



## Conscious sedation versus monitored anaesthesia care

**To the Editor:** I share the concerns of Stefanutto and Ruttmann<sup>1</sup> regarding the safety of sedation practice done by untrained sedation practitioners. Non-anaesthesiologists are involved in sedation worldwide, and I agree that sedation of patients for minor procedures 'is here to stay'. But I am concerned that a dark picture is painted of conscious sedation, which is very safe when done by trained practitioners.

In order to help solve the problem, we need to know who the authors are referring to when they state that 'Currently sedation is a poorly controlled practice, often performed in potentially unsafe environments by unqualified personnel who may be unable to deal with complications'. The authors claim that it is 'common practice with sedation [for] the sedative drugs [to be] given in large doses to attempt to achieve a calm, pain-free patient' – and refer to a 1972 article! There are many publications on conscious sedation and we all know and teach that titration is required to reach an optimal level of sedation and to avoid complications.

The authors' comments on 'Where does this leave us in South Africa?' leave readers, not all of whom are anaesthesiologists, uninformed about what is being done in this country. The South African Dental Association published guidelines<sup>2</sup> on conscious sedation to address uncontrolled practice by 'unqualified practitioners'. The South African Society of Anaesthetists has also published guidelines. In a document on safe sedation the UK Academy of Medical Royal Colleges and their Faculties, chaired by the Royal College of Anaesthetists, stated, 'the key point is that safety will be optimized only if practitioners use defined methods of sedation for which they have received formal training'. The universities of Stellenbosch and the Western Cape have a university-accredited course on sedation and pain control/conscious sedation. It is presented by anaesthesiologists and attended by national and international students. We write a monthly article for the *Journal of the Dental Association of South Africa* covering all aspects of safe sedation practice. We also present a postgraduate university-accredited certificate course on sedation and pain management in association with University College London and are developing conscious sedation programmes. Our symposium in London in November 2006 was accredited for CPD by the Royal College of Anaesthetists.

The authors state that the term 'conscious sedation' has been 'expanded, twisted and manipulated'. This is true – it is a worldwide phenomenon that practitioners do not always do what they are told. A recent survey showed that 70% of sedation practitioners follow guidelines, 20% follow them more or less, and 10% not at all (personal communication).

The authors claim that there are no 'absolute figures of complications related to sedation available in South Africa'. How then can they say that it is poorly controlled? For 15 years

we have run daily sedation clinics at the Tygerberg campus with no mortality, and no major complications in adults or children. Their statement, 'based on the few studies on the subject ... the majority of deaths occur' creates the impression that there are many deaths related to conscious sedation, which is not the case (one of the two studies they refer to was published in 1988!). Are they talking about conscious or deep sedation? In a study on the safety of conscious sedation<sup>3</sup> no complications were reported for 99.1% of those receiving conscious sedation, and 98.5% of those receiving deep sedation/general anaesthesia. This and other studies clearly demonstrate positive outcomes if sedation practitioners are trained.

General anaesthesia should not be compared with conscious sedation as there is a place for both in patient care. Sedation is not perceived as a 'cheap option' by anaesthesiologists. We value the safety and comfort of our patients highly. Operation waiting lists for our patients from the community have been cut substantially, which is a positive factor for patients.

Leaders who influence policies in their field of practice may have strong prejudices and pride in past achievements. It is time we looked beyond our personal status and support the wide variety of practitioners practising sedation.

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**Drs Stefanutto and Ruttmann reply:** Our article seems to have been misread by Professor Roelofse, who projects a sense of feeling 'under attack'. If that is the case, we must apologise. However, we must also point out that as an established university-based sedation centre, the author's unit was most certainly not in any way the forum at which the article was aimed.

What does arise from the letter though, is that there is no clarity on 'what is right and what is wrong' when it comes to the practice of sedation in South Africa. Furthermore, as we also said in our article, there are guidelines available through SASA – however, sedation is usually not practised by anaesthetists.

Roelofse makes it look as though a rate of 98.5% with no complications is laudable. However, this figure means that 15 people out of every 1 000 receiving 'deeper sedation' would have complications. Presumably this could easily equate to 15 people per day in a population of around 40 million? And that is 15 people receiving a 'safe' procedure expected to have no complications!



