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MCCN Supra-Regional Audit of Insomnia Management in Palliative Care

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Outline

- Review of current guidelines & standards
  - Phil Swarbrick
- Literature Review
  - Andrew Khodabukus
- Audit Data
  - Clinical Practice Evaluation: Richard Latten
  - Case-note audit: Jenny Smith & Barbara Humphries
- Proposed new guidelines & standards
  - Carolyn Watt

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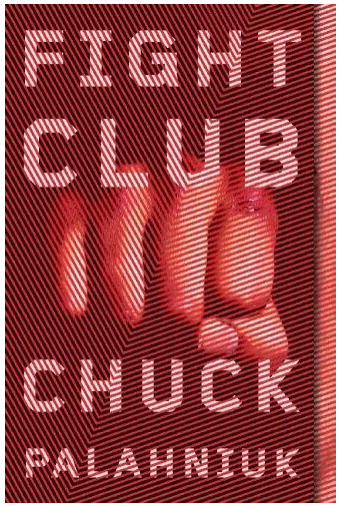
Existing Standards & Guidelines

When you have insomnia,
you're never really asleep, and
you're never really awake.

Chuck Palahniuk



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Guidelines [slide 1/11]

- It is important to **take a sleep history from all patients**. The nature of any disturbance, its duration and effect on every day functioning should be documented in the notes. [Level 4]

- **A cause of the sleep disturbance should be identified** where possible (see Table)

Guidelines [slide 2/11]

Causes of insomnia	
Age related (i.e. Extension of normal physiological changes)	Drug induced (e.g. Diuretics, corticosteriods, stimulants, bronchodilators)
Alcohol	Drug withdrawal (e.g. Benzodiazepines, alcohol)
Anxiety	Environmental (e.g. Noise levels, light)
Breathlessness	Hallucinations / nightmares
Bladder / bowel symptoms (e.g. Nocturia)	Other uncontrolled symptoms e.g. Sweating, pruritus
Cognitive impairment / delirium	Pain
Depression	

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Guidelines [slide 3/11]

- **Depression and anxiety are common causes** of insomnia and should be identified and treated as appropriate. [Level 4]

- **Drugs** which may contribute to insomnia (e.g. corticosteroids, diuretics, stimulant antidepressants and other stimulants) **should be reviewed and discontinued** where possible. If corticosteroids are required they should be administered before 2pm. [Level 4]

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Guidelines [slide 4/11]

- The management of insomnia may include non-pharmacological and pharmacological measures. [Level 4]
- Non-pharmacological measures include:
  - the avoidance of sleep during the day;
  - increasing daytime exercise where appropriate;
  - minimisation of sleep interruption;
  - relaxation techniques;
  - addressing existing fears and anxiety,
  - improvements in sleep hygiene.

Guidelines [slide 5/11]

- **Sleep hygiene** will consist of simple advice such as:
  - get up and go to bed at same time;
  - keep bedroom dark, quiet and cool;
  - avoid reading or watching TV in bed;
  - don’t exercise in the evening;
  - avoid caffeine, alcohol and nicotine in the evening. [Level 4]

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Guidelines [slide 6/11]

- **Pharmacological measures should be used with caution**. Medication should be prescribed at the **lowest possible dose** and for the **shortest period of time**. Table 23.2 lists some of the commonly used drugs in the management of insomnia. [Level 4]

- Patients requiring medication should be **reviewed at regular intervals**. Drugs that are ineffective should be discontinued. [Level 4]

