SASOP and the ketamine position statements

Dr Alan Howard, National Medical Director, KetaMIND *November 2024*

SASOP has issued three position statements since 2022[1] outlining their stance on a current hot topic; administration of low dose ketamine infusion for Treatment Resistant Depression (TRD).

TRD is itself an ill-conceived moniker, predicated on the now deconstructed conclusions of the STAR*D trial, which itself, of necessity, adopted the monoaminergic deficiency hypothesis as the only reasonable explanation for depression. In fairness, there has recently been some shift, and talk of a new term to replace TRD, namely 'Difficult to Treat Depression' has been suggested. Acknowledgement that the monoamine deficiency hypothesis is not the holy grail it once was, has become more widely accepted.

Of course, monoaminergic drugs will work extremely well for many depressed patients and will remain first line agents, except perhaps for newly presenting acute suicidality, when a treatment like ketamine can provide rapid relief as a safety net, while traditional ADs are concurrently prescribed. However their action occurs downstream of glutamate, the most ubiquitous neurotransmitter whose effects are rapidly triggered by ketamine infusion therapy (KIT).

I have now spent five years since opening the first of our seven national ketamine clinics in the KZN Midlands learning not only about ketamine, its remarkable mechanism of action and effects on depression and suicidality, but about the various attitudes, mindsets, and adoption rates amongst medical colleagues from a variety of disciplines. These range from excitement and a hunger to learn more about an agent with proven efficacy and safety, to out-of-hand dismissal bordering on ridicule, or simply adopting a contrary view as a default position. Consequently, when questionable positions (dare I say edicts) are embraced by funders without question, wider consultation, or research, depressed and suicidal patients are the ultimate losers, as accessibility to and affordability of ketamine infusion becomes increasingly unattainable.

Depression represents a major disease burden globally. Fourteen years ago, the WHO considered depression the leading cause of disability as measured by Years Lived with Disability (YLD), and the fourth leading contributor to the global burden of disease overall. Even as far back as 2010, depression was the second cause of Disability Adjusted Life Years (DALY) in the 15-44-year-old category[2]. It is now widely accepted that, particularly since COVID, depression, frequently with concomitant anxiety, is top of the pile.

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[1] https://www.sasop.co.za/position-statements

[2] Reddy MS. Depression: the disorder and the burden. Indian J Psychol Med. 2010 Jan;32(1):1-2. doi: 10.4103/0253-7176.70510. PMID: 21799550; PMCID: PMC3137804.

A survey in the UK six-years ago concluded that 40% of GP consultations back then related to mental health[3], and this burgeoning trend continues in South Africa as well.

SASOP has opined that only a specialist psychiatrist may diagnose TRD and refer a patient for ketamine infusion.

Why is it unacceptable for experienced general practitioners and clinical psychologists to recognize TRD in their patients and recommend KIT?

A few years ago, SASOP launched an initiative in conjunction with Discovery Health (and others) to offer updates and further training to selected general practitioners in recognizing and treating depression, and to follow up the outcomes. Why? Because depression is so prevalent and the need for early diagnosis and treatment so great that the very finite number of psychiatrists in private practice cannot possibly shoulder the burden. And why should they? Experienced general practitioners are as capable of diagnosing depression without psychiatric oversight, as they are heart failure and atrial fibrillation without a cardiologist, impetigo without a dermatologist, and an indirect hernia without a surgeon. In fact, by sheer force of numbers, more patients with depression are of necessity diagnosed and treated by general practitioners than psychiatrists. The problem is, once the GP has diagnosed the infarction or the hernia, the cardiologist and surgeon step in as the only ones with the skill set to place the stent and laparoscopically repair the hernia. However the psychiatrist generally cannot administer the ketamine infusion themselves.

The following are direct quotes from a senior, office-holding SASOP psychiatrist who recently hosted a webinar addressing a cross section of medical professionals on ketamine for depression:

"Treat depression optimally and aggressively and get our patients well."

"We're going to start moving it (ketamine infusion) down the algorithm." (ie: use it sooner in the course of the illness).

To treat something 'sooner and more aggressively' requires, as a start, more immediate access to the treatment, something denied patients if they are forced to endure lengthy waiting periods before a psychiatrist can diagnose TRD and recommend KIT.

