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Original Research

Evaluating regional/rural community pharmacists' confidence and views of prescribing melatonin: A qualitative study

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Abstract

Background: With recent changes to regulations in Australia allowing community pharmacists to prescribe melatonin to people aged 55 and older as a schedule 3 or 'over the counter' medicine, their knowledge of insomnia and the safety of melatonin needs to be assessed.

Objective: The study aims to investigate the perceptions and confidence of community pharmacists on the supply of melatonin to patients with sleep issues. **Methods:** Ten community pharmacists located in regional Victoria participated in semi structured interviews. Interviews were recorded and later transcribed verbatim. Transcriptions were de-identified and thematically analysed. **Results:** Five overarching themes were identified: (1) the accessibility and practicality of pharmacists prescribing melatonin, (2) a lack of confidence in assessing sleep issues (3) a high confidence in the safety of melatonin (4) barriers to prescribing and (5) future recommendations. The results showed that the perceived barriers to pharmacists' safe supply of melatonin included time constraints, the need for supply of melatonin to be recorded and this data shared across pharmacies, as well as the need for dedicated education and training for pharmacists in sleep issues. However, despite these barriers, community pharmacists perceived themselves as suitable prescribers of melatonin, and that with appropriate education and training in insomnia and melatonin safety, their supply of melatonin could be expanded to include other age groups. **Conclusion**: Community pharmacists perceived themselves as being in an appropriate position to supply over the counter melatonin for patients aged 55 years and over. However, there is a need for expanded education and resources to enhance the confidence of community pharmacists in the identification of insomnia presentations and safe supply of melatonin.

Key words: melatonin; sleep; insomnia; pharmacy; community pharmaceutical services; pharmaceutical care

INTRODUCTION

Sleep disorders affect a large proportion of individuals, with estimations of approximately 30% to 50% of adults experiencing insomnia at some point in their lifetime.[1] Long term health consequences of sleep disorders include increased heart rate, blood pressure, blood lipids, and blood glucose, leading to an increased risk of developing chronic diseases such as cardiovascular disease and metabolic disorders.[2] Sleep loss is linked to decreased ability to regulate emotions causing higher rates of psychiatric disorders including mental distress, altered mood and behaviour, depressive symptoms and anxiety.[3]

Insomnia is broadly defined as difficulty falling asleep, staying asleep, or early awakenings that results in daytime fatigue, irritability, and impaired concentration and memory.[1, 4] Modification to sleep hygiene is seen as the first line therapy for treating insomnia, as it is non-invasive and inexpensive. If there is no response to sleep hygiene promotion, pharmacotherapy intervention is often recommended in Australia.[5] The most frequently prescribed sleep medications in Australia are benzodiazepines, zolpidem and zopiclone, which carry a significant side effect burden including daytime drowsiness, dependence, and impaired cognitive functioning.[6-8] Apart from these drugs which require a doctor's prescription, community pharmacists are able to supply several sedating antihistamines to assist with sleep. These, however, are associated with adverse effects such as dizziness, hypotension, falls, and anticholinergic effects, especially in the elderly.[7] In June 2021, controlled-release melatonin underwent down scheduling in Australia from schedule 4 (Prescription Only Medicine) to schedule 3 (Pharmacist Only Medicine) for patients over 55 years of age, allowing another option for over the counter insomnia treatment to be available from community pharmacies.[9] Melatonin is another pharmacological intervention for people who have problems with sleep.[10] It can help regulate the sleep-wake cycle of patients that are experiencing insomnia, and for longer term administration, is generally preferred to other pharmacotherapy options that are associated with more

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sedative and dependence effects.[11] However, there are a range of safety issues to consider prior to prescribing melatonin. Pharmacokinetic issues must be taken into consideration upon supply of melatonin due to interactions with other medications including anti-depressants, benzodiazepines, and oestrogens,[12] as well as substances such as caffeine and cigarette smoke, which may either reduce or accentuate its actions.[13] Additionally, while melatonin may be a useful alterative to more sedating drugs for sleep, there is a lack of research regarding its long-term use, which must be considered by community pharmacists upon over-the-counter supply.[14]

