

SAMA INSIDER

MAY 2020

**COVID-19: Achieving
“Health in All Policies”
– at speed!**

**Mental illness: The
next pandemic?**



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

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Diane de Kock
Editor: *SAMA INSIDER*

The choices we make now could change our lives

Yuval Noah Harari, in an article in the *Financial Times* (20 March), wrote about the coronavirus: "Humankind is now facing a global crisis. Perhaps the biggest crisis of our generation. The decisions people and governments take ... will probably shape the world for years to come. They will shape not just our healthcare systems but also our economy, politics and culture. We must act quickly and decisively." By the time you read this edition of *SAMA Insider*, many of those decisions will have been made, and hopefully the long-term consequences will have been taken into account.

This month our focus is COVID-19 – on page 4, SAMA president Dr Sizeka Maweya questions whether alcohol is a cost driver in our health system: "The country must develop policies on how to care for the homeless and vulnerable drug addicts." The article on achieving health policies at speed, by Shelley McGee and Dr Lindi Shange (page 5), unpacks "the unprecedented flurry of policies, guidelines and, most importantly, regulations published" in the 2 weeks since President Ramaphosa announced lockdown.

Dr Stoffel Grobler (page 7) looks at the psychological impact of social isolation, warning that the next pandemic could be mental illness. COVID-19 and your rights is the subject of Dr William Oosthuizen's article (page 8), while the Medical Protection Society (page 11) advises on some medicolegal dilemmas faced by healthcare professionals during the time of COVID-19.

Managing clinical trials during the pandemic is discussed by Adri van der Walt (page 12), and we introduce the newly established Doctors on Call helpline (page 14), a not-for-profit initiative established to improve access to doctors for the uninsured population, "the most vulnerable [who] don't have access to a GP telephonically".

Brandon Ferlito looks at the ethics of telemedicine in SA (page 16), which "may be used to avoid overwhelming health systems in general". Dr Boitumelo Semete, CEO of the SA Health Products Regulatory Authority (SAHPRA; page 15) warns doctors about the appropriate place for rapid test kits. "SAMA urges its membership to recognise the extreme limitations of rapid testing in the clinical management of COVID-19."

Stay safe, stay healthy and, as Dr Grobler says: "I hope that a positive outcome of this pandemic will be that ... people will find it easier to ask for help in future."

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Is alcohol a cost driver in our health system?



Dr Sizeka Maweya, SAMA President

On 23 March 2020, the President of SA announced measures to control the spread of COVID-19. To show leadership, he introduced regulations regarding the opening of liquor outlets and the sale of cigarettes. The most important regulation for the health sector, with immediate benefits, was the prohibition of alcohol sales during the lockdown period.

The president intended to limit the movement of people in communities. However, for the health sector, this provides additional massive benefits, as alcohol is one of the driving factors when it comes to gender-based violence, trauma, motor vehicle accidents and injuries inflicted by sharp objects, especially in shebeens and taverns.

According to the WHO, worldwide, 3 million deaths every year result from harmful use of alcohol, representing 5.3% of all deaths. Overall, 5.1% of the global burden of disease and injury is attributable to alcohol. Alcohol consumption causes death and disability relatively early in life. In the age group 20 - 39 years, approximately 13.5% of total deaths are alcohol-attributable. The organisation claims that SA's drinking population consumes 28.9 L of pure alcohol per capita a year, the fifth-highest consumption rate in the world. SA is a beer-drinking nation, making up 56% of all alcohol consumed. It is prudent for us as a country to applaud the kind of leadership the President has taken.

During this period of lockdown, healthcare providers have noted a massive decrease in trauma and violent behaviour in hospitals.

The number of patients presenting in health facilities with alcohol-related death has also decreased.

Regulations of this nature must be enforced to reduce the burden of disease due to alcohol consumption. The detrimental effects of alcohol, in the long run, cause a significant proportion of the disease burden, from unintentional and intentional injuries, including those due to road traffic accidents, violence and suicides, and fatal alcohol-related injuries, typically in younger age groups. The negative impact on the younger generation includes violent behaviour. We always say that we have a lost generation. We know that alcohol plays a significant role in this regard, but have never taken action.

One of the most significant lessons learned during this lockdown will be how to deal with the social ills in our society that are driven by alcohol consumption.

The impact of alcohol consumption on chronic and acute health outcomes in populations is largely determined by the total volume of alcohol consumed, and the pattern of drinking. During this lockdown, we have seen a massive change while alcohol is prohibited. Does alcohol contribute to the social ills that are the main cost driver of our healthcare? Countries have a responsibility to formulate, implement, monitor and evaluate public policies to reduce the harmful use of alcohol. The nation as a whole should support the President in changing or formulating policies on alcohol consumption.

According to a study by Matzopoulos *et al.*, the tangible financial cost of harmful alcohol use in 2009 alone was estimated at ZAR37.9 billion, or 1.6% of the GDP. These findings were made 11 years ago. However, the cost to the country's GDP remains high. The amount spent on alcohol could find better usage in essential interventions to reduce the social ills of our country, which themselves lead to massive alcohol consumption.

The major point that the alcohol industry raises is that alcohol brings income to the country that surpasses the harmful costs. The alcohol industry is one of the main sponsors of world sports. This may be accurate, but the risk-benefit ratio must be carefully examined to arrive at an amicable solution.

The benefits of changing alcohol consumption policies outweigh the risks. There are cries from homeless people regarding their addictions, including on the unavailability of cigarettes. Many homeless people are addicted to substances such as nyaope or dagga, and they also sniff glue. There are debates around relaxing regulations on these substances in some parts of the country, the Western Cape in particular. Tragically, homelessness and addiction go hand in hand. In the USA, the National Coalition for the Homeless has found that 38% of homeless people are alcohol-dependent, and 26% are dependent on other harmful chemicals. The same can be said in our country, where we have homeless people complaining that during this lockdown, the challenges of their addictions are not being addressed.

The country must develop policies on caring for the homeless and vulnerable drug addicts

Some homeless people demand that they must be given drugs to help them to fight their addiction, such as methadone. Any regulations of this nature must be made in consultation with all stakeholders, especially poor communities, and in particular, homeless populations.

Homeless people battle also often battle with mental illness, which is a significant cause of homelessness, which in turn often leads to drug and alcohol abuse. Health facilities will struggle with, or have already seen an increase in, patients with mental health conditions such as bipolar mood disorder, schizophrenia and post-traumatic stress disorder during this lockdown period.

The country must develop policies on caring for the homeless and for vulnerable drug addicts. If such policies were available, the current challenges would have been minimised and better mitigated.

In conclusion, the interventions have been crucial. Although every action has unforeseen, unintended effects, consultations must never delay the implementation of regulations.

COVID-19: Achieving “Health in All Policies” – at speed!

Shelley McGee, *SAMA Knowledge Management, Research and Ethics Department*, Dr Lindi Shange, *chair, SAMA Health Policy Committee*

In the 2 weeks since President Ramaphosa announced a national disaster in terms of the Disaster Management Act No. 57 of 2002, we have seen an unprecedented flurry of policies, guidelines and, most importantly, regulations published.

It has been impossible to keep up, and while areas such as health and education were immediately affected, we have really only begun to see the impact of the regulations over the last week on the economy, public transport, workplace safety, financing agreements and public procurement.

This is all in the name of curbing a threat to national public health – to “flatten the curve” of the number of infections of COVID-19 to occur in the population over time. Under the most urgent of circumstances, it seems SA may have finally applied the concept of “Health in All Policies” (HiAP) called for in the 2013 Helsinki Declaration, albeit in the most rushed of circumstances.

The HiAP statement calls on governments to fulfil their obligations to peoples’ health and wellbeing by taking several actions, including committing to health and health equity as a political priority, and taking action on the social determinants of health.

The Declaration also required that governments ensure effective structures, processes and resources to enable HiAP across governments at all levels, and between governments, and for governments to empower their health ministries to engage with other sectors of government through leadership, partnership, advocacy and mediation – all with a view to achieving improved health outcomes.

In addition, communities, social movements and civil society were to be included in the development, implementation and monitoring of HiAP, thereby building health literacy in the population.

While the wheels of policy generally turn slowly, the COVID-19 pandemic has imposed itself on the legislative and policy framework to the extent that we have been able to watch, over an extremely short period of time, the concept of HiAP in action.

Early stages

The National Department of Health (NDoH) was naturally the first department out of the

starting blocks, and the National Institute for Communicable Diseases (NICD), a division of the National Health Laboratory Services, had put in place systems to rapidly identify and detect any imported cases in SA by mid-January.

Together with the NDoH, the NICD developed and distributed clinical guidelines and case definitions for doctors and nurses in both the public and the private sectors to better detect, identify and respond to possible 2019-nCoV cases.

This disaster gives us a sense of what is possible for policy-makers

This work continues at the time of writing, as guidelines are constantly being updated with new information and recommendations.

The NICD Communicable Disease Communiqué in February clarified that COVID-19 was classified as a category 1 notifiable medical condition, and that notification should be made immediately on identification of a case. In the interim, the NICD had already tested 121 returning travellers for the disease.

From the beginning of February, the now-familiar instructions “wash your hands” and “cover your nose and mouth when you sneeze or cough” started to circulate from the NDoH.

