A community pharmacy-based survey of users of over-the-counter sleep aids

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OBJECTIVES **• To investigate the use of over-the-counter sleep aids purchased from community pharmacies in order to establish a demographic profile of users, determine the extent of any inappropriate use, and test the feasibility of community pharmacy-based data collection from medicines users.**

DESIGN **• Pre-piloted self-completion questionnaire. Pharmacists completed a log recording all requests for over-the-counter sleep aids.**

SUBJECTS AND SETTING **• Purchasers of over-the-counter sleep aids from 10 community pharmacies in one health authority area in England during a 24-week period (6 weeks plus 18 weeks).**

RESULTS **• The pharmacists logged 293 requests to purchase sleep aids during the study period, five of which were refused. Of the 288 customers who purchased a product 235 (82%) agreed to participate in the study and 86 (37%) returned a completed questionnaire. Older people were more likely to request their sleep aids from independent or chain pharmacies than supermarket pharmacies. About half of the respondents had sought medical advice about their sleep disorder, and less than a third had told their GP about their use of an over-the-counter sleep aid. A potential problem of inappropriate use was classified among nearly half of survey respondents.**

CONCLUSIONS **• Many purchasers of over-the-counter sleep aids reported long-standing sleep problems. The public health implications of long-term use of these medicines need to be researched and debated. This study confirms the feasibility of conducting research in community pharmacies with the purchasers of over-the-counter medicines but has raised some methodological problems.**

Sleeplessness is commonly reported by the public and symptoms of "insomnia" have been reported in more than one in three adults.[1] Consumer research shows that 15 per cent of adults had experienced sleeping problems in a two-week period.[2] People experiencing problems with sleeping might consult their doctor, try self-treatment with non-prescription medicines or other remedies, or take no action.

Knowledge about the existence, nature and extent of the misuse of over-the-counter (OTC) sleep aid medicines is mostly based on pharmacists' perceptions and anecdotal reports. In a survey in 1999, 79 per cent of community pharmacists believed that sleep aids were the most misused OTC products.[3] In another survey medicines commonly perceived to be misused were codeine-based tablets or mixtures, followed by kaolin and morphine mixture and Nytol tablets.[4]

Community pharmacies are an underused research resource,[5] and could be used for patient recruitment into studies. Community pharmacy research networks have been set up in Aberdeen and North Staffordshire with promising results.[6,7] The North Staffordshire primary care research consortium is an NHS supported network and consists of six general practices and their local community pharmacies.

The use of OTC sleep aids was considered to be an important area for research by the consortium members because of concern about misuse and because of the lack of published research on the topic. The research was primarily intended as an exploratory study to describe patterns of use of these aids among customers of community pharmacies.

METHOD

The study was approved by both the local Scientific Merit and Research Ethics Committees in North Staffordshire and designed with the full involvement of consortium pharmacists.

Study population All customers requesting an OTC sleep aid product from 10 pharmacies (two supermarkets; three chain pharmacies; five independent pharmacies) over a 24-week period (6 weeks plus 18 weeks) between October 1999 and October 2000 were invited to take part in the study. Verbal consent was obtained from customers before giving out a questionnaire. Customers were assured of anonymity. Questionnaires were not given to customers who had previously received one. Proxy purchasers were asked to take a questionnaire and pass it on to the person for whom the medicine was intended. No restrictions were placed on gender or age of customers or the numbers recruited. Although it was preferred that subjects filled in the questionnaire on the premises, the option was given to take it away and subsequently post it to the research team in a pre-paid envelope.

Data collection Data were collected from two sources: a pharmacist log and a customer survey.

Log data A log was completed by pharmacy staff of all customer requests for sleep aid products. Details included age of customer (<30 years, 30–50 years, >50 years), gender, product (Nytol, Sominex, Phenergan), whether there was a consultation or the product was requested by name; whether the customer had used the product before; whether the product was for the customer or for someone else; and whether the customer was "regular" (based on whether or not the logging staff had seen the customer before).

