The role of pharmacists in sleep health – a screening, awareness and monitoring program

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## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>AHI</td>
<td>Apnoea-hypopnoea Index. An index measuring the number of apnoeas and hypopnoea per hour of sleep without considering oxygen desideration.</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>CHD</td>
<td>Chronic Heart Disease</td>
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<tr>
<td>CPAP</td>
<td>Continuous Positive Air Pressure</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>EDS</td>
<td>Excessive Daytime Sleepiness</td>
</tr>
<tr>
<td>EEG</td>
<td>Electroencephalogram</td>
</tr>
<tr>
<td>ESS</td>
<td>Epworth Sleepiness Scale – A scale of propensity for daytime sleepiness in eight situations on a scale of 0-3</td>
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<tr>
<td>IRLS</td>
<td>International Restless Legs Syndrome</td>
</tr>
<tr>
<td>IRLSSG</td>
<td>International Restless Legs Syndrome Study Group – An instrument for classification and frequency of RLS symptoms using 3 items based on diagnostic features for RLS and one item ascertaining frequency of symptoms</td>
</tr>
<tr>
<td>ISI</td>
<td>Insomnia Severity Index – A measurement estimating the risk of having clinical insomnia using 7 criteria and potential QOL impacts of insomnia on a scale 0-4</td>
</tr>
<tr>
<td>MAPI</td>
<td>Multivariable Apnoea Prediction Index - Probability of a respiratory disturbance index of 10 or more that is weighted using three OSA symptoms (loud snoring, gasping, choking), BMI, gender and age.</td>
</tr>
<tr>
<td>nCPAP</td>
<td>Nasal Continuous Positive Air Pressure</td>
</tr>
<tr>
<td>OSA</td>
<td>Obstructive Sleep Apnoea</td>
</tr>
<tr>
<td>OSAS</td>
<td>Obstructive Sleep Apnoea Syndrome</td>
</tr>
<tr>
<td>PhARIA</td>
<td>Pharmacy Access/Remoteness Index of Australia The Pharmacy ARIA (PhaRIA) provides a pharmacy specific measurement of remoteness for over 13000 localities around Australia</td>
</tr>
<tr>
<td>PSG</td>
<td>Polysomnography – a multi-parametric test used as a diagnostic tool in sleep studies.</td>
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<tr>
<td>RDI</td>
<td>Respiratory Disturbance Index - An index of severity of OSA that is often used interchangeably with the AHI, although there are minor technical differences between the two indices.</td>
</tr>
<tr>
<td>RLS</td>
<td>Restless Legs Syndrome</td>
</tr>
<tr>
<td>SaO₂</td>
<td>Oxygen saturation levels.</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation. A statistical measure of the variability of a population.</td>
</tr>
<tr>
<td>SDA</td>
<td>Sleep Disorders Australia. A voluntary organisation that provides information and support about sleep.</td>
</tr>
<tr>
<td>SPSS™</td>
<td>Statistical Package for the Social Sciences. A computer programme used for statistical analysis.</td>
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1.0 Introduction

Sleep is a complex neurochemical process essential in humans for the maintenance of health. The exact mechanisms of sleep are not fully understood at present but, it is known that sleep restores bodily function and has a role in cerebral changes to facilitate memory consolidation and cognitive function. Furthermore, sleep has a close relationship with, and can consequently influence cardiovascular, immune and hormonal diurnal cycles.

Sleep disorders may cause a deficiency of sleep and this can impact on quality of life. Insufficient sleep may manifest as an increased demand for consolidated sleep and can be detrimental to daytime performance, through cognitive impairment, and negatively impacting social and occupational functioning. With insufficient sleep the capability of the brain in concentration and memory is reduced and this may lead to social and occupational problems. Occupational issues that may develop include absenteeism, loss of productivity, workplace accidents and motor vehicle accidents.

In a published economic report, it was estimated that 1.2 million or 6% of the Australian population experience a sleep disorder to some extent with the most prevalent disorders being obstructive sleep apnoea (OSA), insomnia, restless legs syndrome (RLS) and circadian rhythm disorders. This report estimated that sleep disorders account for AUD 10.3 billion (2%) of health expenditure, a magnitude comparable to national health priorities such as asthma and diabetes.

Sleep disturbances accounted for 1.1% of general practice visits in 2006/07, a similar percentage to diabetes and allergic rhinitis.

1.1 Common sleep disorders

1.1.1 Obstructive Sleep Apnoea

OSA is a sleep-breathing disorder associated with the repetitive reduction (hypopnoea) or cessation (apnoea) of airflow due to upper airway instability and closure. These events cause arterial oxygen desaturation terminated by brief micro-arousals and are associated with changes in cardiac rate and rhythm. The frequency of apnoea and hypopnoea episodes per hour during sleep is known as the Apnoea-Hypopnoea Index (AHI). (Note: Some researchers prefer to use the Respiratory Disturbance Index (RDI) which is the number of apnoeas plus hypopnoeas plus respiratory effort-related arousals and other respiratory events per hour of sleep.) An AHI value greater than 5 is used to define the presence of OSA, while values greater than 30 are regarded as severe OSA. OSA with manifest clinical symptoms, (known as OSA syndrome or OSAS), is estimated to be prevalent in 2-4% of the population, while the prevalence of AHI values greater than 5 is reported as 25% for men and 9% for women. There is no strong association between the AHI and presence of symptoms (and hence OSAS). The risk of OSA is increased in people with obesity, hypertension and abnormalities in craniofacial anatomy.

The failure in detecting OSA has been associated with significant morbidity and mortality. OSA has been identified as a risk factor for hypertension, cardiovascular events and insulin resistance. A strong relationship has been established between diagnosed moderate-severe OSA and the risk of mortality (adjusted hazard ratio: 6:24) in a population study conducted in Busselton, Western Australia. The clinical features of OSA are snoring, witnessed apnoeas and momentary choking during sleep but these may not be exclusive. Often sleep partner observations of loud snoring and apnoeic events lead to a suspicion of OSA. The accepted diagnostic method is considered to be a polysomnography (PSG) (See section 1.2.3.2).

The main current treatments for OSA treatment are either nasal continuous positive airway pressure (nCPAP) or mandibular advancement devices. The risk of non-fatal and fatal cardiovascular events with severe OSA (RDI > 30) has been shown to decrease with the introduction of CPAP therapy. However, the full clinical benefits of these devices are often not achieved because of issues relating to inconvenience, poor tolerability and subsequently, non-adherence. At present, there is no evidence to support the efficacy of pharmacological treatments for OSA unless used in the treatment of co-morbid conditions addressing obesity, cardiovascular disease and metabolic disorders.
1.1.2 Chronic insomnia

Chronic insomnia is defined as a difficulty in initiating or maintaining sleep, awakening too early, or the perception of sleep deficiency on at least three nights a week for one month, despite having an opportunity for sleep. Insomnia can be considered both a symptom as well as a disorder. In previous studies, the prevalence of chronic insomnia varied from 5% to 15% and was dependent on the criteria used to classify insomnia, the population observed and whether insomnia was considered as a primary disorder or secondary symptom. In a recent survey of 3300 adults in NSW, it was found that whilst the prevalence of insomnia was 33%, only 11% of respondents had visited a doctor. The causes of primary insomnia are idiopathic, psychophysiological or paradoxical, while secondary insomnia may be contributed to by a combination of sleep hygiene issues, psychiatric disorders, medical conditions or medications. Insomnia may be a symptom of other sleep disorders, such as obstructive sleep apnoea (OSA) and restless legs syndrome (RLS), or a symptom of other medical or psychiatric disorders including depression.

Insomnia may be diagnosed on the basis of clinical symptoms and patient report, by examining sleep diaries maintained by patients, and by the use of validated questionnaires. A PSG is not required for the diagnosis of insomnia, unless it is undertaken to exclude other suspected sleep disorders. Despite the prevalence and costs incurred with insomnia, a large proportion of undiagnosed cases persist in the community. Often insomnia is not brought up as a problem in a regular consultation with a physician. For example, in the survey of adults in NSW, many people with insomnia reported that they had self-medicated. It is important to identify insomnia and its root causes due to its association with psychiatric, respiratory and cardiovascular diseases, which may have been previously subclinical and undetected. Strategies used in the treatment of insomnia vary in effectiveness. These include cognitive behavioural therapy and hypnotics such as benzodiazepine receptor agonists, sedating antidepressants and antihistamines. In Australia, the benzodiazepine, temazepam is the most commonly prescribed hypnotic for the short-term treatment of insomnia. In 2006, the Australian Department of Health and Ageing reported a total of 2.7 million temazepam products dispensed at a total cost of $18.9 million to the community. Thus, insomnia poses a significant burden on the Australian community in economic, clinical and humanistic costs.

In most cases, hypnotic agents are not expected to correct the underlying causes of insomnia, but provide temporary relief by increasing sleep propensity and duration during normal sleep time. The use of hypnotics is limited by tolerance, dependence, and the potential to cause residual sedation during the daytime. Hypnotic agents may also worsen the severity of sleep breathing disorders such as OSA. It is important therefore that insomnia complaints are brought to the attention of health care professionals, and appropriate treatment initiated with discussion of the merits of the available treatment options.

1.1.3 Restless legs syndrome (RLS)

RLS is a neurological sleep disorder characterised by limb discomfort at rest and the desire to move the affected limbs to provide temporary relief. Risk factors include iron deficiency, renal impairment, neuropathy and pregnancy. RLS affects 3-15% of the population, with estimates varying depending on the classification of RLS by symptoms, severity or frequency. Owing to low awareness of the syndrome in the community, RLS is often under diagnosed or not appropriately diagnosed. Sufferers are often unaware that effective treatments are available to alleviate symptoms and hence do not seek nor receive treatment. RLS is diagnosed on clinical criteria based on the characteristic symptoms, but additional information may be of use in the assessment, including the International Restless Legs Syndrome Group rating scale (IRLS), sleep partner observations, or through tests, which measure limb movement. RLS can lead to significant morbidity with strong evidence supporting the relationship between RLS with sleep disturbances and daytime sequelae. Patients with RLS often report difficulty in initiating and maintaining sleep (61%), limb pain (59%), inability to stay motionless (55%) and suboptimal daytime functioning (19-43%). The first line treatment for RLS with strong evidence to provide significant improvement in symptoms and severity consists of the use of the dopaminergic agents: levodopa, pergolide, pramipexole, and ropinirole. Unfortunately, the effectiveness of these agents is limited by tolerance and an unfavourable adverse effect profile including nausea/vomiting, somnolence and recently there has been publicity about disorders of impulse control (e.g. gambling).
The significant financial health costs of sleep disorders suggest that the investment in detection, prevention, and medical supervision is inadequate. For example, it has been estimated that 90% of individuals with OSA in the United States are undiagnosed. The high proportion of those with unrecognised OSA may be attributed to limited accessibility of diagnostic services, such as polysomnography (PSG). In Australia, PSG is a costly procedure and accounted for AUD 26.7 million (0.3%) of public healthcare spending in 2004. During this same time frame, there was a high demand for the procedure leading to waiting periods of 3 to 16 months, potentially compounding the impact of sleep disorders on individuals affected. The supply and provision of CPAP equipment and advice can be sought through many different avenues. Therefore, the fragmented nature of the healthcare system may lead to many individuals in society escaping detection and treatment for sleep disorders.

1.2 The diagnostic spectrum

There are a range of techniques to detect sleep disorders including the use of sleep diaries, questionnaires, portable diagnostic devices, and polysomnography.

1.2.1 Sleep Diaries

Sleep diaries are self-completed and can identify symptoms of insomnia and other potential areas of concern in sleep health and hygiene. The details of the previous night’s sleep, daytime sleep, daytime fatigue and medications are recorded on a daily basis for a certain, prescribed time. When used in conjunction with a patient’s history and other diagnostic techniques, a diary can aid the clinician in detecting the symptoms and possible causes of the sleep disorder.

1.2.2 Questionnaires

Questionnaires ascertain symptoms and/or risk factors involved in having a certain sleep disorder. Using questionnaires to detect sleep disorder risk is advantageous due to easier integration into a range of primary health care settings and with minimal disruption to the usual service provision.

1.2.3 Diagnostic processes and devices

The American Academy of Sleep Medicine classify diagnostic procedures into various classes dependent on the degree of complexity, instrumentation and need for supervision during a sleep study. The categories range from Class I which involves a fully attended PSG with all possible parameters monitored, to Class IV, which comprises an unattended sleep study conducted at home with only 1 or 2 parameters monitored. Class IV devices include wrist actigraphs, oximeters and nasal airflow monitors. As the degree of complexity and instrumentation decreases, the precision and accuracy of the procedure declines, but cost is reduced and of course, there is a less significant invasion to the patient’s lifestyle. (Note: The number of parameters monitored by a device are referred to as ‘channels’, so if a device simply detects oxygen saturations levels, it is referred to as a single channel instrument).

1.2.3.1 Class IV - Single channel monitors

Oximetry involves the monitoring of arterial oxygen saturation levels (SaO\textsubscript{2}) through an oximeter, usually attached on a palm digit. The role of oximetry in diagnosing sleep disorders is in measuring the frequency and severity of apnoea and hypopnoea episodes during sleep in patients suspected of having OSA.

Nasal airflow monitors measure the frequency of nasal airflow cessation during sleep. Such devices can be self-administered by the person and generally require from one to three nights monitoring. (NB: The device used in this study requires continual monitoring for at least 5 hours during sleep on 3 consecutive nights). After analysis, the output score represents the AHI for the period of recording. Subsequently, the data collected from the monitor can be used to determine the presence and severity of OSA.

While the former two types of monitors are predominantly used to detect OSA, other monitors can be used to monitor the presence of sleep or wakefulness. Wrist actigraphy collects data on limb movements during sleep. The device is
attached to the wrist on the non-dominant arm and the detection of movement is interpreted as the absence of sleep. Following total sleep time and the frequency of disturbances during sleep can be quantified from the actigraph.

### 1.2.3.2 Class I - Polysomnography (PSG)

PSG is the gold standard diagnostic procedure in the categorisation of sleep disorders through the measurement of cardio-pulmonary, neurological and skeletal muscle motor parameters. The PSG is performed in a sleep laboratory and involves the observation of brain wave activity through an electroencephalogram (EEG), pulse rate, arterial oxygen saturation (SaO$_2$), electrocardiogram (ECG), nasal airflow, respiratory effort, and the movement of skeletal limb, ocular and facial muscles. Of all the diagnostic tests the PSG collects the most quantitative data on sleep and is used to determine the presence and causes of varied and often non-specific sleep disorder symptoms.

In contrast, diagnostic devices and procedures such as actigraphy, oximetry, nasal airflow monitoring provide limited quantitative data on sleep. The diagnostic services require patient effort in obtaining and using the device or the inconvenience of attending a sleep laboratory and are also more expensive compared to using for example, questionnaires. Most questionnaires have been validated for the purpose of detecting probability or measuring severity of a single sleep disorder. Validation has occurred in clinical populations, most commonly attending specialist medical care, or healthy populations (i.e. students). Questionnaires have rarely been tested in primary care settings, and almost never in a pharmacy population. Recently there has been an upsurge in home-based diagnostic services, which allow patients to utilise diagnostic devices or instruments at home.

### 1.3 Screening for sleep disorders

The detection of sleep disorders is important to facilitate earlier diagnosis and delivery of treatment, reducing the impact on associated health and societal problems. There has been inadequate evidence on the effectiveness of models in specific primary healthcare settings for detecting sleep disorders. The community pharmacy is a feasible setting for screening and intervention services, compared to many other primary healthcare settings, due to higher public exposure and accessibility. Pharmacies are often the first point of entry into the healthcare system for individuals experiencing symptoms of sleep disorders and pharmacists are well placed to check medication profiles that may be suggestive of sleep disorders. In the past, there has been a range of successfully implemented screening systems for cardiovascular risk, diabetes, and *Chlamydia trachomatis* in community pharmacy. However to date, there has only been one study examining screening for sleep disorders in the pharmacy setting.

