

General practitioners' views and experiences of over-the-counter simvastatin in Scotland

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Statins are widely used for the primary and secondary prevention of coronary events in high risk populations.
- In 2004 simvastatin was reclassified in the UK from prescription only to being available over-the-counter (OTC).

WHAT THIS STUDY ADDS

- The majority of GPs do not support the supply of OTC simvastatin by the community pharmacist.
- GPs were particularly concerned by the lack of cholesterol and blood pressure data in the CHD risk assessment prior to sale.

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AIMS

The aims of this study were to determine the views and experiences of Scottish GPs towards CVD risk assessment by community pharmacists and the supply and sale of simvastatin.

METHODS

A cross sectional postal questionnaire survey of all primary care general practices in Scotland was carried out. The main outcome measure was GPs' awareness of and opinions regarding OTC simvastatin use, experience of OTC simvastatin and opinions regarding community pharmacist involvement in CHD risk assessment.

RESULTS

A response rate of 45.7% was obtained. The majority (92.6%, 428) were aware that community pharmacists could sell simvastatin to reduce the risk of a first coronary event in individuals at moderate risk of CHD. However, over half (55.6%, 257) believed that the OTC sale of simvastatin was inappropriate. Just over half were unaware that the pharmacist's CHD risk assessment for the sale of simvastatin did not include lipid (54.8%, $n = 253$) or blood pressure measurement (53.7%, $n = 248$) and 56.7% (262) and 57.8% (267) of respondents, respectively, thought these omissions inappropriate. Almost half of the respondents (48.1%, 222) supported community pharmacists supplying simvastatin as supplementary prescribers while fewer (26.6%, 132) were in favour of supply via an independent prescribing arrangement.

CONCLUSION

This study confirms that the majority of GPs do not support the supply of OTC simvastatin by the community pharmacist, being particularly concerned by the lack of cholesterol and blood pressure data in the CHD risk assessment prior to sale. Other methods of pharmacy based simvastatin supply including supplementary prescribing merit further evaluation.

Introduction

Statins are widely used for the primary and secondary prevention of coronary events in high risk populations [1]. In 2004 simvastatin was reclassified in the UK from prescription only to being available over-the-counter (OTC) under the supervision of a pharmacist [2]. The UK remains the only country in the world to have a statin available OTC without a prescription.

The product licence for OTC simvastatin is for the 10 mg strength only and restricts sale to individuals who have at least a moderate 10-year coronary heart disease (CHD) risk of 10–15% [3]. The definition of moderate risk includes all men aged over 55 years, or men aged 45–54 years and women over 55 years who possess one or more risk factors such as family history, smoking, obesity or are of South Asian ethnic origin. The Royal Pharmaceutical Society of Great Britain (RPSGB) produced practice guidance stating that pharmacists should carry out a cardiovascular risk assessment prior to the sale of OTC simvastatin. However, neither this guidance nor the OTC product licence requires measurement of cholesterol or blood pressure to permit risk assessment prior to sale [4].

Although the move to reclassify simvastatin was strongly backed by the RPSGB there was little support from the medical profession [5–9]. Primarily The Royal College of General Practitioners (RCGP) highlighted the lack of outcome evidence and possible issues concerning patient monitoring. In a previous survey of community pharmacists to assess their levels of confidence regarding CHD risk assessment and simvastatin sale, we found that more than half of the respondents were entirely confident about selling simvastatin and most felt that community pharmacists could make an appropriate risk assessment [10]. No published research has examined OTC statins post launch from the GPs' perspective.

Given the RCGP concerns, the aims of this study were to determine the views and experiences of GPs towards the OTC supply of simvastatin and CVD risk assessment by community pharmacists.

Methods

Following review for face and content validity by five experienced medical and pharmacy practitioners, the pilot questionnaire was mailed to the practice manager of 40 randomly selected primary care general practices in Scotland. A covering letter requested that the questionnaire be completed by a senior partner or a GP with a special interest in cardiovascular medicine. Piloting resulted in minimal changes to the wording and sequencing of some questions. Pilot practices were excluded from the full study. The amended questionnaire was then mailed out to the 1010 remaining primary care general practices in Scotland. Up

to two reminders were sent to non-respondents at 4-weekly intervals.

