March/April 2024. Vol 91 No 2
SA Pharmaceutical Journal

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HALEON

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Recommend Otrivin Plus for nasal congestion and rhinorrhea[1]

Each 1 ml contains 0,6 mg of ipratropium bromide and 0,5 mg of xylometazoline hydrochloride for symptomatic relief with[1]:

- Sinus pressure
- Runny nose
- Blocked nose

3 IN 1

Reference: 1. OTRIVIN PLUS Nasal Metered-dose Spray (Solution) package insert February 2021.

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- SA Association of Hospital and Institutional Pharmacists
- SA Association of Pharmacists in Industry

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CONTENTS

SAPJ Author Guidelines

Thank you for choosing SAPJ in which to publish your paper.

Aims, scope and review policy

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.

The journal is currently indexed by Google Scholar via www.sapj.co.za and enjoys wide international exposure. An 'electronic long, paper short' policy will be followed for original papers where abstracts of original papers are featured in the printed copy with the full version available online.

Online submission

All articles must now be submitted online at www.sapj.co.za

The electronic submission process will prompt you to check off the following declarations:

1. This manuscript has currently only been submitted to SAPJ and has not been published previously.
2. This work is original and all third party contributions (images, ideas and results) have been duly attributed to the originator(s).
3. Permission to publish licensed material (tables, figures, graphs) has been obtained and the letter of approval and proof of payment for royalties have been submitted as supplementary files.
4. The submitting/corresponding author is duly authorised to herewith assign copyright to Medical and Pharmaceutical Publications (Pty) Ltd
5. All co-authors have made significant contributions to the manuscript to qualify as co-authors.
6. Ethics committee approval has been obtained for original studies and is clearly stated in the methodology.
7. A conflict of interest statement has been included where appropriate.
8. A title page has been uploaded as a separate supplementary file and the submission adheres to the instructions to authors in terms of all technical aspects of the manuscript.

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Article sections and length

The following contributions are accepted (word counts include abstracts, tables and references):

Original research:	3 200–4 000 words
Evidence- based pharmacy practice:	3 200–4 000 words
Reviews:	2 400–3 200 words
Case studies:	1 800 words
Scientific letters:	1 200–1 800 words
Letters to the editor:	400–800 words

For a full version of the SAPJ author guidelines, please visit www.sapj.co.za

Advancing pharmaceutical practice in South Africa: embracing the global stage

Natalie Schellack

This year, the profession of pharmacy in South Africa is presented with unique opportunities for growth and innovation. With the prestigious FIP World Congress of Pharmacy and Pharmaceutical Sciences scheduled to take place in Cape Town in 2024, it presents a platform for South African pharmacists to exchange knowledge, collaborate, and address critical issues facing our profession. In preparation it is pertinent to reflect on the pressing challenges and pertinent topics that demand our attention.

One such a major issue and urgent need is to enhance access to healthcare across South Africa. While notable progress has been made, disparities in healthcare provision persist, particularly in underserved and rural areas. Pharmacists play a vital role in bridging this gap, but we must ensure that they are empowered with the necessary resources, training, and support to deliver quality care to all South Africans. The burden of diseases presented to South Africa, are opportunities for pharmacists to assist.

One notable development in HIV service delivery in South Africa is the consideration of Pharmacist-Initiated Management of Antiretroviral Therapy (PIMART) legislation. This initiative aims to enhance access to HIV testing, prevention, and treatment services by allowing pharmacists with supplementary training to prescribe and manage antiretrovirals, including pre-exposure prophylaxis (PrEP), antiretroviral therapy (ART), and post-exposure prophylaxis. However, the implementation of PIMART has faced challenges, including legal

disputes and the need for regulatory pathways to establish pharmacy-delivered HIV services effectively. The ongoing debates and legal proceedings surrounding PIMART underscore the complexities and controversies surrounding the integration of pharmacists into HIV care in South Africa. Despite the potential benefits of expanding access to HIV services through PIMART, the country faces hurdles related to regulatory frameworks, cost considerations, and the need for multi-council collaboration to navigate these challenges effectively. The outcome of this court case will significantly impact the future of HIV care and treatment in South Africa, highlighting the critical intersection of healthcare policy, legislation, and public health initiatives in combating the HIV epidemic.

Another critical concern is the rising burden of non-communicable chronic diseases. South Africa faces a growing prevalence of conditions such as diabetes, hypertension, and cardiovascular diseases. As is often the case, pharmacists are often the first point of contact for managing these conditions, not only by consulting and providing medication but also by actively engaging in patient education, lifestyle interventions, and collaborative care models.

One of the most common chronic diseases in South Africa is diabetes. In 2019, there were approximately 1.63 million people living with diabetes and 1.68 million people living with hypertension in South Africa. This is a significant increase from previous years, and it is expected to continue to rise in the coming years. This is a significant burden on the healthcare system, as both diabetes and hypertension are a major risk factor for cardiovascular disease, stroke, and other serious health conditions. Cardiovascular disease is a major cause of death and disability in South Africa. In 2019, there were approximately 1.57 million people living with cardiovascular disease in South Africa.

Cancer is another major cause of death and disability in South Africa. In 2019, there were approximately 1.32 million people living with cancer in South Africa. This is a significant burden on the healthcare system, as cancer is a complex and often expensive disease to treat.

The burden of chronic diseases in South Africa is a significant public health challenge. It is important for pharmacists within the multidisciplinary team to work together to address this challenge and improve the health and well-being of the South African population. This may involve implementing evidence-based interventions to prevent and manage chronic diseases, improving access to quality healthcare services, and addressing the social determinants of health that contribute to chronic disease risk.

Pharmacists and allied pharmacy personnel in South Africa are essential healthcare professionals who play a critical role in ensuring the quality and accessibility of pharmaceutical services for the country's population.

In addition to these pressing concerns, the FIP World Congress will undoubtedly shed light on other relevant topics, including pharmaceutical regulations, antimicrobial resistance, pharmaceutical education, and the integration of traditional medicine into mainstream healthcare. These discussions will provide international and South African pharmacists with invaluable insights and inspiration to elevate their practice and contribute to the overall advancement of pharmaceutical care.

As the FIP World Congress approaches, let us seize this opportunity to showcase South Africa's commitment to excellence, innovation, and inclusivity within the profession of pharmacy. It is imperative that we engage in meaningful dialogue, share our experiences, and collaborate with international experts to spearhead positive change within our local context.

We encourage all South African pharmacists, and allied pharmacy personnel, to actively participate in the FIP World Congress, whether by attending the sessions, presenting research, or engaging in networking opportunities. Let us collectively seize this moment to amplify our voices, drive innovation, and enhance the role of pharmacists in shaping the future of healthcare in South Africa.

For more information about the FIP World Congress in Cape Town, visit https://capetown2024.fip.org/.

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Presidential report

Tshifhiwa Rabali
PSSA President

The past few months have been busy ones for the Society. One of the issues that we as PSSA have to address is the number of pharmacists who are unemployed after completing their community service. Our members who are not employed will have to come forward so that we can be able to seek clarity from the government. The number of unemployed pharmacists is increasing year after year, and we have advised them to come forward so that we can help to look at solutions, particularly those who are members of the Pharmaceutical Society of South Africa.

SAPHEX 13-14 March 2024

The SAPHEX exhibition was held at the Sandton Convention Centre and as in previous years, the PSSA and its sectors were present. It was a watershed moment as FIP also had a stand, advertising their upcoming congress in Cape Town. All the speakers in our sessions were of high quality with emphasis on our scope of practice which is very wide. We also had good interactions with our colleagues from different stakeholders. This year's SAPHEX exhibition was more on the 4th industrial revolution as most of the exhibitors were showcasing the latest technologies in the health and pharmaceutical industry.

FIP held a reception for the exhibitors on 13 March and PSSA, as FIP member and host organisation on the African continent, was given the opportunity to say something. I, as the President of the Pharmaceutical Society of South Africa, spoke at the reception. It was an opportunity for me to market and give details on who we are as PSSA and pharmacists in general. I would like to urge our members and non-members to attend this memorable congress that will be the 112th Congress of the International Pharmaceutical Federation (FIP) to be held in South Africa and will benefit the African continent as a whole. The PSSA, as the local host, will do everything in its power to support this event to ensure that the whole pharmaceutical profession attends this once in a lifetime event.

Medicines to Africa

Medicines to Africa is an initiative that will assist countries in Africa to obtain medicines and medical supplies should they experience a disaster. This issue is being addressed as the PSSA has a different opinion in as far as the memorandum of understanding (MOU) is concerned. A meeting was held with ICPA and a decision was taken that a committee will be formed in order to look at the wording of the MOU so as to include pharmacists in the document, as this was not the case in the previously signed MOU. A letter was also sent to FIP about these concerns and a meeting with them will be happening soon. The PSSA does not want to be associated with an initiative that excludes pharmacists from overseeing the procuring and distributing of medicines to other countries in need.

Mentorship programme

This programme has been running for some time now and the National Executive Committee of the PSSA has agreed that the current Honorary Treasurer can mentor those who are interested in being elected as Honorary Treasurer in the future. Branches are encouraged to elect their candidates and send the names to the national office. All branches are also encouraged to continue supporting the mentorship programme so that our YPG members continue to benefit from it.

Lastly, as PSSA we will continue to engage with government on the issue of community service placements of pharmacists and the challenges experienced in previous years.

Saying farewell to Ivan Kotzé

Ivan Kotzé has served as Executive Director of the PSSA for 30 years and retired at the end of March 2024. He has a history of life-long service to the profession both locally and internationally and an impeccable record of developing and promoting the PSSA over the past 30 years.

Before he was appointed Executive Director of the PSSA in 1994, Ivan was employed by the Department of Health from 1984-1994, where he held the position of Deputy Director, Medicines Control. His experience included inspections locally and abroad, giving him a deep understanding and insight into the application of medicine law. Amongst others, he represented the South Africa Government at several meetings in Vienna, Austria, of the International Narcotics Control Board of the United Nations. The knowledge thus gained was to stand him in good stead in his new position as Director of PSSA as the country, and its laws went through a vast transformation at the time. Health Councils such as the Pharmacy Council, HPCSA, and Department of Health all underwent a transformation. This required forging new working relationships and insight into developing new laws and standards for pharmacy practice. Ivan's experience and input largely ensured that the best interests of the pharmacy were included in all these changes.

Over the past 30 years, there have been an unprecedented number of changes to all laws pertaining to pharmacy as well as the introduction of new laws and regulations, such as Labour Law, Competition Act, POPIA, Electronic Communications & Transmissions Act, Consumer Protection Act, BEE Act, etc, all of which impact on the practice of pharmacy. There have been challenges, such as the introduction of lay ownership, new pricing regulations, and the introduction of PAs and PCDT pharmacists. Throughout this time, Ivan's insight and knowledge proved to be invaluable. He steered all PSSA presentations made to the Health Committee of Parliament, instructed, briefed, and supported the legal teams in the various court challenges and gave generously of his time and talent in assisting other bodies, such as USAP (now ICPA), e.g. in its representations to the Competition Commission. Particularly noteworthy is the fact that the wording in Hansard of the conditions of open ownership as accepted by Parliament are those used by Ivan in the PSSA submission.

It is no exaggeration to say that the profession owes Ivan a huge debt of gratitude for constantly ensuring that the best interests of pharmacy have been maintained in our laws.

Ivan's insight, patience, and sound legal argument characterised all these submissions and negotiations. This won him great respect from all, including highly-ranked civil servants, Ministers, and lawyers. This is reflected in the fact that his advice is often sought by these people and the fact that he has been invited to serve on a number of national committees, such as the then MCC Veterinary Committee and 22 Appeal committees in terms of Section 24 of the Medicines Act, Act 101 of 1965.

Ivan's expertise and leadership have been recognised in other areas. He has represented the PSSA at PPS since 1994. He is a current Trustee of the PPS Holdings Trust—appointed in August 2001. He has also served for several years on the PPS Insurance Company and the PPS Group Audit Committee. He was appointed as a non-executive Director of PPS Health Care Administrators (Pty) Ltd in June 2017. Under his guidance, PPS has developed some unique services for pharmacists.

In the international pharmacy arena, Ivan is highly regarded and respected. Ivan was elected President of the Commonwealth Pharmacists Association (CPA) in 2007 and served two terms for four years. He also served as a Trustee for the CPA for several years. In recognition of his valuable contribution to the CPA, he was honoured with Fellowship of the CPA in July 2017.

For many years, Ivan has represented the PSSA as a Councillor on the International Pharmaceutical Federation (FIP) Council. His contribution to the work of FIP and wise counsel is much appreciated, and he is highly regarded by his peers internationally.

When Ivan took over as Director of the PSSA, the Society was in dire need of transformation. The Society had sold MediKredit so that future income would rely solely on membership fees and investments. Until then, much committee time and effort were taken up with the business of MediKredit. Now the Society had to change focus, become more inclusive of all practice sectors, and concentrate on the professional interests of its members.

Ivan, using his sound management skills of good planning and organising, considered personnel management, strict financial planning and budgetary control, and clear vision and leadership, saw to the transformation and development of the Society to fulfilling its vision of becoming "*the undisputed leader and guardian of the pharmacy profession.*" The hard work in achieving this enormous task included:

- Writing a new inclusive Constitution providing for all Sectors and Branches.
- Developing a new Vision, Mission and Strategic Goals.
- Forging and maintaining good working relationships with SAPC, other statuary bodies, Government departments and voluntary professional organisations.
- Membership growth and transformation to become more inclusive of all pharmacists. Through ensuring excellent professional service provision membership is valued and has grown steadily.
- Staff management and development to meet the requirements of the transformed organisation. Ivan has a particularly good personnel management style, patient, consistent and encouraging. He has developed a happy, highly competent staff who serve the Society with exemplary professionalism.
- Maintaining good working relations with all Branches and Sectors and their staff. This facilitated Branch and Sector contributions of time, financial and professional support in attaining certain goals in the national interest. e.g. establishment of YPG, FPE, etc.
- Ivan has been pivotal in assisting all Branches and Sectors in their own growth and development, as well as providing unstinted support in times of crisis.
- Ivan also had the insight to include others in the PSSA's work in the best interests of the profession. For example, he was the driving force behind organising the Community Pharmacy Legal Trust, the Pharmacy Stakeholders Forum and the work done in providing input to the Pricing Committee.

The enormity of the task of transforming and developing the Society must not be underestimated. This has been achieved largely through Ivan's management and hard work with the support of his committees. The Committee members and various leaders themselves have benefitted from his expertise, wisdom, and assistance in fulfilling their duties, a fact to which many would testify.

Ivan has served the profession for more than 40 years, and the PSSA in particular, for 30 years since his appointment as Director in 1994. He has done so with dignity, integrity, and exemplary diligence, always using his vast knowledge, experience, and insight into all laws pertaining to pharmacy to the fullest extent in the best interests of the profession.

Welcoming Refiloe Mogale

The Pharmaceutical Society of South Africa (PSSA) is excited to announce the appointment of Ms Refiloe Mogale as the new Executive Director effective 01 February 2024.

Refiloe has served as the Pharmaceutical Services Manager in the Nkangala District under the Mpumalanga Provincial Department of Health since 2011.

She graduated with a BPharm degree from the University of the Witwatersrand, Gauteng, in 1997. In addition to her BPharm degree, Ms Mogale holds a Master's in Business Leadership (MBL) from UNISA and a Postgraduate Diploma in Public Health (Cum Laude) from the University of Pretoria. She has also completed additional courses, including the Advanced Health Management Programme (Cum Laude) and Advanced Programme in Sourcing and Supply Chain Management (Cum Laude).

Refiloe previously served as the Deputy President of the Pharmaceutical Society of South Africa (PSSA) and President of the South African Association of Hospital and Institutional Pharmacists (SAAHIP), so she understands the role and importance of a professional association.

During Refiloe's terms as SAAHIP President and PSSA Deputy President, she has provided ongoing support to branches and individuals. She has been able to recognise development areas in others and facilitate personal development through mentoring and coaching. She knows the South African system for pharmaceutical contracts, essential medicines list and its associated impact.

Refiloe has sound knowledge and understanding of the pharmaceutical legislative framework. She has regularly been involved in teamwork and conflict resolution, and she is able to cooperate with others to work towards a common goal.

She has done project management and policy implementation and has implemented many departmental and pharmaceutical policies. She is performance-driven and strives to provide value-added services and has participated in various services meant to improve systems and processes to facilitate continuous improvement.

The PSSA knows it is in excellent hands and that, under Refiloe's leadership, it will spearhead the profession into the future as a unified body.

82nd World Congress on Pharmacy and Pharmaceutical Sciences in Cape Town, South Africa 1 to 4 September 2024

Understanding the Congress academic programme

The Pharmaceutical Society of South Africa (PSSA) is the congress partner for the 82nd International Pharmaceutical Federation's (FIP) World Congress on Pharmacy and Pharmaceutical Sciences. The Congress will take place in Cape Town, South Africa, from 1-4 September 2024 at the Cape Town International Convention Centre (CTICC).

Attending the annual FIP World Congress is indeed a once-in-a-lifetime experience. Due to the financial commitment of travelling abroad, not many South Africans have been able to utilise the opportunity of attending this global event. Bringing the FIP World Congress to South Africa is the most accessible opportunity for South African pharmacists and pharmacist's assistants to learn from and network with global experts.

Theme of the Congress

The 2024 FIP World Congress theme is **Innovating for the future of healthcare**.

Advancements in technologies, data analytics, practice settings, and collaborations are unavoidable, and innovation in healthcare holds the promise of revolutionising how we prevent, diagnose, and treat diseases. Change is inevitable. Change will not wait until you are comfortable to embrace it. Change is the only constant.

As pharmacists, we are used to changes in our everyday professional (and personal) lives. Changes to the scheduling status of medicines, legislation, minimum standards, formularies, standard operating procedures, and new product launches. Pharmacists play a pivotal role in driving healthcare innovation across all settings.

Our expertise in being the custodians of medication (which derives from our strong pharmacology, pharmaceutics, and pharmaceutical chemistry foundation), accessibility to patients, medication review responsibilities, collaborative nature, participation in public health advancements, technology adoption and contributions to continuity of care, highlight our indispensable position in the health sector.

Pharmacists are faced with many innovations in healthcare these days.

Precision medicine aims to tailor treatments to individual patients based on their unique genetic makeup, lifestyle, and environmental factors. Based on the rapid advances in genomics and molecular biology, healthcare workers can provide targeted interventions with great success and reduced side effect profiles.

Although often feared, it is the reality that artificial intelligence (AI) and machine learning are revolutionising health care in many ways, such as augmenting diagnostic accuracy, predicting disease outcomes, and optimising treatment plans. Continuous collection of patient data is analysed to identify patterns and assist healthcare professionals, researchers and policymakers with decision-making regarding population health management, disease surveillance and public health planning.

In the post-COVID-19 era, telemedicine (also telepharmacy and remote patient monitoring) has emerged exponentially as a transformative innovation in how pharmacists could treat patients, resulting in expanded healthcare services to underserved locations and improving accessibility and patient convenience as more and more healthcare professionals offer virtual consultations. Wearable devices and remote monitoring tools assist healthcare professionals with early interventions and improved disease management through continuous health monitoring.

Over the three days of academic programming (Monday, 2 September to Wednesday, 4 September 2024), every day will focus on a specific sub-theme which supports the main Congress theme.

Sub-theme 1: In the ever-evolving healthcare landscape, the imperative goal of achieving **equitable quality healthcare** goes beyond geographical and socio-economic divides. At the heart of this transformation lies collaboration among healthcare providers, policymakers and pharmacists who unite to reshape the healthcare narrative with humanity. Pharmacists leverage their knowledge to shift from a one-size-fits-all approach to person-centred care, creating tailored solutions for individuals. Integrated care is championed, turning primary healthcare centres into hubs of holistic care. This congress track explores the crucial role of pharmacy in collaborating with diverse stakeholders, forming partnerships, and embracing new roles to advance universal health coverage with meaningful outcomes.

Sub-theme 2: Because innovation is revolutionising health care, a congress track that explores the role of pharmacists in the era of **innovative drug discovery and access** is a priority. Scientific breakthroughs drive transformation, with pharmaceutical research and biotechnology advancements paving the way for cutting-edge therapies. Digitalisation has permeated the pharmaceutical industry, revolutionising the distribution and logistics of medicines. Digital health technologies are pivotal in drug development, utilising real-world data and digital tools to inform every process stage. In this era of innovation, pharmacists play a central role in co-creating health care through our expertise in pharmaco-economics, global partnerships, and open-access

Programme outline

	SUNDAY 1 SEPTEMBER 2024	MONDAY 2 SEPTEMBER 2024	TUESDAY 3 SEPTEMBER 2024	WEDNESDAY 4 SEPTEMBER 2024
Early morning	-	Industry breakfast symposia	Industry breakfast symposia	Industry breakfast symposia
Morning	Workshops & Pharmacy in South Africa	Plenary session & Parallel sessions	Plenary session & Parallel sessions	Plenary session & Parallel sessions
Lunch	Industry lunch symposia	Industry lunch symposia	Industry lunch symposia	Industry lunch symposia
Afternoon	Opening Ceremony	Plenary session & Parallel sessions	Plenary session & Parallel sessions	Plenary session
Evening	Welcome Reception	Section & SIG dinners	ECPG evening	Closing dinner

Figure 1

drug research, making them invaluable contributors to the industry.

Sub-theme 3: A **healthcare revolution through AI** and machine learning aims to co-create superior healthcare ecosystems in which pharmacists play a pivotal role. Predictive analytics take centre stage, offering personalised guidance based on genetic makeup, lifestyle, and medical history. This proactive healthcare approach empowers individuals to take control of their well-being. AI accelerates drug development and facilitates precision medicines by decoding diseases at the molecular level. This collaboration represents a synergy between human innovation, AI and healthcare professionals, ushering in a new era of medicine.

Draft programme

To date, only the Congress theme has been announced. The morning and afternoon plenary sessions will develop from the abovementioned theme and sub-themes.

FIP structures had the opportunity to submit session proposals based on the Congress theme and sub-themes by early January 2024. The Congress Programme Development Group (CPDG) reviewed and evaluated all the submissions received based on criteria that include collaboration between FIP structures, global representation and relevance, and alignment with the Congress theme.

Several parallel sessions will run during the late morning and early afternoon of each congress day, allowing delegates a variety of interesting topics to choose from. In this way, no delegate is forced to sit through a session not ideally aligned with their interest or line of work.

A chairperson or persons facilitate each session, and based on the interactive format of the session, it could have two to three expert speakers or a panel of experts who will delve into the session topic. Each session includes an opportunity for congress delegates (you) to participate in the discussion through a workshop, round-table discussions, or a question-and-answer session towards the end.

Session proposers identify speakers as part of the session proposal process based on the proposed speaker's leadership in their respective fields of excellence. Alternatively, speakers could be identified through the abstracts submitted by interested researchers that align with proposed session objectives and outcomes.

If one is not interested in a podium presentation, authors of an abstract may also indicate to submit the abstract for a poster presentation, which will be displayed in the Exhibition area during the Congress. During the day, but especially during the two-hour lunch break, delegates can walk through the poster boards and engage with authors on their research and projects. It is a great opportunity to network and establish collaborative relationships.

The Congress programme with session information will be available at the end of April 2024 on the Congress website at https://capetown2024.fip.org/programme-per-day-outline/.

Figure 1 indicates a simplistic outline of the Congress programme.

Important date

Early bird registration fee is only valid until 31 May 2024, thereafter the registration fee increases.

Refer to the FIP Congress newsletter distributed by PSSA on 15 January 2024 for more information on registering as South African participants through the unique registration link.

Enquiries

For more information or clarity regarding the 2024 FIP World Congress, send an email to Mariet at mariet@pssa.org.za or call 012 4709560.

All registration queries should be directed to FIP at congress@fip.org.

Visit the official Congress website for more information: https://capetown2024.fip.org/

Feedback on the 2024 Annual Cycle of Pharmaceutical Community Service

As in previous years, it was a privilege for PSSA to serve its members and support them during the Pharmaceutical Community Services process during the second half of 2023.

For many interns, applying for and being allocated to a community service post is filled with uncertainty and fear. In an attempt not only to serve our intern members better, but also to support the National Department of Health (NDoH) and the Intern and Community Service Programme (ICSP) more effectively, PSSA navigates the way for intern members with accurate and reliable information which aims to bring some sense of certainty and to reduce stress and anxiety.

