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Bayesian Approaches to Modeling Uncontrolled Confounding in Biopharmaceutical Data

Randomized controlled trials are often regarded as the most accurate method to assess treatment effects in pharmaceutical studies; however such studies are not always possible or practical. In addition these studies have limitations in that they often under-represent some groups because of the extended time required from trial design to completion and the abbreviated time of drug exposure. For example, groups such as the frail or elderly may be a larger proportion of the drug consumers and therefore experience more adverse events, but only a small proportion of the study design. On the other hand, with observational studies, it is possible to include a wide variety of participants and assess long-term exposures of medications. However since observational studies do not have the benefit of treatment allocation by randomization, bias due to confounding can be present. Some confounding factors are unobserved and others are difficult to measure. For example, in a study of a blood pressure medication researchers will have access to the dosage of medication, but might not have knowledge of whether the participant is a smoker. In another situation, the frailty of an elderly patient may not be unobserved, but not easily measured or assessed. Several methods have been proposed for modeling the effects of these confounders. Schneeweiss (2006) has proposed methods that approach the problem from an epidemiological standpoint. In addition Greenland (2009) and McCandless and Gustafson (2010) consider a Bayesian missing data approach to the problem. These Bayesian methods have not been applied to the meta-analysis case in which the results of several studies or information from several databases are combined. It is the primary goal of this research project to extend the results of McCandless and Gustafson (2010) to modeling data from meta-analyses.