This screening project was reported from Switzerland, and involved a national sleep health campaign which was organised through community pharmacies. Participating Swiss pharmacists were trained to use an online screening tool to detect and refer people with possible sleep disorders. The campaign had very positive outcomes, with about one fourth of the total population screened having been identified with risk factors and provided with referrals. An exploratory study surveyed a convenience sample of community pharmacists in the greater Sydney area of New South Wales, Australia, who were suppliers of sleep-related devices such as Continuous Positive Airway Pressure (CPAP) machines. The pharmacists reported that current sleep health service provision was focussed on CPAP supply, however they were keen to address wider sleep health issues ranging from participation in public health and awareness campaigns, screening, and monitoring of patients with sleep disorders.

In view of the pressing need to enhance the public and health professional awareness about sleep disorders and for testing novel prevention and management strategies, community pharmacies represent an ideal point of care testing site for people with sleep disorders. Including the pharmacist as a member of the sleep disorders care team offers the opportunity to expand the reach of services spanning screening, referral, monitoring and counselling for patients with sleep disorders or those at risk of developing them.

As discussed above, there are major issues in the diagnoses and detection of sleep disorders in the community. Besides low levels of public and health professional awareness, it is well known that the diagnosis of sleep disorders is difficult on the basis of clinical markers alone and hence even when a sleep disorder is suspected General
Practitioners need to refer patients to specialists to provide access to PSG and specialist review. There are limited sleep laboratories and appointment and waiting times to gain access to a sleep laboratory or sleep physician appointment are quite long. The community pharmacy is therefore proposed as a venue for identifying people at risk of sleep disorders with the purpose of facilitating their referral to a physician for review and any ensuing diagnoses.

However whilst the American Academy of Sleep Medicine has recommendations about the usefulness and classification of diagnoses methods that are alternative to a full PSG, there are no guidelines about 'screening' and no currently recommended screening tools. Questionnaires have been the ‘traditional’ screening method in pharmacy based screening studies. In the case of sleep disorders, there is no single questionnaire that can identify several sleep disorders. Questionnaires have been validated for identifying single sleep disorder entities, and in many cases these questionnaires have been shown to have good sensitivity, but poor specificity, e.g. in the case of OSA. Therefore such questionnaires can be used for 'screening' purposes in a primary health care setting such as pharmacy, where the purpose is to identify 'at risk' people and refer them to appropriate channels for diagnoses and treatment. However, these questionnaires have been tested in clinical populations rather than populations that present in a primary care setting. As previous screening studies in community pharmacy for sleep disorders have not been undertaken, prevalence of sleep disorders in this population is not known. A further issue may be that pharmacist referral to physicians resulting from a screening process may or may not be taken up by patients screened. Again, as no previous work in this research area exists, it may be difficult to understand the processes that may be necessary to ensure adequate follow up of referrals provided by screening pharmacists.

Thus in order to consider the benefit of well designed screening programs in Australian community pharmacies, it is imperative that a feasibility study is undertaken. These studies need to develop a screening instrument, explore whether it is feasible to use in a pharmacy setting, and obtain exploratory data on the ability of the instrument to lead to diagnoses. Once it can be established that the screening is feasible in community pharmacy settings (willingness of people to be screened, ability of screening instrument to identify those at risk, processes facilitating uptake of referral by those at risk, and ultimately diagnoses in at least a reasonable proportion of those deemed at high risk), research should be undertaken to establish the validity of the screening instrument tested in the feasibility stage by screening a larger population base from community pharmacies and testing all people screened both with the screening instrument as well as a gold standard sleep disorder diagnostic test. The following report outlines a feasibility project for testing the community pharmacy as a site for screening for sleep disorders.
2.0 PROJECT OBJECTIVES

To develop, implement and evaluate an innovative primary care model in community pharmacy for screening, monitoring and education of people with sleep disorders and those at future risk of developing them.

The project was conducted in phases:

**Phase 1** - Development of pharmacist sleep health education program, screening and project protocols, sleep health awareness campaign material, collaborative sleep health care kits etc.

**Phase 2** – Implementation of sleep health awareness through participating pharmacies to raise awareness about sleep disorders in the community, and recruitment of patients.

**Phase 3** - Implementation of two pharmacy programs;

1) A basic screening program to determine the capacity of community pharmacies to detect undiagnosed sleep disorders in the community in all participating pharmacies AND

2) A comprehensive sleep screening program for those ‘at risk’ of developing a sleep disorder in the intervention arm.

**Phase 4** - Evaluation of the basic and comprehensive screening programs.

In a first of its kind, this project proposed to conduct a screening and awareness program to be run through community pharmacies by specially trained pharmacists. Further, the project aimed to conduct a randomised controlled trial to evaluate the effectiveness of two sleep health models in the community pharmacy setting; a BASIC screening tool for identification of sleep disorders versus a more COMPREHENSIVE sleep screening process including an objective measure of nasal air flow during sleep.

The effectiveness of the 2 randomised arms (BASIC SCREENING VS COMPREHENSIVE SCREENING) would be measured with the following key outcomes.

**Primary outcome**

- Proportion of patients screened who are identified as being at risk of developing a sleep disorder

**Secondary outcome**

- Proportion of patients screened who are diagnosed with a sleep disorder
3.0 METHODS

3.1 Phase 1

3.1.1 Screening tool development

A literature review identified a range of prevalent sleep disorders, associations of sleep disorders with lifestyle, medical conditions and medications, as well as suitable screening instruments or questionnaires. The Pharmacy Tool for Assessment of Sleep Health (POTASH) combined discrete questionnaires/instruments (Appendix 1 & 2) validated for the purpose of detecting the probability of a particular sleep disorder, with lifestyle, medical background and demographic questions into a single tool. The instruments utilised in the screening tool were the Epworth Sleepiness Scale (ESS),\textsuperscript{50} Insomnia Severity Index (ISI),\textsuperscript{51} Multivariable Apnoea Prediction Index (MAPI),\textsuperscript{52} and International Restless Legs Syndrome Study Group Screening Criteria (IRLS)\textsuperscript{53} (Appendix 3).

Lifestyle factors were investigated since individuals experiencing difficulties sleeping are more likely to engage in negative sleep hygiene behaviour, compared to normal sleepers.\textsuperscript{54} Inappropriate sleep practices may worsen or perpetuate sleep disturbances and can include circumstances such as disruptions in normal sleep periods due to shift work, alcohol consumption before bed-time and smoking.\textsuperscript{55-57} Medical history and medication use were included in the screening tool. Several medications are known to affect sleep, and similarly several medical conditions can affect sleep. Some sleep disorders have been associated with certain medical conditions, for example obstructive sleep apnoea with many cardiovascular conditions.\textsuperscript{13-18}

3.1.2. Development of screening / project protocols and materials

These materials included sleep health posters (Appendix 4) to be disseminated in participating pharmacies, a screening protocol to be followed by pharmacists (Appendix 5 & 6), referral methods (including referral templates; Appendix 7 & 8), shelf tags to be placed on pharmacy shelves to create consumer and pharmacy staff awareness (Appendix 9), and a sheet to document refusals by consumers invited by participating pharmacists to participate in the screening (Appendix 10). All materials and protocols were approved by the Human Research Ethics Committee, The University of Sydney (Appendix 11).

3.1.3 Development of the pharmacist sleep health education program

A 1.5 day workshop for pharmacists covering basic aspects of sleep health, as well as public health perspectives on screening was developed and accredited by the Pharmaceutical Society of Australia for 20 CPD points (Appendices 12 & 13).

3.2. Feasibility study

A feasibility study was planned as an additional preparatory phase, (1) to determine the feasibility of the screening process developed above, and (2) to describe the prevalence and trends of sleep disorders in the screened pharmacy population.

3.2.1 Recruitment of participants in the feasibility study

3.2.1.1 Sample size calculation

The sample size was based on published prevalence data of 21% of the study population (Swiss population) reporting an ESS > 10 and 11.7% in a recent New South Wales (Australian population) reporting ESS >10.\textsuperscript{27,44} Given that these data suggest a difference between the general and pharmacy population prevalence of sleep health conditions, an alpha error level of 5% and beta error level of 30%, were used to calculate that 81 participants were required, should such similar difference in general and pharmacy populations in Australia exist.
3.2.1.2 Recruitment strategy

For the purposes of this study, a convenience sample of pharmacies was recruited based on participation in a previous project as well as expressed interest by some pharmacists to participate in sleep health research. The five participating pharmacies were located within two states of Australia: New South Wales and Victoria. Pharmacists received on-site, one-on-one training on the screening protocol, the use of the Pharmacy Tool for Assessment of Sleep Health and were provided a resource package containing awareness (posters and shelf-tags) and screening material. Pharmacists were encouraged to recruit clients at risk of sleep disorders based on triggers outlined in the protocol. Clients requesting sleep aids, or cardiovascular or endocrine medications, or those who expressed interest in the sleep health screening through posters and pharmacy signage were offered screening since these individuals may be at most risk and would benefit from a medical referral. Pharmacists were requested to screen a maximum of 20 patients each. Pharmacists were trained on referral prompts and procedures.

Client participants were excluded at the point of initial recruitment if they have previously been diagnosed with a sleep disorder or were under 18 years. Recruitment for participants was conducted in pharmacies from the 30th July to 30th September, 2008. Completed surveys were scored by researchers to analyse the screening results with feedback provided to pharmacists about patient scores. However, in this pilot study, a follow up of pharmacist or patient actions was not conducted. In addition, as a safety procedure, pharmacists were asked to examine item 8 of the ESS, which asks respondents to rate their likelihood of falling asleep or dozing off in car when stationary such as at traffic lights, on a scale of 0-3 (0=none to 3=high). If any patients scored 1-3 for this item of the ESS, pharmacists were asked to provide an immediate referral to a medical practitioner.

3.2.2 Participating pharmacist feedback

After the screening service, participating pharmacists in the feasibility study were surveyed on their experiences during the program. The survey contained a series of Likert-type scales from 1 to 7 (1 being positive) and explored specific aspects of the screening process such as time constraints, effectiveness and the possibility of an online system.

3.2.3 Feasibility Study Data analysis

Data analysis was conducted with SPSS™ version 17.0. The risk of each sleep disorder was determined by published thresholds for the relevant instruments: ESS > 10 for Excessive Daytime Sleepiness (EDS), ISI ≥ 15 for clinically significant insomnia, MAPI > 0.5 for OSA and a positive response for all three IRLS criteria for RLS. The prevalence of each sleep disorder in the study population was estimated and associations between each sleep disorder with risk factors of interest were analysed through cross-tabulation, with the association described by odds ratio and 95% confidence intervals. All procedures were approved by the Human Research Ethics Committee at the University of Sydney (Appendix 11). The results from this feasibility study were presented to the Steering Committee at a meeting held on the 29th October, 2008. The feedback from the pharmacies was taken on board and other adjustments to the screening tool and the protocol, deemed necessary by the research team and steering committee were also made prior to the next phase.
3.3 Phase 2 & 3 Research design for final study

The research design comprised a randomised parallel group design, with pharmacy recruitment, randomisation into the basic arm (where consumers would be screened by the use of the screening tool only) and the comprehensive arm (where consumers would be screened using the screening tool followed by a home based screening using the FlowWizard®, nasal flow monitor; (Appendix 14)), and screening results compared between the two screening strategies. The FlowWizard® is a home use based nasal flow monitoring device that is easy to set up and use. The device was mailed to patients, nasal flow was measured across three nights of sleep, and the data within the device analysed to obtain a measurement of AHI (Apnoea Hypopnoea index). The rationale for using two separate arms was to test if one of these was more effective in terms of rates of diagnoses or follow up. The screening protocols for both the basic and comprehensive arm of the screening are outlined in Appendices 5 & 6. Protocol booklets were provided to participating pharmacists to enable the recruitment process, and guide screening referral and reporting within the project (see hard copy appendices). Sleep Health Awareness materials tested out in the feasibility study were refined and re-printed/collated (posters, shelf tags). As in the feasibility study, referral was based on identified patients found to be at risk for any of the major sleep disorders as determined by published thresholds for the included instruments. A close out questionnaire was designed as a follow up, so that outcomes of screened patients could be measured. An on-line version of the screening tool was developed on the 28th November, 2008 (Pharmacy Online Tool for Sleep Health (POTASH)). Participating pharmacies could choose to enter the data either online or in hard copy in a paper version that had also been provided, and this decision was left to the pharmacies. The online POTASH instrument was designed to be an exact copy of the hard copy, and was geared at self-administration by those undertaking the screening. The POTASH online version provided an automatic generation of results from the screening tool for pharmacist counselling and referral. The follow up questionnaire was also placed online and again was an exact copy of the hard copy paper version (Appendix 15).

3.3.1 Recruitment of pharmacists and patients into the final study.

Pharmacists were recruited from a sampling frame of those supplying CPAP equipment in their pharmacy. Lists of such suppliers were obtained from three main wholesalers of CPAP machines in NSW (ResMed, Respironics, and Fisher and Paykel). A few pharmacists from inter-state, who had read about the project, sought to participate in the study and were included. Recruitment was undertaken by calling pharmacies, supplying project information, and obtaining consent. After recruitment, pharmacists were stratified as either ‘Metropolitan/Urban or ‘Rural/Regional’ using the PhARIA classifications, and a block randomisation into the basic or comprehensive arm undertaken. Pharmacists were requested to screen 20 patients in their pharmacy, with the patient recruitment following the same protocol as in the feasibility study (Section 3.2.1.2).

3.3.2 PSG sub study

In a preliminary attempt to compare the results of the screening tools developed in this project with a gold standard diagnostic test, 20 patients from the comprehensive arm were invited to undertake a PSG. Comprehensive arm patients recruited through Sydney based pharmacies were identified, and 30 patients randomly selected. These patients were contacted via telephone and invited to attend a PSG test at the Woolcock Institute of Medical Research in Glebe, Sydney. Recruitment was continued until 20 patients completed testing. PSG testing was conducted by trained sleep technicians at the Woolcock Institute of Medical Research. These 20 patients were provided with a free consultation by the research team physician for an explanation of their PSG results.
4.0 RESULTS

4.1. Feasibility study

4.1.1 Feasibility study: sample

Eighty-four (50.3%) of the 167 pharmacy clients approached by the five pilot pharmacists were recruited. Most participants were recruited by pharmacy staff (73.8%), word of mouth (13.1%) or in response to a poster displayed near the pharmacy dispensary (6.0%). Nine clients were excluded, having stated they had been diagnosed with a sleep disorder. Common reasons for refusals were that 37% were too busy, 17% were not interested, and 16% of clients did not believe they had a sleep issue. Patient demographics are reported in Table 1.

Medical histories were obtained by a combination of checklists and open-ended responses. The most prevalent conditions were chronic pain (48.8%), cardiovascular disease (40.5%: dyslipidaemia, coronary heart disease, angina), hypertension (39.3%), gastrointestinal conditions (36.9%: dyspepsia, nausea and others) and insomnia (32.1%). Even though being diagnosed with a sleep disorder was an exclusion criterion, 32.1% of participants reported that they had previously diagnosed insomnia. The magnitude of previously diagnosed insomnia was similar to other medical conditions such as gastrointestinal conditions and depression (28.6%).

4.1.2 Prevalence of sleep disorders in the feasibility study

Sixty two percent of those screened were found to be at risk of at least one of the sleep disorders. In the ESS, item 8 assessed the likelihood of sleepiness “in a car, stationary for a few minutes in traffic,” and 6 participants (9.7%) exhibited some form of sleep propensity in this given situation. These participants received a medical referral. The mean score for the ESS was 4.8 ± 4.1, with 7.1% of those screened over the cut off value of 10 (Score Range 0-24). The mean score for the ISI was 13.4 ± 8.0, with 33% of the screened population above the suggested cut off value of 15 (Score Range 0-28). The mean score for the MAPI was 0.33 ± 0.25, with 21% of those screened determined to be at risk of OSA. In the case of the IRLS, which was a checklist of criteria necessary for a respondent to be deemed at risk of RLS, 27% of those screened met these criteria.