The following are direct quotes from a former SASOP president:

"If Ketamine is more readily available it would be a very good choice if it is well controlled." (Referring to options for patients needing neuromodulation ie: TRD).

"Our view is that the quicker and earlier to get patients with MDD into remission, the better the eventual outcome and long-term prognosis, as the brain damage is time dependant and reduced if early treatment is initiated."

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[3] https://www.mind.org.uk/news-campaigns/news/40-of-all-gp-appointments-about-mental-health/

"Interestingly the treatment resistant group can already be predicted in the first 2 weeks (of traditional AD treatment after the primary diagnosis of MDD)."

"We see no reason why a patient must suffer with depression for more than 4 weeks if there was no response to antidepressants before another intervention like ketamine, ECT or TMS (neuromodulation) is started. Nobody would want a sore tooth for at least a month before surgery is decided upon, neither does the literature now view 1 month of suffering with depression as too short before alternative treatments are considered".

These are all very relevant comments but are clearly at odds with and cannot coexist alongside the dictates of SASOP's latest position statements if it proves impossible for a patient to secure an urgent consultation (often a first meeting, so lengthy of necessity) with a specialist psychiatrist.

So why is it that general practitioners can independently, and *ab initio* diagnose and treat depression, but are not considered able to recognize when the treatment is not helping? This stance is mystifying, particularly when the recognition of TRD, as per SASOP's own care pathway, utilizes a simple algorithmic approach that relies on a subjective score trend (PHQ-9) completed by the patient themselves before and during simple prescription of traditional antidepressants.

I listened to a senior SASOP office holder (a director) who was interviewed on a radio station recently and she stressed more than once how ketamine always had to be prescribed by a specialist psychiatrist and that there were unscrupulous ketamine clinics who would accept walk-in patients. The impression crafted for the interviewer and listeners was that between the extremes of ketamine on demand for 'walk-ins' and those referred exclusively after assessment and diagnosis by a specialist psychiatrist, no alternative options for appropriate diagnosis and referral could reasonably be interpolated.

Individuals who become addicted to the dissociative effects of ketamine after repeated recreational use will actively seek out the experience. Quite obviously, any clinic who entertains approaches from such patients would be grossly negligent, and we at KetaMIND will turn away such requests on principle.

However, the ethical tenet of respecting patient autonomy coupled with a diligently presented history of multiple failed trials of antidepressants, suicidal ideation, an appropriately high PHQ-9 score, and an accessible mental health support network during the treatment period, would collectively render failure to treat grossly negligent, given the evidence of ketamine's efficacy in such cases.

Some patients simply don't want to return to a particular psychiatrist or see a new one. Some simply can't secure an appointment soon enough. Studies have shown that patients, for the most part, want to be involved in the decision-making process where it impacts their own mental health. Many are extremely well informed and researched. Our doctors at KetaMIND (some with post-graduate diplomas in mental health, some very experienced general practitioners) have ready access to our care team (including psychiatrists) should they need advice, but we cannot, in good faith, deny treatment to desperate patients and their families for extended periods based solely on SASOP's position statements.

GP's and psychologists generally know patients and their personal circumstances more intimately than an infrequently visited psychiatrist and are arguably better placed to recognize worrying and subtle changes in mood and react to these. Suicidally depressed patients don't have the luxury of time to wait for an appointment with a psychiatrist (often several weeks). Emergency admission as a mechanism to achieve this access more immediately (assuming a bed is even available) is costly and often unnecessary if outpatient ketamine infusions are more readily accessible and funded.

If cardiologists decreed that GPs could not diagnose myocardial infarctions and surgeons said the same about cholecystitis, there would be an outcry as patients arrested and ruptured their gallbladders waiting for specialist diagnoses. Resistant depression, untreated, is potentially as fatal

Why is ketamine's safety not acknowledged and celebrated more?

"We don't have enough evidence for off-label use", "we don't have enough research available", "we are worried about addiction potential," "ketamine can cause serious bladder problems," are oft voiced concerns and grist for the misinformation mill.

