

SAMA INSIDER

APRIL 2020



**COVID-19 in SA:
ethical implications**

**Antimicrobial
resistance and you –
a personal account**



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

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THE A-ABCD'S OF COVID-19

A

VOID GETTING INFECTED

Avoid close contact with people who are sick.
 Avoid touching your eyes, nose, and mouth.
 Avoid touching objects like door handles or rails
 Avoid shopping centres
 Stay at home when you are sick.
 Cover your cough or sneeze with a tissue, then throw the tissue in the rubbish bin.
 Clean and disinfect frequently touched objects and surfaces using a regular household cleaning spray or wipe.
 Clean your hands often
 Keep a distance of at least 1-2m between you and any person coughing or sneezing

A

IRWAY

COVID-19 presents mainly with symptoms of the airway.
 The main symptoms are fever, sore throat and a dry cough with a few people presenting with difficulty in breathing. Pain in the muscles and extreme tiredness may also be present.

B

E CALM

80% of people who are infected have mild disease and will not have any serious symptoms. People who are at risk of serious symptoms are people with weakened immune systems due to age, or have underlying chronic diseases. Those diseases include chronic lung disease, chronic cardiac disease, diabetes. Only patients with severe pneumonia will be hospitalized, the rest will need to have to stay at home for at least 2weeks.

C

ALL AHEAD

Call ahead to a healthcare professional if you develop a fever and symptoms of airway illness and have been in close contact with a person known to have COVID-19 or if you live in or have recently travelled to an area with ongoing spread. If possible, use a three layered face mask, as to partially prevent you from spreading the virus to other people, especially if you are visiting your doctor or clinic.

D

ON'T PANIC

Listen to your doctor, don't follow your own head and you will be fine.



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Diane de Kock
Editor: *SAMA INSIDER*

A time for unity

President Cyril Ramaphosa has just announced a nationwide lockdown in SA from Thursday 25 March to 16 April. The battle has begun; solidarity and unity are in greater demand than ever.

After meeting in Cape Town, President Ramaphosa and party leaders issued a joint statement on the coronavirus outbreak.

"All leaders agree that the COVID-19 outbreak poses a grave and real threat to the lives, livelihoods and prosperity of our people. Our country finds itself in an extreme situation that requires extraordinary measures. It requires that all South Africans work together in unity and solidarity, in partnership and co-operation. It is, therefore, both appropriate and significant that the 14 political parties in our Parliament are standing together, across party-political divides, to fight this disease together," the statement said.

"SAMA plans to continue to operate and serve our doctors as well as possible," says Shelley McGee, a member of the SAMA Emergency and Disaster ManCom.

In this issue, we look at some ethical implications of COVID-19 in SA (page 5), report on the first conference to address the coronavirus outbreak (page 7), and Shelley McGee writes about SAMA and CMSA addressing standard-setting in medical examinations (page 8).

"Engaging and talking about death is positive and life-affirming, because it brings death front and centre and helps me clarify how I want to live my life now," says Leigh Meinert about the first ever SA conference on death and dying as a life-affirming transition, held in Cape Town in February (page 10).

Dr Zolelwa Sifumba was invited to attend the second Capacity Building and Workforce Development conference hosted by the African Union and Africa CDC in Kenya on antimicrobial resistance. On page 13, she writes about her personal experience as a survivor: "I contracted multidrug-resistant TB because I took a breath."

Some advice from Prof. Zukiswa Zingela, HOD, Psychiatry and Behavioural Sciences, Walter Sisulu University, during these challenging times: "Accept these unusual times as the 'new norm' for now ... prioritise 'me time' as a health worker, even if it's only 5 minutes for every 2 - 3 hours spent taking care of everybody else. Your survival and the survival of everybody else may depend on it."

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Climate change – is it a threat to food security?



Dr Sizeka Maweya, SAMA President

According to *National Geographic*, climate change refers to the long-term alteration of temperature and typical weather patterns, either at a particular location or on the planet as a whole. Climate change may cause weather patterns to be less predictable. These unexpected weather patterns can make it challenging to maintain and grow crops in regions that rely on farming, because the expected temperature and rainfall levels can no longer be relied upon. Climate change has also been connected with damaging weather events such as more frequent and more intense hurricanes, floods, downpours and winter storms.

Climate is sometimes mistaken for the weather. However, the climate is different from the weather because it is measured over a long period, whereas weather can change from day to day, or from year to year.

Often, the term climate change refers specifically to the rise in global temperatures from the mid-20th century to the present. Carbon emissions from fossil fuels used during this period have been linked to global warming and climate change. Fracking, for example, is a controversial form of drilling that uses high-pressure liquid to create cracks in underground shale to extract natural gas and petroleum.

We as a country are not spared these global changes. The concerns about climate change with regard to its impact on food security are of both global and national interest in these times. We have witnessed very severe storms in some parts of our country, and droughts in the Eastern Cape and Northern Cape are of national concern, due to the threat of water scarcity and hunger.

Rural communities rely heavily on subsistence farming in their day-to-day activities for food security. However, due to climate change, their livelihood is now threatened. Climate change has affected the availability of good-quality water, habitats and species distribution, timing and length of the growing season, and the distribution of agro-ecological zones, and caused ecosystem stresses (for example erosion by water and wind, acidification, salinisation and biological degradation). Such changes have not spared our rural communities: when it rains, they spend money on ploughing, only in the end for their crops to burn, meaning this is money down the drain.

People whose livelihoods are climate-sensitive, and disadvantaged or marginalised groups with limited access to resources and information-sharing, are the most affected by climate change. Women in rural sub-Saharan Africa are one of the groups most vulnerable to climate change. There are many rural communities with female-headed households, due to the migrant labour system. They depend on rain-fed agriculture, which is highly climate-sensitive. These women are among the poorest and most marginalised groups in the region.

Household food and nutrition security have received increasing worldwide attention recently, as the impact of climate change and harsh economic conditions put new and additional stresses on food systems. A report by the UN Food and Agriculture Organization warns that the world is not on track to eradicate hunger by 2030, as envisioned in the Sustainable Development Goals. SA is in the process of changing the legislature to allow land expropriation without compensation. Food security is already threatened by other factors, and the impact of this legislation and of climate change pose a threat that must be seriously examined.

The right to food is enshrined in the SA Constitution. Section 27(1)(b) of the Constitution states that “everyone has the right to sufficient food and water,” and section (27)(b) emphasises that “the state must formulate reasonable legislative efforts and take other measures within its available resources to achieve the progressive realisation of these rights.” In the context of climate change, how will the state ensure this right? What about our rural communities who are constantly battling with these basic needs? Are we on track to achieve this right in the context of climate change?

The indirect impacts on health due to climate change are vast, for example, infectious diseases, including waterborne enteric diseases, violence and injury (increased immigration and refugee pressures on the environment and neighbouring countries), mental health problems (anxiety, depression, post-traumatic stress disorder and suicide resulting from displacement), non-communicable chronic diseases (increased risk of respiratory illnesses), malnutrition (impaired agriculture or loss of rural livelihoods), women’s and children’s health effects (vulnerability to heat, water insecurity, extreme events, malnutrition and infectious diseases) and occupational health issues (physical hazard due to temperature extremes causing heat illness and loss of productivity). These conditions are already prevalent in our country. The number of refugees that we are unable to deal with, and the challenges we are facing with them in the Western Cape, are also attributable to climate change, as it is causing people to leave their countries of birth in search of a better life.

Zimbabwe and Zambia, which are part of the Southern African Development Community, are among the top 10 hungriest countries in the world. Most refugees or members of impoverished communities in SA come from these countries. It is high time that we find linkages to the impact of climate change on these communities’ reasons for leaving their countries of birth. The other eight such countries are Afghanistan, Chad, the Central African Republic, Yemen, Timor-Leste, Haiti, Liberia and Madagascar.

There is growing awareness and acknowledgement in the healthcare community that health outcomes and disparities, more often than not, are driven more by social determinants of health than by medical care? The social determinants of health include social, economic, physical or other conditions where people live, learn, work and play that influence their health. Countries such as Madagascar are ravaged continuously by cyclones at the highest rates in Africa, making communities vulnerable to disease and hunger. Liberia is still in recovery from both a civil war and the West African Ebola epidemic – will it ever recover from their devastating impacts?

Poverty and food insecurity are social determinants of health, and are associated with some of the most severe and costly health problems in SA. Climate change continues to affect both.

COVID-19 in SA: Some ethical implications

Brandon Ferlito, *bioethics researcher*, Shelley McGee, *health policy analyst*, SAMA Knowledge Management, Research and Ethics Department

On 5 March, Dr Zweli Mkhize, SA's health minister, confirmed the country's first case of the novel coronavirus, COVID-19. The patient, a 38-year-old male who travelled to Italy with his wife, was part of a group of several people who arrived back in SA on 1 March 2020. It was reported that the patient presented himself to a private GP on March 3 with symptoms of a cough, fever, headache, sore throat and malaise. Both the patient and the doctor have been self-isolating since March 3. While the health ministry and the National Institute for Communicable Diseases have taken steps to control and prevent further spread of COVID-19, there are some ethical implications that may be of concern. These are discussed below.

