COVID-Status Certification Review - Call for evidence

Response from the NHS Reset Ethics Research Team

The NHS Reset Ethics research is funded by the UKRI AHRC rapid Covid call .

The project is being conducted by a multi-disciplinary team led by Dr Lucy Frith, University of Liverpool with Dr Anna Chiumento, Dr Caroline Redhead and Dr Carol Gray (University of Liverpool), Professor Heather Draper and Dr Paul Baines (University of Warwick), and Professor Sara Fovargue (Lancaster University).

Introduction

1. This response to the call for evidence to inform the Government's review into COVID-status certification, has been prepared by the members of the multi-disciplinary team running a UK Research and Innovation Arts and Humanities Research Council (UKRI AHRC) funded study looking at decision-making and the ethical challenges of restarting of NHS services in maternity and paediatrics since April 2020. The team members, from the Universities of Liverpool, Warwick and Lancaster, have expertise in bioethics, law and clinical medicine.

   Our project is entitled *'When pandemic and everyday ethics collide: supporting ethical decision-making in maternity care and paediatrics during the Covid-19 pandemic – NHS Reset Ethics Project'*, and is led from the University of Liverpool by Dr Lucy Frith (PI).

   The coronavirus (COVID-19) pandemic is causing far-reaching consequences for health systems worldwide. In England, the response to the sudden demand for critical care services was to reorient clinical capacity. Many non-urgent services were suspended, and staff and resources were redeployed to acute care. In April 2020, the UK Government declared that non COVID-19 clinical services **must** resume but that capacity to manage subsequent waves of COVID-19 should be maintained. This created a unique 'reset' context in which it became critical to consider how ethical considerations did and should underpin decisions about how to reset health services while new infection control measures were also managed.

2. COVID-status certification refers to the use of testing or vaccination data to confirm **in different settings** that individuals have a lower risk of becoming ill with or transmitting COVID-19 to others. Such certification would be **available both to vaccinated people and to unvaccinated people who have very recently tested negative for SARS-CoV-2**.

   Our response offers a perspective on clinical, legal and ethical issues. We have collected qualitative data by interviewing senior managers and healthcare professionals in four NHS Trusts spread geographically across England and our response is underpinned by this data. These interviews have explored the experiences of senior managers and healthcare professionals in making decisions about how best to restore, recover and reset the services that were suspended or reconfigured in the first wave of the COVID-19 pandemic, whilst continuing to offer care for patients with COVID-19. Our data is drawn from the **hospital setting**.

   Our responses relate to **SARS-CoV-2 testing as a requirement for entry into a hospital**. We have not addressed vaccination certification, as this is not a focus of our research.

3. Our brief, context-specific evidence is offered subject to the need to recognise the importance of **public consultation**, which is a key requirement of any scheme that will impact on the rights and responsibilities of individual members of society. This sould include all COVID-19 public health measures. Ethical analysis of, and debate over, proposals is also needed, alongside public consulation. Transparent decision-making and clear, inclusive communication are fundamental to underpin trust and confidence in the fairness of any COVID-19 status certification scheme.

Responses

Question 1

Which of the following best describes the capacity in which you are responding to this call for evidence? I am a:
a) Business that owns or operates a venue that may make use of a potential certification scheme
b) Business with an interest in supporting a potential certification scheme
c) Other type of business
d) Business representative organisation or trade body
e) Representative of central or local government
f) Charity or social enterprise
g) Individual
h) Academic or researcher
i) Legal representative
j) Trade union or staff association
k) Other (please specify)

Answer (h): Academic or researcher. We are a multi-disciplinary team of UKRI AHRC funded researchers, engaged in the Reset Ethics research briefly described above.

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

(a) Clinical/medical considerations (f) ethical considerations

Note: Our responses are listed in no particular order of priority.

1. ***It is imperative, both for healthcare professionals and for people who need medical attention, that any certification scheme does not operate as a barrier to healthcare services.*** Healthcare professionals must not be put in a position where the rules require that care and/or treatment be withheld where an individual presenting to a healthcare service is unable to provide evidence of having been vaccinated or to have tested negative for the coronavirus. Denying care in these circumstances would force them to violate their professional ethical codes, which require them to make their patient their first concern.

It is equally important that any certification scheme is not ***perceived*** as a barrier to services. It is clear that the 'stay at home' guidance during the pandemic has resulted in fewer attendances at hospital, and healthcare professionals have safeguarding concerns as a result. Informal assessment takes place whenever a healthcare professional observes a child and their parent or carer, or when someone attends for an ante-natal appointment. If the requirements of a certification scheme were perceived to introduce barriers to care (maybe where someone is concerned that they might 'fail' a SARS-CoV-2 test), safeguarding opportunities might be missed.

2. ***Enforcing compliance with any certification scheme must not be made the responsibility of healthcare professionals.*** It is clear from the reflections of the healthcare professionals who have participated in our research, that they experience damaging conflicts of interest where they are expected to enforce existing infection control measures. Maternity and paediatrics are among the services where healthcare professionals, patients and families generally support each other in the provision of care and treatment. The restrictions on visiting in paediatrics, and the strict rules around partners being present for ante-natal screenings and childbirth in maternity services, have been harmful both for those families who have engaged with these services during the COVID-19 pandemic, and for the clinicians involved in their care. Clinicians understand why the restrictions are necessary but find the, often combative, daily 'policing' of compliance very difficult and incompatible with their therapeutic role. Any rules-based certification scheme to be introduced in a healthcare context must be designed around an enforcement/compliance process that **does not** involve healthcare professionals.

3. ***Introducing public health-style infection control measures into the individual healthcare context has the potential to cause significant disruption to established norms of clinical ethics.*** We offer a brief example in the context of a potential requirement to undergo SARS-CoV-2 testing and have a negative result as a precondition to visiting/accompanying a patient in/into a healthcare setting.

