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ISSN: 2221-5875



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References: 1. Predel HG, et al. BMC Musculoskelet Disord 2013;14:250. 2. Duteil L, et al. Clin Exp Dermatol 1990;15:195-9. 3. Müller M, et al. Clin Pharmacol Ther 1997;62:293-9. 4. Singh P, Roberts MS. J Pharmacol Exp Ther 1994;268:144-51. 5. Zacher J, et al. Curr Med Res Opin 2008;24:925-50. 6. Voltaren<sup>®</sup> Schmerzgel 1.16% Gel. Protocol 862-P-201 post-hoc analysis of time to response variables.

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#### **SA Pharmaceutical Journal**

Official journal of the



#### Pharmaceutical Society of SA

incorporating

- Academy of Pharmaceutical SciencesSouth African Association of Community
- Pharmacist Sector of the PSSA
- SA Association of Hospital and Institutional
   Pharmacists
- SA Association of Pharmacists in Industry



www.sapj.co.za ISSN: 2221-5875

ADVERTISING SALES Sandy Laranja (Medpharm) Cell: 082 853 4155 E-mail: sandy@medpharm.co.za

SUBSCRIPTION info@medpharm.co.za

#### PUBLISHER

The Pharmaceutical Society of South Africa in collaboration with Medical & Pharmaceutical Publications (Pty) Ltd trading as Medpharm Publications Registration No 93/0794007

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A Piece of my Mind

Editorial Comment

#### Leadership changes

I love it when I'm right. A young pharmacist once asked me, "What are we going to do when our leaders retire and/or die? We're not going to be able to go forward." I still remember my reply to him, "Don't worry about it. You're busy preparing to become one of the leaders." He was, and he did.

If you read the PSSA newsletter, the YPG newsletter, any of our social media pages and the *SAPJ*, you will surely have noticed that young pharmacists are now dominating the active portion of PSSA membership. So are the older pharmacists who aid and abet them!

There's no doubt that this is an ideal situation. We have the innovation and energy of youth, and the experience and wisdom of the older pharmacists. It's a winning combination.

#### Youth working alone

Obviously there are times when the two groups need to work independently. It isn't only that the young need to make their own mistakes as they learn what works and what doesn't. Their criteria for success are often different from older folks. Not to mention criteria for fun! They also need to explore their own formulae for success. We all know that, in our personal lives, what worked for our parents didn't necessarily work for us, so why should it work in our professional lives?

#### Institutional memory

A good thing, isn't it? My internal jury is out on this one. My immediate reaction was, yes, of course it is. It prevents you from making mistakes because you don't understand historical actions and difficulties. It's easy to jump to conclusions. Surely if you know the history, you can build on successes and avoid repeating mistakes. To a point, this is true. The problem is that it takes two to tango, and if there's more than one party involved, each is likely to believe that they are in the right, and the other side's argument is incorrect.

A case in point is raised in the PSSA Perspectives, on the issue of the dispensing fee. Having been there since the onset, and having experienced every step of the way for many years, I can only heave a sigh of exasperation and exhaustion at the lack of understanding that has produced very little progress in arriving at a dispensing fee that will, on its own, ensure the sustainability of community pharmacy, and at the same time ensure affordability to the population. Are we ever going to have resolution on this one? I suspect it won't be in my (present) lifetime.

Mm. Maybe this is one of those occasions where we need to throw out our entire history and begin from scratch. Or is it? Let me know your thoughts!

#### My mind wanders on ...

Maybe, just maybe ... the logical solution may be found in a well organised, well remunerated national health system, where all health

care providers are adequately remunerated for their services and all people receive adequate health services. Just saying.

#### The loss of a dear friend and colleague

In the last issue of the *SAPJ*, I wrote about how uncomfortable I felt with the use of the word "obituary" and how I prefer the word "tribute". Right now, that's more true than ever before.

Ria Pretorius was more than a colleague and friend – she was a sister and an *alter ego*. We shared many hours together, in the dispensary, in meetings, in conferences, in our homes and with other friends. She could be very annoying – she knew my thoughts and feelings before I did, and she was always right!

I've used other people's words in this column before, so I'll let Yolanda Harding have the last word today.

En so ontaard vandag toe in een groot nagmerrie.

Rus sag liewe Ria Pretorius.

Sy was nie net my baas, my mentor, my "worst nightmare" en my werksmoeder nie. Sy was my kosbare vriendin en my inspirasie.

Sy was AMAZING en elkeen wat ooit die voorreg gehad het om haar te ontmoet, sal dit kan beaam. 'n Regte Hero.

Kyk, sy kon my moermeter in die rooi kry vinniger as wat jy kon sê – mes. Sy het my vele kere (soms te veel) in trane gehad, maar sy was ook altyd daar om my hand te vat en my te help opstaan en weer te probeer. Sy het my gedruk en forseer om beter te kan doen, gedryf al het dit gevoel ek kon nie meer nie maar sy het ook altyd in my geglo en my my vlerke laat sprei en laat vlieg.

Ria was hardegat, 'n "force to be reckoned with", regverdig, ferm en soms 'n regte moeilike tannie maar altyd positief, sag met 'n hart van goud. Sy het 'n manier gehad om jou te oortuig dat jy enige iets kan bereik. Haar energie was aansteeklik. Jy het geweet as sy 'n kamer betree het en al het sy almal om haar een of ander tyd mal gemaak, was daar diep binne tog altyd bewondering vir haar.

Haar werk was haar passie en sy het dit gedoen met soveel oorgawe en liefde. Die industrie verloor waarlik 'n reus ...

Haar seun, Markus was haar lewe en Jessica die dogter waarvan sy altyd gedroom het. Hulle was haar ALLES. Elke oomblik saam met hulle was so kosbaar en in elke storie kon jy die liefde en trots aanvoel.

Ek weet ek sal moet maar hoe ek gaan afskeid neem weet ek waarlik nie? Ek kan vir nou net die Here dank vir die voorreg om haar in my lewe te kon hê. Dankie vir die voorreg om haar met haar familie te kon deel. Dankie vir die trane, drukkies en lag. Dankie dat ek by een van die bestes kon leer ... sommer net dankie vir alles.

Lief vir jou altyd

## President's Message

## Only dead fish go with the flow!

Joggie Hattingh PSSA President

This cliché tends to make people smile at first! It is rather quirky and oh-so-true. The secondary emotion that is evoked is one of dread; what does it say about me? Could I be counted under the "dead fish" in the pharmacy community, who simply accepts what is thrown my way?

Our profession faces so many challenges, and we have to continually respond to new challenges, such as annual fees that are totally out of line with inflation, whilst our own income diminishes in real terms and then the increase in dispensing fee being totally out of sync with the actual cost of dispensing (and has been for some years!) and the latest proposed new fee for the approval for destruction of S6 medicines is also put on the table.

Do you accept this with a shrug of the shoulder, or do you complain vehemently, but actually support it with your inaction?

We, fortunately, have wonderful staff at the PSSA Head Office who respond to all these challenges! They do so in a professional manner, with statistical data as proof of argument and with legal opinions where and when required. This is great for the profession, but unfortunately, there is hardly ever input from the "man in the street", or shall we say, "the pharmacist on the corner".

Some of the issues, such as dispensing fees and annual fees are not new, but as CJ Lewis said: "You can't go back to the beginning, but you can start where you are and change the ending".

I have not seen the robust discussions required in this regard on social media. In fact, I have not seen anything in any media other than comments from PSSA and ICPA.

We do have some strong Branches and Sectors in the PSSA, with many pharmacists contributing from the heart. Allow me to quote the late Nelson Mandela: "There can be no greater gift than that of giving one's time and energy to help others without expecting anything in return". These are true words indeed, but the willing can only continue for so long without the support of their colleagues.

My appeal to each and every pharmacist is to support their local branch and sector. Start reading the PSSA Newsletters and comment on what you read. Take the matters where we get no resolutions from Government or statutory bodies to social media platforms and discuss it in a professional way. We need not attack Government or any organ of state, but we can comment on the wrongs inflicted on our profession in a robust and open discussion.

It is time to start swimming, unless we want to end downstream with the rest of the dead fish!

**PSSA Perspectives** 



Pharmaceutical Society of South Africa

## Legal challenges the PSSA is facing

#### The dispensing fee for pharmacists

It took many years and a court battle to reach a point where the dispensing fee for pharmacists was finally published for implementation on 19 November 2010. The fee is determined by applying a four-tiered formula that has a rand component and a percentage component. The initial targeted fee achieved by the formula in 2010 was R38.00 VAT exclusive. Each year the Pricing Committee should review the fee and advise the Minister on an increase taking into account the annual inflation rates published by Statistics South Africa. The proposed reviewed fee must be published for a three-month comment period.

The first few years, the draft fee was published for comment, the Pharmacy Stakeholders Forum (PSF), of which the PSSA is a member, would submit comment, and most years, the increase was linked to inflation. The draft fee for the next year was usually published around the middle of the year, ensuring an appropriate timeline for the three months comment period and time to review the comments before publishing the final fee.

In recent years the PSF has encountered a number of problems with the dispensing fee, one being the timelines when the draft and final dispensing fees are published.

#### The 2019 dispensing fee

Draft fee published on 9 July 2018

Final fee published on 23 January 2019

#### The 2020 dispensing fee

Draft fee published on 12 July 2019 – notice was signed by the Minister of Health on 15 May 2019

Final fee published on 19 June 2020 – notice was signed by the Minister of Health on 12 December 2019 (6 months to publish signed notice)

#### The 2021 dispensing fee

Draft fee published on 21 August 2020 – notice was signed by the Minister of Health on 5 May 2020

Final fee published on 10 September 2021 – notice was signed by the Minister of Health on 26 January 2021 (9 months to publish signed notice)

#### The 2022 dispensing fee

Draft fee published on 17 December 2021 – notice was signed by the Minister of Health on 19 October 2021

Final fee still to be published.

Another challenge that the PSF is currently facing is the fact that the previous and the current Pricing Committee do not understand that by just adjusting the rand component of the fourtiered formula by inflation does not lead to an inflation percentage increase in the targeted fee.

Each year Mediscor and MediKredit assist the PSF in comparing the current fee to the proposed new fee. The formula adjustment for the 2020 fee resulted in a 1.9% weighted average increase. The formula adjustment for the 2021 fee resulted in a 0.79% weighted average increase and the proposed formula adjustment for the 2022 fee results in a 0.9–1.3% weighted average increase.

The PSF has obtained the services of an actuarial company to assist them in compiling comments to the PSF in such a way that the message about how the four-tiered formula is used to determine the fee and that the fee should increase by at least CPI comes across clearly.

#### **Destruction of Schedule 5 and 6 substances**

On 25 August 2017 the General Regulations to the Medicines and Related Substances Act (Act 101 of 1965) as published in 2003 was repealed in its totality and replaced by a whole new set of General Regulations. One of the changes in the new regulations related to the destruction of medicines.

In the 2003 regulations, it was Regulation 27 that deals with the destruction of medicines and it read as follows:

1. A medicine or scheduled substance may be destroyed as follows:

(a) A medicine containing a Schedule 5, 6, 7 or 8 substance may only be destroyed in the presence of an inspector, an officer of the South African Police Service or any other person authorised by the Director General.

