SAMA INSIDER
September 2017

New NHI White Paper unpacked

Deadline looms for medical-device companies to become licensed

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

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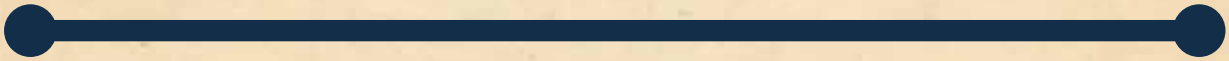

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EDITOR'S NOTE SEPTEMBER 2017

Diane de Kock
Editor: *SAMA INSIDER*

Women's Day in context

Women's Day in SA was commemorated on 9 August – a time to reflect on the status of women in our country. Statistics are not encouraging in most spheres: our rape statistics are still the worst in the world for a country not at war, rural women and children still live in poverty, children are still denied access to education, infant and maternal mortality is still far too high and women without money are still being denied access to healthcare.

In this issue of *SAMA Insider*, we feature two women: Tanya Voigt (page 13), executive officer of the SA Medical Devices Industry, a woman who has great influence in her field, and Dr Anastasia Rossouw, who recently won the 2017 Businesswomen's Association of SA Regional Achievers Award.

SAMA called on all South Africans to reflect on Women's Day, and used the opportunity to highlight the progress made in introducing more women into the field of medicine. "Educating women is of benefit to everyone in the country, on every level. As professionals, we therefore need to take on the responsibility of creating as many opportunities for girls to not only become educated, but to become part of the greater professional landscape in our county. In fact, it's more than our responsibility, it is our moral duty to do so," says SAMA chairperson, Dr Mzukisi Grootboom (page 10). Lowveld branch held a 2-day training session that was motivated by an increase in deaths due to women going for backstreet abortions (page 20).

An article (page 10) on a recent WHO announcement focuses on how the lack of investment in breastfeeding has failed babies and women worldwide. Hence the Global Breastfeeding Collective are calling for action, and highlight the fact that breastfeeding is critical for the achievement of many sustainable development goals.

There is still an almost overwhelming need to empower women in SA, in all spheres – in education, healthcare and the workplace.

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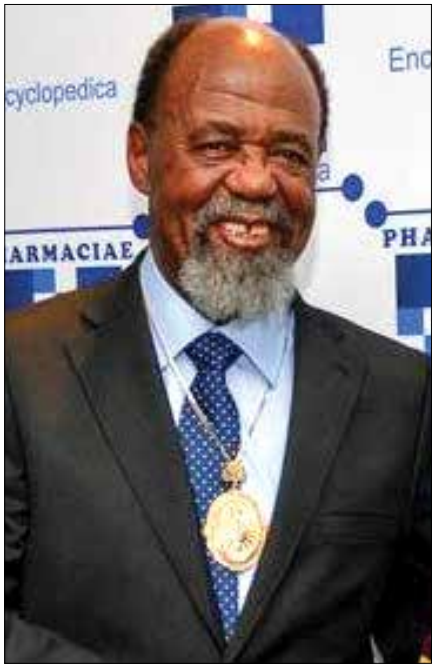
Tim Noakes ''trial'': What was all the kerfuffle about?



Prof. Dan Ncayiyana, *SAMA president*

The recent spectacle of the hearing, conducted much like a judicial trial, against Prof. Tim Noakes by the HPCSA will go down in history as the world's first prosecution of a medical practitioner for giving advice on social or any other kind of public media.

Giving medical advice in the media is an ancient practice that predates the epoch of the internet. According to Wikipedia, "An advice column is a column traditionally presented in a magazine or newspaper, though it can also be delivered through other news media, such as the internet and broadcast news media. The advice column format is question and answer: a (usually anonymous) reader writes to the media outlet with a problem in the form of a question, and the media outlet provides an answer or response." I can recall a time well before the internet when SABC radio had a medical-advice programme in which the doctor was identified only by their first name, such as "Dr John".

Today, medical-advice outlets are ubiquitous all across the globe via both print and electronic media. In the USA, TV personality Dr Oz (who is also a professor of cardiothoracic surgery at Columbia University) probably personifies the genre. It is said of him that "No subject is off-limits, as Dr Oz addresses viewers' questions … about any and all topics, from sex to diet and exercise to diseases and ways to avoid them." Although he apparently continues to teach and practice medicine, his TV show is the main source of his enormous wealth. However, he has also been described (quite rightly) by Wikipedia as a pseudoscience promoter who "has been criticised by physicians, government officials and publications, including *Popular Science* and *The New Yorker*, for giving non-scientific advice". But it has never been suggested that Dr Oz has a doctor-patient relationship with his viewers, nor has such a relationship ever been purported to exist in relation to any other medical media advisers on platforms such as Twitter, Facebook, TV or radio.

Enter Prof. Tim Noakes. To be clear: Prof. Noakes is no Dr Oz. He is an internationally distinguished scholar, and one of the highest-rated NRF scientists, whose research has, among other things, literally revolutionised fluid and nutrition management in marathon running. In 2004, *Runner's World* (USA) listed him among the 40 most important "persons or events" in the sport of running in the preceding 40 years (Noakes is himself a marathon and ultramarathon runner).

The Noakes saga began in February 2014, when a breastfeeding mother reached out to him on Twitter to seek nutritional advice, to which he tweeted back: "Baby doesn't eat the dairy and cauliflower. Just very healthy high fat breast milk. Key is to ween baby onto LCHF [low carb, high fat]" (that includes fish, eggs, poultry, meat and dairy products, along with a limited amount of carbs). This advice so horrified one dietician, Claire Strydom (then president of the Association for Dietetics in SA) that she proceeded to lay a complaint with the HPCSA, claiming that the advice was reckless, "especially dangerous" for infants and could "potentially be life-threatening". The HPCSA in turn moved to charge Prof. Noakes with "unprofessional conduct" (a charge usually invoked for cases of gross misconduct such as negligent iatrogenic death and injury) for providing "unconventional advice on a social network (tweet)". Theoretically, this case should be viewed with concern by hundreds of HPCSA-registered doctors who not only advocate, but openly practise self-confessed unconventional medicine as part of integrative medicine.

In the end, Prof. Noakes was acquitted of all charges.

What this article is not about

This article is not about the merits or otherwise of the LCHF eating formula. The present medical debate rightly belongs in medical journals and conference proceedings. Nor is it about casting aspersions on the HPCSA professionals who, I have no doubt, acted in good faith. Rather, this article is about the wisdom and appropriateness of the HPCSA consenting to get embroiled in what was, foreseeably, a scientific rather than an ethical dispute. Indeed, as the hearing progressed, it very quickly became clear that the inquiry had little or nothing to do with the tweet *per se*; nobody was, and no-one could have been hurt by the advice, as one expert witness for the HPCSA itself conceded, even assuming that giving advice on social media were an ethical infraction.

The hearing was largely perceived by the public media as a perverse "trial" of the newly emerged nutrition guru, and was described (perhaps hyperbolically) by one of Noakes' lawyers as "both a persecution and a prosecution" of Prof. Noakes for daring to challenge prevailing professional dogma that advocates high-carb-low-fat eating. Hearings are traditionally non-adversarial, but the fierceness with which the HPCSA pursued the case ("like a personal litigant with a win-at-all-costs agenda", as his lawyers charged) deviated from this tradition. The hearing on this single 21-word tweet lasted an incredible 3 years, at a cost of millions of rand, by some estimates.

The case raises many questions regarding the Constitutional protections of free speech and academic freedom. Noakes has every right to have his say. There seems little disagreement on the parallel between the exponential growth in recent decades in the consumption of carbs in the form of fast foods, processed foods and sugary beverages, and the alarming epidemic of type-2 diabetes. However, there is a growing and complex debate about the role of cholesterol in cardiovascular disease, and it is perfectly appropriate and even necessary that Noakes's perspectives are interrogated by his peers. But it is also important that scientific evidence that detracts from traditional dogma is not suppressed or vilified, especially by those whose careers and reputations are contingent upon it.

Indaba aims to equip doctors for the health of the nation

SAMA Communications Department

SAMA recently held its KwaZulu-Natal regional indaba at the Southern Sun Elangeni & Maharani Hotel in Durban. The theme of the indaba was "Equipping doctors for the health of the nation", and it was attended by a number of medical professionals in the province. The conference started on Friday 4 August, and ended on Saturday 5 August.

Among the morning presentations on Friday was an address on diabetic emergencies by Dr Freddy Kgongwana, the chief executive officer of the Dr George Mukhari Hospital in Gauteng. Dr Kgongwana explained the clinical presentation and management of hypoglycaemia, as well as the cost of management of the disease, especially in emergency situations.

Dr Kgongwana explained that education is key to preventing the emergencies that arise from the improper handling of diabetes, and urged medical professionals to try to familiarise themselves with local guidelines, in order to avoid risky prescriptions.