As of 2022, PSSA commenced with communication to all intern members regarding Pharmaceutical Community Service long before the ICSP made any national announcements. The first email communication to intern members went out in June 2023, informing members that PSSA will support them when applying for community service. Members were further advised on what they can do to prepare for the commencement of the process, e.g. ensure their personal details are updated with SAPC and that their membership is paid to continue to receive support from PSSA.

Members were also advised that interns should focus on completing their Continuing Professional Development (CPD) entries successfully and as soon as possible. In 2022, for the first time, a situation occurred where some interns were not competent in all six CPD entries by the time the October pre-registration exam was written. These interns were not allowed to write the exam, which resulted in them having to remain interns and attempt the pre-registration exam in March 2023. The dilemma with this scenario was that these interns extended their internship beyond the minimum of 365 days to almost 15 months, some without remuneration for the time period beyond the original contract period and were then not eligible for placements as community service pharmacists (CSPs) as they could only commence with duty in April 2023. At that stage, placements took place based on the availability of posts.

The ICSP held its first stakeholder meeting with Associations on Tuesday, 19 September 2023. By this time in 2022, applications for community service had already opened. Behind the scenes, stakeholders shared communication on social media from the National Treasury to Provincial Treasuries of cost containment measures to assist the National Departments, public entities, and provinces in closing fiscal gaps, informing provinces that the Cabinet approved freezing the hiring of new employees. The Department assured stakeholders that community service would proceed as soon as possible, that a new service provider was appointed to manage the application and allocation process, and that the website portals would be up and running within two weeks.

Although realised at the time, little did we understand just how delayed the process for the 2024 annual cycle would be.

The initial project plan stipulated that applications would be open during the first 3 weeks of October 2023, followed by the release of preliminary allocations by the end of October 2023. Applicants who are satisfied with their allocation could proceed with contracting and registration. In contrast, those who wanted to exchange or appeal their allocation would be allowed to do so during November 2023. All allocations were anticipated to be concluded by the end of November 2023.

PSSA, at the time, expressed its concern that a final deadline of 30 November 2023 to conclude the allocation process is very late in the year, given that this is just for the allocation and that the full employment process with the province must still follow from here. Considering the festive season approaching, provincial human resource departments would have to employ about 11 000 health care professionals in less than three weeks. Interns need the employment contract to register with SAPC as CSPs before they may commence duty on 1 January 2024. Applicants must also have a reasonable opportunity to manage their personal affairs for relocation if needed. The Department assured PSSA and stakeholders that the process would be done in time to allow for the provincial employment process to follow in time.

PSSA further confirmed with ICSP that the posts advertised to applicants will clearly state the commencement date so that candidates can take this into consideration and apply for posts in line with their internship completion date. During previous years, applicants applied for posts only to find out after allocation that the specific post was unavailable on 1 January and that the start date was only in March or April. This inconvenience left applicants without income for a month or three or ended up on the waiting list without a placement, as all available posts had already been allocated.

Applications opened, as planned, during the first week of October 2023. Applicants had to choose five facilities from three provinces from the list of posts. Three or more facilities should be classified as rural, two or fewer should be semi-urban, and a maximum of one may be in an urban area. Bursary holders, on the other hand, should select all five choices from the provinces where the bursary is from.

Applicants who applied for special considerations had to collect the requested supporting documentation and obtain affidavits from certain authorities. Special considerations were only available for scenarios applicable to the applicant's own health, if

the applicant is pregnant, has children in school or has a spouse (not partner) already employed in government or vested in permanent employment.

Applicants then applied on a web-based application form, as the service provider appointed to provide the software to the system could not deliver it in time. The implication was that no "login" details could be created for applicants to create a profile. During the 2023 annual cycle application process, PSSA reported that more than 10% of members had difficulty receiving their login details from ICSP during September 2022, resulting in them not being able to access the platform to apply for community service (read PSSA Perspectives SAPJ 90(1):9-11).

The first hiccup was when some provinces changed the priority level of some facilities after the application process had opened and the list of facilities had been published. The implication of this change (which should have been finalised before the commencement of application) was that some applicants were no longer within the prescribed ratio of choices per rural, semi-rural and urban areas. Because the application process was web-based, applicants couldn't change existing applications; they had to submit a new application with their amended choices. This administrative process resulted in many applicants submitting more than one application, and it took the ICSP team weeks to work through all applications manually and only keep the latest application of an applicant. In fact, more than 47 000 applications were received from 10 461 applicants.

Apart from the administrative challenge with duplicate applications, data quality was sub-standard. Applicants did not follow the application rules, selected the incorrect field of study or category between applying for an internship or community service placement, or made mistakes when entering data.

Although the initial project plan stated that preliminary allocations would be available at the end of October 2023, pharmacy applicants only received their allocations via SMS on 30 November 2023. Of the 943 applications received from pharmacist interns, only 755 were allocated, as 188 applicants were not marked as eligible by SAPC. Reasons for this could be related to the outstanding pre-registration exam, as explained earlier, or awaiting results of master's degree studies (academic internship).

Applicants who were placed outside of their five choices (only about 30% of applicants) were allowed to participate in the swop process, which took place during the first week of December 2023. The swop process allows applicants already allocated to exchange with applicants in similar professions upon mutual agreement. This may be across provincial borders. Unfortunately, the ICSP decided to hold back on emailing all allocation letters, even the 70% of applicants not allowed to participate in the swop process, until the swop process had concluded. The PSSA did not understand this decision and mentioned to ICSP that 70% of applicants who were placed at one of the choices (and who were not eligible to participate in the swop process) could have commenced with the employment process and registration with SAPC had they received their allocation letter via email as stated in the SMS on 30 November 2023.

The swop process was further delayed because swop applications had to be signed off by provincial coordinators of the provinces involved. Many applicants had difficulty reaching the provincial coordinators or receiving feedback on their applications, delaying the process even further. Applicants finally received their allocation letter via email on 19 December 2023, 12 days before they were expected to commence with duty as CSPs and three days before the annual festive break in South Africa.

Based on the size of 'enquiry tsunamis' that PSSA received in the past regarding community service, not many members experienced delays with their employment and registration processes. However, new hiccups were experienced during this cycle:

- Although the ICSP confirmed that all eligible applicants were placed for community service, a few PSSA members informed the National Office that they had not received any allocation information. PSSA supported these members in obtaining outstanding allocation letters or being placed and commencing with duty on the first available date.
- Members informed the PSSA that one particular district, which advertised 12 posts for Pharmaceutical Community Service to commence on 1 January 2024, informed the applicants on Friday, 29 December 2023, that the district did not have any budget to employ them and that they do not have to report for duty on Tuesday 2 January 2024. PSSA engaged with provincial coordinators up to the DDG level to find solutions, speed up the process and enable communication between stakeholders to reallocate the applicants to other districts in the province. All members who requested PSSA's help were reallocated and contracted to commence with duty as agreed on.
- Members informed the PSSA that at a specific Community Health Centre in one of the provinces, five posts to commence on 1 January 2024 were withdrawn as these posts were now only available later in the year, around August 2024. These unexpected but potentially preventable changes resulted in members being without an income and incurring potential additional expenses to relocate once more to another location. At the time of publication, one member was still waiting for reallocation.
- PSSA were approached by members who had been placed at correctional services facilities but could not receive their contracts as due to outstanding fees at the university, they did not receive their BPharm degree certificate. The university, however, issued a statement of degree and letter of completion to confirm that the requirements for the degree had been met, and that these colleagues were able to complete their internship. The vetting process with correctional services is more intense than for other community service posts. At the time of publication, this issue had not yet been resolved.

Conclusion

As expected at the beginning of the project, the timelines were too narrow. The NDoH and ICSP are quick to caution applicants to "not make any irreversible decisions based on the allocation letter" and in the absence of a signed employment contract. But when applicants only receive their allocations at the end of November, it is not fair for the NDoH or ICSP to continue with this caution message, as applicants were left with very little time to make personal decisions regarding relocation, rental agreements, furniture removal, etc. It is unreasonable to expect applicants of the 2024 annual cycle to wait until they receive a signed employment contract in the last week of December to find accommodation at a new location, and give notice to existing rental agreements at the current internship location.

Going forward, PSSA will continue to remind ICSP that the employment conditions stated during the application process for community service will be seen as the first details applicable to the employment contract and that provinces will be held liable where employment conditions are changed after allocations have been released to applicants.

PSSA encourage provincial coordinators to ensure that all conditions listed for a specific post, including requirements, priority level and commencement date, must be checked for correctness before listing the post to applicants, as they might be held liable for unforeseen financial expenses on the side of applicants or administrative workload on the side of ICSP due to administrative negligence on the side of the province. PSSA also request provincial coordinators to ensure sufficient capacity and resources to engage with queries from applicants, whether during the application, swop, or employment processes.

The ticket system, implemented in late 2023, works well. PSSA found that members could easily mail their concerns to the dedicated email address, including any additional email address in the cc field, who all then receive updates on this specific ticket number. This allowed for similar cases/issues to be added to existing ticket numbers and ensured a proper email trail of communication. PSSA also conveyed their satisfaction to ICSP during a stakeholder meeting in January 2024.

The PSSA would like to thank the SAPC staff who were on duty despite the festive season and closing of SAPC offices to support interns with their registration as CSPs and to enable commencement on 1 January 2024. Their efforts and time are appreciated.

The PSSA will continue to support the unplaced candidates as they complete their internship and become eligible for placement. The process will depend on the availability of posts at ICSP. The mid-year cycle will open later this year for commencement of duty on 1 July 2024.

A Young Pharmacist Making waves: Thabang Owen Malatji

In the dynamic and yet small South African world of pharmacy, it is difficult to miss individuals who are remarkable. In 2023, Thabang Owen Malatji was nominated and successfully voted in as one of the members of the South African Pharmacy Council (SAPC).

A pharmacist, leader, mentee, and a mentor, Thabang's journey is nothing short of an inspiration. He is a former President of the South African Pharmaceutical Students' Federation (SAPSF), former Secretary and Chairperson of the University of Limpopo Association for Pharmacy Students (ULAPS), former contact person of the International Pharmaceutical Students Federation (IPSF), and a former Regional Working Group of IPSF-Afro. He is currently a dispensary manager at Dis-Chem Pharmacies and a councillor in the SAPC. We delve into his life so we can get to know him better.

Q: What is the one thing about you that people may not know?

A: I play piano during my spare time and I'm in love with the instrument.

Q: What was your reaction when you first heard that you were successfully elected to SAPC?

The first reaction was shock! I was, and still am, truly humbled to be elected as a member of Council. I do not take that trust lightly; hence I continue to tackle every responsibility with great commitment and dedication.

Q: What does it mean to you to become a young pharmacist in the SAPC? What significance do you think it has?

Age does not really matter; however, I do not undermine the inspiration it has on young pharmacists! It is more inspirational than significant, in a sense that young pharmacists can raise their hands and contribute to Council. Personally, I encourage them to form part in the next term!

Q: What important advice would you give to a young pharmacist (student/intern/CSP/post CSP) that is the most relevant to our profession in 2024?

Be involved in your profession! Be involved in professional organisations! Attend conferences and network with other professionals! Participate in students' organisations and programmes. There is no better teacher than experience, so be involved, learn, and grow!

Being the youngest pharmacist in the Council, Thabang Owen Malatji is exemplary to young pharmacists and is an inspiration for many to continue to have big dreams, work towards them and make an impact in the world of pharmacy.

Start your career: A South African young pharmacists' guide

Congratulations to the 2024 pharmacist interns and community service pharmacists for embarking on their journey as newly employed pharmacists. For many individuals a new environment or experience such as your first job can be terrifying.

For some, there is excitement that comes with the hope of financial freedom and self-gratification after all the hard work they have been putting in during their final year of studying and/or during their internship.

Here are some tips to consider during this short period:

1. **Be a lifelong learner**

   The pharmacy field evolves constantly and requires you to always be updated on the latest technology, medication, and regulations. This will not only make your day-to-day duties easier but will also aid in your completion of your Continuous Professional Development (CPD)s. Attend seminars, workshops, and conferences to stay updated.

2. **Develop strong relationships**
   Cultivate healthy relationships with your colleagues, patients, and other healthcare workers. As a pharmacist this is essential so you can provide your patients with high quality healthcare.
3. **Remain committed to being ethical**
   The pharmacy profession is governed by numerous regulations. Take time to familiarise yourself with them and adhere to them.
4. **Have the right attitude**
   The world of pharmacy is fast paced and can be competitive. It is crucial for you to always stand out from your peers and seniors. By showing initiative and resourcefulness, you position yourself as an asset to your organisation.
5. **Look after your most valuable asset**
   You are your most valuable asset. The pharmacy profession can sometimes be demanding emotionally and mentally. Take breaks, spend time with your loved ones and maintain a healthy balance between professional and personal life.
6. **Seek guidance**
   Your seniors are there for you; you are not alone. Reach out to them for any support you may require for areas you may be unfamiliar with. Never assume and never do anything you are unsure of. Always accept their feedback as an opportunity for growth and improvement. Professional networks such as the PSSA are also available for you to take advantage of.

The PSSA YPG hosts several webinars, programs, and social media campaigns throughout the year to equip young pharmacists with necessary information for the start of their careers. Check our social media pages for regular updates on how to participate in these.

Feel free to reach out to us at
Email: ypg@pssa.org.za
Facebook: Young Pharmacists' Group of PSSA
Instagram: @pssaypg
Young pharmacists – connected, engaged, empowered and inspired!

Dolutegravir and the management of HIV/AIDS in the South African adult population

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Abstract

The safety and efficacy of medicines are important considerations in antiretroviral treatment programmes. Previous first-line regimens that showed initial success have subsequently demonstrated several resistance pathways. Newer medicines such as dolutegravir have the potential to provide a safer and more effective management option for HIV/AIDS patients. This paper aims to provide an overview of dolutegravir and its role in the management of HIV/AIDS in the adult population, addressing the limitations and challenges faced by previous treatment regimens within the South African context. Information in this review was obtained from peer-reviewed articles and organisations' reports related to dolutegravir. We established as the main finding that dolutegravir has a higher genetic barrier to resistance, superior efficacy, tolerability, and durability. However, initial clinical trials, funded by the manufacturer, were done in well-resourced countries. With the high levels of non-nucleoside reverse transcriptase inhibitor resistance and the need for countries to incorporate dolutegravir into national treatment guidelines, poorly resourced countries need to collect further data on its safety and efficacy. Dolutegravir holds great promise and is currently a key medicine in the treatment of HIV/AIDS in the South African population. Findings from this review highlight the importance of dolutegravir being incorporated into national treatment guidelines and the need for ongoing safety data.

Keywords: dolutegravir, integrase strand transfer inhibitors, antiretrovirals, HIV, AIDS

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Introduction

In 2021, an estimated 38.4 million people were living with human immunodeficiency virus (HIV) worldwide.[1] In developing countries such as South Africa (SA), there were approximately 7.5 million people infected with HIV, 210 000 new infections, 51 000 acquired immunodeficiency syndrome (AIDS) related deaths, and roughly 5.5 million people accessing antiretroviral therapy (ART).[2] In addition, the highest prevalence rates (27.0%) were from the KwaZulu-Natal province.[3] Between 2010 and 2020, the number of new HIV infections and AIDS-related deaths in SA had almost halved.[4] Key factors contributing to the reduction in new infections and AIDS-related deaths include the ability to sustain the provision of ART to all people living with HIV/AIDS, and to treat all newly diagnosed patients with ART irrespective of CD4 cell counts.[5]

Traditional first-line ART regimens generally consisted of two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI). While these regimens have been successful in treating millions of people over the past several years, many of these drugs have been shown to have a low barrier to resistance and significant adverse effects.[6]

ART is currently recommended for all HIV-positive individuals and the advantages of early initiation of ART include decreased HIV/AIDS-associated infections, Kaposi sarcoma, tuberculosis, hospitalisations, sexual transmission of HIV,[7] and AIDS-related deaths.[5] Since the introduction of the test and treat policy in 2016, the SA National Department of Health has been faced with the challenge of increasing the eligibility for ART coverage whilst reducing the cost of the treatment.[6] Hence, in 2018, the World Health Organization (WHO) interim guidelines recommended the use of dolutegravir (DTG), an integrase strand transfer inhibitor (INSTI) as first-line as well as second-line treatment regimens.[8]

In September 2017, the SA Government had already negotiated a pricing agreement with international collaborators undertaking to make generic DTG available to low- to middle-income countries (LMICs).[9] As early as November 2017, about 60 LMICs had already undertaken to revise their national treatment guidelines to include DTG. By 2018, some LMICs including Brazil, Botswana, Kenya and Uganda had already started rolling out DTG in public sector health facilities. A fixed-dose combination containing DTG in combination with tenofovir (TDF) and lamivudine (3TC) was proposed to cost $75 per patient per year compared with about $110 for previously available first-line regimens. For SA, this would have translated into an annual cost saving of at least $100 million.[10] Therefore, the SA National Treatment Guidelines were revised in 2019 to include DTG together with TDF and 3TC as a first-line regimen in public sector healthcare facilities.[11]

This paper aims to provide an overview of DTG and its role in addressing the limitations and challenges faced by previous ART regimens within the SA context.

Review findings

Historical background of development, classification, and approval of ART

In 1987, zidovudine was the first antiretroviral (ARV) to receive approval from the United States Food and Drug Administration

(FDA).[12] To date, there are several ARV classes, and more than 20 ARVs that have been approved for the treatment of HIV with each medicine class named as per its mechanism of action.

Triple-medicine regimens of ARVs were introduced in 1998. These regimens known, as highly active antiretroviral therapy (HAART), consist of two classes of ARVs that target the virus at two different stages of their life-cycle and it is the standard of care for HIV/AIDS patients.[13] Highly active ART led to significant suppression of viral replication resulting in better treatment outcomes[14] and subsequently led to the transformation of HIV from a killer disease into a chronic, manageable condition that required a lifelong commitment to treatment adherence.

New ARV medicine classes have been developed to target other stages of the HIV life cycle. Figure 1 shows the HIV life cycle and points of interruption by the various classes of ARV medicines,[15] and Table I summarises the approved ARVs categorised in terms of their mechanism of action, the international non-proprietary name, and approval dates.

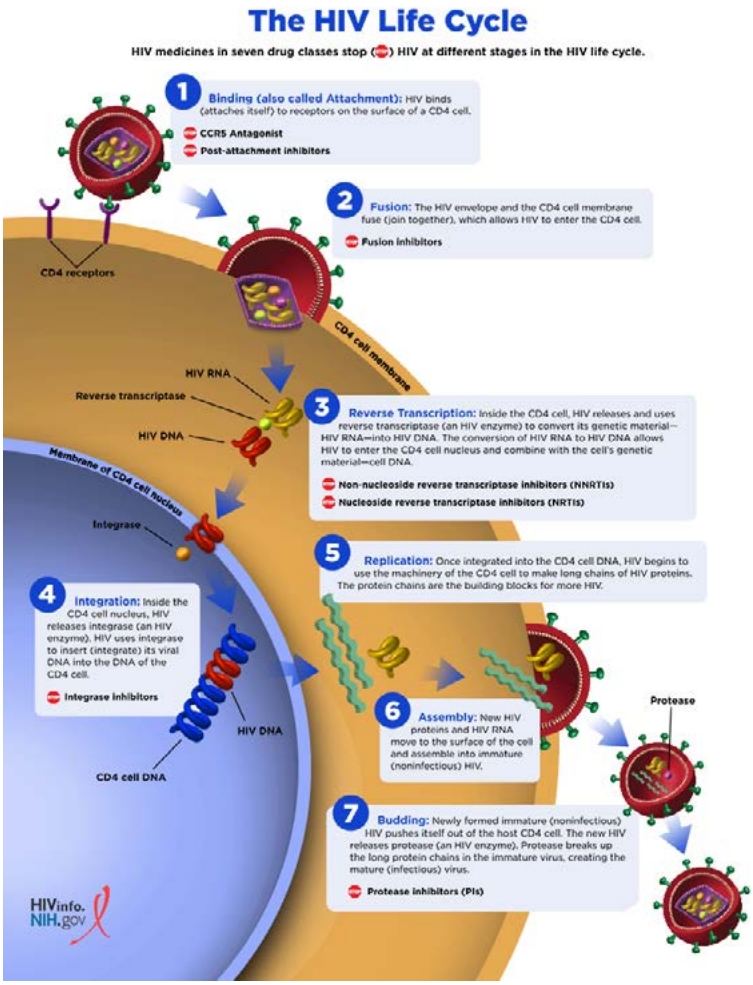

Figure 1: HIV life cycle showing points of interaction of the various ARV classes[15]

Integrase strand transfer inhibitors (INSTIs)

INSTIs are a comparatively newer class of ARVs used in the treatment of HIV-1 infection.[17] They display a unique mode of action against HIV-1 by inhibiting the integrase enzyme.[18] As shown in Table I, there are currently three INSTIs approved by the South African Health Products Regulatory Authority for the treatment of HIV, raltegravir, DTG and bictegravir. Cabotegravir, also an INSTI is registered by the South African Health Products Regulatory Authority for HIV prevention.[16]

Mechanism of action

INSTIs disrupt the HIV life cycle at the point of integration, described as step 4 in Figure 1. Integration is an essential step in the replication cycle of HIV, allowing the transference of virally encoded deoxyribonucleic acid (DNA) into the host chromosome. This step can be described in three stages: formation of a pre-integration viral DNA complex; 3′ processing; and strand transfer. INSTIs prevent the strand transfer stage by interacting with divalent cations of the catalytic core of the integrase enzyme. This inhibition allows INSTIs to maintain activity against strains that have acquired resistance to other classes of ARVs.[17-21]

INSTIs also maintain activity against HIV-1 strains that are resistant to NRTIs, NNRTIs, and protease inhibitors and block integrase enzymes that are virus-specific thereby leading to lower toxicity.[18] INSTIs have shown high virological efficacy, better safety and tolerability, lack of cross-resistance to other antiretroviral drugs, and low incidence of drug-drug interactions.[22]

Dolutegravir (DTG)

Clinical trials have demonstrated that DTG is effective in both the treatment-experienced and treatment-naïve populations.[17,23] Additionally, DTG has a good safety profile, the convenience of once-daily dosing, and a relatively low cost.[14] It was found that DTG was superior to efavirenz (EFV) in terms of viral load suppression.[24] When used as a first-line agent, resistance mutations to DTG by 2018 had not been observed.[8,19,20] Hence its inclusion in the WHO interim guidelines as first-line ARV treatment in adults.[8] However, recent reports have shown evidence of DTG-related resistance.[25-29] DTG does not require a pharmacokinetic booster and can be taken without regard to food. It has also demonstrated a higher genetic barrier to resistance than the first-generation INSTIs: raltegravir and elvitegravir.[13,17,20] There is also evidence that DTG is as effective against HIV-2 as it is against HIV-1.[30]

Pharmacokinetics

Absorption

DTG is well absorbed after oral administration with peak plasma concentrations occurring after two to three hours.[17,31] When co-administered with food, the extent of DTG absorption increases

Table I: Approved medicines for the treatment of HIV/AIDS[15,16]

Medicine class as per mechanism of action	International non-proprietary name	FDA approval date	South African Health Products Regulatory Authority approval date
Nucleoside reverse transcriptase inhibitors	Zidovudine Didanosine Zalcitabine Stavudine Lamivudine Abacavir sulphate Tenofovir disoproxil fumarate Emtricitabine	19 March 1987 09 October 1991 19 June 1992 27 June 1994 17 November 1995 17 December 1998 26 October 2001 2 July 2003	19 August 1995 9 May 2003 – 25 April 2003 13 June 1996 20 June 2001 13 April 2007 13 April 2007
Non-nucleoside reverse transcriptase inhibitors	Nevirapine Delaviridine Efavirenz Etravirine Rilpivirine Doravirine	21 June 1996 4 April 1997 17 September 1998 18 January 2008 20 May 2011 30 August 2018	5 July 2004 – 10 May 2007 – 11 September 2021 31 August 2021
Protease inhibitors	Indinavir Ritonavir Nelfinavir Amprenavir Atazanavir sulphate Fosamprenavir calcium Tipranavir Durunavir	1 March 1996 1 March 1996 14 March 1997 15 April 1999 20 June 2003 20 October 2003 22 June 2005 23 June 2006	30 November 2007 7 September 1997 8 May 2011 8 November 2006 25 November 2005 8 November 2006 – 19 June 2020
Fusion inhibitors	Enfuvirtide	13 March 2003	–
CCRF antagonists	Maraviroc	6 August 2007	3 January 2013
Integrase strand transfer inhibitors	Raltegravir potassium Elvitegravir Dolutegravir sodium Bictegravir	12 October 2007 27 August 2012 12 August 2013 07 February 2018	3 April 2011 – 21 April 2016 7 July 2020
Attachment inhibitors	Fostemsavir tromethamine	2 July 2020	23 August 2022
Post-attachment inhibitors	Ibalizumab-uiyk	6 March 2018	–

and its rate of absorption decreases.[17] These changes are clinically insignificant and DTG can be taken without regard to food.[17,31]

