Te Awakairangi Health NETWORK

Clinical Audit (MOPs accredited until 2018) **March 2014**

Appropriate prescribing of hypnotic medicines in Primary Care

BACKGROUND

Most people develop insomnia secondary to an identifiable stressor - medical or psychiatric condition, poor sleep practice, medicine or substance abuse. Non drug therapies are directed at the physiological, psychological, behavioural and environmental factors that affect sleep. These interventions are considered in the literature to be comparable in efficacy to the use of benzodiazepines and other related medicines. (1)

The Evidence

In short-term insomnia there is good evidence for the efficacy of hypnotic drugs; however, for many years the risks associated with the long term use of hypnotic drugs have been well recognized. These include falls, accidents, cognitive impairment, dependence and withdrawal symptoms. A recent observational study by Billioti de Gage et al in 2012, suggested that benzodiazepines and what are termed the 'Z' drugs (e.g. in New Zealand zopiclone) are also associated with an increased risk of dementia. (4, 6, 8)

In older people in particular, the magnitude of the beneficial effects of hypnotics may not justify the increased risk of adverse effects (e.g. cognitive impairment and increased risk of falls).
A meta-analysis published in the BMJ (2) compared the Numbers Needed to Treat (NNT) to the Numbers Needed to Harm (NNH)

- NNT = 13 people aged $\geq$ 60 years need to be treated with a hypnotic medicines for up to one month, instead of a placebo to improve sleep in 1 person
- NNH = 6 people, less than half that number, treated leads to an adverse effect, including fatigue, cognitive impairment and serious events involving falls, fractures and motor vehicle accidents

Avoiding hypnotic use where possible, especially in older people is advised. If drug treatment cannot be avoided, warn patients and their care givers about the risk of adverse effects. Hypnotic therapy should only be considered after due consideration of the use of non-pharmacological measures and where insomnia is considered severe, disabling or causing the patient extreme stress.

Table 1. Best Practice for prescribing hypnotics

- after due consideration of the use of non-pharmacological interventions
- where the insomnia is severe, disabling or causing extreme stress
- prescribed for short term use (< 4 weeks) only
- regularly reviewed with aim to withdraw therapy with slow tapering over number of months

Long acting benzodiazepines (e.g. diazepam, nitrazepam) should *not* be prescribed in older people as they tend to accumulate and cause excessive sedation (NPS). Short term use of a short acting benzodiazepine (e.g. temazepam) or other related 'Z' drugs (in New Zealand zopiclone) may be required for:

1. Acute insomnia (present for < 4 weeks) if the cause is expected to be short lived (grief or noise) and non-drug therapies cannot be implemented readily
2. Chronic insomnia that has not responded to non-drug therapies alone (1)

According to the literature hypnotic drugs are not recommended for long term use as there is a lack of evidence on their use in long-term insomnia, and there are concerns regarding their safety. (1-8)
Patients should be prescribed the lowest effective dose for the shortest time; regular review should include careful consideration of the requirement for on-going treatment. Patients who are treated long-term with benzodiazepines and other hypnotics for insomnia should be encouraged to gradually withdraw treatment. Slowly tapering the dose over a number of months may help reduce the withdrawal effects such as agitation, anxiety and insomnia. (3)

Simple strategies used in general practice - such as sending a letter advising patients that the practice is currently undertaking a review and encouraging dialogue between the prescriber and patient with the aim to reduce or stop prescribing the medicine long term – are at least twice as likely to lead to benzodiazepines being stopped than usual care or not raising awareness at all. (1, 5)

Recommendations:

1. Given the risks associated with the use of benzodiazepines, patients should be prescribed the lowest effective dose for the shortest time possible. Maximum duration of treatment should be 4 weeks, including a dose tapering phase. (3, 9)

2. All patients on long term therapy (> 4 weeks), especially the older patient, should regularly be reviewed and, if appropriate, prescribing of hypnotics revised to ensure it is in-line with current Best Practice (see Table 1). (3)

Practice Benefits

- Highlighting the requirement for a regular review of all patients on long term hypnotic therapy
- An increased number of patients being appropriately reviewed and managed according to current Best Practice
- Fewer patients will remain on long term therapy with benzodiazepines or zopiclone for insomnia after a slow tapering over a number of months with the aim to ultimately withdraw therapy

AUDIT PLAN

Indications

Any patient enrolled in primary care taking a benzodiazepine or zopiclone for long term (i.e. > 4 weeks) insomnia 65 years and older.

Criteria for positive result

The patient is currently taking a short acting benzodiazepine or zopiclone for insomnia *and* has been clinically reviewed. If appropriate, prescribing has been revised to ensure it is in-line with current Best Practice according to national or international guidelines. (3, 5, 7)

Audit Standards

Given the risks associated with the use of benzodiazepines, especially in the older patient, at least 90% of patients should meet the requirements of a positive audit outcome.