"The collaboration of hospitals, GPs, specialists, NGOs, schools, universities and colleges, ward-based outreach teams, community health workers and primary healthcare clinics is critical in sustaining the battle against non-communicable diseases (NCDs), in particular diabetes mellitus," he said. He also noted that SAMA remains a key champion in combatting NCDs.

Apart from this, Dr Kgongwana said the re-emergence of malnutrition in communities needs serious attention by stakeholders in healthcare, and that poverty and unemployment offer peculiar challenges for SA. He noted that "the need for intervention will always be there".

Other topics covered on the first day included a presentation by Dr Sarah Fakroodeen on the medical and ethical issues in palliative care, and a presentation by Dr M Naidoo on emergency skills for the generalist.

The Saturday session kicked off with a presentation by Dr Stanley Moloabi, the principal officer at Medshield Medical Scheme, on alternative re-imbursement in the private sector. He noted that change in the current model is needed, but stressed that a more holistic approach was necessary to improve the current fragmented way of working. He said this approach needed to include all health stakeholders, for the benefit of all South Africans.

A doctor's perspective, as well as SAMA's perspective on alternative reimbursement models, was also presented.

The conference concluded with presentations on remunerative work outside of the public sector, commuted overtime and a panel discussion on the medicolegal aspects of violence against women.

Attendees listening to an Indaba presentation

Attendees participating in the emergency skills for the generalist practical sessions

Dr Mzukwa presenting a token of appreciation to Dr Kgongwana after his insightful presentation

Cannabis for medicinal (and other) purposes in SA – where are we?

Shelley McGee, Bernard Mutsago, Dr Selaelo Mametja, Jolene Hattingh, *SAMA Knowledge Management and Research Department*

The decriminalisation of cannabis (or if you prefer, marijuana, dagga, spliff, pot and many other colourful names) has long been under debate internationally.

The merits of the plant, its products, multiple uses, genetic variations and, of course, effectiveness for the management of several clinical conditions and symptoms have a considerable history, and remain debated across the globe.

"Cannabis" is the scientific name for the hemp plant. The commonly cultivated forms of cannabis are members of the same species that can be distinguished by the relative yields of cannabinoids such as tetrahydrocannabinol (THC) and cannabidiol (CBD). Main varieties of cannabis include *Cannabis sativa*, *Cannabis indica* and *Cannabis ruderalis*.

The term "cannabinoid" describes any chemical constituent of cannabis that acts on the endocannabinoid system of the human body. These can be synthetic or derived directly from the cannabis plant. *Cannabis sativa* contains over 460 known compounds, of which 60 or more are cannabinoids. While THC is generally accepted to be the compound most responsible for the psychotropic effects of the cannabis plant, many other compounds, including CBD, are increasingly being researched for their clinical and medicinal uses and effects.

Evidence of cannabis use for food and oils dates back to 6 000 BCE in China, with the first evidence of medicinal use in China dating from 2 700 BCE. The plant spread from its origins across the globe over a period of several thousand years, and by the 1600s, reports written by SA colonialists described how native tribes used the plant for intoxication and ceremonial purposes.

Several regulatory developments targeted cannabis for criminalisation in the early 1900s, and it was finally completely criminalised in SA in 1928 by the Medical, Dental and Pharmacy Act (Act No. 13 of 1928).

Today, in terms of the Drugs and Drug Trafficking Act (Act No. 140 of 1992), the cultivation, possession, use, supply and dealing of cannabis is illegal in SA.

Recently, however, several legal developments have fundamentally shaken the current status of cannabis as an illegal substance in the country.

Other countries are also grappling with similar issues, and the World Medical Association (WMA) is currently considering its stance on cannabis use for medicinal purposes. SAMA had contributed substantially to this position, and formal adoption is anticipated at the WMA General Assembly in October 2017.

In short, this position is that there are some promising clinical indications for cannabis and the cannabinoids derived from the plant, but that more research is necessary in most cases before cannabis would be recommended ahead of other well-investigated products. Much of the evidence available for the many purported uses of cannabis remains weak and inconsistent, although with global developments facilitating well-designed research, this can be expected to improve. The WMA remains opposed to the legalisation of cannabis for recreational use.

Recent SA developments

In December 2016, SAMA issued a press release on issues of cannabis for medical use, after the announcement by the Parliament Portfolio Committee on Health in November that the Department of Health (DoH) would soon regulate access to medical cannabis for prescribed health conditions. This was the result of the highly publicised "Medical Innovation Bill" proposed in 2014 by the late Inkatha Freedom Party MP, Mario Oriani-Ambrosini, in the form of a private member's bill.

SAMA welcomed the proposed new regulatory framework to be availed by the DoH in early 2017.

Subsequently, in March 2017, the SA Medicines Control Council (MCC) published the first guideline relating to the cultivation and production of cannabis products for medicinal purposes. This guideline, while proposing to change the scheduling status of cannabis products from schedule 7 to schedule 6, also called for significant control over all the aspects of cannabis-product production, including strict licensing criteria for manufacturers and sellers, strict growing conditions and testing for the raw material plant and strict control over the supply chain for the commodity.

SAMA remains opposed to the legalisation of cannabis for recreational purposes, in line with the WMA position

In the interests of scientific integrity and patient safety, SAMA contributed comments to this guideline, to contribute to the evidence informing the principles applied.

In yet another landmark development, the Western Cape High Court ruled in a case on 31 March 2017 that laws that prohibit the cultivation and use of cannabis in the home for personal use violate the Constitution of SA.

In the wake of these announcements, SAMA has become aware of doctors receiving advertisements for medicinal cannabis products, under the mistaken impression that these are now legal.

For now, cannabis remains illegal in SA for both medicinal and recreational purposes, despite some degrees of clinical efficacy reported internationally for certain health conditions and legalisation of cannabis in other countries. Anyone in possession of or selling cannabis or cannabis derivatives can still be charged in accordance with the Drug and Drug Trafficking Act (Act No. 140 of 1992).

SAMA remains opposed to the legalisation of cannabis for recreational purposes, in line with the WMA position.

While there are clear indications of intention for the regulation of the prescription,

sale, cultivation and production of cannabis-containing products for medicinal purposes, the MCC has yet to implement the necessary legislation to make medical prescribing of cannabis legal, and to approve products derived from *Cannabis sativa*.

In July 2017, the MCC added CBD to schedule 6 – meaning that the compound can now be registered for manufacturing and sale in SA, and supplied to patients on a doctor's prescription. However, this rescheduling still needs to be signed off by the Minister of Health and formalised by publication in the government gazette. There are not yet any CBD-containing products registered with the MCC.

Cannabis and parts of the plant remain in schedule 7. It remains illegal to cultivate, analyse, research, possess, use, sell or supply any of the schedule 7 classified agents without express permission and a permit issued by the DoH. Importation and exportation of such substances is also not allowed without a permit.

In addition, the ruling of the Western Cape High Court on home use has yet to be ratified by the Constitutional Court, and should this happen, the necessary regulatory changes will have to be effected through parliamentary processes, in order to fully decriminalise cannabis. Until such time as this is done, individuals apprehended with cannabis and cannabis-derived products can still be arrested and charged – although it seems likely that prosecution procedures might be lenient, given all the confusion in the marketplace.

There are no legally registered medicinal cannabis products yet. SAMA urges its members not to prescribe or supply any cannabis and cannabis-derived products currently available in the local market, as the products have not undergone MCC approval processes, and the origins and composition of, and quality control over, these products cannot be guaranteed.

Until the legalities have been fully addressed, and the necessary processes completed to ensure prescribing of safe, good-quality commercial product for patients where clinical evidence is strong for the indication, doctors are advised to use the section 21 provision of the Medicine and Related Substances Act (Act No. 101 of 1965) to obtain the products registered by other jurisdictions.

References available on request

New NHI White Paper unpacked

Bernard Mutsago, *SAMA health policy researcher*

The long-awaited White Paper on the National Health Insurance (NHI) was finally approved by Cabinet on 21 June 2017, and officially released by the Minister of Health, Dr Aaron Motsoaledi, on 29 June 2017. SAMA had earlier made its official submission in 2016, and in the interim held a number of consultative meetings with the Department of Health (DoH).

Overall, the White Paper reflects an improvement on the previous version, by way of added details, resulting from engagement of stakeholder inputs, achievements of different work streams, emergent developments in the course of health system re-engineering and lessons from the NHI piloting exercise. SAMA is appreciative of the DoH for encouraging active involvement of stakeholders in the shaping of the policy for a better healthcare system. Indeed, some of the inputs made by SAMA were considered, although some grey areas still remain. SAMA appreciates the following:

- As in the previous White Paper version, primary healthcare and disease prevention remain central features of the NHI, and the principles of a responsive and people-centred health system are reinforced.
- Markedly, the White Paper introduces pronounced recognition of the social determinants of health as key contributors to poor health in SA, and the need for a multisectoral approach to address them. This is a welcome acknowledgement.