As suggested in the past,[15] community pharmacists are in a key position to monitor for conditions such as insomnia as they often see patients on a regular basis compared to their general practitioners (GPs). Community pharmacists are able to be involved in sleep hygiene education as it does not always require direct involvement of a specialist clinician. It is a relatively inexpensive tool which opens up opportunities for community pharmacists to play a role within the team of health professionals assisting with insomnia, as they are very accessible to members of the community.[16,17] There is some research describing the role that community pharmacy plays toward the identification and management of sleep disorders within Australia. Some of the studies have focussed on critiquing community pharmacists' approach to managing case presentations of insomnia, with common reports of ignoring sleep hygiene interventions.[18] While the services offered by community pharmacists are an important component in providing care to the community, it is imperative that there are adequate resources and educational tools available to pharmacists to allow them to be making the most appropriate suggestions and pharmacotherapy advice for patients who experience sleep issues. This is especially so given the current availability of melatonin as a pharmacist prescribed medicine.

There is however a shortage of research exploring the competency and confidence of Australian pharmacists in prescribing melatonin, and whether additional education beyond tertiary and post graduate study may be required to upskill the profession and improve the standard of their competency.[19,20] In order to help address the gaps in current literature surrounding pharmacists prescribing over the counter melatonin, the objective of this study was to assess the perspectives of community pharmacists in regional Victoria, Australia on their confidence and competence in prescribing this medicine, as well as their assessment of insomnia presentations, to patients 55 years of age and over with sleep issues.

Methods

Study design

A qualitative study approach, using semi-structured interviews, was used to collect data. This approach was deemed most appropriate, in order to gather a more in-depth understanding into the attitudes and perspectives of participating pharmacists. Interviews were conducted between August 2023 and February 2024.

Participants

The study targeted local community pharmacists, practicing in regional community pharmacies within central Victoria, Australia. Participants were selected based on their location and current registration as a practicing pharmacist and recruited through professional networks.

Procedure

A semi-structured set of interview questions and prompts were developed by the research team to ensure consistency in the questions asked. Questions included the frequency of over-the-counter melatonin prescribed to patients over 55 years in the past year, the pharmacists' knowledge of melatonin, how they identify whether melatonin is suitable, what resources and information they provide to customers, how confident they are at prescribing melatonin and what they think is needed to improve confidence in prescribing and if they think pharmacists should be prescribing over the counter melatonin. To ensure the script was appropriate and useful in gathering the information required, the interview questions were piloted on individuals (including pharmacists) outside of the research project and revised and amended to improve clarity. Interviews took approximately 10-15 minutes to complete and were audio recorded and transcribed verbatim by the principal investigator at a later date. Each participant was assigned a unique code by the principal investigator to ensure all transcripts, audio recordings, and quotes were de-identified. The same unique codes were used throughout the report to maintain confidentiality.

Ethics

This study was approved by the Human Ethics Committee at La Trobe University (Project Number: HEC23089) in May 2023.

Data analysis

This study used thematic analysis of qualitative data. [21] This required transcription of recorded interviews by the principal investigator. The transcribed data was scrutinised and similarities between participant responses in interviews noted. These similarities were then tabulated, and corresponding quotes of significance from participants reported. The thematic analysis allowed identification of key concepts within the data in order to generate themes. The designated themes were then assigned titles and definitions.

RESULTS

Ten community pharmacists were interviewed. All pharmacists were based in regional locations in Victoria, Australia. Over the counter melatonin was prescribed on a regular basis within community pharmacies. In general, pharmacists recalled prescribing melatonin once a week or more, and only a few participants recalled prescribing melatonin less often (approximately once per month). In addition, most outlined that they dispensed melatonin as a prescription medication (from a doctor), after the patient obtained an initial supply from the pharmacy. In these instances, patients were referred

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back to their doctor for a prescription for ongoing supply, as the current legislation states that the supply of only a single box could be prescribed by pharmacists for each individual. As mentioned by a few participants, there is no financial incentive for patients to initially see a doctor for melatonin prescriptions as this drug is not subsidised by the Australian Pharmaceutical Benefits Scheme, and thus will cost the same amount whether prescribed by a doctor or over the counter by a pharmacist.

