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Viewpoint Article

Research ethics challenges during the COVID-19 pandemic: what should and what should not be done

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Abstract

This article is directed primarily at how clinical trials can be ethically conducted in the midst of the current global COVID-19 pandemic. We explain why ethical issues are more complicated than they once were. Furthermore, we discuss the relevant parties` roles in protecting participants` rights and keeping basic research ethics of justice, respect, equity, and beneficence strongly implemented.

Keywords: COVID-19 pandemic, Ethic committee approval, Article, Saudi Arabia

Background

In the time of COVID-19, where coronavirus disease has spread across the globe infecting the four corners of the Earth, research centers and major laboratories are frantically racing to come forward with a medicinal formula that kills the virus and ends the hardship. Aside from the disease being phenomenally contagious, to date, it has no treatment.

The COVID-19 crisis has emerged first as a health issue and shortly branched around to affect the economy and politics strongly. Moreover, it ruined societies at large, leaving no social life to speak of. As a result of the political conflict as to why and where the pandemic has stemmed from, the global powers came up to heated arguments where every part is determined to win the battle whatever it costs. Amid the unprecedented international storm, research bioethics loom large among the many things that will never be taken for granted again as COVID-19 crises continue.

Researchers' biggest concern is that high authorities might come to a point to put their gains ahead of volunteers' safety. Several ethical concepts are prone to be overlooked. In harsher words, today, research bioethics are more likely to be violated than ever. This academic article will emphasize the research ethics implementation and discuss the major challenges that researchers and regulatory bodies might face. Furthermore, it explores new ways of reciprocity and collaborations among academia, researchers, scientists, and high authorities surrounding the role of both local and international research ethics boards to authorize future research plans during a pandemic in accordance with the ethical principles of respect, beneficence, and justice.

Working in a collaborative team

Today, people worldwide are in one trench facing a common threat, and monitoring the pandemic spread in grave concern. They look highly on scientists and researchers to guide the ship to a safe harbor. It would be preposterous for each research center to work independently. Starting a new trial from scratch means going through the same issues again exposing new volunteers to unnecessary risks. Effective communications among scientists to share preliminary trials` results help them conduct comparable study designs and characteristics that make systematic reviews and meta-analyses, subsequently, easier, and juicier. Clinically actionable data must diffuse rapidly crossing borders, even when such knowledge does not meet the rigorous standards of clinical trials [1,2].

Expedited reports of a study drug

Novel interventions to prevent and treat COVID-19 are needed all over the world. Likewise, there is a similar need for reciprocity. Most of the highly reputable publishing houses have made COVID-19 related research articles open to access in a bid to create a shared pool of data about the pandemic. Sharing the pharmacological data of a drug in a trial is invaluable to reduce adverse drug events that could claim lives [3]. On top of that, sharing information could change the product safety profile and probably helps make more sound decisions by the regulators. Such actions could be in the form of pausing or terminating an ongoing study. Expedited reports should include all severe expected and unexpected; related, and unrelated adverse drug reactions (ADRs). Different jurisdictions

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have different reporting time frames as to routine and expedited reporting.

Debriefing at research centers

Debriefing is an informal experience exchange session designed to improve team performance and effectiveness from lessons learned and reinforce positive behaviors. It is a high quality-standard implemented in different industries, where the health industry is no exception [4]. At world-class businesses, briefing and debriefing are ingrained in the staff`s culture. Sharing debriefing minutes on public health domains helps researchers avoid taking unnecessary risks of trying a drug if proved elsewhere not to be effective. It cannot be overemphasized that scientists worldwide are prompted to stay connected to share relevant drug and device manufacturing information honestly and quickly.

What institutional research boards (IRBs) can do?

