Evening Ethics Discussion

“Ethical Challenges in Pediatric Vaccine Clinical Trials”
with Steven Joffe, MD, MPH
2020-21 David Green Memorial Speaker

Wednesday, April 28, 2021
5:30pm-7pm

To date, the FDA has granted emergency use authorization to three vaccines—from Pfizer/BioNTech, Moderna, and Janssen—against SARS-CoV-2. However, with the exception of the Pfizer/BioNTech vaccine, which has received authorization for adolescents ages 16-17, none of these vaccines is authorized for children. The inability to vaccinate children has implications for their health, for their ability to return to school and other activities, for their parents’ ability to work, and for restoring the nation’s economic and social life. The fact that SARS-CoV-2 vaccines are not authorized for pediatric use reflects children’s limited inclusion in clinical trials of candidate vaccines. The reluctance to pursue pediatric trials of SARS-CoV-2 vaccines is due in turn to ethical concerns with and regulatory barriers to vaccine research in children, concerns that are heightened because severe COVID19 disease is rare in children. In this session, we will discuss the ethical and regulatory hurdles to conducting SARS-CoV-2 vaccine trials in children, explore the rationales for moving forward as rapidly as possible with these trials, and describe the strategies that are available to overcome the challenges.

Background readings for this session: (for pdf’s, contact linda.carrlee@hsc.utah.edu)
“Enrolling Minors in COVID-19 Vaccine Trials,” by Kevin Mintz, PhD, et.al.
“SARS-CoV-2 vaccine testing and trials in the pediatric population: biologic, ethical, research, and implementation challenges,” by Dan M. Cooper, et.al.

Optional:
“Covid Vaccines for Kids Are Coming, but Not for Many Months,” by Apoorva Mandavilli
“Why Kids Might Be Key to Reaching Herd Immunity,” by Sarah Zhang
“The Importance of Advancing Severe Acute Respiratory Syndrome Coronavirus 2 Vaccines in Children,” by Carol M. Kao, et.al.

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