

## Submission to UK Government Consultation on Covid-19 Status Certification

### Evidence submitted by:

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This submission has been authored by a multidisciplinary team of academic researchers including medics, scientists and social scientists, engaged in a systematic international comparative study on the Optimisation of Covid Testing Systems (the OCTS study).<sup>1</sup> The research is supported by the Economic and Social Research Council, through UKRI's Covid-19 programme (Grant reference: ES/W00156X/1).

### Question 1

Which of the following best describes the capacity in which you are responding to this call for evidence?

We are academic researchers

### Question 2

In your view, what are the key considerations, including opportunities and risks, associated with a potential COVID-status certification scheme? We would welcome specific reference to:

- a) Clinical / medical considerations
- b) legal considerations
- c) operational / delivery considerations
- d) considerations relating to the operation of venues that could use a potential COVID-status certification scheme
- e) considerations relating to the responsibilities or actions of employers under a potential COVID-status certification scheme
- f) ethical considerations
- g) equalities considerations
- h) privacy considerations

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<sup>1</sup> [www.octs.info](http://www.octs.info)

## Summary

COVID-status certification is a broad term that encompasses two similar but distinct policy proposals; vaccination certification and infection status certification. While these two can be conceived as one, they present different clinical, operational, ethical, and equity considerations. In each of the sections covered below, we discuss differences between these two options.

In addition, while testing data based on antibodies, either from vaccination or natural infection, may have a future role to play in COVID-status certification, there is still not enough evidence to support the suitability or widespread use of this approach at the current time. As such this submission assumes testing approaches will use PCR and antigen-based Lateral Flow Devices, rather than antibody testing. Further to this, we also recognise that the assumption of PCR-testing as a gold standard can be seen as cautious, based on PCR's theoretical ability to produce positive results in post-infectious individuals. At this time, PCR's ability to detect positive cases earlier is advantageous compared to its false positive risk; this may shift as community transmission reduces with vaccination and more evidence is gathered.

Based on the evidence provided below, it is our opinion that, while vaccination certification is not without its logistical, clinical, and ethical challenges, the use of testing data to certify COVID-status offers far more challenges than use of vaccination status. Testing data should therefore be limited to clearly defined situations, for example, medical reasons precluding vaccination. Whichever form of COVID-status certification is used, it is also important that additional risk reduction measures remain in place (for example, masks and social distancing) as evidence on the protective effects of vaccination and prior infection on infectiousness remains under investigation.

*If COVID-status certification is to be used, it should be used with extreme caution and in conjunction with other risk reduction measures and efforts to address **all** ethical and equality challenges, given the profound differences observed in how the pandemic has harmed different groups in society.*

### a) Clinical/medical considerations

Clinical considerations fall into three categories: testing, natural immunity, and vaccination. On testing, in order to use a SARS-CoV-2 test for certification purposes, the test should be simple enough for public use and should provide accurate, verifiable, results within a few minutes. The WHO 2006 ASSURED benchmark (Affordable, Sensitive, Specific, User friendly, Rapid & Robust, Equipment-free and Delivered to end-users) set out criteria for point-of-care diagnostics.<sup>2</sup> No current covid-19 test in use today satisfies these criteria.<sup>3</sup>

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<sup>2</sup> Peeling RW, Holmes KK, Mabey D, Ronald A. Rapid tests for sexually transmitted infections (STIs): the way forward. *Sex Transm Infect* 2006; 82 (suppl 5): v1–6; Kettler H, White K, Hawkes S. Mapping the landscape of diagnostics for sexually transmitted infections: key findings and recommendations. Geneva: World Health Organization, 2004.

<sup>3</sup> A rapid point-of-care PCR diagnostic that meets the ASSURED criteria will be the ideal technology to support a test-to-enable policy.

Vaccination, along with non-pharmaceutical interventions<sup>4</sup> offers the prospect of reduced need for lockdowns, as studies have shown good efficacy and reduced transmission. However, whether vaccine coverage will be high enough to achieve population immunity, in the face of vaccine hesitancy remains to be seen. The duration of protection offered by vaccination, however, is unknown and it may be that booster doses will be required to protect against emerging vaccine escape variants.<sup>5</sup>

Immunity (and its relationship with transmissibility) is a central challenge for COVID-status certification. In the case of prior infection and in the case of vaccination, immunity is not guaranteed nor is the extent of reduction in transmission known for different available vaccines. While viral load can be correlated with an individual's transmissibility (and thus vaccine/prior infection assumed as protective), there is limited evidence that vaccines or prior infection reduce the likelihood that an individual will transmit the virus to others.<sup>6</sup> However, there are ongoing studies seeking to address this question. It is therefore still premature to assume COVID-status certification would reduce community spread of SARS-CoV-2.

