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

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Executive Summary

Sleep disorders are a significant public health issue. Optimal detection and care provision for sleep disorders in public healthcare seems to be impeded by a lack of awareness, diagnostic resources and continuity of care. Prevalent sleep disorders in the community include insomnia, obstructive sleep apnea (OSA), and restless legs syndrome (RLS). Such sleep conditions may lead to the fragmentation of sleep and symptoms such as excessive daytime sleepiness (EDS) and a decline in cognitive function. Furthermore, sleep disorders are associated with an array of health and lifestyle problems such as a reduction of quality of life (QoL) and the existence of comorbidities. Social issues may arise from injuries and motor vehicle accidents which burden the healthcare system. The current project was designed 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.

In the first development phase of the project, a comprehensive search of the literature was conducted to identify any screening tools that encompassed common sleep disorders. As no such instruments were identifiable, the research team developed a screening instrument- the Pharmacy Tool for Assessment of Sleep Health combined discrete questionnaires/instruments 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), Insomnia Severity Index (ISI), Multivariable Apnea Prediction Index (MAPI) and International Restless Legs Syndrome Study Group Screening Criteria (IRLS). This screening tool was pilot tested for utility, ease of use and screening ability in a convenience sample of 5 pharmacies in NSW (N=4), and Victoria (n=1) after having sought and obtaining ethical approval from the University of Sydney’s Human Research Ethics Committee. On-site training of pharmacists participating in this pilot was provided, followed by an eight week client recruiting and screening period. Feedback was elicited from participating pharmacists and clients. This screening tool was used to predict the participant’s risk of a sleep disorder and the results were compared with reported lifestyle, medical and medication factors.

Of 167 clients who requested or were invited to participate by piloting pharmacists, 84 (50.3%) were screened. Analysis of collected data indicated that 33.3%, 21.4% and 27.4% of participants were at risk of having or developing insomnia, OSA and RLS respectively, while 38.1% were not at risk of any of the screened disorders. OSA odds increased 12.8 times (95% CI: 3.2–50.4) with diabetes and 4.9 times (1.2–20.9) with opioid use, while shift workers were 8.4 times (1.6–43.2) more likely to have insomnia. Participants and pharmacists reported the screening protocol and instrument was user friendly and feasible.

Considering the tool to be useful, it was modified to an online version – the pharmacy online tool for assessment of sleep health (POTASH). Further promotional materials to assist implementing pharmacists recruit and screen patients were developed (posters, shelf tags, brochures). Protocols for the use of the online and hard copy versions of the POTASH were created. These protocols included decision making about action to be taken if screened patients were found to be at risk for any sleep disorder. Actions to be taken were deemed as verbal counselling, information provision or referral using a referral letter with summarized screening results.

In the implementation phase a randomized control trial was conducted to compare the screening efficiency of POTASH on its own (Basic screening arm) with POTASH plus nasal flow monitoring (Comprehensive screening arm). The FlowWizard® device was selected as the nasal flow monitor. Pharmacists who offered continuous positive airways pressure devices (CPAP) in their pharmacies were identified using a list obtained from CPAP manufacturers. A block randomization design was used to randomize pharmacists into the POTASH only or POTASH plus arms. Pharmacists in both arms of the
study were provided with a comprehensive training accredited at 20 CPD points by the Pharmaceutical Society of Australia. From January to April 2009, these pharmacists were asked to recruit and screen 20 patients each.

**Evaluation** phase results - Eleven pharmacists from the basic arm (of 12), and 9 from the comprehensive arm (of 12) completed the study. Between January and April 2009, these 20 pharmacists recruited and screened 295 patients (~15 per pharmacy, 185 in the basic arm, 110 in the comprehensive arm). Of these 44% (n=131), and 56% (n=164) were recruited within the basic vs the comprehensive arm. The demographic characteristics of the screened patients in both groups were similar. Response rate by patients was .... The mean time taken for screening was 11.6 ± 7.5 minutes. On a scale of 1-5 (1 = very easy, 5 = very hard), patients indicated a mean of 1.7 ± 0.6 as their score about ease of use.

As may be expected the population screened (from those presenting at a pharmacy) demonstrated several health and sleep related risk factors.

- The mean BMI was 29.8±6.4 (well over healthy limit of 25),
- 23% of the screened population consumed more than the recommended number of alcoholic drinks in a week,
- 16% of them were current smokers.
- 63% of screened people consumed caffeinated drinks after 1500 hours,
- 51% of those that had alcohol, consumed it after 2000 hours.
- 10% of the population undertook shift work
- The average hours of sleep were 6.45±1.8 (below the reported population median of 7.5 hours)
- Chronic pain (42%), cardiovascular disease/hypertension (40%), dyslipidaemia, coronary heart disease, angina (37%), gastrointestinal conditions (30%) and depression (27%) were common health problems experienced by the screened population.

**Screening results**

- 28% of the screened population appeared to be at risk of having significant insomnia (i.e. those with a score ≥15 on the Insomnia Severity Index).
- 43% of the screened population were at risk of having or developing OSA (probability ≥ 0.5 on the MAPI score)
- 37% percent of people fulfilled the criteria for the diagnosis of restless legs (using the International Restless Legs Syndrome Study Group Screening Criteria).
- Of those screened, 20% (n=85) were at risk of having or developing one sleep disorder, 13% (n=39) were at risk of having or developing two sleep disorders, and 2% (n=7) displayed risk scores commensurate with having/developing all three sleep disorders screened for.
- In the comprehensive arm, the proportion of people identified with a nasal flow indicative of obstructive sleep apnea was 65%.
- Pharmacists recorded a total of 754 interventions delivered to those screened (n=295).
- A total of 94 referrals were recorded (1 in every 3 people screened).

**Follow up evaluation**

- To date, 126 (73 from basic arm, 53 comprehensive arm) participants have completed the follow up visit and returned a close out questionnaire.
- Of these 126, 29 people took up referrals to their doctor provided by the pharmacist.
• Of these 29, 7 people (24% of those who took up referral) were diagnosed, 3 people were diagnosed with OSA, 2 with restless legs, and 1 with insomnia. Five of the 7 diagnosed were from the basic screening arm.
• A further 7 people are currently undergoing testing, or waiting for sleep testing.
• Thus, of 29 people who saw a doctor as a result of being referred by the pharmacist, 14 (48% of those who took up referral) have undergone or are undergoing diagnostic testing.
• In 9 cases (of 29), the referral resulted in outcomes other than a sleep diagnoses/investigation.
• Until the follow up is completed, it is not possible to comment upon the differences in the rate of diagnoses between the comprehensive and basic arms.

This study is the first study nationally to successfully investigate and demonstrate the important role of the pharmacist in screening for sleep disorders and providing sleep health education.

Recommendations
1. 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.
2. The POTASH is a user friendly screening tool that can assist in diagnosis of sleep disorders in people who may otherwise have not been detected. It is recommended that the POTASH be tested further in a larger multicentre trial, and screening results compared with a gold standard diagnostic test for sleep disorders such as polysomnography.
3. Pharmacists should be trained in sleep health and screening for sleep disorders- this can have enormous public health benefit, since detection and management of sleep disorders can possibly reduce comorbidity burden.