



## COVID-19 antibody testing and 'immunity certification'

18 June 2020

### Overview

- People who have recovered from COVID-19 may have acquired a degree of protection and be less likely to transmit the virus to others. It has been suggested that, if these people could be distinguished from others who are more susceptible, they should be freed from general restrictions that are in place to protect public health.
- Antibody testing is currently being rolled out for research purposes but may offer a way to assess an individual's risk of being infected and transmitting the virus to others, and could be used as the basis of a system of 'immunity certification' or more complex risk profiling.
- The idea of immunity certification raises many ethical questions concerning respect for individual rights and interests, public health responsibilities, and social justice.
- At present there is too much scientific uncertainty and there are too many unresolved ethical concerns to support the use of immunity certification as a way of easing restrictions on certain members of the public.
- It is nevertheless foreseeable that private individuals, businesses and organisations will seek to make use of biomedical tests (e.g. antibody tests) to inform their practices and decisions.
- The negative impacts of a certification system are likely to fall disproportionately on those who are already socially marginalised and disadvantaged.
- Urgent action is needed to identify and monitor these impacts, by engaging with and supporting those in positions of vulnerability and disadvantage.
- Regulatory measures may be needed to secure the benefits of testing while defending against morally unacceptable and socially undesirable consequences.

SARS-CoV-2, the virus that causes COVID-19 disease, is a novel pathogen against which human populations have no specific, pre-existing immunity. The virus may be passed on before symptoms appear and many infected people clear the infection without showing any symptoms.<sup>1</sup> Certain groups, particularly older people, are statistically more likely to experience severe forms of the disease.

Until effective vaccines or treatments become widely available most states have sought to protect public health through non-pharmaceutical interventions, such as use of personal protective equipment, the closure of businesses, restrictions on public movement and so-called 'social distancing'. This has required exceptional state action and has had significant impacts on businesses, livelihoods and relationships.

Published by Nuffield Council on Bioethics, 28 Bedford Square, London WC1B 3JS

 [bioethics@nuffieldbioethics.org](mailto:bioethics@nuffieldbioethics.org)

 [@Nuffbioethics](https://twitter.com/Nuffbioethics)

 [NuffieldBioethics](https://www.facebook.com/NuffieldBioethics)

[www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)

People who have recovered from COVID-19 may have acquired a degree of protection and be less able to transmit the virus to others.<sup>2</sup> It has been suggested that, if these people could be distinguished from others who are more susceptible, the general restrictions in force to protect public health need not (and should not) be applied to them.<sup>3,4</sup> Such an approach would allow an increase in social and economic activity, at least for a section of the population. For this to be feasible, at least four things are required:

- an understanding of what factors correlate with increased protection against the virus (for example, the presence of specific antibodies in the circulation),
- a reliable means of detecting these factors in individuals (for example, a validated biomedical test),
- a secure means of authenticating information about these factors relating to particular individual (for example, a fraud-resistant form of certification), and
- the acceptability (or acceptance) of a policy that applies different restrictions to different groups of people based on these results.

A public policy that permits citizens to be treated differently in such a way is likely to be guided by the judgement that it is safe to restore liberties to those at low risk of infection/ transmission while maintaining no greater restrictions on those who remain susceptible than are proportionate to the public health risk. It is far from assured, however, that the benefits of restoring liberties to some will not come at a cost to the interests of others.

## **WHAT WE KNOW AND DON'T KNOW ABOUT SARS-COV-2 PROTECTIVE IMMUNITY**

SARS-CoV-2 is a new virus and knowledge about the human immune response is still developing, including how and why immune response differs between individuals.<sup>5</sup> Biological markers for increased susceptibility to COVID-19 are also being sought.<sup>2</sup> While evidence shows that most people who are infected develop antibodies that are specific to the virus, some apparently recover without showing an antibody response. While antibodies are likely to be involved in protecting against future infection, the presence of antibodies cannot be said to equate to 'immunity'.<sup>2,6</sup> Furthermore, the duration of any protection they confer is, so far, unknown.<sup>2,7</sup>

## **TESTING**

Information relevant to an individual's risk of infection/transmission is provided by a growing range of tests, which have differing performance characteristics.<sup>8</sup> The tests that are principally in view are antibody (serological) tests, but other biomarkers may also be relevant.<sup>2</sup> Individual test results can be interpreted in the light of other relevant information to provide, in effect, a personal risk profile. Confidence in this measure will depend partly on the performance characteristics of the test or tests, and the range of biological and circumstantial factors (many of which are unknown) that contribute to protection and susceptibility.