Metabolism and elimination

DTG has an elimination half-life of 12–15 hours. It is extensively bound to plasma proteins (98.9%) and is metabolised via two metabolic pathways. Whilst metabolism occurs predominantly in the liver by uridine diphosphate glucuronosyltransferases, UGT1A1, the second metabolic pathway (minor) occurs via cytochrome P450 (CYP3A).[17,32] Fifty-three per cent (53%) of the total dose is excreted unchanged in the faeces[17] and metabolites are eliminated in the urine. Co-administration of UGT1A1 inhibitors or inducers will impact DTG levels and dosage adjustment will be necessary in such instances.[31] DTG is metabolised extensively in the liver, however, dosage adjustment is not required in patients with mild to moderate hepatic impairment.[13, 17]

Drug interactions

Rifampicin induces liver enzymes, increasing the metabolism of DTG with a consequent decrease in DTG concentrations. This interaction requires DTG to be dosed at 50 mg twice daily.[21,32,33] Antacids significantly decrease plasma DTG levels and DTG should therefore be administered two hours before or six hours after the administration of antacids.[32-34] DTG has modest interactions with other ARVs and no dosage adjustment is necessary except for etravirine.[32] Owing to organic cation transporter 2 (OCT2) inhibition, DTG results in a significant increase in plasma concentrations of metformin. Dosage adjustment is therefore suggested when DTG is co-administered with metformin.[35] DTG can form complexes with magnesium, aluminium, calcium, and multivitamins, and dosing with DTG should take place two hours before or six hours after their intake.[36] The following medicines: carbamazepine, phenytoin, oxcarbazepine, phenobarbital, dofetilide, and St Johns Wort, when taken in combination with DTG, result in decreased DTG concentrations hence such combination therapy should be avoided.[37]

Side effects

Common side effects noted included diarrhoea, nausea, insomnia and headache,[38] muscle and joint pain, general malaise, and respiratory tract complaints. Side effects are reversible and have been reported to subside upon DTG discontinuation.[39] Other side effects reported in phase II and phase III trials include nasopharyngitis, dizziness, abnormal dreams, pyrexia, depression, pharyngitis, bronchitis, anxiety, cough, rash, asthenia,[40] and weight gain.[41] DTG inhibits OCT2, resulting in a mild increase in

serum creatinine levels.[13,21,33]

Resistance

DTG has been shown to have a higher genetic barrier to resistance than raltegravir and elvitegravir. DTG also remains active against 155, 143, 66, and 92 mutations.[30] Furthermore, mutations at G118, R263, S153, N155, and Q148 can impact the *in vitro* activity of DTG, and cross-resistance to INSTIs can occur when multiple integrase mutations occur.[17] Studies have recommended a twice-daily dose of DTG in patients with known or suspected INSTI-associated resistance substitutions.[13,21] Pharmacokinetic studies have shown that people with undetectable HIV ribonucleic acid can be switched from EFV to DTG. Dolutegravir levels remain lower in the first two weeks of dosing, hence a potential problem for people with NRTI resistance.[10]

Use in pregnancy

Cohort studies in high-income countries reported no increased risk of birth defects in women who conceived while taking DTG.[42] This contrasts with an observational study in Botswana where there was an increase in neural tube defects in women who started DTG before conception, suggesting a potential safety issue.[43] There have been no studies which report increases in adverse birth outcomes if DTG is initiated during pregnancy.[44] The WHO interim guidelines, 2018, recommended that all women of childbearing age who prefer to take DTG must also be on reliable and consistent contraception.[8] However, further guidance in 2019 by the WHO adopted a more women-centred approach and recommended that women of childbearing potential should be advised of the potential risks and benefits and allowed to make a decision regarding the use of DTG.[45] The current SA ART guidelines

Table II: Key studies evaluating DTG in the adult population

Study description	Study location/s	Study outcome
A phase III randomised, double-blind study of the safety and efficacy of GSK1349572 50 mg once daily to raltegravir 400 mg twice daily both administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral therapy naïve adult subjects	USA, Canada, France, Germany, Italy, Spain, the UK, Russia & Australia	DTG demonstrated non-inferior efficacy and a similar safety profile to RAL[47]
A phase III randomised, double-blind study of the safety and efficacy of GSK1349572 plus abacavir/lamivudine fixed-dose combination therapy administered once daily compared to Atripla® over 96 weeks in HIV-1 infected antiretroviral therapy naïve adult subjects	USA, Canada, Australia, the UK, Belgium, Denmark, France, Germany, Italy, Netherlands, Hungary, Romania & Spain	DTG plus abacavir-lamivudine demonstrated a better safety profile and was more effective compared with efavirenz/tenofovir/emtricitabine[48]
A phase IIIb, randomised, open-label study of the safety and efficacy of GSK1349572 50 mg once daily compared to darunavir/ritonavir 800 mg/100 mg once daily each administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral adult subjects	USA, Italy, France, Germany, Romania, Russia, Spain & Switzerland	Once-daily dolutegravir is associated with greater viral suppression than once-daily ritonavir-boosted darunavir. DTG compares favourably in efficacy and safety to a boosted darunavir regimen with a nucleoside reverse transcriptase inhibitor background[49]
A phase IIIb single-arm study of the safety, efficacy and central nervous system and plasma PK of GSK1349572 (dolutegravir, DTG) 50 mg once daily in combination with the abacavir/lamivudine fixed-dose combination tablet over 96 weeks in HIV-1 infected antiretroviral naïve adult subjects	USA	DTG levels in CSF were similar to unbound plasma levels. The HIV-1 RNA reductions were similar in CSF and plasma[50]
A phase IIb study to select a once daily dose of GSK1349572 administered with either abacavir/lamivudine or tenofovir/emtricitabine in HIV-1 infected antiretroviral therapy naïve adult subjects	USA, France, Germany, Italy, Spain & Russia	DTG was effective when administered at a dose of 50 mg without the need for a pharmacokinetic booster[51]
A phase III randomised, double-blind study of the safety and efficacy of GSK1349572 50 mg once daily versus raltegravir 400 mg twice daily, both administered with an investigator-selected background regimen over 48 weeks in HIV-1 infected, integrase inhibitor-naïve, antiretroviral-experienced adults	USA, Canada, Argentina, Brazil, Mexico, Chile, Australia, South Africa, the UK, Belgium, France, Greece, Poland, Hungary, Italy, Netherlands, Romania, Spain, Russia & Taiwan	Viral suppression was greater in the DTG arm. No treatment-emergent phenotypic resistance. A single daily dose of DTG in combination with two other ARVs were well tolerated and achieved greater viral suppression than twice-daily raltegravir[52]
A phase III study to demonstrate the antiviral activity and safety of dolutegravir in HIV-1 infected adult subjects with treatment failure on an integrase inhibitor containing regimen.	USA, Belgium, Canada, France, Italy, Portugal & Spain	The twice-daily dosing of DTG 50 mg showed efficacy in treatment-experienced patients with INSTI resistance[53]
A phase III randomised, double-blind study to demonstrate the antiviral activity of dolutegravir (DTG) 50 mg twice daily versus placebo both co-administered with a failing antiretroviral regimen over seven days, followed by an open-label phase with all subjects receiving DTG 50 mg twice daily co-administered with an optimised background regimen (OBR) in HIV-1 infected, integrase inhibitor therapy-experienced, and resistant, adults	USA	Antiviral activity was observed at day 8 in INSTI-resistant patients due to DTG[54]
A pilot study to assess the antiviral activity of GSK1349572 containing regimen in antiretroviral therapy (ART)-experienced, HIV-1-infected adult subjects with raltegravir resistance	USA, Canada, France, Italy & Spain	Twice daily DTG 50 mg provided greater VL suppression compared to once-daily dosing. Demonstrates activity of the integrase inhibitor in the presence of resistance to RAL[55]

Table III: Summary of key trials with DTG in the SA adult population[56]	
Study description	**Study outcome**
A phase IIb, randomised, partially blind, active-controlled, dose-range finding study of GSK3640254 compared to a reference arm of dolutegravir, each in combination with nucleoside reverse transcriptase inhibitors, in HIV-1 infected antiretroviral treatment-naïve adults	Stopped early/terminated
Standard versus double dose dolutegravir in patients with HIV-associated tuberculosis: a phase II non-comparative randomised controlled trial	Twice daily dolutegravir may not be necessary in people with HIV-associated tuberculosis
A phase IIIb, randomised, open-label study of the antiviral activity and safety of dolutegravir compared to lopinavir/ritonavir both administered with dual nucleoside reverse transcriptase inhibitor therapy in HIV-1 infected adult subjects with treatment failure on first-line therapy	Pending
A phase IIIb, randomised, open-label study of the safety and efficacy of dolutegravir or efavirenz each administered with two NRTIs in HIV-1-infected antiretroviral therapy-naïve adults starting treatment for rifampicin-sensitive tuberculosis	Pending
A phase IIb randomised, active-controlled, staged, open-label trial to investigate safety and efficacy of BMS-955176 in combination with dolutegravir and atazanavir (with or without ritonavir) in treatment-experienced HIV-1 infected adults	Pending
Safety and pharmacokinetics of dolutegravir in pregnant HIV mothers and their neonates: a pilot study	Pending
A phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment-naïve adults	Pending
A randomised clinical trial to evaluate solutions for the management of virological failure for individuals on TLD in sub-Saharan Africa (RESOLVE)	Pending
A cross-sectional, observational study to characterise the transition to dolutegravir-based regimens in South Africa in terms of the emergence of obesity, viral re-suppression and integration into routine programme care	Pending

recommends that due to an absence of increased birth defects, the integration of ART and family planning services should continue to be integrated especially in instances of unsuppressed viral loads.[46] The foetal transfer of DTG was shown to be significant, with infants displaying a terminal half-life of about 35 hours.[13,21]

DTG clinical studies

DTG, developed and licensed by ViiV Healthcare, has been subjected to several studies globally. Some key clinical trials that were conducted to establish the efficacy of DTG are summarised in Table II.

From the various studies described in Table II, only one phase III study included a SA cohort. Several key trials have since been conducted in SA as summarised in Table III. Furthermore, other studies are underway, including the use of DTG in tuberculosis, pregnancy, and switching between regimens.[56]

Currently, available data indicate that dosage adjustment is not required in the elderly population.[21] However, concentrations of DTG can also be higher in patients with low body weights.[57]

A multicentre, post-marketing observational study in the Netherlands found that although well-tolerated, the rate of discontinuation with DTG as part of combination ART was much higher than reported in clinical trials. Intolerability was cited as the reason for DTG discontinuation.[39] The NAMSAL trial in Cameroon did not demonstrate superior efficacy of DTG/TDF/3TC after 48 weeks compared with EFV (400 mg)/TDF/3TC once daily.[58]

While there is evidence from cohort studies in Europe that demonstrate an increased risk of immune reconstitution inflammatory syndrome,[59] other studies have shown that there is no association between the use of DTG and immune reconstitution inflammatory syndrome in LMICs.[43]

Implications of and recommendations for the use of DTG in SA

The increased resistance to NNRTIs once threatened the scale-up of ART. As more asymptomatic HIV and AIDS people are initiated on ART, there is an increasing need for a resilient first-line regimen comprising medicines that demonstrate minimal interactions, lower toxicity, higher barrier to resistance, lower pill burden, and lower costs.

Clinical trials are generally conducted in populations where screening tests for genotypic resistance are routinely done as per study design. Since DTG will be used as the first-line treatment regimen in the SA population, where there is already transmitted resistance to NNRTIs, further general data is needed. Furthermore, in randomised controlled trials, viral testing for resistance is done when there is a viral rebound. This may differ significantly from National ART programmes where patients may remain on a failing regimen for prolonged periods prior to resistance testing being done. Coupled with poor adherence, the development of new viral mutations may occur.[33]

Dolutegravir is increasingly being used in first-line regimens in poorly resourced settings. Data collected from clinical trials, cohort studies, and surveillance registers will be of paramount importance to establish the long-term benefits of DTG. The drug interaction between DTG and rifampicin, requires that DTG be dosed twice daily.[60] However, studies are being undertaken to

determine the efficacy of a single dose DTG in the presence of rifampicin in poor resource settings, where an increased dose of DTG may impact negatively on adherence.[56]

Integrase strand transfer inhibitors are a novel class of medicines that have revolutionised HIV treatment. A transition to the DTG-based regimen in SA is based on cost savings, the efficacy of DTG in the management of HIV-1 infection, the increased resistance to NNRTIs, and their high barrier to resistance. Data from clinical trials have demonstrated the safety and efficacy of DTG. While an increase in viral suppression is expected with the use of DTG as a first-line medicine, issues such as poor adherence and stockouts can lead to the emergence and transmission of drug-resistant HIV.[43]

Whilst DTG-based regimens remain the preferred choice of treatment, the low incidence of reported resistance may restrict the early detection of drug resistance and mutations. While an abundance of literature is available on the use of DTG in various treatment options in clinical studies, data is also needed in patients with advanced HIV, as this population is generally excluded from phase III clinical trials.[61]

There is therefore a definite need to conduct further studies and surveillance data is crucial to establish the long-term safety and efficacy of DTG in the management of HIV/AIDS patients in SA.

Conclusion

A review of the literature shows that DTG is safe and effective and can therefore play a pivotal role in the management of HIV/AIDS in the SA adult population. Being cost-effective is already a major advantage, especially in developing countries where the cost of health care and emergence of resistance, and treatment failures may lead to poor health outcomes in patients.

However, since there have been limited preregistration safety and efficacy trials done in the SA adult population, further clinical trials, cohort, and surveillance studies are required to conclusively assess the safety and efficacy of DTG in the SA adult population as well as to monitor for resistant mutations that may emerge.

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Tonsillitis and strep throat and its management – a brief review

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Abstract

Tonsillitis is a common condition that affects mainly children, but can also affect adults. It is caused by both viral and bacterial infections, with streptococcal species being a common bacterial cause. Differentiation between bacterial and viral causes is important to prevent overuse of antibiotics and potential complications. Management includes controlling pain and fever, hydrating the patient, and administering appropriate antimicrobials. Tonsillectomy is indicated in cases of recurrent or chronic tonsillitis. This article provides an overview of the epidemiology, aetiology, pathophysiology, and evaluation of tonsillitis, as well as current management strategies and recent advances in screening and pain management during tonsillectomy.

Keywords: tonsillitis, strep throat, sore throat, tonsillectomy, screening, group A beta-haemolytic *Streptococcus pyogenes* (GABHS)

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Introduction

Tonsillitis is the inflammation of the palantine tonsils, usually extending to the adenoid and lingual tonsils; therefore, the term pharyngitis may also be use. Often sore throat is one of the symptoms present in uncomplicated tonsillitis (inflammation of the tonsils), pharyngitis (inflammation of the pharynx) and tonsillopharyngitis (inflammation of the pharynx, tonsils or both). Symptoms of acute tonsillitis present with fever, sore throat, tonsillar exudate, foul breath, dysphagia (difficult swallowing), odynophagia (painful swallowing) and headache. Pharyngitis (strep throat) presents with similar symptoms of sudden onset of sore throat, pain with swelling and fever.[1]

Tonsillopharyngitis is generally self-limiting, but approximately 12% of adult patients experience recurrent tonsillitis with debilitating episodes that impair daily functioning.[2] Tonsillitis most often occurs in children; however, the condition rarely occurs in children younger than two years. Tonsillitis may be viral or bacterial, where bacteria causes 15–30% of cases of pharyngotonsillitis.[3] Bacterial infection is typically due to Group A beta-haemolytic *Streptococcus pyogenes* (GABHS).[4] Most viral causes include rhinovirus, respiratory syncytial virus, adenovirus and coronavirus. These typically have low virulence and rarely lead to complications.[5]

Differentiation between bacterial and viral causes may be difficult; however, this is crucial so as to prevent the overuse of antibiotics. Untreated GABHS may lead to complications like acute rheumatic fever, rheumatic heart disease, poststreptococcal glomerulonephritis, bacteraemia and retropharyngeal abscess. Transmission of GABHS results from contact with respiratory tract secretions of infected individuals with an incubation period of two to five days. Treatment reduces the period of communicability to 24 h in 80% of cases.[1]

Management includes controlling pain and fever, adequate hydration and appropriate antimicrobials.[4] Tonsillectomy is indicated in recurrent, chronic tonsillitis. This article summarised the current management of tonsillitis and strep throat and highlights the recent advances in screening and management of this condition as well as pain management in tonsillectomy.

Epidemiology

Tonsillitis is more common in children but rarely occurs in children younger than two years. In adults GABHS accounts for 5–15% of individuals with pharyngitis. Streptococcal species cause 15–30% of tonsillitis cases in children aged 5–15 years, while viral tonsillitis is more prevalent in younger children. One study found that recurrent tonsillitis affects 12,1% of Turkish children while another study estimated that 11,7% of Norwegian children are affected.[3]

Aetiology

The most common viral causes include rhinovirus, respiratory syncytial virus, adenovirus and coronavirus. Epstein-Barr virus (EBV) can cause tonsillitis that may be associated with the presence of palatal petechiae.[3] One study identified *Staphylococcus pyogenes* (14.4%) as the most common isolates in chronic tonsillitis and *H. influenzae* (31.4%), *S. pyogenes* (24.2%), *S. aureus* (22.9%) and *S. pneumoniae* (12.6%) as the most common isolates in tonsillar hypertrophy.[6] Tuberculosis has also been associated with recurrent tonsillitis, so clinicians should assess the patients' risks.[5] Rare cases include pertussis, Fusobacterium, diphtheria, syphilis and gonorrhoea.

Pathophysiology

Tonsillitis refers to inflammation of the tonsils. The tonsils are composed of lymphatic tissue and are a component of *Waldeyer's ring* in the pharynx, consisting of the palatine tonsils, adenoids,

lingual tonsils, and tubal tonsils. They serve as an important defence against inhaled or ingested pathogens by providing the initial immunological barrier to insults.[5] However, by convention, the terms "tonsillitis" and "tonsils" often are used when specifically referring to the palatine tonsils, which are located between the palatoglossal and palatopharyngeal folds in the lateral walls of the oropharynx.[7] Microorganisms that penetrate the tonsillar epithelium are phagocytised and processed by macrophages, presented to B and T lymphocytes and subsequently stimulate both humoral and cell-mediated immune response. Lymphoid hyperplasia and reactivity occur when chronic infection overwhelms the tonsillar defence mechanism.[8]

Evaluation: Examination

The type of tonsillitis (acute, recurrent or chronic) presenting in a patient is determined by their history of previous illness. It is important to visually examine the tonsils and note any features such as swelling, erythema, and exudate. Recurrent streptococcal tonsillitis is diagnosed when a patient has six culture-proven episodes in one year, five infections in two consecutive years or three infections each year for three years consecutively. Patients with strep throat typically do not present with a cough, coryza or conjunctivitis.[3]

Signs and symptoms

Individuals with acute tonsillitis exhibit enlarged inflamed tonsils, fever, sore throat, foul breath, difficulty swallowing, painful swallowing and tender cervical lymph nodes. Airway obstruction may cause mouth breathing, snoring and sleep disorders. Malaise and lethargy are common. A gray membrane may cover tonsils that are inflamed from an EBV infection. This membrane can be removed without bleeding. Palatal mucosal erosions and mucosal petechiae of the hard palate may also be observed.[3]

Physical examination and diagnosis

Evaluation for tonsillitis should begin with a thorough history, physical examination, risk stratification by scoring system and consideration of rapid antigen testing and/or throat culture.

Physical examination of the pharynx may be facilitated by opening the mouth without tongue protrusion, followed by gentle central depression of the tongue.

Flexible fibreoptic nasopharyngoscopy, performed by an ear, nose and throat (ENT) specialist, may be useful in selected cases, particularly in severe trismus (muscle spasms of the temporomandibular joint).[3]

The scoring system uses the following criteria: the presence of a fever, tonsillar enlargement and/or exudates, tender cervical lymphadenopathy and the absence of a cough. Each finding is worth one point. The most commonly used scoring system is the Centor criteria, which is summarised in Table I.[5]

Patients who meet one or no criteria are unlikely to have GABHS and should not undergo rapid testing. Patients who meet two criteria can be tested (RADTs) and those who meet three or four criteria can be tested or treated empirically for GABHS. Patients with higher scores generally have higher probability of positive GABHS test results (4 points, 56%; 3 points, 32%; 2 points, 15%; 1 point,6.5% and 0 points, 0,2.5%).[9]

Table I: Centor score

Signs and symptoms	Point
Tonsillar exudate	1
Tender anterior cervical lymph nodes	1
History of fever > 38 °C	1
No cough	1
Maximum score	4

In South Africa, pharmacists who have a primary care drug therapy (PCDT) permit can diagnose and prescribe antibiotics for acute tonsillitis.[10] In the United Kingdom (UK), the first NHS-funded sore throat test and treatment (STTT) community pharmacy services were implemented in Wales in 2018. Data from a study showed that screening for GABHS has potential benefits such as timely diagnosis, targeted antimicrobial utilisation or promoting symptomatic (non-antibiotic) treatment which would reduce the burden on primary care, limiting unnecessary visits from patients who have non-severe symptoms.[11] The STTT utilises a combination of FeverPAIN score (Table II) and Centor Score. Antibiotics are considered for FeverPAIN score of 2–3, or Centor Score 3–4 with FeverPAIN Score 4–5.[12]

Table II: FeverPAIN score

Signs and symptoms	Point
Fever > 38 °C	1
Purulence	1
Attend within 3 days or less	1
Inflamed tonsils	1
No cough or coryza	1
Maximum score	5

A throat culture can test for GABHS alone or in conjunction with rapid antigen testing. Rapid antigen testing is 88–100% specific with 61–95% sensitive, and false negatives are possible.[5]

The differential diagnosis for tonsillitis is broad and includes pharyngitis, retropharyngeal abscess, epiglottitis and Ludwig angina. The presence of dental or peritonsillar abscess is also a possibility. Kawasaki disease, Ebstein-Barr virus, Coxsackie virus and oral candidiasis may also present with throat pain and differentiation can be via history and other clinical features.[13]

In rare case, syphilis can cause tonsillitis and clinicians should consider also obtaining pharyngeal swabs for gonorrhoea and chlamydia and HIV testing in the appropriate clinical setting.[5] The

prevalence of sexually transmitted diseases (STI) is high in South Africa, with an incidence rate of 20% in women.[14] In individuals presenting with a sore throat, STIs should be considered. In individuals with herpes simplex virus (HSV), pharyngitis presents with red, swollen tonsils that may have aphthous ulcers on their surface.[3]

Management

Given the frequency of viral aetiologies, the mainstay of treatment of acute tonsillitis is supportive care, including hydration, analgesia and patients rarely require hospitalisation.

The goals of treatment for GABHS tonsillitis is:

1. Provide symptom relief
2. Shorten duration of illness
3. Prevent nonsuppurative and suppurative complications
4. Decrease the risk of contagion
5. Decrease the unnecessary use of antibiotics, slowing the development of antibiotic resistance[4]

Non-pharmacological management includes adequate hydration and bed rest. Symptomatic relief includes analgesic and antipyretic agents like paracetamol.

The appropriate antibiotics reduce the duration of illness by approximately one day with the greatest reduction in symptoms seen on the third day of treatment. Several studies note that treatment within 48 h of the onset of symptoms provides the best chance of relief.[4]

The infectious disease society of America (IDSA) guidelines recommends a ten-day course of either penicillin or amoxicillin. Penicillin V is the first-choice antibiotic for GABHS since there is no known resistance to it. Azithromycin, as a five-day course, is an alternative for individuals with penicillin allergy; a ten-day course of cephalosporin or clindamycin are also options.[5]

The Standard Treatment Guidelines/Essential Medicine List (STG/EML) provides similar guidelines: benzathine benzylpenicillin single dose intramuscular (IM) or amoxicillin. Patients with penicillin allergy should receive azithromycin.[15] The use of corticosteroids is not recommended due to limited effectiveness.[2]

When to refer patients

Patients consulting at a public primary health care clinic who have the following symptoms should be referred to a physician, according to the STG/EML guidelines:[15]

- Any suppurative complications e.g. retropharyngeal or peritonsillar abscess, otitis media and sinusitis.
- Tonsillitis accompanied by difficulty in opening the mouth (trismus).
- Recurrent tonsillitis (six or more documented episodes/year) for possible tonsillectomy.
- Suspected acute rheumatic fever.
- Suspected acute glomerulonephritis.
- Heart murmurs not previously diagnosed.
- Patients with severe immunosuppression such as long-term use of steroids, AIDS, neutropenia, congenital or acquired immune defects or severe comorbidities.

