

General practitioners' views on the over-the-counter availability of H₂-antagonists

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SUMMARY

Background. In recent years there has been a trend towards increasing the number of drugs that are available over the counter (OTC) without prescription. Simultaneously, community pharmacists have been encouraged to develop and extend their role. General practitioners (GPs) have been shown to have some reservations about these developments. A group of drugs widely used in general practice, the H₂-antagonists, have recently become available OTC.

Aim. To examine GPs' attitudes towards community pharmacists dispensing H₂-antagonists over the counter (OTC) without prescription.

Method. Postal questionnaire to a sample of GPs from inner and outer London, Surrey, Kent, Hampshire, Northumberland, Newcastle upon Tyne and Leicestershire.

Results. Of 850 questionnaires sent, 515 were returned, an overall response rate of 60.5%. Fifty four per cent of respondents agreed that cimetidine should be available over the counter for dyspepsia in adults under 45 years not responsive to antacids. Ninety per cent of respondents were aware that H₂-antagonists had been deregulated. Most general practitioners learned about the deregulation from professional journals. Very few GPs stated they had changed their prescribing practice since H₂-antagonists became available OTC. The high cost to the patient of the OTC product was the most frequently mentioned reason why respondents did not encourage their patients to switch from prescription to OTC H₂-antagonists. Worries and concerns regarding the OTC availability of H₂-antagonists included masking serious conditions, missed diagnosis, loss of control by the GP and the potential for inappropriate use by patients.

Conclusions. Since 1990, there has been a large increase in GPs' support for the OTC availability of cimetidine. However, according to their stated behaviour, the reclassification of H₂-antagonists does not seem to have changed GPs' prescribing practice, and few appear to be recommending that their patients buy them over the counter.

Keywords: over-the-counter medicines; antiulcer agents; postal questionnaires.

Introduction

IN RECENT years, there has been an increase in the number of medicines that have been made available over the counter.^{1,2} Factors contributing to this trend include government interest in controlling expenditure on health care in general, and prescribing in particular, the pharmaceutical industry's wish to increase sales

and an acceptance of the importance of patient autonomy. General practitioners have been encouraged to support the use of OTC medicines as part of their consultation strategy.³ However, they have been shown to have reservations about the OTC availability of some drugs.^{4,5}

H₂-antagonists (cimetidine, famotidine and ranitidine) became available over the counter in the UK in April 1994. These drugs are widely used in general practice for the treatment of acid-peptic disorders including peptic ulceration, gastro-oesophageal reflux disease and some cases of non-ulcer dyspepsia. Dyspepsia is a common complaint. The 1-year community prevalence of dyspepsia and reflux symptoms is of the order of 40%. Only about 25% of individuals with symptoms of dyspepsia seek medical help.⁶ Even so, it has been estimated that between 1.6% and 5% of all general practice consultations are for dyspepsia.⁷ The costs of prescribing H₂-antagonists are high. In 1994, they made up 5.5% of the total net ingredient costs for prescribed items in England at a cost of over £188 million. Ulcer-healing drugs show wide variations in prescribing rates and indications. In 1994, they made up over 10% of the total net ingredient cost for prescribed items in England, and in the period 1993–94 showed the largest increase in net ingredient cost compared with other British National Formulary sections.⁸ The possibility of inappropriate prescribing of H₂-antagonists has been raised by the Audit Commission and others.^{9,10}

The reclassification of loperamide brought savings in prescribing costs.¹¹ The availability of OTC H₂-antagonists could also potentially shift some of the high costs of prescribing and consulting away from the National Health Service (NHS) with considerable savings. GPs' attitudes towards the OTC availability of the drug are likely to influence the direction of any shift that may occur.

