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References:

For full prescribing information refer to the package insert approved by the medicines regulatory authority.

SCHEDULING STATUS: S5


COMPOSITION:
STILNOX® MR 12.5: Each tablet contains zolpidem tartrate 12.5 mg.

PHARMACOLOGICAL CLASSIFICATION: A 2.2. Sedatives, hypnotics.


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Editorial

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Welcome to the first edition of Sleep matters for 2017. I hope you find these newsletters interesting and useful.

Within the realm of mental health Prof Seedat and her colleague review the psychiatric aspects of sleep disorders according to the new classification of DSM-V. There are a few classification systems for sleep disorders but as psychiatrists use the DSM classification it is useful for all medical practitioners with an interest in sleep to understand how that classification works. Prof Seedat has included the changes since the DSM-IV system. The new international classification of sleep disorders (ICSD) is slightly different although some work was done to try and align the two to make it easier. Another complication is the proposed changes to the ICD-10 coding – soon to be the ICD-11. These changes have been covered in a previous issue of Sleep Matters but will be very similar to the ICSD.

This issue is heavy on ethics and legislation. Firstly, Elsabe Klink expands on the new legislation changes in the Medicines act with particular emphasis on those medications used for mental health. This article provides a useful explanation of the often confusing legislative changes.

Finally we had some interesting speakers at the South African Society for Sleep medicine congress in July this year. We have highlighted key points of three of the speakers. Dr Resuk from Turkey gave two talks focusing on paediatric sleep disordered breathing – an area that is significantly under-resourced in South Africa. The vast majority of sleep laboratories in South Africa do not record the sleep of children partly because of the specific equipment that is required. Also it is important to recognise that the level at which apnea becomes significant and a diagnosis between normal and significant OSA is different between adults and children. In children any apnea is significant whilst in adults a level greater than 5 per hour is required to diagnose clinically significant sleep disordered breathing. Therapy is also different as confirmed by Dr Resuk that adenotonsillectomy remains the mainstay of treatment in all children and adolescents.

In the arena of adult OSA the main speaker was Dr Walter McNicholas from Ireland. He gave a few talks on OSA focusing on cardiometabolic consequences. The evidence is now very clear that the presence of untreated OSA is a major risk for all cardiac disorders.

A very interesting talk was given by Julian Botha of SAMA regarding the legislation of medical devices – very important to the sleep community because of our extensive use of nasal CPAP machines. He stressed the importance of the medical doctor retaining control and responsibility of their patients. Too often now it appears as though other practitioners take over management as soon as patients are diagnosed with significant sleep apnea. As the medical doctor retains responsibility for these patients it is essential that they are central to any future management of patients with OSA.

For the final page we have a new feature – a case study. I have started with one from my practice which indicated how complex a relatively young patient can becomes if you ask the right questions. If you have any case study you would like us to feature please send me all the relevant info and I will be happy to write it up for the newsletter.

I do hope that many of you will be inspired to attend the next sleep congress which should take place in 2018 – venue at present unknown. I would also like to urge as many of you as possible to start research projects on sleep related matters for presentation at that congress as we do not have data on prevalence of any sleep disorder in South Africa and that is not the correct way to practice medicine.

I hope you find this issue interesting and would value your feedback. We look forward to 2017 with renewed excitement and anticipation. Here’s wishing you all a new year of health and prosperity.
Sleep Disorders in Clinical Practice: What is New?

Prof Elisabete Castelon Konkiewitz, Psychiatrist, Faculdade de Ciências da Saúde-Universidade Federal da Grande Dourados, Dourados, Brazil
Prof Soraya Seedat, Psychiatrist, Department of Psychiatry, Stellenbosch University, South Africa

Sleep integrity is fundamental to maintaining mental and physical health and affects behaviour, cognition, endocrine and immunological functions (Faraut, 2012). Sleep disturbances may be a useful indicator of underlying medical, neurological and psychiatric disorders and also commonly co-exist with other medical and psychiatric conditions (e.g. depression, anxiety, cognitive disorders).

In primary care, 10-20% of people complain of significant sleep problems (American Psychiatric Association, 2013). Sleep problems also represent a major public health concern and an economic burden for society (Colten, 2006). Disturbed sleep, whether arising from poor sleep quality, improper sleep timing or insufficient duration, can have many adverse health consequences for individuals, affecting their quality of life and level of functioning. Moreover, sleep disorders, including insomnia and hypersomnolence, are established risk factors for the development of mental and physical disorders (Grandner, 2010).

