Coronavirus antibody tests lack validity and sufficient accuracy to offer reliable guarantee of immunity

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As the global back-to-work drive accelerates, countries, including Britain, Chile, Germany, Italy and parts of the United States, have begun testing sections of their respective populations for coronavirus antibodies. Chile has already announced it will be issuing "health passports" that will provide an excuse to send workers back to the workplace.

Presently, there is no scientifically proven basis for governments to suggest that having acquired antibodies to the SARS-CoV-2 virus guarantees immunity to reinfection, nor should it serve as a basis for an "immunity passport." This was stated most clearly by the World Health Organization last Friday, "There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection."

The WHO continued that, despite claims to the contrary, "there is not enough evidence about the effectiveness of antibody-mediated immunity to guarantee the accuracy of an 'immunity passport' or 'risk-free certificate'." The agency also warned, "People who assume that they are immune to a second infection because they have received a positive test result may ignore public health advice. The use of such certificates may therefore increase the risks of continued transmission."

One of the most well-known attempts to justify sending workers back to offices and factories based on a supposed antibody count comes from the controversial Santa Clara study, as it has come to be known. Jay Bhattacharya, a Stanford researcher, recruited patients through Facebook ads targeted by geography and demographics to determine the prevalence of the virus in the community.

Participants provided blood samples which were tested using Premier Biotech's serology test kit, which looks for antibodies to the virus. Based on a finding of 50 positive tests out of a total of 3,335, they concluded that the prevalence of the disease ranged from 2.5 to 4.2 percent, a 50- to 85-fold increase over the 956 cases then reported by the state of California. The implication was that the infection fatality rate for the coronavirus was about 0.1 to 0.2 percent, much lower than previously thought. The study was published online before going through a peer-review process.

The story was immediately picked up by the mainstream media, claiming that the research demonstrated the pandemic had largely run its course and that it was time to begin opening the country. This became a key part of the narrative presented on behalf of the world's financial oligarchs, by an assortment of corporate executives and government officials, that the population must return to work to save capitalism, regardless of the risks. The antibody test has become their godsend—both a touchstone and an artful dodge.

However, they make no mention of the fact that the data in the Santa Clara study has been widely discredited in the days since its release. An initial review of the statistics by biostatistician Balaji S. Srinivasan provides a step -by-step critique of the errors, showing that anywhere from 35 percent to 100 percent of those testing positive may have been false positives, implying that they did not actually have antibodies to the coronavirus.

Srinivasan also exposed how the recruitment of people for the study inherently biased the results. Instead of a random search of the population, potential subjects were targeted based on whether or not they felt they had been exposed in the recent past even if they had no symptoms. This would potentially select people with antibodies into the study and wrongfully skew the results.

More worrisome in the Santa Clara study is its unfounded conclusion that the lethality of COVID-19 is just slightly higher than that of the flu. This goes against everything that is known about the experience of frontline health care workers in New York City and numerous other countries. If the virus is so much less lethal than previously thought, they do not bother to explain why COVID-19 fatalities have exceeded those from cardiovascular disease and cancer nor acknowledge that in every country the staggering excess deaths reported have been due to COVID-19.

It has also been revealed by BuzzFeed News that the wife of the lead author had sent an email to a Silicon Valley middle school's private email server to recruit subjects, promising they would have peace of mind with regards to their immunity if they would participate. Additionally, the email falsely claimed that the FDA had approved the antibody test and worded the email in a manner that would attract participants who may previously have been ill.

Worth mentioning is one of the co-authors on the study, John Ioannidis, a Stanford public health researcher, who had argued back in March that the mortality rate of COVID-19 may be much lower, potentially making the lockdown "totally irrational." His opinion was published in *STAT* on March 17. Lead authors of the Santa Clara study, also Stanford researchers, Eran Bendavid and Jay Bhattacharya, made similar claims in the *Wall Street Journal* on March 24. Clearly, these investigators had well-formed opinions prior to conducting their investigation.

The conclusions of a similar population-based antibody study in New York, where 3,000 samples were collected from 40 locations across 19 counties, were announced last Thursday by New York Governor Andrew Cuomo, who claimed that about one in five people

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in New York City and nearly 14 percent of the population of his state may have antibodies to the coronavirus.

