## UNIT NO. 3 ADMINISTRATIVE GUIDELINES IN INSOMNIA

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#### ABSTRACT

The Administrative Guidelines in insomnia require the benzodiazepine prescriber to comply with three tasks - (1) Document & keep medical records, (2) Use benzodiazepines appropriately, and (3) make specialist referrals when indicated. To use benzodiazepines appropriately the following questions need to be answered: In acute insomnia - Do you use sleeping pills sparingly: 2-4 weeks, I night in 2-3 nights, lowest dose and shortest duration? In chronic insomnia - Do you use nonpharmacological therapies, practice the rule of no repeat without clinical review, check for abuse and dependence, and consider withdrawal therapy. In depression, pain disorder, schizophrenia - Do you know that you should not use sleeping pills as monotherapy? In anxiety - Do you limit benzodiazepine use to short term relief (2-4 weeks only)? In the elderly - Do you practice the following rules - use non-pharmacological interventions, one half to one quarter dose of adult dose, warn of cognitive impairment and fracture risk in long term use, and withdraw gradually as this may produce improvement in cognitive functions? Benzodiazepines dependence - Is the continued need for benzodiazepines due to dependence? Should you consider benzodiazepine withdrawal for the patient?

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## INTRODUCTION

Best practice in the use of benzodiazepines for insomnia is necessary from both the patient safety and doctor safety points of view. Doctors are still being hauled up by the Singapore Medical Council for unacceptable practice in the use of benzodiazepines and other hypnotics for insomnia. The purpose of this paper is to clarify the tasks that the medical practitioner prescriber need to be mindful of.

In Singapore the two key documents that guide practice in the use of benzodiazepines for insomnia issued in recent years are:

• the administrative guidelines titled Administrative Guidelines On The Prescribing Of Benzodiazepines And Other Hypnotics (MH 70:41/24 Vol. 3 issued on 14 October 2008 and sent to all medical practitioners in practice at that time)

• MOH CPG on Prescribing of benzodiazepines, 2/2008.

## THE ADMINISTRATIVE GUIDELINES

The Administrative Guidelines on the prescribing of benzodiazepines and other hypnotics was issued by the Ministry of Health to all registered medical practitioners on 2008 October 14 (MH 70:41/24 Vol. 3). This document is available on the MOH website. It accompanied the issue of the Clinical Practice Guidelines for Prescribing Benzodiazepines.

The Administrative Guidelines require compliance to the following three tasks:

- Document and keep patient medical records;
- Use benzodiazepines appropriately; and
- Make specialist referrals.

## **Document and Keep Patient Medical Records**

- (a) All information relating to a particular patient must be consolidated as one medical record relating only to that patient. Such information must be legibly documented.
- (b) Each patient's medical record must be entirely reproducible upon request by the Ministry of Health or Singapore Medical Council.
- (c) The following information must be documented in the medical record of every patient who is prescribed with benzodiazepines/ other hypnotics:
  - Comprehensive history, including psychosocial history and previous use of benzodiazepines or other hypnotics;
  - (ii) Comprehensive physical examination findings, including evidence of misuse of benzodiazepines or other drugs; and
  - (iii) Withdrawal symptoms to benzodiazepines/ other hypnotics previously experienced by the patient, if any.
- (d) The following information must be documented in the medical records of every patient each time he/she is prescribed benzodiazepines / other hypnotics either initially or as repeat prescriptions:
  - The prescribed type/name of benzodiazepine/hypnotic, its dosage and duration of use;
  - (ii) Indication(s) and/or justification(s) for prescribing benzodiazepines/ other hypnotics; and
  - (iii) Physical signs or evidence of tolerance, physical/ psychological dependence or any illicit use or misuse of benzodiazepines or other drugs (e.g. needle tracks on skin, inappropriate lethargy).

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**Comment:** Note that one record is to be kept each patient, and each medical record must be entirely reproducible for inspection when requested. An initial thorough history, physical examination, and check for withdrawal symptoms if any, must be obtained. For each visit, careful documentation of benzodiazepines prescribed, indications, physical examination including signs of substance abuse need to be documented.

#### **Use Benzodiazepines Appropriately**

- (e) Medical practitioners are strongly discouraged from prescribing highly addictive benzodiazepines such as midazolam and nimetazepam (except for midazolam use in surgical procedures).
- (f) Benzodiazepines / other hypnotics, when used for treating insomnia, should be prescribed for intermittent use (e.g. I night in 2 or 3 nights) and only when necessary.
- (g) Medical practitioners should routinely warn patients about rebound insomnia with the use of benzodiazepines and document such warning accordingly.
- (h) The dosage of benzodiazepine / other hypnotic used should be the lowest effective dose necessary to achieve symptomatic relief.
- (i) The concurrent prescribing of two or more benzodiazepines should be avoided.
- (j) Repeat prescriptions for benzodiazepines / other hypnotics should not be provided without a clinical review.
- (k) Where there are doubts about dosage prescription or tapering of benzodiazepines/ other hypnotics, a psychiatrist or other specialists should be consulted.
- (I) Care should be taken when prescribing benzodiazepines / other hypnotics to avoid excessive sedation (which may pose a risk to the patient who drives, operates heavy machinery, etc).
- (m) Caution should be exercised when prescribing benzodiazepines for patients with a history or evidence of alcohol or other substance abuse.

