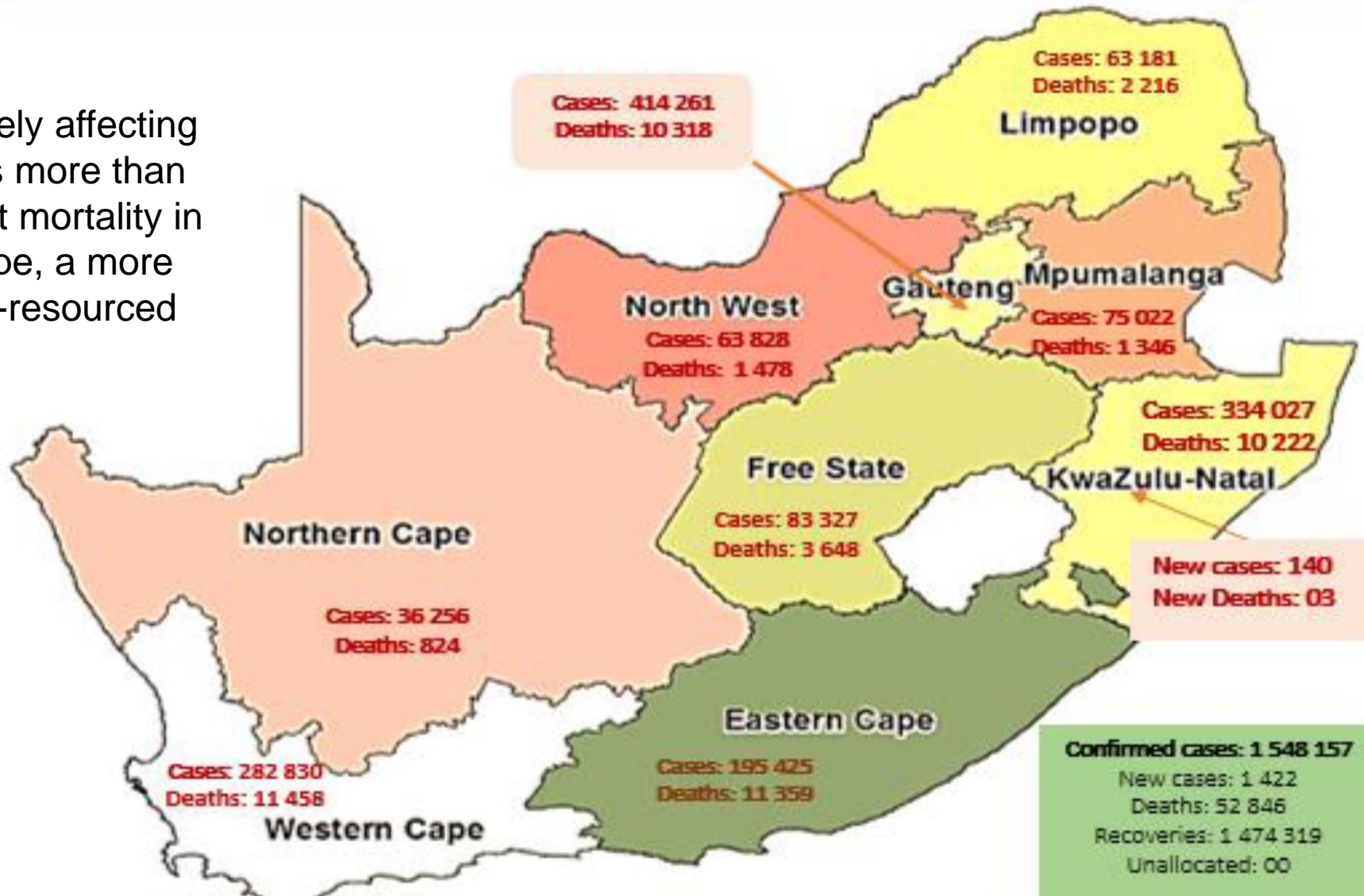


269,102

Vaccines Administered

South Africa: 31 March 2021

Disproportionately affecting some provinces more than others – highest mortality in the Eastern Cape, a more rural and under-resourced province