Resource allocation and priority-setting

The outbreak of COVID-19 raises ethical concerns around resource allocation and priority-setting. Medical and human resources may be strained to the point of exhaustion in an outbreak situation or large-scale disaster. Effective preparation must include action plans to reduce morbidity and mortality in public health, while optimising the effective use of medical and human resources. While the latest novel coronavirus has spread worldwide, it appears (for now) to be less deadly than other groups of coronavirus such as MERS-CoV and SARS-CoV.

However, interest in disease outbreaks and preparation has reignited in light of this new strain of coronavirus. Among the many necessary and life-saving resources needed, such as beds and mechanical ventilators, an important question needs to be answered: how do we decide who has access to these resources, particularly in a country such as SA,

where they are scarce? The limited necessary resources available for the care of ill patients is a major medical and ethical concern. How will healthcare practitioners make the difficult ethical decisions as to who gets first priority to scarce resources as more COVID-19 patients arrive in need of care?

Treatment of frontline healthcare professionals

Another ethical concern that needs to be addressed is the treatment of frontline healthcare professionals, who could potentially become infected with COVID-19: should they get preferential treatment? Usually, a way to decide which patients are treated first is by looking at the severity of the patient's illness, especially in resource-stricken settings. However, since healthcare professionals are needed in order to combat any outbreak, should they receive preferential treatment, given that they could contract the virus while working on the frontline?

Quarantine and isolation

The use of quarantine and isolation raises ethical concerns. Many people believe that quarantine is an unwarranted diminution of personal freedom, while others see it as an integral part of the prevention of communicable diseases. There is no question that transmissible diseases pose a threat to public health; the normal administration of healthcare is inadequate to control the spread of diseases such as COVID-19. An important question to consider is whether the concept of quarantine is ethically justified.

It is also clearly necessary to differentiate between quarantine and isolation. Quarantine refers to the separation of those exposed individuals who are not yet symptomatic

for a period of time (usually the known incubation period of the suspected pathogen) to determine whether they will develop symptoms. Isolation means keeping those who already have symptoms from spreading the virus/disease to the rest of the general population.

Another concern is the isolation of frontline healthcare professionals. The practice of the doctor who saw the first patient in SA on March 3 was immediately closed, and the doctor and staff were put into isolation. If COVID-19 does progress to an outbreak in SA, it will be impossible to isolate every healthcare professional who has come into contact with a confirmed case.

Planning, preparedness and response

The global outbreak of COVID-19 raises ethical concerns around planning, preparedness and response to what could potentially become a deadly global pandemic. In countries such as SA, which has a quadruple burden of disease and an underperforming public health system, it is morally important that outbreak planning, preparedness and response is sufficient and efficient in dealing with a potentially life-threatening outbreak. Many of the ethical concerns can be avoided if planning, preparedness and response are not hindered.

There are no easy answers to many of these questions, but the progression of the disease in the country will no doubt highlight some of the challenges apparent in the system that need to be addressed. Implementation of rational, ethical and effective measures is the only way forward.

References available on request.

SAMA backs government's steps, calls for telemedicine to be included

SAMA Communications Department

SAMA says it supports the measures announced by President Cyril Ramaphosa on 15 and 23 March to contain the spread of coronavirus in the country.

"Mitigation strategies are proving key in addressing the spread of the virus in many countries throughout the world, and appropriate steps such as those announced

by the president will, we believe, have a similar impact locally in mitigating the spread of infection," says Dr Angelique Coetzee, SAMA chairperson.

Dr Coetzee says SAMA is aware that imposing community lockdowns, limiting public gatherings to 100 people and closing schools are drastic steps that have the potential to damage the country's already fragile economy. These measures should not be taken lightly. "However, we have seen that several other countries that have developed heavy caseloads have implemented drastic mitigation strategies. These have depended on strong community responses, led by clear government directives. We urge the same approach in SA," says Dr Coetzee.

SAMA says that in addition to the strategies already announced, two additional steps are needed. Firstly, the association says that it

is imperative that the areas – not just the provinces – of the identified cases be made known. This is a key consideration in dealing with the spread of the coronavirus and must not be seen as alarmist, but instead as providing essential information for the public.

A second additional strategy is to give priority consideration to telemedicine. "Telemedicine has emerged as a crucial element of the response to coronavirus in many countries, and enables patients to contact health providers from their homes, and get appropriate medical advice based on the development of symptoms, without endangering healthcare workers and other patients," says Dr Coetzee.

She says, however, that current HPCSA guidelines make no room for such consultations, and only provide for face-to-face interaction between patient and practitioner.

"In light of the extraordinary situation in which we find ourselves, we call on the Department of Health as well as the HPCSA to advocate in favour of telemedicine as one of the mitigating strategies government must employ to contain the spread of coronavirus. We believe such a move, which will be subject to all ethical rules and recommended record-keeping, is a strategically sound one, and may, ultimately, present more solutions than barriers in this fight," Dr Coetzee concludes.

COVID-19: Ready or not, here we go

Dr Margot Uys, *Head: FPD School of Health Sciences*



On 31 December 2019, a cluster of pneumonia cases in Wuhan, Hubei Province, in China was reported by the regional WHO office. As of 5 March, 98 407 cases have been reported, with more than 3 000 deaths. Most cases are from China, but with secondary hotspots in Italy and Iran, with a high mortality rate in both these countries.

Closer to home, the primary question is whether SA is ready for COVID-19. The National Institute for Communicable Diseases (NICD) has taken comfort in the fact that in the midst of this epidemic, SA has had time to prepare. Considering our already constrained healthcare system and the struggle we face with resources within the system, the general public's opinion is largely that we are not ready. Moreover, the continued media coverage of the worldwide spread of the virus is resulting in mass panic, and SA is no different.

5 March 2020 officially marked our first confirmed case of COVID-19, within one week the number of confirmed cases rose to more than 60, so ready or not, here we go. Health minister Dr Zweli Mkhize urged SA not to panic, but that was to little avail, as schools and universities closed their doors in KZN despite the NICD advising that this is unnecessary. Healthcare systems are gearing up, and stocking up on N95 respirator masks, ensuring adequate infection control measures in practices and areas of work. Ensuring that healthcare workers are educated on the appropriate response has now become a priority, with COVID-19 in our midst.

SA has the added burden that many of our citizens are immunocompromised due to HIV/AIDS, TB and diabetes, which makes this outbreak a cause for concern. The uncertainty that currently exists around the diagnosis and treatment of COVID-19 is making healthcare professionals uneasy in their response to this impending outbreak. It is essential that in the preparation for managing the virus, we educate the public without adding to the panic that the media has caused.

SAMA, the Foundation for Professional Development (FPD), the University of Pretoria and other partners launched the first Health and Welfare Sector Education and Training Authority-sponsored conference on the novel coronavirus on 24 and 25 February at the Council for Scientific and Industrial Research. During these discussions, it has become very

clear that all healthcare practitioners should meticulously apply the principles of infection control in the sphere in which they operate – for self-protection, they should use an N95 respirator mask fitted properly, and implement regular handwashing techniques.

The case definition for persons under investigation for COVID-19 remains specific: (i) onset of acute respiratory infection with at least one of the following: cough, sore throat, shortness of breath; and (ii) in the 14 days prior to onset of symptoms met at least one of the following epidemiological criteria: were in close contact with a confirmed or probable case of COVID-19 infection, or had a history of travel to areas with presumed ongoing community transmission of COVID-19, or worked in a facility where patients with COVID-19 infections were being treated.

With the vision of continually educating healthcare practitioners and ensuring that SA is as ready as it could be, the FPD recorded the conference sessions where leading subject-matter experts discussed various topics relating to COVID-19. These are available on the FPD website (www.foundation.co.za/COVID-19) For private practitioners, however, COVID-19 poses a very specific problem that requires action before the patient with respiratory symptoms enters the practice. The NICD has developed guidelines that the FPD has adapted for use in private practice. They are also available on the FPD website (<https://www.foundation.co.za>) under "COVID-19 update".

FPD hosts first conference to address the novel coronavirus outbreak

Shelley McGee, health policy researcher, SAMA Knowledge Management, Research and Ethics Department

On 24 and 25 February, the Foundation for Professional Development (FPD), in partnership with SAMA and the SA Public Health Medical Association (SAPHMA), hosted the first conference of its kind in SA to discuss the global novel coronavirus (COVID-19) epidemic and address preparedness, containment and management issues in SA.

Over 300 healthcare professionals attended the conference, thanks to a scholarship programme through the Health and Welfare Sector Education and Training Authority (HWSETA).

Dr Margot Uys of FPD, the convenor of the programme, opened, and explained that the meeting had been organised at very short notice, and was based on the urgency of disseminating information to healthcare professionals.

Dr Angelique Coetzee of SAMA delivered an opening address and stressed that the most important issue regarding the coronavirus family and this novel coronavirus is education of both the public and healthcare professionals. She stressed that simple messaging on public hygiene and the spread of disease will be key.

Expert clinical speakers addressed the epidemiology, case identification and clinical management of suspected cases, and included Dr Terry Marshall, clinical virologist at Ampath Laboratories, Prof. Anton Stoltz, head of



Audience at the COVID-19 conference, held at the CSIR Convention Centre

infectious diseases at the University of Pretoria (UP) and Dr Kerrigan McCarthy of the Division of Public Health, Surveillance and Response at the National Institute for Communicable Diseases. In addition, experts in air flow, Mr Toby van Reenen of the Council for Scientific and Industrial Research (CSIR) and Dr Lesego Bogatsu of the Civil Aviation Authority, also weighed in on their areas of expertise.

