

PRACTICE GUIDANCE: CHOLESTEROL TESTING



Royal
Pharmaceutical
Society
of Great Britain

As part of the advanced and enhanced services of the community pharmacy contract, pharmacists will be able to provide medicines use reviews and point-of-care testing (POCT) for cholesterol. This guidance has been produced by the Royal Pharmaceutical Society's Practice Division. The top ten tips has been produced by the MHRA

WHAT IS CHOLESTEROL?

Cholesterol is a waxy substance which is both made in the liver and supplied directly in the diet. It is vital for the body to function properly. Most of the body's cholesterol is produced in the liver, with excess production

occurring when the diet is rich in saturated fats, especially low-density lipoproteins.

Problems arise when either the body makes too much LDL cholesterol, or intake of cholesterol from food exceeds the body's ability to dispose of it. Excess cholesterol can accumulate and form deposits called plaques on artery walls (hardening of the arteries). As plaques

GLOSSARY

CHD	coronary heart disease
HDL	High-density lipoprotein cholesterol ("good" cholesterol)
LDL	Low-density lipoprotein cholesterol ("bad" cholesterol)
TC	Total cholesterol
TC/HDL	Ratio of TC/HDL

continue to grow, blood flow may slow or even stop. This can increase the risk of coronary heart disease (CHD) and strokes.

WHO IS AT RISK?

- *Those with a family history of high cholesterol.* High cholesterol levels can be of genetic origin (familial hypercholesterolaemia).
- *Those with high circulating levels of cholesterol (hyperlipidaemia).* Two-thirds of the adult population have blood total cholesterol over 5mmol/L. In men, the proportion with cholesterol over that level increases from 23 per cent in those aged 16–24, to 82 per cent in those aged 55–64. The proportions are

TOP TEN TIPS FOR CHOLESTEROL TESTING

1. **Involve your local hospital laboratory** Your local hospital laboratory can provide advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, and health and safety.
2. **Choosing the right equipment** There are a variety of analysers available for the measurement of cholesterol and you must use one that is CE marked under the In-vitro Diagnostic Medical Devices directive (ask the manufacturer). Ideally the analyser will have had an independent evaluation and you should contact the Device Evaluation Service for the latest information about reports and advice on purchasing (tel 020 7972 8181).
3. **Management** Many people will be involved in the provision and management of a cholesterol testing service. It is vital that a service co-ordinator is identified who will have overall responsibility for all aspects of the service.
4. **Training** Training must be provided for all staff who will be using the cholesterol testing analyser. Only staff whose training and competence has been established and recorded should be permitted to carry out cholesterol testing.
5. **Standard operating procedures** Standard operating procedures must include the

information provided in the manufacturer's instructions for use.

6. **Health and safety** Be aware of the potential hazards associated with the handling and disposal of blood samples, sharps and reagents from the analyser.
7. **Quality assurance** Encompasses all the steps taken to ensure that measurements are reliable and includes collecting a good quality blood sample, analysing it correctly and dealing with the result appropriately.
8. Internal quality control samples should be run on the analyser to ensure that it is working correctly and that the results are reliable
9. External quality assessment samples should be run periodically to ensure that results are comparable to those from other cholesterol analysers.
10. **Maintenance** In order that equipment continues to perform accurately you must perform maintenance as directed by the manufacturer.
11. **Record keeping** Records are essential and must include date, test strip/reagent, lot number, test result, operator identity and patient identity.
12. **Results** Results should be reviewed by appropriately qualified and trained staff with particular reference to the patient's history and previous results.

higher in women: 27 per cent in those aged 16–24, and 91 per cent in those aged 65–74.

- *Those with diabetes.* Hyperlipidaemia is common in patients with diabetes, and further increases the risk of heart disease. In the UK the prevalence of diabetes is three to five times higher in Indian, Pakistani and Bangladeshi populations than in Caucasians.

- *Obese people.* In the UK almost 20 per cent of adults are obese. Men with a waist measurement over 40in (102cm) and women with a waist measurement over 35in (88cm) are considered obese. Obesity can also be defined as a body mass index (ie, weight in kg divided by square of height in metres) of 30kg/m² or more.