SAMA urges its doctors – individually and as part of SAMA structures – to meticulously examine the contents of the White Paper

While the White Paper is not released for public comment *per se*, SAMA is still further perusing it to gain a detailed understanding of all specifics therein. In the meantime, SAMA urges its doctors – individually and as part of SAMA structures – to meticulously examine the contents of the White Paper, considering that any suggested changes will be difficult to submit once NHI law is in place. Also, the Director General (DG) of the DoH has pledged to hold high-level follow-up meetings with all health professional groups, aimed at soliciting views on the current contents; these follow-up engagements will thrash out the specific details. Extra implementation details will be provided in the NHI Implementation Plan that the DG indicated will accompany the White Paper.

In the aftermath of the release of the White Paper, there have been wide-ranging media comments and public reaction to some of its general propositions, ranging from outdated (2010) projection statistics to the questionable national affordability of implementing NHI.

However, there are aspects of greater relevance to the medical profession. In reviewing the new White Paper content, SAMA urges its doctors to take note of the following doctor-specific salient features, some of them new, emerging:

- Of concern to SAMA is that, contrary to SAMA's earlier suggestion, the DoH is proceeding with NHI based on lessons from the concluded piloting exercise, yet the pilot did not cover all key NHI aspects, and specifically did not pilot private providers.
- "The "contracting" of private providers has strongly been particularised as "contracting in", a model which SAMA rejects. "Contracting out" is contemplated within specific bounds in the White Paper, which states that "contracting out of PHC [primary healthcare] services will require that multidisciplinary practices should be configured into horizontal networks that are contracted through the Contracting Unit for PHC (CUPs)."

- With regard to the reimbursement of contracted providers, at PHC level there will be a performance-based risk-adjusted capitation system, while at hospital level a system of case-mix activity-adjusted payments will be used, such as diagnosis-related groups. Emergency medical services will be reimbursed for using capped case-based fees, with adjustments for case severity. Fee-for-service will be abolished and care will be free at point of use.

The following interim committees and governing bodies will be established to focus on the different aspects of NHI:

- Tertiary Health Services Technical Implementation Committee
- National Governing Body on Training and Development
- National Health Pricing Advisory Committee
- Ministerial Advisory Committee on Health Care Benefits for National Health Insurance (precursor to the NHI Benefits Advisory Committee)
- National Advisory Committee on Consolidation of Financing Arrangements
- Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance
- National Health Commission.

Gazetted details of the above interim structures can be found at the following link: http://www.gov.za/sites/www.gov.za/files/40969_gon660.pdf. The DoH invites comment on these proposed structures. A notice inviting participants to join the above committees will be issued around mid-July.

- The District Clinical Specialist Teams will still be implemented, with a new possibility of introducing an additional cadre – the public-health-medicine specialist.
- The medical-scheme industry will be restructured. The industry will mainly provide "complimentary services". Medical schemes must consolidate their benefit options to end up with only one option per scheme. This will be streamlined with the imminent amendment of the Medical Schemes Act.
- NHI implementation will require massive overhaul of legislation, including changes to the Medical Schemes Act, the National Health Act, the Health Professions Act, the Allied Health Professions Act, the Nursing Act and Provincial Health Act, among others.
- The new White Paper does not talk of a benefit "package". The term has been changed to "service benefits", and some such benefits are suggested, with a disclaimer that this is not an exhaustive list. Details of the benefits will be worked out by the above-mentioned Ministerial Advisory Committee on Health Care Benefits for NHI.

All SAMA doctors and structures, such as branches, are urged to spare some time to consider and deliberate on the content of the White Paper, especially the above-highlighted important issues. Doctors are also urged to keep abreast of developments, and to take part in the aforementioned NHI structures and committees. At an NHI meeting between COSATU and the DoH held on 21 July in Pretoria, which SAMA attended as a COSATU affiliate, it was agreed, at COSATU's request, that a series of provincial workshops targeting organised labour will be held soon, where the Minister of Health will make presentations on the White Paper, followed by discussion.

The SAMA head office will keep you updated on the outcomes of further engagements with the DoH on NHI.

More details and documents on NHI are available on the NHI website: http://www.nhisa.co.za/
For further information on NHI please contact: Selaelo Mametja: selaelom@samedical.org; telephone: 0124812004 /2037, or Bernard Mugatso: bernardm@samedical.org; telephone: 0124812018.

Snakebite now a priority neglected tropical disease

SAMA Communications Department

A recent article in *Medical Brief* reports on a decision by the WHO, which public health activists are calling both landmark and long overdue. "The WHO has placed snakebite envenoming on its list of top 20 priority neglected tropical diseases – giving it the highest possible ranking for diseases of its kind," states the article. *Stat News* reports that the move could spur new efforts in the decades-long battle to limit the global toll of snakebite, which kills more than 100 000 each year and maims and cripples millions more.

"Neglected tropical diseases often affect mostly poor populations, especially people who live with poor sanitation and in close proximity to animals and insects that can spread disease. The WHO's list includes Chagas disease, rabies, leprosy – and now snakebite."

A WHO report says that activists who work on preventing snakebite and creating new antivenoms have criticised the WHO for not making snakebite more of a priority in recent years, even though the death toll from snakes has remained high. Some pharmaceutical companies have withdrawn from the antivenom market because they have found it hard to turn a profit.

"Concerted action is long overdue and exactly what snakebite victims, their families and their communities need and deserve," said Tim Reed, executive director of Health Action International (HAI), a non-governmental organisation that works at the intersection of pharmaceutical policy and public health.

The decision comes after more than a year of lobbying by HAII. The group worked with the government of Costa Rica, a leader in both snakebite prevention efforts and the creation of next-generation antivenoms, and the Australian non-profit Global Snakebite Initiative (GSI), which worked to get official recognition of the huge toll of snakebite in developing countries.

The report says the groups hope WHO action will assist numerous efforts, including a global plan being launched by HAI to train workers in sub-Saharan Africa to collect data on snakebite deaths and to educate local populations about snakebite prevention and treatment.

"The development of a WHO-led global strategy for snakebite intervention is the first step in tackling snakebite, which, until now, has been grossly neglected by the global health community," says David Williams, the herpetologist and toxinologist who serves as executive director for the GSI.

The importance of ownership structure and indemnity forms to a medical practice

Shanné de Klerk, *attorney at Jurgens Bekker Attorneys,* **James Vigne,** *independent financial advisor at Vernon Cloete Broker Services*

Whether you're starting your own practice or converting to a different legal entity, there are requirements and effects that need to be considered when deciding what entity to form.

The Companies Act (Act No. 71 of 2008) specifies the types of business structures recognised in SA. We briefly discuss their advantages and disadvantages.

A *sole proprietorship* is a business owned and run by one individual. There is no agreement to regulate how the business is managed, and the owner contracts in his personal capacity. The owner owns all the assets and is liable for all the debts of the business. The business is not a separate entity, and will cease to exist when the owner dies.

A *partnership* is a relationship based on an agreement between two or more persons, limited to 20 individuals, who each undertake to make a contribution, with the object of making a profit and sharing it. A partnership is not a separate legal entity, and partners are jointly liable for debts incurred on behalf of the partnership.

A *private company* has limited liability and is a separate legal entity from its shareholders, the owners of the business, and its directors, who manage the company. It can sue and be sued, and is liable for its own debt. It is subject to tax implications and is regulated by a shareholders' agreement entered into between the shareholders, and is limited to a maximum of 50 shareholders.

The main differences between a private and a public company are that a public company is established to sell shares to the general public, and can have unlimited shareholders.

Only practitioners registered with the HPCSA can own shares or be partners or associates in either the form of a sole proprietorship, partnership, private company or incorporation for a private practice. The HPCSA regulates the formation of the entity, and it is important for medical practitioners intending to form a private practice or change their current practice structure to familiarise themselves with the regulations set out by the HPCSA.

Part-owners in a practice must ensure they have an agreement in place that deals with the purchasing and sale of shares in the event of the death of a part-owner. This can be funded by specialised life-insurance policies on the lives of the owners, which allow the remaining owner/s to purchase the deceased owner's shares from the estate.

This agreement is important, as it allows the business to conclude the sale transaction quickly and continue operating, and limits interference from outsiders. Also, if funded with specialised life-insurance policies, you limit the "drain" on the cash flow of the business.

There is also a benefit for the estate/heirs of the deceased in that, instead of inheriting interests in a practice, they inherit liquid assets in the form of a cash lump-sum. This may make sense for most doctors in private practice, as only certain persons may own shares in a medical practice.

There are tax implications to consider, including income tax, capital-gains tax and estate duty. Certain exemptions from tax are possible if the agreement is structured in a specific manner.

This agreement is crucial, and should be set up as soon as possible. Consult a financial advisor or attorney to discuss your practice's specific circumstances.

Patients are often required to sign indemnity forms when consulting with a doctor that contain exclusionary clauses that are used by practitioners to protect them against liability, which may arise from, e.g. the doctor's negligence, and which cause a patient harm or loss. Indemnity clauses range from excluding liability if any personal injury occurs while on their premises, or if a car is damaged or stolen while on their premises.

