Health and Self-testing

Debate Motion
This house proposes that self-testing is the future for health management.

Health Self-testing
Self-test diagnostic kits can be purchased over the counter (OTC) or Internet and used at home, independently of health care specialists. Often the tests involve using a sample of urine, blood or faeces. Some simple tests take a few minutes and the results are shown by a colour change in a test material. Others require more complex technology or expertise for analysis. In this case, samples need to be posted to a laboratory for testing. Results may then be returned to the customer or to the customer’s General Practitioner (GP).

Self-testing is particularly useful for illnesses which patients feel embarrassed about, such as sexually transmitted diseases, or if patients are embarrassed to have an examination, for example for colon cancer.

Self-testing may unburden health services, and save lives through early screening and disease prevention. On the other hand, there may be risks in removing control of health care testing from the health care specialists. We discuss the different ethical issues below. However, first we list some example tests which could be used at home and explain some key terms.

Applications
Some self-test diagnostic products are available for purchase OTC. Others are not yet available, or have been prohibited. For example, sale of an HIV/AIDS test has been prohibited in the UK since 1992. 104 unique self-tests related to 24 named conditions including cancers, chronic conditions and infections were found through a systematic search on the Internet in 2006. Prices per self-test kit ranged from less than stg £1 to around stg £76 (Journal of Public Health 2006). There are many different types of tests which could be used at home for different illnesses or conditions (but which are not necessarily on the market yet) and we give some examples here:

- Bowel cancer
- Coeliac disease
- Chlamydia
- Cholesterol level
- Cystic fibrosis
- Cystitis
- Diabetes
- Genetic tests for inherited medical conditions
- Irritable bowel syndrome
- Osteoporosis
- Pregnancy
- Prostate cancer

Stakeholders
The practice of health care self-testing involves many parties:

- Academic and scientific researchers who develop self-test diagnostic kits.
- The diagnostics industry who manufacture and market self-test kits.
- Health care specialists, whose expertise is bypassed with self-testing.
- Health Authorities, who may have reduced financial costs.
- Health insurers, who fund health care.
- Other insurers, whose commercial success depends on knowledge of client health status.
- Employers with work environments where safety depends on knowledge of employee health care status.
- Users of self-tests.
- Governments and regulators responsible for ensuring quality control for self-test products and documentation.
- Ethicists.
**Key Terms**

- **Coeliac disease** is a digestive disorder which prevents people from being able to eat wheat, barley, oats or rye.
- **Cholesterol** is needed in the human body, but too much can increase the risk of heart or artery diseases.
- **HIV/AIDS**. Acquired Immune Deficiency Syndrome (AIDS) is a collection of symptoms and infections resulting from damage to the immune system caused by the human immunodeficiency virus (HIV).
- **Osteoporosis** is a thinning of the bones, and can cause them to break more easily.

**Ethical Questions**

**Privacy vs. Monitoring**

People may prefer to keep knowledge private about an illness, for which they feel sensitive, such as sexually transmitted diseases, or an illness which will affect their own lives and the lives of their families, such as cancer. Upholding the patient’s right to privacy in this way has implications for other parties. For example, insurance companies insure and charge their clients based on knowledge of their health status. Some illnesses may affect whether people are allowed to drive, or to work in environments where they may put themselves or others in danger. Monitoring of contagious or dangerous diseases is also essential in health care so that measures can be taken to restrict disease spread, and to alert people who may be in danger. Such monitoring is impossible with private self-testing, however.

It seems, therefore, that there are other parties interested in the results, outside the immediate family and friends of the patient. Some method of monitoring of results may therefore be necessary. The questions arise, who should have access to the results and how should this be managed? Should self-test kits be on prescription only, so that their use is registered and results can be followed up by the health care service? How can the same sorts of patient privacy rights currently respected by doctors be regulated with insurance companies or other parties, such as employers, who need to have health status information for safety or other reasons?

**More or less expensive?**

Self-tests may be a very good solution for the financial constraints of today’s health care services. With patients self-testing at home, outpatient appointments could be reduced dramatically, freeing up the time of medical specialists, nursing and administrative staff. Self-tests may also reduce health care costs through early detection of illnesses. Early detection allows early preventive treatment and may avoid progression of an illness and the related costs for hospitalization, surgery, drug therapies etc. Hospital beds could be freed up for patients with illnesses for which there are no preventive treatments. Given these reduced health care costs, should health insurers compensate by giving discounts to people who monitor their health through self-testing and report results on a regular basis?

On the other hand, self-tests could have a detrimental effect on health care costs, depending on how the whole practice of self-testing develops. People may do them unnecessarily (the ‘worried well’ syndrome). Routine testing at home by the ‘worried well’ will result in more consultations, which could be better used for people who do have medical grounds for treatment. Most self-test kits advise users to visit a doctor if they are worried about the result, which will also increase the demand for specialist consultations. There will also be additional administrative costs in managing, coordinating and communicating results between individuals, laboratories and/or GPs etc.

**Missing expertise**

As individuals, we like the idea of having control over our own health. Shared decision making has been increasingly adopted in the health care service, rather than health specialists making independent decisions about patient treatments. Shared decision making shifts control, allowing patients to consult with experts, discuss the possibilities and contribute to joint decisions. With self-testing, control is shifted yet again towards the patient and away from the expertise of the doctors and other health care specialists. In fact, the health care specialists are removed from the early stages of testing and illness detection entirely. So what are the risks of this?

Doctors are worried about the implications of patients trying to diagnose their own conditions and interpret their own results (Tarkan 2002). “When a physician makes a diagnosis, 70% is based on history, 20% on physical exam
and 10% on testing. Home testing outside the medical system ignores 90% of the diagnostic process” (Kroger in Brennan 1986). By ‘History’, Kroger is referring to the expertise gained from both the body of established medical knowledge, and also from the doctor’s own experience of identifying symptoms, likely diseases, and how these relate to the particular patient and the patient’s own health history.

