

The J&J COVID-19 vaccine: Fit for purpose in our setting

On 12 April 2021, the US Centers for Disease Control called a halt to the use of the Johnson and Johnson (J&J)'s coronavirus vaccine^[1] while reviewing data on the more than 6.8 million doses that had been administered in the USA as of 12 April, that involved 6 reported US cases of a vanishingly rare but severe blood clot, cerebral venous sinus thrombosis (CVST), seen in combination with thrombocytopenia. All 6 cases occurred in women between the ages of 18 and 48 years, and symptoms developed 6 - 13 days after vaccination. To date, the USA has not resumed vaccination with the J&J COVID-19 vaccine, but it is likely that they will do so.

On 13 April, in a move seen as inexplicable by many local specialists, the South African National Department of Health suspended the Sisonke Protocol, through which our healthcare workers are being vaccinated using the J&J COVID-19 vaccine.^[2] This decision was explained as an abundance of caution based on the advice of local scientists to wait until the causal relationship between the development of clots and the J&J vaccine is fully elucidated. In an ideal world, this might have seemed like a sensible precaution. However, unlike the USA, we have no other vaccines available. To complicate matters further, because our vaccine roll-out is currently under clinical trial protocols, it has been glacially slow, and so far only 289 787 health workers out of at least 1.5 million have been vaccinated. And we may well see a third wave of infections as we go into winter.

As a result there was some urgency to reversing this decision, and on 18 April, the South African Health Products Regulatory Authority (SAHPRA) recommended that the pause in the Sisonke Protocol be lifted, provided that screening and monitoring of participants is strengthened and measures are implemented to ensure the safe management of any participants who develop this extraordinarily rare complication of vaccination.

To this end, the South African Society of Thrombosis and Haemostasis has developed recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia (VITT), which are based on the recommendations for the management of an equally rare disorder, heparin-induced thrombocytopenia with thrombosis (HITT). These will be updated as new evidence becomes available.^[3]

At the time of writing, SAHPRA are still deliberating on exactly when to re-start the Sisonke Protocol. We hope that it will be as soon as possible.

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1. US Food and Drug Administration. Joint CDC and FDA statement on Johnson & Johnson COVID-19 vaccine. 13 April 2021. <https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine> (accessed 19 April 2021).

2. National Department of Health, South Africa, COVID-19 Online Resources & News Portal. Statement by the Minister of Health, on the FDA's temporary suspension of Johnson and Johnson vaccine. 13 April 2021. <https://sacoronavirus.co.za/2021/04/13/statement-by-the-minister-of-health-on-the-fdas-temporary-suspension-of-johnson-and-johnson-vaccine/> (accessed 19 April 2021).

3. Jacobson BF, Schapkaitz E, Mer M, et al. Recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia. *S Afr Med J* 2021 (epub 20 April 2021). <https://doi.org/10.7196/SAMJ.2021.v111i7.15772>