Addiction potential

Concern for ketamine's addiction potential and side-effect profile is somewhat ironic coming amidst a genuine escalation in addictions to opioids and benzodiazepines, often triggered by prescription drugs and about which the level of concern is clearly disparate and much less vocal. GPs would not appear to be as restricted by position statements in their diagnoses of anxiety and insomnia and subsequent prescription of addictive benzodiazepines, as they are TRD and referral for far less addictive ketamine treatment.

It is not uncommon for our clinics to treat patients whose psychotropic smorgasbord cannot fit on one page of a script pad and whose desperation and enduring depression has finally led to their referral for ketamine. Several testimonials from such patients bemoan the fact that remission has escaped them, sometimes for years, while finding the side effects from ever increasing doses of monoaminergic agents, mood stabilizers and atypical antipsychotics intolerable.

A recent Sunday Times feature article on ketamine infusion for depression highlighted the extent of the disinformation perpetuated by self-proclaimed experts who are believed at face value by naïve journalists and, by extension, the public at large. The 'expert' advised the journalist that ketamine was a 'schedule 7 drug' in South Africa, thereby aligning it with methaqualone (Mandrax) and heroin! This was not fact checked by the paper and was incorporated not only within the article, but in the bold subheading.

Where schedule 5 drugs in South Africa are concerned (or class 3 drugs as determined by the DEA as having moderate to low potential for physical and psychological dependence) several display a significantly higher risk of addiction than ketamine. In fact, a deep dive into the physical addiction potential of intermittent, low dose, subanaesthetic ketamine for mood disorders will lead to the

conclusion that it simply doesn't exist. There is even evidence that low dose ketamine infusion may be a useful adjunct in the treatment of benzodiazepine withdrawal.[4]

'n' does matter when assessing risk and safety

Ketamine is unique in the sense that, while only repurposed for use as an antidepressant within the last decade or so, it does in fact have a tried and tested safety record of administration to many thousands of adults and children spanning over 50-years and at considerably higher doses than those used to treat depression. Ketamine finds itself firmly established in the WHO list of 50 most essential drugs[5] and is the most utilised procedural sedative, particularly in children, throughout both the first and third worlds.

Indeed, ketamine can be used repeatedly for painful procedures like burns dressings in both adults and children without the literature bemoaning subsequent addiction and dependency. There is a plethora of research in this regard. Even the formerly held concerns about ketamine raising intracranial pressure in the presence of traumatic brain injury (TBI), increasing risk of laryngospasm when conducting upper airway surgical procedures, and lowering seizure threshold have all been debunked. In fact, ketamine's neuroprotective attributes are now celebrated: It is used to treat status epilepticus in children, and I have personally used it frequently when intubating patients with TBI.

What detractors somewhat disingenuously fail to point out, is that, in all this published research, evidence of associated morbidity and mortality, adverse events, and addiction potential are conspicuous by their absence. Instead, they might say to interviewers and journalists: *"We simply don't have enough research available."* When what they mean is: *"I have not done enough research."*

By the time I opened the first of our ketamine clinics in the Natal Midlands in 2019, I had become extremely familiar with ketamine as an agent for use in drug assisted intubation (DAI) and I used it almost daily as a procedural sedative for painful procedures in the emergency department for both adults and children. In the first year that our flagship clinic opened, I personally administered over 1000-ketamine infusions without mishap. I have only seen laryngospasm twice. Both instances after bolused ketamine used for painful emergent procedures, and both reversed quickly with Larson's manouvre.

Throughout a ketamine infusion, it is not uncommon to see fluctuations in vital signs linked to anxiety caused by dissociation and synesthesia, as well as periods of relaxation and calm when pulse and respiratory rates moderate. The adrenergic or sympathetic surge seen often with bolused ketamine, is not a concern with titrated low doses and should not be considered a noteworthy risk of KIT, particularly in patients without any cardiovascular comorbidities. Several studies point to

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[4] Purcell K, Bianchi PW, Glenn D, Blakey B, Motov S. Ketamine: A Potential Adjunct for Severe Benzodiazepine Withdrawal. Cureus. 2021 Dec 2;13(12):e20114. doi: 10.7759/cureus.20114. PMID: 35003959; PMCID: PMC8723697

[5] WHO Model List of Essential Medicines - 23rd list, 2023

this and lead to the conclusion that, during sub-anaesthetic ketamine infusion, no event met the criteria for 'hypertensive emergency'.[6]

"Ketamine causes bladder problems." It certainly can, however the key contextual points often omitted (by design or ignorance) when this issue is raised, are 'chronic recreational use' and 'high doses'.