Such inspector, person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register

In the 2017 regulations, it is Regulation 44 that deals with the destruction of medicines and it reads as follows:

- 1. A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).
- 5. A Schedule 5 or 6 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of

(a) an inspector;

#### (b) a pharmacist; or

(c) any other person authorised by the Chief Executive Officer.

It is clear from Regulation 44 that pharmacists are authorised to witness the destruction of Schedule 5 and 6 substances without any need for authorisation to destroy. If one looks at Section 22A of the Medicines Act, which deals with the control of medicines, scheduled substances, medical devices and IVDs, pharmacists are authorised to manufacture, import/export, wholesale, acquire, keep and sell Schedule 5 and Schedule 6 substances. So although Section 22A is silent on destruction, one can infer that since a pharmacist is authorised to destroy Schedule 5 and 6 substances as detailed in Regulation 44.

Before the new General Regulations were published in 2017, pharmacists had to obtain authorisation from the then MCC (now SAHPRA) before Schedule 5 and 6 substances could be destroyed. The implication of the changes in the 2017 regulations were not realised as pharmacists continued to apply to SAHPRA for such authorisation.

In September 2021, SAHPRA published a number of guidelines for comment with the closing date for comment being 8 October 2021. Two such guidelines were guideline 5.05 – Guideline for destruction of Schedule 5, 6, 7 and 8 medicines/substances and guideline 5.11 – Guideline for permits and authorisation requiring fee. In terms of guideline 5.05, pharmacists still have to request authorisation from SAHPRA before Schedule 5 and 6 substances can be destroyed and in terms of guideline 5.11 the fee for such an authorisation is R950 per application.

Since these guidelines contain information specific to the manufacturing and wholesale industry, the PSSA agreed that the SAAPI sector of the PSSA would submit comments on the guidelines and in the comments they raised the issue of the guidelines falling outside of Regulation 44.

To date the guideline has not officially been published on the SAHPRA website, however, in January 2022, when pharmacists requested authorisation from SAHPRA for destruction of Schedule 5 and 6 substances they were sent guideline 5.05 as published for comment and were requested to pay the R950 fee.

The Pharmacy First Working Group, comprised of stakeholders in the private pharmacy setting, all agreed that the guideline is *ultra vires* (acting beyond one's legal power or authority) since in terms of Regulation 44, such authorisation is not required. The PSSA and ICPA met with SAHPRA on behalf of the Pharmacy First Working group and explained the challenge SAHPRA is facing.

It has since been explained by SAHPRA that they require information on the quantities of Schedule 5 and 6 substances as they need to report annually to the International Narcotics Control Board (INCB) on the quantities of narcotics imported, manufactured, exported, consumed and destroyed in South Africa. The INCB works closely with the World Health Organization (WHO) and United Nations (UN).

#### Activities of the International Narcotics Control Board

- Administration of a system of estimates for narcotic drugs and a voluntary assessment system for psychotropic substances and monitors licit activities involving drugs through a statistical returns system, with a view to assisting governments in achieving, inter alia, a balance between supply and demand.
- Monitoring and promotion of measures taken by governments to prevent the diversion of substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances and assesses such substances to determine whether there is a need for changes in the scope of control of Tables I and II of the 1988 Convention.
- Analysis of information provided by governments, UN bodies, specialised agencies or other competent international organisations, with a view to ensuring that the provisions of the international drug control treaties are adequately carried out by governments, and recommendation of remedial measures.
- Maintenance of a permanent dialogue with governments to assist them in complying with their obligations under the international drug control treaties and, to that end, recommendations, where appropriate, on technical or financial assistance to be provided.

Based on its activities, INCB publishes an annual report, which provides a comprehensive survey of the drug control situation in various parts of the world. As an impartial body, INCB tries to identify and predict dangerous trends and suggests necessary measures to be taken. The annual report is supplemented by technical reports on narcotic drugs and psychotropic substances, giving a detailed account of estimates of annual legitimate requirements in each country as well as data, the licit production, manufacture, trade and consumption of these drugs worldwide.

South Africa is a member of the INCB and currently Zukiswa Zingela of South Africa is one of the elected Board Members. SAHPRA, therefore, has a duty to report the requested information to the INCB. The challenge is now to find a way whereby SAHPRA receives the required information in order for them to comply with the INCB requirements, without going outside of their legal authority. At the time of writing, a solution had not yet been agreed to as discussions are still taking place.

**PSSA Young Pharmacists' Group** 

Pharmaceutical Society of South Africa

## **PSSA YPG Mentorship** Programme

The Pharmaceutical Society of South Africa (PSSA) Young Pharmacists' Group (YPG) is excited to Purpose host a Mentorship Programme. This programme aims to grow the next pharmacy leaders in the Society and the pharmacy profession. This program supports the leadership objective of PSSA. Through this programme you will be able to develop various personal and career skills, develop relationships with great PSSA role models and grow in your pharmacy career.

### Pilot

- 1 year pilot programme August 2020-October 2021
- Two branches: Cape Western Province & Southern Gauteng
- 6 mentor/mentee pairs
- Phase 1: Leadership webinar: Power of purpose, leading change, empowering people, igniting growth
- Phase 2: Clifton Strength Finder completed by mentors and mentees
- Phase 3: Individual paired session with coach (1.5hours) to tailor goals, objectives and achieve excellence

## **Eligibility Criteria**

#### Paid-up PSSA YPG members from any branch/sector Mentee

- Newly qualified pharmacists (within 5 years of graduation from their first pharmacy degree) OR under the age of 35 OR pharmacists who changed careers/sectors in pharmacy
- Any age group or experience level
- Special focus on younger, less experienced pharmacists

#### Mentor

- PSSA Fellows **OR** pharmacists with a minimum of 10 years', but preferably more than 15 years' experience in the profession
- Ideally, must have been actively involved in the profession in the past (PSSA branch and sector structures or similar bodies)
- Passionate pharmacists with drive and who are considered champions in their specific areas of pharmacy

#### **Programme layout for** National Rollout (2022)

- 1 year programme
- Application process partnership expectation, application form, DOPE Personality test, CV, photo
- Mentorship programme calendar
- Induction session
- Quarterly feedback forms
- Coaching sessions
- Clifton Strength Finder
- Mentor meetings & Mentee meetings
- Mentee guide & Mentor guide
- Farewell event

#### **Feedback From Pilot**

#### Through the pilot, mentees were able to:

- Develop leadership skills
- Experience more job satisfaction
- Identify career and personal goals and achieve goals

#### The strength assessment & coaching:

- Assisted mentees to identify & develop strengths
- Added value to their career & personal life



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sectors as well as anonymous sponsors. Contact us if you are

interested to be a volunteer for our working group.

For more information visit our website: Young Pharmacists' Group of PSSA https://www.pssa.org.za/youngpharmacists-group.html

## Influenza – prevention is better than cure

#### S Davis

Amayeza Information Services, South Africa

Corresponding author, email: sumari@amayeza-info.co.za

#### Abstract

Influenza, caused by influenza A or influenza B viruses, is usually a self-limiting disease in healthy patients but is associated with increased morbidity and mortality in high-risk groups and can result in more than 11 000 deaths annually in South Africa. Non-pharmacological prevention measures reduce the spread of infection, and the incidence of influenza was reduced following the implementation of these measures in 2020 to prevent the spread of coronavirus infections. Influenza vaccination is currently the most effective method to prevent and control influenza infection. It is, on average, around 59% effective depending on the patient's age, comorbidities and accuracy of the strains predicted for the season. Treatment for mild influenza focuses on the management of symptoms. Patients at high risk for severe and/or complicated disease should be treated for five days with antivirals (oseltamivir or zanamivir), preferably within 48 hours of onset of symptoms.

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#### Introduction

In otherwise healthy individuals, influenza is an acute, unpleasant, but usually self-limiting disease caused by influenza A or influenza B viruses and usually resolves within two to seven days.<sup>1</sup> However, it is associated with increased morbidity and mortality in high-risk groups.<sup>2</sup> Three influenza pandemics occurred in the last century (1918, 1957 and 1968), and the first pandemic of this century caused by an influenza A (H1N1) virus was declared by the World Health Organization (WHO) in June 2009.<sup>1</sup>

A modelling study from South Africa estimated that around 10 737 847 (19.8%) of the population was affected annually by influenza-associated illness between 2013 and 2015. The majority of these were mild episodes, 128 173 cases were severe-illness episodes, and 11 536 cases were fatal.<sup>3</sup> Influenza-related deaths were higher among infants younger than one year and individuals older than 65.<sup>3</sup> For patients older than five years, an estimated 30% of influenza-associated deaths were in HIV-infected patients, and mortality rates in pregnant women are three times higher compared to non-pregnant women.<sup>3</sup>

#### **Transmission**

Influenza is spread from person to person through inhalation of droplets or aerosols (expelled through sneezing, coughing or talking) or by touching mucous membranes following contact with contaminated objects.<sup>1,3-6</sup> The incubation period is between 1 and 4 days (2 days on average). Patients are infectious one day before onset of symptoms, most infectious 3–4 days after onset of symptoms, and 5–7 days after onset of symptoms.<sup>3,4</sup> Young children, older patients, patients with chronic medical conditions, obese patients, and immunocompromised patients can shed the virus for more extended periods (weeks to months).<sup>3,6</sup>

#### Prevention

#### Non-pharmacological

It is important to prevent influenza, especially in patients at risk of severe or complicated influenza. Patients with influenza can reduce the spread by staying at home until at least 24 hours after the fever has resolved.<sup>3</sup> Patients should avoid close contact, such as kissing and sharing drinks with others, especially those who are at high risk of severe disease.<sup>3</sup> Patients should sneeze and cough into a tissue or the sleeve and wash hands regularly with soap and water, or disinfect with an alcohol-based hand rub or spray.<sup>3</sup> Surfaces that are regularly touched or shared, such as doorknobs or remote controls, should be wiped regularly with a disinfectant.<sup>3</sup>

In residential homes, isolation for five days from the onset of symptoms or quarantining sick patients together may help contain infections. It may be necessary to close residential homes until the infection is under control. Closing schools (full or partial) is not generally recommended but may be considered for logistical purposes.<sup>3</sup>

Despite continued testing and surveillance, very few cases of influenza were detected in 2020 and 2021, most likely due to the non-pharmaceutical measures implemented to control severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections.<sup>3</sup>

#### The role of antivirals

Antiviral chemoprophylaxis is not currently recommended. However, the WHO guidelines state that patients at high risk of severe disease who have been exposed to influenza, may benefit from presumptive antiviral treatment, or could alternatively be monitored closely to start antiviral treatment as soon as possible after the onset of symptoms.<sup>3</sup>

#### Vaccination

Two inactivated quadrivalent influenza vaccines are currently available in South Africa. Both can be administered either intramuscularly or via deep subcutaneous route (which is preferable for patients with bleeding conditions).