In regard to the thematic analysis, five major themes emerged, including (1) the accessibility and practicality of pharmacists prescribing melatonin, (2) a lack of confidence in assessing sleep issues (3) a high confidence in the safety of melatonin (4) barriers to prescribing and (5) future recommendations.

Accessibility and practicality of prescribing melatonin

The majority of participants thought that community pharmacists were able to increase accessibility of melatonin to patients. For example, participant three stated that by having more drug options available in community pharmacies, barriers to treatment are reduced because there are less "*hurdles [are] put in place to receive treatment*". In addition, providing patients with an option that doesn't require a visit to the GP decreases barriers to treatment as it gives them "*a lot more information to take with them*" (participant three) into GP appointments, saving the patient the cost of multiple appointments.

Participant four stated that "*we definitely see them a lot more than their GP*" and "*we are the ones dealing with their medications*", highlighting that the community pharmacist will be likely to have a full medication history to consider when identifying medications that may be affecting sleep, or identifying when melatonin is suitable for a patient.

Lack of confidence in assessing sleep issues

This theme explores the confidence of community pharmacists in identification of sleep issues as a basis for prescription of melatonin. Most participants rated their confidence of identifying insomnia in patients as between five and six out of ten, with only a small proportion of participants rating their confidence a seven out of ten or higher. Participant nine stated that regarding insomnia, there's: *"always…..room for doubt…..I don't know everything".* When prompted about what can be done to improve the lower scores surrounding identifying insomnia and differentiating insomnia types, answers were unclear, with participant four stating "*in the community we find that it's more you are sleeping, or you aren't. And then we go from there; we aren't really looking at the different types [of insomnia]".* A general uncertainty around identification of sleep issues as a basis for prescription of melatonin was given by Participant nine: "*I wonder how many people tick off that sleep apnoea box differential when someone is coming in for melatonin".*

When it came to identifying and screening for sleep disorders, all participants described thorough screening procedures. For example, asking about sleep patterns and sleep hygiene such as *"I will ask about sleep hygiene… if they can change their sleep habits so that they don't need anything at all which is obviously the ideal scenario." (*Participant four) and *"One of the important questions I ask is 'do you find it difficult to fall asleep initially, or do you fall asleep initially and then wake up later on?, I think that's a really important distinction that often isn't mentioned that people often don't think about. It can be enlightening as to whether the melatonin is going to be useful, but also is there any other mechanism needed instead of sleep" (*Participant ten); as well as discussing any lifestyle factors that may be affecting their sleep like *"Do they know why they're not able to sleep; What else is going on in their life; Do they wake up feeling unrefreshed; Has someone ever complained that they're snoring; Have we ruled out sleep apnoea for example; Are they taking medications that could be impacting sleep; Sleep hygiene*" *(*Participant nine).

Additionally, all participants stated they conduct a short review of the patients' current medications to identify any side effects or recently commenced medications that could be exasperating insomnia. *"Identifying medications that may have been commenced. I guess that's something the pharmacist is looking at specifically". (*Participant two) and *"To make sure it's not drug related, or a side effect [of their medication]" (*Participant five)

Three participants stated they often investigate whether a patient may be at risk of sleep apnoea, such as *"I would educate them on what the consequences of undiagnosed sleep apnoea could be…..and maybe resources on what is proper sleep hygiene, not assuming everyone knows what proper sleep hygiene is*" (Participant nine).

Confident in the safety of melatonin

When asked to score the confidence in the safety of melatonin, answers ranged between seven and ten out of ten, with half of participants scoring their confidence in its safety an eight out of ten. For example, "*I'm pretty confident about the safety – or as much as what we know so far*." (Participant six), a*nd "I feel more comfortable with melatonin than sedating antihistamines, as in, it's better to use that, it's less likely to mask other problems, it's got less issues with drowsiness and sedation…whether it's a therapeutic thing or trying to avoid the negative thing, either way, in my mind the melatonin comes out on top" (*Participant ten).