4.1.3. Process feedback

The participants found that the screening tool was relatively easy to complete, rating it at a median of 1.0 (range: 1–3) on a Likert-type scale from 1 to 5 (1 being very easy). The median time taken by the participant to complete the questionnaire was 10.0 minutes (range: 2–33). Pharmacists mainly initiated participation and it took 5.0 minutes (range: 0.5–20) to carry out the screening protocol, which involved explaining the study, obtaining consent and clarifying queries. After the conclusion of the feasibility trial of the screening service, pharmacists found their time management was fairly reasonable with 2.5 (range: 2–3) on a Likert-type scale of 1 to 7 (1 being very positive). Similarly, the feasibility trial of the service was a success (median: 2.0, range: 2–2) and when pharmacists were proposed with the likelihood of repeating the service as an online form, there was a mixed reception with a score of 2.5 (2–5).
<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>55.9 ± 16.9</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>33 %</td>
</tr>
<tr>
<td>Female</td>
<td>68 %</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>European</td>
<td>58%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>32%</td>
</tr>
<tr>
<td>Other</td>
<td>10%</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>27.9 ± 5.5</td>
</tr>
<tr>
<td>Shift work&lt;sup&gt;a&lt;/sup&gt;</td>
<td>12%</td>
</tr>
<tr>
<td>Alcohol&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>20%</td>
</tr>
<tr>
<td>Monthly or less</td>
<td>30%</td>
</tr>
<tr>
<td>Weekly/fortnightly</td>
<td>21%</td>
</tr>
<tr>
<td>&gt; 1 weekly</td>
<td>29%</td>
</tr>
<tr>
<td>Caffeinated beverages</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>11%</td>
</tr>
<tr>
<td>1</td>
<td>16%</td>
</tr>
<tr>
<td>2 - 3</td>
<td>45%</td>
</tr>
<tr>
<td>4 - 5</td>
<td>19%</td>
</tr>
<tr>
<td>≥ 6</td>
<td>10%</td>
</tr>
<tr>
<td>Smoking habits</td>
<td></td>
</tr>
<tr>
<td>Previous smoker</td>
<td>51%</td>
</tr>
<tr>
<td>Current smoker</td>
<td>17%</td>
</tr>
</tbody>
</table>

Table 1. Demographic and lifestyle profile of the screened population (n = 84)

<sup>a</sup> Any work during 2100 hours–0659 hours in the past fortnight  
<sup>b</sup> Number of standard drinks  
Values are given as mean ± SD unless stated otherwise
4.2. Final Study (Phase 4)

4.2.1 Pharmacist recruitment and training

Twenty-three pharmacists were recruited from a possible 40 on manufacturers’ lists. Twelve pharmacies refused to participate when contacted via telephone. The two major reasons for refusal being “lack of time” (n=6), or “unable to attend the training weekend” (n=3). Of the 23 participating pharmacies, 12 were randomised into the basic screening and 11 into the comprehensive arm. Eleven pharmacists from the basic arm, and 9 from the comprehensive arm completed the study. Three pharmacies withdrew from the study due to staffing problems. Thirteen pharmacies chose to use the paper version of the screening tool whilst 7 pharmacies entered data using the on-line version of the screening tool. A training workshop weekend was held for 13 of the pharmacists and some support staff at the Faculty of Pharmacy, The University of Sydney on the 1st and 2nd November 2008 (Appendices 12 & 13). Lectures were held on various sleep disorders, the project was explained and pharmacists practised screening during the workshop. A ‘catch-up’ workshop was conducted on the 10th January 2009 for those remaining 10 pharmacists that were unable to attend the original training workshop in November 2008 (Appendix 16).

4.2.2 Sleep Heath Awareness Program

From January 1, 2009 to March 31, 2009 pharmacists ran a sleep health awareness program, using the materials provided by the project team as well as their own innovative strategies to encourage patient participation (Appendices 4, 9, & 17).

4.2.3 Patient recruitment and general demographics

Between January and April 2009, the 20 pharmacists recruited and screened 325 patients (approximately 16 per pharmacy). Refusals totalled 333 (approximately 17 per pharmacy). The main reasons for refusal were ‘lack of time’ (34% of refusals) and ‘lack of interest’ (26% of refusals). Of the recruited patients, 47% (n=152), and 53% (n=173) were recruited within the basic and the comprehensive arm respectively. The demographic characteristics of the screened patients are outlined in Appendix 18. There were no significant differences between those screened between the groups. A majority of the patients participated as they were approached by pharmacy staff (62%), some because they saw the sleep health awareness poster (15%), others because they had been at the pharmacy to talk about a sleep problem, and were opportunely recruited and screened, and many were recruited as they had presented at the pharmacy to obtain sleep related (8%) or other medications (20%). In some instances there was more than one reason for having been recruited.

The ease of recruiting varied between the pharmacies. Generally those pharmacies that had a specific staff member dedicated to sleep health found it much easier to recruit patients. Pharmacies that had no specific staff member focussing on sleep health found it difficult to recruit patients due to time constraints. Pharmacies were mostly positive about the implementation of the study protocol and several commented that they found it easier to recruit participants for sleep health screening than for other screening and professional services currently being implemented.

4.2.4 Patient health and sleep related demographics

As expected, the population screened (from those presenting at a pharmacy) demonstrated several health risk factors, the mean BMI was well over healthy limits, a fifth of the population consumed more than the recommended number of alcoholic drinks in a week, and a sixth of them were current smokers (Table 2). These are risk factors for several sleep disorders. From a healthy sleep practice perspective, two thirds of screened people consumed caffeinated drinks after 15.00 hours, of those that had alcohol, half had consumed it after 20.00 hours. A tenth of the population undertook shift work (Table 3).
<table>
<thead>
<tr>
<th></th>
<th>Overall n=325</th>
<th>Basic Arm n=152</th>
<th>Comprehensive arm, n=173</th>
<th>p value# (between group comparisons)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean BMI±SD</strong></td>
<td>29.9±6.4</td>
<td>29.7±5.4</td>
<td>29.9±7.0</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Alcohol Use</strong></td>
<td>23.1</td>
<td>22.4</td>
<td>23.7</td>
<td>0.77</td>
</tr>
<tr>
<td>% consuming an alcoholic drink 4 or more times a week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Caffeine Use</strong></td>
<td>26.7</td>
<td>29.5</td>
<td>24.3</td>
<td>0.30</td>
</tr>
<tr>
<td>% consuming an caffeinated beverage 4 or more times a day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>% Ever smoked</strong></td>
<td>52.6</td>
<td>50.0</td>
<td>54.9</td>
<td>0.38</td>
</tr>
<tr>
<td><strong>% Current Smokers</strong></td>
<td>16.0</td>
<td>14.5</td>
<td>17.4</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>Mean Pack-Years±SD</strong></td>
<td>10.5±17.3</td>
<td>10.8±18.9</td>
<td>10.2±16.1</td>
<td>0.81</td>
</tr>
</tbody>
</table>

**Table 2. General Health Demographics of the Groups**

# Pearson’s Chi-square for proportional data, or Mann Whitney test for non-normally distributed data, or independent samples t-test for normally distributed data.
### Table 3. General Sleep Related Demographics of the Groups

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Overall n=325</th>
<th>Basic Arm n=152</th>
<th>Comprehensive arm, n=173</th>
<th>p value # (between group comparisons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Sleeping alone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>41.5</td>
<td>37.5</td>
<td>45.1</td>
<td>0.16</td>
</tr>
<tr>
<td>% Undertaking shift work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10.2</td>
<td>11.3</td>
<td>9.3</td>
<td>0.46</td>
</tr>
<tr>
<td>% Consuming caffeine after 1500 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>65.9</td>
<td>48.6</td>
<td>51.4</td>
<td>0.33</td>
</tr>
<tr>
<td>% Consuming alcohol after 2000 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>51.9</td>
<td>56.9</td>
<td>43.1</td>
<td>0.06</td>
</tr>
<tr>
<td>Self reported average hours of sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6.41±1.8</td>
<td>6.46±1.7</td>
<td>6.36±1.7</td>
<td>0.60</td>
</tr>
<tr>
<td>Self Reported Quality of Sleep on A scale of 1-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.6 ±1.1</td>
<td>2.2±1.1</td>
<td>2.9±1.1</td>
<td>&lt;0.0</td>
</tr>
<tr>
<td>Self Reported Satisfaction with Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.7±1.3</td>
<td>2.3±1.2</td>
<td>3.0±1.1</td>
<td>&lt;0.0</td>
</tr>
</tbody>
</table>

The most prevalent conditions were chronic pain (41%), cardiovascular disease (hypertension (39%), dyslipidaemia, coronary heart disease, angina (37%)), gastrointestinal conditions (29%: dyspepsia, nausea and others) and depression (27%). Twenty three per cent of participants reported that they had previously diagnosed insomnia. There were no intergroup differences in these medical/medical history demographics.

As expected, the screened population were taking medications to address health issues (Table 4). For almost all health conditions, the proportion of people taking medications for a condition was lower than the proportion of people who had that condition indicating that some people either had milder forms of several conditions, or chose not to take therapy.
### Table 4. Medication taking history for the two groups.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypercholesterolemia/CHD/Angina</td>
<td>31.4</td>
<td>32.9</td>
<td>30.1</td>
<td>0.58</td>
</tr>
<tr>
<td>Diabetes</td>
<td>14.2</td>
<td>15.8</td>
<td>12.7</td>
<td>0.43</td>
</tr>
<tr>
<td>Pain</td>
<td>30.5</td>
<td>24.3</td>
<td>35.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Asthma</td>
<td>13.8</td>
<td>14.5</td>
<td>13.3</td>
<td>0.53</td>
</tr>
<tr>
<td>Depression</td>
<td>20.2</td>
<td>18.4</td>
<td>23.7</td>
<td>0.25</td>
</tr>
<tr>
<td>Insomnia</td>
<td>12.3</td>
<td>11.2</td>
<td>13.3</td>
<td>0.56</td>
</tr>
<tr>
<td>GI complaints (reflux, ulcers, constipation)</td>
<td>22.8</td>
<td>24.3</td>
<td>21.4</td>
<td>0.53</td>
</tr>
<tr>
<td>Sinus /rhinitis problems</td>
<td>8.3</td>
<td>9.2</td>
<td>7.5</td>
<td>0.58</td>
</tr>
</tbody>
</table>

# Pearson's Chi-square

### 4.2.5. Patient risk of having or being at risk of developing key sleep disorders.

These risk rates are presented below in Table 5. The mean score for the ESS (Epworth sleepiness scale, 0-24) was 6.4±4.6, that for the ISI (Insomnia Severity Index, 0-28) was 11.5±7.0, for the IRLS criteria it was 1.6±1.4 (International Restless Legs Syndrome Study Group Criteria, 0-3). The ESS score was significantly lower in the basic arm (p=0.009), but for ISI and IRLS scores, there was no difference between groups (p>0.05). The mean MAPI score for the screened population was 0.45±0.26, with no significant differences between groups (p>0.05). Those at risk of having or developing OSA were 46.7% (42.1% in the basic and 50.8% in the comprehensive arm) of the screened population, and those at risk of having or developing OSAS (taken as having an above threshold value for MAPI and ESS) were 11.7% (n=38) of the screened population. Thirty eight percent of people fulfilled the criteria for the diagnosis of restless legs (34.2% in the basic arm, and 40.4% in the comprehensive arm), of these RLS risk people, 46% indicated they experienced symptoms similar to RLS on more than 4 occasions in a week. Of the 325 screened, 18% were not at risk for developing any sleep disorder, 50.5% (n=164) were at risk of having or developing one sleep disorder, 26.5% (n=86) were at risk of having or developing two sleep disorders, and 4.9% (n=16) displayed risk scores commensurate with having/developing all three sleep disorders screened for.

In the comprehensive screening arm, 132 of the participants (n=173) completed the nasal flow monitor recording. Of these, 87 (66%) had an AHI of greater than 15. The mean AHI was 25.4±16.9, and ranged from 5 to 119.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Overall n=325</th>
<th>Basic Arm n=152</th>
<th>Comprehensive arm, n=173</th>
<th>p value # (between group comparisons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients at risk of increased daytime sleepiness ESS &gt;10 (Score range 0-24)</td>
<td>23.1</td>
<td>17.7</td>
<td>27.7</td>
<td>0.03</td>
</tr>
<tr>
<td>% of patients at risk of significant insomnia (ISI ≥ 15, score range 0-28)</td>
<td>33.8</td>
<td>26.9</td>
<td>39.8</td>
<td>0.01</td>
</tr>
<tr>
<td>% of patients at risk of OSA (MAPI ≥0.5, score range 0-1)</td>
<td>44.3</td>
<td>40.7</td>
<td>47.4</td>
<td>0.23</td>
</tr>
<tr>
<td>% of patients at risk of RLS (IRLSSG Criteria met, score =3, score range 0-3)</td>
<td>37.5</td>
<td>34.2</td>
<td>40.4</td>
<td>0.24</td>
</tr>
<tr>
<td>% of patients at risk of OSAS(ESS Score &gt;10, and MAPI value ≥0.5)</td>
<td>11.7</td>
<td>8.5</td>
<td>14.4</td>
<td>0.04</td>
</tr>
<tr>
<td>% of patients with an AHI &gt;15 (AHI &gt;5= No OSA, 5-15=mild OSA, 15-30= Mild - Moderate OSA, &gt;30 Moderate – severe OSA, n=132 who completed the FlowWizard Recording)</td>
<td>-</td>
<td>-</td>
<td>66.0</td>
<td>-</td>
</tr>
</tbody>
</table>

**Table 5: Risk of having/developing a sleep disorder**

# Pearson’s Chi-square

ESS= Epworth Sleepiness Scale, ISI= Insomnia Severity Index, MAPI= Multivariate Sleep Apnoea Prediction Index, IRLSSG = International Restless Legs Syndrome Study Group Criteria, OSAS=Obstructive Sleep Apnoea Syndrome, AHI=Apoeno Hypopnoea Index

<table>
<thead>
<tr>
<th>Comprehensive arm, n=132</th>
<th>MAPI Scores</th>
<th>FlowWizard® Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of those screened</td>
<td>Number of those screened</td>
</tr>
<tr>
<td>At Risk ( ie MAPI Score ≥0.5, score range 0-1, or AHI &gt;15)</td>
<td>70</td>
<td>87</td>
</tr>
<tr>
<td>Not at Risk</td>
<td>62</td>
<td>45</td>
</tr>
</tbody>
</table>

**Table 6: Comparison of OSA risk scores using the MAPI vs FlowWizard® in the comprehensive arm**
Figure 1. Proportion of people with mild moderate and severe OSA based on AHI readings from the FlowWizard® (n=132), in the comprehensive arm of the study.

4.2.6 Screening process

The online screening option was used by 80 people screened in the basic arm, and 112 people who were screened in the comprehensive arm (Total of 192/325 screened). The mean time taken to complete the screening was 11.6 ± 7.0 minutes. The time taken in the basic screening population was statistically longer (12.7 ± 9.0 minutes) compared to the comprehensive arm (10.6± 4.5 minutes), (p=0.007). This may be due to the higher numbers of people who used the online screening option in the comprehensive arm. On a scale of 1-5 (1 = very easy, 5 = very hard), patients indicated a mean ease of completing the screening at 1.6 ± 0.7. A majority of those who undertook screening at the request of pharmacy staff had been invited for the screening by pharmacists (26% of total screened). Filling out of the screening tool was mostly done independently, and only 22% of those completing the screening tool required assistance. In those people for whom pharmacy staff had to offer assistance, the staff time taken to assist the patient ranged between 0-30 minutes (mean 3.9 ± 5.8 minutes).

