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The Validity of Test-Negative Case-Control Design

We study a test-negative case-control design (TNCC), which is an extension of the traditional case-control design, in which the study population consists of subjects seeking health care services due to acute respiratory illness. Subsequent laboratory testing is then performed to confirm disease outcome. Due to its simplicity, the TNCC has become the “gold standard” for estimating vaccine effectiveness (VE) for influenza and rotavirus. By modeling the case and control series as independent Poisson processes, we show that the TNCC provides a consistent estimate of VE. The rationale, interpretation and several methodological issues of TNCC designs are also discussed.