OTC simvastatin supply — what changes in practice and education do pharmacists want?

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Abstract

Aim
To investigate and appraise the changes required in practice and the training requirements of community pharmacists to enable them to supply simvastatin 10mg over the counter appropriately.

Design
A structured questionnaire, incorporating both quantitative and qualitative research aspects.

Subjects and setting
Pharmacists in charge of a random sample of 200 community pharmacies in the Leeds/Bradford area.

Results
A response rate of 50% (100 questionnaires) was achieved. Views were mixed on the proposed switch. 40% of pharmacists agreed that the deregulation of statins from prescription-only supply to pharmacy sale was a good idea, 24% disagreed and 36% were unsure. There was a difference in opinion on whether the deregulation of statins was a good idea, depending on whether the pharmacy had (or was planning to have) a consultation area or not (chi-squared, $P=0.028$). Those thought that statins being available over-the counter was a good idea also answered more positively to the profession being ready to move forward with a greater prescribing role (chi-squared, $P=0.019$). Two thirds (66%) thought that supplies of OTC statins should be recorded, and a patient medication record-type database was the most popular option for recording the supply.

Conclusion
Nearly all pharmacists agreed that training would be an integral part of the successful implementation of the switch. The centres for pharmacy postgraduate education were the preferred organisations to supply and accredit such training.

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The National Service Framework for Coronary Heart Disease[1] set the programme for updating the health services over 10 years to achieve the Government's target of a reduction in death from CHD, stroke and related diseases in people aged under 75 years by at least 40 per cent by 2010.

The 2003 progress report[2] notes that approximately 1.1 million patients currently receive statin therapy, with a potential of 4,000 to 6,000 lives being saved. An annual increase of 30 per cent in prescribed statins is also being seen, showing that statins have a valuable role in the prevention of CHD. These patients are described as being at "high risk" of developing CHD, currently defined as a 10-year risk of an event of greater than 15 per cent.

For people with a moderate risk, defined as a ten-year risk of an event of between 10 per cent and 15 per cent, the Medicines and Healthcare products Regulatory Agency (MHRA) recently approved the reclassification of simvastatin 10mg tablets from prescription only medicine to pharmacy status. The indication for the reclassified formulation is for the reduction of a first major coronary event in those at moderate risk of developing CHD. Those likely to be at moderate risk are further defined as:

- Men aged 55 years or more
- Men aged 45 and up to 55 years and women over 55 years with one or more of the following risk factors
  - Family history of CHD in a first degree sibling (either a male relative under 55 years, or a female relative under 65 years)
  - Smoker (currently or within the past five years)
  - Overweight (body mass index greater than 26kg/m^2, or a truncal obesity measured through a waist measurement of greater than 40 inches in men or 35 inches in women)
  - South Asian ethnicity

It is expected that OTC simvastatin will be used in combination with dietary and lifestyle changes and that it will produce a reduction in the number of major coronary events of around one third after three years of treatment.

Using a protocol, the pharmacist and customer will together establish the level of CHD risk expected for the individual to see if the customer meets the indications. Those people with pre-existing conditions that would indicate a high CHD risk (eg, diabetes, hypertension, family history of hypercholesterolaemia) that would be best managed by a GP, those with contraindications (eg, liver dysfunction, pregnancy, excessive alcohol intake), and those who are taking other medicines that may interact with simvastatin will not be eligible to purchase OTC simvastatin.

Pharmacists will provide counselling to support the patient and advice will be given on other lifestyle choices that will help with reducing their risk, for example, weight loss, dietary changes, exercise and smoking cessation.

Simvastatin OTC will not be available for those identified with low (<10 per cent) or high (>15 per cent) CHD risk, and consumers returning for repeat purchases will have follow-up discussions with the pharmacist to ensure that their circumstances are the same.

Aim There is no published research on community pharmacists' understanding of the proposed POM-to-P switch or on pharmacists' training needs and the type of training pharmacists might prefer.

