**NT CLINICAL**

**UPDATE**

**Understanding the implications of over the counter statin sales**

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Coronary heart disease (CHD) is the UK’s biggest killer. While recommending that all patients can benefit from lifestyle interventions, the current guidelines focus pharmacological management on those at high risk. An over the counter (OTC) statin would enable people with moderate (10–15 per cent) CHD risk to take preventive action. Pharmacists would be able to recommend OTC simvastatin to those at moderate risk by following a simple pharmacy protocol to assess a person’s risk. A regime of 10mg simvastatin daily would have a significant impact on both the low-density lipoprotein cholesterol (LDL-C) level and the CHD risk of those at moderate risk. Cholesterol testing would not be mandatory but would be available in pharmacy to enable people to monitor their progress.

The cholesterol lowering drugs known as statins are currently prescribed to 1.8 million people in the UK and are believed to save 6,000–7,000 lives a year. The Committee on Safety of Medicines has recommended the switch of simvastatin 10mg from a prescription-only medicine to a pharmacy medicine. They concluded that the benefits greatly outweigh any possible risk. This means those who are at moderate risk of heart disease and who wish to take pharmacological preventive measures will now be able to do so.

The switch has been welcomed by top cardiologists, heart charities British Heart Foundation and HEART UK, the Royal Pharmaceutical Society of Great Britain (RPSGB), and the National Pharmaceutical Association (NPA).

Simvastatin has now become available over the counter as a pharmacy-only medicine:

- Prescription-only medicines are available only with a prescription from a doctor, dentist or nurse prescriber;
- Over the counter (OTC) drugs are those for which a prescription is not required;
- Pharmacy-only (P) medicines can be purchased only from pharmacies;
- General sales list (GLS) medications are available widely.

**Coronary heart disease**

Coronary heart disease (CHD) is the leading cause of death for adults worldwide. Every year, more than 270,000 people in the UK have a heart attack (one heart attack occurs every two minutes) and 120,000 die from CHD. This equates to approximately one in four deaths in men and one in six deaths in women (British Heart Foundation, 2003).

Guidelines on the prevention of CHD have understandably focused interventions on those at highest risk for the disease, prioritising treatment for those at greatest need. The National Service Framework for Coronary Heart Disease (Department of Health, 2000) recommends prescribing statins to those considered to have a CHD risk at or above 30 per cent over 10 years.

However, the first joint British recommendations, for example, recognise there is good evidence for benefit when interventions are given at lower levels of risk (Wood et al, 1998).

The new Joint British Societies guidelines (currently under review and due for release soon) may identify new risk calculation tables, in line with the European guidelines on cardiovascular disease (De Backer et al, 2003) and the new British Hypertension Society guidelines (Williams et al, 2004). The guidelines will continue to be able to identify people at moderate risk.

The DoH is determined to offer patients choice and to allow people who are not yet ‘patients’ to benefit from cardiovascular risk reduction. Indeed as a public health exercise the use of a statin in a large section of the population at moderate risk is still certain to prevent vast numbers of cardiovascular events and deaths.

**Statins**

Statins significantly reduce the risk of heart disease by lowering LDL-C and preventing build-up of plaque in arteries. The Heart Protection Study demonstrated the benefits of lowering LDL-C with a statin in a much wider range of individuals – including those without diagnosed CHD (HPS Collaborative Group, 2002) – and those without raised cholesterol levels. It also showed no significant difference in reported side-effects between those patients on a placebo and those on simvastatin 40mg.

**Moderate risk**

Moderate risk is defined as a 10–15 per cent 10-year risk of having a CHD event when using the joint British recommendations (Wood et al, 1998). Primary care has always been ideally placed to measure CHD risk, as GP surgeries already hold information about patients in medical records. Here, the targeting and pharmacological treatment of those at highest risk of CHD is advocated.