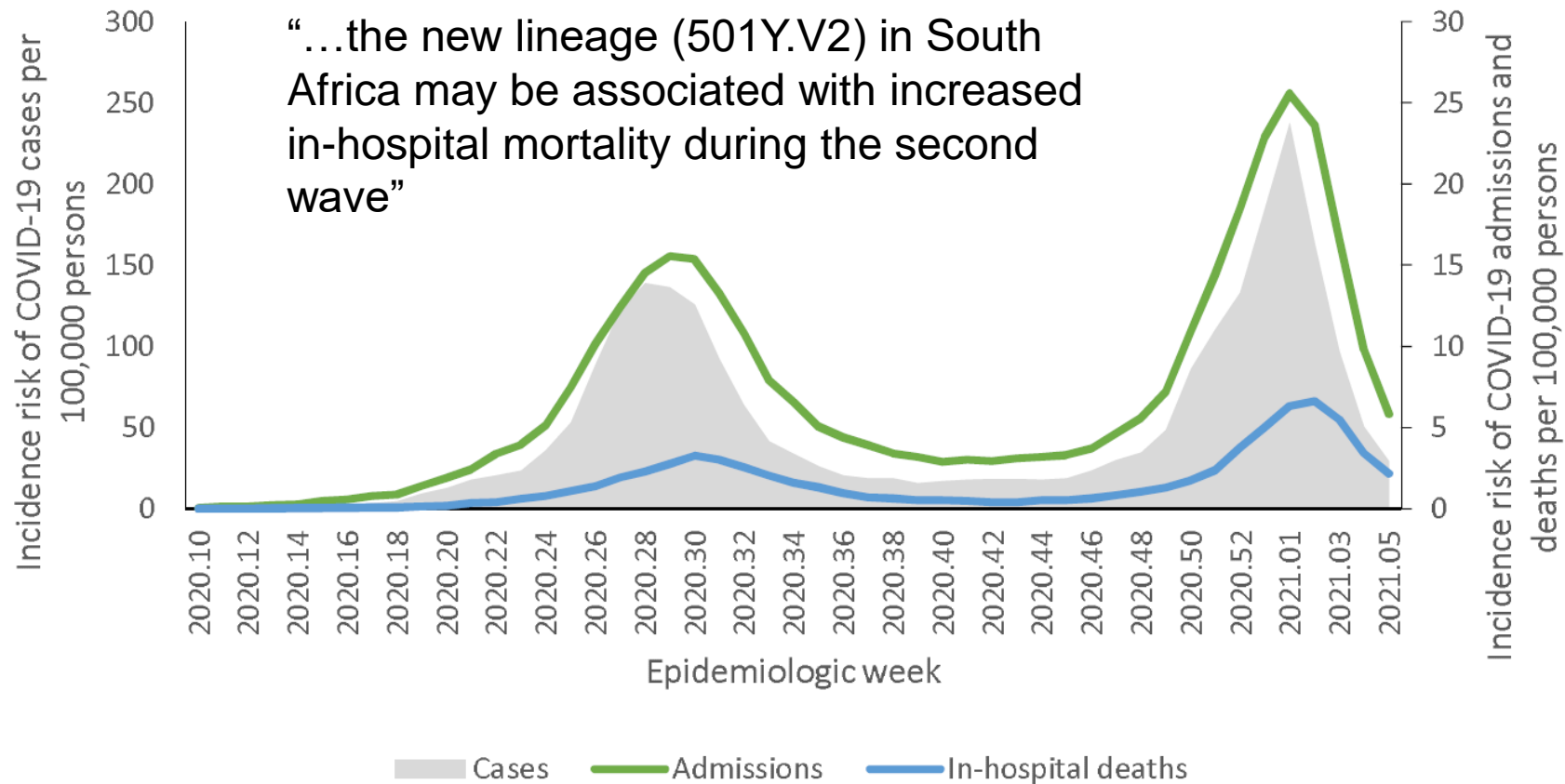


Figure 2. Incidence of reported SARS-Cov-2 cases, COVID-19 admissions and in-hospital deaths by epidemiologic week of diagnosis, South Africa, 5 March 2020-6 February 2021.

