

SAMA

INSIDER

SEPTEMBER 2021

**SAMA urges doctors
to unite and promote
COVID-19 vaccines**

**Cyber risks in healthcare:
Are you ready?**

PUBLISHED AS A SERVICE TO ALL MEMBERS OF
THE SOUTH AFRICAN MEDICAL ASSOCIATION (SAMA)



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SEPTEMBER 2021



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WHAT ARE WE ABOUT

Assisting health professionals to maintain and acquire new and updated levels of knowledge, skills and ethical attitudes that will be of measurable benefit in professional practice and to enhance and promote professional integrity. The SA Medical Association is one of the institutions that have been appointed by the Medical and Dental Professions Board of the Health Professions Council of SA to review and approve CPD applications.

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Diane de Kock
Editor: *SAMA INSIDER*

Looking at the bigger picture

Welcome to the September *SAMA Insider*, an issue that questions the status quo in SA healthcare.

SAMA President Risenga Chauke asks if we are over-regulating medical practitioners, particularly in view of the minimum of seven regulatory bodies that exist to regulate doctors (page 4) and contribute to overwork, burnout and mental health issues. "It goes around in circles – a vicious circle. This needs to be halted."

Recent reports that some healthcare workers have discouraged patients from getting COVID-19 vaccines have caused dismay, prompting SAMA and other organisations to issue statements condemning vaccine hesitancy (page 5). "Medical professionals who propagate COVID-19 misinformation may discourage people from becoming vaccinated, which could lead to preventable loss of life."

Herd immunity is no longer a discussion the world should be having, says Prof. Madhi of Wits. "It's not going to materialise – or it is unlikely to materialise – during our lifetimes (page 6) ... the only sustainable solution is to learn to live with the virus."

Volunteers are able to change lives – a reality at Tintswalo Hospital in Mpumalanga (page 8), where access to specialists is not possible unless volunteers are recruited. The Tshemba Foundation makes this happen. "Skills transfer and a continuous stream of volunteers have changed the landscape for us," says Dr Maebela, senior clinical manager.

Music lifts the soul, and as poet and author Berthold Auerbach said, "Music washes away from the soul the dust of everyday life." Everyday life for healthcare workers during this pandemic has been extremely difficult (page 9). As a token of appreciation, SAMA commissioned Lloyd Cele to compose a song dedicated to SA's healthcare workers. "We are extremely proud of what they're doing, and we hope this song conveys that message," says SAMA head of marketing and communications, Dr Simonia Magardie.

SASOP warns (page 11) that the continuous unrest, looting and violence gripping parts of the country could lead to a spike in PTSD among children. "Take concerns about depression, suicide and anxiety seriously."

The recent publication of the contentious "Certificate of need for health establishments and health agencies" could have a huge impact on healthcare. SAMA expresses concern (page 14), and is negotiating with government on the issue.

When you take time to look at the bigger picture it can cause a shift in perspective and change your judgement and focus, either as an individual or an organisation. The bigger picture can reinforce what's important, and refocus your attention on true priorities.

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Are we over-regulating medical practitioners?



Prof. Risenga Chauke, SAMA President

Up to a minimum of seven regulatory bodies, all geared toward regulating a category of health professionals known as doctors, can be counted in SA.

All these regulatory bodies differ in their complexities and roles. All aim towards controlling doctors as health professionals. This phenomenon is not unique to SA – it replicates itself the world over.

Holding the profession accountable is commendable. But does the number of organisations holding the profession accountable matter? Do these organisations add any value to the way the profession is practised? Can't these organisations be merged into one? Put differently, how did the profession end up with so many regulatory bodies? Why is it that different aspects of the profession of medicine are fragmented to different regulatory bodies, some of which overlap considerably?

Regulators exist to establish national standards for qualification, and to ensure consistent compliance with those standards.

We may not fully understand why they over-regulate, but the effects need to be highlighted.

The costs to the practitioner are enormous. These costs in monetary terms occur in the form of subscription fees. Practitioners need to pay these annual fees to enable them to continue to practise. Those

payments are to be made to the HPCSA, the Board of Healthcare Funders, the professional societies to which they belong and even to the unions that represent them for labour issues. There are also administrative costs, in the form of record-keeping, claiming from medical schemes that require different formats, enlisting a third party to make the claims, managing bad debt, and bureaucracy.

The need to keep ourselves knowledgeable in terms of the recent developments in medicine, in the form of CPD, which does not necessarily come cheap, also adds to the costs. CPD does not only require continuous learning of subject matter in the profession – it is also very specific in terms of the need to acquire ethical points. Acquisition of these ethical points may be challenging at times, but if not acquired, the practitioner stands a good chance of being penalised.

Societal subscription fees need to be settled as well. Professional societies are meant to represent practitioners in various sector negotiations in order to protect the practitioner's rights. There is often a huge overlap between what the professional societies do and what labour unions do. But, more often than not, a practitioner has to belong to both organisations, particularly those who find themselves working both for the state and privately.

Society expects health professionals, and doctors in particular, to always act in its best interest. Doctors are to be at their best socially, financially and in their behaviour at work and elsewhere. This is not always possible. Doctors are fallible. They stumble and fall, and therefore require all the support they can get.

A combination of what is expected of them in terms of financial matters and conduct leads to burnout and mental health issues.

The COVID-19 pandemic has clearly demonstrated this. Over-regulation cannot be excluded as an enabler for this burnout and the associated mental health issues.

Burnout means becoming completely exhausted through overwork. It is a state of emotional, physical and mental exhaustion caused by excessive and prolonged stress. It is indeed correct to link burnout with the development of mental health challenges among doctors.

It is well known that the rate of suicide among doctors is high. This may be a result of viewing over-regulation as unfair treatment. By 2018, the rate of suicide among doctors was the highest among any profession in the USA. This rate was 28 - 40 per 100 000 population. Burnout made it into the 11th revision of the International Classification of Diseases (ICD-11) as an occupational phenomenon.

The rate of suicide among doctors in SA is currently unknown, but for all intents and purposes, it is high.

It is important to improve the wellbeing and mental health of doctors. Doctors should be free to access emotional support, and it should be made affordable for them.

Policy-makers need to rethink the way that doctors are regulated. Regulators need to be reduced to one or two bodies. There should be thought given to tax relief of doctors, given the number of subscriptions they have to pay to remain practising.

Policy-makers need to rethink the way that doctors are regulated

This over-regulation is not only limited to doctors at the coal-face of seeing patients. It also applies to doctors in laboratories and in research.

Over-regulation also necessitates that doctors pay huge insurance fees to cover themselves. This in turn results in overwork, burnout and mental health issues. So it goes around in circles – a vicious circle. This needs to be halted.

Time, energy and effort are required for doctors to meet these regulatory requirements. Fraud and corruption add to the burden that doctors have to practise under, driving costs up.

The state, and indeed the community at large, have to maintain *quid pro quo* to keep the doctors sane. And reduction in over-regulation of this cadre will go a long way toward alleviating this. We, as an association, shall work tirelessly to highlight this plight of over-regulation of health practitioners in an endeavour to reduce its effects on our members.

SAMA urges doctors to unite and promote COVID-19 vaccines

SAMA Communications Department

SAMA is dismayed at reports that some healthcare workers – including doctors – have discouraged patients from getting COVID-19 vaccinations based on doubts about vaccine safety and effectiveness.

"We wholly reject any doubts about the COVID-19 vaccines. There is high confidence among the scientific and medical community about the effectiveness and safety of the vaccines being rolled out in SA, and they have also undergone safety and efficacy tests by the SA Health Products Regulatory Authority. These are overwhelming endorsements of the vaccines, and there should be no doubt that every citizen must get one," says Dr Angelique Coetzee, chairperson of SAMA.

Dr Coetzee says that the medical fraternity must be united in its commitment to ensure wider access to the vaccines. This, she says, must be based on spreading accurate, evidence-based information, dispelling any misinformation and overcoming vaccine hesitancy, which threatens the goal of achieving optimal vaccine coverage. She says that vaccine hesitancy arises from a combination of ignorance, misinformation, conspiracy theories, doubt of scientific evidence, concerns relating to medical histories, and cultural, religious and philosophical beliefs.

"Vaccine hesitancy, however, should be condemned, and so should those who fuel it, particularly doctors who should know better. We share concerns with global and local scientists – and I use that term purposefully – that unfounded objections to COVID-19 vaccines deepen the public health crisis caused by the pandemic," notes Dr Coetzee.

Dr Coetzee says the societal benefits of vaccines have been proven historically over and over again, and that vaccines represent one of the most significant public health innovations to date and have altered the trajectory of human health. She says it is important that South Africans realise the value of vaccines and that the country's vaccine rate rapidly increases from its current low of only 6% of the population. She says that for this reason, SAMA will continue to urge for greater global vaccine equity, and continue to challenge intellectual and property restrictions that are impeding access to COVID-19 tests, treatments and vaccines.

Dr Coetzee further notes that significant strides have been made by prioritising healthcare

workers for vaccines, and that the government should be commended for this action. However, she says that healthcare workers, especially doctors, who have not yet been vaccinated must take the opportunity to do so not only for their own health, but also because of an ethical responsibility to "do no harm".

"We have an obligation to protect our patients from COVID-19, and this includes encouraging vaccination. Encouraging vaccinations means that as medical doctors, we must impart accurate, science-based data, not personal views. This is the only way we afford patients the right to informed consent," Dr Coetzee concludes.

Spreading of false information on the COVID-19 vaccine by doctors is unethical and illegal

SAMA unequivocally supports vaccination as essential in the public health response to the COVID-19 pandemic, and endorses the importance of scientific integrity, transparency and public confidence in COVID-19 vaccines.

SAMA reiterates that COVID-19 poses a significant medical and public health risk, and notes with grave concern the spread of false information about COVID-19 vaccines by individuals within the medical fraternity. Medical professionals who propagate COVID-19 vaccination misinformation may discourage people from becoming vaccinated, which could lead to preventable loss of life.

Medical professionals have an ethical duty, as articulated in the oaths that they take, to prioritise the health and wellbeing of their patients, to practise medicine with conscience and dignity, in line with international best practice standards and evidence-based medical practice, and to serve humanity.

Personal beliefs and opinions must not interfere with sound medical management. In the case of a COVID-19 vaccination that is safe and efficacious and which has been approved for use by the SA Health Products Regulatory Authority, medical professionals have duties as stipulated by the HPSCA to:

- respect patients as individuals, and recognise their inherent worth, dignity and sense of value;
- not cause harm or act against the best interests of patients or society, even when those interests conflict with their own;
- regard truth and truthfulness as the basis of trust in their professional relationships with patients; and
- strive to make a positive contribution to society in accordance with their professional abilities and social position.

Furthermore, on legal grounds, purposeful intent to disseminate harmful, inaccurate and false COVID-19 vaccination information that might result in preventable fatalities is an offence. In terms of section 27(2) of the Disaster Management Act No. 57 of 2002, regulation 11(5) stipulates that:

"Any person who publishes any statement, through any medium, including social media, with the intention to deceive any other person about:

- (a) COVID-19;
- (b) the COVID-19 infection status of any person; or
- (c) any measure taken by the government to address COVID-19, commits an offence and is liable on conviction to a fine or imprisonment for a period not exceeding 6 months, or both such fine and imprisonment."

SAMA will not support any of its members who spread misinformation about COVID-19 vaccines. SAMA does not condone unethical and illegal behaviour by its members, and calls on the HPSCA to discipline medical professionals who breach their ethical duties by spreading COVID-19 vaccine misinformation.

COVID-19 herd immunity? It's not going to happen, so what next?

Shabir A Madhi, dean, Faculty of Health Sciences; professor of vaccinology; and director of the SAMRC Vaccines and Infectious Diseases Analytics Research Unit, University of the Witwatersrand

Any notion in 2020 that COVID-19 was going to last for just a few months was very much misplaced. Especially after it was recognised that the SARS-CoV-2 virus was largely spread through the airborne route, all indications were that it would cause repeat bouts of waves. This is what happened with the flu epidemic of 1918.