The questionnaire comprised four sections composed mostly of closed questions with space for comment. Questions focused on demographics, awareness of and opinions regarding OTC simvastatin use, experience of OTC simvastatin and opinions regarding community pharmacist involvement in CHD risk assessment.

Data were coded and entered into SPSS for Windows version 15 (SPSS Inc.) and analysed using descriptive statistics.

Grampian Research Ethics Committee advised that this study did not require formal review by an NHS Ethics Committee. Approval for the study was obtained from the Ethical Review Panel of the School of Pharmacy at Robert Gordon University.

Results

Four hundred and sixty-two GP practices returned a completed questionnaire giving a response rate of 45.7% of all Scottish general practices. Two-thirds of respondents were male (308, 66.7%), one-third (157, 34.0%) had a special interest in cardiovascular medicine, 75 (16.2%) were GP trainers and 277 (60.0%) had been practising for more than 16 years. The median number of full time equivalent GPs per practice was 3 (interquartile range, IQR, 2–5) and the median practice population was 5000 (IQR 2600–8000).

The majority of respondents (92.6%, 428) were aware that community pharmacists could sell simvastatin to reduce the risk of a first coronary event in individuals at moderate risk of CHD. However, over half (55.6%, 257) believed that the OTC sale of simvastatin was inappropriate. Just over half of respondents were unaware that the pharmacist's CHD risk assessment for the sale of simvastatin did not include cholesterol (54.8%, $n = 253$) or blood pressure measurement (53.7%, $n = 248$) and 56.7% (262) and 57.8% (267) of respondents, respectively, thought these omissions inappropriate. The majority of respondents stated that, having supplied OTC simvastatin, the community pharmacist should also be responsible for patient follow-up and monitoring blood pressure (61%), cholesterol (70.8%), side effects (83.3%) and interactions (75.5%).

Table 1 gives GPs' responses on their experiences and opinions of aspects of OTC simvastatin.

Discussion

This study confirms that the majority of GPs do not support the supply of OTC simvastatin by the community pharmacist, being particularly concerned by the lack of cholesterol and blood pressure data in the CHD risk assessment prior to sale. Few GPs routinely asked patients about OTC statin

Table 1

GPs' experiences and opinions of aspects of OTC simvastatin (n, %) (n = 462)

Question:	Missing	Yes	No
1 Have you come across any patients taking OTC simvastatin?	0	36 (7.8)	426 (92.2)
2 Have you switched any patients from OTC simvastatin to a prescription for simvastatin?	4 (0.9)	13 (2.8)	445 (96.3)
3 Have you recommended any patients to purchase OTC simvastatin?	2 (0.4)	17 (3.7)	443 (95.9)
4 Would you / do you routinely ask patients if they are taking OTC simvastatin?	2 (0.4)	44 (9.5)	416 (90.0)
5 Would you / do you document in their medical notes that patients are on OTC statin?	12 (2.6)	364 (78.8)	86 (18.6)
6 Have you noticed an increase in patient demand for statins?	1 (0.2)	147 (31.8)	314 (68.0)
7 Have you advised any patients to stop taking OTC simvastatin?	6 (1.3)	10 (2.2)	446 (95.5)
8 Have you had any patients referred by a community pharmacist for a full cardiovascular risk assessment?	4 (0.9)	53 (11.6)	405 (88.4)
9 Have you ever discussed with a local community pharmacist(s) local policies on the:			
a. general management of CHD risk and lipid lowering therapy?	8 (1.7)	62 (13.7)	392 (86.3)
b. sharing of information (with patient consent) regarding cholesterol test results?	11 (2.4)	42 (9.3)	409 (90.7)
c. referral of patients to GPs for full CHD risk assessment?	12 (2.6)	44 (9.8)	406 (90.2)
10 Do you feel that community pharmacists should be able to supply statin therapy:			
a. OTC?	25 (5.4)	170 (38.9)	267 (61.1)
b. as a supplementary prescriber?	51 (11.0)	222 (54.0)	189 (46.0)
c. as an independent prescriber?	50 (10.8)	132 (32.0)	280 (68%)
11 Do you feel that community pharmacists should:			
a. have access to information in the medical records to allow them to assess cardiovascular risk?	23 (5.0)	150 (34.2)	289 (65.8)
b. inform GPs of the results of cardiovascular risk assessment?	15 (3.2)	401 (89.7)	46 (10.3)
12 Do you feel that community pharmacists should follow-up patients taking OTC simvastatin by monitoring:			
a. blood pressure?	21 (4.5)	282 (63.9)	159 (36.1)
b. cholesterol levels?	19 (4.1)	327 (73.8)	116 (26.2)
c. for adverse effects and drug interactions?	16 (3.5)	385 (86.3)	61 (13.7)
d. compliance?	19 (4.1)	349 (78.8)	94 (21.2)