By the time SAMA, the SA Public Health Medicine Association and the Foundation for Professional Development held the first conference on the COVID-19 outbreak on 24 and 25 February, these messages were fairly well established, and healthcare workers were beginning to identify the many challenges that would be facing us in the case of a major outbreak (see article in April issue of *SAMA Insider*).

Presidency machinery really starts to move

Shortly after the first positive case was announced on 5 March, the government machinery began to move swiftly. After local

transmission was confirmed on 14 March, President Ramaphosa wasted little time in declaring a national disaster.

Within 2 days of the President’s declaration (15 March 2020), the Department of Cooperative Governance and Traditional Affairs had issued regulations in terms of the Disaster Management Act section 27(2).

The original regulations provided the overarching framework to set the Act in motion. They allowed for the release of necessary resources to fight the outbreak, prohibited public gatherings and visitations to detention facilities and correctional services, and put limitations on the sale, dispensing or transportation of alcohol. They also laid down conditions for compulsory testing for COVID-19, as well as treatment, quarantine and isolation, which can be court-ordered if necessary.

The regulations also provided the power to the ministers of health, justice and correctional services, basic and higher education, police, social development, trade and industry and transport to issue directions to address, prevent and combat the spread of COVID-19 in the areas under their respective jurisdictions nationally.

The regulations also outlined offences and penalties relating to transgressions, and importantly for the healthcare sector, made provision for compulsory submission to testing, prevention, isolation and quarantine of suspected and confirmed COVID patients.

As the numbers of positive cases continued to climb, however, and the Presidency was advised that the country could not cope with the potential caseload, the President further escalated the situation into a full lockdown, starting on 26 March.

The biggest challenge is that the exact number infected is unknown, and the current confirmed figures of positive COVID-19 could be an underestimate of the total number of cases, as our testing is still limited. As of 5 April, SA had recorded 1 585 confirmed infections, and nine deaths.

On 4 April, the President held the first virtual gathering of the presidential co-ordinating council, in which he urged the country to rethink how government, businesses and communities were to work and relate to each other in this COVID-19 fight.

Education, and science and innovation

After the publication of the regulations, basic education minister Angie Motshekga was first to respond, stating that schools had been identified as one of the biggest threats in terms of the transmission, hence the need for closure.

Blade Nzimande, Minister of Higher Education, Science and Innovation, also put out an immediate statement, announcing that the department had redirected ZAR4 million from other projects to some COVID-19-related proposed interventions, and would be costing others and mobilising additional funds going forward. By 24 March, the ministry had allocated an additional ZAR30 million to research projects and the development of local testing kits.

Transport

Minister of Transport Fikile Mbalula has had quite a ride himself throughout this process. The ministry has put out several versions of regulations to address the high-risk areas of aviation and public transport.

Public transport services were addressed in their own set of regulations on 26 March. These required, among other things, that owners of public transport facilities should on regular intervals provide adequate sanitisers or other hygiene dispensers for washing of hands for users. The loading capacity of vehicles was limited, and minibus taxis were only permitted to carry 50% of their capacity. All operators must ensure that public transport vehicles are sanitised before picking up and after dropping off passengers.

These decisions did not sit well with the taxi industry, however, and on 1 April, Minister Mbalula announced that after talks with the taxi industry, mini and midi-bus taxis would

be permitted to carry 100% of their capacity, provided all passengers were wearing surgical masks or N95 respirators. After a public outcry, he reversed this decision and declared that 70% carrying capacity would be permitted.

SAMA issued a statement of concern about this, as the decisions being made were clearly arbitrary and without real considered thought for potential COVID-19 spread. At the time of writing (5 April 2020), amendments to the original regulations had still not been passed.

Trade and industry

The Department of Trade and Industry immediately recognised the potential impact of a disaster declaration on consumers and business, and issued customer and consumer protection regulations on 19 March. These sought to protect the public from excessive pricing of defined goods and services. These goods include basic foods and consumer items, emergency products and services, medical and hygiene supplies and emergency clean-up products and services.

At the same time, an exemption was given to the healthcare sector, from the application of sections 4 and 5 of the Competition Act No. 89 of 1998, in an effort to promote concerted conduct between the public and private sectors to prevent an escalation of the national disaster and promote access to healthcare, prevent exploitation of patients and enable the sharing of healthcare facilities, management of capacity and reduction of prices.

Health

In addition, the health sector has been working at various levels on its preparedness plan through the COVID-19 Command Centre. While a full and published plan is

still anticipated at the time of writing (5 April), sharing of information and discussions between government and the private sector is now commonplace, and plans are being developed together.

The Council for Medical Schemes issued a COVID-19 circular advising on the status of COVID-19 complications as prescribed minimum benefits, and the HPCSA set out new measures and directives regarding telemedicine as a necessary tool for healthcare practitioners.

Community involvement

The President has met with church leaders to discuss COVID-19 prevention strategies, especially around this time of traditional large gatherings over Easter. Co-operative Governance and Traditional Affairs minister Dr Nkosazana Dlamini-Zuma has also reached an agreement with the provincial houses of traditional leaders to suspend all winter circumcision schools.

A door-to-door screening, testing and quarantine campaign, with 10 000 fieldworkers, started on 4 April, in a focused effort directed at vulnerable communities. We will be carefully observing the challenges and opportunities that present themselves from this work.

It is difficult to keep up with the publication of all these directives and regulations, let alone begin to understand what immediate, intermediate and long-term direct and indirect impacts they will have in their various areas.

However, this disaster gives us a sense of what is possible for policy-makers in a short period of time, with a focused set of imperatives and consideration for the health of the nation.

HiAP is complex, especially in the SA context, but it can be done!

COVID-19: SAMA adds SA clinical guidelines

SAMA Communications Department

Clinical guidelines for the management of COVID-19 cases in various disciplines and environments are continually being added to the SAMA guidelines page (https://www.samedical.org/clinical-guidelines-technologies/clinical_guidelines). The situation and the related guidelines are changing rapidly, with amendments being made and new

guidelines added weekly. SAMA will continue to keep the page updated.

Please send any new guideline material through to the SAMA Knowledge Management Team at shelleym@samedical.org.

The National Department of Health (DoH) COVID-19 Infection Prevention and Control Guidelines are available at: <https://www.samedical.org/file/1273>. The guidelines

should be read together with the following documents, which are available at <http://www.health.gov.za/index.php/component/phocadownload/category/626>

National Infection Prevention and Control Strategic Framework, March 2020

Practical Manual for the Implementation of the National IPC Strategic Framework, March 2020

Mental illness: The next pandemic?

Prof. Christoffel Grobler, head of clinical unit, Elizabeth Donkin Hospital



Recently, I wrote an article on LinkedIn about a new word I had thought of in light of the COVID-19 pandemic and subsequent lockdown measures, namely “burn-in”, as opposed to burnout.

I thought of “burn-in” in the context of so-called “cabin fever”, a common term used in especially northern-hemisphere countries to describe the emotional response to being cooped up in confined spaces during the long winter months. Cabin fever supposedly consists of feelings of restlessness, lethargy, sadness, poor concentration, irritability, decreased motivation and inability to cope with stress. All of which sounds very familiar, considering the ways people have been reacting to the lockdown measures. Cabin fever is, however, neither a scientific phenomenon nor a common behavioural science term.

Interestingly, the experience of astronauts regarding social isolation and its psychological effects was not a topic of much research until about 20 years ago. Since then, much research has been done on the psychological demands of isolation, which include interpersonal conflict, depression, dealing with confinement for extended times and problems in coping with separation. Now, many are turning to astronauts and submariners for advice as to how to deal with lockdown.

Burnout has also had a lot of airtime in the literature and, particularly in the medical profession, we are only too familiar with the

concept – sadly, for many of us, from very personal experience.

In my LinkedIn article, I speculated about combining the symptoms of burnout with symptoms commonly associated with social isolation or, if you will, cabin fever, suggesting that the result would be a constellation of symptoms consisting of restlessness, depression, trouble concentrating, impatience, listlessness and decreased motivation, loss of a sense of meaning in life, disengagement and cynicism.

The point I am trying to make is that the COVID-19 pandemic has had an undeniable impact on our emotional state, on both us as healthcare providers and on our families who are not deemed essential workers and have to remain at home during the lockdown.

Research is already showing an increase in the prevalence of mental illness among healthcare providers. In many countries, including SA, the rate of domestic violence has also increased – glaring reminders that we are all suffering psychologically.

COVID-19 has had an undeniable impact on our emotional state

Studies from China show that mental health disorders are increasing in the context of COVID-19. One study looked into the frequency of anxiety, depression, phobias, cognitive change, compulsive behaviour, physical symptoms and social functioning using the COVID-19 Peritraumatic Distress Index, with scoring ranging from 0 to 100. A score between 28 and 51 indicated mild to moderate distress, and a score ≥ 52 indicated severe distress. Almost 35% of respondents experienced psychological distress (29.29% of scores were between 28 and 51, and 5.14% were ≥ 52).

In an article entitled “Mental health problems and social media exposure during COVID-19 outbreak”, Gao *et al.* found the prevalence of depression to be 19.4%, anxiety 22.6% and a combination of depression and anxiety 48.3% during the COVID-19 outbreak in Wuhan, China. Using validated rating scales

to assess anxiety, depression, insomnia and distress/post-traumatic stress symptoms, they found high rates of depression (50%), anxiety (45%), insomnia (34%) and distress (72%) among healthcare workers.

