Background discussion paper

COVID-19 antibody testing and ‘immunity certification’: a discussion paper

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This paper was prepared as background to inform the Nuffield Council on Bioethics policy briefing on *COVID-19 antibody testing and immunity certification*. The paper is intended to provide a more detailed overview of key ethical, social and policy issues, and is published to further promote and stimulate discussion of the issues that it identifies. The paper draws on discussion of testing, immunity and solidarity at an online meeting of experts, hosted by the Nuffield Council on Bioethics on 24 April 2020’.

COVID-19 antibody testing and 'immunity certification': a discussion paper

In the absence of an effective treatment or vaccine, the response to the current COVID-19 pandemic has focussed on non-pharmaceutical interventions (NPIs) to minimise transmission of the SARS-CoV-2 virus among the general population. In many countries, including those of the UK, this has included general restrictions on movement and association ('lockdown').[1] Alongside the direct impact of COVID-19, these restrictions are having a substantial impact on people's physical and mental health, social wellbeing, and economic activity.[2] Many advanced economies are expected to enter recession in 2020.[3]

Governments are therefore exploring options for controlled relaxation of emergency restrictions to enable businesses and services to resume some activities while continuing to protect public health. An effective approach will involve a combination of adjusted measures that responds to the changing situation rather than a single solution. This background paper describes the legal, social, and biomedical context of measures that would selectively modify restrictions on individuals who have a low risk of infection and transmission of SARS-CoV-2 ('immunity certification').

This briefing draws on discussion of testing, immunity, and solidarity at an online meeting of experts, hosted by the Nuffield Council on Bioethics on 24 April 2020.[*] It also draws on earlier in-depth inquiries conducted by the Council, and reports published by the Council.[4,5,6,7,8,9,†]

[*] The participants in this meeting are listed at Appendix 2.

[†] The Council has also collected a suite of materials on ethical issues raised by COVID-19, including policy briefings, reports and blogs, which are regularly supplemented and available via a dedicated section on the Council's website (available at: https://www.nuffieldbioethics.org/topics/health-and-society/COVID-19).

1. The present emergency

COVID-19 is an infectious respiratory disease caused by the SARS-CoV-2 coronavirus that was first identified in December 2019, in Wuhan, China.[10] It has spread rapidly around the world from the beginning of 2020, affecting 215 countries at the time of writing, and was designated a pandemic by the World Health Organization on 12 March.[11] It has caused very significant morbidity and mortality in all affected countries.[12]

Governments have applied emergency measures to protect public health, including isolation of suspected cases and maintaining distance between individuals.[13,*] The enforced closure of business premises and curtailing of activities, together with restrictions on movement and assembly ('lockdown') began in Great Britain following a Prime Ministerial address on 23 March (Northern Ireland followed on 28 March).[14] Some lockdown measures were relaxed at the end of the first week in May and further eased at the end of May/beginning of June, with approaches and timings differing slightly among the home countries.

The rationale for these extraordinary restrictions rests on the judgement that they are necessary to protect the public from COVID-19 and proportionate to that aim. They interfere with the exercise of certain civil and political rights, albeit in a way that is foreseen as exceptional. From the moment these restrictions were imposed it has been, therefore, the duty of government assiduously to pursue the conditions that would permit their easing and removal. This not only invites but requires consideration of measures that might be taken to achieve this, and subjection to the scrutiny necessary to ensure that the continuation of any restrictions in force is proportionate to the need to protect public health.

The end of the emergency is expected to be when the exceptional threat posed by COVID-19 recedes. Given that the SARS-CoV-2 virus is now endemic, this end is likely to be when (and if) an effective vaccine or treatment for COVID-19 disease is found. While extraordinary efforts are being made on both fronts and researchers are publicly optimistic, neither is likely in the short term.[15] Until that point there is expected to be a reliance on non-pharmaceutical interventions (NPIs) requiring behavioural adaptations that continue to restrict the exercise of individual freedoms.

2. Evidence regarding immunity

Immune response

Viruses infect by invading living cells, where they harness the host cell's internal machinery to replicate. To respond to the virus, the host's immune system needs to recognise the invading virus as foreign. The earliest response is a direct one from the infected cell, which releases small messenger proteins, called interferons,

* In the UK this has become known as 'social distancing' although the World Health Organization, which appears to have coined the term in 2005, now prefers the descriptive term 'physical distancing'.

cytokines or chemokines. These proteins alert neighbouring cells and cells of the 'innate' (inbuilt) immune system, which respond to forming an early warning system. In most cases, this alone may eliminate the infection with limited or no disease symptoms.

Infected cells express molecules that will exhibit proteins made by the invading virus on the cell surface. These signal to circulating T and B cells (cells of the 'adaptive' immune system). B cells respond by making specific antibodies, and T cells by making cytokines and/or by killing the infected cells. In some cases, however, the immune system can overreact leading to harmful hyperinflammation known, in its later stages, as 'cytokine storm'.[16] This is considered to be a component of COVID-19 disease but the levels of cytokines found in the serum are not as high as in some other conditions such as sepsis or acute respiratory distress syndrome.

Antibodies are protein molecules with specialised regions that bind specifically to structural proteins of the virus, including the spike proteins on the virus particle. These can prevent the virus entering a cell of the host (neutralises the pathogen) and mark it for disposal by other cells (phagocytes). It takes seven to 28 days for antibodies to be detected, depending on the infection being studied and the assay used to measure the response.[17, 18]

Individual immunity

When a person has been infected with a pathogen that activates an immune response, antibodies continue to circulate and an 'immunological memory' is established for specific pathogens that the host has encountered.[19] This immunological memory means that subsequent reinfection with a previously-experienced pathogen can be met with rapid increase in antibody production and effector T-cell activity. As a result, for most viruses, later infections may result in comparatively mild or absent symptoms. Such protective immunity can also be acquired by vaccination.

Because SARS-CoV-2 is a new virus in humans, nobody had specific immunity to the virus before the 2019 outbreak occurred, although patients who have recovered from closely related SARS-CoV1 coronavirus infection may demonstrate some types of cross-protective antibodies against SARS-CoV-2.[20] Much of what we assume about immunity to SARS-CoV-2 is inferred from what is known about immunity to similar viruses, particularly the four known human common cold coronaviruses, SARS-CoV, MERS-CoV coronaviruses that cause severe respiratory infections, and responses to animal coronaviruses. This background knowledge is helpful but may not be completely reliable, given that SARS-CoV-2 is a new virus in humans.