An important issue to address is the difference between 'sedation' and the drift into anaesthesia that has been defined as 'MAC' (monitored anaesthesia care) in the literature. There is no doubt that a well-trained and experienced health care provider has the ability to give incremental doses of the appropriate drugs to maintain the patient in a relaxed, sedated state, while ensuring that s/he is still fully responsive and not drifting into a non-responsive, deeper state. The question is: Do we in South Africa identify, maintain and monitor this state and therefore prevent the drift into deeper sedation?

We are afraid that Roelofse's letter, which may well be interpreted by some as a 'shotgun approach' to our article, is perhaps not what we need in this country when it comes to the practice of sedation. What is clear from both the article and the letter is that while sedation is here to stay, there are still no clear, basic guidelines for this practice that are understood, accepted and practised across the medical disciplines in South Africa.

We therefore challenge Roelofse, and anyone who has an interest in this, to contact us so that together we can formulate appropriate practice guidelines for South Africa which can be unanimously adopted and adhered to by all medical practitioners administering sedation.

**To the Editor:** As a practising sedationist I share the concerns raised by Stefanutto and Ruttmann in a recent issue of the *Journal*.<sup>1</sup> A sedationist should be an experienced anaesthetist who has training in conscious sedation. Anaesthetic experience does not necessarily mean that one is able to practise conscious sedation, especially in the out-of-theatre environment. That is where GANA (general anaesthesia no airway) or 'anaesthesia lite' originates.

Conscious sedation should only be practised in a safe environment. Monitoring and resuscitation equipment should therefore be on a par with that found in an operating theatre. Patient safety may not be compromised. Here patient selection and the type of procedure performed are also of the utmost importance.

To ensure that safety standards are met the sedationist must be trained. The surgeon or dentist must be informed regarding conscious sedation, as they are also responsible for the safety of their patients. It would be a great advantage if patients also knew more about conscious sedation.

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## Utilisation of pathology procedures

**To the Editor:** The article on utilisation of pathology procedures in the South African private pathology sector, published in the *SAMJ* recently,<sup>1</sup> refers. Solutions are proposed that have no bearing on the 'factual' material presented, and aspersions are cast designed to advance the aspirations of Veripath, a commercial managed care enterprise. The conclusions have long been the credo of Veripath and are not based on the claims database surveyed. Veripath input is acknowledged, but the author should indicate that he is a full-time employee of the managed care company. [*Dr Pretorius declared his relationship with Veripath and the medical aid industry in a letter accompanying the original submission of his article.* – Editor]

Bias and vested interest flaws any useful examination of the material by the author or his cohorts. Although the information bears examination, any extrapolation is flawed because the baselines are neither decided nor constant. The *SAMJ* has been used as a platform to advance not scientific conclusions, but a thinly veiled sales pitch that is being touted to advance their credibility. The CPD questionnaire seems to indicate that the article has been accepted as the final word on the topic. It cannot be. There is no dearth of published articles on laboratory utilisation, but when new pathology tests seem to arrive almost every day, articles published up to 33 years ago might not be entirely relevant except to advance vested interests!

With the advent of ICD-10 much more scientific and locally relevant information related to clinical diagnosis, treatment and outcome will be available, and not postulates that the author questions, but advances as evidence to support the views of Veripath. The latter, like other managed care organisations, extracts its bit of the health care rand. Veripath does not have custodianship of the information, and is not credibly qualified to advance opinions on its clinical application.

It is time to cut out the middlemen, who are not needed by funders or pathologists, between whom a working relationship is possible, as with all professional groups. Pathologists, who it seems are deemed the villains of medicine, will welcome the constructive evaluation of laboratory medicine, which will be possible when ICD-10 data become available. Funders must share and use this information constructively rather than adopt an adversarial approach to problem solving. Pathology is a referral discipline and the referring doctor largely drives the mode of testing. Pathologists are an integral and indispensable part of the health care system, adding significant value to the health care outcome.

The reasons for medical analysis, including pathology, are investigative to ascertain abnormality, quantitative to quantify or stage disease, confirmatory or defensive to confirm disease, and to ensure that litigious liability has not been overlooked. It invites assumption of legal liability should prescription be imposed. Castigating pathologists for using their expertise



to further investigate abnormal findings is tantamount to prescribing to a physician or surgeon that patient care should be related solely to the reason for referral, and that even if additional findings are made, no further investigation or care should be advanced until permission has been obtained.

As with all involved in patient care, pathologists must order further tests based on the outcome of prior testing. This is sometimes life saving. Their expertise is based on general medical training, specialist training in laboratory medicine, and clinicopathological correlation. To suggest otherwise is to relegate pathologists to the level of technicians who merely provide results at the behest of the referring doctor without interpretation.

