STAT

Covid-19 'immunity certificates': practical and ethical conundrums

By Henry T. Greely

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A health worker in a protective mask and suit as extracts blood from a patient to perform an antibody test for Covid-19 at the Dworska Hospital in Krakow, Poland. *Omar Marques/Getty Images*

The media's understandable focus is now on the number of people hospitalized with and dying from Covid-19. Yet most Americans who develop this disease will recover from it on their own after experiencing flu-like symptoms. Some experts see them as a resource for restarting the economy and want to make their status official with the papers to prove it.

We need to think them through first.

German researchers have proposed testing 100,000 people for antibodies to SARS-CoV-2, the virus that causes Covid-19, and giving "immunity certificates" to those who have these antibodies, which presumably make them resistant to reinfection. The United Kingdom has floated the idea of "Covid passports," <u>Italy is discussing the idea</u>, and it is being <u>raised in the U.S.</u> as well.

Immunity certificates offer the enticing promise that an increasing number of people can stop sheltering in place and instead help the world revive. They could play an important role in the period before we have excellent treatments or an effective vaccine. But they raise issues about the science of Covid-19 immunity, about how such certificates would be provided and policed and, most important, about a country split between the free and the confined.

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Let's look at the science first. No one knows whether infection with SARS-CoV-2 confers immunity to reinfection and, if it does, how strong that immunity is and for how long it lasts. Not only is that information missing, but we cannot get it soon — it will be nine months before we can know if antibodies last a year.

People who survived severe acute respiratory syndrome (SARS) in 2003, which was caused by a closely related coronavirus, had antibodies to it for at least several years. Yet whether those antibodies would prevent re-infection is unknown — SARS disappeared by the summer of 2004. Some other coronaviruses, several of which account for a large fraction of common colds, produce antibodies and immunity for only a few months. One questioned study found that some patients who recovered from Covid-19 had few or no antibodies. And a few scattered and poorly documented reports claim that some individuals who recovered from Covid-19 have become re-infected with the coronavirus.

The current best guess is that SARS-CoV-2 infection provides some immunity, probably between the few months of some cold-causing coronaviruses and the several years for SARS. Assuming that's true, how should we determine whether someone has immunity to Covid-19?

The best way would be to test people directly for SARS-CoV-2 antibodies. (This isn't the same as testing for infection, which looks for the genetic material of the virus.) Antibody tests are well-understood, and research laboratories and firms around the world are developing such tests for SARS-CoV-2 antibodies. The Food and Drug Administration recently allowed one such test to be used. More will follow.

But no test is perfect. Some detect antibodies that do not exist (false positives), others miss antibodies that do exist (false negatives). False positives may be a particular problem here, as a test might signal positive for SARS-CoV-2 antibodies when it is really detecting antibodies to cold-causing coronaviruses.

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In normal times, a test is not used until its accuracy and rates of false positives and false negatives have been carefully tested and optimized. But these are not normal times. Such optimization has not yet been done yet for any of the tests under development, and it is not clear how long such a process will take.

Antibody tests are not the only way to decide that an individual is immune to SARS-CoV-2. We could assume that those who have had the disease are now immune and issue them immunity certificates. But how will we know they had Covid-19? Will an applicant need to show a positive virus test to justify a certificate? Without such testing, it can be difficult to know for sure if someone truly had Covid-19 or if they had something else, like the flu, with similar symptoms. But many people with Covid-19 symptoms have been unable to get coronavirus tests and have even been told not to try.

Verifying applicants' claims and identities is another issue. If immunity certificates provide benefits, people will want them. They may be willing to provide test results from phony laboratories (I can imagine an entire underground industry springing up to meet this demand) or might lie about their own past symptoms. Some people would use another's immunity certificate, unless it had a driver's license-like photograph and identifying information or required thumbprints, retinal scans, or other identity verification, raising new privacy issues. And a black market in forged immunity certificates would likely arise.

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The stakes are high. If a person who is not immune has an immunity certificate — because of error, fraud, or other reason — that person might contract the disease, with or without symptoms, and pass it on to others.

Those are the easy issues. Here are the harder ones: If we had sufficiently accurate immunity certificates, how should we use them?

Employers or governments *might* require that only people with immunity certificates be allowed to work in jobs involving substantial human contact, like health care, food, service, retail, transportation, and more. Restaurants, bars, sporting events, concerts, or other so-called public accommodations *might* admit only those with immunity certificates. Travel by public transportation or the privilege to attend classes in person *might* be limited to individuals with immunity certificates. But *should* they be so restricted?

These certificates have appeal — unless you are one of the many people who end up locked out of the world due to no fault of your own. For you, it is discrimination: some people can work, play, or travel while you cannot.

The legal issues aren't clear. The <u>Americans with Disabilities Act</u> (ADA) may be the most relevant federal statute, but it is triggered only by a disability.

Having a Covid-19 infection can be a disability, but can having a normal immune system, one without evidence of a prior infection, count as a disability? If so, how would the act's "direct threat" exception apply? The Equal Employment Opportunity Commission has <u>issued some guidance</u> for employers, saying that Covid-19 qualifies for the "direct threat" exception, but that deals with people who are infected or symptomatic, not those who might become infected.

Other federal and state statutory and constitutional rights might also be invoked, such as the <u>Federal Rehabilitation Act</u>, state statutes similar to the ADA or broad state anti-discrimination legislation, and federal and state due process, equal protection, and possibly right to travel guarantees.

An effective and widely accessible vaccine would ease some of these questions. But we would still have to deal with people who cannot be vaccinated — newborns, those with compromised immune systems, people with egg allergies, and the like — as well as those who object to vaccination.

Immunity certificates may turn out to be an important part of the other side of the Covid-19 pandemic. But, as with everything in human affairs, they are complicated. And getting them wrong could do more harm than good. We need to think carefully about them — starting now.

Henry T. Greely, J.D., is professor of law and professor by courtesy of genetics at Stanford University, where he directs the Stanford Center for Law and the Biosciences and chairs the steering committee for the Stanford Center for Biomedical Ethics.

About the Author

Henry T. Greely

hgreely@stanford.edu @HankGreelyLSJU © 2020 STAT