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Urgent appeal to allow all professional nurses and midwives to prescribe pre-exposure prophylaxis (PrEP) in South Africa

With 1.5 million global incident HIV infections in 2021, of which 210 000 occurred in South Africa (SA),^[1] there is an urgent need to reduce barriers to and simplify provision of pre-exposure prophylaxis (PrEP) for those who need it most.^[2,3] SA has the highest number of people living with HIV in the world, with HIV prevalence rates of up to 41% in pregnant women.^[4] In SA, daily oral PrEP (tenofovir/emtricitabine (TDF/FTC)) has been provided to adolescent girls and young women, sex workers, men who have sex with men, pregnant and breastfeeding women and other populations at risk of HIV acquisition, following the 2015 World Health Organization (WHO) recommendations.^[5] The national PrEP programme in SA reached >880 000 individuals started on daily oral PrEP between June 2016 and February 2023. However, continuation of PrEP remains low, estimated at only 20% of those who start PrEP (based on national PrEP monitoring and evaluation data presented by the National Department of Health in Johannesburg, 19 - 20 April 2023 – unpublished). Furthermore, integration of PrEP delivery into existing services differs across provinces and facilities, frequently being impeded by resource constraints.^[6-8]

The WHO released updated PrEP implementation guidance in July 2022, focusing on simplification, differential service delivery and demedicalisation of PrEP.^[9] This guidance supports out-of-facility delivery models for PrEP, refill-only collection (not clinical reviews), longer PrEP script refills, longer intervals between clinical reviews, and *task sharing, including utilising all cadres of nurses, lay healthcare workers and peers* to increase access to and uptake and effective use of PrEP.^[9] Expanded PrEP access, particularly for PrEP continuation, is urgently required and overdue in SA, where the need for HIV prevention is critical.

NIMART requirement-related barriers to PrEP scale-up and continuation

In SA, national PrEP guidelines state that only nurses with comprehensive antiretroviral therapy (Nurse-Initiated Management of Antiretroviral Therapy (NIMART)) training may prescribe PrEP.^[10,11] However, NIMART-trained nurses are currently responsible for initiating and managing antiretroviral therapy (ART) for >7.5 million people living with HIV, of whom 5.5 million are currently active on ART,^[2] and as a result have a very high workload. Furthermore, there is a high turnover of NIMART-trained nurses, resulting in low availability at public health facilities at the primary care level, especially outside of dedicated HIV services.

Requiring nurses prescribing (and therefore also re-scripting) PrEP to be NIMART trained presents a significant barrier to scale-up and community delivery of PrEP at all health facilities in SA. Furthermore, integration of PrEP within sexual and reproductive health, antenatal care and adolescent health services remains limited because of overburdened NIMART-trained nurses. This is not only because NIMART-trained nurses are a limited resource, but because *populations not living with HIV*, those who benefit from PrEP, do not access HIV services.

PrEP is safe for nurses to prescribe and monitor

There is considerable evidence from the scale-up of PrEP that daily

oral TDF/FTC is well tolerated, with very few, usually mild side-effects, and only in rare cases resistance mutations in individuals with undetected HIV infection.^[12] There is a very small risk of renal and bone mineral density impact, and these effects are very rare in individuals who are young and fit, the population for which PrEP is most urgently needed. In a recent study of >1 200 pregnant and postpartum women on PrEP in Western Cape Province, no cases of renal impact (as indicated by abnormal creatinine clearance) or treatment resistance following seroconversion were identified.^[13] These findings are in line with other studies of oral PrEP in SA and the region.^[14-21] Nurses are able to monitor seroconversion in clients who seroconvert while taking PrEP, and to ensure regular testing and same-day ART initiation. The current integrase strand transfer inhibitor-based treatment regimen in SA is robust, so if a patient seroconverts and continues dual treatment (TDF/FTC), they are still likely to suppress on standard triple therapy even in the face of nucleoside reverse transcriptase inhibitor resistance.

