

Near-patient testing in the pharmacy

In the final article in our series on clinical testing, Pam Mason discusses near-patient tests and the role of pharmacists in providing such services

According to the British In Vitro Diagnostics Association, near-patient tests are those that can be carried out in a few minutes, without the need for complex instruments or equipment. Community pharmacists are in an ideal position to perform such tests. Indeed, several already do so. Most pharmacies also sell testing kits designed to be used at home. Pregnancy and ovulation test kits have been available for many years, but changes in technology are making a much wider range of tests available, including tests for cholesterol and *Helicobacter pylori*.

Accessibility is a key reason for people to visit their pharmacy for a test. Those who decide on the spur of the moment to have a health check can be seen without a long delay — it might be several days before there is an appointment at the local surgery. Near-patient testing in the pharmacy can be used for three main purposes:

- To assess the risk of a disease
- To screen for the presence of disease
- To manage disease

Screening and risk assessment

Various tests can be used to screen for the early signs of disease or to assess the risk of a disease. For example, fasting blood glucose can be used to screen for diabetes mellitus, and systolic blood pressure and the ratio of serum total cholesterol to high density lipoprotein can be measured to help assess the risk of coronary heart disease.

It is sometimes a difficult distinction to draw, but diagnosis is the role of doctor. If disease is suspected, the patient should be referred to his or her GP. Pharmacists can, however, use the results of screening and risk assessment tests to advise patients about diet, exercise, weight management, smoking cessation and other lifestyle issues.

Disease and medicines management

In the context of medicines management, repeat dispensing and supplementary prescribing, near-patient testing offers an opportunity for pharmacists to enhance their services. Blood pressure and lipid profiles can be measured to check disease progression and how patients are responding to cardiovascular drug therapy. Monitoring of international normalised ratio (INR) can be used in the management of anticoagulant therapy. Several pharmacists are already involved in anticoagulant clinics in GP surgeries and, increasingly, in pharmacies. Home tests to manage anticoagulant therapy are also available.

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Drugs with narrow therapeutic margins, such as carbamazepine, digoxin, phenytoin and theophylline should be monitored regularly. There could be scope for therapeutic drug monitoring in pharmacies in the future, particularly as part of supplementary prescribing.

Practical issues in providing a service

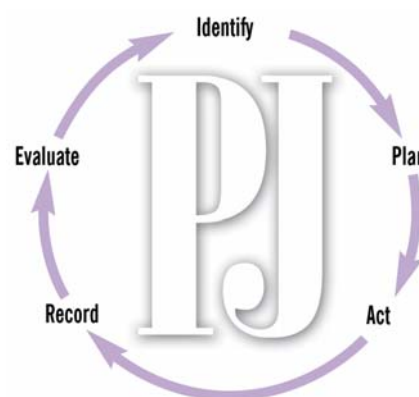
The Royal Pharmaceutical Society gives guidance on diagnostic testing and health screening. This includes the following requirements:

- All staff should be trained to ensure their competence with the equipment and procedures to be used in the interpretation of results — manufacturers of testing equipment sometimes provide training
- Pharmacists and their staff should keep up to date with developments in health screening and other tests
- Pharmacists should be aware of current advice on the therapeutic area in question, any local guidelines and when to refer the patient to the GP
- The pharmacy must have a designated area, not in the dispensary, with suitable facilities to conduct the tests and provide counselling
- An appropriate quality assurance programme must be in place and any equipment must be well maintained
- Patients should give their consent to the test, have the procedure explained to them and the significance of the results communicated to them in a way that they can fully understand
- There should be adequate documentation in place to allow for audit

The methods and equipment chosen should take into account the number of tests likely to be performed each day, how results compare with those from local laboratories and the availability of support from local laboratories. Other factors, such as providing seating for people who might feel faint after a blood test, should also be considered.

It is important to keep records of any tests performed and results can be recorded in the patient's medication record. Ideally, a copy of the result should also be given to the patient. Centralisation of patient records in the NHS would facilitate the recording of test results. Patients could also be given better access to their information if smart cards are used. Standard operating procedures (eg, what to do in the case of an adverse reaction to a test) should be put in place.

The local primary care organisation (PCO) and other stakeholders should be involved in the establishment of the service. Issues, such as whom to target and whom to



Identify knowledge gaps

1. What is the definition of a near-patient test?
2. What guidance is there for pharmacists who want to provide near-patient testing services?
3. List five home testing kits.

Before reading on, think about how this article may help you to do your job better. The Royal Pharmaceutical Society's areas of competence for pharmacists are listed in "Plan and record", (available at: www.rpsgb.org/education). This article relates to "diagnostic tests" and "health education and promotion" (see appendix 4 of "Plan and record").

refer, need to be considered collaboratively and the service must be fully integrated with local health care services. In addition, the issue of cholesterol screening is likely to be reviewed in light of the availability of statins over the counter.