Ms Katekani Ngobeni, infection control specialist and senior researcher at CSIR, demonstrated the correct use of N95 masks to the audience, and Prof. Dries Engelbrecht, head of emergency medicine at UP addressed the clinical management of COVID-19 disease.

SAMA wishes to express its sincere appreciation to the staff and management of FPD, who managed to pull the successful event together in virtually no time at all.



Ms Katekani Ngobeni addresses mask use at the COVID-19 conference

HPCSA increases fees by a massive 21%

SAMA Communications Department

SAMA says it is shocked at the increase in registration fees by the HPCSA for 2020, which it labels extremely high, and out of step with the economic climate in the country. The fees were payable by 1 April.

Annual fees have been increased by 21%, and are payable by persons registered in terms of the Health Professions Act No. 56 of 1974. The non-payment or partial payment of annual fees will result in a registered

person being suspended from the register, and restoration will attract penalty fees.

"On its website, the HPCSA recognises its responsibility to conduct its affairs with prudence, transparency, accountability and fairness, in socially responsible manner, thereby safeguarding the interests of all its stakeholders. We therefore have to ask why they are opting for such an exorbitant increase in fees, without explanation, in already challenging economic times," says

Dr Angelique Coetzee, chairperson of SAMA. She says that at no point was there any opportunity for input, despite the fact that this increase is far above the inflation rate.

"We would have wanted some level of consultation before this huge increase was announced. The HPCSA has moved forward with the increase without talking to the very people it represents. We are concerned, and we will be seeking clarity from them going forward," concludes Dr Coetzee.

SAMA and CMSA address standard-setting in medical examinations

Shelley McGee, health policy researcher, SAMA Knowledge Management and Research Department, on behalf of the SAMA Education, Science and Technology Committee

Over the last few years, methods of standard-setting for medical examinations have come under the spotlight in SA.

In 2019, the news broke that an undergraduate student from Wits University had submitted a complaint to the Human Rights Commission, believing that she had been unfairly failed and excluded from the medical school because of the application of the Cohen 60 method to her examinations. Similarly, during 2019, complaints began to surface from medical registrars, through SAMA's special interest group, the SA Registrars Association (SARA), about the application of the Cohen method of standard-setting to their examinations through the Colleges of Medicine of SA (CMSA).

In response to concerns raised by registrar members within SAMA, the Education, Science and Technology Committee organised a symposium to address the application of standard-setting methods to specialist examinations in SA. This took place on Friday 14 February.

The faculty consisted of Prof. Vanessa Burch (UCT Department of Medicine), Prof. Francois Cilliers (UCT Department of Health Sciences Education), Prof. John Wright (University of Botswana School of Medicine) and Prof. Thifheli Luvhengo (head of surgery at Wits).

The objective of the day was to set a way forward for the use of standard-setting methods for high-stakes examinations.

Standard-setting methods

Prof. Vanessa Burch's keynote presentation on standard-setting methods aimed to lay the groundwork for the symposium, and acknowledge the issues and limitations in standard-setting methods. Standard-setting involves making extremely important decisions.

There are three essential stakeholders party to that discussion – trainees about whom the decision is being made, the patients and the public who are the recipients of these discussions and the training institutions responsible for producing competent candidates.

In this context, a wrong decision might be premature certification of trainees who are not competent, or the delay of the certification of trainees who are competent. Both of these mistakes can have major consequences for trainees, the public and training institutions.

Prof. Burch presented several examples of international and local research that has shown that poor examination performance predicts poorer quality patient care, poor clinical competence and diagnostic reasoning, and litigation.

The country needs a national project to establish workplace-based assessment

Standard-setting is designed to be responsive to the difficulty of an examination. Examination difficulty level does vary, despite best efforts to avoid this.

Different testing methods also test differently. Multiple choice tests behave differently to short-answer questions. A balance has to be struck between the reliability of the examination and the number of items included.

There is no gold standard of standard-setting, and every method requires some degree of human judgement, tempered by reality.

Any chosen method should be easy to learn and do, feasible given resources, sustainable over time and very importantly, depend on the number of candidates writing the examination.

As a way forward, Prof. Burch urged that the rest of the world not place so much emphasis on once-off exit examinations. This is why there is little investment in standard-setting for high-stakes exams. The trend is to identify the levels of competency and milestones expected during training, and make the process for development clear. Accurate training records over the years of training and longitudinal workplace assessments are the frontier of research at the moment.

Prof. Burch recommended that in the future, we will need to look at curricula that address professional activities and training milestones. The evidence of training needs to include a comprehensive portfolio of practice during training. Evidence of competence should include a cumulative longitudinal assessment in the workplace. There must also be ongoing deliberate practice to complete milestones and achieve competence.

Prof. Burch said the country needs a national project to establish workplace-based assessment. We need to increase our local research in this area, and on examination-setting in general.

International trends

Shelley McGee of the SAMA Knowledge Management, Research and Ethics Department then presented on international methods of standard-setting applied to specialist examinations.

The review commenced with a desktop review of several countries, ensuring a mix of rich and poorer countries, with a focus on countries with resource constraints similar to SA's.

Shelley explained that the web-based review had proven difficult because documents were often in foreign languages, or simply not easy to find. The application of standard-setting to examinations appears generally not to be applied very transparently. In summary, there was no gold standard applied across countries.

All countries apply different methods, and often, even different colleges in the same country apply different standard-setting methods.

Most available information came from richer countries – where most commonly, the Angoff or modified Angoff method was applied, in some cases overlaid by a Hofstee method.

What did emerge from the review was that many countries have abandoned a focus on final examinations, and focus instead on appropriate and correct skills development during training, and the assessment of competence on an ongoing basis. Where examinations still exist, these are in addition

to significant formative assessments that take place during training.

Local developments

Prof. Francois Cilliers of UCT then focussed on the situation in SA currently. Any assessment process represents a compromise between the different aspects of assessment. There is no one right answer, and it depends on the context you are in and what is actually doable.

Medical education in Africa is very poorly reported in the literature – the topic has simply not been a focus. The bulk of literature and evidence comes from a very small portion of the practising globe, and we need to think very carefully about how we apply this.

Most literature on the topic comes from well-resourced healthcare systems. There is plenty of scope for additional research locally, but this needs to be funded.

Prof. Cilliers summarised some examples of African research into standard-setting.

Dr Schoeman's thesis, which looked at the introduction of the Cohen method for the College of Physicians in SA, highlights various issues to do with the introduction of the method for specialist examinations in particular. But there have been few studies done on different groups and examining other issues, for example, undergraduate and postgraduate assessment.

There is very little work done in Africa overall and there is very little done on applying these methods in Africa, with much to be done to really understand the impacts in the local context.

Implementing standard-setting at the University of Botswana

Prof. John Wright from the University of Botswana School of Medicine then presented the work that they have been doing related

to standard-setting. The Botswana school is relatively new, and relatively small by international standards, with an intake of around 70 per year. This can also be said for many of the neighbouring countries that have established medical schools.

Standard-setting is designed to be responsive to the difficulty of an examination

The Cohen-type proportionality methods were therefore very attractive because they provided simple methods that Botswana could easily employ in any exam.

Botswana found that when using the university standard 50% pass mark for tests, they had unacceptably high failure rates for about 25% of exams. This was not surprising since the exams are bound to be of varying difficulty and will generate false negatives in difficult exams. It is likely that they will also generate false positives in easier exams.

Using Cohen or modified Cohen standard-setting, the number of exams producing unacceptably high failure rates fell to about 5%, and the differences in numbers of failures between exams were greatly reduced, showing much better uniformity of exam standards.

That said, there were some problems experienced with the Cohen method. Cohen-type methods assume a fixed relationship between the marks of the top-performing students and those of a minimally acceptable candidate.

Taking this on balance, Botswana decided to use the modified Cohen (Taylor) method.

Prof. Wright concluded that we still have work to do to use these methods optimally – to learn how to set exams with good discrimination levels, and to learn what levels we should aim for.

The Cohen method

Prof. Thifheli Luvhengo, head of surgery at Charlotte Maxeke Hospital, explained the background of how he became involved in the process of examining the application of standard-setting.

He stated that any assessment method needs to be defensible. An arbitrary cut-off score for exams is difficult to defend because candidates, topics and examinations are all different.

There are over 50 different standard-setting measures, all with their own important uses and limitations. Commonly used methods internationally are the Angoff, Ebel and Hofstee methods.

He concluded that it is inappropriate to use the Cohen method of standard-setting for a progress examination, and elaborated on several reasons for why this is so. He said that the method does not meet the criteria for a defensible method, in that it doesn't offer evidence of validity, it is not easy to implement, it is not easy to interpret and it is not credible to lay people. The only benefit is that the Cohen score is easy to compute.

Panel discussion and way forward

Dr Flavia Senkubuge of the CMSA led a panel discussion of the invited guests. She believed that the meeting was the beginning of a conversation that should continue for some time.

In conclusion, this first meeting has opened the way for further dialogue into workplace-based assessments, and milestones in training. There was consensus that in specialist training, this really is the way forward.

SAMA aids KZN medical students: An investment in the future of medicine

SAMA Communications Department

On 13 March, SAMA donated ZAR550 000 to assist 118 medical students at the University of KwaZulu-Natal (UKZN) who are in financial distress.