The Diagnostic and Statistical Manual of Mental Disorders (DSM) provides a guide for physicians and researchers to classify and diagnose sleep disorders. This paper describes recent changes to the classification of Sleep-Wake Disorders in the latest edition of the DSM (DSM-5), their presentation (including assessment, consequences and impact on other mental and medical conditions), with a special focus on Insomnia in the DSM-5.

Major changes to the DSM-5 Sleep-Wake Disorders chapter

The changes in the diagnosis and classification of sleep disorders that were introduced in the DSM-5 reflect advances in our understanding of the neurobiology and genetics of sleep (American Psychiatric Association, 2013). The DSM-5 classification encompasses 10 disorders or disorder groups: Insomnia disorder, hypersomnolence disorder, narcolepsy, breathing-related sleep disorders, circadian rhythm sleep disorders, NREM sleep arousal disorders, nightmare disorder, REM sleep behaviour disorder, restless legs syndrome, and substance or medication-induced sleep disorder. All of these disorders share as a core feature some form of dissatisfaction with the quality, timing or amount of sleep and the resulting daytime distress and functional impairment. Two previous diagnoses - sleep disorder related to another mental disorder and sleep disorder related to another medical condition - have been eliminated and greater specification of coexisting conditions is provided in DSM-5 for each sleep-wake disorder.

Instead of presenting different criteria sets for children and adults, DSM-5 integrates a lifespan perspective into the diagnostic criteria and the accompanying text. This reflects an understanding of how neurodevelopmental changes are manifested in sleep disorders. While DSM-IV used a categorical approach to defining sleep disorders, DSM-5 places emphasis on the quantitative assessment of sleep. Thus, DSM-5 incorporates a dimensional component that provides useful quantitative measures of severity, which may also reveal subthreshold or subdiagnostic sleep conditions that could benefit from preventive interventions. For example, the NIH Patient Reported Outcomes Measurement Information System (http://www.nihpromis.org), and the Pittsburgh Sleep Quality Index (Buysse, 1989) are instruments that make possible a quick bedside assessment of the severity of sleep disorders. Also a time criterion was added in DSM-5, so that diagnosis of insomnia, hypersomnia and narcolepsy, requires a minimum of 3 occurrences per week over a period of at least 3 months.

Moreover, DSM-5 has incorporated biomarkers (or biological validators) of the diagnosis. For example, hypocretin deficiency in cerebrospinal fluid has been included as a possible diagnostic criterion for narcolepsy, distinguishing narcolepsy from other forms of hypersomnolence. Another example is the diagnosis of obstructive sleep apnea, which requires polysomnographic evidence of at least five obstructive apneas or hypopneas per hour of sleep.

Further changes that appear in DSM-5 are the acknowledgement of REM Sleep Behaviour Disorder and Restless Legs Syndrome as separate, independent disorders. The subtypes of circadian rhythm sleep-wake disorders have been expanded to include advanced sleep phase syndrome, irregular sleep-wake type, and non-24-hour sleep-wake type. The jet lag type has been removed. NREM parasomnias were aggregated under “confusional arousal disorders” (to include confusional arousal disorder, sleep walking, and sleep terrors). Sleepwalking Disorder and Sleep Terror Disorder have been combined into the category of NREM Sleep Arousal Disorders. DSM-5 separates the unitary DSM-IV “breathing-related sleep disorder” into three distinct syndromes: Obstructive sleep apnea, hypopnea, central sleep apnea, and sleep-related hypoventilation, reflecting the understanding that these conditions arise from different pathophysiological pathways and should be treated differently.