**Comment:** No highly addictive benzodiazepines, routine warning about rebound insomnia, lowest effective dose, no concurrent prescribing two or more benzodiazepines, no repeat prescription and avoidance of prescribing benzodiazepines in patients with alcohol or other substance abuse need to be complied with.

### **Make Specialist Referrals**

- (n) The following categories of patients should not be further prescribed with benzodiazepines / other hypnotics and must be referred to the appropriate specialist for further management:
  - Patients who require or have been prescribed benzodiazepines /other hypnotics beyond a cumulative period of 8 weeks;
  - Patients who are already on high-dose and/or longterm benzodiazepines from their specialists or general hospitals; where possible, these patients should be referred back to their respective specialists for further management until they are weaned off benzodiazepines / other hypnotics; and
  - Patients who are non-compliant with professional advice or warning to reduce intake of benzodiazepines/ other hypnotics.
  - (o) Patients who refuse to be referred to a specialist should be counseled appropriately. Such refusal should be documented in the patients' medical records. Patients who refuse referrals and turn aggressive should be reported to the police.

**Comments**: Those requiring cumulatively more than 8 weeks of benzodiazepines or other hypnotics, those on high dose or long term benzodiazepines, and those non-compliant to professional advice need to be referred to appropriate specialist for further management.

# POINTERS FROM THE CPG 2/2008 ON PRESCRIBING BENZODIAZEPINES

#### (I) Acute Insomnia

- Warn routinely hypnotics/ anxiolytics cause drowsiness; impairs mental alertness, physical incordination (e.g. operating machinery or driving a motor vehicle); avoid concomitant use of alcohol (pg 13). Grade B, Level 2++
- Note the same cautions needed for the Z-drugs Zolpidem and zopiclone – use with the same cautions as benzodiazepines (pg 14). Grade A, Level 1+
- **Sparing use** Use benzodiazepine or a similar hypnotic drug (only) if the acute insomnia is severe, distressing and disabling, and is expected to resolve quickly (pg 16). Grade A, Level 1+
- Minimum effective dose Give minimum effective dose for the shortest duration to minimise side effects and risks of dependence (pg 16). Grade D, Level 4

- **Don't prescribe a second benzodiazepine** If treatment does not work with a shorter-acting benzodiazepine, zolpidem or zopiclone, the doctor should not prescribe one of another shorter-acting benzodiazepine, zolpidem or zopiclone (pg 15). Grade A, Level 1+
- Short term relief only Limit to short-term relief (between 2-4 weeks), at the lowest dose and taken intermittently (e.g. 1 night in 2 or 3 nights) (pg 24). Grade D, Level 4

### (2) Chronic Insomnia

- Use non-pharmacological therapies For chronic insomnia (defined as presence of insomnia 3 nights/week and longer than 4 weeks), non-pharmacological therapies (See box 1 & Box 2) are the mainstay of management (pg 17). Grade A, Level 1+
- Avoid longer term use than 4 weeks Hypnotic drug use in patients with chronic insomnia (longer than 4 weeks) should be avoided as far as possible because efficacy is not clearly established (pg 17). Grade A, Level 1+
- No repeat prescriptions without clinical review

   Repeat prescriptions for benzodiazepines/ other hypnotics should not be provided without a clinical review (Administrative guidelines 2(j)).
- **Consult when in doubt** Where there are doubts about dosage prescription or tapering of benzodiazepines/ other hypnotics, a psychiatrist or other specialists should be consulted (Administrative guidelines 2(k)).
- Avoid extended use beyond 2-4 weeks Extended use of benzodiazepines (especially those with short half-lives) beyond 2-4 weeks is not recommended, even when prescribed at the therapeutic dosages (pg 25). Grade A, Level 1+
- Identify the underlying cause in patient with chronic insomnia In a patient with insomnia longer than 4 weeks, identify and manage the cause (pg17), e.g.
  - Dysfunctional beliefs of amount of sleep needed
  - · Physical and psychological conditions
  - Correctable causes: too much activity before bedtime, day time napping, large meals

## BOX I. Non-pharmacological Therapies (I): Sleep Hygiene

- Avoid caffeine, nicotine, alcohol especially later in the day
- Avoid heavy meals within 2 hours of bedtime
- Only use the bed for sleep
- Establish a routine of getting ready to go to bed
- Set time aside to relax before bed, and utilise relaxation techniques
- When in bed, relax and think pleasant thoughts to help you fall a sleep

## **BOX 2. Non-pharmacological Therapies (I): Stimulus Control Therapy**

- Go to bed only when you feel tired
- Do not read, watch TV, eat, or worry while in bed
- Get out of bed if you do not fall asleep within 20 min.
- Return only when you feel sleepy again. If you cannot fall asleep repeat step 3. Do this as often as necessary through the night.
- Get up at the time every morning regardless of how much sleep you obtained the night before.
- Avoid napping in the day.