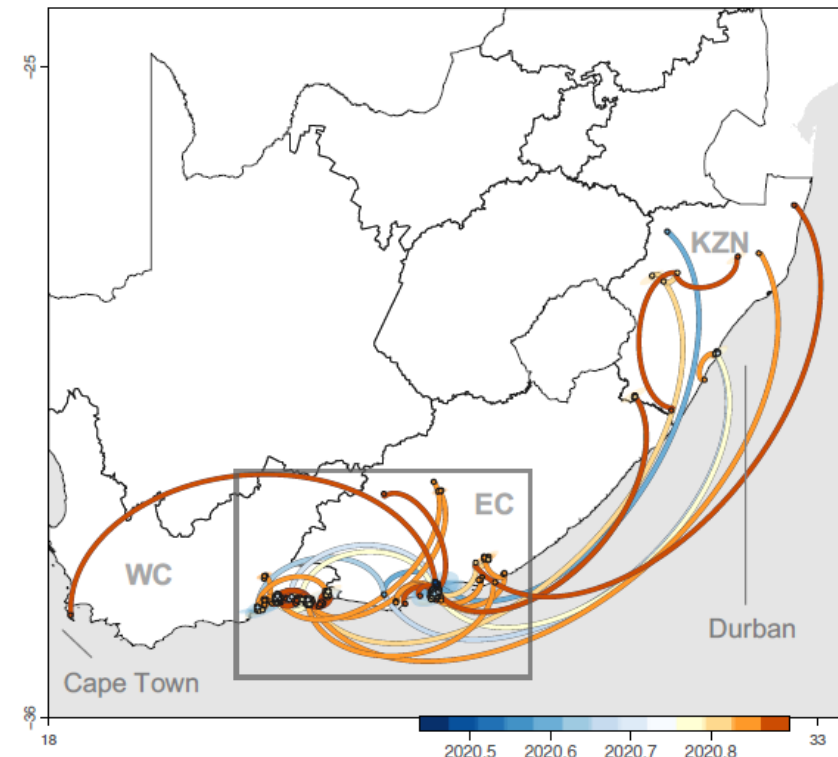
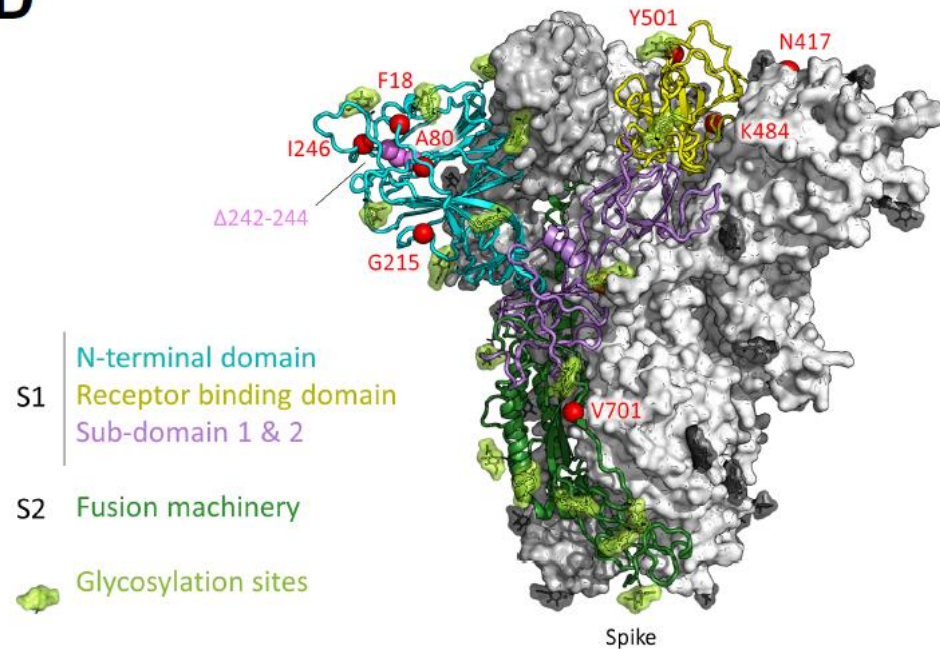
Jassat W *et al.* medRxiv 2021

<https://www.medrxiv.org/content/10.1101/2021.03.09.21253184v1.full.pdf>

Tegally H *et al.* Emergence and rapid spread of a new severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) lineage with multiple spike mutations in South Africa. medRxiv 2020

“...eight lineage-defining mutations in the spike protein, including three at important residues in the receptor-binding domain (K417N, E484K and N501Y)”