Customer survey The questionnaire included three sections, one enquiring about demographic details, one about the medicine, and the other about any sleep problem. Demographics included age (<35 years, 36–55 years, >55 years), gender and employment

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TABLE 1: ASSOCIATION BETWEEN CUSTOMER CHARACTERISTICS AND USE OF OVER-THE-COUNTER SLEEP AIDS, STRATIFIED BY PHARMACY TYPE (N=293)

		Type of pharmacy			Odds ratio (95% CI)*	
		Supermarket (n=102)†	Chain (n=68)†	Independent (n=123)†	Chain§	Independent§
Age	<30‡	18 (18%)	7 (10%)	17 (14%)	1.0	1.0
	30–50	56 (55%)	34 (50%)	47 (38%)	1.5 (0.5–4.4)	1.1 (0.4-2.7)
	>50	28 (28%)	27 (40%)	58 (48%)	2.1 (0.7–6.5)	2.6 (1.0–7.1)
Gender	Female‡	68 (67%)	54 (79%)	75 (65%)	1.0	1.0
	Males	33 (33%)	14 (21%)	40 (35%)	0.6 (0.3–1.4)	1.4 (0.7-2.7)
Product	Nytol‡	99 (97%)	62 (93%)	115 (94%)	1.0	1.0
	Other	3 (3%)	5 (7%)	7 (6%)	2.7 (0.6–12.5)	2.3 (0.5–10.5)
Pharmacist consultation	No‡	92 (90%)	62 (91%)	117 (95%)	1.0	1.0
	Yes	10 (10%)	6 (9%)	6 (5%)	0.7 (0.2–2.6)	0.4 (0.1–1.5)
Used product before	No‡	16 (16%)	12 (18%)	28 (23%)	1.0	1.0
	Yes	84 (84%)	56 (82%)	95 (77%)	0.6 (0.2–1.5)	0.3 (0.1–0.7)
Product requested for use by	Self‡	73 (72%)	52 (76%)	91 (75%)	1.0	1.0
	Someone else	29 (28%)	16 (24%)	31 (25%)	0.9 (0.4–1.9)	1.0 (0.5–2.0)
Regular customer?	No‡	83 (81%)	31 (46%)	46 (38%)	1.0	1.0
	Yes	19 (19%)	37 (54%)	76 (62%)	4.8 (2.3–9.8)	8.1 (4.1–16.0)

** Odds ratios were derived using multinomial logistic regression analysis, adjusting for the other predictor variables in the table. † Frequency counts may not add up to totals because of some missing data. ‡ Reference categories for the predictor variables. § Reference category=supermarket.*

status. The section "about the medicine" asked about the product (Nytol, Sominex, Phenergan), whether the customers paid for their prescriptions, why the customer had chosen this pharmacy, and what had influenced the customer to use a sleep aid. Those who had used OTC sleep aids before were asked how regularly they had used them, the frequency of use in the past six months and when they had first used them. Customers were asked to complete the section about sleep problems if they were currently suffering such problems, and this section addressed the following issues: contact and interaction with the doctor; methods of helping the problem such as having a hot milky drink, exercising or avoiding alcohol/caffeine before going to bed, and the severity of the sleep problem (see Panel 1).

Neither the log nor the questionnaire contained any personal identifiers. "Inappropriate use" of sleep aids was defined according to daily use for more than 30 nights in the past six months, or use at least once a week having first started using sleep aids over two years ago. Customers with a "severe sleep disorder" were also categorised as "inappropriate users", as were those who did not report sleep problems.

Data analysis For the log data, statistical analysis was carried out using the chi-square test for univariate analyses and multinomial logistic regression for multivariate analysis. Statistical tests were assigned a 5 per cent significance level (two-tailed). Estimates of individual associations with pharmacy type are given by odds ratios with 95 per cent confidence intervals. Simple descriptive statistics are presented for the questionnaire data. SPSS version 11.0 was used both to store and to analyse the log and questionnaire databases.