The students faced possible financial exclusion from the institution due to unpaid

historical debt and/or unpaid registration fees. To address the problem, the Medical Campus Representative Council (MCRC) and UKZN launched the #IMadeADoctor campaign, with the aim of raising ZAR1 million to assist the 118 students complete their undergraduate studies.

"The SAMA Junior Doctors' Association also strongly motivated for a donation, and in the end the decision to assist was an easy one for us to make. Investing in future medical professionals is important, and this is a tangible way in which we can make a

difference," says SAMA deputy chairperson Dr Mvuyisi Mzukwa.

According to Ms Xoliswa Njapha, the MCRC "is delighted with the donation from SAMA", which has helped the #IMadeADoctor campaign reach its initial goal of raising ZAR1 million.

Prof. Busisiwe Ncama, Deputy Vice-Chancellor and head of the College of Health Sciences, also thanked SAMA for their kind donation.

"We are overwhelmed with the kind gesture from our colleagues at SAMA. Both their national and provincial offices came together to support our students after hearing their plea. Thank you for assisting in ensuring that we are able to graduate more doctors in the country," she says.

Dr Mzukwa says that apart from investing in future doctors in SA, the donation should also motivate others to participate in making education a reality for those who struggle financially.



At the presentation

"We've taken this step as it involves medical students who form part of our healthcare community as a medical association. But it should also serve as a message to other similar

institutions and associations who represent professionals in other fields that there are students who need financial assistance, and who will benefit from their generosity," he concludes.

First SA conference on death and dying as a life-affirming transition

SAMA Communications Department

The first SA conference on death and dying as a life-affirming transition was held in Cape Town from 7 to 8 February, drawing together a diverse group of end-of-life practitioners, carers, lay persons and experts.

"Engaging and talking about death is positive and life-affirming, because it brings death front and centre and helps me clarify how I want to live my life now," explains Leigh Meinert from Soulfull Collective, the "for-abundance" company responsible for hosting the conference.

Intrigued by the global trend of professional "end-of-life doulas" or "soul midwives", Meinert's search in SA led her to find 150 people who, like her, wanted to learn more about how to provide emotional and spiritual support through dying and death.

The Cape Town conference brought together some of these doulas, nurses, doctors, psychologists, bereavement counsellors, palliative care providers and religious leaders to share the growing knowledge, best practices and resources available on providing

emotional and spiritual care at the end of life or in the event of a sudden death.

One of the conference speakers was Felicity Warner, the founder of Soul Midwives. Through the UK-based organisation, Warner has pioneered an international movement in holistic and spiritual palliative care for more than 20 years. Her methods are now applied globally in hospices, hospitals and care homes. While the conference drew on the work of end-of-life practitioners, carers and experts overseas, the knowledge and experiences of local speakers and session hosts were grounded in the SA context.

Local speakers included Dr Mary Ryan, a theologian, ordained priest and care practitioner with many years' experience as a home-based caregiver and the co-ordinator of the Soul Carers Network. Ryan, who runs a training programme for Soul Carers in Cape Town, discussed "The context and the opportunities in SA for greater integration of soul care in end-of-life care". Prof. Liz Gwyther from UCT, who has worked tirelessly since the 1990s to deliver and promote comprehensive

community-based palliative care for people with life-threatening illnesses, spoke about the history and contribution of palliative care in SA to date, and Sonwabo Jacobs provided a fascinating insight into how his African identity and Christian faith enable his work as a spiritual carer.

There were also sessions held by end-of-life counsellor Keshnie Mathi, who discussed "Emotional and spiritual counselling during death and dying", as well as Dr Helena Dolny and Ngiphiwe Mhlangu who facilitated the "Love Legacy Dignity: Why conversations about mortality are life affirming" session.

Mathi is the founder of End of Life Supportive Alliance (<https://endoflifesa.com>), an alliance that helps educate the public on the various end-of-life practitioners and options in SA, and links the public to individuals who can support them. She is also the creator of a unique end-of-life counselling training course, which is recognised by the Association for Supportive Counsellors and Holistic Practitioners, and enables individuals to offer holistic support to persons who are

dying – from diagnosis through to their final journey – and their families.

“End-of-life counselling is about providing care, but also ensuring that those left behind are not traumatised by the experience, and death.”

According to Mathi, while there are many SA communities who observe various rituals and traditions associated with death, speaking openly about death before it happens is not common in this country. This leaves people feeling unprepared, which adds to feelings of helplessness and dread.

However, for those who are dying, end-of-life counsellors can help them to “unpack their past and make peace with their regrets,” while families can be assisted on their bereavement journey too.

“With the global movement of mindfulness, our clients are vocalising different bedside regrets. The most common ones are that they feel they did not find their purpose, or that they did not leave a legacy. It’s why I always say, you can learn how to live now, by listening to the words of the dying,” adds Mathi.

This is where Dolny and Mhlangu’s work comes in. Through their organisation, Love Legacy Dignity, Dolny and Mhlangu are teaching people how to live while also preparing for their deaths through talks and workshops on topics from relationship mapping, releasing and renewing through forgiveness, to creating an advance healthcare directive and nominating a healthcare proxy.

Dolny, who is the author of *Before Forever After – When Conversations about Living Meet Questions about Dying*, is also an international leadership coach and trained rites of passage guide. She has spent most of her life living closely with death. As an ANC member during apartheid and the wife of the late Joe Slovo, she had to make peace with the possibility of having her husband’s life cut short.

For Dolny, the why of the work she does is clear: “We suffer when loved ones die. We suffer even more when certain conversations haven’t happened.”

“I think that when we live with the strong presence and awareness of our own mortality and the fact that our death could happen anytime, then we live more consciously and less carelessly. We become more careful about our intentions, what matters most to us, and the state of our relationships at any given moment.”

Mhlangu, who worked in the news industry for 25 years and has covered many topical stories such as the Marikana massacre and former President Nelson Mandela’s passing, first



Leigh Meinert, conference spokesperson and one of the organisers

started speaking about death in her own life when her mother was diagnosed with terminal cancer 16 years ago. This announcement prompted Mhlangu to start a conversation with her mother about how she wanted to die.

“This was a culture shock in my family, because in Zulu culture, a young girl is not supposed to take control of her mother’s affairs or decide on matters relating to how her mother wanted to spend the last days of her life. It was hard to get buy-in from the rest of the family, whose worldviews are firmly grounded in Zulu patriarchal culture. My mother had to step in and inform everyone that a well-planned funeral and fewer cultural rituals was her dying wish,” explains Mhlangu.

“We suffered less, because we were not questioning our decisions around every turn.”

While it may seem more commonplace to talk about death and dying when someone has been diagnosed with a terminal illness or when people become older, Mathi, Dolny and Mhlangu all agree that the conversation needs to happen whether one is young and healthy or not.

“We live in a world where people die unexpectedly or after a short or long illness. Making decisions about death and dying before we’re in a crisis situation allows us to think about our options deeply, consult with people like family, friends and doctors, and live life knowing that our wishes have been made clear. As a journalist I have told several stories about death and dying and families being torn apart because of conversations that never happened,” adds Mhlangu.

A list of resources, combined during the conference, is available at: <https://soulfullness.org.za/resources/midwifery-dying-conference/?fbclid=IwAR0xDDa8>



Dr Meg Ryan



Prof. Liz Gwyther

“There is a stigma around people who are dying in our culture, it must not be known that they are sick” – Sonwabo Jacobs, spiritual care worker

“Palliative care is the most important part of what we do as doctors. It can be quite transcendent” – Prof. Liz Gwyther

“The soul deserves to be tendered and nurtured through life to the end” – Dr Meg Ryan

“Only 18% of people in SA are receiving palliative care when they need it” – Prof. Liz Gwyther

Regulating e-cigarettes – what does the evidence say?

Jolene Hattingh, Shelley McGee, *SAMA Knowledge Management, Research and Ethics Department*

In his budget speech on 26 February 2020, Finance Minister Tito Mboweni announced that electronic cigarettes (e-cigarettes) will be taxed from 2021. The full quote from the budget review reads: “Electronic cigarettes are different to heated tobacco products: they do not contain tobacco, but they do contain nicotine or other chemicals. Currently, electronic cigarettes are not taxed. Globally, policymakers are looking at regulating and taxing these products due to concerns about their health effects. Government intends to tax electronic cigarettes in 2021.”

Although the e-cigarette has gained immense popularity over the last couple of years, much remains to be studied with regard to the possible health risks and cessation benefits. Nicotine in tobacco is known to cause addiction and dependence, and the electronic nicotine delivery system (ENDS) can deliver high concentrations of it. This concentration varies depending on the numerous potential components found in e-cigarettes. According to the US Centers for Disease Control (CDC), one JUUL (a popular e-cigarette shaped like a USB flash drive) pod contains nicotine levels equal to one full packet of regular tobacco cigarettes. The JUUL is reported to be the most commonly sold e-cigarette in the USA.

While some of these products have lower emissions than conventional cigarettes, they are not risk-free, and the long-term impact on health and mortality is still unknown. There is still insufficient evidence to support the use of these products as a population-level tobacco cessation intervention. The WHO report on the global tobacco epidemic notes that there have only been a limited number of randomised controlled trials and longitudinal studies investigating the role of ENDS as a potential cessation aid that can be offered to a population, and the conclusions are open to interpretation.

