



CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

Newsletter

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CAPRISA participates in the ENSEMBLE COVID-19 vaccine trial and the Sisonke vaccine roll-out study

In this Issue

Our feature story this month focuses on the historic roll-out of the Sisonke vaccine roll-out study at public hospitals in KwaZulu-Natal led by CAPRISA, the provincial Department of Health and the SAMRC.

On page 2, we congratulate founding CAPRISA member, Prof Lynn Morris on her appointment as Deputy Vice-Chancellor Research at Wits and feature a commentary editorial on the impact of Covid-19 on TB.

We congratulate Prof Quarraisha Abdool Karim on her appointment on ESCAD and as a recipient of the Royal Society of South Africa's 2020 John F.W. Herschel Medal award on page 3. We also report on the appointments of three CAPRISA scientists on the ACTG Coordinating committee network groups.

On page 4, we highlight the recent results from the CORTIS study on a blood biomarker of TB and the study assessing the impact of Covid-19 on HIV in primary health care clinics.



(L –R) Research Pharmacists, Ms Anokhee Leela & Dr Tanuja Gengiah; Research Clinician Dr Nivashnee Naicker; Research Pharmacists Ms Atika Moosa & Ms Maxeen Murugan.

Below (L-R): Dr Disebo Makhaza and Dr Nigel Garrett

On Wednesday 17th February, the Johnson & Johnson (JnJ) vaccines arrived at the CAPRISA eThekweni Research clinic and marked the first phase of the Covid-19 Vaccine rollout to health workers in South Africa.

This is part of the Sisonke ('Together') Early Access Programme, an open-label, single-arm phase 3b vaccine implementation study for up to 500,000 health care workers in South Africa. 'This study aims to provide access to an effective and safe single dose vaccine, while continuing to monitor the effectiveness of the vaccine in preventing severe Covid-19, hospitalizations and deaths', explained CAPRISA's Dr Nigel Garrett (National Co-PI, Sisonke study).

CAPRISA's Head of Pharmacy, Dr Tanuja Gengiah, is leading the pharmacy team which is preparing up to 1000 vaccine doses per day at the Inkosi Albert Luthuli Central Hospital and the Prince Mshiyeni Memorial Hospitals in KwaZulu-Natal, in collaboration with the South African Medical Research Council team.

The safety and efficacy of the vaccine was assessed in the international Phase 3 ENSEMBLE trial, which is being conducted in South Africa, Latin America and USA



with more than 43,000 participants, and included the CAPRISA eThekweni Research clinic (Site PI, Dr Nivashnee Naicker) and Vulindlela Research clinic (Site PI, Dr Disebo Makhaza).

South Africa contributed around 7,000 participants to the trial between October 2020 and February 2021, including participants who were exposed to the 501Y.V2 variant. Naicker said that it was an 'extraordinary effort by the ENSEMBLE team undertaking a Phase 3 trial in a very short timeframe with novel systems.'

The JnJ vaccine, tested in ENSEMBLE and used in the Sisonke programme, was found to provide 57% protection against moderate-severe disease, 85% protection against severe disease and 100% protection against death.

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The impact of Covid-19 on tuberculosis

The Covid-19 pandemic has superseded every other health issue globally, with approximately 4 million incident cases and 70,000 deaths currently reported each week.

Cumulatively, the number of cases has exceeded 111 million and 2.5 million deaths globally since the start of the pandemic, resulting in a severe impact on existing public health issues. In an editorial commentary published in the *Clinical Infectious Diseases* journal in September 2020, CAPRISA scientists reflect on the interactions between the Covid-19 pandemic and tuberculosis (TB), a leading cause of death from a single infectious disease globally.

The inevitable shift in healthcare focus has resulted in marked decrease in TB case notifications rates in early 2020, compared to the same period over the last 2-5 years. TB notification rates have decreased by 78% in India; 52.0% in Jiangsu, China; 47.8% in Shanghai, China; 43% in Uganda; 34% in Nigeria; 33% in South Africa; 33% in Japan; 24% in South

Korea; and 20% in Taiwan during the Covid-19 pandemic. Declines in TB detection, resulting from limited access to healthcare services could potentially result in 6.3 million cases of TB and 1.4 million deaths over the next 5 years.

This translates to a 5- to 8-year setback in TB control, receding even further away from the cardinal objective of TB elimination by 2035 set out by the World Health Organisation End TB strategy.

In order to mitigate the consequences of Covid-19 on TB and preserve the gains made over the last decade in the fight against TB, it is important for control programs to strengthen TB-control strategies and prioritize delivery of TB services.