With tongue in cheek, would one solution not be to ban pathology testing altogether? But that would not be to the financial advantage of the middleman – Veripath!

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1. Pretorius C. Utilisation of pathology procedures in the South African private pathology sector between 2003 and 2005. *S Afr Med J* 2007; 97: 51-57.

**To the Editor:** An editorial<sup>1</sup> referring to an article in the same issue of the *Journal*<sup>2</sup> suggests that more appropriate use of pathology investigations can save up to R115 million. Pretorius<sup>2</sup> states that a cost saving of 15% is potentially achievable if the lowest-cost laboratory is accepted as ideal behaviour, but *'It is debatable whether the lowest utilisation in this sample represents ideal or acceptable test utilisation'* (my emphasis). Neither author justifies or analyses the proposed saving based on patient outcomes or disease profiles. Their apparent objective is to demonstrate laboratory overuse. The debate *should* be about the value and applicability of pathology in patient care. No responsible pathologist supports over-investigation of patients, but neither should under-investigation be sanctioned.

Raath presented data from an industry-wide modelling tool of the annual statutory returns of all registered schemes and options for the period 2002 onwards at the BHF conference in Durban in July 2006, and concluded that the weighted percentage increase in benefits to pathology was a fraction of 1%. His figures contrast sharply with those of Pretorius.<sup>2</sup> The 2.3 billion expenditure on pathology in South Africa constitutes 4.5% of total contributions to medical schemes. Non-health care expenditure absorbs 15% of total contributions. In 2005 non-health care expenditure rose by approximately 9.6% to R7.8 billion, with the major components being administration R5.4 billion (annual increase of 10.5%), managed care fees R1.3 billion, and broker fees R0.8 billion (annual increase of 21.1%). From 2000 to 2005 non-health care expenditure increased by

89.5%.<sup>3</sup> Managed care expenditure therefore amounts to about 50% of expenditure on pathology.

Pathology is a referral specialty. Pathologists are medical specialists and are the bridge between the clinician and the laboratory. The Royal College of Pathologists advocates: 'Other relevant tests may be added to, or substituted for, those originally requested.'<sup>3</sup>

Members of the National Pathology Group (NPG) of SAMA must adhere to specific protocols for laboratory request forms – only academically defensible test profiles may appear, it must be possible to request any test individually, and the content of profiles must be listed on the laboratory request pad. Clinicians are at liberty to request any test individually, or a combination of tests.

Veripath, the managed care company that employs Pretorius, is campaigning to replace current laboratory request forms with blank paper on which tests must be handwritten. This will dramatically increase the error rate. The transcription error rate from incorrectly handwritten laboratory request forms in Australia has been estimated to reach 17%.<sup>4</sup> In fact, online test ordering with data transmission to the laboratory is increasingly the norm.

Is rationing the sole objective? Pathologists contribute significantly to appropriate and cost-effective laboratory testing by publishing investigative guidelines and protocols.<sup>5</sup> Much is made of the fact that the majority of the tests are common, of low complexity, and performed in bulk. The fee for a given test does not vary even if it is done as a single investigation during the day, after hours, or in the most remote laboratory. The cross-subsidisation of these services and tests ensures that a comprehensive laboratory service is broadly available to all patients.

The Australian system is essentially a national health system, with the state as guarantor of payment. The selective choice of certain components will not lead to a sustainable pathology service for South Africa. The Australian Association of Pathology Practices noted some of the other negative effects of the memorandum of understanding between pathologists and the Australian Government, including reforms being funding-based rather than aimed at best medical practice, discouragement of entrepreneurship due to limits to return on investment, and likelihood of unsustainability in the long run.<sup>6</sup>

The NPG is currently in the process of tariff revision. In an extensive preliminary submission to the Council for Medical Schemes in 2006, 17.4 million billing line items were evaluated. This indicated a financial return of approximately 10% for pathology, provided that an increase of 7.5% was to be allocated to the National Health Reference Price List (NHRPL) for 2007. From this report it is obvious that the income for all services by laboratories is not excessive.

The NPG's role is to ensure that pathology continues to fulfil



its vital role as the hidden science that saves lives and is not relegated to a 'cost centre'!

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6. Australian Association of Pathology Practices Submission No 38. Parliament of Australia Inquiry to Health Funding. <http://www.aph.gov.au/house/committee/haa/healthfunding/subs/sub038.pdf> (accessed 22 August 2006).

