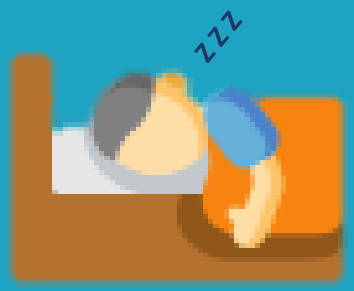
NSW TAG

Getting it right for sleep at night



Guidance for promoting sleep and reducing harm from inappropriate pharmacologic management of sleep disturbance and insomnia in hospitalised patients

December 2021

NSW Therapeutic Advisory Group Inc.

Advancing quality use of medicines in NSW

New South Wales Therapeutic Advisory Group Inc. is an initiative of NSW clinical pharmacologists and pharmacists and is funded by NSW Health.

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Executive summary

This guidance aims to support clinicians and governance bodies in the optimal management of a common condition in hospital, sleep disturbance or insomnia, with a focus on quality use of night sedation medicines in non-critically ill hospitalised patients. The use of medicines for night sedation in hospital challenges each tenet of Australia's quality use of medicines (QUM) principles: judicious selection of management options; use of the appropriate medicine, when a medicine is indicated; and, the safe and effective use of medicines.

Published literature demonstrates limited application of evidence-based non-pharmacological management strategies in Australian and international hospitals. The benefits of medicines for night sedation in hospitalised patients are limited and the harms from these medicines are well known, with evidence of impaired alertness and increased falls and fractures, confusion and delirium, and unplanned hospital readmissions due to their use. However, mortality and morbidity data suggest an under-appreciation of the adverse harm to benefit balance among consumers, their carers and clinicians. The combined use of benzodiazepines and benzodiazepine-like medicines with other centrally-acting medicines such as opioids and gabapentinoids is increasingly identified in medication-related mortality statistics. In addition, the use of medicines for night sedation during hospitalisation often inappropriately continues after the patient leaves hospital. The use of perceived "safer" medicines for night sedation in non-critically ill patients, such as melatonin, is not supported by evidence in this population, and thus often represents the use of an expensive placebo, a paradigm not supported by QUM principles.

Importantly, the solution is not just a reduction in the use of medicines for night sedation but also the implementation of non-pharmacologic management strategies that will promote sleep. This will require significant investment and a change in long-standing behaviours across the healthcare system. Such a change supports a person-centred approach to healthcare, with increased awareness of patients and clinicians to the pros and cons of the clinical scenario and possible management modalities, improved shared decision making, and delivery of a supportive approach that avoids medication initiation and increases deprescribing of medicines that are likely to deliver greater harm than benefit. Given the influence that hospital practice has over community practice, the hospital healthcare system has a responsibility to lead this change in the management of sleep disturbance and insomnia.

This guidance provides an analysis of the current literature regarding sleep disturbance and insomnia and their management in non-critically ill hospitalised patients, practical strategies for hospital governance bodies, and step-by-step approaches for clinicians to manage patients taking medicines for night sedation prior to hospitalisation or those who are treatment-naïve but complaining of sleep disturbance. The prescription of any medicine for night sedation should only occur after careful consideration. This document provides a framework for that consideration. A healthcare system change will be required for the recommendations to be most effective and improve patient outcomes. This guidance provides key recommendations to inform and support this change.

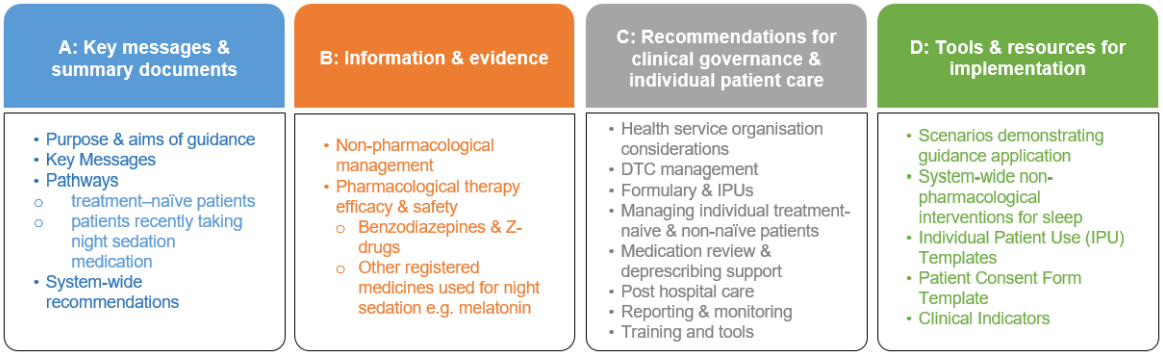


Figure 1: Summary of key sections covered in this guidance document

Part A: Purpose, Key Messages and Summary Documents

1. Purpose of guidance

This person-centred guidance describes best practice for the clinical care of a hospitalised patient experiencing sleep disturbance or insomnia. It supports:

- Providing information and education to patients and carers about sleep during hospitalisation and the care available to support sleep in hospital;
- Shared decision making by patients and clinicians regarding the judicious, appropriate, safe and effective prevention and management of sleep disturbance and insomnia; and,
- Health service organisations providing an environment conducive for sleep (as appropriate and feasible).

A multidisciplinary approach that emphasises non-pharmacological over pharmacological treatment is *always* preferred. The use of sedative and hypnotic medicines such as benzodiazepines and antipsychotics for the management of sleep disturbance or insomnia carries risks of short- and long-term harms, such as falls and hip fractures, cognitive impairment, dependence and unplanned hospital readmissions.

This guidance is intended to assist clinicians and Drug and Therapeutics Committees (DTCs) to implement strategies that promote non-pharmacological management of sleep disturbance and insomnia and reduce inappropriate use of potentially harmful pharmacological management strategies in patients during hospitalisation and after hospital discharge. It particularly aims to support clinicians managing after-hours requests for "night sedation".

Although the guidance focuses on benzodiazepines (BZDs) and Z-drugs (zolpidem and zopiclone), it also discusses the use of other medicines that may be considered as alternative therapies, such as melatonin, antidepressants, antipsychotics and antihistamines. While the focus is on hospital-based care, many of the principles apply to other settings such as custodial health care or community-based care including residential care facilities. The guidance is based on the best available evidence or expert consensus when research evidence is lacking.

The scope of this guidance does not include or discuss:

- *Critically ill patients in high dependency units such as Intensive Care Units.*
- *Patients admitted to hospital for primary management of drug and/or alcohol dependence.*
- *Children and adolescents with sleep disturbance.*
- *Use of sedatives and hypnotics in the management of Behavioural and Psychological Symptoms of Dementia (BPSD) (also called dementia and changed, or responsive, behaviour).*

Specialist advice should be sought for these clinical scenarios.

2. Aims of this guidance document

This guidance has two main goals:

1. NSW hospitals will provide environments that promote sleep without the need to request or prescribe 'night sedation medicines'*, whenever possible.
2. Prescription of medicines for management of sleep disturbance or insomnia in non-critically ill patients will only occur after comprehensive assessment, optimisation of non-pharmacological management, discussion of the limited effectiveness and significant harms of these medicines, acquirement of informed patient consent (or consent of Person responsible) and is only for a limited period of time.

* The term 'night sedation medicines' will be used in this document to describe any medicines with sedative or hypnotic activity that may be used to manage sleep disturbance or insomnia at night (whether on-label or off-label use).

3. Key messages

☆ Practice in hospital influences practice in the community.

☆ First line management of sleep disturbance or insomnia in hospitalised patients is use of a non-pharmacological approach.

☆ Hospitals should implement a governance framework with necessary resourcing and training for multifaceted sleep hygiene strategies that are integrated into patient care plans, and medicine use evaluations for monitoring and supporting quality improvement in patients' sleep management in hospital and at discharge.

☆ Initiation of medicines for management of sleep disturbance or insomnia in hospitalised non-critically ill patients is not recommended.

- Benzodiazepines and Z-drugs (zolpidem, zopiclone) are low-value, high-risk medications for sleep disturbance or insomnia in hospital, often causing preventable harm.
- The use of other medicines for night sedation (e.g. melatonin, antipsychotics, antihistamines, antidepressants, suvorexant) is not recommended, as the evidence does not favour benefit over harm in this setting.

☆ If medicines for night sedation are selected as part of a management plan for sleep disturbance or insomnia in hospital, despite the risk of harm or lack of effectiveness, the following actions are recommended:

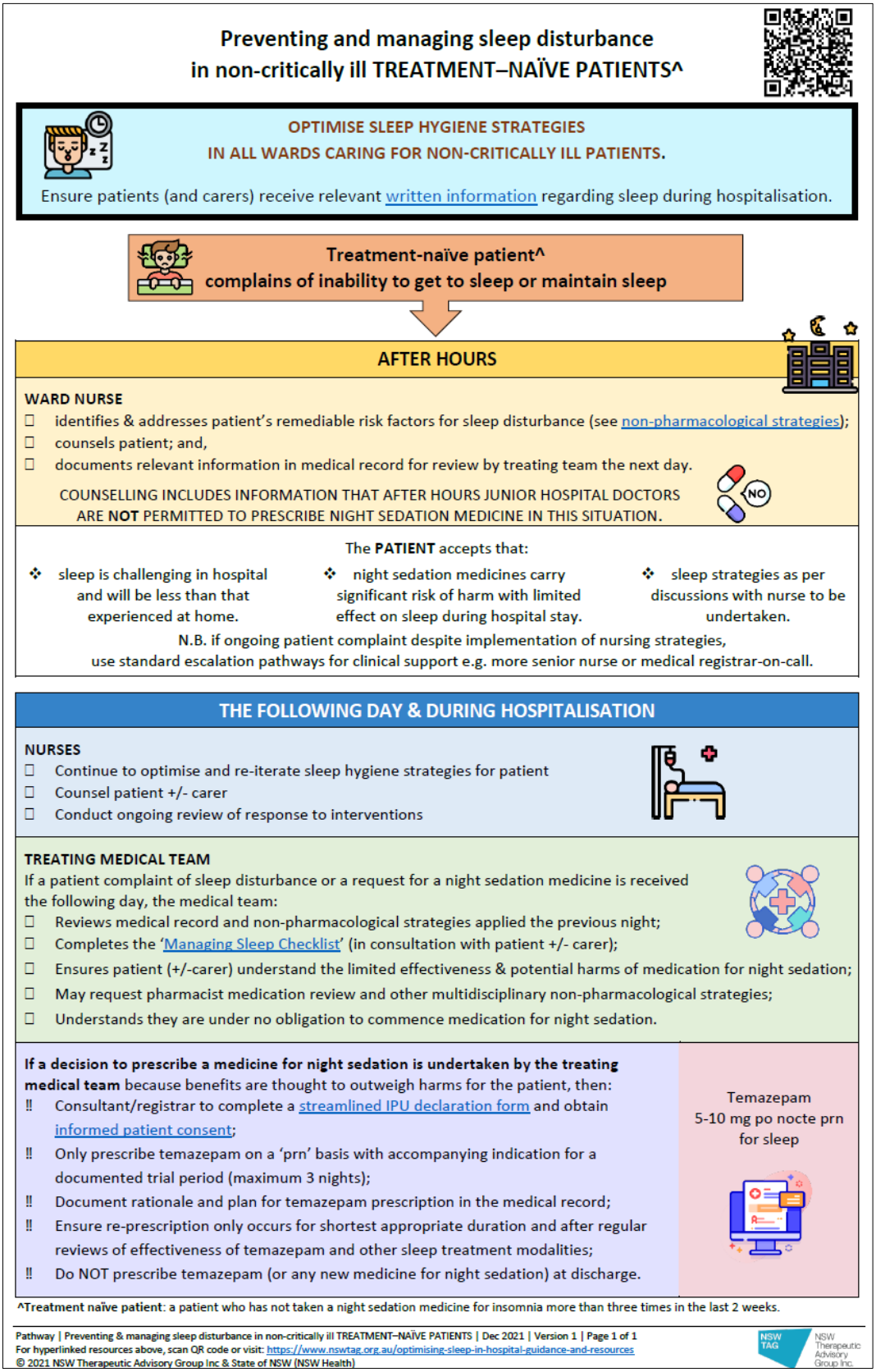
a. Discuss sleep hygiene principles at every opportunity.
b. Communicate the limited effect and significant harm of medicines for night sedation to patients/carers, obtain informed consent and prescribe for an agreed period.
c. Check for aberrant drug-related behaviours and history of substance use disorder.
d. Beware of prescribing medicines for night sedation with other central nervous system depressants, such as opioids and gabapentinoids.
e. Review use and impact of medicine for night sedation on a daily basis.
f. In all patients who have taken medicines for night sedation prior to hospital admission, refer for a medication review and discuss gradually deprescribing night sedation medicines at every opportunity. If deprescribing is commenced in hospital, wean slowly and monitor for withdrawal symptoms.
g. In previously treatment-naïve patients, do not continue medicines for night sedation after discharge.

☆ Sleep disturbance is a frequent feature of delirium in older hospitalised patients. Melatonin has not been shown to conclusively prevent delirium and there is limited evidence for other medicines in the prevention of delirium. Sedative medications may exacerbate delirium.

4. Pathways for managing sleep disturbance/insomnia in non-critically ill hospitalised adults

4.1 Preventing and managing sleep disturbance in non-critically ill treatment–naïve patients

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/



Preventing and managing sleep disturbance in non-critically ill TREATMENT–NAÏVE PATIENTS^

OPTIMISE SLEEP HYGIENE STRATEGIES IN ALL WARDS CARING FOR NON-CRITICALLY ILL PATIENTS.

Ensure patients (and carers) receive relevant written information regarding sleep during hospitalisation.

Treatment-naïve patient^ complains of inability to get to sleep or maintain sleep

AFTER HOURS

WARD NURSE

- identifies & addresses patient's remediable risk factors for sleep disturbance (see non-pharmacological strategies);
- counsels patient; and,
- documents relevant information in medical record for review by treating team the next day.

COUNSELLING INCLUDES INFORMATION THAT AFTER HOURS JUNIOR HOSPITAL DOCTORS ARE **NOT** PERMITTED TO PRESCRIBE NIGHT SEDATION MEDICINE IN THIS SITUATION.

The **PATIENT** accepts that:

- sleep is challenging in hospital and will be less than that experienced at home.
- night sedation medicines carry significant risk of harm with limited effect on sleep during hospital stay.
- sleep strategies as per discussions with nurse to be undertaken.

N.B. if ongoing patient complaint despite implementation of nursing strategies, use standard escalation pathways for clinical support e.g. more senior nurse or medical registrar-on-call.

THE FOLLOWING DAY & DURING HOSPITALISATION

NURSES

- Continue to optimise and re-iterate sleep hygiene strategies for patient
- Counsel patient +/- carer
- Conduct ongoing review of response to interventions

TREATING MEDICAL TEAM

If a patient complaint of sleep disturbance or a request for a night sedation medicine is received the following day, the medical team:

- Reviews medical record and non-pharmacological strategies applied the previous night;
- Completes the 'Managing Sleep Checklist' (in consultation with patient +/- carer);
- Ensures patient (+/-carer) understand the limited effectiveness & potential harms of medication for night sedation;
- May request pharmacist medication review and other multidisciplinary non-pharmacological strategies;
- Understands they are under no obligation to commence medication for night sedation.

If a decision to prescribe a medicine for night sedation is undertaken by the treating medical team because benefits are thought to outweigh harms for the patient, then:

- !! Consultant/registrar to complete a streamlined IPU declaration form and obtain informed patient consent;
- !! Only prescribe temazepam on a 'prn' basis with accompanying indication for a documented trial period (maximum 3 nights);
- !! Document rationale and plan for temazepam prescription in the medical record;
- !! Ensure re-prescription only occurs for shortest appropriate duration and after regular reviews of effectiveness of temazepam and other sleep treatment modalities;
- !! Do NOT prescribe temazepam (or any new medicine for night sedation) at discharge.

Temazepam 5-10 mg po nocte prn for sleep

^Treatment naïve patient: a patient who has not taken a night sedation medicine for insomnia more than three times in the last 2 weeks.

Pathway | Preventing & managing sleep disturbance in non-critically ill TREATMENT–NAÏVE PATIENTS | Dec 2021 | Version 1 | Page 1 of 1
For hyperlinked resources above, scan QR code or visit: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources

4.2 Managing sleep disturbance/insomnia in the non-critically ill patient recently taking a medicine for night sedation

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

Managing sleep disturbance/insomnia in the non-critically ill patient RECENTLY TAKING a MEDICINE for NIGHT SEDATION

OPTIMISE SLEEP HYGIENE STRATEGIES

IN ALL WARDS CARING FOR NON-CRITICALLY ILL PATIENTS.

Ensure patients (and carers) receive relevant written information regarding sleep during hospitalisation.

→ ON ADMISSION TO WARD

NURSING STAFF

- ☐ Identify and address patient's remediable risk factors for sleep disturbance/ insomnia.
- ☐ Assess and optimise non-pharmacological strategies to promote sleep.

TREATING MEDICAL TEAM
(or ADMITTING TEAM if after hours)

- ☐ **Consider need for ongoing medicine for night sedation if:**
  - patient took medicine for night sedation recently or frequently prior to hospitalisation
  OR
  - patient was initiated on medicine for night sedation during hospitalisation e.g. during critical care management

A PRESCRIBER IS UNDER NO OBLIGATION TO COMMENCE OR CONTINUE PRESCRIBING MEDICATION FOR NIGHT SEDATION AGAINST THEIR BETTER JUDGEMENT.
Assess whether any risk of drug withdrawal.

- ☐ **Clinically assess** (see 'Managing Sleep Checklist', for completion in consultation with patient +/- carer)

↔ DURING HOSPITALISATION ↔

IF PHARMACOLOGICAL MANAGEMENT IS REQUIRED:

- ☐ Document clinical assessment, rationale & plan for night sedation medication prescription in medical record.
- ☐ Offer relevant consumer information to ALL patients

TREATING MEDICAL TEAM

- ☐ Prescribe patient's night sedation medication 'PRN' or as a deprescribing plan.

NON-TREATING MEDICAL TEAM

- ☐ Prescribe stat dose of patient's night sedation medication for review by treating team the next day.

AT DISCHARGE →

- ✖ DO **NOT** PRESCRIBE A MEDICINE FOR NIGHT SEDATION AT DISCHARGE IF NOT TAKEN PRIOR TO HOSPITALISATION.
- ✓ The treating team should have already discussed the benefits of DEPRESCRIBING any night sedation medication with the patient +/- carer and promoted sleep hygiene strategies.
- ✓ Communicate implemented or recommended deprescribing plans to the clinician(s) taking over care.
- ✓ Provide patient +/- carer with relevant information including deprescribing and sleep hygiene information.
- ✓ Consider referral to a practitioner who provides Cognitive Behavioral Therapy for Insomnia (CBT-I) or other psychological therapy for insomnia.

ALL MEMBERS OF THE HEALTHCARE TEAM CARING FOR THE PATIENT:

- ✓ Counsel regarding sleep expectations during hospitalisation.
- ✓ Counsel, as appropriate, about the potential harms and limited effectiveness of medicines for night sedation.
- ✓ Frequently review non-pharmacological sleep promoting strategies & reiterate sleep hygiene principles at every opportunity throughout hospitalisation.
- ✓ Frequently review response to interventions and assessment of harms in context of clinical condition.

***Recently taking a medicine for night sedation means the patient is a 'non-treatment- naïve patient':** a patient who regularly uses a medicine for night sedation (i.e. has taken a medication for night sedation more than three times in the last 2 weeks at their place of residence) or a hospital patient who has recently taken medication for night sedation during critical care management.

Summary Guide | Managing sleep disturbance/insomnia in the non-critically ill patient RECENTLY TAKING a MEDICINE for NIGHT SEDATION | Dec 2021 | Version 1 | Page 1 of 1
For hyperlinked resources above, scan QR code or see: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources

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5. Summary of system-wide recommendations

1. System-wide non-pharmacological strategies to minimise sleep disruption while an inpatient should be proactively applied to all hospitalised patients and supported by all disciplines. See section 'Non-pharmacological Management' for further information.

2. Nurses must have tools and strategies to cope with restless, noisy, disruptive and/or anxious patients. Programs that train nurses in implementation of sleep hygiene strategies, that includes appointment of Nursing Unit Managers (NUMs) as champions of sleep and provides support for ward initiatives that promote sleep and reduce 'night sedation medicine' use should be implemented.

3. Proactive management of patient expectations for sleep in addition to identifying those who routinely take night sedation medicines should be undertaken as soon as possible e.g. during pre-admission clinic consultations and at admission. This should assist early intervention e.g. medication review and initiation of patient-targeted non-pharmacological mitigation strategies (see consumer information).