Guidelines *[slide 7/11]*

Drugs used in management of insomnia [Level 4]			
Medication	*Oral dose*	*Duration of action / class of drug*	*Notes*
Diazepam	2mg – 5mg nocte	Long acting benzodiazepine	Useful if there is co-existing anxiety. Monitor for hangover effect
Lorazepam	0.5mg – 1mg nocte (sublingual)	Short acting benzodiazepine	Little hangover effect, promotes sleep onset and maintenance
Lormetazepam	0.5mg – 1mg nocte	Short acting benzodiazepine	Little hangover effect, promotes sleep onset and maintenance
Mirtazepine	7.5mg – 15mg nocte	Long acting NaSSa	Useful if co-existing depression, lower doses more sedative e.g. ≤15mg
Nitrazepam	5mg – 10mg nocte	Long acting benzodiazepine	Monitor for hangover effect, promotes sleep maintenance
Pregabalin	25mg – 300mg nocte	Anti-epileptic	Promotes REM sleep. Appears to be useful in patients with anxiety. Withdraw gradually
Temazepam	10mg – 40mg nocte	Intermediate acting benzodiazepine	Monitor for hangover effect. Promotes sleep onset and maintenance
Zolpidem	5mg – 10mg nocte	Short acting imidazopyridine	Little hangover effect, promotes sleep onset
Zopiclone	3.75mg – 15mg nocte	Short acting cyclopyrrolone	Little hangover effect, promotes sleep onset

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Guidelines [slide 8/11]

- **Caution** must be exercised **in older patients** as many of the drugs used in the management of insomnia cause postural hypotension and urinary retention. These may in turn lead to poor mobility, falls and increasing agitation. [Level 4]

Guidelines [slide 9/11]

- All **benzodiazepines** have a significant side effect profile. These include dizziness, confusion, ataxia, dependence, paradoxical agitation and postural hypotension. [Level 4]

- **Haloperidol** may be used for the management of nightmares and hallucinations but it **has little sedative effect**. [Level 4]

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Guidelines [slide 10/11]

- The **role of antidepressants** in the management of insomnia **is unclear**. If they are used, those with sedative properties should be preferred over drugs such as SSRIs which tend to have more activating properties. The dose should be as low as possible e.g. mirtazapine 7.5mg-15mg; trazodone 50 mg; trimipramine 25mg. [Level 4]

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Guidelines [slide 11/11]

- If **mirtazapine** is used it is important to remember that it may be associated with **blood dyscrasias**. Patients should be advised to report fevers, sore throats, stomatitis or other signs of infection during treatment. A blood count should be performed and the drug stopped immediately if a blood dyscrasia is suspected. [Level 4]

  (see *Guidelines for Managing Depression in Palliative Care*)

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Standards [slide1/2]

1. Any **disturbance** in sleep should be **documented** in the case notes. [Grade D]

2. Any **reversible causes** of insomnia should be **identified and treated** where appropriate. [Grade D]

3. The **regular medication** of all patients with insomnia should be **reviewed** [Grade D]

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Standards [slide 2/2]

4. Current or previous use of **night sedation** and its **effectiveness** should be **documented**. [Grade D]

5. Patients commenced on night sedation should be **reviewed within 4 weeks**. Ineffective medication should be discontinued. [Grade D]

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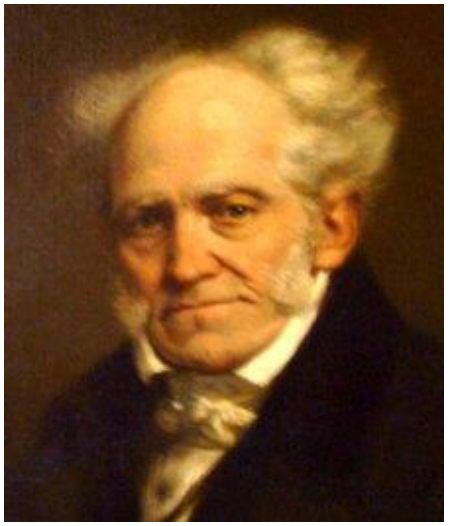
Literature Review

Sleep is the interest we have to pay on the capital which is called in at death; and the higher the rate of interest and the more regularly it is paid, the further the date of redemption is postponed.