Insomnia and the DSM-V

Insomnia is the most frequent sleep-wake disorder, affecting 10% to 20% of adults (Morin, 2006; Walsh, 2011). Insomnia represents a risk factor for developing a range of physical and mental conditions, such as depression, anxiety, fibromyalgia, rheumatoid arthritis, whiplash, artheros, osteoporosis, headache, asthma, myocardial infarction, angina, hypertension, obesity and stroke (Sivertsen, 2014). Insomnia also has economic relevance, as it predicts subsequent work disability (Salo, 2010). Furthermore, insomnia is suggested
Insomnia disorder is characterised by a difficulty initiating sleep, maintaining sleep or as early-morning awakening with an inability to return to sleep, with sleep difficulties occurring at least three times per week, and causing clinically significant distress or impairment in social, occupational or other areas of functioning (American Psychiatric Association, 2013). The core criteria for a diagnosis of chronic insomnia, in brief, are:

- Dissatisfaction with sleep quantity or quality, with one or more of the following symptoms: Difficulty initiating sleep, difficulty maintaining sleep, early-morning awakening
- The sleep disturbance causes significant distress or impairment in social, occupational, educational, academic, behavioural, or other important areas of functioning
- The sleep difficulty occurs at least 3 nights per week, is present for at least 3 months, despite adequate opportunity for sleep
- The insomnia does not co-occur with another sleep disorder
- The insomnia is not adequately explained by coexisting mental disorders or medical conditions or another sleep-wake disorder, and is not due to the physiological effects of a medication or drug of abuse

It is important to keep in mind that several sleep disorders may manifest with complaints of insomnia and for this reason it is important to consider the diagnosis carefully and address lifestyle and sleeping behaviours.

In the DSM-IV, insomnia was classified into primary and secondary insomnia, according to the absence or the presence of a medical or psychiatric diagnosis. This classification implied that insomnia could be caused by other disease states and would, therefore, remit when the underlying disease state was treated. Now, in the DSM-5, this concept has changed, and DSM-5 has moved away from causal attributions of insomnia to underlying disease states and instead recognizes that insomnia can be comorbid with other diagnoses, and should be separately addressed. Consequently, the diagnosis of “primary insomnia” was dropped in favour of “insomnia disorder,” with concurrent specification of clinically comorbid conditions (both medical and psychiatric).

Nevertheless, DSM-5 acknowledges that insomnia and other forms of sleep disorders do not merely coexist with various mental and clinical health conditions, but indeed interact with problems such as anxiety, depression, chronic pain, neurodegenerative disorders (Alzheimer’s disease or Parkinson’s disease), metabolic syndrome, congestive heart failure and chronic obstructive pulmonary disease, and others (DiMaio, 2011). Sleep disorders are not only a risk factor, but may also be a prodromal symptom of several disease states (Sivertsen, 2012; Willison, 2013). Sleep disorders, such as insomnia, are also an increased risk for workplace and home injuries (Kay-Stacey and Attarian, 2016). For this reason, appropriate diagnosis and treatment of sleep disorders can impact on the course and outcomes of other coexisting disorders.

Implications for general practice
Firstly, clinicians should not forget to ask patients the simple question “Do you sleep well?”, always keeping in mind the relevance of sleep for the maintenance of a patient’s health and well-being. This means that the patient’s sleep quality and satisfaction should always be actively taken into account. If necessary, quantitative measures, such as the Pittsburgh Sleep Quality Index (http://www.psychiatry.pitt.edu/node/8240), may be used to specify the patient’s complaints and to estimate their severity. In this context, the physician may explore behaviours (sleep hygiene, sleep environment, circadian rhythm and medications) and beliefs that contribute to sleep difficulties. Sometimes insomnia or other sleep disorders can be hidden behind other complaints, such as headache, diurnal somnolence, fatigue, and cognitive impairment. Furthermore, different sleep disorders may present as insomnia. For instance, obstructive sleep apnea may underlie the more evident complaint of insomnia (Gupta, 2014). If possible, the patient’s history should be taken not only from the patient but also from the patient’s bed partner, who very often is a source of valuable corroborating information.
information. Also, prospective diaries are very useful for assessing behaviours that promote or hinder sleep, and may enable patients to monitor their own progress.

Second, sleep should not be regarded as an isolated problem, but instead it should be considered in the context of the overall health of the patient and any comorbidities that may interact with the insomnia. DSM-5 proposes that insomnia should no longer be seen merely as a consequence of other primary disorders, but be treated separately as a discrete disorder. However, DSM-5 does not suggest segregation of insomnia from other conditions but instead stresses the impact of sleep on health and the necessity of appropriate diagnosis and management.

Third, the gold-standard therapy for insomnia is Cognitive Behavioural Therapy for Insomnia (CBT-I), which can be carried out both individually and in groups and as a face-to-face or as an internet-delivered treatment. The challenges related to CBT-I are the lack of professionals with specific training and the costs. Further efforts should be made to increase its availability.