Testing and diagnosis isn’t the only missing part of the process with the health care specialist excluded. Specialists have the skills and training to explain the test results and their implications, and answer any questions a patient may have. Health care specialists understand the significance of different test results. They know when re-test is necessary because test accuracy is low, or diet may have affected the results (e.g. with coeliac tests), or when alternative tests are needed for back up. All this is missed in the self-test scenario. In particular, following shocking test results, such as a positive HIV/AIDS or cancer test, patients may need counselling. If this type of support is needed before and after testing, how can this service be implemented and managed in a private self-testing scenario? How will health care specialists know that tests are being carried out, and that people need support? To avoid the scenario where a patient discovers they have HIV/AIDS alone, without specialist support, Canada regulates HIV tests so that they can only be performed by health care professionals, but may be completed anonymously. This solution retains the patient’s right to privacy, while still providing them with expert support.

Safety and accuracy
In the self-test scenario, written instructions and explanations become a very important tool for completion of the test. The written instructions for a one-off self-test at home must be sufficiently effective to compensate for the knowledge, experience and ‘familiarity from practice’ which health care specialists bring to the test process. Clearly the instructions need to be effective, but even if they are, is self-testing going to be as effective as health care testing?

Firstly the user has to know exactly what to do (from effective instructions); secondly the user must carry out the instructions accurately (with no medical expertise or practice), and thirdly they must interpret the results and understand what they mean (from effective and informative instructions). What are the risks at each of these stages?

Accurate instructions for use of a product and interpretation of results are essential, as is also knowledge of the accuracy of the test. Users need to understand what the chances are of the result not accurately reflecting their health status. This raises the question of what level of test-accuracy is required for OTC self-test products to be marketed.

Also, how can we be sure that a user is capable of carrying out the instructions? Users may accidentally contaminate samples or test at an inappropriate time etc. Some user groups may be less able than others to complete the tests, e.g. children and the elderly. Should sales of OTC products have age restrictions?

Facts and Figures

**Bowel cancer:** In 2007, the NHS sent out self-testing kits for bowel cancer to men and women in their 60s in the UK. Cancer Research UK predicted that if 80% were used, there would be 25,000 fewer deaths from bowel cancer over the next 20 years. There are around 35,000 cases of bowel cancer diagnosed per year in the UK and more than 16,000 people die. Bowel cancer is the second most common cause of death in the UK (Cancer Research UK 2007). Figures from the National Cancer Registry in Ireland show that approximately 2,000 people in the Republic of Ireland develop bowel cancer each year and half die from it.

**Cervical cancer:** In research comparing cervical smear self-testing with specialist testing, researchers concluded that it would be reasonable to offer self-testing to women who are reluctant to attend for cervical smears. The self-test proved highly acceptable to women (Szarewski et al. 2007). WHO estimated that in 2002 there were 100 deaths in the Republic of Ireland and 1,400 deaths in the UK due to cervical cancer.

**HIV/AIDS:** In research comparing HIV self-tests with specialist testing in Singapore, 85% failed to perform all steps of the test correctly, especially blood sampling, and 56% had invalid results because of incorrect test performance. 12% were unable to correctly interpret the results. 89% of the participants preferred testing in private, although most indicated that confidential counselling by specialists was necessary (Lee et al. 2007).
In research to assess the feelings of people aged 18 to 25 about urine self-test kits for curable sexually transmitted diseases, 73% reported that people their age would use them, if available. Perceived advantages were privacy and convenience. Disadvantages included not being able to discuss positive results with a health specialist (Ford et al. 2004).

Advertising and sale of HIV tests OTC was banned in the UK in 1992. The estimated number of adults and children living with HIV/AIDS in the Republic of Ireland was between 5,000 and 8,500 in 2005; UK figures were between 41,000 and 110,000. Estimated deaths due to AIDS were around 100 in the Republic of Ireland and 1,000 in the UK (WHO 2006). An estimated 31% of people with HIV in the UK are unaware of their HIV Status. Early diagnosis allows the illness to be managed with current therapies, and the patients being aware of positive HIV status allows them to adjust their behaviour to reduce the risk of transmitting HIV to others (Frith 2007).

Cholesterol: One in three Irish adults has a cholesterol level greater than five - the maximum level recommended by health professionals (www.irishhealth.com). In England over 70% of both men and women have levels of five and above. Heart disease is the UK’s and the Republic of Ireland’s number one killer, causing 208,000 deaths per year in the UK, and 10,000 in the Republic of Ireland (British and Irish Heart Foundations).

Coeliac: About 1% of the UK and Irish populations suffer from coeliac disease. Medical treatments are not available for this disease, but a gluten-free diet can reverse damage done by the disease (www.irishhealth.com and www.coeliac.co.uk).

Self-test diagnostic kits are classified as medical devices.

The Irish Medicines Board is the Competent Authority in the Republic of Ireland, authorised to act on behalf of the government to ensure that the requirements of the EU Medical Devices Directive are carried out. In the UK, the Medicines and Health care products Regulatory Agency (MHRA), is responsible for regulating the safety, quality and performance of self-test kits. All kits sold in the UK have to comply with new Medical Devices Regulations (2005), which are intended to ensure that all test kits are safe to use and that they perform as intended by the manufacturer. To show that tests conform, manufacturers must apply an EU quality mark to their products.

For a collection of relevant news stories and references, visit the website of one of the DSI co-ordinating centres:

www.remedi.ie  www.apc.ucc.ie  www.bdi.ie
www.cramn.tcd.ie  www.rcsi.ie  www.w5online.co.uk