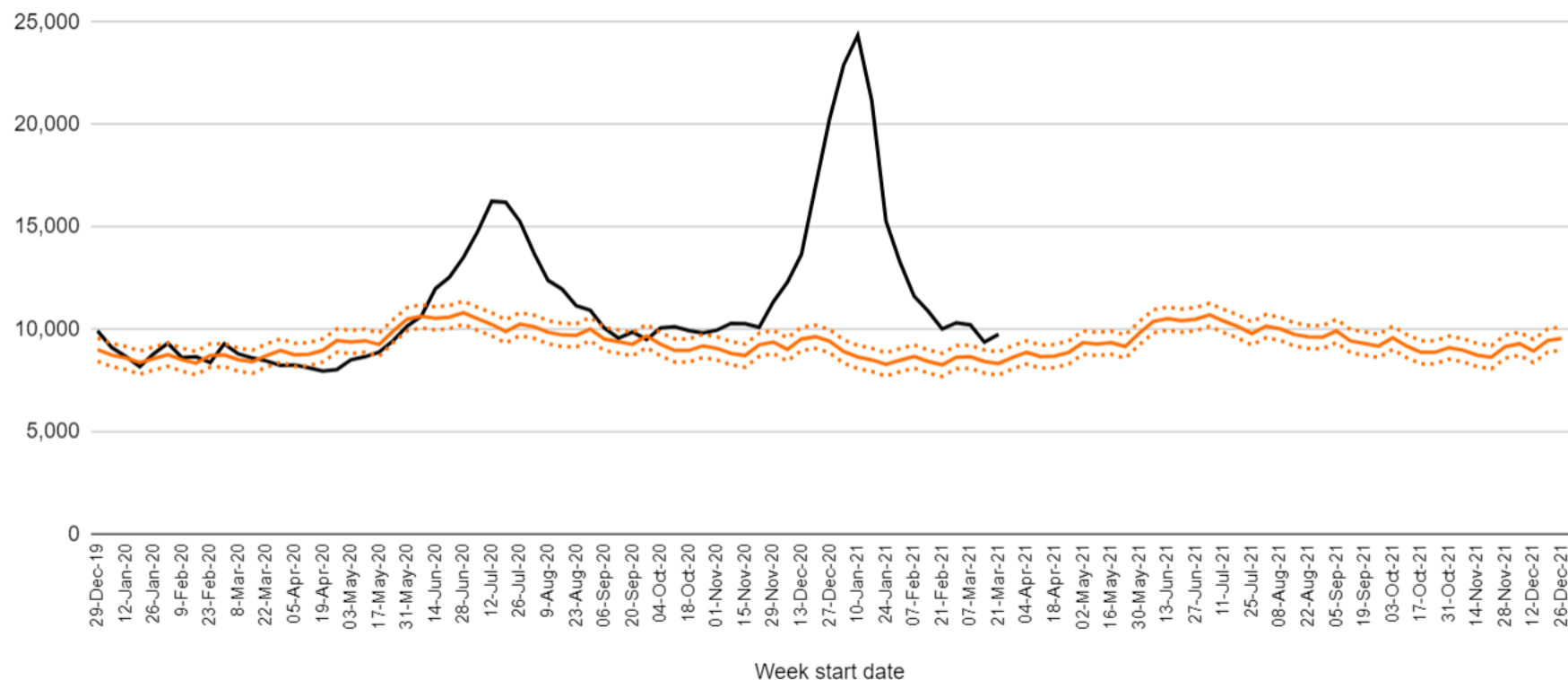
D



<https://www.medrxiv.org/content/10.1101/2020.12.21.20248640v1.full.pdf>

The concept of “excess deaths”

