

November 2021

## Why GAO did this study

The CARES Act included a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report discusses technologies, approaches, and associated challenges for vaccine (1) research and development, (2) testing, and (3) manufacturing, as well as (4) the economic factors that affect vaccine investment.

GAO conducted literature searches including scholarly articles and government reports relevant to these four areas. GAO interviewed stakeholders and experts with a diverse set of perspectives on the science, administration, and economics of vaccine development. GAO also convened a 3-day meeting of 22 experts with expertise in at least one area related to our four objectives with assistance from the National Academies of Sciences, Engineering, and Medicine. GAO received technical comments on a draft of this report from 1 federal agency and 9 participants at its expert meeting, which it incorporated as appropriate.

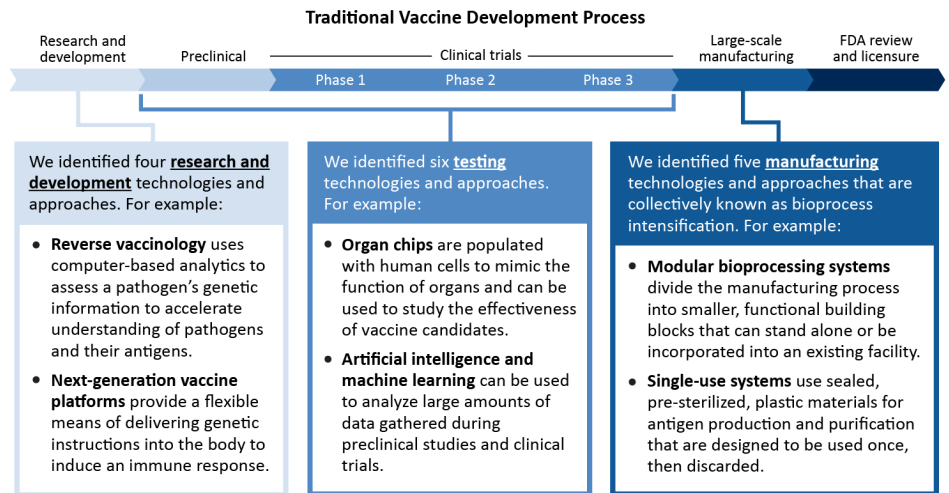
GAO is identifying policy options in this report.

# Vaccine Development

## Capabilities and Challenges for Addressing Infectious Diseases

### What GAO found

Vaccines protect people from disease by preparing the body to respond to an infection. Vaccinations are a key part of individual and community health, but vaccine development remains complex and costly. Innovative technologies and approaches, such as those identified in this report, may enhance the nation's ability to respond to infectious diseases. For example, reverse vaccinology and next-generation platforms—combined with existing research—helped researchers develop some COVID-19 vaccines more quickly and effectively.



Source: GAO analysis. | GAO-22-104371

However, key challenges may hinder the adoption of these innovative technologies and approaches. Some promising technologies face issues and challenges such as inherent technical limitations and high cost. For example, organ chips may facilitate testing, but they are not yet able to replicate many of the complex functions of the human immune system. Similarly, single-use systems may increase the flexibility of vaccine manufacturing facilities, but may require extensive testing to ensure that they do not negatively affect the resulting vaccine. Further, economic challenges may hinder vaccine development. Experts attribute underinvestment in vaccines to market failures (i.e., market interactions that fall short of what would have been socially beneficial). For example, vaccines benefit those who are vaccinated, and, to some degree, those who are not. This additional benefit is not captured in the price, which reduces return on vaccine investment.

GAO identified 9 policy options that may help address challenges hindering the adoption of vaccine development technologies and approaches or economic challenges. These policy options involve possible new actions by policymakers, who may include Congress, federal agencies, state and local governments, academic and research institutions, and industry. See below for details for some of the policy options and relevant opportunities and considerations.

