PROJECT MUSE®

Clinical Research Through the COVID-19 Pandemic: Crisis Response, Consequences and Innovation

David Altschul

Narrative Inquiry in Bioethics, Volume 11, Number 1, Spring 2021, pp. 15-16 (Article)

Published by Johns Hopkins University Press

DOI: <https://doi.org/10.1353/nib.2021.0004>

➔ *For additional information about this article*

<https://muse.jhu.edu/article/800041>

Branch-Elliman, W., Elwy, A.R., & Monach, P. (2020). Bringing new meaning to the term “Adaptive Trial”: Challenges of conducting clinical research during the coronavirus disease 2019 pandemic and implications for implementation science. *Open Forum Infectious Diseases*, 7(11). doi:10.1093/ofid/ofaa490

Clinical Research Through the COVID-19 Pandemic: Crisis Response, Consequences and Innovation

David Altschul

Usually, I am a dual trained open and endovascular neurosurgeon. While working at a prominent academic medical center in New York City, my main focus has always been clinical care first. This all changed at the beginning of March 2020, when our city became inundated with patients severely ill with COVID-19. The health system had to restructure to manage the load, and elective surgeries were canceled and stayed canceled for 3 months while we collectively pivoted primarily towards managing the pandemic.

The research that I had done in the past primarily involved large dataset outcome studies for patients with brain aneurysms or acute ischemic stroke. We had a small team of very capable persons who were adept in curating electronic data from electronic health records. At the beginning of March, many of the early reports were coming in of COVID patients suffering major strokes and other neurologic symptoms. In the middle of March, with a large portion of my usual clinical activity suddenly restricted, we jumped into action designing a retrospective-prospective observational cohort study to try to identify which COVID patients were at risk for developing neurologic manifestations. In order to properly conduct this research, our group needed information on all COVID-19 patients presenting to our health care network.

We were one of the first research groups in our system to submit an IRB protocol, and thankfully through the major healthcare restructuring, the

IRB stayed open. At the time, our local IRB had given utmost priority to COVID-19 related studies. These submissions were given immediate attention and the turnaround time on approval was quite rapid, particularly as it pertained to non-interventional observational studies. The rapidity of our approval gave us a head start and access to invaluable resources within our data warehouse group, which was able to ping us all the patients we were investigating with COVID-19. Probably about a week or two after starting, access to this data became restricted as nearly every research group in the system was having similar ideas. There were also growing institutional concerns about the public health message they were trying to portray, layered with the fear that outcomes in certain areas of New York City appeared worse than others. No one wanted to be considered the system that was doing a bad job managing the pandemic or their patients.

In tandem, it became apparent that many other clinician researchers wanted access to similar information. A counterpart in the Department of Neurology and I teamed up to create a research network of interested researchers who wanted to have access to information on COVID-19 patients. We were able to use Microsoft Teams as a centralized hub to help create networks of research groups for parties with similarly aligned research interests while also preventing overlapping research ideas. We could assign roles within specific projects and defuse any potential squabbles about authorship. As researchers expressed interest, we were able to easily add our IRB to add additional team members with nearly same-day feedback. By the end of the project, there were over 50 researchers involved with various observational projects with clinician researchers looking at a variety of topics including COVID and ischemic stroke, COVID and hemorrhagic stroke, COVID and epilepsy, COVID and encephalopathy, COVID and race/ethnicity, and COVID and neuromuscular disease. While Teams was the hub for our centralized research machine, it was important to keep it maintained and protected and to ensure no patient information was placed in the group. This, in addition to managing the projects and making sure everyone who wanted

to be involved was included, became a large part of my job during the months of April and May. We used RedCap to maintain the protected patient information in a database and monitored access to it to ensure compliance. The effort to maintain compliance could not have been done well without the invaluable work from our research team, including our research coordinator and research nurse.

During this time, the IRB deftly maneuvered and created new action items within the IRB submission process. These action items highlighted the specific needs related to COVID research in order to speed up the approval process. The only major institutional challenge we faced was when it came time to potentially collaborate with other institutions; the policies regarding data sharing when it came to COVID-19 patients were very restrictive initially. It took quite some time to arrange data user agreements in order to be able to look at these issues within a larger patient population.

I believe that, during the worst months of the pandemic, it was likely very hard for the IRB to ensure compliance for researchers actually conducting research. Despite these difficulties, maintaining an active IRB throughout the pandemic to support research endeavors was an essential part of understanding more about this illness. For our group, these endeavors ended up in many manuscript publications that likely improved our understanding of the disease.

Interestingly, however, research outside of COVID-19 did take a back seat. One clinical trial we were beginning to start up right before the pandemic began had to halt. This delay in enrollment lasted 3 months. The clinical research arena suffered, as did the clinical arena. Many patients with diseases not related to COVID-19 suffered as a consequence of this pandemic.

While the pandemic clearly did more harm than good, there were some important lessons learned through it. For one, the idea of in-person informed consent became a serious challenge as hospitals restricted visitors for a portion of the time. Transitioning to a remote world for clinical care and research will likely be invaluable, particularly in our arena of neurologic disease. Many stroke trials

involve patients that lack capacity and require a family member or health care proxy to enroll in studies. Finding these individuals when managing a condition like stroke, where every minute counts in order to save brain tissue, is a major challenge and barrier to enrollment in clinical trial research studies, particularly for disadvantaged groups, which often have complicated social structures.

Creating electronic applications for which e-consents can be performed and time stamped has the chance of increasing enrollment of patients with diverse social, racial, and ethnic backgrounds for whom in-person consent and enrollment may have previously been a barrier to inclusion. Of course, anything electronically driven comes with its own potential ethical risks as they pertain to data security and data permanence.

Sometimes it takes adversity in order to properly reassess the status quo. I am hopeful that through all of this, on the other end of the pandemic, it will be possible to conduct ethical research with less bias and increased accessibility.

COVID-19 Clinical Trials: A Voice From the Front Lines

Eric Lenze

Acknowledgments. Thanks to co-investigators and research staff in the STOP COVID trial.

Funding. COVID Early Treatment Fund (treatearly.org), Taylor Family Institute for Innovative Psychiatric Research, and FastGrants.

Getting Involved in COVID-19 Treatment Research

I am a clinical trialist because I believe that high-quality clinical trials save lives and improve health. They do this both by showing that new treatments are helpful and by determining that potential treatments are unhelpful and should