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## At Home Self-Screening Test Kits: Benefits and Limitations

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Millions of people are now taking their medical tests into their own hands, by using diagnostic testing kits and in the comfort of their own homes. Recent technological advances mean that a huge variety of self-screening test kits now exists. Self-test diagnostic kits can be purchased over the counter or Internet and used at home, independently of health care specialists. There are many different types of tests which could be used at home for an array of conditions and illnesses including cancers, chronic conditions and sexually transmitted infections like HIV with the number of new tests continuing to increase. However these are helping to diagnose illnesses in developing countries where many people have little or no access to medical care. This technology-driven trend is not without limits and could result in serious problems for those who only rely on the self-testing instead of on the medical expertise of health-care professionals.

At-home self-testing offers various advantages, such as privacy, convenience, ease of use, and low cost. Home test kits are classified into 2 categories: **Test Kit**—the patient collects the sample, performs the various steps of the test, and reads the results. **Collection Kit**—the patient collects the sample, sends it to a laboratory, and receives the results via phone. There are simple tests which take a few minutes and the results are shown by a colour change in the test material. Also self-testing kits are used as part of routine medical care, for example, blood glucose testing. Collection kits require more complex technology and expertise for analysis and samples need to be posted to a laboratory for analysis and the results may then be returned to the customer or to the customer's doctor.

Self-testing is particularly useful for illnesses such as sexually transmitted diseases. Screening for sexually transmitted infections can be done easily with home-based self-screening methods. The availability of low-cost home test kits may encourage at-risk young individuals with less access to clinic care, to self-test for sexually transmitted diseases [1]. The trend toward self-diagnosis has to do with the development of similar health monitoring kits which allow early warning of disease symptoms or problems. Self-testing may unburden health services, and save lives through early screening and thus contributing to disease prevention.

Three factors are relating to self-testing: self-efficacy (one's own ability to complete tasks), the degree of physical and mental fatigue and satisfaction with one's health (health satisfaction) [2].

The practice of health care self-testing involves many parties and raises many ethical issues. An important issue concerns health care specialists, whose expertise is bypassed with self-testing [3].

People may prefer to keep knowledge private about an illness, such as sexually transmitted diseases, or cancer. But this patient's right to privacy has implications for other parties like insurance companies and some contagious illnesses may affect other people, work environments putting other people in danger. Monitoring of contagious or dangerous diseases is essential in health care and measures must be taken to restrict disease spread alerting people. Thus, there is a lack of monitoring with private self-testing.

Home-testing low cost may be a very good solution financially concerning the health care services. Appointments could be reduced significantly and the early detection of illnesses reduces the health care costs related with hospitalization, surgery, drug treatments etc. But often people do self-testing unnecessarily (the 'worried well' syndrome) resulting in more consultations for the need of specialists in case they are worried about the result.

Now more and more individuals are playing doctor in the privacy of their own bathrooms, to test for cholesterol, blood glucose, or evidence of colon cancer. They like the idea of having control over their own health. However shared decision making has been increasingly adopted in the health care services, which allows patients to consult with experts, discuss the possibilities taking the optimum decision. With self-testing, control is shifted towards the patient and away from the expertise of the doctors and other health specialists. So there are risks of missing expertise. The patients do self-testing and are trying to interpretate their own results and to "diagnose". The advantage of having a health-care professional involved in a self-testing is that the results can be evaluated within the context of the whole health picture, not just one test. When a doctor makes a diagnosis, is based on history, on physical exam and on testing. Self-testing at home only cannot result in true diagnosis. Only health specialists have the expertise and the necessary knowledge for the interpretation of the test results, assessment of their significance and are able to decide if other complementary tests are needed. All this is missed in the self-testing process. Special attention is needed in case of a positive HIV/ AIDS or cancer test, because these individuals need support. So there are many issues in a self-testing process for these patients. In many countries HIV tests can only be performed by health care professionals in an anonymous mode respecting patient's privacy and supporting them. Information accompanying HIV home tests should describe symptoms of acute infection and the need for additional testing and confirmation. Also different home-test-based screening modalities, and personalized HIV-counselling resources should be examined [4].

Technological advances should allow improvement of sensitivity of HIV self-tests with shorter window periods potentially with antibody/antigen combinations particularly in early HIV infection [5].

Another very important issue is safety and accuracy in self-testing at home. Doctors aren't convinced that all of the tests available for at-home use are necessary, or, *accurate*. The user-patient must perform the kit accurately following the instructions written. Also the user must understand the results and what is the meaning from the instructions given. The knowledge of the accuracy of the test is very important and sometimes the results do not reflect exactly the health status. Test-accuracy is required for at home self-test products. Every test comes with some risk. The risk that the test may produce incorrect results a false positive or a false negative. The patients could misinterpret the results and make health decisions based on them that are unnecessary or sometimes dangerous;

It seems that perceived benefits are strongly associated with self-testing information. Also information must be provided about possible disadvantages in order to inform users with the opportunity to make informed choices. Additionally, besides the self- testing, there are many tools to diagnose a particular disorder or risk factor. Self-testers often do tests for reassurance, without considering the disadvantages, such as the absence of professional counselling and the risk of false-positive or false-negative results [6,7].

The importance of being well informed about the possibility of false-positive and false negative results is essential and the accompanying potential psychological consequences of test results should not be underestimated.

The real harm with this kind of testing has to do with the false positives and to a lesser extent, the false negatives. In the process of gathering information about health status, it should be emphasized that is less important having a lot of information- the more important is having the "right" information. The clinical and academic communities will certainly have an important role to play in ensuring that the users have sufficient information to make informed choices and when they should share information about self-testing with their primary care team [8].

The development of online decision aid contributes to provide sufficient knowledge regarding the reliability of diagnostic self-tests, the advantages and disadvantages of self-tests, enabling informed decision-making and avoiding (unnecessary) anxiety after receiving a positive test result [9]. There is a need for sufficient and right information to consumers, by the health care providers and policymakers, about the pros and cons of at home self-testing. It is known that professional test kits used in clinics and hospitals are required to include sensitivity and specificity information in their labelling, but in home test kits the relating label is unclear. There are many unapproved home test kits without any guarantee of accuracy or sensitivity. So this may be inconsistent and inaccurate.

The Food and Drug Administration warns consumers that a number of unapproved test kits exist through the Internet, as well as through magazine or newspaper promotions, for home use. Many home test kits not approved for use in the United States are available in other countries.

Despite their benefits, it is recommended not to rely solely on at-home self-testing kits, the professional medical help is necessary, given the fact that they are only initial indicators of a disease and confirmation is needed. Home test kits are meant to be an adjunct to doctor visits, not a replacement for them. Regulatory authorities have warned users that at-home tests should be used with caution, and regular visits to the doctor are needed, as they are “*best evaluated together with your medical history, a physical exam, and other testing*” (US FDA) [10].

The pros and cons of self-testing will always have to be weighed for each test and each individual and the users should be able to make an informed decision [11].

In each country Regulatory Agencies are responsible for regulating the safety, quality and performance of self-test kits. Legislation on self-tests and the right accompanying information leaflets are needed. Thus consumers will be able to make an informed decision on the use of a self-test [12].

As advances in technology offer at home tests more sophisticated and varied, regulators, researches and doctors will continue to offer more education to public, granting users-patients access to the tests they want and they need and making sure those tests are safe.

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