Biotechnology platforms enable fast, customizable vaccine production

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When COVID-19 created an urgent need for vaccines that could be made quickly, safely and cost-effectively, traditional manufacturing approaches were not sufficient to meet the demand. Biopharmaceutical

companies therefore shifted to novel biotechnology platform-based techniques that could be more quickly adapted to manufacture COVID-19 vaccines, and that were more robust, customizable and flexible than traditional approaches. An examination of this transition by a Penn State-led team concludes that such smart manufacturing techniques could in the future be applied to other viruses, potentially allowing vaccine development to keep pace with constantly evolving pathogens, according to project lead Soundar Kumara, Allen E. Pearce and Allen M. Pearce Professor of Industrial Engineering at Penn State.

The findings were published online by the American Society of Mechanical Engineers' *Journal of Computing and Information Science in Engineering* and will appear in the journal's August print issue.

"Vaccines based on biotechnology platform-based techniques have 'smart' characteristics that are more versatile than vaccines designed and manufactured using traditional methods," said Vishnu Kumar, industrial engineering doctoral candidate and co-author of the paper.

Biotechnology platform-based vaccine development involves cultivating a flexible baseline structure that can be customized as needed to create new vaccines for related viruses. When pathogens mutate, researchers identify the changes and then apply them to the existing structure. This approach was underway when the COVID-19 pandemic began, and the massive global demand accelerated the large-scale and widespread adoption of the platform, Kumar said.

Pfizer/BioNTech and Moderna used one such platform, based on messenger RNA, to develop their vaccines. The mRNA platform had already been designed to serve as the basis of a vaccine for coronaviruses, which include the common cold and mutate rapidly. SARS-CoV-2, the virus that causes COVID-19, was sequenced within one year of the start of the pandemic. Researchers used this information

to modify the existing mRNA platform to develop a vaccine tailored to that version of SARS-CoV-2—a process that took less than a week once they had the genetic data. Johnson & Johnson used a similar approach called viral vector. In contrast, traditional vaccine manufacturing, which involves the culture of disease-causing pathogens and the injection of some form of these pathogens, can take 10 to 15 years to develop.

Biotechnology-based techniques have the potential to drive future research for viruses beyond COVID-19, such as the flu, according to Kumar. A smart manufacturing approach using systems that gather, store and transmit high-quality process data could facilitate connections between devices during each stage of the vaccine development and manufacturing process.

"With an in-depth understanding of the COVID-19 vaccine as a 'product,' biopharmaceutical firms can appropriately identify and apply strategies, such as modular manufacturing, mass customization, automation and knowledge management to boost the vaccine development and manufacturing process," Kumar said.

More information: Vishnu Kumar et al, Smart Vaccine Manufacturing Using Novel Biotechnology Platforms: A Study During COVID-19, *Journal of Computing and Information Science in Engineering* (2021). DOI: 10.1115/1.4053273

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