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- Testosterone replacement therapy for male hypogonadism in adult men when testosterone deficiency has been confirmed by clinical features and biochemical tests

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3000765-001	S5	Testosterone	50mg/5g	Gel in sachet	30 per box

References: 1. Androgel® Package Insert; 2. Wang C et al.J Clinc Endocrinol Metab 2000;85:2839-2853; 3. Wang C et al.J Clinc Endocril Metab 2004;89:2085-2098; 4. Behre HM et al.Aging Male 2013;15:198-207

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- South African Association of Community Pharmacist Sector of the PSSA
- SA Association of Hospital and Institutional Pharmacists
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SAPJ is aimed at the continuing professional development of the South African pharmacist in a variety of practice settings, including clinical pharmaceutical care practitioners in a community or hospital pharmacy environment, and pharmacists in academic and industrial practice.

The journal accepts specific clinical reviews on self-medication topics (symptomatic therapy) and information on prescription medication (therapy in clinical context), and provides pharmacists with essential information for referring customers for early medical attention should it be required. SAPJ further recognises that the role of the pharmacist continually evolves to meet the needs of the population. An example of this is the provision of accessible, basic primary health care services in community pharmacies.

Papers dealing with medicines safety issues, including the safe and appropriate prescription, administration and use of medication as well as pharmacovigilance, are strongly advocated in SAPJ. SAPJ further supports pharmacists in transforming the pharmacy into an accessible, basic primary health care facility for preventing and treating primary health care conditions through diagnosis, screening and treatment.

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Case studies:	1 800 words
Scientific letters:	1 200–1 800 words
Letters to the editor:	400–800 words

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The health of pharmacy in South Africa: navigating through the challenges

Natalie Schellack

The pharmacy sector in South Africa faces both opportunities and challenges in promoting public health. When evaluating the health of pharmacy in South Africa, I asked experts in the various settings of community service, academia, and pharmaceutical societies (see the list of the contributing authors) for their opinions on the following statements:

1. Adequate workforce capacity and diversity: the profession has sufficient numbers of qualified practitioners to meet societal needs. The workforce demographics also reflect the community it serves.
2. Strong professional standards and ethics: clear codes of conduct, standards of practice, and ethical guidelines help ensure high-quality, safe services and protect the interests of the public.
3. Robust education and training systems: practitioners are well-educated through accredited university programs, and ongoing competency requirements ensure skills and knowledge are up to date.
4. Effective self-regulation: the profession can set its own standards, monitor members' compliance, and discipline any lapses through an independent regulatory body.
5. Workplace well-being: practitioners can sustain healthy, balanced, and fulfilling long-term careers without the risk of burnout or workplace hazards that could compromise care.
6. Public trust and value: the profession is seen as making a valuable contribution to society, and individuals feel comfortable accessing its services.
7. Financial viability: the profession's economic model and compensation structures allow for adequate resources, innovation and continued service improvement.
8. Adaptability to change: the profession can effectively evolve to meet new health needs, technologies, standards of evidence, and community expectations over time.

When asked if we have an adequate workforce pertaining to capacity and diversity:

The overall consensus was no, as South Africa has an inadequate pharmacy workforce compared to other middle-income countries, with World Health Organization (WHO) norms suggesting the need for an additional 9 000 pharmacists. Even with an estimated 30 pharmacists per 100 000 people in the public sector, the current system suffers from a skewed distribution, with overconcentration of services in malls and major cities and a lack of resources in rural areas. Demographics have also changed drastically over the past 20 years, with a transformed workforce that mostly serves higher-income communities instead of their own due to factors such as open ownership, inadequate licensing, improper reimbursement, and inadequate investment in areas of need. There is an even greater gap between urban and rural pharmacies in the public sector. As of March 2022, there were 9.4 pharmacists per 100 000 uninsured population in North West, compared to 18.9 in the Free State. These figures also vary between districts and types of hospitals.

What about the existence of strong professional standards and ethics with clear codes of conduct, standards of practice, and ethical guidelines that help protect the interests of the public?

The general consensus was that the profession is well served by policies on paper, although the Good Pharmacy Practice (GPP) standards require more detail, and the Office of Health Standards Compliance (OHSC) standards for pharmaceutical services are inadequate. Implementation and accountability are weak, particularly in the public sector, but corporate pharmacies are also affected.

The pharmacy regulator in South Africa, the South African Pharmacy Council (SAPC), imposes strong ethical and practice standards and inspects and grades the profession regularly. Medical practitioners and nurses also participate in delivering pharmaceutical services but without the same level of oversight. Recently, medicines have been found to be illegally sold on the street, an issue further aggravated by inadequate resources of the bodies responsible for medicines oversight.

Do we have robust education and training systems? Inferring that practitioners are well-educated through accredited university programs and ongoing competency requirements ensures skills and knowledge are up to date.

Pharmacists are well qualified to meet the country's needs in terms of distributing and dispensing medicines but lack opportunities to make full use of their scope of practice. If allowed to make full use of their scope of practice, they could help reduce the burden of disease and improve patient outcomes. Specialisations in the pharmacy profession are still pending, and there is difficulty recruiting pharmacists with

PhDs for senior lecturer and professor roles in clinical pharmacy, pharmaceutical chemistry, practice and public health management at universities.

Initial undergraduate training is satisfactory and generally meets SAPC accreditation requirements. The pre-registration examination sets a baseline of competence for entry-level pharmacists; however, the current continuing professional development (CPD) system does not provide adequate assurance of ongoing competence. Further, the proposed specialist training system is overly prescriptive and fails to meet the profession's requirements. More flexible options, some relying on the US Board of Pharmacy Specialities, have succeeded in other countries, such as the Gulf.

Effective self-regulation: the profession can set its own standards, monitor members' compliance, and discipline any lapses through an independent regulatory body.

Standards-setting is largely in the hands of the profession via the SAPC, and the disciplinary processes and sanctions applied by the regulator are meaningful. Complaints remain the essential first step in the process, which can be a barrier. Importantly, the punitive approach to medication errors may be too harsh and inhibit self-reporting. To counter this, the profession has provided guidance and tools, including peer review processes in some organisations. Corporate pharmacies must also satisfy shareholders and are under pressure from payers, which may lead to conflicts of interest. In the public sector, the lack of pharmacists' posts means that many duties are handled by pharmacist assistants. These risks reduce processes to merely focus on medicine supply rather than patient outcomes. Without control being vested in the profession, standards are at risk of being compromised.

Workplace well-being: practitioners can sustain healthy, balanced, and fulfilling long-term careers without the risk of burnout or workplace hazards that could compromise care.

Workplace well-being is at risk when pharmacy staff working in community and hospital pharmacies are evaluated in terms of the number of prescriptions dispensed, waiting times, and sales volumes rather than on the quality of a comprehensive pharmacy practice. They are also under pressure due to the limited number of staff employed. In the private sector, this may be linked to the need to protect profits. Although these pressures may be perceived to be more pressing in corporate-owned pharmacies, independent practitioners are also under financial pressure. In the public sector, many pharmacists work under intolerable conditions due to poor infrastructure, persistent stock problems, and very low staff numbers linked to budget limitations. New pharmacy graduates and pharmacy support staff struggle to find positions in both the public and private sectors. Despite the inadequate workforce, there may well be an over-supply of pharmacy personnel relative to the absorptive capacity of the current market. Due to financial constraints in the public sector and profit prioritisation in the private sector, there are insufficient pharmacy positions to meet public needs. At its core, this problem is linked to the current remuneration structure. The current dispensing fee model is not sufficient to ensure long-term viability of a comprehensive, quality pharmaceutical service. There are many uncertainties regarding the reimbursement model to be applied under National Health Insurance (NHI).

A recent study conducted by the Community Pharmacy Section of FIP found that South Africa has been greatly impacted by COVID-19. Apart from the direct loss of life within the profession and among pharmacy staff's families, they experienced the impact of inadequate staffing norms and lack of proper reimbursement for their efforts in the vaccine campaign. These factors have all contributed to severe burnout, creating a lack of sustainable solutions that will affect service delivery in the future, including the risk of life-threatening dispensing errors.

Do pharmacists still have the public trust and value?

Pharmacists are a valuable source of healthcare services for the community. Despite their claims to be the most accessible healthcare professionals, the StatsSA General Household Survey consistently shows a small portion of the public would consider pharmacists as their first point of contact in the event of illness or injury.

COVID-19 has highlighted the vital role of pharmacists in the world, with trust in the profession increasing. To capitalise on this, the payer environment needs to shift to take advantage of pharmacists' training in managing minor ailments at a lower cost. Pharmacists have been vital in the COVID-19 vaccine program, delivering 7 million doses in South Africa. Although only a small proportion of patients served by the Centralised Chronic Medicine Dispensing and Delivery (CCMDD) program access their medicine packets at community pharmacies, this has allowed 350 000 patients to be "decanted" from public sector facilities.

The South African pharmaceutical industry is almost entirely reliant on imported active pharmaceutical ingredients (API). Overconcentration of supply from a limited number of API sources, notably in India and China, threatens the security of local manufacturing. Strengthening industrial pharmacist skills in South Africa would thus be beneficial.

How financially viable is the profession? The profession's economic model and compensation structures allow for adequate resources, innovation and continued improvement in services.

The current private sector dispensing fee is reliant on a zero-based model, used by the Pricing Committee to advise the Minister of Health. However, few payers are willing to pay the maximum dispensing fee allowed by law, resulting in the profession receiving less than the value determined for that service. The SAPC publishes fees for a number of non-dispensing services provided in community and hospital pharmacies each year, but few schemes are willing to reimburse such claims. For the future of the profession, the financial viability of the current models applied in both community and hospital pharmacies needs to be addressed urgently. Professional services in community pharmacies cannot be built on a business model that is based on the sale of goods other than medicines. Likewise, in private hospitals, the lack of any profit margin in the

pharmacy, with complete reliance on ward and theatre charges, hampers the development of comprehensive, quality pharmaceutical services. NHI holds the potential for a wholesale reconsideration of the reimbursement model for pharmaceutical services across both sectors, but also holds the risk that reducing costs will be prioritised ahead of service quality. Particular attention also needs to be paid to interventions that would encourage pharmacists to practise in rural areas, not only in the public sector.

Adaptability to change: can the profession effectively evolve to meet new health needs, technologies, standards of evidence, and community expectations over time?

Pharmacy in South Africa has historically endured past threats and is poised to adapt to needed changes. Government policy, however, has not been effectively conveyed nor adequately detailed. The plans for universal health coverage (via NHI) hold considerable uncertainly for existing service models, without clarity on how new models will be financed. Pharmacy must embrace its full scope of practice to meet the nation's healthcare needs. This needs to expand beyond HIV to include tuberculosis and non-communicable diseases, which are the leading causes of death in this country. Other areas of focus should include gender-based violence and accident-related deaths. Evidence exists of pharmacists' interventions leading to improved outcomes in diabetes, hypertension, blood disorders, and cardiovascular diseases. Technology has long been a crucial element in private sector pharmacy, but largely lacking in the public sector. Direct connections to patients and communities will assist this evolution.

In summary

Looking ahead, with political will and adequate investment, opportunities exist to strengthen the pharmacy workforce and the entire pharmaceutical service. Expanding access to affordable generics and integrating pharmacists as primary care providers could help address the quadruple burden of disease. Greater public-private partnerships and technology adoption may also enhance the monitoring of medicines quality and rational use. However, overcoming systemic inequities requires ongoing commitment to address the social determinants of health through multi-sectoral development.

South Africa's pharmacy sector is experiencing a promising growth, with increased acknowledgement of pharmacists across various domains and appreciation for their valuable knowledge.

This shift is essential to advancing South Africa's healthcare landscape and improving public health outcomes. Challenges around the current lack of internships and community service positions and confusion regarding the future roles of various pharmacy support cadres require urgent attention. Pharmacists have also demonstrated adaptability. In the private sector, the transition from independent, pharmacist-owned pharmacies to larger pharmacy groups and chains is ongoing. NHI promises to blur the boundaries between public and private sectors, but also to improve the quality of service in both sectors in order to better serve all communities. On balance, while progress has been made, much work still lies ahead to realise the vision of equitable and quality pharmacy services for all South Africans.

Natalie Schellack

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President's Message

Personal views on the Pharmacy Profession

Tshifhiwa Rabali
PSSA President

I was given the opportunity to present on the practice of pharmacy in the previously disadvantaged areas during the 60th Pharmaceutical Society of South Africa (PSSA) Annual General Meeting (AGM) held on the 21st to the 24th of May 2005 at the Birchwood Hotel and Conference Centre in Johannesburg, South Africa.

The topic was exploring our past and determining our future. I gave a detailed description of my experience with the general council; on how I practiced in an area where the average income was plus minus a thousand rand per month, as some households were run by grandparents. It was my own decision to open up a pharmacy practice in this area to provide pharmaceutical services to this community, which was not available before.

In this impoverished community, it is not uncommon for patients to come into my pharmacy with a minimum of one hundred rand and request a pharmaceutical service. And being a passionate community pharmacist, I offer the best quality service as best as I can.

I explained to my colleagues then, the satisfaction I still feel on a regular basis when having to come to work and promote public health to this community. It brings me great pride and joy when patients come back after getting treatment and offer me positive feedback regarding their health. I become more encouraged by their positive feedback than monetary rewards.

At that same AGM, during the conclusion of the AGM, I was honored with the certificate of appreciation named "*From Dust to Diamonds*", with the words exploring the past and furthering the future.

The National Health Insurance

The South African government is in the process of introducing the National Health Insurance (NHI) bill, which is being currently debated about at the National Council of Provinces.

Universal health coverage is the only way that we as a country can provide equal quality healthcare to all its citizens. The imbalances of the past must be addressed in some way or another because ignoring these imbalances could lead to detrimental results. As pharmacists and most healthcare professionals we have a problem with the immediate introduction of NHI because the country is not yet in a state where this can be affordable. The funding model that would make us viable as pharmacists has not even been determined or communicated to us as healthcare professionals; this brings many questions to us as there is no clear explanation on how funding will be provided and as pharmacists how we will be reimbursed for our pharmaceutical services.

The NHI scheme in South Africa aims to provide universal healthcare coverage and improve access to healthcare services. Community pharmacies are expected to play a key role in the NHI, delivering primary care services such as chronic disease management, health education and promotion, maternal and child healthcare, and immunisation in both urban and rural areas. However, there are currently no policies specifying the roles and functions of pharmacists in the NHI or in a re-engineered Primary Health Care system. The remuneration of pharmacists is still unclear, and an increased level of clinical and experiential training may be required to take on a more integrated role. Health technology assessment (HTA) is explicitly identified in the proposed NHI legislation and will have a prominent role in informing decisions about adoption and access to health interventions and technologies.

The other major problem that we have is that our country is trying to introduce a bill that is similar to that of the United Kingdom (UK) which has been implemented for a couple of years but is currently going through challenges. And as a country we will have to take cognizance of what is happening in the UK.

As the Pharmaceutical Society of South Africa (PSSA), we will continue to monitor the implementation of NHI as much as we can. We will always try to engage with the National Department of Health to get a better solution towards the implementation of NHI. This solution must at all times benefit the people of South Africa in order to avoid the hinderance of the provision of pharmaceutical and all other healthcare services combined. At the same time, we will also use those engagements to influence the introduction of other health policies that might be in the pipeline to favour us and the community.

All the above can be achieved by ensuring that we as the PSSA always strive for unity, that all our sectors are united and collaborating at all professional levels. Collaboration among sectors must begin at branch level; for example, community pharmacists can start exploring the idea of public-private partnership by engaging with the hospital pharmacists. There is already a programme running in some areas where community pharmacists are supplying chronic medications, immunisations, and contraceptives.

Academic pharmacists will also have to engage with other sectors within pharmacy on how best we can improve the scope of practice of the pharmacy profession.

Pharmacists in industry will have to engage more with community and hospital pharmacists on the availability and shortages of pharmaceutical medicines.

As the host nation of the upcoming 82nd Congress of the International Federation of Pharmacists (FIP), we will be showcasing our diversity, beautiful environment and landscapes as a country and the African continent as a whole. Let us warmly welcome our international colleagues. PSSA and all its branches, sectors and other stake holders will be in the forefront leading this course and we are more than ready to fulfil the tasks. As PSSA, we will make sure that the 2024 FIP Congress becomes a success in honouring the late President of FIP (Mr Domique Jordaan) who was very close to us and the country. He always talks about one FIP and that will be fulfilled by us. May His soul rest in eternal peace.

As PSSA we will always forge for engagements of all sectors in different branch levels.

Lastly, as the President of PSSA I would like to thank the Executive Director, Mr Ivan Kotzé, for dedicating all his life for the advancement of all pharmacists in South Africa and the professional functioning of the PSSA office. My thanks also goes to all the other staff members of the Society.

I would like to wish all the members of the PSSA a happy festive season and prosperous new year.

For all those who will be travelling, I wish them safe journeys to their different destinations.

2023 FIP World Congress on Pharmacy and Pharmaceutical Sciences

A delegation from South Africa, which included representatives from the PSSA, SAAHIP, SAAPI, YPG, South African Pharmacy Council (SAPC), universities, industry, and community pharmacies, attended the 81st FIP World Congress in Brisbane, Australia during September 2023.

The theme for this year's congress was Pharmacy building a sustainable future for healthcare – Aligning goals to 2030. In his first speech as FIP president, Mr Paul Sinclair pointed to increasing incidences of extreme weather and highlighted that poor planetary health is leading to more people needing health care and to the emergence of new health problems. *"Effective action on climate change must be a priority for the pharmacy profession. Every part of pharmacy has a responsibility. From pharmacy associations promoting environmental sustainability and the industry reducing its carbon emissions to net zero, to pharmaceutical scientists practising green medicines development, and regulators collecting standardised national data on pollution. From educators teaching environmentally sustainable pharmacy practice, to practitioners preventing waste through ensuring the optimal use of medicines. Every act will help. We can support the planet while supporting patients."* Mr Sinclair urged the pharmacy profession to remain as united against challenges, as it had been during the COVID-19 pandemic, in order to build a sustainable future for health care. "FIP is confident that our profession will provide solutions to many health challenges," he said.

During the FIP Council meeting, a number of FIP Policy Statements were approved for implementation. For all of these statements, a pharmacist from South Africa was part of the committee who developed the statement:

- FIP Statement of policy on mitigating antimicrobial resistance (AMR) through antimicrobial stewardship (AMS) – replacing the statement of 2017. Prof Sabiha Essack (University of KwaZulu-Natal) contributed to this committee.
- FIP Statement of policy on strategic development of medicines information for the benefit of patients and users of medicines – replacing the statement of 2017. Mandy Ariefdien (UCT Medicine Information Centre) participated in this committee.
- FIP Statement of policy on environment sustainability within pharmacy: A guide to mitigation and adaptation – replacing the statement on Green Pharmacy of 2016. Prof Renier Coetzee (University of Western Cape) was a member of this committee.
- FIP Statement of policy on the role of pharmacists in disaster and emergency management – replacing the statement of 2017. Dr Mariet Eksteen (PSSA) participated in this working group.
- FIP Statement of policy on the role of Pharmacy in life-course vaccination – a new statement. Prof Hannelie Meyer (Sefako Makgatho Health Sciences University) was a member of this working group.

The academic programme stretched over three days from Monday to Wednesday. Delegates could choose between attending one of the seven parallel sessions, the exhibition, or the poster presentations. The sub-theme for Monday 25 September was *It's World Pharmacists Day 2023 — Pharmacists strengthening health systems*, celebrating pharmacists' role in delivering healthcare services to patients. Tuesday's focus was on *Humanitarian crises: Challenges, opportunities and sustainable solutions* and the role that pharmacists could play in medication supply during times of crises. On the last day, the congress academic programme focused on *Technology to strengthen health systems: Challenges, opportunities and sustainable solutions* to ensure pharmacy is adapting to the changes we see in the world.

Several South African colleagues participated in podium or poster presentations:

- Tammy Chetty (Adcock Ingram) presented on *Diethylene Glycol a case study based on falsified medicines, a practical implementation of WHO requirements in an African company*, during the FIP Industrial Pharmacy Section Workshop – Good Manufacturing Practice (GMP)– Where are we now and what does the future look like?
- Renier Coetzee (University of the Western Cape) presented during the session titled Addressing antimicrobial stewardship with the 2030 goals and real-world strategies on *How can hospital pharmacists in low- and high-resource settings support antimicrobial stewardship? A real-world antimicrobial stewardship intervention example from South Africa*.
- Precious Ncayiyana (South African Military Health Services) presented on *medication shelf-life extension proposal for the*

public health institutions in South Africa.

- Sabiha Essack and Andy Gray (both from the University of KwaZulu-Natal) participated in a debate on the topic *Prevention or cure: Focusing pharmacists' efforts on antimicrobial resistance*.
- Sabiha also presented two posters on *Sore throat and antibiotic resistance (STAR) study: Preliminary global findings and opportunities for pharmacists* and *Addressing consumer misconceptions on antibiotic use and resistance in the context of sore throat on social media: teachable moments for pharmacists.*
- Daisy Kahwenga (Sefako Makgatho Health Sciences University) presented her research on *the role of a clinical pharmacist in the treatment and management of psychotic and bipolar disorders*.
- Mariet Eksteen (PSSA) addressed the African Pharmaceutical Forum during their Annual General Meeting to ensure potential issues regarding visa applications for Africans can be addressed in time.
- Sham Moodley (ICPA) was the moderator for the session on *Professional sustainability and positive practice in community pharmacy: Supporting the pharmacy workforce globally*. Mojo Mokoena (SAPC) was a panellist during this session.
- Mariet Eksteen presented during the FIP Workforce Symposium 2023: Accelerating towards 2030: Workforce transformation for better health on *Advancement of practice: Do we know what advanced practice should look like?*
- Nsovo Mayimela (Tshwane University of Technology) presented her PhD research on *the perception of board members on the presence of pharmacists as strategic leaders of manufacturing pharmaceutical companies operating in South Africa: A qualitative study*.

During this year's congress, South Africa had the opportunity to market Cape Town as the 2024 Congress destination. Apart from South African delegates who took turns to man the FIP 2024 stand in the exhibition hall, the South African National Convention Bureau supported the team with souvenirs which could be handed out at the stand, together with a photo opportunity with speech bubbles and a beautiful safari landscape backdrop.

At a summation session of FIP's 81st world congress, Paul Sinclair (FIP President) said that although supply would always be a core competency for pharmacists as medicines experts, the "real future" for pharmacists is in the provision of pharmaceutical care, whether that be through disease state management, the provision of services in a pharmacy in the home model, or extended vaccination. "If we hook our wagon up to the supply model, we will fail," he said. During his four-year presidency, he said, moving both pharmacy and FIP forward would be guided by integrity, passion and performance. "Pharmacists are one of the most trusted health professionals. We should leverage the integrity that is built within everything we do to do more and to promote ourselves more aggressively," he said. He added that passion for the profession should drive performance and he urged pharmacists from around the world to "be the best that they can be".