Doctors have certain duties, ethics and moral obligations to the public, including confidentiality, treating a patient with dignity and respect, and acting in their best interest. Most indemnity clauses indemnify the doctor from liability that may arise as a result of his/her negligence that caused harm or damages, which could lead to civil action against the doctor. Since the implementation of the Consumer Protection Act (CPA, Act No. 68 of 2008), indemnity clauses, in most circumstances, have been rendered invalid and unenforceable.

From left: James Vigne (independent broker, Vernon Cloete Broker Services), Jeanette Snyman (SAMA senior marketing officer) and Jurgens Bekker (attorney, Jurgens Bekker Attorneys)

The CPA not only precludes a supplier from making a transaction or agreement subject to any term or condition if it, directly or indirectly, purports to: waive or deprive a consumer of a right in terms of the CPA; avoid a supplier's obligation or duty; authorise the supplier to do anything unlawful or fail to do anything that is required, but it also provides that when a supplier undertakes to perform services for or on behalf of a consumer, the consumer has a right to the performance of the services in a manner and quality that persons are generally entitled to expect.

Indemnity forms are an attempt by suppliers to avoid their obligations under the CPA, and therefore indemnity clauses deprive a patient of his rights under the CPA. This would render the indemnity form unreasonable, unjust and unfair, and it could therefore not be enforced by either party.

It is important to consider the context of the indemnity form, and whether it is consistent with public policy, to ascertain whether it will be valid and enforceable.

The law is complex, and every practice is distinctive. Circumstances differ, and therefore we advise any person wanting to start their own practice to consult an attorney and a financial advisor prior to commencing business, to familiarise themselves with the laws that regulate the Republic of SA.

Empowering girls is more than a responsibility; it's a moral duty – SAMA

SAMA Communications Department

SAMA has called on all South Africans to pause and reflect on the significance of Women's Day for SA, which was commemorated on 9 August. It also used the opportunity of Women's Day to highlight the progress made in introducing more women into the field of medicine.

"More girls than ever are joining the ranks of medical professionals, and are healthcare workers in all sectors. This is a pleasing development in our country, and we urge all other professions to do the same to empower young girls. The message we must spread is that girls are capable of doing anything they want; we are all obliged to create an enabling environment for them to achieve their dreams," said Dr Mzukisi Grootboom, chairperson of SAMA.

In addition, Dr Grootboom said that the education of women is vital to deal with the social problems in SA. Data from numerous studies show that education is a driving force in improving the lives of all people, but especially those of women and their children. This was again made clear in a lecture delivered by the internationally acclaimed authority on health inequalities, Sir Michael Marmot, on a recent visit to SA.

In his presentation, Sir Michael noted that infant mortality rates, for instance, decrease exponentially as a mother's education increases. Education, he said, also plays a pivotal role in the fertility rates of women (i.e. the number of births per woman), with women bearing fewer children the more educated they are.

Sir Michael says that in Ethiopia, for example, the fertility rate for women with no education is 6.1 births, but drops to 5.1 in women with primary education. This number drops markedly to 2.0 in women with secondary or higher educations. The picture is similar in Nigeria, where the fertility rate is 7.3 for women with no education, but 4.2 for women with secondary or higher educations.

"Educating women is of benefit to everyone in the country, on every level. As professionals, we therefore need to take on the responsibility of creating as many opportunities for girls to not only become educated, but to become part of the greater professional landscape in our country. In fact, it's more than our responsibility, it is our moral duty to do so," said Dr Grootboom.

He added that empowering girl children has positive effects in other areas too. He says statistics show that the number of women who agree that a husband can beat his wife for refusing to have sex with him drops dramatically the more educated the women are.

"This is but one of many examples which prove [that] educating women is vital to improving the social fabric of society. But we cannot simply pay lip service to this notion of uplifting and educating women every August; it is something we need to strive for every day of every year. And we need everyone in society to pull in the same direction, because only then will we make significant changes," Dr Grootboom concluded.

Worldwide lack of investment in breastfeeding

World Health Organization

No country in the world fully meets the recommended standards for breastfeeding, according to a new report by UNICEF and the WHO, in collaboration with the Global Breastfeeding Collective, a new initiative to increase global breastfeeding rates.

The *Global Breastfeeding Scorecard*, which evaluated 194 nations, found that only 40% of children younger than 6 months are breastfed exclusively (given nothing but breastmilk) and only 23 countries have exclusive breastfeeding rates above 60%.

Evidence shows that breastfeeding has cognitive and health benefits for both infants and their mothers. It is especially critical during the first 6 months of life, helping to prevent diarrhoea and pneumonia, two major causes of death in infants. Mothers who breastfeed have a reduced risk of ovarian and breast cancer, two leading causes of death among women.

"Breastfeeding gives babies the best possible start in life," said Dr Tedros Adhanom Ghebreyesus, Director-General of the WHO. "Breastmilk works like a baby's first vaccine, protecting infants from potentially deadly diseases and giving them all the nourishment they need to survive and thrive."

The scorecard was released at the start of World Breastfeeding Week, alongside a new analysis demonstrating that an annual investment of only USD4.70 per newborn is required to increase the global rate of exclusive breastfeeding among children under 6 months to 50% by 2025.

The report – *Nurturing the Health and Wealth of Nations: The Investment Case for Breastfeeding* – suggests that meeting this target could save the lives of 520 000 children under the age of five, and potentially generate USD300 billion in economic gains over 10 years, as a result of reduced illness and healthcare costs and increased productivity.

"Breastfeeding is one of the most effective – and cost-effective – investments nations can make in the health of their youngest members, and the future health of their economies and societies," said UNICEF executive director Anthony Lake. "By failing to invest in breastfeeding, we are failing mothers and their babies – and paying a double price: in lost lives and in lost opportunity."

The investment case shows that in five of the world's largest emerging economies – China, India, Indonesia, Mexico and Nigeria – the lack of investment in breastfeeding results in an estimated 236 000 child deaths

per year, and USD119 billion in economic losses.

Globally, investment in breastfeeding is far too low. Each year, governments in lower- and middle-income countries spend approximately USD250 million on breastfeeding promotion, while donors provide only an additional USD85 million.

The Global Breastfeeding Collective is calling on countries to:

- increase funding to raise breastfeeding rates from birth through 2 years
- fully implement the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions through strong legal measures that are enforced and independently monitored by organisations free from conflicts of interest
- enact paid family leave and workplace breastfeeding policies, building on the International Labour Organisation's maternity protection guidelines as a minimum requirement, including provisions for the informal sector
- implement the *Ten Steps to Successful Breastfeeding* in maternity facilities, including providing breastmilk for sick and vulnerable newborns
- improve access to skilled breastfeeding counselling, as part of comprehensive breastfeeding policies and programmes in health facilities
- strengthen links between health facilities and communities, and encourage community networks that protect, promote and support breastfeeding
- strengthen monitoring systems that track the progress of policies, programmes and funding towards achieving both national and global breastfeeding targets.

Breastfeeding is critical for the achievement of many of the sustainable development goals. It improves nutrition, prevents child mortality and decreases the risk of non-communicable diseases, and supports cognitive development and education. Breastfeeding is also an enabler in ending poverty, promoting economic growth and reducing inequalities.

About the Global Breastfeeding Scorecard

The scorecard compiles data from countries all over the world on the status of seven priorities set by the Global Breastfeeding Collective to increase the rate of breastfeeding.

The 23 countries that have achieved exclusive breastfeeding rates above 60% are: Bolivia, Burundi, Cabo Verde, Cambodia, Democratic People's Republic of Korea, Eritrea, Kenya, Kiribati, Lesotho, Malawi, Micronesia, Federated States of Nauru, Nepal, Peru, Rwanda, São Tome and Principe, Solomon Islands, Sri Lanka, Swaziland, Timor-Leste, Uganda, Vanuatu and Zambia.

SAMA bursaries and scholarships

Karlien Pienaar, *Governance and Legal Unit, SAMA*

SAMA offers the following bursaries and scholarships. More information, as well as the relevant application forms for the bursaries and the supplementary scholarships, may be obtained from the SAMA website (www.samedical.org), or from the bursary officer, Mrs K Pienaar, on karlienp@samedical.org.

SAMA medical education bursary

The SAMA medical education bursary is intended to support SA citizens who live in SA and attend medical school here. The bursaries are to fund study in the medical field, i.e. pre-graduate studies towards an MB ChB or equivalent degree. The bursaries, in the amount of ZAR20 000 per annum per student, will be offered from the first to the fourth year of studies, and will be paid into the students' accounts at the various universities, as they are specifically intended to assist with the tuition fee. Second- and third-year students are encouraged to apply between 1 August and 30 September this year. No applications from first-year students will be accepted, and they are advised to ensure that they register timeously with the university/ies of their choice. We will contact the universities early in 2018 to obtain names of first-year students who have been accepted and registered.