**Dr Pretorius replies:** Attacking the messenger to obfuscate the message is Dr Harrison's prerogative. He dismisses my article outright without providing a measured argument or alternative explanations on any of the findings. In the Council for Medical Schemes (CMS) annual report for 2005/6,<sup>1</sup> the total benefit paid by medical schemes for pathology tests in 2005 increased by 26.6% over 2004 (p. 88). The beneficiaries of all medical schemes increased by 2.6% (p. 47), and the NHRPL tariff increase was 5.2% for 2005. The difference of 18.8% can only represent an increase in utilisation. My article under discussion reported a 14.5% increase in the cost per beneficiary who underwent pathology testing. If anything, the CMS report would suggest that the magnitude of the problem may be even greater than reported in the article.

To satisfy Harrison's quest for recent literature I wish to refer him to an article in *Clinical Chemistry*<sup>2</sup> that expresses similar concerns regarding test utilisation and in which the authors describe an innovative mechanism to manage utilisation at the test initiation stage.

Harrison states that pathology is a 'referral discipline', with testing driven by the referral doctor. He then contradicts himself by pontificating on the reasons why pathologists should be allowed to initiate additional testing without deference to the referring doctor or patient. What was discussed in the article was the phenomenon of reflex testing (a test triggered by the result of another test without pathologist intervention) and not additional tests as a result of clinical interaction. Although not relevant to the article, my personal opinion is that pathologists should play an active role in providing health care; this role extends to not doing tests that are ordered inappropriately, and initiating tests that are appropriate but not requested. What I cannot accept is the notion that as a 'referral discipline' pathologists should do inappropriate tests just because they are instructed to do so by referring doctors, and then in the same breath add tests on the basis that they have a responsibility for patient care.

It is unfortunate that Dr Harrison chose not to contribute to a discussion on the reason/s for the greater-than-anticipated increases in pathology expenditure.

I wish to thank Dr Erasmus for his comments. I am pleased that he agrees with me that both under- and over-investigation of patients should be frowned upon. Taking the cost per active beneficiary of the lowest cost provider and multiplying this amount with the total number of active beneficiaries from all providers in the sample was used to arrive at the quoted figure of a potential 15% saving in expenditure. This theoretical cost was then compared with the actual cost to estimate the quantum of the potential saving. The statement that Erasmus has correctly quoted verbatim, qualified this potential saving.

The purpose of the comments on non-health care expenditure as well as the comments on the costing exercise of the NPG is not relevant to the discussion, and it escapes me why this was raised.

Dr Erasmus misrepresents my efforts to address issues surrounding the design of pathology request notes. The requisitioning of laboratory tests (handwritten or electronic) has been shown in a number of articles to be a crucial interface in promoting appropriate utilisation of resources. I unashamedly advocate unambiguous requesting of individual tests by a competent clinician and fail to see how this can be interpreted as rationing.

In defence of maintaining the current version of the tick box request form, Erasmus quotes an error rate of 17%<sup>3</sup> from an Australian article. This 'evidence' is then used to prove the unworkability of a proposed solution that was modelled on the Australian rules on laboratory request forms. Dr Erasmus is selectively quoting the worst performance achieved in the study. The median error rates, of various categories of errors examined, were in fact between 1.0 and 2.5%. This figure differs markedly from the 17% we are led to believe would be the result of implementing the recommendations in the article. Nowhere in the article by Khoury or in an accompanying editorial<sup>4</sup> were handwritten request forms blamed for errors, nor was it suggested by any of the authors that the rules pertaining to the requisitioning of pathology tests in Australia be changed. Dr Erasmus's concerns about the consequences of increased errors can therefore be dismissed.

Lastly, Dr Erasmus is invited to submit for public scrutiny the academic evidence underlying the composition of the NPG-sanctioned profiles.

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## Medicines Control Council and registration backlog of antiretrovirals

**To the Editor:** Antiretroviral (ARV) medication must be taken faithfully in order to keep HIV in check. Some current regimens of highly active antiretroviral treatment (HAART) require taking many different pills, several times a day. Once-daily ARV formulations simplify dosing and could lead to better compliance.