Testing for functional neutralisation is not routinely performed because it is technically difficult; routine assays tend to test for antibodies binding to spike antigen, as a proxy measurement for protection.[21] (Evidence from macaque studies suggests that virus-neutralising antibody correlates with resistance to infection.[22])

The presence of antibodies cannot be the only requirement, since it is known that people who are immunodeficient and unable to make antibodies, can nevertheless make a good recovery. As multiple factors and systems are implicated in protection against SARS-CoV-2 virus it is more appropriate to speak of ‘correlates of protection’ (CoP) than a single and sufficient source of immunity.[23] However, this does not indicate that the parameter being measured actually causes protection, just that it is associated with it.

Given known variation in persistence of antibodies for other viruses and the novelty of SARS-CoV-2 virus, it cannot, in any case, be known how long any acquired immunity is likely to persist in recovered patients. It is thought that this could range from a few months to many years. (SARS-CoV-1 antibodies have been found to persist for 12 years.[24]) Nonetheless, evidence from recent studies indicates that experimental vaccine-elicited antibodies that prevent SARS-CoV-2 entry into cells correlates with protection against reinfection.[25]

The other major arm of immunological memory is T cells. These cells expand during an infection and increase their specificity for targeting infected cells. Following the resolution of an infection these cells can enter a memory state and persist in the body for many years, able to respond more quickly to subsequent infection with the same pathogen. In a similar way to antibodies, the presence and abundance of specific cytotoxic T cells is a CoP against future infection.

Immunity in populations

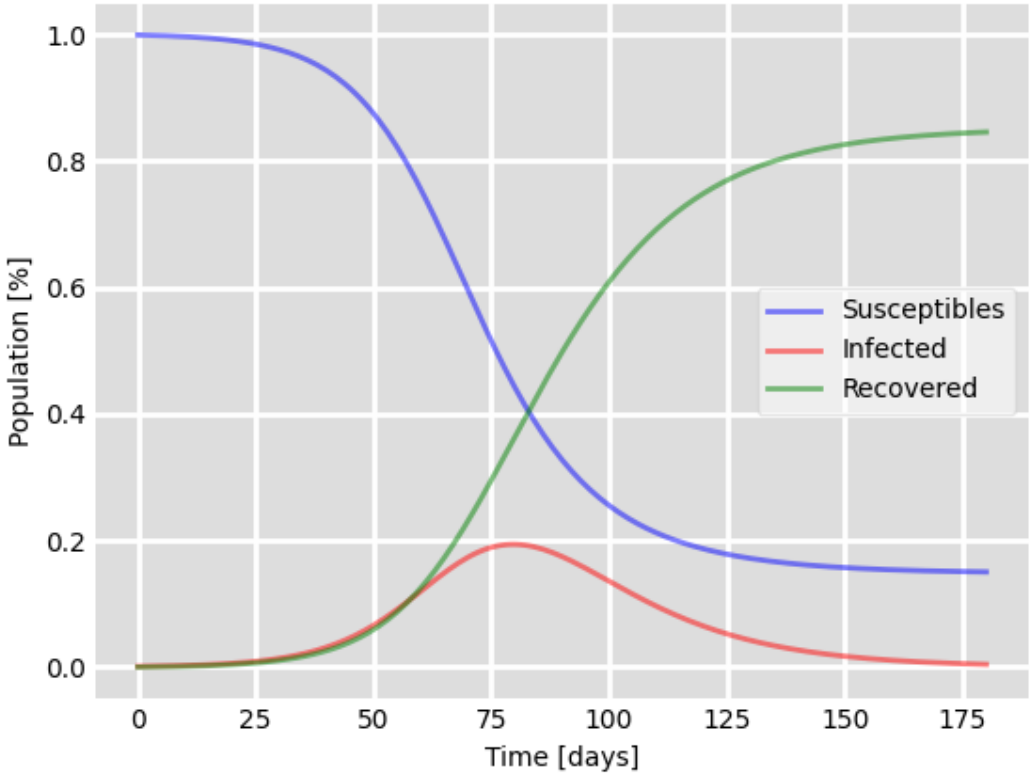
SARS-CoV-2 is highly infectious in humans. Evidence from early outbreaks suggests that, on average, people are infectious from 2.5 days after exposure with infectiousness peaking at around 0.6 days before the onset of symptoms. These appear, on average, five days after exposure.[26] Individuals continue to pose an infection risk to others for some time after the appearance of symptoms: around eight days for those with mild to moderate symptoms and longer for those with severe symptoms.[27] Some infected individuals may spread the virus but remain asymptomatic.[28] Estimates suggest that around 40% but potentially up to 60% of infections arise from pre- or asymptomatic spread.[29]

There is no evidence that the SARS-CoV-2 virus had been encountered by humans before late 2019, and the lack of pre-existing immunity has enabled the virus to spread rapidly through human populations. The ‘basic reproduction number’ (‘R0’) for the virus (the average number of secondary infections from each typical infected individual in a population where everyone is susceptible) is estimated to be between 2.2 and 3.5.[30] Some estimates have put R0 much higher.[31] An R value above one implies exponential spread and keeping R below one has therefore become a high or paramount policy priority.

In an idealised case, during the course of an epidemic where there is no effective vaccination, the expectation is that people move between three classes in sequence by becoming infected, recovering, and acquiring protective immunity:*

(i) **Susceptible** — at risk from others
(ii) **Infected** — risk to others
(iii) **Recovered** (or vaccinated) — negligible risk to / from others

As more people acquire immunity, there are fewer individuals at risk of infection if they are exposed to the virus, the risk of exposure for susceptible individuals decreases, and the R0 number falls asymptotically towards zero. The disruption of chains of infection owing to the presence of individuals with immunity, either as a result of previous infection or vaccination, is often described as 'herd immunity'.[32] On the basis of an R0 of about 3.5, immunity would be needed in over 70% of the population to bring transmission to a halt.[33]



Source: Andrea Capitanelli, 8 March 2020, Modeling the spread of diseases, A simulation exercise with SIR models, *Towards Data Science* website (available at: https://towardsdatascience.com/modeling-the-spread-of-diseases-821fc728990f) using an R0 of 2.28.

* The simple 'SIR' model makes a number of assumptions, including that the population does not change and people who die are classed as 'recovered', as well as that a person who has recovered is immune to re-infection, which may not necessarily be the case.