The aim of this study was to survey some of those pharmacists who will be involved in the OTC supply of statins in order to assess the changes that will be required in their practice and the training needed to enable successful implementation of a protocol to assess the suitability for OTC simvastatin. The objectives were:

- To investigate and appraise the changes required in practice to enable the appropriate supply of OTC simvastatin
- To investigate pharmacists' training requirements for the appropriate supply of OTC simvastatin

Method

A structured questionnaire was used which incorporated both quantitative and qualitative research aspects. The questionnaire covered pharmacists' views about the POM-to-P switch of simvastatin, training needs of pharmacists and medicines counter assistants and demographic information about the pharmacy. Likert scales were used to assess the extent of agreement or disagreement with attitudinal statements.

The draft questionnaire was subject to internal review with academic colleagues before being piloted with 10 pharmacists.

Following the pilot the questionnaire was modified.

A sample of pharmacists from the Leeds/Bradford area was drawn using the Royal Pharmaceutical Society' Register of Premises as the sampling frame. From this database a list of 200 pharmacy premises were randomly selected.

Each of the pharmacies on the list was telephoned to explain the purpose of the project, to obtain the name of the pharmacist in charge and to seek agreement from the pharmacist to send the questionnaire. Pharmacists who did not agree that the questionnaire could be sent were removed from the list and further premises randomly selected from the database as before to reach a target of 200.

Each pharmacist who agreed was sent a questionnaire and a postage paid return envelope. To maintain anonymity, the questionnaire was not coded. The research was undertaken in the spring of 2004, before final approval of the POM-to-P switch of simvastatin was granted by the MHRA.

Results

Of 200 community pharmacists who were sent the questionnaire 50 per cent returned it. Forty-nine respondents were female and 51 were male. Almost three quarters were employees. One in three pharmacies (31 per cent) had a consultation area and 17 per cent were planning to have one in the near future.

Attitudes towards OTC simvastatin Pharmacists were asked whether they agreed that statins should be switched from POM to P. Views were mixed. Forty per cent of pharmacists who agreed that the deregulation of statins from POM to P was a good idea, 24 per cent disagreed and 36 per cent were unsure.

There was a significant difference in opinion on whether the deregulation of statins was a good idea, depending on whether the pharmacy had (or was planning to have) a consultation room or not (chi-squared, P=0.028). Those with a consultation area were more positive towards the switch.

Those who thought OTC statins were a good idea also answered more positively to a question about the profession being ready to move forward with a greater prescribing role (chi-squared, P=0.019).

If statins were to be made available over the counter, 60 per cent of pharmacists stated they would be happy to supply them, 18 per cent stated they would not and 22 per cent were unsure.

Most pharmacists (67 per cent) would be willing to test blood cholesterol in the pharmacy, 18 per cent would not and 15 per cent were unsure if they would or not. If patients were identified with risk factors for CHD, 63 per cent of pharmacists said they would be willing to identify the need for a statin, 19 per cent said they would not and 18 per cent were unsure.

Most respondents (61 per cent) believed that the profession is ready for the additional responsibility of the supply of medicines through a greater prescribing role, 25 per cent disagreed and 14 per cent were unsure.

Practical aspects of the supply of OTC statins All respondents agreed that there should be a protocol and guidelines for the supply of OTC statins.

On the issue of recording the supply of OTC statins, 66 per cent said supplies should be recorded, 22 per cent said they should not and 12 per cent were unsure. Keeping a PMR record was the most popular option for recording the supply, supported by 57 per cent of respondents, with 35 per cent favouring a patient-held record. About one third (34 per cent) said that the GP should be notified.

Fifty per cent of pharmacists would like all of a patient's medical notes to be available, in order to enable efficient and safe supply of OTC statins, with 16 per cent saying the past two years' records and 20 per cent saying the past five years'. Only 6 per cent did not believe that access to patients' records would not be needed.

Just over half of respondents (54 per cent) believed that patients should register with one pharmacy for the supply of statins, but 24 per cent disagreed and 22 per cent were unsure.

Training requirements Nearly all pharmacists believed that additional training was needed to supply OTC statins: 63 per cent strongly agreed and 33 per cent agreed. Pharmacists were asked which organisations they thought should provide training and could select more than one if they wished. For supply and accreditation of such training, the Centre for Pharmacy Postgraduate Education was preferred by 63 per cent of respondents. The Royal Pharmaceutical Society was mentioned by 40 per cent of respondents and the National Pharmaceutical Association by 20 per cent.

