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BMJ INVESTIGATION

The rise of direct-to-consumer testing: is the NHS paying the price?

Dozens of UK companies are offering private tests for a range of conditions and deficiencies. Some make claims that exceed the evidence base, and experts say regulation is needed to protect patients.

Emma Wilkinson reports

Emma Wilkinson *freelance journalist*

“Take your health into your hands today,” reads an advertisement for the Livit app, from Nightingale Health. Costing €179 (£155; \$176), it encourages four blood tests a year, using “highly advanced blood analysis technology,” and promises to predict how many healthy years of life a person has left.¹

The market for direct-to-consumer tests such as Livit is booming, with one piece of market research predicting that the global blood testing market will rise by 60% from around \$80.5bn in 2021 to \$128.45bn in 2028.² Experts are concerned that such companies are making misleading claims and leaving an already overworked NHS to follow up “abnormal results.” Some have also warned of a lack of regulation to ensure that consumers truly know what test results mean.

The BMJ's investigation has led us to refer two companies to the UK Advertising Standards Authority for misleading claims about the accuracy or detection rates associated with at-home tests. Another removed tests from its website after we got in touch (box 1). But in many cases it is the absence of information that is the problem, says Chris Salisbury, professor of primary healthcare at the University of Bristol. “There is a simplistic assumption that more information is better, so why shouldn't you get the tests done? Yet they're making claims without showing any of the disadvantages,” he says.

Box 1: Genetic screening tests offered without counselling

One company removed a series of genetic screening tests from its website after *The BMJ*'s investigation.

MeCheck offered eight different genetic cancer risk screening kits costing between £300 and £800,³ but this concerned University of Bristol primary healthcare professor Chris Salisbury, because no counselling was offered alongside the tests to explain the implications of the results for the patient. MeCheck, run by Biox Medical, removed five of the eight tests from its website when contacted by *The BMJ*, saying that it was no longer interested in providing them to consumers.

MeCheck also sold non-invasive prenatal screening for a wide range of chromosomal abnormalities, until the tests were removed after it was contacted by *The BMJ* about the claims on its website. Such screening for Down's syndrome, Edwards' syndrome, and Patau's syndrome was rolled out on the NHS last year for women at high risk, but there are questions over the accuracy of this type of screening beyond these three, including for sex chromosome aneuploidies and “microdeletions,” and monogenic disorders, explains Lyn Chitty, professor

of genetics and fetal medicine at Great Ormond Street Hospital in London.

Women may be forced into decisions about healthy pregnancies because of misleading test results and may not understand what is being tested for or that these are not diagnostic tests, she warns. The diagnostic tests that would then be needed are also associated with a risk of harm and involve difficult and emotional decisions.

For one test sold by MeCheck, the PrenatalSafe Complete Plus kit, the site had claimed that it “has a sensitivity and specificity higher than 99% with a very low incidence of false positives” and for fetal chromosomal abnormalities it had a detection rate “very similar” to that obtained by invasive prenatal diagnostic techniques. The Advertising Standards Authority said there were specific rules concerning advertising for non-invasive prenatal screening tests that included the need to have clear explanations of any detection rate figures and not to use the word “diagnostic.”

My Baby Company also offers a variety of these tests and states “all of our NIPT tests have an accuracy rate of >99%.”⁴ *The BMJ* put this claim through the advertising authority's complaints process, which called it a “clear problem” and passed the details to its compliance team. *The BMJ* contacted My Baby Company but did not receive a response.

Boom in home testing

In the UK there are now dozens of companies like Nightingale offering home testing kits for health screening for a range of conditions and deficiencies. Consumers are promised that such tests will help them take control of their health and spot problems early. Examples include Medichecks, which offers 250 tests of 450 biomarkers, with results uploaded to a personal dashboard.⁵ It includes the tiredness and fatigue finger prick test that measures iron, thyroid hormones, vitamin levels, and inflammation.⁶

Numan promotes its “fear nothing blood test” at £128 for a screen of up to 21 biomarkers, with the option of a full refund if users' results fall within the normal range.⁷ But test results will lie outside the normal reference range in 5% of cases, says Bernie Croal, president of the Association for Clinical Biochemistry and Laboratory Medicine.⁸ “So if I do 100 tests on you and there's nothing wrong with you, five of your tests will be abnormal,” he points out.

Numan offers a quarterly subscription for tests of cholesterol and HbA1c, thyroid hormones, kidney and liver function, testosterone, vitamins D and B12, folates and ferritin. However, in the case of vitamin D deficiency, if the patient has no clinical signs or

symptoms the advice is not to retest at all, says national guidance on minimum retesting intervals, last updated in 2021.⁹ For low risk patients the advice is to carry out lipid checks every three years, and even for higher risk patients or those on stable treatment only annual testing is recommended. Numan did not respond to *The BMJ*'s request for comment.

The UK National Screening Committee has well defined criteria for assessing whether screening is worthwhile that have been in place for decades. These include whether the condition being screened for is an important health problem, that there is a detectable early stage, and that the physical and psychological risks are outweighed by the benefits.¹⁰ A committee spokesperson said that screening tests were not for people with symptoms. In addition, NHS screening programmes offer care or treatment for people who need it.

Some of the health checks from high street companies are not recommended by the National Screening Committee "because it is not clear that the benefits outweigh the harms," the spokesperson added.

More work for GPs

Most testing companies, such as Thriva¹¹ and the Dublin based Lets Get Checked,¹² send a clinician reviewed report to the patient. Some, including Numan, offer a GP consultation for an additional fee. Croal says, "Most of the online [tests] will send the results to the patient with at best a sort of asterisk next to the ones that are abnormal, with advice to either pay some more money to get some sort of health professional to speak about it or go and see your own GP.