I am not aware of any current studies in SA estimating the increase in mental illness due to the COVID-19 pandemic, but the SA Stress and Health study (2008) found a lifetime prevalence of 30% for any mental health disorder, and 10% for major depression in the past.

The medical profession ought to be ready for this next pandemic

Apart from the psychological distress caused by lockdown, the financial impact on the average SA household will be devastating. Early forecasts suggest that the economic impact of lockdown costs the economy an estimated ZAR13 billion per day, and preliminary projections by the SA Reserve Bank indicate that the country could lose 370 000 jobs in 2020.

If I were to predict the risk of an increase in mental illness in SA, either new diagnoses or the exacerbation of existing mental illnesses, based on the evidence at my disposal, it seems logical to me that the prevalence of mental illness is about to increase exponentially. At the same time, the need for services to treat mental illness will increase considerably in the coming months.

We, as the medical profession, ought to be ready for this next pandemic, and put systems in place to meet the demand. Telepsychiatry and telepsychology are ways of expanding the availability of services. I sincerely hope the HPCSA will consider the risks v. the benefits when reviewing their guidelines on telemedicine after the COVID-19 pandemic is over.

Mental illness has always been a stigmatised domain. I hope that a positive outcome of this pandemic will be that, due to all the education available online regarding how to stay mentally well during the lockdown, as well as recognising the signs of mental illness, people will find it easier to ask for help in future.

COVID-19 and your rights

Dr William Oosthuizen, *manager, SAMA Legal Department*

Healthcare workers on the frontline of the epidemic are at severe risk of exposure to the coronavirus. This could have serious adverse impacts on not only their health and wellbeing, but the health and wellbeing of any patients they treat, their loved ones and the public in general. In addition, healthcare workers who have been exposed to the virus will have to self-quarantine/isolate and refrain from providing much-needed care. Any sudden decrease in the number of available healthcare workers would be disastrous for our already overburdened healthcare system. We simply cannot afford to lose any capacity during this crisis. This is all the more reason to know the law, and comply with the available guidelines.

The Constitution

Section 24 of the Constitution states that “everyone has the right to an environment that is not harmful to their health or wellbeing.” This makes provision for the right to a safe working environment. In the healthcare context, it means that doctors and other healthcare workers should be reasonably protected, and measures need to be put in place to prevent them from contracting occupational and infectious diseases (such as COVID-19).

The Occupational Health and Safety Act

Section 8 of the Occupational Health and Safety Act No. 85 of 1993 (OHS Act) is concerned with the general duties that employers owe to their employees (in our case, healthcare workers). It states that “every employer shall provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risk to the health of his [sic] employees.”

Employers must:

- provide a safe working environment that is without risk to the health of employees;
- organise work, equipment and machinery in such a way that employees are safe;
- provide information and training so that people are aware of risks to health and safety;
- make sure that work is properly supervised;
- enforce necessary health and safety measures;

- inform workers and supervisors about the roles they must play in controlling health and safety problems; and
- ensure the physical safety of their workers while on duty.

A comprehensive approach ... will be vital to ensure that healthcare workers receive protection

Unfortunately, the occupational health and safety rights of healthcare workers are often neglected. Consequently, healthcare workers are often forced to provide health services under hazardous conditions, and to neglect their own health and safety.

It is imperative that heads of department comply with the OHS Act and regulations to protect the wellbeing of the healthcare system’s most valuable asset in this fight against the virus.

In terms of the OHS Act, a worker should report an incident of occupational exposure to the employer or the health and safety representative. Unsafe conditions should be reported to the health and safety representative.

If health and safety concerns are not adequately dealt with in the workplace, complaints can be submitted to the chief inspector at the Department of Labour.

Please alert SAMA too!

The risk of exposure to health hazards is exacerbated by the poor working conditions that healthcare workers often face. Overcrowding, poor ventilation, negligent waste disposal methods, staff shortages, unhygienic environments, aging and poorly maintained infrastructure, and the inadequate supply and use of personal protective equipment (PPE) all contribute to the problem.

The absence of proper PPE could have especially dire consequences for individuals and for the healthcare system as a whole.

The National Health Act

The National Health Act No. 61 of 2003, read with the regulations, also seeks to promote and protect the health and safety of healthcare workers.

Regulation 8 of the norms and standards regulations expressly provides that a “health establishment must maintain an environment [that] minimises the risk of disease outbreaks, [and] the transmission of infection to users, healthcare personnel and visitors”.

It goes on to state that health establishments must:

- ensure that there are handwashing facilities in every service area;
- provide isolation units or cubicles where users with contagious infections can be accommodated;
- ensure that there is clean linen to meet the needs of users; and
- ensure that healthcare personnel are protected from acquiring infections through the use of personal protective equipment and prophylactic immunisations.

Regulation 20 also obliges healthcare establishments to comply with the requirements of the OHS Act.

In addition, regulations relating to the surveillance and control of notifiable medical conditions must also be adhered to at all levels of care.

Conclusion

Healthcare workers are called upon to put their own safety and wellbeing at risk to look after the sick during these trying times. All of us need to do our part to look after healthcare workers themselves. Employers must comply with their statutory obligations. A comprehensive approach, inclusive of adequate infection control programmes, prioritised testing, environmental controls and the provision of proper PPE, will be vital if employers are to ensure that healthcare workers receive the protection they are entitled to.

However, it is not only employers who have a duty towards healthcare workers on the frontline. We must all do our part during these trying times – stay home and self-isolate. Look after those looking after us.

NHI: A stakeholder submission analysis

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

SAMA recently submitted its input to the parliamentary committee on the National Health Insurance (NHI) Bill, which was gazetted on 8 August 2019.

Overall, 17 submissions made to Parliament by various stakeholders were analysed and compared with SAMA's submission. We look at the main concerns and recommendations found across these submissions. Submissions came from civil society groups, other medical societies and policy think-tanks, and many are publicly available.

This is a work in progress, and SAMA is continuing to collect additional submissions to get a view of the opportunities and challenges posed by the Bill, as well as gathering other feasible ideas in support of implementation of universal health coverage (UHC) in SA.

Common themes and issues

Virtually all submissions set out similar views to SAMA, in support of the achievement of UHC for the country. Many also did not object to an NHI as the mechanism. However, all submissions raised significant concerns with the NHI Bill itself, as it has been presented to Parliament.

Most submissions were, overall, positive about the intention, if critical of the specifics of the proposed reforms. Many included offers of engagement and assistance, even while expressing reservations about the proposals.

There was concern expressed about the ability to implement the proposed NHI reforms. Lack of evidence-based examples in the Bill for the implementation of such a health insurance scheme raised concerns regarding the resources that SA currently has (e.g. financial eligibility and necessary human resources).

Addressing the potential for corruption within the healthcare system under a centralised system was of major concern, with most stakeholders pointing out a number of areas where fraud and corruption could become rife in such a large entity.

Governance concerns were raised surrounding the significant powers afforded to the Minister of Health, as all top-level decision-making functions are effectively appointed by and report to the Minister of Health. This includes the board of directors and the CEO of the NHI Fund, as well as the

various ministerial committees that will be set up to regulate prices, benefits and other matters.

There is a great deal of uncertainty regarding the contracting arrangements with hospitals and specialists, and whether doctors will be employed by hospitals. Failure to test these contract and capitation mechanisms only adds to the uncertainty of healthcare professionals. Private practitioners raised concerns regarding reimbursement timelines, as they need a steady cash flow for their practices to survive (e.g. for rental payments, staff salaries, taxes, etc.).

The NHI Bill in its current form is not supported

As was pointed out in SAMA's submission, several stakeholders also commented that the proposals in the Bill lack real-life evidence of success. No costing or feasibility studies were published, and no assessment was done on UHC provision in other countries at a similar stage of development.

Quality concerns featured in most submissions, with most stakeholders concerned that the Bill lacks emphasis on the assessment and maintenance of quality of care. Major quality concerns were identified, including: gaps in ethical leadership, management, and governance; health information system gaps; and fragmentation and limited impact of the quality of care initiatives. A number of stakeholders also highlighted the current limited capacity of the Office of Health Standards Compliance (OHSC), and recommended that this be substantially strengthened.

Civil society and advocacy groups highlighted the plight of asylum seekers and undocumented migrants, for whom the Bill offers limited coverage.

Although the SAMA submission stated that modelling the need for and cost of adequate human resources (HR) for health was of paramount importance in planning in SA, relatively few submissions directly highlighted this as a challenge to the NHI. Most references to HR capacity were with regard to the OHSC.

Several stakeholders asked for more clarity on the role of the private sector, as well as integration plans at district and municipal levels. Stakeholders were divided on the private sector, some believing that it will play a pivotal role in supporting NHI, while others warned of its profiteering nature.

The role of complementary cover by medical schemes and private health insurance, and issues regarding public procurement of healthcare services, medicines, health goods and health-related products were noted as remaining unclear.

