BIOSTATISTICS SEMINAR



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Improving the design of pragmatic clinical trials with real-world data

Clinical trials embedded in health systems can randomize large populations by using automated data sources to determine trial eligibility and assess outcomes. We will describe how health system data was used to design the suicide prevention outreach trial (SPOT). SPOT randomized 18,868 individuals with self-reported thoughts of self-harm or death recorded in the electronic health record across four health systems. This took 3.5 years. While this is a great accomplishment, we would like to evaluate suicide prevention interventions on a faster time scale. We discuss how predictive analytics, specifically a risk prediction tool we have developed through the Mental Health Research Network, can be used to design clinical trials. We compare the populations that might be enrolled using different entry criteria and the necessary sample size to detect a 15%, 25%, and 25% in the 90-day suicide attempt-rate across these different populations.

Thursday October 10, 20193:30 pm - 4:30 pmBlue Cross and Blue Shield of North Carolina Foundation Auditorium



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