Pharmacists recorded a total of 849 interventions (2.6 interventions per patient), a total of 137 referrals were recorded by pharmacists (1 in every 2.3 people screened). Of these 116 (85% of all referrals) referrals were recorded for people whose screening tool scores indicated a risk of having a sleep disorder, or if the respondent reported poor, unsatisfying sleep (Figure 2).
4.2.7 Screening efficiency, comparison of screening outcomes between groups

Two hundred and twenty four (68% of those screened) participants completed the follow up visit and returned a close out questionnaire. Of these, 111 (50.4% of completers) of patients belonged to the comprehensive screening arm of the study. Besides age, there were no statistically significant demographic differences between the population group that completed follow up versus those that did not complete follow up (gender, BMI, shift work, employment status, having been diagnosed with cardiovascular/diabetes problems, combined total risk of having/developing a sleep disorder). The mean age of those that completed the follow up was higher at 56.9 ± 15.8 as compared to 51.1 ± 15.3 (p=0.002) for those that did not complete the follow up. Outcomes are indicated below (Figure 3).
Figure 3. Screening outcomes in both groups
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Overall n=325, Completing Close Out=224</th>
<th>Basic Arm n=152 Completing Close out=111</th>
<th>Comprehensive arm, n=173 Completing Close out=113</th>
<th>p value # (between group comparisons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% who completed of POTASH online</td>
<td>59</td>
<td>52.6</td>
<td>64.7</td>
<td>0.03</td>
</tr>
<tr>
<td>% retention at close out</td>
<td>68.9</td>
<td>73.0</td>
<td>65.3</td>
<td>0.13</td>
</tr>
<tr>
<td>% of patients reporting being referred, of 224 completers</td>
<td>38</td>
<td>33.3</td>
<td>42.4</td>
<td>0.15</td>
</tr>
<tr>
<td>% of patients reporting taking up referral, of the 224 completers</td>
<td>21</td>
<td>20.7</td>
<td>22.1</td>
<td>0.09</td>
</tr>
<tr>
<td>% of patients referred reporting being referred to a sleep physician, of the 224 completers</td>
<td>0</td>
<td>8.0</td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>% of patients reporting having undergone a sleep study</td>
<td>2.7</td>
<td>1.8</td>
<td></td>
<td>0.73</td>
</tr>
<tr>
<td>Mean Total Risk Score in all those screened, where 1= risk of 1 sleep disorder, 2= risk of 2 disorders, 3=risk of 3 disorders</td>
<td>1.03±0.8</td>
<td>1.3±0.7</td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>% of patients diagnosed in those completing the follow up</td>
<td>7</td>
<td>10.8</td>
<td>7.9</td>
<td>0.48</td>
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<tr>
<td>% of patients reporting initiating smoking related changes at follow up</td>
<td>17.1</td>
<td>20.3</td>
<td></td>
<td>0.30</td>
</tr>
<tr>
<td>% of patients reporting initiating alcohol use changes at follow up</td>
<td>14.4</td>
<td>14.1</td>
<td></td>
<td>0.83</td>
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<tr>
<td>% of patients reporting initiating caffeine use changes at follow up</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>% of patients reporting initiating sleep environment changes at follow up</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Table 7. Screening process efficiency in both arms of the study

# Pearson’s Chi-square for proportional data, or Mann Whitney test for non-normally distributed data
Despite the fact that there was a significantly higher total risk level identified in the comprehensive arm, there were no statistically significant differences between the groups with respect to the proportion of patients who were referred, those who took up referrals or received a diagnosis following referral (p > 0.05), (Table 7). Ninety four percent of patients who reported at close out that they were referred, indicated being referred to their own general practitioner (GP). However a significantly higher proportion of patients in the comprehensive reported that their referral made was to a specialist, (p=0.01, Table 7). There were no differences in the number of sleep studies undertaken in either group (p=0.71). Of the 15 diagnoses made, 7 diagnoses occurred in the basic screening arm, and 8 in the comprehensive arm (p=0.19), (Table 8).

<table>
<thead>
<tr>
<th>Condition Diagnosed</th>
<th>No Diagnosed Overall n=224</th>
<th>No Diagnosed Basic arm n=111</th>
<th>No Diagnosed Comprehensive arm, n=113</th>
<th>p value # (between group comparisons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>15</td>
<td>7</td>
<td>8</td>
<td>0.19</td>
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<tr>
<td>OSA</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>CSA</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>RLS</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td></td>
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</table>

Table 8. Sleep Disorder Diagnoses reported by patients completing follow up

# Pearson's Chi-square

Of the 48 referrals (out of 85 reported by completers) that were taken up by patients, 15 resulted in sleep disorder diagnoses (31% of 48). A further five diagnoses have been tentatively made by their physicians pending further confirmation, as there are eight patients awaiting results (six waiting for a sleep laboratory appointment, two awaiting results of sleep laboratory tests). Two cases obtained alternative diagnoses (epilepsy, nasal polyps), and in 20 cases (41%), the referral resulted in outcomes other than a sleep diagnosis or investigation. Of these miscellaneous outcomes (n=20), in three cases the GP did not consider the referral or discuss the patients’ sleep issues and risk scores. In four cases the GP decided to monitor for a while before undertaking further studies. In four instances, GPs considered the risk factors and sleep scores, and advised the patient to make lifestyle changes (lose weight, avoid heavy meals at bedtime). In another case, the GP initiated a specialist investigation as apnoea symptoms seemed to be ‘nasal’, this resulted in a diagnosis of nasal polyps. In one case the GP made a diagnosis of ‘epilepsy’ which was triggered as a result of sleep disturbances rather than a sleep disorder itself. In one case, the GP switched a medication that may have resulted in the patient’s complaints of RLS, and in another the GP initiated a regimen (time of medicine taking) change to minimise sleep symptoms.
4.2.8. Comparison of results from the PSG with the POTASH

PSG testing was completed in 20 randomly selected patients in the comprehensive arm. In these 20 patients, the MAPI scores from the POTASH and the AHI score from the FlowWizard® were tested against the AHI score obtained from the PSG; in both cases the PSG reported AHI scores were significantly correlated with the MAPI score and the FlowWizard® results (p<0.001).

Nine out of the 20 people in this sub-sample were determined at risk of OSA on the basis of a MAPI score of greater than 0.5, and eight people could be deemed to have OSA based on an AHI of greater than 5 from the PSG. Figure 4 cross-tabulates the results from the MAPI vs the PSG. The sensitivity of the MAPI testing in the POTASH in predicting OSA was calculated as 75%, and specificity as 73%. Those predicted by MAPI to be at risk of OSA had a 67% rate of having OSA on PSG (positive predictive value), while those deemed not at risk of OSA had an 80% rate of not having OSA on PSG (negative predictive value).

<table>
<thead>
<tr>
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<th>PSG AHI&gt;=5</th>
<th>PSG AHI&lt;5</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAPI: at risk of OSA</td>
<td>6 (true positives)</td>
<td>3 (false positives)</td>
</tr>
<tr>
<td>MAPI: not at risk of OSA</td>
<td>2 (false negatives)</td>
<td>8 (true negatives)</td>
</tr>
</tbody>
</table>

Table 9. Comparison of the results from the POTASH testing and PSG testing in patient subset.

Severity of insomnia symptoms, as rated by ISI scores from the POTASH, were correlated with three variables obtained from the PSG namely, ‘Sleep Onset Latency’ (time in bed before sleep onset occurs), ‘Total sleep time’ (in hours), and ‘Sleep efficiency’ (time in state of sleep as ratio of time in bed), in all 3 cases the ISI score from the POTASH questionnaire was significantly correlated with PSG variables (p<0.001). The ‘Leg Movement Index’ and the ‘Periodic Limb Movement Arousal Index’ from the PSG were compared between those that had scored ‘3’ on the IRLS versus those that had scores less than 3. No statistically significant differences were found in either case.

Within the close out questionnaire, those screened were asked whether they had instigated changes in their lifestyle as a result of the screening. Four lifestyle variables that can affect sleep were considered – namely smoking, caffeine and alcohol consumption, and sleep environment. Those followed up reported having made several important lifestyle changes, but there were no statistically significant differences in the groups based on these four lifestyle changes made (p>0.05) (Figure 4). One person reported ceasing a medication (anti-depressant) that was causing sleep problems whilst undertaking shift work. Eighty five percent (n=191, 91 in the basic arm, 100 in the comprehensive screening arm) of those screened indicated that they would recommend the screening service to family or friends who may have sleep related issues. Fifty seven percent of those completing the follow up indicated that they would be willing to pay for the screening service (n=128, 65 in the basic arm, 63 in the comprehensive arm). The mean value of what participants were willing to pay for the screenings service was $ 45.4± $90.0, the range for their willingness to pay was from $5 to $200.
Figure 4. Proportion of people who reported instigating good sleep health practices at follow up.

Figure 5. Impact on sleep health understanding

- No impact
- Little-very little impact
- Large-some impact
Participants were asked to rate on a scale of 1 to 5 (1=Large Impact to 5=No Impact), whether the screening process had had an effect on their understanding of good sleep health practices, confidence in managing sleep problems, and asking questions about sleep health from their pharmacist and GP. The results are indicated in Figure 5 above.

When asked what the main outcome of the screening had been most participants completing the survey had very positive comments. A sample is highlighted below.

- Validated my belief that I may have a sleep related problem. Earlier this year I fell asleep momentarily whilst speaking with a client in the middle of the day. I can nod off easily, since a young adult I have been known to fall asleep in lectures and movie theatres.
- It helped me to see GP and ask questions about sleep, gave me a nasal spray to help with breathing
- I found it helpful to sit down and talk to the pharmacist and discover small changes that I would make that have improved the number of hours I sleep, written information was wonderful;
- It has given me a much clearer understanding of the ways and habits I have to adopt in order to improve my sleeping.
- My health has improved 10 fold, I am no longer tired and moody
- I found by keeping the diary I was able to see the pattern my sleep habit followed. I am examining more reasons why my sleep is interrupted for hours at a time, and learning not to be anxious when I cannot get back to sleep. I believe I am now having more nights of good sleep than I was previously as a result.
- Knowing that I don't have any serious sleep-related issues, + that I am in the normal "breathing pattern" parameters is definitely a positive outcome. I also have a better awareness of sleep health.
5.0 DISCUSSION

This study was the first study in Australia that developed and implemented a screening and awareness programme for sleep disorders in Australian community pharmacies. In the future, the screening service may extend the role of pharmacy in sleep health. The results highlight the fact that sleep disorders are an unmet public health problem that can be addressed by utilising trained and specialised pharmacists. In the population screened in community pharmacies, nearly half of those screened were found to be at risk of at least one of the screened disorders. The large proportion of the participants at risk confirms that not only are sleep disorders a possibly quite prevalent issue in the population as reported in the literature, but also in those screened in community pharmacies. This suggests that community pharmacy may be a prime location for sleep disorder detection. Further, those screened indicated that they found the screening process quite easy and quick to undertake. Most pharmacists reported it reasonably easy to recruit patients and deliver the screening. Pharmacists targeted potential ‘at risk’ patients, and patients self selected for the screening based on sleep health awareness materials. These facts are indicative of the demand for sleep screening and sleep health services.

For the sleep disorders that were screened for, the risk estimates in the participants screened were found to be generally higher than in the general population. In a recent study focusing on New South Wales adults by Bartlett et. al., the prevalence of EDS (Excessive Daytime Sleepiness) and insomnia was estimated at 11.7% and 33.0%.[27] The ISI risk estimate for insomnia obtained in our participants were generally consistent with population prevalence studies, i.e. 34%. However, our participants had above threshold EDS of 23%, nearly double that of the previously reported population rate of 11.7%. This reflects a participation bias the sleep health awareness materials and posters in the pharmacies especially targetted those who felt excessively sleepy and tired. A higher OSA probability was also found in our study (44%) compared to population estimates of 9-24% in the United States.[10] Similarly, a higher risk of RLS (37%) was found in the pharmacy screened population compared to reported population rates in other studies (5-10%).[36,58] The higher prevalence rate for OSA and RLS may be associated with the fact that screened population of pharmacy clients had several associated comorbid conditions and medication use, thus they were already at a greater risk than the general population.

There was no difference between the groups in terms of baseline demographics, and scores for insomnia, OSA, or RLS. The comprehensive screening arm had a significantly higher proportion of the population who could be deemed to have or be at risk of developing insomnia using the ISI, even though the actual risk scores for ISI were not significantly different between groups. This higher proportion of those with an ISI greater than15, may be related to the significantly lower sleep quality reported by those in the comprehensive arm of the study (Table 2). Similarly, the comprehensive arm also had a significantly higher proportion of people at risk of developing OSAS (Obstructive sleep apnoea syndrome, i.e. OSA symptoms occurring with manifest excessive daytime sleepiness (EDS)). Again this may be related to the fact the comprehensive group population had a a significantly higher ESS score. The Swiss community pharmacy sleep screening study by Hersberger et. al., found 21% of the screened population to be at risk of a sleep disorder.[44] In our study, 50% of participants were found to be at risk of at least one sleep disorder.

In the final screening study, the targeted sampling by the pharmacists may have inflated the prevalence figures since those selected may be more likely to be at risk of a sleep disorder (selection bias). Moreover, clients who suspected they may have a sleep disorder may also have been more likely to volunteer for the study (participation bias). Other limitations of the developed tool and screening process were that the individual instruments have not been previously validated in a pharmacy setting. It may be that, since the instruments utilised in the study had been validated in non-pharmacy settings, the threshold scores for the instruments did not have optimal sensitivity and specificity, which may contribute to a higher probability of false-positives. Nonetheless, the scores obtained from the PSG for the three conditions of interest were significantly correlated with the scores calculated using the POTASH, the sensitivity and specificity of the POTASH for OSA was reasonably good for a screening tool (75%, 73%). For example, the American Diabetes Association Questionnaire used widely in the past for screening for diabetes has a sensitivity of between 72-78%, and a specificity of between 50-51%.[59]
Only 69% of patients could be followed up within the project time frame. Interestingly, 38% of patients at follow up recalled being referred, but only 21% reported taking up the referral. The rate of diagnoses with a sleep disorder was 7% (n= 224 completers), and another 7% of those completing were still awaiting further testing prior to diagnoses. However, the rate of diagnoses in those who did take up the referral was 31% (1 in 3 who visited the doctor (n=48)). Thus in those referred through the screening program, there was a high efficiency of being identified as being at risk for a sleep disorder. This fact coupled with the reasonable screening sensitivity and specificity demonstrated by the POTASH tool suggest a high potential for utility as a screening tool.

In comparing the two approaches to screening, even though the comprehensive approach involved sequentially more detailed tests (nasal flow monitoring), there were no significant differences in groups between rate of referral, referral uptake, or diagnoses. However, there were some trends in favour of the comprehensive arm. The fact that patients were lost to follow up, or did not take up their referral reduced the numbers and thus may explain the inability to demonstrate statistically significant differences in rates of referral and diagnosis between groups. Thus we cannot confidently conclude that either approach to screening is superior. In future iterations of this screening program, a longer time should be allowed for follow up. It is well known that obtaining specialist appointments is hard because of long waiting times. In many instances, a sleep laboratory study to confirm diagnosis may be required after a specialist referral, adding again to the time lapse between screening based referral and diagnostic outcome. More intensive and dedicated follow up by pharmacists or pharmacy staff in those who were identified at ‘high risk’ and provided a referral may also improve referral uptake rates. This is suggested as this population seems suggestible to health risks. For example, in the population with sleep disorders, even internet based screening can result in a greater proportion of screened people discussing sleep health with their physician. Hence intensive follow up and adequate time may have led to better rates of diagnoses in the study population. Time and resource constraints in the current project limited these steps. The low numbers of diagnoses do not allow for a meaningful cost analysis, however data trends suggest that the basic screening involving an on the spot questionnaire in the pharmacy setting is as effective as screening involving further take home nasal flow monitoring or sleep diary recording.