Achieving herd immunity through infection was reportedly considered as a strategic option within the UK Government although it became clear that unchecked infection would rapidly overwhelm healthcare capacity, a state of affairs that would be morally and politically unacceptable.[34] Furthermore, humanity has never developed 'herd immunity' to any coronavirus; it is, therefore, likely that endemic SARS-CoV-2 will return periodically.[35] Instead, the Government adopted a policy of transmission suppression through NPIs, primarily 'lockdown' followed by 'social distancing'. The suppression of the R number using NPIs also, however, affects the likely incidence of immunity acquisition. At present, knowledge about the parameters of effective immunity and the prevalence of infection and immunity within the general population is still developing.[36] Datasets on seroprevalence are now starting to emerge from a great many affected urban populations around the world, with typically less than 10% seroprevalence.

Research questions

The British Society for Immunology and The Academy of Medical Sciences expert advisory group (established in April 2020) has proposed four research questions that would contribute 'rapid learning about immunity for public health impact', and that could be answered within 12–18 months:[37]

1. What, if any, antibody properties confer protection against the virus, and what proportion of antibody responses are protective?
2. What are the roles of immune cells from the adaptive (T-cells) and innate systems, such as Natural Killer cells and T-cells, in protective immunity?
3. What is the sero-prevalence of SARS-Cov-2 antibodies? What proportion of individuals mount either an antibody, or a cellular response or both after infection?
4. How can laboratory-based antibody tests be safely scaled to reliable commercial equivalents that are not confounded by cross-reactivity to other coronaviruses?

The expert advisory group has also proposed two further, equally important, groups of research questions relating to 'rapid impacts for COVID-19 treatment' (Group 2) and 'key long terms research investments' (Group 3).

Viral mutation

As with other aspects of the current pandemic, the virology of SARS-CoV-2 is a relatively new area of research. The virus appears to have a relatively low mutation rate (around 2.5 mutations/genome/month), similar to other coronaviruses. However, the enormous number of infections has resulted in a large number of mutations and in sequence deletions of unknown significance. Distinct viral lineages have emerged in different geographical regions and many are in circulation in the

UK, suggesting multiple trajectories of entry. However, none of the mutations or deletions detected to date has been associated with the virus evading the human immune response.[38]

3. Testing

If effective correlates of protection (CoP) for COVID-19 can be defined, individual and population levels of protection may be established by testing. This will be an iterative process as the definition of CoP will be refined through empirical study.

The principal tests in use at present are of two types: diagnostic tests (swab samples from nose and throat or sputum to detect the presence of viral RNA in a patient) and antibody tests (to detect the presence of SARS-CoV-2-specific antibodies in the circulation: 'seroprevalence').

UK Government testing policy

The UK Government has set out its testing strategy in four (subsequently five) 'pillars'[39]

- Pillar 1: NHS swab testing for those with a medical need and, where possible, the most critical key workers
- Pillar 2: Mass-swab testing for critical key workers in the NHS, social care, and other sectors
- Pillar 3: Mass-antibody testing to help to determine which people might have immunity to SARS-CoV-2
- Pillar 4: Surveillance testing to learn more about the disease and help develop new tests and treatments
- Pillar 5: Building national mass-testing capacity at a large scale

Pillar 5 has involved a substantial and rapid investment in a network of three new Lighthouse Laboratories in Milton Keynes, Alderley Park in Cheshire, and Glasgow, created through a partnership with the Department of Health and Social Care and Medicines Discovery Catapult with UK Biocentre and the University of Glasgow.

Swab tests

Direct molecular genetic tests can identify SARS-CoV-2 virus with a high degree of specificity. They require careful handling in the laboratory and are therefore best used to confirm the presence of SARS-CoV-2 infection at the time of sampling, rather than to discount SARS-CoV-2.[40,41,42,43] (They may also detect virus fragments that remain in the body after the infectious virus has been eliminated, which appears to account for misleading reports from South Korea of recovered patients being re-infected.[44]) It cannot, however, be confidently inferred from a prior positive swab test

that a recovered patient will have immunity or even antibodies to SARS-CoV-2 detectable by some antibody tests; furthermore, a negative swab test will not confirm absence of the virus with certainty.[45]

Antibody tests

Antibody tests aim to detect virus-specific antibodies in a sample of blood. As antibody production takes time to become established, antibody tests are of little use in identifying acute infection in the early stages. Furthermore, the total measurable antibody level is not only protective, virus-neutralising antibodies that bind to the viral spike to prevent it entering host cells. [46,47] False positive results can also occur with some tests owing to cross-reactivity with antibodies produced in response to infections caused by similar viruses, such as the seasonal coronaviruses that cause cold symptoms.[48,49,50]

A range of serological tests is available that, variously, involve submitting samples for laboratory assay, carrying out testing at the point of care (POCT) or that may be provided to the public either over-the-counter (via pharmacies) or direct-to-consumer (for example, via the internet). These tests have different analytical and utility profiles and require careful evaluation according to the circumstances in which and the purposes for which they will be used.[51,*] Importantly, the lab-based tests tend to supply quantitative data about the amount of antibody, whereas the lateral-flow POCT technologies offer a binary ('yes' or 'no') answer. Both test performance and knowledge of the background prevalence of antibodies are crucial to the utility of the test, particularly if the test is to be relied upon in critical decisions about risk associated with possible exposure.[52]

Other biomarkers

Alongside research to identify correlates of protection for COVID-19, research is also underway to identify biological markers for immune hyper-response and susceptibility to more serious forms of the disease.[53] Just as CoP could come to be used to identify individuals on whom movement restrictions might be eased, so markers for susceptibility may be relevant to identifying individuals requiring enhanced shielding from exposure.[†]

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[*] The UK's Medicines and Healthcare products Regulatory Agency has produced specifications, which are updated as new evidence emerges, to assist manufacturers to design and deliver POCT and self-administered tests that might be useful to support Pillar 3 of the UK Government's testing strategy (see: Medicines and Healthcare products Regulatory Agency (2020) Target Product Profile: antibody tests to help determine if people have immunity to SARS-CoV-2: Version 2 (available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/881162/Target_Product_Profile_antibody_tests_to_help_determine_if_people_have_immunity_to_SARS-CoV-2_Version_2.pdf)

