Pharmacist-initiated management of antiretroviral therapy (PIMART) – a win for South Africa

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Sub-Saharan Africa has the world's largest HIV epidemic, accounting for 70% of the global human immunodeficiency virus (HIV) disease burden with one in every twenty adults (5%) infected yearly. More specifically, South Africa currently has 8.2 million people living with HIV/acquired immunodeficiency syndrome (AIDS). Every year, at least 200 000 people are added to this population. While South Africa has made great strides in the provision of treatment with more than five million people on treatment, with the largest national HIV programme in the world, it has yet to reach the Joint United Nations Programme on HIV/AIDS (UNAIDS)'s 95-95-95 strategy, to ensure that 95% of persons living with HIV and AIDS (PLWA) are aware of their status, 95% of these individuals are on treatment, and 95% of those on treatment are virally suppressed.

Following the World Health Organization's (WHO) policy recommendation of ‘universal’ access to antiretroviral therapy (ART), South Africa was among the first African country to adopt the policy and has officially been implementing the policy since September 2016 (National Department of Health, 2016). Achieving the Joint United Nations Programme on HIV/AIDS (UNAIDS)'s 95-95-95 strategy would require intense domestic and international financial investments, massive social mobilisation, and commitment from all levels of government, professional bodies, and civil societies.

Have we reached this yet? At the 11th SA AIDS Conference in June 2023, Health Minister Joe Phaahla said that 94% of people with HIV in SA knew their status, but only 77% were on antiretroviral treatment. Integral to understanding this challenge is the healthcare worker shortages that South Africa faces, with shortages of doctors and other healthcare professionals, particularly in rural and under-resourced areas where the need for health care is often greatest.

Considered within the ethical framework of utilitarianism, “a consequentialist theory that determines morality based on the outcomes of interventions. The principle of utility asserts that the moral course is one that maximises value over disvalue and seeks the greatest benefit for the greatest number.” South Africa and its healthcare workers are compelled to provide the greatest benefit (of scarce resources, in this case ARVs) for the greatest number. On an individual level of benevolence, the benefit of access to a scarce resource should be considered a morally acceptable choice.

Pharmacist-initiated management of antiretroviral therapy (PIMART) was approved by the South African Pharmacy Council (SAPC) in 2021, with the aim of improving access to antiretroviral therapy, inherently practising distributive justice through egalitarianism (reducing inequalities of distribution), sufficientarianism (maximising the numbers of those who have enough), and prioritarianism (giving priority to those who are in more unfavourable circumstances) – thus making ARVs accessible to diverse communities, enabling better viral suppression and long-term disease management.

Why was PIMART initiated? In 2017, despite programmes such as nurse-initiated management of antiretroviral therapy (NIMART) and treatment points through other clinicians, the insufficient capacity of the then current workforce tasked with the management of HIV became apparent as the nation kept missing targets and HIV-related deaths contributed a large number of national mortalities.

Against this background, the SAPC was approached by the National Department of Health (NDoH) to consider and implement an intervention that would ensure that patients have increased access to antiretroviral medicines for the purposes of providing pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). The motivation was to down-schedule such medicines to Schedule 2, as this would enable pharmacists to prescribe and dispense such medicines without a prescription by another authorised prescriber, as part of PIT in terms of Sections 22A(5) and 22A(6) of the Medicines and Related Substances Act, 101 of 1965 (Medicines Act).

Having considered the options, the SAPC resolved that the most appropriate approach would be to expand the already existing pharmacist-initiated therapy (PIT) intervention, together with supplementary training that focused on PIMART. Once a pharmacist had undergone such supplementary training, they would be required to apply for a PIMART permit issued by the Director General: Health, in terms of Section 22A(15) of the Medicines Act. This would legally enable such pharmacists to prescribe and dispense ART medicines.
for PrEP, PEP and, where appropriate, first-line ARV therapy. Factors which motivated the need for supplementary training, as opposed to a blanket down-scheduling of the identified medicines, included training that would emphasise the distinction and limitations that would be necessary for a pharmacist to treat comprehensively as part of PIT, or refer a patient to the most appropriate healthcare practitioner when necessary.