4. Benzodiazepines, Z-drugs (zolpidem and zopiclone), melatonin, suvorexant, antidepressants, antipsychotics and sedating antihistamines are not indicated for management of sleep disturbance or insomnia in treatment-naïve non-critically ill adult patients and should not be listed on the hospital formulary for initiation in these patients. In the infrequent circumstances where these are considered for use, there should be accompanying documented consent and decision-making processes, preferably using an Individual Patient Use (IPU) process, completed by consultant or registrar. (See Section 8.2.2.1) Hospitals should have electronic templates that support the assessment and decision-making processes required for sleep assessment and management.

5. Hospital formularies should be explicit in the indications for which benzodiazepines and other night sedation medicines may be used. Electronic warning messages providing the approved indications (similar to orange and red antimicrobial messages) would be useful to support appropriate prescribing.

6. 'Night sedation medicines' including benzodiazepines, Z-drugs and melatonin are not useful for management of sleep disturbance associated with acute delirium in older hospitalised patients.

7. Adoption of the processes outlined in the Pathways for managing sleep disturbance/insomnia in non-critically ill hospitalised adults is recommended.

8. Implementation of a tool to assist prescribers determine the harm: benefit balance of prescribing pharmacological therapy for sleep disturbance or insomnia in hospitalised patients is recommended. An example tool is provided in this guidance, the 'Managing Sleep Checklist'.

9. The decision to prescribe night sedation medicines should be undertaken by the primary treating team. Junior medical officers providing after-hours care should not prescribe pharmacological therapy for acute sleep disturbance in an unfamiliar treatment-naïve patient, nor should they be expected to prescribe night sedation medication in non-treatment-naïve patients.

10. Whenever a night sedation medicine is prescribed, assessment of an individual patient's risk must be undertaken. The patient must be informed of their risk of harm, the low probability of benefit, and strategies to mitigate preventable harm must be implemented. Counselling and the potential for deprescribing should be discussed with patients. Referral for in-depth medication review by suitably skilled clinicians and/or other clinical services during hospitalisation should be considered in complex patients.

11. Prescribing of night sedation medicine for acute insomnia is not recommended at discharge in any patient if initiated in hospital. In circumstances where it is considered absolutely necessary for continuation e.g. long term hospital use (> 2-4 weeks), there must be explicit documentation about the rationale and a plan must be in place for the clinician taking over care, which may include post-discharge medication review and a deprescribing plan.

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Part B: Information and evidence

6. Background

Definition and impact of insomnia and sleep disturbance

Insomnia is defined as an individual's report of difficulty with sleep (despite adequate opportunities and conditions for sleep) and is accompanied by impaired daytime functioning.[1,2] Symptoms of insomnia include difficulty initiating sleep, difficulty maintaining sleep with frequent waking (resulting in a reduction in sleep efficiency), waking up too early and, in some cases, non-restorative or poor quality sleep. Sleep disturbance is a commonly experienced when environmental conditions are not conducive to rest and sleep. It is a phenomenon experienced by many in the community but is more common in acute care hospitals. It is important that newly acquired poor sleep during hospitalisation is not diagnosed as insomnia but treated as a temporary consequence of the environment and care received during hospitalisation, where there are often inadequate opportunities and conditions for sleep.

Approximately 30% of the general population self-reports sleep disruption, and 10% experience associated impaired daytime function.[3] Poor sleep and disruption of the circadian rhythm is detrimental to health and recovery from illness or injury. Poor sleep affects multiple organs and is associated with a weakened immune system and poor cognitive function.[4,5,6] In otherwise healthy adults, short-term consequences of sleep disruption include increased stress responsivity, somatic pain, reduced quality of life, emotional distress and mood disorders, and cognitive, memory, and performance deficits.[7]

Changes in sleep patterns are a normal part of ageing and is frequently misunderstood and overtreated. Unfortunately, sedatives and hypnotics are frequently prescribed to treat sleep disturbance.[8] Benzodiazepines are one of the most commonly misused classes of prescription drugs in Australia.[9,10] Similarly, there is increasing off-label prescribing of quetiapine for insomnia in the absence of good evidence to support the practice.[11,12] It is also likely certain antidepressants, namely tricyclic antidepressants, such as amitriptyline, and atypical antidepressants, such as mirtazapine, are prescribed for insomnia.

Impact, incidence, causes of insomnia and use of night sedation medicines in hospitalised patients

Sleep disturbance is to be expected in many hospital patients given that stress, illness, significant life changes and external environmental causes such as noise and bright lights are typical triggers and causes of sleep disturbance. Frequent disturbances due to monitoring or treatment during the night reduce restorative sleep stages[5] and sleep during hospitalisation is predominantly nonrestorative sleep.[13] Arguably the need for sleep to assist recovery from acute illness is most profound during hospitalisation.[5]

Figure 2 displays the potential short- and long-term health ramifications from sleep disturbance in hospitalised patients. Notably, insomnia and medicines commonly used for night sedation, such as benzodiazepines, produce many of the same adverse consequences, such as impaired immune function, cognition and energy metabolism, non-refreshing/non-restorative sleep, falls, and unplanned hospital readmissions.[5,13-15]

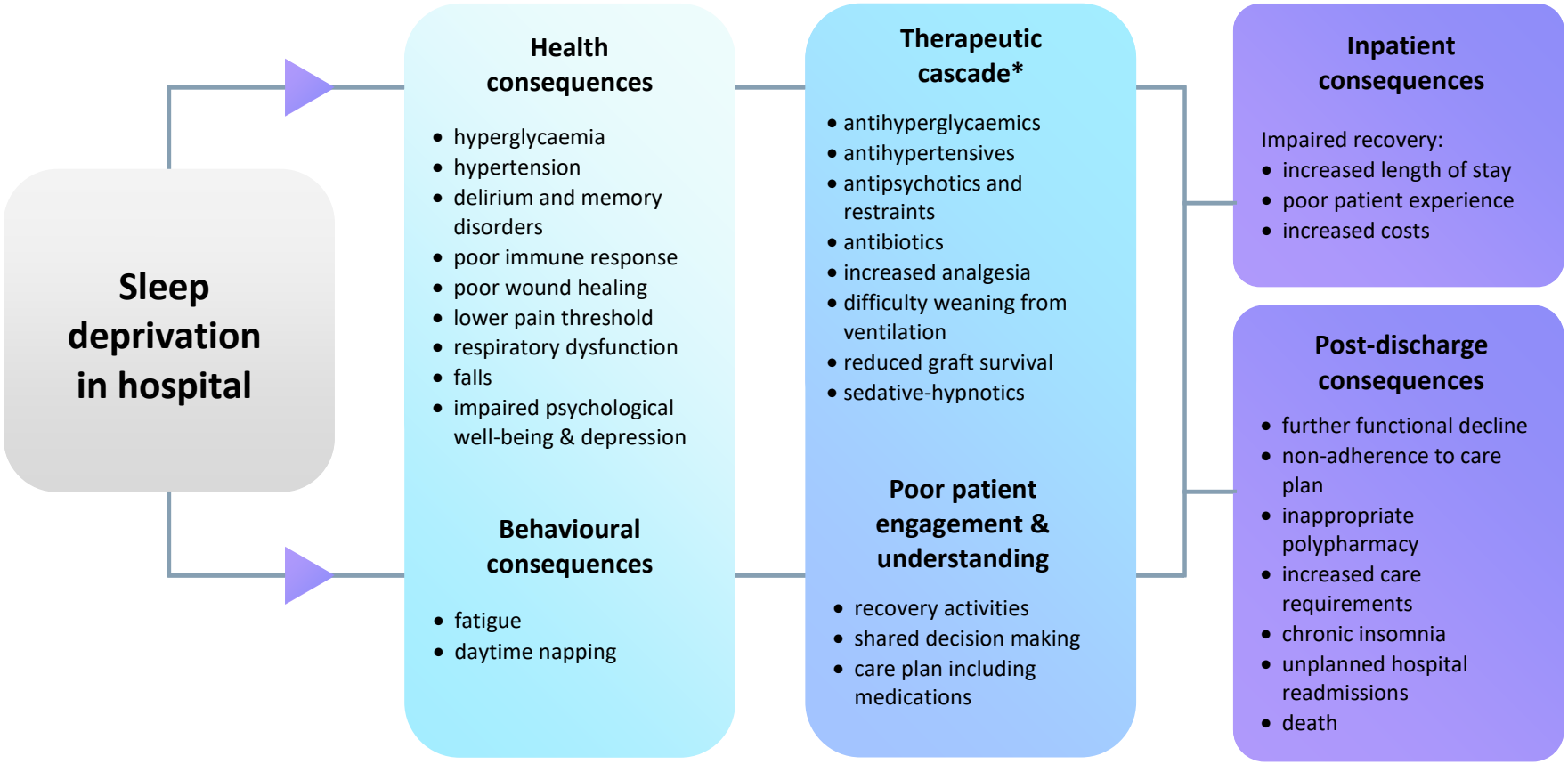

Figure 2: Potential health impacts of sleep disturbance in hospitalised patients

(Figure 2 citations [5-7,14-18])

*The therapeutic cascade refers to the additional prescribing or changes in dosing that may occur as a result of health consequences arising from sleep deprivation in hospital.

Sleep disturbances occur in up to 70% of hospitalised patients with approximately 40% dissatisfied by their rest at night during hospitalisation.[19,20] The extent of sleep disruption varies according to:

- ward location e.g. ICU patients report greater disruption[21];
- type of hospital accommodation e.g. placement in a multi-patient room is a strong predictor of poor sleep in hospital;
- type of intervention e.g. reduced restorative sleep is reported post-surgery[16];
- type of illness e.g. higher incidence of sleep disturbance and insomnia in people with poorly controlled pain, chronic obstructive pulmonary disease, heart failure, gastro-oesophageal reflux, arthritis, sleep apnoea and alcohol/drug withdrawal;
- severity of illness e.g. greater sleep fragmentation with substantial amounts of sleep occurring during daytime hours in people with more severe acute illness[16]; and
- prior diagnosis of a sleep disorder, which is a strong predictor of sleep disturbance or insomnia in hospital[4,22] and is often poorly documented.[23]

Many factors known to disrupt sleep in hospitalised patients are modifiable. Sleep disturbance in acute care hospitals is most effectively prevented by changing the delivery of care and creating an environment conducive to rest and sleep.

Importantly, sleep disturbance and insomnia is more prevalent in hospital than in the community and requires a proactive rather than reactive management approach. In addition to patient- and illness-related factors, a recent multicentre study of sleep in 2005 inpatients found that two-thirds of sleep disturbance cases involved modifiable hospital-related factors (noise of other patients, awakening by hospital staff, noise of hospital equipment, pain and increased toilet visits due to intravenous (IV) fluids and diuretics).[19] In an Australian cross sectional study of sleep in hospital, patients, nurses and observers reported the main factors associated with sleep disruption were clinical care interventions (34%) and environmental noise (32%).[24] Both studies recommended targeting these sleep disturbing factors.

Table 1: Hospital-based factors known to disrupt the sleep of inpatients
(Table 1 citations [25,26])[#]

Individual Patient Factors	Environmental Factors
• Illness and co-morbid conditions including pain • Stress and anxiety • Televisions • Conversations and games on mobile devices • Medications may cause nocturia, nightmares, stimulation, or affect sleep patterns e.g. diuretics, psychotropics, bronchodilators, glucocorticoids (inhaled or systemic), some beta-blockers, caffeine, nicotine products • Toilet visits • Type of chronotype i.e. early or late sleepers such that hospital processes do not suit late sleepers.	• Other patients e.g. snoring, movements, calling out, use of mobile phones/radios/televisions • Staff e.g. talking, walking, pagers • Noise: multiple sources e.g. beeping alarms/pumps, noisy trolleys, drip stands, bins, humidified oxygen, doors closing • Timing of patient care interventions • Lighting (high at night, low during day). • Temperature • Unfamiliar/uncomfortable bed, pillow • Equipment • Smells

[#]*See Box 1 below for strategies to target these hospital-based factors.*

Delirium and sleep disturbance

Delirium is also frequently associated with disturbed sleep patterns, and requires proactive screening and reversal of risk factors and multifactorial interventions .[27] An underlying cause or exacerbating factor should be identified where possible and managed accordingly. Medicines with central nervous system (CNS) effects, including medicines for night sedation such as benzodiazepines, may precipitate or exacerbate delirium.[28]

A 2016 Cochrane Review found no clear evidence that drug therapy (including melatonin, cholinesterase inhibitors and antipsychotics) prevents delirium in hospitalised non-ICU patients.[29] This review and a more recent literature review support the implementation of multicomponent interventions that target prevention of several risk factors and include ward nursing education programs, medication review, sleep promotion, adequate hydration, mobilisation and improvement of the patient environment.[30] An example of an effective program is the Hospital Elder Life Program.[31]

The lack of clear evidence for melatonin in preventing delirium in hospitalised patients has also been reported in a 2020 systematic review and meta-analyses.[32] Suvorexant may have a role in delirium prevention in hospitalised patients.[33] Another recent review has suggested there may be a preventative role for ramelteon, a melatonin receptor agonist, which is currently unregistered in Australia.[34] Further studies of the role of suvorexant and ramelteon alone and in combination for delirium prevention are required. (Further discussion of melatonin and suvorexant as medicines for night sedation in non-critically ill patients can be found in Section 7.2.2).

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7. Management of sleep disturbance and insomnia for hospitalised patients

Non-pharmacological therapy is recommended as the first-line management option for sleep disturbance and insomnia in hospitalised patients and is under-utilised.[35-37] Medicines are often considered a 'quick fix' and are commonly, but inappropriately, used to treat hospital-based insomnia and sleep disturbance (where inappropriate therapy is classified as use of night sedation medicines as first-line therapy in treatment-naïve patients).[35,38-40] An approach that 'de-adopts a harmful non-evidence-based practice', i.e. reduces the use of benzodiazepines and Z-drugs for acute insomnia, is required.[41]

Given the limited effectiveness of medicines as sleep aids and their propensity to cause significant immediate and long-term harm, medicines for night sedation should only be used as a last resort when other approaches have failed, and sleep disturbance or insomnia is causing significant distress or harm. When used, use the lowest dose for the shortest period of time and agree to a definite time limit with the patient.[36]

7.1 Non-pharmacological management

Non-pharmacological management should always be provided for all patients in hospital (and also applied at home).[25] This is consistent with the first principle of Australia's national strategy for Quality Use of Medicines, in which management options are selected while considering the place of medicines in treating illness and maintaining health and recognising that there may be better ways than a medicine to manage many disorders.[42]

A person-centred care approach is required that:

- recognises the essential human need for sleep,
- promotes an appropriate hospital environment,
- incorporates thoughtful approaches to co-ordinating patient care,
- provides patient, carer and staff education, and
- facilitates shared decision making.

Sleep is unlikely to be perfect in hospital; however, there is much that can be improved for little or no cost.[4,43] Non-pharmacological therapy provides a positive and lasting benefit to management of sleep disturbance and insomnia compared to pharmacological therapies, which are of limited value and have significant harmful effects.[44]

Routinely and systematically applied non-pharmacological interventions across the hospital environment are recommended to enhance awareness and efforts to make the ward environment as conducive as possible to promoting and maintaining good quality sleep. Many strategies are also useful in long stay and non-hospital settings and may be recommended to patients for application after hospital discharge.

Box 1 summarises non-pharmacological interventions applicable to hospitalised patients (further details provided in the 'System-wide non-pharmacological interventions for sleep' section). Hyperlinks to useful tools and resources for health professionals to use and provide to patients and carers in the management of sleep disturbance and insomnia can be found in the 'Useful resources for healthcare professionals and patients/carers' section.

Box 1: Non-pharmacological strategies to improve sleep in hospitalised patients

Environmental strategies to be applied at a ward level

- ✓ Reduce noise at night (e.g. silence unnecessary alarms and pagers at night, minimise ward device/appliance movement and talking).
- ✓ Time patient care interventions in order to promote patients' sleep at night. Where possible, avoid awakenings in the early morning when most restorative sleep likely.
- ✓ Expose patients to appropriate circadian levels of day and night light.
- ✓ Turn off/dim lights and close shades at night; consider sensor lighting.
- ✓ Provide or recommend 'sleep packs' containing ear plugs and eye masks.
- ✓ Ensure compliance with visiting hours.
- ✓ Ensure comfortable temperature e.g. not too cold or hot and reduce unpleasant odours.
- ✓ If possible, consider allocations to single rooms for patients who may disrupt others' sleep.
- ✓ Display posters highlighting the importance of quietness at night in the wards.

Individual patient-related strategies

- ✓ Explore and manage a patient's expectations regarding sleep prior to or at admission.
- ✓ Adopt person-centred sleep-promoting strategies e.g. strategies used at home especially in cognitively impaired patients (ask carer) such as familiar bedtime routine, comforter or pillow.
- ✓ Recognise and manage pain, delirium, continence, anxiety and stress.
- ✓ Consider medication review to identify influence of patient's current medications on sleep.
- ✓ Practice sleep hygiene interventions accompanied with patient education:
  - Avoid television watching and use of mobile devices late at night.
  - Use the bathroom prior to bedtime.
  - Consider use of ear plugs and eye masks.
  - Play relaxing music prior to bedtime.
  - Ensure exposure to bright light during the day
  - Limit daytime napping e.g. no napping late in the afternoon and no more than a 40-minute period.
  - Avoid caffeinated beverages close to bedtime; consider supplying de-caffeinated teabags if necessary.
  - Avoid eating large meals before bedtime.

Box 2: Medicines commonly reported to impair sleep

(Box 2 citations [16,25,45])

Central Nervous System	Cardiovascular	Endocrine	Respiratory	Other
Anticholinesterase inhibitors	Amiodarone	Corticosteroids	Beta agonists e.g. salbutamol	Alcohol, caffeine and tobacco
Levodopa	Beta-blockers	Levothyroxine	Sympathomimetics e.g. pseudoephedrine	Antihistamines
Hypnotics	Diuretics		Theophylline	Smoking cessation therapies: bupropion, nicotine
Most antidepressant classes especially SSRIs* e.g. fluoxetine and SNRIs** e.g. venlafaxine	Statins			
CNS stimulants e.g. methylphenidate, appetite suppressants	Vasopressors			

*SSRIs= selective serotonin receptor inhibitors; **SNRIs= serotonin noradrenaline reuptake inhibitors

Medicines may contribute to disturbed sleep by causing nocturia, nightmares, stimulation or by affecting sleep patterns. Consider whether it is possible to stop or modify the regimen of medicines that interfere with sleep. Intentional and unintentional withdrawal of medications may also cause sleep disturbance or insomnia e.g. withdrawal from sedatives/hypnotics, nicotine and corticosteroids.[25] Box 2 provides a summary of medicine classes commonly reported to impair sleep.

The most effective and long-lasting treatment of insomnia is cognitive behavioural therapy for insomnia (CBT-I), which includes stimulus control, sleep restriction, relaxation techniques, cognitive therapy and sleep hygiene principles.[25,46,47] Insomnia-specific brief behavioural therapy is effective in older people.[48] Discussion regarding these services, strategies and post-discharge referral is recommended for patients with insomnia. Notably, there are components of these therapies that can be applied in hospital and should form the basis for staff education in order to empower patients to utilise these strategies.

7.2 Pharmacological therapy

A 2016 systematic review of pharmacological interventions to improve sleep in hospitalised adults found that there was no evidence that drug therapy improved sleep quantity and quality although it conceded there might be some improvement in sleep onset latency.[13] No drug class or specific drug (benzodiazepines, Z-drugs, melatonin, propofol and dexmedetomidine) was identified as superior when compared to placebo or no treatment. The studies included were typically small, often lacked placebo controls, measured outcomes subjectively and most studies did not have a standard approach to the evaluation of safety resulting in a finding of poor quality and inconsistent evidence.

7.2.1 Benzodiazepines and Z-drugs

The most commonly prescribed sleep medicines are the benzodiazepines and the Z-class agents (also known as 'Z-drugs' or 'benzodiazepine-related hypnotics').