[†] Trials have now begun to investigate therapeutic agents that block the activity of Interleukin-6 (see: British Society for Immunology and Academy of Medical Sciences, 1 May 2020, COVID-19 immunology research, what do we know and what are the research priorities? available at: https://www.immunology.org/news/COVID-19-immunology-review-what-we-know-and-priorities-for-research). A whole genome sequencing study, led by Genomics England in partnership with the GenOMICC consortium, Illumina and the NHS, involving up to 20,000

While current antibody tests may not identify the effective correlates of protection against COVID-19, they can, almost certainly, contribute to a meaningful individual risk profile. This might comprise a variety of biological and even behavioural markers. It need not be restricted to identifying those at low risk ('immunity') but also those at high risk (for example, tests for genetic predisposition to severe forms of COVID-19 or even tests or evidence that suggest that an individual could be a 'superspreader').[54] Furthermore, even if some people were shown to have effective immunity, there are likely to be others who are at low (but non-zero) likelihood of infection/transmission. The question arises whether these people should be included in the notional class of protected persons, or whether separate classes (and associated provisions) should be defined for different levels of risk. Defining what constitutes a tolerable risk or a meaningful risk threshold involves a mixture of technical appraisal and moral and political judgements. These include the prevalence of protective immunity in the population, the test performance, the performance of CoP, and the acceptability or desirability of alternative approaches and different outcomes.

4. Testing and public policy

Non-pharmaceutical interventions and 'responsibilisation'

Under the current 'lockdown', infection is controlled largely by NPIs based on verified or assumed infections and exposure. Nicer distinctions have been made on a mixture of pragmatic (essential workers) and clinical (severe hazard due to age or underlying medical conditions) grounds. The current restrictions on movement in the UK are roughly the following:

(i) **Isolated**: those either with clinically ascertained infections (in care settings) or self-diagnosed (in the home).[55]
(ii) **Quarantined**: those believed to have been exposed to infection (self-reported)
(iii) **Shielded**: people in positions of increased vulnerability (those with underlying health conditions[56] and all people of advanced age).
(iv) **Mitigated**: essential workers (e.g. care workers) whose interactions are mitigated by PPE.
(v) **'Socially' distanced** – people at normal risk.
    (a) **Travelling for work**: those unable to work from home are encouraged to work; access to/ use of public space permitted in connection with their duties.
    (b) **Light lockdown**: everyone else should remain at home, with essential and limited recreational use of public space permitted (more social contact was subsequently permitted during June).

NHS patients currently or previously in an intensive care unit, as well as 15,000 patients with mild or moderate symptoms, to identify biomarkers predisposing to more serious forms of COVID-19 and accelerating the search for treatments (see: Department of Health and Social Care, 13 May 2020, New partnership to sequence human genomes in fight against coronavirus, available at: https://www.gov.uk/government/news/new-partnership-to-sequence-human-genomes-in-fight-against-coronavirus).

It is clear that the principles of this classification relate not only to the likelihood of infection but also to the value of different goods of which mobility and interaction with others are conditions. Furthermore, the criteria pertain in some cases to the status of individuals and in other cases to activities that anyone might carry out.

Under the current, modified lockdown citizens are required to regulate their own behaviours according to observational criteria (symptoms and exposure). The enforcement of lockdown measures is made without regard to confirmed clinical or immunological status. Instead, it is carried out on the basis of whether an activity is acceptable (e.g. exercising, travel to work which cannot be done at home) or necessary (e.g. food shopping). This places a high level of responsibility on individuals to determine whether their own actions are compliant ('responsibilisation') but without clear guidance while, nevertheless, under the threat of enforcement.[57] Ordinary citizens are caught in a potential double bind, which requires them to impose on themselves a discipline that reflects the decisions of the governmental authority, without a clear standard to which to appeal.

Immunity certification

If individuals with effective correlates of protection for COVID-19 could be identified, this class of people would be able to move among and interact freely with others without significant direct risk to public health. The idea of 'immunity certification' is based on the 'scientific' ascertainment of protected status as providing a sound understanding of risk that could underwrite more precise and selective forms of social discipline than the vague and indiscriminate 'social distancing'.

Certification links relevant information to an identifiable individual. By hypothesis, immunity certification inscribes sensitive personal information, namely the result of a test that detects markers of immunity to the SARS-CoV-2 virus. This can be encoded in a number of ways, including on a physical certificate, an electronic token (e.g. one recorded on a smartphone app or bracelet), or a unique reference that links to a database.

A simple distinction may be made between certification that functions like a passport, allowing the individual to cross borders into controlled spaces, and certification that functions like a licence, permitting the subject to carry out controlled activities that bring them into contact with others. In the first case, a certificate might be used to permit crossing national borders or to waive quarantine measures applied to incomers. Under the 2005 International Health Regulations, states can implement entry requirements relating to medical examination, vaccination, or other prophylaxis subject to certain conditions.[58] The Yellow Fever 'Carte Jaune' is an existing example. Where certification is used in order to facilitate movement between jurisdictions there will need to be agreements about the standards of certification and interoperability of any supporting certification. Given that many such measures are less than fully effective, they could be regarded as 'immunity theatre' rather than as a

reliable measure to protect public health. Certification might also be used in a domestic context to permit people to leave their homes and move freely in public spaces during a lockdown that otherwise applies generally. The use of certification for specific activities has been proposed as a route to increasing economic activity in many industries and services. In particular, immunity certification may provide an acceptable condition to permit people go to work and therein function close to normally without the requirement to maintain a physical distance of two metres from others.

While certification may be introduced as a matter of public policy (voluntary, but required in order to exempt an individual from general restrictions and subject to enforcement by relevant authorities), it could also be required for certain private purposes (e.g. to be admitted to a venue or to take part in an event) or recognised informally.

5. Social and ethical issues with immunity certification

Potential benefits

The key political objectives of identifying people at low risk of SARS-CoV-2 infection and transmission are to enable the resumption of economically productive activity that has been halted or impeded by the lockdown, and to improve personal and social wellbeing (including restoration of incomes and preservation of jobs) for those who have been locked down. Given the assumed prevalence of recovered COVID-19 patients, the numbers benefitting are, however, likely to be low.[59,*] Nevertheless, these benefits could be multiplied since the advantages of low-risk status apply both to those at low risk and to those who live or work alongside them.

While measures such as infection testing, temperature surveillance, and risk scoring are intrusive and concern personal information, they may provide reassurance to clients, customers and co-workers, and redeploying staff according to risk may create opportunities to re-start or increase business activity. Alternatively, if reliable markers for enhanced susceptibility to severe forms of COVID-19 were to be identified, it is plausible that measures could be implemented to protect those at high risk while restrictions could be removed for others, for whom the virus presents a low risk.

