

1147-62-328

Yu Shen* (yshen@mdanderson.org). *Challenge and promise of observational epidemiological studies in cancer medicine.*

The complexity of sampling mechanisms and various biases associated with epidemiological observational studies raise considerable statistical challenges in both the design and the data analysis. Standard analysis methods and design tools for clinical trials are often not applicable and, in fact, are invalid for prospective cohort studies. The peril of selection bias is exacerbated in prevalent cohort studies, because randomly sampled patients from the cohort are often not random samples of the target population. Although the issues about biased inference have been recognized in the medical, epidemiological and statistical and applied mathematics literature, there are limited tools available for the efficient design of observational studies and flexible modeling of data from these studies. To address the above challenges, we need practical statistical designs and innovative analytic approaches to evaluate clinical effectiveness and healthcare interventions outside of controlled clinical trials. We will show examples and provide practical tools for estimating sample size, and innovative methods for analyzing time-to-event data observed from prevalent cohort studies. (Received January 19, 2019)