During the closing dinner of the congress, the FIP flag was passed from Australia to South Africa. During the handover, FIP president Paul Sinclair said: "I see a very strong future for our profession, but we must stay united to achieve the best possible landscape and horizon for pharmacy. Next year, in Cape Town, the theme of our 82nd world congress will be 'Innovating for the future of health care', and I count on your contribution there so that, together, we can continue to create and establish the future that we desire." FIP's 2024 congress will take place from 1 to 4 September. Find out more here: www.capetown2024.fip.org

PSSA members can look out for special PSSA newsletters focusing on FIP 2024, containing all the necessary information for local delegates.

Image 1: Marketing of Cape Town and South Africa as the destination for the 2024 FIP World Congress with souvenirs received from South African National Convention Bureau.

Image 2: Delegates from South Africa at the FIP stand, promoting Cape Town and South Africa.

Image 3: Delegates from South Africa receiving the flag to safeguard until September 2024, when the next FIP Congress will commence in Cape Town.

Codeine misuse continues

According to the Carte Blanche episode, the South African Health Products Regulatory Authority (SAHPRA) is aware of the illicit bulk sale of codeine-containing mixtures. The report relates to the illicit bulk sales of codeine-based cough mixtures perpetrated by a pharmaceutical group, and this was verified by an ongoing investigation. The individuals under investigation were exposed for violating the Medicines Act and its Regulations (Act 101 of 1965) in terms of the type of pharmacy and the manner under which controlled substances' products were sold amongst other contraventions. The abuse of codeine is becoming a ubiquitous practice and puts the lives of the public at risk and compounds the problem. SAHPRA CEO, Dr Boitumelo Semete-Makokotlela said, "*The extent and severity of the abuse of codeine-containing medicines is especially rife amongst our youth in the country. It is with this mindset that we continue to be on high alert in preventing, detecting, and responding to such unethical behaviour and the illicit sale, use or trafficking of scheduled medicines.*"

During a meeting later that week between the Codeine Care Forum task team, members of the South African Health Products Regulatory Authority (SAHPRA), SAPC, and SANAC Civil Society all members agreed that more direct actions and deliverables are needed. A workshop discussion took place to define the problem, initiative, and potential role players. Subgroup meetings on IT/data, marketing and legislation will be held at the end of October, and the whole team will reconvene in November to determine progress towards the roll out of the Codeine Care Initiative nationally with mandatory participation.

The PSSA calls on all members who are aware of unprofessional and illegal distribution of codeine-containing products in bulk to patients, or other recipients, to please bring this to the attention of the PSSA for escalation to SAHPRA and SAPC. The whole profession needs to work together to end this health threat.

The PSSA/Alpha Pharm distance learning programme 2023

The PSSA/Alpha Pharm distance learning programme continues to offer pharmacists useful, practical, up-to-date information that enables them to provide optimal pharmaceutical care to their patients.

Module 5 – Anaemia and its management

Anaemia is not a diagnosis but a symptom or presentation of an underlying disease. It is a condition in which the number of red blood cells (and consequently their oxygen-carrying capacity) is low and insufficient to meet the body's needs.

According to the World Health Organization (WHO), anaemia is a major public health concern, mainly affecting young children, pregnant and postpartum women, and menstruating adolescent girls and women in developing countries.

Anaemia can result from a wide range of conditions, often with multiple mechanisms at play. For example, anaemia can be caused by poor nutrition, infections, chronic disease, heavy menstruation, and pregnancy issues. It is often caused by a lack of iron in the blood.

Anaemia is preventable and treatable. It is important to identify the underlying cause and then ensure early, appropriate management. This module discusses anaemia, with a focus on iron deficiency anaemia and its prevention and management in a primary healthcare setting.

For more information about this programme, contact Gill or Glynis at Insight Medicine Information on 011 706 6939 or email: cpdalphapharm@insightmed.co.za.

The PSSA/Alpha Pharm clinical education programme 2023 for pharmacy staff

The PSSA/Alpha Pharm pharmacy staff clinical education programme continues to offer front-shop assistants or pharmacist's assistants up-to-date information that enables them to provide optimal pharmaceutical care to their patients. All pharmacy staff need to be familiar with the use of unscheduled medicines and should be reminded of when it is necessary to refer the patient to the pharmacist.

Module 5, 2023 – Skin care in the pharmacy

The skin is the largest organ of the body, accounting for about 7% of the total adult body weight. Its functions go well beyond serving as a covering that protects the body. The skin is pliable yet tough, allowing it to take constant punishment from external physical, chemical and biological agents. Without our skin, we would quickly become ill from bacterial infection or die from water and heat loss.

The desire to have flawless skin is not new and has been documented since the times of ancient Egypt, when unguent, a soothing ointment was used to hydrate the skin. Skin issues can cause low self-esteem, anxiety, depression, and social isolation.

Pharmacists and the front shop members of staff in a community pharmacy play an important role in helping their customers maintain the health of their skin. From appropriate management of simple skin conditions, such as dry or oily skin, to the prevention and treatment of photoaging, the pharmacy staff are frequently the frontline healthcare workers for patients struggling with minor skin conditions or wanting to improve the health and appearance of their skin.

The pharmacy staff are also ideally positioned to educate customers about the importance of appropriate skin care.

If you would like to participate in the PSSA/Alpha Pharm pharmacy staff clinical education programme, please contact Gill or Glynis for further information on 011 706 6939 or email: cpdalphapharm@insightmed.co.za.

PSSA YPG on the release of the SAPC pre-registration examination results

The Pharmaceutical Society of South Africa's Young Pharmacists' Group (PSSA YPG) has written to the South African Pharmacy Council (SAPC) to address the delayed release of Pre-registration Examination results for pharmacist interns. This action underscores the PSSA YPG's commitment to pharmacist interns' rights and welfare.

Prompted by increasing concerns among interns about the long wait for results, the PSSA YPG has highlighted this delay's adverse effects on interns' professional development. The group points out that the delay creates uncertainty, causing emotional distress, and hampers interns' ability to plan future steps, such as job applications and further education.

In its letter, the PSSA YPG urges the SAPC to assure interns of the steps to address the delays and prevent future occurrences. The group proposes an efficient, transparent process for result release, underscoring the importance of timely feedback. This advocacy emphasizes the need for collaboration between professional bodies and regulatory authorities. The PSSA YPG aims to foster constructive dialogue with the SAPC to develop solutions benefiting pharmacy interns and the profession. This approach is hoped to contribute to a more efficient and supportive environment for pharmacy interns.

The PSSA YPG's efforts remind us of the importance of active engagement in effecting positive change in the pharmacy profession. The PSSA YPG's communication intends to engage the SAPC on the importance of listening to feedback from stakeholders through the various channels, a timely result release is not only an administrative efficiency matter but also fundamental to supporting professional growth. Pharmacist interns are encouraged to remain engaged, communicate their concerns, and propose solutions.

The PSSA YPG further recommended that the SAPC establishes clear and prompt communication channels with interns, providing regular updates on result releases. The Council was also encouraged to explore technological solutions for streamlining the result release process to reduce administrative burdens, minimise delays, and improve overall efficiency.

Regular interaction between the PSSA YPG, SAPC, and other stakeholders is essential for creating sustainable change. Through collective efforts, the pharmacy profession in South Africa can ensure a more efficient and nurturing experience for aspiring pharmacists.

PSSA YPG launches a LinkedIn page!

Exciting news! We are thrilled to announce the launch of our brand-new LinkedIn page, the Young Pharmacists' Group (YPG)! This page is the perfect platform for all young and aspiring pharmacists to connect, engage, and grow together. Join the YPG on LinkedIn and be part of the Pharmacy Engagement professional community.

Since the page's debut in September 2023, we have already made a significant impact, with an impressive 403 post impressions and 12 dedicated followers within the first month alone. But this is just the beginning! We want YOU to join us on this exciting journey and be part of our growing community of passionate pharmacists.

Why should you subscribe?

Let us tell you why:

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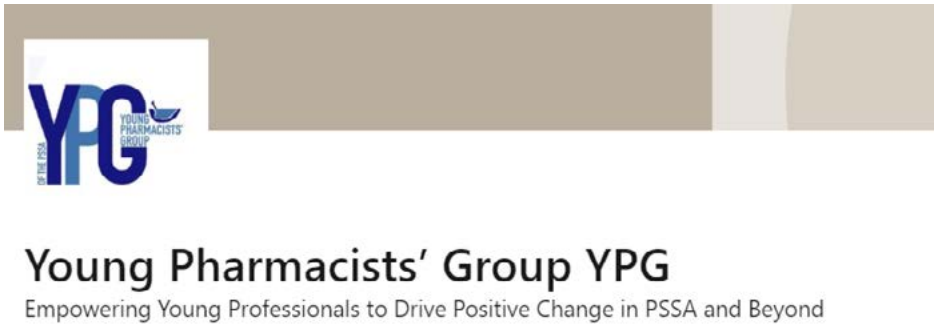
- **Engaging Discussions:** Participate in stimulating discussions, share your experiences, and exchange ideas with fellow pharmacists. Our community is all about fostering collaboration and learning from one another.
- **Exclusive Events and Webinars:** Gain access to exclusive events, webinars, and workshops designed to further your knowledge and skills. Stay ahead of the curve and make the most out of your professional development.

Do not miss out on this incredible opportunity to be part of the vibrant YPG community on LinkedIn. Simply search for "Young Pharmacists' Group YPG" on LinkedIn https://www.pssa.org.za/young-pharmacists-group.html



and hit that "Follow" button to stay connected.

Together, let us revolutionise the pharmacy profession, inspire one another, and make a lasting impact. We cannot wait to have you on board!

Subscribe today and be part of the YPG movement!

Feel free to reach out to us at
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Young pharmacists – connected, engaged, empowered and inspired!

Allergic rhinitis: review of the diagnosis and management: South African Allergic Rhinitis Working Group

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Abstract

Background: Allergic rhinitis (AR) has a significant impact on the community as a whole with regard to quality of life and its relationship to allergic multi-morbidities. Appropriate diagnosis, treatment and review of the efficacy of interventions can ameliorate these effects. Yet, the importance of AR is often overlooked, and appropriate therapy is neglected. The availability of effective medications and knowledge as to management are often lacking in both public and private health systems.

Methods: This review is based on a comprehensive literature search and detailed discussions by the South African Allergic Rhinitis Working Group (SAARWG).

Results: The working group provided up-to-date recommendations on the epidemiology, pathology, diagnosis and management of AR, appropriate to the South African setting.

Conclusion: Allergic rhinitis causes significant, often unappreciated, morbidity. It is a complex disease related to an inflammatory response to environmental allergens. Therapy involves education, evaluation of allergen sensitisation, pharmacological treatment, allergen immunotherapy (AIT) and evaluation of the success of interventions. Regular use of saline; the important role of intranasal corticosteroids (INCS), including those combined with topical antihistamines and reduction in the use of systemic steroids are key. Practitioners should have a thorough knowledge of associated morbidities and the need for specialist referral.

Contribution: This review summarises the latest developments in the diagnosis and management of AR such that it is a resource that allows easy access for family practitioners and specialists alike.

Keywords: allergic rhinitis; intranasal corticosteroids; antihistamines; immunotherapy; saline rinse.

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Introduction

Allergic rhinitis (AR) is one of the most common chronic conditions with a prevalence of 10%–40%.[1-8] It can cause significant discomfort and a marked reduction in productivity and quality of life (QoL).[8] Moreover, its consequences can be serious, including contributing to asthma exacerbations and comorbidities such as rhinosinusitis and otitis media; increasing susceptibility to viral illnesses and impacting on taste, smell and sleep quality.[7-10] Poor sleep quality can result in chronic fatigue, daytime sleepiness and learning problems in children.[11] AR can also aggravate mood disorders such as depression and decrease the ability to concentrate.[12,13] Despite this, it is significantly underdiagnosed and suboptimally treated, particularly in children where AR symptoms may be attributed to viral infections.[7]

AR and asthma often coexist (united airway concept), and AR is a risk factor for the development of asthma.[14] In patients with asthma, AR may be associated with poor control of the disease.[14,15] Appropriate treatment of AR can result in a significant improvement in patients' QoL, as well as improve the control of comorbid conditions such as asthma.[14,15] This can reduce the overall cost of asthma treatment and reduce the number of patients with uncontrolled asthma requiring treatment at the hospital level.

Both the prevalence and consequences of AR have led the World Allergy Organization to label it "a global public health concern".[16] Excellent comprehensive guidelines are available[9,17-21] but are generally written in, and for, high-income countries; whereas they are mostly universally applicable, there are local factors in South Africa (SA) that call for some unique recommendations, including:

- *Economic issues*: South Africa represents a resource-poor setting with priority given to infectious diseases and diseases considered to be more severe. Funds for medications for AR are frequently not a priority in the public health sector. However, untreated or poorly treated AR may have a greater economic cost as a result of absenteeism or reduced productivity.[22]
- *Practical issues*: Distance to hospital or clinic, single-parent households and inability to take time off work make clinic visits difficult.
- *Understanding of health-related issues*: This may be affected by poor health literacy and dominant traditional beliefs, negatively affecting compliance.

The aim of this consensus document, produced by the SAARWG, is to review up-to-date recommendations for AR applicable to SA.

Epidemiology

AR affects between 10%–40% of children and adults worldwide,[1-8] approximately 80% developing before the age of 20 years, with a peak at 20–40 years and then a gradual decline.[6,8] The burden in low- and middle- income countries is similarly substantial and has been increasing since the 1990s.[1,2,6] In the International Study of Asthma and Allergies in Childhood (ISAAC), the SA cohort of 13–14 year olds showed substantial and increasing prevalence from 30.4% in 1995 to 38.5% in 2002.[2] Urbanisation and increasing levels of pollutants, as well as changes in pollen concentrations, allergenic potential and composition because of climate change, have been implicated in the increase in the prevalence of AR.[23,24]

Pathophysiology

AR is a result of a Type 1 hypersensitivity reaction of the nasal mucosa. Allergens deposited onto the nasal mucosa of sensitised individuals bind to allergen- specific immunoglobulin E (IgE) on the surface of mast cells, resulting in the release of preformed mediators such as histamine. This causes the early phase of the allergic response and leads to acute symptoms such as itching, sneezing and rhinorrhoea.[6,7,25] The late phase of the allergic response, which precipitates a cycle of chronic allergic symptoms, manifests 4 h–6 h after allergen exposure, with nasal mucosal inflammation from activation and influx of inflammatory cells, including T-cells, eosinophils, basophils and neutrophils.[6,25]

Priming (increased nasal responsiveness to an allergen with repeated allergen exposure) occurs as a result of increased numbers of mast cells in the epithelium, increased permeability of the epithelium and easier allergen penetration to IgE-bearing cells and exaggerated responses of the nasal end organs.[6,8] Air pollutants can also contribute to priming. Treatment with intranasal corticosteroids (INCS) can suppress the priming response.[6,8,25]

Clinical diagnosis

The diagnosis relies chiefly on clinical assessment and laboratory tests indicating allergic sensitisation. Clinical assessment should include a thorough history recording duration, seasonality and severity of symptoms, and examination.[7] Nasal and non-nasal symptoms can occur.[7,25,26]

Symptoms of AR (which may be prolonged after allergen exposure) include the following:

Nasal symptoms:

- Rhinorrhoea (anterior and posterior), sneezing, nasal blockage and itching and hyperreactivity of the mucosa to other allergens and non-allergic stimuli (e.g., irritants and strong odours)

Non-nasal associations:

- Allergic conjunctivitis, palatal itching, cough from postnasal drip, asthma exacerbations, sinusitis or otitis media.
- An impact on QoL, specifically cognitive dysfunction and sleep disturbance.

Examination

The examination should assess for signs of atopy such as the "allergic facies" (pallor, allergic shiners, nasal creases, Dennie-Morgan lines and mouth breathing). The inferior turbinate should be examined for swelling and pallor. The patient should be evaluated for concomitant allergic diseases such as eczema and asthma. Comorbidities such as chronic rhinosinusitis (CRS), otitis

media and hearing loss should be quantified. Other factors that can also cause nasal obstruction such as nasal polyposis, septal deviation, nasal deformities or mid-facial hypoplasia should be excluded.

Imaging

Plain film sinus X-rays have no place in the diagnosis. Computed tomography scanning should be reserved for suspected chronic sinus disease, particularly where surgery is contemplated.

Classification of severity

In SA, the Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines are widely applied[9,17] despite the recognition of some weaknesses.[26,27] These guidelines divide symptoms into intermittent or persistent and severity into mild or moderate-severe (Figure 1).[7,9]

Differential diagnosis

The differential diagnoses of AR must be considered to plan for appropriate testing (Table I).[6-8,25,28]

Testing for allergen sensitisation

Objective laboratory testing can identify patients at increased risk for severe disease, direct preventative steps to minimise allergen exposure(s) and tailor treatment and allergen immunotherapy (AIT).[29] However, indiscriminate and extensive specific IgE testing is not indicated where history and examination suggest AR.

Various recommendations regarding prevailing aeroallergensin SA have been made and subsequently modified.[29-31] The 2015 iteration included the pooled specific IgE aeroallergen screen (Phadiatop®) for which there is an extensive evidence base to support its use as a single rule-out test.[32]

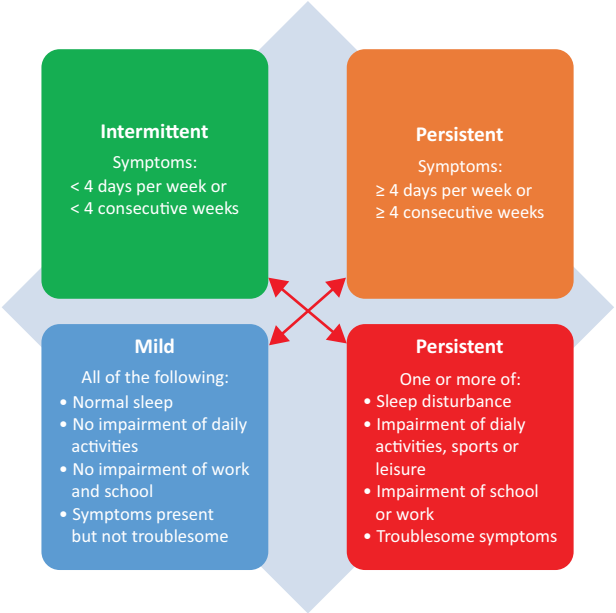

Figure 1: AR and Its Impact on Asthma guidelines on AR categorisation in untreated patients[7,17]

A panel of specific IgEs to aeroallergens deemed most relevant to SA was established in 2014 by the Allergic Rhinitis Diagnostic Working Group (ARDWG). This included indoor allergens (house dust mites (HDM) (*Dermatophagoides pteronissinus* [Der p] and *farinae* [Der f]), cat, dog, moulds (including *Alternaria*, *Epicoccum*, *Cladosporium*, and cockroach), and outdoor allergens (Rye grass, Bermuda grass). Since then, specific IgE testing over 3 years (November 2019–October 2022) from two private laboratories revealed that 36.6% of Phadiatop® tests were negative, confirming its usefulness as a screen-out tool and that testing analysis showed low positivity to the outdoor mould *Cladosporium* (m2).

Table I: Differential diagnosis of AR[6]

Inflammatory	Neurogenic/ Vasomotor	Anatomical
• Occupational rhinitis • Chemical rhinitis • Autoimmune, granulomatous and vascular rhinitis • Fungal rhinosinusitis • Non-steroidal exacerbated rhinitis/ Samter's triad • Acute or recurrent infective rhinosinusitis • Chronic rhinosinusitis with or without nasal polyposis • Primary immune deficiency • Crèche syndrome • Cystic fibrosis	• Vasomotor rhinitis • Rhinitis medicamentosa • Atrophic rhinitis • Age-related rhinitis • Smoke-induced rhinitis • Non-allergic rhinitis with eosinophilia (NARES)	• Deviated septum/ septal spur • Empty nose syndrome • Antrochoanal polyp • Foreign body • Adenoidal hypertrophy • Primary ciliary dyskinesia

On existing evidence, the following are recommended as first line for testing:

- Phadiatop®, although not specific for SA, is a cost-effective screen-out tool in patients with a history of possible AR.
- In patients with a history suggestive of AR, skin prick testing with the suggested ARDWG common allergens or specific IgE testing is indicated (Figure 2).
- If Phadiatop® is positive, further analysis using the modified ARDWG panel may be performed to guide treatment.
- If Phadiatop® is negative, an alternative diagnosis should be sought or local AR should be considered. Further allergy testing is only recommended if history suggests a specific aeroallergen trigger that has no cross reactivity with allergens in the Phadiatop®. Repeat Phadiatop® testing is not recommended.
- *Cladosporium* has been removed from the ARDWG panel, and Plane and Cypress trees (Figure 2) included as early pollen monitoring data from across SA suggest these are the commonest allergenic tree pollens.[33] However, pollen data are not yet comprehensive for all areas across SA, and other allergenic pollens (trees and weeds) may be relevant in

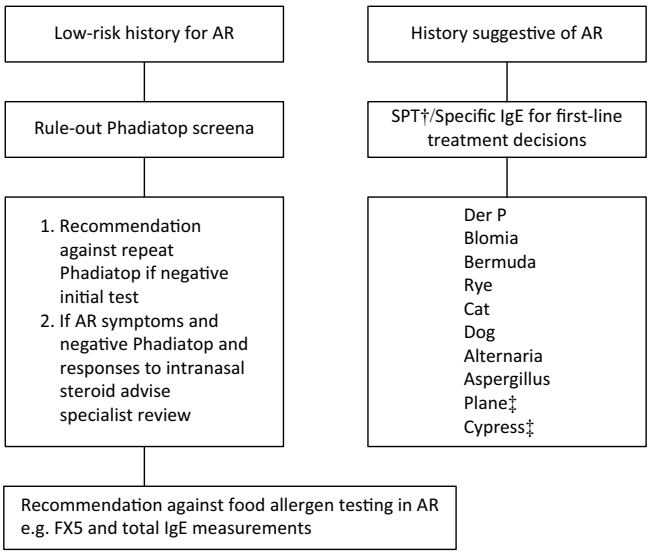

Figure 2: First-line testing recommendations to either rule out AR or guide first-line treatments or allergen avoidance strategies in AR

AR, allergic rhinitis; SPT, skin prick testing; CI, contra indication; Der P, *D. pteronissinus*; Blomia, Blomia tropicalis; IgE, immunoglobulin E.

†, Consider contra indications to SPTs; ‡, consider regional variation in dominant tree species (www.pollencount.co.za)

certain areas[33] (updated pollen data can be found at https://pollencount.co.za/).

- Specific tree panels should be considered based on clinical history, and where available, local sensitisation and pollen data (https://pollencount.co.za/).
- Food allergies very rarely cause AR, and hence, food allergy testing is generally discouraged.

