Treating insomnia
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**Notes**
Among British patients diagnosed with a chronic disease, only 45% had been given a plan for managing their care at home, compared with 68% in New Zealand and 64% in the United States. A growing body of evidence shows that patient engagement in treatment decisions and in managing their own health care can improve patients’ experience and often results in more appropriate and cost effective utilisation of health services and better health outcomes. The key to greater patient engagement lies in building health literacy and ensuring that clinicians help patients to help themselves. In addition to the potential for achieving greater efficiencies in resource use, encouraging patients to take more control when they are ill may also prove to be an effective tool for improving public health, as well as personal health. Paternalistic styles of practice tend to create dependency and undermine self reliance. Promoting involvement, empowerment, and a sense of ownership of their health care could be the best way to ensure that people adopt healthier lifestyles. For public health policy to be realised, paternalism must be replaced by active encouragement of patients to participate in their own care.

The place to start is primary care. Although the general practitioner contract includes incentives to improve performance in relation to dietary advice, smoking prevention, and blood pressure checks, it does little to encourage patient engagement. On the contrary, it promotes an essentially doctor led model, with few incentives for clinicians to empower patients to take control of their own health. Once again there seems to have been a failure to join up the separate strands of health policy. The NHS should be supporting the public health push towards full engagement not working against it.

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Treating insomnia
Use of drugs is rising despite evidence of harm and little meaningful benefit

By the way, doctor, I don’t sleep at night. Can you give me something for that?” or “You can take away any of my other pills, but I have to have something for sleep!” are sentiments heard daily in any general medical environment. Patients with persistent complaints of insomnia—often elderly, frail, with multiple morbidities, multiple medications, already on or previously on a hypnotic medication—become problematic. Once past invoking sleep hygiene guidelines; looking for primary causes of insomnia; discussing medication risks such as falls, impaired cognition, driving crashes, and dependence; or discontinuing sedatives (and grumbling to the nurses for promoting them and to the house staff and referring doctors for prescribing them), what is the doctor to do? Why is this one of the least satisfying symptoms to treat and to educate medical professionals about?

Perhaps because the definition of “normal sleep” remains elusive, as do the determinants of normal sleep, the correlation of psychopathology (which many doctors have neither time nor training to deal with appropriately) with poor sleep satisfaction is strong. The independent prognostic importance of insomnia itself is unknown, and the well known drug treatments for insomnia all have uncertain but worrisome ratios of harm to benefit. Once the time consuming sedative prevention or withdrawal exercise is completed, one has a sense of resigned acknowledgment that most patients persist with their complaint until some doctor finally prescribes and represcribes a sedative.

Despite evidence of major harm and little evidence of clinically meaningful benefit, prescriptions for benzodiazepines continue to grow and are part of a “top 20” list of prescribed drugs in many jurisdictions. Furthermore, although their use is associated with poor functional status, cognitive impairment, daytime sleepiness, falls, and depressed mood, patients’ satisfaction with effectiveness is high. The conclusions of the recent guidance from the National Institute for Clinical Excellence (NICE) on newer hypnotic drugs will be a disappointment to those clinicians who were holding out hope that the newer “Z” drugs (zaleplon, zolpidem, and zopiclone) are superior to benzodiazepines in effectiveness or safety. The guidance, while limited to comparisons between the Z drugs and benzodiazepines, is the usual, high quality NICE product, with a comprehensive systematic review including industry submissions, extensive stakeholder consultation, and a highly readable summary of findings.

Although initially promoted as superior to benzodiazepines in terms of daytime sedation, dependence, and withdrawal, the Z drugs have not delivered on several fronts. On the quality of evidence, of the 17 randomised trials with a total of 1284 patients, all were industry funded, outcomes were poorly and often selectively reported in favour of positive findings, comparators were suboptimal, durations were very short (maximum six weeks), and surrogate
markers (generally sleep variables) were highlighted. On the risk-benefit front, no consistent difference was found between the Z drugs and benzodiazepines for either effectiveness or safety. On the economic front, since the Z drugs are each several times the cost of older benzodiazepines, without evidence of superior effectiveness, they cannot be considered cost effective.

With the NICE guidance added to the weighty pile of negative evidence and expert opinion on hypnotic agents, do reasonable alternatives exist? Drugs are still important considerations in two main areas. Firstly, some commonly used drugs are well known to disrupt normal sleep—notably alcohol, selective serotonin reuptake inhibitors, drugs for Parkinson’s disease, methyloxanthines, and diuretics—and should be considered as potential contributors to the insomnia. Secondly, drugs can be effective for causes of secondary insomnia, especially pain and depression. Antidepressants and anxiolytics are increasingly being prescribed for insomnia; whether they are safe and effective outside of depression-associated insomnia is still controversial. The use of antiparkinsonics, antipsychotics, or anticholinesterase inhibitors for insomnia related to delirium or dementia is also improved.

No drug has yet been shown to be more effective and safer than placebo in primary insomnia for the type of outcomes that matter, such as quality of life, daytime function, cognition, falls and fractures, or dependency. Placebo itself, as in every domain of therapeutics, has been found to be effective—in this case in improving sleep. The current aim of treatment is less focused on reduction of arousal from sleep and more focused on changing beliefs and attitudes about sleep. Thus NICE’s recommendation that long term, non-pharmacological interventions for insomnia should be a primary target for evaluation of cost effectiveness. Although physical exercise shows merit and can be recommended by primary care providers, the current front runner for non-pharmacological treatment is cognitive behaviour therapy, a technique not familiar to providers outside of psychiatry. Trials of different methods of training family doctors in cognitive behaviour therapy are currently under way.

Cognitive behaviour therapy has many elements—stimulus control (your bed is only for sleep), sleep restriction (restrict your time in bed to your usual sleeping time), sleep hygiene, and relaxation therapy. Which of these elements is effective is unclear, but this is worth finding out as more passive interventions, such as audit and feedback to primary care doctors, are not effective. In the meantime, the newer hypnotics remain with the older hypnotics as prime examples of iatrogenesis imperfecta.

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Revisiting phenobarbital for epilepsy
Large gaps in knowledge still exist, but we may be underestimating its clinical value

A recent review of phenobarbital for the treatment of epilepsy draws attention to an ethical dilemma and to the many gaps in our knowledge that have been in use since 1912. Phenobarbital is commonly prescribed in the developing world, but in most developed countries it has fallen into disrepute. The World Health Organization (WHO) recommends it as a first line drug for partial and generalised tonic-clonic seizures in developing countries. Its antiepileptic efficacy is undisputed, but concerns remain about its side effects. If people with epilepsy in Britain are not prescribed phenobarbital because of its toxicity, is it ethical to recommend its use in developing countries? And if the drug is not as toxic as it is believed to be, might it not be used more in the developed world?

Phenobarbital has many favourable features: broad spectrum efficacy against all seizure types other than absence; a starting dose within the clinically effective range; seizure freedom rates comparable to those associated with modern drugs; a very low risk of life-threatening adverse effects; linear pharmacokinetics; long half life compatible with once daily dosing; low propensity to be a target for drug interactions (except for the inhibition of its metabolism by valproate); availability of a parental formulation, and low cost. The perception that phenobarbital is more commonly associated with withdrawal seizures is not supported by the best available evidence. Documented disadvantages include enzyme induction, which may alter response to co-administered drugs such as oral contraceptives, and adverse cognitive and behavioural effects, particularly in children.11