In addition to the primary outcomes of risk evaluation and diagnoses, the screening service had an impact on participants’ understanding of good sleep health practices and confidence in asking questions about sleep health. Pharmacists used the screening process as an opportunity for counselling; a fifth of those who were followed up made changes in their caffeine drinking habits, a tenth changed alcohol usage patterns (decreased) and a seventh of those screened made sleep friendly changes in their sleeping environment. Four percent of those who completed the follow up reported having quit smoking. These patient reported lifestyle changes indicate that the project accrued benefits beyond merely ‘screening’. Pharmacists’ provision of sleep health education led to lifestyle changes that have implications not only for sleep health but for improving cardiovascular risk e.g., smoking cessation, alcohol reduction, weight loss. Whilst the primary aim of the project was to identify those at risk of sleep disorders, it is recommended that in the a larger scale screening program should also include investigation of the effectiveness of pharmacists’ providing sleep health education.

Most of those screened indicated that they considered the screening process worthwhile, and half were willing to pay for such screening services in the future. Eighty five percent at follow up were willing to recommend the screening service to their friends and relatives who may have sleep related health issues. Those screened reported that the screening protocol was quick and easy to complete. The screening resulted in some indirect benefits – diagnoses of other conditions that may be affecting sleep, triggering the need for increased monitoring and vigilance in those at high risk who were not diagnosed at this stage by doctors and changes in medications that may have been causing sleep related side effects in a couple of cases. The large majority of participants indicated at follow up that the main outcome of the screening was having an increased awareness about sleep health and good health practices.

These outcomes highlight the role of the pharmacist in screening for sleep disorders and sleep health education. It is well known that specific medication classes have the potential to disturb sleep-wake cycles. Pharmacists are in the position to observe medication use and can flag those at a higher risk of having or developing a sleep disorder. Since pharmacists are privy to their patients medical and medication histories, they can easily reasonably assist in identifying at risk patients. Pharmacists are well placed to provide information on medications and their potential adverse effects
on sleep, and to indentify contributing causes for sleep disorder symptoms in presenting clientele, hence data from the current study supports research on using community pharmacy as a screening venue.

Study limitations include the fact that it is difficult to know the general characteristics of the pharmacy population, to determine whether the population screened represented a more unwell subset (i.e., there is no procedure in the protocol to collect symptom information on all pharmacy attendees). The instruments used rely on self-report, and have not been validated previously, but not in a pharmacy population. At this point in time there are no published studies of primary care screening for sleep disorders, hence the screening efficiency of our screening instrument cannot be compared with screening for sleep disorders at other primary health care sites.

The sensitivity and specificity of the screening tool as a whole (for all three disorders) used in our study has not been demonstrated. Whilst the sensitivity and specificity of the screening tool have been reported in our study for OSA, for a small subset of 20 patients in whom polysomnography was conducted (this testing was conducted in addition to primary objectives of the study), these results need to be interpreted with caution. The researchers did not attempt to conduct diagnostic accuracy of the newly developed screening instrument, for reasons highlighted in the introduction, this study represented a feasibility study of sleep disorders screening in community pharmacy, and testing the diagnostic accuracy of the newly developed screening instrument was not part of the study aim. In a formal diagnostic accuracy study, all participants, whether or not deemed to be at risk of any of the 3 disorders (Obstructive Sleep Apnea (OSA), Restless Legs Syndrome (RLS) and Insomnia) that were being explored would also be tested against reference tests for diagnosing each of the 3 conditions. The reference test for OSA would consist of a laboratory sleep study (polysomnograph), while RLS and Insomnia are diagnosed on clinical criteria and hence require sleep specialist assessment (ICSD criteria). As the average cost of conducting a PSG is $600, this was beyond the budget for this smaller scale feasibility project.

It may be argued that if instead of considering testing all patients against a reference standard such as polysomnography, one could consider the diagnosis by a physician, as reported by some patients at follow up as a reference standard ‘diagnostic test’, then perhaps some calculation of the POTASH accuracy could be carried out. However as confirmatory testing was not built into the protocol, but only done as clinically indicated when patients were referred for further evaluation, there is an issue of differential verification bias. Differential verification bias refers to the distortion of the performance of a diagnostic or screening test if its result influences whether patients undergo confirmation by the reference standard. This is a phenomenon built into our trial as only those identified as ‘at risk’ by the screening are referred for further assessment. Those not identified as at risk may also have chosen to seek further referrals, and we have tried to collect information about their subsequent test findings as part of the follow-up for the trial. Nevertheless, it is erroneous to cross-tabulate the screening and reference standard results of only those who have received further assessment for the purposes of reporting diagnostic accuracy statistics. From the ‘feasibility’ perspective, the testing of all those screened would interfere with our ability to observe how the screening procedures affected subsequent behaviours, including the pursuit of further health care, including specialist, assessment and management, in as ‘natural’ a setting as possible. Other issues include the fact that the diagnosis was self reported by patients in a follow up by their pharmacist, and the diagnosis was not confirmed by a physician. Moreover in the follow up study not all patients referred to a physician actually took up referrals. This leaves very few people referred for a particular disorder, that took up the referral and in turn were diagnosed making this process statistically meaningless if undertaken (See Appendix 18 (Figures 1 to 7) for clarification).

Ultimately it would be important to show that the screening instituted a change in management and improved patient outcomes. Whilst our study recorded patient sleep health behaviour changes at follow up, the study was not designed to test the effectiveness of the pharmacist interventions as a result of screening outcomes, this element should be built into future studies. The study has provided baseline data to conduct future larger scale screening studies for sleep disorders in community pharmacy. Future studies should consider a screening trial with confirmatory testing for all patients screened, and should evaluate whether the cost of case-findings (including diagnosis and treatment of patients diagnosed) is economically balanced in relation to possible expenditure on medical care as a whole.
6.0 CONCLUSION

In conclusion, this innovative primary care model for screening, monitoring and the education of people with sleep disorders developed in this project has the capacity to improve the detection and management of people with sleep disorders and those at future risk of developing them. This model also has the capacity to enhance the contribution of community pharmacies in the care of patients with sleep disorders.
7.0 REFERENCES


THE ROLE OF PHARMACISTS IN SLEEP HEALTH – A screening, awareness and monitoring program.

Researchers: Bandana Saini, Keith Wong, Ines Krass, Ron Grunstein
Project Officer: Joanne Fuller

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# Appendices

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Pharmacy Tool for Assessment of Sleep Health

Role of pharmacists in sleep health - a screening, awareness and monitoring program

A project funded through the 4th Community Pharmacy Guild Government Agreement as part of the Investigator Initiated Grants Scheme
## PART 1: Personal Details

1. **Age**
   
   ............ years

2. **Gender**
   
   0 Female  1 Male
   *(please tick)*

3. **Height**
   
   ............ cm (or metres or feet/inches)
   *(please circle unit used)*

4. **Weight**
   
   ............ Kg

5. **Ethnic Background**
   
   0 European
   1 Caucasian
   2 Eurasian
   3 Asian
   4 African
   5 Creole
   6 Indigenous and Torres Strait Islander
   7 Other: .........................

6. **Sleep environment**
   *(please tick more than 1 category if it applies)*
   
   0 Bed partner
   1 Room mate
   2 Child in room
   3 Sleeping alone
   4 Other .........................

7. **Employment status**
   *(please tick more than 1 category if it applies)*
   
   0 Full-time
   1 Part-time
   2 Casual
   3 Self-employed
   4 Unemployed
   5 Student
   6 Retired
   7 Other .........................
8. Occupation/profession
(please tick more than 1 category if it applies OR if you are retired tick as appropriate what your previous occupation was)

1  Manager
2  Professional
3  Technician or Trade
4  Community & Personal Service
5  Clerical and Administration
6  Sales
7  Machinery Operator and Driver
8  Labourer

9. Shift work
In the past fortnight, have you finished any work shift outside the 7 am - 9 pm time period?

☐ No  ☐ Yes
If no, go to question 10

Please briefly describe your shift work/roster (shift times, number of times shift undertaken in last fortnight)

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

PLEASE GO TO PART 2
PART 2: Lifestyle

**Smoking**

10. Have you ever been a smoker?
   - [ ] No
   - [x] Yes
   If no, go to question 14

11. Are you currently a smoker?
   - [ ] No
   - [x] Yes
   If no, go to question 14

12. If you have EVER smoked or are CURRENTLY smoking, please indicate the total length of time you have smoked for
   - ... years/months
   *(Please write the length of time, and circle years or months as appropriate)*

13. If you have EVER smoked or are CURRENTLY smoking, please indicate how many cigarettes did you/do you smoke in 1 day on average
   - .................number of cigarettes/day

**Alcoholic beverages**

14. How often would you have an alcoholic drink?
   - [ ] Never
   - [ ] 1-2 a month
   - [ ] 1-2 times a week
   - [ ] 2-3 times a week
   - [x] 4 or more times a week
   If ‘never’, go to question 16
15. On the occasions when you do have an alcoholic drink, when would you typically have your last drink?

\[ \text{\ldots...} : \text{\ldots...} \quad \text{am/pm} \]
\((\text{time of the day})\)

**Caffeinated beverages**

16. How many caffeinated beverages would you have on a typical day?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2 - 3</td>
</tr>
<tr>
<td>3</td>
<td>4 - 5</td>
</tr>
<tr>
<td>4</td>
<td>6 or more</td>
</tr>
</tbody>
</table>

Includes:
- Coffee
- Tea
- Caffeinated energy drinks (e.g. red bull, V, Guarana drinks etc)
- Caffeinated soft drinks (e.g. cola)

17. When would your last drink containing caffeine on a typical day be?

\[ \text{\ldots...} : \text{\ldots...} \quad \text{am/pm} \]
\((\text{time of the day})\)

**PLEASE GO TO PART 3**
PART 3: Medical History

18. Please fill in the following table regarding your medical history

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HEALTH CONDITION/PROBLEM</strong>&lt;br&gt;Have you ever been told that you have any of the following conditions listed below?&lt;br&gt;(Please tick boxes that apply to you)</td>
<td><strong>MEDICATIONS</strong>&lt;br&gt;Are you taking any medication for this condition?&lt;br&gt;(includes prescription, non-prescription and herbal medicines, vitamins, and supplements)</td>
</tr>
<tr>
<td>1. High blood pressure</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>2. High cholesterol, coronary heart disease, and/or angina</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>3. Diabetes</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>4. Pain (e.g. osteoarthritis, back pain)</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>5. Asthma</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>6. Depression</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>7. Insomnia</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>8. Gastrointestinal (e.g. reflux, ulcers, constipation)</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>9. Persistent rhinitis/sinusitis</td>
<td>🟢 1. Yes</td>
</tr>
<tr>
<td>10. Others: (please list)</td>
<td>🟢 1. Yes</td>
</tr>
</tbody>
</table>

If you tick ‘yes’ to any item, in Column A, please complete Column B for that item
19. Have you taken any OTHER prescription or non-prescription medicines/vitamins/herbal medicines in the past fortnight? (i.e. those not included above) If inadequate space provided please use space at the end of this SECTION

20. Do you believe that any of your medicines/medications affect the way you sleep? If yes, please list which ones,

If inadequate space provided please use space at the end of this SECTION and indicate which question number the information refers to e.g. Q 20

PLEASE GO TO PART 4
PART 4: Sleep Health

21. How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired?

This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for that situation.

Scale of 0-3, where 0= None, 1=Slight, 2= Moderate, 3=High
TICK APPROPRIATE BOX FOR EACH SITUATION

<table>
<thead>
<tr>
<th>Situation</th>
<th>None</th>
<th>Slight</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting and reading</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Sitting inactive in a public place (e.g. theatre, meeting, bus stop)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>As a passenger in a car for an hour without a break</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Lying to rest in the afternoon when circumstances permit</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Sitting and talking to someone</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Sitting quietly after lunch without alcohol</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>In a car, stationary for a few minutes in traffic</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Office use only
TOTAL SCORE ESS

........................................

TICK APPROPRIATE BOX FOR EACH SITUATION
22. This question concerns whether you may have INSOMNIA, which is an inability to obtain adequate sleep. Please answer each of the questions below by ticking the appropriate box which best describes your sleep patterns in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>In the past 2 weeks, rate the SEVERITY of any of your insomnia problem(s)</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Difficulty falling asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>b. Difficulty staying asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>c. Problem waking up too early</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How SATISFIED/DISSATISFIED are you with your current sleep patterns?</th>
<th>Very satisfied</th>
<th>Satisfied</th>
<th>Neutral</th>
<th>Dissatisfied</th>
<th>Very dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To what extent do you consider that your sleep problem INTERFERES with your daily functioning (e.g. daytime fatigue, ability to function at work, concentration, memory, mood, etc.)</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How NOTICEABLE to other people do you think your sleeping problem is in terms of impairing your quality of life?</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How WORRIED/DISTRESSED are you about your current sleep problem?</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Office use only

TOTAL SCORE : ISI

..............................................
23. Please complete the question below by ticking the appropriate box which best describes the quality of your sleep in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>How SATISFIED are you with the length of your sleep?</th>
<th>Very Satisfied</th>
<th>Satisfied</th>
<th>Neutral</th>
<th>Dissatisfied</th>
<th>Very dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

24. Please complete the question below by ticking the appropriate box which best describes the quality of your sleep in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>How would you rate the QUALITY of your sleep?</th>
<th>Very good</th>
<th>Good</th>
<th>Neutral</th>
<th>Poor</th>
<th>Very poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

25. On average how many hours would you sleep on a typical night?

........................... Hours

26. Please indicate how frequently have you experienced or been told that during sleep you:

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Less than once a week</th>
<th>1 - 2 times a week</th>
<th>3 - 4 times a week</th>
<th>5 - 7 times a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snort or grasp</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Choke, struggle for breath, or stop breathing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Snore loudly</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

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AVERAGE SCORE

..................................................

MAPI SCORE FROM CALCULATOR

..................................................
27. Some people may experience unpleasant sensations with an urge to move their limbs. Have you ever had similar experiences to these?

☐ No ☑ Yes  If no, please go to question 28

Do these experiences occur mainly/only at rest and do they improve with movement?

☐ No ☑ Yes

Are these feelings worse in the evening/night than in the morning?

☐ No ☑ Yes

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TOTAL IRLSSG Criteria Score .................................................................

If you ticked “yes” to any statements in the box above, please indicate how often do any of the above experiences occur?

☐ Less than once a year
☐ At least once a year but less than once a month
☐ 1 time a month
☐ 2 - 3 times a month
☐ 4 - 5 times a week
☐ 6 - 7 times a week

PLEASE GO TO PART 5
PART 5: Process Related Questions

28. How did you find out about this questionnaire? (please tick 1 or more categories)
   1. Saw the poster
   2. Through word-of-mouth
   3. Approached by pharmacy staff as I came into the pharmacy to:
      4. see the pharmacist because of a sleep related problem
      5. see the pharmacist because of another health related problem
      6. collect/purchase a medication (sleep related)
      7. collect/purchase a medication (non-sleep related)
      8. purchase other pharmacy products
      9. Other reasons: (please specify)
         ………………………………………………..

29. How would you rate the process of completing this questionnaire?

<table>
<thead>
<tr>
<th>Very easy</th>
<th>Easy</th>
<th>Neither easy nor difficult</th>
<th>Difficult</th>
<th>Very difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

30. Approximately how long did it take you to complete this survey?
[ ] minutes

Thank you for answering these questions. Your pharmacist will now be able to talk to you about your risk of having or developing a sleep health problem.
PLEASE ATTACH THE PARTICIPANT’S DISPENSED MEDICATION HISTORY
FOR THE PAST 12 MONTHS
For OFFICE USE ONLY:
TO BE COMPLETED BY PHARMACY STAFF

4.3. Which staff member invited this participant to complete the screening questionnaire?

☐ Pharmacy Manager
☐ Pharmacist in charge (on the day)
☐ Pharmacy Assistant
☐ Pharmacy Technician
☐ Dispensary Technician
☐ Sleep Technician
☐ Shop Assistant
☐ Other, please specify .....................................

2. Was any assistance provided to the participant to complete the screening questionnaire?

☐ Yes  ☐ No

Briefly mention what assistance was provided:

☐ The meaning of a questionnaire item/s term had to be clarified
☐ Assistance with completing the medication section
☐ Other, please specify .................................