Antibody tests are being rolled out for the purpose of research, which is needed to establish the background prevalence of past infection and thus the confidence that can be placed in individual test results. Health and social care workers are currently being offered antibody tests as part of research studies.<sup>9</sup> Organisations and businesses may have other reasons to want their staff to be tested, for example, to manage infection risk, and to provide reassurance to colleagues, clients and customers.

Individual citizens may also have incentives to take tests to manage their personal risk of infection (for example, in relation to susceptible family members) or to gain access to goods or services for which a positive test result may be required. Some direct-to-consumer tests are becoming available that claim to give customers information about their antibody status (i.e. the kind of information that will be available to those who participate in research).



## CERTIFICATION

The significance of any given level of risk in a particular context is always a matter of judgement, which depends on how different hazards and benefits, and their likelihood of occurring are valued. Certification turns a judgement about risk into a binary value that is invested with political significance (for example, a specific permission or exclusion).

Certification can function like a passport (for example, as a condition to be admitted to a country or a controlled space, or to waive entry quarantine requirements) or like a licence (for example, to permit someone to carry out a particular function, such as serving customers). To be valuable it must be resistant to fraud by reliably encoding authentic information (for example, a test result) and linking that information securely to an identifiable individual (the person who was tested). Different forms of certification have been proposed in the context of COVID-19, including personal smartphone apps that encode or securely exchange relevant data, wristbands that combine location and health tracking but could also be set to signal risk status, and identity verification systems linked to a centralised database of test results and relevant information.<sup>10</sup>

## IMPLICATIONS

### Individual rights and interests

In normal circumstances, taking a biomedical test is a voluntary act. Having a meaningful choice, however, depends on there being a range of options with tolerable consequences available. The context in which testing is offered may, for example, put pressure on individuals to conform with an expectation that they should be tested. The choice to decline testing may raise suspicions in others or lead to stigmatisation. Testing offered in the context of employment (even if the primary purpose is research) can put pressure on employees owing to the hierarchical power structures in most workplaces; co-workers who have adopted organisational norms may also exert peer pressure to conform.

Biological risk markers fall into a 'special category' of personal information.<sup>11</sup> If pressure exists to take a test, similar pressure is likely to exist to disclose the results. Again, others will make inferences from an individual's unwillingness to disclose their result if disclosure becomes a social norm, and those who do not comply with the norm may be stigmatised.

The normalisation of testing is important, arguably, less because of the somewhat abstract value of personal autonomy than because of the consequences of test results. If a test result becomes a condition of access to goods or services, or to carry out certain professional duties, it will have significant practical consequences.

### Public health and social justice

Largely due to the effectiveness of lockdown restrictions, the number of those who have been infected and recovered from COVID-19 in the general UK population has been kept at a level that makes it implausible that they should or could carry the burdens of national economic productivity on behalf of those who remain susceptible.<sup>12</sup> It also seems improbable that there will ever be enough immunologically protected individuals to achieve 'herd immunity'. Testing and certification may, nevertheless, have a function in public policy, for example to waive quarantine restrictions on incoming international travellers.

Testing could also, however, be used in private contexts, as a condition of access to commercial goods or services (e.g. to be admitted to a venue) or for certain professional duties (e.g. dealing face-to-face with customers). This is likely to induce people to seek out tests privately and to stimulate a commercial testing market. A proliferation of non-standard tests entering use creates incentives to 'game' tests to get the desired result (perversely tending to make poorer performing



tests more economically valuable), or to disassemble, misreport or fake test results.<sup>13</sup> Private testing potentially enables individuals to seek personal benefits while externalising the associated risk. Individuals may be prepared to accept lower test performance characteristics to inform decisions about their own behaviour than those judged appropriate to protect public health.