Coercive contexts

* No good data for seroprevalence are available in the UK. The latest available figures (up to week 21; w/b 27 April, i.e. 8th week after lockdown, when infections just prior to lockdown, which should show antibodies in returning blood donors, have plateaued owing to lockdown) show the highest seroprevalence in London (15.6%) with other areas probably below 10%.However, this is based on low samples (1000 representative/region of NHSBT blood donors) and limited performance tests (Euroimmun test of sensitivity/specificity of 79%/99%). Other regions were lower but figures earlier. See: PHE Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report, Week 23 (available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889981/Weekly_COVID19_Epidemiological_Summary_w23.pdf)

Testing for research

Major research projects with access to laboratory facilities are underway to identify the prevalence of past infection in the UK ('Pillar 4').* On 21 May the UK Government announced that, starting from the week beginning 24 May, all NHS and care staff in England would be offered an antibody test, with patients and care residents eligible at their clinician's request, as part of generalised surveillance to understand the virus.[60] Although the guidance is careful to advise that a positive antibody test result does not imply immunity or that individuals testing positive can set aside social distancing measures, the implications of the test result may not be confined to the research context.[61] In the context of testing programmes and the discourse on 'duty' associated with responding to COVID-19, taking or not taking a test (or not revealing whether one has taken a test) may lead to social stigmatisation.

Testing in employment

The context in which a test is provided may have significant implications for the interests of the people being tested. People may feel pressurised to take a test if it is offered in the context of employment, especially where this may alter the range of options available to them (in terms of duties or opportunities). New guidance has been produced by the Information Commissioner's Office (ICO) on workplace testing on returning to work in the context of epidemic COVID-19, which highlights the application of data protection principles and the obligation to protect the health of the workforce.[62] However, the existence of antibody testing is capable of having a significant impact on individual autonomy, as expectations are raised that employees submit to anything from temperature tests to blood tests.[63†]

Although testing would in principle be voluntary, if it becomes widespread, both taking a test and disclosing the result may become, in practice, all but coercive. With widespread availability of testing it is possible that it will become an expectation that people 'voluntarily' reveal test results or, if they do not, that there is a reason for concealment. Furthermore, there will be strong individual incentives to take tests if they become a condition of access to certain goods. Test results may also have implications for the allocation of resources in work contexts: there may be incentives for employers to refer to test results rather than providing alternative pathways to safe working, for example, effective personal protective equipment.

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* Two studies measuring prevalence of antibodies were initiated as well as a swab test study to identify current infections (see: Department of Health and Social Care (press release), 23 April 2020, Government begins large-scale virus infection and antibody test study, available at: https://www.gov.uk/government/news/government-begins-large-scale-virus-infection-and-antibody-test-study and Department of Health and Social Care (press release), 17 May 2020, Government begins large scale study of coronavirus immunity, available at: https://www.gov.uk/government/news/government-begins-large-scale-study-of-coronavirus-immunity?utm_source=28200532-9b29-48b0-9945-870387796b61&utm_medium=email&utm_campaign=govuk-notifications&utm_content=daily)

† The use of thermal camera surveillance is covered by the Surveillance Camera Commissioner (SCC) and the Information Commissioner's Office (ICO) guidance (see: https://www.gov.uk/government/news/updated-data-protection-impact-assessment-template-and-guidance-launched)

Direct-to-consumer testing

Direct-to-consumer tests might be used by individuals to make decisions that could confound or compromise public health measures. Someone might, for example, take a private antibody test to inform behaviour based on their personal risk of infection rather than risk of spreading disease. Individuals may be prepared to accept lower test performance characteristics than those judged appropriate to protect public health. The performance characteristics of home tests are likely to be lower than laboratory tests and the context of test provision may also affect test safety and performance (for example, where tests are provided direct-to-consumer or over-the-counter at pharmacies), as well as interpretation and reporting of results. Tests provided directly to the public may have adverse consequences for some people (for example, because there is no further medical or social support). Access to testing, and to any consequential benefits of testing, may also compound existing inequalities (for example, if provided on a paid-for basis or ordered online) or contribute to stigmatisation (if subsidised for or targeted at certain groups). Any charge for testing is likely to raise barriers to access for those who are most in need of the associated benefits (for example, those on low or precarious incomes, for whom access to paid work may be essential for food and shelter).[64]

Refusal of testing

Through the Coronavirus Act 2020 the State has the power to place in quarantine people who are suspected of having an infection but who refuse to self-isolate and to require them to be tested.[65] It would be a short step to amend this to create a power to enforce lengthier quarantine on a person who refuses to undergo testing.

Adverse and unintended consequences

Social disruption

It is conceivable that some businesses, such as those in the hospitality sector, may preferentially start to employ a seropositive workforce. This could lead to major social upheaval (as seronegative employees potentially lose opportunities to seropositive applicants).[*] Economic incentives invite 'immunocapitalism', which puts a premium on immunity status, for example, making it worth an employer taking on an 'immune' worker in the belief that they are less likely to fall sick or to infect co-workers or customers.[66] It is reported that, in the US, life and health insurance companies are already writing COVID-19 'immunity' into policies, increasing the incentives to take tests.

[*] This does not imply that the prior situation was intrinsically just, only that reconfiguring opportunities in accordance with COVID-19 infection is likely to be highly disruptive.

Social justice

The current COVID-19 pandemic and the national response has had a significant impact on economic and social life, but that impact has not been evenly distributed across populations. In particular, the lockdown has had a disproportionately adverse effect 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 keyworkers who continue to work.[67] Concerns have already been expressed (for example, in Singapore) that test results that correlate with protection against COVID-19 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.

The pandemic has also had a disproportionate adverse effect, including in terms of mortality, on those from Black, Asian, and minority ethnic (BAME) backgrounds. The reasons for this have not been fully researched, but it is beyond question that the underlying structural disadvantages contribute significantly to this disparity.[68] People from BAME backgrounds are more likely to experience the social determinants of health that contribute to higher risk of infection and poorer outcomes, such as unemployment or employment in low-paid occupations that more often involve close contact with the public, and living in overcrowded accommodation. Census-based data from the Office for National Statistics in England, adjusted for contingent factors, shows that the odds of people from Bangladeshi/Pakistani and Black ethnic backgrounds dying from COVID-19 are between three and five times those for white people.[69]

People from BAME backgrounds are also overrepresented among workers providing front line care. It is likely that a component of the enhanced disease risk for BAME individuals resides in socioeconomic factors such as urban housing, use of public transport, and occupations offering exposure to higher viral loads. If high viral load is the key driver of high antibody levels, a certification policy runs the risk of inadvertently stratifying a subset of highly exposed, antibody-positive, BAME individuals, perceived as safe to do the high-risk jobs. A selective approach to modifying lockdown restrictions undoubtedly has the capacity to compound or exacerbate these effects.