- Vaxigrip Tetra is registered as a 0.5 ml dose for patients 6 months and older.<sup>7</sup>
- Influvac Tetra is also given as a 0.5 ml dose but is registered for use only from 3 years of age.<sup>8</sup>

For children 6 months through 8 years of age, a second dose of the flu vaccine is recommended, if it is the first time ever that the child is receiving a flu vaccine.<sup>3</sup> In subsequent seasons, only one dose will be required.<sup>3</sup>

Influenza vaccines are indicated for active immunisation throughout pregnancy and also provide passive protection of infants from birth to ~6 months of age following vaccination of pregnant women.<sup>7</sup> Patients with a mild allergic reaction to egg (hives only), may receive the flu vaccine whilst patients who had an anaphylactic reaction to egg may have the vaccine administered in a facility under the supervision of a health care provider who can recognise and manage severe allergic reactions.<sup>9</sup>

Protective antibody responses take about two weeks to develop. Therefore, the vaccine should be given as soon as it becomes available in the new influenza season (usually around March in the southern hemisphere), to provide protection before the influenza season starts. Since the incubation period for influenza is less than four days, and protection only occurs two weeks after vaccination, the vaccine is not effective as post-exposure prophylaxis.<sup>3</sup>

Between 2005 and 2015, estimated vaccine efficacy varied between 46% and 87% when there was a good match with circulating strains and between 14% and 38% when there was a mismatch. Overall efficacy was estimated to be around 59% in healthy adults. The vaccine may be less effective in certain groups such as immunocompromised individuals, infants, and the elderly. However, vaccination may reduce the incidence of severe disease and mortality and is recommended for these patients.<sup>3</sup>

Vaccination is also recommended for all healthcare workers, all patients at high risk of severe and/or complicated disease, anyone in contact with high-risk patients, and anyone wishing to minimise their risk of contracting influenza.<sup>3</sup>

#### Signs and symptoms of influenza

Adult patients usually present with an abrupt onset of fever (ranging between 37.8 °C and up to 41.1 °C), myalgia and a non-productive cough.<sup>4</sup> Other symptoms may include malaise, sore throat, nausea, nasal congestion, rhinitis, arthralgia, and headache.<sup>3,4</sup>

Children are more likely to present with higher fevers, febrile seizures, and gastrointestinal symptoms such as nausea, vomiting, poor appetite, and diarrhoea.<sup>3,5</sup>

Older patients ( $\geq$  65 years of age) and immunosuppressed patients are more likely to have subtle signs and symptoms. In older patients, typical symptoms such as sore throat, myalgias and fever may be absent, while symptoms such as altered mental status, weakness, dizziness, anorexia, and malaise are often more prominent.<sup>4</sup>

Symptoms may also vary between different types and subtypes of influenza. For instance, influenza B is more typically associated with musculoskeletal findings than influenza A. Gastrointestinal symptoms were more commonly reported with the 2009 H1N1 influenza pandemic when compared to other seasonal influenza strains.<sup>1</sup>

Symptoms usually start improving after three days, with full recovery within 10 to 14 days (longer in patients  $\geq$  65 years). Symptoms like cough may persist, especially in younger children and weakness and fatigue may last for several weeks in older children and adults.<sup>45</sup>

## Risk factors for severe or complicated influenza

Certain groups of people are at greater risk of developing severe or complicated influenza. They include:<sup>3</sup>

- Young children (particularly those younger than two years of age)
- Patients  $\geq$  65 years of age
- Patients ≤ 18 years on chronic aspirin therapy
- Pregnant women (including up to 2 weeks post-partum)
- HIV-infected patients
- Patients with tuberculosis
- Morbidly obese patients (body mass index ≥ 40)
- Patients with other chronic medical conditions
  - Immunosuppression, e.g. due to medication use or malignancies
  - Pulmonary diseases such as asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis
  - Cardiovascular diseases such as congenital heart disease, congestive heart failure, coronary artery disease (excluding hypertension)
  - Metabolic diseases such as diabetes
  - Renal disease
  - Hepatic disease
  - · Haemoglobinopathies such as sickle cell disease
  - Neurologic and neurodevelopmental diseases such as disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, seizure disorders, stroke, mental retardation, moderate to severe developmental delay, muscular dystrophy, or spinal cord injury

#### Complications

Patients with complicated influenza may present with symptoms and signs of lower respiratory tract infection (hypoxaemia,



## Easing the symptoms of colds and flu



- 500 mg Paracetamol
- 4 mg Chlorphenamine maleate
- 50 mg Pseudoephedrine hydrochloride
- 330 mg Vitamin C
- Sugar free

## Dosage for adults and children over 12 years.

tablet dissolved in warm
 water can be taken every
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dyspnoea, tachypnoea, lower chest wall indrawing and inability to feed), central nervous system (CNS) involvement and/or a significant exacerbation of an underlying medical condition, including COPD, asthma, coronary artery disease or heart failure.<sup>3,4</sup>

Pneumonia is the most common complication of influenza. It can include secondary bacterial pneumonia (often with *S. pneumoniae*, *S. aureus* or *S. pyogenes*), mixed bacterial and viral pneumonia or primary influenza pneumonia. Primary influenza pneumonia should be suspected if patients have persistent symptoms including fever and dyspnoea. Patients with secondary bacterial pneumonia often demonstrate initial improvement of influenza symptoms, including fever, followed by a relapse of fever with a cough productive of purulent sputum. Mixed viral and bacterial pneumonia may present as either gradual progressive disease or transient improvement followed by worsening.<sup>4</sup>

Cardiovascular complications may include myocardial infarction, heart failure, myositis, myocarditis, and pericarditis, whilst CNS complications may include seizures, encephalopathy, encephalitis, cerebrovascular accident, acute disseminated encephalomyelitis, and Guillain-Barré syndrome. Musculoskeletal complications such as myositis and rhabdomyolysis occur more frequently in children than in adults. Other complications may include parotitis, bronchitis, sinusitis, and reactive airway disease.<sup>3,4</sup>

#### Treatment

Patients should take in sufficient amounts of fluids to prevent dehydration. Consumption of warm liquids may help thin secretions, soothe the mucosa, and increase the flow of nasal mucus, making it easier to remove.<sup>10</sup>

Paracetamol or nonsteroidal anti-inflammatory drugs (NSAIDs) are indicated as analgesics and to manage fever.<sup>11,12</sup> Paracetamol remains the first choice of treatment for sore throat, headache, myalgia, and fever in pregnancy.<sup>11</sup> Aspirin and ibuprofen have been associated with adverse pregnancy and infant outcomes. Aspirin is not recommended for children due to the risk of Reye's syndrome.<sup>12</sup>

Symptomatic treatment of cough and rhinorrhoea with overthe-counter (OTC) combination products is not recommended in children as they have no proven benefit and have been associated with fatal overdose in children.<sup>12</sup> Normal saline nose drops may be used to remove mucus from nasal passages and reduce nasal congestion, whilst saline irrigations (using sterile or bottled water) may also be used in older children.<sup>10</sup>

For children older than 12 years and adults, antihistamine and decongestant combination products may be more beneficial than either component alone to relieve symptoms of nasal congestion and rhinorrhoea.<sup>13</sup> Nasal sprays containing cromolyn or ipratropium are options for treating nasal symptoms in pregnancy.<sup>11</sup>

Antibiotics are not effective for the treatment of influenza but may be indicated for the treatment of bacterial complications such as bacterial pneumonia, otitis media or sinusitis.<sup>3,11</sup>

Antiviral treatment is only recommended for patients with complicated or severe illness (including all hospitalised patients) and for patients at higher risk of influenza complications.<sup>3</sup> Treatment should be started as soon as possible (preferably within 48 hours of symptom onset). Antiviral treatment is not recommended for patients who do not fall into high-risk groups or present with uncomplicated influenza.<sup>3</sup> In hospitalised patients with severe, complicated, or progressive disease, antiviral treatment may still be beneficial even when started more than 48 hours after onset of symptoms.<sup>3</sup>

Neuraminidase inhibitors available for the treatment of influenza in South Africa include oseltamivir (Tamiflu) and zanamivir (Relenza). Adults should be treated with 75 mg oseltamivir twice daily for 5 days, while dosing for children depends on the age and weight of the child (Table I).

| Table I: Recommended dosage and duration of oseltamivir treatment           for influenza in children <sup>3</sup> |  |  |
|--|--|--|
| Age  | Dose   |  |
| Premature neonates born at < 38 weeks gestation  | 1 mg/kg twice daily for 5 days   |  |
| Neonates born at 38–40 weeks<br>(full-term)  | 1.5 mg/kg twice daily for 5 days   |  |
| Infants aged between 1 day and 12 months   | 3 mg/kg twice daily for 5 days   |  |
| Infants and children ≥ 1 year<br>• ≤ 15 kg<br>• > 15-23 kg<br>• > 23-40 kg<br>• > 40 kg                            | <ul> <li>30 mg twice daily for 5 days</li> <li>45 mg twice daily for 5 days</li> <li>60 mg twice daily for 5 days</li> <li>75 mg twice daily for 5 days</li> </ul> |  |

The dose for treatment with zanamivir in adults and children older than 7 years is 10 mg (2 x 5 mg inhalations) twice daily for 5 days.<sup>3</sup>

#### Conclusion

Most influenza infections are mild, and symptoms can be managed effectively at home.<sup>3</sup> However, influenza can cause severe illness in certain high-risk patients and can result in complications (that may require hospitalisation), or even death.<sup>1</sup> Symptomatic treatment may relieve symptoms, but patients at high risk should receive antiviral treatment, preferably within 48 hours after onset of symptoms.<sup>3</sup> Vaccination is the most effective method available for the prevention and control of influenza infection and is recommended for all healthcare workers, patients in high-risk groups and any person who wants to reduce the risk of contracting influenza.<sup>3</sup>

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References available on request

## The pharmacotherapy of lower back pain

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Updated from Prof Nurs Today 2017;21(4):13-16

S Afr Pharm J 2022;89(2):13-15

#### Introduction

About 60–80% of patients visiting their family practitioner have at some stage in their lives suffered from lower back pain. The annual incidence in adults aged 35–55 years in developed countries is up to 45%. The differential diagnosis is broad and includes muscular strain, primary spine disease like disc herniation or degenerative arthritis, systemic diseases like metastatic cancer and regional diseases like aortic aneurisms. In the majority of cases, a specific diagnosis can not be made.

Most patients will improve in 1–4 weeks and will only need treatment for the acute symptoms after the initial history and physical examination. If, however, the pain recurs or gets worse, the patient must be thoroughly examined, and a specific diagnosis can become a challenge.

#### **Causes of lower back pain**

There are multiple causes of lower back pain and the physician will always attempt to get to the correct cause in order to assure the most effective treatment is recommended. Modern imaging techniques have contributed significantly to arrive at the correct diagnosis. The following conditions may cause lower back pain: cancer, cauda equina syndrome, herniated intervertebral disc, severe or progressive neurological deficits, spinal stenosis, vertebral compression fracture or vertebral infection.

When examining and communicating with the patient, the practitioner must take special care if the patient complains of severe back pain that:

- · Followed a fall, blow to the back or other injury
- · Is constant or severe
- Worsens during rest or at night
- Spreads down one or both legs causes weakness, numbness or tingling in one or both legs
- · Is associated with new bowel or bladder problems
- · Is accompanied by fever
- Is associated with pain or throbbing in the abdomen
- Is accompanied by unexplained weight loss

This will ensure that serious causes of lower back pain are not overseen.