Employers may prefer to employ or deploy seropositive workers, believing they are less likely to fall sick or to infect co-workers or customers. An immune certified workforce may offer businesses a commercial or reputational advantage over competitors.<sup>14</sup> Pursuing these incentives could lead to major social upheaval (as seronegative employees potentially lose opportunities to seropositive colleagues or applicants) and create coercive and stigmatising work environments. It could also create perverse incentives for people (particularly those who are unemployed, or who were dismissed or furloughed as a result of the pandemic) deliberately to expose themselves to infection in order to obtain a positive result. By doing so they may unintentionally contribute to the health crisis by transmitting the virus to others and requiring medical care.<sup>15</sup>

These effects are likely to fall disproportionately on those who are already socially marginalised and disadvantaged. The lockdown has had a disproportionate impact on workers in low-paid sections of the economy, depriving them of income if they remain at home or forcing them to risk exposure if they are among the key workers who have continued to work (groups in which those from Black, Asian and minority ethnic backgrounds are significantly overrepresented).<sup>16</sup> Positive tests may be used to require sections of the workforce to return to work, impacting unequally on those who are unable, through lack of wealth or power, to make the choice for themselves. Those with precarious incomes and working in low paying jobs, often in the service or industrial sector, are already more likely to experience social determinants of poorer health (unemployment, poor quality housing, less personal space, etc.), and worse outcomes of SARS-CoV-2 infection, than those in more privileged groups.<sup>16</sup> Selective uses of certification are more likely to compound than redress these structural disadvantages and to add to the social stigmatisation of these groups.<sup>17</sup>

### **Embedding surveillance technologies**

The form of certification also creates both commercial and political opportunities. Technologies, such as smartphone apps, that have advantages of resistance to fraud also have the potential for expanded functionality, for example collecting data for disease surveillance and epidemiological research. They also have the potential to be used for identity verification, more sophisticated risk profiling (rather than simply inscribing the result of a single test) and generalised surveillance.<sup>10</sup> Once testing is available for one purpose (for example, public health surveillance), incentives to use it for additional purposes are likely to emerge.

If access to goods and other benefits are attached to the use of a particular form of technology, the technology is more likely to be adopted voluntarily by those who have access. This can easily lead to widespread diffusion and embedding of proprietary technologies, especially if they are endorsed by Government. Access to and acceptance of technology are not, however, equally distributed and the choice of technology may exclude or deter individuals and groups from obtaining the potential benefits available.

The question of protecting freedoms must, therefore, be addressed at the level of policy (i.e. the uses to which test results may be put) rather than simply at the level of individual choice (i.e. ensuring that tests are taken and results shared voluntarily). Regulatory measures may be needed to secure the benefits of testing while defending against morally unacceptable and socially undesirable consequences.



## CONCLUSIONS AND IMPLICATIONS

The following conclusions draw on previous Council inquiries and discussions at an online meeting of experts on 24 April.