Some participant's comments however highlight uncertainties around its safety including participant five who said *" We don't have enough studies about the long-term effects of it, so we can't really be confident."* and that they are a bit *"on the fence, and dubious, about the long-term impacts of supplementing something chronically that our body produces naturally" (*Participant nine); some were also concerned that customers are misinformed about melatonin and that it will help with another underlying sleep disorder *"….it could cause harm if you're putting a band aid on sleep apnoea if that hasn't been treated accordingly or appropriately" (*Participant nine).

Barriers to prescribing

Participants identified a number of barriers that have the

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potential to interfere with best practice of care when prescribing melatonin within community pharmacy. One of the major barriers centred around monitoring the supply of melatonin. While regulations state that a patient may only be prescribed a single box of melatonin as over counter supply from a pharmacist, it is possible that patients may attempt to obtain supply from more than one pharmacy. Participant eight in this study stated that as melatonin was to only be supplied once there needed to be a way of "*record[ing] how often its being prescribed*". A database accessible by all pharmacists such as the ProjectStop program for pseudoephedrine supply (in Australia) was discussed. In the interviews, a significant proportion of participants stated that there was ambiguity surrounding the current regulations of supplying melatonin, drawing attention to the current Therapeutics Goods Administration approval of melatonin for "monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over".[22]

There was significant focus within some interviews on the risk of inaccurate or incorrect information provided by patients when requesting melatonin. As community pharmacies do not share dispensing records, if a person seeking melatonin visited a pharmacy for the first time, then pharmacists have to rely on the details provided by the patients regarding their current medications and assessment of sleep dysfunction. As highlighted by participant two, for some patients requesting melatonin "*there will be things that they don't want to mention, or that they forget*", reducing accurate diagnosis and making assessment of symptoms challenging. Further barriers to prescribing discussed in interviews were the diversity of information that patients were exposed to regarding melatonin, the misunderstanding of the causes of sleep issues, and perceived lack of efficacy associated with the use of melatonin. All of the interviewed pharmacists stated that patients' requests for melatonin were based on information from varying sources, such as: "*saw it on the television*", "*heard about it from a friend*" or someone "*suggested to trial it*". Another issue is that when pharmacists provide melatonin, patients may lack the understanding of insomnia as a secondary cause of an underlying or unmanaged condition and as such, melatonin may not particularly be effective for that individual. As stated by one participant, if melatonin is supplied and found to be ineffective, people may "*be a bit disappointed*" as it "*doesn't work for everybody and it's a lot of money*" (participant one).

Future recommendations

Within this theme, the views of future prescribing of melatonin and suggested recommendations for enhancing the delivery of melatonin to patients within the community were considered. As discussed in the '*Accessibility and practicality'* theme, all participants believed community pharmacists were in an ideal position to be having conversations with patients about their sleep and providing sleep hygiene recommendations. Possible areas of improvement in melatonin supply by pharmacists were identified. The lowest scored category of confidence was identifying insomnia symptoms within presenting patients. For instance, one participant scored their confidence an eight out of ten in identifying insomnia, with the remaining participants scoring between five and seven out of ten. Participant two stated their confidence of identifying insomnia was *"not a strong point"* of the process of melatonin prescribing, and participant four stated their confidence of identifying insomnia was *"probably not as good, I probably need to brush up on that".*

Addressing the current gaps in knowledge was discussed throughout interviews. One participant suggested that there was a general issue with the lack of understanding of the importance of sleep: "*Taking the emphasis off melatonin and putting the emphasis on sleep would be great. I don't think it is covered all that much through the pharmacy course. I think it's underestimated in practice by pharmacists, doctors, patients. ……. Why not learn about the sleep side of things? I think the confidence would come from the bigger picture, not from learning more about melatonin necessarily" (*participant ten). Some suggestions that came out in the interviews include a lack of available continued professional development (CPD) training modules, *"I don't even remember seeing anything on melatonin in my CPD training to be honest"* (participant four) and *"I can't recall something specific to melatonin that was highlighted"* (participant two). Participant five stated supply of written information from drug companies would be most useful to reduce ambiguity of eligible patients for sleep issues. Participant five also said that there was "*limited data and information about the effectiveness [of melatonin*]" which made it difficult for pharmacists to be completely confident of melatonin in the eligible population. However, a number of participants proposed expanding the scope of melatonin supply, such as extending the length of supply beyond 'short term', and for other populations or conditions. Half of the participants suggested they would like to see over the counter melatonin supply approved for younger populations, with participants observing that it was common for people to purchase melatonin online from overseas sources. "*Why is it over 55? Surely there'd be other age groups, even if you change the criteria for it, you could still have it more accessible, compared to the risks of something like sedating antihistamines. And that is kind of given out willy-nilly"* (participant ten).