Arthur Schopenhauer



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Outline

- Definitions
- Updated Evidence
- Updated Guidelines

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Definitions

- International Classification of Sleep Disorders
- International Classification of Diseases (ICD-10)
- Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)

Definition of insomnia: Diagnostic criteria

	A	B	C
International Classification of Sleep Disorders (ICSD) and Research Diagnostic Criteria for Insomnia (RDC) (Edinger et al., 2004)	Difficulty – initiating sleep, – maintaining sleep, – waking up too early or – sleep is chronically non-restorative or poor in quality	Occurs despite adequate opportunity and circumstances for sleep	At least one form of daytime impairment i. Fatigue or malaise ii. Attention, concentration, or memory impairment iii. Social or vocational dysfunction or poor school performance iv. Mood disturbance or irritability v. Daytime sleepiness vi. Motivation, energy, or initiative reduction vii. Proneness for errors or accidents at work or while driving viii. Tension, headaches, or gastrointestinal symptoms in response to sleep loss ix. Concerns or worries about sleep
International Classification of Diseases ICD-10 (1992)	Difficulty – falling asleep, – maintaining sleep or – non-refreshing sleep	3 times a week and for longer than 1 month	Marked personal distress or interference with personal functioning in daily living
Diagnostic and Statistical Manual of Mental Disorders DSM-IV	Predominant complaint – difficulty initiating sleep – difficulty maintaining sleep or – non-restorative sleep	For at least 1 month	Clinically significant distress or impairment in social, occupational, or other important areas of functioning

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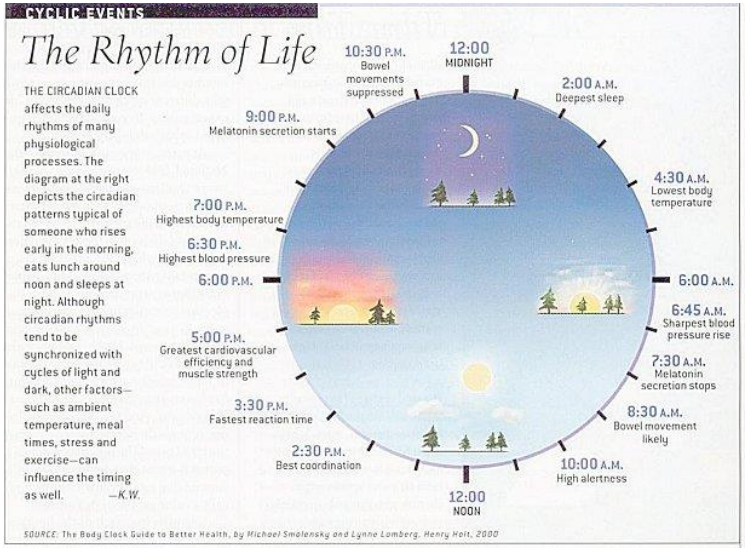
Sleep Disorders

- Insomnia
- Circadian Rhythm Disorder
- Parasomnia



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Epidemiology

- General Population
  - 5%-15%[1]
- Chronic Ill Health
  - 15%-30%[2]
- Palliative Care Populations
  - 23%-70%[3,4]

1. Costa e Silva JA, Chase M, Sartorius M, Roth T. Special report from a symposium held by the World Health Organization and the World Federation of Sleep Research Societies: an overview of insomnias and related disorders -- recognition, epidemiology, and rational management. *Sleep* 1996;19:412-416
2. Morin CM, Hauri PJ, Espie CA, Spielman AJ,Buysse DJ, Bootzin RR. Nonpharmacologic treatment of chronic insomnia: an American Academy of Sleep Medicine review. Sleep1999;22:1134-1156
3. Sela RA, Watanbe S andNekolaichuk CL.Sleep disturbances in palliative cancer patients attending a pain and symptom control clinic. *Palliative & Supportive Care* 2005, 3 , pp 23-31
4. Kvale EA, Shuster JL. Sleep disturbance in supportive care of cancer: a review. *Journal of Palliative Medicine*. 2006, 9(2): 437-450

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Literature Search

Insomnia Terms	Palliative Terms
Medline: 117953 SCOPUS: 318480 WoK: 439105 CiNAHL: 28003	Medline: 58400 SCOPUS: 23099 WoK: 136893 CiNAHL: 33683