Numerous benzodiazepines, including alprazolam, diazepam, lorazepam, nitrazepam, oxazepam, temazepam are marketed in Australia but only some have the registered indications for treatment of insomnia (temazepam, flunitrazepam and nitrazepam) or insomnia with anxiety (clobazam and lorazepam) despite apparent widespread use for insomnia with or without anxiety.[8,36]

The Z-drugs registered in Australia are zolpidem (Stilnox®) and zopiclone (Imovane®).[49]

Effectiveness

The effectiveness of benzodiazepines and Z-drugs for insomnia is limited. Although they may increase sleep duration slightly by reducing sleep latency and increasing total sleep time, the increase occurs in the non-refreshing phases of sleep, (notably the phases most prone to noise disturbance[50]). As a result, many people report their sleep is not refreshing.[3]

Benzodiazepines are not effective for chronic insomnia or late-night insomnia, which is the most common type of insomnia experienced by older patients.[9] When used for insomnia, their use should not be extended past 2–4 weeks as hypnotic efficacy, if present, is lost after approximately 14 days and physical and psychological dependency and tolerance can develop quickly.[25] Withdrawal effects and rebound insomnia occur in 45% of patients stopping low therapeutic doses. Any use for insomnia should be accompanied by an agreed definite time limit for use at the lowest possible dose of a short-acting benzodiazepine.

Although Z-drugs were initially marketed as a safer alternative to benzodiazepines for management of insomnia, no convincing evidence of significant differences in efficacy or safety with Z-drugs compared to benzodiazepines has been identified.[51-53] The literature suggests there is an under-appreciation of their poor effectiveness and safety profiles by healthcare professionals.[54] Furthermore, Z-drugs have been associated with potentially dangerous complex sleep-related behaviours such as sleep walking and sleep driving, particularly when used with other CNS medications or alcohol.[49]

The chief differences between the various benzodiazepines including Z-drugs lie in their potential for drug interactions and their pharmacokinetics, specifically:

- rapidity of onset;
- half-life (longer half-life is associated with greater propensity for next day somnolence and impaired performance upon waking); and,
- presence of active metabolites (prolong activity and may also have potential issues in severe liver impairment, if hepatically cleared).

The pharmacokinetics of benzodiazepines and Z-drugs are summarised in Table 2, page 8 '*Prescribing drugs of dependence in general practice, Part B*' by The Royal Australian College of General Practitioners (RACGP).[9]

Adverse effects and safety

The use of benzodiazepines and Z-drugs is associated with significant adverse effects.

Night sedation medicines such as benzodiazepines and Z-drugs improve sleep quality in 1 in 13 patients while adverse effects occur in 1 in 6 patients.[55]

Figure 3 displays a snapshot of common adverse effects and harms from use of benzodiazepines and Z-drugs. A more detailed list can be found in the 'Summary of adverse effects of benzodiazepines and Z-drugs' section. Adverse effects are more common at initiation, at higher doses, with longer duration and when combined with other psychotropic medicines.[56-58] Older people are especially vulnerable to the adverse effects of benzodiazepines and Z-drugs.[59] The use of benzodiazepines is associated with a 4-6-fold increased risk of death from all causes.[60]

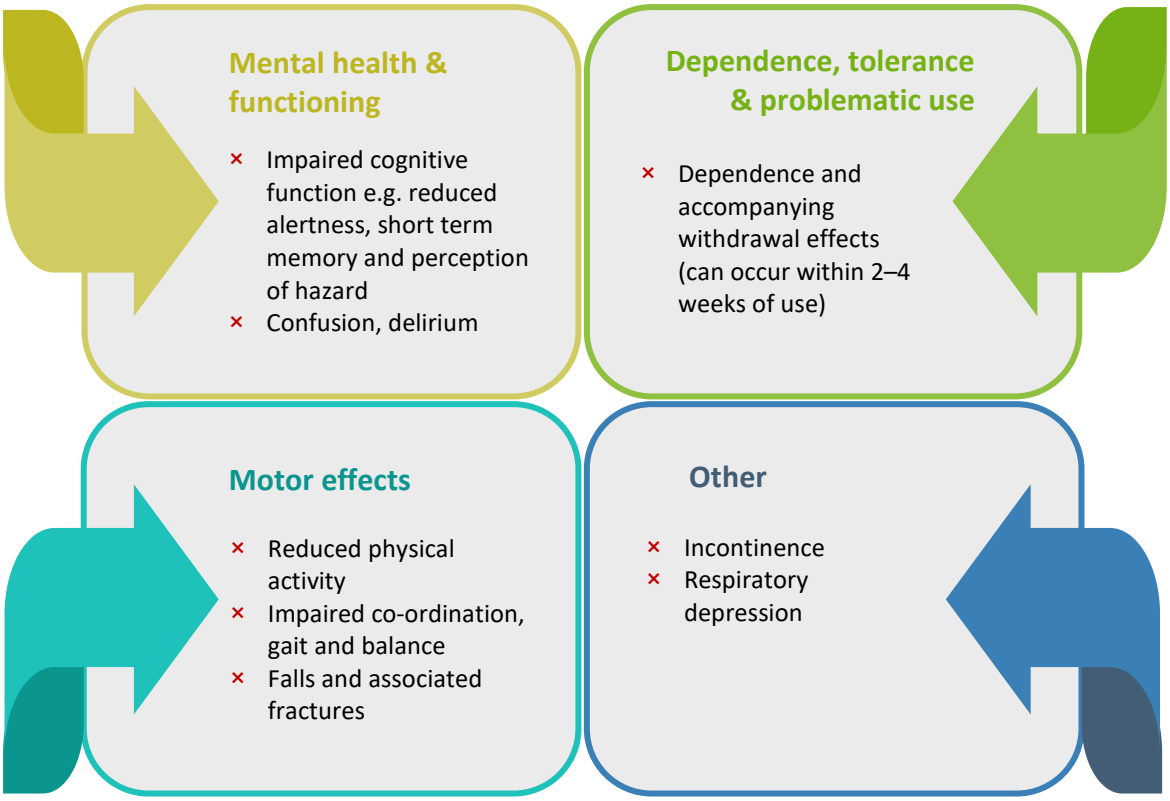


Figure 3: A snapshot of common harms from use of benzodiazepines and Z-drugs

Sedative medicines such as benzodiazepines and Z-drugs are associated with increased impairment of cognitive and physical function and increasing vulnerability to these adverse effects when other medications with sedative or anticholinergic effects are also used.[61-65]

Because dependency to benzodiazepines and Z-drugs can develop and they may be overused, misused or diverted[66], prior to prescription, clinicians should assess for signs of aberrant behaviour such as:

- unsanctioned dose increases;
- unapproved use of the drug to treat another symptom;
- deterioration in function related to drug use; and,
- additional prescriptions sought from other prescribers.[67]

If aberrant behaviours are noted, discussion with the patient should occur with the aim that the medicine be deprescribed or therapeutic boundaries tightened.

Adverse effects in hospitalised patients

Inpatients who receive benzodiazepine medicines have a greater length of stay than those who do not[68,69] and are more likely to have unplanned hospital re-admissions.[15] Moreover, non-adherence to best practice prescribing recommendations that mitigate potential harm in hospitalised patients is frequently identified.[39,70,71]

Benzodiazepine use in hospitalised patients is associated with more than a 2-fold increased risk in falls, with a higher proportion of those who fall receiving benzodiazepines for the first time.[72,73] A similar study of zolpidem showed more than a 4-fold increased risk in falls.[51] Older hospitalised patients have an especially high prevalence of falls, resulting in longer hospital stays and increasing costs for the individual and health care system.[74]

Although delirium is often multifactorial, benzodiazepines and other CNS medicines are often implicated in the development or worsening of confusion and delirium in hospitalised patients.[28,75] Delirium can be associated with irreversible decline in physical and cognitive function, resulting in residential care placement and increased mortality; hence, early identification and avoidance of potential and actual risk factors are important.

Drug interactions

Commonly encountered and clinically significant interactions involving benzodiazepines and Z-drugs can occur via both pharmacokinetic and pharmacodynamic mechanisms, see Table 2. These can result in increased risk of falls and delirium as well as CNS and respiratory depression. Fatalities have been reported when concomitantly used with respiratory or central nervous system (CNS) depressants including opioid analgesics, clozapine, gabapentinoids and alcohol.[66,76-79] For example, a 10-fold risk of overdose death in patients co-prescribed opioids and benzodiazepines has been reported.[80] Concomitant use of benzodiazepines and opioids is frequent in older Australians[81] and not uncommon in hospital patients. These patients require increased monitoring and frequent review including medication review.

Table 2: Important interactions between commonly used medications and oral benzodiazepines and Z-drugs

Interaction	Mechanism	Medication class	Examples of medications
Pharmacokinetic drug metabolism interactions that affect serum concentrations	Inhibition and induction of cytochrome P450 (CYP) metabolism of some benzodiazepines e.g. diazepam and Z-drugs. See AMH CYP tables[82]	Antifungals	Itraconazole, Ketoconazole, Fluconazole, Posaconazole, Voriconazole
		Macrolides	Clarithromycin, Erythromycin
		Selective serotonin reuptake inhibitors (SSRIs)	Fluoxetine, Fluvoxamine
		Calcium channel blockers	Verapamil, Diltiazem
		HIV protease inhibitors	Atazanavir, darunavir, lopinavir
		Antiepileptic medicines	Phenytoin (variable effect on phenytoin concentration by diazepam)
Pharmacodynamic enhancement of CNS and respiratory depression	Additive effects	Opioids	Oxycodone, Morphine, Fentanyl
		Antipsychotics	Chlorpromazine, Clozapine
		Sedating antihistamines	Diphenhydramine, Promethazine
		Gabapentinoids	Pregabalin, Gabapentin
Pharmacodynamic enhancement of other adverse effects such as falls and delirium	Combination use with medicines that may also increase falls (frequently referred to as Falls Risk Increasing Drugs, FRIDs) and impairment of cognitive and physical function (medicines with sedative and/or anticholinergic properties).	Psychotropics	Antipsychotics, antidepressants, anxiolytics, drugs with sedative properties, dopamine D2 agonists, opioids
		Cardiovascular agents	Antihypertensives, anti-arrhythmics, digoxin, nitrates and other vasodilators.
		Other: Anticholinergic drugs[83] antihistamines, anti-vertigo drugs, hypoglycaemics, opioids.	

Adapted from Judicious Prescribing of Benzodiazepines for Anxiety and Insomnia 2017[84]

Risk factors for adverse outcomes from use of benzodiazepines and Z-drugs

The judicious selection of management options for acute insomnia should include an assessment for the presence of the risk factors shown in Table 3. Given the wide range of risk factors, daily review is recommended when benzodiazepines and Z-drugs are prescribed during hospitalisation.

Table 3: Risk factors for adverse outcomes from use of benzodiazepines and Z-drugs

Use of medication and other drugs	Presence of morbidities	Geriatric-associated factors
At initiation; previous high dose or prolonged use (>4 weeks) of benzodiazepines/Z-drugs.	Respiratory disease or pulmonary insufficiency, hepatic or renal impairment.	Age >65 years.
Concomitant use of interacting medicines (regular and as needed (PRN); see Table 2.	Mental health conditions (e.g. depression, psychosis or schizophrenia). There is potential for the condition to worsen (including risk of suicide). N.B. combining zolpidem with drugs used to treat these conditions may also increase the likelihood of dangerous behaviour e.g. sleepwalking.	Existing cognitive impairment.
Concomitant use of alcohol or other illicit drugs.		Pre-existing falls risk.

References: AMH Aged Care Companion[25] & RACGP Prescribing drugs of dependence in general practice Part A.[85]

Impact of hospital initiation and discontinuation of benzodiazepines and Z-drugs for insomnia

Initiation of benzodiazepines during hospitalisation is associated with initiation of chronic benzodiazepine use post-hospitalisation in older patients.[40,71,86-88] Many older patients become first time users of night sedation medicines in hospital (37%) and a significant proportion of these wish to continue them post-hospitalisation (27%) because of improved sleep onset during hospitalisation.[86] Moreover, there is evidence of nonintentional continuation of benzodiazepines (and other medications such as antipsychotics, gastric acid suppressants and inhalers) after hospitalisation for acute illness, particularly in older patients, those with multiple co-morbidities, emergency hospitalisations or when length of stay is greater than 7 days.[89] In one study of Israeli hospitalised patients aged 70 years and over, previously treatment-naïve patients who commenced night sedation medicines during hospitalisation were approximately 4 times more likely to be using them at 1 month and 3 months post-hospitalisation.[87]

In the same study, discontinuation of night sedation medicines during hospitalisation in those who had previously used them was significantly associated with continued post-discharge discontinuation at 1 month.

These studies underscore the importance of promoting non-pharmacological approaches to sleep optimisation during hospitalisation, the judicious and appropriate use of night sedation medicines and the opportunities offered by hospitalisation for cessation of night sedation medicines and education regarding long-term self-care management.

Further guidance, tools and resources are located in Part D: Tools and resources for implementation.

Summary of use of benzodiazepines and Z-drugs for night sedation in non-critically ill hospitalised patients

- The lowest possible dose of a short-acting benzodiazepine, such as temazepam, should only be used short term as a last resort when other non-pharmacological approaches have failed, and sleep disturbance or insomnia is causing significant distress or harm.
- Given their low-value, high-risk status, in-hospital discussion regarding ceasing or weaning benzodiazepines and Z-drugs in long-term users should occur. Discussion should include their significant harms (that also increase with age and co-morbidity), the benefits that arise with no or reduced use and their likely long-term ineffectiveness. A validated deprescribing guide and patient information document are available on the NSW TAG website.

7.2.2 Other medicines used for night sedation in non-critically ill inpatients

7.2.2.1 Melatonin

Both prescribers and patients commonly have misconceptions regarding melatonin. Melatonin does not participate in the entrainment of the circadian clock in either the initiation or maintenance of circadian rhythms. Rather, the circadian clock is synchronised to light through photosensitive retinal ganglion cells which are directly connected to the central circadian oscillator in the suprachiasmatic nucleus (SCN) of the brain. In lay terms, melatonin does not improve circadian rhythms.

While melatonin participates in the regulation of the sleep-wake cycle, its role as a therapeutic drug in promoting sleep is controversial with contradictory or negative results seen in numerous studies.[90]

The pivotal trials supporting the registration of modified release (MR) melatonin in Australia for use in primary insomnia showed only modest improvements in sleep and a substantial proportion of subjects (74%) experienced no improvement.[91] People living with severe neurological, neurosurgical and psychiatric conditions, those taking CNS medicines, and people aged under 55 years were not included in the clinical trials. The MR formulation is designed to mimic endogenous melatonin concentrations; however, the delay in onset of action means it is unlikely to be useful for those having difficulty getting to sleep. Although the MR formulation of melatonin is not PBS-subsidised, its use has gradually increased in Australian general practice since its registration in 2009[92], especially for insomnia in previously untreated persons, possibly because it is perceived to be a benign sleep aid.[8,93]

Formulations

A 2 mg modified release tablet (MR) formulation of melatonin (Circadin® plus generic brands) was registered as a Schedule 4 (S4) oral medicine in Australia for monotherapy of short-term (<13 weeks) primary insomnia characterised by poor quality of sleep in those aged 55 years and over in 2009.[94]

As of 1 June 2021, MR tablets containing 2 mg or less of melatonin in packs of no more than thirty tablets will become Schedule 3 when used as short term (3 weeks) monotherapy for the same indication and age group i.e. for primary insomnia characterised by poor quality of sleep in those aged 55 years and over.[95]

Other melatonin formulations will remain Schedule 4 (prescription-only) and include 1 mg and 5 mg MR formulations of melatonin (SLENYTO®), which has recently been registered for treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and/or Smith-Magenis Syndrome (SMS), where sleep hygiene measures have been insufficient. (In March 2021, the Pharmaceutical Benefits Advisory Committee (PBAC) rejected PBS–subsidisation for these conditions citing that the effect was highly variable and of uncertain and likely modest clinical benefit. A re-submission for SMS may be accepted for reconsideration in the future).

A variety of melatonin formulations are listed under TGA's Special Access Scheme Category C, and include capsules, 3 mg lozenges, syrup and immediate release (1 mg) and other modified release tablets, all for treatment of sleep disorders.[96] Melatonin may also be obtained with a prescription from compounding chemists in a variety of dosing formulations and doses (0.3 – 8 mg). Anecdotally, it is also obtained during overseas travel or via international online retailers. The variation in formulations and dosing has made comparisons across studies difficult. There is inconsistent information regarding the most appropriate dose.

Pharmacokinetics and interactions

The pharmacokinetics of Circadin® and compounded oral formulations are not well elucidated. Melatonin has significant first pass effect leading to poor (approximately 15%) and variable bioavailability. The presence of food delays absorption. Its half-life is reported to be 20–50 minutes.[97]

Given it is metabolised by the cytochrome P450 1A subfamily enzymes (and possibly CYP2C9), drugs that inhibit CYP1A enzymes, such as quinolones and drugs/substances that induce these enzymes e.g. carbamazepine, fluvoxamine, caffeine and cigarette smoking may affect melatonin concentrations leading to enhancement or reduction of melatonin activity, respectively. Use of melatonin with other sedatives (including alcohol, which may also affect its prolonged release pharmacokinetics) is not recommended. The sedative effects of zolpidem are potentiated when combined with melatonin.[98]

Effectiveness

Evidence to date suggests that, although melatonin may improve sleep efficiency in some hospitalised patients, most do not respond.[13,99,100] Moreover, the registered proprietary product is a MR formulation and as such the onset of effect is delayed and not useful for inducing sleep acutely, a required attribute for treating sleep onset insomnia.

Following a literature search and systematic review, the American Academy of Sleep Medicine do not recommend its use in chronic sleep latency or sleep maintenance insomnia in adults due to the poor evidence base.[93] Improvement in sleep quality was not clinically significant and there was insufficient evidence regarding safety. The National Institute of Clinical Excellence's clinical knowledge summary on managing long-term insomnia recommends that, if melatonin is to be used, an initial trial period of no longer than 3 weeks is implemented.[101] It is worth noting that melatonin has shown a lack of efficacy in several clinical scenarios where it is often prescribed. These include:

- Reducing delirium in older hospitalised patients[29]
- Sleep disturbance in patients with dementia due to Alzheimer's disease[102]
- Patients with end-stage cancer receiving palliative care[103]

In addition, there is a lack of evidence to support the use of melatonin in patients with sleep disturbance associated with either acute or chronic pain or as an adjunctive therapy for mental health inpatients.

There may be a role for melatonin in REM sleep behaviour disorder (RBD) in doses higher than 2mg when pharmacological therapy is deemed necessary although robust clinical trials are lacking.[104,105]

Safety considerations

Melatonin is often advocated as a safer alternative to other night sedation medicines, particularly in the community.[97] Melatonin is generally well-tolerated with adverse effects such as back pain and arthralgia listed as common (>1%).[94] However, less frequent effects (<1%) including neuropsychological disorders e.g. weakness, headache, fainting, anxiety, depression, convulsions, and gastro-intestinal disorders e.g. vomiting and constipation, have been reported. Cardiac arrhythmias, which resolved on melatonin cessation, have been reported rarely (<0.1%).[94,106] Post-marketing data has reported vivid distressing nightmares (unknown frequency).[94]

A systematic review of melatonin-associated adverse events found that they were generally minor, short-lived and easily managed with most related to fatigue, mood, psychomotor and neurocognitive performance.[107] A few studies noted adverse events related to endocrine function (glucose metabolism, reproductive parameters) and cardiovascular function (increased blood pressure and heart rate), which appeared to be influenced by dosage, dose timing and interactions with cardiovascular medicines such as nifedipine. Sedative effects are unlikely to impact on safety to drive or cognition the following day.[97] There is very little information regarding long-term effects.

A 2016 retrospective cohort study raised the possibility that ongoing melatonin use in community-based users may adversely affect fracture risk.[108] Further investigation is required including the reason for increased fractures.

It is recommended that melatonin is not used in patients: a) with hepatic impairment or autoimmune disease; b) who are pregnant or breast-feeding; or, c) using medicines with sedative effects, alcohol or interacting medicines such as fluvoxamine.[97] Tolerance, dependence, withdrawal effects or rebound insomnia have not been reported with melatonin use.[97,109]

Summary of recommendations for use of melatonin for night sedation in non-critically ill patients

- Listing on the hospital formulary for night sedation in non-critically ill hospitalised patients is not recommended.
- Approval of use in individual patients should only be considered in the context of an evidence gap and written informed consent and processes for its evaluation to address the evidence gap should be established prior to approval.
- Effectiveness and safety should be evaluated prior to continued prescription in those who have been using melatonin for sleep disturbance prior to hospitalisation and when considering prolonged use.

7.2.2.2 Suvorexant

Suvorexant is an orexin receptor antagonist registered in Australia under the trade name Belsomra®, for treatment of insomnia characterised by difficulties with sleep onset and/or sleep maintenance.[110,111] The recently discovered orexin neuropeptide signalling system arising in the lateral hypothalamus plays an important role in maintaining wakefulness and inhibitors of this system have the potential to enhance sleep.