"Using ketamine at least three times a week over a period of two years has been shown to result in altered bladder function..."[7] (Underlined for emphasis).

Nevertheless, caution, even when administering low-dose infusions should be exercised and any history of cystitis, vesico-ureteric reflux or renal failure should be carefully evaluated and documented.

'n' does matter. How many times should a drug be administered for a certain indication without mishap before the agent and its posology could be considered 'safe'?

At our clinics alone, over 10 000 ketamine infusions have been administered safely over the past four years. This indisputable evidence of safety when low dose ketamine infusion is properly administered is seldom raised, let alone celebrated.

The first ever published naturalistic study out of South Africa

In February 2024 the first independently conducted research into the efficacy and safety of ketamine infusion for depression in Africa was published in the South African Journal of Psychiatry.[8] Having been approached by Prof Bonga Chiliza (former SASOP president) a few years ago, I made all the patient records and sequential PHQ-9 scores from our Hilton clinic available to his research team. After ethics approval, the outcomes and their conclusions were published in the SAJP.

The results among the 154-patients who collectively received over 860-ketamine infusions for depression were consistent with or exceeded other internationally conducted and published outcomes, with the authors concluding:

"Incorporating intravenous ketamine into the existing treatment regimens at a private clinic was associated with reduced acuteness of depression severity and suicidal ideation. This approach appeared safe and tolerable, showing no signs of abuse or dependence".

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[6] Yip R, Swainson J, Khullar A, McIntyre RS and Skoblenick K (2022) Intravenous ketamine for depression: A clinical discussion reconsidering best practices in acute hypertension management. Front. Psychiatry 13:1017504. doi: 10.3389/fpsyt.2022.1017504

[7] (Mak et al, 2011)

[8] Juby VM, Paruk S, Tomita M, Chiliza B. Ketamine for depressive symptoms: A retrospective chart review of a private ketamine clinic S Afr J Psychiat. 2024;30(0), a2176. https://doi.org/10.4102/ sajpsychiatry.v30i0.2176

We now have local data that should, reasonably, be included in any guidelines and position statements. We at KetaMIND would welcome ongoing collaboration, research, and a strengthening of ties with academia and SASOP.

Why is ketamine held to a different standard?

I have always believed that the standard by which ketamine is judged is disparate when compared with efficacy of other agents used to treat depression and suicidality. The bar always seems to be raised that little bit higher, and this is puzzling. Or maybe it shouldn't be.

Consistently, as evidenced by several metanalyses, suicidality reduces dramatically or remits in over 70% of patients after ketamine infusion. There is no other agent amongst myriad where this is the case. Yet ketamine remains in the background. Racemic ketamine cannot be monetized, and this, coupled with its incomparable efficacy raises concerns that those most in need are potentially denied rapid, relatively inexpensive access to an efficacious treatment.

It should be noted that esketamine nasal spray (shown to be about half as effective as the racemic infusion for treating depression)[9] is FDA approved and patented. Its cost prohibits availability in South Africa.

"The beneficial effect of a ketamine infusion is of short duration," I hear frequently. Absolutely. Ketamine is a treatment not a cure, which is equally true of every single other traditional or atypical agent prescribed to treat depression.

One wouldn't rubbish escitalopram, bupropion, or venalafaxine when, after 3 or 4 doses a patient hasn't been 'cured' of their depression or suicidality. So why apply a different standard to ketamine?

To effectively treat MDD, an induction series of six-infusions over two or three weeks is usually advised, and a tailored maintenance program (together with other agents and psychotherapy) is always recommended.

To belabour the infrequent, usually negligible, transient, and manageable side-effects of low-dose ketamine infusion in the face of significantly greater and more durable ones amongst other repeatedly prescribed agents, is surely unreasonable.