For further reading

Dookie N, et al. *Tuberculosis Elimination in the Era of COVID-19: A Moving Target. Clin Infect Dis.* 2020 Sep. <https://pubmed.ncbi.nlm.nih.gov/32927477/>

Prof Lynn Morris appointed to lead research at the University of Witwatersrand



Lynn Morris, a founding member of CAPRISA, has been appointed as the Deputy Vice Chancellor of Research and Innovation at the University of the Witwatersrand. This follows on from her 3-year term as the Interim Executive Director of the National Institute for Communicable Diseases (NICD), where she led the institute through 2 major outbreaks caused by Listeria and Covid-19.

She will take up her new position from 1 April 2021 but will maintain her

links with the NICD/NHLS and CAPRISA and plans to stay research-active. "There are a number of projects that I want to see to fruition and it is wonderful that I can continue to stay engaged" she says. "But I am also very excited about joining Wits which has been at the forefront of dealing with multiple aspects of the Covid-19 pandemic". Lynn has a long history with Wits; she was an undergraduate student in the Faculty of Science over 40 years ago and is currently a Research Professor in the Faculty of Health Sciences.

International Day of Women and Girls in Science

CAPRISA Scientists Dr Lenine Liebenberg (Mucosal Immunology) - right in the photograph and Prof Quarraisha Abdool Karim (Associate Scientific Director) featured in an online campaign to recognise the International Day of Women and Girls in Science on 11 February. The piece was hosted on Instagram by Research2Reality, a science communication network

partnering with the Gairdner Foundation, and showcased the achievements of women in science from around the world. According to Dr Liebenberg, "by highlighting the achievements of women in science we dispel harmful, negative stereotypes. I am pleased to participate in this fantastic initiative to inspire and empower new generations of women in science."





Former President Motlanthe appoints Quarraisha Abdool Karim to serve on the ESACD



Former President of South Africa the honourable Kgalema Motlanthe has invited Professor Quarraisha Abdool Karim, Associate Scientific Director of CAPRISA, to serve on the Eastern and Southern Africa Commission on Drugs (ESACD), a high-level regional advocacy mechanism that aims to

bring to the regional framework an informed, science-based discussion about humane and effective drug policies.

He said, Abdool Karim's 'experience and knowledge can bring significant contributions for better drug control in our region... and recognised her commitment to the development of science-based health policy and advancing the rights of those living with HIV/ AIDS'.

Mr Motlanthe, the founding chair of ESACD and member of the Global Commission on Drug Policy, established a regional commission in line with other regional efforts led by members of the Global Commission. This followed an analysis of current drug policies in the region - their processes, implementation and outcomes and a call by civil society, experts and communities.

Honoured for her 'pioneering work'

Professor Quarraisha Abdool Karim is a recipient of the **Royal Society of South Africa's 2020 John F.W. Herschel Medal**, awarded to 'those who are outstanding in either a field of research that straddles disciplines or in more than one unrelated field'. The Society acknowledged Abdool Karim is 'widely recognised for her scientific contributions to HIV prevention in women in Africa'.



Stellenbosch University (SU) bestowed an honorary doctorate on Prof Quarraisha Abdool Karim at SU's December graduation ceremony, 'for her pioneering research in the field of HIV and for advocating for the rights of people living with and affected by HIV.' Abdool Karim received the degree Doctor of Science (DSc), *honoris causa* at a small physical graduation ceremony for doctoral graduates from the Faculty of Medicine and Health Sciences held on the Stellenbosch campus.

In her acceptance speech, Abdool Karim said she was "deeply honoured and felt very privileged to be the recipient of this honorary doctorate and it's been made even more special with having this conferred to me by the Chancellor (Justice Edwin Cameron, in the photo) who is a very dear friend, a friendship that goes back over three decades." <http://www.sun.ac.za/english/Lists/news/DispForm.aspx?ID=7917>

Scientists elected to serve on the ACTG Network Groups

We congratulate CAPRISA colleagues, Prof Kogie Naidoo (Deputy Director), Dr Tanuja Gengiah (Head: Pharmacy) and Dr Anushka Naidoo (Scientist) on their election to serve on the ACTG Network Coordinating Center's committee groups following a 'competitive' application process. The scientists were elected on their 'very impressive' qualifications.



Prof Naidoo has been elected to serve as an investigator on the Tuberculosis Transformative Science Group (TB TSG); Dr Tanuja Gengiah has been elected to serve as an investigator on the Women's Health Collaborative Science Group (Women's CSG); and Dr Anushka Naidoo has been elected to serve as a pharmacologist on the Tuberculosis Transformative Science Group (TB TSG).