Pharmacokinetics and interactions

Suvorexant has a bioavailability of 55-70% with peak blood concentrations occurring at 2 hours. Suvorexant is mainly eliminated by metabolism, primarily by CYP3A with a minor contribution from CYP2C19. The major circulating entities are suvorexant and a non-pharmacologically active metabolite and elimination is predominantly as metabolites in the faeces. Its half-life is 12 hours. Suvorexant exposure is slightly higher in females than males and significantly higher in obesity. Moderate hepatic impairment delays elimination and its use is not recommended in severe hepatic impairment.

There are significant drug interactions with other CNS depressant medicines and strong/moderate CYP3A4 inducers and inhibitors.[82] Combined use is not recommended.

Effectiveness

Suvorexant may be useful for patients who have difficulty staying asleep; however, its benefit for patients who have difficulty falling asleep is uncertain and comparative trials with other hypnotics are lacking.[111] The 2017 American Academy of Sleep Medicine's systematic review suggests that it can be used as a treatment for sleep maintenance insomnia in doses of 10-20 mg (versus no treatment) in adults (weak recommendation).[93]

Safety considerations

Further data are required about adverse effects and misuse potential as patients with a history of substance misuse were excluded from clinical trials. Reported adverse effects include somnolence, fatigue, psychiatric disorder including anxiety, nightmare, hallucination, sleep paralysis, mild cataplexy, psychomotor hyperactivity, complex sleep behaviour e.g. sleep driving, walking, preparing/ eating food; tachycardia and palpitations. Further information is required including frequency data.

Summary of suvorexant use for night sedation in non-critically ill hospitalised patients:
Until further evidence regarding effectiveness and safety is obtained, suvorexant is not recommended for the treatment of acute insomnia and sleep disturbance in hospitalised non-critically ill patients.

7.2.2.3 Other registered medicines used for night sedation

Many other medications (both prescription and over-the-counter), with and without approved indications for insomnia, are used for the treatment of insomnia and include:

a) antidepressants such as amitriptyline, doxepin and mirtazapine*
b) antipsychotics such as quetiapine*
c) sedating antihistamines such as doxylamine, promethazine and diphenhydramine*
d) chloral hydrate**
e) valerian*** and other complementary medicines. Referral to the CATAG Position statement for the use of complementary and alternative medicines is recommended.[112]

Additionally, patients sometimes use analgesics such as paracetamol to help with sleep, which suggests that pain may be the cause of the sleep disturbance or insomnia in these patients.[19]

*Many of these medicines have significant adverse effects related to their anticholinergic effects including daytime sedation, cognitive impairment and delirium. Mirtazapine's sedative effect is due to its antihistaminic (not anticholinergic) activity. These medicines are not recommended as hypnotics unless indicated for treating other conditions as they have an unfavourable harm: benefit balance when used for sleep disturbance or insomnia alone.

**Significant adverse effects e.g. dependence, gastritis, renal toxicity, hangover, paradoxical excitement and has been superseded by less toxic agents.[113]

***Although valerian is thought to be relatively safe, it has not been shown to have meaningful effects on sleep quality.[114] Interactions with other medicines may also occur.[115]

Summary of other registered medicines used for night sedation in non-critically ill patients: These medicines are not indicated or recommended for prevention or treatment of sleep disturbance or insomnia in hospitalised patients, given the lack of high-quality evidence demonstrating their effectiveness and the high risk of adverse effects associated with most of these medicines.

Part C: Recommendations for health service organisations: clinical governance and individual patient care

8. Reducing harm from use of medicines for night sedation

Sleep is an essential human need and never more so than when recovering from illness or a surgical intervention. The use of pharmacological interventions that can cause significant harm, in the absence of non-pharmacological strategies, is contrary to the quality use of medicines principles in Australia's National Medicines Policy.[42]

In-hospital sleep medication prescribing policies must recognise the impact that hospital-based initiation and discontinuation of night sedation medication has on use of night sedation medicines after hospital discharge.[87] Health department and executive-supported local and system-wide processes promoting non-pharmacological management of sleep disturbance as routine care are required. Health Service Organisations should consider undertaking dedicated change management projects to optimise sleep in hospital patients and provide dedicated sleep psychologists who can assist individual patients and clinicians and drive system-wide reform. Given the longstanding neglect of sleep optimisation in the hospital sector, system-wide seamless improvement strategies should use electronic documentation and decision support wherever possible and routinely provide patient-centred supporting tools and equipment e.g. relevant technology, ear plugs, eye masks.

National Safety and Quality Health Service Standards outline the standard of care that consumers can expect from hospitals.[116] A number of the Standards are pertinent to the use of night sedation medicines in hospitals: Clinical Governance, Partnering with Consumers, Medication Safety, Comprehensive Care, Communicating for Safety and Recognising and Responding to Acute Deterioration. In version 2 of the Standards, an increased emphasis has been placed on person-centred care and addressing the needs of those at greater risk of harm. The Comprehensive Care Standard has items targeting prevention of falls and harm from falls and prevention of delirium and cognitive impairment; 'night sedation medicines' may contribute to these adverse events.

Furthermore, the facilitation of quality and safety under Activity Based Funding is enabled by the measurement of 16 hospital-acquired complications (HACs) including several that may be associated with the use of 'night sedation medicines': falls resulting in fracture or intracranial injury; delirium; and, medication-related respiratory complications/respiratory depression.[117] Funding reductions related to the presence of one or more HACs during a hospital stay were introduced in 2019. This funding model aims to facilitate implementation of risk mitigation strategies for avoidable harms by hospitals and clinicians.[117,118]

8.1 Clinical governance

Drug and Therapeutics Committees (DTCs) have oversight of medication management processes that involve use of 'night sedation medicines' in hospitals. This includes responsibility for formulary management and promotion of safe and quality use of medicines throughout the medication management pathway with monitoring of use, outcomes, and adverse events from medicines.[119] Other governance committees within a health service organisation or district that may also have an interest in hospital 'night sedation medicine' use include the falls committee and the serious adverse events committee. It is recommended that hospitals include clinical pharmacology or pharmacy expertise in the membership of these other committees and that regular formal communication related to night sedation medicine use occurs between the relevant committees.

An awareness by all health care workers and patients/carers of a safety culture that includes reducing harm from 'night sedation medicine' use should be emphasised. Such a culture can be emphasised through training, promoting non-pharmacological management of sleep disturbance and insomnia and promotion of an environment conducive to rest and sleep especially at night. DTCs (and/or the Hospital Executive) have a responsibility to ensure escalation of concerns to relevant state committees or organisations when new or potentially widespread concerns related to night sedation medicines use arise.

Provision of sleep-friendly hospital environments and non-pharmacological sleep hygiene protocols is beyond the jurisdiction of DTCs and requires broad commitment across the health service. It is recommended that the health service organisation's Patient Safety Units and/or Medical and Nursing Executives undertake comprehensive programs to promote and maintain environments and practices that promote sleep and reduce the inappropriate use of pharmacological management for sleep disturbance or acute insomnia in non-critically ill adult patients. There should be DTC representation on steering committees of these programs.

8.2 Recommendations for DTCs

8.2.1 Formulary management

Formulary management regarding the use of medicines for night sedation may involve decisions of whether to list or not list on formulary and whether, if listed, to apply restrictions to indications, prescriber groups and patient groups (see 8.2.1.1). When not listed on formulary, consideration for Individual Patient Use (IPU) may be acceptable (see 8.2.1.2). The result of the IPU decision should be documented in the patient's medical notes. Justification of the use of any night sedation medicine such as melatonin as a safe placebo does not conform to Quality Use of Medicines principles and is insufficient justification for its use.

8.2.1.1 Formulary listing of night sedation medicines

The initiation of night sedation medicines (benzodiazepines, Z-drugs, melatonin or other drugs e.g. antidepressants, antipsychotics, antihistamines) for sleep in treatment naïve, non-critically ill adult patients in hospital is not an acceptable indication for unrestricted access on formulary.

All night sedation medicines have adverse effects and many have uncertain efficacy in hospitalised non-critically ill patients. All formulary medicines commonly but inappropriately used solely for night sedation e.g. quetiapine, promethazine and mirtazapine should have a restricted listing and formulary-approved indications specified. Indications should accompany all prescriptions of these medicines. Periodic monitoring for and reporting of inappropriate use is recommended.

Acknowledging the frequent applications to DTCs to approve the initiation of melatonin in the management of sleep disturbance or acute insomnia in non-critically ill hospitalised patients, its use and listing on formulary for this indication is not recommended due to:

- the lack of high quality evidence for meaningful sleep benefit in hospitalised non-critically ill patients;
- the inappropriate use of proprietary modified release (MR) formulation to manage acute sleep disturbance;
- its uncertain safety in this population; and,
- the potential adverse impact on the hospital budget if widespread use occurs.

It may be acceptable to list medicines for night sedation on the formulary for continuation of treatment of insomnia during hospitalisation. However, the ongoing use of these drugs should be reviewed in hospital as described in section '8.2.2.2 Non-treatment-naïve non-critically Ill patients' below.

In the case of melatonin, its continuation may be considered in patients who have been taking melatonin prior to hospitalisation after evaluation of its effectiveness and safety in the individual patient. See section 8.2.2.2 *Melatonin-treated patients* for further discussion.

See 'Acceptable indications for listing benzodiazepines on the hospital formulary' for acceptable indications.

When listing medicines on formulary, DTCs should consider recommendations or referrals for implementation of electronic strategies. Some electronic Medical Records (eMR) strategies include use of electronic medication order sentences with 'STAT' or 'PRN' directions and limiting therapy duration, an electronic form for the Managing Sleep Checklist and other electronic proformas or templates to assist assessment, review, prescription, documentation and communications.

8.2.1.2 Individual Patient Use (IPU) Applications

There are two scenarios, discussed below, where Individual Patient Use applications for pharmacological management of night sedation in treatment-naïve non-critically ill patients may be considered by the DTC **if non-pharmacological therapies have been tried but deemed ineffective and sleep disturbance is causing significant distress or harm:**
1) a medication is deemed effective for night sedation but has significant safety considerations e.g. benzodiazepine use (see Streamlined IPU for Temazepam); and,
2) where there is a gap in the evidence for effectiveness in sleep disturbance but the safety profile is acceptable e.g. melatonin use.

Streamlined IPU Declaration for Temazepam

A streamlined Individual Patient Use (IPU) process is a reasonable approach to the quality use of medicines for night sedation in treatment-naïve patients where evidence for efficacy is established. The Streamlined IPU Declaration for Temazepam, completed by the consultant or registrar, should ensure that the harm: benefit balance in the individual patient has been considered and that patient consent (or consent of Person responsible) has been obtained. The 'Managing Sleep Checklist' provides the necessary considerations for evaluation of the harm: benefit balance and its completion can accompany the streamlined IPU documentation. (While DTC approval will not be required prior to prescription in these patients, compliance with the process, the number of streamlined IPU declaration forms made and the completion of the applications should be periodically audited, see Clinical indicators discussion).

A streamlined IPU declaration form template for temazepam can be found here. With the exception of the scenario below, any other medications for night sedation in treatment-naïve patients will require evidence, safety and cost considerations as per the usual IPU application procedures.

IPU applications for Melatonin

There are frequent requests to DTCs for melatonin initiation in non-critically ill hospitalised patients and inconsistency in approvals/rejections.

Given the current evidence does not demonstrate efficacy in non-critically ill hospitalised patients, the case for initiation of melatonin in individual hospitalised patients should only be considered where there is an evidence gap and should be undertaken in the context of evidence generation. Clinical decision making should align with the criteria for Off-Label Use of Medicines for "Conditional Use, with Evidence Development", outlined in the Council of Australian Therapeutic Advisory Groups' (CATAG) Guiding principles.[112] Institutional governance can be managed through the Individual Patient Use procedure. Approval should provide conditions for approved use (e.g. specific patient cohort, authorised prescribers) and include requirements for shared decision making and informed consent involving the patient (or Person responsible), and entry of patient data into a registry for evidence development. In these circumstances, a streamlined IPU Declaration for melatonin (similar to the IPU Declaration for Temazepam) may also be useful for the approved cohort of patients. Rigorous monitoring for adverse drug events and reporting of these is essential. The registry should be designed to inform future use of melatonin. Currently local sites are responsible for their own registry. It is recommended that local registry data be collated to better address the evidence gap and that a state-wide registry is established in the future to facilitate the collection of information on use and outcomes when melatonin is initiated for non-critically ill patients in hospital outside a clinical trial.

8.2.2 Recommendations for management of sleep disturbance and insomnia in non-critically ill hospitalised patients

The following general principles should be considered when managing sleep disturbance or insomnia in all non-critically ill patients in hospital:

- ☆ Night sedation medicines are high risk medicines.
- ☆ Hospital practice in the use of 'night sedation medicines' should demonstrate best practice for community-based care and non-pharmacological management should always be promoted. Hospital practice should not reinforce previous poor quality use of medicines.
- ☆ A prescriber is under no obligation to commence or continue prescribing night sedation medicines for sleep disturbance or insomnia against their better judgement. Be aware of the potential risk of benzodiazepine/Z-drug withdrawal in some patients and the possibility that it may not be disclosed and seek advice, as necessary.
- ☆ Environmental sleep disturbance factors are not ameliorated using pharmacological interventions.
- ☆ The prescriber can recommend non-pharmacological management and/or dose reduction/cessation and/or consult a specialist e.g. geriatrician, psychiatrist for advice. Guidance for medication deprescribing should be readily accessible.
- ☆ New or ongoing requirements for a 'night sedation medicine' to manage sleep disturbance or insomnia in a hospitalised patient should be determined during the usual clinical assessment of the patient. When possible, provision of verbal and written patient information about sleep and its management during hospitalisation including a discussion about mitigation of sleep disturbance should occur prior to hospital admission including pre-admission clinics.
- ☆ An indication (i.e. insomnia, sleep) must be documented with any prescription of a 'night sedation medicine' irrespective of the dosing regimen (stat, PRN or regular).
- ☆ Evening/night shift junior medical officers should not be asked to prescribe medicines for sleep disturbance or insomnia in treatment-naïve patients by other clinicians or upon patient request. This is a decision for the primary treating team and may require streamlined individual patient use (IPU) documentation.

Tools to support these principles such as written patient information about sleeping in hospital and how to minimise sleep disturbances, clinician information about non-pharmacological strategies to manage sleep disturbance and insomnia, clinician guides for deprescribing and consumer information about deprescribing can be found in Part D: Tools and resources for implementation and on the NSW TAG website.

The initial management approach depends on whether the non-critically ill patient has routinely taken medication for night sedation (i.e. non-treatment-naïve) or not (i.e. treatment-naïve). The non-treatment-naïve patient group includes patients who have routinely taken medicines for night sedation in ambulatory care and those who have been critically ill and received medicines for night sedation during critical care.

Sections 8.2.2.1 and 8.2.2.2 discuss the additional management approaches for treatment-naïve and non-treatment-naïve patients. Pathways of the management approaches for these two patient groups are provided in the 'Pathways for managing sleep disturbance/insomnia in non-critically ill hospitalised adults' section.

8.2.2.1 Treatment-naïve non-critically ill patients

For the purposes of this document, treatment-naïve patients are those who have not taken medicine for night sedation more than three times in the last 2 weeks. Prescribers should also use their clinical judgment to consider whether a patient is treatment-naïve or not. Clinicians should be aware that the risk of falls from night sedation medicines in treatment-naïve patients is greatest in the first few days of therapy.[57,58,120,121]

Key messages regarding pharmacological management in treatment-naïve patients:

- The initiation of medicines for night sedation (*benzodiazepines, Z-drugs, melatonin, antidepressants, antipsychotics, antihistamines*) is NOT recommended.
- Risk of falls is greatest in the first few days of therapy.
- Do not prescribe medicines for night sedation at discharge.

The decision to prescribe a medicine for night sedation in treatment-naïve patients is a decision for the primary treating team. After hours junior medical officers should not be asked to prescribe night sedation medication for unfamiliar patients by other clinicians or upon patient request. Occasionally, despite implementation of non-pharmacological strategies and counselling that it is acceptable in these circumstances to have a less than satisfactory sleep, a patient may become agitated and continue to complain. In this situation, standard escalation pathways for clinical support e.g. referral to the senior nurse or registrar-on-call may be undertaken. Education of clinicians in managing such a scenario should include an understanding that falls risk from night sedation is greatest on medicine initiation i.e. there is potential for harm from a single dose.

If, as a last resort, the primary treating team makes a clinical decision in normal business hours to prescribe a medicine for night sedation in a treatment-naïve patient, then it is recommended to:

(1) Explicitly document in the medical record, ideally in conjunction with a streamlined IPU form (template) (which is completed by the registrar/consultant), compliance with the following criteria:

a) other non-pharmacological approaches, including addressing modifiable causes, have been tried and proven inadequate;
b) sleep disturbance is causing significant distress or harm;
c) an assessment of the harm to benefit ratio from benzodiazepine use has been undertaken (see Managing Sleep Checklist);
d) the patient is aware of and counselled on the potential harms and benefits, and has provided written or verbal informed consent (Written form or verbal guide may be used);
e) the initial prescription is for a 'trial' period 1-3 nights (requires explicit documentation of trial period), until the patient is next reviewed by the treating team to decide whether to continue it 'PRN' or cease;
f) if continued after the 'trial' period, the cause of the sleep disturbance, the effect of the prescribed night sedation medicine on sleep during the trial period, and the effect of other initiated sleep management modalities will be documented in the clinical record;
g) if continued after the 'trial' period, the prescription for temazepam is written for the shortest appropriate duration and, if in the circumstances of an above-average length of stay, will not be used for more than 2 weeks (which includes the trial period);
h) during this time, the treating team will undertake a daily review of effectiveness and safety; and,
i) the prescription of the benzodiazepine will not be continued at discharge;

AND,

(2) Prescribe a benzodiazepine with a short half-life (i.e. temazepam) at the lowest possible dose (10 mg or 5 mg in older patients)[122] on a 'PRN' basis with accompanying indication.

Routinely audit compliance with this process and apply continuous improvement processes.

8.2.2.2 Non-treatment-naïve non-critically Ill patients

Identification of non-treatment-naïve non-critically Ill patients

Non-treatment-naïve patients are those who routinely use medicines for night sedation (e.g. have taken a medication for night sedation more than three times in the last 2 weeks) at their place of residence or hospital patients who have recently taken medication for night sedation during critical care management.

Community-based use of medicines for night sedation should be identified in pre-admission clinics and/or during admission medication reconciliation and managed as below.

Key messages regarding pharmacological management in non-treatment-naïve patients:

- Undertake clinical review that includes:
  - harm: benefit calculation,
  - sleep-hygiene practices,
  - consideration of deprescribing,
  - consideration of formal medication review,
  - patient counselling and education
- Document the outcomes of the review.

Prescription of night sedation medicines used for chronic insomnia

During the usual clinical work-up including a clinical review that has considered the medication's risk of harm versus potential benefits as well as the risk of continuation versus weaning during hospitalisation (see 'Managing Sleep Checklist'), the patient may be prescribed their usual medication for night sedation (preferably as part of a deprescribing plan). After-hours prescription for 'night sedation medicines' is not recommended practice. These recommendations underscore the importance of obtaining a Best Possible Medication History and proactive management by the treating team.

If prescribed by the treating team, the 'night sedation medicine' should either be written as part of a deprescribing plan (see below) or written as a 'prn' medication with the supporting indication ('insomnia'/'sleep').

In the event prescription by a member of a non-treating team is required, having completed a clinical review (see the Managing Sleep Checklist), prescribe a stat dose (or a dose of time-limited duration, if on a weekend) of the patient's 'night sedation medication' for review by the treating team the next working day. Regardless of whether prescribing is by the treating or non-treating team, the assessment, rationale and plan for night sedation medication prescription should be documented in the medical record. Nursing staff administering medicines at night should ensure 'PRN' night sedation medication is provided only when required and patients are not woken.

Any decisions to continue a prescription should be guided by regular review and monitoring. Ongoing prescription of a medicine for night sedation, if needed at all, should normally be limited to less than 2 weeks.[3] Intermittent therapy may be considered for those with severe longstanding insomnia that is not relieved by non-pharmacological management with referral to follow-up services as recommended below.

Benzodiazepine/Z-drug-treated patients

Given that dependence on medicines for night sedation such as benzodiazepines and Z-drugs can occur within 2–4 weeks of commencement, these patients are deemed to be potentially dependent on their medication for night sedation and may have poor sleep hygiene practices. They will require clinical review regarding use of their medicine for night sedation, patient counselling and education and a deprescribing plan initiated, if possible. Hospital practice should champion quality use of medicines for night sedation. Clinical judgement should also be exercised to determine whether a patient is deemed treatment-naïve or not.