As researchers and participants' safety is concerned, IRB should ensure that data collectors must adhere to social distancing rules and wear personal protective equipment such as face masks and shields, gowns, gloves, and whatever applies at this time. Moreover, for observational studies where face-to-face interviewing and focus grouping are necessary, they should be either adjourned or carried out electronically. Electronic communication could be live, in-writing, or videotaped. In addition to meeting the safety requirements, many secure online platforms provide the privacy and confidentiality researchers need. The downside of electronic communication is making de-identification more complex and data breaches possible as participants could be identified even if they subscribed using a pseudonym. There are several ways to resolve these issues, such as turning off the camera and making phone interviews. Still, they mean that the researchers and participants cannot see each other during the interview. Submitting research proposals, in-paper, to IRBs must be banned, as only electronic submissions should be permitted. Studied surrounding COVID-19 should not wait for their turn to be reviewed by the entire ethical board members. Instead, they should be put on a fast-track approval process. To qualify for priority review, the application must be for a drug that treats a serious condition and, if approved, would significantly improve safety or effectiveness; such criteria are fully met by the COVID-19 condition [5]. Adhering to the expedited review policy, unarguably, saves time that could be translated to saving lives.

The disadvantaged communities

As with other pandemics, COVID-19 has revealed the interdependence of a globalized world. We must bear shared responsibility for solutions as we collectively confront the problem. On a closer look, COVID-19 infection is behaving fairly in the sense that it affects poor and rich countries equally. Being impartial makes treating the two groups the same from a research ethics perspective. That is to say, selecting volunteers to participate in a study pertaining to a new vaccine, for instance, would require the two parties to be tried on unbiasedly. Ethically, when a poor population is tried on medicine, they should not be denied a full management course if the studied medicine proved effective. Failure in doing so is going, once again, through a classic example of a research ethics challenge that goes back to 1996 when the first antiretroviral drug had revolutionized the treatment of acquired immunodeficiency syndrome (AIDS), for sub-Saharan African sufferers. Unlike indigent nations, affluent often have the capability to conduct the clinical trials as wished for. The knowledge clinical trials produce and the innovations that result must be disseminated by a commitment to justice in ensuring equitable access to resultant guidance [6].

Judicious utilization of resources

In areas with limited resources where the stock of standard treatment or tests for COVID-19 is short, judicious utilization of what is available is a great ethical concern. As COVID-19 cannot be diagnosed reliably on a symptomatic basis because its manifestations mimic the seasonal Flu, the insufficient testing kits should be spared for the neediest individuals. Dispensing a valuable test kit or medicine at these critical situations should be according to a priority list. Critically ill patients with suggestive symptoms must top the list, followed by hospitalized individuals and health-care workers (HCWs). The latter is viewed as soldiers in battling the virus. When HCWs are served early, they would be able to go back soon to work and fight the virus again to save lives. Among hospitalized patients, those who are fighting to live must be prioritized. Screening the community for COVID-19 should come down to a complete halt when resources are scarce. In areas where poor governments require their people to undertake their public liability by purchasing the diagnostic test and doing it at home, an intricate issue might arise. Nasopharyngeal swabbing is not an easy technique that ordinary people could reliably perform at home. That would be a huge breakthrough if the healthcare system was flooded with false-negative results of COVID-19 giving a false impression of an infection-free community. Major world authorities such as world health organization (WHO) usually take the lead in supporting developing nations.

Treating vulnerable groups

Minorities, prisoners, and illegal immigrants should not be discriminated against in peace, not to mention in crises such as natural disasters and epidemics [7]. In more specific terms, vulnerable populations must not be obliged to partake in experiments against their will. It is essential to ensure that participants are aware of their unconditional right to withdraw at any time during the study and the potential risks in taking part in given research, including the risk of an online session being overheard on either end of devices. It is unfair to select vulnerable individuals to be enrolled in a study sparing the rest of the population. In doing so, the study results would carry many specifications to the minority worked upon, and, therefore, it will not be reliably generalizable – ruining the external validity of the research. Participants, whatever minority they belong to, should not be denied health services related to COVID-19 as public health is the major concern at this point. Jurisdictions should not deport infected illegal immigrants before treating them. Looking at the picture at large, deporting poor infected individuals will help spread the disease elsewhere on the planet. Besides, the infection would cross back to where it came from, probably, in a severer form.