However, given the reported specificity of their antibody test, Dr. Anisha Jha of Harvard's Global Health Institute pointed out on Twitter that the real rate of infections in New York could be as low as seven percent, and possibly half of those testing positive may actually be designated as "false positives" and not really carrying protective antibodies, and therefore are susceptible to contracting and possibly dying from the disease.

These and other ultimately misleading studies prompted Dr. Mike Ryan, the head of the WHO's emergencies program, to say, "There's been an expectation that herd immunity may have been achieved and that the majority of people in society may already have developed antibodies. I think the general evidence is pointing against that and pointing towards a much lower seroprevalence" of COVID-19.

As an aside, terms like sensitivity and specificity of a test can be misleading to the layman. Adding complexity to understanding these "statistical" categories are critical distinctions and differences that have to be made between diagnostic and screening tests. It is one matter to see if a known infected patient has antibodies to SARS-CoV-2. But when the test is applied to a healthy, not infected population, where the prevalence for the disease is low, the test would likely generate a disastrous outcome.

According to Richard Hoffman, MD, MPH, director of the Division of General Internal Medicine at the University of Iowa Carver College of Medicine, "When [a test is] applied to a lower risk population the predictive value [of the test] drops. … This is particularly a problem when you are talking about screening, where the prevalence of disease in the population is usually quite low. This has important public health implications because the number of false positive tests can be in the hundreds of thousands or even millions."

The dangers of sending people back to work without protection against the coronavirus, without immunity or otherwise, was underscored by the increase in cases and deaths over the weekend. The total number of cases globally surpassed three million as the pace of new cases has remained steady for more than three weeks. According to official figures, over 200,000 people have died since the COVID-19 pandemic erupted on to the world stage, a figure which is still significantly undercounted .

The reason that there are doubts about any immunity to the coronavirus is because that process within the body is complex, and the response by the body to the antigen is still not well understood. In general, the development of immunity to a pathogen is a multistep process that takes two to three weeks to complete. The initial response is called an innate, non-specific response in which the body's immune system directs white blood cells such as neutrophils, macrophages and dendritic cells to the site of infection to slow the progress of the virus.

The adaptive response is much slower, requiring days or weeks to be established. Components of the virus are initially presented to white blood cells—T-cells and B-cells—which then develop a highly specific response to that pathogen. The coordinated effort leads to the production of antibodies, which are specialized proteins that travel through the blood and lymphatic systems. When they encounter the virus, they bind to it, preventing the virus from causing disease.

However, reports of early reinfections in Japan, as well as concerns over dozens of individuals in South Korea who tested positive after a documented COVID-19 infection, have health authorities and scientists perplexed. According to the spokesman for the South Korean health and welfare minister, Son Young-rae, these positive results occurred between two days and two weeks after patients were released from quarantine. Some had developed fevers and respiratory symptoms as well. They were placed back into isolation. Data from China on patients discharged from a Wuhan hospital corroborates these unusual developments, with approximately 5-10 percent of patients who had been pronounced "recovered" have tested positive for the virus again.

Though most studies to date have shown that patients who have recovered produced antibodies to the virus, there is also evidence from a Shanghai-based university reporting on 175 patients with confirmed COVID-19, that in one-third of them, low antibody levels were detected, and in a small subset of patients, the neutralizing antibodies were undetectable by study assays. The data also suggests there is a more complex interplay between the virus and the person's immune response.

There have not been any studies conducted that indicate that the presence of antibodies to SARS-CoV-2 has conferred immunity to subsequent infection. There have only been speculations based on experiences of previous viral infections.

Recognizing that all individuals lack immunity to the novel coronavirus, surveillance of people who have antibodies to the SARS-COV-2 in a population can allow inferences about the extent of infection. Antibody tests, when adequately validated and appropriately used, can assist with such public health measures. These efforts should be coordinated to answer essential questions such as determining the extent of infection in the general population, including age-specific cumulative incidence, as well as assessing the fraction of asymptomatic infections. Eventually, this will also better define the case fatality ratio. No such scientifically planned national effort has been put forth in the United States.

The coordinated attack on science, dismantling the rigors and principles of the scientific process, is not a new phenomenon but has taken on a dangerously absurd turn when, in the name of science, the ruling elites attempt to support the unconfirmed hypothesis that it is safe to return to work based on screening tests for antibodies that may produce high rates of "false positives." These endeavors are intended to force a Rubicon, committing the working class to endure the diktats of the markets, to making the coronavirus endemic in society, never mind the staggering potential loss in human life that such measures may cause.

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