Management of allergic rhinitis in children and adults

Management rests on seven integrated pillars.[19] They are:

- Education about AR and its therapy.
- Practical allergen avoidance and exposure reduction strategies.
- Nasal douching/irrigation and rinses.
- Pharmacological treatment:
  - INCS
  - Oral and intranasal antihistamines (INAH)
  - Other (including leukotriene receptor antagonists [LTRA]).
- Patient evaluation for AIT.
- Measuring response to therapy.
- Patient evaluation for referral to a specialist.

Education

Education is the cornerstone of effective management. Key points include explaining that AR is a chronic disease and that, apart from AIT, there is no curative treatment. Treatment options should be discussed with regard to cost, efficacy, ease of use and side-effect profile.

Shared decision-making is of utmost importance. One of the main goals of shared decision-making is long-term adherence to treatment,[34,35] which is required for the successful treatment of AR.[36] This is achieved through discussing the available therapeutic options and agreeing on a treatment plan that best serves the needs of the patient and which ensures compliance with and persistence with the plan.[34,35]

Daily medication for persistent symptoms or intermittent use for seasonal symptoms should be discussed, as should the correct dosage, frequency and time of dosing.

Poor treatment adherence is an important barrier to treatment success, and questionnaires, such as the Medication Adherence Report Scale, a validated 5-item tool that assesses adherence, can be used in routine clinical practice.[28]

The correct method of using an INCS, by means of a physical demonstration, should be emphasised at the initial visit:

- After shaking and removing the lid, the nasal spray should be aimed towards the turbinates, which are on the lateral wall of the nasal passage.

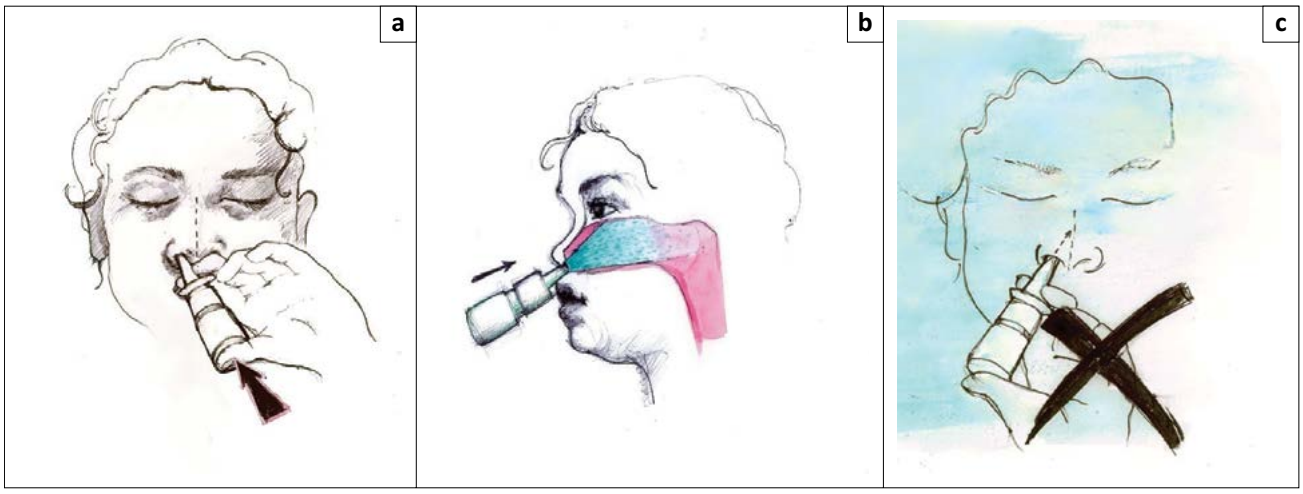

Figure 3: Technique for using nasal sprays. (a) Correct technique, (b) direction of spray using correct technique and (c) incorrect technique.

Source: Images by Dr Nicole Shaer, used with permission

- Ideally, the head should be tilted slightly forwards and, while closing the opposite nostril, one puff should be administered towards the outer side wall of the nose, aiming towards the ear and the back of the head, avoiding the nasal septum (Figure 3).
- Repeat the process in the other nostril.
- After each puff, the patient should try not to sniff, but rather pinch the nose between the thumb and index finger, holding the head neutrally forwards for a count of 10.
- Afterwards, the nose may be wiped, without blowing.

Written educational material containing this information may be helpful to cement the key points.

Practical allergen avoidance and exposure reduction strategies

Allergen avoidance and environmental control measures aim to decrease exposure to aeroallergens and irritants to reduce the severity of symptoms (Table II).[37-40] The major outdoor allergens are pollens and fungal spores, while the major indoor allergens include HDM, pets, moulds and cockroaches. Avoidance measures can be cumbersome, expensive and not always practical, and hence, allergen sensitisation needs to be proven before advising on allergen reduction strategies.

Nasal saline douches/irrigation and rinses

Nasal irrigation with hypertonic or isotonic saline is a simple, inexpensive and effective adjunct to therapy, by squirt, pump, gravity (e.g., 'neti-pot') or spray bottle systems. Nasal rinses remove allergens, irritants and inflammatory mediators and clear accumulated mucus, optimising mucociliary clearance. Saline rinsing is safe in children and adults and reduces disease severity and symptom scores.[41]

Whenever possible, saline irrigation should precede the administration of INCS to remove debris for better delivery of INCS.

In a resource-constrained environment, the following recipe can be used in place of commercially available products for nasal irrigation[42]:

- In a clean container, mix 3 teaspoons iodide-free salt with 1 teaspoon bicarbonate of soda.
- Add 1 teaspoon of this mixture to 250 mL of lukewarm distilled or boiled water.
- Using a soft ear bulb or a commercial device, draw up the solution, lean over a sink with the head held sideways and insert the mixture into the top nostril till it comes out of the bottom nostril.
- Then repeat on the opposite side.

Pharmacological treatment of allergic rhinitis

The efficacy of the various classes of drugs for the treatment of AR is listed in Table III[43,44] and Figure 4.[19]

Table II: Environmental control and allergen avoidance measures[37]

Allergens	Control and measures
House dust mites	• Use occlusive air-permeable fabric protectors for pillows, mattresses and duvets. • Bedding should be washed in hot water and exposed to direct sunlight. • Replace carpets with wooden floors or tiles. • Loose carpets should be cleaned regularly and sun dried • Vacuum with a vacuum cleaner with a high-efficiency. particulate air (HEPA) filter – adequate disposal of vacuum bag is important thereafter. • Vacuum cleaning increases room dust, so a mask should be worn while vacuuming – leave the room for 20 min after vacuuming. • Remove soft toys from the bedroom. • Air conditioners are not advisable, as filters often contain house dust mite allergens, which may be recycled through rooms. • Benzyl benzoate, tannic acid, acaricides and other anti-mite sprays have very little or unproven benefit. • Humidifiers increase mould and HDM.
Cockroach	• Do not leave food open overnight. • Do not leave dishes in the sink overnight. • Seal cracks and crevices. • Vacuum or sweep the floor after every meal. • The use of professional exterminators is advised. • Use cockroach traps.
Pet allergens	• Removal of pets only after proof of sensitisation with clinical symptoms directly related to pet exposure (patients and families are unlikely to adhere to this). • Regular washing of pets. • Keep pets out of the bedroom. • Frequent vacuuming with vacuum cleaner equipped with a HEPA filter. • Encase pillows and mattresses. • There is no evidence that any breed of dog or cat is hypoallergenic.
Indoor moulds	• Ensure adequate ventilation. • Limit the number of indoor plants. • Clean mould-infested surfaces with bleach. • Repair of leaks. • Removal of water-damaged materials. • Run (exhaust) vents advisable in bathroom and kitchen. • Regular vacuuming may reduce fungal spores, but replacing carpets with other types of flooring seems more effective.
Outdoor allergens (pollens and fungal spores)	• Avoid outdoor activities and wear masks outdoors during peak pollen and mould periods by consulting pollen calendars and pollen forecasts/monitoring websites. • Keep doors and windows closed. • Change clothing when returning home. • Mould-sensitive patients should avoid contact with decomposing leaves, grasses and grains.

Note: Further information on reduction of common allergens is available on the Allergy Foundation website – https://www.allergyfoundation.co.za/patient-information/en/allergens/.

HDM, house dust mites.

Table III: Efficacy of various classes of drugs for AR[43]

Pharmacological agent	Nasal obstruction	Rhinorrhoea	Sneezing	Nasal itching
Intranasal corticosteroids	+++	+++	++	+
Antihistamines	+	+++	+++	+++
Combination intranasal corticosteroids and antihistamines	+++	+++	+++	+++
Intranasal cromones	+	+	+	+
Intranasal decongestants	++++	-	-	-
Anticholinergics	-	++	-	-
Leukotriene-receptor antagonists	++	+	-	-

Intranasal corticosteroids

INCS are the pharmacological treatment of choice for all forms of AR as they are effective against a wide range of symptoms.[17,19,25,29] They are used intermittently for seasonal disease and continuously for perennial disease.[30] Efficacy should be reviewed after 2–4 weeks in treatment- naïve patients. If still symptomatic, a combination of INCS and antihistamine is advised.

Side effects of INCS are mostly because of local irritation and include nasal dryness, a burning sensation inside the nose, blood-tinged nasal secretions and epistaxis.[21] Hydrating the nose with saline may reduce these side effects. Erroneously aiming the spray towards the nasal septum is an important contributor to local side effects.

All newer INCS are safe and effective. However, these molecules have structural differences that influence glucocorticoid receptor-binding affinity and topical anti- inflammatory potency. These differences also alter the physicochemical properties such as solubility, lipophilicity and permeability, which in turn influence the pharmacokinetic properties and the systemic activity and therapeutic index.[45,46] Molecules such as fluticasone propionate, fluticasone furoate, ciclesonide and mometasone furoate have increased glucocorticoid receptor selectivity and binding affinity and greater uptake and retention in the nasal tissue and have negligible systemic bioavailability (< 1%) compared to molecules such as budesonide, beclomethasone dipropionate and triamcinolone.[46,47]

Intranasal corticosteroids decrease the release of inflammatory mediators and cytokines from inflammatory cells and provide effective symptomatic relief when used continuously or as needed. They are most effective when used regularly, or at least in prolonged 'blocks' of treatment, as the onset of action is

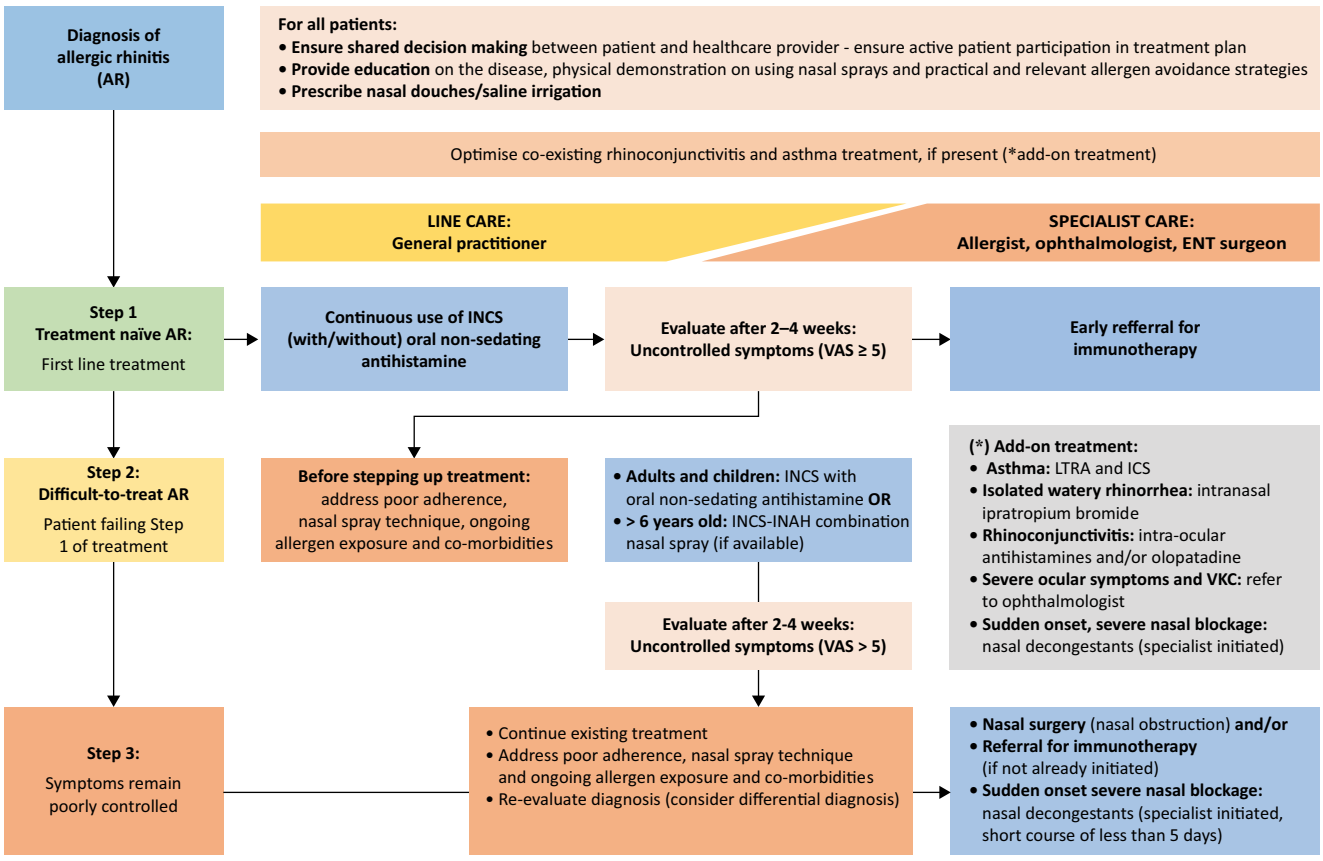

Figure 4: Flow diagram describing Management of AR[19]

SAR, seasonal allergic rhinis; PAR, perennial allergic rhinis; INCS, intranasal corcosteroid; INAH, intranasal anhistamine; VAS, visual analogue scale; LTRA, leukotriene receptor antagonists; ICS, inhaled corcosteroids; VKC, vernal keratoconjunctivitis; ENT, ear, nose and throat.

Table IV: Summary of SAARWG -recommended practice points for the pharmacological treatment of AR[30]

No.	Recommended practice points
1	INCS are considered the first-line treatment for AR and are effective for all the nasal symptoms of AR.
2	Maximal effect of INCS on symptom relief occurs only after 2 weeks of continuous use.
3	The use of saline sprays or rinses is effective to remove mucus, allergens and inflammatory cells, and regular use, preceding the use of INCS, should be encouraged.
4	For moderate to severe allergic rhinitis, a combination INCS-local AH spray should be considered early in the treatment ladder, if available.
5	Newer-generation oral AH should be used as add-on therapy to INCS, if necessary.
6	No newer-generation oral AH have been consistently shown to be more efficacious than another.
7	AH address pruritus, sneezing and rhinorrhoea but, as opposed to the INCS, have minimal effects on nasal congestion.
8	Newer generation oral AH can be used as monotherapy (first line), but only if a patient is reluctant to use INCS
9	The choice of newer generation AH should be individualised, considering issues such as pregnancy, drug interactions and cost.
10	Some non-sedating (newer generation) oral AH are registered for use in children aged 6 months and older (and are often prescribed "off-label"), while most other AH are registered for safe use in children older than 2 years of age.[61,62]
11	Older generation AH (alone or in combination with systemic corticosteroids or systemic decongestants) should not be used to treat viral infections.
12	AH do not prevent asthma in children with AR and/or eczema.
13	In children (< 6 years of age), faster drug elimination may require twice daily instead of daily dosing (e.g., cetirizine and levocetirizine).
14	Currently, no data have been published on the 'development of tolerance' to AH, and no scientific evidence exists that encourages patients to rotate through different AH after a certain period of using a specific drug.
15	Because of unnecessary medication costs involved in dual therapy, the SAARWG, in line with the ARIA guideline, discourages the use of LTRA combined with oral AH in AR, unless concomitant asthma (especially exercise-induced and/or aspirin-exacerbated respiratory disease) is present. If this is the case, an LTRA (rather than an oral AH) is the drug of choice as add-on with INCS.[17]

AR, allergic rhinitis; ARIA, Allergic Rhinitis and Its Impact on Asthma; INCS, intranasal corticosteroids; LTRA, leukotriene receptor antagonists

7 h–12 h, with maximum benefit after 2 weeks of regular use. Intranasal corticosteroids with increased topical potency do not necessarily offer a therapeutic advantage relative to those with less potency.[47-50]

INCS are less likely to cause systemic side effects (e.g., adrenal suppression, bone fractures, growth suppression and ocular side effects) compared to oral and inhaled corticosteroids (ICS) because of the lower dose and lower bioavailability.[48] Care should still be taken when multiple different steroid formulations (e.g., topical, inhaled and intranasal) are used.

Short-term use of INCS drops can be considered for severe congestion (1–2 weeks), but long-term use of INCS drops, as opposed to nasal sprays, is strongly discouraged, as these have higher systemic bioavailability and are significantly more likely to cause systemic side effects.

Depot intramuscular steroid injections should not be used for the treatment of AR.[9,51] Complications associated with their use include hypothalamic–pituitary–adrenal-axis (HPA) suppression, hyperglycaemia, osteoporosis, avascular necrosis of the femoral head and gluteal subcutaneous atrophy.[51]

Systemic antihistamines

H1-AH dampen the effects of histamine during the early and late phase of allergic reactions. They are effective against itching, sneezing and rhinorrhoea but have little efficacy against congestion.

H1-AH are functionally classified as first- or newer- (second and third) generation AH. Third-generation formulations (e.g., desloratadine, levocetirizine and fexofenadine) are metabolites or enantiomers of second-generation AH and are theoretically safer and more efficacious than second- generation types.[52]

First-generation AH have poor receptor selectivity (also acts on serotonergic, cholinergic, α-adrenergic receptors, also act on cardiac potassium ion channels)[53] and high lipid solubility, causing significant blood–brain barrier transgression. Because of the non-selectivity of receptor binding and propensity to side effects (including cardiac and gastrointestinal side effects, sedation, dry mouth, blurred vision),[52,53] SAARWG strongly discourages the use of first-generation AH in the routine management of AR.[30] Second- and third-generation AH are less sedating than the first-generation AH because of reduced brain H1 receptor occupancy.[54] Fexofenadine does not cross the blood–brain barrier. Rupatadine is a platelet-activating factor antagonist in addition to its antihistaminic properties.[55] In a systematic review of 45 randomised controlled trials, second- generation AH use in children was generally safe; however, some may cause sedation in certain patients.[56]

The SAARWG recommends the *exclusive use of newer generation AH* for AR treatment, with careful selection based on each patient's unique profile. If side effects occur, a different, non-sedating AH may be tried; however, the EUFOREA guidelines on AR in children discourage AH switching, and an intranasal AH or INCS is preferred.[57]

Intranasal antihistamines (INAH)

Topical INAH act rapidly (within 15 min) and have proven to be more effective than oral AH in the control of AR.[58] They are effective and safe in children with AR.[17,57,58] The major side effect is a bitter taste in the mouth, which is less with olopatadine than azelastine.[57] However, INAH (e.g., olopatadine and azelastine) are costly and not readily available in SA. In 2021, a combination intranasal spray, mometasone/olopatadine became available in SA, with approval for use in teenagers and adults.

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References: 1. Patel P, Salaptek AM, Tantry SK. Effect of olopatidine-mometasone combination nasal spray on seasonal rhinitis symptoms in an environmental exposure chamber study. American College of Allergy, Asthma & Immunology. 2019;122(2):160-166.e.1. **2**. Gross GN, Berman G, Amar NJ, et al. Efficacy and safety of olopatadine-mometasone combination nasal spray for the treatment of seasonal allergic rhinitis. Ann Allergy Asthma Immunol, 2019;122:630-638.

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Topical nasal decongestants

Nasal decongestants contain phenylephrine, oxymetazoline and xylometazoline that cause vasoconstriction of the nasal mucosa when applied topically, increasing airflow and relieving congestion. However, they have no effects on the other symptoms of AR and may worsen rhinorrhoea. Use for more than 5 to 10 consecutive days can cause rhinitis medicamentosa (rebound congestion). They should be used only for a short period when nasal congestion is dominant and always with an INCS.[59]

Leukotriene receptor antagonists

LTRAs are similar in efficacy to oral AH but are more effective in improving night-time than daytime nasal symptoms than AH.[59] They are less effective than INCS in improving overall symptoms and QoL and should not be used as first-line treatment.[25] Combinations of AH and LTRA are discouraged because of cost, unless concomitant asthma (especially exercise-induced and/or aspirin-exacerbated respiratory disease) is present.[17] In this case, an LTRA (rather than an oral AH) should be considered as an add-on to INCS, together with guideline-directed asthma treatment.[60] A summary of SAARWG – recommended practice points for the pharmacological treatment of AR is available in Table IV.[60]

Allergen immunotherapy

AIT is a desensitisation process for IgE- mediated hypersensitivity to common allergens such as pollens, HDM and insect venoms. It is the only disease- modifying treatment available for AR.[17]

The administration of high-dose allergen, using sublingual (SLIT) or subcutaneous (SCIT) immunotherapy, suppresses the pro-allergic dendritic cell phenotype by inducing T-cell differentiation to regulatory phenotypes (Tregs). Induction of B regulatory cells to stimulate blocking antibodies further reduces mast cell degranulation.[63]

AIT improves short- and long-term symptom severity, decreasing the need for medication for AR and protecting against the progression from AR to asthma.[64-66] AIT studies have further demonstrated a reduced need for asthma medications[67] and a reduction in new aeroallergen sensitisations.[65]

SCIT and SLIT are both effective once the causative allergen has been accurately identified by history and allergen sensitisation tests. Allergen provocation tests might be necessary in cases of high suspicion and inconclusive allergy test results.[57,68]

According to the ARIA-EAACI care pathway, both monosensitised (single dominant antigen) and polysensitised (multiple antigens) patients can benefit.[57,68]

Patients who should be considered for AIT include the following:

- Those in whom symptom control is not achieved with pharmacotherapy and allergen avoidance.
- Those in whom high medication doses with potential side effects are required, particularly corticosteroids.
- Those in whom adverse events have occurred on normal doses of pharmacotherapy.
- Those who would prefer not to have to take pharmacotherapy for prolonged periods.
- Children in whom AIT would potentially be a modifying intervention to prevent further sensitisations and to reduce the chance of developing asthma.
- Potentially adolescents or adults with pollen-food syndrome.

The duration of treatment should be for at least 3 years but needs to be individualised and might need to be continued for up to 5 years according to symptom severity and control.[69]

Asthma should be well controlled, and practitioners should be well versed in the management of adverse events, including rare cases of anaphylaxis.[70,71]

Currently, acquisition of AIT is made difficult by the fact that it is an expensive, unlicensed product with a single distributor in SA. For greater access, it would be preferable for products to be registered with the South African Health Products Regulatory Authority (SAHPRA). The acquisition cost of AIT is high, but the reduction in morbidity and medication costs makes it cost-effective.