Panel 1: Severity of sleep problem

Thinking back over the past month, did you:

a. Have trouble falling asleep?
b. Wake up several times per night?
c. Have trouble staying asleep?
d. Wake up after your usual amount of sleep feeling tired and worn out?

- Mild sleep disorder — answered "on some nights" to at least one question
- Moderate sleep disorder — answered "on most nights" to at least one question
- Severe sleep disorder — answered "on most nights" to all questions

RESULTS

Recruitment and response A total of 293 requests for sleep aids was recorded in the 10 participating pharmacies during the 24-week period of the study. This is an average of 1.2 requests for sleep aid products per pharmacy per week. Of these, 288 (98 per cent) resulted in sales and five did not result in sales due to breast-feeding, use of prescribed hypnotic and price. Of the customers who made a purchase 235 (82 per cent) agreed to complete the study questionnaire, and 86 (37 per cent) of these returned the questionnaire (range 15 per cent to 71 per cent across pharmacies).

Total customer cohort — log data (n=293) The age category 30–50 years was associated with the highest number of recorded sleep aid requests, as was female gender (see Table 1). Older people were significantly more likely to request their sleep aids from independent and chain pharmacies than from supermarket pharmacies (c^2=10.7, 4df, P=0.030).

Nytol was sold to 276 customers (96 per cent). About nine in 10 customers requested their sleep aid by name (n=271, 92 per cent) with only 22 requesting advice. One in four requests was for sleep aids for someone else (n=76, 26 per cent). Previous users of sleep aids amounted to 235 (81 per cent); previous use was significantly higher among supermarket customers than those in independent pharmacies (see Table 1). Less than half of the customers (n=132, 45 per cent) were considered to be "regular" customers, and independent pharmacies were estimated to be eight times more likely to have requests for sleep aids from "regular" as opposed to "non-regular" customers compared with supermarket pharmacies.

TABLE 2: INFLUENCES ON THE DECISION TO USE SLEEP AIDS (N=86)

	Number reported
Doctor	8
Pharmacist	10
Advertisement	34
Family/friend	23
Other	10

TABLE 3: INFLUENCES ON THE DECISION TO VISIT "THIS PHARMACY" (N=86)

	Number reported
Near to home	35
Near to work	9
Get what I want	3
Like the service	15
Other	22

Survey responders (n=86) The 86 responders to the survey had a similar age-sex profile to the 293-customer cohort. However, customers visiting chain and independent pharmacies were more likely to respond to the study questionnaire than those visiting supermarket pharmacies.

Advertising was reported to be the biggest influence on the decision to purchase (see Table 2). The most common reason for the choice of pharmacy was its proximity to where the respondent lived (see Table 3). Of the 22 "other" responses to this question, 19 specified reasons for using the

TABLE 4: CHARACTERISTICS RELATING TO OVER-THE-COUNTER SLEEP AID USE AND SLEEP PROBLEMS

	Number of respondents (%)
Use of OTC sleep aids (n=70)*	
Frequency of use per week	
Daily	10 (15%)
More often than once a week, but not daily	23 (35%)
Once a week	19 (29%)
Less often than once a week	14 (21%)
Frequency of use in past 6 months	
Fewer than 30 nights (1 month) in total	43 (61%)
Between 30–90 nights (1–3 months) in total	20 (29%)
Greater than 90 nights (4–6 months) in total	7 (10%)
When first started using OTC sleep aids	
0–6 months ago	12 (17%)
7–12 months ago	6 (9%)
1–2 years ago	25 (36%)
>2 years ago	27 (39%)
Bought a sleep aid medicine from the same pharmacy before	
No	18 (26%)
Yes	52 (74%)
About the sleep problem (n=79)†	
Severity of sleep problem	
Mild	33 (43%)
Moderate	28 (36%)
Severe	16 (21%)
Discussed sleep problem with a doctor	
No	38 (48%)
Yes	41 (52%)
Doctor knows about OTC sleep aid use	
No	54 (69%)
Yes	24 (31%)
Tried any of the following before going to bed to help with the problem‡	
Having a hot milky drink (but not tea/coffee)	46 (58%)
Exercise	21 (27%)
Avoiding alcohol or caffeine	42 (53%)