The Independent Practitioners Association Foundation (IPAF) filed an application in the North Gauteng high court in February 2022, seeking review and dismissal of the SAPC’s decision to implement PIMART through the publication of a Board Notice, which detailed the PIMART scope of practice, the competency standards the PIMART pharmacist would be required to have and the criteria for the approval for a PIMART supplementary training course. The implementation of PIMART was put on hold by the legal challenge of the IPAF, which represents doctors in private practice. The IPAF leveraged this challenge based on their preconceived idea that pharmacists would be encroaching on the domain of doctors and asked the Court to set aside the SAPC’s decision to introduce PIMART into the scope of practice of suitably trained pharmacists. Further to this in its application, the IPAF argued that the provision of PIMART services falls within the domain of medical doctors and that pharmacists do not have the required training and competencies to provide these services. The IPAF further argued that the SAPC does not have the legislative mandate to introduce PIMART, that the SAPC’s reasons for implementing PIMART were not adequately explained, and that the SAPC’s procedures for implementing PIMART were not procedurally fair and did not provide adequate opportunity for interested parties to comment.

What was the collateral damage of this legal challenge from the IPAF, when the NDH requested pharmacists to collaborate with other healthcare workers (HCWs) in meeting the UNAIDS goal, and in 2021, when the PIMART board notice was published? HIV-cases in South Africa increased by 910 000 persons, from 7,32 million to 8,23 million PLHIV. On average, 227 500 new infections occurred every year during this period alone. According to data from the Department of Home Affairs and Statistics South Africa, HIV remains one of the top five underlying causes of all natural deaths in South Africa. This crisis has been worsened by less-than-optimal adherence rates (estimated at between 63–83% [Moosa et al. 2019]) and a lack of access to testing and treatment services.

The financial collateral damage of the delay in providing equal access to antiretrovirals, is the HIV budget which has grown exponentially over the years. The NDH spent more than R20 billion on HIV alone in the fiscal year 2019–2020 (NDH Annual Report, 2019/2020) – more than any other disease that existed before the novel coronavirus (COVID-19).

It is important to note that the initiation of PIMART is not unique to South Africa. Pharmacists in South Africa have been providing PIT across the health spectrum and most HIV/Aids healthcare services for as long as any other personal healthcare worker (HCW) group has. For instance, patients may access HIV testing, and emergency post coital contraception, pregnancy testing, urine test analysis, patient wellness in respect of sexual health. In addition, occupational post-exposure HIV prophylaxis for healthcare workers at the pharmacy, in line with Primary Care Drug Therapy algorithms (first introduced in 1995). As such, PIMART adds to these services by allowing pharmacists to provide PEP and PrEP as well as dispense first-line ART to uncomplicated and non-immunocompromised HIV-positive persons.

Internationally various countries are managing HIV and Aids by utilising all their health workforce, including pharmacists to make an impact on the global efforts to combat HIV and Aids. The following countries, amongst others, have programmes similar to PIMART.

- United States of America has a programme called Pharmacist-Administered, Antiretroviral Therapy Adherence Clinic that offers initiation or re-initiation, management of ART and adherence, monitoring of adverse reaction.
- Within Africa, Nigeria has a programme called Global HIV/AIDS Initiative Nigeria (GHAIN) which offers screening, testing, initiating and management of ART.
- Malaysia has a programme called Pharmacist Independent Prescriber that allows pharmacists to assess and then proceed with the initiation and management of ART and adherence monitoring.