Medline: 397 → 17
SCOPUS: 1214 → 24
WoK: 582 → 26
CiNAHL: 273 → 20
Combined: → 45, 8 since 2009 update

- Search Terms:
  - insomni* OR sleep* OR "sleep-disorders" OR "sleep disorders" OR "sleep disturbance*" OR sleeplessness.
  - palliative care OR (palliative treatment or palliative medicine) OR terminal care OR terminally ill OR end-of-life care OR end-of-life
- These were then combined
- Inclusion – English, review or study articles focussing on insomnia

Recent Articles - Trials

- **Barton et al 2011**: 227 patients randomised to receive valerian and placebo. 119 completed study. No significant difference in insomnia

Barton DL, Atherton PJ, Buer BA *et* al. The Use of Valeriana officinalis (Valerian) in Improving Sleep in Patients Who Are Undergoing Treatment for Cancer: A Phase III Randomized, Placebo-Controlled, Double-Blind Study (NCCTG Trial, N01C5) *The Journal of supportive oncology 2011,* [1544-6794] 9 (1) 24 -31

Recent Articles – Observational Studies

- **Delgado-Guay et al 2011**: completed Edmonton Symptom Assessment Scale and Philadelphia Sleep Quality Inventory assessments of 101 US patients with advanced cancer who were receiving palliative care.
  - Sleep disturbance is associated with increased frequency of pain, depression, anxiety, and a worse sense of well-being.

Delgado-Guay M, Yennurajalingam S, Parsons H *et al*. Association Between Self-Reported Sleep Disturbance and Other Symptoms in Patients with Advanced Cancer, *Journal of Pain and Symptom Management*, Volume 41, Issue 5, May 2011, Pages 819-827

Recent Articles – Observational Studies

- **Eyigor et al 2010**: 53 <60yrs and 47 >60yrs hospitalised US patients assessed
  - showed significant association between pain, fatigue and sleep problems.
  - No difference between the two groups

Eyigor S, Eyigor C, Uslu R. Assessment of pain, fatigue, sleep and quality of life (QoL) in elderly hospitalized cancer patients, *Archives of Gerontology and Geriatrics*, 51(3), 2010, e57-e61

Recent Articles – Observational Studies

- **Wells-Di Gregorio et al 2010**: assessed 168 consecutive US palliative care outpatients.
  - 85% reported difficulty sleeping,
  - 55% reporting severe distress related to not sleeping well.
  - Worry was a significant predictor of insomnia beyond pain and depression (p 0.028)

Wells-Di Gregorio S, Gustin J, Marks D *et al*. Worry as a Significant Predictor of Insomnia among Palliative Care Patients with Advanced Cancer, *Journal of Pain and Symptom Management*, 39(2), 2010, 335-336

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Recent Articles – Observational Studies

- **Mystakidou et al 2010**: assessed 82 advanced cancer patients referred to a palliative care unit in Greece
  - 96% reported poor sleep,
  - Strongest predictors of poor sleep were SF physical and mental quality of life and post traumatic stress disorder (via IES-R questionnaire)

Mystakidou K, Parpa E, Tsilika E *et al*. How is sleep quality affected by the psychological and symptom distress of advanced cancer patients? *Palliative Medicine*. 23(1) 2009 46-53

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Recent Articles – Reports & Reviews

- **Dando et al 2009:** Case report of insomnia due to obstructuve sleep apnoea from tonsillar carcinoma exacerbated by temazepam
- **Innominato et al 2009**: reviewed the effect of circadian disruption and its effects on fatigue and anorexia. Suggests developing medication to help target this

Dando N, England S, Ford-Dunn S. An unusual cause of insomnia. *Palliative Medicine*, 23(5), 2009, 471-472
Innominato PF, Mormont M-C, Rich TA *et al*. Circadian Disruption, Fatigue, and Anorexia Clustering in Advanced Cancer Patients: Implications for Innovative Therapeutic Approaches. *Integrated Cancer Therapies* 8(4) 2009: 361-370

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Updated Guidelines

- NICE TA077 (newer hypnotic drugs) *April 2004* → static guidance list *August 2010*

- British Association for Psychopharmacology (BAP) consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders *September 2010*

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BAP Consensus Statement – Psychological Treatment

- CBT-based treatment packages for chronic insomnia including sleep restriction and stimulus control are effective and therefore should be offered to patients as a first-line treatment (Grade A).