In addition, very few scientists predicted that we would see the types of mutations that have occurred over such a short period of time. These have resulted in the virus becoming both more transmissible and more able to evade immune responses.

The evolution of the virus has been so rapid that the Delta variant, which is currently dominating the world, is at least twice as transmissible as the ancestral virus.

What this means is that herd immunity is no longer a discussion the world should be having. We should start to avoid using that term in the context of SARS-CoV-2, because it's not going to materialise – or is unlikely to materialise – during our lifetimes.

When politicians and others speak about herd immunity, unfortunately, they are under the misconception that the current tools we have are adequate to eliminate the virus. It's not what we have at hand right now.

Instead we should be talking about how to live with the virus. The tremendous success that's materialised with COVID-19 vaccines allows us to do this, without actually getting into the herd immunity threshold.

Peddling the concept of herd immunity creates a misconception that we are actually going to get to a stage where this virus is going to be eliminated. That's unlikely to happen. It will continue circulating.

There are a number of dangers in continuing to make people believe it's possible.

Firstly, it could dent confidence in vaccines. Even if SA gets to its target of 67% of the population being vaccinated – as set out by the Department of Health – there will still be outbreaks of COVID-19. The result will be that people begin to doubt the benefits of being vaccinated. Also, for the now-dominant Delta variant, immunity against infection (not only COVID-19 illness) would need to be closer to



84% for the “herd immunity” threshold to be reached.

Secondly, failing to face up to the reality that herd immunity can't be achieved will mean that countries such as SA will continue to believe that ongoing restrictions will get them there. That will compromise the lives of people on multiple fronts – including education and livelihoods.

What is herd immunity?

Herd immunity is when someone infected by the virus won't, on average, infect another person. So you reach a state where the immunity in the population against infection by the virus is such that there are too few people in the environment for sustained onward transmission to take place.

This is because they've developed immunity against being infected, or at least have developed immunity to the extent where even if they were infected, they would be able to clear the virus very quickly, and not transmit it to other people.

So herd immunity essentially means that you have brought about an absolute interruption in the chain of transmission of the virus in the population in the absence of other interventions that too could interrupt virus transmission, such as wearing of face masks.

But some changes have forced a shift in our thinking about herd immunity. It's now viewed much more as an aspiration than an actual goal.

What's changed

Firstly, the evolution of the virus and the mutations that have occurred.

One set of mutations made the virus much more transmissible or infectious. The Delta variant is just such an example. Initially, we thought the

SARS-CoV-2 reproductive rate was between 2.5 and 4. In other words, in a fully susceptible population, every one person infected would on average infect about two-and-a-half to four other people. But the Delta variant is at least twofold more transmissible. That means that the reproductive rate of the Delta variant is probably closer to six rather than three.

The second change is that the virus has shown an ability to have mutations that make it resistant to antibody-neutralising activity induced by past infection from the original virus, as well as antibody responses induced by most of the current COVID-19 vaccines.

The third big issue centres on the durability of protection. Our memory responses are lasting for at least 6 - 9 months at the moment. But that doesn't mean that they will protect us against infection from variants that are evolving, even if such memory responses do assist in attenuating the clinical course of the infection leading to less severe COVID-19.

The fourth issue conspiring against us being able to reach a herd immunity threshold any time soon is the inequitable distribution of vaccines across the world, the slow uptake and the sluggish rollout. Unfortunately, this provides fertile ground for ongoing evolution of the virus.

No country is going to lock its borders perpetually. This means that the entire global population needs to reach the same sort of threshold round about the same time. At the moment, just 1% of the populations of low-income countries have been vaccinated, and 27% of the global population.

With the Delta variant, we would need to get close to 84% of the global population developing protection against infection (in the absence of non-pharmacological interventions) in as brief a period of time as possible.

Next steps

The only sustainable solution is to learn to live with the virus.

This will require ensuring that we get the majority of individuals, especially adults, and particularly those at a higher risk of developing severe COVID-19 and dying, vaccinated as quickly as possible. In my view this could be achieved in SA with 20 million people vaccinated – not the 40 million target set by the government. But the 20 million would need to include 90% of people above the age of 60, and 90% of people above the age of 35 who have comorbidities.

If SA achieved this milestone, it could get back to a relatively normal lifestyle even with the virus continuing to circulate and causing the occasional outbreak. It would also ensure a threshold that guaranteed that its healthcare

systems weren't going to be overwhelmed, and that people were not going to die in large numbers.

We are simply going to have to become comfortable with the idea that SARS-CoV-2 is going to be like one of the numerous other viruses that circulate and cause respiratory illness each day. Usually mild infections, and less often a severe disease.

So people will, unfortunately, continue dying of COVID-19, but certainly not at the magnitude that's been seen over the past 18 months. A major advance would be for COVID-19 to be no more severe than what is seen every influenza season (10 000 to 11 000 deaths) in SA.

The UK experience is where we should be heading. That is, getting back to a relatively normal lifestyle, provided that we have an

adequate number of people vaccinated, and particularly people who are at higher risk of developing severe COVID-19.

The UK is currently close to reaching 85% of adults who have already received at least a single dose of the vaccine. As a result, they have been able to remove almost all restrictions.

The UK is seeing an increase in the number of cases of the Delta variant. But they've seen very nominal changes when it comes to hospitalisation and death. The vast majority of people (97%) who still end up being hospitalised and dying of COVID-19 in the UK are those who have decided not to be vaccinated.

Source: The Conversation, 3 August 2021. <https://theconversation.com/covid-19-herd-immunity-its-not-going-to-happen-so-what-next-165471>.

Warning on vaccinations and ivermectin

SAMA Communications Department

The Critical Care Society of Southern Africa (CCSSA) and the SA Society of Anaesthesiologists (SASA) have issued a statement regarding vaccinations and ivermectin use in critically ill patients with COVID-19 infection.

Both of these professional organisations are concerned about the large numbers of patients requiring critical care, especially in provinces such as Gauteng. Their concerns are further escalated by several society members highlighting that many patients under their clinical care in the third wave have not received the COVID-19 vaccination, and that a large majority of these patients have been treated with ivermectin.

The current COVID-19 pandemic has had a massive impact on the medical and scientific community. The collaborative work by many role-players has seen the rapid and safe development of vaccines against the SARS-CoV-2 virus, an amazing achievement in a limited time. Vaccinations, along with stringent public health measures, remain the most crucial steps of our response to the pandemic.

While there has been much debate around vaccination options and effectiveness, current evidence clearly points to the need for as much of the population to be vaccinated against the SARS-CoV-2 virus as soon as possible. Despite initial challenges in the rollout of the COVID-19 vaccination programme in SA, the programme is expanding, and the public is encouraged to get vaccinated urgently. There is no substitute for vaccination.

CCSSA and SASA are also deeply concerned that many patients and their families view treatment with ivermectin as an alternative to getting vaccinated.

Ivermectin has been plagued with controversy since the initial consideration of its possible role in the management of COVID-19, with advocates both for and against its use. Many anecdotal reports are circulating in the press and social media as to the drug's effectiveness, with it being erroneously seen as a "miracle cure." Such assertions have been based on poor-quality evidence, including studies such as the recently retracted Egyptian study that purported to show very positive outcomes, only to be subsequently found to be fraught with allegations of scientific fraud and plagiarism. As with all interventions that are applied in clinical care, careful consideration needs to be given to the body of evidence available to evaluate effectiveness and harm in relation to therapies.

The recent updated SA National Department of Health rapid review report on ivermectin for treatment of COVID-19 describes a well-conducted, detailed evidence review of clinical benefits and harms of ivermectin with or without other medicines for patients with COVID-19. The report highlights the fact that the available randomised controlled trials have considerable differences with respect to interventions and comparator groups, and many suffer from significant methodological limitations that limit

the confidence in any conclusions that can be drawn. The current evidence for the use of ivermectin in COVID-19 does not suggest any clear benefits with respect to mortality, clinical improvement or viral clearance.

This was followed by SA Health Products Regulatory Authority CEO Boitumelo Semete-Makokotlela that "ivermectin should not be used routinely in the management of any stage of COVID-19, except in the context of sufficiently powered randomised clinical trials (RCTs), with well-defined study endpoints intended for regulatory marketing authorisation."

CCSSA and SASA are supportive of this recommended approach currently, while further trials are awaited. We do not recommend the use of ivermectin for either prophylaxis or therapy in patients with COVID-19 outside an ethically approved formal study.

Additionally, a major mutual protection organisation for healthcare professionals recently cautioned practitioners who are considering prescribing ivermectin to be aware of the potential pitfalls in doing so, as this could have implications for practitioners' indemnity if specific stipulations are not followed. Healthcare practitioners are urged to heed this caution.

Source: Medical Brief, 28 July 2021. <https://www.medicalbrief.co.za/warning-from-ccssa-and-sasa-on-vaccinations-and-ivermectin>.

How healthcare volunteers are changing lives at a rural district hospital

SAMA Communications Department

Tintswalo Hospital is a 423-bed public hospital located in Acornhoek in Mpumalanga. It is one of the largest district hospitals in the province, serving a population of approximately 300 000 people, most of whom live in poverty without basic necessities.

"Our biggest challenge isn't that we are busy, it's that due to severe budget constraints, we can only recruit junior doctors and nurses. If a senior or grade 3 staff member leaves, we often can't replace them at all," says Dr Maebela, senior clinical manager.

It's not a situation unique to Tintswalo, particularly in district hospitals. The situation is exacerbated by the fact that such district healthcare facilities are staffed by medical officers who offer primary care, but there are no specialists, such as cardiologists, gynaecologists, ophthalmologists or anaesthetists, on staff. Specialists are reserved for regional hospitals and private healthcare facilities.

The result is that rural patients in the catchment areas of district hospitals can access primary healthcare, but not specialists – unless there are volunteers.

The critical role of volunteers

The Tshemba Foundation is a unique non-profit organisation that recruits volunteers to give life-changing support at Tintswalo Hospital and its surrounding clinics.

"Our goal is to make it as simple and comfortable as possible for SA and international volunteers to make an impact in the lives of patients," says Barbara McGorian, CEO of the Tshemba Foundation. "Very often, healthcare professionals want to give back, but they don't know where to begin, and that's where Tshemba comes in."

The volunteers themselves find it to be a deeply rewarding experience. Dr Mary-Anne Hartley, an international volunteer who is head of Intelligent Global Health (iGH), recounts an experience she had while volunteering at the hospital: "I saw a very ill patient who waited for 6 hours in the blazing sun with nowhere to sit but the queue that forms outside the hospital.

"With no other options, I performed an intimate examination on her in a room with no curtains or doors for privacy. Throughout,

she was extremely polite and patient. There is a deep gratitude for access to medicine and doctors at Tintswalo. While it is unfortunate that volunteers are needed at all, the extreme lack of resources and staffing means that volunteers are absolutely essential to ensure basic service delivery and improve the quality of care in rural hospitals," says Dr Hartley.

Supporting local patients and doctors

"The Tshemba Foundation has had an incredibly positive impact on Tintswalo," says Dr Maebela. "Tshemba has donated a fully equipped eye clinic, which has changed the lives of hundreds of local residents already, but the real value lies in volunteers."

Volunteer groups cover a wide range of disciplines, from generalists to ophthalmologists who perform cataract surgeries, and specialist researchers who are spearheading a rural ultrasound project. "We even had one international volunteer set up a funding project to renovate our emergency ward. That support is invaluable to us," says Dr Maebela.

"A few weeks ago, we had an anaesthetist volunteering with us, and she offered to train one of our doctors. Access to specialists is extremely motivating for our junior doctors. They receive valuable experience, upskilling and access to someone who continues to support them, even when they have left the hospital and returned to their practices," says Dr Maebela.

"Whether a volunteer is from Germany or Gauteng, remote support means that even after they have left, our doctors can check in and ask how best to manage a specific case. This extension of expertise to support a district hospital is lifesaving. It also keeps our doctors motivated because they know that there is support available to them when they need it.

