Postmodern Openings
ISSN: 2068-0236 | e-ISSN: 2069-9387
Covered in: Web of Sciences (WOS); EBSCO; ERIH+; Google Scholar; Index Copernicus; Ideas RePeC; Econpapers; Socionet; CEEOL; Ulrich ProQuest; Cabell, Journalseek; Scipio; Philpapers; SHERPA/RoMEO repositories; KVK; WorldCat; CrossRef; CrossCheck

2020, Volume 11, Issue 1 Supl. 2, pages: 20-28 | https://doi.org/10.18662/po/11.1sup2/136

Some Research Ethics Questions during the COVID-19 Pandemics. What Prospects for the Future?

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Abstract: This article attempts to review a few of the most pressing questions that have been discussed in the aftermath of the COVID-19 outbreak. The general questions concerning research of potentially dangerous viruses, the ethical issued connected to the clinical trials that are undergone, as well as the relationship between benefits and risks involved in vaccine research are considered. The characteristics of the present emergency situation causes sometimes the ethical principles to be adapted. Therefore, those who chose to modify the ethical principles must act in a responsible way, even if this responsibility is of a moral nature, instead of a juridical one.

Keywords: *research ethics; COVID-19; pandemics; viruses; clinical trials; vaccine research.*

How to cite: Frunză, M. (2020). Some Research Ethics Questions during the COVID-19 Pandemics. What Prospects for the Future?. *Postmodern Openings, 11*(1Supl2), 20-28. https://doi.org/10.18662/po/11.1sup2/136

1. Introduction

The novel coronavirus that leads to the COVID-19 disease has brought about a situation that forced us, as a society, to take some unprecedented global measures in order to limit its spread. As of mid-April 2020, the disease affected close to two million people around the globe and claimed more than 150.000 lives. As in any global pandemic, the actual number of cases is probably under-reported, and scientists estimate the number of real cases to be at least 10 times bigger (Javan et al, 2020). As no effective treatment is yet available, many countries are focusing their efforts towards researching the disease, either for finding a therapy, or for discovering a more suitable way of preventing people from infection in the future.

In this article, I made an attempt to review several areas of research ethics that are particularly relevant in these conditions, namely:

• Safety questions triggered by the research on potentially dangerous viruses;

• Ethical issues connected to the projected and on-going clinical trials that attempt to find a cure for the already infected patients;

• The benefits vs. risks involved in the process of developing a vaccine.

Apart from these questions, there are at least two areas of research ethics I am not going to specifically address here, because I have written elsewhere: the questions regarding vulnerability, and the pressing issues related to ethics of allocating scarce resources (Frunza, 2020a, in press).

Concerning the vulnerability issues, I have argued elsewhere that although the official discourse describes the disease as the grand equalizer that erases all kinds of differences among patients by threatening all of them, in reality some categories of individuals are more affected than others, especially because they cannot self-isolate themselves the way the rest of us can (Frunza, 2020b).

There are several limitations of the present article that I want to openly discuss from the beginning. As many aspects concerning the present pandemic are still unknown, there are many ways in which any prospective analysis, even the ones guided by the best intentions, could go wrong.

There were very few times in history when Socrates' famous saying "I know that I know nothing" has offered such an accurate description for a globally ongoing crisis. Moreover, this crisis overpasses everyone's general expertise, and there is no single discipline to provide a set of coherent

answers regarding how to best solve the crisis. State authorities and public experts are divided concerning the near future: how long is this pandemic going to affect us? how soon are we going to find effective ways to cure it and to prevent it? which is the best exit strategy from the current lockdown? etc.

I therefore agree to Alex Broadbent's opinion that the voice of philosophers is important in the present debate, as "this pandemic is subject to nobody's expertise" (2020). What philosophy can offer is, on the one hand, the long-standing practice of "epistemic humility" (Angner, 2020) – a more fancy name for the longstanding Socratic philosophical tradition of knowing the inherent limits of one's analytical power in uncertain times. If the biggest thing to avoid when assessing the unknown is epistemic biases and over-confidence (Angner, 2020; Koriat, Lichtenstein & Fischhoff, 1980, 108), as philosophers we can attempt to counter them by critically scrutinizing all the claims we make, and being prepared to retract them when proved wrong by future developments. This is a caveat I am willing to assume – so consider yourselves warned.