3.1. Approximately, how much of staff time was taken in assisting or facilitating the completion of the questionnaire

............. minutes
**For OFFICE USE ONLY**

TO BE COMPLETED BY PHARMACISTS ONLY

PHARMACISTS PLEASE TICK BOXES TO DOCUMENT ANY ACTIONS YOU HAVE TAKEN BY PLACING (✓) TICK IN THE APPROPRIATE BOX

### SECTION 1 AND 2 LIFESTYLE/DEMOGRAPHICS

<table>
<thead>
<tr>
<th></th>
<th>VERBAL COUNSELLING</th>
<th>INFO PROVISION</th>
<th>REFERRAL</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Smoker</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeinated/stimulating drinks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &gt;30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Environment issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shift work/Occupational issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 3 MEDICAL AND MEDICATION HISTORY

<table>
<thead>
<tr>
<th></th>
<th>VERBAL COUNSELLING</th>
<th>INFO PROVISION</th>
<th>REFERRAL</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications affecting sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conditions affecting sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management of health conditions suboptimal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications need review</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 4 SLEEP HEALTH

<table>
<thead>
<tr>
<th></th>
<th>VERBAL COUNSELLING</th>
<th>INFO PROVISION</th>
<th>REFERRAL</th>
<th>OTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS Score ≥17 (Q21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESS Item 8 - marked 1-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISI Score ≥15 (Q22)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average sleep time &lt;6 HOURS per night (Q25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissatisfaction with sleep (Q23)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor reported sleep quality (Q24)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAPI &gt;0.5 (Q26)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRLSSGQ =3 (Q27)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PLEASE ENSURE THAT:

- You have checked that participant consent forms have been obtained and filed
- You have attached a dispensed medication history for the participant
- You have obtained the best patient contact number/address for follow up, and filed this.
- You have reminded the patient about the close out questionnaire, and the fact they will receive their ‘participation’ incentive payment after the close out questionnaire.

THANK YOU FOR FACILITATING THE RESEARCH PROCESS!
Appendix 2: The Pharmacy Tool for Assessment of Sleep Health – Comprehensive Arm

Pharmacy Tool for Assessment of Sleep Health

Role of pharmacists in sleep health - a screening, awareness and monitoring program

A project funded through the 4th Community Pharmacy Guild Government Agreement as part of the Investigator Initiated Grants Scheme
PART 1: Personal Details

1. Age ......... years

2. Gender
   - Female
   - Male
   (please tick)

3. Height ......... cm (or metres or feet/inches)
   (please circle unit used)

4. Weight ......... Kg

5. Ethnic Background
   - European
   - Caucasian
   - Eurasian
   - Asian
   - African
   - Creole
   - Indigenous and Torres Strait Islander
   - Other: ......................

6. Sleep environment
   (please tick more than 1 category if it applies)
   - Bed partner
   - Room mate
   - Child in room
   - Sleeping alone
   - Other ......................

7. Employment status
   (please tick more than 1 category if it applies)
   - Full-time
   - Part-time
   - Casual
   - Self-employed
   - Unemployed
   - Student
   - Retired
   - Other ......................
8. Occupation/profession  
(please tick more than 1 category if it applies OR if you are retired tick as appropriate what your previous occupation was)

1. Manager  
2. Professional  
3. Technician or Trade  
4. Community & Personal Service  
5. Clerical and Administration  
6. Sales  
7. Machinery Operator and Driver  
8. Labourer

9. Shift work  
In the past fortnight, have you finished any work shift outside the 7 am - 9 pm time period?

0. No  1. Yes

If no, go to question 10

Please briefly describe your shift work/roster (shift times, number of times shift undertaken in last fortnight)

........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

PLEASE GO TO PART 2
PART 2: Lifestyle

**Smoking**

10. Have you ever been a smoker?
   - □ No
   - □ Yes
   If no, go to question 14

11. Are you currently a smoker?
   - □ No
   - □ Yes
   If no, go to question 14

12. If you have EVER smoked or are CURRENTLY smoking, please indicate the total length of time you have smoked for
   - .......... years/months
   *(Please write the length of time, and circle years or months as appropriate)*

13. If you have EVER smoked or are CURRENTLY smoking, please indicate how many cigarettes did you/do you smoke in 1 day on average
   - ......................number of cigarettes/day

**Alcoholic beverages**

14. How often would you have an alcoholic drink?
   - □ Never
   - □ 1-2 a month
   - □ 1-2 times a week
   - □ 2-3 times a week
   - □ 4 or more times a week
   If ‘never’, go to question 16
15. On the occasions when you do have an alcoholic drink, when would you typically have your last drink?

\[ \ldots : \ldots \ am/pm \]
\( time \ of \ the \ day \)

**Caffeinated beverages**

16. How many caffeinated beverages would you have on a typical day?

\[ \square \ 0 \quad \square \ 1 \quad \square \ 2 - 3 \quad \square \ 4 - 5 \quad \square \ 6 \ or \ more \]

Includes:
- Coffee
- Tea
- Caffeinated energy drinks (e.g. red bull, V, Guarana drinks etc)
- Caffeinated soft drinks (e.g. cola)

17. When would your last drink containing caffeine on a typical day be?

\[ \ldots : \ldots \ am/pm \]
\( time \ of \ the \ day \)

**PLEASE GO TO PART 3**
## PART 3: Medical History

18. Please fill in the following table regarding your medical history

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HEALTH CONDITION/PROBLEM</strong></td>
<td><strong>MEDICATIONS</strong></td>
</tr>
<tr>
<td>Have you ever been told that you have any of the following conditions listed below?</td>
<td>Are you taking any medication for this condition?</td>
</tr>
<tr>
<td>(Please tick boxes that apply to you)</td>
<td>(includes prescription, non-prescription and herbal medicines, vitamins, and supplements) You may wish to consult your pharmacist to assist you in filling this</td>
</tr>
<tr>
<td>1. High blood pressure</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>2. High cholesterol, coronary heart disease, and/or angina</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>3. Diabetes</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>4. Pain (e.g. osteoarthritis, back pain)</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>5. Asthma</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>6. Depression</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>7. Insomnia</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>8. Gastrointestinal (e.g. reflux, ulcers, constipation)</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>9. Persistent rhinitis/sinusitis</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>10. Others: (please list)</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>..................................................</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>..................................................</td>
<td>➔ 1. Yes</td>
</tr>
<tr>
<td>..................................................</td>
<td>➔ 1. Yes</td>
</tr>
</tbody>
</table>
19. Have you taken any OTHER prescription or non-prescription medicines/vitamins/herbal medicines in the past fortnight? (i.e. those not included above) If inadequate space provided please use space at the end of this SECTION

20. Do you believe that any of your medicines/medications affect the way you sleep?

   □ No  □ Yes

   If yes, please list which ones,

   If inadequate space provided please use space at the end of this SECTION and indicate which question number the information refers to e.g. Q 20


PLEASE GO TO PART 4
## PART 4: Sleep Health

21. How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired?

   This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for that situation.

Scale of 0-3, where 0= None, 1=Slight, 2= Moderate, 3=High

**TICK APPROPRIATE BOX FOR EACH SITUATION**

<table>
<thead>
<tr>
<th>Situation</th>
<th>Chances of dozing off (please tick appropriate box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting and reading</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Watching television</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Sitting inactive in a public place (e.g. theatre, meeting, bus stop)</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>As a passenger in a car for an hour without a break</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Lying to rest in the afternoon when circumstances permit</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Sitting and talking to someone</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Sitting quietly after lunch without alcohol</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>In a car, stationary for a few minutes in traffic</td>
<td>[ ] None [ ] Slight [ ] Moderate [ ] High</td>
</tr>
<tr>
<td>Office use only</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL SCORE ESS</strong></td>
<td></td>
</tr>
</tbody>
</table>
22. This question concerns whether you may have INSOMNIA, which is an inability to obtain adequate sleep. Please answer each of the questions below by ticking the appropriate box which best describes your sleep patterns in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>Question</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>d. Difficulty falling asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>e. Difficulty staying asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>f. Problem waking up too early</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How satisfied/dissatisfied are you with your current sleep patterns?</th>
<th>Very satisfied</th>
<th>Satisfied</th>
<th>Neutral</th>
<th>Dissatisfied</th>
<th>Very dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To what extent do you consider that your sleep problem interferes with your daily functioning (e.g. daytime fatigue, ability to function at work, concentration, memory, mood, etc.)</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How noticeable to other people do you think your sleeping problem is in terms of impairing your quality of life?</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How worried/distressed are you about your current sleep problem?</th>
<th>Not at all</th>
<th>A little</th>
<th>Some what</th>
<th>Much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Office use only</th>
<th>TOTAL SCORE : ISI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>..........................</td>
</tr>
</tbody>
</table>
23. Please complete the question below by ticking the appropriate box which best describes the quality of your sleep in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>How SATISFIED are you with the length of your sleep?</th>
<th>Very Satisfied</th>
<th>Satisfied</th>
<th>Neutral</th>
<th>Dissatisfied</th>
<th>Very dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

24. Please complete the question below by ticking the appropriate box which best describes the quality of your sleep in the PAST 2 WEEKS.

<table>
<thead>
<tr>
<th>How would you rate the QUALITY of your sleep?</th>
<th>Very good</th>
<th>Good</th>
<th>Neutral</th>
<th>Poor</th>
<th>Very poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

25. On average how many hours would you sleep on a typical night?
   
   ............................. Hours

26. Please indicate how frequently have you experienced or been told that during sleep you:

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Less than once a week</th>
<th>1 - 2 times a week</th>
<th>3 - 4 times a week</th>
<th>5 - 7 times a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snort or grasp</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Choke, struggle for breath, or stop breathing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Snore loudly</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Office use only

| AVERAGE SCORE                   | .......................................................... |
| MAPI SCORE FROM CALCULATOR      | .......................................................... |
27. Some people may experience unpleasant sensations with an urge to move their limbs. Have you ever had similar experiences to these?

☐ No  ☑ Yes  If no, please go to question 28

Do these experiences occur mainly/only at rest and do they improve with movement?

☐ No  ☑ Yes

Are these feelings worse in the evening/night than in the morning?

☐ No  ☑ Yes

Office use only
TOTAL IRLSSG Criteria Score ..........................................................

If you ticked “yes” to any statements in the box above, please indicate how often do any of the above experiences occur?

☐ Less than once a year
☐ At least once a year but less than once a month
☐ 1 time a month
☐ 2 - 3 times a month
☐ 4 - 5 times a week
☐ 6 - 7 times a week

PLEASE GO TO PART 5
PART 5: Process Related Questions

28. How did you find out about this questionnaire? (please tick 1 or more categories)
   1. Saw the poster
   2. Through word-of-mouth
   3. Approached by pharmacy staff as I came into the pharmacy to:
      4. See the pharmacist because of a sleep related problem
      5. See the pharmacist because of another health related problem
      6. Collect/purchase a medication (sleep related)
      7. Collect/purchase a medication (non-sleep related)
      8. Purchase other pharmacy products
      9. Other reasons: (please specify)
         .................................................................

29. How would you rate the process of completing this questionnaire?

<table>
<thead>
<tr>
<th>Very easy</th>
<th>Easy</th>
<th>Neither easy nor difficult</th>
<th>Difficult</th>
<th>Very difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

30. Approximately how long did it take you to complete this survey?

   [ ] minutes

Thank you for answering these questions. Your pharmacist will now be able to talk to you about your risk of having or developing a sleep health problem.
Please attach the participant's dispensed medication history for the past 12 months.
**For OFFICE USE ONLY:**

**TO BE COMPLETED BY PHARMACY STAFF**

<table>
<thead>
<tr>
<th>4.6. Which staff member invited this participant to complete the screening questionnaire?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Pharmacy Manager</td>
</tr>
<tr>
<td>☐ Pharmacist in charge (on the day)</td>
</tr>
<tr>
<td>☐ Pharmacy Assistant</td>
</tr>
<tr>
<td>☐ Pharmacy Technician</td>
</tr>
<tr>
<td>☐ Dispensary Technician</td>
</tr>
<tr>
<td>☐ Sleep Technician</td>
</tr>
<tr>
<td>☐ Shop Assistant</td>
</tr>
<tr>
<td>☐ Other, please specify ........................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.5. Was any assistance provided to the participant to complete the screening questionnaire?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

Briefly mention what assistance was provided:
- ☐ The meaning of a questionnaire item/s term had to be clarified
- ☐ Assistance with completing the medication section
- ☐ Other, please specify ........................................

<table>
<thead>
<tr>
<th>3.4. Approximately, how much of staff time was taken in assisting or facilitating the completion of the questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>............ minutes</td>
</tr>
</tbody>
</table>

---

**PLEASE FILL AND FAX THE FLOWWIZARD FORM TO THE PROJECT OFFICER**

- Hand the patient a sleep diary &
- Make an appointment 15 days later to review
For OFFICE USE ONLY

TO BE COMPLETED BY PHARMACISTS ONLY

PHARMACISTS PLEASE TICK BOXES TO DOCUMENT ANY ACTIONS YOU HAVE TAKEN BY PLACING (✔️) TICK IN THE APPROPRIATE BOX- After patient returns with completed diary and you have Flow Wizard Summary Results

### SECTION 1 AND 2 LIFESTYLE/DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Verbal Counselling</th>
<th>Info Provision</th>
<th>Referral</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeinated/stimulating drinks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &gt;30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Environment issues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shift work/Occupational issues</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 3 MEDICAL AND MEDICATION HISTORY

<table>
<thead>
<tr>
<th>Verbal Counselling</th>
<th>Info Provision</th>
<th>Referral</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications affecting sleep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conditions affecting sleep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management of health conditions suboptimal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications need review</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 4 SLEEP HEALTH

<table>
<thead>
<tr>
<th>Verbal Counselling</th>
<th>Info Provision</th>
<th>Referral</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS Score ≥17 (Q21)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESS Item 8 - marked 1-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISI Score ≥15 (Q22)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average sleep time &lt;6 HOURS per night (Q25)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissatisfaction with sleep (Q23)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor reported sleep quality (Q24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAPI &gt;0.5 (Q26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRLSSGQ =3 (Q27)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PLEASE ENSURE THAT:

- You have checked that participant consent forms have been obtained and filed
- You have attached a dispensed medication history for the participant
- You have obtained the best patient contact number/address for follow up, and filed this.
- You have attached the sleep diary and FlowWizard® summary to the patient file.
- You have reminded the patient about the close out questionnaire, and the fact they will receive their ‘participation’ incentive payment after the close out questionnaire.

THANK YOU FOR FACILITATING THE RESEARCH PROCESS!
## Appendix 3: The validated instruments used in the screening tool

<table>
<thead>
<tr>
<th>Tool</th>
<th>Measurement</th>
<th>Scale</th>
<th>Range</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epworth sleepiness scale&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Excessive daytime sleepiness</td>
<td>Propensity for daytime sleepiness in eight situations on a scale of 0–3</td>
<td>0–24</td>
<td>&gt; 10</td>
</tr>
<tr>
<td>- ESS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia Severity Index&lt;sup&gt;49&lt;/sup&gt;</td>
<td>Risk of having clinical insomnia</td>
<td>Seven criteria and potential QoL impacts of insomnia on a scale of 0–4</td>
<td>0–28</td>
<td>≥ 15</td>
</tr>
<tr>
<td>- ISI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multivariable Apnea Prediction Index&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Probability of a respiratory disturbance index of 10 or more</td>
<td>Weighted index factoring three OSA symptoms (loud snoring, grasping, choking), BMI, gender and age</td>
<td>$0 &lt; p &lt; 1$</td>
<td>$&gt; 0.5$</td>
</tr>
<tr>
<td>- MAPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Restless Legs Syndrome Study Group Screening Criteria&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Classification and frequency of RLS symptoms</td>
<td>Three items based on diagnostic features for RLS and one item ascertaining frequency of symptoms</td>
<td>0–3</td>
<td>= 3</td>
</tr>
<tr>
<td>- IRLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4: Sleep Health Awareness Campaign Poster

Sleep – When it is not enough!