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BAP Consensus Statement – Hypnotics

- Factors which clinicians need to take into account when prescribing are efficacy, safety, and duration of action (Grade A).
- Other factors are previous efficacy of the drug or adverse effects, history of substance abuse or dependence (Grade D).
- Use as clinically indicated (Grade A).

BAP Consensus Statement – Antidepressants

- Use drugs according to a knowledge of pharmacology (Grade A).
- Consider antidepressants when there is coexistent mood disorder but then use at therapeutic doses (Grade A).
- Beware toxicity of tricyclic antidepressants in overdose even when low unit doses prescribed (Grade A).

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BAP Consensus Statement – Antipsychotics & Antihistamines

- Side effects are common because of the pharmacological actions of anti-psychotics and there are a few reports of abuse.

- Antihistamines have a limited role in psychiatric and primary care practice for the management of insomnia (Grade D).

- Together these indicate no indication for use as first-line treatment (Grade D).

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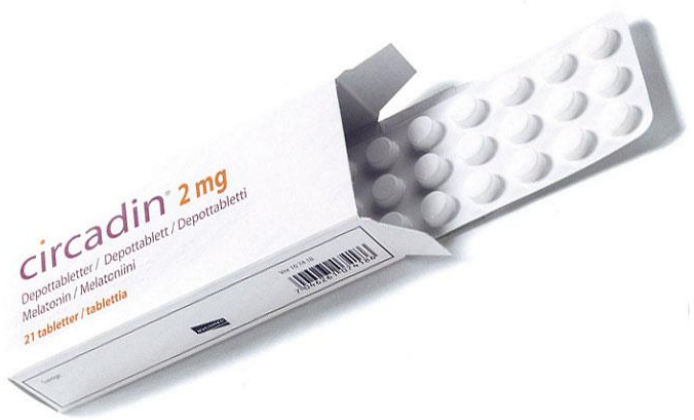
BAP Consensus Statement – Insomnia in Elderly Populations

- CBT is effective and should be offered as a first line where available (Grade A)
- When a hypnotic is indicated in patients over 55, prolonged- release melatonin should be tried first (Grade B)
- If a $GABA_A$ hypnotic is used then a shorter half-life will minimize unwanted hangover (Grade A)

Melatonin

- 2mg tablets taken 1-2hrs before bedtime & after food
  - Licensed for up to 13 weeks for insomnia in those aged 55 and older as monotherapy
  - Well tolerated in trials
- Effect of benzodiazepines and opiates with Circadin not studied (naturally interfere with endogenous melatonin metabolism)
- Cost (BNF Sep 2011)
  - Melatonin 2mg: 51p
  - Zopiclone 7.5mg = 6p
  - Lorazepam 1mg = 23p



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Existing Standards

1. Any disturbance in sleep should be documented in the case notes. ☑

2. Any reversible causes of insomnia should be identified and treated where appropriate. ☑

3. The regular medication of all patients with insomnia should be reviewed ?

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Existing Standards

4. Current or previous use of night sedation and its effectiveness should be documented.

5. Patients commenced on night sedation should be reviewed within 4 weeks. Ineffective medication should be discontinued.

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Proposed New Standards & Guidelines

It is a common experience that a problem difficult at night is resolved in the morning after the committee of sleep has worked on it..

