Going first: the ethics of vaccine self-experimentation in coronavirus times

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In the context of the COVID-19 pandemic, a number of scientists have been conducting experiments on themselves voluntarily and deliberately, with the goal of finding a vaccine against the virus. This practice is not new. In the past, scientists and physicians embarked on self-experimentation to develop polio, typhoid and rabies vaccines. Famous self-experimentation research includes Barry Marshall's ingestion of helicobacter culture to prove that the bacteria cause gastrointestinal disease and Werner Forssmann's insertion of a catheter into his own heart to demonstrate this procedure could be done safely [1]. Although self-experimentation has helped to elucidate the aetiology of treatable diseases and to advance in medical procedures, some self-experiments led their subjects to permanent disability and death [2].

Self-experimentation was a common practice in medical research before the institutionalisation of ethical research through the Nuremberg Code, the Helsinki Declaration, institutional review boards and research regulations. Until the late 20th century, researchers viewed self-experimentation as an ethical approach to doing science, given the ethical implications of exposing others to the potential negative effects of untested interventions. Today, this idea is far from mainstream research ethics. However, based on the premise that exceptional times demand exceptional actions, the urgency to find and develop a vaccine for COVID-19 has fuelled a renewed debate on the ethics of self-experimentation [3].

In early 2020, a group called Rapid Deployment Vaccine Collaborative (RaDVac) [4] began the design, production and self-administration of progressive generations of nasal inoculations, which could potentially act as a vaccine against COVID-19. At least 20 scientists and inventors are participating in this so-called "citizen science" vaccine initiative and are taking the inoculation, including George Church and Preston Estep, two renowned researchers at Harvard University. The RaDVac group is developing its vaccine without the permission of the US Food and Drugs Administration (FDA) nor with any ethics board approval, and they have so far not published any results showing that their vaccine leads to the creation of antibodies against the virus in humans [5]. Other self-experiments for a COVID-19 vaccine include scientists working in China, Germany, Russia and the United States [6].

Some authors have argued that scientists' enthusiasm with their own experiments may get in the way of good judgement, and that modern regulatory and ethics review systems provide a better route to determine when, how and who should participate in an experiment [7]. Although this argument opposes some of the recent self-experiments that have been carried out to find a COVID-19 vaccine, it is not necessarily in conflict with self-experimentation per se. Scientists could in principle request approval from their ethics boards to conduct self-experiments, although it is doubtful they would be prepared to grant it. Even though the Nuremberg Code authorised self-experimentation, most subsequent ethics regulations (e.g., the Declaration of Helsinki) do not address the matter directly, leaving self-experimenters in a grey zone. Given the resurgence of this type of initiative in the unprecedented situation that we are in, we think it is worthwhile to ask: Is self-experimentation ethical in a pandemic, and if so, under what conditions?

An important argument against self-experimentation is its potential risk of exerting undue pressure on research team members. Think of a team of senior and junior scientists, in which senior scientists suggest embarking on self-experimentation. Junior members may not wish to participate as study subjects in the experiment, but fear that by refusing to participate they might not be invited to future projects. To overcome this potential pressure, junior team members may be excluded from participating as research subjects when their employers or supervisors lead the study. This would still allow junior researchers to self-experiment on studies led by themselves.

In the context of vaccine development, self-experimentation may be harmful in at least three ways. First, it may cause dangerous immune reactions. However, as a counter-argument, all new vaccines are potentially risky, and if the risks have been properly assessed, there are no reasons to believe that self-experimenters would be exposed to higher risks compared with participants of standard vaccine trials. Second, self-experimentation in vaccine development could pave the way for quackery, where experimenters may be tempted to sell or give away products they found to work well on themselves but have not passed standard testing. Drug regulation would typically take care of this issue. Third, potential vaccines developed through self-experimentation may give a false sense of protection to

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users outside the research community. Recently, a professor in Brazil communicated the RaDVaC group his intention to produce their nasal inoculation against COVID-19 in his laboratory and to distribute it for free [6]. Given the absence of scientific evidence regarding the effectiveness and safety of this product, distributing it among the public could create a false sense of protection (as users may relax protective measures) and provoke direct negative health effects. This case illustrates the blurry boundaries between self-experimental studies and early use of new vaccines that have not undergone standard testing.

Arguments raised to support self-experimentation include its potential to benefit humanity, to foster scientists' education, and to promote a culture of responsibility and public trust. Self-experimenters have played a crucial role in vaccine research by taking the initial risk of injecting themselves as a quick and cheap way to get new data, making it safer for others to follow [2]. Another reason to support self-experimentation is its potential as an educational method. As study subjects, researchers can obtain valuable information about their work and this experience may increase the quality of their investigations [8]. Moreover, scientists who participate as study subjects express solidarity towards their study participants, fostering a "culture of responsibility" in which researchers understand and embrace ethical requirements [8]. Relatedly, self-experimentation is also a way to earn public trust in research because it demonstrates the researcher's genuine commitment to the quest for knowledge [8].

In the times of the coronavirus pandemic, the timely development of a vaccine has an immense potential to improve global health. In this context, self-experimentation may be a valuable means to achieve faster pre-research results, which, if promising, could undergo standard vaccine trials. Moreover, considering that vaccine hesitancy has been identified as one of the world's top global health threats by the World Health Organization [9], self-experimentation in the development of a COVID-19 vaccine may increase public trust in vaccination.

However, self-experiments may also backfire on public trust if done in risky ways. If self-experimentation is conducted without ethical approval, if researchers are put under undue pressure to try vaccines in themselves, or if self-experimenters start distributing vaccines that have not undergone standard trials, the public may lose confidence in science. The potential role of self-experimentation in the search for a vaccine is in urgent need of further clarification.

Invitation

Forum for Global Health Ethics: Self-Experimentation in Times of Covid-19 (online event)

The Institute of Biomedical Ethics and History of Medicine (IBME) of the University of Zurich together with the Swiss Medical Weekly have organised a forum to discuss the ethics of self-experimentation with international experts who hold different views on the matter.

Speakers:

- *Prof Rebecca Dresser (Daniel Noyes Kirby Professor, Washington University in St. Louis)*
- *Prof Preston Estep (Founder, Rapid Deployment Vaccine Collaborative – RaDVac)*
- *Prof Samia Hurst-Majno (Director of the Institute for Ethics, History and Humanities, University of Geneva)*
- *Dr Peter Kleist (Director, Zurich Cantonal Ethics Committee)*

December 16, 2020

10:00 am to 11:30 pm ET / 15:00 pm to 16:30 pm CET

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