Procedures involving patients and testing of body fluids demand strict adherence to health and hygiene and safety standards. Pharmacists should ensure that they, their staff and their premises are insured with respect to performing tests where appropriate. The Control of Substances Hazardous to Health (COSHH) regulations also apply because body fluids are a potential source of infection (eg, hepatitis B and human immunodeficiency virus). It is advisable for pharmacists and any staff handling body fluids to be immunised against hepatitis B. Safety standards in relation to collection, storage, labelling, segregation, transportation and disposal of samples and other waste must be followed. Full practice guidance for pharmacists on these issues can be found in "Practice guidance on testing of body fluids" available on the Society's website (www.rpsgb.org/practice). Other Society guidance of relevance to providing testing services is listed in Panel 1 (p709).

Funding is a continuing difficulty for pharmacists wanting to provide testing services. Some patients concerned about their

health might be willing to pay for health screening, but disease management testing is currently provided free by the NHS. The new contractual framework published by the Department of Health opens the door to the provision of new pharmacy services (eg, health checks), which could be funded by PCOs.

Home testing

Many home-testing kits exist and deciding which to stock or recommend can be a challenge. Testing procedures and kit contents can vary, but the mechanism of action for each category of test is, usually, the same. The Society's technical information service has produced a bibliography of articles on diagnostic testing in community pharmacy, which also provides details of commonly available test kits.

The main criteria to consider when selecting a home testing kit, include:

- How complex the test is to perform
- The ease of reading results
- The presence of a control (to ensure that the test is functioning properly)
- Cost

Each step required in a test is a potential source of error, so simplicity of use is important. Some tests are more user-friendly than others. Pharmacists must ensure that the user understands the importance of following the instructions exactly and in sequence, noting the time of day the test is to be conducted and the length of time each step requires, where appropriate. The instructions should be read carefully before the test is attempted.

For many home test kits, results are indicated by a change in colour or colour intensity. This is easily discernible in some products (eg, a plus sign or check mark) but people with colour defective vision or other visual impairment can find other tests difficult to use.

Cholesterol There are several cholesterol test kits that allow patients to measure their total blood cholesterol levels at home. The cholesterol present in a blood sample reacts with a dye to produce colour. Colour intensity is measured using a visual scale or a photometer (with LCD display), depending on the kit.

Good finger pricking technique is essential to obtain the blood sample. Excessive squeezing of the finger could negatively affect the quality of the blood sample by contaminating it with tissue fluids. Too little blood,



Cholesterol testing is likely to be reviewed

blood collected over a period of longer than five minutes or a second application of blood to the test area could also decrease the reliability of results. Excessive bleeding can occur in patients with coagulation disorders and such patients should not self-test for cholesterol levels.

Some home cholesterol tests measure total cholesterol while others measure both total and high density lipoprotein (HDL) cholesterol. A low level of HDL increases risk of coronary heart disease. Pharmacists should be aware that these tests can cause undue anxiety or, conversely, provide false reassurance. For example, people with a high total cholesterol result could think that they have heart disease, when other risk factors must be taken into account. Therefore, good patient education is essential. Before recommending a cholesterol kit, pharmacists should find out if the patient has been diagnosed with heart disease or has another reason (eg, family history) to be concerned about cholesterol levels. The person should be encouraged to return to the pharmacy to discuss his or her test result and any dietary and lifestyle issues that could affect the result. If total cholesterol is high, full lipid profiles can be investigated.

Faecal occult blood In the UK, bowel cancer is the third most common cancer in men, and the second most common in women. One early symptom is rectal bleeding. Checking for hidden (occult) blood in the stool is one way to screen for potential colon problems (not just cancer) and faecal blood testing products can be used as an adjunct to more invasive tests, such as colonoscopy (see *PJ*, 8 May, p574).

Patients who wish to test for faecal occult blood at home should be carefully counselled, in particular on the range of medical conditions and drugs that can affect test results (*PJ*, 1 May, p546). It is important to remember that the test is not specific to any disease.

Glucose and glycated haemoglobin Patients with diabetes mellitus are encouraged to monitor their glucose levels. However, monitoring only improves diabetes control if performed properly and the results applied appropriately. Patients must, therefore, be

trained in the technique and given guidelines on result interpretation.

