

## **Questions for Dr. Anthony S. Fauci**

Director

National Institute of Allergy and Infectious Diseases

Friday, July 31, 2020, Hearing: “The Urgent Need for a National Plan to Contain the Coronavirus”

### **Questions from Rep. Jamie Raskin (MD-08)**

1. Even in the best case scenario, we are apparently months away from widespread distribution of a safe and effective vaccine. What are your thoughts on the use of live attenuated vaccines in general—and the Sabin Oral Polio Vaccine (OPV) in particular—as a way to boost immune responses and induce non-specific protection against COVID-19, while work on a targeted vaccine continues?

### **NIAID Response**

The National Institute of Allergy and Infectious Diseases (NIAID) is the lead Institute at the National Institutes of Health (NIH) for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19 and the virus that causes it, SARS-CoV-2. NIAID is an active member of Operation Warp Speed (OWS), a Federal partnership led by the Department of Health and Human Services that aims to deliver as many as 300 million doses of a safe, effective SARS-CoV-2 vaccine by mid-2021. To achieve this goal, OWS is currently supporting the most promising SARS-CoV-2 vaccine candidates.

NIAID, in support of OWS, is prioritizing the development of vaccine candidates intended to protect specifically against COVID-19. NIAID scientists and the vaccine working group of the NIH’s Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership also have reviewed the concept of using live-attenuated vaccines, including the oral polio vaccine (OPV) and/or the Bacille Calmette-Guérin (BCG) tuberculosis vaccine, to prevent severe COVID-19 disease. After these extensive reviews, it was determined that the use of the BCG vaccine warranted further research at this time. It also was determined that the OPV vaccine did not warrant further research due to safety concerns. Earlier this year, NIAID scientists and their collaborators identified a strong correlation between the degree of BCG vaccination at a country level and COVID-19 mortality.<sup>1</sup> Additional studies, including clinical trials, are needed to corroborate this intriguing finding. Currently, there is insufficient data to support the use of BCG vaccination for the prevention of COVID-19 as a stopgap or bridge measure. NIAID-supported research to further investigate the use of BCG for protection against COVID-19 is described in the response to Question 2.

Efforts to develop and test targeted SARS-CoV-2 vaccine candidates continue to proceed at an unprecedented pace. NIAID recently established the COVID-19 Prevention Network (CoVPN), a functional unit of OWS, to enroll tens of thousands of volunteers in large-scale clinical trials to

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<sup>1</sup> BCG vaccine protection from severe COVID-19: <https://pubmed.ncbi.nlm.nih.gov/32647056/>

test a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19. The CoVPN is engaged in a Phase 3 trial of one SARS-CoV-2 vaccine candidate, mRNA-1273 (Moderna, Inc.), with additional Phase 3 clinical trials of OWS selected candidates scheduled to begin in late summer and early fall. NIAID is committed to pursuing the development of safe and effective SARS-CoV-2 vaccine candidates to protect against COVID-19 and continues to work with OWS to coordinate clinical trials of promising candidates.

2. Is the NIH, NIAID, or any other U.S. government entity currently studying the potential use of OPV, the tuberculosis vaccine BCG, or any other existing live attenuated vaccination, either as a stopgap or bridge measure, for therapeutic use (including to reduce severity of COVID-19), or to otherwise protect vulnerable populations? If so, when do you expect to see the results of these studies? If not, why not? Why isn't this advisable given the fact that OPV is widely available and has a proven safety record with very limited adverse reactions?

### **NIAID Response**

NIAID currently is conducting research on the use of the BCG tuberculosis vaccine for the prevention of severe COVID-19 disease. NIAID intramural scientists are playing a major role in a multi-center clinical trial in India studying the effect of BCG vaccination on SARS-CoV-2 infection and on the immune response to SARS-CoV-2 infection in elderly populations, who are likely BCG vaccination naïve. Initial results from this study are expected in early 2021. NIAID also is in discussions with extramural researchers to potentially initiate a clinical trial evaluating BCG vaccination for protection against COVID-19 in the United States. In addition, NIAID scientists are conducting early stage preclinical research to determine if BCG vaccination protects mice from severe COVID-19. These animal studies may help identify the mechanism(s) responsible for any observed protection and results from these studies will be reported as expeditiously as possible to inform future clinical studies.

NIAID is not currently supporting research on the use of OPV for the prevention of severe COVID-19 disease. Although OPV has been administered to billions of children and is approved for use in other countries, use of OPV is not without risk and the risk/benefit ratio changes in countries that have eradicated polio. OPV can cause a rare adverse event known as vaccine-associated paralytic polio (VAPP), which results in a paralysis that is identical to that caused by wild polio virus. In the context of COVID-19, it is important to note that VAPP is more likely to occur in individuals 18 years of age and older who receive OPV.<sup>2</sup> This risk of VAPP associated with OPV is the reason that only the inactivated polio vaccine (IPV) has been administered in the United States since 2000. The public health community and the World Health Organization also have made a significant effort to discontinue the use of OPV in favor of IPV due to the risk of VAPP and vaccine-derived polioviruses (VDPV).<sup>3</sup> Circulation of VDPV can occur in rare cases when the vaccine strain mutates in vaccinated individuals and reacquires the ability to infect others.<sup>4</sup> NIAID scientists and the vaccine working group of the NIH's ACTIV public private partnership have carefully evaluated the use of OPV and determined that,

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<sup>2</sup> CDC Pinkbook – Poliomyelitis: <https://www.cdc.gov/vaccines/pubs/pinkbook/polio.html>

<sup>3</sup> Polio vaccines: WHO position paper – March, 2016: <https://www.who.int/wer/2016/wer9112.pdf>

<sup>4</sup> OPV Cessation. The Global Polio Eradication Initiative. <http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/opv-cessation/>

in regard to non-specific vaccination strategies, research on the use of BCG should be prioritized at this time. NIAID will continue to explore and evaluate the latest scientific evidence as we plan for future studies.