It is worth noting that most cases of viral pharyngitis or tonsillitis are self-limiting with clinical improvement in three to four days without the need of antibiotics. Clinical practice guidelines recommend avoiding antibiotic therapy during this time period as it is safe to do so. A delay of up to nine days from symptom onset to antimicrobial treatment should still prevent the major complications of GABHS (such as rheumatic fever).[3]

Tonsillectomy

Tonsillectomy is a surgical procedure recommended for individuals who have had more than six confirmed cases of streptococcal pharyngitis in a year, five cases in two consecutive years or three or more infections for three years in a row. The severity of illness and time missed from school or work are also important factors in deciding whether to recommend tonsillectomy. In some cases, an adenoidectomy may also be performed if the adenoids are inflamed and present. Tonsillectomy reduces the bacterial load of GABHS and may also allow increase in alpha-Streptococcus, which protects against GABHS infection. Recurrent tonsillitis is usually due to regrowth of tonsillar tissue, but is extremely rare.[3]

Complications and risks associated with tonsillectomy include risk of postoperative bleeding, which increases with age (between 9 and 18 years).[16] In published reports, the rate of primary bleeding (within 24 h after surgery) ranges from 0.2–2.2%, while the secondary bleeding rate (more than 24 h after surgery), ranges from 0.1–3%.[17] A 2016 study found that obesity increases the risk for haemorrhage by about 2.3 times.[16]

Postoperative pain management

Tonsillectomy is ranked among the top 25 procedures with the highest pain intensities. Patients with preoperative chronic pain due to other diseases, females and young adults are associated with higher postoperative pain intensity. A recent systematic review analysed preoperative and intraoperative interventions to reduce postoperative pain. Paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), ketamine, gabapentinoids, dexmedetomidine improved postoperative pain. Pain management with non-opioid analgesics, should be initiated during tonsillectomy. Mono-analgesics only have a limited analgesic efficacy in the postoperative setting after tonsillectomy. Therefore, it is recommended to use analgesic in combination (e.g. paracetamol plus NSAID). There is no evidence that NSAIDs increase the risk of postoperative bleeding. Opioids are only recommended as rescue analgesics. Codeine is forbidden in many countries for children. The patient can expect to have high pain scores typically for three to five days after surgery.[2]

Conclusion

Recurrent acute tonsillitis is a common condition affecting both children and adults worldwide. To determine the appropriate treatment, each sore throat/tonsillitis episode should be evaluated to differentiate between viral and bacterial GABHS infection. If the probability of a bacterial infection is high, the recommended antibiotic regimen should be followed to prevent the unnecessary use of antibiotics. Additionally, since tonsillectomy is ranked among the top 25 procedures with the highest pain intensities, it is important to manage pain optimally to improve the patient's quality of life

Conflict of interest

The author declares that there are no conflicts of interest.

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SGLT2 inhibitors for treatment of chronic kidney disease

S Davis

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Abstract

There are several mechanisms underlying chronic kidney disease progression and they can be categorised in three major pathways: haemodynamic, metabolic, and inflammatory or fibrotic.[1] Sodium-glucose cotransporter-2 (SGLT2) inhibitors reduce glomerular hyperfiltration,[1] improve energy utilisation and mitochondrial function,[2] and lower inflammatory mediators, resulting in nephroprotective effects in both diabetic as well as non-diabetic patients.[3] Although SGLT2 inhibitors are well-tolerated with a low risk of serious adverse effects, patients need to be counselled on expected adverse events such as the increased risk for genital and urinary infections and how to prevent these, as well as the need to withhold SGLT2 inhibitors during periods of acute illness with vomiting and diarrhoea to prevent volume depletion.[4]

Keywords: chronic kidney disease, sodium-glucose cotransporter-2

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Introduction

Chronic kidney disease (CKD) of any aetiology is on the rise on a global scale.[5] An estimated 840 million people worldwide have chronic kidney disease, which was responsible for 1.2 million deaths and 35.8 million disability-adjusted life years in 2017.[6] Canagliflozin, dapagliflozin and empagliflozin have shown reduced risk of kidney-specific outcomes and death from kidney-related causes.[7] Of these, only dapagliflozin is currently registered for treatment of CKD in South Africa.[8] This article will discuss the role of SGLT2 inhibitors in patients with CKD.

Chronic kidney disease (CKD)

Damage to the kidney can result in a variety of clinical manifestations, ranging from asymptomatic haematuria to kidney failure requiring dialysis, depending on how the kidney responds to injury.[9] The kidney adapts to damage by increasing the glomerular filtration rate (GFR) in undamaged nephrons which is called adaptive hyperfiltration. Although initially beneficial, adaptive hyperfiltration eventually causes damage to the glomeruli of the remaining nephrons which may manifest as proteinuria and progressive kidney failure.[9]

The gradual decline in kidney function in CKD is initially asymptomatic. However, different signs and symptoms may only be observed with advanced kidney failure, including volume overload, hyperkalaemia, metabolic acidosis, hypertension, anaemia, and mineral and bone disorders.[9] The majority of individuals with CKD are therefore only diagnosed at the advanced stage of disease.[7] The onset of end stage kidney disease (ESKD) results as a constellation of signs and symptoms referred to as uraemia. Uraemia may manifest as anorexia, nausea, vomiting, pericarditis, peripheral neuropathy, and central nervous system abnormalities such as loss of concentration, lethargy, seizures, coma, and death.[9]

To prevent late diagnosis of CKD, the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines recommend monitoring for CKD progression by assessing both eGFR (estimated GFR) and urine albumin-creatinine ratio (UACR) at least annually and more frequently for those at higher risk (patients with hypertension, cardiovascular disease and diabetes).[7]

Initiating treatment with angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blocker (ARB) and sodium-glucose cotransporter-2 (SGLT2) inhibitors, can slow progressive disease and even preserve kidney function. Treatment provides most benefit if started before much irreversible scarring has occurred.[9]

Mechanism of action of SGLT2 inhibitors

It is difficult to pinpoint a single mechanism responsible for the protective effect of SGLT2 inhibitors on CKD progression. The most probable hypothesis is that a combination of factors has led to the benefits on renal function observed in clinical trials.[2]

Inhibition of SGLT2 reduces reabsorption of glucose from the glomerular filtrate in the proximal renal tubule with a concomitant reduction in sodium reabsorption, leading to urinary excretion of glucose (without causing hypoglycaemic events) and osmotic diuresis.[8] Lower glycaemia and improvement of insulin resistance lead to a reduction in microvascular complications in the long term.[2]

Additional metabolic changes contribute to the renal protective effects. The higher glucagon/insulin ratio increases production of ketone bodies that may improve energy utilisation and mitochondrial function. The reduction in glucose reabsorption at the tubular level leads to a reduction in energy expenditure to maintain the sodium gradient necessary for luminal cotransport.[2] This conservation of energy may attenuate renal hypoxia.[4]

SGLT2 inhibitors increase the delivery of sodium to the distal tubule which increases tubulo-glomerular feedback.[8] This, combined with osmotic diuresis, leads to a reduction in volume overload, reduced blood pressure, lower preload and afterload, and results in restoration of intraglomerular pressure.[2,8] These changes can cause an initial dip in GFR when patients initiate SGLT2-inhibitor treatment that should be seen as an indication of haemodynamic efficacy rather than representing a matter of concern, since the dip in GFR is transient with no short- or long-term negative consequences.[2,5]

The cardio-renal benefits are not solely dependent on the blood glucose lowering effect and not limited to patients with diabetes mellitus. In addition to the osmotic diuretic and related haemodynamic actions of SGLT2 inhibition, potential secondary effects on myocardial metabolism, ion channels, fibrosis, adipokines and uric acid may be mechanisms underlying the cardio-renal beneficial effects.[8]

Efficacy

The DAPA-CKD trial included 4 304 diabetic and non-diabetic patients to determine whether the nephroprotection conferred by SGLT2 inhibitors could also extend to CKD patients without diabetes.[2] Patients with CKD (eGFR of 25–75 ml/min/1.73 m^2) were on a stable dose of renin-angiotensin system (RAS) blockers for at least four weeks before enrolment. Treatment with dapagliflozin reduced the risk of GFR decline of > 50%, ESKD or death from renal or cardiovascular causes by 39%.[2] Dapagliflozin was equally effective in diabetic and non-diabetic patients.[2] SGLT2 inhibitors are the most effective class of drugs for the prevention of CKD progression since the discovery of the RAS inhibitors. The trial was stopped early after a median follow-up of 2.4 years after demonstrating overwhelming efficacy.[6] Trial-level estimates from DAPA-CKD estimated that for a 50-year-old patient until the age of 75, the drug combination of RAS inhibitors and SGLT2 inhibitors provided a 7.4 year gain in kidney-failure-free survival compared to a theoretical control not receiving any treatment.[2]

Recently published results from the EMPA-KIDNEY trial confirmed and expanded these findings. The trial enrolled 6 609 patients on background RAS inhibition which included 3 569 non-diabetic patients and patients with advanced CKD. The trial was stopped at a median follow-up of two years because empagliflozin demonstrated clear benefits in reducing eGFR of ≥ 40% from baseline, ESKD or death from renal causes and cardiovascular death. Empagliflozin was equally effective in diabetic and non-diabetic patients and confirmed that even patients with advanced CKD benefit from SGLT2 inhibitors.[2]

A recent meta-analysis of 13 randomised controlled trials extracted data from 90 413 patients from available reports and unpublished information provided by trial investigators. The authors reported that treatment with SGLT2 inhibitors reduced the risk of CKD (defined by sustained eGFR decrease of ≥ 50% or < 15 ml/min/1.73m^2, ESKD or death from kidney failure) by 37%. SGLT2 inhibitors conferred protection from CKD progression of 40% in diabetic kidney disease, 30% in patients with ischaemic/hypertensive kidney disease, 40% in patients with glomerulonephritis and 26% in patients with CKD of unknown aetiology. SGLT2 inhibitors also conferred protection from acute kidney injury and cardiovascular events.[2]

Adverse effects

SGLT2 inhibitors are well-tolerated with a low risk of serious adverse effects.[3]

Due to the excretion of glucose in urine, one of the first safety signals reported was a higher rate of mycotic genital infections and patients who are prescribed SGLT2 inhibitors are 3.57 times more likely to develop this adverse event.[2] There was also a significant but modest increase in the risk of urinary tract infections, particularly in female patients.[2,4,10] Necrotising fasciitis of the perineum, called Fournier's gangrene, is a significant adverse event, although post-marketing case reviews show a lower incidence than initially reported.[10] It is prudent though to use SGLT2 inhibitors with caution in patients with a history of complicated or recurrent urinary tract infections including those with chronic indwelling Foley catheters.[4] In most cases, either a topical or an oral course of antifungal therapy is sufficient to treat the infection effectively, thus termination of therapy may not be necessary.[3] Patients should be informed to maintain genital hygiene and to keep the genital region dry to prevent infections.[4]

In patients with a very low GFR, the initial dip in GFR associated with initiation of SGLT2 inhibitors could accentuate the risk of an acute adverse event[11] and therefore guidelines do not recommend initiation of an SGLT2 inhibitor for treatment of CKD if eGFR is < 20 ml/min/1.73 m^2. If eGFR falls below 20ml/min/1.73 m^2 after initiation of treatment, SGLT2 inhibitors may be continued for kidney protection unless it is not tolerated or kidney replacement therapy is initiated.[7] However, relevant studies in the meantime have shown that SGLT2 inhibitors greatly decrease the risk for acute kidney injury.[5]

Another concern for clinicians has been the presumed higher risk of hypoglycaemia. However, no significant hypoglycaemia events were noted in large randomised controlled trials that included patients without diabetes. This is because SGLT2 inhibitors only reduce plasma glucose levels by blocking the reabsorption of glucose and this is reduced as plasma levels fall. Thus, the risk of hypoglycaemia is low in the absence of other hypoglycaemic therapies.[3]

Although euglycaemic diabetic ketoacidosis is among the most concerning adverse effects associated with the use of SGLT2

inhibitors, the risk among patients without diabetes is minimal with only one event noted in a large meta-analysis during 30 000 participant years of follow-up.[3]

Practical recommendations for the use of SGLT2 inhibitors

SGLT2 inhibitors are recommended for treatment of CKD in patients who are stable on RAS inhibitor treatment and can be initiated in patients with an eGFR > 20 ml/min/1.73m^2.[7,10] They are effective in both diabetic and non-diabetic patients.

Dapagliflozin is indicated for treatment of CKD if eGFR ≥ 25 ml/min/1.73 m^2.[12] The package insert for dapagliflozin recommends a dose of 10 mg taken orally once daily, at any time of the day regardless of meals.[8]

Patients should be monitored for early signs of genital and urinary tract infection. Monitoring of blood pressure at home, volume status, weight, and blood glucose levels is also recommended. Patients should be counselled on maintaining proper hygiene when commencing an SGLT2 inhibitor. Patients should also be advised to withhold their SGLT2 inhibitor for two to three days before scheduled surgery, during episodes of acute illness, vomiting, diarrhoea, or inability to eat or drink for any reason. SGLT2 inhibitors may typically be resumed 24 to 48 hours following recovery.[4]

Conclusion

SGLT2 inhibitors have emerged as a key therapy in the treatment of CKD,[4] offering a myriad of direct and indirect renoprotective effects, halting the progression of CKD even in patients without diabetes and reducing the risk of all-cause mortality.[1,5]

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Clearing the blur: a microbial menace in focus – understanding bacterial conjunctivitis

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Abstract

Bacterial conjunctivitis (BC), colloquially known as "pink eye", typically presents with redness, purulent discharge (sticky eyelids), itching, and a foreign body sensation in the eye. The common pathogens that cause the condition are *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. Presentation of the condition can be acute or chronic, depending on the duration of the symptoms. Although BC is self-limiting, antibiotic treatment in the form of an eye drop or ointment is sometimes prescribed to reduce discomfort. BC is a contagious infection, and hand hygiene should be encouraged to reduce the risk of transmission.

Keywords: bacterial conjunctivitis, pink eye

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Introduction

The conjunctiva is a thin, translucent membrane found inside the eyelid and the anterior part of the sclera. Inflammation of the conjunctiva can lead to itching, pain, swelling, and discharge, which may be purulent, serous, or mucopurulent. This condition is commonly known as conjunctivitis or "pink eye".[1,2] Inflammation may result from immunological reactions, infection (viral, bacterial, or parasitic), allergic or mechanical irritation, neoplasia, or toxic substances.[3-5] In addition to aetiology, conjunctivitis can also be classified based on chronicity, severity, and the extent of involvement of the surrounding tissue.[1]

Conjunctivitis poses an immense economic burden within the healthcare system and is one of the leading reasons for medical or ophthalmological visits.[1,6,7] In the United States of America, approximately 2% of medical visits are due to conjunctivitis, and BC costs the country approximately $857 million annually. It can affect a person at any age, demographic, or socio-economic status.[1,6] Viral and bacterial conjunctivitis (BC) can become contagious, with BC epidemics being most prevalent in winter and early spring.[7] This article aims to provide insight into the causes of BC and the appropriate treatment.

Causes

BC is most often caused by the bacteria *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. Among these pathogens, *Staphylococcus aureus* is more prevalent in adults, while the other pathogens are more commonly found in children.[8,9]

Gram-positive organisms are responsible for most ophthalmic infections, whilst Gram-negative organisms are more likely to be the causative agents in contact lens wearers.[10] Gram stains and conjunctival cultures are the gold standards for identifying pathogens; however, in some instances, the nature of the conjunctivitis can suggest the pathogen. For example, *Neisseria gonorrhoeae* is usually found in hyperacute purulent conjunctivitis, while *Staphylococcus aureus* is found in patients with chronic conjunctivitis.[11] Additionally, severe bacterial infections that are linked to sexually transmitted infections can often lead to complications if left untreated. Incidentally, *Neisseria gonorrhoeae* tend to progress rapidly to corneal perforation, while chlamydia can also cause chronic conjunctivitis.[8]

Newborn infants face a heightened risk of developing BC within the first 28 days of life. This condition is known as ophthalmia neonatorum (ON) because of vertical transfer through an infected birth canal during the delivery process. ON caused by gonorrhoea typically manifests within the initial five days after birth but can extend up to three weeks, while chlamydia-related ON usually presents between five and 14 days after birth.[12]

Immunocompromised individuals, such as those with human immunodeficiency virus (HIV) or transplant recipients taking specific immunosuppressive medications, may have an elevated susceptibility to BC.[13]

Risk factors

Potential risk factors for BC include conditions such as dry eye, defective tear film, systemic immunosuppression, prior infections, ocular trauma, and a history of hospitalisation or eye cosmetic application.[11] Moreover, air pollution has been increasingly recognised as an important risk factor for conjunctivitis.[14]

Signs and symptoms

The clinical presentation of BC can aid in its diagnosis. Common early symptoms include bilateral symptoms, redness, discharge,

Table I: Common conjunctivitis pathogens and associated signs and symptoms[11,15]

Bacteria	Area affected	Presentation	Points to note
Staphylococcus *Staphylococcus aureus* Most common pathogen of adult BC	Papillary conjunctivitis Affects the bulbar	Acute BC Mucoid or mucopurulent Matting and sticky closure of the eyelashes Can become chronic conjunctivitis if there is associated blepharitis	The purulence is due to dead tissue, degenerated white blood cells, and bacteria
Streptococcus *Streptococcus pneumoniae* Occurs in temperate climates in winter and is often seen in children	Papillary	Acute Mucopurulent discharge Papillary reaction	
Haemophilus *Haemophilus influenzae* Most common cause in children		Two forms: 1. Encapsulated form presents with mucoid or mucopurulent conjunctivitis, which is highly contagious 2. Non-encapsulated form seen in springtime and associated with upper respiratory tract infections It is self-limiting and resolves within 1–2 weeks of onset	Children with concurrent otitis and conjunctivitis are more likely to have *Haemophilus* conjunctivitis
Neisseria *Neisseria gonorrhoeae*		Hyperacute, profuse, purulent conjunctivitis with chemosis, eyelid swelling, and keratitis Urethral symptoms precede the ocular symptoms by several weeks	If untreated, gonococcal conjunctivitis can result in corneal perforation within 24 hours
Chlamydia *Chlamydia trachomatis* Serovars A–C are associated with trachoma	Follicular conjunctivitis	Mucoid discharge and hyperaemia Classified as chronic conjunctivitis	Serovars A–C are the leading cause of preventable blindness
Moraxella *Moraxella catarrhalis*		Causes chronic conjunctivitis and is often associated with angular blepharitis	Can be misdiagnosed as adenovirus, chlamydia, or herpes virus

itching, and a foreign body sensation in the eye. One of the most common complaints is feeling that the eyelids are "stuck together" early in the morning.

BC usually peaks within 2–3 days after the onset of symptoms and generally resolves within two weeks. Chronic conjunctivitis typically lasts longer than four weeks, while acute conjunctivitis has an onset of less than four weeks. Complications may include corneal ulceration, corneal perforation, xerosis (dry eye), and preseptal cellulitis.[11] Table I describes the pathogens and associated signs and symptoms.

History[2]

Accurately identifying the nature of a condition, whether infectious or not, requires taking a careful patient history. The pharmacist, therefore, must enquire about:

- the duration of the symptoms (hyperacute, acute, or chronic);
- a description of the discharge (purulent or mucopurulent);
- associated symptoms (pain, itching, photophobia, or vision loss);
- possible trauma; previous similar episodes; prior treatment; contact lens use; immune status; sexual history; and
- the presence of otitis media, as BC can present with optic symptoms.

Treatment

Antibiotic resistance is a growing concern in treating bacterial infections, including BC.[16] While BC is generally self-limiting, treatment is recommended to reduce discomfort. Eye ointments tend to last longer; however, they can impair vision. Consequently, drops are the preferred route of administration. Table II provides the recommended treatment for BC.

Besifloxacin has been identified as an effective option for treating BC, showing efficacy against various bacterial species commonly implicated in the infection.[17,18] Studies have compared the efficacy of different antibiotics in treating BC, demonstrating the clinical and microbiological efficacy of medications like lomefloxacin and tobramycin.[18]

New treatment developments

Research has also focused on identifying biomarkers to differentiate bacterial from non-bacterial infections, aiding in accurately diagnosing and treating conditions like BC.[11,19] Moreover, strategies targeting bacterial biofilms, such as those discussed in combating bacterial biofilms, could be valuable in managing chronic or recurrent cases of BC.[20]Alternative therapies, including phage therapy, have emerged as potential options to address antibiotic-resistant bacterial infections.[21] Phage cocktails have been recognised as a strategy to limit the emergence of phage resistance in bacterial targets.[22] Furthermore, using bacteriophages as biocontrol agents presents a promising avenue for sustainable agriculture and could be adapted for ocular infections.[23]

Innovative delivery systems, such as liposomes, have been explored to combat antimicrobial resistance and enhance

Table II: Recommended treatment for BC[8,5]

Type of conjunctivitis	Treatment	Dosage
Moderate to severe BC	Aminoglycosides: • tobramycin • neomycin	Use every 4 hours Use ointment every 8 hours for 7 days
	Bacitracin/polymyxin B ointment	Every 3–4 hours for 7–10 days
	Chloramphenicol 1% ointment Chloramphenicol 0.5% drops	Every 8 hours for 5 days Every 2–4 hours for 5 days
	Fluoroquinolones: • ciprofloxacin • ofloxacin • levofloxacin • moxifloxacin • gatifloxacin • besifloxacin	Every 4 hours for 2 days, then every 6 hours for 5 days
	Fusidic acid 1% drops	Twice daily until it resolves
Gonococcal conjunctivitis	Ceftriaxone 1 g intramuscular	Once
Chlamydial infection	Azithromycin 1 g orally	Once
	Doxycycline 100 mg orally	Twice daily for 7 days

Note:
- The latest generation fluoroquinolones provide both strong Gram-negative and some Gram-positive coverage.
- Bacitracin, erythromycin, and ciprofloxacin can be administered as an ointment.
- Fluoroquinolones are ideal for contact lens wearers for empiric *Pseudomonas* coverage.

the efficacy of antibiotics.[24] Functionalising nanoparticles for enhanced penetration through biofilm matrices could improve the targeting of bacterial cells within biofilms, offering a potential solution for persistent infections.[25] Additionally, the use of cationic antimicrobial peptides in combination with histone deacetylase inhibitors has shown promise in enhancing antimicrobial activity against bacteria.[26] Also, advancements in drug delivery systems, such as intravitreal implants releasing antibiotics like ciprofloxacin, have shown promise in treating bacterial infections in the eye, including conjunctivitis.[27]

Non-pharmacological interventions

BC is easily spread through direct contact, and educating patients on prevention methods remains the best way to reduce the risk of transmission. A study found that approximately 46% of patients had positive cultures when their hands were swabbed, proving that hand hygiene remains fundamental in reducing the transmission of BC.

If infected with BC, simple measures such as avoiding swimming pools, shaking hands, touching eyes, and sharing personal items should be practised.[5] Non-pharmacological treatments may include applying warm compresses to the eyes to alleviate discomfort and reduce inflammation and practising proper eye hygiene, such as regularly cleaning the eyelids with a warm, gentle soapy solution.[28]

Conclusion

BC is a common complaint that accounts for numerous doctor visits. While it is often a self-limiting condition, antibacterial treatment can help reduce the discomfort. Topical antibacterial ointments and drops are usually the first-line treatments, but advising the patient on proper hand-washing techniques and eye hygiene is instrumental in preventing transmission.

Conflict of interest

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The impact of unprofessional behaviour on patient safety in South Africa: two cautionary tales

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Abstract

In terms of the Rules relating to the Code of Conduct, every pharmacist's prime concern in the performance of his/her professional duties must be for the wellbeing of both the patient and other members of the public. A pharmacist must uphold the honour and dignity of the profession and may not engage in any activity which could bring the profession into disrepute.