The committee term will be for two years, starting on March 1, 2021 and ending on November 30, 2022.



CORTIS study shows that diagnosis of asymptomatic TB remains elusive

The results from a Correlate of Risk Targeted Intervention Study (CORTIS), into a blood-based RNA biomarker which tested diagnostic and prognostic performance for tuberculosis (TB) and the efficacy of TB preventive therapy for biomarker-positive individuals was published in *The Lancet Infectious Diseases* journal.

The results showed that the blood biomarker of TB differentiates between people at high risk for TB and those who remained healthy, but an effective preventive therapy for people at risk remains a challenge.

Researchers from the South African Tuberculosis Vaccine Initiative at the University of Cape Town, the Centre for the AIDS Programme of Research in South Africa, the Aurum Institute, Stellenbosch University, the London School of Hygiene and Tropical Medicine and the Fred Hutchinson Cancer Research Center published the findings of a study of a host blood signature of TB that differentiated between people who had or would develop active TB and those who remained healthy, and investigated in parallel the effect of giving TB preventive therapy based on a positive signature result.

The study was conducted between 2016 and 2019 across five geographic communities in South Africa. A

total 20,207 adult volunteers from communities across South Africa were screened for participation. The research team set out to test the performance of a transcriptomic signature of TB (RISK11), as well as the efficacy of signature-guided preventive therapy using a parallel, three-arm hybrid study design.

The RISK11 blood test differentiated between individuals with current TB disease or those who would progress to incident TB within 6 months after testing, and individuals who remained healthy, with excellent performance. Another key finding was the high prevalence of asymptomatic TB in South African communities.

The study showed that the provision of a 3-month regimen of once-weekly, high-dose isoniazid and rifapentine (3HP), which is effective in treating latent TB infection, did not reduce the rate of TB disease in correlate of risk persons. The diagnosis of asymptomatic TB can be in high burden communities remains a challenge.

For further reading

Scriba TJ, et al. Biomarker-guided tuberculosis preventive therapy (CORTIS): a randomised controlled trial. *Lancet Infect Dis*. 2021; doi: 10.1016/S1473-3099(20)30914-2. <https://pubmed.ncbi.nlm.nih.gov/33508224/>

Limited impact on ART provision in South African primary care clinics during Covid-19 lockdown

HIV testing and antiretroviral therapy (ART) initiations dropped by almost 50% at the beginning of the Covid-19 lockdown, while there was no marked change in ART collections, according to a collaborative team of researchers at CAPRISA, the eThekweni Municipality, Bethesda Hospital, the University of Oxford and the London School of Hygiene & Tropical Medicine.

The study, *The impact of the coronavirus disease 2019 lockdown on HIV care in 65 South African primary care clinics: an interrupted time series analysis*, was recently published in the journal, *The Lancet HIV*.

The authors assessed trends in the numbers of HIV tests, ART initiations and ART collection visits before and after the South African national Covid-19 lockdown was

introduced in March 2020. They used routinely collected data from 65 primary care clinics run by the eThekweni Municipality and Bethesda Hospital in KwaZulu-Natal, South Africa.

The results show that HIV testing dropped by 47.6% and ART initiations decreased by 46.2% (Figure) when the lockdown was first introduced, although numbers increased gradually as lockdown measures were eased. Reassuringly, there was no marked decrease in ART collection visits.

For further reading

Dorward J, et al. The impact of the COVID-19 lockdown on HIV care in 65 South African primary care clinics: an interrupted time series analysis. 2021 Feb. <https://pubmed.ncbi.nlm.nih.gov/33549166/>

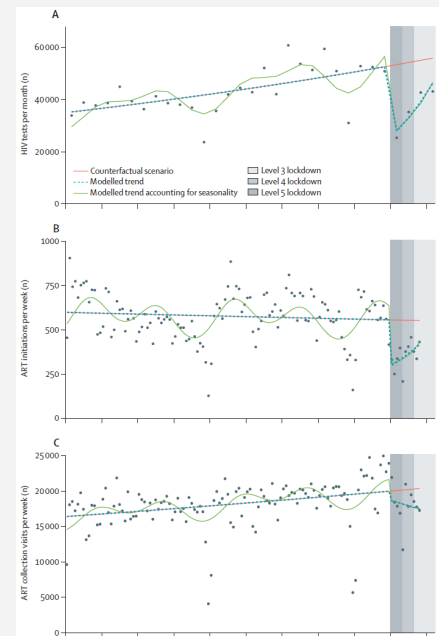


Figure: Poisson segmented regression analyses of A) HIV testing, B) ART initiations, and C) ART collection visits, and missed visits, before and after the COVID-19 lockdown in 65 clinics in KwaZulu-Natal, South Africa