SAMA PhD supplementary scholarship

This award is intended to encourage postgraduate research in the medical field, specifically with a view to promoting research and development in medicine for medical doctors in SA. The candidate must be a SA citizen and a graduate of any university in SA, doing their PhD at a SA university. The PhD study must have been started **one year prior to applying** for this supplementary scholarship, as the committee members will be taking into account the progress which has been made in the first year. The value of the supplementary scholarship is ZAR100 000 per annum, plus the relevant year's tuition fee. The academic quality of the research proposal, as well as the suitability of the project for SA's research programme, is at the top of the list of selection criteria. Applications will be received between 1 August and 30 September, strictly.

SAMA research master's supplementary scholarship

The purpose of this award is to encourage postgraduate research and foster the development of research competencies in medical practitioners, to promote academic medicine in SA. The research master's may serve as a prerequisite for doctoral studies. This award will not be granted for a professional master's degree, such as the Master's in Medicine, taken as a requirement for specialist training. The candidate must be a SA citizen and a medical graduate of any university in SA who has started their research master's study **one year prior to applying** for this award. The amount of ZAR50 000 will be awarded to the successful candidate in equal parts over 2 years. The main selection criteria are the academic quality of the research proposal and the suitability of the project to the SA environment. Applications will be received between 1 August and 30 September, strictly.

SAMA and MedSci conduct a corporate wellness programme

Bokang Motlhaga, *junior marketing officer*

On 4 and 5 July, SAMA, in collaboration with MedSci, conducted a corporate wellness programme, whereby the SAMA staff had various tests of their body composition run for a maximum period of 5 minutes for each participant. The programme was conducted at the SAMA head office.

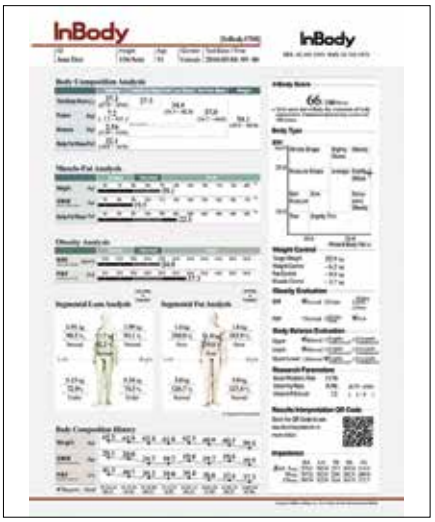
MedSci drove this initiative through the use of highly efficient technology: the BSM370, an automatic portable stadiometer, and the InBody370, a convenient and accurate body-composition analyser. Through the use of these two devices, the participants ended up with a hardcopy providing an informative analysis of their overall body composition.

The MedSci representatives explained the outcomes of each individual's analysis to him or her. The information is represented in a user-friendly manner such that the print feedback reveals the contrast between an individual's score for a specific test, and the value that is perceived to be normal for humans.

The Inbody feedback not only analyses the participant's body composition, but also provides advice pertaining to what improvements the participant needs to implement in order to pursue a healthy lifestyle.

SAMA employees doing the Inbody test

Inbody 370



An example of the Inbody test feedback

New HPCSA CPD guidelines

SAMA Communications Department

In July, the HPCSA published an update on continuous professional development (CPD) guidelines.

According to the HPCSA, the ethical practice of the health professions requires consistent and ongoing commitment to lifelong learning by all health practitioners, through the process of CPD. This assists health professionals to update and develop the knowledge, skills and ethical attitudes that underpin competent practice.

Health professionals can acquire continuing education units (CEUs) through traditional learning experiences, such as attendance of conference presentations and workshops, and through structured courses and quality-assurance audits of practices of groups of professionals in their work environments.

Although no major changes have been made in the recent update, SAMA advises members to note some adjustments that have been made.

One of the more important changes to the guidelines is that anyone hosting a learning activity who would like accreditation for it must now apply for such accreditation at least 10 days prior to the activity taking place. This is in line with the HPCSA CPD guidelines, which stipulate that no retrospective applications for accreditation will be approved.

Other adjustments to the guidelines include that attendance at workshops, lectures and seminars on ethics will now accrue one point per hour, as opposed to the two points per hour in previous guidelines.

In addition, presenters at workshops or conferences will now been approved under level 1 activities instead of level 2.

Lastly, the content of multiple-choice questions can be either clinical or ethical in a peer-reviewed/non-peer-reviewed journal, or stand-alone activities (for example, a newsletter or content provider with multiple choice questions). CEUs may be granted with a maximum of three points per questionnaire, regardless of whether the content is clinical or ethical.

For more information on CEUs and CPD, please contact Lisa Reid at lisar@samedical.org or on 012 481 2082.

Deadline looms for medical-device companies to become licensed

SAMA Communications Department

In February, the government published a notice giving companies until 24 August to make applications for licences to manufacture, export, import and distribute medical devices and *in vitro* diagnostic devices (IVDs). Wholesalers have until February 2018 to apply for their licence.

According to the SA Medical Technology Industry Association (SAMED), regulations on medical devices and IVDs were published in December 2016.

"These regulations called for a licence, and in February 2017 a published government gazette gave the August deadline. They also referred to a second call-up for products, but this has not yet been published," explains Tanya Vogt, executive officer of SAMED.

Healthcare professionals manufacturing or importing medical devices, and on-selling them to their patients, may well now be defined as either "manufacturers" or "distributors", who would have to apply for a licence and comply with the requirements of the regulations.

The licence fees that apply, as stipulated under "Fees Payable" in terms of the provisions of the Medicines and Related Substances Act (Act No. 101 of 1965), are: manufacturing, ZAR21 800; distribution, ZAR13 000; and wholesale, ZAR13 000.

It is now illegal to reuse a single-use device, something SAMED has advocated for many years

Vogt says that as part of the licence application process, companies must classify their products according to four risk categories: low (Class A), moderate (Class B), moderate-high (Class C) and high (Class D). Risk is calculated in terms of risk to the patient, the user, or to public health.

In addition, companies must start putting in place a quality management system (QMS). The current thinking is that SA ISO 13485: 2016 will be the applicable standard. But although companies can prepare themselves for this, they cannot yet be accredited to ISO 13485: 2016.

"By the end of this year, companies without a licence to sell medical devices will be conducting their business unlawfully in SA"

"The SA National Accreditation System (SANAS) must first audit the conformity-assessment bodies (CABs), who, in turn, must then accredit device companies to the ISO standard. That process hasn't started, although SANAS has set up a working group and has advertised for technical experts who will be trained up as auditors," says Vogt.

The implementation, and indeed, the impact, of the new medical device regulations will therefore be phased in: first, establishment licensing, then product registration, then SANAS must be made ready to accredit CABs – all while companies are investigating putting QMSes in place.

It must also be noted that in June the legislation was passed that allows for the establishment of the SA Health Products Regulatory Agency (SAHPRA). SAHPRA will encompass regulating both medical devices and medicines.

To facilitate the regulatory process, the regulator has held several workshops with industry. SAMED suggested workshops also be held for procurers and users of medical devices and IVDs, as they too, stand to be impacted. As with any new regulation or piece of legislation, there are potentially many interpretations, and there is a need for clarity.

Apart from the licensing requirements, the regulations also state that "a user who

Tanya Vogt is the executive officer of the SA Medical Devices Industry Association (SAMED), a position she has held since January 2007. SAMED represents the interests of more than 160 medical device, medical equipment and *in vitro* diagnostics (IVD) companies in SA.

Tanya sits on the Nappi Advisory Board, which is responsible for making policies that promote codes for reimbursement purposes for ethical, surgical and consumable products. She is also a member of the Industry Task Group, a grouping of pharma, veterinary and medical-device industry representatives who engage with the SA Medicines Control Council on regulatory matters.

In addition, Tanya sits on the steering committee of the Strategic Health Innovation Partnership, an innovative product-development programme within the SA MRC. This group has the goal of developing new or improved diagnostics, vaccines, prevention strategies and treatments to address SA's major health problems.

Internationally, Tanya is the SA medical-devices industry's main representative on the Asian Harmonisation Working Party, a non-profit organisation facilitating harmonisation of medical device regulations in the Asia Pacific region. She is also a board member of the Global Medical Technology Alliance (GMTA). GMTA members are national or regional medical technology associations from around the globe.

becomes aware of an adverse event caused by a medical device must report the event either to the licensee or the Council".

Furthermore, "A permanent record in respect of certain classes of implantable medical device(s) and a high-risk custom-made medical device must be kept on the premises by the healthcare institution or healthcare professional where the medical devices are sold to the patient, and must contain, [among] others, name and product code of the device, date on which the order for the device was raised, patient name, address and identity number, name and address of the health establishment, name of the manufacturer, etc."

Also notable is the definition of "single use" – "one use of a medical device on an individual or IVD on a sample, during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again". This would mean that it is now illegal to reuse a single-use device, something SAMED has advocated for many years, due to safety and infection-control concerns surrounding the reuse of single use medical devices.