Perverse incentives

Implementing a policy that applies different requirements or grants different freedoms to citizens creates perverse incentives that may lead to unintended or adverse consequences, some of which have been recognised by government advisors. [70] These may include incentives to avoid testing, or to dissemble, misreport or fake test results. More troublingly, perhaps, it may incentivise people to put their own health at risk. For example, people who are unemployed, or were dismissed or furloughed as a result of the pandemic may deliberately expose themselves to

infection in order, later, to obtain positive result. In the process they may potentially contribute to the health crisis by transmitting the virus to others and requiring medical care. Particularly in the absence of universal access to healthcare, those most incentivised to seek infection might also be those least able or willing to seek healthcare. Such incentives are likely to apply disproportionately to those with precarious incomes and working in low paying jobs in the service or industrial sector.

Infrastructural and technological implications

The use of test results for purposes other than individual diagnosis and epidemiological research requires a reliable means of verification that can be produced and inspected as required. In order to prevent fraud this must do two things: it must authenticate the test result and to link the result to the person who was tested. Three forms of certification have been considered in relation to COVID-19: 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.[*]

The commitment to a particular kind of technological solution, creates the potential for path dependencies and function creep. If immunity certification provides its users with access to individual benefits (like opportunities to work and social freedom) it is likely to be more enthusiastically embraced by a section of the population (i.e. those who believe themselves to be immune and have something to gain from installing it), although this is likely to be a small section initially. Once established, such a technology might be updated, in due course, to provide vaccination certification, or a more complex risk profile, or even become repurposed (for example, as a general biometric identification system, or international health card).[†] The introduction of a government-sanctioned app may also create irreversibilities (so the technology will

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[*] The wristbands could be adapted from those introduced for COVID-19 surveillance, for example in Bulgaria (https://www.bbc.co.uk/news/technology-52409893) and Lichtenstein. An Ada Lovelace Institute rapid evidence review identified the potential for data to be held in a number of centralised locations: "digitally recorded in an NHS personal health record, digitally recorded in other health information systems (like the Child Health Information System), digitally recorded in other government information systems (for example passport or welfare systems), digitally recorded in a new central database (for example the new NHS Coronavirus data store)" or decentralised locations: "physically recorded on new physical documentation (like yellow fever), physically appended to existing state provided physical documentation (for example passports), a digital token on a smartphone, a digital attribute as part of a (new) digital identity system." Ada Lovelace Institute, *Exit through the App Store?* 20 April 2020 (available at: https://www.adalovelaceinstitute.org/our-work/COVID-19/COVID-19-exit-through-the-app-store/) A 'white paper' from the Edmond J Safra Center for Ethics at Harvard University states that "efforts to create centralized credentialing programs should be actively opposed by civil society" in the interests of privacy; see: Gruener, Dakota (2020) *Immunity Certificates: If We Must Have Them, We Must Do It Right*, 20 April 2020 (available at: https://ethics.harvard.edu/files/center-for-ethics/files/safracent()erforethicswhitepaper8.pdf) For suggested principles and specifications for 'privacy protecting' QR-based apps, see Hicks, Chris, David Butler, Carsten Maple and Jon Crowcroft (2020) SecureABC: Secure AntiBody Certificates for COVID-19, *arXiv*:2005.11833 [cs.CR], 24 May 2020 (available at: https://arxiv.org/pdf/2005.11833v1.pdf)

[†] The proposal from technology firm Pangea, to link a biometric identity card with a medical database containing relevant test results, envisages the 'next step' as being "to turn the 'passport' into a full digital medical profile of the cardholder, which will be available for medical providers around the world to access..."; see: Israeli tech firm develops digital coronavirus 'passport', *The Jerusalem Post,* 17 June 2020 (available at: https://www.jpost.com/israel-news/israeli-tech-firm-develops-digital-coronavirus-passport-631761)

persist regardless of the persistence of the COVID-19 emergency) and potentially lock in a proprietary technology (foreclosing alternative technological pathways).

Expansion of surveillance

While, given the commercial incentives, COVID-19 risk certification could become privately available in the absence of any legislative prohibition, there is a clear public health interest in the collection of risk-relevant data by public authorities. This would support both a more informed public health response and create the potential for public epidemiological research, for example, through UK Biobank.[71] The COVID-19 emergency creates the conditions for both the rapid collection of population data and the rapid entrenchment of research infrastructures. Expanding testing of populations will potentially mean that personal information about substantial new cohorts of people is collected and potentially retained on research databases or public databases. Indeed, the creation of an infrastructure capable of securing, expanding, and pooling health data has long been the vision of the UK life sciences sector and of the UK Government. The infrastructure used in the current crisis may define a pathway for the substantial expansion of population data and acceleration of research along certain trajectories. Concerns have been expressed, including by government officials, about the collation of this information, access to the information by private companies, and its retention beyond the term of the pandemic.[72]

6. Context of ethical public policy

Immunity certification has been proposed as a way to modify lockdown restrictions for some members of a population without increasing the level of risk in the population in general. For this to be feasible, at least four things are required:

- an understanding of the correlates of protection,
- a reliable means of detecting these in individuals,
- a secure means of authenticating test results, and
- the acceptability (or acceptance) of a policy of differential restrictions based on these results.

Each of these requirements raises complex questions that are, at least partly, questions of ethics.

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.