Previous information found in various controlled studies all showed that e-cigarettes have a definite value as a cessation tool for the conventional tobacco cigarette. However, more recent reviews found that only ENDS provide these results – not to mention that some individuals who have never smoked a day in their lives have picked up smoking e-cigarettes.

A concern raised by the National Academy of Sciences in the USA is the emerging use of e-cigarettes and other devices to aerosolise cannabis plants, oils and waxes, which can also lead to non-smokers picking up the trend. Estimates found that rates of using an e-cigarette device to aerosolise cannabis products in young adults across North America ranged from 8 to 29%. With the legislation of cannabis use increasing, commercial cannabis industries are likely to become more involved. Recent CDC statistics in the USA have linked e-cigarette use with up to 1 080 lung injury cases, and 18 deaths. With no clear evidence of cause for these infections and deaths, the CDC suspects chemical exposure from toxins in products containing tetrahydrocannabinol (THC).

By the end of July 2019, the American Association of Poison Control Centers had managed 2 439 reported closed exposure cases. The Association reports that some children and toddlers who are exposed to e-cigarette devices or liquid nicotine have become very ill, with the most significant symptoms being nausea and vomiting. Often ENDS contain greater concentrations of nicotine than other nicotine and tobacco products on the market. A recent systematic review found that the majority of studies presented with findings towards harmful side-effects resulting from continued e-cigarette use.

An analysis of the composition of e-cigarette products looked at the toxic and carcinogenic compound analysis of the aerosol from twelve brands of e-cigarettes compared to a conventional cigarette and a nicotine inhaler. The levels of toxicants in the aerosol were found to be 1 to 2 orders of magnitude lower than that found in cigarette smoke. However, it was found to be higher than the toxicant levels found in the nicotine inhaler.

Little local research is available on the attitudes, perceptions and utilisation of e-cigarettes, but the market has been estimated to be worth over ZAR1 billion, and growing. With evidence remaining weak at this point, the recent announcement by the National Treasury that it will regulate and tax e-cigarettes will be welcomed by some groups and condemned by others.

The inflation implemented for 2020 on currently taxed tobacco products included a

74c increase on a conventional packet of 20 cigarettes, a ZAR6.73 increase on a 23 g cigar, and a rate of 75% of the rate of cigarettes was set for all heated tobacco products, including “hubbly bubbly”. No rates have been set for e-cigarettes yet; however, we expect that legislation will be released for public comment in due time, as tax will be implemented from 2021.

The announcement by the Treasury may also reignite discussions on and progression of the Control of Tobacco Products and Electronic Delivery Systems Bill of 2018, which aims to subject e-cigarettes to the same set of laws that regulate tobacco cigarettes in SA. However, the amendment Bill is still under consideration and has not yet been approved. In 2018, SAMA welcomed the introduction and contents of the Bill and supported most of the proposals, including increasing taxes on tobacco products. We also believe an age restriction needs to be placed on the purchase of e-cigarettes and liquids to prevent early-onset by non-smoking youths due to the popularity of “vaping”, as well as prohibit the colourful packaging and flavourings used to lure young adults.

An additional complication in both regulation and taxation relates to nicotine, which is found in e-cigarettes, and currently straddles two different legislations, namely the Medicines and Related Substances Act No. 101 of 1965 and the Tobacco Products Control Act No. 83 of 1993. According to the Medicines Act, nicotine as a ‘medicine’ should be registered with the SA Health Products Regulatory Authority (SAHPRA) and be available only by prescription, but the industry uses it not as a medicine but as a recreational substance and thus evades regulation by the Medicines Act.

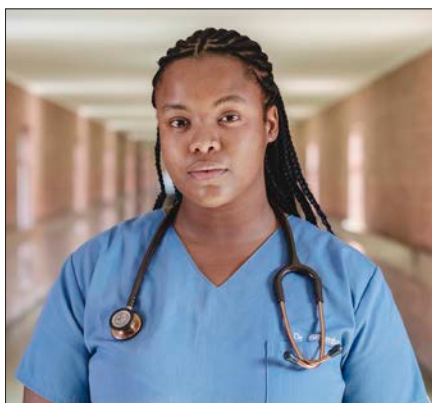
Conversely, e-cigarettes do not contain “tobacco” and therefore cannot be regulated by the existing Tobacco Products Control Act, so control of these products has been nearly impossible up to now.

SAMA hopes for an active and productive year ahead in addressing e-cigarettes and tobacco products, so that we can gain clarity on the regulatory situation as we strive to deliver evidence on the benefits and harms of e-cigarettes.

References available on request.

Antimicrobial resistance and you – a personal account from a survivor

Dr Zolelwa Sifumba



In February, I attended the second Capacity Building and Workforce Development conference hosted by the African Union and the Africa Centers for Disease Control and Prevention (Africa CDC) in Nairobi, Kenya.

The conference, held on 20 and 21 February, brought together civil society organisations (CSOs) who focus on antimicrobial resistance (AMR). Supporting partners were the Southern African Centre for Infectious Disease Surveillance, the Food and Agriculture Organization, the World Organisation for Animal Health, ReAct and the WHO.

Representatives from CSOs all over Africa attended. As an occupational multidrug-resistant TB survivor and global advocate who speaks on the global rise of AMR, I also attended.

The Africa CDC and its partners are committed to fighting AMR in Africa, and have developed a framework for AMR. The workshop I attended brought together those working on the ground in different communities around Africa fighting AMR in the fields of human health, animal health and environmental health.

Antimicrobials include antibiotics/antibacterials, antivirals, antiparasitic agents and antifungals, which comprise most of the drugs we prescribe as doctors. Resistance can be found in most of these classes.

Antibiotic resistance, a type of AMR, is a global issue that exists on all continents, affects both low- and high-income countries, and affects both strong and weak health systems. It is a threat to global health, which

is why it has become increasingly important that all continents, including Africa, mobilise to quantify and solve the crisis.

Antibiotic resistance is the ability of bacteria to protect themselves against the effects of an antibiotic. In large bacterial populations, there are often a few resistant bacteria. Antibiotics select for resistant bacteria, meaning that they kill or stop the growth of susceptible bacteria, resulting in the surviving population consisting of mostly resistant bacteria. The overall effect of this treatment therefore fails, and this threatens our ability to perform modern medical procedures.

Essentially, this results from the misuse of antibiotics in the human health sector, their use in farming and industry, and contamination of the environment by improper waste management at hospitals, or by pharmaceutical companies. It also results from the consumption of antibiotics through food, such as antibiotic-fed cattle.

The problem is that such resistant bacteria are developing faster than new antibiotics, meaning that one day we may find ourselves in a world without effective antibiotics.

This will result in an inability to treat easily treatable infections such as urinary tract infections (UTIs), pneumonia, meningitis and others. This has the potential knock-on effect that minor ailments may become life-threatening.

Further outcomes of this development may include increased mortality among those with weakened immune systems, such as cancer patients and preterm babies, who need antibiotics to survive, and the inability to cover patients using antibiotics in surgical procedures such as caesarean sections, hip replacements and even dental extractions.

All of these developments will ultimately increase the cost of healthcare, prolonging hospital stays and affecting vulnerable groups such as the young, old, immunocompromised and the poorest in our communities.

Unfortunately, the spread of resistant bacteria has become easier as people travel all over the world using all modes of transportation, especially those that are airborne, and those linked with poor hygiene.

I remember managing the case of a child with severe acute malnutrition who was failing to thrive due to a UTI resistant to all antibiotics. I am sure most of us must deal with cases of antibiotic resistance in the clinics and hospitals we work in that leave us feeling confused and helpless.

Antibiotic resistance kills more than 750 000 people every year, and the threat goes beyond health.

Resistant bacteria pose a risk with regard to food and feed production, trade and climate change, as well as causing economic damage due to increased health expenditure and decreased productivity. The World Bank estimates that nearly 28 million people will fall into extreme poverty by 2050 due to bacterial resistance.

Resistant bacteria are developing faster than new antibiotics

AMR has been on the global agenda since 2001, and over the past few years, countries all over the world have been developing and implementing national action plans to target it.

My role at the February workshop was to represent the human element of AMR.

I was there as a face and a story behind the global crisis: as a survivor. I highlighted the difficulties I faced battling a drug-resistant infection, my experiences treating infections in my capacity as a medical doctor and the importance of the work we do.

The following AMR management strategies were discussed:

- infection prevention: reducing disease incidence, prevention of spread of infections, vaccinations and hand washing
- surveillance: monitoring resistance patterns, antibiotic use and healthcare-associated infections
- access and rational use: research and development of new antibiotics and diagnostics, improving the use of

- existing diagnostics, and regulations and guidelines
- non-human usage: monitoring veterinary use, as well as use in livestock, aquaculture and horticulture
- environmental aspects: waste management.

What can you do in your place of work to help fight this crisis?

- prescribe antibiotics rationally
- remember that antibiotics only cover bacterial infections
- bear in mind that the overuse of antibiotics results in the increase in drug-resistant bacteria, resulting in infections that cannot be treated
- do your best to wash your hands regularly so as not to spread infections, and teach this to everyone
- raise awareness about AMR

- educate the people around you how on to use antibiotics.

Remember, this is an issue that can affect anyone; everyone is susceptible to contracting a drug-resistant infection. I contracted multidrug-resistant TB because I took a breath.