Blood glucose meters give a more precise reading than urine dipsticks and are also useful for people with poor vision or who are colour blind. Urine glucose tests only give an idea of what the blood glucose level has been in the past few hours and not what it is currently. However, they can be useful for patients who cannot measure their blood glucose. Diabetes UK recommends that people with diabetes aim to keep preprandial blood glucose between 4 and 7mmol/L and postprandial blood glucose no higher than 10mmol/L.

Tests for the amount of glycated haemoglobin (HbA_{1c}) in a blood sample give an indication of blood glucose concentration over the previous three to four months. Haemoglobin becomes glycated when it joins with a glucose molecule. HbA_{1c} tests, combined with education, can help patients with poorly controlled diabetes better manage their disease. Traditionally, HbA_{1c} tests were carried out in hospitals, but kits are now available for use in GP surgeries, pharmacies and at home. Reference ranges vary, depending on laboratory or test kit, but people with well-controlled diabetes should have an HbA_{1c} below 7.5 per cent. People without diabetes will have values between 4 and 6 per cent.

If a patient with diabetes asks for advice about a high blood glucose or HbA_{1c} result, pharmacists could check compliance with antidiabetes medicines. They could also check for interactions with over-the-counter products and explore lifestyle factors.

People who are worried about diabetes (eg, they have diabetes in their family or symptoms such as extreme hunger, polydipsia, polyuria and fatigue) can easily have their blood glucose tested. People with abnormal results should be referred to their GP, who can send them for a glucose challenge test.

Helicobacter pylori *Helicobacter pylori* is implicated in peptic ulcer disease and its eradication can lead to ulcer healing. However, *H pylori* testing does not detect patients with *H pylori*-related disease. The gold standard *H pylori* test (performed in hospital or in GP surgeries) is a carbon urea breath test which requires the patient to swallow a radiolabelled carbon isotope. However, *H pylori* is commonly detected by taking a biopsy of the stomach lining and testing for the enzyme urease. Home tests detect *H pylori* antibodies in the blood, but concerns have been raised about their accuracy. Breath tests are more accurate, with higher sensitivity and specificity than either laboratory-based or near-patient serological tests. Stool antigen tests are also available. These appear to be accurate, but are not widely used.

Osteoporosis DEXA (dual energy x-ray absorptiometry) scanning of the bones is the most accurate way to determine bone mineral density and diagnose osteoporosis. Home testing kits measure the level of deoxyypyridinoline (DPD) in the urine. DPD is present

Panel 1: Practice guidance for testing services

- Practice guidance on testing of body fluids
- Practice guidance on early identification of diabetes by community pharmacists
- Practice guidance on cholesterol testing
- Practice guidance on blood pressure monitoring
- Pregnancy testing in the pharmacy

Action: practice points

Reading is only one way to undertake CPD and the Society will expect to see various approaches in a pharmacist's CPD portfolio.

1. Check that you are comfortable in counselling on the use of a peak flow meter.
2. Train a member of staff to provide support to people choosing a home testing kit.
3. Obtain health promotion leaflets that can be given out when a home test is sold.

Evaluate

For your work to be presented as CPD, you need to evaluate your reading and any other activities. Answer the following questions: What have you learnt? How has it added value to your practice? (Have you applied this learning or had any feedback?) What will you do now and how will this be achieved?

mainly in type 1 collagen of bone. As bone degrades, DPD is released into the blood and cleared by the kidneys. Hence, DPD is thought to be a biochemical indicator of bone resorption. The higher the level of DPD in the urine, the greater the risk of developing osteoporosis. However, this relationship is considered to be weak. Levels of DPD are diet- and exercise-dependent and can change from day to day. Results also vary with the technique used. These kits are, therefore, unsuitable for diagnosing osteoporosis.

People with a raised DPD level should be checked for other risk factors and if the overall risk of osteoporosis is considered to be raised, they should be given preventive advice and a bone scan can be recommended, if appropriate (see *PJ*, 8 May, p574).

Ovulation and pregnancy Ovulation can be detected by looking for small increases in body temperature, but ovulation prediction tests that use monoclonal antibodies specific to luteinising hormone (LH) are available. These detect the surge in this hormone that occurs 24 to 48 hours before ovulation. Urine should be collected at the same time each day (some kits specify early morning collection) and testing should begin two to four days before the estimated day of ovulation.

False positives can be caused by medicines affecting the menstrual cycle (eg, some fertility treatments) and conditions associated with high levels of LH (eg, menopause, polycystic ovary syndrome), impaired liver or kidney function, breast feeding and pregnancy. Women who have recently been pregnant, stopped breast feeding or stopped using oral contraceptives are advised to wait until they have had two natural cycles before using an ovulation test kit.

