***The 2021 Medicine for Ethicists Paper Topic:***

***Ebola Vaccines***

The Ebola virus is responsible for a hemorrhagic fever that starts with fever, sore throat, muscular pain and headaches and can progress to liver and kidney dysfunction causing internal and external bleeding. The average mortality rate from the disease is 50%. In March, 2014, an outbreak in Guinea exploded, spreading to Liberia and Sierra Leone. This outbreak caused over 11,000 deaths, with approximately 10% of those being health care workers. More recent outbreaks in 2017 and 2018 have occurred in The Democratic Republic of Congo.

Several vaccines are in development against Ebola in an incredible, massively coordinated public health effort, the likes of which had been seen prior to COVID – for-profit corporations, NGOs, Western and African governments, WHO, MSF. The rVSV-ZEBOV vaccine, for example, is a genetically-engineered “vesicular stomatitis virus” vaccine which was developed by the Canadian National Microbiology Laboratory and was licensed to a small firm, NewLink Genetics. The vaccine was subsequently sublicensed to Merck, which “assumed responsibility for ongoing research and development.” The vaccine was used in these countries by Western institutions “experimentally” with the approval of the Democratic Republic of Congo.

The FDA approved the rVSV-ZEBOV “Ervebo” vaccine for use in the United States in 2019. The FDA granted the application [Priority Review](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review) and a [Tropical Disease Priority Review Voucher](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program) under a program intended to encourage development of new drugs and biologics for the prevention and treatment of certain tropical diseases. The FDA also granted [Breakthrough Therapy designation](https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy) for Ervebo to facilitate the development and scientific evaluation of the vaccine. Because of the public health importance of a vaccine to prevent EVD, the FDA worked closely with the company and completed its evaluation of the safety and effectiveness of Ervebo in less than six months.

For an in-depth monograph on the subject, see *Integrating Clinical Research into Epidemic Response: The Ebola Experience*, a publication of the National Academies Press (available for free download online). This committee is critical of the Phase III trial that showed the vaccine to be remarkably effective. Note the involvement of bioethics in this publication – Michelle Mello was on the committee and I. Glenn Cohen was a reviewer.

“Health care and public health, like science itself, are built on the cumulative experience of the past, which serves as the basis for our expectations and the foundation for new knowledge generation.”

Please write an 8-14-page paper, double spaced, in 12 point font about some topic having to do with Ebola vaccines and Ebola vaccine trials. The topic can be one of your choosing, but please do clear the topic with me before you start writing. Please focus on **ethics** and include some **evidence-based medicine analyses** in your paper. If you really get into it, write something you can publish.