Fourth, pharmacologic treatments should not be the first line of treatment, but if necessary they should be used with caution, intermittently at first, and reassessed every three to six months (Wilson, 2010). Benzodiazepines, zolpidem and tricyclic antidepressants have evidence for efficacy. Suvorexant, a reversible dual orexin receptor antagonist, is the newest drug available on the market. At low doses (5-20mg/day), suvorexant has a favourable side effect profile but higher doses have been associated with unfavourable side effects (e.g., motor impairment, driving impairment, sleepwalking, suicidal ideation). Long-term data are needed on its safety, tolerability and efficacy.

Finally, DSM-5 provides guidance as to when referral to a sleep specialist is advisable, such as when the patient presents with severe daytime sleepiness, unusual or dangerous behaviours during sleep (REM sleep behaviour disorder), when sleep apnea is suspected (snoring, overweight, thick neck, hypertension, hypothyroidism, morning headache, daytime sleepiness), or when refractory insomnia is present.

References available on request.

For full prescribing information refer to the package insert approved by the medicines regulatory authority.

SCHEDULING STATUS: S5

PROPRIETARY NAME (AND DOSAGE FORM): Urbanol® 5 mg capsules; Urbanol® 10 mg tablets.

COMPOSITION: 5 mg or 10 mg clobazam.

REGISTRATION NUMBERS: Urbanol® 5 mg: L/2.6/52; Urbanol® 10 mg: M/2.6/128.


SAUN-CLB-16.11.0683
The Medicines Act and its most recent amendments: implications for mental healthcare professionals

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Medicines legislation has always been an important part of the practice of medicine. Not only does it regulate the quality, safety and efficacy of products before they come onto the market, it also provides a regulatory framework for prescription, possession and various activities associated with sales, such as advertisements and pricing.

The 1965 Medicines and Related Substances Act (Medicines Act) has been amended numerous times over the years, and its most recent amendments will also bring medical devices (i.e. consumables, equipment, implants and various technologies) and in vitro diagnostics (IVDs) into the regulatory fold. These two amendments are Act 72 of 2008, and Act 14 of 2015. They are not yet in force and effect, and will be brought into effect once the regulatory framework for medical devices has been finalised. In the meantime, however, medical device companies have had to start processes to license their companies as manufacturers, importers and distributors under the existing Medicines Act.

Key changes brought about by amendment Acts

The current Medicines Control Council (MCC) will be changed to the South African Health Products Regulatory Authority (SAHPRA). One of the most positive amendments is that the law will now compel the authority to register medicines, devices and IVDs “timeously”. It also empowers the authority to liaise with other authorities, to exchange information, and to enter into co-operation agreements which may reduce registration times in South Africa as the authority would be able to rely on assessments conducted in other countries.

The provisions pertaining to pricing and commercial matters, most notably sections 18A (bonuses, rebates and incentive schemes) and 18B (sampling) have been amended to now mandate consultation between the Minister of Health and the Pricing Committee when making regulations on section 18A. The same provisions also allow for sampling to take place in accordance with regulations still to be published “for appraisal purposes”. Whereas these sections in the current Act only apply to medicines, it will now also apply to medical devices and IVDs. This may have a profound effect on the device market, where devices have been donated to indigent patients in the past, discounted to scheme-reimbursable levels in specific cases or where parts of a device (e.g. a glucometer) were provided for free, but consumables would have to be bought.

Section 22A has remained relatively unchanged

A section that has been of serious implications in mental healthcare, namely section 22A, on the prescription, sale, use and possession of certain schedules medicines, have remained largely unaffected by the amendments. This is understandable, but a lost opportunity, as the amendments focused on creating a more efficient regulatory body. Future amendments to the Act could provide an opportunity for mental health practitioners and specifically psychiatrists, to address the impracticalities created by, particularly, the rules around schedules 5 and 6 medicines as used in the provision of mental healthcare.