PrEP prescription approaches to learn from in SA

As of February 2023, PrEP has been integrated into most public healthcare facilities at the primary care level in Eastern Cape, Gauteng, KwaZulu-Natal and Mpumalanga provinces.^[6] However, the remaining provinces offer limited access to PrEP, with <50% of health facilities in Limpopo, Northern Cape and Western Cape provinces offering PrEP. This limited access is partially the result of limited numbers of NIMART-trained nurses, who often do not have time to prescribe PrEP. Between April 2022 and February 2023, 355 000 clients initiated PrEP in SA (84% of the national target of 422 924 people). Over half of these initiations were in Gauteng and KwaZulu-Natal, where NIMART has been integrated into nursing school training curricula, allowing all nurse graduates to prescribe ART and PrEP, which may be a longer-term strategy nationwide to ensure adequate training in the future.

Dispensing licence requirement-related barriers to PrEP scale-up and continuation

SA national PrEP guidelines^[10] and training state that the following providers can prescribe PrEP: 'doctor, NIMART authorized professional nurse, and PIMART [pharmacist-initiated management of antiretroviral therapy] authorized pharmacist'. NIMART-trained nurses must hold a dispensing licence to dispense (or pre-dispense for distribution or collection) prescribed PrEP. This imposes a double barrier for nurses providing PrEP outside of health facilities. Finding or capacitating nurses who fulfil both dispensing licence and NIMART training credentials creates unnecessary complexity and cost for the health system and significantly constrains PrEP roll-out.

SA has no legislative barriers to nurses prescribing PrEP

According to existing legislation (see box), nurses can legally prescribe and supply medicines including PrEP. ARVs are not restricted. Historically, nurses have been required to obtain a licence to prescribe after completing a course with the South African

Pharmacy Council (SAPC). However, this is not required according to legislation and presents additional, unnecessary barriers to nurse provision of PrEP.

The way forward for safe and simplified differentiated PrEP service delivery

We call on the National Department of Health, the SAPC, nurse training institutions and authorities implementing permits for nurses and midwives to enable simplified and de-medicalised PrEP with an urgent focus on expanding the PrEP service delivery workforce by taking the following steps.

Short-term urgent steps:

- Allow any professional nurse or midwife to attend existing PrEP training, regardless of prior NIMART training.
- Include PrEP training in existing Department of Health training curricula for sexual and reproductive health and updated prevention of vertical transmission guidelines and curricula, as well as basic antenatal care.
- Allow PrEP-orientated nurses and midwives to prescribe and manage PrEP for patients in their care, including in integrated adolescent, maternal and sexual reproductive health services.

Longer-term step:

Include PrEP training in all pre-services/undergraduate curricula so that all graduating nurses are PrEP competent on completion of their training.

Making these changes will simplify and significantly improve access to PrEP services, contributing to increased PrEP initiation, and facilitate effective use of PrEP, thereby helping to move SA closer to HIV epidemic control.

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The Nursing Act 33 of 2005 enables nurses with section 56(6) permits to legally prescribe and supply medicines listed on their permits without a dispensing licence. At present, those permits are issued to all primary healthcare nurses, including those with NIMART training, but the details reflected on the permits vary. Most mention the Primary Healthcare Standard Treatment Guidelines and Essential Medicines List. Updated regulations have not been issued for this permit. The previous regulations issued in terms of the previous Nursing Act in 1984 (for section 38A permits) remain in effect, and restrict nurses to Schedule 4 medicines at a maximum. Antiretrovirals are listed as Schedule 4 medicines, and, are therefore not restricted.

In the private sector, some organisations have been designated by the Director-General of Health as being able to issue section 56(6) permits, but most rely on section 22A(15) permits issued in terms of the Medicines and Related Substances Act 101 of 1965. Historically these nurses have been required to obtain a dispensing licence, after completing a training course accredited by the SAPC. The training requirements for both the abovementioned permits are not prescribed in law, but can be specified and implemented by the authorities issuing such permits.

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