



London, UK

Cite this as: *BMJ* 2020;371:m4744<http://dx.doi.org/10.1136/bmj.m4744>

Published: 04 December 2020

Covid-19: Safety of lateral flow tests questioned after they are found to miss half of cases

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The lateral flow devices used in the community testing pilot in Liverpool only picked up half the covid-19 cases detected by polymerase chain reaction (PCR) tests and missed three out of 10 cases with higher viral loads, according to the government's own policy paper.¹

Given the low sensitivity of the Innova lateral flow devices when used in the field, experts are questioning how they can be used to allow care home residents to have contact with relatives over Christmas safely or for students to know for certain that they are not infected before returning home.

The information can only be found by looking in annex B of the document, *Community testing: a guide for local delivery*, which was published on 30 November. This is the first publicly available information about the field evaluation of the Innova tests in Liverpool which has been criticised for its lack of transparency, accuracy of the tests used, and costs and potential harms.^{2 3}

Jon Deeks, professor of biostatistics at the University of Birmingham and leader of the Cochrane Collaboration's covid-19 test evaluation activities, told *The BMJ*, "The results are hidden as a single sentence in the annex of a document. This is not the way important scientific findings should be made public, particularly when the test is going to be used off label with hundreds of thousands of people."

The Department of Health and Social Care said that over a million lateral flow tests have already been sent to 385 care homes and more would be sent over December to roll out visiting by Christmas.

A spokesperson said, "Extensive testing has shown that lateral flow devices are suitable for use in care homes where they can identify people who are the most likely to spread the virus further and prevent transmission of the disease from staff and visitors. Testing is only part of the approach and it's essential visitors wear personal protective equipment and follow all infection control methods to keep their loved ones, other residents, and staff safe."

Susan Hopkins, senior medical adviser to Public Health England and NHS Test and Trace, told *The BMJ*, "These tests are an additional tool in helping us detect cases that we wouldn't otherwise know about, in doing so helping us to break chains of transmission and save lives. No test will detect every single case, but these tests are proving to be accurate and reliable and we are confident that they can be used to rapidly identify many people who are silently carrying the virus."

She added, "In care homes, these tests can help make planned visits safer by identifying visitors that are

unknowingly carrying high levels of virus, and so prevent them from passing it on to their loved one."

However, public health and social care directors in some areas, including Greater Manchester and Sheffield, have written to care homes warning them not to use the rapid tests until they have had more information from the government on the accuracy of the tests and training in how to use them.⁴

The government has invited all tier 3 areas to offer community testing of asymptomatic people after what it described as "the positive impact" of the Liverpool pilot scheme. The guidance says that the Innova lateral flow tests offer 99.6% specificity and "the measured test sensitivity, in ideal hands is 76.8%" but "is likely to be lower under operational conditions."

The document then adds, "In the field evaluation in Liverpool, compared with PCR tests, these tests picked up five out of 10 of the cases PCR detected and more than seven out of 10 cases with higher viral loads, who are likely to be the most infectious."

Deeks said, "These results are devastating—they are missing a third of those with high viral loads. How can these tests be used for safe entry into care homes, for healthcare workers to safely return to work, or for the safe return of students? They are not fit for purpose."

Allyson Pollock, director of the Newcastle University Centre for Excellence in Regulatory Science and a member of Independent SAGE, said, "This is scandalous. Where are the data underpinning the statement in the document? Mass testing should be paused until we see the evidence and Liverpool evaluation."

She added, "The Liverpool public who went for testing seem to have been grossly deceived and misinformed about the usefulness of the test and purpose of testing. They were not told that one of the purposes was research on the lateral flow test in healthy people." She said that the pilot should have first gone for advice to the UK national screening committee and have had ethics approval.

The Scottish National Party MP Neale Hanvey has submitted two written parliamentary questions calling for publication of the full data about the community testing pilot in Liverpool. He told *The BMJ*, "My main concern is false reassurance. There is a clear risk that those with a false negative result will feel overly confident about mixing with vulnerable people over Christmas."

An earlier assessment of the Innova test by Public Health England's Porton Down laboratory and the University of Oxford found an overall sensitivity of

76.8%, but said that sensitivity dropped to 58% when carried out by self-trained members of the public.⁵ However, when health secretary Matt Hancock was asked at a health select committee about the test missing almost half of cases, he said he “didn’t recognise” the 58% figure.

- 1 Community testing: a guide for local delivery. 30 November 2020. www.gov.uk/government/publications/community-testing-explainer/community-testing-a-guide-for-local-delivery#what-the-community-testing-programme-is
- 2 Wise J. Covid-19: Concerns persist about purpose, ethics, and effect of rapid testing in Liverpool. *BMJ* 2020;371:m4690. doi: 10.1136/bmj.m4690 pmid: 33268336
- 3 Mahase E. Covid-19: Innova lateral flow test is not fit for “test and release” strategy, say experts. *BMJ* 2020;371:m4469doi: 10.1136/bmj.m4469.
- 4 Williams J. Greater Manchester tells care homes not to use rapid tests for visitors as government roll-out faces “chaos.” 2 December 2020. www.manchestereveningnews.co.uk/news/greater-manchester-news/greater-manchester-tells-care-homes-19389593.
- 5 Preliminary report from the Joint PHE Porton Down and University of Oxford SARS-CoV-2 test development and validation cell: rapid evaluation of lateral flow viral antigen detection devices (LFDs) for mass community testing. 8 November 2020. www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University%20of%20Oxford_final.pdf.