

*Honest Inference From Observational Database Studies*

David Madigan, Columbia University

Observational healthcare data, such as administrative claims and electronic health records, play an increasingly prominent role in healthcare. Pharmacoepidemiologic studies in particular routinely estimate temporal associations between medical product exposure and subsequent health outcomes of interest and such studies influence prescribing patterns and healthcare policy more generally. Some authors have questioned the reliability and accuracy of such studies, but few previous efforts have attempted to measure their performance. We have conducted a series of experiments to empirically measure the performance of various observational study designs with regard to predictive accuracy for discriminating between true drug effects and negative controls. I describe this work, explore opportunities to expand the use of observational data to further our understanding of medical products, and highlight areas for future research and development.