### c) Operational /delivery considerations

Logistically, occasional vaccination is less complicated and less costly to operationalise than ongoing repeated testing across populations of individuals. Vaccination also has the added advantage that proof of status is easier to verify (and even can be associated with particular products, which may have differential levels of effectiveness, according to prevalent variants).

In a situation where a negative test is required, for example to gain access to a restaurant, a PCR test certified by a healthcare provider, would likely not be appropriate as the turnaround time is not rapid enough. It may not be practical for restaurant operators to offer customers SARS-CoV-2 tests before assigning them a table. The authenticity of a negative self-swab using lateral flow test done at home cannot be verified and false negative rates may be deemed unacceptably high for the above scenario,<sup>7</sup> and the WHO does not recommend using a lateral flow test for a one-off assessment of status, due to the risk of false negative result.

Operationally, a distinction must also be made between certification for access to social, civic, and economic activities, and access to the UK via international travel. For international travel, a rapid point-of-care PCR test, which is self-administered under supervision at the airport before boarding a plane, ferry or train, may be a useful additional measure. Obtaining a negative result in this way just before travel is more reassuring than a negative test obtained 72 hours before departure. The rapid point-of-care PCR test requires a 'pop up' laboratory, but is highly mobile and therefore is useful for high-throughput areas like airports.<sup>8</sup>

For domestic access to social, civic, and economic activities, the feasibility of testing as a route is more complex. Rapid PCR tests in this case are not viable because of low throughput and 90-minute test-time. Lateral flow devices could be used in place of these PCR tests as they are both cheap and produce results in under an hour. However, available lateral flow tests do not yet have sufficient sensitivity during the infectious stage of disease to certify an

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<sup>4</sup> Moore et al, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00143-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00143-2/fulltext)

<sup>5</sup> Allie Nawrat, <https://www.pharmaceutical-technology.com/features/covid19-vaccine-boosters-pandemic/>

<sup>6</sup> Smriti Mallapaty, Nature, <https://www.nature.com/articles/d41586-021-00450-z>

<sup>7</sup> Crozier et al. BMJ 2021; 372 doi: <https://doi.org/10.1136/bmj.n208> (Published 03 February 2021)

<sup>8</sup> <https://www.gov.uk/government/news/roll-out-of-2-new-rapid-coronavirus-tests-ahead-of-winter>

individual as low risk.<sup>5</sup> Use of these tests therefore requires repeat-testing every 3-5 days for accurate certification, which is not necessarily feasible prior to accessing, say, a restaurant.

e) Considerations relating to the responsibilities or actions of employers under a potential COVID-status certification scheme

Employers in certain lines of business, for example, with employees who are in frequent, prolonged, indoor contact with large groups of the public, could be allowed to use vaccination status to decide whether individuals should be allowed to perform certain tasks. A precedent exists here in which healthcare workers with blood borne viruses are only allowed to perform exposure prone procedures if they meet certain criteria.<sup>9</sup> Vaccination status here is used to determine which individuals can perform tasks, but not whether or not an individual can be employed.

Employers may allow regular repeated testing as an alternative to vaccination, but the type of technology to be used for this purpose as discussed above will need to be agreed on and offer a safe and effective solution to COVID-19 risk. There is also the issue of who would pay for repeat testing; the employer, the employee or the government. Employers may decide they would not pay for the test because a safe vaccine is available for free. However, a lack of testing alternatives, where individuals may have reasonable medical or equality grounds for not being vaccinated, may be deemed inequitable and even discriminatory.

f) Ethical considerations

Tensions between individual rights and public health safety are not new.<sup>10</sup> The debates around the rise in vaccine hesitancy and the perceived risks of the MMR vaccine demonstrate this acutely.<sup>11</sup> Vaccination is inherently related to the ethical principle of bodily autonomy and an individual's right to refuse, while the public health rationale of vaccination campaigns emphasises the benefit of collective immunity. The individual's risks and benefits of vaccination are balanced against the collective risks and benefits of herd immunity. The prime consideration for vaccination-requirements for access to social, civic, and economic activities is the counter-factual: can risk be reduced acceptably through other measures?

For example, for activities where it may not be reasonably practicable to provide proof of negative COVID-19 test immediately prior, and other measures of risk reduction are impossible, vaccination mandates might be considered. However, vaccination might not need to be mandated if a verified negative PCR test can be provided suitably in advance. In such situations, the individual should also be required to wear a mask as an additional layer of protection, for example if in confined spaces close to others. The above arguments do, however, ignore the equity of vaccine access which we discuss below.