SYMPTOMS INDICATING HIGH CHOLESTEROL LEVELS

External cholesterol deposits may be seen as pigmented rings in the iris (Kayser-Fleischer rings) and within loose skin around the eye. These symptoms are often seen in the elderly due to an age-related increase in cholesterol.

FACTORS AFFECTING CHOLESTEROL LEVELS

Community pharmacists, in conjunction with local GP surgeries, can help people reduce their risk of CHD by helping them to reduce their cholesterol level. Cholesterol can be reduced by lifestyle changes — following a cholesterol-lowering diet, losing weight, quitting smoking, and increasing physical activity. Such changes can be difficult for many people, and in some cases pharmacists can play a motivational as well as an advisory role. Periodic lipid testing can be a motivational tool because people can see how they have improved.

Diet People should be advised to increase their fruit and vegetable intake and reduce their intake of saturated fat. A regular intake of fresh fruit and vegetables has been found to reduce the risk of heart disease and increase HDL ("good") cholesterol. The Department of Health recommends five portions of fresh fruit or vegetables a day. Eating saturated fats (which include hydrogenated fats) increases LDL ("bad") cholesterol, which ends up on artery walls. Fats found in meat, poultry, whole dairy products, lard, and coconut and palm oils are the worst offenders. HDL cholesterol reduces the build-up of fatty plaques, so it is desirable to increase intake of foods high in unsaturated fats, such as fish and fish oil supplements.

The Mediterranean diet has been advocated as a healthier diet. The risk of a heart attack in people on

such a diet is about 50 per cent lower than in those on a UK diet. The Mediterranean diet is low in saturated fats and high in monounsaturated fat (eg, olive oil), fruits, vegetables and oily fish. It also includes red wine. A moderate intake of any alcohol each day (1–2 units for women; 2–3 for men) has been found to reduce the risk of heart attacks.

Losing weight Shedding excess weight can help raise HDL cholesterol and lower LDL cholesterol.

Smoking Smoking is the main cause of preventable deaths. It increases the risk of a heart attack threefold, lowers HDL cholesterol, and increases blood pressure.

Exercise Aerobic fitness relates to the ability to exercise for more than 20 minutes. Good examples are brisk walking, jogging, cycling or swimming. Regular aerobic exercise (at least two 20 minute sessions each week) can reduce TC and LDL, and raise HDL.

DRUG THERAPIES

Where lifestyle changes are not sufficient, or not possible, there is a clear opportunity for pharmacists to discuss drug therapy with clients. In addition, pharmacists can promote compliance and alleviate fears.

Fibrates have variable effects on LDL cholesterol, but they lower triglyceride levels and raise HDL cholesterol levels.

Bile acid-binding resins, such as cholestyramine and colestipol, work in the intestine to prevent the reabsorption of bile acids. This means that more cholesterol is converted into bile by the liver, and the LDL cholesterol level is lowered.

Ezetimibe reduces the absorption of cholesterol in the intestine. It does not interfere with the absorption of fat-soluble vitamins.

Nicotinic acid works on the liver to lower both triglyceride and LDL cholesterol levels. It also substantially increases HDL cholesterol levels.

Statins block cholesterol production in the liver. They are particularly effective in reducing LDL cholesterol. According to the National Service Framework for Coronary Heart Disease,¹ patients at high risk of CHD (defined as ≥ 30 per cent 10-year CHD event risk) should receive statins to reduce serum cholesterol concentrations either to $< 5\text{mmol/L}$ (LDL cholesterol to $< 3\text{mmol/L}$) or by 30 per cent, whichever is greater. The indication for

simvastatin supplied over the counter by a pharmacist is for people likely to be at moderate (10–15 per cent) risk of a first major coronary event. Pharmacists or their representatives are advised to agree and document a local policy for referral with their primary care organisation or their local GPs.

ALTERNATIVE REMEDIES

Pharmacists can encourage people to improve their management of modern-day life stresses, which are harmful to the heart. Anti-stress techniques such as relaxation, meditation and massage can be useful, and could be recommended. Exercise and aerobic fitness are also effective anti-stress devices.

