BMJ 2020;369:m1816 doi: 10.1136/bmj.m1816 (Published 4 May 2020)

NEWS

Covid-19: Confidentiality agreements allow antibody test manufacturers to withhold evaluation results

Elisabeth Mahase

The BMJ

Commercial agreements between the UK government and manufacturers of covid-19 antibody tests are allowing the latter to control whether evaluation results of their products are made publicly available.

This matter came to light when a pre-print paper[1] assessing nine different antibody tests for covid-19 was published with the names of the tests anonymised. The paper reported that none of the devices were adequate, with sensitivity ranging from 55 to 70% and specificity from 95 to 100%. This was against the Medicines and Healthcare Products Regulatory Agency's 98% specificity target, which is high because of the risk false positive results could pose if these tests were used to ease lockdown.

The study, conducted by the National Covid Testing Scientific Advisory Panel, said, "Individual manufacturers did not approve release of device level data, so device names are anonymised."

This has raised serious concerns over how much power the manufacturing companies—who have a financial interest in their product selling well—should have in determining what information is or is not made public.

Speaking on the BMJ Talk Evidence podcast, Jon Deeks, professor of biostatistics at the University of Birmingham, said, "That seems close to immorally wrong—that the world now cannot tell what tests there were in that study. It was a well done study, it was paid for with taxpayers money, but the only people who know what tests were in that study are the people in the UK government and probably the researchers, and they are bound by confidentiality not to let the rest of the world know what tests were actually evaluated."

He added, "Frankly, I can't believe that we would think this is a reasonable way to behave—to let the test companies make the decision about whether information is published or not. We all know about publication bias, conflicts of interest. The biomarker companies are the only ones making money in this pandemic, and there is a lot of money to be made. We should not put them in a position where they are in charge of letting us know or not know the results of our studies. It should all be out there for us to understand."

Deeks said that the regulatory processes for tests needs to be improved.

"The regulators now need to take a long look—often in the history of medicine when things have gone wrong we reflect on our regulation and see it's lacking. I'm sure that we are at that point now with biomarker tests," he said.

A spokesperson from the Department of Health and Social Care's Office for Life Sciences confirmed to *The BMJ* that the names of the tests were withheld because of "commercial confidentiality."

They said, "You will appreciate that we can't share the details of all partners and providers of testing materials, as these are subject to commercially sensitive agreements, and in many cases subject to commercial confidentiality."

1 Evaluation of antibody testing for SARS-CoV-2 using ELISA and lateral flow immunoassays. April 2020. www.medrxiv.org/content/10.1101/2020.04.15.20066407v1.full.pdf.