South Africa Weekly Deaths from All Causes 1+ years : 29 Dec 2019 - 27 Mar 2021



<https://www.samrc.ac.za/reports/report-weekly-deaths-south-africa>

SAHPRA –national medicines regulatory authority



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PRESS RELEASE

SAHPRA and the SputnikV Vaccine Update

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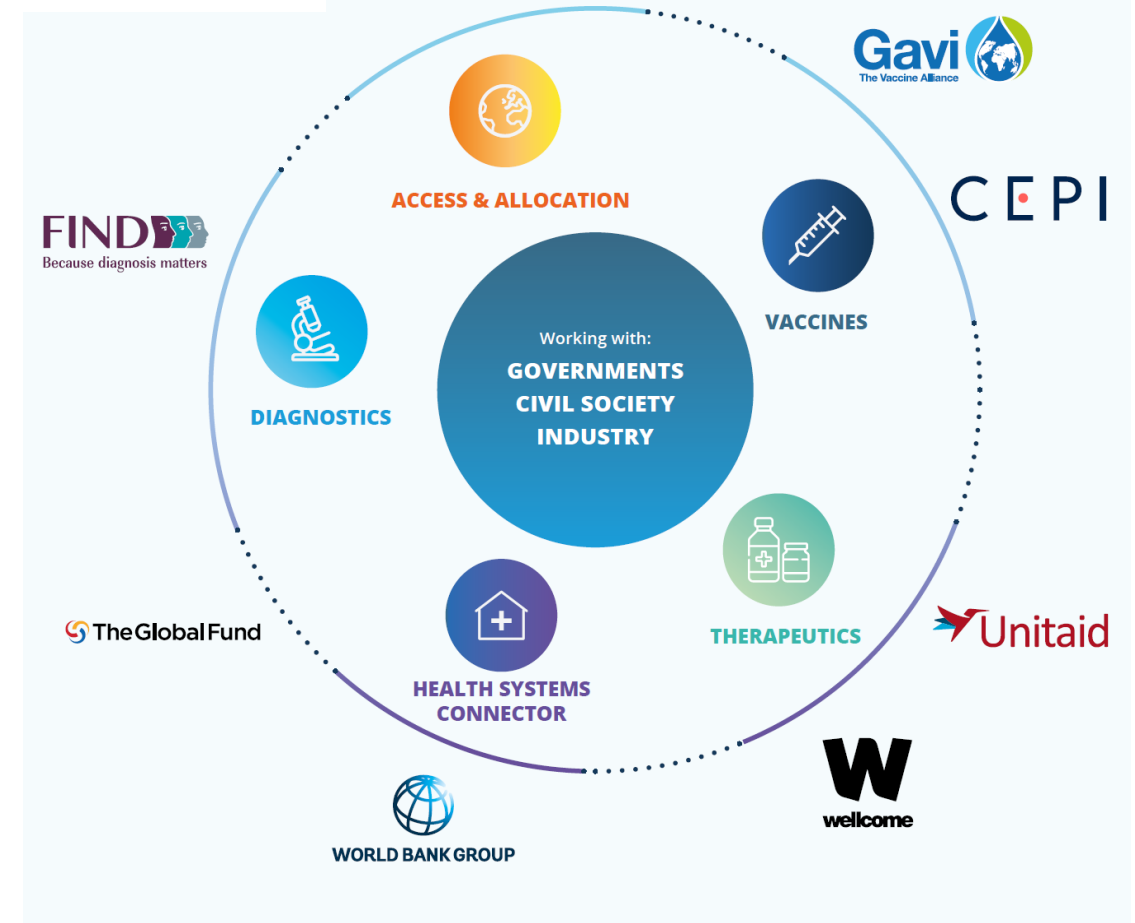
Human medicines | Veterinary medicines | Medical devices (inclg IVDs) | Clinical trials | Radionuclides

Vaccine procurement options – mid-2020

Theoretically

- COVAX (the vaccine pillar of ACT-A)
- African Union (AVATT)
- BRICS
- Bilateral procurement
- Local production (under licence)

