1 Centre for Academic Primary Care, University of Bristol, UK

2 University of St Andrews, UK

Correspondence to: J Watson
Jessica.Watson@bristol.ac.uk

Cite this as: *BMJ* 2025;390:r1476
http://doi.org/10.1136/bmj.r1476

The pitfalls of diagnostic self-tests

Tests should be clinically useful and part of an evidence based pathway

Jessica Watson, [1] Margaret McCartney[2]

Rapid advances in diagnostic technology, coupled with persuasive advertising, have resulted in a surge of direct-to-consumer self-tests, often sold under the banner of "wellness." Marketed as tools for empowerment and early detection, these self-tests promise convenience and autonomy and are promoted as tools for individuals to proactively manage their health. Self-testing can also offer an anticipated alternative route for health management, given the challenges in accessing primary care. But behind the glossy marketing lies multiple difficulties with real world use, and considerable potential for harm.

The two linked analyses illuminate the current state of self-tests available on the UK market. In the first, Davenport and colleagues (doi:10.1136/bmj-2025-085546) examined the information provided to consumers in information leaflets,[1] and in the second, Hillier and colleagues (doi:10.1136/bmj-2025-085547) interrogated manufacturers' claims about test performance.[2] The findings are concerning as consumers are not given the information they need to enable informed decision making. Claims about test accuracy are often unsubstantiated, and the evidence base is worryingly thin. When tests are available, both direct to consumer and through the NHS, the pathways differ substantially. For instance, NHS guidance makes it clear that screening for prostate specific antigen should be done only after discussing the complexity of the meaning of the test result—and not simply ordered.[3]

Poor quality tests can cause real harm to patients. As well as the impact on individuals, healthcare systems are likely to be affected by the downstream consequences of interpreting and acting on dubious test results. False positive results may lead to anxiety, unnecessary investigations, overdiagnosis, and overtreatment. False negative results can offer erroneous reassurance, which could potentially lead to delays in seeking appropriate medical care, with risks of delayed diagnosis and treatment. For example, using a "bowel health" self-test to detect "early stages of colon cancer" is not only misleading, it can also be dangerous. Even accurate results may not be useful to those wanting to self-monitor, owing to physiological variation.[4]

Self-tests should not be dismissed outright though. History offers cautionary tales: when home pregnancy tests were first introduced, some doctors argued that women could not be trusted to use them.[5] Clearly that is not the case. The use of HIV self-tests has been extensively and carefully evaluated, with decades of research, including large randomised controlled trials.[6 7] UK guidelines now recommend self-testing for HIV in at risk groups in areas of high seroprevalence, to increase uptake and frequency of testing and help overcome barriers to testing.[8] These tests are, however, "binary," with a yes or no answer, integrated within healthcare systems, and with clear actions to be taken based on the results. Many of the tests evaluated in the linked analyses yielded ambiguous results, meaning that the interpretation, and the actions resulting from them, were more complex.[1 2]

Giving people access to information and tools to understand their health is not in itself inherently problematic. But tools must be fit for purpose. Currently, consumers do not routinely have access to independent information before purchase, are not diverted from purchasing inappropriate tests when symptoms are present, and do not usually receive the result in a system designed to support understanding of the results. In the meantime, NHS general practitioners could be called upon to assist with the interpretation of a test that may not have been warranted, or, alternatively, could have been justified within the NHS.

To be useful, tests must be more than accurate—they should also have clinical utility. To be of genuine value, tests are one part of a system where the meaning of a result can be contextualised with the rationale for performing it, leading to evidence based actions and improved outcomes. Tests alone do not improve health.

To make informed decisions about self-testing, consumers must be provided with clear, balanced information about what a test can and cannot do. This information should be independently created, tested with the help of people, and mandatorily supplied. Meantime, the sale of tests lacking clinical utility should not be allowed. The NHS should not be expected to provide a "free" follow-up service for companies offering inappropriate, oversold, and low value tests. However, it could do more to explain to people what tests are available when symptoms are not manifest, and what the evidence is for other commonly marketed self-tests. This information could be placed prominently on NHS websites and placed on social media platforms where much of the advertising takes place, offering people a trusted source of informed advice.

Regulation should ensure that tests meet appropriate standards for accuracy, not just based on controlled laboratory settings but on real world use, building on existing guidance for best practice in test evaluation.[9] Commercial developers should work in partnership with clinicians and patients to ensure that innovations address genuine clinical need and do not prey on or create health anxieties to generate profit. Research to measure the impact of self-testing

on patient outcomes and workload effects on healthcare systems would be welcomed. Empowering individuals to take an active role in their health is an important goal, but if self-tests are to be sold directly to the public, they must be supported by high quality evidence, robust regulation, trustworthy public information, and clear pathways for interpretation and follow up.

Competing interests: The BMJ has judged that there are no disqualifying financial ties to commercial companies. The authors declare the following other interests: MM was on the organising committee of the Evidence Based Early Diagnosis conference held in St Andrews last year along with Jon Deeks. MM has written paid journalism about early diagnostic tests and is completing a study on this topic with students at the University of St Andrews. JW declares no other interests.

Further details of The BMJ policy on financial interests is here: https://www.bmj.com/sites/default/files/attachments/resources/2016/03/16-current-bmj-education-coi-form.pdf.

Provenance and peer review: Commissioned; not externally peer reviewed.

1 Davenport C, Richter A, Hillier B, etal. Direct-to-consumer self-tests sold in the UK in 2023: cross sectional review of information on intended use, instructions for use, and post-test decision making. *BMJ* 2025;390:e085546.

2 Hillier B, Deeks JJ, Alderman J, etal. Direct-to-consumer self-tests sold in the UK in 2023: cross sectional review of regulation and evidence of performance. *BMJ* 2025;390:e085547.

3 Guidance GOVUK. Advising men without symptoms of prostate disease who ask about the PSA test 2024. https://www.gov.uk/government/publications/prostate-specific-antigen-testing-explanation-and-implementation/advising-well-men-about-the-psa-test-for-prostate-cancer-information-for-gps (accessed 12 Jul 2025).

4 McCormack JP, Holmes DT. Your results may vary: the imprecision of medical measurements. *BMJ* 2020;368:. doi:doi: 10.1136/bmj.m149. pmid: 32079593

5 Entwistle PA. Do-it-yourself pregnancy tests: the tip of the iceberg. *Am J Public Health* 1976;66:-9. doi:doi: 10.2105/ajph.66.11.1108-b. pmid: 984284

6 Jamil MS, Eshun-Wilson I, Witzel TC, etal. Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis. *EClinicalMedicine* 2021;38:100991. doi:doi: 10.1016/j.eclinm.2021.100991. pmid: 34278282

7 Rodger AJ, McCabe L, Phillips AN, etal. Free HIV self-test for identification and linkage to care of previously undetected HIV infection in men who have sex with men in England and Wales (SELPHI): an open-label, internet-based, randomised controlled trial. *Lancet HIV* 2022;9:-47. doi:doi: 10.1016/S2352-3018(22)00266-1. pmid: 36460023

8 Palfreeman A, Sullivan A, Rayment M, etal. British HIV association/British association for sexual health and HIV/British infection association adult HIV testing guidelines 2020. *HIV Med* 2020;21(Suppl 6):-26.pmid: 33333625

9 Ashby D, Deeks J, Bird S. *Royal statistical society diagnostic tests working group report.* Royal Statistical Society, 2021.