Methods

The sampling strategy was influenced by the fact that, as part of a wider study, both GPs and community pharmacists were to be approached to give their views on OTC medicines. It was decided to base sampling on family health services authorities (FHSAs) rather than on national registers so that the views of GPs and community pharmacists working in the same geographical areas could be obtained. Eight FHSAs were selected randomly from a list of FHSAs in England. They were located in inner and outer London, Surrey, Kent, Hampshire, Northumberland, Newcastle upon Tyne and Leicestershire. The combined lists gave 1301 practices; these included 250 fundholding practices and 389 urban and 657 rural non-fundholding practices. In order to allow for a statistically meaningful comparison of fundholding and non-fundholding practices, all 250 fundholding practices were selected. A random sample of 250 urban and 350 rural non-fundholding practices was also taken. Given that fundholding practices tend to be in more rural areas, this sampling strategy allowed for the comparison of fundholding and rural non-fundholding practices and of urban and rural non-fundholding practices. The larger number of rural non-fundholding practices was included so as to increase the statistical power of the study. The questionnaire was piloted by distribution to 50 GPs from the selected FHSAs.

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One doctor was randomly selected from each practice in the sample to receive the questionnaire, which was dispatched in November 1994. The questionnaire sought information on the basic characteristics of the practice and the responding GP, including the number of patients and full-time equivalent doctors in the practice, fundholding status, location of the practice and the age of the respondent. This was followed by a series of questions relating to the respondent's attitudes to the supplying of drugs by community pharmacists without a doctor's prescription. This section was adapted from a questionnaire used by Spencer and Edwards⁴. It provided 14 clinical scenarios. In each scenario, a specific drug and clinical indication was given, and respondents were asked to indicate whether they agreed, disagreed or were uncertain that the drug should be supplied without a prescription. GPs were then asked a number of closed questions relating to their awareness of the availability of H₂-antagonists; whether the OTC availability of H₂-antagonists had altered their prescribing practice and whether they had encouraged patients to switch to OTC H₂-antagonists. They were also asked a number of open questions asking them to describe how their prescribing habits had changed, who they had encouraged to make the switch to OTC and why, and, for those who had not encouraged a switch, why this was so. Finally, GPs were asked to describe any worries or concerns they had regarding the OTC availability of H₂-antagonists. A reminder letter was sent to GPs who had not responded by December 1994. The data collected from the questionnaire were analysed using SPSS-PC, and differences between groups were tested using two-tailed Student's *t*-test χ^2 and paired comparison tests. The responses to open questions were systematically examined to identify themes. These were then grouped, coded and developed into categories.

Results

Of the 850 questionnaires dispatched, 394 were initially returned, with a total return of 515 after the reminder letter, giving an overall response rate of 60.6%. The response rates by region ranged from 47.6% (outer London) to 64.4% (Kent) ($\chi^2 = 11.04$; *df* = 7; *P* < 0.020); the response rate for fundholding practices was 68.8% and for non-fundholding practices 57.1% ($\chi^2 = 9.85$; *df* = 1; *P* < 0.01). The distributions of practice size, doctors' ages and average list size for the survey, for the FHSAs sampled and for

England are shown in Table 1. Younger GPs are somewhat under-represented in our sample compared with most of the FHSAs and England as a whole.

Respondents were asked their opinion about the OTC availability of a number of drugs, including cimetidine, for dyspepsia in adults under 45 years not responsive to antacids. Fifty four per cent of respondents agreed to it being made available, 31% disagreed and 14% were uncertain. There was no significant difference in the level of agreement between GPs from fundholding practices and practices in their preparatory fundholding year and GPs from non-fundholding practices, or in the level of agreement between urban and rural GPs.

The majority of respondents (90%) were aware that some H₂-antagonists had been deregulated and were available from retail pharmacists. When asked how they first found out about H₂-antagonists becoming available OTC, 43% of respondents mentioned a professional journal, 26% mentioned the television or radio and 16% mentioned the popular press. Very few GPs (4%) indicated that their prescribing habits had changed since H₂-antagonists became available OTC. There was no significant difference by fundholding status or by location of the practice. Only 6% of respondents had encouraged any of their patients to switch from prescription to OTC H₂-antagonists. Again, there was no significant difference by fundholding status or by location of the practice.

When asked why they had not encouraged patients to switch from prescription to OTC H₂-antagonists, the respondents gave a wide range of replies. The 360 (69.9%) GPs who responded to this question mentioned one or more of the concerns listed in Table 2.

A much larger proportion of non-fundholding respondents mentioned loss of control by GPs than fundholding respondents (28% vs 17%) ($\chi^2 = 4.69$; *df* = 1; *P* < 0.05).