ACTaccelerator
ACCESS TO COVID-19 TOOLS



Candidates in Clinical Phases I-III

Whole virus

8

Protein subunit

13

Nucleic

14

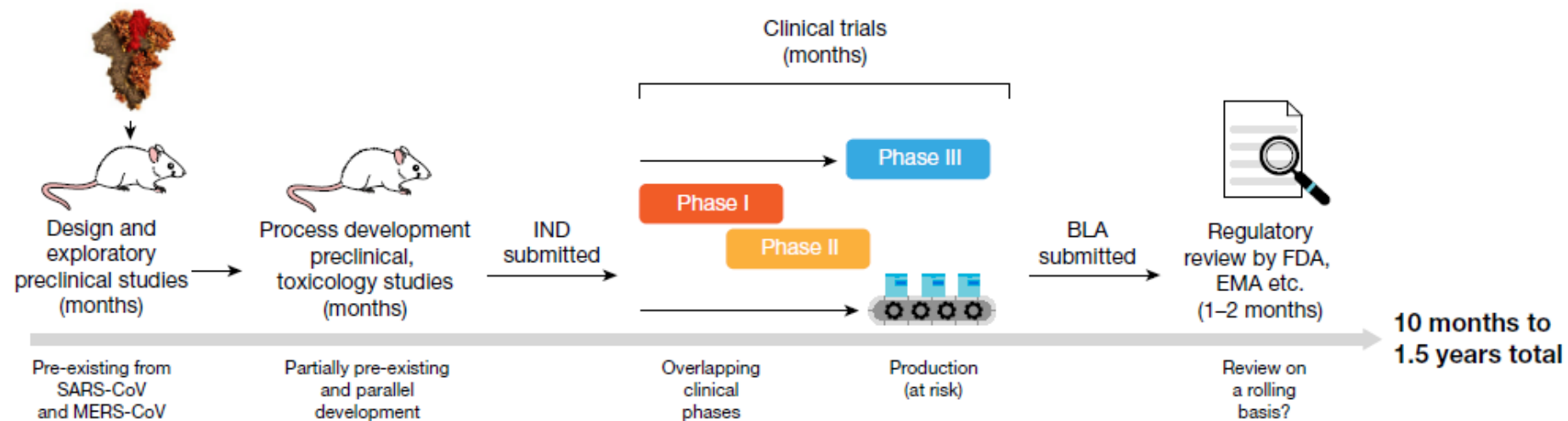
Viral vector

16

As of 15/12/2020

Source: [WHO: Draft landscape of COVID-19 candidate vaccines](#) • Created with [Datawrapper](#)

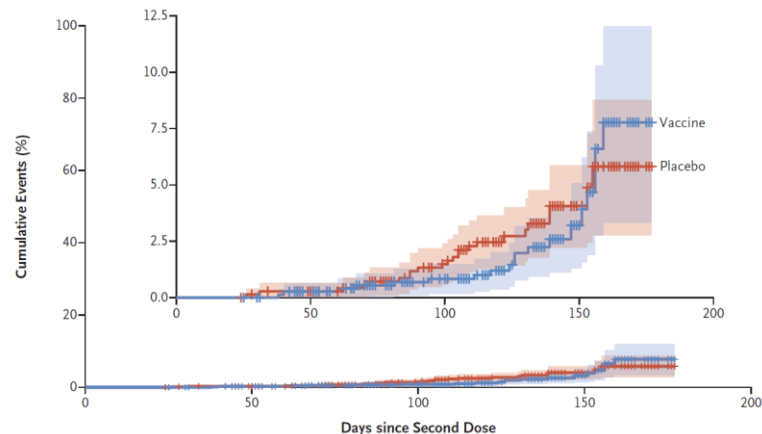
SARS-CoV-2 vaccine development



ORIGINAL ARTICLE

Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant

S.A. Madhi, V. Baillie, C.L. Cutland, M. Voysey, A.L. Koen, L. Fairlie, S.D. Padayachee, K. Dheda, S.L. Barnabas, Q.E. Bhorat, C. Briner, G. Kwatra, K. Ahmed, P. Aley, S. Bhikha, J.N. Bhiman, A.'E. Bhorat, J. du Plessis, A. Esmail, M. Groenewald, E. Horne, S.-H. Hwa, A. Jose, T. Lambe, M. Laubscher, M. Malahleha, M. Masenya, M. Masilela, S. McKenzie, K. Molapo, A. Moultrie, S. Oelofse, F. Patel, S. Pillay, S. Rhead, H. Rodell, L. Rossouw, C. Taoushanis, H. Tegally, A. Thombrayil, S. van Eck, C.K. Wibmer, N.M. Durham, E.J. Kelly, T.L. Villafana, S. Gilbert, A.J. Pollard, T. de Oliveira, P.L. Moore, A. Sigal, and A. Izu, for the NGS-SA Group Wits-VIDA COVID Group*



n = 2026 HIV-negative adults (median age, 30 years)
Vaccine efficacy was 10.4% (95% CI: -76.8 to 54.8).