"Skills transfer and a continuous stream of volunteers has changed the landscape for us. We have a true partner that isn't only trying to help – they are listening to what we need, and making a meaningful impact.

"For anyone thinking of volunteering – please do," says Dr Maebela. "Just a few days will not only change your life, which we've



Tshemba's medical director, Prof. John Gear, and clinics co-ordinator, Inez Allin, with a patient



Volunteer chats to a patient

seen time and time again, particularly from volunteers who come back each year, but it will also change the lives of our doctors and community. There are so many ways to add value, and the team at Tshemba can guide you around how you can make an impact."

Book your #LeaveOfPurpose today

While the Tshemba Foundation's volunteer programme is best suited for longer stays, there are short-term opportunities available that can accommodate busy schedules while still maximising the impact of volunteering at Tintswalo and the local clinics in the area.

To find out more, visit <https://www.tshembafoundation.org/our-volunteer-programme>.

SAMA says thank you: Caring for the carers

SAMA Communications Department

SAMA recently commissioned a song to celebrate Mandela Day on 18 July, but its message resonates further than that single day. Composed by award-winning singer, songwriter and producer Lloyd Cele, the song, "Thank you, Caring for the carers", honours healthcare workers in SA.

"The purpose of the song is twofold: I want healthcare workers to realise how blessed we are to have them, and the second is for the public to appreciate what healthcare workers do for them, and to encourage all South Africans to rally around healthcare workers," says Lloyd.

He says that the past year has been especially difficult for healthcare workers, and that many of them are under severe physical and mental strain. Yet, he says, doctors, nurses and other healthcare workers work from early in the morning to late at night, always with a smile, because they are doing what they love and are fulfilling their obligations to care for others.

"When I was approached to compose the song, I did a lot of research and spoke

to many friends who are healthcare workers. I quickly realised that they are overworked and under-resourced, and many of them are carrying extreme emotional burdens. It's something not all of us realise, and it's only when you dig a little that you realise how difficult their lives are. On top of all of this, these people put their own and their families' lives at risk every day, and that also plays a major role in their overall wellbeing," notes Lloyd.

SAMA Head of Marketing and Communications, Dr Simonia Magardie, says the association wanted to do something that extended beyond Mandela Day.

"Healthcare workers across SA have worked tirelessly every day since the pandemic first hit our shores, and we can't just recognise them for one day of the year. It's also important for us that healthcare workers understand that the public genuinely respects their efforts, and that the work they are doing is not taken for granted. We're extremely proud of what they're doing, and we hope this song conveys that message," says Dr Magardie.



Lloyd Cele composed the song

"Healthcare workers are heroes who walk among us, and I hope this song makes these heroes feel proud of themselves. We can never take our healthcare workers for granted, and my hope is that anyone who interacts with a healthcare worker in future tells them how valued they are, that they are not alone, and that we stand united behind them," says Lloyd.

The full lyrics of "Thank you, Caring for the carers" are:

VERSE 1

We see the tears on your face
The weight of the world on your shoulders
Abandoned your needs for the cause
Saving lives selflessly

PRECHORUS

Your will to fight
You're patient and you're kind
For your sacrifice
Don't give up

CHORUS

All we wanna say is thank you
For laying down your life
For every sacrifice
Thank you
We wanna say it loud
We're grateful and we're proud
Every single moment
Late and early mornings
Every sleepless hour
You're always
With a smile

VERSE 2

You're a hero with no cape
Your superpower is love
With courage and bravery you stand
You must be an angel
Our angel in disguise
Must be an angel,
Our angel in disguise

PRECHORUS

We will win this fight (oh yes we will)
Through your strength we'll survive
We'll face the night
We won't give up

CHORUS

Thank you
For laying down your life
For every sacrifice
Thank you
We wanna say it loud
We're grateful and we're proud
Every single moment
Late and early mornings

Through the sleepless hours
You always
Smile

BRIDGE

We care for our carers
Yes we do
You're not alone
We wanna say it loud

CHORUS

Thank you
For laying down your life
For every sacrifice
SAMA thanks you
We wanna say it loud
We're grateful and we're proud
Every single moment
Late and early mornings
Through the sleepless hours
You always
Smile
So we say thank you, thank you

"Thank you, Caring for the carers" is available on all digital platforms, and can also be viewed/downloaded on http://africori.to/lloydcele_thankyou.

This is no time to neglect hepatitis – 70 million Africans are infected

Pauline Bakibinga, *associate research scientist, African Population and Health Research Center*

In 2016, the WHO set an ambitious target to eliminate viral hepatitis by 2030. This was followed by commitments from governments – including those of African countries – to develop national strategic plans for viral hepatitis, and to earmark resources to eliminate the disease.

Hepatitis results in the inflammation of the liver. There are different forms of hepatitis – A, B, C, D and E – each attributed to a different type of virus. Unfortunately, most people who have the most serious forms of the disease, particularly the B and C viruses, are unaware of infection. This allows the infection to spread unchecked, leading to serious damage to the liver.

This year, World Hepatitis Day is marked under the theme “Hepatitis can’t wait”. It is a clear call to improve efforts toward eliminating a disease that kills one person every 30 seconds globally.

Many African countries that committed to eliminating the disease have either not ratified their guidelines, or not increased access to hepatitis care. Of the 47 countries in the WHO Africa region, 28 have developed national plans to eliminate the disease. However, only 13 countries have disseminated them.

The childhood vaccine given at birth is effective, but in many rural and remote parts of Africa, over 40% of children are still unable to get the vaccines when they need them. Reasons for this include erratic vaccine supplies and outdated vaccination schedules.

These challenges have been further compounded by the COVID-19 pandemic, which has eroded some of the gains that had been made in the past few years. With movement restrictions and social distancing as part of the responses to curb the spread of infections, people have been less able to use services to prevent and cure hepatitis and other diseases.

The disease

In Africa, 70 million people are infected, and 200 000 die annually from hepatitis. This is despite the availability of treatment.

Hepatitis B is the most common form of the illness. It is spread through infected body fluids, either through sex with an infected partner, at birth (from an infected mother to her baby), via direct contact with open wounds or blood of

an infected person, or through sharing syringes, razors or toothbrushes with infected persons.

The mainstay strategy for managing hepatitis B is prevention, through the administration of a vaccine. It is also treatable through oral antiviral drugs that in most cases must be taken for life. This is because the treatment, in most people, only leads to the suppression of the virus and not its complete eradication.

To prevent disease progression, it is highly recommended that treatment begins within the first 3 months of infection.

Positive lessons

The call again this year is therefore for renewed efforts to ensure that no baby is born with hepatitis, pregnant women get tested and treated, awareness is raised about the disease as well as testing and treatment and governments invest more in efforts to end the disease. More concerted efforts are needed to keep services going even amid the disruptions caused by the pandemic. Countries need to commit more domestic resources to fast track elimination. Cape Verde, Uganda and Rwanda provide positive lessons. They have committed resources to ensure a 99% birth dose vaccination rate, free national hepatitis B treatment and free treatment for hepatitis B and C. This shows what political will can achieve.

Cape Verde’s government funds all vaccine services, and implemented hepatitis screening for pregnant women in 2002 and the pentavalent vaccine in 2010 (this is a combination vaccine that protects against five killer diseases: diphtheria, pertussis, tetanus, hepatitis B and *Haemophilus influenzae* type b (Hib)). The country has maintained almost 98% vaccine coverage for decades, an example other countries in the region need to follow. This is as a result of its commitment to using an equity lens in its health and social services, combined with a multisectoral approach to health and wellbeing.

Next steps

Mobile health services have worked effectively in Madagascar and SA in increasing access to vaccines and family planning services. Using mobile clinics that can reach communities in far-flung areas could enable health workers to provide hepatitis screening and treatment services.

These would be supported by mainstream and social media platforms, as well as opinion leaders, to create more awareness about the disease and planned community outreach services. Platforms such as this are also needed to conduct advocacy to raise awareness and generate more support for prevention and treatment programmes. Successful campaigns have been run to create awareness about HIV/AIDS, the dangers of drugs and substance abuse and road safety, among other issues.

In Africa, 70 million people are infected, and 200 000 die annually

Through virtual spaces, communities of practice can be created to share best practices that enhance awareness and resources essential in the elimination of the disease.

Hepatitis services are not as adequately funded as other priority areas such as HIV, immunisation and reproductive health. This means that hepatitis care needs to be integrated into programmes promoting access to healthcare. For instance, this would help ensure that regular hepatitis screening is made available to women who go to health facilities for antenatal services, or to patients under treatment for HIV infection.

Integration of services has worked effectively for HIV and TB. These methods need to be considered for hepatitis management.

And because of the important role that vaccinations serve, more efforts need to be invested in ensuring that women and children receive their vaccines on time.

Though the pandemic presents challenges to eliminating hepatitis, African countries can recover some of the lost time. It requires taking more innovative approaches to promoting access to information and services.

Source: The Conversation, 27 July 2021. <https://theconversation.com/this-is-no-time-to-neglect-hepatitis-70-million-africans-are-infected-165030>.

Unrest in SA – children vulnerable to PTSD

SAMA Communications Department

The continuous civil unrest, looting and violence gripping parts of our country could see a spike in post-traumatic stress disorder (PTSD) among children, even those not directly impacted, warns the SA Society of Psychiatrists (SASOP).

Dr Anusha Lachman, child psychiatrist and SASOP board member, said that children are highly susceptible to fear and feeling overwhelmed as they witness the unsettling current events via social media and the news, and through adult conversations.

She says parents and care-givers play the most crucial role in assisting children to deal with the current uncertainty, and they need to recognise that simply hearing about the violence, and observing adults' responses to the situation, can cause child a child to become anxious and traumatised.

Feeling out of control

"There is ongoing trauma, fear and helplessness across the country. Parents are traumatised by what is happening and are largely helpless onlookers to the destruction and violence. The trouble is that amidst the sense of helplessness, people look for ways to be more in control. One of the ways is to 'doom scroll', seeking to constantly be informed, sharing videos, voice notes, photos, etc., anything that is recording and keeping track of the ongoing unrest," says Dr Lachman.

"However, these constant reminders can re-traumatise parents, and instead of feeling more in control by being informed, it reinforces their sense of a lack of control because they are unable to act. Not being able to prevent it and witnessing people getting away with the destruction becomes more traumatising. Many parents and grandparents recall the same kind of helplessness and fear leading up to the 1994 unrest and curfews in KwaZulu-Natal, as well as fears of civil unrest around the first democratic elections. Witnessing the current riots and looting could result in flashbacks and re-experiences for many adults."

Dr Lachman says the challenge for parents is how to remain vigilant without re-traumatising themselves – and thereby exposing their children to trauma.

"Adults can limit exposure to news, social media updates and WhatsApp messages doing the rounds and, importantly, recognise the role they play in their children's lives. As

caregivers, they are meant to buffer and scaffold children and adolescents – filtering news and supporting children to prevent further traumatising. This is challenging if parents are themselves traumatised. However, there needs to be an awareness that children need to be restricted from controllable exposures such as the news and social media.

"While they cannot be protected or prevented from witnessing things in the environment, they can be prevented from hearing about it or seeing it on other platforms. As many parents continue to talk, share and express distress about that which is out of their control, there must be an active attempt to prevent children from being unnecessarily traumatised."

What is PTSD?

Dr Lachman says that PTSD is triggered during a traumatic event, such as the reality in our country at the moment, and can manifest either immediately after or during a stressful event, or only after 6 months or more. It can also result in anxiety and depression in the long term.

"PTSD is a result of something happening to a child or to someone close to them, or being exposed to adult conversation, social media, the news or via a video. It's important to note that children do not have to be directly involved in the events for them to be traumatised, and that heightened anxiety is not only limited to those children physically exposed to the violence and disruption.