According to Vogt, the regulatory process is a learning curve for both industry and the regulator. She says that it's essential both work closely together, stressing SAMED as a partner, and emphasising the platform it provides for industry engagement with the regulator. "I believe the regulatory changes are absolutely necessary, but we can't underestimate the impact these are having on the industry, especially given the costs."

She adds that SAMED is hoping the product registration fees won't be a "deterrent", and that, with SAHPRA, processes around decision-making will be efficient, with quick turnaround times.

"By the end of this year, companies without a licence to sell medical devices will be conducting their business unlawfully in SA. But the detail is in the implementation," says Vogt.

"Our industry welcomes the additional support from the regulator to help us gear up for, and abide by, the regulations. We require additional workshops and guidelines, and welcome more opportunities to engage with the regulator to give input on regulations and guidelines prior to their finalisation," Vogt concludes.

Dr Anastasia Rossouw wins regional achiever's award

SAMA Communications Department

Dr Anastasia Rossouw, the vice-chair of SAMA Border Coastal branch, has won the 2017 Businesswomen's Association (BWA) of SA Regional Business Achievers Award.

The BWA is a platform that inspires and empowers women by building strategic relationships with leading experts in a particular field, and through various networking opportunities. It also facilitates personal development through a mentorship programme and a bursary programme, while providing a platform for promoting one's business through various entrepreneurial workshops.

Each year, the association celebrates the contribution made by and the achievements of women, across various categories. Dr Rossouw won in the Women in Government category, celebrating the contribution she has made, and the achievements she has attained, in improving healthcare services in the Eastern Cape.

"Winning the award means a lot to me and my team, and I am extremely humbled to be honoured in this way," says Dr Rossouw.

Currently, Dr Rossouw is a specialist neurologist at Frere Hospital, in the Eastern Cape. She says the investment in the establishment of neurological services at the hospital over the past 3 years has yielded the desired results.

Dr Rossouw and her husband Mario Adonis

Kidney health – vital for life

Fanie du Toit, *National Kidney Foundation of SA*

According to some of the latest available statistics, a startling 15% of the world's population suffers from some form of kidney disease. In SA, kidney failure is mainly the result of inherited hypertension and type-2 diabetes, while the figures for HIV-related kidney disease are the highest in the world. The National Kidney Foundation of SA (NKFSA) believes that if both hypertension and diabetes can be detected early, and then treated effectively, up to 70 - 80% of chronic kidney-failure incidence in the country could be prevented. Unfortunately, the incidence of undiagnosed health issues is still very high, and often the kidneys are affected without the individual being aware that they are ill. Presentation of the illness often occurs very late, and only when the kidneys completely fail. This kidney failure would then mean that the affected person would be in need of dialysis or a kidney transplant. Dialysis in SA is, however, expensive, and therefore extremely limited in the public sector, and doctors are often faced with the very difficult task of having to tell patients that there is no dialysis treatment available. This underpins the vitally important aspect of prevention.

One of the important focus areas of the NKFSA in the prevention of kidney disease is awareness about kidney disorders.

To understand the importance of kidney health, it's essential that we remind ourselves of just what it is that the kidneys do for our bodies. On a daily basis, they filter about 150 - 180 L of fluid, but keep back and reabsorb useful substances such as water and minerals, and only excrete an average of 2 L of waste in the form of urine. More specifically, the kidneys excrete drugs, medicines and poisons; provide nutrients to take care of bones and joints; control the pH balance of the body; and produce chemicals that help to control blood pressure, and chemicals that are used to produce red blood cells (that carry oxygen throughout the body). The kidneys also process chemicals and hormones that the body no longer needs.

This in short means that together with the liver, which performs some similar "cleansing" functions, the body relies on the kidneys for its overall health. So, it stands to reason that kidneys not working optimally would have a devastating effect on the body, with the following occurring:

- swelling of the body
- shortness of breath
- weakness
- poor appetite
- aches and pains
- insomnia
- impairment of thought processes
- headaches
- high blood pressure.

Basically, the body and mind can become poisoned from the kidneys not being able to perform their filtering and cleansing duties.

Aside from hypertension- and diabetes-related kidney disease, conditions that affect these organs also include:

Polycystic kidney disease (PKD): an inherited condition associated with the development of cysts in a kidney, leading to kidney failure. Normally only seen in people over the age of 40, there are limited treatment options available, although these are shown to be relatively successful. Rigorous blood-pressure control helps to prevent complications. The genetic factor in PKD requires that children with a parent with PKD be screened regularly from an early age, to ensure timeous and effective treatment.

The burden of CKD on the health sector is a growing epidemic that should be addressed strategically

Glomerular nephritis and auto-immune disorders: These conditions can be caused by a variety of factors – too many to mention in this article, but suffice it to say that they cause harm to the kidneys that prevents them from working optimally.

Kidney stones: Rock-like crystals form, ranging in size from as small as a grain of sand to as big as a golf ball. This common disorder of the urinary tract may require surgery if the stone is too large to pass, is blocking urine flow or is causing bleeding and infection. It is extremely painful to pass a kidney stone!

Having noted some disorders, it is, however, possible for people to take care of their kidney health by taking some preventative actions. This means adopting healthy lifestyle practices and ensuring that you have your blood-pressure and blood-sugar levels checked regularly. It is recommended that from the age of 30, these checks should be done at least once a year, and more often if the individual falls into a high-risk category. High risk would be indicated by a family history of hypertension or diabetes, or problems such as being overweight or being obese. Help to keep your kidneys healthy by:

- not smoking
- limiting alcohol intake
- eating a balanced diet, low in salt and sugar, and limiting caffeine and cola intake
- regulating your weight
- keeping hydrated by drinking water when you're thirsty
- taking part in an exercise you enjoy, for example, swimming, cycling or brisk walking for 30 minutes three to five times a week.

Individuals with hypertension or type-2 diabetes should follow their prescribed treatment, diet and blood-testing regimens very strictly, to prevent the progression of these conditions and to prevent the possible effects on the kidneys. The best strategy would still be prevention of the risk factors, and to achieve this, the NKFSA has developed a protocol to educate and screen senior learners at schools. This protocol has been implemented in a limited number of schools to date, but the NKFSA believes that it should be rolled out on a national level. Initial results from the project have been analysed, and show that in SA, the presentation of these contributing risk factors in learners aged, on average, between 16.5 and 18 years, were as high as 18% in certain groups. When taking into consideration the later presentation of the contributing risks for kidney disease, it becomes clear that figures for chronic kidney

disease (CKD) incidence in SA might be much higher than believed – even more reason for prevention to be the first item on the agenda for future healthcare in SA.

As an organisation involved with all aspects of kidney health, it is important that mention should be made of the role of the NKFSA in current developments in the SA health sector, and two major issues should be noted. Firstly, the NKFSA has been involved in the development of treatment guidelines for dialysis in SA. This has created a vitally important document that is needed not only to ensure the standard of treatment in accredited facilities, but also to assist doctors in ensuring that patients are fairly and equitably treated within the limited resource environment of healthcare. The document is currently in draft format, and has been presented to the National Health Directorate for Non-Communicable Diseases, and we trust that the importance of and dire need for these guidelines will ensure speedy action to have this issue included in the legislative framework for healthcare in SA.

Secondly, the role of kidney disease (especially the progressive stages of CKD) within the proposed National Health Insurance (NHI) framework is not clearly defined as yet, and the NKFSA would like to see the handling of kidney disease positioned as a measure of the successful implementation (or otherwise) of the focus of the NHI, namely primary healthcare (PHC). PHC, if implemented effectively, would lead to the early detection and treatment of the chronic conditions that cause most of the kidney-disease burden in the healthcare system. If these chronic conditions, such as hypertension and diabetes, are effectively addressed at a PHC level, then the prevention of end-stage renal disease would be one of the desired outcomes. However, the early detection and effective treatment and control of these conditions would be pivotal to this outcome. The scope of the Renal Registry that was established with input and continued support from the NKFSA should be broadened to include statistics of patients affected by early-stage renal disease, in order to measure the rate of progress under NHI.

The burden of CKD on the health sector is a growing epidemic that should be addressed strategically by limiting the risk factors. This can be achieved through early screening, awareness and education. The NKFSA as an organisation is involved in all of these aspects, but urges all individuals to become aware of the important role that the kidneys play in overall health, and to take responsibility for their kidney health.

The NKFSA can be contacted on email at nkfsa@mweb.co.za, or by visiting our Facebook page "nkfsa".

Maternity department receives MEC's Award for Service Excellence

Dr Mergan Naidoo

The maternity department at Mahatma Gandhi Memorial Hospital (MGMH), a Level-2 hospital in Phoenix, Durban, was recently awarded the MEC's Award for Service Excellence for a significant reduction in maternal deaths. The number of maternal deaths (pregnant women who die before, during or shortly after childbirth) decreased from 27 in 2010, to 2 in 2016. Maternal death rates are used internationally to judge the quality of healthcare that governments provide to their citizens. This drastic reduction in deaths was achieved by hard work, commitment and teamwork from all levels of staff, which included doctors from obstetrics, anaesthetics and medicine, nursing staff in obstetrics and the operating-theatre and support staff.