The NHI Bill proposes changes to other legislative documents, which will have significant impacts. These documents include: the National Health Act No. 61 of 2003; the Occupational Diseases in Mines and Works Act No. 78 of 1973; the Compensation for Occupational Injuries and Disease Act No. 130 of 1993; the Medicines and Related Substances Act No. 101 of 1965; and the Competition Act No. 89 of 1998.

There were concerns raised regarding the limited reference to medicolegal liability in the Bill. While provinces currently accept liability on behalf of all employees, the NHI model removes specialised, regional, central and tertiary hospitals from the provincial sphere. There is no indication whether the NHI Fund will accept any such liability, or will include medicolegal insurance as a cost component in both state and private facility fees.

Recommendations

Based on the concerns raised throughout the reviewed submissions, the following overlapping recommendations were made:

- that an oversight function is established to monitor the activities and finances of the Fund, and the appointment and accountability of the NHI Board, which is to include parliamentary and other stakeholders, to avoid undue political influence;
- that the initiatives in their infancy in the public and private sector be carefully followed in terms of their impacts and outcomes, and their ability to actually deal with corrupt and fraudulent activities before the proposed centralised structures are signed into law;
- that the proposed payment mechanisms are adequately piloted before they are included in an Act of law or any regulation,

- and that other alternative reimbursement mechanisms be sought, and properly investigated (e.g. pay-for-performance);
- that a funding model for academic/training posts needs to be considered urgently;
- that a costing document be published for clarification on the current basket-of-services costs to be delivered to patients receiving the services on a "per-service" basis;
- that quality outcomes be incorporated into cost-efficient contracting models for specialists;
- that the possibility of a public-private partnership in the health sector be investigated;
- that an inventory of resources (physical, medical, administrative and managerial) be compiled;

- that treatment guidelines be set in accordance with the recommendations of the Health Market Inquiry (HMI), and that the comprehensive reform framework recommended by the HMI be fully implemented; and
- that bioethicists be appointed to provide expertise regarding decision-making in the NHI, especially relating to the clauses that limit access to services provided to any and all vulnerable groups within SA, highlighting asylum seekers and undocumented migrants.

Conclusion

In the group of stakeholders analysed, all recognised the huge potential of the policy of progressive realisation of UHC to influence

the delivery of equitable, quality, affordable and safe healthcare in SA. Many are also not opposed to the NHI as a funding mechanism. However, it was a general finding in the submissions analysed that the NHI Bill in its current form is not supported. Many of the concerns raised are going to be difficult to address in the short term, and can certainly not easily be addressed before the Bill is scheduled to be considered in Parliament (although, given the current COVID-19 outbreak, much other work has been put on hold). The recommendations require a good deal of progressive work to be put in to the system, as is the nature of the movement towards UHC, and may all involve complex solutions, alongside significant time and investment.

SAMAREC begins the decade with a new tradition

Adri van der Walt, SAMAREC officer

The SAMA Research Ethics Committee (SAMAREC) was established in 1992 to evaluate the ethics of research protocols developed for clinical trials to be conducted in the private healthcare sector. In terms of national and international regulatory requirements, all health research involving human participants must undergo an independent ethics review. The National Health Act No. 62 of 2003, as amended, provides for the establishment of a National Health Research Ethics Council (NHREC) with which all research ethics committees are required to be registered.

SAMAREC was audited in 2018 by the NHREC and was re-registered as a human ethics committee the very same year.

At the first SAMAREC meeting of 2020, held in February, a photograph of the SAMAREC committee was taken. As noted by Dr Marcelle Groenewald, a founding and still active member, and vice chairperson of the committee, this notes a historic moment in SAMAREC history, as this was the first known photograph ever to be taken of the entire committee. This is something we trust will be done in future as well.

SAMAREC is proud to comply with the NHREC requirements for the composition of the committee. This compliance can be seen from their qualifications, and the descriptions of the committee members.

Prof. Jacques Snyman: MB ChB, M Pharm Med, MD; chairperson and SAMA member; pharmacologist



SAMAREC committee. Back, left to right: Tanya Coetzee, Wendy Massangaie, Mark le Roux, Brenda Fineberg, Thabo Lengana. Front: Marcelle Groenewald (vice-chairperson), Jacques Snyman (chairperson), Mandisa Kakaza, Ulundi Behrtel

Dr Marcelle Groenewald: MB ChB, DCH (SA), PG Dip Int Res Ethics; vice chairperson and SAMA member; general practitioner

Prof. Mandisa Kakaza: MB ChB, MMed (Neuro); SAMA member; specialist neurologist

Ms Ulundi Behrtel: BLC, LLB, Cert Med Law, PG Dip Int Res Ethics; attorney

Ms Tanya Coetzee: PG Dip (Health Res Ethics), M Phil (Applied Ethics); research integrity officer

Ms Wendy Massangaie: LLB Cert Med Negligence Health Sector Mediation; attorney

Mr Mark le Roux: BTh, MDiv; legal secretary

Ms Brenda Fineberg: BSc (Hons); HDE; educator

Dr Thabo Lengana: MB BCh, MSc Med (Bioethics Health Law), FCNP (SA), MMed (Nuclear Med); SAMA member; specialist nuclear physician

Should you have any queries regarding the committee please feel free to contact the secretariat at samarec@samedial.org.

COVID-19 medicolegal dilemmas in SA

Medical Protection Society

Dr Graham Howarth, head of medical services, Africa, at the Medical Protection Society (MPS), advises on some medicolegal dilemmas faced by healthcare professionals managing COVID-19 in SA. This guidance was up to date at the time of writing (27 March).

The HPCSA has issued new guidance on the application of telemedicine.

Q: I am having to do increasingly more remote consultations – is there any advice, and how does this affect my indemnity?

A: The use of telemedicine has been advocated, including by the SA president, as one of the ways of delivering healthcare during the crisis. At the time of writing, the HPCSA had issued updated guidance on the application of telemedicine during the COVID-19 pandemic.

This new guidance states:

- Telemedicine is replaced by “telehealth”, which includes telemedicine, telepsychology, telepsychiatry and telerehabilitation.
- Telehealth is only permissible where there is an already established practitioner-patient relationship. The only exception is for telepsychology, in which telehealth is permissible without an established practitioner-patient relationship.
- Practitioners may charge a fee for telehealth services.
- Where practitioners are in doubt as to whether a telehealth consultation will be in the best interests of the patient, they are encouraged to advise patients to present themselves for a face-to-face consultation to seek assistance at the healthcare facility closest to them.

These guidelines are only applicable during the COVID-19 pandemic, and the HPCSA will inform practitioners when they cease to apply.

We recognise that this is an extremely challenging time for all healthcare professionals, and MPS is here to support you. The treatment of patients is of paramount importance, and we want you to be able to deliver this in a safe and effective way.

MPS has published advice relating to practicing telemedicine in response to the crisis. Visit www.medicalprotection.org to read about COVID-19 and remote consultations – how we can help.

If you are undertaking a remote consultation:

When considering a remote consultation, you should weigh up whether you can adequately assess the patient remotely. If you have doubts, you should recommend the most appropriate route for the patient to seek medical assistance, in accordance with local public health/government guidance.

Where face-to-face consultations are not feasible, you need to be satisfied that proceeding in this way is in the patient's best interests, and that you can adequately assess the patient remotely. You should document that you have undertaken this consideration in the clinical records. Unless there are exceptional circumstances, it is preferable that remote consultations will relate to patients already known to you, or where you have access to their full medical records.

During any remote consultation, both doctor and patient should be able to reliably identify each other. If a face-to-face consultation is preferred, but not possible, then you should inform the patient of this and explain why you have, on this occasion, pursued a teleconsultation.

In cases of emergency, patients should be encouraged to seek assistance via the recommended route, in accordance with the most recent government and/or public health guidance.

Practising safely, and your indemnity position: In all remote consultation situations, it is your responsibility to ensure that you practise in accordance with any applicable laws and regulations around the diagnosis, treatment, prescription and provision of medication to patients.

If the patient is not able to access local, face-to-face medical advice due to quarantine protocols, and you are satisfied that this is the case and have documented this rationale, then you will be able to request assistance from MPS for incidents that arise from the consultation, where the complaints or claims are brought in SA (the jurisdiction in which you hold your membership).

However, you should be aware that you will not be able to seek assistance from MPS for remote consultations undertaken with a new patient in another country.

Further information can also be found on www.medicalprotection.org, including

advice on remote consultation with an existing patient in another country, remote consultation with a new patient in the same country as you, and your indemnity position.

Q: Do I have to see patients if I do not have adequate PPE?

A: The WHO advises that provision of appropriate personal protective equipment (PPE) supplies should be an institutional priority for infection prevention and control measures for healthcare workers caring for suspected COVID-19 patients. Your own health is important, and regulators in other jurisdictions have reminded doctors of their ethical duty of self-care in order to protect themselves, their colleagues and their patients.

SAMA has advised members not to see patients if they do not have sufficient equipment to protect against COVID-19. They advise doctors, where possible, to carry out a teleconsultation for COVID-19 patients, in order to lessen the risk to staff and other patients.

If you have pre-existing health conditions that place you at increased risk of infection, you should discuss working arrangements with colleagues or your employer. It may be appropriate to ask a suitably qualified clinician to take over care of COVID-19 patients.

Q: If the government co-opts private hospitals for state patients, will I be indemnified for treatment carried out while working in this hospital?