"That is coming in when primary care is so stretched, and it will just create a lot of work."¹³

Another testing boom that was recently highlighted in an NHS England bulletin to GPs was for privately purchased human papillomavirus tests, which cannot be acted on by the NHS Cervical Screening Programme or entered into the patient record.¹⁴

In 2019 the Royal College of General Practitioners published a position statement about private health screening, warning that "the organisation initiating the screening should not assume that GPs will deal with the results."¹⁵ This puts GPs in a very difficult position, says Ben Lees, a GP in Cheltenham, as they see patients coming in "clutching the results of private screening tests" that are not indicated or ones that they would not have done.

In addition to the risk of false positive results, which may lead to a catalogue of unnecessary and potentially invasive tests and anxiety for the patient, things may be missed, says Jessica Watson, a GP in Bristol who also researches the rational use of testing in primary care. "There's the risk a patient is falsely reassured because they're told there's nothing wrong, but they haven't had the right test and they then delay seeking help."

Variation in information

However, the companies selling tests believe there is a role for private testing in the health ecosystem. Sam Rodgers, a practising GP in southeast London and chief medical officer at Medichcks, points out that the company has been operating for 21 years and that clinical governance has always been important to it. "Many customers come to us either because they are having trouble accessing NHS services or because the NHS does not provide the service they are looking for," he says. People are directed to their GP after its testing in about 7% of cases, he says, adding that the company had chosen not to provide a subscription service as they don't believe it to be "clinically appropriate."

A spokesperson for Nightingale said its tests were for "prediction and prevention rather than diagnosis or treatment" and it didn't provide test results as such but overall risk information and lifestyle guidance. Randox also responded to say that its testing service was "complementary to, and supportive of, the work of the NHS at a time it is under unprecedented pressure."

Yet it is clear there is wide variation in the amount and accuracy of information provided to consumers when purchasing tests online. Under the national prostate cancer risk management programme, prostate specific antigen (PSA) testing is available on the NHS for asymptomatic men over the age of 50, after a discussion with a GP about the risks and benefits.¹⁶ Yet private tests are easily available with no age recommendation at all, including from Optimale and the London Medical Laboratory.^{17 18} The Health Check Shop also advertised PSA testing with no age recommendation and said the test had an accuracy of more than 96%, contradicting official advice of the chance of both false positives and negatives,¹⁹ until it was contacted by *The BMJ* and changed its website.

John Rees, director of JR Biomedical, the clinical diagnostics company behind the Health Check Shop, says the figures quoted for the PSA test on the website were provided by the manufacturer, which itself is subject to regulatory requirements.

Private tests promoted by NHS endorsed app

When using the NHS endorsed Patient Access app to book an appointment with his own GP, Salisbury was shocked to see an advertisement for a general health screen, which after a few clicks took him to the London Medical Laboratory, which offers a variety of home testing kits, including for tiredness and fatigue, and a prostate profile. The general health profile being promoted costs £79 and tests 27 biomarkers.¹⁷ EMIS, the healthcare IT company behind the app, says it has 14 million users.²⁰

"It first says this is in partnership with the NHS, then it says, 'Would you like to have some blood tests?' It's only when you click through you realise it's private testing. This is the NHS being seen to promote something that the NHS positively discourages."

London Medical Laboratory recommends that users of its health test contact their GP "for a full interpretation of the results."

London Medical Laboratory's cofounder and chief executive, Seth Rankin, who has also worked as an NHS GP, told *The BMJ* that he strongly believes in "democratising healthcare," because there are around one million people with undiagnosed type 2 diabetes and countless asymptomatic people with high cholesterol concentrations, thyroid disorders, and vitamin D deficiency. "It must surely be only a tiny minority of the most reactionary GPs that would wish to deny our increasingly educated population access to something as valuable to their health as a blood test," he says.

Shaun O'Hanlon, EMIS Group's chief medical officer, says that all private provider testing services listed on Patient Access have been selected after a thorough review by the clinical team, which includes UK GPs. An NHS Digital spokesperson says that services offered through third party apps or websites connected to the NHS login service are the responsibility of the companies providing them.

Some NHS laboratories also offer a small amount of private testing. Monitor My Health is a venture from the Royal Devon University Healthcare NHS Foundation Trust, with, it says, money raised from its home diabetes, vitamin D, cholesterol, and thyroid screening tests going back into the NHS.²¹ The NHS Black Country Pathology Services also offers vitamin D testing directly to the public, with packs of 50 available.²² Croal says there are "ethical questions"

about NHS laboratories offering private tests. Both laboratories declined to comment when contacted by *The BMJ*.

Regulation

Croal would like to see better regulation of direct-to-consumer tests. The Care Quality Commission in theory oversees services in England that perform tests and analysis, but marketing, consumer outreach, and the sending of home kits are all outside its remit. Some laboratories are accredited to the UK Accreditation Service, but this is voluntary.

The Advertising Standards Authority does investigate misleading claims, should a complaint be made. An authority spokesperson said it had received just under 250 complaints about health screening advertisements and acted on 52. Nine were formally investigated, and four rulings were upheld. Another 21 resulted in informal investigations, and 22 advertisers received advice.

Croal says the Royal College of Pathologists, Association for Clinical Biochemistry and Laboratory Medicine, and other stakeholders are in the process of drafting a consensus statement on private tests “to put a marker in the sand.”

Salisbury says the NHS needs clearer guidelines on what staff should be expected to do after patients have opted for private tests. He adds, “I think the advertising could be regulated much better so companies have to tell you about the harms as well as the benefits.”

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