

Home self-testing kits: helpful or harmful?

Dr Elizabeth J. Tidy, Academic Clinical Fellow in General Practice, Nuffield Department of Primary Care Health Sciences, University of Oxford

Dr Brian Shine, Consultant Chemical Pathologist, Oxford University Hospitals NHS Foundation Trust

Dr Jason Oke, Senior Statistician, Nuffield Department of Primary Care Health Sciences, University of Oxford

Dr Gail Hayward, Deputy Director NIHR Community Healthcare MedTech and IVD Cooperative and Academic Clinical Lecturer, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Over recent years access to self-testing kits (part of the direct-to-consumer testing market) has been expanding (1). These tests may be purchased online or in pharmacies and are performed without input from health professionals. Samples taken are either processed at home or sent to a laboratory, and may offer screening, diagnosis, monitoring or information about the risk of a disease. These tests are likely to generate additional primary care consultations as they become more widely available. We consider the processes by which self-tests conducted at home are regulated, their accuracy and the benefits and risks of this new diagnostic process.

What is available and how much does it cost?

A UK review in 2006 found 104 kits to test at home or send away, covering 24 conditions (2). These included tests for: diagnosing cancer (e.g. faecal occult blood and PSA); monitoring of chronic conditions (e.g. diabetes); urinary tract infections and sexually transmitted infection tests including HIV. Prices ranged from less than £1 to £76.

What information do you get about how well the test can detect disease?

A review of the information available with self-tests found that it was “generally inadequate” and “often restricted to little more than the prices and instructions for use”(3). Another study found that although some information was provided about the reliability of results, this was most often in the form of “a brief statement such as ‘false-positive or false-negative results may occur’”(4). It is often not possible to find out whether a self-test has the CE marking (indicating compliance with EU regulations) before purchasing it over the Internet (3).

How are these tests regulated?

Self-testing kits are regulated under the In-vitro Diagnostics Directive (EU 98/79/EC) (IVDD) with the majority of self-test kits falling into a lower risk category for which manufacturers evaluate the performance of their own test (though an independent notified body must review whether the test is appropriate for lay use). There is no evaluation of analytical performance for the majority of tests, though if specific claims are made by the manufacturer, they may be required to provide evidence to support these. Information regarding the frequency of requests for such evidence is not publicly available. Higher risk self-test kits, e.g. HIV, require more extensive evaluation by the notified body including verification that the product meets specified performance criteria and batch testing.

Efficacy of current regulations and changes in progress

Evidence suggests that this regulation has allowed tests to be marketed with poor analytical and

clinical performance. Multiple studies have found that self-test kits do not live up to the accuracy claims made by manufacturers (5, 6). An evaluation of 20 tests (including home, send-away and genetic tests) found that only three could be recommended on the basis of scientific evidence (3). The authors conclude that “either the required evaluation is not carried out, or the requirements are interpreted in a minimal manner.” They criticize self-evaluation by manufacturers, suggest that notified bodies may have insufficient epidemiological training to conduct assessments, and argue that evaluative files should be made public.

Some of these issues may be addressed by current changes to regulation: the IVD Regulations (IVDR) have been implemented from June 2017 and will replace the IVDD. There is a transition period during which tests can be approved under either the IVDD or IVDR, though to remain on sale all tests will have to meet the IVDR by 2022. Under the IVDR the majority of self-tests are likely to require a more thorough assessment by a notified body, and an assessment (methods as yet unclear) of the clinical utility (comprising scientific validity, analytical performance and clinical performance).

Can patients reliably perform these tests?

The IVDD requires manufacturers of all self-tests to provide evidence to a notified body that the test has been evaluated with lay users unless similarity to a previous device renders this unnecessary; however the Health Council of the Netherlands was only able to identify evidence of testing in lay persons for 2 of 13 self-tests evaluated (3). In contrast a review of 29 self-test kits found that “with few exceptions... most participants in the studies reviewed were able to properly perform home tests and obtain accurate results, yielding high correlations with laboratory and health professional-performed tests” (7). Historically doubts were expressed regarding the ability of women to conduct a self-test for pregnancy, something that would now be considered routine (8).

What are the arguments for and against the availability of these tests?

Greater pick-up rates for disease?

Proponents argue that self-test kits help detect cases that would not otherwise be diagnosed by offering convenience and avoiding embarrassing consultations (6, 9). One study assessing the impact of HIV self-testing found that uptake of testing was doubled (10); however, self-testing for sexually transmitted diseases raises concerns regarding contact tracing, and investigations for other coincident infections.

In contrast, self-testers may be more likely to be the “worried well” than those attending primary care. This is supported by evidence that self-tests are often used as a “routine check or out of curiosity” and that reassurance is an important motivating factor(9). If the prevalence of pathology is lower, this alters the positive predictive value (the proportion of self-testers who have the disease out of those in whom the test is positive) and the negative predictive value of the test (the proportion of self-testers who do not have the disease out of those in whom the test is negative) from that demonstrated in evaluations performed using existing clinical phenotypes.

Time- and cost -saving?

Some suggest that self-tests save clinicians time and money by providing information that they would otherwise have had to obtain themselves. There is also evidence that those with normal results are unlikely to go on to consult with a doctor, thereby reducing consultations (11); however, manufacturers are required under the IVDD to advise users to seek medical advice before responding to results. Furthermore, time- and cost-saving benefits may be eliminated by clinicians repeating the test if they feel (perhaps justifiably) unable to rely on the results.

Self-tests are initiated in the private sector and it remains unclear how the costs of follow-up should be borne in a publicly-funded healthcare system.

Empowering?

There is a trend in healthcare towards consumerism and increasing respect for the autonomy of patients. In this context self-tests can be empowering. Some are concerned as to whether people will be able to make good decisions about the use of these tests, though these concerns may be seen as paternalistic when compared to other spheres of life involving equally complex issues (e.g. financial investments) in which we presume the ability to make good choices.

Whilst self-testing has the potential to improve uptake and patient engagement, the benefits will only outweigh the possible harms if regulatory systems are rigorous in assessing clinical performance in the population for whom the tests are marketed, and if high-quality comprehensible information about the performance of tests is made available to clinicians and the public.

Competing interests

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Appendix 1

Table 1. Effect of population prevalence on the relative numbers of true and false positives using the sensitivity (78%) and specificity (99%) for *Trichomonas vaginalis* self-tests quoted by Huppert et al. (12).

Presumed population prevalence	Number with Trichomoniasis per 1000 women self testing	Number with Trich. detected by self-test (%)	Number of false-positives	Ratio of false positives to true positives
2.00%	20	16	10	0.63
1.00%	10	8	10	1.3
0.50%	5	4	10	2.6

Table 2. Effect of population prevalence on the relative numbers of true and false positives using the specificity for *Trichomonas vaginalis* self-test from the lower bound of confidence interval from Huppert et al. i.e. sensitivity = 78%, specificity = 96%

Presumed population prevalence	Number with Trichomoniasis per 1000 women self testing	Number with Trich detected by self-test (%)	Number of false-positives	Ratio of false positives to true positives
2.00%	20	16	39	2.5
1.00%	10	8	40	5.1
0.50%	5	4	40	10

Table 3. A hypothetical future test with “not unrealistically poor” sensitivity and specificity: sensitivity = 0.9, specificity = 0.9

Presumed population prevalence	Number with hypothetical condition per 1000 women self testing	Number with hypothetical condition detected by self-test (%)	Number of false-positives	Ratio of false positives to true positives
2.00%	20	18	98	5.4
1.00%	10	9	99	11
0.50%	5	4.5	100	22