U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

HEARING CHARTER

COVID-19 Variants and Evolving Research Needs

Wednesday, May 12, 2021
10:00 a.m. EDT – 12:00 p.m. EDT
Zoom

PURPOSE

The purpose of this hearing is to discuss how variants develop, how researchers identify and sequence variants, and how this information can be utilized by public health officials, government agencies, and medical practitioners to make decisions. The hearing will examine the ways the Federal government can meet the research and forecasting needs that evolve as the virus continues to mutate. Members and witnesses will discuss how the federal government can better coordinate its approach to best serve the American people through this pandemic and beyond.

WITNESSES

- **Dr. Salim Abdool Karim**, Director of CAPRISA
- **Dr. Nathan Grubaugh**, Assistant Professor of Epidemiology, Yale School of Public Health
- **Dr. Stephen Streiffer**, Deputy Laboratory Director for Science and Technology, Argonne National Laboratory
- **Dr. Caitlin Rivers**, Senior Scholar, Johns Hopkins Center for Health Security

OVERARCHING QUESTIONS

- How do COVID-19 variants emerge and spread, and how do public health decisions influence the proliferation of variants?
- What is the state of data sharing among U.S. states and among countries regarding variants developing and spreading around the globe?
- Are existing tests and vaccines effective for the known COVID-19 variants? How do variant-specific tests bolster public health decision-making? What role do vaccines play in reducing the spread and emergence of variants?
- Have the models built to track and predict the spread of COVID-19 around the globe adapted with the emergence and spread of variants?
- How can the federal government serve as a resource during and between pandemics when it comes to information aggregation and accessibility and disease forecasting?

Variants in the United States

As viruses spread, small errors – called mutations – arise in the genetic material during replication. Many of these mutations are repaired or die off as the virus continues to move through a population. Mutations that enhance the virus's ability to replicate, transmit, or survive in a host allow the virus to spread more quickly through a population, or become more resistant to immune system defenses, thereby increasing the mutations' prevalence and creating a new strain of the virus.[1] Almost a year and a half into the global battle against COVID-19, the United States faces five known Variants of Concern (VOCs). According to the Centers for Disease Control[2], these are as follows:

- **B.1.1.7:** First identified in the U.K. in November 2020 and identified in the U.S. in December 2020. This variant increased transmissibility of the virus by about 50% and research suggests there is a potential – but not confirmed – increase in severity of cases.[3]
- **B.1.351:** First identified in South Africa in December 2020 and identified I the U.S. at the end of January 2021. This variant increased transmissibility of the virus by about 50%. Certain monoclonal antibody treatments and vaccine-induced immunity have been shown to be less effective against B.1.351.[4]
- **P.1:** First identified in Japan in early January 2021 among travelers from Brazil, where it likely originated in November 2020.[5] Identified in the U.S. in January 2021. Research indicates P.1 is twice as transmissible as earlier strains and is less susceptible to immune defenses built by previous infections and vaccination.[6]
- **B.1.427 and B.1.429:** First identified in California in February 2021. This variant increased transmissibility of the virus by about 20%. Certain monoclonal antibody treatments and vaccine-induced immunity have been shown to be less effective against these variants.[7]

As variants of concern, these strains have evidence of an increase in transmissibility, more severe disease, significant reduction in susceptibility to infection- or vaccine-induced immunity, or diagnostic detection failures.[8] These variants are closely monitored by federal health agencies and are analyzed to determine whether additional diagnostics, vaccines, or treatment are needed. If clear evidence of reduced effectiveness of prevention measures, vaccines, or approved therapeutics arises, a variant could be classified as a Variant of High Consequence. Currently, no COVID-19 variants rise to this level.

[1] https://www.gavi.org/vaccineswork/patient-zero-understanding-how-new-coronavirus-variants-emerge
[2] https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html
[3] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html
[4] Ibid.
[5] https://www.sciencenews.org/article/covid-coronavirus-p1-variant-brazil-strain-transmission-immunity
[6] Ibis.
[7] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html
[8] Ibid.