STAR*D and the monoaminergic deficiency hypothesis

There is a plethora of published evidence deconstructing the outcomes of STAR*D and proving that the reported *"sixty-seven percent effectiveness rate for antidepressant medication"* was based on

[9] Comparative efficacy of racemic ketamine and esketamine for depression: a systematic review and meta-analysis J Affect Disord. 2021 January 01; 278: 542–555. doi:10.1016/j.jad.2020.09.071.

scientific misconduct and what has been described as 'orchestrated psychiatric fraud.'[10] I urge anyone who has not yet researched this for themselves, to do so.

Double standards

Qualification and experience required to administer ketamine

Having worked as a Consultant in Emergency Medicine for 12-years in Ireland (2008-2019) tasked with *inter alia* recruitment of SHOs and registrars for posts in a large emergency department (many young South Africans), and having served on the faculty for Advanced Trauma Life Support (ATLS) in this country for over 25-years as a lecturer and examiner, I am in a position to comment on qualification and level of experience in junior doctors.

I recently registered for and sat through a one-hour webinar hosted by a psychiatrist serving in a senior position on a SASOP special interest group tasked with ketamine policy. She had recently opened her own ketamine clinic. She was at pains to emphasize her adherence to and steadfast support of the SASOP position statements on more than one occasion but it became apparent to me that perhaps a 'rules for thee but not for me' might apply.

SASOP's position statements stipulate that ketamine should only be administered by an anaesthesiologist or medical practitioner with a post graduate diploma in anaesthetics, alternatively described in the statements as an 'anaesthetically trained GP'.

Perusal of this psychiatrist's team of doctors engaged at her clinic to administer the ketamine and whose expertise is promoted on her website, and after checking the HPCSA register, reveals the following:

- The senior medical practitioner in this team has an MBChB and completed community service last year in January 2023. At time of writing, he had no post-graduate diploma in anaesthesiology or emergency medicine. He is promoted as having **'extensive experience in emergency medicine'** (a direct quote). Of further concern is the calculated appending of acronyms for several short courses behind his name to bolster the impression of 'super-qualification'. *Inter alia* 'FEC', which is a one-day UCT course open to doctors, nursing sisters and paramedics revising 'Fundamentals of Emergency Care'. Such short course certifications (like ACLS and ATLS) should only ever be mentioned within the body of a CV, bio, or resume and this hyperbole does not succeed in elevating qualification or experience to the level contemplated by SASOP or SASA in the position statements.

- The other four doctors in the psychiatrist's team tasked with administering the ketamine, completed community service in January this year (a few short months ago) and none has post graduate diplomas in anaesthesiology or emergency medicine. One young doctor is described as having a 'special interest in sedation'. Unfortunately, 'interest' does not bestow a level of competence and expertise that elevates a skill set to that required by

[10] Mad in America, Science, Psychiatry and Social Justice, Nov 7, 2024

SASA and espoused by SASOP.

While SASOP insists that diagnosis of TRD falls exclusively within the skillset of a psychiatrist, the dictates of SASA can apparently be adjusted when it comes to the competency and experience required to actually administer the ketamine.

The psychiatrist had an interesting response to a question from one of the 500-plus attendees after her webinar presentation as to whether a GP may administer ketamine in their rooms. After reiterating the experience and training required of a doctor to safely administer the ketamine she replied:

"Document that you have had some sort of communication with a psychiatrist."

SASOP's position statements also include the following clear directives:

"There is not sufficient evidence to support the use of IM Ketamine..."

"The recommended route of administration is ivi..."

and yet the psychiatrist in question openly offers intramuscular ketamine injections at her clinic, informing prospective patients of: *"Reliable and precise intramuscular injections for rapid and effective medication delivery"*.

SAHPRA

KetaMIND was formerly 'Ketamine Clinics of South Africa'. We were reported to SAHPRA for use of the word 'ketamine' in our name and in the public domain. What followed was a costly rebranding and entire remake of our website, patient information brochures, and clinic signage to avoid prosecution. A 'disclaimer and declaration' buffer had to be included within our website for medical professionals to access the literature section where, of necessity, 'ketamine' is mentioned within the text.