The department hopes to maintain this reduction by continuing with their commitment in prioritising pregnant women and babies. Many initiatives have been implemented to improve the quality of healthcare in resource-limited environments such as the public health sector in SA. In order to maintain this high-quality output, the service is dependent on an adequate number of skilled staff, as well as equipment and infrastructure.

In a message to the community, Dr B Hira, Head: Clinical Unit at MGMH, urged pregnant women to attend their local clinic for antenatal care, a free service offered by all primary healthcare clinics, as soon as they suspect that they are pregnant. Pregnant women also need to attend regularly, so that if problems occur, they can be quickly identified and referral to hospital urgently instituted. Pregnant women are also urged to maintain a healthy lifestyle, and to seek medical care early if there are any complications.

Maternal deaths decreased from 27 in 2010, to 2 in 2016

Dr Neil Moran, provincial head of obstetrics and gynaecology for KZN, addressed participants at the SAMA KZN Regional Indaba in Durban on 5 August 2017, and encouraged all doctors and nurses who provide antenatal care to use comprehensive antenatal records, so that high-risk pregnancies can be timeously identified and referred to the appropriate level of care. Dr Moran also encouraged GPs and private specialists to use the Antenatal Record provided by the National Department of Health.

Some of the healthcare team from MGMH, left to right: K Govender, S Thambaran. S Sewpersad, U Panday, B Hira, L L Makunyane, S Venkat, N Cairncross, V Moonsamy, D Rungan

Award-winning nurses, left to right: Z Sompa, G Ngodwana, R Roopchand, F K Gumede, C V Rooplall, A L Mkhize

Negligence in the workplace

Modisane Lelaka, *industrial relations advisor*

This article will concentrate on the definition of negligence and how it is managed by an employer. In some cases, employees are charged with gross negligence, but the employer fails to indicate what is "gross" about the negligence. When a healthcare practitioner is employed, it is expected that he or she abide by a code of conduct or ethics, and there is also a standard of care expected from that practitioner when performing his or her duties. Of importance is that patients, when presenting themselves to medical practitioners, are able to put their trust in them.

Negligence

Negligence can be defined as follows:

Conduct that falls below the standards of behavior established by law for the protection of others against unreasonable risk of harm. An employee is negligent when he or she fails to exercise the standard of care required to perform his or her job.

In Moema and Zanzu (2011) 32ILJ 484 (CCMA), negligence is defined as the failure to comply with the standard of care that would be exercised in the circumstances by a reasonable person.

The extent of negligence differs. There is negligence which is regarded as ordinary, and there is gross negligence. Gross negligence is conduct which is extreme compared with ordinary negligence. Examples of gross negligence are:

- endangering the lives of self or others by disregarding safety rules or regulations
- persistence in the act of negligence
- the use of an ineffective treatment plan, which results in a change of condition of the patient or death
- giving the wrong prescription, which results in complications and misdiagnoses of a patient.

Processes to be followed when there is negligence or malpractice

Often a complaint will be made by patients or clinical managers against a practitioner for mismanagement of a patient, or for medical malpractice. The complaint is handed over to the quality assurance manager (QAM) for investigation and advice. The QAM often handles complaints related to the community or to clients. In a case where there is suspicion of medical negligence, the QAM and his/her team will investigate to determine whether there was any fault or negligence on the part of the health practitioner. Should the investigation find that the practitioner may have been negligent, the case is then reported to Labour Relations for further investigation, and the investigation may lead to disciplinary action against the practitioner.

Vicarious liability

Sometimes when the patient or the family wants to pursue litigation for medical negligence or malpractice, the employer carries the duty of vicarious liability. Vicarious liability means that the employer takes responsibility for the employee's wrong doing. In this case, it means that the court case and its costs will be borne by the employer.

Where the incident is regarded as gross negligence, warnings are not necessary.

In 2016, a medical practitioner was charged for negligence when he delayed the delivery of a baby, which resulted in the baby being delivered as stillborn. The delay, without proper reason, was regarded as a violation of the patient's right to access to timely emergency care, and as gross negligence, and because there was also the death of the baby, this is a dismissible offence. The practitioner was subjected to a disciplinary hearing, and was found guilty of gross negligence. Added to the charge was that the practitioner also failed to make notes about the treatment and diagnosis of the patient, including the treatment plan, which would mean that the next practitioner would not have a history of the patient nor the treatment given, or the status of the patient. The practitioner was subsequently dismissed after a disciplinary hearing.

To dismiss an employee, the incident must be regarded as gross negligence. The employee's actions must be regarded as reckless, and repeatedly committed, and on face value the incident must appear to be serious. There must also be a loss incurred that prejudices the employer.

BCB decry lack of security measures in hospitals

SAMA Communications Department

Dr Mzu Nodikida, chairman of the SAMA Border Coastal branch (BCB) in the Eastern Cape, stated on 10 August that the branch decries and views as completely unacceptable the lack of proper security measures in public hospitals.

"The incident at Cecilia Makiwane Hospital on Saturday 5 August, where one of our members, Dr Archie Solombela, was attacked and assaulted by a patient, is a clear indication of how weak the security measures in our public hospitals are.

"Dr Solombela sustained a fracture to his right arm during the incident. He is now recovering at home after he had an operation on the fractured arm. SAMA wishes both Dr Solombela and the general worker who was also involved in the incident, a speedy recovery.

"The fact that the patient was known to have a violent history and no precautionary measures were taken, is concerning."

Representatives of SAMA BCB have visited Dr Solombela at his home, and have also met with the management of Cecilia Makiwane Hospital. "As an association, we are convinced that the incident could have been avoided, and we urge the authorities to do everything they can to protect our members and our patients in hospitals. A violent patient is a danger, not only to healthcare workers, but also to other patients. Patient safety is one of the six priorities in healthcare in our country," said BCB representative Dr Nodikida.

SAMA will work with the authorities to ensure patient safety and the safety of all healthcare workers.

Wrong drug, no negligence

The Medical Protection Society shares a case report from their files

Mrs M was a 64-year-old care assistant in a retirement home. She visited her GP with a 2-month history of blood in her stools, altered bowel habit, and intermittent lower-abdominal discomfort. On examination, the GP found haemorrhoids, and referred her to her local hospital to see Dr P, a gastrointestinal surgeon.

Mrs M was found to be overweight, with a BMI of 32, and was a smoker. Dr P performed routine blood tests, and booked Mrs M to undergo gastroscopy, proctoscopy, colonoscopy, biopsies and injection of haemorrhoids, under general anaesthesia.

She was seen pre-operatively by Dr D, consultant anaesthetist. Dr D noted that Mrs M was on a number of medications, including metoprolol and quinapril for hypertension, simvastatin for raised lipids and inhalers for a diagnosis of chronic obstructive airways disease. She was documented to be allergic to the antibiotic augmentin, which she had taken some years previously, and which had caused a rash and wheeze.

Mrs M reported that her brother had suffered a severe reaction to general anaesthesia, and had spent 2 days in intensive care following a hernia operation. However, she was unable to provide more details, and her brother had subsequently moved overseas. Mrs M had previously undergone two uneventful general anaesthetics at that hospital.

Dr D decided to proceed with general anaesthesia. The procedure was uneventful, but at one point, Dr D administered 1.2 g of augmentin. In the recovery area, Mrs M was noted to have a widespread itchy rash and was complaining of wheeze. However, her pulse, blood pressure, saturations and conscious level remained normal.

She was treated with antihistamines and hydrocortisone. As a precaution, she was admitted to the hospital overnight, where the rash and wheeze resolved, and she was discharged the following day following a further set of blood tests.

During her stay, she was visited by Dr D, who documented that he had apologised to her for the accidental administration of augmentin. Dr D wrote a letter to the GP explaining what had happened, and gave Mrs M a copy. Dr P was also noted to have visited her, but did not document his visit or discussion.

Approximately 1 week later, Mrs M developed a high fever and abdominal pain, and was admitted to the hospital under Dr P. She was noted to be jaundiced, and her other liver function tests were deranged. Investigations suggested a diagnosis of acute cholecystitis, and she was treated with antibiotics. The episode settled and she was sent home with an appointment for an elective laparoscopic cholecystectomy.

Mrs M brought a claim against Dr D and Dr P, alleging that the incorrect administration of augmentin had brought about her cholecystitis as part of an allergic reaction. Dr D, the anaesthetist, stated that he had given the antibiotic on the directions of the surgeon, Dr P. However, Dr P stated that he had left it up to Dr D to choose which antibiotic to give.