1. Research into the immunology of SARS-CoV-2, such as that proposed by the British Society for Immunology and Academy of Medical Sciences expert advisory group, is an urgent priority.<sup>2</sup>
2. In the present state of knowledge, there is too much scientific uncertainty and there are too many unresolved ethical concerns to support the use of immunity certification as a way of managing the selective modification of general restrictions on public movement and assembly. The likely, relatively low population prevalence of SARS-CoV-2 infection makes this impractical in any case.<sup>12</sup>
3. It is nevertheless foreseeable that private individuals, businesses and organisations will seek to make use of biomedical tests (e.g. antibody tests) to inform their practices and decisions. Existing legal provisions and guidance from the Government and the Information Commissioner's Office address, to some extent, the impacts on individuals but they do not address the wider implications for structural disadvantage, technological change and public good.<sup>18</sup>
4. Substantial concerns exist about the differential impact of a selective modification of restrictions based on risk profiling (as there are about the impact of restrictions themselves): that benefits will be pursued by individuals at some risk to public health; and that those benefits will be captured by those already privileged and the costs borne by those who are already structurally disadvantaged. These impacts need to be identified and monitored by engaging with and supporting those in positions of vulnerability and disadvantage.
5. The likelihood of adverse impacts may be sufficient to warrant the use of regulatory measures specifically to control the private use of testing and certification technologies and/or to avert or redress their effects. Urgent policy consideration is needed.
6. There is a need to give anticipatory ethical consideration to the development of technologies and services around testing, and to the potential for innovation that takes place in circumstances of national emergency inadvertently to embed approaches, research infrastructures and relationships that may limit future options.<sup>19</sup>
7. There is, similarly, a need for public debate about how well the proposed infrastructures and the possible involvement of private actors promote the public good, taking into account the diversity of generations, genders, localities, and socio-cultural groupings, and how these approaches compare with possible alternatives, before they become the default model for the future expansion of testing, profiling and surveillance.<sup>20</sup>



## References

- 1 Li Q, Xuhua G, Wu P, *et al.* (2020) [Early transmission dynamics in Wuhan, China, of novel coronavirus–infected pneumonia](#), *New England Journal of Medicine* **382**: 1199-1207.
- 2 British Society for Immunology and Academy of Medical Sciences (2020) [Covid-19 immunology research, what do we know and what are the research priorities?](#)
- 3 Persad G and Emanuel EJ (2020) [The ethics of COVID-19 immunity-based licenses \(“immunity passports”\)](#) *Journal of the American Medical Association*.
- 4 Brown R, Savulescu J, Williams B and Wilkinson D (2020) [How much certainty is enough? Immunity passports and COVID-19](#) *Journal of Medical Ethics blog*
- 5 Altmann DM, Douek DC, and Boyton RJ (2020) [What policy makers need to know about COVID-19 protective immunity](#) *The Lancet*.
- 6 Wu F, Wang A, Liu M, *et al.* (2020) [Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications](#) *medRxiv* preprint.
- 7 Galanti M and Shaman J (2020) [Direct observation of repeated infections with endemic coronaviruses](#), *medRxiv* preprint.
- 8 Royal College of Pathologists (2 April 2020) [Statement from RCPATH’s Immunology Specialty Advisory Committee on COVID-19 / SARS CoV2 antibody evaluation](#).
- 9 Department of Health and Social Care press release (21 May 2020) [Government to offer antibody tests to health and social care staff and patients in England](#).
- 10 Ada Lovelace Institute (2020) [Exit through the App Store?](#)
- 11 The EU General Data Protection Regulation 2016/679, Art.9(1) and Data Protection Act 2018, s.10.
- 12 Public Health England (2020) [Weekly coronavirus disease 2019 \(COVID-19\) surveillance report, week 24](#).
- 13 Hall MA and Studdert DM (2020) [Privileges and immunity certification during the COVID-19 pandemic](#), *Journal of the American Medical Association*.
- 14 The Guardian (10 June 2020) [‘Are you immune?’ The new class system that could shape the Covid-19 world](#).
- 15 Hemel DJ and Malani A (2020) [Immunity passports and moral hazard](#), *SSRN*.
- 16 Office for National Statistics (7 May 2020) [Beyond the data: understanding the impact of COVID-19 on BAME groups](#).
- 17 Olivarius K (2019) [Immunity, capital, and power in antebellum New Orleans](#) *The American Historical Review* **124**(2): 425–55.
- 18 Information Commissioner’s Office (2020) [Workplace testing – guidance for employers](#).
- 19 Nuffield Council on Bioethics (2012) [Emerging Biotechnologies: technology, choice and the public good](#).
- 20 Nuffield Council on Bioethics (2015) [The collection, linking and use of data in biomedical research and health care: ethical issues](#).