B.1.617 and the Importance of Vaccines in Squelching Variants

The variant currently dominating the news cycle was discovered in India. India is now experiencing the sharpest spike in coronavirus cases in the world, with a record of 400,000 new COVID-19 cases for the first time on May 1.[9] One variant – B.1.617 – has become the dominant strain in some areas. Media coverage of this variant has dubbed it a "double mutant," as it contains specific similarities to the mutation present in the California strain as well as one found in both the South African and Brazilian strains. However, this name implies that the strain has only two mutations, or that having two mutations is unusual; in fact, B.1.617 has about a dozen mutations, which is not uncommon.[10]

While B.1.617 is not the only mutation driving up infections in India, it appears that people who already had COVID-19 during an earlier surge are susceptible to reinfection with B.1.617. Existing vaccines appear to work against B.1.617, but could be slightly less effective.[11]

Exacerbating this deadly wave in India is the country's vaccine shortage. India is the largest vaccine manufacturer in the world, but just about 3 percent of the country – 30 million out of 1.3 billion people – had been fully vaccinated as of May 8.[12] Expanding vaccine access is not only imperative to save lives in India during this devastating wave, but to stem the spread of the virus and the inevitable mutations that will develop as it makes its way through the population. In late April, the Biden administration announced that it would share 60 million doses of the AstraZeneca vaccine – which is not authorized for use in the United States by the Food and Drug Administration (FDA) – with countries around the world.[13]

On May 5, 2021, the Administration announced that it supports the temporary lifting of intellectual property protections for COVID-19 vaccines.[14] Lifting these protections would allow the production of generic versions of the vaccines to supplement the doses made available directly from brand-name pharmaceutical companies, from other countries, or through international programs such as COVAX, which aims to provide equitable access to tests, treatments, and vaccines.[15] Pharmaceutical companies are opposed to lifting these protections, arguing that the increased competition for supplies could slow their production.

The more the virus circulates, the more variants will emerge, increasing the risk of a deadlier, more contagious strain of the disease. Though the exact effectiveness varies among vaccines and among variants, all approved vaccines appear to be effective in preventing infection from known variants. Last week, studies were published that showed the Pfizer-BioNTech vaccine to be 100 percent effective at preventing severe disease caused by B.1.351 (South African variant) and

[9] https://www.reuters.com/world/asia-pacific/india-posts-record-daily-rise-covid-19-cases-401993-2021-05-01/
[10] https://www.npr.org/sections/goatsandsoda/2021/04/24/988744811/people-are-talking-about-a-double-mutant-variant-in-india-what-does-that-mean
[11] Ibid.
[12] https://www.nytimes.com/live/2021/05/06/world/covid-vaccine-coronavirus-cases
[13] https://www.washingtonpost.com/politics/us-to-share-up-to-60-million-doses-of-astrazeneca-coronavirus-vaccine-with-other-countries-official-says/2021/04/26/b2dab8a0-a694-11eb-bca5-048b2759a489_story.html
[14] https://twitter.com/ambassadortai/status/1390021205974003720?s=21
[15] https://www.who.int/initiatives/act-accelerator/covax

B.1.1.7 (U.K. variant), and 72-89.5 percent effective at preventing infection.[16] Suppressing the spread and inevitable mutation of the coronavirus – especially as the world is opening back up – requires robust vaccination in the United States and abroad.[17]

Variant Testing

Though the tests used to detect the coronavirus were developed in the flurry of the early days of the pandemic, there is no evidence that they are less effective at detecting the newer strains of the virus.[18] Polymerase chain reaction tests – or PCR tests – detect multiple sequences of the coronavirus genome. The detection of any one of these sequences will trigger a positive test result, meaning that the mutation of one gene target will not render the test ineffective. However, it is important that researchers, test manufacturers, and regulatory bodies remain vigilant in assessing the continued effectiveness of tests as the virus continues to mutate. The FDA maintains a list of EUA-authorized tests whose performance may be impacted by mutations[19], and has issued policy guidance and recommendations for evaluating the impact of variants on tests.[20]

Because certain variants are deadlier, more contagious, or respond differently to preventative measures or treatments, it is important that public health agencies understand where particular variants are emerging and circulating. While not in use diagnostically, genomic sequencing is used to identify specific strains of the coronavirus, after a sample comes back positive. PCR tests that identify which specific variant a patient is carrying have been developed to assess positive samples for a variety of known strains. But because different variants possess similar mutations, definitive PCR tests are difficult to develop, and full genomic sequencing is a more reliable way to detect what variant is present in a particular sample.

The FDA does not currently authorize the use of any variant-specific tests for diagnostic use. Commercial and public health entities that process PCR testing and genomic sequencing for the purpose of variant identification are bound by patient privacy rules. Therefore, virtually everything we know about the presence of variants is at the public, not individual, level. This means that medical practitioners do not make treatment decisions based on the particular strain of the virus a patient has contracted. Rather, an awareness of the variants circulating in a particular region can inform public health decisions at large.

