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Perspective

Self-experimentation in the COVID Era: Is it morally justifiable? – A perspective

1. Introduction

Self-experimentation refers to when researchers have conducted experiments on themselves. Many self-experimentation studies are not published due to the lack of ethical approval, fear of employers' consequences or social punishment. The urgency to develop a vaccine for COVID-19 has refueled the tradition of self-experimentation and has sparked extensive discussion in the world of research ethics about the morality of self-experimentation.

1.1. 'Prevalence and practices' of recent self-experimentation

To date, the 'Nuremberg Code' is the only direct address to self-experimentation for medical ethics regulations. Article five says: "No experiments should be conducted where there is a prior reason to believe that death or injury will occur; except, perhaps, in those experiments where experimental physicians also serve as subjects" [1].

A group called RaDVaC (Rapid Deployment Vaccine Collaborative) started the design, production, and self-administration of several progressive generations of nasal inoculations, which could potentially become a vaccine for COVID-19 infection [2]. Over 20 scientists have participated in this so-called 'Citizen Science' COVID-19 vaccine research and this group has been working without approval from FDA (Food and Drugs Administration) or any other ethics committee, with similar projects being carried by many other groups [3].

1.2. Ethics of self-experimentation in the 21st century

The ethics of self-experimentation lies in a gray zone for morality, law, and policy. A 2019 survey looking at the documents addressing self-experimentation found that Institutional Review Boards (research ethics committees in the USA) differed widely in their opinion about "whether self-experimentation even warrants ethical review" and they concluded that there was no consensus on this vital issue, highlighting the discordance at even the highest levels of research oversight [4].

Two types of ethical arguments have been proposed to support self-experimentation in the current era: 'Beneficence-based arguments' and 'Liberal arguments'.

1.2.1. 'Beneficence-based arguments'

'Beneficence-based arguments' advocate self-experimentation, as they will benefit the participants and the society at large. For example, the recent RaDVaC group's approach to the development of a nasal vaccine has allowed the participants to use an intervention that might reduce the risk of a deadly disease like COVID-19 when no alternative was available and mortality was a very real outcome [2]. The RadVaC group published its white paper (first version) in July 2020, months before any approved vaccine was available. The group was able to do this as the development and testing bypassed various regulatory approval, which is mandatory for any formal clinical trial. The 'Beneficence-based arguments' assume that the potential benefits of the self-experimentation via open-source approaches exceeds the potential harm, hence it is a positive step in the current crisis.

However, benefits and meaningfulness of self-experimentation are also vital issues. The question of benefit is inextricable from whether 'n-of-1' experiments, like case reports, have any meaning. However, a case report originates from a random, uncontrolled experience, whereas self-experimentation can be performed in a planned and controlled environment. Hence, even with the power of 'n-of-1', self-experimentation may reflect improved experimental outcomes.

1.2.2. 'Liberal arguments'

'Liberal arguments' are arguably more compelling than 'Beneficence-based arguments' as they are based on the value of individual freedom and allow people to make their own decision about what risks are acceptable for them in self-experimentation when only limited information available and life could be at risk without doing anything. John Stuart Mill's advocates that "–the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others" [5]. So, if self-experimentation is not harming others it would be unjustifiable and unduly paternalistic to prohibit it, even if the expected self-harms are larger than the expected benefits.

However, if the vaccine is ineffective or administered wrongly, this will give false security to the participants with disastrous consequences. Those participants would be engaged in a higher risk of transmission and failing to take an effective vaccine would leave them vulnerable to the full brunt of the disease themselves. Widespread confidence in the vaccine is essential for its acceptance. The failure of a self-experimented, unapproved vaccine could potentially jeopardise the confidence of the public for all vaccines, leading to vaccine hesitancy, a real challenge to the COVID-19 vaccination drive. In the worst case, if the self-experimented vaccines cause harm, that will cause a further burden on the already stretched health system.

It is also possible that many of the participants will be influenced by the hierarchy of their research group. The junior staff or students of the group may not wish to participate, but they may fear that by refusing they might not be part of the team in future projects and affect their career progression. Hence, they may become vulnerable to coercion.

2. Conclusion

If self-experimentation is recognised formally, more self-experimenters would seek oversight and review. The role of the ethics committee for the review of self-experimentation should be inspiring and persuasive, acting as a mirror for better self-reflection. Ethics committee oversight should be available for self-experimenters to a similar extent as any other formally organised research. The process should be inexpensive and simple so that self-experimenters feel empowered to access this facility. Without the threat of redundancy or social ostracism, self-experimentation may gain a spotlight with champions leading from the front rather than hiding their work and results.

It has also been shown that most self-experimentation is conducted secretly [4]. Hence, an attempt to ban self-experimentation is likely to be self-defeating and potentially encourage further secrecy. It is more advisable to attain a balance between institutional hostility and scientists' overenthusiasm. Ideally, the experimenters should be encouraged to take ethics approval with the aim to help their work be peer-reviewed, providing appropriate guidance to reduce the risk of self-harm and also facilitate their work for publication in leading journals.

It is important to recognise the potential pitfalls of coercion, quackery, and jeopardisation of public confidence with self-experimentation, but is equally important to recognise the freedom and agility it gives researchers to exponentially accelerate scientific advancement. Therefore, with appropriate oversight of the of ethics boards and destigmatisation of the practice itself, many of the dangers may be avoided while retaining the benefits of self-experimentation, as ultimately we all share the same goals towards public safety and should work together to achieve it.

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