Pharmacists may sell schedule 1’s, and medical practitioners and dentists may only dispense those medicines if they have a dispensing licence. Other practitioners, e.g. nurses, emergency care providers or other HPCSA-empowered professionals can only prescribe schedule 1’s within their scope of practice. To exactly delineate what specific medicines may be prescribed by these other healthcare professionals, the schedules to the Medicines Act contains a Schedule 1 Annexures 1A and 1B for paramedics and emergency care practitioners, Annexure 2 for dental therapists and Annexure 3 for optometrists. Similar Annexures exist for emergency staff for schedules 2 to 6, whereas dental therapists have prescription rights in relation to schedule 2 medicines listed in Annexure 2 to that schedule and optometrists can prescribe medicines listed in Annexures 3 to schedules 1 to 4.

Schedules 2 to 6 medicines can be prescribed only by medical practitioners.
and dentists, and by any other healthcare professional only as identified in the schedules, e.g. a dental therapist would have prescribing rights on schedule 2 products, but not any others. Further rules in this regard relate to the period of validity of a prescription, i.e. it must be filled within 30 days, that a verbal instruction to dispense can only be for 7 days of treatment. Repeat prescriptions can be issued for schedule 2 to 4 medicines up to six months at a time, but with schedule 5 medicines a repeat after six months is possible for longer than six months.

Repeat prescriptions for schedule 5 medicines that are anxiolytic, anti-depressant, tranquilizing or analgesic in nature, can only be continued after 6 months if the prescriber has consulted another psychiatrist (in the case of medicines used in mental health) or with another medical practitioner, in the case of analgesics. These requirements are widely regarded as impractical, and hampering access to healthcare, given the shortage of psychiatrists, and the practical difficulty to “consult” with another practitioner on a substantial number of prescriptions in a day.

No repeats of schedule 6 medicines are possible, which also pose not only an access barrier, but imposes an additional financial hurdle – very few, if any, medical schemes will pay for 12 consultations with a medical practitioner (and in particular specialists) per year.

Due to the shortages of practitioners, it is also often impossible to get a monthly appointment with a practitioner, due to the vast numbers of patients they have to serve.

Schedule 6 medicines may be provided in an emergency, but then only in the smallest pack available, and it must be followed up with a written prescription within 7 days.

Section 22F: Mandatory generic substitution
Section 22F is also widely regarded by practitioners as being impractical, as it requires a hand-written statement next to each medicines line item of “no substitution”, should the practitioner want the product not to be substituted. In settings such as ICU or in-hospital wards, where medicine instructions are provided on patient charts or files, it may be near impossible to clearly indicate such an instruction.

If there is no such instruction (compliant with the law), a pharmacist must, by law, then dispense “an interchangeable multi-source medicine instead of the medicine prescribed”, i.e. a generic product. A multisource medicine is described in the Medicines Act as “medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed”, with therapeutic equivalence being described in the 2003 General Medicines Regulations as follows:

1. A medicine is considered therapeutically equivalent to another medicine—
   a. (i) are pharmaceutically equivalent, i.e., contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; or
   (ii) are pharmaceutical alternatives, i.e., contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength; and
   b. after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.

2. Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamic, clinical or in vitro studies which meet the requirements and accepted criteria for bioequivalence as determined by the Council.

No details are provided in section 22F as to which alternative the pharmacist must dispense, and the only prohibition is that the substituting product may not be more expensive than the product to be substituted. There is no prohibition on substitution with different products month on month, or substituting one generic with another. In the field of mental health, being stable and controlled on a medicine may be of cardinal importance. In such cases, practitioners should write “no substitution” even if the prescribed product is a generic, or a cheaper alternative.

Where to, now?
It is possible that the Medicines Act may be taken back to Parliament at some stage for further amendments, such as that there is no appeal provision for decisions made by either the Minister or the Pricing Committee, only decisions of SAHPRA and the Director-General may be used to trigger an internal appeals process.

However, if such an opportunity does not arise, stakeholder-prescribers can approach the Health Portfolio Committee in Parliament, to highlight their concerns, and could propose amendments to the Act to address those matters. Parliament, through its Committees and structures, is bound by the South African Constitution of 1996 to provide oversight over the implementation of legislation, and this mandate should also protect the interests of patients and prescribers alike.