Melatonin-treated patients

For those routinely taking melatonin in the community, continued prescription of melatonin to treat insomnia may be justified noting that the current registered product for use in Australia is for monotherapy of short-term (<13 weeks) primary insomnia in those aged 55 years and over. In addition, from 1 June 2021, patients may present with a Schedule 3 (Pharmacist Only Medicines) melatonin product, which is approved monotherapy for <3 weeks use for the same indication and patient group. Continued use for more than 13 weeks should be considered off-label and its effectiveness and safety should be evaluated prior to ongoing prescription.

Patients may also present with compounded products of melatonin. The CATAG Position statement for the use of complementary and alternative medicines (CAM) is a recommended resource to guide prescription of CAM in hospital.[112] There is no evidence that abrupt cessation of melatonin is harmful. Non-pharmacological strategies should also be implemented including adequate exposure to appropriate levels of light at appropriate times. Medicine utilisation evaluation (MUE) studies of melatonin use may be warranted.

Deprescribing

Abrupt cessation of benzodiazepines can be associated with withdrawal symptoms such as anxiety, insomnia, nightmares, changes to memory and concentration as well as muscle symptoms.[9] Withdrawal symptoms are more likely and more serious (e.g. convulsions) when benzodiazepines are used at high doses, involve high potency benzodiazepines (e.g. alprazolam) or have been used for a prolonged period of time. Deprescribing protocols facilitate appropriate weaning to avoid withdrawal syndromes. DTC-approved protocols for deprescribing of medicines for night sedation during hospitalisation and/or following hospital discharge should be available and promoted by relevant clinicians and committees. Deprescribing should also be instituted in non-critically ill patients who have been taking a night sedation medicine as part of critical care management. Relevant deprescribing guide resources are available at https://www.nswtag.org.au/deprescribing-tools/ and https://deprescribing.org/resources/.

While there are advantages to commencing deprescribing in hospital, the acute stresses of hospitalisation and the risk of rebound insomnia during hospitalisation may mean that initiation of a deprescribing plan after hospital discharge may be more appropriate in some patients. Clear communication with the clinician taking over care after discharge is required (see Section 9. Post hospital care: discharge prescription, supply and communication).

Patient counselling

Discussions with the patient regarding the poor effectiveness and significant potential harms of night sedation medicines and information about deprescribing should be undertaken by the treating team. Consumer information leaflets about sleep and sleep hygiene strategies (e.g. Consumer information booklet: Sleeping well in hospital) and Consumer Information Leaflets about deprescribing (e.g. Stopping My Benzodiazepine or Z-drug) should be provided to patients. Referral to a practitioner offering CBT-I or brief behavioural therapy should be considered for patients suffering chronic insomnia. The 'Summary table of useful resources for healthcare professionals and patients/carers' outlines various patient and health care practitioner resource.

8.3 Individual patient care

The Managing Sleep Checklist

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

The Managing Sleep Checklist

A checklist for managing sleep complaints in hospitalised non-critically ill adult patients
To be used in consultation with patient and/or carer

Assessment Checklist	Conversation guide	Notes
Assess the patient's usual sleep pattern and current concerns		
What is the type of sleep disturbance?	Obtain a thorough sleep history: • Is this a new problem or also experienced when not in hospital? • Does the patient have a diagnosed sleep disorder such as sleep apnoea; circadian rhythm disorder; restless leg syndrome? If OSA, do they use CPAP machine? • What is the patient's normal sleep pattern? • Has the patient slept much during the day? (including napping since 2 pm?) • Does the patient have realistic expectations for sleep in hospital?	
Strategies used to promote sleep?	• What does the patient do at home to promote sleep? • What has been tried already during hospitalisation? • What hasn't been tried?	
Previous use of night sedation medicines?	• Does the patient usually take medicines to promote sleep at home? o Which one(s)? o When: never, regular or 'as needed' use? o If regular or as 'needed', how frequently? o What dose? • Is the patient likely to be dependent on the night sedation medication? Also refer to Best Possible Medication History (BPMH).	
Specific sleep complaint?	• Is it getting to sleep, staying asleep and/or disrupted sleep the main complaint(s)?	
What are the precipitants/triggers?	• Environmental: noise, patient care interventions, light exposure, other patients?	
	• Non-environmental: current illness, injury, pain; medication side effects, sensory impairment, delirium. (See Table 1: Hospital-based factors known to disrupt the sleep of inpatients in the guidance document)	
	• Can these be addressed? E.g. will pain relief assist? Does the patient usually use a CPAP machine or other device for sleep? Are ear plugs/eye mask available and acceptable e.g. does hearing loss/visual loss inhibit use of aids e.g. ear plugs, eye masks? Is delirium addressed according to local policy? (See non-pharmacological management section)	
If it is still considered that use of a night sedation medicine may be an appropriate option, use the following to assess the harm: benefit balance for the patient.		
Assessment Checklist	**Conversation guide**	**Notes**
What comorbidities and conditions including presence of undiagnosed co-morbidities are present?	• Previous history of falls; confusion or dementia; COPD; heart failure, pain. • Could it be undiagnosed obstructive sleep apnoea or episodic movement disorders e.g. restless legs syndrome? • Could it be rebound insomnia (as a withdrawal symptom), delirium, alcohol abuse or mental disorder such as anxiety or depression?	
Are there potential drug interactions?	• Presence of other sedative and respiratory depressant medications e.g. opioids? • Presence of other fall risk-increasing medications e.g. antihypertensives? See Table 2: Important interactions between commonly used medications and oral benzodiazepines and Z-drugs	
Is the patient aware of the limited efficacy and potential harms from night sedation medicines?	• Is the patient aware of the little difference these medicines make to sleep duration and quality? Is the patient aware that these medicines may cause falls, hip fractures, impaired cognition, dependence, drowsiness the next day and possibly slow recovery?	
What are the potential consequences on hospitalisation	• What impact might use of night sedation medicine have on recovery? E.g. is it likely to affect allied health sessions; lengthen hospital stay?	
Has shared decision-making and informed consent taken place?	Has the patient: • participated in the consultation, • understood the information, • given informed consent to the prescription of the 'night sedation medicine', • considered a deprescribing plan (if a previous user),	

OSA= Obstructive Sleep Apnoea; CPAP= Continuous Positive Airway Pressure

9. Post hospital care: discharge prescription, supply and communication

9.1 General principles to ensure continuity of care on discharge from hospital

- Any prescription of a 'night sedation medicine' at discharge should be accompanied by the indication for which it is being prescribed.

- Any 'night sedation medicine' initiated for sleep disturbance or insomnia during hospitalisation should not be prescribed for ongoing therapy at discharge.
    - Discharge prescription of a 'night sedation medicine' used for other approved indications should include: the indication, dosing changes (if applicable), duration of intended treatment, monitoring and review requirements. Documentation should also include any education and counselling provided to the patient regarding risks of harm and potential benefits of treatment.

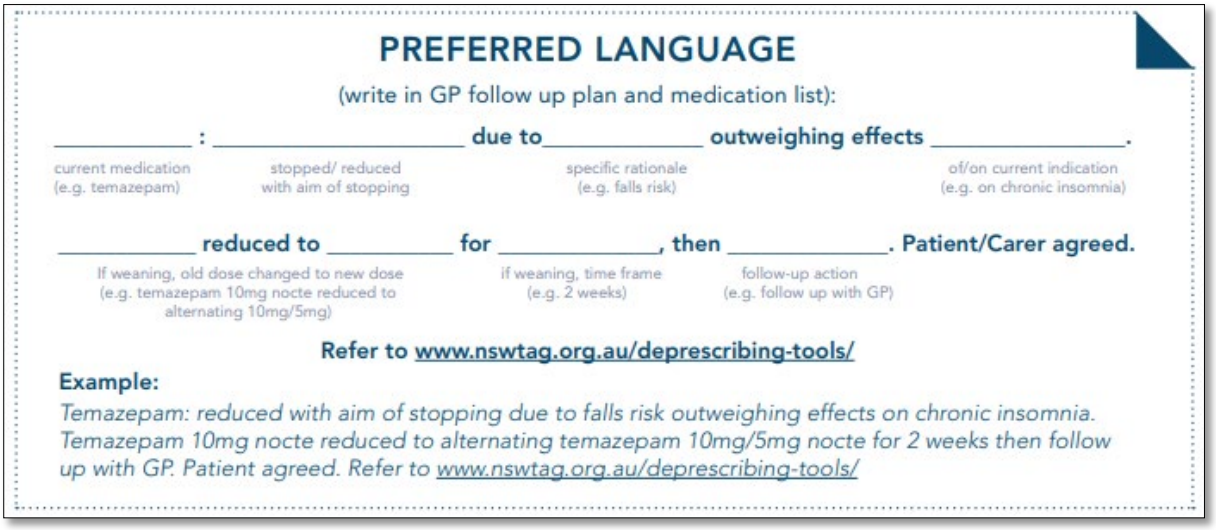
- Any continuation of previously prescribed 'night sedation medicine' (or other medicine used for its sedative properties), requires a discussion with the patient and/or carer regarding benefits of a deprescribing plan prior to discharge.
    - A consumer information leaflet for *Stopping My Benzodiazepine or Z drug* can be found here.
    - Deprescribing guides for prescribers for benzodiazepines/Z-drugs and tricyclic antidepressants can be found here.
    - Consumer information for reducing antipsychotic use can be found here.
    - Information for prescribers about deprescribing antipsychotics that have been used for insomnia can be found here.
    - If implemented, the deprescribing plan and its details including rationale and any dose reductions that have already commenced should be documented in the discharge summary. Consent documentation of patient/person responsible is recommended. Ideally verbal communication with the primary healthcare provider about the plan should occur. Communication of the plan with the patient's community pharmacy is recommended and will assist ongoing support.
    - If deprescribing has not been implemented during hospitalisation, recommendations for the clinician taking over care to consider deprescribing should be documented in the discharge summary.
    - Electronic medical record systems should facilitate documentation of initiated or recommended deprescribing plans in the discharge summary and links to resources. The aforementioned deprescribing guides for prescribers for benzodiazepines/Z-drugs and tricyclic antidepressants are also useful for GPs and informative for community-based pharmacists.

- Hospital staff may assist patients with relevant appointments on discharge with their local health care providers and discharge plans such as follow up timeframes.

- Consider referring patients suffering chronic insomnia to a sleep specialist, a sleep psychologist or other allied health professional as clinically indicated.

9.2 Practical tips for communicating deprescribing plans

The following preferred language to adequately describe the deprescribing plan at hospital discharge has been validated during a study involving hospital and primary care clinicians.[123] Refer to www.nswtag.org.au/deprescribing-tools/ for further support.



PREFERRED LANGUAGE

(write in GP follow up plan and medication list):

_____ : _____ due to_____ outweighing effects _____.

current medication (e.g. temazepam) | stopped/ reduced with aim of stopping | specific rationale (e.g. falls risk) | of/on current indication (e.g. on chronic insomnia)

_____ reduced to _____ for _____, then _____. Patient/Carer agreed.

If weaning, old dose changed to new dose (e.g. temazepam 10mg nocte reduced to alternating 10mg/5mg) | if weaning, time frame (e.g. 2 weeks) | follow-up action (e.g. follow up with GP)

Refer to www.nswtag.org.au/deprescribing-tools/

Example:

Temazepam: reduced with aim of stopping due to falls risk outweighing effects on chronic insomnia. Temazepam 10mg nocte reduced to alternating temazepam 10mg/5mg nocte for 2 weeks then follow up with GP. Patient agreed. Refer to www.nswtag.org.au/deprescribing-tools/

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10. Other clinical governance activities

10.1 Reporting and monitoring to governance bodies

DTCs should include a standing item in their meeting agenda to report:

a) adverse events related to 'night sedation medicines' use;
b) monitoring of 'night sedation medicine' prescribing trends according to wards and treating teams;
c) development and implementation of systematic processes to identify patients at risk of the adverse consequences of 'night sedation medicine' use; and
d) implementation of global and individual risk mitigation strategies, as necessary.

Suggested indicators for monitoring performance in this practice area are provided under the section 17. Measuring for improvement: Clinical indicators for optimising sleep in hospital. Particular attention should be given to performance in vulnerable populations such as patients with confusion, cognitive impairment and delirium.

It is recommended that prior to implementation of this guidance, a medicine use evaluation (MUE) study is undertaken in order to identify clinical areas which may require additional support during implementation and to evaluate changes to practice post-implementation. The MUE study should measure and monitor indications, prescribed registered or off-label 'night sedation medicines' and the status of the patient (treatment naïve versus non-naive; non-critically ill versus critically ill). DTCs should encourage and support quality improvement projects that seek to promote non-pharmacological management of sleep disturbance and insomnia and reduce night sedation medicine use. Choosing Wisely Australia provides a useful Hospital implementation toolkit, which includes guidance for governance, change management and design, to assist implementation of the recommendations in this guidance.[124] A dashboard of relevant measures relating to use of medicines for night sedation and associated harms should be available to relevant clinicians. This could also be accompanied by periodic surveys of patients' sleep quality or quantity (as Patient Reported Experience Measures).

10.2 Provision of training, services, and tools

The DTC (and/or medication safety subcommittee) is responsible for ensuring that processes, such as access to resources and tools, are in place that enable assessment of potential or actual harm from the use of 'night sedation medicines' in hospitalised patients. Access to tools that mitigate harm, such as deprescribing plans, should link to formulary listing and 'night sedation medicine' prescription. Health service organisations should also provide patient-friendly information regarding 'night sedation medicines' and deprescribing. Discharge communications to general practitioners and other relevant healthcare professionals should provide clear information regarding changes in medication, reasons for changes, goal of therapy and associated plan and trouble-shooting assistance during weaning.

Reactive approaches to sleep disturbance and insomnia management are discouraged. Instead, training and services should ensure a proactive approach whereby early identification of patients at-risk of sleep disturbance or insomnia during hospitalisation and early relevant referral for specific or individual interventions is encouraged e.g. sleep hygiene education, provision of sleep aids such as ear plugs, eye masks, and medication review[125] in addition to general ward interventions that promote sleep. Choosing Wisely Australia provides a Toolkit for Clinical Educators that may assist health professionals' training.[126]

Contacting the after-hours junior doctor to prescribe a 'night sedation medicine' is not recommended. The 'Managing Sleep Checklist' assists clinical review for prescribers prior to prescription and in accordance with formulary requirements should be available and require completion prior to prescription of a 'night sedation medicine' for sleep disturbance or insomnia.

Medical, nursing and pharmacy staff should receive training regarding medication review and deprescribing, and be aware that the use of these medicines may be monitored.

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Part D: Tools and resources for implementation

11. Scenarios demonstrating guidance application

Scenario 1: Junior Medical Officer (JMO) called to chart night sedation medicine

You are the after-hours JMO covering the wards and have been contacted by the nursing staff to review Mr TM, who is requesting a 'sleeping tablet'. The nurses inform you that while Mr TM does not take any regular medicines to help him sleep, he used them during his last admission, and is requesting them again. On further enquiry, you find out that Mr TM is an 80-year-old man admitted under the aged care team following a fall precipitated by a urinary tract infection. He mobilises independently and lives at home with his wife. He has a history of previous falls, including an inpatient fall during his last admission, after which he fractured his neck of femur and required a total hip replacement. The pharmacist's documented medication history confirms that Mr TM was not taking any night sedation medicines at home.

Recommended approach:

- **Information gathering**
  You find out that frequency in micturition and the noise in the hallways is disturbing Mr TM.

- **Education and advice to patient (and/or carer)**
  - You explain that urinary frequency will pass as the antibiotics start to work and that any sleeping tablet would put him at increased risk of falling if he does need to visit the bathroom. He is given advice about going to the toilet while he is in hospital.
  - You advise that according to the hospital policy on prescribing medicines for sleep disturbance and insomnia, you cannot prescribe sleeping tablets, and that this has to be done by his treating team because they are in charge of his care and know more about his health condition and what treatments they may have planned for him. If feasible, you also take time to inform the patient on the known harms of using medicines for sleep and that they are actually not very effective in promoting a restful sleep and can delay his recovery (see quick guide question and answer tool as well as the Consumer information booklet).

- **Shared decision-making with the patient (and/or carer)**
  Mr TM appreciates the advice. He is happy to drift off to sleep listening to the radio with his earphones and will use a urine bottle overnight. You suggest that his wife might also wish to bring in an eye mask and ear plugs from home (if unavailable from the hospital) for any further nights he has in hospital. You provide MR TM with consumer information about sleeping in hospital.

- **Communicate with the multidisciplinary team**
  You discuss the patient's main concerns with the ward nurses and agree upon implementing non-pharmacological methods of treating the patient's complaint of disrupted sleep, including the timing of observations and medication administration, reducing noise in the hallway and managing visitor, nursing and equipment noise, and ensuring that the ward is conducive to sleep for not only Mr TM but also for all other patients. You thank the nurses for their preparedness to adapt their care to assist Mr TM's sleep.

- **Document findings and the implemented and proposed interventions**
  You document the advice and actions taken clearly in the medical record so that the following day, the treating team is informed of the patient's request, and can address this on the morning round. Through further discussion with the team, the patient feels that their concerns have been heard and they decide to utilise the non-pharmacological methods that have been suggested.

KEY MESSAGES

- All members of the multidisciplinary team have a role to play in managing patients' sleep complaints.
- A non-pharmacological approach is the recommended first-line treatment for sleep disturbance/insomnia. Consider and discuss environmental and individual-specific triggers and solutions with the patient and clinicians caring for patient.
- Evidence does not support the routine use of medicines for night sedation (at any dose) due to their unfavourable harm: benefit ratio.
- Clarify medications taken at home. Check if there is a documented Best Possible Medication History that can provide some information.
- Documentation of findings and interventions is important to ensure seamless person-centred care and reduce avoidable harm.

Scenario 2: Younger patient with multiple chronic conditions that may be exacerbated with use of off-label medicine for night sedation

You are the JMO in a surgical pre-admission clinic. You are admitting Mr BW, who is a 45 years old taxi driver and scheduled to be admitted for elective coronary artery bypass surgery in 2 weeks. He has a past history of diabetes, hypertension, ischemic heart disease, peripheral vascular disease, obesity and depression. Amongst his medications are prescriptions for mirtazapine 30 mg for depression and quetiapine 50 mg (2 × 25 mg immediate release) at night.

- **Information gathering**

He has been taking quetiapine for the past 6 months to assist with sleep disturbance. There appear to be no concerns around aberrant drug related behaviours and other than smoking, he has no history of substance use disorder. His mood has been OK for the last 6 months. You suspect he may also have obstructive sleep apnoea. You ask Mr BW if it is okay to talk to his GP to confirm his medications and their indications. Unfortunately the GP is not available.

- **Education and advice to patient (and/or carer)**

You explain that quetiapine is an antipsychotic, and that while it can have calming relaxing effects, it is not registered to treat insomnia, and there is limited evidence that it is effective for this condition, which comes as a surprise to BW.

You explain that amongst other side effects, it can cause weight gain and contribute to metabolic syndrome and cardiovascular disease. You advise that you are concerned because he already has diabetes and vascular disease.

You raise concerns that his sleep disturbance may in part be related to potential sleep apnoea and that he should consider seeing a sleep specialist about this. You advise that any sleeping tablets may make this worse. (See also quick guide question and answer tool and the Consumer information booklet).

- **Shared decision-making with the patient (and/or carer)**

Given his surgery isn't for another 2 weeks, you discuss the opportunity for BW to stop the quetiapine gradually before the surgery, tapering by 25 mg every 3 days to abstinence. (Low dose antipsychotics used for insomnia can generally be ceased quickly).[127] BW agrees to stop the quetiapine according to your suggested plan. He requests written information about use of quetiapine for insomnia to show his wife, which you are able to give him from the www.deprescribing.org site. You also give him the consumer information that discusses management of sleep while in hospital.

You advise him to prepare for the hospital environment at night with good sleep hygiene, nicotine replacement therapy and ear plugs. BW is grateful for the information. He is happy to see his GP to get a referral to a sleep specialist and to try and avoid sleeping tablets.

- **Document findings and implemented and proposed interventions**

You document the discussion, findings and plan clearly in the preadmission clinic notes.

- **Communicate with the multidisciplinary team**

You inform the surgeon of your documented findings and also inform the anaesthetist about your concerns around obstructive sleep apnoea. You also send a summary of the pre-admission clinic notes to the GP and follow up with a phone call to the GP to highlight your suggested weaning of the quetiapine. The GP is happy to wean and cease the quetiapine, and refer him to a sleep specialist.