Rather than being seen as an alternative, the switch in the status of statins would complement the current recommendations. Not only will pharmacists be able to
identify people at moderate risk, they will also be able to recognise those whose risk may be higher and refer them towards general practice, where appropriate.

Pharmacists will use a protocol to identify patients at moderate risk, based on age, lifestyle, and other risk factors (Box 1). This protocol will also indicate those who are at higher risk who should be referred to their GP for treatment, and those at lower risk who can be offered lifestyle advice alone. Statins will still be available on prescription for those patients at higher risk of CHD.

### Cholesterol testing

The overall aim of the change is to reduce CHD risk by lowering cholesterol – this risk reduction is independent of the starting levels in the blood. Therefore, there is no prerequisite for people to have a cholesterol test before starting to take OTC statin medication.

However, many people would want to know what their cholesterol levels were. Additionally, concordance may be encouraged by a knowledge of the starting cholesterol level (either before or in the first few days of statin use) to monitor how cholesterol levels are dropping. Cholesterol testing is likely to be made available in pharmacy stores, either directly or through ‘send-away’ tests to a central laboratory.

### Dosage

The 10mg daily dose has been subject to much debate since the switch was proposed. Simvastatin 10mg had traditionally been widely prescribed by GPs although there has been a move to higher doses in populations at high risk. This is primarily due to evidence that, where a patient’s best chance of significantly reducing their risk of CHD is through a maximum reduction in their LDL-C, a higher dose is the most effective way of achieving this.

However, in the moderate risk category where an OTC statin would be used, a reduction in one or more risk factors (such as ceasing smoking, increasing aerobic activity, and losing weight), together with a reduction of LDL-C, would have a significant effect on the overall risk.

The relationship between a simvastatin dose and the reduction of LDL-C is log-linear. By doubling the dose, you do not double the efficacy. An increase from 10mg to 20mg increases the relative reduction of LDL-C from around 27 per cent to 32 per cent. Doubling the dose again to 40mg produces a further five per cent incremental improvement (Law et al, 2003).

The absolute reduction of LDL-C achievable with 10mg simvastatin, if sustained, will produce around a 30 per cent relative reduction in CHD risk compared with an approximately 37 per cent reduction with a 40mg dose (Law et al, 2003). Therefore, a 10mg dose will produce a valuable overall risk reduction in those at moderate risk. If this is combined with the recommended lifestyle changes, the benefits will be considerable.

### Pharmacy package

Community pharmacists and their pharmacies’ growing role in the NHS have been highlighted in a DoH report on primary care (DoH, 2003). The advent of this change in status for simvastatin will further develop this area. Recent nationally available training for pharmacists focused on switching prescription-only medicines to pharmacy medicines and highlighted, as an example, simvastatin 10mg.

Pharmacists are often ‘first line’ in seeing people both when they are well and unwell. They are often located in the heart of the community and are easily accessible. Some pharmacists proactively screen to identify people at moderate risk, while more reactive pharmacists may wait for people to present themselves. However, within this expanding role, anyone within the moderate risk category seeking advice from their pharmacist can be advised on a more ‘holistic’ approach to managing their heart health, including lifestyle changes.

### What does this mean for nurses?

The role of the nurse, and in particular the practice nurse, should not be underestimated in the discussion and possible recommendation of the switch to OTC status for simvastatin. Many people who may be at moderate risk will be regular visitors to the practice nurse and may even directly seek advice about the use of OTC simvastatin. Nurses are well placed to provide advice and recommendations as, generally, they spend more time with patients and will often be aware of those people who fit the moderate risk criteria.

Increasingly people seek more details from general practice about subjects they have heard discussed in the media. It is not uncommon for practice nurses and GPs to have pages of information presented to them that patients have downloaded from the internet. Therefore, it is important for nurses to be well informed of the growth in the promotion of self-care and the control people wish to exercise over their treatment.

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**KEYWORDS**  ■ Medicine  ■ Simvastatin  ■ Coronary heart disease

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**REFERENCES**


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