#### Management of lower back pain

The state of Oregon in the USA some time ago published guidelines for the evaluation and management of low back pain. Table I gives a good summary of current medical practice.

From Table I it is apparent that self-care, non-pharmacologic therapy and interdisciplinary therapy are important in the total intervention programme. We will focus on the pharmacologic therapy of lower back pain.

#### Pharmacotherapy of lower back pain

The most commonly used medicines in the treatment of lower back pain are the analgesics. Therapy will be discussed as follows:

- Non-opioid analgesics
- Opioids
- Skeletal muscle relaxants
- Other central nervous system (CNS) drugs

#### The non-opioid analgesics

- Paracetamol (acetaminophen) is the most commonly used and prescribed analgesic for lower back pain. It has equivalent analgesic efficacy to aspirin with no useful anti-inflammatory action. Paracetamol has a central antinociceptive effect through selective inhibition of prostaglandin H<sub>2</sub> synthetase. It serves as a reducing co-substrate for the peroxidase-active site of the enzyme (i.e. a POX inhibitor). It is conjugated in the liver as inactive glucuronate and sulphate. Adverse effects are rare in therapeutic usage – occasional rash and allergy. Dosage orally should not exceed 4 g/day and intravenously a loading dose of 2 g, followed by 1 g 4-hourly to a maximum of 4 g/day (PERFALGAN).
- Aspirin is the oldest, most well known and widely used analgesic. It has analgesic, antipyretic and anti-inflammatory actions and causes respiratory stimulation. It can cause respiratory alkalosis, renal loss of electrolytes with dehydration plus a disturbance of glucose metabolism. Aspirin has a uricosuric effect in dosages between 5–8 g/day. It reduces platelet adhesion and causes hypothrombonaemia in dosages
   5 g/day. The normal dosage of aspirin is 325–650 mg every 4–6 hours for pain and fever.

| Table I: Interventions            |  |                 |                                |
|-----------------------------------|--|-----------------|--------------------------------|
| Intervention category             | Intervention   | Acute < 4 weeks | Subacute and chronic > 4 weeks |
| Self-care                         | Advice to remain active  | •               | •                              |
|                                   | Books, handouts  | •               | •                              |
|                                   | Application of superficial heat  | •               |                                |
| Non-pharmacologic therapy         | Spinal manipulation  | •               | •                              |
|                                   | Exercise therapy   |                 | •                              |
|                                   | Massage  |                 | •                              |
|                                   | Acupuncture  |                 | •                              |
|                                   | Yoga   |                 | •                              |
|                                   | Cognitive behavioural therapy  |                 | •                              |
|                                   | Progressive relaxation   |                 | •                              |
| Pharamacologic therapy (Carefully | Paracetamol  | •               | •                              |
| consider risks/harms)             | NSAIDs   | • ▲             | • 🔺                            |
|                                   | Skeletal muscle relaxants e.g. orphenadrine, methocarbamol and cyclobenzaprine | •               |                                |
|                                   | Antidepressants (TCA)  |                 | •                              |
|                                   | Benzodiazepines  | • ▲             | • ▲                            |
|                                   | Tramadol, opioids  | • ▲             | • ▲                            |
| Interdisciplinary therapy         | Intensive interdisciplinary rehabilitation                                     |                 | •                              |

• Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade A evidence (good-quality evidence of substantial benefit).

▲ Carries greater risk of harms than other agents in table.

 The nonsteroidal anti-inflammatory drugs (NSAIDs) inhibit cyclooxygenase (prostaglandin synthase) that is responsible for conversion of arachidonic acid to cyclic endoperoxidases. There are two isoforms – COX-1 and COX-2, which led to the sub-group of COX-2 selective inhibitors. Their main actions are analgesic, anti-inflammatory, antipyretic and anti-platelet (prevent thromboxane production). The side-effects include gastric and intestinal mucosal damage, disturbances of fluid and electrolyte balance and they can cause analgesic nephropathy. Dosages vary in the different sub-classes.

#### The opioids

There are four types of G-protein-coupled opioid receptors, each having a different pharmacological effect – mu, kappa, delta and the ORL-1 receptors. The affinity for these receptors parallels their analgesic potency. Morphine is the prototype opioid and has the following effects: Analgesia, euphoria, respiratory depression, depression of the cough reflex, nausea and vomiting and pupillary constriction. It also has significant effects on the GIT – increased tone, decreased motility, constriction of the biliary sphincter and delayed absorption of other drugs. Morphine is used for severe or overwhelming pain. Oral dosage is 30 mg every 3–4 hours and 10 mg 3–4 hours parenterally.

#### The skeletal muscle relaxants

The term is commonly used to refer to heterogeneous group of pharmacologically unrelated medications approved to treat two distinct conditions: spasticity from upper motor neuron syndromes and pain or spasms from musculoskeletal conditions such as non-specific low back pain. These include carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol and orphenadrine.

- Cyclobenzaprine is the best studied drug for relief of skeletal muscle spasms and has also shown effectiveness in the treatment of fibromyalgia. It is a centrally acting skeletal muscle relaxant with antidepressant activity. Cyclobenzaprine seems to act primarily at the brain stem to reduce tonic muscle motor activity, influencing both gamma and alpha motor neurons leading to a reduction in muscle spasms. Dosage is 15–30 mg once daily.
- Methocarbamol is a central acting muscle relaxant which may inhibit carbonic anhydrase and the NMDA receptor. Peripherally it prolongs the muscle refractory period. The initial dosage is 1.5 g four times a day.
- Orphenadrine is a nonselective mACh receptor antagonist and a H<sub>1</sub> receptor antagonist which is used to treat muscle pain and motor control in Parkinson's disease. It also has NMDA receptor antagonist activity which may contribute to its muscle relaxing activity. The dosage is 100 mg two to three times daily.

A Cochrane review for acute lower back pain which included eight trials found that these drugs were superior to placebo for short term pain relief and global efficacy. It also found these drugs are associated with more total adverse events and sedation than placebo, though most events were self-limited and serious complications appeared rare.

## Other central nervous system drugs used in lower back pain

- Antidepressants. The tricyclic antidepressants like amitriptyline are often used in the treatment of chronic back pain. They block the uptake of amines by nerve terminals. Duloxetine has been studied extensively for use in pain conditions and is approved for the treatment of fibromyalgia and chronic musculoskeletal pain, including discomfort from osteoarthritis and chronic lower back pain.
- The benzodiazepines, specifically diazepam, is used for muscle spasms, but it is not approved for this indication.
- Gabapentin is an anti-epileptic drug which modulates the action of two enzymes involved in GABA biosynthesis and

binds to the alpha2delta subunit of voltage-gated calcium ion channels. It is recommended as a first-line medication for the treatment of neuropathic pain in diabetes, herpes and central neuropathic pain.

• Pregabalin is also an anti-epileptic that acts on the calcium ion channels which is used in neuropathic pain.

Pharmacists see many prescriptions for patients suffering from lower back pain. These are frequently an analgesic, an NSAID and a CNS drug used for neuropathic pain. It is important that various options should be explored to help to patient to obtain the best control of pain.

This article was compiled from a lecture given by the author and the references are available on request.

## Pregabalin

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#### Abstract

Pregabalin is a newer generation gabapentinoid and is structurally similar to the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). Gabapentin was initially synthesised over forty years ago as an adjuvant antiepileptic drug but has since become widely prescribed to treat neuropathic pain. Similarly, pregabalin use in epilepsy is limited and its use has been targeted for the treatment of neuropathic pain.<sup>1,2</sup>

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#### Indications

Pregabalin is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, fibromyalgia, post-herpetic neuralgia, neuropathic pain associated with spinal cord injury, and as adjunctive therapy for the treatment of partialonset seizures in patients one month of age and older.<sup>1</sup>

Pregabalin has FDA approval for the treatment of peripheral neuropathic pain, generalised anxiety disorder and as an adjunct therapy for epilepsy.<sup>3</sup>

In South Africa, pregabalin is registered for post-herpetic neuralgia and painful diabetic polyneuropathy in adults.<sup>4</sup>

Neuropathic pain is an unpleasant emotional and sensory experience that can have a major impact on a person's general health, social and economic wellbeing, psychological health and overall quality of life. It is defined by the International Association for the Study of Pain (IASP 2011) as "pain caused by a lesion or disease of the somatosensory nervous system." Neuropathic pain is classified as central or peripheral.<sup>5</sup>

- Central neuropathic pain is caused by a disease or lesion of the central somatosensory nervous system.
- Peripheral neuropathic pain is caused by a disease or lesion of the peripheral somatosensory nervous system.

## Common symptoms of neuropathic pain description include the following:<sup>4,5</sup>

- Burning feeling
- Tingling sensation
- Electric shock
- Numbness
- Itching
- Prickling
- Pins and needles sensation
- Hyperalgesia (increased response to a normally painful stimulus)
- Anaesthesia dolorosa (pain felt in an anaesthetic region)
- Allodynia (pain caused by a stimulus that does not normally provoke pain

#### **Pharmacokinetics**

The pharmacokinetic parameter profile of pregabalin is similar to many psychotropic drugs.<sup>6-9</sup>

**Absorption** – rapidly and extensively absorbed with plasma peak concentration within 1.5 hours after administration and plasma concentration increases proportionately with increasing dose.<sup>67</sup> The absolute bioavailability remains constant at approximately 90% irrespective of dosage. Food decreases the rate of absorption resulting in lower and delayed maximum plasma concentration but does not affect the extent of absorption. Therefore, pregabalin can be administered without regard to meals.<sup>69</sup>

**Metabolism** – pregabalin undergoes negligible metabolism. It is not metabolised by nor does it inhibit hepatic enzymes that are responsible for the metabolism of other drugs.<sup>6-9</sup>

**Elimination** – pregabalin is more than 90% eliminated by renal excretion as unchanged drug, with an elimination half-life of approximately 6 hours. Steady-state is reached within two days of regular dosing.<sup>6-9</sup>

#### Pharmacodynamics

Pregabalin has a similar structure to gamma-aminobutyric acid (GABA) but does not bind to the GABA receptors. Instead, pregabalin exerts its effects by binding to the alpha2-delta subunit of voltage-dependent calcium channels in the central nervous system (CNS).<sup>67</sup> Pregabalin does not modulate cyclooxygenase activity, serotonin receptors, opiate receptors, dopamine receptors or sodium channels. Another contributing factor to the mechanism of action of pregabalin is that it prevents the alpha2-delta subunit from being attached from the dorsal root ganglia to the spinal dorsal horn.<sup>1,3</sup>

#### **Mechanism of action**

Pregabalin modulates the release of several excitatory neurotransmitters such as substance-P, glutamate, norepinephrine and calcitonin gene-related peptide, by binding pre-synaptically to the alpha2-delta subunit of voltage-gated calcium channels in the CNS.<sup>1,10</sup>























# Pregabalin

Reduces neuropathic pain in adults. Improves functioning.<sup>1,2</sup>

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 SepREGABALIN MYLAN 25 mg (Capsule), Reg. No.: 46/2.5/0219. Each hard capsule contains 25 mg of pregabalin.