** Questions about use of OTC sleep aids apply to those 70 respondents who had used them before (frequency counts may not add up to 70 because of some missing data)*
† Questions about sleep problems apply to those 79 respondents who filled in the section about sleep problems (frequency counts may not add up to 79 because of some missing data)
‡ Multiple response question to which numbers and percentages refer to positive responses to each of these items

pharmacy; of these 15 cited "convenience" or "where I shop" as their response (10 of these were supermarket customers).

Forty-eight respondents (56 per cent) reported that they would have to pay prescription charges, which may have encouraged sleep aid use rather than GP consultation.

A total of 70 respondents (81 per cent) reported using OTC sleep aids before, and summary results for the characteristics of OTC sleep aids use among these 70 previous users are shown in Table 4. Also presented in Table 4 are the summary results for the 79 respondents (92 per cent) who answered the section on sleep problems. More than half of these respondents had "moderate" or "severe" problems according to our definition (Panel 1). Among the 41 respondents who had previously discussed their sleep problem with their GP, 17 (41 per cent) reported having tried taking a prescription medicine for their sleep problems.

Using data shown in Table 4 we have derived an estimate of "inappropriate use". Daily use for more than 30 nights in the past six months was reported by eight respondents; 19 respondents were taking sleep aids at least once a week having first started using sleep aids over two years ago; 16 customers had a "severe sleep disorder"; seven did not report sleep problems. These categories were not mutually exclusive, and in total there were 42 (49 per cent) who could be classified as "inappropriate users" among the 86 respondents to the survey. "Inappropriate use" was not associated with age, gender or pharmacy type: values ranged between 39 per cent and 54 per cent across all categories of these variables.

DISCUSSION

This is the first study to report how OTC sleep aids are used by people in the UK. The profile of users of sleep aids and usage patterns described in this study lay down markers for further research into use of sleep aids. The study has also defined a method to examine the potential inappropriate use of sleep aids. At the same time, the feasibility of conducting research from community pharmacies has been confirmed.

Sales request levels were half of those recorded by the national audit carried out by the Royal Pharmaceutical Society in 1997.[8] None of the 10 participating pharmacies was located in areas experiencing high volume sales requests for sleep aids and, therefore, caution must be exercised in making the assumption that our survey respondents represent the profile of total UK OTC sleep aid users. The response rate to the survey of 37 per cent limits the generalisability of the findings. However, the age-sex profile of respondents was similar to that for the total population of customers requesting the products. The response rate varied markedly between pharmacies (15 per cent to 71 per cent). Lower response rates might be expected if customers are seeking anonymity in purchasing. Previous studies using similar methods have shown response rates ranging from 0 to 88 per cent.[9–13] None of these studies addressed topics that were as sensitive as sleep aids which, because of the potential for misuse, is likely to have had an effect on customer response. More respondents indicated that they were regular customers of the pharmacy they used than had been estimated by the pharmacy staff in the total customer cohort log, and may reflect poor recall by the pharmacy staff or a high response rate among regular customers.

The majority of purchases followed a request for a named product. Studies have shown advice rates in pharmacies ranging from 10 per cent to 30 per cent.[14–17] Similarly, in our study only 8 per cent of customers requested advice. This may be partially explained by the fact that over 80 per cent of customers had used the product before, and therefore requests for advice would be expected to be low. A single product, Nytol, accounted for 95 per cent of requests and is also the only product that is promoted to the public through radio and television advertising. Advertising was a major influence on customers' decisions to purchase. Most respondents said they had tried non-medicinal measures to help them sleep and a sizeable proportion (20 per cent) reported previous prescribed medicine use.