Response to treatment

Visual analogue scales (VAS) (visual aids 100 mm long with descriptors of severity on opposite ends) or AR control tests are increasingly used to evaluate control and treatment response, to detect adverse effects and to gauge the need for treatment adjustment in a reproducible manner.[72] Tests of control should be validated and quick and easy to perform in routine clinical practice.[73] Validated control tests include the "Control of Allergic Rhinitis and Asthma Test" (CARAT), "Rhinitis Control Assessment Test" (RCAT), "Allergic Rhinitis Control Test" (ARCT) and "Sinonasal Outcome Test" (SNOT) for CRS.[8,28] The RQLQ questionnaire has been translated into Afrikaans, isiXhosa and isiZulu.[74] The clinician should use the same control test consistently and regularly to monitor the AR.

Indications for referral

Patients with AR can be successfully initiated on AR treatment by general practitioners. Treatment success should be evaluated 2–4 weeks after the initiation of therapy.

The following are indications for referral to a specialist (e.g., allergologist, ear, nose and throat [ENT] surgeon or ophthalmologist, according to symptoms):

- Poor or no response to treatment (based on VAS assessment).
- Need for initiation of AIT.
- Assessment of aeroallergen sensitisation if not available at the primary health care level.
- Atypical nasal symptoms and signs, including unilateral involvement, epistaxis and anosmia.
- The presence of nasal polyps, septal perforation, facial

deformities and significant cervical lymphadenopathy.

- Severe co-morbid allergic diseases (e.g., atopic dermatitis, asthma and food allergy).
- Warning symptoms and signs of a possible underlying immune deficiency (e.g., cystic fibrosis, inborn errors of immunity and primary ciliary dyskinesia).
- The presence of severe ocular involvement (e.g., vernal keratoconjunctivitis).

Indications for surgery in allergic rhinitis

Surgery for "pure" AR is rarely needed but may be needed in severe cases to improve airflow (inferior turbinate surgery, adenoidectomy, septoplasty and polypectomy)[75,76]; to improve access to topical medications and to decrease disease burden before other procedures such as AIT, aspirin desensitisation or initiation of biological therapies.[77-79]

Surgery may be needed to manage complications of AR such as chronic or recurrent otitis media or for overlapping chronic conditions involving the nose and sinuses such as CRS with and without nasal polyps, non-steroidal (aspirin) exacerbated respiratory disease, cystic fibrosis, eosinophilic granulomatous polyangiitis (Churg-Strauss syndrome) and allergic fungal rhinosinusitis.[18] Such patients should be referred for appropriate procedures by a surgeon skilled in rhinology and base of skull surgery.

Multi-morbidities

Multi-morbidity is defined as the presence of one or more additional disorders co-occurring with a primary disorder. Multi-morbidities associated with AR include the following:

- Allergic disorder spectrum: asthma, atopic dermatitis, food allergy, eosinophilic oesophagitis, allergic conjunctivitis and anaphylaxis.
- Disorders of the upper airway, middle ear and Eustachian tube disease, sinusitis, turbinate and adenoid hypertrophy and pharyngeal and laryngeal disorders.
- Sleep disorders with secondary effects on concentration, behaviour and mood.

Treatment of AR will often result in an improvement of these associated multi-morbidities.[80]

Conclusion

AR causes significant, often unappreciated, morbidity in the community. It is a complex disease related to an inflammatory response to environmental allergens. Therapy involves education, evaluation of allergen sensitisation, pharmacological treatment, AIT and evaluation of the success of interventions. Regular use of saline, the important role of INCS, including those combined with topical antihistamines and the reduction in the use of systemic steroids are key. Practitioners should have a thorough knowledge of associated morbidities and the need for specialist referral.

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Authors' contributions

All members participated in the SAARWG meeting except C.F., and thereafter, each member contributed portions to the manuscript, which was consolidated by G.A.R. and C.G. C.F. provided consultative advice.

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The authors confirm that the data supporting the findings of this study are available within the article.

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Gender perspectives on the current application of young responsible pharmacist management competencies

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Abstract

Background: There are five management functions essential to effective management. The South African Pharmacy Council (SAPC) outlines six competency standards relating to management. Pharmacists can become responsible pharmacists (RPs) directly after completion of their internship i.e. in their community service year.

Methods: Quantitative research with a cross-sectional component, which falls into the positivist approach, was used. Questionnaires were sent out to all RPs in South Africa under the age of 35.

Results: Most female RPs were found to be at entry level when measured using the competency standards, while the male respondents were between intermediate and advanced, even though the female respondents had been pharmacists for longer and had more years of experience.

Conclusion: Gender does not play a significant role in the RP's ability to manage a pharmacy, but training does. More research needs to be done to determine if this gender disparity can be addressed by the development of a management training course that is focused on the operation of a pharmacy. Likewise the possibility of introducing a minimum level of training to be registered as an RP, needs to be considered.

Keywords: young responsible pharmacist, management training

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Introduction

Competency is when an individual possesses the required practical and theoretical knowledge, cognitive skills and attributes that enable the individual to perform tasks and duties as effectively as possible. Within the context of pharmacists or the pharmacy profession, the responsible pharmacist's (RP's) competencies would refer to the skills and knowledge base necessary to perform the RP duties as stipulated in the competency standards.[1] There are five critical management functions for effective management: operations, human resources, marketing, finance, and logistics.[2] The South African Pharmacy Council (SAPC) outlined six competency standards related to management that an entry-level pharmacist must understand.[1] The management module in the Bachelor of Pharmacy degree curriculum in most South African pharmacy schools consists of several themes, including basic change, financial management, human resource management, logistics, marketing, quality improvement, risk management, strategic management and policy development, relationship management, and laws and regulations, with an average of 18 credits allocated.[3,4,5] The competency standards expect pharmacists to execute management skills at the intermediate-to-advanced level, which typically takes more than three years of practice to achieve. However, in South Africa, a pharmacist can become a RP in their first year of practice post-internship. In other countries, such as Ukraine and Poland, postgraduate training or further studies in pharmacy management are required to become a pharmacy manager, or RP. In Spain, a pharmacist must have at least five years of experience as a pharmacist in a pharmacy before applying to become the pharmacy manager.[6] Moreover, gender disparity still exists in terms of representation in management in science, technology, engineering, and mathematics (STEM) professions and management roles.[7]

There is an ongoing debate as to whether gender affects management ability. There are arguments that gender does not play a significant role in management ability and that it is dependent on an individual's skills, experience, and education. Women continue to be underrepresented in these fields, with only a small percentage of women occupying leadership positions. According to a report by Catalyst, a global non-profit organisation, women hold only 29% of senior management roles in STEM industries.[7]

The gap that exists is therefore in the area of management where RPs may not be adequately trained and this may impact their ability to effectively manage. This article seeks to investigate the current application of competencies, management areas where RPs may not have adequate training, if this has an impact on their ability to manage, and whether significant differences exist

between gender groups.

Methods

Research approach

Quantitative research with a cross-sectional component, which falls into the positivist approach, was used. Questionnaires focusing on management were sent to all RPs under the age of 35 years who were registered with the SAPC. Analyses and numerical data were used to identify patterns and find averages to make predictions and form conclusions.[7] The data collected from the questionnaires were used to conduct the study and formulate conclusions without resending the questionnaires to the participants over an extended time. Using this method ensured that the study could be correctly and reliably conducted in the period assigned to it.[8] Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS). Reliability and validity were determined using exploratory factor analysis and Cronbach's alpha coefficients. Pearson's correlation analyses and hierarchical regression analyses were applied to determine the relationships between the variables in this study. Descriptive statistics (i.e. frequencies, means, standard deviation, skewness, kurtosis) were used to analyse the data. The factor structure of the measuring instrument was determined by using a combination of exploratory and confirmatory factor analyses.[9] The reliability of the questionnaire was determined by using the guidelines of Cohen of $\alpha \geq 0.70$. The four-point Likert scale offers options for "Definitely do not need training", "Do not need training", "Do need training" and "Definitely do need training". This allows for a more accurate measurement of the data received from the participants.

Sample

The target population for this study was registered RPs under the age of 35 years of age in the South African pharmacy profession. This sample was purposefully chosen based on the age of the population group. A total of 956 questionnaires were distributed; 188 completed questionnaires were received, of which 123 were suitable for further analysis. The response rate was 18%. The demographic characteristics of the participants are presented per gender group in Table I.

From Table I it is evident that both male and female RPs were mostly represented in the 24 to 35 years age group and held an undergraduate qualification. The respondents primarily worked

Table I: Demographic characteristics by gender

	Category	Male		Female	
		F	%	*F*	%
Age	19 to 23 years	5	12,82	12	14,29
	24 to 35 years	34	87,18	72	85,71
Qualification	Bachelor's Degree	32	82,05	71	84,52
	Postgraduate	5	12,82	11	13,10
	Other	2	5,13	2	2,38
Years of work as a pharmacist	0 to 3 years	14	35,90	18	21,43
	between 3 and 7 years	13	33,33	43	51,19
	more than 7 years	12	30,77	23	27,38
Years of work as a RP	0 to 3 years	29	74,36	64	76,19
	between 3 and 7 years	10	25,64	13	15,48
	more than 7 years	0	0,00	7	8,33
Type of pharmacy	Corporate community pharmacy	37	40,22	14	33,33
	Hospital pharmacy private	7	7,61	3	7,14
	Hospital pharmacy public	4	4,35	8	19,05
	Independent community pharmacy	30	32,61	11	26,19
	Manufacturing pharmacy	3	3,26	2	4,76
	Other	4	4,35	1	2,38
	Wholesale pharmacy private	6	6,52	3	7,14
	Wholesale pharmacy public	1	1,09	0	0,00
Business management training received	No	27	69,23	78	92,86
	Yes	12	30,77	6	7,14
Entrepreneurship experience	No	28	71,79	72	85,71
	Yes	11	28,21	12	14,29

between nought and three years as RPs, and between three and seven years as pharmacists They were mostly employed in the private sector in corporate and independent community pharmacy. From their training, it is evident that males were exposed to more training in business management and entrepreneurship than females.

Measuring instrument

A self-developed measurement instrument was used to determine the current application of RP management competencies based on the competency standards of the SAPC. Five competency standards were identified, namely Human Resource Management (four items), Financial Management (four items), Infrastructure Management (six items), Change Management (two items), and Policy Development (one item). In accordance with the competency requirements, the responses were measured on three levels: entry, intermediate, and advanced. The self-developed measurement tool was distributed to subject matter experts to ensure the face and content validity.

Biographical information that was collected included gender, age, the highest educational qualification, years of work as a pharmacist, years of work as an RP, the type of South African pharmacy they were employed in, and any additional training received.

Research procedure

Permission to do the study was obtained from the North-West University Business School. The questionnaires were distributed electronically through a gatekeeper. The questionnaire was accompanied with an informed consent letter explaining the purpose of the study as well the respondent's rights. Participation was voluntary and confidentiality of responses was maintained at all times. Ethical approval for the project was obtained from North-West University (NWU-00729-22-A4) prior to the execution thereof. This research conforms to all ethical rules and regulations pertaining to empirical scientific research.

Statistical analyses

The statistical analyses were done with SPSS (SPSS Inc. 28, 2022). Disruptive statistics such as frequencies were applied. T-tests were used to determine whether significant differences exist between gender based on the pharmaceutical competencies measured in this study. A guideline of $p \leq 0.05$ was used to determine the significance of the results.[10]

Results and discussion

The results of the research are presented in the section below. The analyses were done in line with the main research objective of the study, that is to determine gender perspective of the current application of management practices by RPs.

Table II: Human resource management

		Levels	Male		Female		Total	Gap	*p*
			F	%	*F*	%			
Staff management	Contribute to the effective management of pharmacy personnel.	Entry	13	34,2	39	45,9	52,0	-11,7	0,042
	Effectively manage pharmacy personnel under personal supervision.	Intermediate	7	18,4	32	37,6	39,0	-19,2	
	Identify human resources requirements and manage human resources effectively.	Advanced	18	47,4	14	16,5	32,0	30,9	
Staff training and Development	Undertake continuing professional development.	Entry	10	26,3	26	30,6	36,0	-4,3	0,83
	Participate in the provision of staff training and continuing professional development.	Intermediate	9	23,7	22	25,9	31,0	-2,2	
	Identify staff training needs, facilitate appropriate training opportunities, and participate in continuing professional development.	Advanced	19	50,0	37	43,5	56,0	6,5	
Performance management	Conduct self-assessments or appraisals in line with the performance management policy.	Entry	12	31,6	30	35,3	42,0	-3,7	0,34
	Conduct staff assessments or appraisals in line with the performance management policy.	Intermediate	19	50,0	45	52,9	64,0	-2,9	
	Review performance management policies and processes.	Advanced	7	18,4	10	11,8	17,0	6,7	
Labour relations	Adhere to basic human resources management legislation, e.g. Labour Relations Act and Basic Conditions of Employment Act.	Entry	20	52,6	45	52,9	65,0	-0,3	0,08
	Monitor adherence to relevant human resources management legislation, e.g. Labour Relations Act and Basic Conditions of Employment Act.	Intermediate	10	26,3	31	36,5	41,0	-10,2	
	Develop and train pharmacy personnel in basic human resources management legislation, e.g. Labour Relations Act and Basic Conditions of Employment Act.	Advanced	8	21,1	9	10,6	17,0	10,5	

Human resource (HR) management

The respondents were required to report the current demonstration of management competencies in four areas of human resource management in the South African pharmacy profession and labour relations, namely, staff management, staff training and development, performance management. The results are reported in Table II.

In the HR management needs assessment, when looking at staff management, female RPs mostly functioned at entry level by contributing to the effective management of pharmacy staff. Male RPs functioned mostly at the advanced level by identifying HR requirements and managing HR effectively. In 2019 Charles Summerlin conducted a study on what training was done to prepare pharmacy students to manage a pharmacy effectively. In the study it was found that female students excelled in areas of training, but male students were more likely to embrace the management role when given the opportunity.[11] This is in stark contrast to the findings in this study. When considering the data collected on staff training and development, both male and female RPs displayed behaviours in keeping with entry level when identifying staff training needs, facilitating appropriate training opportunities, and participating in continuing professional development (CPD). When considering performance management and conducting staff assessments or appraisals in line with the performance management policy, both male and female RPs displayed behaviours linked to competency standards at the intermediate level.

Lastly, when considering labour relations, both male and female RPs were still at the entry level of competency, with RPs indicating that they adhered to basic HR management legislation, e.g. the Labour Relations Act and the Basic Conditions of Employment Act.

Financial management

The respondents were required to report the current demonstration of management competencies in four areas of financial management in the South African pharmacy profession, namely medical finance, budgeting, legislative prescriptions and pharma-economic principles and assessments. The results are reported in Table III.

The results in Table III show that male and female participants mainly applied entry-level management competencies relating to medical finance. The focus was mostly on submitting patient prescription claims to health funders to ensure the optimum use of patient benefits. Concerning budgeting, female RPs mostly functioned at the entry level by working according to an approved budget. Male RPs functioned mostly on the intermediate level by monitoring income and expenditure in line with budget prescriptions. Both male and female RPs complied with all the relevant legislative requirements at the entry level. Lastly, both male and female RPs performed cost-benefit analyses at the entry level of financial management. Male RPs, however, also applied the principles of pharmacoeconomic assessments on an intermediate level and not yet on an advanced level.

Table III: Financial management

	Items	Level	Male		Female		Total	Gap	*p*
			F	%	*F*	%			
Medical finance	Submit patient prescription claims to health funders to ensure optimum use of patient benefits.	Entry	21	55,26	45	52,94	66	2,32	0,59
	Monitor patient prescription claims submitted to health funders to ensure optimum use of patient benefits.	Intermediate	11	28,95	29	34,12	40	-5,17	
	Determine dispensing and professional fees to be charged in line with legislation.	Advanced	6	15,79	11	12,94	17	2,85	
Budgeting	Work according to approved budget.	Entry	11	28,95	40	47,06	51	-18,11	0,08
	Monitor income and expenditure in line withbudget prescripts.	Intermediate	19	50,00	30	35,29	49	14,71	
	Develop and effectively analyse and manage financial data and budgets.	Advanced	8	21,05	15	17,65	23	3,41	
Legislative prescriptions	Comply with all relevant legislative prescripts.	Entry	17	44,74	37	43,53	54	1,21	0,04
	Monitor adherence to allrelevant legislative prescripts	Intermediate	2	5,26	17	20,00	19	-14,74	
	Ensure adherence to all relevant legislative prescripts.	Advanced	19	50,00	31	36,47	50	13,53	
Pharma-Economic principles and assessments	Perform cost benefit analysis.	Entry	20	52,63	52	61,18	72	-8,54	0,74
	Apply the principles of pharmacoeconomic assessments.	Intermediate	14	36,84	25	29,41	39	7,43	
	Apply the principles of pharmacoeconomic assessments.	Advanced	4	10,53	8	9,41	12	1,11	

Pharmaceutical infrastructure management

The respondents were required to report the current demonstration of management competencies in six areas of pharmaceutical infrastructure management in the South African pharmacy profession, namely pharmaceutical infrastructure needs assessment, facilities and equipment assessment, procedures and policies management, time management, pharmaceutical infrastructure management and document and record keeping management. The results are reported in Table IV.

In the pharmaceutical infrastructure needs assessment, female RPs mostly functioned at the entry level by participating in identifying pharmaceutical facility and equipment needs. Male RPs functioned mostly at the advanced level by identifying pharmaceutical facility and equipment needs and developing a plan to achieve and meet those needs.

When looking at the facilities and equipment assessment, the female RPs were on the entry level. They participated in monitoring the suitability of pharmaceutical facilities and equipment. Male RPs were on the advanced level because they showed that they managed pharmaceutical facilities and equipment.

When looking at procedures and policies management, females were on an entry level, with most females indicating that they worked according to the approved workplace procedures and policies. The males indicated that they implemented and monitored workplace procedures and policies, which showed they were on the intermediate level. Both male and female RPs complied with all the relevant time management requirements at the intermediate level.

When looking at the responses for pharmaceutical infrastructure management, females were on the intermediate level, with the

Table IV: Pharmaceutical infrastructure management

	Items	Level	Male		Female		Total	Gap	*p*
			F	%	*F*	%			
Pharmaceutical infrastructure needs assessment	Identify pharmaceutical facility and equipment needs.	Entry	15	39,47	37	43,53	52	-4,06	0,25
	Identify pharmaceutical facility and equipment needs.	Intermediate	6	15,79	19	22,35	25	-6,56	
	Identify pharmaceutical facility and equipment needs and develop a plan to achieve and meet the needs.	Advance	17	44,74	29	34,12	46	10,62	
Facilities and equipment assessment	Monitor the suitability of pharmaceutical facilities and equipment.	Entry	14	36,84	40	47,06	54	-10,22	0,76
	Monitor the suitability of pharmaceutical facilities and equipment.	Intermediate	8	21,05	20	23,53	28	-2,48	
	Manage pharmaceutical facilities and equipment.	Advance	16	42,11	25	29,41	41	12,69	
Procedures and policies management	Work according to the approved workplace procedures and policies.	Entry	13	34,21	30	35,29	43	-1,08	0,58
	Implement and monitor workplace procedures and policies.	Intermediate	14	36,84	26	30,59	40	6,25	
	Develop and review workplace procedures and policies as required.	Advance	11	28,95	29	34,12	40	-5,17	
Time management	Prioritise and organise workflow and demonstrate time management skills.	Entry	8	21,05	21	24,71	29	-3,65	0,67
	Manage, prioritise, and organise workflow and demonstrate time management skills.	Intermediate	17	44,74	34	40,00	51	4,74	
	Develop and review workflow systems to manage, prioritise and organise daily work and demonstrate time management skills	Advance	13	34,21	30	35,29	43	-1,08	
Pharmaceutical infrastructure management	Maintain the existing pharmaceutical infrastructure.	Entry	11	28,95	26	30,59	37	-1,64	0,27
	Contribute to the improvement of the existing pharmaceutical infrastructure.	Intermediate	10	26,32	30	35,29	40	-8,98	
	Ensure pharmaceutical infrastructure is in line with legislative requirements.	Advance	17	44,74	29	34,12	46	10,62	
Document and record keeping management	Work according to the approved document management and recordkeeping systems.	Entry	13	34,21	35	41,18	48	-6,97	0,98
	Implement a system for documentation and recordkeeping for quality assurance purposes.	Intermediate	10	26,32	23	27,06	33	-0,74	
	Develop and update systems for documentation and recordkeeping for quality assurance purposes.	Advance	15	39,47	27	31,76	42	7,71	

Table V: Change management

	Items	Level	Male		Female		Total	Gap	*p*
			F	%	*F*	%			
Management participation in change	Participate in change management processes within the team.	Entry	14	36,84	37	43,53	51	-6,69	0,25
	Manage a change management process for the team.	Intermediate	7	18,42	24	28,24	31	-9,81	
	Contribute to and lead a change management process beyond the team/workplace or across disciplines.	Advance	17	44,74	24	28,24	41	16,50	
Overcoming barriers to change	Overcome internal barriers and self-limiting beliefs to change by analysing the climate and the readiness for change followed by measures to improve personnel growth and contribute to organisational success and outcomes.	Entry	7	18,42	37	43,53	44	-25,1	0,41
	Motivate staff to overcome barriers to change to drive organisational success and outcomes.	Intermediate	17	44,74	24	28,24	41	16,5	
	Develop strategies to inspire and motivate staff to overcome barriers to change to drive organisational success and outcomes.	Advance	14	36,84	24	28,24	38	8,6	

majority indicating that they contributed to the improvement of the existing pharmaceutical infrastructure. The male respondents showed that they were on an advanced level, with the majority indicating they ensured pharmaceutical infrastructure was in line with legislative requirements.

Lastly, female RPs performed document and recordkeeping management at the entry level, with the majority indicating that they worked according to the approved document management and recordkeeping systems. Male RPs, however, showed they were on an intermediate level, with the majority indicating that they developed and updated systems for documentation and recordkeeping for quality assurance purposes.

Change management

The respondents were required to report the current demonstration of management competencies in two areas of change management in the South African pharmacy profession, namely management participation in change, and overcoming barriers to change. The results are reported in Table V.

In the change management needs assessment, when looking at management participation in change, female RPs mostly functioned at the entry level by participating in change management processes within the team. Male RPs functioned mostly on the advanced level by contributing to and leading a change management process beyond the team/workplace or across disciplines. When considering overcoming barriers to change, the female RPs were on the entry level, indicating that they overcame internal barriers and self-limiting beliefs to change by analysing the climate and the readiness for change, followed by measures to improve personnel growth and contribute to organisational goals. Male RPs were on the intermediate level, with the majority indicating that they motivated staff to overcome barriers to change to drive organisational success and outcomes.