Do you/ your partner or someone you know have problems with sleep such as:

- Disturbed sleep
- Snoring
- Falling asleep too easily
- Feeling tired constantly
- Uncomfortable feelings that disturb sleep

Talk to your Pharmacist about sleep health screening today!

Pharmacists and sleep health - a research project being conducted through the Faculty of Pharmacy, University of Sydney and the Woolcock Institute of Medical Research, Sydney.
Appendix 5: Screening Protocol for the Basic Arm

**SCREENING PROTOCOL**

**JAN 09**
Patient/client sees poster/fliers

- Presents at pharmacy
- Pharmacists approach patient, provide info and consent forms

**MAR 09**
Patient taken to private area to complete hand/online version of screening questionnaire

**JUN 09**
Follow up 3 months

**AUG 09**
Follow up 2 months

**DEBRIEF**

**INCLUSION EXCLUSION CRITERIA**

**Inclusion Criteria**
- Age > 18 years or over
- Patient presents after seeing materials
- Pharmacists invite patient

**Exclusion Criteria**
- Patient not undergoing treatment for any sleep disorder
- Patient physically unable to complete the screening in the pharmacist's opinion
- Patient does not consent to complete consent questionnaire
- Patient not fluent in English and cannot arrange for a translator themselves OR translator not available for completion of consent questionnaire
COUNSELLING PROTOCOL

- If **ESS score** ≥17 → counselling and (use SDA brochures) referral as needed by matching other results if Q8 on ESS is marked 1-3, →REFER

- If **MAPI Index** >0.5 →, refer and counsel (use SDA brochures)

- If **IRLSSGQ** =3 → refer and counsel (use SDA brochures)

- If **ISI** >15, → refer and counsel (on healthy sleep practices, use SDA brochures)

- If lifestyle habits contradict good sleep practice → counsel (smoking, alcohol, caffeine – effect on sleep)

- **Review Medication Use** – If any medications may be affecting sleep, refer for therapy recommendation/counsel
Appendix 6: Screening Protocol for the Comprehensive Arm

DEBRIEF

Follow up 3 months

Pharmacist looks at screening instrument & brief Flow Wizard®

Patient initiates Diary & Records Flow Wizard®

Pharmacist receives Form & Hands over Diary & Consultant

Fully H1 identity patient

Present at pharmacy

Counselling + Referral

Inclusion: Eligible

Exclusion: ineligible

No medication or treatment at present

Patient refuses OR

Patient attends clinic

Pharmacist complete referral

Screening protocol
COUNSELLING PROTOCOL

- If **ESS score ≥17** → counselling and (use SDA brochures) referral as needed by matching other results if Q8 on ESS is marked 1-3, → REFER

- If **MAAPI index >0.5** → refer and counsel (use SDA brochures)

- If **FlowWizard® indicates risk of OSA>0.5** → refer

- If **sleep diary** indicates sleep loss/fragmented sleep → counsel on healthy sleep practices, or if ESS is also high, refer

- If **IQLSSGQ ≥3** → refer and counsel (use SDA brochures)

- If **ISI >15**, → refer and counsel (on healthy sleep practices, use SDA brochures)

- If lifestyle habits contradict good sleep practice → counsel (smoking, alcohol, caffeine – effect on sleep)

- **Review Medication Use-** If any medications may be affecting sleep, refer for therapy recommendation/counsel
Pharmacists and Sleep Health Project

GP Referral Form

Referral Date:

Referring Pharmacist
Pharmacist Name:
Pharmacy Name
Street Address
Suburb
State               Post Code
Phone: Fax:
Email:

Pharmacy Approval No …….

Consumer details:
Name:
Preferred Name/s:
Gender:

Contact Address:
Street Address
Suburb
State               Post Code
Phone:

Alternative Contact:

Medicare Number:
DVA Number:

Private Health Insurance: Yes               No

Pension Card Number:

Consent to referral:  Yes

Pharmacist Signature
Dear Doctor,

As you may be aware, our pharmacy has been participating in a research project entitled “Role of pharmacists in sleep health – a screening, awareness and monitoring program”, which is being conducted jointly by researchers from the Faculty of Pharmacy, University of Sydney and the Woolcock Institute of Medical Research. As part of this project, consumers volunteering to participate were screened in the pharmacy using a battery of validated tests for three common sleep conditions in the Australian community. Additionally, the person’s medical history/medication use and major lifestyle issues were noted and examined with respect to a potential risk of the person either having or developing a sleep disorder.

Reason for referral:

Examination of data collected and collated from this person appears to indicate that he/she may be at risk of having/developing the following conditions

- Obstructive Sleep Apnea
- Insomnia
- Restless Legs Syndrome

Screening also revealed the presence of symptoms such as:

- Excessive daytime sleepiness
- Bothersome snoring
- Partner reported/witnessed apneas
- Fatigue/concentration issues

Prominent risk factors noted for this patient included

- Family history of sleep disorders
- Presence of a cardiovascular/endocrine condition
- Lifestyle issues
  - Smoking
  - Alcohol
  - Body Mass Index
  - Dysfunctional sleep habits
  - Shiftwork
  - Use of sleep aids/pills..........................
  - Use of medicines that may affect sleep.........

Other relevant data collected from this person through the research protocol are attached with this referral. A brief discussion about the possibility of having a sleep disorder and the need to seek further physician input was held. I therefore refer ..................................... to you for further examination regarding their sleep health issues. Please do not hesitate to contact me if you have any queries.

Yours sincerely
Appendix 9: Sleep Health Awareness Campaign Shelf Tags

Please remember to ask customers requesting this product to complete the *SLEEP SCREENING QUESTIONNAIRE*.

Please remember to ask customers requesting SCRIPTS for CVS/Sleep/Endocrine/Rhinitis conditions to complete the *SLEEP SCREENING QUESTIONNAIRE*.

Please ask Your Pharmacist/Pharmacy Staff for a FREE SLEEP SCREENING TEST.

Please remember to ask customers requesting prescriptions related to cardiovascular/endocrine/sleep rhinitis/sinusitis type conditions to complete the *SLEEP SCREENING QUESTIONNAIRE*.
Appendix 10: Refusals Tally

FOR PHARMACY STAFF ASSISTING IN PROJECT RECRUITMENT

Please do assist in completing this tally for people who were approached about the sleep screening tool and have refused participation. This will enable the research team to understand the level of work involved in screening a certain number of people and is important from a research and economic analysis.

<table>
<thead>
<tr>
<th>REASONS FOR REFUSAL</th>
<th>TALLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too Busy</td>
<td></td>
</tr>
<tr>
<td>Not Interested</td>
<td></td>
</tr>
<tr>
<td>Work/Family/Social Commitment</td>
<td></td>
</tr>
<tr>
<td>Feeling Unwell</td>
<td></td>
</tr>
<tr>
<td>Already have a sleep problem</td>
<td></td>
</tr>
<tr>
<td>Already discussed sleep problems with doctor</td>
<td></td>
</tr>
<tr>
<td>Don’t think I have a sleep problem</td>
<td></td>
</tr>
<tr>
<td>Other reasons, specify</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Other reasons, specify</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Other reasons, specify</td>
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</table>
23 June 2008

Dr B Saini
Faculty of Pharmacy
Pharmacy Building – A15
The University of Sydney

Dear Dr. Saini

I am pleased to inform you that the Human Research Ethics Committee (HREC) at its meeting on 17 June 2008 approved your protocol entitled "Role of pharmacists in sleep health - a screening, awareness and monitoring program". Details of the approval are as follows:

Ref No.: 10765
Approval Period: 30 June 2008 – 30 June 2009
Authorised Personnel: Dr. B. Saini, Dr. K. Wong, Associate Professor I. Krass, Professor R. Grunstein

The HREC is a fully constituted Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans—March 2007 under Section 5.1.29.

The approval of this project is conditional upon your continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans. We draw to your attention the requirement that a report on this research must be submitted every 12 months from the date of the approval or on completion of the project, whichever occurs first. Failure to submit reports will result in withdrawal of consent for the project to proceed.

Chief Investigator / Supervisor’s responsibilities to ensure that:

(1) All serious and unexpected adverse events should be reported to the HREC as soon as possible.

(2) All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
(3) The HREC must be notified as soon as possible of any changes to the protocol. All changes must be approved by the HREC before continuation of the research project. These include:
   - If any of the investigators change or leave the University.
   - Any changes to the Participant Information Statement and/or Consent Form.

(4) All research participants are to be provided with a Participant Information Statement and Consent Form, unless otherwise agreed by the Committee. The Participant Information Statement and Consent Form are to be on University of Sydney letterhead and include the full title of the research project and telephone contacts for the researchers, unless otherwise agreed by the Committee and the following statement must appear on the bottom of the Participant Information Statement. Any person with concerns or complaints about the conduct of a research study can contact the Senior Ethics Officer, University of Sydney, on (02) 9351 4811 (Telephone); (02) 9351 6796 (Facsimile) or phbv@sydney.edu.au (Email).

(5) Copies of all signed Consent Forms must be retained and made available to the HREC on request.

(6) It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

(7) The HREC approval is valid for four (4) years from the Approval Period stated in this letter. Investigators are requested to submit a progress report annually.

(8) A report and a copy of any published material should be provided at the completion of the Project.

Yours sincerely

[Signature]

Dr P Beale
Chairman
Human Research Ethics Committee

Enc. Poster
Participant Consent Form
Participant Information Statement (Patients)
Participant Information Statement (Pharmacists)
GP Letter of Explanation
GP Referral Form
Pharmacy Tool for Assessment of Sleep Health
Pittsburgh Sleep Diary
Invitation to Potential Pharmacist Participants
TRAINING DAY MATERIALS

Learning Objectives for the Training Program

At the end of the 2-day training program, participants should be able to:

- Demonstrate a reasonable understanding of basic sleep physiology and typical sleep architecture
- Recognise the effect of various conditions, factors and medications that can affect sleep and sleep architecture
- Describe the epidemiological issues with respect to main sleep disorders (Obstructive Sleep Apnea, Restless Legs Syndrome and Insomnia)
- Describe the Risk Factors associated with main sleep disorders (Obstructive Sleep Apnea, Restless Legs Syndrome and Insomnia)
- Recognise the signs and symptoms of main sleep disorders
- List the key non-pharmacological treatment and management approaches for the main sleep disorders
List the key pharmacological treatment and management approaches for the main sleep disorders

Be able to understand the limitations and application of treatment and management approaches with respect to both condition and patient related factors

Exhibit an awareness of tests and measures used in monitoring, diagnosing and recognizing sleep disorders and their consequences

Be able to describe issues in the quality use of medicines in sleep disorders

Be able to recognize the classes of medications that can affect sleep and sleep disorders

Be able to counsel patients on healthy sleep practices

Be aware of health system approached and limitations to the identification, management and treatment of sleep disorders

Identify the role of pharmacists in the health system with respect to identification, management and treatment of sleep disorders

Be able to use a basic screening tool to identify patient at risk of having or developing sleep disorders

Demonstrate ability to follow research and documentation protocols associated with the affiliated research project
Pharmacists’ Specialised Sleep Health Training Program

**DAY 1**
NOVEMBER 1, 2008 9:00 AM-5:00PM

<table>
<thead>
<tr>
<th>Session</th>
<th>Time</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep Basics</td>
<td>9:00-10:00 AM</td>
<td>Keith Wong</td>
</tr>
<tr>
<td>Obstructive sleep apnea I</td>
<td>10:00-10:45 AM</td>
<td>Andrew Chan</td>
</tr>
<tr>
<td>Morning Tea</td>
<td>10:45-11:00 AM</td>
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</tr>
<tr>
<td>Obstructive sleep apnea II</td>
<td>11:00-11:45 PM</td>
<td>Andrew Chan</td>
</tr>
<tr>
<td>Parasomnias &amp; narcolepsy</td>
<td>11:45-12:45 PM</td>
<td>Brendon Yee</td>
</tr>
<tr>
<td>Lunch</td>
<td>12:45-1:30 PM</td>
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</tr>
<tr>
<td>Screening for sleep disorders</td>
<td>1:30-2:30 PM</td>
<td>Keith Wong</td>
</tr>
<tr>
<td>Insomnia, medications and sleep</td>
<td>2:30-3:30 PM</td>
<td>Joanne Fuller</td>
</tr>
<tr>
<td>Afternoon Tea</td>
<td>3:30-3:45 PM</td>
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</tr>
<tr>
<td>Practical session: polysomnography</td>
<td>4:00-5:00 PM</td>
<td>Keith Wong</td>
</tr>
</tbody>
</table>

*Mission: Pharmacists’ Specialised Sleep Health Training Program*

*Role of pharmacists in sleep health—a screening, awareness and monitoring program*.
Pharmacists’ Specialised Sleep Health Training Program

**DAY 2**  
NOVEMBER 2, 2009 9:00 AM-3:00PM

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Time</th>
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<tbody>
<tr>
<td>Insomnia</td>
<td>9:00-10:00 AM</td>
<td>Dianne Richards</td>
</tr>
<tr>
<td>Practical session: OSA therapy</td>
<td>10:00-10:45AM</td>
<td>Dianne Richards</td>
</tr>
<tr>
<td>Morning Tea</td>
<td>10:45-11:00 AM</td>
<td></td>
</tr>
<tr>
<td>Role of pharmacists in the screening for sleep disorders- project protocols</td>
<td>11:00-1:15 PM</td>
<td>Study Project Staff</td>
</tr>
<tr>
<td>Luncheon</td>
<td>1:15-2:00PM</td>
<td></td>
</tr>
<tr>
<td>Project Protocols-Practice</td>
<td>2:00-2:45PM</td>
<td></td>
</tr>
<tr>
<td>Troubleshooting and Practical Tips</td>
<td>2:45-3:00 PM</td>
<td></td>
</tr>
</tbody>
</table>

*Role of pharmacists in sleep health—a screening, awareness and monitoring program*. 
Appendix 14: FlowWizard Information

Welcome to Flow Wizard, an easy-to-use device designed to record your nasal airflow while you sleep.

**Flow Wizard Kit** - You will have received the following:

- **Flow Wizard recorder**
  The Flow Wizard recorder has a lock at one end (where the cannula will be attached), a start button on the top and a light to indicate when it is recording.

- **Nasal Cannula**
  The nasal cannula (clear tubing) has a straight end with a plastic lock and a circular end with two small nasal prongs (openings) that are designed to sit inside your nose during sleep.

**Instructions for Use**

It is important to note the Flow Wizard works while you sleep. Make sure you are comfortable and ready to sleep before you start the recorder.

To assemble and attach the Flow Wizard correctly, please follow steps 1 to 5.

1. **Connect the cannula to the Flow Wizard recorder** by connecting the plastic lock on the cannula (located at the straight end of the tubing) to the lock at the end of the recorder (located at the same end the Flow Wizard logo appears on the recorder).

2. **The lock on the cannula should be turned in a clockwise direction until firmly fastened (do not over-tighten).**

3. **Hold the circular section of the cannula with both hands, placing one hand either side of the nasal prongs, approximately 30 centimeters apart.** The prongs should be facing upwards, sloping towards your face.

4. **Insert cannula into lock end**

5. **Insert nasal prongs into nostrils**
Position the nasal prongs in your nostrils. Slight discomfort is normal.

With the prongs sitting within each of your nostrils, loop the tubing over each of your ears and tighten the toggle firmly beneath the chin to keep the tubing in place. Look in the mirror to make sure the prongs remain positioned within your nostrils.

When you are in bed and ready to sleep, press and hold down the button (located on the centre, or top of the recorder) until the light comes on. This will take approximately three (3) seconds. The light will come on to indicate the recorder is working. Then face slightly to ensure your sleep is not disturbed.

Place the device on the bedside table or on the floor beside the bed, whichever is most comfortable. Enjoy a good night's sleep.

Press button to start Flow Wizard.

