

GAO Highlights

Highlights of [GAO-23-105455](#), a report to congressional committees

Why GAO Did This Study

Research involving pandemic pathogens is crucial to ensure the nation's ability to prepare for, respond to, and recover from public health threats. For example, such research resulted in COVID-19 vaccines and therapeutics to prevent severe disease or death. However, a number of incidents and research projects—including research that enhanced the transmissibility of influenza between mammals—have raised questions about the adequacy of HHS oversight of the safety of such research.

The CARES Act includes a provision for GAO to report on ongoing federal efforts to prepare for, respond to, and recover from COVID-19. This report examines the extent to which HHS's oversight Framework for enhanced potential pandemic pathogen research is effective; and gaps that exist in HHS's broader oversight of such research, among other things.

GAO reviewed HHS's oversight policies and programs as well as documentation for selected research grants. GAO also assessed the Framework against GAO's elements of effective oversight. GAO interviewed HHS officials and select subject matter experts from the research biosafety and biosecurity community.

What GAO Recommends

GAO is making three recommendations to improve HHS's oversight of research, including developing and documenting a standard for "reasonably anticipated" and assessing the risk of statutory limitations. HHS neither agreed nor disagreed with two of the recommendations and agreed with the third.

View [GAO-23-105455](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or DeniganMacauleyM@gao.gov.

January 2023

PUBLIC HEALTH PREPAREDNESS

HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens

What GAO Found

The Department of Health and Human Services (HHS) oversees high-risk research involving potential pandemic pathogens, which are defined as likely highly transmissible and virulent, and capable of causing significant morbidity or mortality. SARS-CoV-2, which causes COVID-19 disease, is an example of a pandemic pathogen. In 2017, HHS developed an oversight policy (the Framework) that requires funding agencies to refer proposed research that is "reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens" to the Department for an additional review of associated risks and benefits, among other things.

Researcher conducting high-risk research



Source: Centers for Disease Control and Prevention. | [GAO-23-105455](#)

GAO found that HHS's Framework does not fully meet the key elements of effective oversight identified in past work. For example, the Framework does not provide a standard to help funding agencies interpret what "reasonably anticipated" means. Until HHS develops and documents such a standard, the Framework allows for subjective and potentially inconsistent interpretations of the requirement—leaving HHS without assurance the department is reviewing all necessary research proposals.

HHS also oversees research involving certain pandemic pathogens through its Federal Select Agent Program—a list-based program regulating the possession, use, and transfer of certain pathogens. However, HHS faces trade-offs in adding newly emerged pathogens, like SARS-CoV-2, to the list because, as officials told GAO, doing so would impede the public health response by burdening diagnostic and treatment facilities with additional reporting and inspection requirements. The statute authorizing the Federal Select Agent Program limits HHS's ability to waive or postpone these requirements during public health emergencies for a maximum of 60 days. HHS has not assessed the risk this limitation poses to its oversight of known pandemic pathogens. Until the risk of this statutory limitation is assessed and action taken to mitigate any risks, HHS will continue to face tradeoffs between impeding public health response efforts and allowing high-risk research involving known pandemic pathogens to be conducted without appropriate HHS oversight.