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Rushing COVID-19 Vaccine Development: Is It Justified?

The U.S. is joining the COVID-19 vaccine race with a massive testing effort planned for this year, and Russia might start vaccinations this autumn. While many warn against rushing the vaccine development, others point to ethical ways to potentially accelerate the trials.

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Massive Testing in U.S.

With the aim of delivering a vaccine by the end of 2020, the testing in the U.S. will involve over 100,000 volunteers and several vaccine candidates, Reuters reports. To complete the process, which can usually take years, competing vaccine manufacturers have agreed to share data and clinical trial networks with each other, if needed. After small early studies the safest candidates will be tested in trials, expected to begin in July, of 20,000 to 30,000 subjects. The total number of enrolees may be as large as 150,000 people.

This initiative is part of Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), a public-private partnership, and of the research and development arm of 'Operation Warp Speed,' the national programme of coronavirus vaccine development.

There are 14 candidates on the list, including a Moderna Inc. vaccine, developed in partnership with the National Institutes of Health (NIH). At a later stage it may be joined by a vaccine from the UK's Oxford University and AstraZeneca Plc., and from some other giants, such as Johnson & Johnson, Sanofi and Merck & Co.

According to Dr Anthony Fauci, director of the National Institutes of Allergy and Infectious Diseases at NIH, the vaccine could be available by December or January. However, Merck CEO Kenneth Frazier in an interview to CNBC said that although he was not in a position to give any timelines, in general "clinical trials take a long time." In another interview, he noted that targets of 12-18 months were "very aggressive" – a point reiterated, among others, in a discussion on Medscape.

According to the World Health Organization's draft landscape of COVID-19 candidate vaccines, as of 27 May, there are 10 candidate vaccines in clinical evaluation and 155 in preclinical evaluation.

Desperation vs. Scientific Rigour

In a recent article in JAMA, Trogen and colleagues warn about adverse consequences of rushing a COVID-19 vaccine. "Good science requires rigor, discipline, and deliberate caution. Any medical therapy approved for public use in the absence of extensive safeguards has the potential to cause harm, not only for COVID-19 prevention efforts and vaccine recipients, but also for public trust in vaccination efforts worldwide," they write.

Among the potential issues they list vaccine hesitancy and refusal resulting from negative past experiences as well as inability to ensure fast and efficient distribution of a vaccine. While acknowledging the improvement in the vaccine-related policies, they caution that, "what cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values."

Likewise, European Medicines Agency (EMA) Executive Director Guido Rasi noted that "the rapid approval of therapeutics and vaccines will only be possible if applications are supported by robust and sound scientific evidence that allows the EMA to conclude on a positive benefit-risk balance for these products."

Human Challenge Trials

Another research, published in the Journal of Medicine Ethics, focusses on how a vaccine development could potentially be accelerated by allowing consenting volunteers to be deliberately infected with COVID-19 in an ethical way. The article analyses arguments for and against such methods and provides broad guidelines concluding that human challenge trials can be permitted in a context where delay is critical.

Meanwhile, in Russia, developers of a coronavirus vaccine at the Gamaleya Scientific Research Institute of Epidemiology and Microbiology have self-administered the vaccine and are reported to have developed immunity to the infection. According to the organisation's head Alexander Ginzburg, they did it not so much as testing, but rather to protect themselves to continue working. In another interview Ginzburg said that mass COVID-19 vaccination in Russia might start later in autumn while Russia's health minister Mikhail Murashko told the State Duma that the first batch could be available as early as in July.

There are, however, reservations about how much the world can expect from the vaccines against the novel coronavirus. It may as well be that with COVID-19 achieving sterilising immunity with a vaccine will not be possible, since immunity with human coronaviruses and other pathogens that cause respiratory tract infections may last as little as months.

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