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Pregabalin does not interact with either  $GABA_A$  or  $GABA_B$  receptors. It is also not converted metabolically into GABA or a GABA agonist, nor is it an inhibitor of GABA uptake or degradation.<sup>4</sup>

#### Dosage

The recommended starting dose of pregabalin is 75 mg twice daily with or without food. The dose may be increased to 150 mg twice daily after three to seven days based on individual patient tolerability and response.<sup>4</sup>

Refer to Table I for dosage and adjustments in special population groups. Also refer to Table II for pregabalin dosage adjustment for renal impairment.

| Table I: Dosage and adjustments in special population groups <sup>4,11,12</sup> |  |  |
|---|--|--|
| Patient group   | Dosage and adjustments   |  |
| Use in patients under<br>18 years   | The safety and effectiveness of pregabalin in patients with neuropathic pain under 18 years of age have not been established.  |  |
| Use in the elderly<br>(> 65 years of age)                                       | No dosage adjustment is required for elderly patients unless they have compromised renal function.   |  |
| Use in patients with<br>hepatic impairment                                      | No dosage adjustment is necessary for patients with hepatic impairment.  |  |
| Use in patients with renal impairment   | Pregabalin undergoes renal excretion from<br>systemic circulation as an unchanged drug.<br>Dosage reduction is required in patients with<br>compromised renal function as the clearance<br>is directly proportional to creatinine clearance.<br>Refer to Table II. |  |
| Patients receiving<br>haemodialysis   | The pregabalin dose should be adjusted<br>according to the renal function. A<br>supplementary dose should be given<br>immediately after every 4-hour haemodialysis<br>treatment, in addition to the daily dose. Refer<br>to Table II.                              |  |

| Table II: Pregabalin dosage adjustment for renal impairment <sup>4,11,12</sup> |                                 |                               |  |
|--|---------------------------------|-------------------------------|--|
| Creatinine clearance<br>(CL <sub>cr</sub> ) (ml/min)                           | Starting dose                   | Maximum dose<br>(mg/day)      |  |
| ≥ 60   | 150 mg twice daily              | 300 mg twice daily            |  |
| 30–60  | 75 mg once or twice<br>daily    | 150 mg once or twice<br>daily |  |
| 15–30  | 25–50 mg once or<br>twice daily | 75 mg once or twice<br>daily  |  |
| < 15   | 25 mg once daily                | 25–50 mg once daily           |  |
| Supplementary dose<br>after every 4-hour<br>baemodialysis                      | 25 mg as a single<br>dose       | 50 mg as a single dose        |  |

#### Pregabalin in diabetic peripheral neuropathy

Chronically elevated high blood sugar levels in type II diabetics cause nerve damage resulting in diabetic peripheral neuropathy.

Nerve damage occurs from microvascular damage to blood vessels supply nerves. Pregabalin is an effective treatment for the symptoms of diabetic peripheral neuropathy, with a recommended dose of 300–600 mg daily. Pregabalin suppresses

the activity of the excitatory primary afferent fibres that carry nociceptive information to the spinal dorsal horn.<sup>3</sup>

#### Pregabalin in postherpetic neuralgia

Herpes zoster occurs when the Varicellar zoster virus that causes chickenpox is reactivated from its latent state up to decades later. Herpes zoster manifests as a painful rash commonly known as shingles. The virus can be treated with antivirals, but the painful sensation following the attack can persist for months or years without the continuing rash. Almost 20% of those suffering from herpes zoster develop post-herpetic neuralgia due to the damage of nerve fibres from the inflammatory response accompanying the reactivation of the Varicellar zoster virus.<sup>3</sup>

The gabapentinoids are first-line treatment with pregabalin having preference to gabapentin at one-sixth of the dose. The recommended dose of 150–600 mg daily shows consistent improvement in pain scores in patients with post-herpetic neuralgia.<sup>3</sup>

## Pregabalin in neuropathic pain associated with spinal cord injury

Neuropathic pain is reported in almost two-thirds of patients that have motor and sensory deficits following an injury to the spinal cord. Pregabalin has been shown to be effective in treating patients with neuropathic pain associated with spinal cord injury. Pregabalin also improves anxiety, sleep and general patient wellbeing in these patients. A recent study by Sun et al. has shown that gabapentinoids promote regeneration of corticospinal axons in mice subsequent to spinal cord injury.<sup>13</sup>

Pregabalin also augments myelin repair in rat models, which may contribute to its effectiveness in treating damage caused by spinal cord injury.<sup>3</sup>

#### Withdrawal symptoms

Abrupt discontinuation of pregabalin treatment can result in withdrawal symptoms in some patients. These symptoms include nausea, sweating, insomnia, diarrhoea, headache and anxiety.<sup>6,12</sup>

Therefore, it is recommended that patients undergo a taper period of about one week when treatment needs to be discontinued.<sup>4,6,12</sup>

#### **Safety profile**

Studies have shown that the adverse effect profile of pregabalin is well tolerated. The majority of the adverse events experienced in premarketing clinical studies or post-release studies are mild to moderate in severity. The most common adverse events seen in trials are dizziness and somnolence, the incidence of which is dose related.<sup>2,4</sup>

Other possible adverse events include euphoria, gait imbalance, visual blurring and cognitive difficulties. Possible systemic effects include dry mouth, weight gain, increased appetite, peripheral oedema, infection and constipation.<sup>2,4</sup>

#### **Special precautions**

Patients are recommended not to drive or operate complex machinery or engage in other potentially hazardous activities as pregabalin often causes somnolence and dizziness. Patients with glucose-galactose malabsorption, Lapp lactase deficiency or galactose deficiency should not take pregabalin. There have been rare post-marketing reports of hypersensitivity reactions such as urticaria and angioedema.<sup>4,12</sup>

Special precaution needs to be taken for the following patients:<sup>4</sup>

- Renal impairment
- Substance abuse
- · Patients with cardiovascular disease (including heart failure)
- History of angioedema

Patients should be monitored for signs of suicidal ideation and behaviour.<sup>4,12</sup>

#### **Pregnancy and lactation**

Pregabalin should not be used during pregnancy as animal studies have shown reproductive toxicity and the potential risk to humans is unknown. Pregabalin is excreted in the milk of rats but it is not known if pregabalin is excreted in breast milk of humans. Therefore, pregabalin is not recommended for use during pregnancy and lactation.<sup>2,12</sup>

#### Interactions

Pregabalin may cause additive CNS depressant effects with opiates (e.g. oxycodone) and benzodiazepines (e.g. lorazepam). The risk of angioedema with ACE inhibitors may also be increased.

Pregabalin may also augment the CNS depressant effects of alcohol.<sup>1,4,12</sup>

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## Focus on....

## Carbocisteine

#### S Davis

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Mucus is the first line of defence against harmful pathogens for various epithelia in the body. Mucus acts as a physical barrier against gastrointestinal and respiratory irritants and pathogens. It also contains proteins such as immunoglobulins, glycoproteins, and antimicrobial enzymes (such as lysozyme) that inhibit bacterial growth and biofilm production to protect against infection.<sup>1</sup>

Mucus production is regulated by two mechanisms: the mucussecreting cells and the mucociliary escalator. In patients with chronic obstructive pulmonary disease (COPD) or asthma, chronic irritation of the airways can lead to mucus hypersecretion, which can overwhelm the mucociliary clearance mechanisms, resulting in excess mucus and the formation of mucus plugs that further reduce clearance. The airways then secrete an excess of inflammatory mediators to clear the obstruction, increasing the viscosity of mucus, resulting in a further decrease in clearance and initiation of inflammation and fibrosis. This cycle invariably results in infection of the static mucus and acute exacerbation of the condition.<sup>1</sup>

Mucolytic agents are used to manage mucus hypersecretion and its sequelae, such as recurrent infections in patients with COPD.<sup>1</sup> Carbocisteine is classified as a classic mucolytic<sup>1</sup> and is thought to reduce the viscosity of secretions by splitting disulphide bonds in mucoproteins.<sup>2</sup> Carbocisteine also increases the volume of sputum, producing an additional expectorative effect.<sup>1</sup> Administration of carbocisteine has been shown to improve sputum fluidity and normalise the bronchial epithelium.<sup>3</sup>

#### Indications

Carbocisteine is indicated as adjunctive therapy in respiratory tract disorders characterised by excessive viscous mucus in the absence of infection.<sup>4</sup>

#### **Pharmacokinetics**

Carbocisteine is rapidly and well absorbed following oral administration of 750 mg, with maximum concentration reached within 77 minutes for the syrup, 120 minutes for tablets and 130 minutes for capsules.<sup>3</sup> Carbocisteine was detected in the mucosa of the ear and paranasal sinuses of healthy subjects following a single dose of 2.7 g and penetrates well into the lung and bronchial secretions.<sup>3,5</sup> Carbocisteine undergoes partial metabolism in the liver<sup>1</sup> with a diurnal variation resulting in different metabolites forming at different times of the day. Some evidence suggests that higher concentrations of active compounds are achieved with noctur nal administration.<sup>1</sup> Elimination half-life ranges between 90–120 minutes with the different dose forms, and between 30% and 60% of the drug is excreted unchanged in the urine.<sup>1,5</sup>

#### Dosing

| Children<br>(2–5 years)  | 62.5–125 mg three times daily  |
|--------------------------|--|
| Children<br>(5–12 years) | 250 mg three times daily   |
| Adults                   | 750 mg three times daily, reducing to 375 mg four times daily when a satisfactory response has been obtained |

#### Efficacy

In a systematic review and meta-analysis by Zeng et al. that included data from four studies involving 1 357 patients:<sup>7</sup>

- There was a decrease in the rate of total number of exacerbations with carbocisteine compared with placebo (-0.43; 95% confidence interval [CI] -0.57, -0.29, *p* < 0.01).
- Carbocisteine improved quality of life (-6.29; 95% CI -9.30, -3.27) and reduced the number of patients with at least one exacerbation (0.86; 95% CI 0.78, 0.95) compared with placebo.
- There was no significant difference in the FEV1 and adverse effects and hospitalisation rate.

The authors concluded that long-term use of carbocisteine (500 mg three times a day) may be associated with lower exacerbation rates, smaller number of patients with at least one exacerbation and higher quality of life for patients with COPD.<sup>7</sup>

A meta-analysis by Cazzola et al. demonstrated that mucolytic drugs effectively protect patients against COPD exacerbations. This beneficial effect was more significant in patients treated for one year or longer. Carbocisteine, erdosteine, and N-acetylcysteine administered at high doses (600 mg twice daily, corresponding to 1 200 mg/day) were the most effective agents.<sup>8</sup>

In the Chinese PEACE study, 709 patients with moderate-tosevere COPD were randomised in a double-blind trial to receive



## Target mucus with the MUCOSPECT

With **MUCOSPECT** you have the reassurance of the same active ingredient, Carbocisteine, available in 3 different dosage forms, to reduce the viscosity of non-infected mucus in the respiratory tract.

#### **BENEFITS**

- MUCOSPECT Capsules are suitable for adults
- MUCOSPECT offers two pleasant tasting syrups:

#### **MUCOSPECT** Syrup

Pleasant cherry flavour for adults & children from 5 to12 years

### MUCOSPECT Ped syrup

Pleasant raspberry flavour for children from 2 to 12 years

#### INDICATION

Adjunctive therapy in respiratory tract disorders characterised by **EXCESSIVE VISCOUS MUCUS** in the absence of infection.