Fair play to whomever was responsible for reporting a breach of which we were not aware. In South Africa, medication with a scheduling status above '2' may not be mentioned by name in the public domain. We learned a valuable lesson yet it appeared, at the time, that SAHPRA had no intention of imposing this regulation on others, a regulation which SASOP now pertinently mentions in their position statement.

We furnished SAHPRA with evidence of and links to promotions by several fringe providers of ketamine who were brazenly advertising to the public in breach of this regulation. Nothing was done.

Irregular methods of administering ketamine are rife and contravene SASOP and SASA's guidelines, which only endorse infused or intranasal ketamine. These include nurses administering ketamine intramuscularly to a patient relaxing in a beanbag without monitoring, and ketamine, prescribed by a psychiatrist, but administered intravenously by an unsupervised nurse at a nurse-run general infusion clinic. The list goes on.

SASOP was repeatedly notified about all of this. There was never any meaningful response, let alone sanction.

Why is ketamine's efficacy for other mood disorders and conditions so often dismissed out of hand?

SASOP's latest position statement includes the following clause:

"SASOP … does not currently support the use of ketamine for psychiatric conditions other than Treatment Resistant Depression (TRD)".

It then, rather curiously, states a little later in the document:

"Off-label usage and prescription of ketamine for indications other than TRD, as well as the illegal usage or prescription of psychedelics within the clinical space, remain in contravention of the HPCSA ethical rules and the South African Law".

The first part of the sentence is inherently contradictory because the use of ketamine for TRD is, itself, 'off-label'. Does SASOP's position statement that ketamine may in fact be prescribed for TRD in certain circumstances somehow trump the HPCSA, SAHPRA and transcend South African Law?

"Off-label use of drugs is common, constituting up to one-third of all prescriptions for common drugs in the United States overall, and up to 97% of drug use in some patient populations".[11]

"Off-label use of antipsychotic drugs in adult patients, for example, approaches 75%, and in pediatric patients, off-label use of these drugs approaches a whopping 93%.[12]

How would the potential side effect profile of antipsychotics in children stack up against that of a few low-dose ketamine infusions? This is somewhat rhetorical given the abundance of published evidence confirming ketamine's safety profile in children, as alluded to previously.

I am absolutely opposed to brazen experimentation. Advice from MPS is very clear in this regard. MPS also acknowledges that: *"… off-label prescribing is pervasive, and we all have done it and continue to do so".*[13]

MPS offers sound advice in the form of bulleted points a practitioner should consider when prescribing off-label. Of particular relevance to ketamine infusion for TRD and suicidality, but also certain other indications, are the following three points, with my comment thereafter:

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[11] Van Norman GA. Off-Label Use vs Off-Label Marketing of Drugs: JACC Basic Transl Sci. 2023 Feb 27;8(2):224-233. doi: 10.1016/j.jacbts.2022.12.011. PMID: 36908673; PMCID: PMC9998554

[12] Bell J.S., Richards G.C. Off-label medicine use: ethics, practice and future directions. Aust J Gen Pract. 2021;50(5):329–331. doi: 10.31128/AJGP-08-20-5591.

[13] https://www.medicalprotection.org/southafrica/casebook-and-resources/medicolegal-articles-and-features/view/off-label-prescribing-rsa

- **What evidence can you offer regarding the safety of the drug?**
  Evidence of ketamine's safety in a controlled clinical environment is legion. It is indisputable across the age spectrum, and this safety profile has endured for more than half a century.

- **What registered alternatives did you consider?**
  For almost all of our patients it is a 'been there, done that' scenario. Most of their failed trials constitute multiple medications (both registered and off-label) prescribed by psychiatrists and GPs.

- **What did you discuss with the patient and where is it documented?**
  Recognizing and respecting patient autonomy in shared decision making and documenting their informed consent for an off-label agent is important. One wonders how often this is done when trazodone, for example, is prescribed for insomnia?

  "In fact, trazodone is one of the most prescribed treatments for chronic insomnia in general, despite the fact that it is being used off-label and limited data exist characterizing its efficacy and side-effect profile in the treatment of insomnia".[14]

There is a substantial body of evidence pointing to ketamine's efficacy for conditions on the anxiety spectrum like PTSD and OCD, as well as bipolar disorder and others. We have seen dramatic improvements in many patients, several of whom have written testimonials to the effect that nothing before ketamine had helped them.