Disease Modeling and Forecasting

Infectious disease models are critical planning tools for policymakers and healthcare providers. Officials use them to allocate resources, such as medical staff and supplies, forecast the spread or severity of a disease, and predict the effects and costs of different intervention options. Models can also be used to anticipate future outbreaks based on past experiences. Accurate models must

[16] https://www.nytimes.com/live/2021/05/05/world/covid-vaccine-coronavirus-cases#pfizer-vaccine-variants-covid
[17] https://www.seattletimes.com/opinion/rise-of-variants-underscores-importance-of-covid-19-vaccination/
[18] https://www.nytimes.com/2021/04/14/health/coronavirus-testing-variants.html
[19] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests

incorporate what is known about the mechanics of the virus spread itself, how human behaviors adapt over the course of the pandemic, and, increasingly, how prevalent particular strains of the virus are in a given area.

Accurately and robustly incorporating variants into disease forecasting models would require an increased capacity for genomic surveillance and data sharing.[21] At the end of 2020, the United States ranked 28th in percentage of coronavirus samples sequenced to detect variants – up from 43rd at the end of 2020[22], but still far behind many of our global peers.[23] Genetic sequencing data is currently shared and accessed by researchers primarily on GISAID, a nonprofit started to share avian flu data.[24] Federal investments in data aggregation tools are necessary to ensure researchers, public health officials, and the American public have reliable models and forecasts through this pandemic and beyond.

Federal Activities on Variants[25]

In 2014, the White House National Science and Technology Council (NSTC) chartered a new Pandemic Prediction and Forecasting Science and Technology Working Group to coordinate Federal outbreak prediction capabilities, including capabilities to predict variants. In late 2016, this Working Group issued a roadmap report, "Towards Epidemic Prediction: Federal Efforts and Opportunities in Outbreak Modeling."[26] It included a list of 14 high-level policy recommendations for a coordinated multi-agency effort provide for robust data and information sharing, stronger outbreak model development and decision support tools, and a "One Health" strategy for integrating scientific information from various sources to more effectively predict infectious disease outbreaks. The report also presented a table of various activities in infectious disease modeling being conducted across 11 different federal agencies, such as modeling of foreign animal disease activities being conducted by USDA's Animal and Plant Health Inspection Service (APHIS) and the Biosurveillance Ecosystem activities at DOE's Los Alamos National Laboratory.

The ability to sequence the genome of a viral sample is critical to establishing what disease variant has led to a patient's infection. In May 2020, the CDC's Advanced Molecular Detection program established a new lab consortium called the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance, or SPHERES, dedicated to collaborating on and aggregating results from genome sequencing of viral samples. SPHERES convenes scientists and data contributions from state and local public health laboratories, clinical laboratories, universities, and the private sector. Its objectives include identifying resource needs across the country so that genome sequencing can be more widely deployed, but also

[21] https://www.latimes.com/science/story/2021-02-07/how-the-u-s-plans-to-keep-tabs-on-the-coronavirus-variants-in-circulation-here
[22] https://www.washingtonpost.com/world/2020/12/23/us-leads-world-coronavirus-cases-ranks-43rd-sequencing-check-variants/
[23] https://covidcg.org/?tab=global_sequencing
[24] https://www.gisaid.org/hcov19-variants/
[25] https://www.nytimes.com/2021/04/14/health/coronavirus-testing-variants.html
[26] towards_epidemic_prediction-federal_efforts_and_opportunities.pdf (archives.gov)

championing principles of quick and open data sharing and the use of common data and analysis standards.[27]

In a January 21, 2021 Executive Order, President Biden proposed a new interagency National Center for Epidemic Forecasting and Outbreak Analytics, which would support global efforts to prevent, detect, respond to, and recover from emerging biological threats.[28] In January 2021, CDC introduced the National SARS-CoV-2 Strain Surveillance (NS3) program, which asked state laboratories to remit viral sample data to CDC on a weekly basis in order to help establish a national picture of how variants are spreading and affecting patients.[29] On April 16, the Administration announced that the CDC will allocate $1.7 billion to states to scale up science capabilities for tracking and monitoring COVID-19 variants.[30]

[27] SPHERES | CDC
[28] National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness | The White House
[29] FEB 2021 Revised NS3 FAQ_02052021 FNL.pdf (aphl.org)
[30] https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/16/fact-sheet-biden-administration-announces-1-7-billion-investment-to-fight-covid-19-variants/