John Steinbeck

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Proposed Guidelines [slide1/13]

- It is important to take a sleep history from all patients. The nature of any disturbance, its duration and effect on every day functioning should be documented in the notes. [Level 4]

- A cause of the sleep disturbance should be identified where possible (see Table) [Level 4]

Proposed Guidelines [slide 2/13]

Causes of insomnia	
Age related (i.e. Extension of normal physiological changes)	Medication induced (e.g. Diuretics, corticosteriods, stimulants, bronchodilators, stimulant anti-depressants)
Alcohol	Medication withdrawal (e.g. Benzodiazepines, alcohol)
Anxiety	Drug withdrawal e.g. Alcohol, nicotine, recreational drugs
Breathlessness	Environmental (e.g. Noise levels, light)
Bladder / bowel symptoms (e.g. Nocturia)	Hallucinations / nightmares
Cognitive impairment / delirium	Other uncontrolled symptoms e.g. Sweating, pruritus
Depression	Pain

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Proposed Guidelines [slide 3/13]

- Pain, depression and anxiety are common causes of insomnia and should be identified and treated as appropriate. [Level 4]

- Drugs which may contribute to insomnia (e.g. corticosteroids, diuretics, stimulant antidepressants and other stimulants) should be reviewed and discontinued where possible. If corticosteroids are required they should be administered before 2pm. [Level 4]

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Proposed Guidelines [slide 4/13]

- The management of insomnia may include non-pharmacological and pharmacological measures. [Level 4]
- Non-pharmacological measures include:
  - Psychological interventions e.g. Cognitive Behavioral Therapy
  - the avoidance of sleep during the day;
  - increasing daytime exercise where appropriate;
  - minimisation of sleep interruption;
  - relaxation techniques;
  - addressing existing fears and anxiety,
  - improvements in sleep hygiene.

Proposed Guidelines [slide 5/13]

- Sleep hygiene will consist of simple advice such as:
  - get up and go to bed at same time;
  - keep bedroom dark, quiet and cool;
  - avoid reading or watching TV in bed;
  - don't exercise in the evening;
  - avoid caffeine, alcohol and nicotine in the evening. [Level 4]

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Proposed Guidelines [slide 6/13]

- Pharmacological measures should be used with caution. Medication should be prescribed at the lowest possible dose and for the shortest period of time. Table 23.2 lists some of the commonly used drugs in the management of insomnia. [Level 4]

- Patients requiring medication should be reviewed at regular intervals. Drugs that are ineffective should be discontinued. [Level 4]

Proposed guidelines [slide 7/13]

Hypnotic drugs used in management of insomnia [Level 4]			
Medication	*Oral dose*	*Duration of action / class of drug*	*Notes*
Diazepam	2mg – 5mg nocte	Long acting benzodiazepine	Useful if there is co-existing anxiety. Monitor for hangover effect
Lorazepam	0.5mg – 1mg nocte (sublingual)	Short acting benzodiazepine	Little hangover effect, promotes sleep onset and maintenance
Lormetazepam	0.5mg – 1mg nocte	Short acting benzodiazepine	Little hangover effect, promotes sleep onset and maintenance
Nitrazepam	5mg – 10mg nocte	Long acting benzodiazepine	Monitor for hangover effect, promotes sleep maintenance
Temazepam	10mg – 40mg nocte	Intermediate acting benzodiazepine	Monitor for hangover effect. Promotes sleep onset and maintenance
Zolpidem	5mg – 10mg nocte	Short acting imidazopyridine	Little hangover effect, promotes sleep onset
Zopiclone	3.75mg – 15mg nocte	Short acting cyclopyrrolone	Little hangover effect, promotes sleep onset

Proposed guidelines [slide 8/13]

Adjuvant drugs used in management of insomnia [Level 4]			
Medication	*Oral dose*	*Duration of action / class of drug*	*Notes*
Mirtazepine	7.5mg – 15mg nocte	Long acting NaSSa	Useful if co-existing depression, lower doses more sedative e.g. ≤15mg
Pregabalin	25mg – 300mg nocte	Anti-epileptic	Promotes REM sleep. Appears to be useful in patients with anxiety. Withdraw gradually
Haloperidol	See guidelines for management of delirium	Long acting dopamine antagonist	Haloperidol may be used for the management of nightmares and hallucinations but it has little sedative effect.

