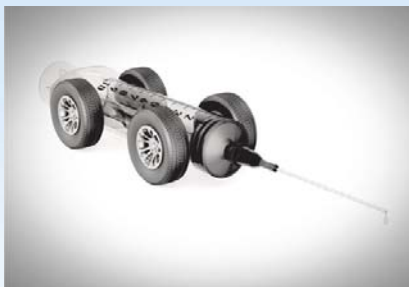


Accelerating Vaccine Development

"As a society, we must continue to insist that vaccine development and production be held to the highest ethical standards, especially during the accelerated push arising from the present pandemic."



Creating a new vaccine and bringing it to market typically requires more than a decade of research and clinical testing. Many companies and research groups are working overtime to shorten this timeline dramatically in the wake of the Covid-19 pandemic.

Some have suggested it may be possible to develop a vaccine within a year or two, but such a feat would be a first, especially considering that no vaccine for any type of coronavirus has ever been successfully developed.

The former director at the Food and Drug Administration's Office of Biotechnology put it this way:

"Scientists have tried unsuccessfully for decades to develop a vaccine to prevent HIV/AIDS and a 'universal' flu vaccine that wouldn't need to be reformulated and readministered every year. All have been duds."

Another specialist in the field of infectious diseases, when asked about the prospects of a quick Covid-19 vaccine, demurred, saying it would require a "home run" and "nearly everything to go right."

Some vaccines end up taking so long to develop that the original

threat disappears by the time they become available, as happened, for example, with the Ebola vaccine after the original viral outbreak in Africa.

Nevertheless, scores of laboratories are now urgently working to develop a Covid-19 vaccine. Their haste in trying not only to save lives, but also to beat their competitors, raises the concern that biomedical researchers may succumb to temptations to cut corners ethically in the research and development phases of their work.

One concern involves safety testing. The bar for safety has always been very high for vaccines that are to be administered to healthy people, and typically tens of thousands of people need to be systematically tested before a new vaccine receives approval and becomes widely available. The first rotavirus vaccine (RotaTeq) was tested on 72,000 healthy infants, while the newest shingles vaccine (Shingrix) underwent safety testing on about 29,000 people. And those tests were done only after extensive testing on animals had been completed.

Such large-scale testing is a formidable and meticulous task requiring a good deal of time and

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expense so that the purported treatment doesn't unintentionally harm those it intends to help. In terms of Covid-19, the concerns about safety are even greater, since some developers are looking at novel and largely unproven technologies, like mRNA vaccines and DNA vaccines, raising further safety questions that may require additional time to sort through during the phase of clinical trials.

Another concern involves the proposal to shorten the timeline by soliciting young, uninfected volunteers who would be intentionally infected with the virus after having been given either the potential vaccine or a placebo. This "challenge trial" approach would enable researchers to assess the effectiveness of a proposed vaccine more rapidly than a traditional clinical trial, which would require waiting for some of the participants to become infected in the course of ordinary life.

Experts who favor this approach say that they have already heard from many people willing to volunteer. Carrying out a challenge trial for a virus with no known cure clearly involves risk. There is no way to predict what kind of reaction a volunteer may have from either the virus or the proposed vaccine; even

the young and healthy could end up hospitalized or dying.

While it is not intrinsically unethical to take actions with a degree of risk for the good of the community, provided that it comes with the patients' full and informed consent, questions about whether it would be prudent to do so need to be carefully addressed. Given the significant competitive pressures arising from many dozens of companies and research teams trying to get to the finish line first, big pharma needs to remain vigilant about over-stepping the boundaries of reasonable risk.

A final concern in attempting to speed up vaccine development involves the use of human cell lines derived from abortions. A variety of cell lines are available for Covid-19 research and vaccine development, some originating from hamsters, mice or other mammals, some from insects, and some from humans. The cell lines from humans may come from acceptable sources, like human skin, or from problematic sources, like direct abortions. Regrettably, several of the Covid-19 vaccine candidates that are being developed today have relied on cell lines that were harvested from aborted fetuses. Scientists have a duty to avoid the use of

such unethically derived cell lines and should instead select available alternatives as they ramp up their research programs.

Vaccines, of course, are real "game changers" in public health. As a society, we must continue to insist that vaccine development and production be held to the highest ethical standards. This is especially true during the accelerated push arising from the present pandemic, lest we foster practices meant to save lives by risking the lives of other vulnerable human beings.

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