treatment as part of their CHD risk assessment. This should be done routinely and if identified a full risk assessment performed. Furthermore few GPs had been involved in discussions with their local community pharmacists regarding CHD risk assessment policies, initiation of statin therapy in the community and clinical information sharing.

The lack of a formal CHD risk assessment using cholesterol and blood pressure measurements by the pharmacist was a source of concern to GPs as it has been to other professional groups [8, 9].

Although community pharmacists are encouraged to discuss CHD policies with GPs [4], our results suggest little inter-professional interaction regarding OTC simvastatin and CHD management. Given the accessibility of the community pharmacy and the large number of patients who visit daily this may be a missed opportunity to optimize CHD management.

More than half of respondents were supportive of statin prescribing by a pharmacist supplementary prescriber working within a patient specific clinical management plan.

These findings should, however, be interpreted with some caution. We sampled only one GP per practice and achieved a response rate of lower than 50%. It may be that non-respondents had a different awareness of licence restrictions and appropriateness. These factors may limit the generalizability of the findings. There is little evidence of support from GPs to further the role of the community

pharmacist as part of the medical team in formal CHD risk assessment. This potential opportunity merits further investigation.

Competing interests

There are no competing interests to declare.

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REFERENCES

- 1 Baigent C, Keech A, Kearney PM, Blackwell L, Buck G, Pollicino C, Kirby A, Sourjina T, Peto R, Collins R, Simes R on behalf of the Cholesterol Treatment Trialists' Collaborators. Efficacy and safety of cholesterol-lowering treatment prospective meta-analysis of data from 90,056 participants in 14 randomised trials of statins. *Lancet* 2005; 366: 1267–78.
- 2 Medicines and Healthcare Products Regulatory Agency. Reclassification summary for simvastatin POM to P. 2004. Available at <http://medicines.mhra.gov.uk> (last accessed 10 March 2009).

- 3** Johnson & Johnson MSD Consumer Pharmaceuticals. Zocor Heart-Pro Pharmacist Training Guide. 2004.
- 4** Royal Pharmaceutical Society of Great Britain. Practice guidance: OTC simvastatin 10 mg. *Pharm J* 2004; 273: 169–70.
- 5** Medicines and Healthcare Products Regulatory Agency. Responses to ARM18: request to reclassify simvastatin 10 mg. 2003. Available at <http://medicines.mhra.gov.uk> (last accessed 10 March 2009).
- 6** Bayliss E, Rutter P. General practitioners' views on recent and proposed switches from POM to P. *Pharm J* 2004; 273: 819–21.
- 7** Anonymous. Editorial. Over-the-counter simvastatin given the go-ahead. *Pharm J* 2004; 272: 595.
- 8** Gibson L. Moves to sell statins over the counter raises concerns. *Br Med J* 2004; 328: 1221.
- 9** Anonymous. Editorial. OTC Statins: a bad decision for public health. *Lancet* 2004; 363: 9422.
- 10** Hansford D, Cunningham S, John D, McCaig D, Stewart D. Community pharmacists' views, attitudes and early experiences of over-the-counter simvastatin. *Pharm World Sci* 2007; 29: 380–5.