DATA

Eligible people

Any patient currently enrolled in primary care taking a benzodiazepine or 'Z' drugs for long term insomnia, 65 years and older is eligible for this audit.

Identifying patients

The general practice will need to have a system in place that allows identification of eligible patients. Pharmacist Facilitators within PHOs can assist to create query builders through the patient management system (e.g. MedTech®) that will identify patients fitting the set inclusion criteria. This will provide the practice with a list of patients for review.

Pharmacist Facilitators can assist the review by providing useful resources to general practice (e.g. Welsh Medicines Partnership Educational pack).
Practice nurses and administration staff can be involved in stages of the review.

Sample size

The number of eligible patients will vary according to practice demographics (e.g. practices with a high number of older patients or GPs involved in care of older patients in Rest Home care facilities). If you identify a large number of patients, take a random sample of 30 patients for the audit.

Data analysis

Using the data sheet below to record your data, calculate percentages by taking the number of people who are a 'positive result' as per audit criteria, divided by the total number of people audited (e.g. 30 people audited and 22 on a short acting benzodiazepine or zopiclone have been reviewed).

References & Resources:

1. Addressing hypnotic medicine use in primary care NPS News No. 67 2010
2. Glass J, Lanctot KL, Herrmann N, et al. Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. BMJ 2005;331:1169.
3. Hypnotics and anxiolytics – a wake up call Prescriber Update Medsafe 2010
4. Hypnotics. Key Therapeutic Topics Medicines management options for local implementation QIPP NICE NHS January 2013
5. Material to support appropriate prescribing of hypnotics and anxiolytics Welsh Medicines Partnership Educational pack April 2011 http://www.awmsg.org/docs/awmsg/medman/Educational%20Resource%20Pack%20-%20Material%20to%20support%20appropriate%20prescribing%20of%20hypnotics%20and%20anxiolytics%20across%20Wales.pdf
6. Billioti de gage et al Benzodiazepine use and risk of dementia: prospective population based study BMJ 2012:345:e6231
7. Guidance on the use of zopiclone for short term management of insomnia NICE NHS Technology Appraisal 77 April 2004
8. Insomnia Clinical Knowledge Summary (CKS) NICE pathways cks.nice.org.uk/insomnia
9. Addiction to benzodiazepines and codeine: supporting safer use Hot Topic Drug Safety Update

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DATA SHEET - cycle 1

Audit: Appropriate prescribing of hypnotic medicines in Primary Care

Patient	On treatment for long term insomnia (yes/no)	On a short-term benzodiazepine (yes/no)	Prescribing has recently been reviewed according to Best Practice - see Table 1 (yes/no)
1			
2			
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28			
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30			
Total Yes			
% Yes			

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DATA SHEET - cycle 2

Audit: Appropriate prescribing of hypnotic medicines in Primary Care

Patient	On treatment for long term insomnia? (yes/no)	On a short-term benzodiazepine (yes/no)	Prescribing has recently been reviewed according to Best Practice - see Table 1 (yes/no)
1			
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30			
Total Yes			
% Yes			

IDENTIFYING OPPORTUNTIES FOR CQI

Taking action

The first step to improving medical practice is to identify the criteria where gaps exist between expected and actual performance and then to decide how to change practice.

Decide on a set of priorities for change and develop an action plan to implement any changes.

It may be useful to consider the following points when developing a plan for action.

Problem solving process

- What is the problem or underlying problem(s)?
- Change it to an aim
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

Overcoming barriers

- Identifying barriers can provide a basis for change
- What is achievable – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting
- Identify the barriers
- Develop a priority list
- Choose one or two achievable goals

Effective interventions

▪ No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change

▪ Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour

REVIEW

Monitoring change and progress

It is important to review the action plan against the timeline at regular intervals. It may be helpful to consider the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that the doctor completes the first part of the CQI activity summary sheet.

Undertaking a second cycle

In addition to regular reviews of progress, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that doctors complete the remainder of the CQI activity summary sheet.

Claiming MOPS credits

This audit has been endorsed by the RNZCGP as a CQI Activity for allocation of MOPS credits. General practitioners taking part in this audit can claim credits in accordance with the current MOPS programme. This status will remain in place until December 2018.

To claim points for MOPS or CPD online please enter your credits on your web records. Go to the RNZCGP website **www.rnzcgp.org.nz** and claim your points on 'MOPS online' for vocationally registered doctors, or 'CPD online' for general registrants. Alternatively MOPS participants can indicate completion of the audit on the annual credit summary sheet which is available from the College on request.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected
2. A Continuous Quality Improvement (CQI) Activity summary sheet