2. Bio-safety issues of research on dangerous pathogens

The history of research ethics has been marked by (in)famous cases when people have unnecessarily and deliberately been subjected to various diseases and dangers, without being able to assess the degree of risk, in order for the researchers to test different remedies. Cases such as the experiments on prisoners in the Nazi concentration camps from the second World War, the syphilis Tuskegee study, the radiation studies at the University of Cincinnati and many others have shown that in the absence of an ethical framework, research can go wrong in many ways that are detrimental for participants' well-being and in extreme cases can claim their lives (Loue, 2007, pp. 1-35).

In this context, the existing allegations that the current COVID-19 outbreak could be in any way connected to the activity of a Wuhan-based research lab specialized on research on bat viruses have to be carefully considered (Rogin, 2020). Although they are more than likely false allegations, at present there is still incertitude concerning the precise way the pandemics started, as the so-called "patient 0" has not been found yet and the current working hypothesis that connects the pandemics to the Wuhan wet market remains to be confirmed. It is problematic that these allegations are currently supported by the current US presidential administration, as

they have the potential of shattering public trust and fueling the ongoing conspiracy theories that are deleterious for any research environment.

Even if these allegations are going to finally be dismissed, the activity of all research institutes involved in similar research is probably going to be more closely scrutinized and possibly even limited by moratoriums similar to the 2014 moratorium in US for research on viruses that cause SARS (Butler, 2015). There are disagreements in the scientific community concerning the bio-safety issues of some aspects of viruses research, particularly the "gain-of-function" studies (where researchers increase the risky characteristics of pathogens) ("Biosafety in the balance", 2014).

Although the scientists directing these studies claim they show how understudied pathogens could develop into foreseeable threats, thus helping us to better prepare for future pandemics, critics question their relevance, as it is unclear whether in real life actual pathogens will mutate into something that resembles the researchers' models. Moreover, critics warn about the risks these "chimaeric viruses" pose, if accidentally leaked from the laboratories. As studies show, accidents do happen even in the most carefully organized laboratories, some having dire consequences ("Biosafety in the balance", 2014).

In the near future, it is possible that research on such human-made or human-enhanced pathogens will have more restrictions, laboratory activity will be more regulated, and resources (that have already been severely affected by the present pandemics) will be redirected towards other areas.

3. Ethical challenges of clinical trials of COVID-19

Concerning the existing research directed towards finding an effective cure for the ongoing and future COVID-19 patients, there are researchers claiming that not involving current patients in rigorous clinical trials represents both wasting valuable resources and subjecting vulnerable persons to unnecessary risks. There is the risk to repeat the mistakes from the Ebola outbreak in 2014, where no new therapies were discovered, because almost no one attempted to validate the efficacy of their attempted cures via a controlled clinical trial (Kalil, 2020).

The implications of not conducting research are ethically worrisome, as many promising drugs in vitro have proved ineffective in clinical trials, many drugs that are currently used in hospitals have serious known side effects that could worsen the patients' condition, and may have additional effects that have not been studied because of their limited administration.

Furthermore, not involving participants in controlled research will only perpetuate a spiral of non-participation, mistrust and fear that are going to be detrimental in the long run (Kalil, 2020).

When researchers do involve patients in clinical trials, it is imperative that the ethical principles generally governing research with human subjects remain in place and are specified to the characteristics of this pandemics (Tansey, 2020).

One important pre-condition is obtaining participants' consent, while preserving the scientific characteristics of the study – but sticking to the rigorous inclusion and exclusion criteria (Sandu &Frunza, 2019). Researchers have to take into account that patients will be especially vulnerable and desperate to try anything that resembles a therapeutic intervention. When they request consent, they will have to make sure they are not fuelling unrealistic hopes, and inform participants of the incertitude of benefits vs. risks involved. They have to accurately transmit the information that some participants might still not receive the desired intervention, but will be given a placebo instead. Various alternatives might be needed to grant consent, as a significant proportion of participants might be seriously ill and/or unconscious – in these cases, proxy consent or even deferred consent (obtained after the patient has been stabilized) could be considered (Tansey, 2020).