A: Our expectation is that the state will indemnify members treating public patients, even if private hospitals are being utilised to provide the care. MPS will of course provide advice and representation for non-claims matters (e.g. HPCSA matters, inquests, complaints, reports, etc.) arising from this work.

Doctors will face enormous challenges in the months ahead, and we will work with the government to ensure that there is clarity on indemnity arrangements, which will allow doctors to focus on treating patients.

Q: I'm concerned I will be required to undertake duties outside my specialty or expertise. What is the advice, and what are the indemnity arrangements?

A: It is highly likely that many clinicians will be asked to support the response by performing duties they would not normally undertake.

Many state-employed doctors may also have an employment contract stipulating that they are obliged to follow reasonable instructions, which could extend to seeing emergency patients even if outside the scope of their specialty.

If a doctor is asked to perform a duty that they would not normally undertake, they need to assess whether they feel they have the skills and competence to proceed. This will include considering what is in the best interests of the patient. If they do not feel that it is safe to proceed, and that to do so will place the patient at greater risk of harm than not undertaking the duty requested, then they should advise whoever has asked them to do so of this, and explain their concerns.

Our advice is to record the details of this deliberation in case it becomes necessary to explain the reasoning behind the decision.

If MPS members have any concerns about the duties that they are currently performing to help manage COVID-19, they can contact us for advice.

Q: Can I decline if I am asked to work beyond my clinical competence? If so, how?

A: Doctors should make patient care their first concern. In the national State of Disaster, the expectation is that all doctors will do the best they can for their patients in the circumstances in which they find themselves, and act in good faith.

If a doctor believes that (s)he is being asked to work in a way that is placing patients at risk of harm, (s)he should raise these concerns by following workplace policy and the HPCSA's guidance. When deciding how to

act, doctors must consider the best interests of their patients, and be prepared to explain and justify their decisions and actions.

Q: I anticipate that my clinic/hospital, like many, will not have sufficient resources (for example, ventilators and ICU beds) to treat all patients at the peak of the outbreak. What clinical decisions should I make to best treat patients?

A: We appreciate that this is the most challenging calling for any health professional. As in any crisis, doctors should make patient care their first concern. The expectation is that all doctors will do the best they can for their patients in the circumstances in which they find themselves, and act in good faith.

The National Department of Health and National Institute for Communicable Diseases have developed clinical guidelines and FAQs. Doctors are encouraged to check for updated guidance.

When faced with challenging clinical decisions, doctors should continue to familiarise themselves with existing protocols, get a second opinion about diagnosis and treatment options and document their decision-making process.

Q: I'm worried that my working conditions and environment during this crisis may be unsafe. How can I protect my own health, and protect myself from potential errors resulting from these circumstances?

A: If you work in a large organisation, it would be wise to discuss the contingency plans that are in place, so that everyone has a clear understanding of the risks and procedures in place to protect staff.

Your own health, and that of your family, is important, and regulators in other jurisdictions have reminded doctors of their ethical duty of self-care in order to protect themselves, their colleagues and their patients.

There is a high risk that systems in the healthcare sector – already under pressure – may fail to cope, or break down. If you are worried that patient safety or care may be compromised you should raise your concerns with other clinicians in order to agree the best course of action to ensure the best care for patients.

Doctors should record any concerns in writing, setting out reasons for their concerns, and any potential impact on patient safety. Keep a record of any discussions about the problems you have raised and the steps that you have taken to try to remedy matters.

Here to help

With the continued spread of COVID-19, we know that this is a worrying time for everyone, but particularly for those healthcare practitioners who are providing frontline services and advice to patients. We understand your concerns, and are here to offer support and advice if you need it.

Medical Protection's website (www.medicalprotection.org) includes information on how to contact us, and will be updated with any further guidance as the situation changes.

The response to COVID-19 is rapidly changing, and we encourage you to visit www.medicalprotection.org to check the latest guidance

Managing clinical trials during the COVID-19 crisis

Adri van der Walt, SAMAREC officer

Self-isolation, travel restrictions and delivery of essential services only are major features in our current reality. As necessary as these measures have been during the COVID-19 crisis, the clinical research industry worldwide, and in SA, has also been effected.

In the management of clinical trials in SA during this pandemic, the SA Health Products Regulatory Authority (SAHPRA) has issued a policy on the conduct of clinical trials of

health products during the current COVID-19 pandemic.

A link to the full policy can be found at http://www.sahpra.org.za/wp-content/uploads/2020/03/SAHPRA-Communication_COVID_19-Final-25032020.pdf.

In summary, the policy addresses the following matters.

Amendments to protocols: An unavoidable measure that has had to be imple-

mented regards amendments to existing approved protocols. Measures to, where possible, reschedule protocol-mandated visits, data collection and investigational product challenges (be that the distribution to the patient or the actual availability of the product) need to be clearly described in the amended protocol. The amendment, with the necessary infection prevention measures to be implemented, will naturally depend

on the study design, study population and the infrastructure used where the study is conducted.

Safety of participants/patients: “Sponsors should consider each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly.”

Safety precautions for trial staff: It is crucial that all study staff adhere to basic infection prevention practices. However, the additional measures to control COVID-19 (as described by the National Department of Health and the WHO) must also be adhered to.

In-study informed consent: As stated above, protocols will have to be amended to include the required measures to be taken to reduce the spread of COVID-19. As with any amendment to the protocols, approval from the regulatory authority (SAHPRA) as well as the applicable ethics committee must be obtained. Where applicable, the amendment changes must also be incorporated into the patient information and informed consent documents. These patient-facing documents must then also be approved by the aforementioned

regulatory bodies, so as to ensure continued patient safety and transparency.

Impact of social distancing measures on study logistics: Alternative feasible measures must be taken to ensure that social distance is maintained, while also ensuring that data collection integrity is upheld. The logistics of in-person visits for trial-related procedures will depend on study specifics. As such, means of compliance with social distancing measures need to be determined by the sponsor and the principal investigator.

Impact of social distancing measures on participant monitoring: It is essential that participants/patients are continuously monitored, whether they are receiving the investigational product or not (due to withdrawal or secession of the study). Passive or remote monitoring programmes are imperative.

Record of in-study protocol deviations: The matter of various protocol deviations is a very real concern. Missed visits, inability to obtain the investigator product and challenges around attending face-to-face study visits have and will all lead to protocol deviations. These must be reported (and described in the

context of the current pandemic) to SAHPRA as well as to the applicable ethics committee. Statistical analysis plans should be in place on the way protocol deviations related to COVID-19 will be handled during analysis.

Investigational and other product administration: Due to social distancing measures, SAHPRA encourages sponsors to plan for alternative administration (e.g. home nursing or alternative sites). Existing regulatory requirements and accountability of investigational products must continue to be applied and documented.

Conclusion

The policy states that “robust efforts by sponsors, principal investigators and research ethics committees to maintain the safety of trial participants and study data integrity are expected, and such efforts should be documented.”

For any further queries, kindly contact Ms K Malatji (kedibone.malatji@sahpra.org.za) or Ms D Thosago (dominicah.thosago@shapra.org.za). You are also welcome to contact the SAMAREC secretariat at samarec@samedical.org.

Dr Lindsay Demes – at home and abroad

SAMA Communications Department

In April 2020, Dr Lindsay Demes joined the Doctors Without Borders/Médecins Sans Frontières (MSF) team in Johannesburg as part of the national response to the COVID-19 outbreak. “We’ve been assessing the needs in mostly smaller primary healthcare clinics, as well as in homeless shelters,” he tells us. “A lot of the smaller clinics are already well prepared but, as we see wherever we go with MSF, there are gaps and things that can be improved – and hopefully we can work on those.”

“SA doctors are taught to think on their feet from a very early stage,” says Dr Demes, “but where MSF works, things are even more difficult, so we have to find different ways of working.”

Prior to working in the COVID-19 response, Dr Demes found himself thrown into the middle of a measles outbreak in South Sudan. In 2019, the Cape Town doctor spent 7 months working with MSF in Maban county, an isolated area near the South Sudanese border with Sudan. This was his second assignment with MSF. Maban is home to thousands of refugees and internally displaced

people who often face additional challenges such as serious flooding, as the camps were constructed on a natural flood plain.

On routine days, Dr Demes would review the most critically ill patients with the medical staff, discuss optimisation of prescriptions and engage in bedside teaching related to the patient conditions. Most afternoons were filled with further staff training.

On not-so-ordinary days, he faced more daunting challenges, such as the measles outbreak. “On one Friday evening we received three patients presenting with measles,” Dr Demes explains. “Within 30 minutes of the patients arriving, about 12 colleagues arrived from the compound and worked late into the night to set up an isolation ward with a 30-bed capacity. It really shows the amazing teamwork we have at MSF.”

Another highlight was the running of a crucial measles vaccination campaign to reach 7 000 children aged between 6 months and 15 years old. “In some places, the villages were



Dr Lindsay Demes ©MSF

only accessible using quad bikes, which meant that we had to pack the bikes with the day’s supplies and set out early in the morning and start vaccinating, often under a tree.”