Pharmacists engaging in unprofessional conduct or conduct where their regard for their profession is disrespectful, may be involved in activities such as the selling of counterfeit medicines, dispensing medication without prescription, and selling excessive quantities of medicines liable for misuse or abuse, i.e. drug trafficking. These actions can be attributed to factors such as financial incentives, inadequate training, or personal challenges, none of which are acceptable. These pharmacists are viewed as rogue pharmacists with severe implications for patient safety and significant risk of bringing the profession into disrepute.

There are also instances where pharmacists make dispensing errors, supplying incorrect medicines, incorrect strength of medicines or incorrect dosage instructions. These errors are generally inadvertent but can obviously have a negative impact on patient safety. As the custodian of medicine, it is crucial that the pharmacist makes every effort to prevent medication errors. Pharmacists must be aware of areas where the chances of dispensing errors are high, especially those caused by look-alike sound-alike (LASA) medications, as they can lead to adverse reactions or even death. Preventing LASA medication errors requires awareness, generic prescribing, pop-up alerts in computer systems, eye-catching labels and warnings, patient education, and the establishment of process and outcome measures. Pharmacists can also organise high-risk LASA drugs on separate shelves and implement double-checking systems for accuracy when dispensing medications. Dispensing errors can have severe consequences for the pharmacist, including monetary fines, registration suspension or removal, and public scrutiny.

The misuse and abuse of codeine-containing medications pose significant health risks and pharmacists play a crucial role in harm reduction. Measures to address codeine overuse, misuse and abuse include enhanced regulatory measures, public health interventions, surveillance, training, and education. Without some form of centralised database, it is very challenging for a pharmacist to manage this problem as individuals utilise different pharmacies and their medication history is not linked. To address this problem, pharmacists can participate in initiatives such as the Codeine Care Initiative, a centralised data base of codeine-containing medicine use. This allows the monitoring of frequent purchasers of codeine and gives the pharmacist an opportunity to address codeine misuse at the point of dispensing.

Keywords: unprofessional behaviour, patient safety, Code of Conduct

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Introduction

Unprofessional conduct by pharmacy professionals in pharmacy poses a significant challenge to the healthcare system in South Africa. These professionals engage in misconduct by dispensing unsafe or counterfeit medicines, selling excessive quantities of dangerous drugs, and dispensing medications without proper oversight or scrutiny.[1] Inadequate regulation has created an environment where rogue pharmacists can operate unchecked, leading to serious public health concerns.[2] Additionally, the shortage of pharmacists in South Africa, with a ratio of one pharmacist for every 23 375 people, complicates the monitoring and regulation of pharmacists' activities, especially in underserved areas.[3] As a point of interest, the World Health Organization (WHO) guidelines state that the ideal ratio should be one pharmacist for every 2 000 persons.[4]

The impact of unprofessional conduct is further exacerbated by the prevalence of counterfeit drugs distributed through illegal online pharmacies.[2] Unprofessional conduct includes dispensing unsafe or counterfeit medicines, dispensing without a prescription, and selling excessive quantities of dangerous medicines.[5] This not only poses a significant risk to patient safety, but also contributes to the development of drug resistance and has led to a substantial number of deaths, particularly in low- and middle-income countries, including those in Africa.[2] The lack of accountability and the potential for purchasing stolen or counterfeit drugs from these online sources further compound the challenges faced by regulatory bodies and healthcare providers in South Africa.[2,6]

Various actions may contribute to pharmacists engaging in unprofessional conduct, factors such as financial incentives, inadequate training, or personal challenges. These actions can be considered misconduct and/or unprofessional behaviour. Examples of such behaviour include participating in illegal activities like selling medications without prescriptions, or engaging in drug trafficking, and dispensing medications without proper oversight or scrutiny.[5,7,8]

Codeine use in South Africa

The overuse, misuse, and abuse of codeine in South Africa presents significant health risks for the public, and pharmacists play a crucial role in mitigating the associated risks. Codeine, a short-acting opiate, is commonly used to treat mild to moderate pain, as well as coughs and diarrhoea. However, its sedating and euphoric effects make it susceptible to abuse, placing the onus of harm reduction on pharmacists, who are often the first point of contact for over-the-counter (OTC) codeine-containing medicines.[9-11] The misuse and abuse of OTC codeine-containing medications is of growing concern, with the accessibility of these drugs and their potential for psychological dependence and harm from overuse prompting calls for enhanced regulatory measures and public health interventions. Case study 1 highlights the experience of a 32-year-old construction worker who became addicted to Stilpane® capsules, prescribed for postoperative pain relief following a work-related injury.

Case 1 – A case study of codeine addiction and prescription fraud

A 32-year-old hardworking construction worker had been prescribed Stilpane® capsules (containing codeine, meprobamate and paracetamol) for postoperative pain relief following a work-related injury.

As time went on, he found himself needing higher doses of Stilpane® to achieve the desired pain relief which then led to unintended euphoric effects. Eventually, he began to misuse Stilpane®, taking it even when he was not in pain, solely to experience its mood-altering properties. This misuse led to dependence and a full-blown addiction, with his life becoming centred around obtaining and using Stilpane®. He started looking for any codeine-containing products that could be obtained OTC. However none of these products gave him the same euphoric effect as Stilpane®.

Facing challenges in obtaining Stilpane® through legitimate means, he resorted to forging prescriptions to maintain his supply. He would imitate the handwriting of healthcare professionals, create fraudulent prescription pads, and manipulate pharmacy records to obtain Stilpane® illegally. This led to dependence on the drug and a cycle of ever-increasing Stilpane® consumption as he sought to prolong these pleasurable effects.

As his addiction deepened, he faced significant challenges within his personal and professional life. He began to prioritise obtaining Stilpane® over his responsibilities at work, resulting in decreased productivity and strained relationships with colleagues. Financial strain also emerged as he spent a substantial portion of his income purchasing Stilpane® illegally through the illicit market when his prescription ran out.

He realised that he needed help but faced several barriers when attempting to find help for his addiction. Limited access to addiction treatment resources, such as specialised rehabilitation centres and addiction support groups, made it difficult for him to find support and the appropriate assistance he needed. Additionally, societal stigma surrounding addiction hindered him from openly discussing his struggles, leading to feelings of isolation and despair.

Research has indicated that easy access, infrequent refusal, standard questioning, and limited interventions by pharmacists have contributed to the misuse of OTC codeine-containing medicines. Furthermore, reports have highlighted instances of unprofessional conduct by pharmacists selling OTC codeine-containing medicines to patients without providing adequate pharmaceutical care. This deviant behaviour is particularly concerning given the trust placed in pharmacists to improve and assist with patient health outcomes, as outlined in their code of conduct and ethical rules.[12]

Despite legislative measures, such as the stipulation of the maximum recommended dose in the Medicines and Related Substances Act 101 of 1965, codeine misuse and abuse continue to be of growing concern in South Africa.[9,13] A comparative analysis of pharmacists' perspectives on codeine use and misuse in South Africa, Ireland, and the UK revealed that the majority of participants saw codeine misuse as a public health issue, with a high proportion of South African participants expressing the need for greater codeine control.[14]

The misuse of codeine is a significant public health issue, particularly concerning OTC pain and cough relief medication. In South Africa, OTC preparations containing 20 mg or less of codeine per dosage unit can be sold without a prescription under the supervision of pharmacists, with sales required to be recorded in the pharmacy. However, the regularity of purchase of these products, indicative of their popularity, may also be a potential indicator of misuse.[14]

Considering these challenges, there is a need for comprehensive measures to address codeine misuse and dependence in South Africa, including enhanced surveillance, revised scheduling, and increased awareness among healthcare professionals and the public about the potential risks associated with codeine misuse. Furthermore, efforts to strengthen the addiction treatment sector and provide appropriate training for dealing with codeine-related problems are essential to effectively tackle this issue.[15]

Pharmacists in South Africa can help reduce codeine misuse by implementing several measures. Firstly, they can participate in the Codeine Care Initiative, which identifies at-risk patients and educates pharmacists on the issue.[15,16] Pharmacists can also monitor patients who frequently request excessive amounts of codeine, using their professional judgement to identify potential

misuse. This proactive approach is crucial in addressing the global public health concern around codeine dependence.[15,16] Therefore, pharmacists would benefit from enhanced training and education to effectively address codeine misuse and dependence.[15,16]

Case 2 – A case study of look-alike sound-alike (LASA) medications: Cyclogest® and Cytotec®

Preventing dispensing errors is essential for patient safety and preventing negative outcomes in health care. These errors can occur for several reasons, including similar-looking and -sounding medications, improper labelling, inadequate staffing, and lack of training, or oversight. The confusion caused by LASA medications can lead to serious consequences for patients, such as adverse reactions, prolonged hospital stays, or even death.[17]

LASA medications are drugs that resemble other medicines dispensed by healthcare professionals. This can lead to confusion and errors, as these medications have similar names, packaging, appearance, and mode of administration. Studies have shown that LASA medications account for a significant portion of medication errors, with 4% considered near misses and a range of 6.2% to 14.7% documented.[17] Some of these errors have resulted in serious harm and even death. Case 2 highlights the importance of preventing LASA medication errors in health care and the need for healthcare providers and pharmacists to be vigilant in differentiating between LASA medications to ensure patient safety.

Case 2 exemplifies the serious consequences of medication errors in health care. Underscoring the need for a comprehensive approach to medication safety, including measures to prevent LASA medication errors by addressing these challenges, healthcare systems can work towards minimising the occurrence of medication errors and safeguarding patient well-being.

To prevent and address LASA medication errors, pharmacists can adopt the following strategies:[18]

- *Awareness of LASA medications:* Healthcare professionals and organisations should be aware of problematic drug names and maintain a comprehensive list of confused drug names, including look-alike and/or sound-alike medication names (Refer to Table I).
- *Prescribing medications by their generic names:* Prescribing medications by their generic names can help reduce confusion and minimise the risk of LASA medication errors.
- *Installing pop-up alerts in computer systems:* Implementing pop-up alerts in computer systems can help healthcare professionals identify potential LASA medication errors and prevent them.
- *Placing eye-catching labels and warnings:* Using eye-catching labels and warnings on medications can help healthcare professionals and patients distinguish between similar-looking medications.
- *Patient education:* Educating patients about common errors and encouraging them to question medications that look different than expected can help detect LASA medication errors. Furthermore, including the indication on a prescription has been suggested as a potential intervention to impact prescribing practice and reduce the risk of dispensing errors.
- *Mandatory patient education:* Requiring mandatory patient education in outpatient settings before dispensing a medication with a problematic look-alike and/or sound-alike name can help ensure that patients are aware of the potential risks.
- *Opening prescription bottles with patients:* When possible, opening the prescription bottle with the patient to visually confirm the expected medication can help prevent LASA medication errors.
- *Establishing process and outcome measures:* Collecting data periodically to assess the effectiveness of LASA medication error prevention strategies and implementing process and outcome measures can help improve patient safety.
- *Inventory management:* Organise the pharmacy's high-risk LASA drugs on distinct shelves.[19] To minimise these risks, implement guidelines or standard operating procedures.[19]
- *Systems in place:* Dispensers should implement a rigorous double-checking system to ensure accuracy when dispensing medications. This includes verifying the name and strength of the medication. Patient counselling can also help identify any discrepancies. Furthermore, a built-in scanning system can be used to confirm that the dispensed medication matches the one captured in the system, providing an additional layer of security.

Table I: Similar sounding drugs

Drug name	Confused drug name
Accuretic	Amiloretic
Allergex	Aterax
Arycor	Aspavor
Casodex	Bisodex
Brexicam	Brazepam
Cardicor	Concor
Cefoxitin	Cefotaxime
Cefotaxime	Ceftriaxone
Cortaject	Caverject
Ciprobay	Cipralex
Cytotec	Cyclogest
Diflucan	Diprivan
Diovan	Zyban
Doribax	Dobutrex
Diprivan	Ditropan
Dormicum	Dormonoct
Humalog	Humulin
Hydralazine	Hydroxyzine
Keppra	Kaletra
Lasix	Losec
Nifedipine	Lexamil
Solu-Cortef	Nomodipine
Streptomycin	Solu-Medrol

Tertroxin	Streptase
Tertroxin	Eltroxin
Tobrex	Diotroxin
Taziject	Tobradex
Xatelto	Tazobax
Xefo	Xyzal
Tienam	Zofer
Ivedal	Invanz
Cardicor	Winthrop clopidogrel
Macaine with adrenaline	Concor
Cefazolin	Macaine with dextrose
Cefazolin	Ceftriaxone
Sabax metoclopramide	Cefuroxime
Stilamin	Sabax Magnesium Sulphate
Solu-Medrol	Sandostatin
Diflucan	Depo-Medrol
Tareg	Dalacin-C
Heparin	Tegretol
Cefazolin	Adrenaline
Cyklokapron	Cefuroxime
Solucortef	

In South Africa, as in other countries, it is essential for pharmacies to implement measures to reduce the risk of dispensing errors, including the use of technology, staff training, and standardised procedures for dispensing medications to mitigate the probability of dispensing LASA medicines incorrectly.

The impact of dispensing errors: understanding the consequences

Over and above the potential civil litigation and the costs associated with medical malpractice, there are also the professional misconduct consequences in terms of the Rules relating to acts or omissions for which the Council may take disciplinary steps[20] ([GNR. 599, published on 31 March 1989] read together with Section 45 of the Pharmacy Act, 53 of 1974).[21] In the case of dispensing errors, and related to the LASA case study, the consequences can be a high fine of R25 000 per charge, the suspension of registration or removal of registration. One must also bear in mind that when the dispensing error is by a pharmacist's assistant, the responsible pharmacist and/or supervising pharmacist is also held liable for the dispensing error as well as other collateral charges relating to a lack of implementation of systems to mitigate dispensing errors (responsible pharmacist), the lack of supervision of pharmacy support personnel (responsible pharmacist or supervising pharmacist), and persons acting outside their scope of practice (pharmacist's assistant dispensing without consulting the supervising pharmacist).

Serious dispensing errors and dispensing errors caused by gross negligence may result in the matters being referred to the Committee of Formal Inquiry (CFI). When this happens, the outcome of a guilty finding is published on public forums such as the SAPC website.[22] These guilty judgements remain against a person's name for a minimum of five years, which means that such person is not professionally in good standing with the SAPC.

Conclusion

The consequences of pharmacists engaging in unprofessional conduct can be severe, causing patient harm and subsequent legal implications. Dispensing errors, including dispensing the wrong medication and providing incorrect dosages or directions for administration, are also of significant concern as they can result in adverse drug events causing morbidity or even mortality. It is essential for pharmacists to implement measures to prevent such errors, particularly those caused by LASA medications. To address this, various measures such as awareness, vigilance, generic prescribing, pop-up alerts in computer systems, eye-catching labels and warnings, patient education, and establishing process and outcome measures are crucial. Additionally, pharmacists can play a pivotal role in preventing medication errors by organising high-risk LASA drugs on separate shelves and implementing double-checking systems for accuracy when dispensing medications. Furthermore, the overuse, misuse and abuse of codeine-containing medications pose significant health risks, and pharmacists can contribute to harm reduction through enhanced regulatory measures, public health interventions, surveillance, training, and education. It is imperative to recognise the potential legal and ethical implications of medication errors and to prioritise patient safety through comprehensive measures and ongoing professional development.

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What South Africa can learn from other countries for a successful implementation of National Health Insurance – a review of the literature

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Abstract

Objective: This review paper aimed to provide a qualitative summary of evidence on how other countries that have had some success in implementing some form of Universal Health Coverage (UHC) have navigated the structural problems in the health system and used the lessons to inform the implementation of the National Health Insurance (NHI) in South Africa (SA).

Methods: The literature search was undertaken from December 2020 to December 2022 and included literature dated 2010 to 2022. The criteria for selecting the literature was limited to papers written in English and involving discussions on what and how all stakeholders (public and private sectors) can contribute to ensuring the smooth implementation of UHC. A narrative, rather than systematic review, was considered more appropriate.

Results: The review paper has identified opportunities that, if exploited, may clear the way for an all-inclusive stakeholder collaboration to see a successful delivery of the NHI project in SA. The opportunities identified sought to address leadership and governance, healthcare financing, service delivery and health workforce challenges. The challenges of managing the cost escalation and maintaining coverage for vulnerable groups were explored.

Conclusions: The NHI project requires a clear understanding and appreciation of the collaborative efforts expected from all stakeholders. The findings of the review suggest that while the NHI building blocks have been described in legislation, there is deficiency of the detail required to deal with the implementation nuances. This requires further research to unpack the detail required to exploit the opportunities identified for the implementation of the NHI.

Keywords: healthcare reform, health policy, health insurance, stakeholders, policy implementation, public health, private sector, health financing, health inequalities

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Introduction and background

The National Health Insurance (NHI) is designed to pool funds and actively purchase services with these funds to provide universal access to quality, affordable personal health services for all South Africans based on their health needs, irrespective of their socioeconomic status. This represents a substantial policy shift from the current segregated, unequal and more often ineffective healthcare system that sees a huge chunk of economic resources directed to approximately 18% of the population in the private sector whilst a huge section of the population relies on the state to provide health care.[1] The NHI White Paper details the challenges inherent in the current system as the inability to address the poor social determinants of health (SDH), the increasing burden of disease, and the structural problems in the health system.[1] According to the White Paper on the NHI, the structural problems are a consequence of the inability of the system to effectively implement the six healthcare system building blocks, being: (i) Leadership and governance; (ii) Healthcare financing; (iii) Health workforce; (iv) Medical products and technologies; (v) Information and research' and (vi) Service delivery.[1] It is the goal of the authors of this paper to review the strategies that other countries have followed to deal with the structural challenges or problems that adversely affect the implementation of the NHI building blocks.

The goal of Universal Health Coverage (UHC) becomes more realistic when a population has access to prepayment and pooling mechanisms.[2] The World Health Report on Health Systems Financing identifies three fundamental questions that governments face in striving to achieve the goal of UHC.[2] These fundamental questions are:

i. How is such a health system to be financed?
ii. How can people be protected from the financial consequences of ill-health and paying for health services?
iii. How can the optimum use of available resources be encouraged?

This review paper aimed to provide a qualitative summary of evidence on how other countries that have had some success in implementing some form of UHC have navigated the structural problems in the health system, and to use their lessons and experiences to inform the implementation of the NHI in SA. Those structural problems are leadership and governance, service delivery challenges, health workforce challenges, availability of medical products and technologies and healthcare financing challenges. Availability of medical products and technologies were not discussed in this review since it is considered a subset of the policy issues, specifically health technology assessment (HTA) policy which is addressed in service delivery coverage.

Methods

This review was not performed as a comprehensive, systematic review, because the goal was to answer a focused research question. The literature search was undertaken from December 2020 to December 2022 and included literature dated 2010 to 2022. Google Chrome was used to search for the relevant articles. The keywords used were:

- Implementation of Universal Health Coverage
- Universal Health Coverage
- National Health Insurance
- Stakeholders' Universal Health Coverage
- Public Private Partnerships
- Role of State in Universal Health Coverage
- Health care
- Implementation
- Role of Government
- Private Insurance
- Private Medical Aids

The criteria for selecting papers for review were limited to literature published in English; literature involving discussions of what and how all stakeholders (public and private sectors) could contribute to ensuring the smooth implementation of UHC in one form or another, and literature on how and what these stakeholders have contributed to the implementation of a specific form of UHC and the achievements attained.

The primary author identified the papers for review and shared the references with the supervisor who provided input on how these are likely to address the research question. The supervisor also provided possible papers for inclusion in the review.

The focus in this review was on literature concerning the contribution that all stakeholders (public and private) made in the implementation of some aspect of the UHC.

The literature review undertaken sought to unearth what other countries – where some level of UHC had been achieved – had undertaken their journey to address specific aspects of the healthcare system building blocks as identified in the NHI White Paper (2017). The outcomes of the review were then compared to the progress or otherwise of the NHI project in SA.

Conceptual literature review

The aspects addressed below are all-encompassing and were not intended to address verbatim the six building blocks as per the NHI White Paper but to address the broad approaches or concepts that the different countries undertook.

Leadership and governance

Leadership and governance continue to be one of the issues that impacts the attainment of the objectives for UHC implementation. Advocacy for multi-sectoral and participatory governance is a core area of leadership and governance. These actions, though challenging, are directly needed for countries to be able to effectively and sustainably move towards UHC.[3] This aspect was considered at a side event at the 72nd World Health Assembly in Geneva on 22 May 2019 by high profile UHC specialists. The comments of the participants emphasised the importance of having a legislative framework to promote good governance. They argued that the legislative framework must focus on unpacking and understanding the dimensions of participation of all stakeholders, demonstrate political will, and define the responsibility of the private sector in making affordable medicines more accessible.[3]

The importance of ensuring a space for civic engagement, systems to deliver on the right to health for all without discrimination, responding to the needs of all, the ability to engage in decision-making and holding different actors to account was also viewed as one of the important implementation enablers.[3] Similarly, another review found that though countries in the Asia-Pacific region deployed all the necessary governance functions to facilitate progress towards UHC, those countries still face challenges with respect to governance for UHC.[4] This included difficulties in creating policies and management strategies that work across rural-urban settings and which affected both high- and low-income countries.[4] The authors contend that though leadership and governance are considered the most important function of governments in health systems, they are also complex and poorly understood.

Hence, the need for leadership to set direction and develop strategies, create institutions and organise people for implementation, to gather information for evidence-based policies and monitoring were seen as key to enabling progress in the implementation of UHC.[4]

According to Clarke et al. (2019), major gaps in knowledge about the benefits of private care provision remain. In addition, many countries do not have an explicit government policy position on the role of the private healthcare sector, nor concrete plans to implement public policy on the private sector.[5] Explicitly spelling out the role of the private sector will certainly go a long way in alleviating some of the contradictions and skepticism that exist between affected stakeholders.

In an earlier commentary, Greer et al. (2015) argued that politics and governance have been undervalued as key drivers for UHC. They purport that the attainment of UHC is political and cite the fact that governments are faced with the difficult task of prioritising the relative importance of "vertical" priorities such as disease eradication and broader "horizontal" system-strengthening proposals.[6] They assert that there is tension between global health politics and domestic health politics. On the other hand, they state that authoritarian regimes are less responsive to the broad population and often focus benefits on a narrower sector of the population.[6]

Leadership and governance configuration for the implementation of UHC is another important consideration. This does not only complicate delivery and in other instances compromise the attainment thereof, but it also affects the speed at which reforms are implemented.[7] A comparative study of organisational transformation within the health sector in four upper- and middle-income countries identified constraints posed by the complex relationships in the power dynamics in governance institutions and organisations in governments.[7]

These constraints are:[7]

i. Seldom do health systems change after reforms, resulting in the homogeneous single model instead of a complex system of new interactions that emerge, that require new or adaptive leadership skills to navigate.
ii. The exercise of responsibilities after the reforms often takes a different form from the expected or calculated change.
iii. The MOH's ability to act alone and or stamp its authority is limited due to the widespread organisational transformation accompanying such changes.

Given the power dynamics in the governance institutions and organisations in governments, the study identified four mechanisms which a ministry of health (MOH) can use to drive organisational change.[7]

Those strategies aim to create political commitment through a high-level interministerial ministry, translate strategic decisions into implementable steps through a change team, modify the institutional environment to enable changes needed by enacting enabling legislation and by capitalising on political windows of opportunity.

Healthcare financing challenges

Chu et al. (2019), in an article titled Health Financing Reforms for Moving Towards UHC in the World Health Organization (WHO) Western Pacific Region – a region covering 37 countries and areas in East Asia, South-East Asia, and the Pacific Islands – detailed the challenges faced by these countries. Chief amongst the challenges experienced were changes in their disease patterns and populations, rapid socioeconomic developments and the increasing expectations from citizens to access better quality health services. Despite these challenges, several Asian countries (in the WHO Western Pacific Region) in particular have accelerated their movement toward UHC.[8] This is said to be due to high political commitment to their health-sector reforms which is triggered by pressing health financing issues and the need to strengthen the foundations of primary health care.[8]

Likewise, high-income countries in the Western Pacific Region, such as Japan, the Republic of Korea, Australia, Singapore, and New Zealand, experienced similar challenges as they faced mounting pressures to address the financial sustainability of their health systems, including cost control measures and adoption of new medicines and technologies.[8]

Despite these challenges, the authors record that countries in the Western Pacific region have been introducing health financing policies that sought to advance UHC.