KEY MESSAGES

- Early discussion (in pre-admission clinic/ at admission) with the patient's GP may clarify medications and their indications, uncover other relevant information and assist building a partnership with respect to shared decision-making for appropriate weaning and cessation of quetiapine and referral to sleep specialist post-discharge.
- A non-pharmacological approach is the first-line recommended treatment for sleep disturbance/insomnia. Providing written consumer information will assist management of sleep in hospital (and at home).
- Chronic insomnia has many causes and appropriate investigations/referrals should be made to investigate these.
- Patients on pre-existing treatment for chronic insomnia should be informed of the harms, benefits and existing evidence for the chosen treatment.
- Informed consent should be obtained if treatment is off-label prescribing.
- Once the decision to wean/cease has been made, an appropriate deprescribing strategy should be implemented, accounting for risk of withdrawal, destabilisation of underlying mental health issues and urgency. Consider when specialist advice is required.

Scenario 3: An older person suffering unintentional iatrogenic harm

An 89-year-old patient, admitted with an upper respiratory tract infection, was given codeine 30 mg for cough suppression and temazepam 10 mg for difficulty sleeping due to the cough and her illness; both were given in the evening. The next morning, the patient reported that she had fallen in the night and returned to bed herself. There was no apparent injury, but the onset of slurred speech prompted computed tomography scanning of her head. She was found to have a subdural haematoma.

Recommended approach to prevent iatrogenic harm:

- **Information gathering**
  - A proactive and comprehensive clinical assessment of this patient's falls risk should be undertaken at admission and periodically thereafter.
  - Medication review that assesses the appropriateness, efficacy and safety of any current (or potential) medicines in older persons should include risk of falls and fall-related injuries, and cognitive and physical impairment. In this case:
    - Alternative cough suppressants e.g. pholcodine should be considered before the use of codeine, which is likely to have greater CNS adverse effects (drowsiness, respiratory depression).[128] The potential harms from codeine as an antitussive are likely to outweigh the potential benefits, especially in the elderly.

- **Treatment of underlying condition**
  - Treatment of her cough should be a priority as it is the underlying cause of her difficulty sleeping. Treatment for an upper respiratory infection and response to cough treatment should therefore be reviewed before considering pharmacological management for sleep disturbance.

- **Best practice sleep disturbance/insomnia management**
  - Non-pharmacological management for sleep disturbance/insomnia including positioning e.g. high fowlers or high sided lounge chair should be tried before considering initiation of temazepam.
  - The Managing Sleep Checklist assists in systematically evaluating the patient's suitability for a night sedation prescription. In this case, the potential harms of temazepam were likely to outweigh the potential benefit.

- **Promote shared-care decision-making with the patient and/or carer**
  - Discussion with the patient and/or carer with supporting written information is required to increase awareness of adverse effects including falls risk associated with medication use (prescription and non-prescription medications), prior to prescription of new medicines.

KEY MESSAGES:

- The roles and responsibilities of the multidisciplinary team for assessing falls risk and potential iatrogenic harm during hospitalisation should be clearly articulated and co-ordinated.
- Older patients, even when on only a few medications, which may have been initiated in hospital, should be reviewed by a clinical pharmacist (or geriatric team, if available) during or soon after admission and considered for medication review. This will include assessment of a patient's complete therapy for drug interactions or risk of additive effects on the CNS/respiratory system, falls risk and other adverse effects when considering the prescribing of 'night sedation medicines'.
- Avoid prescribing medications that cause additive CNS and respiratory depression effects.
- The harm: benefit ratio for night sedation medicine use in the older person is generally unfavourable, particularly for sleep disturbance/insomnia. Risk of falls is greatest in the first few nights following initiation of a night sedation medicine.

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12. System-wide non-pharmacological interventions for sleep

12.1 Table of system-wide non-pharmacological interventions to promote sleep in hospital

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

SYSTEM-WIDE NON-PHARMACOLOGICAL INTERVENTIONS TO PROMOTE SLEEP IN NON-CRITICALLY ILL HOSPITAL PATIENTS*

System-wide Environmental Strategies: Apply at a ward level	
Appoint clinician champions	Appoint clinician champion(s) at the ward level to: • Prioritise sleep for patients. • Promote, implement, monitor and report non-pharmacological interventions. • Develop local ward-based sleep protocols (specific to ward's characteristics). • Monitor and report use of medicines for night sedation and adverse effects such as falls, delirium. • Promote resourcing of non-pharmacological sleep aids e.g. ear plugs, eye masks. • Identify clinician champion position in hospital's strategic plan of quality improvement activities ensuring succession & ongoing support.
Reduce noise at night *Multiple sources of noise in hospital. WHO recommends sound pressure level should not exceed 30 decibels (dB) at night.* [1]	Methods to reduce noise and/or its effects include use of: • Silent staff footwear e.g. soft-soled shoes. • Sound-reducing rubber on the wheels of hospital beds and trolleys • Sound masking for white noise, music may create appropriate ambience and act as 'white noise'. App examples include https://www.tmsoft.com/white-noise/; https://mynoise.net/; White noise playlists from music apps e.g. in Spotify® or Apple Music®. • Ear muffs/plugs for patients. • Silent mode on mobile phones at night. • A lower ring volume on telephones and pagers at night. • Noise metres, or a "sound ear" to help minimise noise. The "sound ear" machine features the silhouette of an ear, which turns green, yellow or red depending on noise levels and is a visual warning cue to staff, patients and family in the area when it is getting too noisy. Mobile phone apps which measure noise level include Decibel-Noise and Sound Meter, NIOSH Sound Level Meter, Noise Meter 32 db. • Ward-based behavioural modifications e.g. "quiet time" protocols. • Remote alarms in staff rooms and potential use of visualisation strategies e.g. switchable glass, webcams for nocturnal checks (check local policy). • Soft close doors. (Fix any squeaky doors). • Sound proofing acoustic materials e.g. lightweight materials with porous surfaces, such as textiles and fabrics, absorb sound better than concrete or glass. Check with relevant departments e.g. Facilities Management Department and Infection Prevention Control Department In addition: • Limit patient television viewing at night during normal sleeping hours in shared rooms. • Ensure staff conversations are away from ward areas during the night. • Avoid room changes, and other noisy procedures e.g. use of pill crushers, floor waxing during normal sleeping times. • Reduce alarms, which are especially disruptive noises, and paging.[1]

System-wide Environmental Strategies: Apply at a ward level	
Reduce disturbances *One-third of patients reported nocturnal monitoring as a major sleep disrupter.[2] Sedative use halved (32% to 16%) in inpatients when vital sign monitoring and medication administration was confined to 6am to 10pm.[3]*	Consider re-arrangement of workflow: • Limit interactions during typical sleep hours to those that are truly required for patient care. • Review and modify all treatments, procedures, and morning rounds to minimise awakenings (especially in the early morning). Liaise with medical team(s) as necessary. • Do not wake patient to administer night sedation medicine. • Investigate/consider use of wireless or wearable monitoring technologies.
Expose patients to appropriate levels of day and night light *Many hospital patient care areas have lighting that impairs sleep and disrupts circadian rhythm such as constant bright light conditions and low 24 hour light amplitudes. [4]*	Promote adherence to normal circadian rhythm (and appropriate melatonin release) by establishing a clear day/night light exposure protocol consistent with environmental norms. • Use dimmed lights in corridors and patient rooms at night as excessive evening light stimulates alertness. Adjustable LED systems allowing for blue-depleted lighting in the evening and overnight reduces disruptive effects of conventional artificial light on circadian rhythm and sleep.[5] • Large windows in patients' rooms exposing patients to natural light and smart light bulb systems that mimic natural light variations are helpful. • Provide eye masks at night as appropriate (consider providing for admitted patients or ask them to bring from home).
Reduce wakefulness stimuli at night	• Discourage activities such as eating, using computers or devices and watching TV during normal sleeping hours. • Discourage intake of caffeine-containing beverages towards end of day (within 4-6 hours of bedtime).
Other	• If appropriate, pre-sleep shower may be helpful. • When appropriate, avoid visual access to clock when in bed to reduce patient anxiety about how much sleep they have 'lost'. • Create a sleep conducive environment e.g. free of clutter, appropriate temperature and a comfortable bed and pillow. • There are harmful effects associated with unnecessary bed rest[6,7], which may occur with the use of night sedation medicines. When appropriate, encourage patients to not lie in bed during the day-get dressed, sit in chair if possible and return to bed to sleep at night. Consider movements such as 'endPJparalysis'.[8,9] • Encourage onsite retail outlets to stock ear muffs/plugs, eye masks, headphones and ensure staff are aware that patients can obtain them from these outlets. • Consider having ear muffs/plugs and eye masks available from the hospital newspaper/magazine trolley run.

System-wide Patient-related Strategies: Consider with each patient	
Ensure a patient-centred approach *Apply individualised, flexible and informed strategies rather than a task-focused approach.*	• Assess risk of disturbed sleep during hospitalisation and identify effective home-based strategies (if previously used) for hospital implementation. Tailor sleep hygiene education as appropriate. • Counsel patients to manage patient expectations regarding sleep and its management during hospital stay, ideally before admission e.g. in pre-admission clinic. • Counsel patients that treatment of the underlying medical or surgical condition e.g. pain, dyspnoea, coughing etc. should improve sleep quality and quantity.
Routinely provide sleep hygiene education *A recent randomised controlled trial demonstrated improvement of sleep and fatigue in non-critically ill patients with the provision of patient education and empowerment about the use of various sleep-enhancing tools e.g. ear plugs.*[10]	• Counsel and educate patients complaining of sleep disturbance on how to adopt and/or maintain good sleep practices prior to and during hospitalisation and on discharge. • Educate patients about excessive napping. Naps should be purposeful. Although some napping may compensate for a previous night's sleep disturbance and assist recovery from acute illness, it may interfere with the next night's sleep. Excessive napping may also indicate Obstructive Sleep Apnoea. • Provide patient-friendly supplemental written and/or electronic resources for relevant information.[11,12]
Identify the patient's chronotype *Are they early chronotypes, 'larks', and more alert and active in the morning or late chronotypes, 'night-owls', and more alert and active at night?*	• Hospitals usually operate an early sleep-wake schedule. Hence hospitalised night-owls may experience more sleep disruption. • A mixture of 'larks' and 'night-owls' in the one hospital room can be problematic. Cluster similar chronotypes and adjust hospital care routines to match chronotype if possible. • Single room allocations for poor sleepers is preferable but may not be possible.
Recognise & manage anxiety & stress & promote relaxation *Anxiety symptoms reported in 33% ICU survivors and 20% of general ward patients identified as a cause of insomnia.*[2,13]	Apply strategies to reduce anxiety and stress: • Ensure good communication between clinicians and patients/carers and responsiveness to patient needs. • Allay/normalise patient's anxiety given that unfamiliar surroundings, lack of control, uncertainty and worry regarding illness and possible disease progression can be expected to increase anxiety in hospitalised patients. • Promote shared decision making. • Encourage patients to use relaxation techniques, especially if they have previously used them. Consider strategies such as deep breathing, music, visual imagery, mindfulness and progressive muscle relaxation for patients who have trouble relaxing or winding down.
Medication, fluid and food adjustments *A variety of medications can impair sleep and include CNS and respiratory stimulants, antidepressants, some beta blockers and glucocorticoids.*	Carefully consider presence of adverse effects from medications and diet. • When possible, administer medications with activating properties in the morning, and sedating medications in the evening. • Consult a clinical pharmacist for advice. • Avoid caffeine-containing drinks such as coffee, tea or soft drinks at least 4-6 hours before bed.
Exercise or physiotherapy	• Increase mobilisation during the earlier part of the day and avoid exercise close to bedtime.
Screen for Obstructive Sleep Apnoea (OSA) in high risk patient groups	• Referral for definitive diagnosis and treatment of OSA can be facilitated during hospitalisation.

*Many strategies are also useful in long stay and non-hospital settings and may be recommended to patients for post-discharge management.

Strategies applicable to longer stay hospital areas (e.g. rehabilitation and dementia units) and for patients following discharge include:

a) Associating BED with only SLEEP - Condition the patient to expect that bed is for sleeping only and no stimulating activities in order to promote a positive association between bedroom environment and sleepiness. Promote getting up at the same time each day, no matter the quantity of sleep in the previous night. Ensure adequate exposure to sunlight during the day. Ensure a quiet, dark and comfortable temperature environment for sleep.

b) Encouraging daytime exercise and relaxing evening activities, where feasible.

c) Using relaxation therapies described above. Relaxation techniques are most effective if practised during the day, before going to bed and also in the middle of the night if the person is unable to go back to sleep. Usually several weeks of practise of these methods are required to improve sleep.

d) Utilising Cognitive Behavioural Therapy (CBT) – CBT targets the anxiety-producing maladaptive beliefs and attitudes about sleep and sleep loss that can drive insomnia. Identifies and targets beliefs that may be interfering with adherence to stimulus control and sleep restriction. Uses mindfulness to alter approach to sleep.[14]

These interventions are effective and do produce more durable, safer benefits than drug treatment, although they may have limitations such as the need for skilled practitioners (e.g. CBT) or a change in culture and belief systems, the potential expense and time-consuming nature of the interventions, and the delay in improving sleep disturbances.[15,16]

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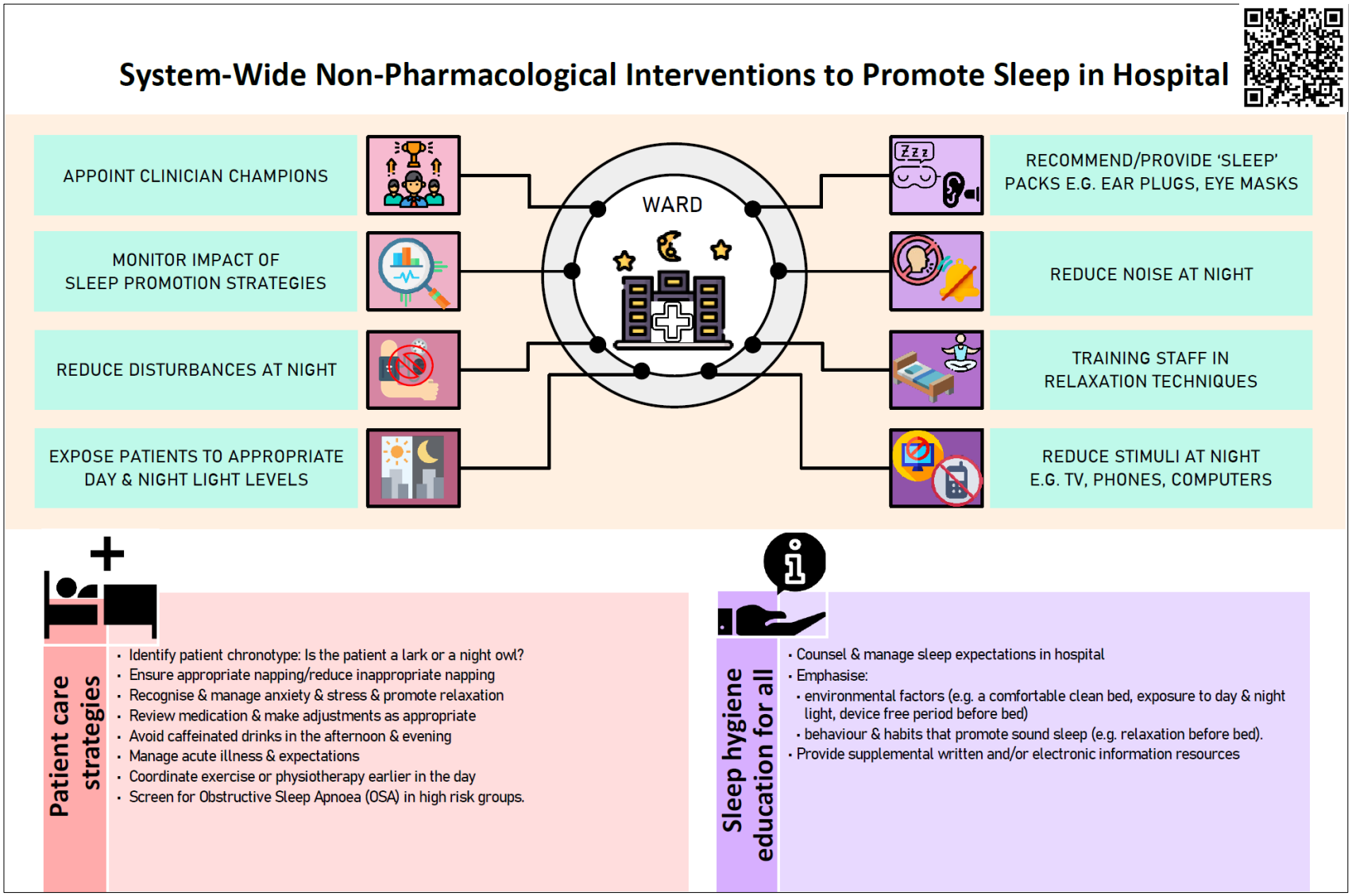
12.2 Summary poster & checklist of system-wide non-pharmacological interventions to promote sleep in hospital

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/



Checklist for Implementation of Ward Strategies Promoting Good Patient Sleep

	1. Yes/ Fully implemented	2. Partially implemented	3. No/ Not implemented	Comments
Hospital/Ward Policies				
Hospital/ward policy for sleep promotion in patients finalised and distributed to patient care areas	○	○	○	
Policy contains information/ direction regarding non-pharmacological and pharmacological management of sleep disturbance	○	○	○	
Other relevant policies/ procedures/ guidelines consider impact on patient sleep and outline mitigation strategies	○	○	○	
Compliance with policy/policies routinely reported to relevant ward/hospital governance committees	○	○	○	
Implementation of night noise reduction strategies				
Ear muffs/plugs routinely offered to all relevant patients	○	○	○	
Sound-reducing rubber on wheels of hospital beds, trolleys and other equipment	○	○	○	
Hardware optimised e.g. soft door close, not squeaky.	○	○	○	
Designated area for staff discussions at night away from patients.	○	○	○	
Scheduled use of noise meters to measure noise levels.	○	○	○	
Minimisation of care interventions at night				
Patient care interactions occur during awake times whenever possible.	○	○	○	
Patients ae not administered prescribed night sedation medications, if asleep.	○	○	○	
Patient exposure to appropriate day & night light levels				
Window curtains/ blinds opened and closed appropriately.	○	○	○	
Eye masks routinely offered for patient use.	○	○	○	
Wakefulness stimuli discouraged at night				
Caffeine-containing beverages not routinely offered to patients within 4-6 hours of bedtime.	○	○	○	
Patient use of TV, phones and computers during sleeping hours discouraged by nurses	○	○	○	

	1. Yes/ Fully implemented	2. Partially implemented	3. No/ Not implemented	Comments
Staff training				
All staff are aware of hospital/ward policies to manage sleep disturbance				
Nursing staff routinely enquire about patient's sleep during hospitalisation				
Written and/or electronic information resources are routinely offered by nurses to newly admitted patients and questions answered				
All clinical staff are aware of common triggers for sleep disturbance/insomnia				
Nursing staff monitor individual patient's daytime napping on daily basis				
Night clinical staff have received patient-centred training to promote sleep including non-pharmacological strategies such as relaxation/mindfulness techniques				
Clinical staff consider and make referrals as necessary e.g. formal medication review, screening for Obstructive Sleep Apnoea (OSA) in high risk patient groups				
Patient education and counselling				
Patients are counselled pre-admission or at admission about expectations regarding sleep and its management during hospital stay				
Patients receive counselling about sleep when requested				
Patients encouraged to report sleep quality and causes of disturbance				
Establishment of Quality Improvement (QI) Project				
Clinician champion(s) appointed to lead/facilitate interventions and project				
Multidisciplinary project team for QI established				
Clinical indicators chosen to measure baseline management and success of interventions				
Baseline audit completed				

For more details refer to: Table of non-Pharmacological Interventions To Promote Sleep In Non-Critically Ill Hospital Patients

For hyperlinked resources above, scan QR code or visit: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources

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13. Useful resources for healthcare professionals and patients/carers

13.1 Quick guide: 5 questions to ask your healthcare team about sleep in hospital and why medicines for sleep are not a good idea

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

5 QUESTIONS to ask your healthcare team about sleep in hospital and why medicines for sleep are not a good idea

1	DO I REALLY NEED THIS TREATMENT?	*Treatments, such as medicines, and procedures may help to treat your problem.*	No, while you can expect some sleep disturbance during your hospital stay, you shouldn't need a medicine to help you sleep. The recommended management of sleep disturbance uses a non-medicine approach, which is safer and effective.
2	WHAT ARE THE RISKS?	*Will there be side effects to the treatment? Could that lead to extra testing or treatments?*	Medicines used for sleep can lead to medical complications or worsen your current medical conditions e.g. falls, fractures, confusion and breathing difficulties, even death. The side effects can delay recovery and rehabilitation.
3	ARE THERE SIMPLER, SAFER OPTIONS?	*Ask if there are alternative options to treatment that could work, such as lifestyle changes.*	Yes, there are safe & effective options to help you sleep in hospital. Many patients find eye masks, earplugs, relaxation therapies and soft music useful. Ask for advice and an information booklet on tips for sleeping in hospital.
4	WHAT HAPPENS IF I DON'T DO ANYTHING?	*Ask if your condition might get worse — or better — if you don't have the treatment right away.*	Your everyday health and recovery can be affected if you don't get enough sleep. However, it is best to use non-medicine approaches for sleep because the harms from medicine are likely to outweigh any benefits they might offer.
5	WHAT ELSE SHOULD I KNOW?	*Are there any financial, emotional or other impacts?*	There are no out-of-ordinary medicine costs. Apart from increasing the risk of falls and confusion, they are addictive and can be more harmful if used with other medicines. Overall, it's best to avoid medicines for sleep. Always ask for advice.