It certainly won't work for every patient but, on balance, the potential benefit surely outweighs risk. The greater risk, perhaps, is continued polypharmacy, increasing doses, and mounting side effects.

"SASOP … does not currently support the use of ketamine for psychiatric conditions other than Treatment Resistant Depression (TRD)". (Extracted from a position statement).

Yet, the aforementioned senior SASOP psychiatrist who has launched her own ketamine infusion clinic and presented a CPD-accredited webinar recently had the following to say to the 500-plus attendees about ketamine for indications other than TRD:

"We individualize" (when considering ketamine for indications like PTSD, OCD, eating disorders, substance abuse).

"Give a patient the benefit of the doubt"

"Bipolar TRD responds really well."

These responses, as is promotion of intramuscular ketamine and the qualification and skill set of what is described as a *"seasoned team"* on the website, are at odds with SASOP's position statements. The psychiatrist's role in establishing SASOP's policy and her *'dedication'* to advancing

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[14] Pelayo R, Bertisch SM, Morin CM, Winkelman JW, Zee PC, Krystal AD. Should Trazodone Be First-Line Therapy for Insomnia? A Clinical Suitability Appraisal. J Clin Med. 2023 Apr 18;12(8):2933. doi: 10.3390/jcm12082933. PMID: 37109268; PMCID: PMC10146758

use of ketamine is pertinently mentioned within the website that directly points out her *"involvement in drafting national guidelines"*.

Suicidality in children

Without exception, the suicidal children treated at our clinics have all responded well, some remarkably so. All were referred by psychiatrists, one the son of a psychiatrist herself. Case studies of some have been published in *South African Psychiatry*[15]. Yet another senior SASOP psychiatrist stated when interviewed for a mainstream magazine article, not yet published:

"The use of ketamine treatment in a child would be considered highly unethical practice."

and:

"... the research base is inadequate and long-term effects on the developing brain are as yet unknown, so we do not advocate its use".

However, after decades of using ketamine in the paediatric population, the literature is hardly bursting with stories of neurodevelopmental disasters in children receiving boluses every few days for burns dressings, or daily in countless emergency departments across the world.

What might be said by those (like the psychiatrist in question) who reject ketamine's use in suicidal children out of hand to the mother of the girl who attempted to hang herself in a bathroom and then stuck a knife in her groin? In fact, this mother sent me a letter saying: *"Thank you for giving us our daughter back."* What would be said to the child and adolescent psychiatry specialist, who referred her for ketamine in the first instance?

Neuropathic pain

Chronic pain and depression are common bedfellows. Although ketamine is a potent short-term analgesic for nociceptive pain, through its action on NMDA receptors, its more enduring effect when administered in low dose infusions for certain types of neuropathic pain has garnered considerable support and research. Much has been published on its efficacy for responsive patients suffering from CRPS, post herpetic and trigeminal neuralgias and other diverse conditions like levodopa induced dyskinesia and even multiple sclerosis.

Our clinics treat referrals from neurologists (one in fact a neurologist's own wife), physicians, and even pain clinics that don't offer ketamine infusion as an option. While certainly not effective for all patients with intractable and unresponsive neuropathic pain, for some KIT has proved lifechanging, as evidenced by several published testimonials. None, even the non-responders, has been harmed by low dose ketamine at our clinics.

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[15] SOUTH AFRICAN PSYCHIATRY issue 34 2023 19-21

Although ketamine infusion for chronic neuropathic pain is as much 'off-label' as its use for TRD and other mood disorders, we have not seen a call to action or a rush to produce dictatorial position statements from the Neurological Association of South Africa, Pain SA, PalPrac, Faculty of Consulting Physicians of South Africa, South African Society of Medical Oncology, or any other body or society that may have a stake or special interest in chronic pain management.

CRPS is dubbed 'the suicide disease' for a reason. Through our practice of using not only the subjective DVPRS rating scale for neuropathic pain patients, which charts the VAS pain score as well as four other psychosocial parameters, and the standard PHQ-9 and GAD-7 scores, the intertwined comorbidity of chronic pain and depression is obvious in almost all cases.