"Children and adolescents may feel a lot of emotional and physical distress when exposed to situations of trauma or reminders of a traumatic event. They may relive these events, even if they were not directly involved, as a result of repeated exposure to reminders on television, adults talking about the situation or via social media."

PTSD symptoms include nightmares, flashbacks, poor sleep, disturbing memories and anxiety-related behaviours, such as being clingy, jittery, nervous, more alert or on watch.

Other behaviours include feeling depressed, being grouchy, having trouble focusing, worrying about safety, fearing death, having trouble feeling affectionate, aggression, or avoiding going outside or staying away from situations that can trigger memories of the trauma. These can also include regressive behaviours such as thumb-



sucking, bedwetting, baby-like behaviours or somatic symptoms such as sore stomach or headaches.

Dr Lachman says that not every child or teenager exposed directly or indirectly to trauma will suffer from PTSD. "Diagnosis by a mental health professional is only made once the symptoms present themselves for a month or more. However, children can experience acute stress reactions while the trauma is ongoing or in the immediate aftermath, and symptoms can persist for months after the trigger."

What can parents do to prevent PTSD during this stressful time?

Admit that the event happened. Acknowledge the reality of being scared, worried or upset.

Do not pretend that this is all normal. Rather focus on the positives, such as the assistance and help from police and other groups, how communities are working together and supporting each other, and that the situation is improving.

Even though as an adult, you might feel frustrated that the help and protection offered is perhaps not enough or quick enough, it is helpful to communicate the optimism of support, especially since children rely on adults to take care of them.

Explain that the situation is anxiety-provoking for everyone, and be supportive around the idea that there is expected anxiety and fear. Offer support/help/counselling via connections such

as SADAG, a psychologist or your GP if persistent symptoms become apparent.

Provide structure. Children already lack routine due to the lockdown and extended school closures. Try and make practical attempts to provide structure by scheduling activities indoors such as watching a movie together, building puzzles, cooking, baking and arts and crafts – anything that is able to move them away from focusing on the trauma.

Encourage children to express their fears and anxiety openly by talking, drawing, and writing, and encourage connection online with friends and family.

Focus on the positive. You and your child/children are safe, they have a home/shelter and food. If they worry about food shortages, focus on everyone being in the same situation, and remind them that there are many organisations/NPOs and people across the country stepping in to help and to keep children safe and fed.

Allow children to feel that they can also help. They can post creative messages of care, collect food for donations (especially those in other provinces not directly affected), or join you as you assist with clean-ups in communities impacted. To foster a sense

of purpose, children can also collect toys, games and stationery for less privileged children and distribute these in communities most hard-hit.

Look after your own mental health and anxiety. If you need help, seek assistance from your GP or other professional, or a close friend. Do not share your anxiety with your children. Rather be the one seeking help, and become a role model for your child in acknowledging the need for help.

Take concerns about depression, suicide and anxiety seriously, and contact a professional immediately for support.

Vaccine inequity undermining global economic recovery

United Nations Development Programme, World Health Organization, University of Oxford

A new Global Dashboard for Vaccine Equity on COVID-19 finds that low-income countries would have added USD38 billion to their GDP forecast for 2021 if they had the same vaccination rate as high-income countries. Global economic recovery is at risk if vaccines are not equitably manufactured, scaled up and distributed.

COVID-19 vaccine inequity will have a lasting and profound impact on socioeconomic recovery in low- and lower-middle-income countries without urgent action to boost supply and assure equitable access for every country, including through dose sharing, according to new data released on 22 July 2021 by the United Nations Development Programme (UNDP), the WHO and the University of Oxford.

An acceleration in scaling up manufacturing and sharing enough vaccine doses with low-income countries could have added USD38 billion to their GDP forecast for 2021 if they had similar vaccination rates as high-income countries. At a time when richer countries have paid trillions in stimulus to prop up flagging economies, now is the moment to ensure that vaccine doses are shared quickly, all barriers to increasing vaccine manufacturing are removed and financing support is secured so that vaccines are distributed equitably and a truly global economic recovery can take place.

A high price per COVID-19 vaccine dose relative to other vaccines and delivery costs – including for the health workforce surge – could put a huge strain on fragile health systems and undermine routine immunisation and essential health services, and could cause alarming spikes

in measles, pneumonia and diarrhoea. There is also a clear risk in terms of foregone opportunities for the expansion of other immunisation services, for example, the safe and effective rollout of HPV vaccines. Lower-income countries need timely access to sustainably priced vaccines, and timely financial support.

These insights come from the Global Dashboard for Vaccine Equity, a joint initiative from the UNDP, the WHO and the University of Oxford's Blavatnik School of Government, which combines the latest information on COVID-19 vaccination with the most recent socioeconomic data to illustrate why accelerating vaccine equity is not only critical to saving lives, but also to driving a faster and fairer recovery from the pandemic with benefits for all.

"In some low- and middle-income countries, less than 1% of the population is vaccinated – this is contributing to a two-track recovery from the COVID-19 pandemic," said UNDP administrator Achim Steiner. "It's time for swift, collective action – this new COVID-19 vaccine equity dashboard will provide governments, policy-makers and international organisations with unique insights to accelerate the global delivery of vaccines and mitigate the devastating socioeconomic impacts of the pandemic."

According to the new dashboard, which builds on data from multiple entities including the IMF, World Bank, UNICEF and Gavi, and analysis on per capita GDP growth rates from the *World Economic Outlook* survey, richer countries are projected to vaccinate more quickly and recover faster economically from COVID-19, while poorer countries have not even been able

to vaccinate their health workers or most at-risk populations, and may not achieve pre-COVID-19 levels of growth until 2024. Meanwhile, Delta and other variants are driving some countries to reinstate strict public health social measures. This is further worsening the social, economic and health impacts, especially for the most vulnerable and marginalised people. Vaccine inequity threatens all countries and risks reversing hard-won progress on the Sustainable Development Goals (SDGs).

"Vaccine inequity is the world's biggest obstacle to ending this pandemic and recovering from COVID-19," said Dr Tedros Adhanom Ghebreyesus, director-general of the WHO. "Economically, epidemiologically and morally, it is in all countries' best interest to use the latest available data to make lifesaving vaccines available to all."

Designed to empower policy-makers and development partners to take urgent action to reduce vaccine inequity, the global dashboard breaks down the impact of accessibility against a target for countries to vaccinate their at-risk populations first to reduce mortality and protect the health system, and then move on to vaccinating larger shares of the population to reduce disease burden and reopen socioeconomic activity.

The dashboard is facilitated by the Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP), which aims to improve collaboration across the multilateral system to support an equitable and resilient recovery from the pandemic, and drive progress towards the health-related SDGs.

World Brain Day 2021 dedicated to multiple sclerosis

SAMA Communications Department

It has been called an invisible or silent disease – the symptoms of multiple sclerosis (MS) are not always obvious, but the disease can cut short the life ambitions of young, economically active people. However, earlier diagnosis and better access to treatment can offer better quality of life to those affected by a disease for which there is no cure.

This year's World Brain Day on 22 July was themed "Stop multiple sclerosis", and aimed to raise awareness of the debilitating neurological disease that impacts every aspect of a person's life, with effects ranging from cognitive impairment to severe physical disability.

MS is an immune-mediated disease, one of the most common diseases of the brain and spinal cord (central nervous system), and affects more than 2.8 million people of all ages around the world – approximately 36 in 100 000 people. Although the prevalence of MS in SA has not been sufficiently researched, the MS World Atlas 2020 estimates it at 8 per 100 000 people.

Pretoria neurologist Dr Chris Retief, who co-authored the SA guidelines for diagnosis and management of MS, said the disease afflicts predominantly young, economically active people, with 32 years the average age of diagnosis globally. It is the most important cause of neurological disability in people under the age of 60.

The Neurological Association of SA (NASA) is collaborating with the World Federation of Neurology (WFN) and the MS International Federation (MSIF) on World Brain Day 2021, aiming to raise awareness so that MS can be diagnosed earlier, promoting better access to life-changing treatments, and advocating for improved quality of life for those living with MS and their caregivers.

"Every 5 minutes, someone somewhere in the world receives the life-altering diagnosis of MS, so the urgency of this matter could not be more apparent," said Prof. Tissa Wijeratne, the World Brain Day chair and director of the neuroscience research unit at Western Hospital in Melbourne, Australia.

"More than 2.8 million people of all ages live with MS around the world, and every one of those people has a story, friends, family and dreams," says WFN President Prof. William Carroll. "Our goal is to raise awareness of MS and its impact on the individuals who live with it, their loved ones and society, to improve



access to quality neurological care and life-changing treatments."

What is multiple sclerosis?

MS is characterised by inflammation and damage to myelin, the coating that insulates and protects the nerves. MS inflammation involves the brain, spinal cord and optic nerves. This inflammation typically results in episodes of neurological disability (called relapses), including visual loss, inco-ordination, walking impairment, weakness or paralysis of a limb, loss of sensation, loss of control of the bladder and impairment of mental functions. Cognitive or mental impairment includes difficulties in thinking, concentration and memory.

The inflammation may also be mild but ongoing, resulting in mild unrecognised relapses, or silent gradual deterioration.

MS also includes an assortment of "invisible" symptoms including fatigue, pain, and cognitive and emotional issues.

The precise trigger of inflammation is unknown, although research clearly implicates abnormal behaviour of B-lymphocytes. Epstein-Barr virus, commonly known as the cause of glandular fever, is strongly suspected to trigger the MS immune cascade, especially if contracted after childhood.

What is the impact?

Dr Retief further explains: "Relapses are characteristic of the initial or early phase of the disease. Treatment of a relapse consists of high-dose steroids administered through a drip

over a few days. Initially the relapses actually resolve quite well, perhaps giving one a false sense of security that the disease can easily be kept under control with only steroids."

However, if the disease is not treated more intensively, the abnormal B-cells can become clustered in the brain, resulting in chronic continuous inflammation. This is called secondary progressive MS, which leads to progressive disability.

Hence it is vitally important to attempt to prevent or at least delay this phase of the disease.

"It is important to appreciate the concept of neurological reserve. Children and young people have enormous neurological reserve, and generally recover very well from a neurological insult such as a head injury or a MS relapse. Unfortunately, recurrent relapses and silent ongoing inflammation deplete this neurological reserve, and leave the patient disabled in middle age when their professional demands and family responsibilities are greatest.

"In short: untreated MS makes a patient's brain grow old a lot faster," Dr Retief said.

MS must be recognised and treated early, even if the person feels well in the beginning, he advised.

What can we do?

Dr Retief said that 25 years ago, there was no treatment for MS, and up to 10 years ago only one tier of treatment was available.

"In 2021, fortunately, we have several treatment modalities," he said.

These range from immunomodulators (which change the immune system, but are very safe to use), immunosuppressive medications (which suppress the immune system), lymphocyte sequestrators (which prevent the abnormal B-lymphocytes from entering the brain), immune reconstitution therapies (which reset the immune system for a number of years), to bone marrow transplantation (in which the immune system is eradicated and replaced).

The more recent treatments are very effective. However, even after bone marrow

transplantation, about a third of people develop symptoms again after 5 years, he said.

NASA president Dr Patty Francis highlighted the need for patient advocacy.

"The unseen symptoms of fatigue, depression, chronic pain, subtle mental difficulties, impaired bladder and bowel control and sexual dysfunction are often the most disabling. People with MS hate hearing the words: 'But you look so good!'. They may look good, but they feel horrible.

"Simply going by the physical may cause doctors to undertreat patients, employers and

insurance companies to not accommodate people adequately and medical funders to be reluctant to pay for the required medication," Dr Francis said.

As part of the World Brain Day 2021 campaign, NASA, WFN and the MSIF invite patients with MS, their loved ones, healthcare providers, MS organisations and the public to join in and raise awareness of MS through the use of the hashtag #WorldBrainDay2021.

To learn more about MS and to participate in the global awareness activities, please visit <https://wfneurology.org/world-brain-day-2021>.