Adapted from material developed by Choosing Wisely Australia® see choosingwisely.org.au for more information.

Choosing Wisely Australia — An initiative of NPS MedicineWise
NSW TAG — NSW Therapeutic Advisory Group Inc.

13.2 Consumer information booklet: Sleeping in hospital

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

Sleeping In Hospital

Consumer Information Booklet

This booklet contains advice about how to sleep well while you are in hospital as well as when you leave hospital (please keep this)

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Talk to your nurse if you are worried about sleep while you are in hospital.

- It is often difficult to sleep well in hospital, especially when you are ill or sharing a room with others. Reasons for changes to your sleep pattern during your hospital stay may include:
  - Room lighting that's too bright.
  - Night-time treatments and check-ups for you or your room-mate.
  - Noise from conversations, visitors, snoring, machines and televisions.
  - Side effects from medicines. These might keep you awake at night or make you sleepy during the day so you can't fall asleep at night.
  - Your illness and symptoms such as stress, pain, shortness of breath, or needing to go often to the toilet.
- It is important not to get too worried if you have less sleep than normal. This is to be expected given the change in your health and environment.
- Avoid requesting sleeping tablets in hospital as they have many side effects.

Potential hazards of sleeping tablets

- *Can cause daytime drowsiness, confusion and agitation;*
- *Lead to falls and fractures;*
- *Prevent or reduce activities that help recovery;*
- *Interact with other medicines; and,*
- *Can be difficult to stop if taken for a long time.*

Tips for sleeping in hospital

Consider bringing items in this information booklet from home that may make you feel more comfortable and help you sleep.

Certain activities, books, audiobooks and music may help you relax while in hospital.

At night

Read more about things you can do at night to help you sleep better.

During the day

Read more about things you can do during the day to help you sleep better.

1

AT NIGHT

Limit food and drinks containing caffeine

- × Avoid caffeine, such as coffee, black or green tea, soft drink/soda, and chocolate at least 4-6 hours before bedtime.
- × Finish eating dinner at least 3 hours before you want to go to sleep.

Relax before bed

To relax before going to sleep, try any of the following relaxation activities:

- ✓ Deep breathing exercises. Ask your nurse for instructions.
- ✓ Listen to soothing music.
- ✓ Read.
- ✓ Have a shower before bed (check with your nurse if okay)
- ✓ Meditation & Mindfulness.

If you have a smartphone or tablet, you can find free apps to help sleep.

The Mindfulness app (free version available)

Mindfulness

Smiling Mind (free)

Smiling Mind

Keep the room dark

- ✓ Ask the nurse if you can close the door & close the curtains.
- ✓ Turn off the TV, computer/laptop screens and mobile phone.
- ✓ Use an eye mask.

AT NIGHT

Keep the room quiet

- ✓ Silence/turn off your mobile devices after 10:00 pm.
- ✓ Use earplugs or noise cancelling headphones to block out noise.
- ✓ Listen to white noise, such as a playlist with ocean sounds. Remember to use headphones if you have roommates. If you have a smartphone or tablet with apps such as Apple Music or Spotify, search for a 'white noise' playlist.

Sleep in comfort

- ✓ If possible, wear comfortable clothes (bring your own).
- ✓ Have enough blankets to keep you warm but not too hot, ask the nurse if you need more blankets as often hospitals can be a bit colder than you may be used to. Bring your own familiar pillow.
- ✓ Go to the toilet before bed.
- ✓ If pain is making it difficult to sleep, talk to your nurse about your pain and options to reduce pain.

If you can't fall asleep

Try to ease your mind with these strategies:

- ✓ If you're worried, make a list of things you're worried about and then put them aside to deal with the next day.
- ✓ Drift off listening to music or an audiobook.
- ✓ Try a relaxation activity, such as reading a book (using a dim light) or practice mindfulness for about 30 minutes or until you are tired again.
- ✓ Talk to the nurse if the environment is too noisy.

DURING THE DAY

Let light into your room

Light helps your body know what time of the day it is.

- ✓ Open the curtains in the morning.
- ✓ Turn the lights on if it is a dull day

Get as much exercise as you can

- ✓ Try to do some light physical exercise activities, if you can.
- ✓ Walk around the ward, if you can.
- ✓ Do exercises in your bed or chair. Ask your nurse or physiotherapist for suitable exercises.

Limit your napping

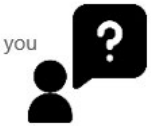
Taking naps in the late afternoon can make it harder for you to fall asleep at night.

- ✓ Try to stay awake during the day and only sleep at night.
- ✓ Keep yourself occupied during the day to avoid wanting to nap during the day.
- ✓ If you feel like you need to nap, take a short one earlier in the day and set an alarm to wake you up after 15-30 minutes (but no more than 40 minutes because this can make it difficult to sleep at night).

DURING THE DAY

Speak with your healthcare worker

- → Ask your doctor, pharmacist or nurse about your schedule: if possible, request all medication and check-up times occur when you are awake, not after bedtime.
- → Ask if the hospital has any services such as music therapy and relaxation therapy.



Where can I find out more information?

Please talk to your nurse or another member of the healthcare team about your sleep if you have concerns.

The following websites may be useful:

- → *www.sleep.org.au*
- → *www.sleephealthfoundation.org.au*

My notes:

Sleeping in hospital – Consumer information booklet, Version 1, Dec 2021

This document has been approved for use at:
[ ]

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13.3 Summary table of useful resources for healthcare professionals and patients/carers

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

This document has been approved for use at [ ]

Summary table of useful resources for healthcare professionals and patients/carers

Summary of useful resources for healthcare professionals and patients/carers

Please note that this list is not exhaustive and it is recommended that sites develop their own tailored resource kit for promoting good sleep practices for all hospitalised patients.

Organisation	General clinician resources	Patient resources
Better Health Channel		• Sleep explained - link • Sleep – insomnia - link • Sleep hygiene - link • Mood and sleep – link • Sleep apnoea - link
NSW TAG		• Sleeping well in hospitals: Consumer Information Leaflet - link
Therapeutic Guidelines	• Topic: Insomnia, parasomnias and jet lag	• Advice on good sleep practices - link
TED-Ed		• YouTube video: What causes insomnia? - Dan Kwartler - link • YouTube video: A walk through the stages of sleep – link • YouTube video: 6 tips for better sleep - link
Hilmer SN et al. TRGS 274 *"Reducing inappropriate polypharmacy in older inpatients"*, hosted on NSW TAG website.	• Deprescribing guides - link	• Deprescribing Consumer Information Leaflets - link
Primary Health Tasmania (Tasmania PHN)	• Deprescribing resources – link (A guide to deprescribing antipsychotics, benzodiazepines & other medications) • A series of short videos about the deprescribing cycle - link	• Managing Your Medications brochure - link • Managing Your Medications card - link

Canadian Deprescribing Network	Website: https://www.deprescribingnetwork.ca/useful-resources	• You may be at risk if you are:
		  ○ taking one of the sedative-hypnotic medications – link
		  ○ currently taking an antipsychotic drug – link
		• How to get a good night's sleep without medication - link

NPS MedicineWise	• Benzodiazepine dependence: reduce the risk - link Dementia specific resources • Health professionals' guide to person-centred dementia care - link • Dementia and psychotropic medicines - link • Reviewing and tapering antipsychotic medicines for changed behaviour - link Australian Prescriber articles • Hypnotic hazards: adverse effects of zolpidem and other z-drugs - link • Concerns about quetiapine - link • Prescribing psychotropic drugs to adults with an intellectual disability - link	• How to sleep right – link • Sleeping pills and older people: the risks - link Dementia specific resources • Medicines and dementia: other conditions - link

The Clinical Excellence Commission (CEC)	• Reducing The Use Of Night Sedation: Information For Clinicians & Health Professionals - link • Reducing Fall Risk for Patients on Sedating Medications: Information For Clinicians & Health Professionals - link	
The Royal Australian College of General Practitioners (RACGP)	• Prescribing drugs of dependence in general practice, Part B – Benzodiazepines - link • Brief behavioural therapy: insomnia in adults - link • GP guide to behavioural therapy for insomnia - link	
Medical Journal of Australia	• Sleep Disorders: A practical guide for Australian health care practitioners - link	

South Australia Health	• Sleep problems - Insomnia Management Kit (including assessment tools and fact sheets) - link	• Risks associated with benzodiazepines - link
		• Sleep Medication fact sheet - link
		• Management tools/fact sheets
		  ○ Sleep: Facts and Hygiene - link
		  ○ Stimulus Control Therapy - link
		  ○ Bedtime Restriction Therapy - link
		  ○ Bright Light Therapy - link
		  ○ Relaxation Therapy - link

Sleep Health Foundation	https://www.sleephealthfoundation.org.au/	YouTube Videos suggested by the Sleep Health Foundation: • Sleep Regulation - the two processes that control when and why we sleep – link • Sleep Hygiene - How to Sleep Better! - link • Dementia related: The Four Ps: Danielle's tips on getting a good night's sleep - video
Sleep Disorders Australia	https://www.sleepoz.org.au/	
Australasian Sleep Association	• On-the-spot Management Information For Health Professionals: Insomnia - link • Search for an accredited sleep service • Sleep Services Directory - link	Patient information sheets: • Sleeping tablets • Good sleep habits • Insomnia • Dementia and sleep • and more available on website.
Reconnexion	• Treatment, support and information about benzodiazepine dependency and withdrawal, anxiety, insomnia and depression http://www.reconnexion.org.au/	
Best Practice Advocacy Centre New Zealand (BPACNZ)	• I dream of sleep: managing insomnia in adults. • Part 1: Diagnosis and non-pharmacological treatment - link • Part 2: The ideal pharmacological approach for improving sleep - link	• Insomnia patient information leaflet (includes sleep hygiene information and an individualised sleep restriction form) - link
Health Education and Training Institute (HETI) NSW	• eLearning module Safe use of benzodiazepines in the older person - link	
Veterans' MATES	• Helping veterans learn to sleep well - link	• SLEEP WELL, FEEL WELL - link

Dementia specific resources		
NSW Agency for Clinical Innovation	Aged Health Network • Key Principles for Improving Healthcare Environments for People with Dementia - link	
NSW Agency for Clinical Innovation (ACI) and the NHMRC Cognitive Decline Partnership Centre (CDPC)	CHOPs (Care of Confused Hospitalised Older Persons) Program • Management of older people with confusion - link • Resources and useful links - link	
NSW Health	Assessment and Management of People with Behavioural and Psychological Symptoms of Dementia (BPSD). A Handbook for NSW Health Clinicians - link	
Dementia Australia	• Home page: https://www.dementia.org.au/	• Help sheet: Caring for someone with dementia: Sleeping - link
Veterans' MATES	• Reducing the load: Medicines best avoided in patients with dementia - link	

Safety information from regulatory authorities and professional organisations	
Australian and New Zealand College of Anaesthetists (ANZCA) and ScriptWise - Combined use of opioids and benzodiazepines can be fatal, FPM and ScriptWise warn - link Therapeutic Goods Administration (TGA) Australia - Opioids: boxed warning and class statements - link (Sedation, respiratory depression, coma and death may result from concomitant prescribing of opioids with CNS depressant medicines, such as other opioid analgesics, benzodiazepines, gabapentinoids, cannabis, sedatives, hypnotics, tricyclic antidepressants, antipsychotics, antihistamines, centrally-active anti-emetics and other CNS depressants)	Food and Drugs Administration (FDA) United States - FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class. Includes potential for abuse, addiction, and other serious risks (23/9/20) - summary; news release; podcast; Viewpoint published in JAMA[1] - Drug Safety Communication: serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning (31/08/16) - link- Drug Safety Communication: caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks (20/08/17) - link Health Canada - Updates to safety labelling for benzodiazepines and benzodiazepine-like drugs (30/10/2020) - link Medicines & Healthcare products Regulatory Agency (MHRA) United Kingdom - Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression (18/03/2020) - link

References:

1. Hirschtritt ME, Olfson M, Kroenke K. Balancing the Risks and Benefits of Benzodiazepines. *JAMA*. 2021;325(4):347-348.

For hyperlinked resources above, scan QR code or see: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources

NSW TAG NSW Therapeutic Advisory Group Inc.

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14. Summary of adverse effects of benzodiazepines and Z-drugs

Citations for this summary figure[3,9,52,56,101,129-131]

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

Worsening of mental health & functioning

- Impaired alertness & over-sedation including 'hangover effect' next day.
- Confusion, cognitive impairment (may not be fully reversible after long term use).
- Short term memory impairment.
- Delirium.
- Impaired perception of hazard; Learning impairment.
- Anxiety & depression: both may commence or worsen.
- Paradoxical stimulation & disinhibition. Abnormal potentially dangerous sleep related behaviours such as sleepwalking and sleep driving and paradoxical reactions (e.g. hallucinations, rage).
- Emerging evidence of dementia.

Motor impairment

- Reduction of physical movements as part of psychomotor impairment: can hinder recovery and rehabilitation.
- Impaired gait, balance and co-ordination.
- Falls and fall-related injuries e.g. fractures: associated with increased mortality, especially in older patients. Risk of falls and death increases with higher doses and longer duration of use.
- Psychomotor impairment: daytime dizziness/light-headedness; can lead to motor vehicle accidents post-discharge.

Dependence, tolerance & problematic use

- Dependence after 2-4 weeks: withdrawal effects seen in up to 45% of patients ceasing low doses. Approximately one-third of patients taking long term benzodiazepines have difficulty reducing or ceasing them. Withdrawal effects include rebound insomnia, vivid dreams, irritability, myoclonic jerks, paraesthesia, palpitations, tinnitus, headaches, poor concentration, sensory disturbances and seizures. Rebound insomnia and vivid dreams could mistakenly lead to resumption of hypnotics. (Deprescribing plans information available here: www.nswtag.org.au/deprescribing-tools/).
- Tolerance to sedative effects: can occur within 2 weeks of continued use. Degree of tolerance varies between patients. Propensity varies between drugs.
- Misuse: due to euphoric and sedative effects especially with those with rapid onset of action e.g. diazepam. More likely in those abusing alcohol and other drugs.

Other

- Respiratory depression particularly at high doses or in combination with respiratory/CNS depressants.
- Pneumonia: Increased risk of pneumonia resulting in hospitalisation or death in dementia patients with BZD use, particularly during first 30 days of BZD use.
- Incontinence

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15. Acceptable indications for listing benzodiazepines on the hospital formulary

Download a copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

N.B. The use of benzodiazepines is not recommended in the treatment of muscle spasm with the exception of muscle spasm associated with multiple sclerosis and spasticity.

There are no acceptable indications to support hospital formulary listing of Z-drugs for initiation in non-critically ill patients.

There are no acceptable indications to support hospital formulary listing of melatonin or other medicines that might be used for night sedation in non-critically ill adult patients.

Acknowledgments: Hunter New England LHD Clinical Guideline[132]

16. Templates

16.1 Streamlined Individual Patient Use (IPU) declaration form for prescribing Temazepam for sleep disturbance in non-critically ill treatment-naïve adults

Download a fillable copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

This document has been approved for use at [ ]

Streamlined IPU Declaration Form
Temazepam for Sleep Disturbance in Non-Critically Ill Treatment-Naïve^ Adults

This form should be completed prior to prescribing temazepam for sleep disturbance/insomnia in treatment-naïve patients^. Failure to meet the requirements of this form will necessitate a full IPU application. The form should be completed by a consultant or registrar.
^A treatment-naïve patient is a patient who has not taken a medicine for night sedation more than three times in the last 2 weeks.

A. Patient Details

Affix patient label or provide details →	MRN:
	Given names:
	Family name:
	D.O.B or Age:
	Address:

B. Medicine Name and Proposed Dose

Name	Proposed dose
Temazepam 10mg tablet	☐ **5mg at night PRN for sleep** OR ☐ **10mg PO at night PRN for sleep** (Tick dose. Note: 5mg is the recommended dose for older patients)

C. Other Treatment Details

I declare that (tick as appropriate):

☐ the patient does not regularly take temazepam or other benzodiazepines (when at place of residence);
☐ other non-pharmacological approaches, including addressing modifiable causes, have been tried and proven inadequate (but will continue);
☐ sleep disturbance is causing significant distress or harm;
☐ an assessment of the harm to benefit ratio from benzodiazepine use has been undertaken (see Checklist documentation);
☐ the patient is aware of and counselled on the potential harms and benefits, and has provided informed consent (form/verbal guide available);
☐ the initial prescription is for a 'trial' period of 1-3 nights, until the patient is next reviewed by the treating team to decide whether to continue it 'PRN';
☐ if continued after the 'trial' period, the cause of the sleep disturbance, the effect of temazepam on sleep during the trial period, and the effect of other initiated sleep management modalities will be documented in the clinical record;
☐ the treating team will regularly review effectiveness and safety;
☐ the prescription of temazepam will NOT be longer than 2 weeks; and,
☐ the prescription of the temazepam will NOT be continued at discharge or transfer to another unit.

D. Supporting documentation & declaration

☐ *Attach the competed "Checklist for managing sleep complaints in hospitalised non-critically ill adult patients (undertaken in consultation with patient and/or carer)"*

I, _____ , of Treating Team _____,
Name of Consultant or Registrar

have determined it is clinically appropriate to initiate temazepam for inpatient treatment of sleep disturbance for the patient identified above.

►Forward completed form to the Pharmacy Department/ local Drug and Therapeutics Committee delegate

FOR DTC USE ONLY

Date received:

Signed *on behalf of the DTC*: _____ Name:

16.2 Written patient consent form

Initiation of Temazepam for night sedation for sleep disturbance/insomnia

Download a fillable copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

This document has been approved for use at [ ]

WRITTEN PATIENT CONSENT FORM
INITIATION OF TEMAZEPAM FOR NIGHT SEDATION IN ADULTS

The use of sleep medicines such as temazepam, a benzodiazepine, for sleep disturbance or insomnia during hospitalisation carries significant potential for harm with little gain in sleep quality and quantity. Poorer sleep than normal is to be expected in hospital. Non-drug therapy including sleep hygiene measures is the most effective safe treatment for sleep disturbance or insomnia.

This consent form is to ensure that the patient is informed and understands the potential negative consequences of temazepam use. The patient (and/or person responsible) should also receive information about temazepam and sleeping in hospital (booklet) including useful sleep hygiene measures before signing this consent form.

PATIENT CONSENT

By signing this form, I _____ understand that:
(write name of patient / person responsible)

- I /the person I am responsible for will also use sleep hygiene measures to promote sleep during the hospital stay;
- there are no guarantees that temazepam will improve the quantity or quality of sleep during the hospital stay;
- temazepam may cause serious side effects in me/the person I am responsible for including muscle weakness such as falls and fractures, confusion and agitation, short term memory loss, poorer breathing and incontinence and longer hospital stay;
- use of temazepam for more than a few weeks can lead to dependence and cause unwanted effects such as anxiety or sleeplessness if not stopped carefully;
- temazepam will be used at the lowest possible dose for the shortest possible time only when required;
- temazepam may be stopped or the dose reduced during the hospital stay if it is causing harm or is ineffective; and,
- temazepam will not be prescribed for me/the person I am responsible for when leaving this hospital.

I confirm that I have had the opportunity to ask questions and I am satisfied with the explanation and the answers to my questions.