While working for MSF was always something he’d considered, Dr Demes didn’t expect to do more than one assignment. “I



A vaccination campaign in Maban, South Sudan ©Corinne Baker

thought I would try MSF to see if it was for me, and now I'm awaiting my third international assignment. It's something that I absolutely love," he said. "You have people from so many different backgrounds, bringing something different to the table each time. So, when you

have to brainstorm how to solve a problem, you have people offering advice and opinions you would never think of yourself."

MSF teams in SA and around the world are reorienting their activities and taking on extra responsibilities to prepare for and respond

to COVID-19, while keeping essential MSF existing services running. In southern Africa, they are supporting the response through contact tracing, health promotion, *ad hoc* assistance to clinics and health authorities and, in particular contexts, patient care. In Khayelitsha in the Western Cape, MSF is spearheading community screening and taking swabs on behalf of the National Department of Health.

During this unprecedented crisis MSF wishes to send a message of solidarity and encouragement to all our fellow healthcare workers. MSF wishes to thank you for your dedication and commitment to the health and welfare of all people in our global community.

Doctors on Call – establishing a coronavirus helpline

SAMA Communications Department

COVID-19 is in SA, and if we follow the path of other countries, such as Italy and France, then we can expect the prevalence of COVID-19 to escalate very quickly over the next 1 - 2 months, as the epidemic management principals are given time to "flatten the curve".

In addition to the highly infectious nature of the virus, the pathogen also threatens to topple our entire health system, social infrastructure and national economy. The National Institute for Communicable Diseases (NICD) has implemented strict guidelines, which include a defined diagnostic protocol, a clinical management algorithm and a reporting framework.

The NICD has also recommended that concerned members of the public contact their doctors first if they suspect infection, rather than present at their surgeries, clinics or emergency rooms. Many people, particularly the uninsured and vulnerable groups, do not have direct access to a doctor, hence they are at greater risk of exposure and becoming destitute.

Doctors on Call

One of the largest doctor associations in SA, the KwaZulu-Natal (KZN) Doctors Healthcare Coalition (KZNDHC), in partnership with Usizo Advisory Solutions and Vula, is providing a not-for-profit COVID-19 helpline, Doctors on Call,

operating during the hours of 08h00 - 17h00, Monday - Friday.

Although the project started in KZN, it grew rapidly. The line is now manned by a dedicated community of over 450 trained doctors from around the country, and new doctors join every day.

We need to enable access to doctors for vulnerable communities

Administered by a local call centre, all calls are received by a trained call centre agent, screened and then routed to a doctor-on-call, for advice related to COVID-19. Callers only pay for a normal phone call, and not for the discussion with the doctor. If a caller runs out of airtime, the doctors call back to ensure that the discussion is completed.

The doctor network receives prior training, and provides advice according to the NICD guidelines. All calls are documented and reported on. Referrals are made directly in the Vula app, which is linked to the NICD. The KZNDHC, together with Usizo and Vula, ensures that the programme abides by strict clinical protocols.

Within less than 3 weeks of starting operations, the programme is now taking up to 1 000 calls per day, many of which are referred to the line by national health agencies, concerned employer groups, vulnerable communities and anxious citizens from all nine provinces of SA.

Call to action

The group believes that defeating this epidemic will require unprecedented support from the private sector in SA. "Not only will this support demonstrate good corporate citizenship, but it will also contribute towards protecting our employees and customers and the sustainability of business in our country.

"The uninsured population in SA are the most vulnerable – they don't have access to a GP telephonically, and are forced to turn to a clinic system that is already overwhelmed. This group is unfortunately also more prone to rapid spread of infectious diseases, given the lack of social infrastructure.

"If we don't enable access to doctors for vulnerable communities, our already burdened system will be put under further pressure and may eventually collapse. Our lockdown will then possibly increase, decimating the economy even further with little hope of recovery, let alone the unquantifiable loss of lives. If ever there was a call for a change in mindset to become good citizens, this is it!"

All doctors around the country are invited to join the programme. Your support for this not-for-profit programme, Doctors on Call, could help flatten the curve, save our health system from being overwhelmed, protect our economy and save lives.

Way forward

For more information, please contact Dr Anuschka Coovadia (anuschka.coovadia@usizoas.co.za), Prof. Morgan Chetty (mncetty@iafrica) or Farzanah Mall (082 719 2285 or Farzanah.mall@usizoas.co.za) if you are interested in supporting this programme.

Doctors on Call helpline

If you have any coronavirus queries, call 087 0550 234 for free advice.

The appropriate place for rapid test kits

Dr Boitumelo Semete, *CEO, SAHPRA*

In line with the recommendation of the SA National Institute for Communicable Diseases (NICD) and the recommendations of the WHO, the SA Health Products Regulatory Authority (SAHPRA) wishes to point out that the so-called rapid test kits (serological test kits) that are being offered for the diagnosis of COVID-19 are not suitable for this purpose. They are not helpful in guiding decision-making regarding patient management or decisions around the need for quarantine, isolation or contact tracing. Serological tests are used for epidemiological surveys, but not for the diagnosis of acute infections.

Clarity on COVID-19

COVID-19 is the disease caused when a person is infected by the novel coronavirus called SARS-CoV-2. A test can be performed to determine if a person has been infected with the SARS-CoV-2 virus and has the COVID-19 disease. There are two types of tests that can be used:

- Molecular (or PCR) test: a test that detects the presence of the actual SARS-CoV-2 virus in your body, by detecting the genetic material of the actual virus. This test is done by taking a swab from your mouth or nose. This test is complicated, and needs to be done in a laboratory. The test can detect the virus even before a patient becomes unwell.
- Serological (or rapid) test: a test that detects whether your body has produced antibodies to the SARS-CoV-2 infection. This is done through a finger-prick blood test. It takes many days for the body to develop these antibodies, so people can already have the SARS-CoV-2 virus and be spreading the infection to other people before we can detect the antibodies.

Rapid test kits

Since the beginning of the COVID-19 pandemic, a number of manufacturers have developed tests that are referred to as serological, rapid or point-of-care (PoC) tests. They are sometimes referred to as IgG or IgM tests. These tests are

SAMA statement on rapid tests for COVID-19

SAMA and our partners have received numerous emails requesting advice on testing patients using the rapid point-of-care serological tests entering the country.

The current choice of detection method for the SARS-CoV-2 is by molecular detection with a PCR assay. All the laboratories in SA currently use this method for the detection of COVID-19.

There is still very limited information on the antibody response to COVID-19 in infected patients, and the timing of the formation of antibodies in infected individuals is still undefined.

Additionally, very little information is available and validated about the overall sensitivity and specificity of these tests, particularly where they have not been approved by any regulatory bodies.

However, we do know that antibody formation may be delayed following infection and even symptom presentation.

This may result in infected and symptomatic patients testing negative for COVID-19 early in the infection progression. COVID-19 remains a notifiable disease, so all confirmed cases are currently notifiable, and will require PCR testing whether they be negative or positive.

A negative test cannot be interpreted to mean that a symptomatic patient has not been infected.

According to the WHO: "Serological assays will play an important role in research and surveillance, but are not currently recommended for case detection" (see: <https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>).

SAMA urges its membership to recognise the extreme limitations of rapid testing in the clinical management of COVID-19 disease, and not to consider these tests appropriate for determining a patient's exposure history or potential immunity to the SARS-2 coronavirus.

not intended for diagnosis of acute infections, and should not be relied upon for self-testing, as they may be interpreted as meaning that someone is not infected with the virus when they are actually infected already. These tests are designed to be used under the direct supervision of a healthcare professional in epidemiological surveys.

"It is vital that all COVID-19 tests should be conducted by a healthcare professional and processed by a certified laboratory, to ensure accuracy of decision-making, treatment and advice. The healthcare professional can also decide on whether to alert the relevant health authorities and conduct contact tracing. This will ensure that authorities can trace infections and take action to stop further spread of the infection. The SA public is reminded that at this stage, the use of serological test kits is not recommended. The public is discouraged from using rapid (serological) test kits, or claiming

that you can test yourself at home or test yourself under the supervision of healthcare professional, to determine whether or not you have a COVID-19 infection. Furthermore, all tests and establishments manufacturing or distributing such tests should be licensed by SAHPRA.

SAHPRA has implemented an expedited licence process for new applications and amendments to current licences, in order to support the supply of medical devices that may be required in response to the COVID-19 pandemic.

SAHPRA appeals to the public to report to SAHPRA any company/individual/website selling COVID-19 rapid test kits, so that SAHPRA can take the necessary action in this regard. Please provide details to the Law Enforcement Unit (Ms Daphney Fafudi on 066 301 1878 or at Mokgadi.fafudi@sahpra.org.za).

Ethics of telemedicine in SA: Benefits and challenges

Brandon Ferlito, bioethics researcher, SAMA Knowledge Management, Research and Ethics Department



Globally, COVID-19 is crippling healthcare systems, and in SA, there is a high possibility that the virus could wreak havoc on our already dysfunctional and overwhelmed healthcare system. Telemedicine, also referred to as telehealth, is proving to be an effective public health strategy during the pandemic in countries in which it is being used, by responding “to the needs of [patients] who have contracted the virus and [to those] who need to touch base with their providers on the status of their health” (Siwicki, 2020).