Scientific papers published in 2021

- 1 Fidler S, Lewin S, Deeks S, Sogaard OS, Vanderkerckhove L, Collins S, Kelly D, **Singh J**, Caskey M, Frater J. HIV cure research in the time of COVID-19 - Antiretroviral therapy treatment interruption trials: A discussion paper. *Journal of Virus Eradication* 2021;7(1):100025. doi: 10.1016/j.jve.2020.100025.
- 2 Tago A, **McKinnon LR**, Wanjiru T, Muriuki F, Munyao J, Gakii G, Akolo M, Kariri A, Reed N, Shaw SY, Gelmon LJ, Kimani J. Declines in HIV prevalence in female sex workers (FSWs) accessing an HIV treatment and prevention programme in Nairobi, Kenya over a 10-year period. *AIDS* 2021; 35(2):317-324.
- 3 Maughan-Brown B, Beckett S, **Kharsany ABM**, Cawood C, Khanyile D, **Lewis L**, Venkataramani A, George G. Poor rates of linkage to HIV care and uptake of treatment after home-based HIV testing among newly diagnosed 15-to-49 year-old men and women in a high HIV prevalence setting in South Africa. *AIDS Care* 2021; 33(1):70-79.
- 4 Mpofo R, Otwombe K, **Mlisana K**, Nchabeleng M, Allen M, Kublin J, McElrath MJ, Bekker LG, Churchyard G, Gray G, Laher F. Benign ethnic neutropenia in a South African population, and its association with HIV acquisition and adverse event reporting in an HIV vaccine clinical trial. *PLoS One* 2021; 16(1):e0241708. doi: 10.1371/journal.pone.0241708.
- 5 Douglass N, van Diepen MT, Chapman R, Galant S, Margolin E, Ximba P, Hermanus T, **Moore PL**, Williamson AL. Modifications to the HIV-1 SAAVI MVA-C vaccine improve in vitro expression and in vivo immunogenicity. *Vaccine* 2021; 15;39(3):463-468.
- 6 **Cromarty R**, Sigal A, **Liebenberg LJ**, **McKinnon LR**, **Abdool Karim SS**, **Passmore JS**, **Archary D**. Betamethasone induces potent immunosuppression and reduces HIV infection in a PBMC in vitro model. *Journal of Investigative Medicine* 2021; 69(1):28-40.
- 7 Huang Y, Naidoo L, Zhang L, Carpp LN, Rudnicki E, Randhawa A, Gonzales P, McDermott A, Ledgerwood J, Lorenzo MMG, Burns D, DeCamp A, Juraska M, Mascola J, Edupuganti S, Mgodini N, Cohen M, Corey L, Andrew P, Karuna S, Gilbert PB, **Mngadi K**, Lazarus E. Pharmacokinetics and predicted neutralisation coverage of VRC01 in HIV-uninfected participants of the Antibody Mediated Prevention (AMP) trials. *EBioMedicine* 2021; 64:103203. doi: 10.1016/j.ebiom.2020.103203.
- 8 Scriba* TJ, Fiore-Gartland* A, Penn-Nicholson A, Mulenga H, Mbandi SK, Borate B, Mendelsohn SC, Hadley K, Hikuam C, Kaskar M, Musvosvi M, Bilek N, Self S, Sumner T, White RG, Erasmus M, Jaxa L, Raphela R, Innes C, Brumskine W, Hiemstra A, Malherbe ST, Hassan-Moosa R, Tameris M, Walz G, **Naidoo K**, Churchyard G, Hatherill M, and the CORTIS-01 Study Team. Biomarker-guided tuberculosis preventive therapy (CORTIS): a randomised controlled trial. *Lancet Infectious Diseases* 2021. S1473-3099(20)30914-2. doi: 10.1016/S1473-3099(20)30914-2
- 9 **Dookie N**, **Padayatchi N**, **Naidoo K**. Tuberculosis Elimination in the Era of COVID-19: A Moving Target. *Clinical Infectious Diseases* 2020; ciaa1400. doi: 10.1093/cid/ciaa1400
- 10 **Dorward J**, Khubone T, Gate K, Ngobese H, Sookrajh Y, Mkhize S, **Jeewa A**, Bottomley C, **Lewis L**, Baisley K, Butler CC, Gxagxisa N, **Garrett N**. The impact of the COVID-19 lockdown on HIV care in 65 South African primary care clinics: an interrupted time series analysis. *Lancet HIV* 2021; 4:S2352-3018(20)30359-3.

*continuation from previous newsletter



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