The "human challenge trials"

Producing a timely, reliable Covid-19 test that can be deployed among the population would be a concrete step to flatten the curve and limit the pandemic's impact. But even once an effective solution could be discovered and deployed on the ground, this comes with its own set of ethical issues. Practically, infecting volunteers with the virus or part of it could accelerate developing a vaccine; but raises tough ethical questions. The ethical challenge is that; is it acceptable to deliberately infect healthy people with a disease that could kill them, and for which there is no cure? An ethical question that demands answers [8,9]. The United States Food and Drug Administration (FDA) has offered to work with those interested in conducting human challenge trials to evaluate these issues. The WHO has issued a paper outlining the key criteria for Covid-19 human challenge studies' ethical acceptability. Among these, the initial studies should be limited to healthy young adults aging 18 to 30 yrs., in whom fatal infection rates are estimated at 0.03%. In an attempt to minimize the potential biohazard on participants, health workers, and research sites, The NIH group suggests developing a special “challenge strain” with reduced virulence to administer in challenge trials.

Conclusion

The research community must work as one team across continents. They are required to be flexible at research methodologies, yet rigid in implementing research ethics in the time of COVID-19 pandemic and beyond.

Abbreviations

ADRs: Adverse Drug Reactions; AIDS: Acquired Immunodeficiency Syndrome; IRBs: Institutional Research Boards; HCWs: Health-Care Workers; WHO: World Health Organization; FDA: United States Food and Drug Administration

Declarations

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Availability of data and materials

Data will be available by emailing atifkatib@gmail.com

Authors’ contributions

Atif Abdulhamid Katib (AAK) is the principal investigator of this manuscript (Viewpoint). AAK is the responsible author for the study concept, design, writing, reviewing, editing, and approving the manuscript in its final form. AAK has read and approved the final manuscript.

Ethics approval and consent to participate

We conducted the research following the Declaration of Helsinki. However, Viewpoint Articles need no ethics committee approval.

Consent for publication

Not applicable

Competing interest

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References

1. Moorthy V, Restrepo H, Preziosi MP, Swaminathan S. Data sharing for novel coronavirus (COVID-19). Bull World Health Organ. 2020; 98: 150. http://dx.doi.org/10.2471/BLT.20.251561
2. Angus DC. Optimizing the trade-off between learning and doing in a pandemic. Epub ahead of print, 2020. https://doi.org/10.1001/jama.2020.4984)JAMA
3. Park YR, Koo H, Yoon YK, Park S, Lim Y-S, Baek S, et al. Expedited Safety Reporting to Sponsors Through the Implementation of an Alert System for Clinical Trial Management at an Academic Medical Center: Retrospective Design Study. JMIR Med Inform. 2020;8(2): e14379. https://doi.org/10.2196/14379.
4. Bae J, Lee J, Jang Y, Lee Y. Development of simulation education debriefing protocol with faculty guide for enhancement clinical reasoning. BMC Med Educ. 2019;19(1):197. https://doi.org/10.1186/s12909-019-1633-8.
5. Cox EM, Edmund AV, Kratz E, Lockwood SH, Shankar A. Regulatory Affairs 101: Introduction to Expedited Regulatory Pathways. Clin Transl Sci. 2020;13(3):451-461. https://doi.org/10.1111/cts.12745. Epub 2020 Feb 6.
6. Rivenbark JG, Ichou M. Discrimination in healthcare as a barrier to care: experiences of socially disadvantaged populations in France from a nationally representative survey. BMC Public Health. 2020;20(1):31. https://doi.org/10.1186/s12889-019-8124-z
7. Arsenijevic J, Tummers L, Bosma N. Adherence to Electronic Health Tools Among Vulnerable Groups: Systematic Literature Review and Meta-Analysis. J Med Internet Res. 2020;22(2): e11613. https://doi.org/10.2196/11613
8. Plotkin S, Robinson JM, Cunningham G, Iqbal R, Larsen S. The complexity and cost of vaccine manufacturing: An overview. Vaccine. 2017;35(33):4064–71. https://doi.org/10.1016/j.vaccine.2017.06.003.
9. Deming D. Do extraordinary claims require extraordinary evidence? Philosophia (Ramat Gan). 2016;44(4):1319-1331. https://doi.org/10.3389/fpsyg.2011.00117