AMR is solvable, but if we do not take action, we will risk returning to the dark ages of medicine, where antibiotics are ineffective.

Ill health, incapacity and the employee's rights

Ruan Vlok, *employee relations advisor, SAMA ER department*

Incapacity due to ill health refers to the inability, mentally and/or physically, to perform the duties for which a person is employed, either temporarily or permanently. Should an employer decide to terminate the employment due to ill health, it should be proven that it was both substantively and procedurally fair, with specific reference to item 10 of the Code of Good Practice. When this process is initiated by the employer, an employee is usually unaware of the strict rules guiding the employer in this regard. This article will discuss and provide employed medical doctors with details of their rights, as per applicable legislative framework and case law, in this regard.

Legislation

Items 10 and 11 of schedule 8 of the Labour Relations Act No. 66 of 1995 give effect to the duties of employers and rights of employees in this regard, and this article will specifically focus on these items;

"10 – Incapacity: Ill health or injury

(1) Incapacity on the grounds of ill health or injury may be temporary or permanent. If an employee is temporarily unable to work in these circumstances, the employer should investigate the extent of the incapacity or the injury. If the employee is likely to be absent for a time that is unreasonably long in the circumstances, the employer should investigate all the possible alternatives short of dismissal. When alternatives are considered, relevant factors might include the nature of the job, the period of absence, the seriousness of the illness or injury and the possibility of securing a temporary replacement. In cases of permanent incapacity, the employer should ascertain the possibility of securing alternative employment, or adapting the duties or work circumstances of the employee to accommodate the employee's disability.

(2) In the process of the investigation referred to in subsection (1) the employee should be allowed the opportunity to state a case in response and to be assisted by a trade union representative or fellow employee.

(3) The degree of incapacity is relevant to the fairness of any dismissal. The cause of the incapacity may also be relevant. In cases of certain kinds of incapacity, for example alcoholism or drug abuse, counselling and rehabilitation may be appropriate steps for an employer to consider.

Particular consideration should be given to employees who are injured at work or who are incapacitated by work-related illness. The courts have indicated that the duty on the employer to accommodate the incapacity of the employee is more onerous in these circumstances.

"11 – Guidelines in cases of dismissal arising from ill health or injury

Any person determining whether a dismissal arising from ill health or injury is unfair should consider–

- Whether or not the employee is capable of performing the work; and
- if the employee is not capable –
 - the extent to which the employee is able to perform the work;
 - the extent to which the employee's work circumstances might be adapted to accommodate disability, or, where this is not possible, the extent to which the employee's duties might be adapted; and
 - the availability of any suitable alternative work."

The Employment Equity Act No. 55 of 1998 also contains a code of good practice regulating the employment of persons with disabilities. While conducting incapacity procedures, the

employer is obliged to keep in mind this code, which is based on the constitutional principle that no one may unfairly discriminate against a person on the grounds of disability.

Specifically, referring to the rights of employees and obligations of employers in the public sector, both parties will be bound by resolution 12 of 1999 of the Public Service Co-ordinating Bargaining Council (PSCBC), which gives effect to items 10 and 11 of schedule 8.

Case Law

In the matter of IMATU obo Strydom v Witzenburg Municipality & Others (2012) JOL 28586 (LAC), the issues raised on appeal were whether the employer failed to give any effect to its obligations as prescribed in items 10 and 11 of schedule 8, and whether such non-compliance resulted in the employee being unfairly dismissed. The Labour Appeal Court found that non-compliance with these items would result in the dismissal being both procedurally and substantively unfair.

In the matter of E C Lenning Ltd t/a Besaans Du Plessis Foundries v Engelbrecht (1999) 20 ILJ 2516 (LAC), the Labour Appeal Court confirmed the principle that when an employee has been injured and/or contracted a disease during the course of his/her employment, the duty on the employer to accommodate is onerous, emphasising item 10(4).

Conclusion

From the above, one can see that the onus on the employer is enormous to prove that the termination of an employee's services due to ill health was fair and proper in terms of items 10 and 11. Should any SAMA member face this type of procedure in the workplace, please contact SAMA's Employee Relations Department to exercise your rights in terms of item 10(2).

Documents to submit when applying for ethics approval

Adri van der Walt, SAMAREC officer

The submission of an ethics application for review by an ethics committee can be a daunting task, especially if you're a first-timer, or you do not work with the committee and their requirements regularly.

It is prudent to always consult with the specific ethics committee you are using before submitting an application, to ensure that the relevant documents and the correct format of said documents are submitted. This will, in the long run, save valuable time and assist in getting your study started without unnecessary logistic delays.

The following serves as an outline of what documents to submit, as per the National Department of Health's *Ethics in Health Research – Principles, Processes and Structures* (2015). The SAMA Research Ethics Committee (SAMAREC) has used these guidelines to prepare its standard operating procedures, which can be accessed online at: <https://www.samedical.org/cpd-hpcs/research>.

Covering letter

The covering letter should give the committee an overview of the planned study, including a short description of the methodology to be used, the study staff involved and what you plan to do with the results once finished (e.g. the study may be for publishing purposes only). Any important and foreseen risks or discomfort to participants must also be declared and highlighted here.

SAHPRA

Although most applicable to the pharmaceutical industry, who use investigational products as well as devices, SA Health Products Regulatory Authority (SAHPRA) notification and approval must be obtained before a study may commence.

SAHPRA is a statutory body of the Department of Health "tasked with ensuring that the pharmaceutical drugs available for use in SA are safe, are of the requisite quality, and have the required efficacy."

The SAHPRA review process is independent from that of the ethics committee, and limited to interventions. The researcher should contact SAHPRA directly for confirmation of review or notification.

More detail about SAHPRA is available at <https://www.sahpra.org.za>.

NHREC/SANCTR

Registration of clinical trials with the SA National Clinical Trials Registry (SANCTR) is required by law, and proof thereof must be provided to the ethics committee. The registry is kept to ensure that there is a formal record of biomedical clinical trial research being done within SA. Observational studies need not be registered on this system. The National Health Research Ethics Council (NHREC) will automatically upload the information to the SANCTR. The onus of registration of the study (<http://www.ethicsapp.co.za>) is on the researcher.

Protocol

The protocol is a blueprint for the entire study, and must provide a detailed description of every aspect. Although not an exclusive list, the major topics to include are:

- a literature review
- methodology
- risk vs benefit ratio – should there be an intervention?
- method of ensuring participant/patient safety, whether physical safety or data protection
- planned outcome distribution, e.g. publish the results or use for a future study.

Different ethics committees have differing guidelines on how long the protocol document should be. The committee will guide you and formally make recommendations about omissions on topics that need more in-depth clarification.

Investigator's brochure

This is mainly relevant to the pharmaceutical industry, as the investigator's brochure is a collection of all the information gathered on a specific investigational product or device.

Informed consent document

This is the most important document the committee will wish to review, and will most likely also be the document returned to you with the most queries and recommendation. Participant/patient safety is vital, and the ethics committee has a responsibility towards the patient to ensure that the researcher is guided to carry out the study ethically.

The following major criteria will be measured in this document:

- It must be reader-friendly: consider your target population. A questionnaire for doctors will use different language to a questionnaire for patients. For patients/participants, ensure the use of grade 7 language, and limit the use of medical terminology and jargon.
- Any and all potential risks must be clearly defined: this must be done in writing, and in terminology the patient will be familiar with. For example, hypertension must be described as high blood pressure for the patient's consideration.
- The mention of an incentive is discouraged. Although participants/patients are at times reimbursed for visits attended, this must not be declared as a monetary sum in this document, as this might be seen as coercion.

Insurance document

If applicable (however, this is mainly limited to full-scale clinical trials), the appropriate study insurance, covering the number of patients randomised as well as the anticipated duration of the study, must be obtained.

Patient-/participant-facing documents

Any item or document that will be presented to the participant/patient must be declared, and reviewed by the committee. This will usually include data collection tools, such as questionnaires.

Advertisement for patient recruitment is allowed; however, the advertisement (regardless of the intended advertisement media) must be reviewed and approved by the ethics committee before use.

Study staff supporting documents

Study staff embarking on research involving human participants must be equipped with the relevant academic knowledge, as well as the clinical skill set, to ensure that quality data are obtained, and that patient/participant safety is sustained.

As such, the ethics committee might require (not exclusively) the following documentation for every study staff member:

- Curriculum vitae (CV): a detailed description of formal academic training, clinical experience and participation in previous studies must be given.

- Declaration: the declaration must reflect the name of the sponsoring company (if applicable), the protocol number and title and the study staffs' names and designations. The declaration provides the researcher with the relevant information on what should be declared, and the researcher's willingness to comply with current local legislation and good clinical practice.
- Good clinical practice (GCP) training: this requirement might be waived, depending on the study methodology. For example, a non-intervention retro-

spective patient-record study will not require GCP training.

- Current registration with a regulatory authority, e.g. the HPCSA. Researchers need to be qualified professionals, and proof of their current status of registration must be provided. This also guides best practice in clinical research, as data collection (by a trained professional) is vital. Blood samples, for example, must be taken by a formally trained and registered professional, and not a "supervised" lay person.
- Updated malpractice insurance: as with

registration with a regulatory authority, any study staff members need up-to-date malpractice insurance if they are to perform any patient "hands-on" duties.

