

Report on Research Compliance Volume 20, Number 4. March 23, 2023 Standing on Shoulders of 'Scientific Forbears,' NIH, Research Community Rose to COVID-19 Challenges

By Jane Anderson

"Perhaps the most valuable lesson that COVID-19 has taught the research community—and hopefully society more broadly—is the importance of collective effort and continuous investment in basic and applied research."

So wrote nearly three dozen authors, led by former NIH Director Francis Collins, reflecting on lessons learned during the COVID-19 public health emergency. [1] NIH responded to the COVID-19 pandemic by investing in vaccine development and evaluation, prioritizing diversity in clinical trials, focusing on therapeutic trials and streamlining development of diagnostic tests, efforts that were largely successful. Yet the experiences also showed the need for improvements to address future crises, they wrote in a recent paper published in *Science*.

"It takes more than individual ingenuity and hard work for biomedical research to respond swiftly and effectively to a rapidly emerging public health challenge. This pandemic required the coordinated efforts of thousands of creative researchers, administrators, and community partners who were supported by much needed resources and provided with rapid, free access to decades of discoveries made by their scientific forebears," the authors pointed out.

To date, 6.5 million individuals worldwide have died in the pandemic, including more than 1.1 million in the United States, and it isn't over yet. But "it is not too soon to consider the strengths and weaknesses of the research response and some of the lessons that can be learned," the article said.

Research Community Rose to Challenges

Collins was NIH director through the first two years of the pandemic. He resigned in December 2021 and now leads the Molecular Genetics Section at NIH's National Human Genome Research Institute. In addition to other NIH leaders, coauthors include officials from the Food and Drug Administration (FDA), international investigators, and representatives of pharmaceutical firms involved in COVID-19 vaccine and treatment research.

Vaccine, Therapeutics Research Successes

Studies of key public health and clinical issues such as masking and indoor air ventilation were useful in addressing the pandemic, the article said. However, research surrounding vaccines, therapeutics and diagnostics was the most innovative and significant in combating COVID-19, the authors wrote.

"Decades of basic research in virology, molecular biology, epidemiology, and multiple other scientific fields made it possible to mount therapeutic and vaccine efforts within days of the public release of the sequence of the viral genome," they said. "Before the COVID-19 pandemic, mRNA vaccines had not yet been proven safe and effective for any infectious disease. However, data that had been gathered over the past two decades, including codon optimization and refinement of delivery systems, provided confidence that this approach could work—and ultimately saved months in the face of a rapidly spreading pandemic."

Operation Warp Speed provided support for large-scale vaccine and therapeutic trials and manufacturing of millions of doses of vaccines at financial risk to the U.S. government as their safety and efficacy were still unproven, the article said.

Clinical trial endpoints were harmonized, and five of the six pivotal studies were overseen by a single NIH-convened data and safety monitoring board. As part of this, NIH HIV vaccine evaluation networks partnered with contract research organizations (CROs), the authors noted.

"In just 11 months from identification of the pathogen, two vaccines received emergency use authorization (EUA) from [the FDA]. Most other vaccines have taken at least a decade to develop," the authors wrote.

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