Medium-scale and large-scale clinical trials have already started worldwide, such as "Solidarity", coordinated by WHO (Savulescu, 2020) or "Recovery", with more than 5000 participants, in UK (Boseley, 2020). Even if researchers are reserved for the moment and do not want to rise false hopes, it is presumed that their results will show which of the current therapies have better prospects for the patients (Boseley, 2020).

For future research, it is important for researchers to present in a transparent and timely way their results, in order to increase the chances of patients facing the disease worldwide. As soon as results are going to be released, the future clinical research will be better calibrated to explore novel therapies, as the new ones will be compared with the new standard treatment, instead of non-intervention (placebo). In the present conditions of shrinking economies, it is going to be challenging both to make the treatment available globally and to maintain its costs at an affordable level for everyone. However, the responsibility towards "maximizing preparedness", that includes the capacity to produce antiviral treatments, is an ethical recommendation that has been articulated by CDC already in 2007 (Kinlaw & Levine, 2007, p. 1).

4. Ethical issues in vaccine development

Vaccine research represents an area of research ethics that the scientist and the general public are looking into with great hopes, as it would offer a more effective way of preventing the transmission of the virus while allowing large categories of population to resume their activities. However, developing, testing, certifying and mass-producing large amounts of doses of a novel vaccine is a timely process that usually takes between 18 and 36 months (Kahn, 2020). The first problem is whether this process can be sped up without loosening the ethics and endangering lives.

As of mid-April 2020, there are currently 78 vaccine projects launched around the world, several of them already in phase one trials – in US, China and the UK (McKie, 2020; Thanh Le et al., 2020).

One way of speeding up the process is by eliminating a part of the steps in the usual process – skipping the testing on animals before administering it to healthy human volunteers (Kahn, 2020), a process that has been done both in the US and China. If this is the case, participants to trials must be informed on the skipping of steps, and their consent should reflect this.

A more ambitious way of speeding the process is by simultaneously mass-producing the vaccine doses while still undergoing the trials, an attempt pursued by the Oxford University team of researchers who have started phase one human trials while simultaneously started to mass produce one million of doses to be ready in September 2020 (Kelland, 2020). In this case, the benefits of the attempt, if successful, will be enormous, but the risks of ending up with a million doses of inefficient substance are also considerable. "Who can afford to finance a similar project?" is by no means a purely rhetorical question, as costs estimates are in the order of millions.

Yet another way to hasten the process is a "human challenge study": to deliberately infect healthy volunteers with the virus, in order to see whether a candidate vaccine is effective (Savulescu, 2020; Eyal, as cited by McKie, 2020). The main ethical problem is that, in this particular kind of study, volunteers are deliberately exposed to a disease that is incurable with the risk of complications and death. Currently, the existing ethical framework specifically prevents research with human participants that may lead to the death of the participants (Loue, 2007, pp. 32-34). However, scientists are considering the controlled exposure of volunteers, simultaneously with providing them the best medical care available (McKie, 2020).

It can be safely predicted that this area of research will be ardently explored in the upcoming months and years. Some worries could concern the possibility of duplicating efforts: if researchers' teams will not cooperate, valuable financial resources, time, and human lives will be wasted. The other type of worries stems from allowing scientists to expose volunteers to unknown risks, including the risk of death, as part of the most ambitious attempts to hasten the producing of a new vaccine.

5. Conclusion

Ethical principles are important to be preserved, even during the exceptional situation of a global pandemic. However, the characteristics of the present emergency situation sometimes require the ethical principles to be balanced and specified, and even adapted (Akrami et al., 2018). Therefore, those who chose to modify the ethical principles must act in a responsible way, even if this responsibility is of a moral nature, instead of a juridical one.

Acknowledgment

The author has benefitted from financial support of Babes-Bolyai University in the framework of a grant for supporting research, competiveness and excellence at institutional level No. AGC-32948/31.07.2019.

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