In addition, the study by Chu et al. (2019), showed that risk pooling helps in the redistribution of resources and protects against the individual risk of becoming ill and paying high costs for health services by spreading the risk across the greater population.[8]

Simplice Dagnan (2018) in "Health System Reforms to Accelerate Universal Health Coverage in Côte d'Ivoire, Health Systems & Reform" also deals with approaches to sustainable funding for health services to achieve health reforms. From an accountability perspective, the government has paired domestic resource mobilisation with efforts to increase transparency in resource management by implementing an internal audit function within the Ministry of Health and Public Hygiene (MHPH).[9]

In addition to pointing to the willingness of the countries to ensure sustainable funding of their UHC efforts, the review also showed that these countries took practical steps that made it possible for them to address the healthcare financing hurdles.

This again is debatable in the South African setting where uncertainty lingers on the exact funding policy arrangements.

According to an Econex study published in Health Reform Note 13, April 2011, Voluntary Health Insurance (VHI) – known as medical aid insurance in South Africa – plays a vital role not only in countries which have not yet achieved universal health coverage, but importantly also in countries which have already done so. The study set out to answer the question "what possible future role will the VHI providers play in the NHI" by focusing on the role of VHI providers in comparable countries with Universal Coverage (UC) schemes.[10]

The study points to an interesting phenomenon of co-existence of private health care in the form of VHI with universal health coverage in several Organization for Economic Co-operation and Development (OECD) countries. The study highlights the following as prevailing occurrences in OECD countries where some sort of UHC is in place:[10]

i. That most private health insurance markets are voluntary with some exceptions.
ii. Even some OECD countries which have a mandatory public healthcare system have an element of compulsory private health insurance.

Most importantly the study identified gaps (real and perceived), these being: waiting times; increasing demand for choice; and perceptions of inadequacy of public systems as factors that drive the extent of private health insurance or VHI in some of the OECD countries.

The Econex study cites the following issues relating to the role of VHI in the NHI project in SA:[10]

i. Like other developing countries, there are still largely perceived quality differences between the public and private sectors, thus private VHI of a duplicative nature will enable individuals to seek better quality care.

ii. The quality differences between the public and private sectors are likely to persist after the NHI implementation and, should this materialise, duplicative private VHI is likely to continue, however the affordability of VHI might be affected due to the proposed removal of tax subsidies for medical schemes' contribution. The possible effect of this in SA is the fact that those opting for VHI will feel that they are taxed twice.

In the same vein, a WHO health financing policy brief published on 12 September 2018, whose purpose was to explore the potentials and limits of VHI for progress towards UHC in low- and middle-income countries, concluded that unmanaged (where there is no public policy) VHI is likely to pose a threat to UHC goals.[11]

Closer to home, the impact of VHI was explored by Goudge et al. (2018) in their paper where they ask whether the Government Employees Medical Scheme (GEMS) has further institutionalised inequities in access to health care. They examined whether insurance status and socio-economic status influenced access to care, and secondly, by investigating whether the design of the scheme has contributed to inequities in utilisation of services. The authors conclude that while GEMS has widened the scope and breadth of coverage for some civil servants, in doing so it has increased inequities in healthcare access in the country as a whole.[12]

In SA, the policy uncertainty regarding the future role of private voluntary health insurance in the context of the NHI financing remains an elusive subject.[13] The Staff Writer reports that Price Waterhouse Coopers (PwC) has surveyed 31 C-suite leaders (senior executives) of the SAn healthcare public, private and donor organisations by conducting in-depth interviews and on-line digital surveys. The report found that the healthcare reforms on the role of medical aids has stagnated and, after decades of discussion, the non-state stakeholders are wary and do not trust each other. Another article in BusinessTech (June 2022) indicates that both government representatives and public commentators are concerned about the sources of funding for the NHI. Whilst government expresses the view that a large part of the NHI's funding will be made up of the reallocation of health funding as well as existing tax credits, it goes further to acknowledge that additional taxes in the form of increase in value-added tax (VAT), change in general taxation and additional payroll tax might have to be introduced. The reaction of commentators and opposition parties is that the planned NHI will be unaffordable since it is going to impose an additional tax burden on the middle class. They argue that only 9% of South Africans are contributing to the 40% of SA's total tax revenue.[14]

Service delivery challenges

A review paper by Fusheini & Eyles (2016) explored service delivery coverage as being one of the essential building blocks for NHI and points out that the District Health System (DHS) has been a backbone of every health system on the continent of Africa, and in SA the DHS has been central to the health system since 1997.[15] The implementation of the DHS is dependent on every country's local context. They point out that South Africa's path to UHC is complicated not only by its history but also by the size of the private health sector and its present political complexion, which is still dominated by liberation ideology and the importance of solidarity and inclusion.[15] The DHS model, with its indicative impact areas, is said to foster local government involvement. Using the DHS model, healthcare services are organised and coordinated at a local level using decentralised, area-based and people-centred approaches, and these approaches are seen as central to the SAn context.[16]

The study by Fusheini & Eyles (2016) aimed to establish whether the DHS could provide service availability, given the well-known inequities between districts with respect to population health status in the NHI. The study dealt with both the normative and ideological differences of the DHS, where the ideological approach is concerned with the need for decentralisation and community involvement and programme integration.[15] From a normative approach the focus on districts is underpinned by the fact that to achieve equity, the organisation of health care should be according to geographic sub-divisions of a country, managed through decentralised management structures.[15]

According to Fushein & Eyles (2016), despite the challenges observed in the various districts, it remains to be seen whether the financial and ideological challenges will undermine this intent – achieving the WHO-defined goal of UHC.

Campos & Reich (2019) examined another aspect of implementation – the politics of policy implementation for the health sector, particularly the management of stakeholders in order to help change management teams to improve the chances of achieving policy objectives. In the paper "Political Analysis for Health Policy Implementation", the authors identified six major categories of stakeholder groups that are likely to influence implementation, namely, interest group politics, bureaucratic politics, budget politics, leadership politics, beneficiary politics, and external actor politics.[17] The authors stated that understanding and addressing conflict, resistance and cooperation among stakeholders were key to managing the implementation process. They advised that systematic and continuous political analysis can help decision makers and change management teams to improve the chances for successful implementation. The article identified different challenges posed by the complex interaction among the stakeholders and offered examples of effective strategies that can be employed to manage policy implementation.[17]

Still another role-player, the private sector, cannot be ignored in the implementation of UHC. According to Clarke et al. (2019), it is necessary to consider what role the private sector should play in delivering healthcare services. Certainty of the private sector involvement in the provision of health care in UHC must

be established. The role of (multi)national companies, non-governmental organisations, and non-profit entities involved in the supply of healthcare-related goods, healthcare financing and the direct provision of health care has been in existence for a long time; this being as a result of private actors already operating in healthcare provision. In cases where there is no engagement between the state and private sector stakeholders, a public policy vacuum exists regarding the private sector and UHC. According to the authors, in this vacuum, the private sector could pursue its own objectives, which may or may not be closely aligned to UHC; hence the need for streamlined government policy.[5]

Suggestions of the possible participation in UHC by the private sector has been espoused by authors in commentaries and reviews.[18,19] A commentary by Kai Hong Phua (2017) suggests that the reason why, for instance, the concept of public-private partnerships (PPPs) is attracting interest and being well-received in Asia, is because it avoids the often-negative effects of monopolistic public ownership and delivery of services on the one hand, and unbridled privatisation on the other. PPPs are thought to combine the best of both worlds: the private sector with its efficient management and use of incentives; and the public sector with its regulatory actions and protection of the public interest.[18] Hallo De Wolf & Toebes (2016) in their review state that the private sector could be involved in the provision of health care as payers or financers (private health insurance companies, charities), providers (private hospitals, pharmacies and clinics, healthcare personnel, civil society organisations and charities) and suppliers (pharmaceutical companies and suppliers of medical equipment).[19]

Of the two modes of possible participation by the private sector – privatisation and public-private partnerships – the authors noted that countries have had mixed experiences when it comes to privatisation efforts enabling the realisation of the right to health.[19]

The Working Party on Aid Effectiveness hosted by the OECD Development Assistance Committee (DAC), initiated a work stream to look at "The role of the private sector in the context of Aid Effectiveness" ahead of the 4th High Level Forum on Aid Effectiveness (HLF 4) that took place in Busan, Korea from 29 November to 1 December 2011. Some of the responses received by the workstream included the following:[20]

- Mobilisers of resources
- Contributors of financial and in-kind resources
- Providers of goods and services as implementers/contractors in aid projects, including recipients of funding
- Dialogue partners and advocacy
- Partners in PPPs through cost- and risk-sharing
- Drivers of innovation

The workstream report asserts that whilst there is no consensus on what roles the for-profit private sector should play in aid, several donors and partner countries stress "partners in PPPs", "implementers of projects" and "equal dialogue partners".[20]

In a report published in 2018 titled "What works, the triple win, rethinking public private partnerships" by Klynveld Peat Marwick Goerdeler (KPMG) – a global network of professional firms providing audit, tax and advisory services – the authors showcased the success of a PPP that ensured the delivery of quality services to a population of more than 300 000 people in Portugal. The report notes the success of PPPs in developed countries in health care where these PPPs were seen to propel the development and renewal of infrastructure, where, for instance, hundreds of new hospitals and clinics were built across Australia, Canada, France, Spain, and the UK at a scale that could never have been afforded by their governments alone. On the other hand, investment partners were said to be unlikely to make investments in emerging economies where a host of legal, political, economic, and operational risks were deemed to be a challenge.[21]

Whilst identifying some common mistakes to be avoided to ensure the success of PPPs, the authors concluded that the success or failure of PPPs in helping to achieve UHC will stand or fall on the ability to combine the lessons of the past with the creativity of the future.[21]

The picture that emerges from the various presentations and conversations around NHI at stakeholder engagement is that hardly anyone is inherently against NHI, but people in public health circles, including public service managers in the Gauteng district, have several concerns about the details of how NHI, as outlined in the bill, might work.[22] This is the reason why the nuances of these concerns and the associated themes on how exactly the service delivery will be undertaken are worth unpacking.

Health workforce challenges

A shortage and a maldistribution of qualified healthcare workers is one the most common barriers countries face in being able to expand and achieve UHC.[23,24] The WHO and the Global Health Workforce Alliance reported on the status of 186 countries where they estimated a deficit of approximately 7.2 million health workers globally and predicted that this shortage will grow to 18 million by 2030.[24]

In SA, this dynamic is further complicated by the unequal distribution of healthcare workers (HCW) between the private and public health sectors with the latter servicing the majority of the population (approximately 83%). Approximately 40% of general practitioners and nurses work in the private sector where they only provide services to those with private health insurance, which accounts for approximately 17% of the population.[25]

The state of affairs of health workers in SA has recently been described as "shocking" by the Minister of Health, Dr Joe Phaahla, citing a doctor-patient ratio of 1:3 198. This dictates a need to have a clearly outlined strategy to have "the right mix of skills and people" for the success of the NHI.[13]

The SAn context as described above spells an almost near chronic

and complex emergency that, according to a study by Cometto et al. (2020), requires government intervention to mobilise a political commitment. The study suggested that a mechanism for health workforce policy dialogue and planning be established, in addition to appropriate monitoring and financing mechanisms.[23] Kai Hong Phua (2017) identified how the public and private sectors complement each other to drive health workforce policy dialogue and planning. They state that the PPPs bring the private sector efficiencies and incentive management, and the public sectors regulatory actions and protection of the public interest which are important considerations for the health workforce policy dialogue and planning.[18]

The PPPs, according to Hallo De Wolf & Toebes (2016), will also bring providers from the private sector who can serve as healthcare personnel to alleviate the healthcare workforce shortage to the public sector.[19]

Other aspects related to healthcare financing challenges – managing cost escalation and overall population coverage

For completeness it is worth discussing managing cost escalation without eroding coverage, as an aspect of healthcare financing challenges, as well as ensuring sufficient coverage for the ageing population.

According to the White Paper on NHI, irrespective of the structure and financing arrangements in place, the continuing management of cost escalation without eroding coverage becomes crucial due to the continued upward pressure on costs.[1] Another consideration raised in the White Paper on NHI is the linkage of overall population coverage – especially the ageing population – to broader social security reforms. Lessons on the two subjects can be drawn from the OECD report.[26]

The OECD report states that UHC is affordable for a large number of middle-income countries but requires strong political commitment and additionally often requires the active intervention by governments.[26]

The authors note that the ability to extend coverage to certain groups has been a bottleneck in many countries with contributory systems of UHC. These groups include the self-employed and smaller unregulated firms in Germany, and the previously uncovered– especially the poor – in underserved rural villages in Japan, Korea and Thailand. In all of the above instances the governments intervened actively in order to drive the attainment of UHC.[2]

The next prerogative that the Health Coverage and Health Outcomes Final Report (Paris, 22 July 2016) alluded to, was a need for UHC because of the ageing populations. The report stated that the rate at which populations age has recently accelerated in many emerging economies such as in Asia and elsewhere, and this is likely to increase further over the coming decades. The report stated that while on average OECD countries took 63 years to double the share of the population aged over 65, BRICS countries (Brazil, Russia, India, China, and South Africa) will take only about 20 years, with the global average being 42 years. This also means that fewer and fewer working-age people will be able to support elderly populations.[26]

The report emphasised the fact that in many OECD countries the inactive pensioner and the unemployed have not been excluded because of health risks, but instead these countries have included policies to exempt welfare beneficiaries from out-of-pocket payments, and set the upper limits for cost-sharing depending on income, age, and case-mix for the disadvantaged population groups, including those with specific diseases and conditions.

These facts call for a more pragmatic approach in unravelling the policy directive to ensure a sustainable funding of the NHI without eroding or even interrupting cover as well as defining the role of private voluntary health insurance. Secondly, consideration and thought should be given to the cross-subsidisation of the elderly or invoking similar policy measures from the OECD countries such as exempting welfare beneficiaries from out-of-pocket payments, setting the upper limits for cost-sharing depending on income and age, and finally case-mix for the disadvantaged population groups including those with specific diseases and conditions.

Discussion

This review on the implementation considerations for NHI in SA described several evidence-based primary findings relevant to the role of leadership and governance, healthcare financing approaches, impact of ideological and financial challenges on service delivery – called political economy – healthcare worker availability, as well as management of cost escalation.

Alongside each of the structural challenges or problems that adversely affect the implementation of the NHI building blocks, the review paper has identified key opportunities that have had a positive impact on the implementation of UHC as observed in other countries that could be explored in the NHI project for SA. These are displayed in Table I.

The White Paper on the NHI goes to great lengths to describe the challenges facing the health system transformation efforts that lie ahead that have to be overcome in order to achieve the NHI objectives.

Whilst the White Paper on NHI (2017) has spelt out the problems faced by SA and set the scene for the legislative framework as well as implementation parameters, there is an unmistakable gap in strategies to address the likely power dynamics emerging within the state itself as well as between the state and the private sector. Additionally, there is lack of clarity about the public and private sectors' institutional arrangements.

Leadership and governance challenges

The findings of the review show that leadership and governance challenges continue to negatively affect the implementation requirements of the NHI. There are two main reasons according

Table I: Structural challenges or problems that adversely affect the implementation of the NHI in SA and key opportunities

NHI structural challenges	Opportunities identified/findings
Leadership and governance	A legislative framework to promote good governance[3] A space for civic engagement[3] Set direction and develop strategies[4] Explicit government policy position on the role of the private health sector[5] Balancing domestic health requirements with universal aspirations[6] Leadership and governance configuration[7]
Healthcare financing challenges	Funding approach is dependent on the context of the country[8] Accountability perspective addressed by transparency in resource management[9] Transparency of funding policies and co-existence of VHI with NHI[10,11,12]
Service delivery challenges	Implementation approach is dependent on every country's local context[15] Understanding and addressing conflict, resistance, and cooperation among stakeholders[16] A clear definition of all role players[16] A clearly defined, policy-informed role of the private sector[5, 18,19]
Health workforce challenges	Prevent talent loss by dialogue with stakeholders[23] Role PPPs to capacitate the production of the requisite healthcare workers[18,19]
Managing cost escalation and overall population coverage	Coverage arrangements must be linked with drivers of cost[26] Identify and prioritise critical areas that should be aligned with political commitment to attain UHC[26]

to the 2011 South African Health Review (SAHR 2011) as to why leadership and governance matters to the health system transformative agenda in SA.[27] Firstly, the efforts to strengthen the health system though primary health care re-engineering and the introduction of the NHI are underpinned by complex policy implementation and place high demands on leadership and governance abilities. The new policies, according to the SAHR 2011, "have generated unexpected and sometimes negatives outcomes", those negative outcomes being:

- throwing up barriers to access rather than removing them;
- resistance to equity-promoting health management action;
- undermining quality-of-care rather than improving resource use efficiency;
- undermining provider-patient relationships rather than strengthening them;
- undermining health provider motivation rather than strengthening it.

Secondly, leadership is required to spearhead the transformation of organisational structures and culture of the public sector to do business in a new way.[27] As for the second challenge – organisational structures and culture – the SAHR (2011) asserts that these often act as a barrier to new policies intended to establish a PHC-oriented health system and promote health equity and human rights.[27] The sentiments expressed by those employed in the public sector at every level are that they work in isolation and there is often a top-heavy and rigid management that imposes conflicting demands.

As a way of ensuring that the health transformation agenda remains on course, the following leadership and governance opportunities have been identified:

i. A requirement by government to ensure that the set up and support of a legislative framework to promote good governance is met.

ii. Government must provide a space for civic engagement for all relevant stakeholders.

iii. Government needs to set direction and develop strategies in collaboration with all relevant stakeholders.

iv. Government needs to be explicit about its policy position on the role of the private health sector.

v. Government need to balance domestic health requirements with universal aspirations.

vi. Government needs to ensure that there are appropriate leadership and governance configurations.

Exploiting the above opportunities will ensure that the challenges often experienced with policy implementation and challenges to organisational structures and culture are overcome.

Healthcare financing challenges

The healthcare financing challenges have been elucidated in a number of studies.[10,12,13,14] Those challenges were identified as:

i. The role of VHI, private medical insurance in the face of quality differences between the private and public sector.

ii. VHI has increased inequities in access to health care – the GEMS study.

iii. The future role of VHI.

iv. NHI being unaffordable since it is going to impose an additional tax burden on the middle class.

In the main, these healthcare challenges are an expression of a dire need to achieve the goal of strengthening the healthcare system in order to achieve equity in health care. This should strengthen the political commitment to forge ahead with the health-sector reforms which are triggered by pressing health financing issues and the need to strengthen the foundations of primary health care.

The opportunities identified align with the two stated features of the NHI. Firstly, progressive universalism where all South Africans will have access to much needed promotive, preventive, curative, rehabilitative and palliative health services that are of sufficient quality and are affordable, without exposing them to financial hardships.[1] Secondly, financial risk protection where individuals and households will not suffer financial hardship and/or not be deterred from accessing and utilising needed health services.[1]

There is therefore a need to ensure that there is a clear policy position on the future role of VHI or private medical insurance in the NHI environment, the level of care that NHI beneficiaries will be eligible for, as well as clarity on the utilisation of the tax regimen to fund the NHI.

Service delivery challenges

The challenges with regard to service delivery were identified as:

i. Whether the DHS could provide service availability, given the well-known inequities between districts with respect to population health status in the NHI.
ii. Finding the right balance of cooperation and collaboration between the private and public sectors.

The review findings are that certainly the DHS has been the backbone of every healthcare system in Africa and for SA since 1997. The stated goal for the DHS model in SA is that healthcare services are organised and coordinated at a local level using decentralised, area-based and people-centred approaches and this approach is seen as central to the SA context.

Consistent with other studies, the findings of this review are that the DHS model is dependent on a collaborative district development requiring a shared vision by participants,[28] hence the need to capitalise on the opportunity to "have a clear definition of all role players" and "cooperation among stakeholders".

A study by Tshabalala et al. (2023) highlights the sentiments that have an adverse impact on the realisation of the goal of the DHS. They state that fragile governance arrangements and functionality, fraught intergovernmental relationships (IGR), peripheral community participation or accountability, and resource constraints and contestations impact negatively on a functional DHS model. These need to be addressed to enable SA to benefit "by understanding and addressing conflict, resistance, and cooperation among stakeholders".

Health workforce challenges

The review found that there is no mechanism for health workforce policy dialogue and planning. In addition, appropriate monitoring and financing mechanisms need to be established.

The study by Kai Hong Phua (2017) addresses the role of PPPs' ability to bring the good attributes of the public and private sectors together and accordingly this will aid in solving the health workforce challenges.

If SA were to adopt the lessons from other countries, the talent loss could be prevented since the policy dialogue with the health workforce would mobilise a political commitment. The "right mix of skills" will be achieved where there is strong public and private sector cooperation in the form of PPPs.

Other aspects related to healthcare financing challenges – managing cost escalation and overall population coverage

The challenges identified are: (i) the management of cost escalation without eroding cover, and (ii) overall population coverage. The literature review pointed to the fact that countries found unique, country-specific ways of managing the cost of covering the vulnerable groups, the poor, previously uncovered, self-employed and those living in underserviced communities. These social determinants match those in SA and hence the identified opportunities could be exploited to achieve coverage of those vulnerable groups and manage cost escalation without compromising coverage.

Conclusion and recommendations

This review paper explored how other countries have managed the challenges that had a bearing on the implementation and achievement of the NHI objectives of providing quality health care to all without exerting undue financial pressures.

It further highlighted how the challenges that were identified were matched with opportunities, which, if exploited, could assist SA in overcoming its challenges and attaining the NHI objectives.

Addressing the NHI financing issues, the imperative is to protect people from the financial consequences of ill-health, paying for health services, and finding ways to encourage the optimum use of available resources. The study also contributes to the discourse of health system governance.

Further research to interrogate the opportunities identified to formulate a detailed implementation framework that will contribute to a coordinated roll-out of the NHI needs to be undertaken. The research should enable the stakeholders to find ways of exploiting the opportunities in a systematic and well-coordinated manner.

Conflict of interest

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Factors that hamper the effective implementation of the building blocks for National Health Insurance in South Africa

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Abstract

Background: The National Health Insurance (NHI) project requires a clear understanding and appreciation of the collaborative efforts expected from all stakeholders and a clear policy perspective that identifies the role of all stakeholders and aligns them to the objectives of the programme.

The objective of the study was to investigate the factors that contribute to the inability of the health system to effectively and sustainably implement the six NHI building blocks: (a) Leadership and governance; (b) Healthcare financing; (c) Health workforce; (d) Medical products and technologies; (e) Information and research; and (f) Service delivery.

Methods: An exploratory, qualitative study design was used to investigate and describe these factors. This took the form of focus group discussions where a semi-structured questionnaire was used to collect the data for this research. There were five focus groups with participants varying from three to five depending on their availability. The participants were from health statutory bodies, voluntary bodies concerned with healthcare issues, medical aid schemes and medical aid administrators.

Results: Five themes and their attendant sub-themes were identified. These were found to embody the contributing factors to the inability of the healthcare system to sustainably and consistently implement the NHI building blocks. The sub-themes provided the detailed and pertinent areas where appropriate intervention needs to take place in order to ensure that the NHI project is a success.

Conclusion: The study suggests five key considerations to enable the effective and sustainable implementation of the NHI building blocks. These align to similar findings in related studies undertaken in low- to middle-income countries.

Keywords: healthcare reform, health policy, health insurance, stakeholders, public/private, policy implementation, public health, government, private sector, health financing

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Introduction

The end state of the South African (SAn) healthcare system is to ensure it is accessible and equitable and does not place undue financial pressures on the population, this is articulated in the provisions of the National Health Act (Act 61 of 2003: National Health Act, 2003), White Paper National Health Insurance (NHI).[1] This is echoed in the World Bank articulation of Universal Health Coverage (UHC) as a sustainable development goal.[2]

The White Paper singles out the fragmentation in funding pools as a major characteristic of the SAn health system. This is also one of the main thrusts of UHC as defined by the World Health Organization (WHO). The WHO states that UHC means that all people have access to the full range of quality health services that they need, when and where they need them, irrespective of financial hardship.[1] It is for this reason that SA envisions that the implementation will result in a significant and better spread of the economic and social benefits to the SAn population. The envisaged benefits, amongst others, include improved financial risk protection, reduced fragmentation in both funding and provisioning of health services in both the public and private sectors, reducing inequities and improving access to quality healthcare.