I understand that I can change my mind and withdraw my consent to being treated with temazepam at any time.

With this knowledge, I **consent** to the use of temazepam in the treatment of me/the person I am responsible for.

Patient's name: _____ **MRN:** _____ **Age:** _____

Signature of patient (or person responsible*): _____ **Date:** ___/___/___

If applicable, name & signature of witness: _____ **Date:** ___/___/___
Witness is not to be a member of the treating team. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

*If the person responsible has signed, please provide details below:

Name: _____ **Date of Birth:** ___/___/___

Address: _____ **Contact Number:** _____

Relationship to patient: _____ **Reason for representation:** _____

DOCTOR'S DECLARATION

☐ I have provided to the patient/their person responsible an explanation of the use of temazepam, its potential benefits and harms and the relevant written patient information. I believe the information has been understood.

Please print & sign this form and file with the patients' Health Record.

Doctors name & designation: _____

Signature: _____ **Date:** ___/___/___

If the patient cannot converse adequately in English, please use an accredited Health Care interpreter. Do not rely on relatives or other parties for interpreting.

Language: _____ **Name of interpreter & ID #:** _____

Signature: _____ **Date:** ___/___/___

Completed signed form should be kept in the patient's Health Record.

This consent form is provided to support clinicians when a medicine for night sedation is used in treatment-naive patients.
See http://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/ for further details including a verbal consent guide.
Page 1 of 1 | Initiation of medicine for night sedation | Patient Consent | Dec 2021 | Version 1

16.3 Verbal consent form/guide: Temazepam initiation for night sedation

Download a fillable copy at: https://www.nswtag.org.au/optimising-sleep-in-hospital-guidance-and-resources/

This document has been approved for use at [Click or tap here to enter text.]

Verbal consent form / guide for clinician
Temazepam initiation for night sedation in adults

Alternatively a written consent form may be used. This is also available on the NSW TAG website.

Introduction

1. Introduce yourself to the patient/person responsible. Confirm relevant patient-identifying information.

Verbal consent information provision

2. *I'm here to provide information about the medicine, temazepam, which is being considered to manage your sleep disturbance during your hospital stay. I need to tell you about it and get your consent before prescribing it. Because the use of sleep medicines during hospitalisation carries significant potential for harm with little gain in sleep quality and quantity, it is important you understand the possible benefits and harms of temazepam.*
3. *Here is the Consumer Medicines Information (CMI) leaflet for temazepam, as well as the Sleeping in Hospital Booklet which provides information about useful tips for sleeping in hospital, which is often difficult for many patients.*
   Remember to consider whether further explanation will be needed for some populations e.g. pregnancy/breastfeeding.
   Whenever possible, provide the relevant written information to the patient/person responsible well before requesting consent.

Temazepam
• *Temazepam belongs to a group of medicines called benzodiazepines. These medicines work by acting on brain chemicals that can send you to sleep and may slightly increase sleep time.*
• *These same brain chemicals can also produce unwanted side effects such as [see list below/ CMI]. Benzodiazepines can interact with other medicines such as pain relievers and increase the risk of side effects. Sometimes these medicines make people stay in hospital longer. Use for longer than a few weeks can lead to dependence and withdrawal effects such as anxiety or sleeplessness can occur if stopped suddenly. The CMI leaflet gives more details of side effects.*
• *Temazepam is considered safer than other benzodiazepines because it is shorter acting but still has unwanted side effects.*
• *Temazepam is a tablet and is taken by mouth with a glass of water at night.*
• *It should only be given after careful consideration of whether it might improve sleep with minimal chance of serious side effects.*

4. *It is important for you to know and understand that:*
   - *you /the person you are responsible for will also use sleep hygiene measures to promote sleep during the hospital stay;*
   - *there are no guarantees that temazepam will improve the quantity or quality of sleep during the hospital stay;*
   - *temazepam may cause serious side effects in you/the person you are responsible for including muscle weakness leading to falls and fractures, confusion and agitation, short term memory loss, daytime sleepiness, poorer breathing, incontinence and lengthen the hospital stay;*
   - *use of temazepam for more than a few weeks can lead to dependence and cause unwanted effects if not stopped carefully;*
   - *temazepam will be used at the lowest possible dose for the shortest possible time only when required;*
   - *temazepam may be stopped or the dose reduced during the hospital stay if it is causing harm or is ineffective; and,*
   - *temazepam will not be prescribed for you/ the person you are responsible for when leaving this hospital.*
5. *Your consent to treatment with temazepam is voluntary. If you do not want to have treatment with temazepam, you do not have to. You can always change your mind about temazepam treatment and withdraw consent at any time; just let a member of the healthcare team know.*
6. *Do you have any questions in regard to the information provided, or any other questions about sleeping or temazepam?*
   If yes, answer any questions the patient may have. If no, continue to collect consent.

Patient confirmation of consent

7. *Now that I have provided you with this information, can you [state name of patient/person responsible] please confirm that you:*
   - *understand the proposed use of temazepam including the possible effect on your sleep and possible side effects?*
   - *have had an opportunity to ask questions and that you are satisfied with the answers you have received?*
   - *freely agree to treatment with temazepam?*
     - If no, thank the participant for their time and end the consent process.
     - If yes, ensure you record the date the verbal consent was collected (see documentation guide below).
8. *Thank you for your time.*

Documentation

Either print this form and sign the Doctor's Declaration below and place/scan in medical record OR copy and paste the Doctor's Declaration and insert into patent's electronic medical records with electronic sign-off. Include translator details (as below) if used.

Doctor's declaration: I have provided to the patient/the person responsible an explanation of the use of temazepam, the potential benefit and harms, the relevant CMI leaflet and information about sleeping in hospital. I believe the information has been understood.

Doctor's name & designation: Click or tap here to enter text. **Signature:** _____ **Date:** ___/___/___

If Accredited Health Care Interpreter used, **provide language, Translator's Name, ID#:** Click or tap here to enter text.

Signature: _____ **Date:** ___/___/___

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17. Measuring for improvement: Clinical indicators for optimising sleep in hospital

Health service organisations should regularly assess the implementation of quality use of night sedation medicines and use of non-pharmacological therapies thereby identifying opportunities for improvement. Trends and variations according to wards and treating teams should be identified. The age and patient status for risk of medication-related harm should also be identified. A dashboard and/or reports of relevant process and outcome measures with discussion at the ward level (similar to other hospital-acquired complications) is recommended.

Cost-effectiveness projects incorporating outcome measures and Patient Reported Experience Measures (PREMS) have potential to enable ongoing resourcing of sleep promoting activities and interventions.

Collection of qualitative information regarding the environment (hospital infrastructure, systems, policies and activities) is recommended prior to baseline auditing of night sedation medicines use and related hospital processes. It is recommended that, prior to baseline auditing, the following actions be undertaken:

- a multidisciplinary advisory group of clinicians is convened to advise on the process. (See National Quality Use of Medicines Indicators for Australian Hospitals 2014, pages 6-16);
- executive support for the audit and potential project is sought;
- the context in which the current prescribing of oral night sedation medicines and non-pharmacological interventions occurs is considered and described; and,
- the context in which system-wide strategies that optimise sleep is considered and described. Consider environmental factors, governance frameworks, staff competency and education, patient education, quality processes and risk management to describe the current hospital practices regarding sleep optimisation.

Hospital policy and guidance for sleep optimisation

- Is there executive support for a hospital program to optimise sleep?
- Does the hospital have local policy or guidelines for clinicians that aim to optimise a patient's sleeping in hospital?
- Is a local protocol for sleep hygiene strategies available for clinical use?
    - List system-wide practices including environmental and patient-related strategies that the policy targets and document any potential gaps. Refer to 'Summary poster and checklist of system-wide non-pharmacological interventions to promote sleep in hospital' for examples of strategies to consider.
- Does the hospital have written information about sleeping in hospital including its management that can be provided to patients?
- Does the hospital monitor noise levels in wards at night?
- Does a hospital policy incorporate strategies that determine appropriate lighting, reduce noise and clinical care interruptions at night?
- Does the hospital provide sleep aids such as eye masks, ear plugs or provide an opportunity for purchase?
- Does the health service (routinely) measure the sleep quality of patients (as reported by patients)?
- Do ward meetings routinely discuss patient complaints of sleep disturbance/insomnia, patient reports of sleep quality, use of 'night sedation medicines' and use of sleep hygiene strategies?
- Do (any) wards have clinical champions for optimising patients' sleep?

Presence of hospital training programs

- Do clinicians e.g. ward nurses receive training about counselling and managing sleep disturbances in hospital, particularly non-pharmacological management?
- Do clinicians receive training regarding the harms associated with oral night sedation medication use? For example, is it part of JMO and nursing orientation? Is there dashboard reporting of night sedation issues including adverse events?
- Do clinicians receive training/have access to deprescribing tools for oral night sedation medicines and supporting resources?

DTC processes

- What oral medicines are available/listed on the formulary for night sedation?
- What restrictions are placed on their use? (e.g. prescriber, condition)
- What IPUs are received for oral night sedation medicines?
- Is there a standing agenda item for reporting of oral night sedation medicine use/ incidents related to oral night sedation medicine use?
- Does the eMR provide clinical decision support for the prescribing of oral night sedation medicines?

Risk mitigation processes

- Is there routine reporting of the use of all oral night sedation medicines implicated in incidents to relevant committees including the DTC?
- Does the hospital have a formal referral process for medication review in patients identified at high risk of harm from night sedation medicines?

17.1 Key Performance Indicator bundle

The following clinical indicators are recommended as a starting point for a hospital assessing sleep management in non-critically ill hospitalised patients to obtain baseline data and for measuring ongoing performance following implementation of quality improvement strategies. Additional indicators may be considered by the multidisciplinary clinician expert advisory group (EAG). If possible, balancing measures (to check improvement in one part of the system does not cause new problems in another part of the system) should be included in the baseline audit. The project's multidisciplinary clinician EAG should determine which indicators should be used, the composition of the sample and its size.

Purpose of indicator bundle: Assess the effectiveness and safety of processes that encourage optimal non-pharmacological and pharmacological management of sleep disturbance or insomnia in hospitalised non-critically ill patients.

Sample: all non-critically ill adult patients in ward(s).
(The sample may be further restricted but this is not recommended for baseline audit when the current effectiveness and safety of pharmacological and non-pharmacological management for sleep in the hospital is being studied. An example of a restricted sample would be to limit to those aged over 60 years of age who are the most likely to experience adverse events. See NSW TAG Polypharmacy Indicators).

Exclusions: palliative care patients, patients in critical care wards, children and adolescents <16 years of age.

Primary outcome measures: percentage of all/treatment-naïve/non-treatment-naïve patients prescribed an oral medication for night sedation during hospitalisation.

Secondary outcome measures:

- adherence to requirements for appropriate prescribing i.e. documented indication, appropriate dose, appropriate dosing instructions i.e. PRN/stat inclusion and documentation of prescribed duration, time of prescribing (e.g. before or after 8pm); prescribing at discharge; frequency of actual use.
- incidence of adverse events related to night sedation use e.g. falls, delirium, confusion, daytime sedation, incidents of respiratory depression.
- use of non-pharmacological measures that promote sleep. Consider measuring individual utilisation of sleep hygiene practices and identification of individual patient's remediable risk factors for sleep disturbance.

Included in the data collection for all the indicators should be treatment status prior to hospitalisation (i.e. naïve/ non-naïve/ unknown), age and sex, the prescriber status (i.e. JMO, registrar, consultant, nurse practitioner), prescribing team, treating team, ward, the specific oral night sedation medicine prescribed and ideally the patient's potential risk of harm status from night sedation medicines (see NSW TAG Polypharmacy tools). Also consider inclusion of interacting medicines e.g. opioids and relevant co-morbidities (possibly free-text). Choice of which night sedation medicines to audit will be influenced by contextual information. The multidisciplinary clinician EAG should consider balancing indicators that require measurement at baseline such as non-benzodiazepine prescriptions in case their prescribing in treatment-naïve patients accompanies reduced benzodiazepine prescribing after quality improvement strategies are implemented.

Some of the proposed indicators could be collated in the one data collection tool given they share the same denominator.

Ideally Patient Reported Experience and Outcome Measures would be included in a future Core Key Performance Indicator Bundle. However, at this stage, there are no validated PREMs or PROMs for measuring sleep experience or outcomes in this patient population of hospitalised non-critically ill patients.

Prescribing of night sedation medicines

Appropriate medicine prescribing:

- *Percentage of non-critically ill patients prescribed an oral night sedation medicine with documented indication and appropriate dosing.*

Safe prescribing:

- *Percentage of non-critically ill patients prescribed an oral night sedation medicine who experience an adverse event (in-hospital fall, confusion, delirium, respiratory depression).*
- *Percentage of non-critically ill patients prescribed an oral night sedation medication on index admission who are re-admitted within 30* days.
- *Percentage of non-critically ill patients who are prescribed a night sedation medicine at discharge.*
- *Percentage of non-critically ill patients prescribed a night sedation medicine who have been appropriately assessed for risk of night sedation medicine-related impairment of cognitive and/or physical function including falls.*
- *Percentage of non-critically ill patients prescribed a night sedation medicine who receive a hospital-based medication review and/or a deprescribing plan.*

Implementation of individual-related non-pharmacological interventions

- *Percentage of non-critically ill patients who have clinical care interventions at night.*
- *Percentage of non-critically ill patients who utilise sleep hygiene strategies.*

Included in the data collection for the above indicator would be individual sleep hygiene measures e.g. no television watching or use of mobile devices after 10pm, use of eye masks, use of ear plugs, use of white noise, or other strategies utilised by hospital staff or planned as part of a quality improvement project.

Information provision

- *Percentage of non-critically ill patients who receive written and verbal information regarding the non-pharmacological and pharmacological management of sleep.*

Included in the data collection for the above indicator should be when the patient received the information: 1) prior to or at admission; after hospitalisation, prior to or at discharge; or both. Location of information provision and by whom may also be informative.

17.2 Other relevant indicators

NSW TAG has developed relevant validated process indicators that may be used to monitor quality use of night sedation medicines.[133] These indicators (5.7, 8.2, 8.3, 8.4, 8.5) and supporting resources can be found at https://www.nswtag.org.au/qum-indicators/.

Risk Assessment

- Polypharmacy QUM Indicator 8.2: Percentage of older patients that are appropriately assessed for risk of medication-related falls.
- Polypharmacy QUM Indicator 8.3: Percentage of older patients that are appropriately assessed for risk of medication-related impairment of cognitive and/or physical function.

Discharge

- Continuity of care indicator 5.7: Percentage of patients receiving sedative/hypnotics at discharge that were not taking them at admission.

Medication review

- Polypharmacy QUM Indicator 8.4: Percentage of older patients identified at high risk for medication-related harms that receive a hospital-based medication review and, if applicable, a deprescribing plan. (Many patients prescribed night sedation medicines will meet high risk of medication –related harm criteria.)
- Polypharmacy QUM Indicator 8.5: Percentage of older patients at high risk of medication-related harms with a recommendation for a post-discharge medication review, when hospital-based medication review is not performed.

Other process measures (generally non-validated) have been identified during the literature review[134], medicine use evaluation projects at Australian health service organisations[135,136] and reviews of hospital policies and clinical guidelines.[132]

17.3 Patient Reported Measures

The application of Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) to evaluate patient reported experience and outcomes is encouraged to highlight the importance of good sleep in hospital and evaluate the success of any implemented strategies. Current validated sleep measures are usually used for research purposes, are often long and do not focus on the non-critically ill patients. Further work in this area is recommended.

Some examples include:

- Polypharmacy Patient Reported Experience Measures on deprescribing and medication changes. See: https://www.nswtag.org.au/wp-content/uploads/2020/11/Polypharmacy-Patient-Reported-Experience-Measures_Nov2020.pdf
- Validated sleep measures include the Richards-Campbell Sleep Questionnaire (RCSQ), the Pittsburgh Sleep Quality Index[137,138], the NRS—Sleep scale[139] and St Mary's Sleep Questionnaire[140].

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Part E: Abbreviations

ABF: Activity Based Funding

BZDs: Benzodiazepines

CBT-I: Cognitive Behavioural Therapy for Insomnia

CNS: Central Nervous System

COPD: Chronic obstructive pulmonary disease

DTC: Drug and Therapeutics Committee

IPU: Individual Patient Use

GABA: Gamma aminobutyric acid

HAC: Hospital Acquired Complications

PBS: Pharmaceutical Benefits Scheme

PRN: Pro re nata

QUM: Quality Use of Medicines

TGA: Therapeutic Goods Administration

Part F: Glossary

Activity Based Funding: describes a hospital funding model whereby hospitals are paid for the number and mix of patients they treat thereby facilitating efficiency, safety and quality consistent with national standards.

Benzodiazepines (sometimes abbreviated to BZDs): a class of medicines used as anxiolytics, sedatives, hypnotics, anticonvulsants and skeletal muscle relaxants.[141] They enhance $GABA_A$ receptor function, by increasing the affinity of the receptor to GABA, leading to inhibition of various central nervous system activity. All benzodiazepines have similar pharmacological profiles and clinical effects but differ in their selectivity to the various $GABA_A$ receptors. Their use in various conditions is a reflection of the way specific benzodiazepines have been marketed and their pharmacokinetic and potency differences.

Drug and Therapeutics Committee: a multidisciplinary committee assigned the responsibility for governance of the medicines management system in their health service organisation to ensure judicious, appropriate, safe, effective and cost-effective use of medicines.

Cognitive behavioural therapy: Treatment with educational, cognitive and behavioural interventions that aim to change unhelpful thoughts, habits and beliefs about sleep.[142] It may include stimulus control, sleep restriction therapy, relaxation techniques, cognitive therapy and sleep hygiene education. It may be provided in-person or be internet-based.

Hypnotic drugs: produce drowsiness and facilitate the onset and maintenance of a state of sleep and from which the recipient can be aroused easily.[141]

Non-restorative sleep: is characterised by a lack of slow wave sleep and REM sleep (which normally provides the physiological and psychologically restorative components of sleep). Critical care research indicates these two restorative stages of sleep are rarely achieved and potentially this might be reflected in non-critical care areas due to the sleep disturbing factors.[6]

Night sedation medicines: for the purposes of this document, describes any medicine with sedative or hypnotic activity that may be used to manage night-time sleep disturbance or insomnia (on-label or off-label use).

Non-treatment naïve patient: for the purposes of this document, a patient who routinely uses night sedation medicines for chronic insomnia (e.g. has taken a 'night sedation medication' more than three times in the last 2 weeks) at their place of residence or a hospital patient who has recently taken 'night sedation medication' during critical care management.

Off-label (vs on-label): The term 'off-label' is applied when a medicine is used in ways other than specified in the Australian Therapeutic Goods Administration (TGA) approved product information.

Person-centred care: an approach to the planning, delivery and evaluation of health care that is founded in mutually beneficial partnerships among clinicians and patients. Person-centred care is respectful of, and responsive to, the preferences, needs and values of patients and consumers. Key dimensions of person-centred care include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of family and carers, and access to care.[143]

PRN: as required/ when necessary

Sedative drugs: decrease activity, moderate excitement, and calm the recipient. Many drugs that are not CNS depressants have sedative activity e.g. antihistamines and antipsychotics.[141]

Sleep hygiene education: Educational non-pharmacological program that emphasises environmental and non-environmental factors, behaviour and habits that promote sleep.[9] It includes reduced caffeine intake, avoidance of alcohol, adequate exercise (not before bedtime), not napping, avoidance of electronic devices before bedtime and regular sleep and wake times.

Sleep onset latency: the time it takes to fall asleep.

Treatment naïve patient: for the purposes of this document, a patient who has not taken a 'night sedation medicine' for sleep disturbance/insomnia more than three times in the last 2 weeks.

Z-class drugs: are also known as 'Z-drugs' or 'benzodiazepine-related hypnotics'. Registered Z-class drugs in Australia are Zopiclone and zolpidem.

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Part G: References

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PART H: Guidance development & acknowledgments

Guidance development

This guidance was prepared by a Project Team (SB, SD and SH), with the support and advice regarding content and scenario development from a multidisciplinary Subject Matter Expert Advisory Group (see acknowledgements for detail), which was convened by the NSW Therapeutic Advisory Group (TAG) Editorial Committee, as per its published guidance development processes [link]. Guidance development included a) review of published research evidence; b) input from a multi-disciplinary group of health professionals from hospital and primary care settings with recognised expertise in geriatric medicine; adult clinical pharmacology and therapeutics; addiction medicine; health technology assessment and medicines evaluation and clinical pharmacy; and, c) external consultation via invitation with recognised expertise in sleep management and/or hospital work practices.

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