SAMAREC has a full-time dedicated secretariat to assist with the preparation of applications to the committee. SAMAREC is registered as a research ethics committee for the review of studies in the private sector.

For more information, contact Adri van der Walt on 012 481 2046, or email samarec@samedical.org.

MPS survey shows doctors want more guidance on record-keeping

SAMA Communications Department

A recent Medical Protection Society (MPS) survey of SA doctors found that an overwhelming majority have not undertaken specific training in and want more guidance on record-keeping.

The survey asked a sample of MPS members about their experience of keeping medical records, and received a response from 838 doctors. Respondents were from a variety of clinical backgrounds, including consultants and GPs in both public and private practice.

Almost all survey respondents (94%) agreed that accurate record-keeping was part of their professional responsibility. Despite acknowledging the importance of good record-keeping, the survey found that just under 12% of doctors had undertaken specific training in keeping medical records. Most doctors also indicated that they would like more guidance on good record-keeping.

The vast majority of doctors felt that they kept good records, and half the survey respondents reported that they had been

complimented on the quality of their record-keeping. However, challenges remain, as 8% have had a colleague complain about their record-keeping and 14% have had a patient complaint, claim or local issue where record-keeping was identified as a component.

When asked about the challenges of record-keeping, prominent barriers included the fact that the process was time-consuming and doctors had a high workload. Other barriers included habit, insufficient computer skills and lack of training.

Graham Howarth, Head of Medical Services, Africa for MPS said: "Doctors understand the importance of good record-keeping, both for themselves and for the welfare of their patients. Good clinical records are a prerequisite to delivering high-quality care and ensuring continuity when a number of different clinicians are contributing simultaneously to patient care.

"The constant drive to improve the quality and safety of medical practice, and the increasing

expectations around and costs of medical care, means the structure and content of the clinical record is becoming ever more important.

"Poor record-keeping can contribute to an adverse outcome such as a delayed diagnosis, and could lead to a complaint, claim or a referral to the HPCSA.

"Maintaining complete contemporaneous records enables a doctor to provide evidence of the care given, and thus is invaluable if they have a complaint or claim of clinical negligence."

MPS advises that there are four crucial components to a good medical record, which must be:

- legible
- contemporaneous, with accurate dates and times
- identifiable, i.e. printed name and signature
- up to date.

MPS will be providing further training on medical record-keeping later this year.

SAMAREC bids farewell to Dr Sterna Franzsen

Adri van der Walt, SAMAREC officer

It is with great sadness that the SAMA Research Ethics Committee (SAMAREC) bids farewell to Dr Sterna Franzsen. Dr Franzsen completed her term on SAMAREC at the end of 2019.

This vibrant doctor needs little introduction. She matriculated at Pretoria Afrikaanse Girls High School and has since resided permanently in Pretoria. After completing her MB ChB at the University of Pretoria,

she worked as a medical doctor in various departments at Tembisa Hospital.

The rotation proved to be invaluable, and led her to her preferred choice of specialisation at the time – obstetrics and gynaecology. She



Dr Franzsen and her daughter Tanja after the Warrior Race

obtained her Master's degree from her alma mater, the University of Pretoria.

With her specialty qualification completed, she started a private practice as a gynaecologist in Pretoria.

Her assorted interests in alternative/natural medicine led her to also start an integrated medical practice while practising gynaecology.

Enhancing her integrated medicinal practice skills, she obtained training in the very intricate science of darkfield microscopy at the Cheney Clinic in Charlotte USA.

Discovering that she had an aptitude for video microscopy, chelation therapy and bio-oxidative therapy, she retired from gynaecology and advanced her knowledge in these fields by completing the American College for the Advancement of Medicine chelation therapy course and exam in Washington, USA

Her experience with darkfield and video microscopy respectively led her to develop an interest in stem cell therapy. She obtained stem cell therapy training at Adistem in Australia.

This interest also led her to complete a course in biomolecular and essential fatty acid metabolism and lipid detoxification. Working at Burghwood Clinic in London under the supervision of Dr Shideh Pouria led to valuable experience in this field – experience she once again brought back to her hometown. In 2012 she started a clinic in Pretoria doing single-

session stem cell treatments, as well as lipid detoxification.

Her knowledge base and experience in stem cell treatment led her to become an external consultant for SAMAREC. With her diverse interests, extensive knowledge base and valuable experience, she was soon appointed as a permanent member, serving in a clinical member capacity of the committee.

Sadly, her official term on the committee has come to an end. She will, however, still serve on the SAMAREC expert panel – a panel of experts SAMAREC uses *ad lib* as external consultants for specialised fields of study.

On a personal level, Dr Franzsen enjoys the outdoors, loves to travel and has also completed a BA Degree in Theology.

On behalf of SAMA and SAMAREC we would like to extend our gratitude to Dr Sterna. Her knowledge, gentle nature, and extreme empathy have made her a valuable asset to SAMAREC and in turn, to all the studies she has reviewed. Her fulltime presence on the committee will be sorely missed.

Portugal brings down obesity by taxing sugary drinks

World Health Organization

On World Obesity Day, 4 March, the success Portugal has had in tackling childhood obesity – one of the main health challenges in the WHO European region – with their sugary drinks tax was highlighted.

Childhood obesity is a complex public health issue caused by many factors. It intersects significantly with socioeconomic status. As behaviours leading to obesity can be established at a young and vulnerable age, countries have a duty to protect children from a phenomenon that can become a health burden for the rest of their lives.

In Portugal, the combination of unhealthy diet and a rise in sedentary lifestyles has precipitated a public health struggle with childhood obesity. The consequences of this have implications in terms of Portugal achieving their wider targets for non-communicable diseases (NCDs) by 2030.

The importance of monitoring health trends

However, one monitoring programme, the WHO European Childhood Obesity Surveillance Initiative (COSI), has attempted

to take a firm hold on the crisis. COSI has been tracking the trend in childhood obesity for 12 years, and seen the numbers in Portugal slowly but surely turn around. The initiative has surveyed the weight of school-aged children every 2 - 3 years in over 40 member states of the European region since 2008. It has delivered invaluable data to governments across the region in that time.

Sales of sugary drinks have fallen overall

Dr Ana Rito, Portugal's principal investigator for COSI, walks us through the component parts of this critical monitoring initiative. "Between 2008 and 2016 we can see a drop in overweight children [in Portugal] from 37.9% to 30.7%, and in obese children from 15.3% to 11.7%. However, it remains one of the highest rates in Europe," she explains. Thanks to COSI, it is not just prevalence that can be assessed, but also the behavioural aspects of healthy

lifestyles, including diets and physical habits. The programme also goes beyond the children themselves to assess their environments, such as schools and family. This detailed level of analysis showed that despite the decreasing rates of obesity overall, dietary patterns seemed to be resistant to change.

Healthy lifestyles

Most importantly, COSI identified one of the main culprits. It seemed that the number of children who regularly drink soft drinks – a significant influence on weight gain – had increased over time to over 80.1% of children aged 6 - 8 years in 2016. "This data provided scientific evidence essential to support the implementation of the sugary drinks tax," Ana tells me.

Taxation is often an effective way of nudging behaviour change, and is far more successful than targeting or shaming individuals. However, building political momentum for such legislative change often proves challenging, particularly when it tackles an industry that puts profit before the health priorities of young people. Nonetheless,

leading public health institutions in Portugal helped drive taxes on sweet beverages up the agenda, and in January 2017, Portugal brought into force a sugary drinks tax.

Big steps forward

The results are impressive. Many companies have radically reduced the amount of sugar in their products, and sales of sugary drinks have fallen overall. Future rounds of the COSI Portugal study will be able to track the full impact on children's consumption patterns, but the initial plunge in high-sugar beverage sales and the significant reformulation of products is impressive.

Dr Francisco Goiana da Silva was part of the Portuguese Ministry of Health when the sugary drinks tax was implemented, and is confident about the tax: "This policy intervention is estimated to have had a far greater impact on the population's diet than all the education and self-regulated mechanisms combined. The tax also serves as a measure to tackle health inequalities." Unhealthy diets and obesity are strongly related to social determinants of health in Portugal – people with lower income and education levels are the most vulnerable to developing NCDs. "By promoting transfer of consumption to healthier choices, such as water, which is less expensive, this policy will reduce the risk of developing NCDs among

the most vulnerable population groups," added Dr da Silva.

Dr da Silva also stresses the importance of investing revenue raised by the sugary drinks tax in health promotion initiatives. "It allows the creation of a multiplier effect," he said. "It brings to light the positive impacts of the tax, and prevents criticism from stakeholders in the industry arguing that the tax serves only to generate revenue."

Surveillance systems such as COSI are clearly not just monitors of change – they have a huge amount of agency in driving through reforms and building change themselves. When policy-makers, politicians and academics collaborate flexibly, they can have a significant impact on the healthy behaviour of populations.

COSI is just one of the WHO tools that Portugal has adopted to tackle childhood obesity and other NCD risk factors. National-level stakeholders have recognised the importance of such tools and resources. "Having tools that can be readily used by policy-makers and ministries of health to assess the potential impact of policy scenarios is extremely useful. In the past, we have also used WHO tools to estimate the potential health impact of the Portuguese sweetened beverages tax, and we are currently considering their application in other policies," said Dr Maria João Gregório, director of the

Portuguese National Programme for the Promotion of Healthy Eating.

