CBER BEST Initiative Seminar Series

Date:
April 27, 2022

Time:
11:00 -12:00 PM EST

Topic:
Addressing Selection and Confounding Bias in Test-Negative Study Designs for Flu and COVID-19 Monitoring

Background:
The CBER BEST Initiative Seminar Series is designed to share and discuss recent research of relevance to ongoing and future surveillance activities of CBER regulated products, namely biologics. The series focuses on safety and effectiveness of biologics including vaccines, blood components, blood-derived products, tissues and advanced therapies. The seminars will provide information on characteristics of biologics, required infrastructure, study designs, and analytic methods utilized for pharmacovigilance and pharmacoepidemiologic studies of biologics. They will also cover information regarding potential data sources, informatics challenges and requirements, utilization of real-world data and evidence, and risk-benefit analysis for biologic products. The length of each session may vary, and the presenters will be invited from outside FDA. Please see the details below for our upcoming seminar. **Anyone can register and join for free.** Stay tuned for more details and additional webinars during the course of the year.

Description:
The test-negative design (TND) has become a standard approach to evaluate vaccine effectiveness against the risk of acquiring infectious diseases such as Influenza, Rotavirus, Dengue fever and more recently COVID-19 in real world settings. Despite the TND's potential to reduce unobserved differences in healthcare seeking behavior (HSB) between vaccinated and unvaccinated subjects, substantial variability in unobserved HSB may remain among study participants. As latent HSB is likely also a strong predictor of selection into the TND sample, confounding bias of the vaccine's causal effect by latent HSB may be induced by collider stratification bias resulting from the TND. Other potential sources of confounding may include occupation as healthcare worker or previous infection history. If not directly addressed, such confounding bias and collider stratification bias can lead to misleading conclusions about vaccine effectiveness. In this article, we propose a novel approach to identify and estimate vaccine effectiveness in the target population based on the TND sample, by carefully leveraging a pair of negative control exposure and outcome variables to account for confounding bias induced by either a hidden common cause of vaccine and infection, or vaccine and selection into the TND sample, or infection and selection into the TND sample. Our simulation studies confirm that our proposed estimators can effectively account for unmeasured confounding and outcome-dependent selection into the TND sample. We apply our method to study COVID-19 vaccine effectiveness using data from University of Michigan Health System.

Presenter:
Dr. Eric Tchetgen Tchetgen

Eric J. Tchetgen Tchetgen is the Luddy Family President's Distinguished Professor at the Wharton School of the University of Pennsylvania. Professor Tchetgen Tchetgen comes to the University of Pennsylvania from Harvard University, where he has served since 2008 as Professor of Biostatistics and Epidemiologic Methods with joint appointments in the departments of Biostatistics and Epidemiology at the T.H. Chan School of Public Health. He researches infectious diseases, including HIV/AIDS, and the role of genetic and social factors in the patterns, causes, and effects of public health. Professor Tchetgen Tchetgen has received grants from the National Institutes of Health and the Centers for Disease Control. He completed his Ph.D. in Biostatistics at Harvard University in 2006 under the supervision of Professor James M. Robins. He received his B.S. in Electrical Engineering from Yale University in 1999.

Registration:
https://northeastern.zoom.us/webinar/register/WN_Q2Cu83c2T2KEauCph5KFxw