The use of test results to access goods, so long as it does not disadvantage others is likely to be unobjectionable to those who place a high value on individual

freedoms. A principle of the ‘least restrictive alternative’ has been advanced in support of the use of immunity certification if it becomes technically feasible.[73] The argument is that, where public health is the priority, the burden should be on justifying a more restrictive policy (general lockdown) where a less restrictive one (based on immunity testing) is available.[74] Some have even argued that, because infection and, therefore, immunity are concentrated in disadvantaged socioeconomic groups, immunity testing could have a progressive effect.[75] However, if this were introduced in a ‘market society’, it is more likely to compound structural inequalities.[76] History offers many stark warnings about the rapidity with which differences in biological advantage may be colonised by capital.[77]

Unease with the implications of unbridled ‘immunocapitalism’ would suggest that, at the very least, some form of regulation should be required to control the externalities that are generated by the potential pursuit of perverse incentives (e.g. infection of others and impact on health systems). [78] While, as with existing forms of discrimination, it is conceivable that the use of risk profiling could be met with protective regulation, instituting a system that requires such redress is unlikely to have any impact on structural inequalities. [79] Given that there is public interest in expanded testing and that individuals will have access to the results of immunology tests (whether from publicly commissioned research or private tests), it is likely that the results will be invested with significance in private contexts. The likelihood of a surge of individuals self-declaring on the basis of a variety of non-standardised tests has led some to argue that the whole system should be taken over by the state.[80]

While specific questions about risk-based interventions may be posed in terms of balancing the individual interests against public good, when these are viewed as part of a whole system response, the COVID-19 crisis can be seen as leading to more critical questions about how health is valued as a public good alongside other goods such as economic and social wellbeing. This invites a more radical reflection, not only the comparative value of different goods – a ‘wicked’ enough problem of public policy – but on the ways in which different citizens value goods and what constitutes their fair distribution – a question of fundamental politics. Accordingly, the language of ‘social contract’ has entered into the discussion of emergence from the pandemic, as an encouragement to democratic engagement about the conditions through which different goods and freedoms are pursued, secured, and distributed in society.[81] As the COVID-19 emergency has brought the current arrangements into crisis, the way forward presents both opportunities and dangers.

7. Conclusions and implications

The Nuffield Council on Bioethics has conducted a number of inquiries and published reports that are relevant to the questions addressed in this note. The following advice is drawn, in part, from a reflection on this previous work, supplemented by discussions at an online meeting of experts convened under the auspices of the Council on 24 April.

(1) The immunology of COVID-19 is unknown, but knowledge is developing all the time as evidence accumulates around the world. Simple antibody tests are not a marker of immunity and thus, until far more is known, should be regarded as having poor predictive value for future risk. Research proposed by the British Society for Immunology and Academy of Medical Sciences expert advisory group to define correlates of protection against SARS-COV-2 virus should be supported as a national priority (see box on p. 7 above).

Research should be guided by the values and principles of fairness, equal respect, and helping reduce suffering as set out in research in our report *Research in Global Health Emergencies*.[82] Recognising that COVID-19 is a global pandemic, fair and equitable research collaborations should be promoted between research organisations, particularly between external research institutions and their local partners in high- and low-income settings, including equitable and responsible sharing of data and samples.[83]

(2) In the present state of knowledge there is far too much scientific uncertainty and too many unresolved ethical concerns to support the use of immunity certification as a safe way of managing the selective qualification of current restrictions on public movement and assembly.

The prevalence of protective immunity in the general population is likely to be low, and the benefits too marginal, to justify modification of general restrictions on public movement on this basis. However, what is in view is, in effect, not immunity testing as such (since the immunity factors are not known), but individual risk profiling, which may have a number of determinants and a number of potential uses.[84] It is possible that private individuals, businesses, and organisations will seek to make use of tests (e.g. antibody tests) to inform their behaviour and decisions, within the law and in conformity to the guidance from the Government and the Information Commissioner's Office. As we recommended in our report on *Data in biological research and healthcare*, research is required into the potential harms associated with abuse of biological and health data, as well as the benefits of responsible data use.[85] At the very least, this should be kept under review, so that provision can be made to avert potential social harms before they occur.

(3) Among the issues that require careful consideration are the potential of policies to support or encourage the expectation that individuals should submit to biomedical testing to gain access to benefits and that they will disclose the results of those tests to others (including in the context of employment).

Testing for immunological markers for SARS-CoV-2 is valuable for research in the public interest. However, testing of individuals may have implications beyond COVID-19, including for broader risk profiling. It is important that there should be transparency about who may have access to data. In particular, as we recommend in

our report on *Data in biological research and healthcare*, a clear public statement should be given of the expectations about who may be given access to test results and for what purposes; those processing test results should publish data sharing agreements; and individual results should only be disclosed to researchers (including international collaborators) who are subject to institutional oversight and effective sanction.[86] However, having the choice not to take a test or disclose the results is not meaningful if the cost of exercising it is prohibitive. Accordingly, public participation should be involved in defining the set of reasonable expectations about the use of test results.[87] This should take into account the likelihood that some may be significantly disadvantaged in accessing public goods and services as a result of exercising a personal choice about testing and the extent to which these personal costs should be shared.[88]

(4) There are substantial concerns about the differential impact of a selective modification of restrictions based on risk profiling (as there are about the impact of restrictions themselves).

Risk profiling may contribute to the view that those at low risk should not be expected to bear costs (e.g. in terms of restrictions on their activities) that those at higher risk must accept. The possibility of differentiation could enable some individuals to benefit from their lower risk status. This is more likely to occur at the expense of others under conditions in which market mechanisms are involved in the distribution goods. Particular attention should be given to the potential of interventions to compound existing structural disadvantage, and increase marginalisation or stigmatisation of particular communities. In assessing potential impacts, attention should be given to the voices of people in positions of potential disadvantage that may be obscured by the views of those more numerous, more obvious, or more powerful. As we have concluded in other contexts, in the formation of policy, special efforts are needed to engage in open and inclusive consultation with those whose vulnerability to adverse impacts might be increased by the interventions in view.[89]

(5) Ethical debate should not await the emergence of clearer scientific understanding and testing capability but aim to anticipate and influence the definition of research programmes, policy formation, and technological innovation.

Incentives may exist to introduce COVID-19 risk profiling and certification technologies regardless of the soundness of immunological knowledge or the performance of the testing procedures used. Research and innovation pathways are formed on the basis of judgements that are not simply scientific or technical but involve the complex interweaving of fact and value.[90] As we recommend in our report on *Emerging Biotechnologies*, ethical reflection should be anticipatory rather than reactive so that this can play into the shaping of options rather than simply

inform decisions between options that have already been determined on the basis of unexamined assumptions or vested interests.[91]

(6) Anticipatory consideration should be given to the potential for innovation in emergency circumstances to lock-in certification technologies, research infrastructures, and relationships.