Dismay at certificate of need regulations

SAMA Communications Department

SAMA notes the publishing of the contentious "Certificate of need for health establishments and health agencies" regulations, and again raises its concerns about this proposed legislation.

The regulations seek to activate provisions in the National Health Act No. 61 of 2003 that require a certificate of need (CoN) to run, establish, construct, modify or acquire a health establishment. The initial period for commentary on the regulations has been extended from 15 July to 15 August, following objections from various stakeholders, including SAMA.

"Firstly, we are disappointed at the sudden, surreptitious publication of the regulations without prior notification. That aside, SAMA has serious concerns about the implications of this legislation, particularly as we believe it could be detrimental to the provision of health services in a country already struggling to provide these services effectively. Introducing these regulations could, we believe, have the unintended consequence of unnecessarily closing doctors' practices, and triggering an exodus of doctors to other countries," says Dr Angelique Coetzee, chairperson of SAMA.

In addition, Dr Coetzee says that the regulations could create barriers of entry into the market by reducing competition, which will cause a rise in healthcare costs that will be unaffordable for the majority of South Africans.

Dr Coetzee says, "We further believe that the Constitutional rights of individual medical doctors, such as freedom of movement and residence, freedom of trade, occupation and profession, the right to property and the right to human dignity will be negatively impacted. We

simply cannot abide by these proposals, and they should be urgently rescinded."

Of equal concern, she says, is the fact that the legislation gives unfettered powers to the health minister over the health industry, and denies patients the right to be serviced by a medical doctor or establishment of their choice.

SAMA says that should the CoN regulations be implemented, existing medical practices would be under threat, as they will not be allowed to continue their business without applying for – and being granted – a CoN to render services in a government-approved geographical area.

Current proposals are that existing health establishments – if they are granted approval – would receive a CoN which is valid for only 3 years. New establishments would receive certificates valid for 20 years, but these would have to be renewed annually.

"Of concern is that these CoNs can be revoked at any time by government who would, effectively, create criminals out of doctors overnight. This is because the failure to obtain a CoN carries a prison sentence of up to 5 years, or an as-yet-unspecified fine amount, or both. We cannot allow such a situation to occur, not only for the sake of our members, but, more importantly, for the sake of their patients," says Dr Coetzee.

Dr Coetzee says that SAMA has spoken of these and other concerns in its interactions with the Minister and Director-General of Health.

"Despite these engagements, we are still faced with an extraordinarily short time in which to make formal submissions on this matter. The brief period to provide commentary illustrates the Department of Health (DoH)'s insensitivity towards its stakeholders, including SAMA. We

are a member-based association and, as such, we must have widespread and exhaustive consultations to ensure that we accurately represent the interests of all our members across various disciplines. This timeframe does not adequately allow for that outcome," says Dr Coetzee.

Dr Coetzee says the concerns around the timing of the submissions are shared by other medical and health bodies, but that despite the DoH's assurance that the process would not proceed without consultation, this appears to be an attempt to limit that consultation. She says SAMA urges the DoH to reconsider its timeframes, especially as it believes the department should work with other stakeholders instead of only reviewing their submissions on the CoN regulations.

SAMA says that in the event that its negotiations with government on this issue break down, it will have no alternative but to partner with other affected stakeholders to find reasonable solutions, and to take appropriate action. It says it will attempt to avoid taking a legal route as far as possible, but that it may have to consider this option if a reasonable solution is not forthcoming.

"Ultimately, we cannot comment on the present regulations without referring to the original CoN provisions contained in the National Health Act, which reflect more clearly the intentions of the CoN, and which contain more comprehensive criteria for awarding or denying such certificates to be issued. However, even these are confounded by certification processes and standards of the Office of Health Standards Compliance, and we will change these," concludes Dr Coetzee.

Dr Suveer Jhugroo fights TB in Pinetown

Dr Buyisile Chibi, project manager, Connect TB

Dr Suveer Jhugroo greets me with a big smile as I enter his practice to present his award. He is a friendly man who cares passionately about his patients, and the evidence is on the faces of the staff and patients in his waiting room. It's not an easy time to be a GP; in the midst of SA's third wave of COVID-19, patients and staff are anxious. The recent KwaZulu-Natal unrest has also affected doctors in the area. But it takes more than that to keep Dr Jhugroo down. He shows up bright and early to start his day. If a patient is coughing, he takes appropriate precautions and asks the patient for more detail. You see, COVID-19 is not the only cause for concern. EThekweni District has one of the highest rates of TB nationally, the number one cause of death by infectious disease in the country.

Like COVID-19, cough is a common symptom of TB, which most often affects the lungs. TB is also spread through contact between people, but differs in that it is only spread through the air by cough, and not through contact with surfaces and personal contact such as hugs and handshakes. TB symptoms also take longer to develop after exposure than COVID-19. Symptoms take several weeks or even years to develop, as the bacteria can hibernate in the lungs or other parts of the body for long periods. Other common TB symptoms can include weight loss, night sweats and fever. Importantly, TB is curable with treatment. The sooner a person is diagnosed and started on treatment, the better chance they have of making a full recovery. That's where Dr Jhugroo comes in. Through his participation in a University of KwaZulu-Natal (UKZN) pilot study called Connect TB, Dr Jhugroo is able to collect a spit sample from patients with TB-like symptoms for free TB testing through the National Health Laboratory Services (NHLS).

The pilot study is intended to reduce delays in TB testing for patients who first present to the private sector. Previous research has shown that patients with TB symptoms who seek help first with private GPs are either sent home with ineffective antibiotic treatment or referred to the public sector to access free TB testing. Both these practices can delay diagnosis, which contributes to poorer patient outcomes and



Dr Jhugroo submitted the highest number of patient samples for testing since the project began in May. From left to right: Sr Denise Moodley, Sr Vanessa Naidoo, Sr Nomusa Ngcobo, Dr Buyisile Chibi, Dr Suveer Jhugroo, Dr Tsholofelo Mhlaba, Sr Sibusisiwe Mzamo and Sr Tlalane Nthoba

ongoing TB transmission. The overlapping symptoms of TB and COVID-19 have also resulted in further delays, as patients with cough are often assumed to have COVID-19. Signing on to Connect TB has helped local GPs connect symptomatic patients to TB testing without having to leave the GP's office, making it simple to test for both COVID-19 and TB when necessary. Patients who are diagnosed with TB through the study are referred for treatment via SMS, which speeds up the process and reduces the number of healthcare visits. Patients are also supported through 6 months of treatment by adherence facilitators who contact them regularly by phone to check on their wellbeing and assist with resolving treatment barriers. Adherence facilitators are then able to give feedback on patient progress to participating GPs, closing the loop when patients choose to receive TB treatment through the public sector.

Recognising the importance of early TB detection and of differentiating TB from COVID-19, Dr Jhugroo signed on early to the Connect TB project. On 6 August, the Connect TB team had the honour of awarding him for submitting the highest number of patient samples for testing since the project began in May of this year. Almost a quarter of the samples submitted by Dr Jhugroo tested positive for TB – a sign that

the project is helping to find people with TB who might otherwise have been delayed or lost to the system – and all of whom were quickly able to link to treatment. True to form, Dr Jhugroo's response to receiving the award was to place the focus back on his community: "My patients are very happy about the support for testing. I am just glad to be part of this initiative, and make a difference."

The pilot study is intended to reduce delays in TB testing for patients who first present to the private sector

The Connect TB project is led by Dr Jody Boffa (principal investigator), Dr Tsholofelo Mhlaba (principal investigator) and Dr Buyisile Chibi (project manager) at UKZN, and made possible through a partnership with the KZN Department of Health, eThekweni Health District and NHLS, and funding from the Stop TB Partnership and the Bill & Melinda Gates Foundation.

Cyber risks in healthcare: Are you ready?

Rosanna Hayes, *STORM Guidance*

While 2020 saw an alarming rise in cases of cyber incidents, 2021 has continued to see these climb. Attacks are more sophisticated than ever before, and nation-states such as Russia, China and North Korea are increasingly ambitious in their approach, with targeted attacks on a range of businesses and service providers, including supply chains and critical national infrastructure. Globally, we are failing to curb the escalation in digital violations, and it is clear that we are now in the age of the cyber-attack.

Earlier this year, Check Point reported a 45% increase in attacks targeting healthcare organisations globally, and the threat landscape is no better in SA. As the perfect storm for cyber-criminals brews, medical associations are becoming a favourite target among hacker groups. In January of this year, IOL reported a breach of several of SA's leading hospitals and healthcare organisations. The surge in ransomware attacks caused severe disruption to systems, and the effects this had on the delivery of care leaves no question over the sheer lack of morality of these criminals, or their absence of regard for the lives they endanger.

In June 2020, the Life Healthcare hospital chain fell victim to an attack causing massive damage across their 66 hospitals in SA. Admissions systems, business processing systems and email servers were targeted, causing administrative delays, and a reversion to manual processing had to be deployed. However, it seems that this was simply the start of what would be the new focus for cyber-criminals, as the healthcare industry's urgent need for restoration of critical services places them as a front-runner for fast money.

The Check Point report named the healthcare sector as the most commonly targeted industry in the world, with the average number of attacks to health organisations rising to 626 per organisation in December 2020, from around 430 in October of the same year. The most frequently reported forms of attack were ransomware, botnets, remote code execution and distributed denial-of-service (DDoS). Hospitals now record the highest frequency of ransomware attacks of any sector. According to the report, many hospitals rush to pay these ransoms, fearing disruption to the delivery of care, while hacker demands piggy-back on the pressures the hospitals already face from COVID-19 cases.

It must be stressed that hospitals are not alone in this plight, as hackers also seek the



health and banking data of medical practices, in many cases to assist in the commission of fraud.

It is important for individual surgeries to be aware that even when they are not the direct target, they can still be liable for data lost. Doctors must work together with hospitals and laboratories to keep patient and financial data secure.

In light of the cyber-crime pandemic, on 1 July 2021 SA introduced the Protection of Personal Information Act No. 4 of 2013 (POPIA), which legislates the protection of personal information processed by public and private bodies. POPIA outlines the rights of data subjects, regulates cross-border flow of personal information, mandates security over personal data, introduces mandatory obligations to report and notify data breach incidents and imposes statutory penalties for violations of the law.

POPIA makes very clear the obligations of SA businesses, and especially those storing and processing sensitive health data. When incidents occur, the regulatory scrutiny is likely to identify any organisations that do not respond effectively to reduce their impact on data subjects.

SA medical practices and healthcare organisations that are already challenged with cyber-security concerns are unlikely to be able to respond well to a devastating incident, and many have not yet considered what they will do when a cyber incident occurs. IT providers are unlikely to have the skills and experience to assist effectively, or they may be conflicted in the provision of cyber investigation services if they are already tasked with security implementation or monitoring.

Healthcare businesses and the professionals who run them need to be concerned with the increasing cyber threat faced by the sector. It is important to address cyber risk exposure,

implement security measures and ensure access to a suitably independent and highly skilled cyber incident response team when breaches occur. Reputational harm, another concern for healthcare providers, can also be amplified if response to a cyber incident is not handled by experienced cyber investigators.

The new levels of accountability brought about by the introduction of POPIA must guide healthcare organisations and practices towards addressing the current risk posed to their systems and patient data, either before or in the wake of an incident. With the industry currently in the spotlight of cyber-criminals, failure to comply with the regulations of the Act could result in being found guilty of an offence or being issued with a penalty or administrative fine. For the more serious offences, the maximum penalties are a ZAR10 million fine, imprisonment for a period not exceeding 10 years, or both.

SA is now listed as one of the top countries globally for instances of system breaches, and healthcare and financial companies are the most targeted of any sector. We are continuously seeing the new and sophisticated methods cyber-criminals adopt to pilfer valuable personal healthcare data and sell it on the dark web. It is time that healthcare organisations prioritise educating their staff in cyber-security best practices and consider employing skilled IT and security teams who will implement essential security measures, engage in regular risk analysis and provide immediate incident response in the event of a breach.