Table VI: Policy development

	Items	Levels	Male		Female		Total	Gap	*P*
			F	%	*F*	%			
Apply, implement, develop and monitor polices	Apply policies and SOPs.	Entry	10	26,32	31	36,47	41	-10,15	0,59
	Implement and monitor policies and SOPs.	Intermediate	17	44,74	37	43,53	54	1,21	
	Develop a policy framework and SOPs	Advanced	11	28,95	17	20,00	28	8,95	

Table VII: Summary of results

	MALE			FEMALE		
	Entry	Intermediate	Advanced	Entry	Intermediate	Advanced
Human resource management		X		X		
Financial management		X		X		
Infrastructure management			X	X		
Change management			X	X		
Policy development		X			X	

Policy development

The respondents were required to report the current demonstration of management competencies in one area of policy development in the South African pharmacy profession, namely applying, implementing, developing and monitoring polices. The results are reported in Table VI.

The results in Table VI show that male and female participants mainly applied intermediate management competencies relating to policy development. They mostly concentrated on applying, implementing, developing and monitoring polices.

Conclusions

When looking at human resource and financial management, female RPs were still at the entry level of competency, with male RPs predominantly showing that they were on an intermediate level. Under infrastructure and change management, female RPs functioned mostly at entry level while the male RPs show a strong leaning to advanced management competency. Policy development is the only area where male and female RPs both showed that they were on the intermediate level of competency, which may be due to the fact that most RPs strictly adhere to the Pharmacy Act and other legislation.

Referring to the data, most female RPs were at the entry level when measured using the competency standards, while the male respondents were between intermediate and advanced, even though the female respondents had been registered as pharmacists for longer and had more years of experience. The data indicates that the discrepancy could be attributed to management training as more male respondents had attended management training than their female counterparts, with 30.8% of males indicating they received some form of business training compared to only 7.1% of females.

Further research into additional management training and perhaps a dedicated course focusing on pharmacy management for RPs is supported by the data collected

Recommendations

Based on the findings of the article, it is recommended that the SAPC consider developing management training for RPs to enhance their management skills. The study has shown there is a gap in the management competencies of RPs under the age of 35 in South Africa, which highlights the need for targeted training to address these deficiencies. Management training programmes could help the participants develop a better understanding of essential management functions, such as operations management, HR management, marketing management, financial management, and logistics management. Additionally, training could improve the participants' competencies in areas such as change management, strategic management and policy and relationship management. The development of these skills could help the participants perform their management duties more effectively.

This may be in the form of an RP-specific CPD or postgraduate diploma in management, similar to the current PCDT (Primary Care Drug Therapy) course currently being offered to pharmacists who would like to become prescribing pharmacists.

Conflict of interest

This study formed part of the dissertation Mr P Boonzaier completed for his MBA; there is no conflict of interest between any parties involved in the study.

Funding source

The study was self-funded by the student, Mr P Boonzaier.

Ethics approval

This study was approved by the Ethics Committee of the NWU Business school prior to commencement of the data collection. Ethics number *NWU-00729-22-S4*.

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2023 ART Clinical Guidelines

for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates

June 2023 Version 4

Republic of South Africa National Department of Health

S Afr Pharm J 2023;90(6):35-50

Foreword

South Africa is committed to attaining the UNAIDS 95-95-95 targets to control the HIV epidemic by providing quality healthcare services using highly effective antiretroviral treatment (ART). The principal goal of ART is to attain and maintain viral suppression, which will prevent new HIV infections, increase life expectancy, decrease morbidity and mortality as well as improve the quality of lives of all South Africans, thus contributing to realising the vision of A LONG AND HEALTHY LIFE FOR ALL.

The "Test and Treat All" approach has allowed people living with HIV (PLHIV) to access ART timeously.

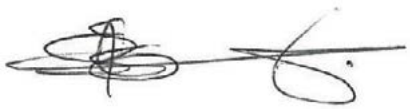
South Africa is committed to using available technology and evidence to continue the fight against HIV. The 2019 guidelines have been revised to include more optimised treatment regimens for all clients, including pregnant and breastfeeding women and children. The National Health Council (NHC) has adopted the new World Health Organization (WHO) recommended first, second and third-line regimens that include Dolutegravir (DTG) as the preferred antiretroviral drug.

I am introducing the 2023 ART guideline, which introduces simplified ART provision and harmonised methods of management of children, adolescents and adults, as well as pregnant women living with HIV/AIDS, TB and other common opportunistic infections. The guidelines also provide guidance on the use of Dolutegravir (DTG) dispersible tablets for children from 3 kg and 4 weeks old.

These guidelines have been revised with the Differentiated Models of Care SOPs to ensure simultaneous consideration and alignment of clinical, adherence and service delivery updates. The Differentiated Models of Care SOPs form part of this guidance to enable optimal use of decentralised and integrated service delivery to promote a patient-centred approach. Effective implementation of these guidelines will increase access to ART services, advance South Africa's ability to control the epidemic and help to achieve the 2030 SDG goals.

I urge all clinicians at PHC clinics, community health centres and hospitals across the board to use these guidelines diligently to offer quality, comprehensive services to the public.

I would like to sincerely thank all the internal and external stakeholders who actively contributed to developing these guidelines.



Dr SSS Buthelezi
Director-General: Health
Date: 24-04-2023

What is New in this Guideline?

Terminology	**TLD 1** (or ALD 1 in children)	Clients on a DTG-containing regimen, who have **never failed** any other regimen (previous "first-line" terminology)
	TLD 2 (or ALD 2 in children)	Clients on a DTG-containing regimen, who **have failed** an earlier regimen (previous "second-line" terminology)
	Dispensing cycle:	A dispensing cycle (DC) is defined as the number of days for which a client would have treatment if a single standard "monthly" quantity of tablets were dispensed. The term DC is preferred to the previously used term 'month' due to the potential discrepancy that may arise between the days of treatment dispensed (if 28-day pack sizes are used) and the days in a month (on average, 30 days)
ART Regimens	**All adult and adolescent clients > 30 kg and > 10 years of age, including pregnant and breastfeeding women**	• The preferred first-line ART regimen is **tenofovir disoproxil fumarate-lamivudine- dolutegravir (TLD)** for those adult and adolescent clients initiating ART. • TDF weight-related eligibility criteria decreased from **35 kg to 30 kg** • All clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for a switch to a dolutegravir-containing regimen.
		• TDF may safely be reused in 2nd-line therapy following 1st-line failure with TDF-containing regimens. TLD will therefore be used as both first (TLD 1) and second (TLD 2) line regimens and in certain cases, 3rd line regimens as well • Simplified **switching from TEE to TLD not dependant on VL**
	New formulations	• **DTG 10 mg dispersible tablets** for children from ≥ 3 kg and ≥ 4 weeks of age • DTG-containing fixed-dose combination: Abacavir (ABC) 600 mg + lamivudine (3TC) 300 mg + DTG 50 mg (ALD FDC). ALD FDC can be prescribed for clients ≥ 25 kg
	Children ≥ 3 kg and ≥ 4 weeks of age until 29,9 kg or 9 years of age	• The preferred first-line ART regimen is **abacavir-lamivudine-dolutegravir (ALD)**. • All paediatric clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for a switch to a dolutegravir-containing regimen.
	Other antiretrovirals	• **Abacavir** is the preferred alternative agent if TDF cannot be used • Zidovudine (AZT) no longer part of any standard ART regimen. AZT will be reserved only for cases with **both** renal failure **and** ABC hypersensitivity • **Atazanavir/r** replaces lopinavir/r as the preferred protease inhibitor except when on TB treatment
Monitoring on ART	**VL monitoring**	**First VL** after ART initiation to be done after 3 dispensing cycles
	Creatinine and eGFR	eGFR previously done at 'month' 6 moves to 'month' 3 (i.e. after 3 dispensing cycles) to align with the new VL monitoring schedule
Virological Failure	• **Definition:** two or more VLs ≥ 1000 c/mL taken two or more years after starting a DTG/PI-containing regimen and adherence > 80% • **Focus on improved adherence:** Resistance to DTG is very uncommon. If other reasons for an unsuppressed VL (including drug interactions) have been addressed or excluded, the highest probability of improving adherence would be to remain on a once-daily, well-tolerated, fixed-dose combination regimen (TLD) while identifying and addressing the underlying root causes of non-adherence. • **No regimen changes without a resistance test:** Switching off a DTG-containing regimen should only happen if InSTI resistance has been confirmed by a resistance test • Resistance testing can only be authorised by a member of the National Third-line committee, one of the helpline consultants, or a nominated provincial expert	

Other updates	• 2 high quality counselling sessions at ART start and at follow-up a month later
	• Reduces health facility visits in the first year on ART to support continued engagement in care, including visit schedule for first year on treatment.
	• Removes time on ART from repeat prescription collection strategies (RPCs) eligibility criteria, enabling access as soon as first VL is suppressed.
	• Reduces visits once enrolled in RPCs with a maximum of 2 visits per 6-month scripting cycle.
	• Returns clients in RPCs with VL 50-1000 c/mL to clinician care for TLD switch and VL management
	• Enables multi-month dispensing (MMD) by the facility between clinical visits including for people not eligible for RPCs - children from 6 months of age, post-natal women, people co-infected with TB, with elevated viral loads or re-engaging in care.
	• Introduces a differentiated approach to management on re-engagement.
	• Integrates contraception and TB preventative therapy into all service delivery models
	• Aligns ART visit schedules to TB management and infant EPI schedules to enable integration
	• Incorporates tools for:
	  • enhanced adherence counselling
	  • mental health assessment	

Overview

This ART Clinical Guideline is intended to serve as a quick reference guide for antiretroviral treatment (ART) in adults, pregnant and breastfeeding women, adolescents and paediatric clients, and as a job aide for healthcare workers and implementing partners. This document is not intended to be exhaustive; for more information or details on any recommendations, or on the prevention of vertical transmission, please refer to the comprehensive Consolidated HIV Guidelines document and the Guideline for Family-Centred Transmission Prevention of Communicable Infections (HIV, Hepatitis, Listeriosis, Malaria, Syphilis and TB) 2023.

These guidelines have been revised with the Differentiated Models of Care (DMOC) Standard Operating Procedures (SOPs) to ensure simultaneous consideration and alignment of clinical, adherence and service delivery updates. The DMOC SOPs form part of this guidance to enable optimal use of decentralised and integrated service delivery and should be read concurrently with this clinical guideline.

The objectives of this document are to:

- Provide guidance on initiation of ART in antiretroviral-naïve clients as well as those returning to care in the era of dolutegravir (DTG)
- Provide guidance for switching of clients already on ART to DTG-containing regimens
- Provide guidance on routine management of clients on ART to promote viral suppression
- Highlight critical areas for provision of integrated ART, TB, and family planning services, and the use of differentiated models of care

The preferred first-line ART regimen is tenofovir disoproxil fumarate-lamivudine-dolutegravir (TLD) for those adult and adolescent clients initiating ART, and abacavir-lamivudine-dolutegravir (ALD) in children . All clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for switch to a dolutegravir-containing regimen.

In the new ART era of dolutegravir, TLD will be used as a first-line and a second-line ART regimen, and as part of certain third-line regimens with other medicines. This has necessitated a change of the previous "first-line" and "second-line" terminology to the following:

TLD1: Clients on a DTG-containing regimen, having never failed a previous regimen (old "first-line" terminology)

TLD2: Clients on a DTG-containing regimen, who have failed a previous regimen (old "second- line" terminology)

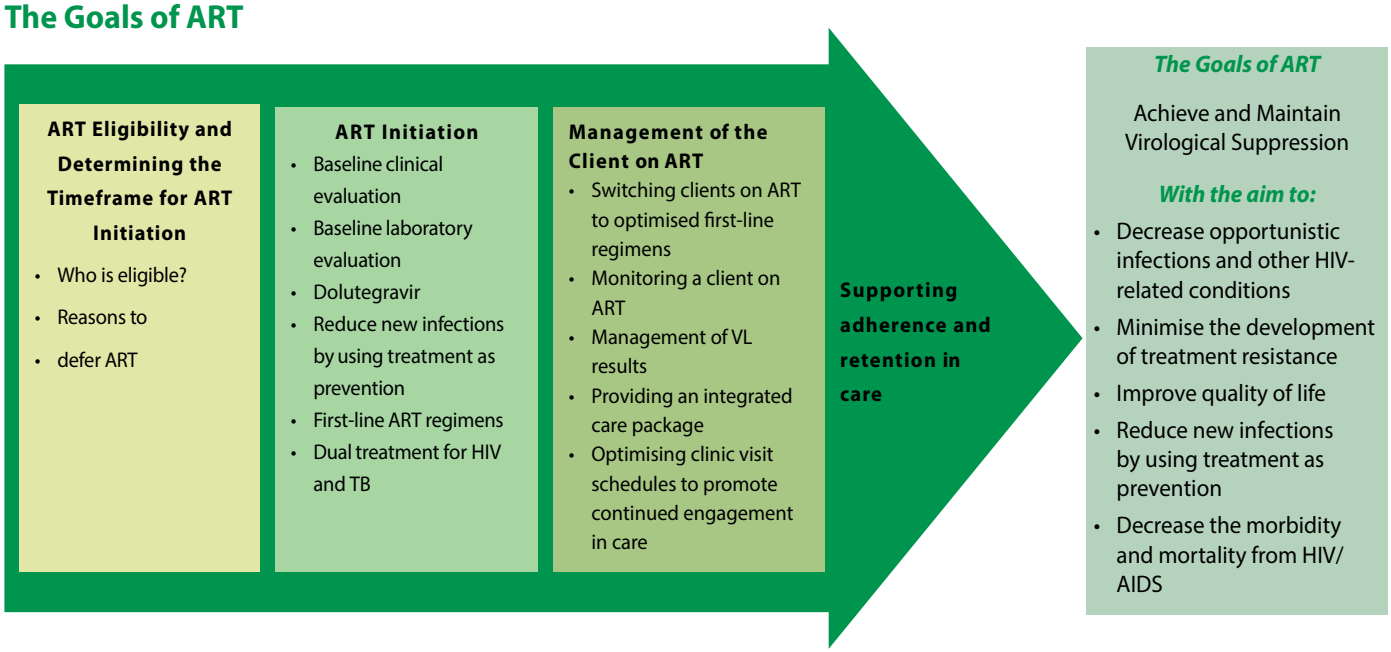
The safety of DTG in women of childbearing-potential has been firmly established and neural tube defects are no longer a concern that influences regimen choice in women. However, the integration of family planning and ART services remain of paramount importance, and issues of family planning and contraception should be discussed at every clinical interaction to understand the client's current fertility desires and healthcare needs.

All people either currently on ART, or newly initiated on ART, should be screened for TB and assessed for TB preventive therapy (TPT) as indicated. All individuals should be assessed for advanced HIV disease (AHD) and provided with a comprehensive package of care, including cotrimoxazole prophylaxis, as needed.

The guideline broadly follows the process of care, namely:

1. ART eligibility and determining the timeframe for ART initiation
2. ART initiation
3. Management of the client on ART
4. Supporting adherence, sustained viral suppression and retention in care

The Goals of ART



ART Eligibility

All people living with HIV (PLHIV) are eligible to start ART regardless of age, CD4 cell count and clinical stage. For all clients without contra-indications, ART should be initiated within 7 days, and on the same day if possible.

Pregnant women, infants and children under five years, and clients with advanced HIV disease should be prioritised for rapid initiation. Many clients (including pregnant women) may be able to initiate ART on the same day as their HIV diagnosis, provided that they are clinically well, and are motivated to start ART. While rapid, and same-day ART initiation is encouraged where possible, all clients, particularly those with advanced HIV disease, should be carefully assessed for opportunistic infections (OIs) that may necessitate ART deferral.

Medical Indications to Defer ART

Medical Indications to Defer ART	
Indication	**Action**
TB symptoms (cough, night sweats, fever, recent weight loss)	Investigate symptomatic clients for TB before initiating ART. If TB is excluded, proceed with ART initiation and TB preventive therapy (after excluding contra- indications to TPT). If TB is diagnosed, initiate TB treatment and defer ART. The timing of ART initiation will be determined by the site of TB infection and the client's CD4 cell count
Diagnosis of drug-sensitive (DS) TB at a non-neurological site (e.g. pulmonary TB, abdominal TB, or TB lymphadenitis)	Defer ART initiation as follows: • If CD4 < 50 cells/µL – initiate ART within 2 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated • If CD4 ≥ 50 cells/µL – initiate ART 8 weeks after starting TB treatment • In pregnant and breastfeeding women (PBFW) initiate ART within 2 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated. Defer ART for 4–6 weeks if symptoms of meningitis are present. For further details, refer to the Family-Centered Transmission Prevention Guideline 2023
Diagnosis of drug-resistant (DR) TB at a non-neurological site (e.g. pulmonary TB, abdominal TB, or TB lymphadenitis)	Initiate ART after 2 weeks of TB treatment, when the client's symptoms are improving, and TB treatment is tolerated
Diagnosis of DS-TB or DR-TB at a neurological site (e.g. TB meningitis or tuberculoma)	Defer ART until 4–8 weeks after start of TB treatment
Signs and symptoms of meningitis	Investigate for meningitis before starting ART
Cryptococcal antigen (CrAg) positive in the absence of symptoms or signs of meningitis and if lumbar puncture is (LP) negative for cryptococcal meningitis (CM)	No need to delay ART. ART can be started immediately.
Confirmed cryptococcal meningitis	Defer ART until 4–6 weeks of antifungal treatment has been completed
Other acute illnesses e.g. *Pneumocystis jirovecii* pneumonia (PJP) or bacterial pneumonia	Defer ART for 1–2 weeks after commencing treatment for the infection
Clinical symptoms or signs of liver disease	Confirm liver injury using ALT and total bilirubin levels. ALT elevations > 120 IU/L with symptoms of hepatitis, and/or total serum bilirubin concentrations > 40 µmol/L are significant. Investigate and manage possible causes including TB, hepatitis B, drug-induced liver injury (DILI), or alcohol abuse
Note: Clients who are already on ART should NOT have their treatment interrupted upon diagnosis of the above conditions	

ART Initiation

A clinical assessment and laboratory baseline investigations should be done in order to initiate ART. However, laboratory results do not need to be available to start clients on ART on the same day, provided they have no clinical evidence of TB, meningitis or renal disease. In addition, all clients, and caregivers of paediatric clients, must receive counselling on how to administer medication, monitor side-effects and deal with challenges to adherence.

Baseline Clinical Evaluation for Adults and Adolescents, Pregnant Women, and Children < 10 Years

The baseline clinical evaluation of a client about to start ART requires a thorough **history and clinical examination**.

Interventions to support adherence to ART

ART literacy education and fast-track initiation counselling (FTIC) empower clients to adhere to treatment, and positively influence clinical outcomes. Adherence counselling at ART initiation and first follow-up visit should focus on:

- providing the client with an understanding of HIV, ART, and the importance of VL suppression
- providing the client with practical skills to adhere to ART
- identifying any potential risk factors for adherence in the future
- An individualized adherence plan should be developed with clear treatment milestones, including an undetectable viral load

The minimum components of the baseline clinical evaluation are outlined in the following table:

Component of the Baseline Clinical Evaluation	Purpose	Further Action Required		
		Adolescents (10–19 years) and Adults	Pregnant Women	Children (< 10 years)
Recognise the client with respiratory, neurological, or abdominal **danger signs needing urgent care**	To identify opportunistic infections and conditions needing urgent care or referral See also the section on ***"Advanced HIV Disease" in the 2023 Consolidated ART Guideline***	Identify respiratory, neurological, or abdominal danger signs as outlined in Adult Primary Care (APC) guideline	Identify danger signs as outlined in the Maternity Care guidelines	Identify danger signs as classified in the IMCI Chart booklet
Nutritional Assessment	To identify recent weight loss that may indicate an active opportunistic infection (OI) or other pathology. To identify underweight/ obese clients requiring nutritional and lifestyle support	Measure weight and height and determine BMI (kg/m^2): < 18.5 = underweight; 18.5 to 25 = normal; > 25 to < 30 = overweight; ≥ 30 = obese	Measure mid upper arm circumference (MUAC) Women with MUAC < 23 cm require additional nutritional support/ referral	Plot weight, height and head circumference (if < 2 years) on growth chart, and measure MUAC to identify moderate and severe malnutrition
Test for TB	To identify clients who require treatment for TB To identify clients who do not have active TB and who may be eligible for TPT ***see "TB Preventive Therapy" on page 9***	At enrolment into care/ ART start: • TB symptom screen and clinical examination • Routine MTB/Rif Ultra (Xpert) on all PLHIV at enrolment into ART care (regardless of TB symptoms)	For all HIV-positive women at first visit in antenatal clinic, do a: • TB symptom screen and clinical examination • Routine MTB/ Rif Ultra (Xpert) (regardless of TB symptoms)	Identify symptoms of cough, night sweats, fever, failure to thrive as outlined in the TB screening tool Attempt sputum testing (and Xpert) where feasible Enquire about TB contacts

Additional TB Investigations for Symptomatic Clients:

For symptomatic PLHIV admitted to hospital [in addition to the MTB/Rif Ultra (Xpert)]
• Do a U-LAM test
• Do a chest X-ray if clinically indicated
• Do other investigations for extra-pulmonary TB if clinically indicated
 	
Enquire about TB contacts
	For symptomatic PLHIV seen in an outpatient setting [in addition to the MTB/Rif Ultra (Xpert)]
	• Do a U-LAM test if:
	  • CD4 count <200 within the last 6 months, or
	  • advanced HIV disease, or
	  • current serious illness.
	• Do a chest X-ray if clinically indicated

Component of the Baseline Clinical Evaluation continued	Purpose	Further Action Required		
		Adolescents (10–19 years) and Adults	Pregnant Women	Children (< 10 years)
Screen for symptoms of meningitis	To diagnose and treat clients with cryptococcal and other forms of meningitis and reduce associated morbidity and mortality	**Identify symptoms of headache, confusion** or **visual disturbances.** With cryptococcal meningitis, clients may only present with a recurrent headache. Other symptoms may include fever, neck stiffness or coma. Do/refer the client for a **lumbar puncture**. Defer ART if meningitis is confirmed as outlined in ***"Medical Indications to Defer ART" on page 4***		
Screen for active depression, other **mental health** issues or substance abuse	Mental health conditions and substance use can affect adherence and the client's quality of life. In general, ART can be initiated, and cautiously monitored see also ***"Mental Health Assessment" on page 31***	Screen for symptoms of depression, psychosis, and substance abuse		Screen for symptoms of depression in older children
Screen for major chronic **non- communicable diseases (NCDs)** (diabetes, hypertension, epilepsy)	To identify and manage clients with major chronic NCDs and/or comorbidities. To identify and prevent potential drug interactions with ART e.g. metformin and anti-epileptic medications	Do blood pressure (BP), and urine dipstix for proteinuria and glucose. Identify other risk factors (smoking, increased waist circumference, age) and determine cardiovascular (CVS) risk. Manage NCDs and CVS risk factors as outlined in the PHC EML	Do blood pressure (BP), and urine dipstix for proteinuria and glucose	Identify the child with epilepsy and be aware of potential drug interactions of anti-epileptic treatment and ART

Screen for **pregnancy** and ask if planning to conceive	To identify pregnancy and facilitate early referral for antenatal care (ANC) and measures to prevent vertical transmission. To assess fertility intentions and contraceptive needs if not pregnant.	Ask if the client is currently using contraception and if her last menstrual period occurred at the expected time. If she answered "no" to either question, do a urine pregnancy test	N/A	N/A
Symptom screen for **sexually transmitted infections** (STIs)	To identify and treat STIs in sexually active clients	STI screening should include the following three questions: "Do you have any genital discharge?" "Do you have any genital ulcers?" "Has/have your partner(s) been treated for an STI in the last 8 weeks?		N/A
Neurodevelopmental screen	To identify children with neurodevelopmental delay requiring intervention/referral and follow-up	N/A	N/A	Screen for developmental delays as outlined in the child's Road to Health Booklet (RTHB)
WHO clinical stage	**After the baseline clinical evaluation has been completed by means of a thorough history and clinical examination, the client's WHO clinical stage can be determined:** **At ART initiation**, WHO clinical stage helps us to: Understand the severity of the client's clinical condition and the associated risk of mortality Determine the urgency and timing of ART initiation Determine if cotrimoxazole prophylaxis (CPT) is indicated see ***"Indications for Starting and Stopping Cotrimoxazole Preventive Therapy" on page 8***			

Baseline Laboratory Evaluation for Adults and Adolescents, Pregnant Women, and Children

The following baseline laboratory investigations should be performed routinely before a client initiates ART. Clients are not required to wait for the results of the baseline investigations prior to starting ART, but results should be checked at the next visit.