On 12 July 2006 Bristol-Myers Squibb and Gilead Sciences announced that the US Food and Drug Administration (FDA) had cleared Atripla, their fixed-dose combination tablet containing Stocrin/Sustiva (efavirenz) and Truvada (tenofovir and emtricitabine). Atripla is the second once-daily HAART regimen taken as a single pill to be approved by the FDA. Of the three ARVs in Atripla, only efavirenz is currently available in South Africa. The first fixed-dose combination of ARV medications to be approved by the FDA in January 2005 was Aspen Pharmacare's generic combination of lamivudine, zidovudine and nevirapine. It is a highly effective and widely used 3-in-1 combination, but unfortunately not available in South Africa as Aspen appears not yet to have applied for its registration with the Medicines Control Council (MCC).

When Aspen was asked in September 2006 whether it has applied to the MCC for registration of the generic combination of lamivudine, zidovudine and nevirapine, Gavin Wiggill, Product Manager for Aspen, provided an evasive equivocal statement from which it was unclear whether they had applied. If not, it is imperative that they do so immediately.

Research indicates that stavudine, used as part of the standard first-line regimen in the Department of Health's HIV treatment guidelines, should be replaced by tenofovir, which is a potent, safe and well-tolerated ARV. Stavudine-related toxicity is one of the main reasons for discontinuation and/or changing the first-line regimen.

Few people on ARV treatment are accessing tenofovir in terms of the Medicines and Related Substances Act, as it is a time-consuming and onerous process to initiate that has to be reviewed every 6 months. Tenofovir is therefore effectively not available for treatment in public health clinics.

Both Gilead and Aspen pharmaceutical companies have applied for registration of tenofovir over the past few years but the MCC has yet to approve its registration, in spite of Aspen requesting fast-track review status for its registration in November 2005. On 24 September 2006 Aspen supplied

additional information on tenofovir requested by the MCC, which has since indicated that tenofovir may possibly be registered by early 2007.

In a recent issue of the *Sunday Times*<sup>1</sup> Mandisa Hela, the MCC registrar, admitted that there is a drug registration backlog, with an average registration time of between 2 and 3 years for new drugs (including ARVs) entering the South African market. Experts working for the MCC indicate that this is largely owing to the exodus of skilled staff and increasing numbers of new drug applications. Reviews and evaluations of new drugs for registration are mostly outsourced to busy academics. The MCC therefore appears to be badly resourced and unable to cope with its mandate. Hela claimed that applications for registration of ARVs were automatically fast-tracked, but declined to comment on the pending tenofovir application saying 'that is confidential information'.

The MCC should review new drugs that are fast-tracked by first checking if the FDA and European Union (EU) have approved them. If so, the MCC should only check if there are any issues specific to South Africa that merit concern and then immediately register them. Atripla was approved in less than 3 months in the USA under the FDA's fast-track programme, and was made available within days following its approval. In spite of this good news about the availability of Atripla in the USA, it may take a long time before it becomes available in South Africa given the tardiness of the MCC in registering new medications, including ARVs.

Given the extent of the HIV/AIDS pandemic in South Africa, it is essential that the MCC facilitate the registration of these life-extending medications as rapidly as possible. The MCC should encourage pharmaceutical companies to apply for the registration of new ARVs as soon as they become available and ensure that the fast-track registration process is significantly improved to make these life-extending medications available much sooner.

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1. Registration backlogs block life-saving drugs. *Sunday Times* 17 September 2006. Sources: <http://www.aidsmeds.com/drugs/atrilpa.htm>, [http://www.tac.org.za/newsletter/2006/ns30\\_01\\_2006.html](http://www.tac.org.za/newsletter/2006/ns30_01_2006.html), <http://www.medpagetoday.com/InfectiousDisease/HIV/AIDS/tb/3727>, [http://www.ciplamedpro.co.za/dyn\\_pdf/news/Triomune-CapeTimes.pdf](http://www.ciplamedpro.co.za/dyn_pdf/news/Triomune-CapeTimes.pdf), [http://66.249.93.104/search?q=cache:vzVN7skMW1AJ:www.haart4africa.com/oid1/pub\\_item.asp%3FItemID%3D249%26tname%3DtbiComponent1%26oname%3DFront%2520page+emtricitabine&hl=en&gl=za&ct=clnk&cd=2](http://66.249.93.104/search?q=cache:vzVN7skMW1AJ:www.haart4africa.com/oid1/pub_item.asp%3FItemID%3D249%26tname%3DtbiComponent1%26oname%3DFront%2520page+emtricitabine&hl=en&gl=za&ct=clnk&cd=2), <http://www.sundaytimes.co.za/Articles/TarkArticle.aspx?ID=2230774>