### Selected Policy Options to Address Challenges in Vaccine Development

|  | Opportunities  | Considerations   |
|--|--|--|
| <p><b>Prioritize infectious disease pathogens</b> (report page 21)</p> <p>Policymakers could collaborate across sectors (e.g., government, academia, researchers, industry, and nonprofit organizations) to prioritize infectious disease pathogens with pandemic potential for vaccine R&amp;D.</p> <p>For example, policymakers could develop a working group to prioritize pathogens with pandemic potential and work more closely with international organizations to prioritize vaccine development as well as develop monoclonal antibodies.</p> | <ul style="list-style-type: none"> <li>• Prioritizing pathogens with pandemic potential could improve strategic vaccine R&amp;D decision-making and help focus resources on developing and adopting key technologies and approaches that most effectively address those pathogens.</li> <li>• Appropriately matching the technologies and approaches to the prioritized potential pandemic pathogens then leveraging technologies may help address certain technical limitations and cost.</li> <li>• With greater leadership and strategic partnerships, policymakers could more quickly address threats to the U.S. population.</li> </ul> | <ul style="list-style-type: none"> <li>• As new threats are identified, priorities may change, which may cause uncertainty for vaccine developers.</li> <li>• Policymakers may have different priorities based on their respective missions.</li> <li>• There may be disagreements as to which key technologies should be prioritized and used, resulting in the need for policymakers to weigh the potential advantages and disadvantages associated with various options.</li> </ul> |
| <p><b>Improve preparedness</b> (report page 21)</p> <p>Policymakers could provide support for public-private partnerships to strategically address potential pandemic pathogens identified as priorities. These partnerships could, for example, develop and test vaccine candidates that may provide protection from pathogens with pandemic potential.</p>   | <ul style="list-style-type: none"> <li>• This early development could provide a coordinated foundation that can be mobilized in an emergency. Such an approach could speed vaccine development as well as potentially reduce risk for vaccine researchers and developers concerning questions of safety, efficacy, and manufacturability.</li> </ul>   | <ul style="list-style-type: none"> <li>• The lack of certainty of the commercial market and government funding for vaccines against pathogens with pandemic potential may be too risky for the private sector to undertake.</li> </ul>   |
| <p><b>Further support development of data standards</b> (report page 32)</p> <p>Policymakers could further support coordinated efforts to obtain the views of all stakeholders and to develop standards for health data and their use in clinical trials.</p>  | <ul style="list-style-type: none"> <li>• Integrating researchers' needs into the standards development process could better ensure the necessary data are available.</li> <li>• Access to high-quality data in a standardized format may allow streamlined patient recruitment for clinical trials.</li> </ul>   | <ul style="list-style-type: none"> <li>• Expanding access to patient health data requires attention to ensure privacy.</li> <li>• Developing and implementing standardized data formats and IT infrastructure is time-consuming and costly.</li> </ul>   |
| <p><b>Improve preparedness</b> (report page 41)</p> <p>Policymakers could provide support for public/private partnerships to strategically develop manufacturing capacity to respond to surge requirements. To maintain this capacity, partnerships could manufacture prototype vaccine candidates against high-priority pathogens.</p>  | <ul style="list-style-type: none"> <li>• Manufacturing, testing, and stockpiling vaccines could be mobilized in an emergency and more rapidly mitigate future pandemics.</li> <li>• By leveraging strategic partnerships, policymakers could take steps to increase the availability of vaccines to more quickly address threats to the U.S. population.</li> </ul>  | <ul style="list-style-type: none"> <li>• May require new resources or reallocation of resources from other efforts.</li> <li>• There may be a risk that the vaccines manufactured, tested, and stockpiled against prioritized pathogen classes miss certain pandemic pathogens.</li> <li>• The stockpiled vaccines would need to be regularly replenished prior to expiration.</li> </ul>  |
| <p><b>Evaluate factors that inhibit vaccine investment and mechanisms to increase it</b> (report page 54)</p> <p>Policymakers could collaborate across sectors, such as government, academia, and industry, to conduct a systematic evaluation of factors that inhibit developers from investing in new vaccines.</p>  | <ul style="list-style-type: none"> <li>• A clear understanding of the range of factors discouraging vaccine investment would provide the basis for effectively addressing those factors.</li> </ul>  | <ul style="list-style-type: none"> <li>• Collaboration between policymakers and other stakeholders to obtain all relevant viewpoints can be time-consuming and it may be hard to reach a consensus.</li> </ul>   |