Laboratory evaluation	Purpose	Adolescents (10–19 years) and Adults	Pregnant Women	Children (< 10 years)
Confirm HIV test result	To confirm HIV status for those without documented HIV status	✓	✓	✓
CD4 cell count/ %	To identify eligibility for CPT	See ***"Indications for Starting and Stopping Cotrimoxazole Preventive Therapy" on page 8***		
	To identify eligibility for cryptococcal antigen (CrAg) screening	A reflex CrAg test will be done automatically by the laboratory on all CD4 counts < 100 cells/µL		N/A
Creatinine and eGFR if TDF used	To assess renal insufficiency	See table titled ***"Assessing Renal Function" on page 8***		N/A
Haemoglobin (Hb)	To identify and manage anaemia; to determine eligibility for zidovudine (AZT) where necessary	If Hb is low, do a full blood count (FBC). Characterise according to mean corpuscular volume (MCV) as either microcytic, normocytic, or macrocytic and manage accordingly[1]	Treat with ferrous sulphate tds if Hb < 10 g/dL. Refer if < 8 g/dL and symptoms, if anaemia diagnosed at 36 weeks gestation or later, or if no response to treatment	Children < 5 years: Treat with iron supplements and deworm the child[1] Children ≥ 5 years: Do FBC. Characterise according to MCV and manage accordingly[1]
GeneXpert (MTB/Rif Ultra)	To diagnose TB	For any client with a positive TB symptom screen For people living with HIV, regardless of TB symptoms: At the time of HIV diagnosis On enrolment in antenatal care for pregnant women		
Cryptococcal antigen test (CrAg) if CD4 < 100 cells/µL	To identify asymptomatic clients who need pre-emptive fluconazole treatment	A reflex CrAg test will be done automatically by the laboratory on all CD4 counts < 100 cells/µL If CrAg-negative, no fluconazole is required If CrAg-positive, the client will require treatment of the infection All CrAg-positive clients should be referred for a lumbar puncture, regardless of symptoms	All pregnant women with a positive CrAg should be referred for a lumbar puncture, regardless of symptoms. The results of the lumbar puncture and further management should be discussed with an expert, or one of the ***"Helplines" on page 23***	N/A

Cervical cancer screening	To identify women with cervical lesions and manage appropriately	All HIV-positive women should be screened for cervical cancer at diagnosis and subsequently every 3 years if the screening test is negative. If the cervical screening results suggest a possible abnormality of the cervical cells, then a clear plan for further investigation and treatment (e.g. colposcopy and LLETZ procedure) should be determined according to the local referral guidelines.	Pregnancy does not preclude screening for cervical cancer and it can be performed up to 20 weeks of gestation. If the cervical screening results suggest a possible abnormality of the cervical cells, then a clear plan for further investigation (e.g., colposcopy) should be determined according to the local referral guidelines	N/A
HBsAg	To identify those co-infected with hepatitis B (HBV)	If positive, exercise caution in stopping TDF-containing regimens, to prevent hepatitis flares		N/A

[1] As outlined in the PHC EML 2020

Assessing Renal Function

! A low absolute creatinine level is of no concern and needs no intervention. It may be an indication of low muscle mass. However, a low creatinine clearance (eGFR) is of concern and indicates reduced renal function.

Assessing Renal Function			
Age/pregnancy Status	**What must be measured?**	**Acceptable level for TDF use**	**Counahan Barratt formula** $\text{eGFR (mL/min/1.73 m}^2\text{)} = \frac{\text{height [cm]} \times 40}{\text{creatinine [µmol/L]}}$
≥ 10 and < 16 years of age	eGFR using Counahan Barratt formula	> 80 mL/min/1.73 m^2	
Adults and adolescents ≥ 16 years	eGFR using MDRD equation[1]	> 50 mL/min/1.73m^2	
Pregnant women	Absolute serum creatinine level	< 85 µmol/L	
DTG is known to decrease tubular secretion of creatinine without affecting glomerular filtration. Serum creatinine concentrations increase early in treatment (by less than 15%), remain stable throughout therapy, and are not an indication to stop DTG. A creatinine level that keeps on rising, is however a cause for concern and could indicate TDF toxicity or other underlying pathology.			

[1] Modification of Diet in Renal Disease Study (MDRD) equation. The MDRD formula is automatically calculated by the laboratory for those 18 years and older. For assistance in manually calculating the eGFR for adolescents between 16 and 18 years of age, please contact one of the ***"Helplines" on page 23.*** Alternatively, use the calculator provided at https://www.mdcalc.com/mdrd-gfr-equation, or one of numerous smartphone applications available for this purpose. Ensure that the website/application uses the correct unit of measurement (i.e. µmol/L) for the creatinine level

Indications for Starting and Stopping Cotrimoxazole Preventive Therapy (CPT)

Age and HIV status	When to Start	When to Stop
HIV-positive infant under 1 year of age	All children under 1 year should be on cotrimoxazole irrespective of CD4% or clinical stage	
HIV-positive child 1-5 years of age	CD4% ≤ 25 %, WHO Stage 2, 3, and 4	Discontinue if CD4 count > 25 %, regardless of clinical stage
HIV-positive child under 5 years of age with PJP infection	Start CPT after PJP treatment is completed	Continue CPT until 5 years of age and stop thereafter only if CD4 criteria in the older-than- five category are met
HIV-positive adults and children older than 5 years	CD4 count ≤ 200 cells/µL, WHO Stage 2, 3 and 4	Discontinue if CD4 count > 200 cells/µL, regardless of clinical stage

TB Preventive Therapy

All clients starting ART, or already on ART, and who have not yet received TB Preventive Therapy (TPT), should be considered for TPT. Prior to initiating TPT, active TB should be ruled out through a clinical evaluation and by testing for TB. If the client is asymptomatic, TPT initiation need not be delayed if TB GeneXpert results are outstanding. TPT and ART can be initiated on the same day. A Tuberculin skin test (TST) is not required prior to starting TPT. TB testing strategies will vary by age as younger children cannot spontaneously expectorate sputum. In well children without symptoms, neither sputum testing nor CXR are therefore requirements to start TPT. Sputum testing should be attempted in children who can expectorate spontaneously (typically > 25kg), but if they are well (without symptoms) and unable to expectorate, they should start TPT, even if no CXR or sputum testing is available.

Category of Client	Specific Eligibility Criteria	Treatment and Duration
Adult or adolescent ≥ 15 years (non-pregnant)	Any CD4 count. Exclude active liver disease, alcohol abuse, or known hypersensitivity to isoniazid	Isoniazid, oral, 300 mg daily for 12 months (12H) and pyridoxine 25 mg daily Rifapentine and isoniazid weekly (3HP) may be available in selected locations*
Children living with HIV who are < 15 years of age	• Children undergoing their first evaluation for HIV and ART, from 14 weeks of age • All children (including neonates) with significant exposure to TB	Isoniazid, oral, 10 mg/kg/day for 6 months (maximum dose 300 mg daily) and pyridoxine daily
Pregnant women	Any CD4 count. Exclude active liver disease, alcohol abuse, or known hypersensitivity to isoniazid	Isoniazid, oral, 300 mg daily for 12 months and pyridoxine 25 mg daily

* Alternative TPT regimen for adults, adolescents and children ≥ 25 kg: Where available, 3HP (weekly isoniazid and rifapentine) can be used in clients on a DTG-containing regimen who have a VL < 50 c/mL in the last 6 months. 3HP should NOT be used in new clients initiating a DTG-containing regimen. In these clients, 12H is still the preferred TPT regimen. Where 12H/3HP is prescribed for a client in an RPCs, no additional clinician review visits are required (the full 3 months 3HP supply/6 months of 12H can be scripted).

Dolutegravir

For further detail on switching **existing stable clients on ART** between regimens, see ***"Switching existing clients to DTG-containing regimens" on page 14***

Dolutegravir (DTG) Overview

Class of ARV: Integrase Inhibitor (InSTI)

Benefits: DTG is a potent antiretroviral that provides rapid viral suppression, has a high genetic barrier to resistance, and has minimal side effects and drug interactions. It is well tolerated by clients and contributes positively to adherence and retention on ART.

Formulations:

- Fixed-dose combination: tenofovir (TDF) 300 mg + lamivudine (3TC) 300 mg + DTG 50 mg (TLD). TLD can be prescribed for clients ≥ 30 kg and ≥ 10 years of age
- Abacavir (ABC) 600 mg + lamivudine (3TC) 300 mg + DTG 50 mg (ALD). ALD can be prescribed for clients ≥ 25 kg
- DTG 50 mg tablet
- DTG 10 mg dispersible tablet
- Please note that the adult film coated 50 mg tablet and the paediatric dispersible 10 mg tablet are not bioequivalent. The 50 mg film coated tablet is the equivalent of 30 mg of the dispersible tablets.

Standard Dose: Children ≥ 20 kg; adolescents and adults: DTG 50 mg daily
Children > 4 weeks of age and 3–19 kg: As per ***"Drug Dosing Chart" on page 34***

DTG dose with concomitant rifampicin-containing TB treatment: Increase DTG dose to 50 mg 12-hourly. If on TLD or ALD FDC, add DTG 50 mg 12 hours after TLD or ALD dose. If on paediatric DTG, follow ***"Drug Dosing Chart" on page 34*** for DTG and concomitant rifampicin-containing TB treatment

Side-effects: Usually mild and self-limiting. Side-effects include insomnia, headache, central nervous system (CNS) effects, and gastrointestinal effects. DTG can be taken in the evening or the morning as per the client's preference. However, if the client develops insomnia, TLD should be taken in the morning.

Contrary to initial speculation that the integrase inhibitor class may be causing **weight gain**, the association now appears not to be causal. Instead, the association may be the result of comparatively less metabolic toxicity than alternative older ART regimens (that mitigate weight gain through toxicity) combined with an initial return-to-health phenomenon, and an obesogenic environment. Dolutegravir-based ART regimens have numerous advantages over comparators and are still recommended first-line agents for people living with HIV. There is no role for switching from dolutegravir-containing regimens in patients gaining weight.

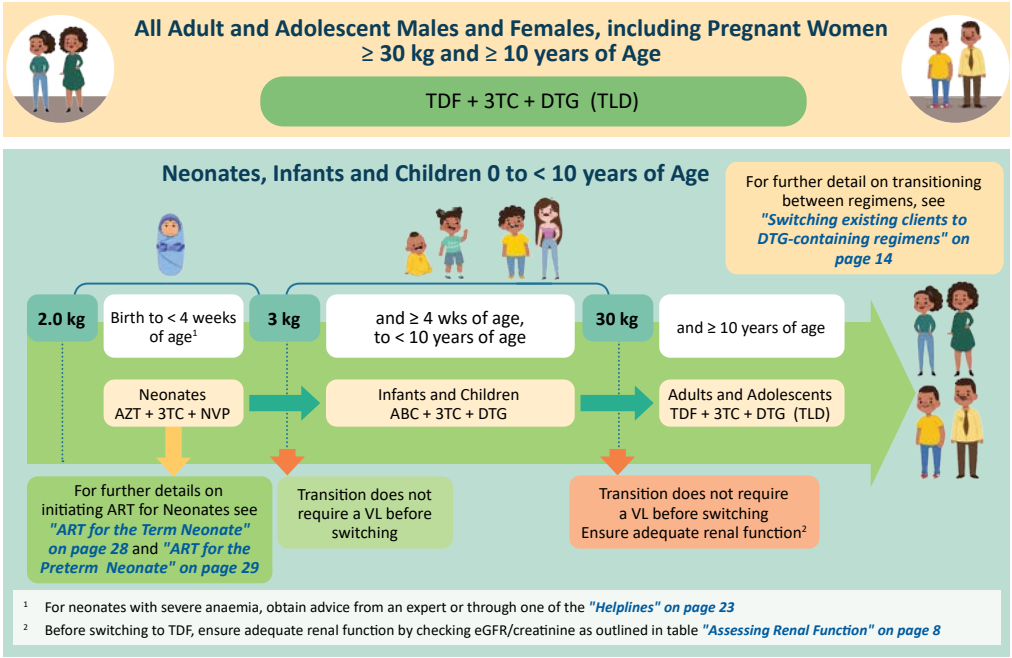
Drug Interactions with Dolutegravir

!	Drug interactions can result in suboptimal drug concentrations which can cause • an elevated HIV viral load • drug resistance, due to replicating virus in the presence of subtherapeutic drug concentrations • For interactions with paediatric regimens see *"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13*

Interacting Drug[1]	Effect of Co-Administration	Recommendation
Rifampicin	↓ Dolutegravir	Increase DTG dose to 50 mg 12-hourly. If on TLD FDC, add DTG 50 mg 12 hours after TLD dose. For interactions with paediatric regimens see *"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13*
Polyvalent cations (Mg^{2+}, Fe^{2+}, Ca^{2+}, Al^{3+}, Zn^{2+}) e.g. antacids, sucralfate, multivitamin and nutritional supplements*	↓ Dolutegravir	Calcium supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and calcium supplements can be taken at the same time if taken with food. It is safe to dissolve the DTG dispersible tablets in breast milk. Iron supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and iron supplements can be taken at the same time if taken with food. However, calcium and iron supplements must be taken at least 4 hours apart. Magnesium/aluminium containing antacids decrease DTG concentrations regardless of food intake and should be taken a minimum of 2 hours after or 6 hours before DTG
	* Many over the counter (OTC) medications contain polyvalent cations. Clinicians should regularly ask clients about OTC medication use and advise about possible interactions	
Anticonvulsants: • Carbamazepine • Phenobarbital • Phenytoin	↓ Dolutegravir	Avoid coadministration if possible. Alternative agents that do not interact with DTG include valproate, lamotrigine, levetiracetam, and topiramate. Remember that valproate is contra-indicated during pregnancy. Double DTG dose to 50 mg 12-hourly for carbamazepine, phenytoin, or phenobarbital if an alternative anticonvulsant cannot be used
Metformin/DTG	↑ Metformin	DTG increases metformin concentrations. Maximum metformin dose 500 mg 12-hourly

[1] This table includes some of the most important drug interactions with DTG. For more information, please refer to the following resources: *www.hiv-druginteractions.org/checker*, the Liverpool HIV iChart application for smart phones, or any of the *"Helplines" on page 23*

First-Line ART Regimens in Adults, Adolescents, Pregnant Women, Children, Infants, and Neonates



[1] For neonates with severe anaemia, obtain advice from an expert or through one of the *"Helplines" on page 23*

[2] Before switching to TDF, ensure adequate renal function by checking eGFR/creatinine as outlined in table *"Assessing Renal Function" on page 8*

ART Initiation in Women and Adolescent Girls Diagnosed with HIV during Labour

During labour, give a stat single fixed-dose combination tablet of TLD and a stat single dose of nevirapine (NVP). Lifelong ART should be initiated the following day. TLD and a contraceptive method is recommended. Provide information on different contraceptive methods available. Provide her with a choice of contraceptive options as desired.

Appropriate ART literacy education should be given to the woman before she leaves the facility. Also provide her with information on infant feeding, infant HIV prophylaxis, and follow-up infant HIV testing. Provide a 2-month supply of her ART regimen at discharge from labour ward (see DMOC SOP 4).

Concerns regarding neural tubes defects (NTDs) on DTG in previous years created an important focus on the integration of family planning into ART services. Although evidence has shown that there is no increased risk for NTDs on DTG-containing regimens[3], family planning services should continue to be offered with ART and child health services in an integrated and patient-centred manner. This is especially urgent if the women's VL is not suppressed.

Women should be **provided a choice of contraceptive options**, which includes condoms, oral contraceptives, implants, injectables, and intra-uterine contraceptive devices (IUCDs). Dual methods are recommended, and consist of a hormonal method or IUCD to prevent pregnancy, and a barrier method (male/female condoms) to prevent STIs and HIV transmission.

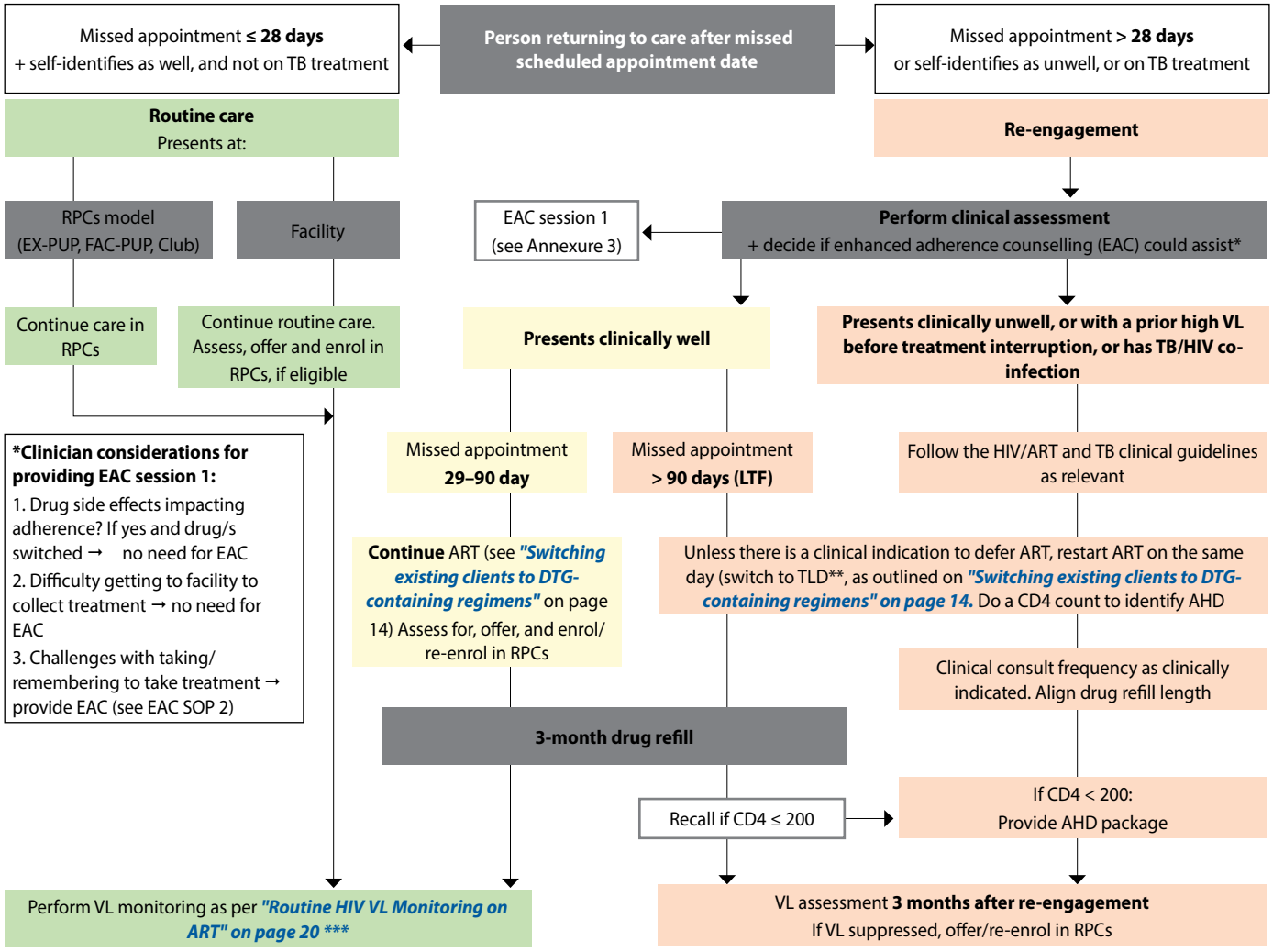
Contraceptive choices need to respect and fulfill human rights and enable clients to make informed choices for themselves. Client contraceptive choices, however, are often influenced directly or indirectly by social, economic and cultural factors. It is in this context that clients should be given comprehensive, scientifically accurate information in order to assist them to make an informed, voluntary choice of a contraceptive method. A woman's choice of contraceptive method may be influenced by her ART service delivery model to allow for better visit alignment. See also the ***"Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment" on page 26***

Should a woman desire pregnancy, counsel her regarding optimal timing for a healthy pregnancy. Recommend that ART is established, viral suppression is attained, and that she has no current OIs before she tries to become pregnant.

Issues of family planning and contraception should be discussed at every clinical interaction.
Where feasible, every attempt should be made to provide ART and family planning from the same service delivery point

[3] NDoH NEMLC PHC-Adult Medicine review DTG in Pregnancy 17June 2021

Re-initiating ART in Non-pregnant Clients who have Interrupted Treatment



AHD = Advanced HIV Disease; EX-PUP = External pick-up point; FAC-PUP = Facility pick-up point; RPCs = Repeat Prescription Collection Strategies

** All clients returning to care after > 90 days, and who were previously on TEE, TLD, or a PI-based regimen, should re-initiate a DTG-containing regimen. Clients who became LTFU on third-line should re-initiate their third-line regimen

*** Where the patient is overdue for their routine assessment at return, only perform the assessment once the patient has taken treatment for 3 months (or if in RPCs, the closest clinical review date thereafter).