#### (3) Schizophrenia, Depression, Pain Disorder

- Schizophrenia, schizophrenia-like psychosis, acute psychotic behaviour Benzodiazepines should not be used as monotherapy (pg 18). Grade A, Level 1+
- **Depression** Benzodiazepines should not to be used as monotherapy (pg 19). Grade A, Level 1+
- **Pain disorder and co-morbid depression** Benzodiazepines should not to be used as monotherapy (pg 20). Grade A, Level 1+

## (4) Anxiety

- Anxiety Benzodiazepines are indicated for short term relief (2-4 weeks only) of anxiety that is severe, disabling or subjecting the individual to unacceptable distress, occurring alone or in association with insomnia or short term psychosomatic, organic or psychotic illness. (pg 19). Grade D, Level 4.
- Anxiety in patients with co-morbid alcohol/substance abuse or dependence – Best to avoid benzodiazepines. (pg 20). Grade D, Level 4.

### (5) Elderly with Insomnia

- Elderly with insomnia: non pharmacological interventions first Non-pharmacological interventions to be initiated first before prescribing benzodiazepines (pg 29). Grade A, Level 1++.
- Elderly with insomnia: long term use be avoided -Long term use to be avoided because of increased risk of cognitive impairment and fractures (pg 29). Grade C, Level 2+.
- Elderly with insomnia on benzodiazepines: should gradually withdraw Benzodiazepines should be gradually withdrawn as this may improve cognitive functions (pg 30). Grade B, Level 1+.
- Elderly with insomnia: start with quarter adult dose – Dose of benzodiazepines should be only one quarter to half of normal adult dose (pg 30). Grade D, Level 4.

## (6) Benzodiazepine Abuse and Dependence

- Check if dependence is the reason for continued request for benzodiazepines – Dependence is manifested by:
  - Withdrawal symptoms on discontinuation
  - Evidence of tolerance
  - Strong desire to take the drugs and difficulties controlling the drug taking behaviour (pg 24). Grade D, Level 4
- Consider benzodiazepine withdrawal if dependence is diagnosed –
  - Benzodiazepine withdrawal for patients on less than 4 weeks of benzodiazepine therapy Discontinue over 1-2 weeks (pg 27). GPP
  - Benzodiazepine withdrawal for patients on more than 4 weeks of benzodiazepine therapy Follow CPG withdrawal protocol in Box 3.

## **Box 3. BENZODIAZEPINE WITHDRAWAL PROTOCOL**

- Calculate approximate equivalent oral daily dose of diazepam (a) if more than 30 mg/day start reduction from half this amount or 30mg/day, whichever is lower (b) if less than 30 mg/day or less, reduce from this dose.
- Reduce oral diazepam dose every 1-2 weeks in steps of 2-5mg.
- If withdrawal symptoms are severe, reduce dose in smaller steps.
- If patient unable to stop completely by 4-8 weeks, or if complications arise, consider referral to the appropriate specialist or general hospital.
- Monitor closely for benzodiazepine withdrawal for patients Monitor closely for complicated withdrawal symptoms (e.g. seizures, delirium), and serious psychiatric complications (e.g. psychotic symptoms, suicidal tendency).
- Refer patients with benzodiazepine withdrawal problems to specialist or general hospital.

#### REFERENCES

1. MOH. Administrative Guidelines On The Prescribing Of Benzodiazepines And Other Hypnotics (MH 70:41/24 Vol. 3 -- 14 October 2008 issued to all registered medical practitioners in practice at the time). Available at URL:

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2. MOH. Clinical Practice Guidelines 2/2008. Prescribing of Benzodiazepines. Singapore, 2008 - Full document:

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3. MOH. Clinical Practice Guidelines 2/2008. Prescribing of Benzodiazepines. Singapore, 2008 - Summary card:

http://www.moh.gov.sg/mohcorp/uploadedFiles/Publications/ Guidelines/Clinical\_Practice\_ Guidelines/ Prescribing%20of%20 Benzodiazepines%20(summary%20card).pdf

#### LEARNING POINTS

- Administrative Guidelines Do you (1) Document and keep medical records, (2) Use benzodiazepines appropriately, and (3) Make specialist referrals when indicated?
- Acute insomnia Do you use sleeping pills sparingly: 2-4 weeks, I night in 2-3 nights, lowest dose & shortest duration?
- Chronic insomnia Do you use non-pharmacological therapies, practice the rule of no repeat without clinical review, check for abuse & dependence, and consider withdrawal therapy?
- Schizophrenia, Depression, Pain disorder Do you know that you should not use sleeping pills as monotherapy?
- Anxiety Do you limit benzodiazepine use to short term relief (2-4 weeks only)?
- Elderly with Insomnia Do you practice the following rules use non-pharmacological interventions, one half to one quarter dose of adult dose, warn of cognitive impairment and fracture risk in long term use, and withdraw gradually as this may produce improvement in cognitive functions?
- Benzodiazepines dependence Is the continued need for benzodiazepines due to dependence? Should you consider benzodiazepine withdrawal for the patient?