We have seen a spectrum of outcomes in neuropathic pain patients treated with KIT reflected in unpredictable combinations of rating scale reductions. Almost all are taking antidepressants. Sometimes the VAS might only drop a point or two, while improvement in depressive symptoms is marked, and reflected in a significant decline in DVPRS overall, and a much happier patient. Where do the SASOP position statements and guidelines address this cohort of patients with blended comorbidities?

Conclusion

In 2022 I was invited to attend a workshop in Johannesburg convened by SASOP to discuss the unfolding ketamine landscape and offer input on the proposed guidelines and first position statement. This never materialized and I was later told in a text message: *"...we decided that we want to draw up our guidelines independently"*.

Subsequent promising meetings with Discovery Health held in conjunction with SASOP and PsychMG representatives came to naught. I was full of hope in the early days.

We have endured theft of our intellectual property, plagiarism of our website, been reported to SAHPRA, been misquoted, threatened, and had our standpoints and perspectives misrepresented.

This is the price we have paid for diligently, professionally and transparently administering over ten-thousand ketamine infusions safely and by properly qualified and experienced practitioners in appropriately staffed clinical surroundings in, what is now, a group of seven clinics countrywide.

I have joined societies, both psychiatric (SASOP) and sedation (SOSPOSA, membership of which I initially mandated for all of our doctors), the American Society of Ketamine Practitioners (ASKP[3]), journal clubs, presented webinars, created numerous newsletters, built up a comprehensive literature section on our website, joined eminent psychiatrists on podcasts, written several emails to and met with SASOP representatives on a number of occasions, had our clinics accredited. We have a robust internal audit system in place at all our clinics to maintain standards. And always with a single-minded focus on making this remarkable treatment safely accessible to numerous deserving patients and educating colleagues about ketamine's efficacy and safety.

I even launched the Society of Ketamine Practitioners of South Africa (SOKePSA) in 2020, convened a multidisciplinary board, sought guidance from SASOP and PsychMG representatives, and tried to

incorporate this society under the SASOP umbrella. Early promise rapidly and inexplicably dissolved.

I spent two years of careful planning, consultation and interaction with SASOP and funders regarding the appropriate role and positioning of SOKePSA. I was alarmed that an alternate 'pop-up' society with outlandish promises of 'medical aid recognition as an accredited ketamine and psychedelic provider' and 'medical aid funding at equivalent specialist-based rates' suddenly appeared a few months ago, potentially undoing the work already done. This society, convened by two individuals in whom I had confided and shared my vision for SOKePSA, has now been named and shamed in SASOP's latest position statement, and SASOP's members alerted to the 'concern' both SASOP and SASA have with the stated aims of this society.

What inspired me, as an emergency medicine consultant, to enter this space back in 2019 was my distressing and direct involvement in the attempted resuscitations of several adolescents and young adults in Ireland who all committed or attempted suicide by hanging or overdose within a fairly short timeframe. I watched them die, some in front of me, some in ICU days after we had worked on them, and I witnessed firsthand the devastating effect on families, one of a consultant colleague. A friend of mine who worked in the emergency department hung himself from a balustrade. All these cases affected me profoundly.

The seminal case for me, about which I have written often and which has also been published in *South African Psychiatry*[16], was an older suicidal woman who slit her own throat in front of paramedics. My frequent, but in this case particularly serendipitous use of ketamine in the emergency department to repair the damage to her neck, led to a remarkable and, at the time, inexplicable reversal of her suicidality that endured days later.

When I realized what a profound difference ketamine could make in the lives of deserving patients and their families, I left Ireland permanently, returned home to South Africa, and launched KCSA. When I now read and re-read testimonials from countless patients, parents, siblings and spouses gathered over four years, I'm so glad I did.

A direct quote from a SASOP director in an email I received in February this year reads as follows:

"The diagnosis of TRD lives in the sole arena of psychiatrists, and I do not foresee this to change".

If this mindset persists, ketamine infusion may yet be denied to many deserving patients for years to come.

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[16] SOUTH AFRICAN PSYCHIATRY issue 24 2020 34-37