Co-treatment of HIV and Active TB in Neonates, Infants, Children, Adolescents and Adults

TB/HIV co-infection impacts on ART in a number of ways. It affects:

1. **The timing of ART initiation** *see"Medical Indications to Defer ART" on page 4*
2. **Drug selection** in clients who are not yet on ART when TB treatment is initiated
3. Drug levels, due to significant **drug interactions** that reduce ART concentrations in the blood
4. **Adherence**, due to increased pill burden
5. **Side-effects** due to overlapping toxicities, e.g. hepatic toxicity

Clients who are not yet on ART when TB treatment is initiated

- Children and adolescents should initiate ART with a DTG-containing regimen, with boosting of DTG as explained below.
- Adults should initiate ART with either:
  i. a DTG-containing regimen, with boosting of DTG as explained below, or
  ii. an EFV-containing regimen, provided the client is ART treatment-naive. EFV has no significant drug interaction with rifampicin and has the benefit of being a once-daily regimen which supports adherence.

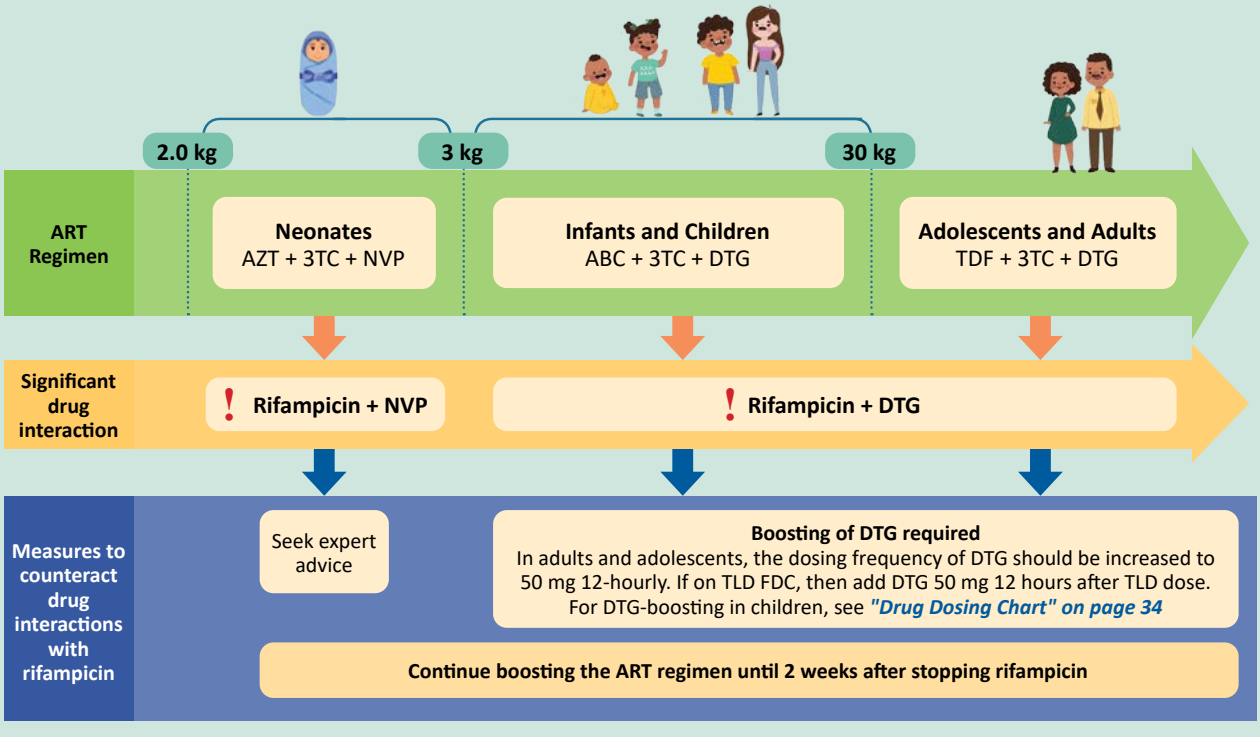
Clients who are already on ART when TB treatment is initiated

- All clients who are already on a DTG-containing regimen when TB treatment is initiated should continue the DTG-containing regimen whilst also taking TB treatment, with boosting of DTG as explained below.
- Clients who are already virally suppressed on an EFV-containing regimen when TB treatment is initiated should continue the EFV-containing regimen whilst also taking TB treatment. The EFV-containing regimen should be continued until two weeks after TB treatment is completed. Thereafter, EFV can be switched to DTG.

! Clinicians should provide integrated TB and ART management at clinical consultation visits. Failure to combine care leads to increased visits and significantly increases the risk of disengagement. See also *"Integrated Visit Schedule for Clients on ART and Drug-Sensitive TB Treatment" on page 26*

Drug Interactions with DTG and Rifampicin-containing TB Treatment

Rifampicin-containing TB treatment has significant drug interactions with all paediatric ART regimens, as well as with adult/adolescent regimens containing DTG:



Drug Interactions with Protease Inhibitors, e.g., Lopinavir/ritonavir

Every effort should be made to switch clients to DTG-containing regimens. However, during the transition process, some clients may still be on PI-containing regimens and may also require TB treatment. Rifampicin cannot be given with ATV/r or DRV/r. Significant drug interactions between LPV/r and rifampicin should be managed as follows:

LPV/r tablets: Double-dose LPV/r tablets in adults, adolescents and children able to swallow whole LPV/r tablets. See *"Drug Dosing Chart" on page 34*. Tablet must not be crushed, broken or chewed. If the client is unable to tolerate LPV/r at double doses, consult one of the *"Helplines" on page 23*.

LPV/r solution or pellets or 4 in 1 (ABC/3TC/LPV/r): Super-boosting with additional ritonavir powder: maintain standard LPV/r dose but add additional ritonavir twice daily as per *"Drug Dosing Chart" on page 34*. If no powder is available, consult an expert for a suitable alternative. Ritonavir powder has a shelf-life of 36 months. Note that ritonavir 100 mg tablets must not be crushed, broken or chewed.

Optimising Regimens and Visit Schedules for the Client on ART

Switching Existing Clients to DTG-containing Regimens (Adults, adolescents or children)

Non VL-dependent regimen switches Regimens where the VL result will not influence nor delay the decision to switch to a DTG-containing regimen			
VL considerations	**Current Regimen**	**Criteria for switch**	**Regimen if change indicated**
Switching regardless of VL result	**TEE** ABC/3TC/EFV (or NVP*) AZT/3TC/EFV (or NVP*) AZT/3TC/DTG Any LPV/r or ATV/r regimen for **less than 2 years**	**Switch all to a DTG-containing regimen, regardless of VL result** Review VL in last 12 months. If VL in last 12 months was not suppressed, continue to switch same day, but do ABCDE assessment and provide enhanced adherence counseling (EAC) if needed. If VL was not done in last 12 months, do it at this visit, but do not wait for the result to switch	**TLD** provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If client does not qualify for TDF **ABC[1]/3TC/DTG** If client does not qualify for TDF and has ABC hypersensitivity **AZT/3TC/DTG**

! * There should no longer be any client (older than one month and > 3 kg) using a NVP-containing treatment regimen.
Clients who previously used NVP as an alternative to EFV for psychiatric reasons, should be switched to DTG as a matter of urgency

Be sure to check for possible drug interactions when switching to DTG and manage as per ***"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13***

! Clients on TEE and receiving treatment through an RPCs can be switched to TLD at their next re-scripting visit and can remain in their RPCs, provided they have a VL < 50 c/mL in the last 12 months. No additional facility visits are required (see DMOC SOP 6).
Any client in an RPCs with a VL ≥ 50 c/mL in the last 12 months, should be recalled to the facility for further clinical management. If the client is on TEE, continue to switch same day to TLD, but do an ABCDE assessment and provide enhanced adherence counselling (EAC) if indicated. If clinically well, 3MMD can be provided by the facility until the repeat VL assessment (see DMOC SOP 4) in 3 months, as per ***"VL Monitoring for Clients on TLD" on page 21***. Review the repeat VL result. If suppressed again, re-enrol in RPCs. If the VL remains unsuppressed, manage as per the ***"VL Monitoring for Clients on TLD" on page 21***. Clients with clinician confirmed low-level viraemia can be re- enrolled in RPCs.

Switching Existing Clients to DTG-containing Regimens (Adults, adolescents or children who have never used a DTG-containing regimen in the past)

[1] If clients are not eligible to use TDF and they had an ABC hypersensitivity reaction, use AZT/3TC/DTG

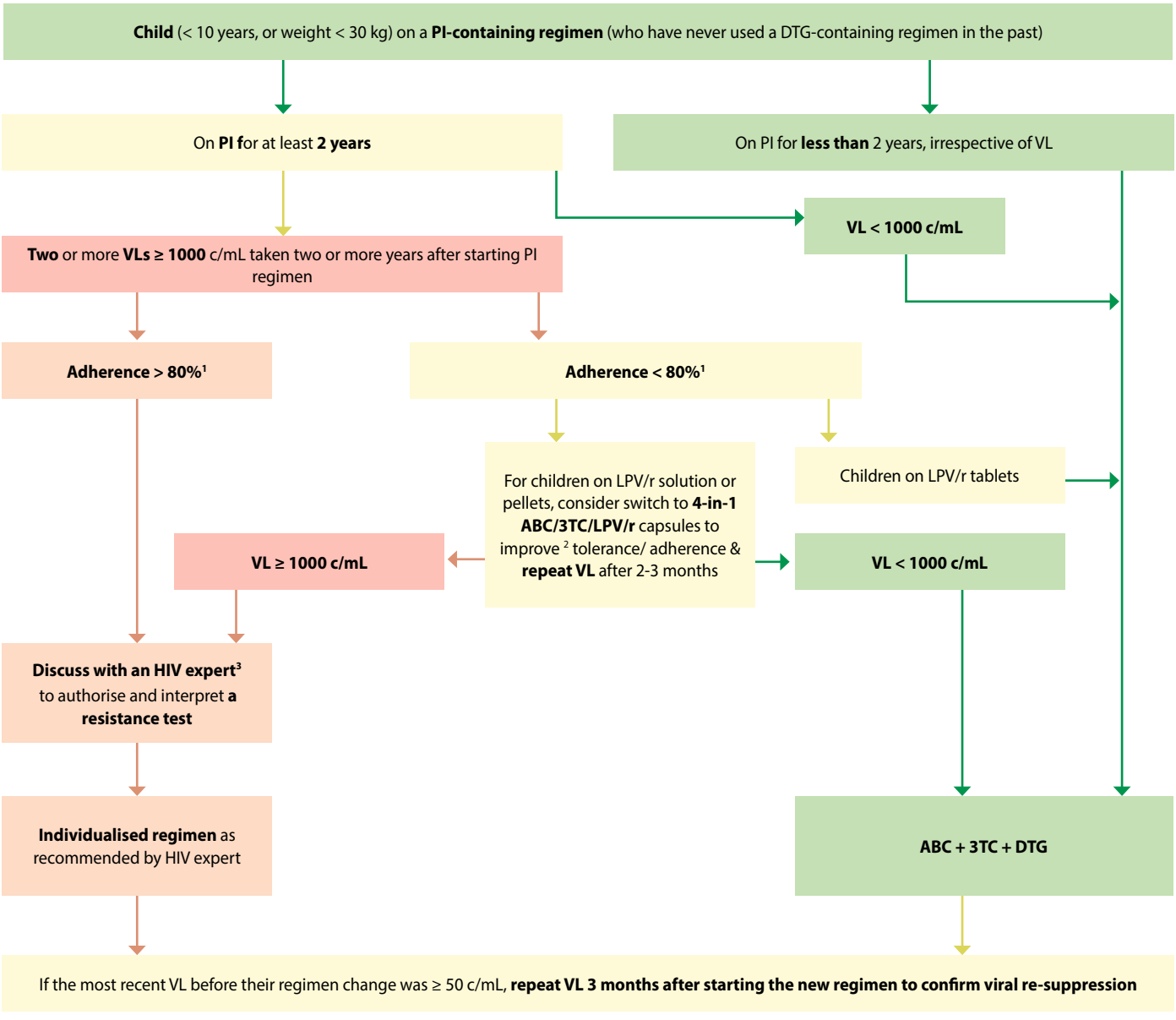
VL-dependent regimen switches Relevant to all clients who have been on PI-based regimens for more than two years: their VL result in the last 12 months will influence the decision of how and when to switch to a DTG-containing regimen			
VL considerations	**Current Regimen**	**Criteria for switch**	**Regimen if change indicated**
VL < 1000 c/mL	**Any LPV/r or ATV/r regimen** for **more than 2** years	**Switch all to a DTG-containing regimen** If VL in last 12 months was ≥ 50 c/mL, continue to switch same day, but do ABCDE assessment, provide EAC if needed, and repeat the VL after 3 months as per ***"The VL non-suppression algorithm" on page 21***	**TLD** provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If clients does not qualify for TDF ABC[1]/3TC/DTG
[2] **Two or more consecutive VLs ≥ 1000 c/mL** taken **two or more years** after starting PI regimen	Adult or adolescent on any **LPV/r or ATV/r** regimen and adherence **less than 80%**[3]	**Switch all to a DTG-containing regimen** **Do not do a resistance test** These clients are unlikely to have PI resistance mutations. Rather switch to a more tolerable once daily FDC regimen which is likely to support adherence. Manage as per ***"The VL non-suppression algorithm" on page 21***	**TLD** provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If clients does not qualify for TDF **ABC[1]/3TC/DTG**
	Adult or adolescent on any **LPV/r or ATV/r** regimen and adherence **more than 80%**[3]	Clients who meet the definition of confirmed virological failure and have confirmed adherence more than 80% may need a resistance test. **These clients do not qualify for a same-day switch.** Discuss with an HIV expert[4] to authorise and interpret a resistance test. Provide individualised regimen as recommended by HIV expert. Repeat VL 3 months after the regimen change to confirm re-suppression, as per the ***"Management of Confirmed Virological Failure on TLD" on page 23***	
	Child < 10 years, or weight < 30 kg on any **LPV/r or ATV/r regimen**	These clients do not yet qualify for TLD and may require a resistance test. Refer to algorithm ***"Switching children on PI-containing regimens to DTG- containing regimens" on page 16***	

1. If clients are not eligible to use TDF and they have ABC hypersensitivity, use AZT/3TC/DTG
2. Confirmed virological failure is defined as two or more VLs ≥ 1000 c/mL taken two or more years after starting a DTG or PI containing regimen, despite adherence > 80% by objective measurement. A patient who has only 1 VL > 1000 after 2 years on a PI-based regimen should have an ABCDE assessment, EAC if applicable, and their VL repeated in 3 months. The result of the repeat VL will allow the patient to be grouped into one of the categories in the table above and will inform the further course of action
3. Objective measures of good adherence include at least one of:
   - Pharmacy refills > 80% in the last 6-12 months (if this is known)
   - Attendance of > 80% of scheduled clinic visits in the last 6-12 months (if this is known)
   - Detection of current antiretroviral drug/s in the client's blood or urine, if available [e.g. TFV urine lateral flow assay (LFA) for presence of TDF in urine, TFV diphosphate (detects TDF on dried blood spot samples), DTG plasma levels]

Note: Self-reported adherence is not considered a reliable measure of good adherence!

4. For advice from an HIV expert, approach an HIV Hotline, an infectious disease specialist, or the Third Line ART committee

Switching Children on PI-containing Regimens to DTG-containing Regimens



1. Although objective measures of poor adherence include pharmacy refills or attendance of scheduled clinic visits in the previous 6-12 months of <80%, adherence difficulties in young children are often linked to poor tolerability of unpalatable formulations, particularly LPV/r solution. It is important to ask the caregiver about how the child tolerates the medication e.g., does the child refuse to swallow the medicine or spit out or vomit the medicine, and whether the caregiver has been able to overcome this. Considering these limitations, objective measures of good adherence could include one of the following:
   a. Pharmacy refills > 80% in the last 6-12 months (if this is known)
   b. Attendance of > 80% of scheduled clinic visits in the last 6-12 months (if this is known)
   c. Detection of current antiretroviral drug/s in the client's blood or urine, if available
2. If a switch to the 4-in1 capsules does not improve adherence, or is not available, continue to switch to ABC + 3TC + DTG as for non- adherent children on LPV/r tablets
3. The following would qualify as HIV experts: the HIV Helplines, a paediatric infectious disease specialist or the paediatric Third line ART committee

Summary of the Care Continuum for Clients 5 years of age and older on ART

Clients on ART can be differentiated into those who are 1) clinically well and adherent on ART and 2) those who are clinically non-stable and/or struggling with adherence. Clients that are clinically well at their first clinical review one month after starting ART, only need to be seen again 2 months later for clinical review and their first viral load and serum creatinine. After that, taking treatment and clinical follow-up should be made as convenient as possible for the client. Therefore, they may continue to receive ART using a differentiated care approach, provided they meet the eligibility criteria of 1) having a suppressed VL, 2) being clinically well with no opportunistic infections (OIs), 3) not having any other uncontrolled chronic conditions that require clinical review more frequently than 6-monthly, and 4) not being pregnant.

The diagram ***"Visit Schedule for Adults, Adolescents and Children 5 Years and Older on ART" on page 18*** provides a summary of the components of care at different visits for clinically well and adherent clients during the first year on ART. Clients who are enrolled in repeat prescription collection strategies (RPCs) should be rescripted for RPCs at their comprehensive clinical review at which a further VL will be taken. Clients should not be required to come back the following month for VL result review prior to rescript. Rather, recall to the facility only those clients with elevated VL. For more detail on repeat prescription strategies (RPCs), see the DMOC standard operating procedure (SOP) 5 (facility-pick-up points, adherence clubs and external pick-up points).

See also ***"Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment" on page 26*** and ***"Visit Schedule for Integrated Care for the Mother-baby Pair Living with HIV" on page 24***

! If a patient comes from a different facility, it is critical that the patient be provided with treatment on the day of presentation to limit any further treatment interruption and its impact on viral suppression. While referral letters are helpful, a patient cannot be required to leave the facility without treatment to first obtain a referral/transfer letter.

Women with contraceptive needs should have contraceptive method options explained, specifically how each method impacts all required return visits' location (facility or outside of the facility) and visit frequency:

- Long-acting reversible contraception (LARC) removes any increased visit frequency or alignment concerns.
- The combined oral contraceptive pill (COCP) can be repeated 3-monthly, aligns well with ART and well-baby visit schedules (if applicable), and can be scripted through her preferred RPCs.
- The DMPA 3-monthly injection must be administered by a clinician but aligns with ART and well-baby visit schedules
- The NET-EN 2-monthly injection also needs to be administered by a clinician, but will require additional visits by the mother.
- Where a woman chooses to continue clinician administered short-acting injectable contraception (e.g., DMPA or NET-EN), a facility-based pick-up point (FAC-PUP) or facility-based adherence club may be the preferred option provided visit alignment can be ensured.

HELPLINES

If in doubt about any aspect of viral load management or switching to second-line, contact one of the following resources:

National HIV & TB Health Care Worker Hotline: **0800 212 506**

Right to Care Paediatric, Adolescent and Adult HIV Helpline: **082 352 6642**

KZN Paediatric Hotline: **0800 006 603**

Visit Schedule for Adults, Adolescents and Children 5 Years and Older on ART

DC/ Months* on ART	Routine monitoring tests	Overview of Management
0	**Baseline clinical and lab assessment as outlined on pages 4 to 6 ART initiation and session 1 of fast track initiation counselling**	
1	**Review test results**	• Session 2 of fast track initiation counselling including planning for travel and VL education • Clinical assessment and routine monitoring as outlined on page 19 • Integrated services for family planning and NCDs • **2 months ART dispensed (2MMD) - DMOC SOP 4**
3	**3-month* VL sCR and eGFR**	• Clinical assessment including VL and any other routine • monitoring bloods as outlined on page 19 • • Integrated services for family planning and NCDs

4	**Review test results**	• Clinical assessment and review of VL and any other monitoring results
		• Integrated services for family planning and NCDs
		• Assess eligibility for Repeat Prescription Collection strategies (RPCs) (South Africa's differentiated models of care for stable patients)
		  • VL < 50 c/mL
		  • Clinically well
		  • No OIs, including TB
		  • Not pregnant
		Repeat Prescription Collection strategies (DMOC for stable patients)
		Facility Pick-up Point (FAC-PUP) (DMOC SOP 5.1) | Adherence Clubs (AC) Facility or community-based support groups (DMOC SOP 5.2) | External Pick-up point (EX-PUP) (DMOC SOP 5.3)
		• Renew prescription for next 6 months, with first 3 month's supply issued today from the facility
		• If not eligible for RPCs or refused RPCs:
		Assess eligibility for facility provided multi-month dispensing (MMD) – DMOC SOP 4

7		• Collect medication from preferred RPCs
10	**10-month* VL sCR and eGFR CD4 count**	• Clinical assessment including VL and any other monitoring bloods as per ***"Monitoring on ART" on page 19*** • Integrated services for family planning and NCDs • Check TPT eligibility • Renew prescription for next 6 months • Do not require clients to return to the facility in 1 month to review the VL results, unless other clinical indications exist that require review. Rather, recall to the facility only those clients with elevated VLs
11+		• 12-monthly clinical assessment and family planning review as per ***"Monitoring on ART" on page 19*** • 12-monthly routine monitoring of VL, sCR and eGFR • Check that chosen RPCs option is still suitable • Collect medication from preferred RPCs

Non-stable clients

If at any stage the client becomes clinically non-stable and /or non-adherent i.e. a client who has:

- missed a scheduled appointment by more than 28 days (including in an RPCs) (see also ***"Re-engagement algorithm" on page 12***)
- a VL ≥ 50 c/ml
- possible signs or symptoms of clinical failure, e.g. if the client is acutely unwell, or develops a new OI such as TB

A clinician should:

- If in an RPCs, return the client to regular care to ensure more frequent clinical follow-up until they are stable again.
- Provide appropriate clinical management
- If clinically well and struggling with visit frequency: provide multi-month dispensing (DMOC SOP 4)
- If experiencing side effects or the child cannot tolerate their medication: switch drugs/formulation
- If struggling to take ART as prescribed: enhanced adherence counselling (See Annexure 3)

! Clients on TEE and receiving treatment through RPCs can be switched to TLD and remain in their RPCs if they have a VL < 50 c/mL in the last 12 months.

*The term dispensing cycle (DC) is defined as the number of days for which a client would have treatment if a single standard "monthly" quantity of tablets was dispensed (usually 28 days). Although it is understood that the time frame for a month and a DC are not necessarily the same, for ease of reading, the term 'DC' and 'month' are used interchangeably in this table, and should be considered synonymous.