The experts concluded that there had been a clear lapse in standards, where it had been documented that Mrs M had received an antibiotic to which she was allergic. However, they complimented Dr D on his handling of the incident. They concluded that Mrs M's cholecystitis was unrelated to the accidental administration of augmentin. In the absence of demonstrable causation, Mrs M withdrew her claim.

The hospital subsequently changed several of its policies and procedures, including implementing a "time-out" check at the start of each endoscopy procedure.

Learning points

- Adherence to simple protocols, such as the WHO Surgical Safety Checklist, can help prevent problems of this kind, where a known and documented allergy was overlooked. See www.who.int/patientsafety/safesurgery/ss_checklist/en/.
- In choosing a total intravenous anaesthesia (TIVA) technique for anaesthesia, Dr D was attempting to avoid a rare but dramatic problem, malignant hyperthermia: Mrs M might have been at risk, given what had happened to her brother. However, this may have distracted his attention from a much more common problem, which is allergy to antibiotics. Take extra care when performing a technique that is unusual for you.
- Good documentation is the cornerstone of your defence. In this case, Dr P didn't document anything that had been discussed or shared. If a junior doctor is making the notes, ensure you check their entries.
- Human error is inevitable in medicine, but doctors should always be open with patients and their families following an adverse event. An open and frank apology can often help to defuse anger. In this case, Dr D was praised for his handling of the incident afterwards.

Western Cape visit forensic ward at Valkenberg Hospital

The Western Cape branch visited the male forensic ward at Valkenberg Hospital on Mandela Day, and donated two boxes of socks, which were donated by Western Cape branch councillors.

The branch also held a successful CPD meeting in July at Old Mutual on the topic of private wealth.

Emily Nel, Chenienne Gerike, Mr Lethoko (forensic Ward 20 area manager) and Maryam Abbas

Discussing the termination of pregnancies

Lowveld branch, in partnership with the Medical Women Association of SA (MWASA), hosted a training session on the termination of pregnancies at the clean, state-of-the-art Nelspruit Community Centre.

Dr Bongi Baloyi of MWASA said that an increase in deaths due to women going for backstreet abortions was the motivation behind hosting the 2-day training session for doctors and medical staff. "There has been an outcry in ERs because of an increase in women arriving with septic abortions," said Dr Baloyi, explaining that many women went to non-professionals who performed procedures in unhygienic conditions and surroundings. Some bled to death or died from septicaemia. "Some suffer from lifetime damages. They will never be able to have children again, or they get perforated uteruses and hysterectomies. The complications are endless. We have a long way to go to empower women to know their rights in this country."

Guest speaker Dr Patrick Godi said the objective was to train doctors in the province to do the procedures safely and legally. Theory, law, administration and ethical matters were discussed on the first day, while the second day dealt with real-life practicals. "The termination can be done from 12 weeks and below, and up to 20 weeks of pregnancy," said Dr Godi, who explained that medical staff could not impose their own personal beliefs on their patients, and had to perform their duties. He added that it was a very important service, especially with regard to rape cases.

Front row, left to right: Prof. Eddie Mhlanga, Dr Nokuthla Mzimba, Dr Portia Dibakwane, Dr Bruce Malumane (chairperson, SAMA), Dr Neli Tomova, Dr Nelson Igaba, Dr Mukladi Kabambe. Back row, left to right: Dr Patrick Godi (black shirt), Dr Meshack Maile and Dr Gantcho Gantchev

Lowveld visit clinic on Mandela day

Lowveld branch celebrated Mandela Day on 18 July at the Volksrust Clinic in the Gert Sibande district.

SAMA member and head of department at the Department of Health, Dr Savera Mohangi, and the honorable MEC of Health, Mr Mashego, visited the clinic with other members of the branch. Dr Mohangi assisted in patient care, and even painted a wall!

MEC of Health, Mr Mashego, toured the wards with Dr Mohangi

Dr Savera Mohangi (middle) chats to a patient at the Volksrust Clinic

Eastern Province CPD meeting

The SAMA Eastern Province (EP) branch hosted a vibrant and well-attended CPD meeting in Somerset East on 29 June 2017. In an effort to support district doctors, both in state and private practice, the EP branch council had decided to host CPD functions away from the bright lights of Port Elizabeth (PE).

The two main speakers were Dr JC Vosloo, a retired GP, and Dr J Vermeulen, a paediatric oncologist based at PE Provincial Hospital.

Dr Vosloo shared many interesting highlights of his career, and stressed the importance of a detailed history and clinical examination. Dr Vermeulen gave an informative presentation on the common presentation of childhood malignancies.

In conclusion, Dr Farhaad Khan, EP branch chair, provided an update on the current status of the proposed Commuted Overtime Policy.

The medical community of Somerset East are to be commended for their hospitality and their attendance on a cold winter's evening.

Dr Franke Moolman, Dr Julie Jordaan and Dr Nicolene van der Westhuizen

Griqualand West discuss diabetic retinopathy

The Griqualand West branch hosted a CPD meeting on Tuesday, 25 July 2017, at the Horseshoe Inn, Kimberley. The topic discussed at the meeting, which was presented by Dr M J Booysen, was "Recent developments in the management in diabetic retinopathy".

Dr Booysen completed his MB ChB and MMed Ophthalmology degrees at Stellenbosch University, and he has a Diploma in Ophthalmology from the Colleges of Medicine of SA. He is currently in full-time private practice in Kimberley, SA. He is the past head of department of the Kimberley Hospital Complex Department of Ophthalmology. His clinical interests include cataract surgery, retinopathy of prematurity and medical retina.

In his presentation, he used a case study to lead an interactive discussion on how to deal with/treat issues that arise from clinical-practice work.

Dr M J Booysen (right), with SAMA Griqualand West branch chairperson Dr M J Ngundu

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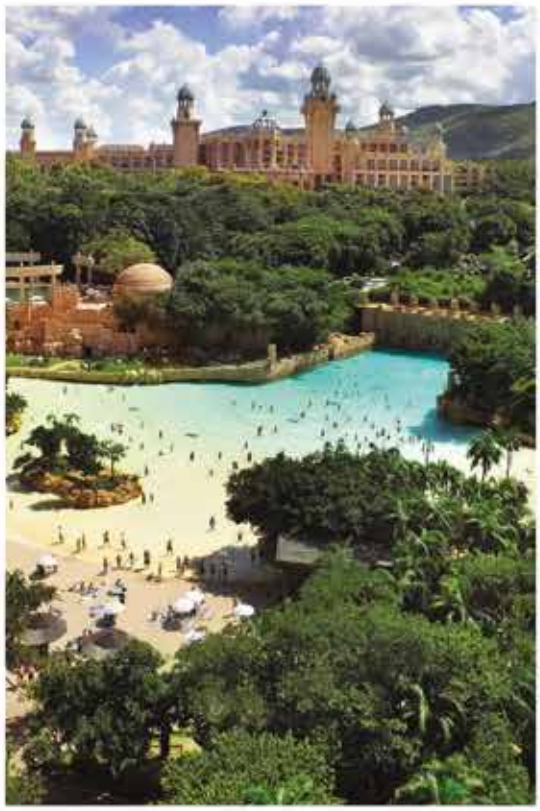

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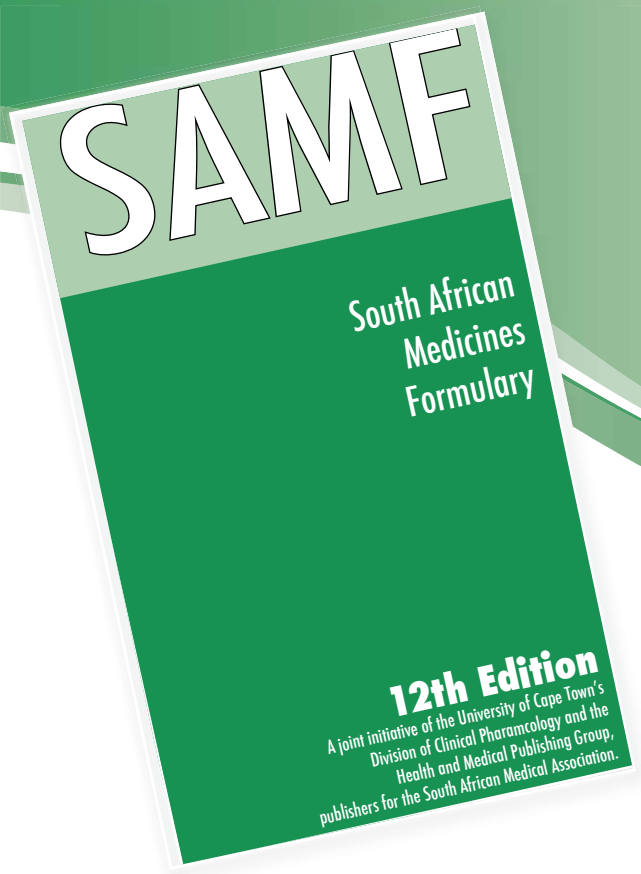

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