The introduction of UHC in the form of NHI, as it is known in SA, is informed by the disparate conditions which exist between the private and public healthcare sectors.[3] As part of the health transformative process, the National Development Plan 2030 (NDP 2030) also incorporated the implementation of the NHI which outlined the objectives of the NHI. The objectives seek to address access to health care by all inhabitants whilst considering right level of care, quality, and affordability. The phasing in of the NHI, with a focus on upgrading public health facilities, producing more health professionals, and reducing the relative cost of private health care is one of ten critical action points of the national development agenda or policy.[4]

Given this context, which includes the policy prioritisation and enormity of the challenges engulfing healthcare, it comes as no surprise that aspects considered to be structural problems in the healthcare system were identified in the NHI policy document.[1] Weighing in on all of this is a legitimate concern about whether SA will successfully transition to an NHI programme given its existing financial, operational, and institutional challenges.

Hence this study aimed to interrogate the factors influencing the structural problems in the key building blocks in the implementation of the NHI in South Africa.

Study design, setting, population sampling and sampling size

An exploratory, qualitative study design was used to examine and define the factors influencing the mutual understanding, buy-in and cooperation levels of affected stakeholders in the SAn setting for the implementation of the NHI. It was necessary to employ a qualitative research approach in order to capture the essence of how the participants feel about the NHI project and to document their experiences regarding the factors influencing the NHI implementation pillars as described in the NHI White Paper (2017). Busetto et al. (2020) in their definition of qualitative research captures this approach succinctly – "the study of the nature of phenomena", including "their quality, different manifestations, the context in which they appear or the perspectives from which they can be perceived", but excluding "their range, frequency and place in an objectively determined chain of cause and effect".[5]

Purposeful sampling was employed to identify the target populations who were the Statutory Health Councils, Regulatory Bodies, Medical Aid Administrators, Medical Schemes and Voluntary Bodies/organisations concerned with health issues. They were identified as leaders in health from an operational, policy and legislation level. The target population was selected on the basis that they are an important and interested stakeholder with the potential of contributing meaningfully to the NHI discourse due to their wealth of experience in the various spheres. In addition, they are at the forefront of the healthcare industry engagements, have a keen interest in the developments around NHI and have the capacity to influence sentiment.

A request for permission and a subsequent invitation to participate in the research was sent to these organisations requesting the participation of the CEO and Senior Management (at least two members per organisation). Five focus group discussions (FGDs) were proposed to accommodate the availability of the representatives from the identified stakeholders. The number in each group was determined by the responses received. Thirty invitations were sent out to senior management accompanied by a letter of introduction explaining the study. On receiving senior management's permission, a further letter of introduction and an informed consent (IC) form was sent to the representatives that were identified by the organisation to participate. Invitations to participate in the focus group discussions via the Microsoft Teams™ platform for the five sessions were sent to all representatives that signed the IC form. Table I below shows the number of participants invited per organisation type and the number of participants who accepted the invitation to participate in the FGDs. Care was taken to have only one person per organisation in the focus group meetings in order to avoid dominance of views from one organisation as well as avoid group-think as far as possible.

The size of the sample was determined by the responses received as per Table I.

Table I: Number of FGD invitees and participants per organisation type

Focus group #	Organisation	# Invited	# Participated
Focus group 1	Statutory councils	1	0
	Voluntary professional associations and industry representative organisations	3	3
	Medical aid schemes	2	0
	Medical aid administrators	1	0
Focus group 2	Statutory councils	1	0
	Voluntary professional associations and industry representative organisations	2	1
	Medical aid schemes	2	2
	Medical aid administrators	1	1
Focus group 3	Statutory councils	2	2
	Voluntary professional associations and industry representative organisations	1	0
	Medical aid schemes	2	1
	Medical aid administrators	1	0
Focus group 4	Statutory councils	1	1
	Voluntary professional associations and industry representative organisations	2	2
	Medical aid schemes	1	0
	Medical aid administrators	2	1
Focus group 5	Statutory councils	0	0
	Voluntary professional associations and industry representative organisations	2	2
	Medical aid schemes	1	0
	Medical aid administrators	2	2
Total		30	18

number

Data collection tool and procedure

Five focus group discussions were held over a period of about two weeks from 25 November 2021 with the last focus group discussion held on 6 December 2021. Focus group discussions were conducted on-line via the Microsoft Teams™ platform. The same semi-structured questionnaire was administered to the five FGD to collect the data for this research. The questionnaire had an introductory section that introduced the researcher, reminding the participants of the consent that they have given earlier in writing as per the introductory letter and informed consent letter sent to them. The participants were informed that the FGD was to be recorded and that the recordings were to be used to report the results, upon which consent was obtained from all. The objectives of the study were reiterated. The questionnaire consisted of questions that sought to elicit the response of the participants on the following issues:

1. Leadership and governance – policy to ensure there are appropriate controls and accountability.
2. Healthcare financing – strategies to get more value for money.
3. Addressing the health worker shortage and improving the performance of healthcare workers.
4. Finding the right mix of policies that help contain unnecessary cost growth without eroding coverage.
5. Service delivery coverage.

It is important to note that for each question that was asked, direct quotes from the participants are given after each theme. The attribution of the direct quotes to the participants is identified in square brackets as [Participant and a numeral, FGD and a numeral], where, for example, [Participant 1, FGD 3] refers to a quote from Participant 1 who was in Focus Group Discussion (FGD) 3. In addition, a summary or overview of the themes is provided as an introduction to the responses to each of the questions. Direct reference to study participants has been expunged.

Data analysis

The focus group audio recordings were transcribed and NVivo™ (A qualitative data analysis (QDA) computer-aided software) was used to analyse the data collected. To bring order, structure and meaning to the mass of data collected, a qualitative data analysis approach was taken.[6] Since the author was working with semi-structured interviews (where participants are asked the same set of questions), the heading style on Nvivo™ was used to automatically organise the responses. The responses were gathered per question in one place and auto coded into themes.

In order to see the connections between themes and move toward analytical insight, a list of codes was developed. At regular intervals, the list was groomed – checking whether related themes could be grouped together in a hierarchy.

Trustworthiness

The researchers adhered to the criterion to develop trustworthiness namely transferability, dependability, confirmability, and credibility.[7]

Transferability of the study[7,9] – the capacity of the findings to be applied in another context – was enhanced by using a purposive sampling method and providing a thick description of the sample requirements and how the participants were selected. To achieve dependability the research design and methods were clearly articulated to ensure that other researchers can replicate and reproduce the study.[7,9]

Confirmability of the research was adhered to to ensure that the researcher was unbiased.[6,7-9] To achieve credibility of the research, the researcher adhered to the documented research design and methods.[9] The participants' responses were transcribed from the recordings by an independent scribe. The independently transcribed responses were subjected to Qualitative Data Analysis (QDA) computer software for analysis out of which the themes were auto generated.

Results

This section provides a detailed analysis of the main themes and sub-themes that emerged based on the interrogation of the six health system building blocks, these being: (a) Leadership and governance; (b) Healthcare financing; (c) Health workforce; (d) Medical products and technologies; (e) Information and research; and (f) Service delivery as identified in the NHI White Paper (NHI 2017).[1] According to the NHI White Paper, the challenges facing the healthcare system, including the high burden of disease, are to a large extent, the inability of the health system to effectively implement these six health system building blocks.[1]

Table II depicts the themes and sub-themes which were found to embody the contributing factors to the inability of the healthcare system to sustainably and consistently implement the NHI building blocks. The subthemes provided the detailed and pertinent areas where appropriate interventions need to take place.

Committed political leadership

Based on the responses that were given, the participants are of the view that political leadership should be the overarching aspect to drive the performance of the healthcare system supported by managed care and healthcare administration. Others are of the view that the spectrum of stakeholders, including the medical aid administrators and the service providers must be part of an expert committee to drive healthcare innovation.

"One, the political aspect is important but of most importance is that one of the managed care organisations and an administrator to be put into the fold so that they're responsible because the political aspect looks at overarching aspects but does not get to the details." [Participant 1, FGD 2]

Still others see a need for closer collaboration and communication between subject matter experts and other stakeholders to bolster the political leadership to drive healthcare performance. As one of the participants puts it:

Table II: Themes: Factors influencing structural problems in the key building blocks for NHI in South Africa

Theme	Subtheme
Committed political leadership	Performance of the healthcare system. Closer collaboration and communication. Need for diverse skill contribution (both bureaucratic and technocratic). Source of expertise for implementation. The management of resources for public education about the NHI.
Continuity of leadership	Changes in leadership disrupt the speed of implementation. Conflicting priorities might lead to deviation on policy approach.
Stakeholder involvement, engagement, and policy socialisation	The controversies and uncertainties that surround the way in which policy makers intend to deal with medical schemes. Historically, policy issues were not sufficiently socialised with the stakeholders leaving the population at the mercy of unscrupulous healthcare professionals.
Implementation capacity and capability	Both positive and negative signs on policy-design and implementation. Failure to implement due to a lack of relevant human resources – specialists in those specific areas. Lack of interdepartmental collaboration to address the basic determinants of health.
Service delivery mechanism	A hybrid approach to a centralised and decentralised approach will assist the ability to deliver healthcare services.

"There is the need for multiple stakeholder engagement to enhance all perspectives, which range from political which has to deal with issues of technical elements that can lead to the success of NHI." [Participant 2, FGD 2]

The participants are of the view that no single layer of government would be able to pull off the challenge of the healthcare reforms from conceptualisation to implementation despite the best political will. The need for diverse skill contribution is echoed by several participants as evidenced by the following quotes:

"The technical elements would involve things like actuarial models, manage healthcare models which needs technical expertise." [Participant 2 FGD 2] and

"Those stakeholders that you've outlined will possess very specific and expert skills that would contribute to the policy as it were." [Participant 1, FGD 4] and

"Well, at a political level, there is a clear prerogative, the role of these subject matter experts, and stakeholders, the voices, and the collaboration becomes quite important, and I think that speaks to the statement that you're making." [Participant 3, FGD 4]

The participants indicate that the expertise for implementation lies with the stakeholders, being the healthcare providers who are the people who know the industry and have the detailed knowledge and in instances institutional knowledge of the healthcare operations. They think that it is important to have more people who are at the coalface of implementation, both in the public and private sectors, to be part of the dialogue, since they have many years of providing healthcare services to the population, as stated by one of the participants:

"And we need to have more coalface people into these discussions, bring them in to help with a way forward than having only politicians. The political leadership above, as you know, haven't been in private practice for many years or even in public sector in a role where they service the patient." [Participant 2, FGD 5]

The participants express a view that there is a need to translate policy, as expressed in the NHI bill, to a more technical document to enable implementation.

Implementation capacity and capabilities

Based on the responses that were given, the participants are of the view that SA is making sufficient progress in the design and implementation of policies within specific SAn context that will facilitate the implementation of the NHI when compared to other sub-Saharan countries with strong governments. The participants note that several Southern African Development Community (SADC) countries have looked up to SA on the implementation of several initiatives in health care. Those initiatives include pharmaceutical service policy, as one respondent stated:

"So, in a way if I used pharmacy as an example, I think we do well, and I'm saying so because we got a number of visits in the SADC countries coming to us to check on how South Africa is looking at pharmaceutical services." [Participant 1, FGD 1]

The participants are of the view that whilst the policy conception and design might be impeccable, the challenge is in the implementation, as was the case with the policy to improve access to pharmaceutical services, as one participant stated:

"A simple example, an opening of ownership of pharmacies, the intention was to create more pharmacies where there is no access to pharmacy services and what happened is we have actually got a bulk majority of pharmacies now in shopping malls and certain areas and less pharmacies in more rural areas." [Participant 3, FGD 1]

The participants also feel that though there is clear engagement and or consultation process on policy making, the policy makers often implement without due consideration of the inputs, and the feeling is:

"They did not have an open mind, you kind of felt, it's a tick box exercise." [Participant 1, FGD 1]

Yet other participants attribute the failure to implement to a lack of relevant human resources – specialists in those specific areas.

The participants note the need for dialogue, adequate consultation, open mindedness, and deployment of adequate skilled resources in public policy formulation and implementation as key in the implementation of the NHI.

Continuity of leadership

The participants are of the view that for the NHI project to remain on course, there must be continuity of leadership. Their view is that though leadership changes can take place due to normal democratic processes, policy should not change. They view such changes as stalling the implementation of policy initiatives such as the NHI. One participant said:

"So, if we had a strong proponent of National Health Insurance, and he's a president and he could be there for longer like some of the presidents north of Limpopo, then maybe, then there would be a better success." [Participant 4, FGD 2]

Another aspect of leadership discontinuity is also seen in the change of provincial and national health leadership as soon as there is a new political boss, or even as a result of complete change in a ruling party as was experienced in the 2021 local government elections where the governing party was unseated in major cities which might affect the NHI project. A participant stated:

"And I also completely want to agree that this business of having provincial and national health leadership sort of changing at the whim of the politicians is the biggest part of our problem, because there isn't that continuity in thinking and planning and coordination of implementation." [Participant 4, FGD 4]

This sentiment even goes as far as the 2024 national elections where they say we might have coalition governments and maybe even a coalition president which further derails the NHI project. A respondent said:

"People are already thinking that in 2024 we will have a coalition government; some are even bold to say we may have a coalition president." [Participant 1, FGD 1]

On the flip side, the participants are also wary of a situation where an individual stays in a position for a long time, to the extent that they might believe they own the NHI project.

Given the endless list of possible deviations or changes to the policy, the participants are of the view that the NHI task team, or structure put together to formulate policy, retain a composition that ensures institutional memory.

One participant said:

"So political leadership probably still needs to be there to provide the political strategy in terms of what the countries but I think there should be fundamental policies and guiding principle that would go beyond the politics and that needs to be driven by the technocrats, behind the scenes." [Participant 1, FGD 4]

Stakeholder involvement, engagement, and policy socialisation

The participants acknowledged that a lot of work has been done to enable the healthcare reforms, however they are quick to point out the controversies and uncertainties that surround the way in which policy makers intend to deal with medical schemes, as one participant retorted:

"The answer is no. So, if you just think, the whole issue of the role of medical schemes, how controversial and uncertain it was from the time the policy document came out." [Participant 4, FGD 2]

Specifically on the role of the medical aids, the participants feel that the policy makers just assumed that medical aids are going to disappear, and everybody will move to NHI, and all private sector infrastructure and resources will just fall under NHI, as pointed out by one participant:

"I actually want to say I think I get the feeling that no consideration was actually given in the drafting of the NHI bill on the existing entities. It was as if they just assumed all the medical aids are going to cease to exist, everybody's just going to move to the NHI fund and all the private sector suppliers, hospitals, doctors, whatever, are all just going to fall under NHI." [Participant 3, FGD 1]

The participants seem to point to a further deepening of the confusion around the future role of medical aid schemes.

The participants see these as more reasons for the provider/patient intervention mechanisms to be socialised with the relevant stakeholders. This, coupled with adequate compensation to ensure fairness in the process, is seen by participants as ensuring there is no exploitation and abuse of funds in the supply of services.

Service delivery mechanism

The participants noted that the decision on the approach of whether to centralise or decentralise the policy development and implementation initiatives for the NHI, will be context specific. They are of the view that the government is correct in their approach to centralise the funding of the NHI. They also think a centralised approach will assist in the delivery of healthcare services, since national government will be the central purchaser and as such has the ability to utilise scale and procurement power, as is evident in the procurement of medicine, especially HIV medicine.

To make the point, one participant cited the roll-out of the COVID -19 vaccination as follows:

"And I think if implementation of the vaccine was centralised, then I think we would have been in a worse position because we would have had probably a more generalised approach and wouldn't have been able to accommodate the specific underground issues that require a tailored solution and addressing a more targeted approach within the different regions." [Participant 3, FGD 4]

And another one said:

"So, if you were to be able to do this, I probably would be leaning towards more of a centralised approach with the strengthening of the municipality, at that level basically to be able to deliver." [Participant 1, FGD 4]

Still other participants believe that there is a need for a middle ground where government's role becomes that of centralised planning to ensure that all requirements are planned for on the one hand, and on the other hand the efficiency and infrastructure endowment of the private sector is utilised.

One participant said:

"And I think that's something if we do go decentralised, we must make sure there is written in steps and ways where National can step in and say this one is not functioning as a decentralised entity correctly and somebody should take charge." [Participant 3, FDG 1]

They also note that the country would have been in a worse position concerning the COVID-19 vaccination drive if this was centralised because it would have failed to recognise the implementation nuances at local level.

The participants go further to suggest a hybrid model where centralisation needs to happen with regards to management and policy making, and more accountability be devolved to the local level.

One participant said:

"So, this top-down approach of policy being drawn at high level and suddenly we expect that things will somehow happen at local level, I think has been a huge problem." [Participant 1, FGD 5]

Thus, the participants believe that the people on the ground (implementation level) should be empowered with the knowledge, and expertise – as well as being given adequate authority to run the project.

Discussion

Political leadership emerged as one of the major issues that has an impact on the delivery of UHC in the form of NHI in SA. In effect, for the NHI project to be successful, it must be embraced as a political goal, a view held by the World Bank,[10] espoused by Palu and Inden (2020) in World Bank Blogs,[11] and shared by Japan at the summit of the Group of Seven (G7) industrialised nations.[12,13] Leadership, and in particular political leadership, was identified as a major issue that will drive the performance of the envisaged healthcare system, guide the context for closer collaboration and communication among stakeholders and ensure that there is a recognition of diverse skills (bureaucratic and technocratic). This statement is supported by a number of studies, notable amongst those, an article by Witter et al. (2022) who stated that leadership and management are recognised as important enablers for improving programme performance, strengthening health system capacity, enhancing connections with target populations, increasing the ability of health systems to respond effectively to change and, at a high level, achieving country ownership of health policy goals.[14] This fact is attested to by Venkateswaran et al. (2022) where they assert that the drivers for universal health coverage go beyond the macro-economic context of a nation and the availability of solutions but the extent of political attention and prioritisation in influencing progress on health.[15] A World Bank press release on a study of low- to middle-income countries alludes to strong political leadership and long-term commitment as key policy messages for successful UHC adoption and expansion.[16]

This led to another theme that the participants referred to, that being the disruption in continuity of leadership which was seen as a co-contributor in slowing down the speed of implementation. The participants pointed out that conflicting priorities might lead to deviation on policy approach. This has been asserted by Venkateswaran et al. (2022) where they posit that attention by political leaders and policy makers increases the probability of policy reforms and that public investments are needed for progress on health reforms.[15]

Implementation capacity (including scaling up the health workforce) and capability along with participatory governance and responsive governance legislated in UHC policies, and sustained commitment to the policies, are important in ensuring UHC meets citizen health needs and sustainable UHC.[17] Viroj et al. (2019) argues that the early expansion of a strong public primary healthcare (PHC) system in Thailand set the foundation for future scale-up of UHC.[18] The participants lament failure to deploy available specialists in those specific areas, this against study findings stating that evidence-based human resources for health (HRH) policies and plans are critical in guiding the actions of the various actors towards achieving UHC and the Sustainable Development Goals (SDGs).[19]

The ingredients of responsive governance, a key goal for a health system, requires public participation and engagement in decision-making to improve public services, patient satisfaction, increase utilisation and compliance to treatment, with an overall contribution to better health outcomes and well-being of the population. The stated outcomes are unlikely to be realised in the SA context given the still lurking controversies and uncertainties over the way in which policy makers intend to deal with existing institutions providing healthcare services as private administrators, medical aids, etc.

On the ideal delivery mechanism for the healthcare services through the NHI, the participants agree that a hybrid approach of a centralised and decentralised governance policy will be ideal. This includes the utilisation of the existing private sector infrastructure and resources. This is consistent with the WHO undertaking that they will support member states to strengthen governance of mixed health systems and assure alignment of the private sector for UHC, to promote equity, access, quality, and financial protection for the population.[20]

Strengths and limitations of the study

The views of the participants expressed are of a systemic nature and can therefore be applied to the form and shape that the NHI project will take by similar communities.

The researcher obtained a large enough sample size, representative of the affected and relevant stakeholders and we believe that these views can be replicated in a similar sample.

However, the limitations could be related to the responses provided by the participants who may have been influenced by their specific contexts, various organisations' stance or position on elements of the implementation of the NHI and may therefore contain some bias.

Conclusion

The study revealed that though there are glaring gaps in addressing the building blocks for NHI in South Africa, the participants representing relevant stakeholders are keen to make a positive contribution for the success of the NHI project.

Their responses confirm their genuine concerns, highlighting clear precedence of where successes in projects of a similar nature to the NHI has been achieved. The paper suggests that acknowledging and taking on board existing capacity and capabilities, participatory governance and stakeholder engagement, as well as suited service delivery mechanisms, are key to addressing the NHI building blocks. Commitment and continuity in political leadership is viewed as an absolute necessity to maintain the impetus to achieve NHI. This conclusion aligns to the key policy messages arising out of related studies and commentary on countries that are in the process of implementing, or have implemented some form of NHI.

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Conflict of interest

The authors state that they have no conflict of interest, financial or personal affiliations that might have affected their decision to write this paper.

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Ethical approval

Approval for the research study was obtained from the University of KwaZulu-Natal's Humanities and Social Sciences Research Ethics Committee (HSSREC). The Ethics approval reference number is: HSREC 00002565/2021.

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SEE-SAW – what was, what is and what will be

Nhlanhla G Mafarafara
President, SAAHIP

I often refer to John Maxwell's famous quote, *"everything rises and falls on leadership,"* because I believe it is a timeless principle that every organisation that's about sustainability, growth and impact ought to embrace. The practice of pharmacy is built on ideals of our past leaders, embraced by those of the current generation who will pass the legacy to the next generation. Every generation of leaders writes the past for the next generation. It is up to the leaders at any given moment to ensure that the next generation does not suffer. This three-generation view is a statement of responsibility and accountability that has been passed from different leaders through time and shall continue to be so**.** I want to highlight four pivotal issues that, in my view, will necessitate collaborative leadership efforts.

Unemployment

Just over a decade ago, a pharmacy student would graduate and have three to four internship opportunities and go on to complete community service that concludes with multiple offers. Never in my life did I imagine that a pharmacist would struggle to find employment. Recently, graduates in different fields of health struggle to find entry level jobs. The impact is dire. And this story needs to change for the better. Several countries struggle with this challenge.

Harmonisation of Pharmaceutical Services

South Africa's healthcare system grapples with many challenges that have been almost the same since years past. From shortage of pharmacists to shortage of medicines, poor infrastructure to different practice systems in all provinces and different applications of practice models. Every province has its own unique challenges, but there remain certain pockets that could potentially be made uniform in some way. For example, reengineering of primary healthcare is a government policy initiative that seeks to improve systems and practice in the delivery of healthcare services in PHC, however the country is still far from reaching its objective in this area.

Some provinces have district pharmacists tasked with the governance of the systems at district level, some have sub-district and cluster PHC pharmacists who manage quality systems, distribution of medicines, monitor compliance with standards, implement patient safety systems and dispensing of medicines, while other provinces do not. Other provinces have invested heavily in hospital pharmacy governance by employing managers and supervisors according to level of care, while in some areas, the pace is slow.

It is important to note that in the area where there is high patient volumes, open dispensing and consumption of information, there is a need to invest, as a country, in the placement of highly skilled pharmacists across all the pharmacy practice areas to ensure safe and effective use of medicines, patient safety and up-beat implementation of policies.

Nhlanhla G Mafarafara

Application of Basel Statement

The Basel Statements were created in 2008 and revised in 2014 and reflect the vision of Hospital Pharmacy practice. The Basel Statements are used to improve Hospital Pharmacy practice around the world using the Basel Statement Assessment tool and provides a set of policy directions for the future of hospital pharmacy to remain relevant as ideal standards in all World Health Organization (WHO) regions. These statements cover seven best practice areas: procurement, influence on prescribing, preparation and delivery, administration, monitoring of medicines use, human resource training and development, and some overarching and governance statements. The Basel Statements have been used worldwide and offer valuable insights into safe systems in pharmacy. Hospital pharmacists can access the Basel-statement self-assessment tool on the FIP website (https://www.fip.org/basel-statements).

The realisation of these ideals requires effort, financial resources, time, and commitment from different stakeholders. South Africa has the potential to set a benchmark in the African region by making advancements in this domain, given the resources available. The Basel Statements were last updated in Bangkok in 2014.

Patient Centred care

The world is moving from a disease centred care to patient centred care. Among the many lessons that were delivered during the FIP World Congress in Brisbane, patient centred care is one that fits this topic currently (see Figure 1 below). It is suggested that systems and plans move towards patient centred care.