S2 MUCOSPECT Syrup. Reg. No.: L/10.1/318. Each 5 ml contains 250 mg carbocisteine. S2 MUCOSPECT Ped (syrup). Reg. No.: W/10.1/216. Each 5 ml contains 125 mg carbocisteine. S2 MUCOSPECT Capsules. Reg. No.: P/10.1/186. Each capsule contains 375 mg

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#### FOCUS ON....

500 mg carbocisteine (S-carboxymethyl cysteine) or placebo, three times a day for 12 months. Compared to placebo, patients on carbocisteine had a 0.34 mean reduction in exacerbations per patient per year (1.35 vs 1.01, respectively). As measured by the St. George's Respiratory Questionnaire, quality of life was also significantly improved at 12 months in patients taking carbocisteine.<sup>9</sup>

Following an observational, non-interventional, multicentre, cohort study in 501 patients with COPD who were administrated carbocisteine 375 mg (two capsules three times a day for five days, followed by one capsule four times a day for 10 days) and followed up during the next 15 days, carbocisteine was shown to be effective and well-tolerated and improved quality of life in these patients.<sup>10</sup>

#### Safety

#### **Contraindications**

Carbocisteine should not be administered to patients with active gastric ulceration.<sup>4</sup>

#### Special warnings and precautions for use

Caution is recommended in the elderly, those with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue the medication.<sup>6</sup>

Carbocisteine syrup contains sucrose that may affect glycaemic control in patients with diabetes mellitus. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take carbocisteine syrup.<sup>4,6</sup>

#### **Adverse effects**

Gastrointestinal discomfort, nausea, vomiting, diarrhoea, heartburn, gastric ulceration, and gastritis have been reported after the administration of carbocisteine.<sup>3,4,6</sup> Other side effects may include headache, dizziness, and palpitations.<sup>4</sup> Gastrointestinal bleeding, skin rash and fixed drug eruptions may occur rarely.<sup>1,4</sup>

#### **Drug interactions**

There are no known interactions with other medicinal products.<sup>4,6</sup>

#### Important prescribing points

- Mucolytics may be beneficial in selected cases with chronic, tenacious sputum production.
- Sufficient hydration is vital to reducing sputum viscosity.<sup>2</sup>
- Suppression of a productive cough is not recommended as this may cause mucus retention, promote stasis, and encourage the development of infection.<sup>2</sup>

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## Forum

SA Association of Hospital and Institutional Pharmacists

## The South African Association of Hospital and Institutional Pharmacists (SAAHIP)

37<sup>th</sup> Annual Conference and 66<sup>th</sup> Annual General Meeting (AGM) 2–5 March 2023

## "Time to Thrive"

#### Trials, tribulations & triumphs



#### **Call for abstracts**

In 2023, join the South African Association of Hospital and Institutional Pharmacists Southern Gauteng branch in recognising the trials and tribulations endured while celebrating the triumphs of innovative strategies and evolution of our profession during this global crisis. **It is our time to thrive**.

COVID-19, the global health crisis, has tested our health systems to its limits, even in the world's wealthiest and healthiest nations. This crisis has also made it clear that pharmacists and pharmacies are a crucial and integral part of health systems. Never have the trials and tribulations on the pharmacy profession been so great. During this time of uncertainty and emergency, our profession has demonstrated its expertise, strength, courage and dedication to care at the highest level.

Academics have worked tirelessly to safeguard the continuation of education of our students despite lockdowns to facilitate a workforce that is adequately equipped to meet the evolving needs of our patients. Community pharmacists have performed triage, vaccine administration, supported governments' pandemic initiatives, and ensured patients have continued access to their medicines, in spite of the risk of infection. Hospital pharmacists continue to face huge intakes of patients into their hospitals, with many of them moving beyond their specialties to provide critical care and dealing with ICU and hospital medicine shortages, setting up of field hospitals and vaccination centres, contributing towards the advancement of knowledge around COVID-19 treatment, monitoring drug outcomes and collaborating in the constant updating of treatment guidelines. Moreover, pharmacy students have been volunteering to reduce workforce shortages while pharmacists from all sectors continue to provide reliable information for preventing, detecting, and treating and managing coronavirus infections.

These are but a few examples from a plethora of triumphs which pharmacists have accomplished through their agility, innovativeness, intellect and resilience during the pandemic. We invite and encourage abstract submissions from all practising hospital and institutional pharmacists, community service pharmacists, pharmacist interns and academics. We also challenge pharmacists to be at the forefront of adopting programmes in their work environments that bolster public health.

#### **Categories for submission of abstracts**

Submit your abstracts in the following categories:

#### Pharmacovigilance

- · Adverse drug reaction reporting
- Monitoring of drug safety, quality and efficacy

#### Health system strengthening

• Developing and putting systems in place for sustainable care

#### Differentiated service delivery

 Implementing and providing care and services using task shifting, providing services in a different location, using a different cadre, e.g., PIMART, PCDT

#### Supply chain management

• The rationing of limited medicines and resources

#### **Clinical pharmacy**

• Treatment of ambulatory conditions

## Acceleration of "virtual" practice and adopting of new and current technologies to advance patient care

#### The pharmacist's role during COVID-19

Facing and overcoming challenges such as medicine shortages, general supply shortages (face masks, sanitiser), unfair patient expectations, prescription surges as a result of patient stockpiling, PPE shortages, lack of time for clinical counselling, medical aid challenges, inadequate time for breaks, staff shortages, HR-related issues, discomfort in extension of care (e.g. with opioids) and lack of priority access to COVID-19 testing, to name a few.

#### FORUM

- · Policy, guidelines and SOP adaptation
- Use of technology
- Innovative ways to ensure access to medicines
- · The vaccine roll-out and vaccine administration
- Contributions within a multidisciplinary team during the pandemic
- Prescription extensions, renewals and emergency supplies

The above is by no means an exclusive list. Other topics may be worthy of presentation.

#### **Presentation categories**

Using the following categories, determine the most appropriate format for your presentation:

- **Podium presentations**: A formal 10-minute oral presentation. A further five minutes will be allowed for discussion and to receive questions from the audience. A podium presentation is generally a structured research project with aims, methods, results and conclusions.
- Scenario presentations: A formal 10-minute oral presentation. A
  further five minutes will be allowed for discussion and to receive
  questions from the audience. A scenario could involve an indepth study of a specific real-world event or a particular problem
  that was encountered and solved in a clinical or practice-related
  environment. Scenario presentations should illustrate a good
  understanding of why the event happened or why the problem
  occurred. Presentations should highlight the concerns that arise
  from a scenario (that requires further investigation) and how the
  problem can be solved.
- **Pearl presentations**: A short five-minute oral presentation. "Pearls" are a fun-filled way of presenting a serious topic, but with a different slant. Just as a pearl has an intrinsic value, these presentations should focus on something exceptional, precious and not well known generally. The presentation should convey a useful, punchy message that has not been widely published or taught. The ideas could be from any practice setting, e.g. clinical, administrative, pharmaceutical care or quality improvement. Although both a title and an abstract will need to be submitted for the selection process, only the title will be published in the conference programme. This is to preserve the essence of a pearl presentation. No discussion will take place. Questions will not be invited from the audience.

• **Poster presentations**: A visual display that facilitates discussion. A poster could be research, a case study or a real-life event as outlined in the scenario presentations above. Presenters can display their posters for three days and deliver a formal 2–3 minute talk to the full audience during the scheduled poster session. Discussion and questions from the audience will take place at the poster during the subsequent tea or lunch break.

#### Awards

The following awards will be presented:

- Best podium presentation by a practising hospital or institutional pharmacist
- Best poster presentation by practising hospital or institutional pharmacist
- Best scenario presentation by a practising hospital institutional pharmacist
- Best presentation by an academic pharmacist
- Best pearl presentation

Only paid-up SAAHIP members will qualify for awards. Award winners from the previous two conferences and members of the judging panel will not be eligible for an award.

#### **Abstract submission**

Visit the SAAHIP website for information on the format of abstracts and guidelines for authors: http://www.saahip.org.za/

The information is outlined in the Abstract Submission Guideline document.

Abstracts can be submitted electronically via the link: https://forms. gle/sSbChghWbJG5dXzf8

For more information, you can send an email to: liezl.fourie14@gmail. com

#### **Important dates**

Abstract submission deadline: 16 September 2022

Notification of acceptance or rejection from the Academic Committee: 21 October 2022

## CTICC Vaccination Centre of Hope: The value of a pharmacist in a nurse driven mass vaccination centre in the Western Cape

Caroline de Beer, Dominique Boswell-October

Since the end of March 2020, pharmacists have worked on the frontline of the COVID-19 pandemic response and prevention, and as the world grappled to find solutions to abate the ongoing waves, the formulation of viable vaccines became a reality.<sup>1</sup> Today, with the ongoing pandemic, COVID-19 testing and roll-out of approved vaccines introduced to combat the spread of the virus, pharmacists continue to play a crucial role in our country's recovery.<sup>2</sup>

Once the COVID-19 vaccines were made available in South Africa, the government focused on providing and implementing a vaccine programme to ensure maximum inoculation of the population in the shortest possible time frame. This led to the establishment of a number of vaccination centres which included the Cape Town International Convention Centre (CTICC) Vaccination Centre of Hope.<sup>3</sup> The CTICC had previously served as a world-class field hospital at the beginning of the pandemic so was perfectly placed to fulfil this role as the Western Cape's first mass vaccination site.<sup>4</sup> What made this site unique was that it was a pioneering public-private collaboration between the Western Cape Government Health, the City of Cape Town, Discovery Health and the CTICC. The City of Cape Town worked to ensure the site was fully operational before handing over to the Western Cape Government and Discovery Health. The Western Cape Government was primarily responsible for the overall coordination, supply of vaccines, clinical and facilities management, and Discovery Health was responsible for the client experience, various aspects of the technology solutions and some administrative functions.<sup>5</sup>The Lean Institute Africa was appointed by WCGH as support to the management team to help improve the operational system of the vaccination site. By leveraging the combined resources and capacity of both the public and private sectors, it was set to be one of the largest and most sophisticated vaccination sites in the country and with ease of access, it was envisaged that the site would be equipped for high volumes of vaccinations.

The CTICC Mass Vaccination Centre opened its doors on Wednesday, 7 July 2021, and at its peak, it was estimated to have the capacity to vaccinate just over 4 000 people per day, with 50 vaccination stations, each of which being capable of administering 100 vaccinations daily.<sup>6</sup> As per the trend countrywide and as at other vaccination sites, vaccine hesitancy led to lower than expected numbers in vaccinees presenting, so the team strategised and looked at options to reach the greater community. CTICC was registered as a fixed site linked to New Somerset Hospital that provided the oversight. Groote Schuur Hospital was also linked, and an outreach to the out-patient department at Groote Schuur Hospital was started whereby vaccinators travelled to the hospital with vaccines. Question and answer sessions were also held at some of the bigger businesses in the city centre to promote the use of COVID-19 vaccines. As of 3 December 2021, when the site was officially closed, 140 486 people had received their COVID-19 vaccination here, earning it the title of having the largest number of people vaccinated at a single site in the Western Cape.