Managing the Client on ART

Monitoring on ART

! Remember to check adherence at every clinical follow-up visit, in a non-judgemental way. Ask open ended questions e.g. "Is there anything that makes it difficult for you to take your treatment?" See also the 'Adherence' section of the ***"ABCDE assessment of an Elevated Viral Load" on page 22***

Providing quality care at the follow-up visit is essential to promote adherence, achieve and sustain viral suppression, minimise side-effects and toxicities, and promote quality of life. A client on ART should be monitored to:

1 Determine clinical response to ART

2 Determine the virological and immunological response to ART

3 Detect and manage any side-effects and toxicities

The following components should be included in the **clinical assessment:**	**Viral load** should be measured to timeously detect problems with adherence or treatment failure	**Side-effects and ART toxicities** can affect adherence and endanger the client's health:
Weight (adults) An assessment of trends in weight in adults	! Remember, any elevated VL > 50 c/mL is a medical emergency! Assess and manage according to the algorithm ***"VL Monitoring for Clients on TLD" on page 21***	**Drug side-effects** Ask about side-effects at each visit (e.g. sleep or gastrointestinal disturbances)
Growth and neurodevelopment (children) An assessment of trends in weight, height, head circumference, and neurodevelopment ! Remember to increase the ART dosage as weight increases!	**The CD4 count** monitors susceptibility to opportunistic infections, identifies clients with advanced HIV disease and informs eligibility for OI prophylaxis.	**TDF-induced nephrotoxicity** If on TDF, do creatinine and eGFR* at months 3 and 10 (aligned with VL monitoring schedule) Thereafter, repeat every 12 months See also ***"Assessing Renal Function" on page 8***
Screen for TB (see below *) **and other OIs:** to diagnose and provide treatment; to adjust ART regimen if required; to provide a package of care for AHD if required; to determine if TB preventive therapy is required	Monitor routinely after 10 months/DCs on ART (aligned with VL). Thereafter, stop CD4 monitoring unless: • CD4 still ≤ 200 cells/mm^3: repeat every 6 months until CD4 > 200 • VL ≥ 1000 c/mL: repeat CD4 every 6 months until VL < 1000 c/mL • A clinical indication arises, such as a new WHO Stage 3 or 4 condition in a previously well client Repeat CD4 for clients returning > 90 days after missing a scheduled appointment (see ***"re-engagement algorithm" on page 12***)	**Dyslipidaemia** If on a PI-based regimen, do total cholesterol and triglycerides (TGs) at month 3 If above acceptable range, do fasting cholesterol and TGs and if still above acceptable range, obtain expert advice
WHO clinical staging to determine response to ART, and CPT eligibility		**Anaemia and neutropaenia** If on AZT, do a full blood count and differential white cell count at months 1 and 3 Thereafter, repeat if clinically indicated
Screen for pregnancy and ask if planning to conceive as outlined in the table for ***"Baseline Clinical Evaluation" on page 5***		

* Screening for TB at follow-up Visits

At every routine follow-up visit:	At every 12-monthly clinical review on ART (aligned with 12-monthly VL)	For symptomatic PLHIV admitted to hospital [in addition to the MTB/Rif Ultra (Xpert)]	For symptomatic PLHIV seen in an outpatient setting [in addition to the MTB/Rif Ultra (Xpert)]

• Do a TB symptom screen. If symptomatic, do a MTB/Rif Ultra (Xpert)	• Routine MTB/Rif Ultra (Xpert) (regardless of TB symptoms)	• Do a U-LAM test	• Do a U-LAM test if:
			  • CD4 count <200 within the last 6 months, or
			  • advanced HIV disease, or
			  • current serious illness.

For more information on the package of care for AHD and the management of specific OIs, please refer to the ***Consolidated ART guideline***

! When monitoring on ART, also integrate monitoring for other chronic conditions (HPT, DM, and mental health) and routinely offer reliable contraception and cervical cancer screening to female clients.

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Reference: 1. Van Galen KA, Nellen JF, Nieuwkerk PT. The effect on treatment adherence of administering drugs as fixed-dose combinations versus as separate pills: systematic review and meta-analysis. *AIDS Research and Treatment* 2014. http://dx.doi.org/10.1155/2014/967073.

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The Academy of Pharmaceutical Sciences of South Africa Conference 2023

Prof Varsha Bangalee
Conference convener

 S Afr Pharm J 2023;90(6):52-53

Set against the breathtaking backdrop of Durban's pristine coastline, The Capital Zimbali Resort provided the perfect setting for this academic and scientific rendezvous. Nestled within lush vegetation and overlooking the Indian Ocean, the resort not only offered a tranquil ambiance but also inspired creative thinking and collaboration, ensuring that the impact of this event would resonate long after its conclusion.

Themed Riding the Waves of Change, the event not only embraced change but also surmounted it with resounding success, exceeding all expectations in terms of attendance, content, and networking opportunities. The conference featured a rich and diverse array of sessions and discussions as well as international guests and local industry luminaries. The programme catered to a wide spectrum of interests and expertise giving participants opportunities to delve into the latest trends, research findings and best practices in pharmaceutical sciences.

Conference 2023 did not stop with knowledge exchange but also celebrated excellence. Awards were presented to recognise outstanding contributions by young scientists, distinguished teachers, best publications in the various core fields of Pharmacy and best poster presentations. These awards highlighted the significance of innovation and dedication fostered across all Pharmacy schools.

Awards

Young Scientist Winner – Laboratory Sciences

Emmanuel Kiyonga (SMU)

Co-crystal systems for solubility enhancement of raloxifene HCl in breast cancer and osteoporosis therapy

Distinguished Teacher of the Year

The 2023 winner was Dr Jacques Joubert from the University of the Western Cape.

Publication Awards

Pharmaceutical Chemistry

Lesetja Legoabe (NWU)

Investigation of quinolone-tethered aminoguanidine as novel antibacterial agents

Pharmaceutics

Yahya Choonara (Wits)

A nano-enabled biotinylated anti-LDL theranostic system to modulate systemic LDL cholesterol

Pharmacology

Nicole Keuler (UWC)

Sub-analysis of CYP-GUIDES data: Assessing the prevalence and impact of drug-gene interactions in an ethnically diverse cohort of depressed individuals

Pharmacy Practice

Hannelie Meyer (SMU)

Vaccine hesitancy drives low human papillomavirus vaccination coverage in girls attending public schools in South Africa

Poster award

Monique Labuschagne from North-West University

One of the most remarkable aspects of the conference was the exceptional presentations delivered by the dedicated postgraduate students. Their enthusiasm, innovation, and commitment to advancing pharmaceutical research were truly inspiring. The organisers express deep gratitude to the supervisors and mentors who nurtured and supported these budding scientists, guiding them to excel and shine on such a prestigious platform. The supervisors' tireless efforts and guidance have played a pivotal role in shaping the future of pharmaceutical sciences, and the organisers are immensely proud of the outstanding work accomplished by both students and their mentors.

The APSSA Conference 2023 was an exceptional platform for learning, sharing, and preparing for the dynamic future of pharmaceutical sciences. As the waves of change continue to reshape our field, the knowledge and insights gained at this event will undoubtedly steer the pharmaceutical community towards excellence and innovation.

We extend our gratitude to the University of KwaZulu-Natal for hosting this extraordinary event, the speakers and presenters for their valuable contributions, and all attendees for their enthusiastic participation. We are particularly proud of the remarkable presentations delivered by our postgraduate students, showcasing the bright future of pharmaceutical research.

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Until we meet again at the next APSSA Conference, let's continue "Riding the Waves of Change" together, advancing healthcare for a brighter tomorrow.

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Delegates that attended the APSSA conference

Young Scientist winner Emmanuel Kiyonga with Lorraine Thom (APSSA Chair)

Ready or not…Change is happening

Nhlanhla G Mafarafara

President, SAAHIP

Nhlanhla G Mafarafara

Change is a continuous phenomenon which must be properly managed to ensure success at all times. If not anticipated nor handled with care, it can leave both individuals and institutions confounded.[1] Change management is the ability to constantly review and renew the organisation's outlook, functional structures and performance capabilities, to achieve the fast-changing demands that emerge from both internal and external stakeholders of the organisation.[2] It is crucial for healthcare workers to develop the ability to manage change (both individually and organisationally) in order to thrive in a fast-changing health care environment. In order to successfully manage and accept the complexity of change, there should be a conducive environment for ongoing open learning by ensuring that there are tools and systems for change readiness and to facilitate a step-by-step approach to change management.[3]

Since change is a constant, not embracing change is denial of its inevitability which ultimately leads to failure to implement or deal with it more effectively. Good ideas and initiatives could fail to achieve their intended outcomes when approached reactively or in ways that suggests inconsistent sharpening of systems for such. South Africa and the global health community is experiencing changes that require reorganisation of ideas and approaches. Changes such as digital health innovation, universal health coverage and professional scope evolution. For example, one needs to believe and embrace that digital technology is not here to take away jobs, but to enhance performance, thus professionals with digital skills will be more market attractive than those without. The role of pharmacists has now shifted to prescribing and co-prescribing for improved access to care and better patient outcomes. It's a matter of mental orientation around the change that is now here.

Change in and by itself is never a problem, it is an opportunity. The real challenge is people's ability to reorganise themselves for the need for change and developing practical strategies to respond to, initiate and implement change. According to Self & Schraeder (2009), there are three factors to this effect:[4]

- Personal factors: concerns about change and the qualities which lead to change aversion. Some of these makes one to feel less equipped for the change, and thus making it less attractive.
- Organisational factors: previous experience of similar changes or credibility of the organisation in handling change could make people sceptical about it.
- Change specific factors: the change process or what the change brings to the environment can prevent the actual change, delay it or alter it negatively.

To deal with change and avoid both personal and organisational shock when it finally happens, there are a few things I want to suggest:[5,6]

- People involvement. Involve the people who will be affected by change ahead of time before it happens. And as individuals, develop a keen sense of optimism and desire or willingness to be involved in the changes that affect you by acquiring the knowledge required for the post change environment and/or get involved in leading it.
- Plan for change. There should be systems, plans, pathways, and tools properly aligned for all the phases of change. Change should be dealt with using project management principles. It should have scope, clear objectives, time frames and resources aligned with it.
- Managing the people. Every step of change should be clearly communicated. People should always know what will and will not change and allow them to engage, grieve or disengage with the process. Engaging people allows the organisation to reduce or prevent unnecessary pressure on people and the systems involved.
- Evaluate change. Constantly monitor the progress, the impact and the outcomes and provide feedback to all stakeholders involved or affected.

What does this mean for pharmacists

It is important for pharmacists to position themselves for new paradigms. Academic institutions should also infuse new graduates with fluid skills for pharmacists on the subject of change (initiation and embracing it). Abednico Makina once said "*human beings are created with capacity to create circumstances favourable for his/her living conditions. If you wait for circumstances to be created for you, you will always be forced to adapt to what life throws at you.*" What the world is, it's not what it was, and what it will be is not what it is. Pharmacists need to position themselves as strategic contributors in the global decision making, pharmacy programs design gallery and systems innovation for better pharmacy practice. It will also require strategic collaborations, commitments and advocacy locally, regionally and globally as well rapid adaptation and evolution in thinking, research, policy and boardroom engagements for practice innovation. But more so, it requires acceptance that nothing stays the same.

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"We are the Children…. Hear our Voices": Improving Access to Child-Friendly Formulations of Drug Resistant Tuberculosis Medicine: The KwaZulu-Natal Experience

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This paper is based on the best scenario presentation at the SAAHIP Conference 2023

Background

The past five years have seen revolutionary changes in the diagnosis and management of rifampicin-resistant tuberculosis (RR-TB), including the use of new and repurposed drugs and novel therapeutic approaches.[1] Following years of stagnation in the drug development pipeline, the introduction of two new agents, bedaquiline and delaminid, and the use of the repurposed medicines, clofazimine and linezolid, have provided hope for patients globally, reducing the pill burden and duration of treatment.[2] Critically, this has also enabled all-oral regimens, avoiding the adverse events associated with aminoglycosides and the need for in-hospital treatment.

Based on new evidence of safety and efficacy of the new and repurposed medicines emanating from research studies conducted globally, with South Africa (SA) being a major contributor, the World Health Organization (WHO) issued a "Rapid Communication" on 17 August 2018.[3] The WHO communication included radically altered recommendations for the treatment of drug-resistant tuberculosis. These recommendations were made based on an individual patient data meta-analysis of more than 12,000 adults and programmatic data from more than 50 countries and data from phase II and III randomised controlled trials. For the first time ever, WHO was recommending all-oral treatment regimens for the majority of individuals with drug resistant TB (DR-TB) and revised the priority "groupings" of individual medications that should be used for regimen design (Figure 1). The new and repurposed medicines were now included as core medicine in the treatment regimen.

Group	Medicine	Abbreviation
Group A: Include all three medicines (unless they cannot be used)	Levofloxacin OR Moxifloxacin	Lfx Mfx
	Bedaquiline[1,4]	Bdq
	Linezolid[2]	Lzd
Group B: Add both medicines (unless they cannot be used)	Clofazimine	Cfz
	Cycloserine OR Terizidone	Cs Trd
Group C: Add to complete the regimen and when medicines from Goup A and B cannot be used	Ethambutol	E
	Delamanid[3,4]	Dlm
	Pyrazinamide[5]	Z
	Imipenem-cilastatin OR Meropenem[6]	Imp-Cln Mpm
	Amikacin (OR Streptomycin)[7]	Am (S)
	Ethionamide OR Prothionamide	Eto Pto
	p-aminosalicylic acid	PAS

[1] Evidence of the safety and effectiveness of Bdq beyond 6 months was insufficient for review; extended Bdq use in individual patients will need to follow 'off-label' use best practice

[2] Optimal duration of use of Lzd is not established. Use for at least 6 months was shown to be highly effective, although toxicity may limit use.

Figure 1: Grouping of medicine recommended for use in longer MDR TB regimens

Source: WHO Rapid communication: key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB)[3]

The gap

Although the analyses and recommendations were largely focused on adults as only a small number of children are diagnosed and treated for DR-TB each year, and thus the evidence base in children is not as robust as that for adults, the new WHO recommendations for regimen design also apply to the treatment of paediatric DR-TB. It was recommended that regimen construction for children should prioritise *Group A and B medications,* where possible. Children should be offered regimens containing medications that have been shown to be associated with improved outcomes and a lower risk of mortality in adults, including bedaquiline, linezolid, clofazimine and the later-generation fluoroquinolones.[4]

SA as a global leader in introducing innovation to the field of DR-TB rapidly adopted the WHO recommendations into their policy guidelines.[2–7] The announcement by the National Department of Health of the adoption of the injectable-free regimen in patients 12 years and older, with bedaquiline replacing kanamycin, an injectable agent that cause nephron- and ototoxicity (irreversible) in many patients[8], was applauded by activists and healthcare workers. However, many raised concerns that children's needs were not being met due to the absence of child friendly formulations of second line DR-TB medicine.[9-11] Whilst children represent a substantial proportion of persons with TB disease, with an estimated 30,000 children becoming sick with multidrug resistant tuberculosis (MDR-TB) globally each year, they lack the same access to diagnosis and treatment as their adult counterparts.

In the SA public sector, medicine is generally procured on the basis of transversal tenders. A review of the tuberculosis tender confirmed that only adult formulations of second-line DR-TB medicine, with limited availability of linezolid suspension, had been awarded. It was noted that children were treated with adult formulations that had to be cut, crushed and mixed. This may result in incorrect dosing, prolonged hospitalisation, and significant staff time for preparing and delivering medications. This was the accepted standard for many years as there were no alternatives.

The opportunity

In 2017, dispersible child-friendly formulations of DR-TB medicine became available on the global market. The Global Drug Facility (GDF), in collaboration with Sentinel Project on Pediatric Drug-Resistant Tuberculosis, proposed a global pooled procurement strategy with all countries contributing to the demand. GDF donated an initial supply to countries with the aim of encouraging countries to gain programmatic experience with these medications, and to facilitate the global roll-out of these products. These novel new formulations were scored to ensure consistency in dosing, dispersible to dissolve easily in water, with smaller sizes for more precise dosing and easier administration and were quality assured. Their availability meant that using adult tablets that had to be manipulated could no longer be justified. These were not new drugs, but different formulations of existing drugs to make treating children with DR-TB easier, safer and more tolerable.

The journey

Optimal stakeholder engagement was needed to improve access to the child-friendly formulations. The new formulations were not registered in SA and an application had to be made to the South African Health Products Regulatory Authority (SAHPRA), to obtain permission to use an unregistered product in the country.[12] Representation was made to the National Department of Health Affordable Medicines Directorate to motivate for the need for the child friendly formulations, requesting support to accept the donation as per policy guidelines.[13] The need for the child-friendly formulations and products available for donation from GDF was also supported by the KwaZulu-Natal (KZN) Provincial Pharmaceutical and Therapeutics Committee. Quantification and forecasting were done for each product available from GDF, based on the past 3 years' case registrations of children under 10 years in KZN and the current DR-TB treatment guidelines. A need for ethambutol 100mg, pyrazinamide 150mg, levofloxacin 100mg and clofazimine 50mg dispersible tablets was identified. A submission to accept the donation of child-friendly formulations was drafted from the KZN Head of Pharmaceutical Services and HIV and AIDS/STI/TB (HAST) Manager to the KZN Head of Health, which was approved. A grant agreement between GDF and KZN was signed and a procurement request form was signed by the HAST Manager. Equity Pharmaceuticals was approached to facilitate clearing and forwarding of the medicine from the airport to King Dinuzulu Hospital Complex (KDHC). In 2020, KZN received dispersible tablets of ethambutol100mg, pyrazinamide 150mg and levofloxacin. In 2021, dispersible clofazimine 50mg was received.

Standard operating procedures (SOPs) for the pharmacist, nurse and doctor were developed based on actual experience. Training of end users and caregivers regarding the products and regulatory requirements such as informed consent forms to be completed prior to initiation and six-monthly progress reports that monitored outcomes and adverse events. A total of 24 children benefited from the access to the child-friendly formulations.

Lessons learnt

The KZN experience has shown that convincing the regulatory bodies to approve the use of child-friendly formulations in the absence of robust evidence in children is challenging, but possible. Lack of evidence of safety and efficacy in children hinders inclusion into the NDoH's Standard Treatment Guidelines (STGs) and Essential Medicines List (EMLs). Children, caregivers, nurses and clinicians reported good adherence, ease of administration and better dosing with child-friendly formulations.

Way forward

The KZN experience has changed the narrative from lack of child-friendly formulations to **"Where are the Children?"**. The focus has to move to finding the missing cases of children, placing them on appropriate treatment and building the evidence base to lobby for a sustainable supply of child-friendly formulations.

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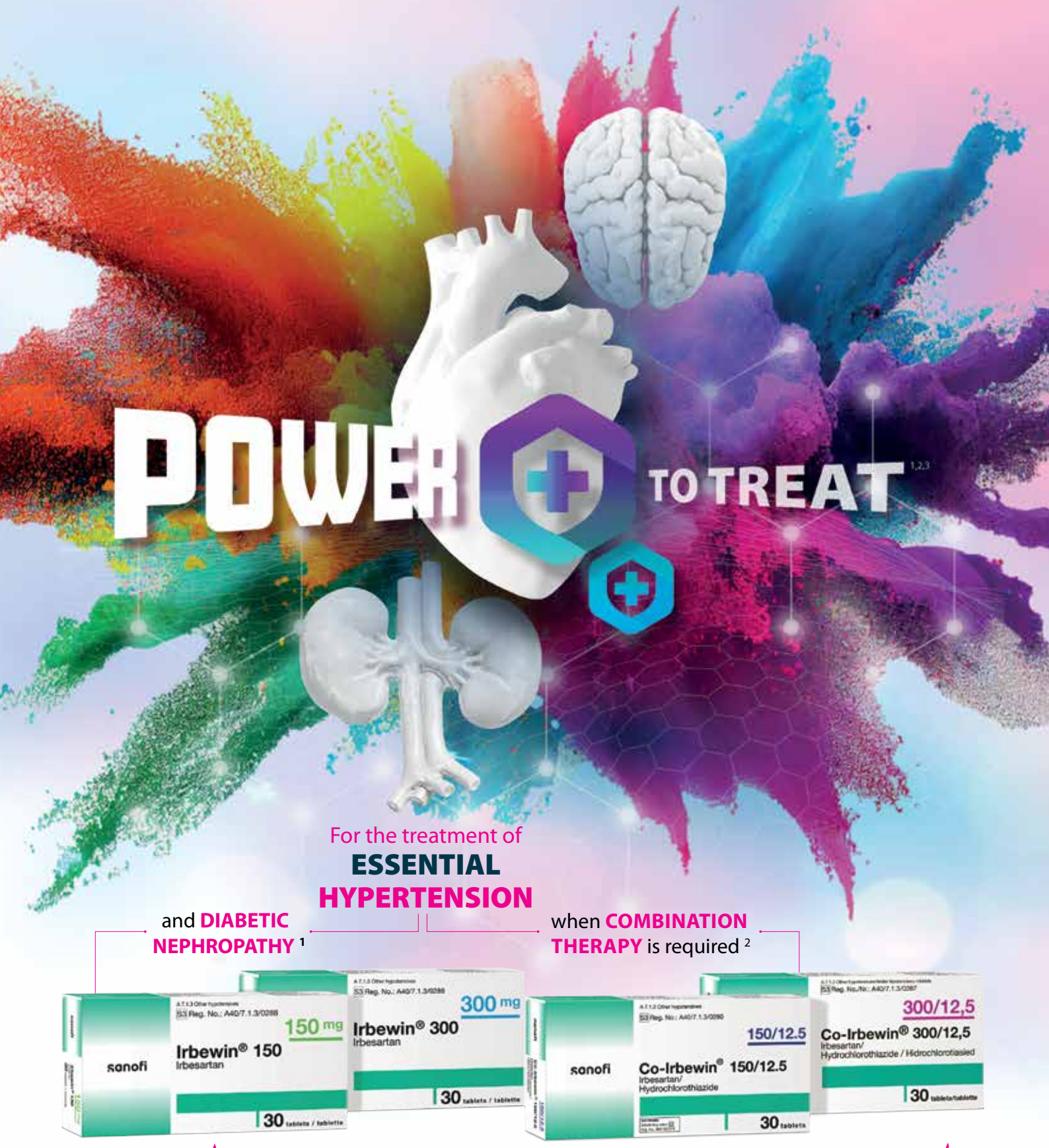

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irbesartan/hydrochlorothiazide

References: 1. IRBEWIN 75 mg, 150 mg & 300 mg tablets professional information approved by the medicines regulatory authority. 31 July 2019. **2.** CO-IRBEWIN 150/12,5, 300/12,5 tablets professional information approved by the medicines regulatory authority. 31 July 2019. **3.** Hypertension guideline working group, Seedat YK, Rayner BL, Veriava Y. South African hypertension practice guideline 2014. *Cardiovasc J Afr.* 2014;25(6):288-294.

SCHEDULING STATUS S3 **IRBEWIN® 150/300** (Tablets). **COMPOSITION:** Each tablet contains 150/300 mg of irbesartan respectively. **REGISTRATION NUMBERS:** A40/7.1.3/0288; A40/7.1.3/0289. **SCHEDULING STATUS** S3 **CO-IRBEWIN® 150/12.5; 300/12.5** (Tablets). **COMPOSITION:** Each tablet contains 150/300 mg of irbesartan and 12.5 mg Hydrochlorothiazide respectively. **REGISTRATION NUMBERS:** A40/7.1.3/0290; A40/7.1.3/0288.

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