Portugal's fiscal measures are taking on entrenched challenges and defending the right to health for all – including children. Although there is more work to be done on healthy behaviours, these measures offer a guide to best practice in turning the tide of the childhood obesity epidemic.

Push to increase SA's sugar tax

Non-profit organisation the Healthy Living Alliance (HEALA) has asked Treasury to increase and expand SA's sugar tax as the country deals with growing health issues.

The sugar tax – formally known as the health promotion levy – was first introduced by Treasury in 2018. The levy is attached to sugary beverages that have been manufactured in or imported into SA.

Currently the tax applies to carbonated beverages such as Coca-Cola, but HEALA says that it wants the levy to be expanded to include fruit juices, which also have high sugar content.

The group is also lobbying for a general increase on the tax to 20%.

Source: BusinessTech.co.za (12 February 2020)

Top Pretoria lawyer to lead expansion of MPS in SA

SAMA Communications Department

The Medical Protection Society (MPS) has announced that its members in SA will soon benefit from a more local service, with cases and clinical negligence claims to be handled within the country, and Pretoria-based expert Ulundi Behrtel appointed to head up the expansion.

MPS is the world's leading protection organisation for doctors, dentists and healthcare professionals, supporting more than 300 000 members around the world – with nearly 32 000 of those in SA. In 2019 alone, it supported members in the country with more than 3 000 medical and dental cases – ranging from complaints through to more complex issues such as claims of clinical negligence, HPCSA matters, inquests and criminal investigations.

With the additional services soon to be available in-country, MPS's support for

members will be geographically more accessible than ever before. The move will enable MPS to better understand and address the concerns of members in SA, and will also provide it with greater clarity on the risks and trends faced by practitioners.

Appointed as head of service delivery in SA, clinical negligence expert Ulundi Behrtel will join MPS on 2 March, with a remit to manage the delivery of the new services, and a plan to have the office – which is likely to be situated in Pretoria – fully operational in the next 12 – 18 months.

Ulundi is a lawyer, holding a Certificate in Medicine and Law from UNISA, with an extensive background in medical law and malpractice. She has worked as in-house legal adviser on professional conduct to the Registrar at the SA Nursing Council, as senior military law officer in the SA Military

Health Service, as senior state law adviser and researcher to the SA Law Reform Commission and as the head of the Human Rights, Law and Ethics Unit at SAMA.

Most recently, Ulundi has been a claims manager at EthiQal Medical Risk Protection in SA.

The expanding MPS business in SA has also been boosted by another key appointment. Graham Craig has taken up the post of new regional business development lead, bringing his wealth of experience from the financial services industry, including in several senior executive roles, and most recently the position of CEO of AA Insurance. During Graham's career he has been responsible for geographical expansion, strategy and innovation for several national and multinational companies.

Ulundi Behrtel commented: "I am delighted to join MPS and play a leading role

in continuing the growth and development it has seen for more than 60 years in SA. MPS has a long tradition of supporting doctors and dentists in SA, and I am looking forward to building on this and becoming even closer to members than we have been previously." Graham Craig said that "MPS is a market leader with a proud history, and I was attracted to the fact that MPS operates across the world, which will enable me to gain insight and access

trends that are happening globally. The MPS values are extremely closely aligned to my personal values. I am ambitious, tenacious and customer-focused, and thrive in environments where accountability and empowerment are the norm."

Melanie Rowles, director of claims delivery services at MPS, added: "Getting closer to members wherever they are in the world is a key part of the MPS strategy, which

is designed to ensure we are best placed to meet the increasingly diverse range of issues faced by doctors, dentists and other healthcare professionals.

"I am thrilled to welcome both Ulundi and Graham into the organisation. With the appointment of two such high-calibre individuals, members in SA are going to benefit enormously from the expertise that they bring."

Spinal surgery blamed for worsening symptoms

The Medical Protection Society shares a case report from their files

Miss L, a 39-year-old horse groom, had a long-standing history of lower back pain, for which she had previously consulted a chiropractor. She attended her GP after experiencing a sudden worsening of pain along with saddle paraesthesia, bilateral leg numbness and urinary incontinence. Her GP was concerned about a possible diagnosis of cauda equina syndrome, and referred Miss L to the emergency department.

An MRI scan performed the same day showed a bulging intervertebral disc at L5/S1, and she was referred to the neurosurgical team who, following a review of the images, recommended that Miss L was discharged home with analgesia.

However, Miss L continued to experience significant back pain, now radiating down her left leg with ongoing paraesthesia to both buttocks, and requested to be seen by a spinal surgeon again on a private basis. She was therefore referred to Dr W, specialist spinal surgeon, and was reviewed several weeks later following her discharge from hospital.

On examination, Dr W identified a reduction in lumbar flexion and a severely limited straight leg raise on the left side, with the right side normal. Sensation was reduced to her left calf and foot, her right foot and both buttocks. Power to the left ankle was reduced, but otherwise normal to the lower limbs. Miss L also complained of ongoing episodes of urinary incontinence.

Dr W reviewed the MRI scan from the hospital, and considered this demonstrated disc degeneration at L4/5 and L5/S1, with a left-sided disc protrusion at L5/S1 that was migrating centrally.

Dr W recommended surgery in the form of a posterior lumbar interbody fusion, cautioning Miss L that this may not relieve

all of her pain and other symptoms, and was primarily intended to prevent further deterioration. She was informed that there was a small risk that surgery would make matters worse, and that an alternative option was to continue conservative management.

Miss L consented to surgery after considering her options, and this proceeded uneventfully.

A month following the surgery, Dr W reviewed Miss L. Miss L reported that the back pain had resolved, her leg pain had lessened and, while her incontinence and numbness had not completely resolved, both were improved from the situation prior to surgery.

However, around a year later, Miss L once again developed back pain, with worsening bladder dysfunction and numbness to her feet and buttocks, along with disturbance of bowel function, stating these symptoms to be worse than those she had experienced prior to her surgery. A further MRI scan was arranged, which did not demonstrate a cause for the symptoms.

Miss L brought a claim against both the hospital and Dr W, alleging that the hospital had failed to diagnose acute lumbosacral radiculopathy by means of a lumbar puncture and neurophysiological studies, that Dr W advised and performed unnecessary spinal surgery and that both the hospital and Dr W should have prescribed a course of high-dose oral steroids, which would have relieved her symptoms and prevented their recurrence. It was further alleged that the surgery was the cause of her worsened symptoms.

Outcome

The case was considered by the Medical Protection Society (MPS) to be complex, with a number of allegations against both the

hospital and Dr W, and with Miss L's attorneys suggesting that the investigations and treatment that were performed would not be routinely carried out for such symptoms.

Opinion on Dr W's actions was sought from an expert spinal surgeon, who concluded that surgery was an appropriate course of action to offer under the circumstances, and that although Miss L continued to experience symptoms, her medical records indicated that she had experienced improvement following the surgery, and there was no indication that it had caused harm.

On receipt of the expert report, the case was again fully reviewed by MPS's medical and legal team, and it was considered that the case should be robustly defended. An advocate was therefore instructed to draft a formal defence on Dr W's behalf and, following receipt of this, Miss L's attorneys discontinued the claim.

Learning points

- Comprehensive and clear documentation of any history and examination performed is vital, should there be a later challenge to the diagnosis made at the time of the consultation.
- Risks and benefits of any surgical procedure offered, and the alternative options available (including the option of doing nothing), should be fully explained and documented to ensure that decision-making and consent are informed.
- In an elective situation, time should be provided after the consultation and prior to scheduling surgery to allow the patient to weigh up the options and form a considered view as to whether or not they wish to proceed.

Helen Joseph Hospital intern meeting

SAMA Gauteng Branch sponsored 75 personalised stamps at the Helen Joseph Hospital intern meeting for junior doctors from both Helen Joseph and Rahima Moosa Hospitals on 24 February 2020. The stamps aim to encourage junior doctors to abide by clinical guidelines and sign off clinical notes, request forms and prescriptions with their name, qualification and HPCSA number.



Doctors who attended the intern meeting at Helen Joseph Hospital

Successful CPD meeting at Maphutha Malatji Hospital

SAMA hosted a CPD meeting at Maphutha Malatji Hospital in Phalaborwa on 5 March 2020. Dr Brenda Nemukongwe presented on the topic of social media and its impact on healthcare. She advised attendees to be vigilant of what they post on social media, and how they send confidential patient information through WhatsApp messages.

She also highlighted the following dangers of using social media:

- damage to professional image
- breaches of patient privacy
- violation of patient-healthcare professional boundary
- licensing issues
- legal issues.

Dr Nemukongwe recommended that the attendees read the HPCSA ethical guidelines on social media.



The CPD meeting at Maphutha Malatji Hospital was well attended

Letters to the Editor

The *Letters to the Editor* page aims to give members the opportunity to comment on, query, complain or compliment on any matter, topic, incident, event or issue in their particular field or with regard to general healthcare, which you feel should be shared with your colleagues and fellow readers.

Please note that letters:

- should be no longer than 500 words
- can be published anonymously, but writer details must be submitted to the editor in confidence
- must be on subjects pertinent to healthcare delivery
- should be submitted before the 6th of the month in order to be published in the next issue of *SAMA Insider*.

Please email contributions to: Diane de Kock, dianed@samedical.org.





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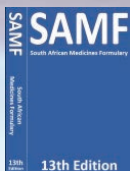
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