The integration of all the various teams assigned to working at the site led to its success and highlighted the benefit of cooperation. From the onset, pharmacy services were involved at the site, right through from commissioning to decommissioning. The added benefit was also in the appointment of a full-time pharmacist and pharmacist assistant who would be based at the site and would be actively involved in the COVID-19 vaccination programme. Nursing staff were primarily responsible for the clinical aspects of the vaccination, including the preparation and administration of the vaccine, whilst the pharmacist had several responsibilities pertaining to, but not limited to, vaccine supply management. This required solid integrated working relationships with the various role players and health disciplines.

In most clinical settings and community pharmacies, the pharmacist will mainly be found in the dispensary, thus limiting interaction and working relationships with other healthcare workers. It was therefore quite unique to have the preparation process of the vaccines, by professional nurses, led by a pharmacist. The teamwork proved to be beneficial to the success of the Vaccination Centre. The pharmacist was able to support and work with the nursing staff in the prefilling area, a separate restricted access room where the vaccines were reconstituted for distribution to the vaccinators. This was to ensure as far as possible all aseptic techniques could be strictly adhered to, and to ensure the high quality of prefilled vaccine syringes.<sup>7-9</sup> The pharmacist oversaw and managed the process pertaining to vaccine preparation, all documentation and record-keeping of vaccines supplied.

The role of the pharmacist at the Vaccination Centre included: (1) stock management, (2) vaccine storage and monitoring, (3) oversight of the vaccine preparation process, (4) managing the demand for vaccines, (5) documenting and reporting stats, and (6) ensuring pharmacy regulations and laws pertaining to cold chain management were adhered to.

**1. Stock management.** Due to the large scale, the management of the COVID-19 vaccines required a hands-on approach. The ordering process was based on the ever-fluctuating increase or decrease in demand for vaccinations and, as such, the continual monitoring of the varying expiration dates of the vaccines was imperative to ensure minimal wastage and expiry of vaccines. Demand varied

substantially week on week, and vaccine usage was monitored daily and then analysed to project weekly order quantities. To highlight this, it can be noted that in August, we reached over 3 000 vaccinees per day yet reaching as low as 336 vaccinees per day by November (Figure 1). These projections were essential as once an order was placed, the Cape Medical Depot, the distributors of the vaccine for the Western Cape Government (WCG), would remove the bulk stock from the -70 °C /- 20 °C freezers, thus resulting in a 31 day/3 month expiry of the thawed Pfizer-BioNTech COVID-19 Vaccine and Janssen Ad266.COV2.S COVID-19 vaccines respectively.<sup>10</sup> Other factors, such as a set weekly delivery day for the vaccines, had to be taken into consideration to ensure that the site did not run the risk of depleting all available stock before the next possible delivery.

As the demand for the vaccine decreased significantly towards the latter quarter of 2021, the various vaccination sites of the WCG as well as some private sector vaccine sites collaborated by using a common platform of communication set up for managers and facilities to collaborate and redistribute vaccines as needed. This platform was an efficient and effective system and unique in having many districts and sub-district working together in partnership on one platform.

- **2. Vaccine storage and monitoring.** Maintaining the cold chain process throughout from receipt of delivery to ultimate usage was extremely important to ensure the quality, viability, and stability of the vaccines. A continuous temperature monitoring device with a built-in SMS warning system was used at all times to monitor the vaccine fridge (ensuring 2–8 degrees range), and twice daily temperatures were recorded.
- **3. Oversight of the vaccine preparation process.** A separate access controlled and designated cordoned off area, away from the public (to ensure safety of the vaccines), was set up whereby the trained professional nurses prepared the vaccines and accurately prefilled syringes for administration.<sup>7-9</sup> This was to ensure strict aseptic technique and accurate preparation of the doses. The entire process was overseen by the pharmacist who, as support, ensured that the professional nurses all had the required equipment, consumables, documentation such as stats sheets and labels to fulfil their duties.
- 4. Managing the demand for vaccines by determining the number of vaccines to be prepared. The pharmacist was tasked with ensuring the steady flow and distribution of vaccines into the vaccination area to limit vaccinees waiting times. This required careful monitoring of expiry times of both the prefilled vaccines in the vaccination area as well as any unused prefilled vaccines at the vaccinator stations (even more so as the various vaccination teams rotated through their respective tea and lunch breaks). Systems, which included tracking sheets, were designed, and implemented that aided in determining the demand vs excess at any given time. This included tracking the vaccine vial from the time of removal from the fridge, to the vial subsequently being pierced to start the prefilling process, through to the safe distribution of the vaccines to the vaccinator. This was a complex process, bearing in mind the very high throughput initially of just over 3 000 vaccinees per day, and it also required two systems to be used, one for the Pfizer-BioNTech COVID-19 vaccine and one system for the Janssen Ad26.COV2.S COVID-19 vaccine.

In the morning, a push system in conjunction with an electronic client data system (managed by Discovery Health which gave a live count of the number of vaccinees presenting at the site), was used by the pharmacist to determine the quantity or number of Pfizer-BioNTech COVID-19 vaccine prefilled vaccine syringes that would be required to allow for a "buffer" or excess. Designated staff members at the site were used to evenly distribute the prefilled vaccine syringes to the vaccination stations, ensuring each vaccinator had anywhere between 1 to 4 prepared and prefilled vaccine syringes at any given time during the first half of the day.

At 14:00, all operations were temporarily halted whilst a live count of waiting vaccinees vs prefilled syringes was done. Vaccine preparation was then adjusted according to a pull system whereby only the exact number of vaccines would be prepared according to the number of presenting vaccinees. This process required constant communication between the vaccinators and the pharmacist to ensure a steady supply of vaccines, and to not increase the waiting times of the vaccinees. It also meant we could keep wastage to an absolute minimum.

- 5. Documenting and reporting stats. Various tracking systems and controlled measures were implemented to ensure that the most accurate and precise vaccine usage and wastage was documented. Each Professional Nurse in the prefill area had their own stat sheet which had a unique code so that the pharmacist could track by name the amount of prefilled vaccine syringes prepared and to which vaccinator these had been issued. This was essential in ensuring accountability but also meant that each vaccinator was assured of receiving vaccines of the highest quality and that if there were any queries, we were able to identify who had drawn the syringe. At the end of each working day all stats were reconciled and recorded on the National Department of Health's Stock Visibility System (SVS) (a mobile application that enables the electronic communication of medicine data from primary healthcare level into an upstream electronic stock management systems). The pharmacist also reported accurate daily stats, which were submitted to the head of operations of health in the Western Cape.
- 6. Ensuring pharmacy regulations and laws pertaining to cold chain management were followed. The pharmacist was responsible for ensuring that vaccines are transported, stored, and managed according to Good Pharmacy Practice cold chain requirements as well as keeping and maintaining temperature logs and updating all stock cards. The correct removal and destruction of all waste generated in the prefill area was also managed by the pharmacist.

#### **Main challenges**

There were a few challenges pertaining to the management of vaccines on such a large scale, and consistent monitoring of the vaccines was required due to their sensitivity to light, temperature, and short expiration time.

One of the biggest challenges was to ensure that vaccinators received vaccines delivered to their individual stations timeously whilst ensuring vaccinees had minimal waiting time. Pre-empting this without the assurance that vaccinees would present meant consistently monitoring demand vs supply to prevent wastage.

Managing two different vaccines was a challenge due to the differences in preparation requirements, expiry times and the criteria for administration.

Frequent questions from vaccinees were often directed to the pharmacist and besides the time this demanded, the pharmacist needed to be well informed to provide the correct information and advice. Vaccine hesitancy became an increasing challenge as time went on and this added to the unpredictable demand and need for vaccines.

## Strategies that were developed and implemented

- Various tracking mechanisms: These included tracking sheets noting when vaccines were removed from the refrigerator, reconstitution, and expiry times, and were constantly updated with updated relevant information being displayed to the staff in the prefill area. Each Professional Nurse who prefilled vaccines had their own stat sheet, which had a trackable unique code.
- 2. Prefilled vaccine delivery system: Prefilled vaccine syringes with capped needles were distributed in sealable containers (two per container and sanitised between issues) which included a label with a unique code, batch number, manufacturer and name of vaccine, and expiration times. This was crucial to ensure the vaccines were delivered safely and the quality was not compromised.
- 3. Control measures: The pharmacist and pharmacist assistant were the only one allowed to receive and manage the delivery of vaccines. Various stock cards and dispensing sheets were used daily to track the vaccines. The refrigerators were locked at the end of each day and only the pharmacist and pharmacist assistant had access to the storage area of the vaccines.
- 4. Training sessions with the nurses: The pharmacist assisted with the training of all professional nurses on aseptic and reconstitution techniques in short information sessions. Additional ongoing training and oversight was provided in the prefill area. All relevant standard operating procedures (SOPs) were written and approved.

#### Highlights

The WCG opened further mass vaccination sites after the opening of the CTICC Mass Vaccination Centre of Hope. One of which was the Athlone Stadium Vaccination Centre of Hope which officially opened on 17 August 2022, for both walk-in vaccinations as well as offering a drive-through section, which at full capacity was set to be on par with the CTICC site, followed by the UCT Community of Hope Vaccination Centre, which opened on 30 August 2022. As we had efficient systems in place, we were asked to assist and guide the pharmacy teams in the setting up of these vaccination sites.

The International Association of Public Health Logisticians (IAPHL) together with SAPICS (an organisation providing training and conferences to supply chain professionals that support public health) asked Professor Norman Faull, of the Lean Institute, to speak on the overall contribution that the Lean Institute Africa made, both nationally

and in the Western Cape, to the South African vaccination campaign. As part of this, Dominique was invited to speak on the "journey" of the vaccine from receipt at CTICC through to delivery of the prefilled syringes at the vaccination cubicles, and in particular the system that has enabled the CTICC to have a very low wastage of doses.

"I was extremely honoured to share my experience and the processes that I had implemented on an international platform. As a newly qualified pharmacist, I was given quite an extensive task of managing the vaccines on such a mass scale and I did not take this responsibility lightly. I gave over and above of what was expected from me and I always strived to ensure that I would add value to the vaccination programme. The working relationships that was developed between the entire team was truly the biggest highlight for me and I was so proud to be part of the entire programme. I am especially grateful to my mentor, Carrie de Beer, for her guidance, support and trust in my capabilities" Dominique Boswell-October, Pharmacist.

"New Somerset Hospital was identified as the pharmacy to be partnered with the Vaccination Site, and as such, I was involved from relatively early in the planning of the project. Being involved with the initial set up of both the site and initial operational systems, solidified for me the importance of accessible, efficient, available, and integrated healthcare for all. Once I had appointed Dominique, I managed pharmacy services mostly off-site, which afforded me the opportunity to empower, guide and coach Dominique, who proved herself to be an invaluable member of the vaccination team" Carrie De Beer, Assistant Manager Pharmacy Services, New Somerset Hospital.