Concerns regarding expanding the scope of practice were also discussed. More than half of participants noted that if the criteria for over-the-counter melatonin was expanded, further training and more data on melatonin safety and effectiveness would be needed to improve confidence. For example, participant eight stated that broadening the criteria for supply may invite complicated patients to community pharmacies for melatonin, and a pharmacist in this situation may not be able to effectively consider the underlying conditions that may be affecting sleep, such as "*pain, mental health, or any other major conditions could be causing insomnia*". The concern was that this may lead to inaccurate management of the primary conditions causing insomnia. The issue of time constraints within community pharmacy was also discussed, highlighting this and the lack of remuneration for pharmacists as barriers to pharmacists providing expanded services to the community.

DISCUSSION

Our study found that overall community pharmacists were relatively confident and competent in prescribing melatonin to people 55 years of age or older. However, whilst community pharmacists believe they are in a good position to supply over the counter melatonin, the study highlighted that more focus was needed to educate and upskill pharmacists to undertake this role.

Sufficient education and training

As community pharmacists are presented with more frequent melatonin requests, enhancing their competency in delivering appropriate counselling to patients on effectiveness and current data surrounding melatonin as a treatment for insomnia may ensure safe delivery of this drug, and that consumer expectations are met. Further, more frequent melatonin requests will possibly allow pharmacists to uncover primary conditions underlying sleep issues and refer these patients to their doctor for appropriate management. However, this study highlighted that if community pharmacists were to take on a greater role of melatonin prescribing, they would also need to be equipped with appropriate training and education. This would enable them to feel more confident to increase the scope of supply of melatonin to expanded populations within the community for extended periods. To achieve this, they need to obtain the necessary training and education in order to increase their understanding of sleep issues, and how and whether melatonin may be of benefit. This education may include updated tertiary education, increasing availability of CPD modules for pharmacists to participate in, or resources from manufacturers and professional bodies to build their current knowledge. This is a similar finding to other research which found that one of the major barriers of practicing pharmacists expanding public health accessibility and services was the lack of training and education in providing high standard health care to the community.[23] However, pharmacists who are provided with extensive accredited training which covered the condition of insomnia, its impacts on health and wellbeing, pharmacological treatment options, and information on sleep hygiene modification, would be better placed to assist patients with sleep issues. A feasibility study specifically found that patients who received behavioural intervention by trained pharmacists reported a 63% improvement in insomnia as determined by their insomnia severity index survey results, as opposed to 26% improvement in the control group who had intervention based on the pharmacists' previous knowledge.[24] This study demonstrated that sufficiently educated community pharmacists can have the potential to improve symptoms in patients experiencing insomnia.

Pharmacists' role

This study showed that community pharmacists perceived themselves as being in an ideal position to monitor patients with sleep issues, as they are an accessible option for healthcare advice and have a good understanding of the medication and health status of regular patients. There are already several commonly used pharmacological sleep aids which are prescribed by community pharmacists. Sedating antihistamines cross the blood brain barrier and block histamine-1 receptors in the central nervous system, causing sleepiness.[25] In Australia, first generation antihistamines doxylamine, dexchlorpheniramine and diphenhydramine, are approved by the Therapeutic Goods Administration for the treatment of short-term insomnia.[26] Other first-generation antihistamines, such as promethazine, are often misused both intentionally and unintentionally for their sedating properties. Over-use of these sedating antihistamines can lead to dependence and withdrawal issues causing worsening of a patients existing insomnia.[27] The accessibility to these drugs is of major concern due to their sedating effects increasing possibility of unintentional overdose, overuse, drug interactions, or falls risks in the elderly.[28] Additionally, community pharmacists already help manage sleep services, and more pharmacies are now offering services for conducting sleep studies, initiating continuous positive airway pressure (CPAP) machine trials, and providing sleep apnoea education and products within the community.[29] Pharmacists are already involved in the supply of melatonin, either by leading the consultation directly or by dispensing the prescriptions from GPs and thus should be seen as a profession that can offer complementary service. Indeed, the effective utilization of pharmacy services has been shown to save time for GPs.[30] If melatonin was only available via a GP's prescription, patients may delay treating or managing their insomnia as they may have to book an appointment with their doctor, putting them at greater risk of developing secondary health conditions from untreated sleep disorders.