PROVIDING A TESTING SERVICE

Offering a cholesterol-testing service is not mandatory for the sale of simvastatin over the counter (as a 10mg tablet), but it is deemed to be good practice by the Royal Pharmaceutical Society. Providing such a service in a pharmacy setting requires significant resources, and these need to be considered carefully.

Basic requirements

- A designated area for cholesterol testing, with a functioning sink.
- Devoted time to provide the necessary support to both clients and staff.
- Proper training for all staff involved in the testing process.
- Adequate insurance cover for both staff and clients.
- All staff handling blood samples should be inoculated against hepatitis B. This could be provided free of charge if the local GP provides an occupational health vaccination service.

Staff requirements All staff must be aware of the following:

- There must be sufficient staff to support the pharmacy while testing is undertaken to minimise risk to all clients
- The importance of professional conduct
- The confidential nature of personal health information
- Standards for the designated area (no food or drink to be consumed)

- Contra-infection measures, for example prevention of accidental puncture wounds and correct disposal of clinical waste
- How to deal with emergency situations, such as fainting
- The importance of accurate reporting and documentation of results.

Marketing the service Pharmacists should consider how best to target those most in need of the service. Attention must be paid to the Code of Ethics governing the publicity and promotion of the services, as detailed in ‘Medicines, ethics and practice’.² Ideas could include:

- Putting leaflets through doors, or in shopping and prescription bags
- Displaying posters in the pharmacy, surgery, community centre, post office or library
- Local newspaper, television or radio interviews to highlight the service
- Special campaigns in local businesses or health clubs
- Patient selection, either by surgeries’ involvement or from patient medical records, to identify likely users of the service
- Liaison with local GPs so that a policy for referrals can be agreed
- Co-ordination with local NHS organisations
- Refer to local primary care organisations and other healthcare professions

TESTING CHOLESTEROL

Equipment A variety of devices are available to test cholesterol levels, including portable and desktop analysers. You should choose one with a satisfactory full evaluation by the Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk).

Testing equipment represents a significant investment (from hundreds of pounds to several thousand). Review what services you could potentially be offering in the future. For example, it is important to consider whether you might want to offer other tests, such as blood glucose or liver function tests.

Other considerations in choosing equipment include the ease of performing the test, the time taken for a result, the level of analytical accuracy required, whether or not training is included, whether calibration is manual or automatic and whether there is the option to print out results, or just a visual display.

Involve your local hospital laboratory. They can often offer a supportive role, providing advice on a range of issues including purchasing devices, training, interpreting results, troubleshooting, quality control, and health and safety.

Quality assurance Whatever device is chosen, regular quality assurance will be essential to keep the machine in calibration and offer a consistent, high-quality service. Accurate and precise measurements are critical for the classification and referral of individuals. Internal quality control procedures and external quality assessment enable laboratory standards to be met in pharmacy settings. Some manufacturers offer quality assessment support, and this may be a consideration when choosing a device.

Collecting a good quality blood sample When obtaining whole blood finger-prick samples for lipid measurement, it is important to follow a protocol to help you collect good samples consistently, with no contamination by fats from soaps, make-up, etc. The client does not need to fast if only TC and HDL cholesterol are measured. If a more complete lipid profile is required (including triglyceride level), the individual should fast for between 9 and 12 hours. This means that it is probably best to do a full lipid profile in the morning.

Result interpretation and handling Two or more cholesterol measurements need to be performed to establish a diagnosis of high blood cholesterol – readings can vary from day to day, and at different times of day

Feedback When discussing test results with clients, care and sensitivity are needed. All information should be delivered in language that individuals will understand, so try to avoid unnecessary technical terms and jargon. Clients should also be provided with their results in written form. Any lifestyle advice should be supported by information that the client can take away and read. It is particularly important to make lifestyle changes manageable (eg, divide them into achievable increments). All advice given should be documented for clinical governance.

If cholesterol levels are not within the desired range, the client’s consent must be sought for this information to be sent to their GP. Clients should be given their own copy of the referral. If they do not consent, they must be advised to seek medical advice.