The judgment in the IPAF case was handed down by Judge Elmarie van der Schyff on 14 August 2023 — almost two years after legislation introducing PIMART was published by the SAPC (Board Notice 101 of 2021 was published on 13 August 2021). While PIMART has been delayed for two years by the IPAF’s legal challenge, Judge Van der Schyff’s judgment included amongst others the following:

- Regarding encroaching on the medical doctors domain – “competition, per se, does not limit or curtail the rights of medical practitioners to continue providing the services that they currently provide,” further stating that “even if the assumed competition is regarded to affect family practitioner’s rights adversely, the alleged adverse effect it holds for medical practitioners has to be considered against the need to expand primary healthcare services aimed at preventing and treating HIV”.
- The IPAF’s argument that the SAPC is not mandated to introduce PIMART was dismissed by Judge Van der Schyff stating that “the SAPC is empowered to prescribe the scope of practice of the various categories of persons registered in terms of the Pharmacy Act”. She added, “The development and implementation of PIMART does not expand the existing scope of practice of pharmacists that generically provide for PIT [pharmacist-initiated therapy] and PCDT [primary care drug therapy]. It introduced a specialised category of PIT and PCDT focused on preventing and treating HIV”.
- The IPAF’s arguments that the introduction of PIMART was procedurally unfair and the decision for its implementation was not properly explained, arbitrary, or capricious, were also rejected by Judge Van der Schyff. She said that “… through its collaboration with the Southern African HIV Clinicians Society, whose members include numerous medical doctors, the development of PIMART was given great exposure”.

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She also stated, “The need to widen access to first-line ART [antiretroviral therapy] and TPT [TB preventative therapy] on a community level is not a figment of SAPC's imagination, but a dire need that is also evinced in other countries”.

The IPAF's contention that pharmacists are not adequately trained to provide PIMART was also rejected by Judge Van der Schyff stating, “The PIMART training course was developed to ensure that pharmacists who successfully completed the training would be 'suitably qualified to safely and effectively assist in providing ART'. She adds that the PIMART training course was ‘developed by suitably qualified experts in the field, which experts include medical practitioners’.

It is important to realise that PIMART will not be free. Pharmacists will be able to charge the single exit price for the medicine plus a professional fee, as set by the SAPC. The cost of treatment in the private sector, therefore, could be a barrier to people who use government facilities. Despite having to pay for the medicine, the hidden expenses of getting treatment, such as travelling to a government facility and waiting in line, add considerable cost to treatment, which could make getting medicines at a private pharmacy attractive. In future, these costs may be mitigated by public-private sector models, for example the National Immunisation Programme that provides free childhood vaccines to both private and public institutions. This intervention (private/public partnership) in South Africa, through routine childhood immunisation, is reported to avert an estimated 2.5 million deaths annually. We hope to see the same results through this partnership with ARVs.

Pharmacists that were successful in completion of their supplemental training must apply for a PIMART permit in terms of Section 22A (15) of the Medicines and Related Substances Act, 101 of 1965 from the Department of Health.

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulations 3 and 4 of the Regulations relating to the practice of Pharmacy (GNR 1158, published on 20 November 2000), a pharmacist who has completed the PIMART supplementary training, and once they are in possession of a PIMART permit in terms of Section 22A(15) of the Medicines and Related Substances Act, 101 of 1965, may be allowed to perform consultations and provide the relevant treatment to the patients at a pharmacy or in an approved primary healthcare setting.

PIMART is a victory for South Africa, as health care through pharmacies is typically more accessible from people's homes, schools, and workplaces, has better opening hours than clinics and general practitioners and can provide greater anonymity to their patients. HIV/AIDS has no preference to demographics, however visiting a pharmacist to access treatment for an uncomplicated case may not only be destigmatising, but may reduce the cost incurred by transport, amongst other things, from the pharmacist to the GP. Thus, by making ARVs accessible to diverse communities, there will be better viral suppression and long-term disease management. Having said that men and adolescents face unique challenges in accessing HIV-testing and treatment, we hope that PIMART may provide a destigmatising environment, in public and private healthcare settings.

PIMART may also help scale up PrEP and PEP usage for adolescents, and young women who seek emergency contraception in private pharmacies in South Africa. Besides seeking emergency contraception, young women commonly visit pharmacies for family planning services and to vaccinate their infants and young children, which provides further opportunities to discuss and offer PrEP.

PIMART is designed to foster collaboration with other healthcare professionals (including nurses and doctors) in the provision of HIV care that is aimed at increasing accessibility to prevention and treatment in line with the national treatment guidelines. Having the pharmacist on board as part of the healthcare team, therefore reaching more patients, is a win for all.