Very few respondents (6%) had discussed the appropriate management of customers seeking OTC H₂-antagonists with their local community pharmacist. Twelve per cent of respondents said that patients seeking H₂-antagonists had been referred to them by pharmacists and 13% did not know whether patients had been referred or not.

A total of 467 respondents (91%) expressed a number of worries or concerns regarding the OTC availability of H₂-antagonists.

Table 1. GP and practice characteristics in survey, FHSAs surveyed and England as a whole.*

	Survey	Lambeth S & L	Enfield Haringey	Surrey	Kent	Leicester- shire	Northum- berland	Newcastle	Hampshire	England
Average list size	1963	20560	2151	1902	1910	1919	1632	1725	1787	1900
No. of GPs	515	412	262	559	839	491	189	166	914	26567
Age of GP (%)										
Under 35	7	11	5	16	13	20	5	24	17	18
35-44	30	36	31	39	37	40	39	40	40	37
45-54	34	31	42	29	31	28	30	19	28	29
55-64	26	17	20	15	17	11	6	11	11	14
65+	2	3	2	14	1	2	0	0	2	1
No. of partnerships	515	173	127	149	319	150	52	46	226	9100
Size (%)										
Single GP	25	43	49	19	40	27	19	20	15	31
2	16	21	25	15	17	17	13	13	15	20
3	19	14	13	11	12	13	15	13	13	15
4	18	9	5	17	14	18	19	24	18	13
5 or more	21	13	9	38	16	25	32	30	39	20

*Figures for FHSAs and England are for 1 October 1995.¹² The figures refer to unrestricted principals. Percentages may not add to 100 because of rounding.

Respondents mentioned one or more of the concerns listed in Table 3.

Twenty eight per cent of fundholding GPs (including those in their preparatory year) and 19% of non-fundholding GPs stated that they had no concerns about the OTC availability of H₂-antagonists ($\chi^2 = 5.2$; $df = 1$; $P < 0.05$).

Discussion

Since 1990, there has been a considerable increase in GPs' support for the OTC availability of cimetidine. In a 1990 study by Spencer and Edwards,⁴ only 11% of respondents agreed to cimetidine being made available OTC. By 1994, the level of agreement had risen to 54% but a substantial minority remain opposed to or uncertain about the dispensing of this drug by community pharmacists without a doctor's prescription. Few respondents indicated that they had encouraged patients to purchase OTC H₂-antagonists. The reason most often given for this was the high cost to the patient rather than clinical issues. This may reflect the prescription payment situation in England, where 50% of patients do not pay for prescriptions.⁸ In Denmark, 5 years after deregulation of H₂-antagonists, only 5% of H₂-antagonists were being sold OTC because of subsidized prescriptions in general practice.¹³ Nearly one-quarter of respondents mentioned loss of control of the patient in terms of monitoring and management as

a reason why they had not encouraged a switch to OTC H₂-antagonists, and it was also mentioned as a reason for concern about their availability. This concern is not restricted to H₂-antagonists but is a worry expressed about a range of OTC medications.¹⁴

When asked to express their worries or concerns regarding the OTC availability of H₂-antagonists, by far the most frequently voiced concern was that their use might mask serious conditions or lead to missed diagnosis. There is particular concern about possible delay in the diagnosis and treatment of peptic ulcers and gastric cancer. Studies have been undertaken in Denmark to define the effect of OTC availability of H₂-antagonists on hospital admissions for complicated peptic ulcer or problems related to incorrect therapy or delayed diagnosis.¹⁵ No significant effects were observed, although, given the small proportion of H₂-antagonists sold over the counter, extrapolation to other countries is problematic.¹⁶ The majority of general practice prescriptions for antisecretory and antacid drugs are given for non-ulcer indications.⁹ Concerns about masking serious problems with lower doses of H₂-antagonists are both paradoxical and unfounded.

The study reveals that discussion between GPs and community pharmacists over appropriate management of patients seeking OTC H₂-antagonists has been minimal. Some of the comments by GPs in the survey on the 'inadequacy' of the OTC H₂-antagonist dose would suggest that some are not clear about the use for

Table 2. Why general practitioners have not encouraged patients to switch from prescription to OTC H₂-antagonists.