Little is known about the general frequency and patterns of sleep aid use. Customer profiles based on market research from one UK manufacturer (Stafford Miller) indicated that one in three adults suffers from temporary sleeplessness from time to time with just over half of sufferers actively treating it, ie, one in six adults. Of these, 21 per cent use P category medicines. This could mean that between 5 and 7.5 million adults in the UK may treat temporary sleeplessness and 1 to 1.6 million adults might use P category sleep aid medicines. A study of American university students reported that 79 per cent of females and 71 per cent of males had trouble falling asleep, and of these 11 per cent of females and 6 per cent of males reported using OTC sleep aids.[18] It is a matter of concern that half of respondents in our study had not discussed their sleep problem with their GP and less than a third had mentioned their use of purchased sleep aids.

In this study, most purchasers were women and this may reflect two things. First, it may reflect the profile of pharmacy users, which is known to be predominantly female. Secondly, a higher proportion of women (over 60 per cent) have been reported to suffer from insomnia.[19,20] The age profile of sleep aid users also reflects the known increase in the prevalence of sleep disorders with age.

The terms "misuse" and "abuse" have not been clearly defined and in many instances are taken to be synonymous. Misuse definitions include "to use to bad effect" and "to use wrongly or to apply to the wrong purpose",[21] and "consumption over a lengthy period and/or consumption of doses substantially higher than recommended".[22] Abuse has been defined as the voluntary ingestion for the purpose of inducing, from the perspective of the individual in question, favourable changes in mood, energy levels or cognition.[23]

In this study we chose to consider "inappropriate use". Although the definition of "inappropriate use" is a matter for debate and needs to take into account both the licensed indications for the medicines and the wider public health issues, we have interpreted it as meaning use outside the generally recommended dose or period or frequency. The summary of product characteristics quotes the therapeutic indication for Nytol as "an aid to the relief of temporary sleep disturbance" and for Phenergan Nightime as "for short-term treatment of insomnia (sleeplessness) in adults". Sleep disorders are generally classified as "short-term" (up to three weeks) or "chronic" (lasting for several months or years)[20] and in recent years prescribing of benzodiazepines and other hypnotics other than for short-term use has been strongly discouraged.[24] The number of prescriptions for benzodiazepines, for example, fell from 16.5 million in 1991 to 13.2 million in 2000.[25] Some of the respondents in our study were taking these products on a regular basis and had been doing so for some months or years. We have estimated on the basis of our study that about 50 per cent of respondents might be using sleep aid products inappropriately in relation to their licensed indications and duration of treatment, and our findings suggest that a substantial proportion of "inappropriate" users have moderate to severe sleep problems. The public health issues raised by these findings are complex. A lot of people might be developing dependency. However, there is the question of what users of OTC sleep aids would do if they were refused sales of these products. If they consulted their GP, the prescription medicine alternatives are recommended only for short-term use and some have a high potential for dependence.

Centrally acting sedative antihistamines are used to treat sleeplessness and diphenhydramine and promethazine are marketed as "sleep aid" medicines that can be purchased OTC without a prescription. Under their professional code of ethics pharmacists are required to have in-house procedures for such medicines sales as a means of ensuring that the sale of the product is appropriate.[22]

This study has confirmed the feasibility of conducting community pharmacy-based research on usage of OTC medicines, and has formed a basis for the demographic profile of users of OTC sleep aids and identified patterns of use. However, the difficulties inherent in researching this particular group of medicines were recognised; the nature of the product group with its potential for misuse could make recruitment of purchasers difficult.

Many purchasers of OTC sleep aids reported long-standing use over periods of months and years. Much of this usage is outside the licensed indications for OTC sleep aid products. The public health implications of long-term use of these medicines need further discussion.

This paper was accepted for publication on 7 August 2002.

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