The Flow Wizard is designed to turn off automatically after a period of nine (9) hours. When you finish sleeping, simply remove the cannula from your head and store the Flow Wizard safely before returning it to your health care provider. Please note that the light on the recorder may remain on for several hours after you have removed the cannula. This is normal and will not affect your results.

What if...

The nasal prongs are really uncomfortable.

Make sure the nasal prongs are sloping toward your nostrils when you insert them, not away from you. A small degree of discomfort is unfortunately unavoidable.

The light on the device doesn't come on.

Hold down the button for a little longer. It can take up to five (5) seconds to activate. If the light still doesn't come on, the Flow Wizard will need to be returned to your health care provider.

I need to get up in the middle of the night, what should I do?

That's OK, simply remove the prongs from your nostrils and re-attach them when you return to your bed. The light on the Flow Wizard recorder will remain on during these short breaks from sleep and no attempt should be made to turn the recorder off. It will turn off automatically after a period of nine (9) hours.

I have decided not to go to sleep yet, how do I stop the recording and start again?

Turn the Flow Wizard on before you are ready to sleep should be avoided if possible. However, if this occurs, you can turn the Flow Wizard off by holding down the button (located in the centre, or top of the recorder) until the light goes off. This will take approximately three (3) seconds. When you are ready to sleep, you will need to turn the Flow Wizard on again by repeating step 5 above.

I need to use the cannula for another recording. Can I reuse it?

You can wipe the cannula clean with a damp cloth if it is required for additional recordings. Please ensure the cannula is dry before reusing and keep the Flow Wizard recorder away from any liquids.

Please handle the Flow Wizard with care and return it to your health care provider as directed.
Pharmacy Tool for Assessment of Sleep Health

Role of pharmacists in sleep health - a screening, awareness and monitoring program

PLEASE COMPLETE

<table>
<thead>
<tr>
<th>Date Today</th>
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<tbody>
<tr>
<td>Date of Initial Screening</td>
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<tr>
<td>Participant ID</td>
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A project funded through the 4th Community Pharmacy Guild Government Agreement as part of the Investigator Initiated Grants Scheme
Thank you for your participation in the Pharmacy Sleep Health Screening Project. A few months ago, you and your pharmacist may have discussed aspects of your own sleep health. The aim of this brief follow up is to explore how the screening program has worked for YOU. Your responses will help improve the process, so that such screening programs can be made more widely available in the community in the future.

The first part of this follow up asks you if any of your personal details or lifestyle issues that affect sleep health may have changed. The next part of the follow up asks you about any changes in your medical/medication/treatment profile. Following that, you will be asked about the outcomes of the screening process that you and your pharmacist carried out. Finally, there are some queries about what you thought of the process.

The follow up should take approximately 10 minutes to complete.

If you have any questions please do not hesitate to ask the pharmacist, however this follow up is intended for you to be able to complete yourself.
PART 1: Changes in Personal/Lifestyle Details

The following questions relate to any changes that may have occurred SINCE you completed the screening program in the pharmacy 3-4 months ago.

1. Have there been any changes in your body weight SINCE the pharmacy screening? Please tick ‘Yes’ or “No’
   1 ☐ Yes   0 ☐ No    If No, please go to Q3.

2. What is your current body weight? ...............kg

3. Have there been any changes in your SMOKING STATUS?
   1 ☐ Yes   0 ☐ No    If No, please go to Q4.

4. Please indicate what has changed in your smoking status, by ticking the appropriate box/s below.
   0 ☐ Quit smoking completely
   1 ☐ Have tried to quit by
   If yes please tick as many of the boxes below that may apply:
   2 ☐ Cutting down number of cigarettes
   3 ☐ Using nicotine replacement therapy
   4 ☐ Using a prescription medicine to help quit
   5 ☐ Contacting Quitline
   6 ☐ Joining a self help group
   7 ☐ Talking to your doctor about quitting
   8 ☐ Talking to a friend about quitting
   9 ☐ Setting a date to quit smoking

5. Have there been any changes in your use of ALCOHOL?
   1 ☐ Yes   0 ☐ No    If No, please go to Q6.

If your ALCOHOL USE habits have changed, please tick as many of the box/es below that may apply:
   I have
   2 ☐ Decreased the number of alcoholic drinks per week I consume
   3 ☐ Increased the number of alcoholic drinks per week I consume
   4 ☐ Stopped alcohol consumption
   5 ☐ Started alcohol consumption
   6 ☐ Set a time before which I consume my last alcoholic drink of the day (...........PM)
6. Have there been any changes in your use of CAFFEINATED BEVERAGES?

  1 ☐ Yes     0 ☐ No     If No, please go to Q7.

If your CAFFEINE USE habits have changed, please tick as many of the box/es below that apply:

I have

  2 ☐ Decreased the number of caffeinated beverages I drink per day
  3 ☐ Increased the number of caffeinated beverages I drink per day
  4 ☐ Stopped the consumption of caffeinated beverages
  5 ☐ Switched to non-caffeinated alternative (herbals teas, decaf drinks)
  6 ☐ Set a time before which I consume my last caffeinated beverage of the day
      (…………..PM)

7. Have there been any changes in your SLEEPING ENVIRONMENT?

  1 ☐ Yes     0 ☐ No     If No, please go to NEXT SECTION

If your SLEEP ENVIRONMENT has changed, please tick as many of the box/es below that apply

I have:

  2 ☐ Purchased a new mattress/new bedding
  3 ☐ Changed lighting/temperature settings in bedroom
  4 ☐ Removed reading materials from bedroom
  5 ☐ Removed sources of noise from my bedroom (eg ticking clocks, humming air conditioners)
  6 ☐ Changed quality of air in room (by adding de-humidifier, air purifier, etc)
  7 ☐ Removed pet from bedroom
  8 ☐ Other, please specify………………………………………………
**PART 2: Health Related Changes**

8. At the end of your survey, were you provided with a referral to see another health care professional?
   - Yes
   - No
   If No, please go to Q13.

If yes, to whom did the pharmacist refer you? Please tick as many of the box/es below that may apply:

- My GP (General Practitioner)
- Another GP
- A sleep specialist
- A respiratory specialist
- Another specialist
- A sleep nurse
- A sleep laboratory
- Dentist
- Other, please specify………………………………..

9. If your pharmacist did refer you, have you had the opportunity to follow up the referral (i.e. see your doctor):
   - Yes
   - No
   If No, please go to Q13.

10. If you have followed up on the referral your pharmacist provided what is the outcome? Please tick as many of the box/es below that apply:

- Diagnosed with a sleep problem
- Diagnosed with a medical problem
- Suspected of having a specific sleep problem
- Treatment for sleep problem initiated
- Referred to a sleep specialist
- Awaiting appointment to undertake an overnight sleep study
- Underwent an overnight sleep study
- Awaiting results of overnight sleep study
- Been prescribed a new medication for my health
- Been prescribed a new medication for my sleep health/ sleep problem
- Been prescribed with a device for my sleep health problem
- Other, please specify …………………………………………………
11. If you have been **DIAGNOSED** with a SLEEP PROBLEM, or your doctor has talked to you about the **POSSIBILITY** of you having a SLEEP PROBLEM, please list the condition/s below:

- ...........................................
- ...........................................
- ...........................................
- ...........................................
- ...........................................

12. If you have **NOT** been able to follow up on the referral your pharmacist provided you, please specify the reason/s for this:

0 □ Unable to make time
1 □ Not able to make an appointment with a GP
2 □ Not able to make an appointment with a sleep physician
3 □ Awaiting appointment with a GP
4 □ Awaiting appointment with a sleep physician
5 □ Feel that the sleep related problem has improved
6 □ Feel that you generally don’t need to see another health care professional
7 □ Cannot afford it at the moment
8 □ Other, please specify .................................................................

13. In the last 3-4 months, have you had the opportunity to see a health care professional (such as a doctor, pharmacist, nurse, etc), for reasons unrelated to this project?

1 □ Yes 0 □ No  
If Yes, please go to the NEXT SECTION.

If you have seen a health care professional in the last 3-4 months, please specify?

*Which health care professional did you see?* ..........................................

*Why?* ........................................................................................................
PART 3: Quality of Pharmacy Sleep Health Survey

How much has the screening program helped your sleep health? Please indicate (1-5) along this scale how you feel your sleep health has been changed as a result of the service: 1 stands for ‘to a large extent’ and 5 stands for ‘not at all’.

14. What impact, IF ANY, do you feel the service had on your understanding of GOOD SLEEP HEALTH PRACTICES?

A large impact Some impact A little impact Very little impact No impact

1 2 3 4 5

15. What impact, IF ANY, has the service had on your confidence in managing your SLEEP PROBLEMS?

A large impact Some impact A little impact Very little impact No impact

1 2 3 4 5

16. What impact, IF ANY, has the service had on your confidence of asking questions about SLEEP HEALTH from your pharmacist?

A large impact Some impact A little impact Very little impact No impact

1 2 3 4 5

17. What impact, IF ANY, has the service had on your confidence of asking questions about SLEEP HEALTH from your GP?

A large impact Some impact A little impact Very little impact No impact

1 2 3 4 5
18. From your perspective, please list what the main outcome/s of the pharmacy screening survey process have been for you:

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19. If you knew someone with a sleep related complaint, would you suggest the pharmacy screening survey to them?

1 □ Yes 0 □ No. Please outline your reasons.

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20. This screening process was a research project and therefore offered as a ‘free’ service to the community. If this were not the case, would you be willing to pay for having such a screening service for sleep problems offered through your pharmacy?

1 □ Yes 0 □ No

If yes, please indicate an amount that you would be willing to pay for this service? 

.................................Dollars

Thank you for your ongoing participation and support in this project. Please do collect your voucher from your pharmacist as a small token of our appreciation.
Pharmacists’ Specialised Sleep Health Training Program

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:45-11:00 AM</td>
<td>Morning Tea</td>
</tr>
<tr>
<td>11:00-1:15 PM</td>
<td>Role of pharmacists in the screening for sleep disorders- project protocols Study Project Staff</td>
</tr>
<tr>
<td>1:15-2:00 PM</td>
<td>Luncheon</td>
</tr>
<tr>
<td>2:00-2:45 PM</td>
<td>Project Protocols-Practice</td>
</tr>
<tr>
<td>2:45-3:00 PM</td>
<td>Troubleshooting and Practical Tips</td>
</tr>
</tbody>
</table>

号称"Role of pharmacists in sleep health – a screening, awareness and monitoring program"。
Appendix 17: Recruitment Strategies example

[Image of a storefront with a sign that reads:]

**Blooms The Chemist**

HAVE TROUBLE SLEEPING?
JOIN OUR SLEEP STUDY INSTORE

OPEN 7 DAYS
Sam to 8pm Mon - Fri
9am to 6pm Sat - Sun

**WARNING**

Please do not touch the products in the store.

[Further image of the same storefront with a sign that reads:]

**Have you tried our new product?**

[Another image showing a queue of people outside the store.]
Eligible patients – patients were not randomly selected into the screening process. They may have been self selected on the basis of health promotion materials in the pharmacy, or deemed to have ‘risk factors’ for a sleep disorder.

The index test - in our case is not a single ‘risk score’ or ‘diagnostic score’. It consisted of a risk score calculated on the basis of separate questionnaires for 3 sleep disorders (Obstructive Sleep Apnea, Insomnia and Restless Legs Syndrome). In addition pharmacists were asked to refer people based on their symptoms of excessive daytime sleepiness or if patients professed dissatisfaction with sleep.

The index test - In this arm in addition to the screening instrument, those being screened also completed a sleep diary for 15 days and a nasal flow recording for 3 consecutive nights.

Figure 1 - Issues in comparing PTASH/POTASH with a reference test for diagnostic accuracy

In a concept testing for the newly developed screening instrument, 20 randomly selected patients from this arm of the study were tested against a Polysomnography, and results reported in Section 4.28.
### BASIC ARM
- Total number Screened=152
- Total number at risk of OSA, n=64
- Those ‘At risk’ who completed close out questionnaire, n=45
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, n=18
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n=10
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who were diagnose with OSA, n=4

### COMPREHENSIVE ARM
- Total number Screened=173
- Total number at risk of OSA, n=83
- Those ‘At risk’ who completed close out questionnaire, n=56
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, n=34
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n=17
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who were diagnose with OSA, n=3

Figure 2- Flow through of patient numbers with respect to being at risk for obstructive sleep apnea
If an attempt to define the sensitivity and specificity of the screening instrument versus a doctor diagnosis is made for OSA (in the Basic arm, as an example), the 2 x 2 table for this scenario would be:

Obstructive sleep apnea as determined by Doctor Diagnosis in the **BASIC ARM of the study**

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>4</td>
</tr>
<tr>
<td>Negative</td>
<td>?</td>
</tr>
</tbody>
</table>

Figure 3- Sensitivity/Specificity analyses for OSA in the basic arm comparing the POTASH to doctor diagnoses
The figures for identifying those not at risk of OSA as identified by pharmacists using the questionnaire—POTASH are hard to meaningfully collate. This is because those not at risk of OSA, may have been at risk of other conditions and may have presented to a doctor. However most of those who did not have a risk for OSA (OR ANY OTHER SLEEP DISORDER) identified, had no reason to consult a doctor as part of this project, hence making the calculation of sensitivity/specificity of the POTASH instrument difficult when tested against a doctor diagnosis. Even in those at risk of OSA in the Basic arm example shown above, 45/64 of those who were at risk, were followed, of those followed only 10 had taken up a referral (10/64 at risk), and of these 10, 4 were diagnosed. The same situation arises for the comprehensive arm, and for insomnia and RLS. The flow diagrams are repeated (Figure 4, 6) here for RLS and INSOMNIA. Figure 5 and 7 highlight the issues in attempting a sensitivity/specificity using physician diagnoses as a ‘reference’ for the PTASH/POTASH.

The incomplete values (?) in Figure 3 indicate that to complete this Table, one needed to have followed patients screened for OSA, and found NOT to be at risk, and requested them to present at a doctor to allow for picking up those who may have been false negatives and true negatives based on the newly developed screening tool (POTASH) as tested against a doctor diagnosis.

<table>
<thead>
<tr>
<th>BASIC ARM</th>
<th>COMPREHENSIVE ARM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total number Screened=152</strong></td>
<td><strong>Total number Screened=173</strong></td>
</tr>
<tr>
<td><strong>Total number at risk of INSOMNIA, n=41</strong></td>
<td><strong>Total number at risk of INSOMNIA, n=69</strong></td>
</tr>
<tr>
<td>Those ‘At risk’ who completed close out questionnaire, n=26</td>
<td>Those ‘At risk’ who completed close out questionnaire, n=44</td>
</tr>
<tr>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, n=13</td>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, n=19</td>
</tr>
<tr>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n=11</td>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n=6</td>
</tr>
<tr>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, AND who were diagnose with INSOMNIA, n=1</td>
<td>Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, AND who were diagnose with INSOMNIA, n=0</td>
</tr>
</tbody>
</table>

Figure 4- Flow through of patient numbers with respect to being at risk for insomnia
### BASIC ARM
- Total number Screened = 152
- Total number at risk of RLS, n = 52
- Those ‘At risk’ who completed close out questionnaire, n = 39
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, n = 19
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n = 11
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, AND who were diagnosed with RLS, n = 0

### COMPREHENSIVE ARM
- Total number Screened = 173
- Total number at risk of RLS, n = 70
- Those ‘At risk’ who completed close out questionnaire, n = 48
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, n = 22
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, n = 11
- Those ‘At risk’ who completed close out questionnaire and reported having been referred, AND who took up the referral, AND who were diagnosed with RLS, n = 3

---

**Figure 5** Insomnia as determined by Doctor Diagnosis in the BASIC ARM of the study

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Negative</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

---

**Figure 6** Flow through of patient numbers with respect to being at risk for Restless Legs Syndrome
RLS as picked up the POTASH tool

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Negative</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

Figure 7- RLS as determined by Doctor Diagnosis in the BASIC ARM of the study