Bioethics and informatics in medical studies during the coronavirus disease 2019 pandemic

To the editor We have recently read with great interest the special report on the ethical dimensions of the coronavirus disease 2019 (COVID-19) pandemic by Dr Jakub Pawlikowski,[1] published in the May issue of *Polish Archives of Internal Medicine* (*Pol Arch Intern Med*). The intense focus on COVID-19 is certainly warranted.[2] But in addition to those directly affected by the pandemic, the disease has also an indirect ethical impact. For example, continuing medical studies must face the challenge of accounting for patients' added COVID-19 risks.

Ethically, we are responsible for monitoring patients under the protocols of the study for risks that may affect their health. By taking part, patients are already exposing themselves to some level of risk associated with study participation. In the era of increased risk to one's health, that risk can compound. Informing patients of potential risks, monitoring, and testing are critical, not only ethical but also methodological, considerations.

From a methodological perspective, COVID-19, even if not fatal, can significantly affect overall health and therefore the response to the studied treatment.[3] The individual risk of patients contracting COVID-19 is not stochastic but rather varies geographically. In April 2020, the risk of dying of COVID-19 in New York City was significantly higher than in other Unites States locations.[4] As a result, any geographic concentration among patients can affect the results of the study, as control or experimental groups may include different numbers of affected individuals. The risk of getting sick from the virus is therefore essential to model statistically, which cannot be successful without careful patient monitoring.

And even if only a minimum number of patients in the study contract COVID-19, self-isolation and social distancing may affect patients' health, including mental health.[5] If patients differently self-isolate and quarantines vary in length in different places, the effects on every patient will range geographically and will need monitoring.

Careful monitoring of patients is necessary for many ongoing medical trials, because the implications for not doing so are both methodological and ethical. Social science methodologies, such as interviews, surveys, and ethnography, may provide effective tools for this type of work and may do so with an eye toward the growing costs.

ARTICLE INFORMATION

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