References available on request.
Key messages from Invited speakers at the SASSM congress July 2016

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Paediatric sleep disordered breathing - Dr Refika Ersu (Turkey)

Dr Refika Ersu from Turkey spoke on Paediatric sleep disordered breathing and provided an update on this topic. Here are some of the key points:

1. Caffeine is given to treat premature infants with apnea but animal studies suggest that caffeine may have long-term detrimental effects on sleep and control of breathing in older children. A recent study looked at children of 5-12 years old who were premature - half of whom had been treated with caffeine. Between 8% (caffeine group) and 11% (control group) of the children had OSA and between 17 and 11% had periodic limb movements. While the values are high there was no difference between the two groups of children indicating that the treatment of premature infants with caffeine did not increase the prevalence of sleep related disorders in childhood.

2. It is unclear whether the primary cause of obstructive sleep apnea in adolescents is obesity or something else. In younger children the most common cause of OSA is adenotonsillar hypertrophy. An MRI study comparing obese adolescents without apnea to obese adolescents with apnea showed that enlarged lymphoid tissue (i.e. adenotonsillar hypertrophy) was the primary cause of apnea not the obesity itself. Thus removal of tonsils and adenoids in adolescents with OSA should still be the primary treatment modality.

3. A number of studies looked at the feasibility of doing home based studies for paediatric patients. Home based studies have been widely accepted for adult patients as being valid. Two separate studies showed a sensitivity of 90.1% and a specificity of 94.1% which means that home based studies can be used for paediatric patients. The home-based monitoring was also extended to using oximetry with pulse rate variability using a smartphone which was also found to provide an area under the ROC curve of 88% and therefore to be of interest in screening children who may need a more formal study.

4. What about the response to adenotonsillectomy? One of the issues with OSA in children is the effect on growth with reduction of growth hormone due to disruption of slow wave sleep. Failure-to-thrive is a well-known consequence of OSA in young children.

A study on children aged 5-10 years old all of whom had OSA some of whom had adenoids and tonsils removed versus a group that were watched showed that those children with previous failure-to-thrive all put on weight after surgery. However, surgical removal of obstruction also increased the risk of obesity in children who were overweight. Thus surgical removal of obstruction should be matched with dietary advice in those children who have a normal or increased weight before surgery.

Adult obstructive sleep apnea - Prof Walter McNicol (Dublin)

Prof Walter McNicol from Dublin in Ireland spoke about adult obstructive sleep apnea and particularly the cardiometabolic consequences. Key points from his talks include:

1. The odds of having hypertension increases significantly with increasing AHI. The risk increases with increasing levels of apnea ending with an AHI >30 per hour increasing the odds of having current hypertension by 37%. The risk of developing hypertension on follow up with an AHI greater than 5 is reported to be 3 times that of controls. He also confirmed that due to the lack of nocturnal dipping in patients with sleep apnea they are more likely to have drug resistant hypertension.

2. New relationships with more subtle coronary signs have also been investigated. The level of OSA was also correlated to the coronary artery plaque burden as well as the coronary artery calcium although the influence of obesity could not be excluded for the data on calcium.

3. The presence of OSA was found to significantly increase the risk of early morning myocardial infarction between 06:00 and 12:00 but not at any other time of the day. There is also a strong relationship between OSA and atrial fibrillation with a large number of patients (49%) with atrial fibrillation having a diagnosis of OSA on testing compared to general cardiology patients (30%). Also patients with OSA are more likely to develop atrial fibrillation (10%) over 15 years of follow up compared to people without OSA (3%).

4. A number of studies have linked OSA and stroke and the data is conflicting. It seems as though the reason why the data is conflicting is gender-
based. It appears that the higher risk of stroke is in untreated women with OSA but not in men.

5. What is becoming clear is that treatment of OSA with CPAP has a significant effect on cardiovascular events post treatment – both for non-fatal and fatal events (Figure 1).

Under the ethical principles and rules of the HPCSA under the heading of preferential usage or prescriptions it states that doctors may have:

- No engagement in or advocacy of the preferential use of any health establishment or medical device which provides improper financial gain.
- In relation to the sale of medical devices doctors are not allowed to participate in the manufacture sale, advertising or promotion of any medical device.

Presently there are no regulations governing the sale and use of medical devices in South Africa although draft regulations are in place (see article by Elsabe Klinck in this issue for more detail).

Thus the industry has to self-regulate under the SAMED Code of business practices and the South African Code of Practice for the marketing of Health Products. Both of these entities are voluntary and can only enforce their codes on member entities.