Proposed guidelines [slide 9/13]

- Caution must be exercised in older patients as many of the drugs used in the management of insomnia cause postural hypotension and urinary retention. These may in turn lead to poor mobility, falls and increasing agitation. [Level 4]

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Proposed guidelines [slide 10/13]

- Zopiclone is a short acting cyclopyrrolone and aims to initiate sleep. A dose of 7.5mg is recommended, with 3.75mg initially for older patients. Maximum plasma concentrations are achieved after 1½ - 2 hours and is not affected by food. The most common side effect is a metallic taste. Withdrawal and rebound insomnia have occasionally been observed on discontinuation of treatment, mainly in association with prolonged treatment.

(source Summary of product characteristics, eMedicines)

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Proposed guidelines [slide 11/13]

- All benzodiazepines have a significant side effect profile. These include dizziness, confusion, ataxia, dependence, paradoxical agitation and postural hypotension. [Level 4]

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Proposed guidelines [slide 12/13]

- The role of antidepressants in the management of insomnia is unclear. If they are used, those with sedative properties should be preferred over drugs such as SSRIs which tend to have more activating properties. The dose should be as low as possible [Level 4] ~~e.g. mirtazapine 7.5mg-15mg; trazodone 50 mg; trimipramine 25mg.~~

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Proposed guidelines [slide 13/13]

- If mirtazapine is used it is important to remember that it may be associated with blood dyscrasias. Patients should be advised to report fevers, sore throats, stomatitis or other signs of infection during treatment. A blood count should be performed and the drug stopped immediately if a blood dyscrasia is suspected. Lower doses (≤15mg) are more sedative. [Level 4]

  (see *Guidelines for Managing Depression in Palliative Care*)

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Proposed standards

1. Assessment and documentation of patient quality of sleep should be part of specialist palliative care assessment [Grade D]

Existing standard:

Any disturbance in sleep should be documented in the case notes. [Grade D]

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Proposed standards

2. For patients with insomnia, reversible causes (see table) should be identified, treated where appropriate and recorded in case-notes [Grade D]

Existing standards:

- *Any reversible causes of insomnia should be identified and treated where appropriate. [Grade D]*
- *The regular medication of all patients with insomnia should be reviewed [Grade D]*

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Proposed standards

3. Measures (pharmacological and non-pharmacological) taken to improve sleep quality should be reviewed and effectiveness documented. [Grade D]

Existing standard:

Current or previous use of night sedation and its effectiveness should be documented. [Grade D]

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Proposed standards

4. Patients commenced on hypnotic medication should be reviewed within 7 days for inpatient settings and 14 days for community setting. Ineffective medication should be discontinued following dose optimisation [Grade D]

Existing standard:

Patients commenced on night sedation should be reviewed within 4 weeks. Ineffective medication should be discontinued. [Grade D]

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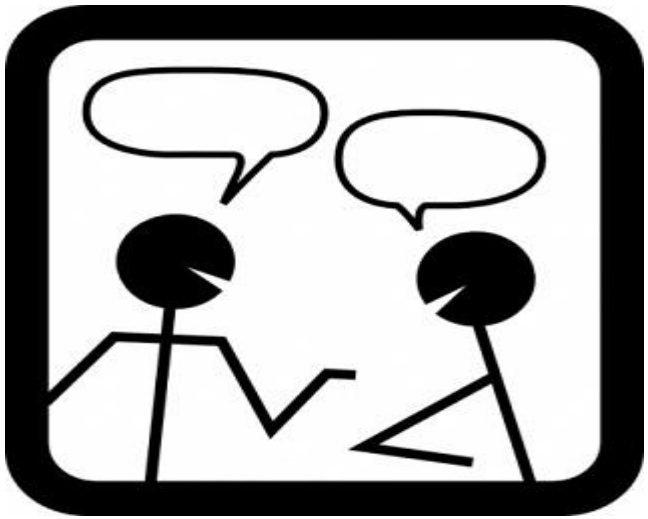
Some Points for Debate

- Should timing of reassessment be shortened from 4 weeks – 1-2 weeks?
- Should timing of reassessment differ between healthcare setting?



- Your other thoughts and comments