Home pregnancy tests are designed to detect the presence of human chorionic gonadotrophin (HCG, the hormone produced by the trophoblast of a fertilised ovum)

in the urine. HCG is detectable in the urine within one to two weeks after conception so is a diagnostic indicator of pregnancy. The test uses monoclonal or polyclonal antibodies in an enzyme immunoassay and is highly sensitive and specific. If correctly used, reported accuracy is 98 to 100 per cent.

False negatives can occur with home pregnancy tests if they are performed before the first day of the missed period, if refrigerated urine is not allowed to warm to room temperature before testing or if household containers containing soap residues are used to collect the urine. False positives can occur if a woman is taking fertility drugs (eg, chorionic gonadotrophins), has had a miscarriage or given birth within the past eight weeks. Unreliable results can occur in women with ovarian cysts or ectopic pregnancy. Oral contraceptives do not affect test results.

Peak expiratory flow rate Peak expiratory flow rate (PEFR) is a measure of the forced expiratory flow in litres per minute. It is used to monitor disease progression and response to therapy in conditions such as asthma. It is also used in plans for the self-management of asthma. For example, patients can be instructed to use their inhaler if their PEFR falls below a specified level.

Pharmacists can play a valuable role in explaining how a peak flow meter should be used. PEFR can be monitored at home or in the pharmacy with a small, hand-held peak flow meter. Typically, peak flow is measured each morning and evening, before inhalers are used, and the best of three readings is recorded. Peak flow will vary according to age, height, sex and disease severity, but a 6'1" 25-year-old man could be expected to have an average peak flow of 635L/min.

Prostate disorders Home kits measuring prostate specific antigen (PSA) in the blood are available. Raised PSA can indicate infection or enlargement of the prostate. About 30 per cent of men with raised PSA will have prostate cancer, while about 20 per cent of men with prostate cancer do not have raised PSA levels. The PSA test can, therefore, provide false reassurance or lead to anxiety. However, it could result in prostate cancer being diagnosed and treated early.

Other home tests Other home tests include those for vitamin and mineral status, fertility, Alzheimer's disease, hepatitis C, blood groups, drug abuse, male and female hormones, human immunodeficiency virus, thyroid disease and urinary tract infections. New tests frequently appear on the market.

Conclusion

Pharmacists have an important role to play in near-patient testing in the pharmacy, particularly in the context of health promotion and medicines management. Setting up a testing service requires a great deal of thought and planning, not to mention appropriate training, but the results can be worthwhile.

As people become more informed about their health, home tests are becoming increasingly popular and pharmacists can advise on their appropriate use and the importance of following kit instructions. They should ensure purchasers know that such kits can, at best, give only an indication of risk and are not diagnostic. Most importantly, pharmacists should encourage people to return to the pharmacy to discuss their results. This will allow lifestyle advice to be given. Stocking information leaflets about conditions for which you provide tests is useful.

Clarification

The section on positron emission tomography (*PJ*, 8 May pp573–5) confused positron emission tomography with the broader practice of diagnostic nuclear medicine. Diagnostic nuclear medicine studies monitor the decay of a gamma emitting radionuclide that has been incorporated into a pharmaceutical to form a radiopharmaceutical. Following intravenous injection of the radiopharmaceutical, a digital image or scan is acquired using a gamma camera linked to a computer system. This shows the 2-D biodistribution of the radiopharmaceutical and is a measure of the function of an organ or tissue as well as revealing information on size and shape.

3-D images can be acquired using the technique of tomography. In nuclear medicine this is called SPECT (single photon emission computed tomography). A further specialist application called PET (positron emission tomography), where the decay of positrons is plotted, is also available in a few specialist centres. Abnormalities are usually demonstrated as either increased ("hot spots") or decreased ("cold spots") uptake in areas of otherwise uniform distribution.

The most commonly used radionuclide in nuclear medicine is technetium (^{99m}Tc). This has a short half-life of six hours, so the radiation dose to the patient is low. Investigations undertaken include bone scans for the detection and monitoring of metabolic and metastatic disease, lung scans to detect pulmonary embolus, myocardial perfusion scans to determine the extent of coronary artery disease and thyroid scans to assess thyrotoxicosis.

Diagnostic radiopharmaceuticals have minimal pharmacological effects due to the small quantities used. Adverse reactions are rare. However, the uptake of radiopharmaceuticals can be considerably altered by other medicines. Some drugs can be used purposely to achieve this. For example, adenosine and dobutamine are given to increase myocardial uptake. Drugs can also be given to alter the pharmacokinetics of the radiopharmaceutical and thus enable disease differentiation.

As a consequence of possible interactions, patients may well be asked to refrain from taking a medicine before scintigraphic imaging. — contributed by Paul Maltby, radiopharmacy department, Royal Liverpool University Hospital