In SA, telemedicine could make a very positive and progressive contribution to public health during the COVID-19 pandemic, and used in a variety of ways. However, telemedicine technologies and interventions present medical practitioners with particular ethical challenges when it comes to caring for and treating those infected by the virus, as well as patients with other ailments, during the pandemic. This article highlights some of the benefits and ethical challenges of telemedicine during the COVID-19 pandemic, as well as the role of regulators during this unprecedented time in SA’s history.

Telemedicine: Benefits

During the pandemic, telemedicine could emerge as an effective and workable solution for the prevention and treatment of COVID-19 in SA. It could bridge “the gap between people, [practitioners] and health systems, enabling everyone, especially symptomatic patients, to stay at home and communicate with [practitioners] through virtual channels, helping to reduce the spread of the virus to mass populations and the [healthcare] staff on the frontlines” (Siwicki, 2020). One of the most obvious and important benefits of telemedicine during the pandemic is the

minimisation of spread to healthcare workers and the general population.

In response to COVID-19, telemedicine is ideal for managing the many challenges facing healthcare practitioners. Challenges include exposure – telemedicine can mitigate and prevent overcrowding in hospitals, clinics and private rooms, “while providing the reassurance and guidance that patients are seeking” in terms of healthcare, which may reduce the burden on the healthcare system. Additionally, it may also prove to be useful “to address the ongoing healthcare needs of patients with chronic illnesses, to reduce in-person clinic visits” (Rockwell and Gilroy, 2020). Such uses of telemedicine would decrease human exposure between practitioners and patients to COVID-19 and a variety of other infectious diseases, and this could ensure that health supplies are reserved for those who need them.

Moreover, telemedicine may reduce the high demand for personal protective equipment (PPE). There is a global, chronic shortage of PPE, which the WHO has described as “one of the most urgent threats to our collective ability to save lives” (Rockwell and Gilroy, 2020).

Role of regulators

The role and immense power of regulators during pandemics such as COVID-19 should not be underestimated. In SA, the use and regulation of telemedicine is governed by the HPCSA. Booklet 10 of the HPCSA’s guidelines on telemedicine gives practitioners registered with the council rules on the use of telemedicine. Notably, rule 1.3. states: “All telemedicine services should involve a healthcare provider where there is an **actual face-to-face consultation and physical examination of the patient** [emphasis mine] in a clinical setting.” The key benefit of telemedicine for practitioners during the pandemic is to avoid face-to-face consultations, and thus reduce the spread of COVID-19.

Many practitioners and healthcare and membership organisations publicised their concerns with the HPCSA’s guidelines, and called for a relaxation of the guidelines during the pandemic. Although the HPCSA heeded their concerns and released a statement that seemingly relaxed the guidelines for the purpose of the pandemic only, the updated telemedicine guideline stated that telemedicine

“Telehealth should preferably be practised in circumstances where there is an already established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using telehealth provided that such consultations are done in the best clinical interest of patients.” *HPCSA updated guidelines, 3 April*

“is only permissible in circumstances where there is an already established practitioner-patient relationship.” This inferred that during the COVID-19 crisis, practitioners were still required to conduct a face-to-face consultation and physical examination of new patients, in order to establish a practitioner-patient relationship, which may assist in the spreading of the disease. SAMA, the Board of Healthcare Funders, the Health Funders Association, the SA Private Practitioners Forum, the SA Society of Anaesthesiologists, the United Forum of Family Practitioners and the IPA Foundation publicly called the updated guideline wrong and dangerous. Further, they claimed there was no rational basis for the guideline, and questioned “why [a practitioner would] need a prior relationship with a patient” during the pandemic.

Regulators and organisations worldwide, such as the Centers for Disease Control, have indicated that “telemedicine systems should be considered as part of healthcare provider coronavirus response systems.”

On 3 April, the HPCSA again updated its telemedicine guidelines, this time stating: “Telehealth should preferably be practised in circumstances where there is an already established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using telehealth provided that such consultations are done in the best clinical interest of patients.”

Ethical challenges

Although telemedicine can be a powerful tool for preventing and managing COVID-19 and other illnesses, there are ethical challenges that may present themselves to practitioners.

Hindrance by regulators: Even though practitioners can now practise telemedicine without having a prior relationship with a patient, the HPCSA failed to address the

concerns of practitioners timeously – during a crisis when time is literally of the essence. This failure has already had a ripple effect, as there have been media reports that some practitioners have refused to see patients physically, which creates an ethical dilemma of its own: are practitioners allowed to refuse to see patients, citing COVID-19 as a concern?

Not equipped for telemedicine: The reality in SA is that most practitioners, hospitals, clinics and patients are not equipped to utilise even the most basic services of telemedicine as an online consultation. Although “telemedicine hasn’t traditionally been used in response to public health crises” (Siwicky, 2020), COVID-19 seems to be changing this narrative. Even if practitioners were to be allowed to practise telemedicine in SA without the requirement of an established practitioner-patient relationship, who would provide the necessary services for telemedicine to be effective, especially for poor patients and patients in rural settings? There are other equally moral socioeconomic concerns to consider.

A lack of hardware: Practitioners, hospitals and clinics do not need especially powerful technology to practise telemedicine, but lack of infrastructure (WiFi, computers, separate telecom rooms, etc.), especially in the public sector, may be a cause for concern. Given that the state has a moral and legal duty to provide adequate healthcare services, within its available resources, telemedicine and its required infrastructure may not be a priority for policy-makers.

No compromise: Telemedicine practitioners should not compromise their ethical obligations when making use of such services. The same ethical and professional standards that apply during face-to-face consultations apply to telemedicine. Practitioners have a duty to act in the best interests of the wellbeing of the patient, respect the patient’s human rights and inform the patient of who will access their information and for what purpose, and what the implications of this are.



Respect for autonomy: For a patient to make an informed decision, patients need to be fully informed about telemedicine, and what it entails.

Informed consent: To achieve a meaningful and genuinely informed consent process, it is imperative that patients fully understand both the benefits and risks involved in the use of telemedicine. Blanket consent cannot be applied in the use and application of telemedicine.

Confidentiality: Practitioners should not breach patient confidentiality by sharing medical information with third parties without the patient’s consent to do so. The patient’s privacy should be respected at all times.

Non-maleficence/beneficence: The use of telemedicine should not harm patients. Similarly, the use of telemedicine should benefit patients and advance their interests.

Justice: Telemedicine has the potential to help the healthcare system to provide higher quality care to a larger number of people, thus making the system more equitable through improved efficiency and effectiveness, especially during times such as the COVID-19 pandemic.

Take-away points

Government and the HPCSA should ensure that their policies “incorporate telemedicine systems

Telemedicine may be used to avoid overwhelming health systems in general

to address some of the unique challenges posed by infectious disease outbreaks such as COVID-19” (Rockwell and Gilroy, 2020).

COVID-19 threatens to overwhelm the SA healthcare system. Telemedicine may be used to avoid overwhelming health systems in general, and to flatten the curve of COVID-19 infection.

Nonetheless, “there is a learning curve to using telemedicine in the traditional provider/patient relationship” (Siwicky, 2020). Practitioners should remember that in all circumstances, they must do their utmost to maintain the highest professional and ethical standards.

Disclaimer: The information in this article is correct at the time of writing (3 April 2020).

References available on request.

Lack of PPE and other controls concerning

SAMA Communications Department

SAMA says it notes with concern reports from many of its members in the public sector that they either do not have the correct personal protective equipment (PPE), or that the PPE is in short supply. Frontline

healthcare workers cannot be expected to place themselves at risk.

“This is an untenable situation. Frontline medical staff must be protected at all times. This is especially essential for those medical

practitioners treating patients with, or who are suspected of having, COVID-19. The reliable supply of proper PPE is simply non-negotiable, and SAMA demands that this happens,” says Dr Angelique Coetzee, chairperson of SAMA.

She says SA needs all of its doctors and healthcare workers to be safeguarded, as they are the most valuable resource in fighting the coronavirus. "Doctors and other healthcare workers cannot be expected to expose themselves to unreasonable risks, and provincial health departments and healthcare facilities have a legal, ethical and moral responsibility to protect healthcare workers who may be exposed to the coronavirus. MECs and heads of department must ensure that enough reliable masks, gloves, goggles and gowns are available at all times," she notes.

An added issue for many healthcare practitioners is that the facilities established

at several hospitals are not in line with recommendations for adequate administrative and environmental controls to protect staff from infection.

"Apart from the lack of reliable PPE, facilities that do not meet the required standards pose a severe risk to not only practitioners and patients, but also all their loved ones at home, and our entire overburdened healthcare system. We cannot afford to risk exposure, and for healthcare workers to become ill, or have to self-isolate, as a result thereof," says Dr Coetzee.

She says healthcare workers sitting at home, self-isolating, will not be able to provide

much-needed care, and the capacity of the healthcare system will face potential collapse. Dr Coetzee adds that members who are not furnished with adequate PPE proportionate to their risk of exposure should not be expected to render services that may endanger their lives and the lives of others.

"We advise doctors who do not have access to proper PPE to refrain from activities that may result in exposure. We also call on them to alert SAMA immediately if there is no, or limited access to, PPE, or if their facility does not meet the requirements for adequate administration and environmental controls," Dr Coetzee concludes.