RECOMMENDATIONS AND CHANGES

Even though pharmacists believed it was appropriate for them to prescribe melatonin, concerns were raised by participants surrounding the time constraints present within community pharmacies and adding to the already excessive workload. Past research highlights that pharmacists already have significant time constraints[31], and may struggle to effectively monitor and follow-up on patients. Greater remuneration and compensation for their services, to acknowledge the dedication and care to their patients is needed. Participants in this study also suggested that there was a need for improved guidelines and clarity regarding eligibility of patients, length of supply, and recording processes to ensure consistency and continuity of care regarding over-the-counter supply of melatonin by community pharmacists. To aid in this, a recording system was recommended by participants of this study. Having processes that allow pharmacists to observe if melatonin has been previously supplied, when it was last supplied, and from which pharmacy, would enable informed decisions based on a patient's past and current usage. The recording system could also be directed towards monitoring the management of the insomnia symptoms, and possibly identifying causative factors if not managed appropriately. Such a recording system could also assist with assessment of the safety of melatonin, and whether it interacts with the patient's other medicines. This is an important issue, and despite most participants perceiving melatonin as a safe therapy compared to other medications

for sleep, the pharmacokinetic properties of melatonin open the potential for significant drug interactions. To this end, more education could be directed towards improving pharmacists' knowledge of the safety of melatonin to ensure that drug interactions and precautions are being assessed upon prescribing. Future changes to prescription guidelines should be made following pharmacist consultation to ensure community pharmacists are equipped with the resources and skills to deliver these programs effectively and safely.

STRENGTHS AND LIMITATIONS

The use of semi structured interviews in this study allowed further discussion and investigation of responses and comments provided by participants. However, this form of data collection also has recognised limitations, in that it may lead to response bias because of fear of judgement or modifying information to present it in a more favourable light. Whilst the flexibility of semi structured interviews allowed topics brought up by participants to be explored further with follow up questions, the lack of standardisation between interviews reduced capacity to draw conclusions on specific aspects of melatonin confidence. Further, as this study was performed with a small group of regional pharmacists, generalisations are limited. Future studies should aim to perform interviews with a greater sample size distributed across a wider geographic and demographic area to address these limitations.

CONCLUSION

There is an abundance of research showing the negative health consequences of unmanaged sleep issues. Pharmacists are perfectly placed to play a vital role in sleep management issues within the community alongside other health professionals. In this study, community pharmacists identified themselves as being in an appropriate position to supply over the counter melatonin, not just to people over 55 years of age, but the wider population. However, there were reservations in regards to their competency and knowledge, with the study highlighting the need to expand education and resources to enhance the support community pharmacists have and can provide when identifying sleep issues and prescribing melatonin. Future research is recommended to investigate the prescribing of melatonin by pharmacists at more diverse geographic locations and to examine the suitability of the expansion of melatonin supply, by community pharmacies, to other populations.

CONFLICT OF INTEREST AND FUNDING STATEMENT

No authors have any conflict of interest to declare, and the project did not receive funding.

AUTHOR CONTRIBUTIONS

All authors contributed to the study's conception and design. LB and BN wrote the first draft of the manuscript, and all authors (BN, AM, JT and LB) have commented on the previous versions of the manuscript. Data collection was performed by BN and AM and analysis by BN and LB. All authors have read and approved the final version of the manuscript.

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