CyberCare SA is the STORM Guidance response service in SA, made up of a highly skilled and experienced cyber investigations team. For more information email: contact@stormguidance.com or phone: +230-434-1277.

Unpacking the SA GCP guidelines 2020

Adri van der Walt, SAMAREC officer

The conducting of biomedical research is dependent on various considerations, including local legal and ethical requirements and clinical trial and regulatory authority regulations, as well as ensuring compatibility with international standards.

Within SA, two major sources are available to address the abovementioned considerations:

- the national research ethics guidelines: *Ethics in Health Research: Principles, Processes and Structures* (National Department of Health, 2015)
- the *South African Good Clinical Practice: Clinical Trial Guidelines* (2020).

The good clinical practice (GCP) guidelines focus on the planning, managing and conduct of clinical trials, while the national research ethics guidelines detail research infrastructure, as well as research ethics principles and the operations of research ethics committees.

Both of these guidelines are established under the National Health Act No. 61 of 2003, as well as the Medicines and Related Substances Act No. 101 of 1965. Compliance with these guidelines is compulsory for any and all biomedical researchers under the direction of the Director-General of Health.

SAGCP 2020

The 3rd edition of the SA GCP Guidelines was updated in 2020. The guidelines were formally published on 15 June 2021, and researchers are expected to implement the new guidelines by 1 October 2021.

Formal training by a reputable GCP course trainer must be undertaken for beginners as well as for renewals, and the training certificate is valid for a 3-year period.

There are logistical challenges involved in ensuring that all researchers receive formal updated training before 1 October 2021. As such, it is recommended that internal training

and self-study be implemented, and a record of this training/study be kept.

Important considerations for the SAGCP 2020 edition

Regulatory bodies for clinical research in SA:

- SAHPRA: the SA Health Products Regulatory Authority has a dedicated clinical trial unit that provides a legal framework for the review of clinical trial and bioequivalence studies
- NHREC: the National Health Research Ethics Council governs the registration and function of all local research ethics committees; their role and responsibilities are governed by the Department of Health guidelines
- SANCTR: the SA National Clinical Trial Register is a web-based platform where all clinical trials in SA must be registered – this is a public accessible website, where all clinical trials in SA are listed; its main function is the prevention of duplication of research projects, as well as enhancing collaboration between researchers.

Study outcomes and results must be shared with the various regulatory bodies mentioned above, as well as participant communities (where appropriate).

Socioeconomic status increases the vulnerability of potential participants significantly, and this must be taken into account.

Currently, there is no formal prescribed reimbursement amount in SA. However, reimbursement of participants can be calculated by using the SAHPRA clinical trial participant time, inconvenience and expense (TIE) compensation model.

Categories of investigators are described, as well their respective roles and responsibilities, specifically in terms of compliance to the

protocol, progress reports and reporting of adverse events, management of the investigational product(s) and the informed consent process.

Essential documents must be kept for at least 10 years after completion of the research project.

Continuation of care after research, also known as compassionate use, should be considered for certain phase III studies – SAHPRA has developed guidelines on this matter titled “Post clinical trial access (PTA)/ continued access”.

Electronic signatures are allowed, but must contain the printed name of the signer, the date and time when the signature was executed, and the meaning associated with the signature (if the signature is in the form of e.g. a series of symbols).

Various logistical issues encountered during the current COVID-19 pandemic have been identified. Maintaining social distance and ensuring the implementation of infection control and prevention methods provide numerous challenges to researchers in terms of site visits, sample collection and investigational product management. The guidelines provide an umbrella recommendation that all researchers should consult SAHPRA or their ethics committee for assistance and advice in managing these matters. This will be highly study-specific.

For more information, please feel free to contact the SAMAREC secretariat at samarec@samedical.org.

The full updated guidelines can be found at https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf.

The Department of Health guidelines can be found at <https://www.ul.ac.za/research/application/downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf>.

Congratulations Dr Lengana

The SAMA Research Ethics Committee (SAMAREC) strives to ensure that members appointed to the committee are not only experts in research ethics, but also highly qualified in their respective fields. We are therefore very proud to share that Dr Thabo Lengana (clinical member of the committee) has recently obtained his doctoral degree in nuclear medical sciences.



Status on paternity leave within the public sector

Ruan Vlok, employee relations advisor, SAMA employee relations department



The Labour Laws Amendment Act No. 10 of 2018 was signed into law by President Cyril Ramaphosa in November 2018, with the intent to amend the Basic Conditions of Employment Act No. 75 of 1997 to provide for parental leave, and took effect from 1 January 2020. This amendment allow parents, inclusive of fathers, adopting parents and surrogates, to apply for 10 days' paternity leave upon the birth of a child. Since the signature of the aforementioned law, SAMA been inundated with queries from members employed within the public sector enquiring into the status of their rights with regard to parental leave benefits. In this article we will discuss the new law and its current position within the public sector, while comparing it with differences from the position within the private sector.

Section 25A of the Basic Conditions of Employment Act No. 75 of 1997 regulates parental leave, and states as follows:

- "(1) An employee, who is a parent of a child, is entitled to at least 10 consecutive days' parental leave.
- (2) An employee may commence parental leave on –
 - (a) the day that the employee's child is born;
 - or

- (b) the date –
 - (i) that the adoption order is granted; or
 - (ii) that a child is placed in the care of a prospective adoptive parent by a competent court, pending the finalisation of an adoption order in respect of that child, whichever date occurs first.
- (3) An employee must notify an employer in writing, unless the employee is unable to do so, of the date on which the employee intends to –
 - (a) commence parental leave; and
 - (b) return to work after parental leave.
- (4) Notification in terms of subsection (3) must be given –
 - (a) at least 1 month before the –
 - (i) employee's child is expected to be born; or
 - (ii) date referred to in subsection 2 (b); or
 - (b) if it is not reasonably practicable to do so, as soon as is reasonably practicable
- (5) The payment of parental benefits will be determined by the Minister, subject to the provisions of the Unemployment Insurance Act, 2001 (Act No. 63 of 2001)."

With regard to the current position within the public sector, clause 5 of the Public Service Co-ordinating Bargaining Council (PSCBC) resolution 2 of 2015 states as follows:

"5.1 Introduction of three (3) working days per calendar year of paternity leave with effect from the date of signing of the agreement, for utilisation if the employee's spouse or life partner gives birth to a child or adopts a child not older than two (2) years.

5.2 An employee who has used all his/her paternity leave may, subject to the approval of the Head of Department, apply to:

5.2.1. use his/her part or all of five (5) working days' family responsibility leave as provided for; or

5.2.2 use available annual leave; or

5.2.3 use up to 184 calendar days of unpaid leave.

5.3 An application for paternity leave shall be supported by reasonable proof."

It is important to note that the 3 days' paternity leave provided for within the public sector to employees will be provided with full pay, while the Labour Laws Amendment Act provides for 10 consecutive days of unpaid parental leave.

Conclusion

As per the above, it is clear that the above-mentioned 10 consecutive days are applicable within the private sector with no obligation on the employer to remunerate the employee during this period, while the 3 days within the public sector will be with full pay. Since the PSCBC resolution 2 of 2015 regulates the position within the public sector, the laws signed by the President during November 2018 are not applicable within the public sector. The status quo of the 3 days' paternity leave will remain, pending ongoing negotiations at the PSCBC. In summary, medical practitioners employed within the private sector are entitled to unpaid parental leave of 10 days, with the option to claim from the Unemployment Insurance Fund, while medical practitioners employed within the public sector are entitled to paternity leave of 3 days on full pay.

Integrating with HPCSA for CPD management

SAMA Communications Department

SAMA is currently working with Medical Practice Consulting (MPC) on integrating their SAMA-accredited MPC CPD compliance platform with the HPCSA system. This forms part of the integration upgrades of CPD portfolios between MPC healthcare practitioner portfolios and the HPCSA system.

The HPCSA recently introduced a CPD self-service platform that enables medical professionals to upload their own certificates. Practitioners submit queries and upload

necessary evidence of compliance with CPD programmes in order to meet requirements in terms of the HPCSA Act No. 56 of 1974. The practice of randomly sampling practitioners from the HPCSA database to verify compliance with CPD requirements has been discontinued, and all practitioners can now upload their CPD certificates as and when they become available on the HPCSA website.

"This will enable seamless updates of CPD portfolios between healthcare practitioners

and the HPCSA system," says Dr Angelique Coetzee, SAMA chairperson. "SAMA is proactively monitoring the process to ensure it is complete as soon as possible, without interruption. Our members can therefore look forward to less time spent trying to upload certificates, and have the peace of mind that attendance to CPD events will automatically reflect against their MP number, with points being allocated accordingly."

COVID-19 in children: The SA experience, and way forward

Tendesayi Kufa-Chakezha, *epidemiologist and public health specialist*, **Cheryl Cohen**, *co-head of the Centre for Respiratory Disease and Meningitis*, **Sibongile Walaza**, *medical epidemiologist and lecturer at the School of Public Health, University of the Witwatersrand*, **Nicola Chiwandire**, *epidemiologist*, **Waasila Jassat**, *public health medicine specialist, National Institute for Communicable Diseases*

Since its emergence in late 2019, SARS-CoV-2 has caused illness (COVID-19) and death in all countries in the world. The restrictions put in place to reduce the spread of this virus have devastated economies and livelihoods the world over. By the end of June 2021, the WHO estimated that there had been 180.4 million cases of COVID-19, and 3.9 million associated deaths globally.

From the outset, communities were concerned about the impact of SARS-CoV-2 on children. This was justifiable because many other respiratory viruses such as influenza and respiratory syncytial virus disproportionately affect children. With their immature and developing immune systems, children have larger amounts of virus in their respiratory tract, and release the virus for longer durations. This puts them at the centre of transmission of those viruses – to each other at schools, and to adults and siblings at home. It was not surprising that early interventions to delay the spread of COVID-19 included shutting down schools.

But COVID-19 has bucked this trend of affecting children more than adults. SARS-CoV-2 is known to infect children of all ages, from newborns to older adolescents and teens. Nevertheless, children have not been the drivers of the COVID-19 pandemic to date.

This is because children are less likely to:

- be infected with the SARS-CoV-2 virus when exposed to it
- develop symptomatic disease when infected
- be hospitalised or die from COVID-19 when they do develop severe disease compared with adults
- transmit the SARS-CoV-2 virus to others.

Our surveillance data in SA indicate that this lower risk of infection, disease, death or transmission experienced by children is age-dependent. Among children, the likelihood of infection, disease or death generally increases with age. Older teens and adolescents acquire COVID-19 at rates similar to adults, in some instances. This routine surveillance has been in place since the beginning of the COVID-



19 pandemic. The aim is to monitor disease trends in children, and inform policy around prevention, care and treatment for children.

The SA experience

By mid-June 2021, SA had conducted 12.3 million tests and detected 1.8 million cases. Children 19 years or younger accounted for 13.4% of tests conducted, 10.2% of new cases reported, 4.2% of COVID-19-associated hospital admissions and 0.7% of COVID-19-associated deaths. This is despite children this age accounting for 36.6% of the SA population.

This age group was 3.7 times less likely to test for COVID-19, 5.7 times less likely to test positive for COVID-19, 13.3 times less likely to be admitted to hospital with COVID-19 and 6.7 times less likely to die in hospital once admitted, compared with adults older than 19 years.

The data to date have not shown or suggested an association between case or admission rates with the opening and closing of schools in the country.

Given the adverse social and psychological impacts of closures on schools, it is encouraging to know that schools are not driving the COVID-19 pandemic. They can safely remain open provided there is implementation of and adherence to non-

pharmaceutical interventions for COVID-19 prevention.

Some groups among children experience higher rates of illness, and these bear more discussion.

Firstly, the increased case rates in older teens and adolescents, at rates similar to adults older than 19 years in the third wave, require monitoring. From the onset of the third wave to the peak, the fraction of all COVID-19 cases aged 19 years or younger averaged 14.6%, as opposed to around 9% in the first and second waves. Half of the cases occurred in older teens and adolescents aged 15 - 19 years, bringing the case rate in this group on par with adults older than 19 years.