Poor work performance and procedure

Simon Buthelezi, *employee relations advisor, SAMA Employee Relations Department*

In an employment contract, it is implied that the employee agrees to perform his/her work according to the employer's expectations. In this article, we will examine these expectations, the measures employers commonly resort to in order to manage them and the ways in which employees might fall short of them.

Definition

Poor work performance may be the result of either ill-health, or a lack of training, qualifications or experience. It is the latter that we will investigate here, as matters relating to ill-health are clearly outlined in the Code of Good Practice in the Labour Relations Act No. 66 of 1995.

Managing poor work performance

When an employee fails to reach and maintain the employer's stipulated work performance standards in terms of quantity and quality of output, this is of great concern to the employer. Such work standards should be lawful and attainable, and clearly defined and set by the employer. Should an employee fail to fulfil the requirements, this can be seen as either the result of misconduct, or otherwise of incapacity, and the employer has the right to resolve the issue by dismissing the employee, within well-defined boundaries of fairness both procedurally and substantively.

Separating misconduct from incapability

Although this may seem burdensome, the employer has a duty not to rush into dismissal, as there is a need to meticulously rule out possibilities such as alcohol or drug addiction, financial difficulties, or work- or home-related stress, as these should be dealt with through an employee assistance programme.

The employer may decide that the poor work performance is instead classified as misconduct, which may include insubordination. This is commonly seen when an employee has at a previous stage performed well, but has suddenly "gone off the rails" for no apparent reason. It is in such an instance that disciplinary action becomes applicable.

Generally, incapacity due to a lack of training, qualification or experience should have been established at the interview and selection stage. Poorly qualified candidates, or those who lack the inherent requirements to do the job, should be avoided, unless the employer intends to fully capacitate the employee, or in cases of learnership. Only suitably qualified candidates should be shortlisted, and even in the case of a learnership, it should be established that the candidate has a reasonable chance of success before employment is agreed upon – in other words, (s)he should possess the basic ability to perform the inherent requirements of the job, which can then be developed by further training.

Procedure

A case of incapacity results in what is seen as no-fault poor performance, and therefore the employee cannot be disciplined. Instead, the following steps must be followed in dealing with the matter:

- establish that the problem is not a result of misconduct
- identify the areas in which the employee is not performing as expected
- arrange a meeting with the employee to establish the causes of poor performance – this should be a two-way engagement, to obtain the employee's reasons for the poor performance and to explain the issues that concern the employer
- evaluate the employee's reasons for the poor performance
- obtain a commitment from the employee regarding the action to be taken to rectify the problem
- inform the employee of the action the employer will take to assist in this process, such as training, coaching and making necessary resources available to the employee
- agree on a reasonable time period for improvement
- follow up and monitor progress.

If all these steps fail, then a dismissal meeting should be held.

Forgotten blood test results: Forgotten patient

The Medical Protection Society shares a case report from their files

Baby L, a term baby with an unremarkable antenatal history, was brought to Dr W for a hepatitis B vaccination at around 6 weeks of age. The baby was noted to be mildly jaundiced.

On further questioning, the mother stated that the baby's stools were pale. Blood tests were taken, including a total bilirubin level and conjugated bilirubin level. Dr W advised the mother that she would be called if the blood test results were abnormal. Unfortunately, following a busy clinic, Dr W misplaced Baby L's details, so was unable to trace the results.

The results showed a total bilirubin of 110 $\mu\text{mol/L}$ and a conjugated bilirubin of 55 $\mu\text{mol/L}$. When the results were received at the practice, Dr W happened to accidentally mark them as normal, so they were automatically filed in Baby L's record without any further action being undertaken.

One month later, the baby's mother attended the surgery with her other child, and asked about Baby L's results. The abnormal bilirubin levels from 4 weeks ago were identified at this point. Bilirubin levels repeated that day showed a total of 124 $\mu\text{mol/L}$ and a conjugated level of 70 $\mu\text{mol/L}$.

Baby L was urgently referred to the local paediatric department for further assessment and management. He was diagnosed with biliary atresia and underwent a Kasai procedure 4 days later. The baby was 70 days old at the time. He made an initial good recovery, but 2 months later deteriorated and needed a liver transplant. He remained on immunosuppressants with an optimistic 10-year prognosis.

The parents of Baby L brought a claim against Dr W, alleging a failure to follow up and act on the first set of abnormal bilirubin results, leading to delayed diagnosis and management of biliary atresia. They claimed that as a result of the delay, the Kasai procedure had a suboptimal outcome, and so led to the need for a liver transplant.

Dr W contacted the Medical Protection Society (MPS) and requested assistance.

Expert opinion

The expert instructed by MPS was critical of Dr W's management, citing his loss of the baby's details, which meant he could not



follow up the blood test results – despite the advice he had provided to the mother – followed by signing off an abnormal set of results. These errors led to a delay in diagnosis, which was only circumvented by the mother asking about the results while in attendance at the practice for another reason. Expert opinion also found that a full liver panel should have been requested at the time of the original testing.

Expert opinion on causation concluded that the delayed diagnosis did not cause the need for a Kasai procedure, but the consensus was that early surgery (within the first 8 weeks of life – some even say the first 4 weeks) would have led to a better outcome. In addition, they noted that although a Kasai procedure can address biliary atresia in the short term (and eliminate the need for a transplant in up to 25% of patients), by the age of 20, some 70 - 80% of patients would need a liver transplant regardless. Thus on balance, they concluded that Baby L was more likely than not to have needed a liver transplant at some point in his life regardless. However, the early failure of the Kasai procedure had expedited this need and prolonged the time he would spend on immunosuppressants.

MPS settled the claim for a moderate amount.

A full liver panel should have been requested at the time of the original testing

Learning points

Clinicians can deal with hundreds of blood test results every day. Having a plan about which ones to follow up, and how these results might be communicated to the patient, is crucial.

Clear messages to patients about whether they will or will not hear about results is important. This plan should also be documented in the medical records.

A plan on handling normal and abnormal results is needed. Even normal results may require further action, let alone abnormal ones.

Be careful when reviewing results electronically, in case the wrong button is clicked and they are filed instead of actioned.

GPs: Dealing with COVID-19

Functioning during the COVID-19 pandemic lockdown has proven extremely challenging for general practitioners. We asked SAMA branches to share some feedback from their local GPs on how they are dealing with COVID-19 in their practices.

Western Cape

The following message from a practice in Cape Town was emailed to patients:

"When arriving at the practice, our doorman (wearing a mask) will check you in at your car. We have ensured staggered appointments so that everyone will be able to park outside our door. When your doctor is ready, you will be notified to go directly from your car to your doctor's rooms. Your doctor's consultation room chairs and surfaces will be sterilised after every consultation, and the doctor will wear a mask during examinations. On leaving, you can pay at reception if your card has a tap facility, otherwise we will email your invoice so that you can do an EFT. Anyone with respiratory symptoms, including those with concerns regarding COVID-19, will be booked in for a telephonic consult. Telephonic consults will be available for ailments that can be handled over the phone; however, we will not engage in email consults, and where we feel examination is essential will insist on patients coming to the rooms."

Gauteng North

Says **Dr Angelique Coetzee**, "We do triaging over the phone, and only patients are allowed into the surgery. Others have to wait outside in their car, under a tree or wherever they feel comfortable waiting. Only minor children with mothers are allowed. In the waiting room, all chairs are 1.5 m apart, with clear markings on the floor and in front of the reception desk.



Severely ill patients are asked to sit outside – our set-up allows for this. We regularly disinfect the area with bleach mixture on all chairs. There is a wash basin with soap and water for hand sanitising. There is only one chair in the examination room, 1.5 m from me, also clearly marked, and using the same disinfection procedure. Any respiratory patient must be in and out of the exam room in less than 8 minutes, followed by hand washing and also disinfecting of the stethoscope. If a patient is coughing in the exam room or the waiting room, tissues are provided to the patient. We don't have masks or gowns; therefore, social distancing and triaging are important."

Dr Julius Kunzmann says: "We removed chairs so that patients have to sit at least 1 m apart. A maximum of three people are allowed in the waiting room at a time if one is a child; otherwise only two are allowed. Everyone coming in through the doors must wash their hands with soap and water first, and dry them with a paper towel. Nobody stays in the examination room for more than 15 minutes. The doctor wears gloves and a normal surgical mask (N95 masks are unobtainable). There have been only two

people since 22 March who may have had reason to be tested. We chased them out in less than a minute, filled in request forms and told them to go home and self-isolate, and call NICD [the National Institute for Communicable Diseases] or me when they developed symptoms. One lost his fever in 2 days; the other had returned from the USA before President Ramaphosa made the first speech. This patient was not tested, and after 2 weeks had developed no symptoms.

Dr Pamela Bongeka Mathebula says: "My rooms are closed and I am only seeing emergency cases that come via casualty. Screening is done and everyone on duty wears a mask and gloves when they see a patient."

Central Gauteng

Dr Faruk Mahomed says: "We experienced something worth noting regarding COVID-19 in the past week at the practice: dishonesty on the part of patients who requested testing. A couple presented at our rooms and were found to be dishonest regarding their symptoms and contact history. Subsequent to that experience, we put up a notice in the rooms warning patients not to be dishonest."

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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
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- must be on subjects pertinent to healthcare delivery
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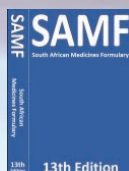
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