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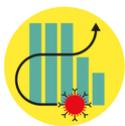
## 'Shambolic' Covid PCR testing rules meant one in three who isolated were never contagious

Many forced to quarantine did not need to because threshold for positive tests was set very low, says study

By Sarah Knapton, SCIENCE EDITOR

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      178



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Up to a third of people who tested positive for coronavirus by [Polymerase Chain Reaction \(PCR\) tests](#) were not contagious and did not need to self-isolate, a new study suggests.

Research led by academics from the University of Oxford found that many laboratories are setting the positivity bar very low, meaning they are picking up people who are “a danger to no one”.

PCR tests work by cycling swab samples through different temperatures to trigger replication, which releases a chemical showing that the virus is present.

The fewer cycles that are needed to detect the chemical, the greater the viral load and the more likely someone is infected.

There is no definitive cycle threshold level for positivity. However, a review by the University of Oxford found that 30 was a good cut-off, because the virus was unlikely to replicate after

that - particularly in asymptomatic people. Other groups have suggested around 32 to 33.

However, Freedom of Information requests made by members of the public and compiled by the University of Oxford show that NHS trusts are using vastly different cut-off thresholds, with little regulation from the Government. Some are as low as 25, while others are as high as 45.

The figures also show that between 23 and 37 per cent of people who were told they were positive had a cycle threshold value above 30. For one in 20, it was higher than 40.

## Covid PCR test system is 'absolute chaos'

Dr Tom Jefferson, co-author and an epidemiologist at the Centre for Evidence-Based Medicine at the University of Oxford, said: "We found that about one-third of people who isolated probably didn't need to.

"PCR positivity means that you can tell people to isolate and ruin their lives basically, even though in a large proportion of these cases, they are not infectious.

"It's absolute chaos. The whole regulation of these tests seems to be shambolic."

Maidstone and Tunbridge Wells NHS Trust counts a PCR test as positive if it is detectable within 27 or fewer cycles. The trust also changes its criteria during periods of low community prevalence, dropping the bar to below 25.

Likewise, Milton Keynes University Hospital NHS Foundation Trust has one test picking up cases below 25 and another below 31.

At the other end of the scale, NHS trusts setting the bar at 45 include Manchester University, County Durham and Darlington, Mid and South Essex and Royal United Hospitals Bath.

Likewise Plymouth NHS Trust, Coventry and Warwickshire NHS Trust, Greater Glasgow NHS Board, University Hospitals Sussex, Torbay and South Devon NHS Foundation Trust and North Cumbria operate between 40 and 45 cycles.

At Wye Valley NHS Trust, the cut-off is lower than 38 cycles. Liverpool also has a cut-off of lower than 38, but any higher counts are sent to an analyst to assess whether it is a weak positive or requires a repeat test.

Other NHS trusts do not know what the threshold for positivity is, because they are using “black box” tests that only give a positive or negative result.

The UK Health Security Agency said there are at least 80 different PCR platforms in use across the country. Each has its own different limit of detection – the lowest concentration of virus that can be reliably and consistently detected by the assay - making threshold values incomparable.

However, the new study showed that in one instance, five NHS trusts were using the same Cepheid GenXpert test, yet were working from four different positivity thresholds - between 35 and 45.

Leeds was using a cut-off of 35 while Blackpool was using 38, North Cumbria 41, Chester 45 and Glasgow 45. Guy's and St Thomas' said it was a “black box” test and they did not know the threshold.

Critics argue that high cycle threshold scores may simply be picking up the virus at trace levels in the community and do not indicate an infection.

A three-point increase in CT value is roughly equivalent to a 10-fold decrease in the quantity of viral genetic material, so the difference between detection at 25 and 45 is sizeable.

### **‘We cannot afford to keep isolating people’**

Scientists have called for the cycle thresholds to be made public, so it is possible to see the level of infection for each test - as happens in Switzerland - amid fears many people are being swept up in the figures who are not infectious.

Currently, laboratories must report positive cases to the UKHSA but do not need to say which one of 80 tests they are using, or reveal the threshold at which they deem a test to be positive.

They also said it would help to monitor the effectiveness of the vaccine and how the infection differs by age group.

Professor Sheila Bird, formerly programme leader at the MRC Biostatistics Unit, University of Cambridge, said it might be helpful for cycle threshold levels to be given alongside each positive test.

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Prof Carl Heneghan, director of the Centre for Evidence-Based Medicine at the University of Oxford, said: "It's deeply worrying. When you have more virus circulating in the community, the potential for contamination is greater. Studies have shown that people can be easily contaminated with a viral fragment.

"The problem is the panic of the pandemic meant that we developed policies at a speed we've never seen before and we haven't looked at them to find out which are evidence-based.

"Accurately knowing who is infectious is incredibly important for people going about their daily lives, the economy, our social lives and our wellbeing. The impact on the economy is now coming home, and it is clear that we [cannot afford to keep isolating people](#).


"It's also clear that members of the public were worried about this and submitting sensible Freedom of Information requests, but were met with contradictory responses attempting to explain a system which is shambolic in terms of governance and regulation."

The study will be published on the website of Collateral Global, a charity committed to researching the impact of Covid measures.

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