Pharmacists said that the ideal contents to be included in the training package were:

- Mode of action, contraindications, precautions for use and adverse effects of statins (100 per cent)
- Interventions to reduce risk, including lifestyle changes (97 per cent)
- Pathophysiology and major risk factors of CHD (94 per cent)
- Advice on counselling about statins (91 per cent)

Respondents were asked whether pharmacists should be required to show evidence of successful completion of training on OTC statins. Thirty-nine per cent of pharmacists agreed that an examination of competence would be appropriate, 45 per cent disagreed and 16 per cent were unsure. Most pharmacists (81 per cent) indicated that they would prefer training to be done during work time, compared with 19 per cent who indicated private time was more appropriate.

Discussion

Most pharmacists said they would be happy to supply OTC simvastatin. However there was more uncertainty about whether they believed the switch was a good idea. These findings show that, despite ambivalent feelings about the principle of the switch, most pharmacists were happy to implement it in practice. Pharmacists' additional comments show that some of the concerns expressed over OTC statins were not relevant to the proposed simvastatin OTC product. This suggested that there were some gaps in pharmacists' understanding of how the proposed product would be licensed for use and its place in the prevention of CHD in a "moderate risk" population as opposed to its place in the treatment of an established CHD patient.

With regards to possible practice changes associated with the switch, pharmacists surveyed agreed that a protocol and guidelines should be established for the supply of OTC simvastatin. Most said they would be willing to consider the need for a statin if they identified that a patient had risk factors for CHD.

Around two thirds of respondents said they would be willing to carry out cholesterol testing in the pharmacy, but only one third currently have a private consultation area. The consultation between pharmacist and customer about possible use of OTC statins would benefit from greater privacy than is possible at the medicines counter. This represents one of the key changes in practice that will have to take place, not only for the supply of statins over the counter but also for the transition of the pharmacist from the dispensary to a more front-line role.

In this study pharmacists who had a consultation area, answered the question of whether OTC statins are a good idea more positively. It is possible those who have a consultation area may be more forward-looking and supportive of changes in their role, and this is reinforced by the finding that those who were positive about the profession being ready for a more enhanced role also thought that OTC statins were a good idea.

A major issue about supplying a statin over the counter is whether the supply should be recorded. The results show that most pharmacists surveyed believed that it should. This is an important issue because there are few products currently available OTC that a patient will be taking long term, and patients may not inform health professionals in all settings about the OTC medicines they are taking.

Finding a suitable method of recording a supply made over the counter is problematic. The results of this study show that a patient medication record system is the most popular choice for this, most probably due to it being the easiest option to put into effect immediately. However it is, at present, an ineffective option for sharing information with others. A patient-held record might be a more effective means of making information available to those who need it.

Training will play an integral part in the successful implementation of the POM-to-P

switch. Ninety-six per cent of pharmacists agreed or strongly agreed that a pharmacist who wishes to supply OTC statins should undergo training. This was also reflected in the verbatim comments of many respondents, who observed that training will be essential. The most popular organisations to provide this were the CPPEs, which are acknowledged as being well established and known for providing well-presented and effective training packages. The other two options that followed in popularity were the Royal Pharmaceutical Society, which recently issued guidance on practice issues and training,[3] and the National Pharmaceutical Association.

Formal testing as a means of assessing training was less well received by respondents. Assessment however is an important component of training, not only to the individual undertaking the training as a means of gauging their learning, but as a way of ensuring that a minimum standard is being achieved.

Conclusion

Most pharmacists would be happy to supply statins over the counter, and nearly all want an appropriate protocol and guidelines. There was some uncertainty over whether OTC simvastatin was altogether a good idea, but pharmacists' comments showed their uncertainty was often due to misunderstandings and preconceptions about how the product would be used.

The key practice changes identified for a successful transition from prescription only to an over-the-counter statin product include the presence of consultation areas, improving inter-profession communication, and record keeping.

DECLARATION OF INTEREST John Blenkinsopp has been a paid adviser to Johnson & Johnson MSD on the switch of simvastatin 10mg from prescription-only to pharmacy supply status.

This paper was accepted for publication on 27 July 2004.

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