When it comes to the relationship between the patient, doctors and medical devices Julian was very clear that the medical practitioner is ultimately responsible for the management and care of patients. Even in situations where functions are outsourced, the responsibility and liability remains with the practitioner even in the case of interpretation of results and reports received from third party service providers. It is, however, permissible to receive reports from other practitioners and prescribe accordingly. This has repercussions on the relationship between doctors and neurophysiologists or other bodies conducting sleep studies or CPAP titrations. The implication is that the referring doctor must still retain responsibility for the patient and he/she should not assume that the responsibility has been handed over to someone else. This should imply that results of an overnight polysomnogram must be sent back to the referring doctor and that the doctor is thus responsible for the decision as to whether the patients should go onto CPAP therapy.

Generally, the audience was reminded that the medico-legal environment was becoming more litigious and doctors were urged to adhere to legislation, ethics and industry codes. It was also important to remember that patient care was the primary responsibility of the practitioner and this should not be diluted by financial considerations. Finally medical device utilisation is essential but is only one component of holistic patient care and management.

Overall, the message I got was that doctors should not just accept that their patients have been put onto CPAP and thus management, and their responsibility, was over. The doctor was still responsible to continue making sure that patients were compliant with the use of CPAP device just as they would with medical management. Patients therefore are required to come back for regular follow up with their doctors including the checking for other co-morbidities that can occur with untreated OSA such as the cardiovascular problems mentioned above.

Another interesting talk was given by Julian Botha on *Sleep medicine – ethical and legislative considerations*. Julian is the strategic accounts manager at the South African Medical Association and his talk was different and raised some interesting issues:

A significant part of the talk revolved around the relationship doctors have with medical devices – obviously CPAP machines come to mind for the sleep world.
This case was one seen by me in my practice. It is interesting because when assessed in a formal way the original sleep disorder is only the tip of the iceberg. I have presented here the kinds of questions I ask patients. The answers given by this patient and in brackets my understanding of the answers.

Presenting symptoms
A 19 year old male university student studying second year engineering. He has a presenting complaint of insomnia – “sometimes I can’t fall asleep and at other times I do fall asleep but then I wake up many times during the night”

Sleep Specifics (What, why, when, how, who?):
- **What:** He has a problem falling asleep and staying asleep
- **Why:** “No idea” but he is not really sleepy when he goes to bed (incorrect sleep time?)
- **When:** “Started in primary school” (long-term)
- **Where:** Sleeps in bed but much easier to fall asleep on couch watching TV (psychophysiological issues)
- **How:** “Just stay in bed and try to sleep” (poor sleep hygiene)
- **Who:** No family history

Sleep disorders
- **Psychophysiological insomnia:** Does have anxiety about sleeping
- **Circadian rhythm disorders:** Much easier to fall asleep at 3 a.m. than 10 p.m. and can sleep late in the morning (delayed sleep phase syndrome)
- **RLS:** No evidence
- **OSA:** Snoring, witnessed apneas, long-standing nasal blockage

Daytime routine
- **Dysfunction related to sleep:** Very tired all day
- **Diet:** Has to take energy drinks
- **Stress:** Is stressed at university – mainly because he can’t study due to fatigue
- **Naps:** No

Medical disorders
Any disorder or new medication that started about the same time as the sleep disorder: None

Treatments used
Used a hypnotic but it doesn’t really help with his sleep. He is taking it most nights

Summary diagnosis and proposed management
A young student with significant sleep disruption probably due to a combination of:
- **Delayed sleep phase syndrome:** Often starts in school-aged boys and persists for many years. Start melatonin at 10 pm to initiate sleep onset at 11:30 pm.
- **Obstructive sleep apnea:** To Ear, Nose and Throat specialist to see what can be done about nasal obstruction. After that to reassess symptoms and if still present to have an overnight apnea screen
- **Psychophysiological insomnia:** True case of final stage of chronic insomnia with anxiety about sleep developing after the precipitating cause of the delayed sleep phase syndrome
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References:

For full prescribing information refer to the package insert approved by the medicines regulatory authority.

SCHEDULING STATUS: S5


COMPOSITION: STILNOX® MR 12.5: Each tablet contains zolpidem tartrate 12.5 mg.

PHARMACOLOGICAL CLASSIFICATION: A 2.2. Sedatives, hypnotics.

REGISTRATION NUMBERS: STILNOX® MR 12.5: A40/2.2/0441.