   SARS-CoV-2 tests may not currently be perceived as distinctly medical tests. This may be because they are frequently self-administered (even by school children) and because we are often encouraged to self-test *for the benefit of others*. But we might ask whether the perceived status of the test changes when i) it is performed by a healthcare professional and ii) for a diagnostic reason. If, as would (presumably) be the underlying rationale in the context of a mandatory COVID-19 status certification, the test would be performed by a healthcare professional but *for the benefit of others* and not as part of the treatment/care for an individual patient, what is required in terms of consent from the person undergoing the test? Is the usual test of informed consent appropriate? Or does that norm cease to be appropriate if a test is being performed by a healthcare professional (because, e.g., lateral flow tests are perceived to be more accurate when carried out by a trained professional) and some good (in this scenario, the ability to visit a patient or accompany a partner for the birth of a child) will be withheld if the person does not consent to testing?

   This is just one example of a combination of the clinical, legal and ethical considerations that would be engaged by the introduction of a compulsory COVID-status certification scheme that would sit uncomfortably with existing clinical ethics norms. The design of any such scheme must thus attend to the potential impact on existing ethical norms in the clinical context.

4. The potential harms and benefits of COVID-19 certification

We also briefly touch on the issues of normalising, expanding and then stopping any requirement to certify COVID-19 status.

Clearly it is possible, on the positive side, that a certification scheme would have the potential to reduce hospital acquired Covid-19 infection rates. We note, however, that insufficient data is currently available to underpin a firm conclusion that people who have been vaccinated do not act as vectors for its onward transmission. Neither is it certain that people who are infected with the coronavirus but are asymptomatic have sufficient viral load to produce a positive lateral flow test result.

A certification scheme requiring regular testing (and we note that at the time of writing lateral flow tests are becoming a feature of many people's daily life) will normalise health status surveillance by creating a long-term infrastructure in response to the COVID-19 crisis. In the hospital context, it would normalise a process of testing visitors to hospitals for a range (conceivably an expanding range) of potentially dangerous and readily transmissible pathogens. COVID-19 screening is likely to be a starting point for a more widespread change. Normalising and expanding such testing might lead to a decision, in due course, not to re-open hospitals to visitors or those accompanying patients to provide comfort/support, save for clearly defined exceptions. This would have some advantages: it would make hospitals safer places that are easier to police, cleaner spaces, and more focused on patient care than crowd control. It might be argued, for example with respect to people who are only in hospital for a short stay, that hospital visiting makes very little difference now that patients are permitted to use mobile devices. This argument, however, takes no account of the likelihood that many patients will not have access to personal mobile devices, and that the comfort of 'virtual care and support' by a friend or family member would, therefore, not necessarily be available to all patients equally.

A compromise based on obvious exceptions might seem sensible, so that dying patients and patients likely to receive bad news would be permitted (appropriately certified) visitors. (Or maybe non-certification might be an exception in appropriate circumstances?) These exceptions would need to be explicit and potentially rigid, for reasons of apparent fairness. But our research has found that huge damage has been caused in individual circumstances that were not anticipated by the rules. Where staff have tried to mitigate damage in such circumstances, (e.g allow extra visitors because of an imminent death) this has not been understood by observers, (e.g., other parents on the same children's ward), in part because medical confidentiality meant that the circumstances could not be explained.

It would appear logical that paediatrics and maternity services would fall within an obvious exception. The family is generally considered part of the team and restricting their access not only introduces the possibility of distress for patients and family members, but also increases the burden on staff. The role of parents in providing/supplementing care is not insignificant. However, would all visitors be permitted, or would limitations be introduced? Would there be limitations on numbers, or on length of stay? Would only certain designated (and certified) visitors be permitted?

If certification is introduced with the intention that it is a temporary measure, what might be the cut-off point? And presumably any further surges (of COVID-19 and/or other viruses?) would mean the certification requirement could be re-activated?

5. **Proper consideration of the ethical aspects of a potential certification scheme requires more than a call for evidence and an associated public consultation**. Ethical analysis requires clarity about the meaning of relevant concepts, and their implications in the context in question. Any justification for a COVID-19 status certification scheme (or schemes) necessarily has ethical values at its core. Such justification, and the subsequent operationalisation of the scheme, will need to be consciously designed around, and reflect these values. Consideration also needs to be given to the implications in the many settings in which the certification scheme might be used to control or restrict public access. This call for evidence can only be seen as the first step in the process.

Question 3

Are there any other comments you would like to make to inform the COVID-status certification review?

In this section, we offer two general comments that are not limited to our research findings but based on our academic expertise in bioethics and medical law.

A. Clearly any set of rules will have to apply to a very diverse range of settings. We have illustrated our responses with examples from paediatric and maternity services. However, these are but two of an incredibly diverse range of healthcare specialties. Outside of the healthcare context, the potential benefits and harms of a COVID-status certification scheme will be different again. We re-iterate the need for considered and contextual application, both in healthcare and more widely, based on clearly articulated ethical values and principles.

B. We note that, during the pandemic, many countries have lifted restrictions on healthcare access for e.g. asylum seekers or non-citizens for whom there are usually costs of access. The reason for this was obvious: we need everyone to come forward for SARS-CoV-2 testing and/or COVID-19 care and treatment. This further underscores the importance of ensuring that any certification scheme does not operate as, or be perceived to be, a barrier to healthcare services, or compound existing health inequalities.

Concluding comment

Our response is, of necessity, brief, reflecting the tight timetable for submission and our ongoing research activity. We would be pleased, if it were to be of assistance, to report on subsequent findings, or to expand our response as our project progresses.

NHS Reset Ethics research team
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