The ethical dimensions of using prior infection as a marker for immunity and low-risk status, however, are much more worrying. The primary issue with using prior-infection to allow entry to social, civic, and economic activities is that of perverse incentives. For those without access to vaccines the incentive to actively seek out infection so as to re-join active society is

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<sup>9</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/909553/Integrated\\_guidance\\_for\\_management\\_of\\_BBV\\_in\\_HCW.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/909553/Integrated_guidance_for_management_of_BBV_in_HCW.pdf)

<sup>10</sup> Bayer R; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2267241/>

<sup>11</sup> Eleanor Draeger et al; <https://www.bmj.com/content/365/bmj.l2359>

deeply concerning, particularly if COVID-status becomes entwined with employment and not simply leisure.<sup>12</sup> This has occurred in the past in New Orleans where prior infection with yellow fever became a passport for access to economic activities.<sup>13</sup> In a world where the likelihood of surviving COVID-19 is heavily dependent upon socio-economic advantages, race, and gender, the ethical impact of this perverse incentive is not just a risk for public health but exacerbates existing injustices.<sup>14</sup>

#### g) Equalities considerations

Equality dimensions of COVID-status certification are discussed here under considerations of international and domestic scope. On international scope, the poor access to COVID-19 vaccines in many countries would mean that individuals who reside in the UK but have family members in countries with poor vaccine access would be impacted to a much greater extent than those who have family in countries with good vaccine access. Given the global distribution of vaccines, this would disproportionately affect individuals with ethnic minority backgrounds whose families in countries with limited vaccine access may not be able to fulfil the entry requirements to visit the UK.

It is conceivable that other countries could also make COVID-19 vaccination a condition for entry or airline operators could make it a prerequisite for boarding. Some countries require all travellers to carry proof of yellow fever vaccination in order to be allowed entry into those countries<sup>15</sup> in accordance with the revised International Health Regulations (2005). Yellow fever vaccines, however, are widely available, and relatively equally distributed. This sits in stark contrast with COVID-19 vaccines where gross inequity in access exists such that poorer countries have not been able to make vaccines available to their citizens.

Within the UK, where vaccination is progressing at pace, equitable access to, and uptake of, vaccines amongst all individuals regardless of socioeconomic status or ethnic background is important. Some individuals cannot be vaccinated for medical reasons, and others (often from poorer or minority backgrounds) are hesitant of vaccines due to issues of trust in government or medical institutions. Further to this, some communities are poorly communicated to and have poor uptake of basic healthcare resources due to language or community constraints. This exacerbates inequity in the uptake of vaccination and thus the ability of many to provide evidence of their COVID-status.

Individuals who do not accept vaccination (for medical, religious, or access reasons) may also be subject to stigmatisation or discrimination. For example, some employers may decide whether an individual should be allowed to undertake certain tasks based on their vaccination status, or even whether to hire an individual or not; access to certain economic or welfare activities (e.g. food banks) could be restricted; and perceptions of those with visible disabilities as infectious could be exacerbated. This stigmatisation is common in communicable diseases (e.g. stigmatisation of men-having-sex-with-men within the HIV pandemic) and can often cause some individuals to actively avoid accessing medical services out of fear.

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<sup>12</sup> Phelan AL; [https://doi.org/10.1016/S0140-6736\(20\)31034-5](https://doi.org/10.1016/S0140-6736(20)31034-5). Published **Online** May 4, 2020

<sup>13</sup> Olivarius K. <https://doi.org/10.1093/ahr/rhz176>, Volume 124, Issue 2, April 2019, Pages 425–455).

<sup>14</sup> Golestaneh L et al; <https://doi.org/10.1016/j.eclinm.2020.100455>. Published: July 14, 2020

<sup>15</sup> [https://www.who.int/ith/ith\\_country\\_list.pdf](https://www.who.int/ith/ith_country_list.pdf)

On testing, minority ethnic groups have been disproportionately affected by the pandemic because they are disproportionately represented in frontline roles that expose them to large volumes of the public and COVID-19 risk. Vaccine hesitancy is also often high in these groups due to entrenched government mistrust. Hence using COVID-19 tests for certification would indirectly disadvantage this group the most because of the kind of jobs they do. Mandating testing for infection status as prerequisite for employment therefore also risks exacerbating existing inequalities.

COVID-status certification, therefore, poses significant issues for equality and ethics. Addressing international equality issues requires increased global access to vaccines, while addressing domestic equality issues requires a series of actions on behalf of the government to prevent misuse and abuse of COVID-status certificates.