"Although CTICC Vaccination Center of Hope was a nurse driven service, the pharmacist role was pivotal in making the site a success. The pharmacist was instrumental in managing the vaccine supply daily with the expectation to have zero wastage. The site wastage for the period was less than 1% for the whole duration of operation. This can be contributed to the creativity and the initiatives of the pharmacist. Standard operating procedures and tools were created to monitor and evaluate the flow and improvement strategies were implemented on reviews. The aforesaid could not be achieved without having a pharmacist on-site with the support and supervision from an off-site pharmacist supervisor. It was an immense honour to have worked with such a dynamic team that had such an immense contribution to the success of the site" Laetitia Saville, Deputy Manager Nursing, Facility Manager CTICC Vaccination Centre of Hope.

With thanks to Helen Hayes, Manager Pharmaceutical Services Western Cape Health; Jacqueline Voget, Pharmaceutical Policy specialist Western Cape Health; and Helimamy Moeng, Manager Pharmaceutical Services Western Cape Health.

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#### Total number of vaccines administered per month (7 July 2021–December 2021)

#### Figure 1: Total number of COVID-19 vaccines administered at CTICC Mass Vaccination Centre of Hope



Professional nursing staff drawing up COVID-19 vaccines

Left to right: Nomthandazo Tabhu, Lizanne Jansen, Ntabiseng Baza, Elizabeth Ernstzen, Ayanda Bashe, Beverley Kaylor, Nondumiso Feleza, Charlene Jasson, Annzita November, Thembani Ndlovu, Farren Franke, Andrienne van Gensen

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**Back row left to right:** Elizabeth Ernstzen, Andrienne van Gensen, Farren Franke, Ayanda Bashe, Annzita November, Charlene Jasson, Nozipho Dlamini, Nondumiso Feleza, Nomthandazo Tabhu, Nenekazi Khubani, Nthabiseng Baza

Front row left to right: Caroline de Beer, Dominique Boswell-October



Front to back: Thembani Ndlovu, Dominique Boswell-October, Simbongile Mengezeleli



**Left to right:** Dominique Boswell-October, Nozipho Dlamini (pharmacist and pharmacist assistant)



## **Pharmaceutical Practitioner**

South African Association of Community Pharmacists

## What makes a leader (diamond) is character

Simbongile Patrick Pambuka

How far can we see? Can we see a SAACP and PSSA that is united and stronger? That will drive us, that will motivate us, that will improve us – if we can see that far with our hearts, then a UNITED and STRONGER PSSA and SAACP is possible!

"I think that the greatest gift God ever gave man is not the gift of sight but the gift of vision. Sight is a function of the eyes, but vision is a function of the heart" – Dr Myles Munroe

#### **Formation of diamonds**

The name *diamond* is derived from the ancient Greek term called *adámas*, meaning "proper", "unalterable", "unbreakable", and "untamed" and diamonds are extremely rare.

Natural diamonds were formed under conditions of extreme pressure (45 to 60 kilobars) and heat (900 to 1 300 degrees Celsius). Nowadays, laboratory-grown diamonds are created using either a high-pressure high-temperature process or a chemical vapour deposition process.

Diamonds are eventually cut, but they must be polished and shaped so that they refract and reflect white light. This is what gives them their brilliance.

A perfect diamond is produced following a process that takes time and patience!

#### Forming pharmacy diamonds

All pharmacy students, from first to final year, go through tutorials, practicals, tests and examinations. These tutorials, practicals and tests put pressure on them and shape them as pharmacists. The exams generate extreme heat so that they can shine. The continuous repetition of the same process from first to final year polishes them as character is tested through a continuous process. We start as student leaders in student associations like PEPSA, RUPSA or SAPSF.

Pharmacists then join branches and sectors of the PSSA, and some eventually join the national executive committees of SAACP or PSSA.

#### Protecting ourselves from falling and failing

When we become leaders in national structures, we have character that protects us from falling and failing.

Character is what makes a person who they are.

Dr Myles Munroe puts it this way...

"Character protects power and vision. Your gift can never protect your character but your character will protect your gift. Character is developed; you can't pray for it or fast for it. Character is a word that means statue; it means to be set like dried cement. Character is image; you are stable, predictable, and dependable. Character is a dedication to a set of standards without wavering. Character is a constant effort to integrate one's words, deeds, and actions. Let God chisel character in your life. What makes a leader is character and NOT colour nor cash."

#### **Pharmacists as diamonds**

We must understand that these challenges presented to us are opportunities to be put under pressure, in extreme heat and then cut and polished into diamonds called leaders in society. I strongly believe that in every pharmacist, there is a leader.

"The same boiling water that softens the potato hardens the egg. It's about what you're made of, not the circumstances" – unknown

Let us promote and protect our profession with passion and participation with the power provided to us and lead our society fearlessly and confidently!

## Obituary

## Maria (Ria) Jacoba Pretorius 12 September 1957 – 6 March 2022

Ria Pretorius, née Van der Walt, grew up with her three siblings in a farming community and never lost her love of the bushveld. She also remained focussed on family. Her son, Markus, and daughterin-law, Jess, were the centre of her universe, which included her brother Sarel and sisters Rina and Hettie, as well their families.

After matriculating from Brits High School, she followed in her older brother's footsteps, and like Sarel, obtained a BPharm from the University of Potchefstroom, now North-West University. Throughout her career, Ria remained committed to staying abreast of current professional matters and to developing her management, leadership and clinical skills by completing an impressive list of certificate courses.

After completing her internship in a community pharmacy, Ria worked at Kalafong Hospital in Atteridgeville, Pretoria, for six years. This was followed by two years as a community pharmacy manager in Mthatha, Transkei.

Ria's career in the public sector began in 1991, when she joined COMED, the public sector coordinating body for procurement of medicines and medical supplies at the National Department of Health.

When Ria joined the City of Tshwane four years later, she discovered her true calling and her passion – ensuring that patients obtained good pharmaceutical care at primary health clinics.

As Deputy Director of Pharmaceutical Services for the last 20 years of her career, she put the City of Tshwane on the map regarding the delivery of pharmaceutical services, especially at local government level. Her work and contribution have been recognised nationally, with Tshwane being used many times as a reference for pharmaceutical service delivery, including being a pilot site for the National Health Insurance.

People who have worked under Ria stand out by the way they carry themselves. Ria's discipline, integrity and diligence are characteristics that she imparted to those who work with her. Her mentoring skills were recognised as exceptional. One of her pharmacist's assistants, who was mentored and encouraged by her, is a pharmacist today. Ria was involved through the assistant's journey, from planting the seed for her to go to university, to counselling and guiding and supporting her through family and financial challenges.

Ria contributed significantly to the PSSA, directly through the North Gauteng PSSA Branch and Committee, and through



SAAHIP's Northern Gauteng Branch and Committee. At branch level, she was pivotal in driving transformation in the leadership structure. For example, many years ago, she campaigned for the inclusion of people who felt excluded by the existing language policy of the branch. She was never afraid of challenging the status quo, and was passionate about the need to make all leadership structures, branch and national committees, representative of various groupings, i.e. by age, race, gender and, importantly, professionally. She was passionate about bringing pharmacist's assistants into positions of leadership, as well.

Within SAAHIP, Ria has presented frequently at the annual conference. Her presentations enhanced the image of the pharmacy profession and encouraged many pharmacists in practice to look at things differently and with an inquisitive mind. Numerous pharmacists and pharmacist's assistants found themselves presenting at the SAAHIP conference, when they had thought that they were incapable of public speaking, let alone presenting in front of their colleagues. Her reassuring albeit "gentle forceful" encouragement saw several people grow professionally and in their personal lives.

Ria managed to work behind the scenes and help many people, including very senior people in leadership positions at national SAAHIP and PSSA level, to achieve their full potential in their positions. She was amazed to be given the well-deserved honour of Fellowship of the Pharmaceutical Society of South Africa. Her legacy will live on for years.

SAAHIP and the PSSA extend their sincere condolences to her family, and especially to Markus and Jess.

## Pharma Dynamics marks 20-year milestone with sonic art



FROM THE HEART

This year, leading local pharmaceutical company, Pharma Dynamics, celebrates 20 years of increasing access to healthcare.

To mark the important milestone, it is inviting staff, patients, pharmacists, healthcare practitioners and all those who helped to shape the company in the last two decades to collaboratively participate in the creation of a digital artwork that will take on the form of a heart.

Erik Roos, CEO of Pharma Dynamics says choosing the illustration of a heart is not only a symbol of the company's long-standing position as the market leader in cardiovascular medication, but also symbolises the heartbeat of the organisation.

"The artwork is our story that defines and articulates the way in which each employee and the company as a whole, is improving the human condition in a meaningful and sustainable way. Furthermore, it is symbolic of the connection and causal effect between the company and its stakeholders – together making a difference in the world".

#### Pharma Dynamics CEO, Erik Roos

Pharma Dynamics' digital sculpture takes shape in response to sound. The more people contribute their voices in the form of voice messages, the more intricate the sculpture becomes.

Since the introduction of digital technology, sound art is becoming more popular and comes in various forms, including kinetic sound sculptures,

sound-walks, poetry and in Pharma Dynamics' case, the spoken word. It's a new wave of sonic artistry that uses tones and audio effects to create an artistic expression – the same way a painter uses colours on a canvas.

Roos says just like every business is unique and follows a different growth journey of expansion and consolidation, no one journey is ever the same.

"The artwork represents our transformative business journey from start-up to maturity and is meant to be a compilation of heartfelt stories from people who helped us to get where we are now." Pharma Dynamics has much to celebrate. It is the ninth-largest pharmaceutical and sixth largest generic company in South Africa, with 19 market-leading brands, operating in 30 therapeutic areas, which include cardiovascular, neuroscience, pain, digestive health, female healthcare, critical care, antibiotics, complementary and alternative medicines (CAMS), amongst others.

It is a level 4 BBBEE company and has remained the no.1 supplier of cardiovascular medication in the country for over a decade, amid fierce competition.

Roos says it's difficult to fathom that the small company which started with only a handful of people some 20 years ago, now employs over 160 staff countrywide. Over the years, the company has significantly contributed to the South African economy, not only in terms of broadening medicine access, but also job creation and social investment.

"As we look back on our growth, accomplishments and relationships built with our customers, we would like to thank everyone who has been involved in supporting Pharma Dynamics in reaching 20 years of success. It has been made possible, because of the trust that healthcare professionals and patients put in our products and our incredible team who go the extra mile every day to service customers the best they can.

"In a way, companies are like families. We build them with all our heart, putting our blood, sweat and tears into making it grow and flourish. At Pharma Dynamics, we are a family and our values of integrity, passion for service excellence, teamwork, respect and care and entrepreneurial spirit underpin everything we do. Our values shape our culture and is our unique heartbeat. Together we have created a company known for its quality products, services and commitment to making healthcare affordable and accessible to all.

"While we celebrate our 20-year success, we remain futurefocused. We have already set new goals and benchmarks that we look forward to achieving in the coming years and are directing our talent, focus and energy toward applying new ideas and tools for improving health for all," says Roos.

To participate in Pharma Dynamics' sonic sculpture, visit <u>https://</u><u>mydynamics.co.za/20years/</u> to add your voice. Your unique contribution is downloadable for you to keep.





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