A variety of antibody testing, data processing, and immunity certification 'solutions' have been proposed in the context of the COVID-19 epidemic. The selection of technological systems can have social consequences, creating momentum for particular strategies, privileging and embedding certain value hierarchies, and creating potential for function creep (for example, from immunity certification to biometric identification systems). Particularly where the circumstances make difficult full and inclusive assessments of impacts on business, privacy, and equality, precautionary measures should be exercised to mitigate the potential for locking in particular technological pathways, to accept as the default a technological rather than social solution to problems with substantial social dimensions (as we recommended in our report *Emerging Biotechnologies*).[92] In particular, as we recommend in our report on *Data in biological research and healthcare*, opportunities should be set aside for further public consideration of the appropriateness of relationships between the public and private actors to secure public benefit and before existing infrastructures become the default model for the future expansion of testing.[93]

(7) The consequences of interventions, such as immunity certification, depend substantially on the conditions of the system in which they are implemented. The COVID-19 crisis will have had a potentially disruptive effect on those conditions, not merely on public health.

The way in which the United Kingdom emerges from the current emergency will implicitly both reflect and consolidate relative values placed on a variety of public goods (including public health, social wellbeing, environmental protection, national security, and economic prosperity, all of which have been affected by the COVID-19 crisis). At present, in the countries of the UK, emergency measures are in effect to manage the COVID-19 crisis. The removal of those measures is likely to reveal the disruptive effect of COVID-19 not merely on health, but on all aspects of common life. This is likely to be a time of significant national insecurity. In this context, it will be more important than ever to foster an effective and inclusive sphere of public debate connected to political discourse.[94]

Appendix 1

Current national proposals to implement forms of immunity certification

The UK has not disclosed any concrete plans to implement immunity certification but the issue has been ventilated extensively in the media and grey literature.[95] The fact that the idea is being considered was apparently confirmed by the Secretary of State for Health and Social Care.[96] Immunity certification has been placed explicitly within the remit of Baroness Harding, chair of the UK Government's coronavirus 'test and trace' programme.[97]

Plans have also been raised, discussed, and proposed in other states, regions, and localities (such as major cities).

Diagnostic swab testing, temperature monitoring, and health/exposure questionnaires have been implemented in a number of places on entry. For example, Caribbean nations (Bahamas and Haiti) are reported to have implemented swab testing of returning nationals as an alternative to quarantine.[98] Greece is considering health testing requirements for visitors in what is expected to be a truncated tourist season.[99]

In more than 200 cities in China, since February, citizens have been able to apply to be assigned a QR code based on information they provide about their travel history and exposure risk during the previous 14 days or an antibody test. The code changes colour, using a traffic light system, and must be shown to gain access to restaurants and shopping centres.[100]

Many more countries have programmes of antibody testing which could be associated with immunity certification depending whether the scientific and policy questions can be resolved. These include Andorra (which purchased antibody tests for its entire population of ~77,000 citizens), Luxembourg, Switzerland, and some regions in Italy.[101, 102]

Systems of immunity certification are under serious consideration as an option for making exceptions to lockdown restrictions in other countries. Germany, which was an early adopter of the Roche antibody test (ordering 3 million tests in May and 5 million monthly thereafter), is considering the option but has sought advice from the German Ethics Council on the compatibility of the scheme with human rights before proceeding.[103] The possibility has also been raised in Russia, where the Healthcare Minister suggested it would not be a challenging task and could be accomplished relatively quickly. [104] Proposals have also been submitted to the French Prime Minister by the Mayor of Paris to alleviate the lockdown restrictions in the French capital that include possible immunity certification.[105]

Concrete proposals to implement immunity certification based on antibody tests were made in Chile, which was had one of the earliest and most extensive testing programmes in Latin America. Plans for issuing physical cards and digital certificates

were announced in April for recovered patients and possibly also those with positive antibody test results (despite advice of Chilean Immunological Society and the World Health Organization).[106] The scheme was postponed on 11 May, however, owing to concerns about discrimination in employment.[107,108] ‘Discharge certificates’ are now being issued to those who have completed treatment.

Estonia, which has relatively low number of COVID-19 cases, has actively initiated a digital immunity certification trial using a smartphone app that allows citizens to share validated ‘immunity’ status with a third party, such as their employer, using a QR-code.[109]

Appendix 2

The Nuffield Council on Bioethics*	**Participants, 24 April expert meeting**
Professor David Archard – Chair	Professor Bobbie Farsides – Chair (Brighton & Sussex Medical School)
Professor Shaun Pattinson – Deputy Chair	Prof.Dr Steffen Augsberg (University of Giessen)
Professor Carol Brayne	Victoria Butler-Cole QC (39 Essex Chambers)
Simon Burall	Professor John Coggon (University of Bristol)
Victoria Butler-Cole QC	Professor Cam Donaldson (Glasgow Caledonian University)
Melanie Challenger	Dr Jennie Evans (British Society for Immunology)
Dr Clare Chambers	Dr Agamoni Ganguli-Mitra (University of Edinburgh)
Dr Tara Clancy	Dr Carolina Haefliger (AstraZeneca)
Professor John Coggon	Professor Jonathan Heeney (University of Cambridge)
Professor John Dupré	Dr Stephen John (University of Cambridge)
Professor Frances Flinter	Professor Jeffrey Kahn (Johns Hopkins University)
Dr Elaine Gadd	Professor Anne Kerr (University of Glasgow)
Professor Anne Kerr	Dr Pete Mills (Nuffield Council on Bioethics)
Professor Michael J Reiss	Dr Alison Powell (LSE and Ada Lovelace Institute)
Dr Mehrunisha Suleman	Professor Barbara Prainsack (University of Vienna and KCL)
Dr Susan Tansey	Dr Julian Sheather (BMA and Médecins Sans Frontières)
Professor Christine Watson	Professor Effy Vayena (University of Zurich)
	Professor Jantina de Vries (University of Cape Town)

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Disclaimer: This discussion paper has benefited from the advice of a number of reviewers, including participants in the April 24 meeting and members of the British Society of Immunology COVID-19 and immunology taskforce. Inevitably, it has not been possible to include or reconcile all of the advice received. The discussion paper does not necessarily reflect the views of any of those consulted nor those of the Nuffield Council on Bioethics.

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Note. Due to the rapidly evolving nature of the COVID-19 emergency, exact dates of publication are given for references from 2020 wherever possible, although the content may be out of date by the time of the present publication. Where resources are continually, regularly or periodically updated this is also indicated. Links to open access online sources are given where possible. All links were accessed on 5 June.

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