Antibody injections could become more affordable with new production method

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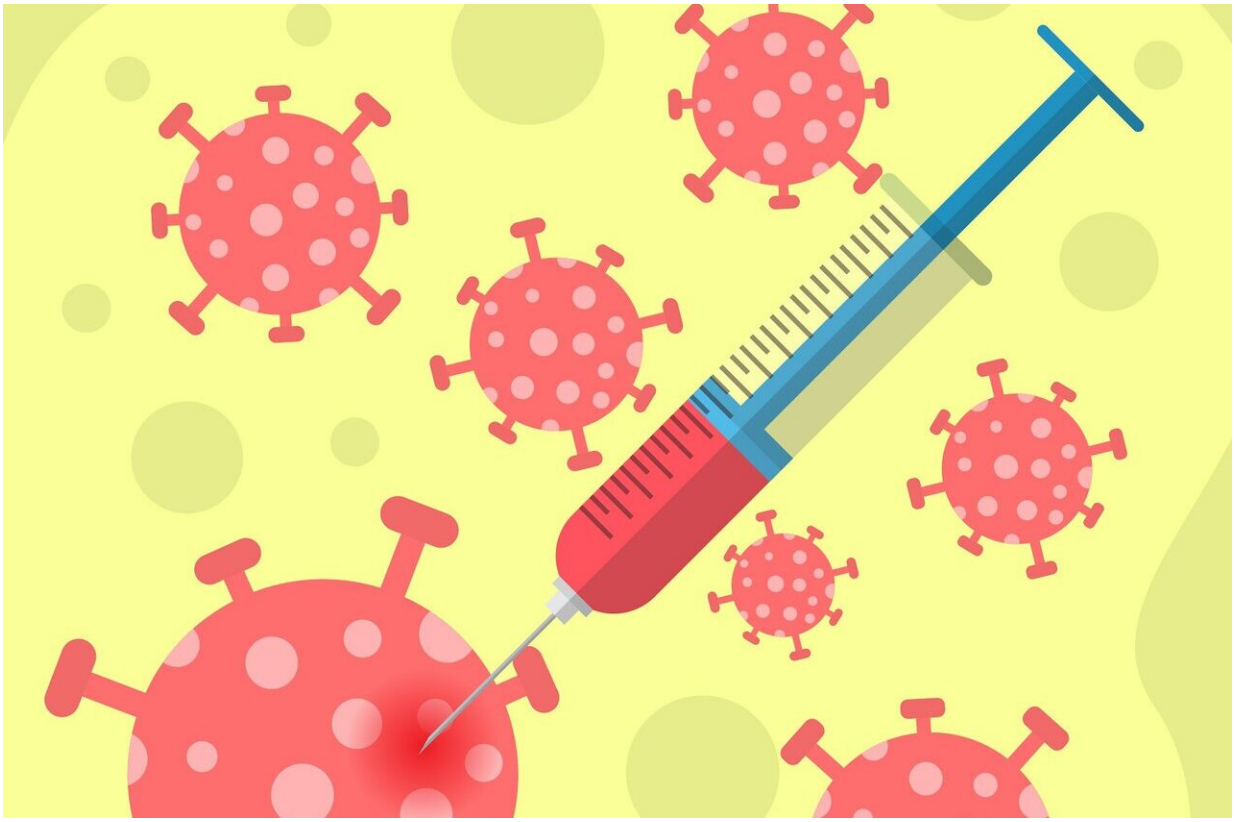

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Antibody injections are a highly desirable treatment for people with chronic diseases such as cancer, psoriasis, Crohn's disease and arthritis. And recently, antibodies have been in the news as a promising treatment

for severe cases of COVID-19.

But the costly, time-consuming manufacturing process to produce antibodies prevents these treatments from being accessible to most patients.

Andrew Zydney, Bayard D. Kunkle Chair and professor of chemical engineering at Penn State, has identified a new method to manufacture antibodies, which could drive down the production cost. His research results were recently published in *Biotechnology Progress*.

"If you look at the top 10 best-selling medications, by annual sales, eight are in the category of monoclonal antibodies," Zydney said. "And every year, individuals and insurance companies spend upwards of $100 billion on antibodies, with costs to treat a single patient often exceeding $50,000. There remains a huge unmet need for these products in treating a growing range of diseases."

Known as precipitation, Zydney's new protein purification process involves adding zinc chloride and polyethylene glycol, a water-soluble polymer, to a solution containing the antibody. This causes the antibody to precipitate so that the impurities can be washed away.

Though the precipitation process has been used for 70 years in blood plasma processing, it has never been used for the commercial production of antibodies, according to Zydney.

"To precipitate means 'to come out' of a solution in a solid form," he said. "For example, when you put salt in warm water, it dissolves. But if you put a lot of salt into cold water, some of that salt will remain as solid crystals. In the same way, proteins would normally dissolve in a solution, but you can find certain conditions where they come out as solid."

Zydney explained that the zinc chloride used in precipitation is a simple salt, making it much cheaper than other purification methods. It also saves time, as it is possible to yield large quantities of proteins in short periods of time.

Currently, antibodies are produced using a process called Protein A affinity chromatography, where the antibody binds to Protein A, which is immobilized in a chromatography column. The impurities can be washed away from the bound antibody, after which the pH level is adjusted to recover the purified antibody product. A single Protein A chromatography column can cost more than $10 million.

"That is just one step in the current manufacturing process, and it is what makes antibody manufacturing so expensive," Zydney said. "All of the major biotechnology companies are big players in this space."

The precipitation process eliminates the need for the costly chromatography process, as antibodies are purified directly from the solution by filtration through hollow fiber membranes.

"What we do in our research group is relatively small scale," He said. "But the precipitation process has the potential to be easily scaled up, potentially enabling biopharmaceutical companies to produce lower-cost antibodies for the patients who need them."

More information: Zhao Li et al, Enhanced filtration performance using feed-and-bleed configuration for purification of antibody precipitates, *Biotechnology Progress* (2020). DOI: 10.1002/btpr.3082

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