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BRIEFING

Covid-19: Which rapid tests is the UK pinning its hopes on?

Rapid diagnostic tests are integral to the government's Moonshot plan to carry out up to 10 million covid-19 tests a day by early next year. Jacqui Wise looks at the options being developed and trialled

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The UK's testing system is currently under immense strain partly owing to a lack of laboratory capacity for the gold standard polymerase chain reaction (PCR) test.[1]

The government wants mass testing of the population to "support economic activity and a return to normal life" under its £100bn Operation Moonshot programme, according to documents seen by *The BMJ*.[2] They say that "alongside increased PCR capacity, we are also seeking to validate, buy, trial and scale a number of new technologies."

One of the new technologies being heavily promoted by the government is the NudgeBox machine, developed by DnaNudge. This is basically a laboratory in a box that uses reverse transcription (RT) PCR technology. A nose swab is inserted into a handheld reader, and a result is provided in less than 90 minutes. The kits have been trialled in eight London hospitals and have been useful in specific care pathways where doctors need a quick answer, such as for patients who require urgent surgery after a major trauma or stroke. The government has bought 5000 of these machines, which will be rolled out across the UK. A recent paper in *Lancet Microbe* found the test to have an overall sensitivity of 94% and a specificity of 100%.[3]

The government has also purchased 450 000 LamPORE tests developed by Oxford Nanopore. These, which come in a laboratory version and a portable version, can process swab or saliva samples. A preprint published on 25 September found a diagnostic sensitivity of 99.1% and a diagnostic specificity of 99.6%.[4]

The LamPORE test was hailed by England's health and social care secretary, Matt Hancock, as giving results in just 90 minutes. "That was very misleading," says Jon Deeks, professor of biostatistics at the University of Birmingham, "as it actually takes about 6.5 hours to go from sample to result. Its benefits will be in [supplementing PCR test] capacity, not in being point-of-care."

The Department for Health and Social Care said the intention is that tests using LamPORE technology will help to expand general testing capacity. They will be processed in laboratory settings because they need a trained operator and so are not being rolled out in individual care homes. The machines are currently being piloted for operational validation in several laboratories and are to be rolled out to laboratories across the country over the autumn.

Saliva versus swabs

What is potentially faster is using saliva samples rather than nasal swabs. A saliva test also has the advantage of being easier to use at home and is likely to be more acceptable if repeated testing is needed.

The government is evaluating several options. A saliva test from a company called Optigene is currently being piloted in Southampton, and a community testing pilot is due to start in Salford. It has also been reported that ministers are in discussions with Halo, a UK biotechnology company that has developed a saliva based quantitative (RT-qPCR) test, potentially combining the benefits of PCR testing with easier use and a faster result. The company says the test is 100% specific and results can be sent directly to a phone app in as little as seven hours. The University of Exeter has agreed a deal with Halo to use this test.

Other saliva based tests from the UK companies Chronomics, Avacta, MAP Science, and Oxford Nanoimaging are also being investigated. Deeks, however, thinks this is a bit of a distraction. "The UK seems a bit transfixed by getting a point-of-care antigen saliva test, which is giving us an extra technical challenge and seems to be proving more difficult to get to work than tests that use a nasal swab," he says. He thinks it may be better to focus effort and resources on overcoming the logistical problems with the current testing system instead.

At the moment there are few published data on rapid tests. The Royal Statistical Society has set up a working group in response to concerns about the lack of basic statistical evidence on the performance of new diagnostic tests.[5] The society says that accuracy and performance of such tests are not currently held to a common statistical standard in the UK, US, or EU.

"There is a massive opportunity for companies to get very rich selling poor tests, particularly if they get a government contract," warns Deeks. "Our current regulations don't protect us. You don't need to have a good test to be able to sell it."

WHO standard

In September the World Health Organization approved two "lateral flow" antigen tests, which display a result like a pregnancy test, are small and portable, and deliver a result in just 15-30 minutes.[6] Made by the South Korean company SD Biosensor and the US company Abbott, they are the first rapid tests to meet WHO's specifications. An independent

evaluation of the SD Biosensor test by the Foundation for Innovative New Diagnostics (FIND) found that it had a clinical specificity of 99.3% and a clinical sensitivity of 76.6%.[7] No independent evaluation of the Abbott test is yet available.

Deeks called these tests a "game changer" for low and middle income countries, where RT-PCR tests are not widely available, because they can be done without a laboratory, running water, or electricity.

Such benefits are attracting interest from higher income countries, too: Germany has already ordered 20 million of the tests, and France and Switzerland have also announced intentions to purchase.

It is not yet clear whether the UK will follow suit. Deeks says we need to assess carefully the benefits and the harms of using a more accessible and quicker but less accurate test.

The FIND study shows the Abbott and SD Biosensor tests to be about 20% less sensitive than PCR, Deeks told *The BMJ*. He says, "They miss cases with lower viral loads, as they don't do the amplification stages like a PCR test. This means they may miss people who are at an early stage of infection and give them a false negative.

"This could give people false confidence that they are not infected, which would be a problem if people stopped social distancing—for example, if it was used to allow people to go into a football match."

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