Responses	Fundholder n=126	Non-fundholder n=234	Rural n=245	Urban n=115	Number n=360
High cost of OTC products to patient	54 (43)	97 (41)	103 (42)	48 (42)	151 (42)
Loss of control by the GP	22 (17)	65 (28)	63 (26)	24 (21)	87 (24)
Inadequate dose in OTC preparation	18 (14)	36 (15)	38 (16)	16 (14)	54 (15)
Situation not arisen	13 (10)	13 (5)	22 (9)	4 (3)	26 (7)
Disagree with OTC H ₂ -antagonists in principle	3 (2)	13 (5)	8 (3)	8 (7)	16 (4)
Risk of missing more serious conditions	3 (2)	10 (4)	4 (2)	9 (8)	13 (4)
It is the obligation of a GP to prescribe	1 (1)	8 (3)	5 (2)	4 (3)	9 (2)
Distance of pharmacy from GP practice	2 (2)	6 (2)	8 (3)	0 (0)	8 (2)
Potential for inappropriate use by patients	2 (2)	4 (2)	4 (2)	2 (2)	6 (2)
OTC products unsuitable for long-term management	3 (2)	3 (1)	4 (2)	2 (2)	6 (2)
Concern over competence of pharmacists to give appropriate assessment and advice	3 (2)	2 (1)	5 (2)	0 (0)	5 (1)
Concern over drug safety/drug interactions	0 (0)	4 (2)	3 (1)	1 (1)	4 (1)
OTC switch was 'political'	0 (0)	2 (1)	2 (1)	0 (0)	2 (1)
Don't know	1 (1)	4 (2)	3 (1)	2 (2)	5 (1)

n=number of respondents. Each respondent may have given one or more response. Percentages in brackets have been rounded to nearest whole number.

Table 3. Worries or concerns regarding the OTC availability of H₂-antagonists.

Responses	Fundholder n=148	Non-fundholder n=319	Rural n=323	Urban n=144	Number n=467
Concern over masking serious conditions or missed diagnosis	62 (42)	149 (47)	133 (41)	78 (37)	211 (45)
Loss of control by the GP	18 (12)	40 (12)	43 (13)	15 (10)	58 (12)
Potential for inappropriate use by patients	20 (13)	38 (12)	40 (12)	18 (12)	58 (12)
Age criterion – appropriate consideration	13 (9)	17 (5)	19 (6)	11 (8)	30 (6)
Drug interactions, side effects or contraindications	6 (4)	14 (4)	14 (4)	6 (4)	20 (4)
Delay in appropriate investigation	5 (3)	7 (2)	8 (2)	4 (3)	12 (3)
Concern over competence of pharmacists in this area	6 (4)	5 (1)	9 (3)	2 (1)	11 (2)
Inadequate dose in OTC products	4 (3)	7 (2)	8 (2)	3 (2)	11 (2)
Conflict of ethical traditions between GP and pharmacist	2 (1)	2 (1)	3 (1)	1 (1)	4 (1)
No concerns	41 (28)	62 (19)	75 (2)	28 (2)	103 (22)

n=number of respondents. Each respondent may have given one or more response. Percentages in brackets have been rounded to nearest whole number.

which the OTC products are licensed, i.e. for the short-term relief of dyspepsia, not for the treatment of ulcers. The level of communication must increase to minimize the possible risks to the patient associated with the continued reclassification of pharmacy only drugs.¹⁷

In order to comment categorically on the effect of OTC availability of H₂-antagonists on GP practice, an analysis of the prescribing habits would be necessary. This was beyond the scope of the present study. In this study, we recorded GPs' stated behaviour and not actual behaviour and, therefore, some caution must be exercised in interpreting the results. However, it would appear that the reclassification of H₂-antagonists is not changing GP prescribing practice and that few are recommending that their patients buy these drugs OTC. This would suggest that large savings will not be made on H₂-antagonist prescribing costs by the NHS, in part because GPs are unwilling to transfer these costs to their patients. It remains to be seen whether the availability of OTC H₂-antagonists and the intense advertising campaigns associated with their arrival on the market will act to increase patient demand for these as prescription drugs.

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