The next steps

There is more work to be done. In the next few months, SAAHIP will embark on internal work to realign our strategies with current

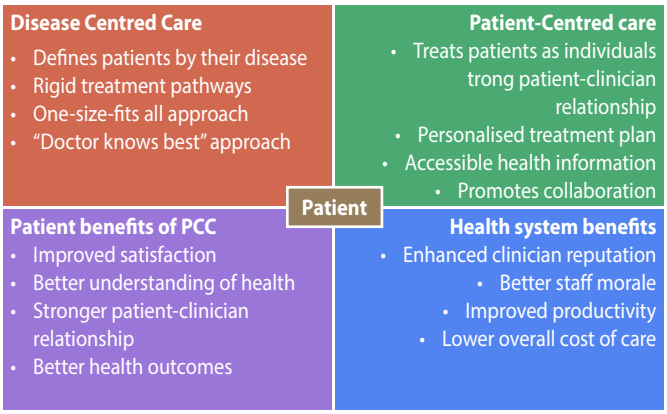

Figure 1: Patient Centred Care[i]

Susan Cheng. 2023. Designing patient centered digital models of care. Presented during the FIP World Congress, Brisbane (23 September 2023)

demands. Hospital pharmacy remains a critical component in the delivery of healthcare with the bulk of patients passing through the hands of a hospital pharmacist every working minute. Our efforts should embody the desired holistic improvement of the systems that deliver the service, the service delivery pathways, the personnel who deliver the service and the patient. The shortage of personnel, inequalities in the system and non-application of scientific evidence guiding planning, resources allocation and delivery of care is evident when looking at time movement and see stagnancy over events.

Over and above, pharmacists should make themselves available to lead in designing the system they desire to operate in. There is a need to strengthen collaboration, inter-stakeholder/shared valued communication and systems redesign and synchronised movement. The solutions we desire will not come when we call, they will come when pharmacists take the burden of conceiving, growing and birthing the innovation they desire, jointly.

Application of Basel Statement in South Africa: lessons from Brisbane and the world

Nhlanhla G Mafarafara, Michael Stepanovic, Stephen F Eckel

Introduction

The Basel Statements are a set of hospital pharmacy practice standards developed by the International Pharmaceutical Federation (FIP) Hospital Pharmacy Section (HPS) to reflect the global pharmacy profession's preferred vision of practice in the hospital setting and serve as a resource for pharmacists, departments of pharmacy, and pharmacy organizations to ensure the collective group of hospital pharmacists are working toward a shared vision.

The Basel Statements were birthed in a historic two-day-meeting of FIP-HPS in 2008 during the inaugural Global Conference on the Future of Hospital Pharmacy in Basel, Switzerland.[1] During the time, 75 statements were adopted and reflected the vision of hospital pharmacy practice globally. The statements have since gone through a major revision process known as the "Bangkok Updates" in 2014 at the 74th FIP World Congress in Bangkok, Thailand resulting in 65 statements organized as we know them today:

- Overarching and Governance Statements
- Theme 1: Procurement
- Theme 2: Influences on Prescribing
- Theme 3: Preparation and Delivery
- Theme 4: Administration
- Theme 5: Monitoring of Medicines Use
- Theme 6: Human Resources, Training and Development

In September 2023 at the 81st FIP World Congress of Pharmacy and Pharmaceutical Sciences, the FIP-HPS hosted a Basel Statement Update Workshop with the dual aim of ensuring the Basel Statements remain relevant in the practice of hospital pharmacy in all World Health Organization (WHO) regions and developing implementation guides for enhanced utilisation of the Basel Statements worldwide. This workshop drew a diverse audience of experts and professionals from all WHO regions who were eager to engage in insightful discussions and activities to maintain contemporaneity of the Basel Statements and explore ways to utilise the Basel Statements in their respective countries. The workshop served as the final phase of a four phase FIP-HPS project to update the statements. The four phases were designed to achieve the project aims through creation of the "Brisbane Updates" to the Basel Statements:

- Phase 1: Gap Analysis and Document Mapping
  - Goal: Map the Basel Statements to the FIP Development Goals, FIP Global Competency Framework, FIP Global Advanced Development Framework, FIP Statements of Policy, hospital pharmacy association statements, and WHO supporting documents.
- Phase 2: Analysis and Verification of Gaps
  - Goal: Identify gaps in Basel Statements based on document mapping in Phase 1, identify gaps in hospital pharmacy association statements, and member checking gaps with organisations to confirm findings of gap analysis.
- Phase 3: FIP-HPS Membership Survey
  - Goal: Understand how the membership is using the Basel Statements and what changes are desired.
- Phase 4: Basel Statement Update Workshop & Finalizing Brisbane Updates to the Basel Statements
  - Goal: Gain consensus from workshop attendees through discussion and activities on the Brisbane Updates to the Basel Statements and utilise the consensus building approach to develop implementation guides for the three most utilised Basel Statements.

Evidence-based practice has supported the adoption, implementation and use of the Basel Statements as a source for policy direction and practice standards in an ever-changing healthcare environment.[2,3] The statements are universally relevant and provide a scientific context to maximise the value of hospital pharmacists in delivering care for the wellbeing of patients.[4] In a review paper published by the Canadian Journal of Hospital Pharmacy, Panm, *et al* (2016) shows that Basel statements have led to multiple initiatives in more than 70 countries with most initiatives happening in European and Western Pacific regions.[5] This report shares insights into the workshop, the FIP-HPS strategic direction, and South Africa's need for alignment in light with existing evidence.

Brisbane Updates to the Basel Statements

During the Basel Statement workshop on 24 September 2023 in Brisbane, the FIP-HPS reiterated their mission, to advocate and support full utilisation of hospital pharmacists and support staff's expertise for the benefit of people and healthcare systems. This mission is delivered through four strategic goals, one of which is establishing standards for hospital pharmacy practice and workforce, underpinned by patient safety. Attainment of this goal relies on the consistent maintenance and promotion of the Basel Statements.

The foundation for achieving this goal is a comprehensive understanding of the Basel Statements by pharmacists as a reflection of the global pharmacy profession's preferred vision of practice in the hospital setting. These statements serve three main purposes:

- To set standards for hospital pharmacy practice and workforce (Basel Statements) underpinned by patient safety.
- To serve as a resource for pharmacists, departments of pharmacy,

and pharmacy organisations to ensure the collective group of hospital pharmacists are working towards a shared vision.

- To propel international initiatives to support and develop hospital pharmacy.

While this vision holds the potential for an ideal global hospital pharmacy practice, some hospital associations in certain countries do not include the Basel Statements in their strategic objectives. The workshop served as a platform to re-emphasise these statements to both FIP members and member states, driving the global vision forward. Gap analysis and membership survey results presented during the workshop indicated:

- The necessity for national hospital associations to recognise the Basel Statements to achieve global coherence.
- The lack of alignment of the statements with activities at the country level suggesting the potential need for WHO region specific statements and validating the need for the Brisbane Updates.
- Need for implementation guides to help incorporation of Basel Statements into practice.

A recurring theme in the conversations held during the Basel Statement Update Workshop activities was patient-centred care. Much of the consensus activity discussion also included ways to update the statements related to utilising pharmacists' full clinical expertise, the expansion of specialisations within the pharmacy workforce, and alignment with practice changes since the past update. These discussions and consensus outcomes align with the emerging trends and priorities in hospital pharmacy, as recorded in the FIP-HPS strategic plan for 2022-2027, alongside technology and workforce sustainability and development. At the centre of emerging trends is the utilisation of pharmacists' full clinical expertise, specialisation, stewardship programs, pharmacogenomics, and personalised medicines (see Figure 1).[6]

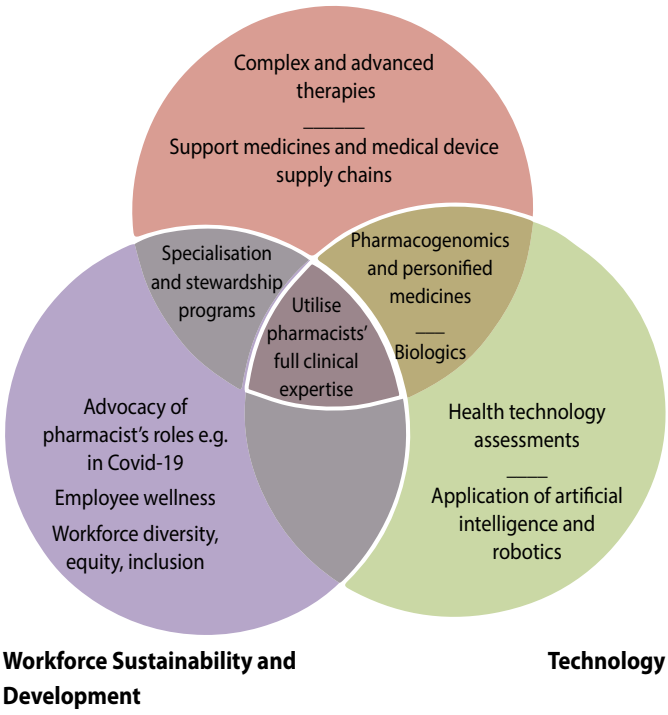

Figure 1: Emerging trends in hospital pharmacy

Alignment of Basel Statements in Africa

Basel Statement alignment is assessed through a four-tier[7] (see Table I) self-assessment tool published by FIP-HPS that puts patient safety at the centre of practice allowing pharmacists to understand how daily activities compare against the Basel Statements. The tier system also considers the advancement in pharmacy practice, availability of resources per facility, training, and support of pharmacy personnel.

Table I: Basel Statement Tiering System

Tier	Description
Zero	Below minimum standards
One	Good Hospital Pharmacy Practice which supports the safety of procurement, preparation, distribution, and administration of medicines no matter the available resources
Two	Clinical service activities which address appropriate use of medicines but do not serve every patient, due to available resources
Three	Best practice, robust clinical services, and integrated information technology systems in place to serve every patient

In a 2020 study conducted at 24 hospitals in Namibia, results show that although pharmacists have a strong desire to take active roles in optimising medicines outcomes and solving public health problems, in alignment with Tier Two and Three Basel Statements, they tend to focus mostly on Tier One statements and associated activities of the Basel Statements such as medicine procurement, preparation, and distribution. Despite this desire, they spend as little as 2% of their efforts on clinical service activities (i.e. Tier Two).[8] In another study conducted at 44 institutions from six African countries, results show a high concentration on activities related to Tier One statements (82%), followed by 71% achievement in Tier Two, and 31% on Tier Three statements.[9]

The South African Association of Hospital and Institutional Pharmacists (SAAHIP) discussed the application of the Basel Statements in South Africa during the 2010 and 2011 annual conferences. Both the conferences raised human resource constraints within the public sector and physician's freedom of choice as opposed to using standardised formularies in the private sector as contributing hindrances to the implementation of the Statements.[10,11] Since then, there has not been a country focused assessment of the alignment between South African hospital pharmacy practices and the Basel Statements.

In 2023, however, the FIP-HPS conducted a global survey of their members to understand how the membership is using the Basel Statements and what changes are desired. Of the 146 submitted responses, 10 (6.9%) respondents were from the WHO African Region. In a WHO AFRO sub-analysis, researchers identified the 10 respondents were from 6 African countries: Cameroon (1), Malawi (1), Nigeria (1) South Africa (5), Tanzania (1) and Zambia (1).[12] The sub-analysis shows that respondents access the Basel Statements 2.4 (SD 2.4) times per

year and 60% (6) said that the Basel Statements reflected contemporary practice. Additionally, the sub-analysis shows that 60% (6) of the respondents plan to utilise the Basel Statements in the next year to assist in implementing innovations at their respective institutions and 20% (2) confirming they have referenced the Basel Statements in the previous year's innovations.

When reporting on how African respondents plan to utilise the Basel Statements by theme for innovations in the next year, the responses are presented below with an exclusion of theme 4 (see Table II).

Table II: Basel Statement use in next year by Theme within WHO region Africa

Theme	Count
Overarching and governance statements	2
Theme 1 - Procurement	2
Theme 2 - Influences on Prescribing	2
Theme 3 - Preparation and Delivery of medicines	1
Theme 5 - Monitoring of Medicines Use	4
Theme 6 – Human Resource, Training and Development	2

While there is a universal agreement that the Basel Statements provide significant tools to advance and standardise hospital pharmacy, participants in the survey had similar recommendations:

- Provision of standardised tools and implementation guides with monitoring and evaluation tools.
- Provision of training on the Basel Statements, including inclusion in undergraduate training.
- A context specific approach for using the tools in low- and middle-income countries.
- Provision of guidance on how the Basel Statements can be applied by pharmacy support personnel.

Conclusion

The Basel Statements remain a progressive tool to guide national policies, provision of ideas for engagement with strategic stakeholders and government, resource mobilisation, and practice specific innovations for provision of accessible and quality patient-centred pharmaceutical care. The South African's proposed National Health Insurance (NHI) also provides a clear-cut opportunity within Tier One of the Basel Statements where medicines procurement is emphasised as one of the critical roles that pharmacists will play. It also offers a new opportunity for higher level specialisation for supply chain management macro-environment.[13] The application of Tier Two and Three both present an untapped specialised opportunity in both private and public sector practice in South Africa. However, the realisation of the ideals of the FIP-HPS as presented in the Basel Statements requires joint efforts, collaborations, and vision-driven advocacy and equitable resources allocation at all levels. There is also a need for nationwide scientific studies on the use of and congruence of Basel Statements in South Africa to be able to formulate local evidence-based opinion for training, resource allocation and practice innovations. With the 82nd FIP World Congress of Pharmacy and Pharmaceutical Sciences coming to Cape Town in September of 2024, we look forward to additional workshops held by FIP-HPS to promote nation and regionwide alignment with the Basel Statements, in addition to focusing on region specific challenges highlighted in the Brisbane workshop. These workshops may then highlight the need for country and association specific workshops dedicated to the development of hospital pharmacy best practice to ensure the provision of accessible and quality patient-centred pharmaceutical care to all patients.

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Pharmaceutical Practitioner

South African Association of Community Pharmacists

Bright future looming for PCDT pharmacists!

Johannes Ravele

PCDT Task Team Chairperson

For many years, Primary Care Drug Therapy (PCDT) pharmacists have been dreaming about the day they would be recognised in the medical arena for the role they play in healthcare and the value they can add to the health system.

PCDT is a supplementary training course accredited with the South African Pharmacy Council (SAPC). The scope of practice, competency standards and accreditation standards were published in Board Notice 384 of 2023, on 27 January 2023. According to SAPC's website, there is currently only one provider accredited to offer the course, namely the North-West University. After successful completion of the course, pharmacists must register the supplementary training with SAPC whereafter they may apply for a Section 22A(15) permit with the Director-General. After the permit has been issued, the pharmacist could apply for a practice number with the Board of Healthcare Funders, to claim consultation fees and prescribed medication through medical aids.

When I finished my studies as a PCDT pharmacist, I was expecting to have the support of a well-established platform for the PCDT pharmacist and to join a network of PCDT pharmacists that already offered the service to their patients and on behalf of medical aids. Great was the shock to find that the field was almost untouched, and we had to find our feet in the bigger picture and prove that the service we can offer is crucial for the primary healthcare setting. The world out there knew nothing about PCDT pharmacists. We had to start from scratch, but if there is one thing I can tell you, without any doubt, it is that starting a PCDT Clinic in your pharmacy will give your pharmacy a huge growth and cash flow injection.

About two years ago, the PCDT Task Team was formed to try and focus on certain key areas, such as:

1. Marketing of the service to patients in a uniform manner, in other words make sure that patients get the same professional service whenever they see a PCDT pharmacist, regardless of location.
2. Forming a platform where PCDT pharmacists can communicate with each other.
3. Introducing and negotiating with medical aids to include PCDT in their member benefits.
4. Making sure PCDT pharmacists are updated regularly with new clinical knowledge.
5. Increasing and broadening the scope of practice of the PCDT pharmacist.

In 2023, the PCDT Task Team was formally adopted under the wings of the South African Association of Community Pharmacists (SAACP) as a special task group with their full support. We are very thankful for this. This was a huge step forward having a recognised and established body in the healthcare arena supporting us and helping PCDT find its rightful place in the South Africa healthcare system.

2024 seems to be the year of breakthroughs for PCDT pharmacists as Discovery Health Medical Aid endorsed and adopted the services offered by a PCDT pharmacist under their umbrella of approved healthcare services they offer to their members. Several other medical aids are also starting to pay for the services that PCDT pharmacists offer. With the number of PCDT pharmacists increasing yearly, it is envisioned that PCDT pharmacists will start to play a bigger integral role in the healthcare sector on primary care level.

I encourage each PCDT pharmacist to join the PSSA as a member and select SAACP as sector of choice going forward in 2024. SAACP has opened its doors to us and enabled us to use their platform as the PCDT Task Team. We can only benefit from the support they give us. Our aim is to make the PCDT pharmacist way more visible and prominent and offer a support service to all PCDT pharmacists wanting to start their own PCDT clinic. We know the obstacles PCDT pharmacists are facing out there, and we want to make sure we break through those barriers and obstacles currently prohibiting or delaying PCDT pharmacists from getting their clinics off the ground.

I want to encourage PCDT pharmacists to join our Task Team and SAACP. Make sure you are a SAACP member so that we can unite in our numbers and build PCDT into its rightful place. If you are not yet a PSSA member apply online at https://www.pssa.org.za/online-application.html. If you are a PSSA member and wish to check/change your sector, then send an email to info@pssa.org.za and include your SAPC P-number.

They have given us their commitment and support. Let us do the same and join them by becoming members. As a member you will also be included in all important PCDT updates and communication going forward.

SAACP PCDT
Primary Care Drug Therapy Pharmacists

Infant and child immunisation – an increased scope of practice for community pharmacists

Jameel Kariem

As a community pharmacist, an additional scope of practice you can perform is to offer the Expanded Programme on Immunisation in South Africa (EPI-SA) within your range of clinic services. This service covers the administration of vaccines to infants and children from birth up to the age of 12 years, and offers immunisation that protects against: pneumonia, meningitis, diarrhoea (caused by rotavirus), measles, TB, polio, whooping cough, diphtheria, liver diseases (caused by Hepatitis B), and tetanus. Besides being an effective and cost-efficient health intervention, it is also a potential growth opportunity and income stream for a community pharmacy.

The South African Pharmacy Council (SAPC) has published the scope of practice and competency standards for pharmacists providing immunisation, and the need for pharmacists to complete a short course in immunisation and injection technique in Board Notice 241 of 2022 on the 22nd of April the same year. Such a course would allow you as a pharmacist to understand the principles of immunisation, interpret immunisation schedules, perform safe immunisations, and understand adverse events following immunisation.

According to the SAPC, a pharmacist who has completed the supplementary training on immunisation and injection technique, and has obtained a section 22A(15) permit, may be allowed to administer vaccines at a SAPC compliant pharmacy, in line with the EPI-SA. Although not the only service allowed, pharmacists may also administer any other vaccine as part of a vaccine programme approved by the Director-General of Health, like the Covid-19 vaccine, as well as the influenza vaccine. All vaccines included in the EPI-SA list have schedule 2 status and thus do not require a prescription.

To perform immunisation as per the EPI-SA, pharmacists need to have the necessary knowledge and skills to deliver the best possible service. To this end we need to have a certain competency. This competency should also suitably train us to monitor the outcomes of the immunisation, to treat and report any adverse events, to refer to another health care worker where necessary, and to have accurate record keeping and to maintain confidentiality. Recently the National Department of Health (NDoH), via the EPI directorate, has advised of changes to the EPI childhood immunisation schedule, effective from January 2024. The key changes include:

- Pneumococcal conjugated vaccine (PCV) changes from 13 to 10 serotypes.
- Measles vaccine changes to the Measles-Rubella vaccine.
- Tetanus Diphtheria (Td) vaccine changes to Tetanus, reduced diphtheria and acellular pertussis (Tdap) vaccine.

Immunisation is a way of protecting against disease. As pharmacists trained in immunisation and injection technique, and programmes like the EPI, we can help to vaccinate our children. An immunised child can help protect the health of the community. Let's play our part.

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Expanded Programme on Immunisation

EPI (SA) Revised Childhood Immunisation schedule from January 2024

PROTECTION

Age of child	Vaccines needed	How & where it is given
At birth	BCG Bacilles Calmette Guerin	Right arm
	OPV (0) Oral Polio Vaccine	Drops by mouth
6 Weeks	OPV (1) Oral Polio Vaccine	Drops by mouth
	RV (1) Rotavirus Vaccine	Liquid by mouth
	DTaP-IPV-Hib-HBV (1) Diphtheria. Tetanus, Acellular Pertussis, Inactivated Polio Vaccine and Haemophilus Influenzae Type B and Hepatitis B Combined	Intramuscular/left thigh
	PCV (1) Pneumococcal Conjugated Vaccine	Intramuscular/right thigh
10 weeks	DTaP-IPV-Hib-HBV (2) Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Vaccine and Haemophilus Influenzae Type B and Hepatitis B Combined	Intramuscular/left thigh
14 weeks	RV (2) Rotavirus Vaccine*	Liquid by mouth
	DTaP-IPV-Hib-HBV (3) Diphtheria. Tetanus, Acellular Pertussis, Inactivated Polio Vaccine and Haemophilus Influenzae Type B and Hepatitis B Combined	Intramuscular/left thigh
	PCV (2) Pneumococcal Conjugated Vaccine	Intramuscular/right thigh
6 months	Measles Rubella Vaccine (1)**	Subcutaneous/left thigh
9 months	PCV(3) Pneumococcal Conjugated Vaccine	Intramuscular/right thigh
12 months	Measles Rubella Vaccine (2)	Subcutaneous/right arm
18 months	DTaP-IPV-Hib-HBV (4) Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio Vaccine and Haemophilus Influenzae Type B and Hepatitis B Combined	Intramuscular/left arm
6 years (both boys and girls)	Tdap: Tetanus, reduced strength Diphtheria and acellular Pertussis Vaccine	Intramuscular/left arm
12 years (both boys and girls)	Tdap: Tetanus, reduced strength Diphtheria and acellular Pertussis Vaccine	Intramuscular/left arm

*Rotavirus Vaccine should NOT be administered after 24 weeks
**Do not administer with any other vaccine unless the child is nine months or older

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Evening Cocktail Function: Thursday, 6th June 2024

Registration Cost:
From: 25 April '24 – 22 May '24
Members: R6 500
Non-Members: R7 500

Early Bird:	Day Registration:	Late Registration:
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For more information contact SAAPI via email:
info@saapi.org.za

sapj

CPD questionnaire • March/April

Tonsillitis and strep throat and its management- a brief review

1. Which bacteria are most commonly involved in acute tonsillitis?

a *Streptococcus pyogenes*
b *Escherichia coli*
c *Treponema pallidum* (Syphilis)
d *Corynebacterium diphtheriae*

2. When should antibiotics be administed for the treatment of tonsillitis?

a Patients presenting with coryza and a cough.
b Patients with a Centor score of 2.
c Patients with a FeverPAIN score of 4
d Patients with a Centor Score of 3 with a FeverPAIN score of 5

3. When is tonsillectomy indicated for the treatment of tonsillitis?

a Patient with six or more episodes per year, five infections in two consecutive years, three infections each year for three years consecutively.
b Patients with seven of more episodes per year, four infections in two consecutive years, three infections per year.
c Patients younger than 24 months.
d Patients older than six years.

4. Which antibiotic is indicated for patients, with acute tonsillitis, with allergy to penicillin?

a Vancomycin
b Macrolide e.g. erythromycin/azithromycin
c Rifampicin
d Co-trimoxazole

Dolutegravir and the management of HIV/AIDS in the South African adult population

5. Which class of drugs did DTG replace in the first-line treatment regimen?

a NNRTIs
b NRTIs
c PIs
d aINSTIs

6. DTG dosing is influenced by:

a Pharmacokinetic boosters
b Meals
c Mild to moderate liver impairment
d None of the above

7. DTG interacts with the following drugs resulting in decreased concentrations of DTG:

a Metformin
b Phenytoin
c St John's Wort
d Rifampicin

8. Which is false with regards to DTG?

a The half-life is between 12-15 hours
b Metabolism occurs via more than 1 pathway
c Neuropsychiatric side-effects are common
d Weight loss is common side-effect

The answers for these CPD questions will be in the upcoming issue of the SAPJ.
This activity can contribute towards your CPD compliance.

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