1.5 million doses of the Oxford/AZ vaccine
procured from Serum Institute of India



<https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>



Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial

Jan 28, 2021 at 4:05 PM EST

South Africa Results: Approximately 90% of COVID-19 cases attributed to South Africa escape variant

In the South Africa Phase 2b clinical trial, 60% efficacy (95% CI: 19.9 – 80.1) for the prevention of mild, moderate and severe COVID-19 disease was observed in the 94% of the study population that was HIV-negative. Twenty-nine cases were observed in the placebo group and 15 in the vaccine group. One severe case occurred in the placebo group and all other cases were mild or moderate. The clinical trial also achieved its primary efficacy endpoint in the overall trial population, including HIV-positive and HIV-negative subjects (efficacy of 49.4%; 95% CI: 6.1 – 72.8).

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Sisonke study

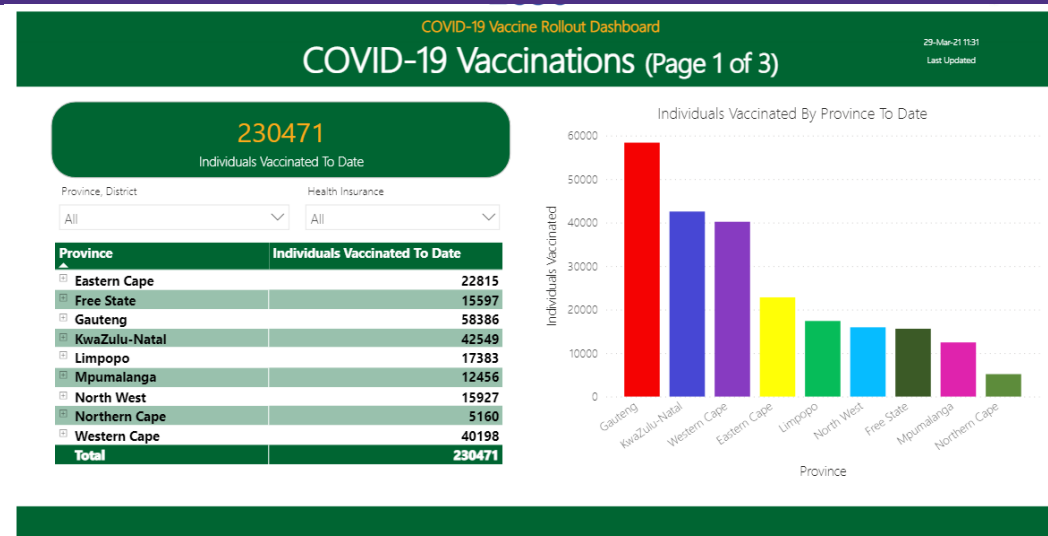
a pragmatic, real world Phase 3b clinical trial of the single-dose COVID-19 vaccine candidate among frontline healthcare workers in South Africa

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500 000 doses of the Janssen (J&J) vaccine obtained from clinical trial stock

70% allocated to the public sector; 30% to the private sector

Previously showed 64% vaccine efficacy in SA study (82% against severe disease)



One person, one dose: Hundreds of millions of J&J Covid-19 vaccines to be produced in the Eastern Cape

By Estelle Ellis • 31 March 2021





Current announced procurement

- Janssen (J&J)
 - 11 million doses, filled by Aspen Pharmacare confirmed
 - 20 million doses under negotiation
- Pfizer
 - 20 million doses confirmed
- COVAX
 - Can only offer AstraZeneca and Novavax at present
- Others
 - Ongoing discussions for Sputnik V, Sinovac and Sinopharm

Timelines (at present)

ROLL-OUT PHASES

	Phase I	Phase II		Phase III
	Feb 17 – May 17	May 17 – July 31	Aug – Oct 31	Nov – Feb 28
PEOPLE	608,295	5,449,980	12,900,160	22,600,640
TARGET POPULATION	Health Care Workers	Over-60s <ul style="list-style-type: none"> Workers through OHS stream People in congregate settings General population through Community Stream 	Over-40s <ul style="list-style-type: none"> Workers through OHS stream People in congregate settings General population through Community stream <p>Those with co-morbidities Workers in high risk settings</p>	All other residents

So, where are we now?

- Slow, delayed, stop-start ... complicated by the emergent variant (and other factors)
- Still to put a no-fault compensation scheme in place
- Poised for take-off?