This could have been as a result of:

- generally increased testing in children in the third wave: more testing would pick up more cases, including mild or asymptomatic ones
- increased testing in response to cluster outbreaks in schools, leading to more testing among symptomatic or mildly symptomatic children and adolescents
- increasing vaccination rates among adults, leaving younger individuals contributing more cases
- the Delta variant itself – which may have a greater predilection for children, although there is not yet any conclusive data to support this.

Secondly, infants under the age of 1 year have experienced higher hospital admission rates compared with other children, especially after the second wave. In our most recent report, infants made up 2.2% of cases 19 years or younger, but contributed 19.3% of the admissions and 31.8% of deaths in this group.

It is unclear why these infants are admitted to start with, or what the causes of deaths are. Generally, infants are much more likely to be admitted with non-COVID-19 conditions than older children. There is routine testing of all admissions at many hospitals, so it is possible that many of these admissions are for other reasons, with COVID-19 an incidental finding. More data are needed to investigate reasons for admission in this age group.

Lastly, children with underlying conditions made up 19.3% of children admitted with COVID-19, but 56% of those who died.

The most commonly reported underlying conditions among those admitted were chronic respiratory diseases, diabetes, HIV and TB (active and previous). HIV, diabetes and TB were common among those who died.

What about vaccination?

SA children are not yet eligible for COVID-19 vaccination, and may not be for a while. The reasons for this include their lower risk of disease and the need to prioritise the elderly, limited information on the efficacy and safety of the vaccines in children and the limited number of vaccines licensed for use in children.

Some countries in Europe and North America have opened up vaccination to children aged 12 - 16 years, although coverage in this age group is still low. As more children are vaccinated in these countries, more data

on side effects and effectiveness will be collected, and many lessons to inform rollout in SA will be learnt.

In the SA setting, there is a case for the expedited vaccination of children with underlying conditions, and older teens and adolescents, based on burden of cases and hospitalisations in these two groups, respectively.

Until then, the onus is on everyone to ensure vaccination of adults around children to achieve herd immunity, and adherence to non-pharmaceutical intervention, to reduce transmission in the community and spillover into schools.

Source: The Conversation, July 2021. <https://theconversation.com/covid-19-in-children-the-south-african-experience-and-way-forward-164586>.

Questions and answers on COVID-19 vaccines

World Health Organization

The WHO has compiled the following list of questions and answers to assist healthcare professionals when discussing vaccination against COVID-19 with their patients.

How have the vaccines been developed so quickly? Does this mean that their safety and efficacy has been compromised? The speed of development of COVID-19 vaccines has been unprecedented for several reasons, but the safety and efficacy requirements for vaccines have not been compromised. Vaccine development was facilitated by:

- Massive financial investment by governments, industry and philanthropic organisations in vaccine development, and the redirection of much of the global research and commercial infrastructure for the development and manufacture of vaccines. Governments also enabled companies to take the commercial risk of manufacturing some vaccine stocks ahead of regulatory approvals.
- New technologies adapted from the development of other vaccines – mRNA vaccines were developed for COVID-19 very rapidly after the sequence of the

COVID-19 virus was determined, but the underlying technology had been under development for much longer, and production could be scaled up very quickly. The adenovirus technology used for adenovirus vector vaccines was first tested with the SARS, MERS and Ebola viruses over the last 20 years, and so was able to be adapted quickly to COVID-19, which has several similarities to these viruses.

- Clinical trial successes – it has been possible to rapidly recruit large numbers of volunteers into clinical trials and, with unfortunately high rates of infection in several countries, to complete trials with 10 000 - 50 000 people in a short period of time. Under normal circumstances, it may take many months or even a few years to carry out trials of this size to determine whether a vaccine is effective.
- Very close collaboration between regulators, industry and clinical researchers enabled clear indications of regulatory requirements, and early access to results.
- Intensive and insightful research – researchers predicted that the “spike protein” on the virus would be a good target for vaccine development, and

almost all vaccines have been designed to induce a response to this protein. So far, the spike protein has produced a strong immune response in those vaccinated, and those vaccines that have reported clinical results are highly protective from COVID-19 disease.

Will mRNA vaccines affect the DNA of vaccine recipients? No. The mRNA in the vaccine has not been shown to incorporate itself into the genes of vaccine recipients, and breaks down in the weeks after vaccination. mRNA vaccines contain genetic instructions for our cells, which only read them and provide copies of the SARS-CoV2 spike protein. This enables the body's natural immune systems to cause a response in vaccine recipients if they are later exposed to the virus.

How long will COVID-19 vaccination provide protection for immunised people? We do not yet know how long protection from any of these vaccines lasts. We will get better insights over the next 12 months.

The duration of protection provided by vaccines can vary. For example, the seasonal influenza vaccine is given annually,

because the influenza virus mutates, and protection wanes over a number of months. Other vaccines, such as those for rubella or measles, provide multi-year or even life-long protection from disease. Mutations in key viral proteins can mean that virus variants emerge. The SARS-CoV-2-coronavirus is prone to mutations that creates variants, some of which have become established in a number of regions of the world. The scientific community and regulators are very actively monitoring whether the current vaccines can continue protecting people from infection with new variants.

A number of vaccine developers are currently developing vaccines against the range of variants, and it is likely that booster shots with these vaccines will increase protection against known variants. Regulators have agreed that review of data on vaccines against variants will be facilitated based on assessment of immune response to the variant, in the same way that new seasonal influenza vaccines are evaluated each year.

Why are there so many vaccine candidates?

As the global seriousness of the pandemic became rapidly apparent, development of effective vaccines for COVID-19 became the top priority of many pharmaceutical companies and medical research institutes. There was also unprecedented government and private sector investment in vaccine development. There is now a wide range of technologies for developing new vaccines – and many of the organisations developing COVID-19 vaccines have particular experience in one or more of these technologies. This ensured that there would still be vaccines available if some were not approved for reasons of efficacy, safety or manufacturing challenges.

What if many people start getting a reaction from a particular COVID-19 vaccine? Short-term reactions, such as soreness at the injection site, fatigue or headache are common following any vaccination with COVID-19 vaccines. These reactions usually pass in a day or two. If new evidence becomes available that suggests that a specific serious adverse event may be linked to a particular COVID-19 vaccine, then regulators will take action, working collaboratively on a global basis and liaising with public health authorities. The type of actions that can be taken depend on the nature of the adverse event, and



could range from issuing safety warnings for patients, healthcare professionals and the community, to updating the product information or consumer information for the vaccine to show contra-indications for the use in particular patients (e.g. those with certain comorbidities), to closely monitoring adverse events in certain groups of patients, to preventing the release of a particular batch of vaccine, through to temporary suspension of the use of the vaccine until more is known.

How are regulators speeding up the time it takes to authorise a COVID-19 vaccine? Many regulators globally have implemented faster access pathways for COVID-19 vaccines, without compromising on strict standards of safety, quality and efficacy.

Some countries have emergency use authorisation pathways that assess the available data at the time of authorisation. Exercising these provisions is a matter for those countries, taking into account the benefits v. risks in the context of the prevailing domestic pandemic situation. Different countries may utilise this pathway or the authorisation routes differently, but essentially, they follow the same principles.

Other countries have implemented accelerated/priority, conditional or provisional approval schemes.

Under normal circumstances, regulatory assessment begins once all information to support registration is available. For COVID-19 vaccines, many regulators have agreed to accept data on a rolling basis to enable early evaluation of data as they become available. Regulators will only be in a position to make a provisional approval decision for a vaccine once there are sufficient data to

adequately support the safety, quality and effectiveness of the vaccine for its intended use. If a decision is made to grant provisional or conditional approval, it will be based on the requirement for the sponsor to submit more comprehensive, longer-term clinical data, stability data and other information with agreed time lines.

Did our country approve this COVID-19 vaccine, or are we relying on another country's approval? Most countries are carrying out independent regulatory evaluations on the submitted data for each vaccine. However, to ensure a more efficient use of resources and expertise, regulators in different countries are communicating closely on safety, efficacy and quality data, and discussing technical issues as they may arise. In many cases, principles of WHO good reliance practices and collaborative mechanisms leverage the output of other regulators.

Why weren't very rare blood clots with low platelets with the AstraZeneca or Johnson & Johnson vaccines picked up during clinical trials? Thromboembolic events with concurrent thrombocytopenia are very rare – with estimates based on the number of spontaneous reports, suggesting an overall incidence on the order of 10 - 15 cases per million doses. The clinical trials of these vaccines included large numbers of people, often with 10 000 - 20 000 individuals in the active vaccine arms, but even in trials of this size it was statistically unlikely that such very rare events would be detected. This shows the importance of continual safety monitoring during the use of these vaccines, to allow very rare events to be detected and investigated further.

How the Credit Ombud works for you

Howard Gabriels, *Credit Ombud*

The Credit Ombud was established in 2004 as an independent body to effectively resolve disputes between members of the credit industry and consumers of credit with regard to credit information and credit matters.

The Credit Ombud will at all times act honestly, independently and fairly, balancing the rights of all parties. In addition, the Credit Ombud plays an important role in educating the public on matters pertaining to the credit industry.

In 2006, the Credit Ombud was recognised by the Financial Services Ombud Schemes (FSOS) Council as an “ombud with jurisdiction” in terms of the FSOS Act No. 37 of 2004. Initially, the Credit Ombud was recognised for dealing with credit information matters. However, this mandate was subsequently expanded to include investigation of non-bank credit agreement matters in 2009.

Our services are free of charge to consumers

Our value proposition is that we provide a cost-effective and a user-friendly environment to resolve disputes for companies and consumers in the credit industry. Our services are free of charge to consumers. We are funded through a membership fee paid by our industry members. Our work takes pressure off the formal dispute settlement processes which otherwise would require consumers to approach the courts and bear the burden of additional costs and time.

From its inception, the Credit Ombud has supported credit consumers broadly, irrespective of whether disputes raised were related to members or not. The rationale was to ensure a positive role for the office, as well as to protect the reputation of the credit industry. There has been some change in this as the rising costs of delivering services to non-members led to the decision of the Credit Ombud Council in 2019 to cease with investigation of disputes relating to non-members.

Chapter 14 of the Financial Sector Regulation Act No. 9 of 2017 (FSRA) came into effect on 1 November 2020. The FSRA makes it obligatory for an entity offering services related



to the provision of credit to be a member of a relevant industry ombud scheme. Industry participants who are not currently members of the Credit Ombud are encouraged to engage with our office to investigate the benefits and relative costs of membership.

We open disputes only after consumers have received a reference number from the credit provider or the credit bureau. Consumers are required to give credit providers and credit bureaux 20 business days to resolve the dispute. Disputes will only be logged if the 20 days have expired and consumers remain unhappy with the outcome.

In this past year, we have closed more than 3 200 disputes. In 2019, about 57% of the disputes were settled in favour of consumers.

Through dispute resolution, the Credit Ombud plays an important role in building business confidence. It is a globally accepted principle that governments, financial businesses and consumers all benefit when consumers have confidence in the financial markets. Consumers will have greater confidence in financial services if they know that any dispute they have will be dealt with by an impartial body that will resolve issues quickly and informally, without formal legal proceedings.

By empowering consumers, the industry benefits as it is more likely to build trusting relationships with consumers. We have seen that consumers engage confidently when they understand that the cost of resolving disputes is kept to a minimum, as well as when unscrupulous competitors are held accountable.

We also address issues in the interests of a better industry, and in order to resolve problems before they create systemic risks.

While the primary business of doctors is to take care of the health of patients, when patients fail to meet their financial obligations, doctors often impose interest on outstanding accounts, or list patients’ details on the credit bureau. These actions are covered by the provisions of the National Credit Act No. 34 of 2005. Patients who believe that their rights have been infringed then have the right to lodge a complaint with the National Credit Regulator (NCR), or alternatively may seek relief through the courts.

