Out of Many, One: Collaborating is the Way to Accelerate COVID 19 Vaccine Development

https://www.healthcarebusinesstoday.com/out-of-many-one-collaborating-is-the-way-to-accelerate-covid-19-vaccine-development/

October 20, 2020

By John Loike, Matthew Cobb, Patricia J. Williams and Robert Pollack

The best way to recover from today's global economic and health crises brought on by the Covid-19 pandemic is to create, widely distribute and administer an effective vaccine. There are about 200 vaccine trials either in progress or in development around the world and nine of which are in crucial phase three trials. The scientific success rate for vaccine development over the past 80 years is about 17%. This means that we will have about 14 successful vaccines for COVID. The US government supported-vaccine development is strong, having already invested vaccine grants in excess of $2 billion dollars into many companies and research institutions. This broad approach is to be welcomed, as the larger the number of potential vaccines, the more likely it is that we will hit upon at least one that works. One major difference today is that the pipeline of new vaccine candidates is the involvement of large pharmaceutical companies in vaccine development. In contrast, from 1990 to 2012, vaccines entering clinical trials emerged mainly from small and medium-size companies, not from large companies.

The US government can speed up the vaccine development process by requiring better collaboration among all companies and institutions working to develop and to assess safety of their vaccines. In normal times, patents and intellectual property rights are seen as essential in promoting drug development, whether by big pharma or by publicly-funded research institutions. This is not necessarily the case – Jonas Salk famously did not retain the rights to his polio vaccine, asking "Could you patent the sun?" Even today Imperial College London is developing its Covid-19 vaccine through a social enterprise that will waive royalties for low-income countries.

Nevertheless, obtaining regulatory approval for vaccines can take years. Flexibility by regulators and above all, collaborative research and the sharing of intellectual property on vaccine development will accelerate this process of assessing efficacy and safety. Is there any way to further accelerate vaccine development? Yes: sharing what we know with each other, freely and openly.

In order to produce sufficient amounts of an effective vaccine in time to save hundreds of thousands of innocent lives, it is now time to first encourage – and then to mandate – that all companies and research institutions receiving government grants temporarily ignore patents and intellectual property rights and to collaborate instead, through agreements brokered by the relevant national bodies.

This is not a pipe dream. Many governments across the globe have the power to temporarily override patents. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permits countries to declare a national emergency and then issue a compulsory license, including for expensive branded drugs. The 2001 Doha Declaration

on the TRIPS Agreement and Public Health affirmed countries' prerogative to take such actions, including for public health crisis, which enable people to access patented medicines at affordable prices.

In vaccine development, there are three milestones. The first is developing a vaccine that works in vitro, or in animal models. The second is determining how best to deliver the vaccine to people across the globe. The last is initiating the appropriate clinical trials to test efficacy and identify potential side effects. Collaborations can be effective in rapidly achieving all three milestones. For example, to accelerate milestone one, companies should share data on the risks and benefits of using RNA vs DNA vaccines over conventional vaccines; on types of vaccines;; and on the best methods to strengthen a vaccine. This last issue is particularly important because recent studies report a rapid loss of antibodies to COVID-19 in survivors of the disease.

Achieving milestone 2 will require collaboration to determine the best ways to package attenuated vaccines at room temperature in the absence of glass vials, and to the best routes for vaccine delivery, from among the four current options: oral, IV, intramuscular, or subcutaneous. Finally, for milestone 3, the various pharmaceutical and research institutions would be able to collaborate to recruit sufficient volunteers for phases 1-2 and 3 clinical trials, and would be free to share data outcomes.

How would such collaboration work? Collaborations are an intrinsic activity in science. Scientists around the world, including researchers in the US, Europe, the UK and China, are collaborating at a higher rate than ever before to address COVID-19. Under the guidance of the WHO, companies and research institutions could provide internal research data documents to the expert reviewers of the WHO. In addition, every few weeks they would zoom together to discuss the details of their research progress and offer suggestions or recommendations how to move forward.

Since we are only focusing on COVID-19 vaccine development, this collaboration should not have a major effect on the patents and intellectual property rights of other drug development projects that they are developing. In fact, while vaccines can generate significant profits, they are usually limited to the pandemic times, whereas drugs like statins are used for decades to lower cholesterol. If done correctly, this singular act of altruistic collaboration would not significantly affect the bottom-line profits of most companies. This collaboration would help ensure that we don't sacrifice safety or efficacy for approval. Rather its impact on the global economy, by allowing the reversing of social distancing and quarantines, would be dramatic, saving the world economy billions, if not trillions of dollars.

John Loike *is a bioethicist and professor of biology at Touro College in New York;* ***Matthew Cobb*** *is a professor in the Division of Evolution & Genomic Sciences at University of Manchester in Manchester;* ***Patricia J. Williams*** *is* ***University Distinguished Professor of Law and Humanities*** *at Northeastern University School of Law in Boston;* ***Robert Pollack*** *is a professor of biological sciences at Columbia University in New York*