In March 2021, the Credit Ombud signed a memorandum of understanding (MoU) with the NCR. The MoU provides that any complaint lodged with the NCR against a subscribing member of the Credit Ombud will be referred to the ombud to resolve the dispute. It was further agreed that the Credit Ombud will provide quarterly reports to the NCR on matters referred to it.

The Credit Ombud is registered with the SA Revenue Services as a public benefit organisation. This allows the Credit Ombud to treat any financial contribution from its members as donations, and these donations can be a tax deduction for prospective members. The Credit Ombud will provide members with the necessary documentation to enable members to treat the donation as a tax deductible.

We would like to invite members of SAMA to become members of the Credit Ombud to ensure fair and responsible leadership in our industry.

For more information, visit our website: www.creditombud.org.za. Contact us to arrange a follow-up meeting at ombud@creditombud.org.za.

Complications of colonoscopy

The Medical Protection Society shares a case report from their files

A 50-year-old patient, Mrs A, developed altered bowel habit and rectal bleeding. She saw consultant colorectal surgeon Mr C, who found large prolapsing haemorrhoids, and recommended a haemorrhoidectomy and colonoscopy. Dr C removed a 5 mm polyp in the caecum with a snare, and then went on to perform a haemorrhoidectomy. Both procedures were described as uneventful and Mrs A was stable throughout the anaesthetic.

A few hours later, after the operation, Dr C noted that Mrs A was well and ready for discharge. She subsequently developed minor rectal bleeding and abdominal discomfort, and was kept in overnight. The following morning, her routine blood tests were normal and her observation chart had been unremarkable, but the abdominal pain persisted.

A chest X-ray revealed bilateral sub-diaphragmatic free gas. Dr C prescribed broad-spectrum antibiotics, intravenous fluids and kept Mrs A "nil by mouth". An urgent CT scan confirmed an extensive pneumo-peritoneum but no signs of any fluid collection.

Dr C examined Mrs A and found a "completely soft abdomen with no peritonism and normal bowel sounds". He explained that the perforation had probably occurred at the polypectomy site, but appeared to have sealed, as Mrs A was well and the CT scan had revealed no fluid collection.

Dr C recommended conservative management with surgical intervention only in the event of septic complications. Over the next few days, Mrs A remained well, was afebrile and had normal inflammatory markers. She commenced oral fluids and was discharged home with 7 days of antibiotics.

Dr C reviewed her at the end of the week and noted that "she continued to feel well, clinical examination was normal and the site of her haemorrhoidectomy was healing nicely." The pathology report of the polyp revealed a completely excised low-grade tubulo-villous adenoma, and Dr C explained the need for surveillance colonoscopy.

Two weeks later Mrs A contacted Dr C complaining of night sweats, abdominal pain and vomiting. He saw her immediately and



arranged an ultrasound scan, which revealed a large pelvic abscess. Dr C organised her admission to another hospital for radiologically guided drainage of the abscess, but this proved unsuccessful. Her condition deteriorated and Dr B, the consultant surgeon on call at this hospital, undertook an emergency laparotomy to drain the abscess and perform a defunctioning ileostomy.

Mrs A had a stormy postoperative recovery, initially requiring ICU support, and spent 3 weeks in hospital. Dr B subsequently reversed her ileostomy, but Mrs A developed problems with an incisional hernia, requiring several attempts at repair. She also needed psychological support for post-traumatic stress disorder, resulting in prolonged absences from work.

Two years later, Mrs A brought negligence proceedings against Dr C. It was claimed that Dr C should have acted sooner by performing an X-ray and CT scan on the evening when Mrs A initially developed pain. It was also alleged that Dr C had selected inappropriate antibiotics and had discharged her too early, allowing the development of her abscess. It was suggested that these acts of negligence had delayed appropriate surgical treatment and led directly to all of Mrs A's subsequent complications.

Expert opinion

Expert opinion for MPS did not substantiate any of these claims. It was agreed that non-operative management for perforations after colonoscopy was an acceptable practice if the patient was stable, exhibited no signs of

Learning points

- Complications after procedures can occur, and are not necessarily the result of negligence. Claims can be defended if clinicians are able to demonstrate that they acted appropriately in the detection and subsequent management of complications. Evidence of a high-volume practice with a low complication rate (as in this case) can strengthen the defence.
- Claims often arise many years after the event. The careful documentation of events and discussions with the patient 2 years earlier enabled the facts of the case to be established, and a successful defence of the allegations.

sepsis and the perforation appeared to have sealed.

The CT result, together with the carefully documented clinical findings, nursing charts and absence of a rise in the patient's inflammatory markers over several days all supported this approach. Microbiology experts agreed that the antibiotics prescribed were appropriate and the length of administration sufficient. Dr C was also able to produce audit evidence of his colonoscopy practice, demonstrating a high volume (400 per annum) with a very low complication rate.

MPS defended the case, and the claimant discontinued on the first day of trial, with full recovery of costs.



Welcome to SAMA

SAMA welcomes the following new members who joined our association in June and July 2021:

Border Coastal branch

Tandanani Gwedlana
Sandisiwe Tshizana

Cape Western branch

Fazilah Dawood
Suzette Fourie
Charnotte Margot Gabriels
Gideon Gerhardus Joubert
Justin Muller
Shaldon Lee Naidoo

Charl Lourens Prinsloo
Ramatsobane Tebogo Ratsoma
Adelinda Jacoba Johanna Smit
Kim Renate Sonntag

Saabira Swart
Christelle van Rooyen
Mustafa Zalgaoanker

Eastern Highveld branch

Chantelle Barnard
Humayra Essat
Thabang Macmillan Makgabutlane
Surandran Yelliah Naidoo
Steffani Ovadia
Kiveshen Pillay
Gerhardus Bernardus Visser
Lloyd Zwenyere

Eastern Province Branch

Eileen van der Westhuizen
Caitlin Ann Williams

Free State branch

Riza Ehlers
Ipeleng Khunou
Maria Catherina Laing
Relebohile Patricia Lethoba
Nyakallo Patience Makatsa
Lebogang Sylvia Mofokeng
Dimpho Mkoloko
Ismarie Oosthuizen
Veruschka Rademan
Kanisha Teniel Kathleen Rensburg
Ahmad Khayam Saleem
Tseko Gift Sawula
Tiaan Pieter Steyn
Diane Kena Tengu
Charl Julian Theron
Bianca van Wyngaard

Gauteng branch

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Zaheda Bhabha
Ruvimbo Chantel Chiswo
Simon Fraser
Robyn Fyvie
Yumna Minty
Kabo Mogorosi

Nonhlanhla Reatile Moletsane
Loshnee Luvendrie Moodley

Katelyn Pye

Yastira Ramdas

Lorenzo Rampini

Brad Segal

Alon Hillel Shulman

Oneile Slave

Nicola Annalise Vosloo

Chani Wiesner

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Tombo Bongongo
Theo Herman de Klerk
Sabastiano Neville dos Santos

Frances Earle

Gratia-Marie Fischer

Miems Fourie

Odette Koch

Africa Dumsane Lubisi

Kgothatso Obakeng Mateme

Jancke Mentz

Abueng Modise

Lukas Johannes Moolman

Grizelda Neethling

Johan Izak Potgieter

Gerhardus Jacobus Steyn

Matsobane Gift Teffo

Griqualand West branch

Raymond Bosch

Tshibangu Bukasa

Jean Marie Kazadi Lumbala

Bradwill Hamolton Okhuis

Elrico Ricardo Oliphant

KwaZulu Natal Coastal branch

Ahul Bagratee

Emmanuela Boachie

Sebenzile Princess Chonco

Samkelo Phumla Dube

David Govender

Kistensamy Govender

Fathima Bibi Khan

Ramesur Maharaj

Theleshni Mannaru

Muhammad Muzzammil Mansab

Sandile Thabang Mbokazi

Nokwanda Ayanda Mkhize

Sarisha Mothalal

Khethokuhle Andiswa Mthiyane

Maheshree Naidoo

Parushinee Naidoo

Bulunga Ndumiso Mpumelelo

Lungelo Nkosi

Bonginkosi Nowatha

Leanne Reddy

Kgaugelo Laurancia Sebola

Khushboo Tewari

Werner Pierre Wassermann

Mxolisi Njabulo Xulu

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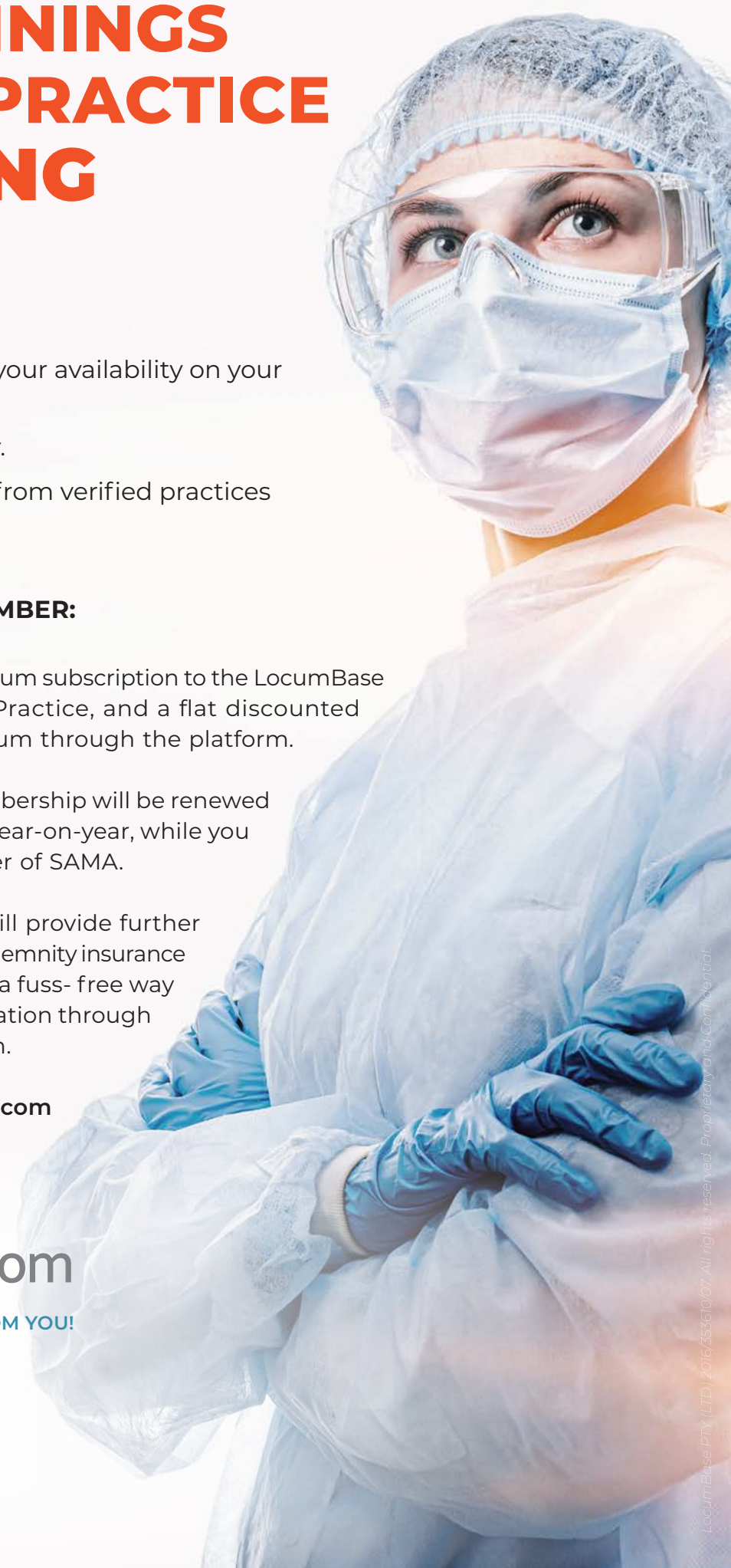
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