### METHODS

- A targeted review was conducted in PubMed using the key term “propensity score” for years 2014 and 2015 in the following five leading pharmacoepidemiology journals: American Journal of Epidemiology, Drug Safety, Epidemiology, European Journal of Epidemiology, and Pharmacoepidemiology and Drug Safety.

- Articles were included if they were nonrandomized cohort studies with at least one principal objective of examining treatment safety and presented results from a sample using the following PS analysis methods: stratification, matching, regression adjustment, or inverse probability weighting. The PS analysis could have served as a primary, secondary, or sensitivity analysis.

- In addition, each study was evaluated to determine if any sample reduction was reported and whether this determination was based on a detailed description and summary information on patient characteristics and safety outcomes for the overall population and the excluded population.

- The review was conducted in January 2016. Two independent reviewers examined each article to determine eligibility and classification. In the event of a conflicting review, a third opinion determined eligibility.

### RESULTS

**Summary of PS Methods and Sample Size Reduction**

- PS matching was used by 13 articles, making it the most frequently used method among the 18 eligible articles, followed by regression adjustment (4 articles) and inverse probability weighting (3 articles); stratification was implemented in 2 of the articles (Table S1). Note that 3 articles applied more than one PS method (e.g., a reported primary and secondary analysis using different PS methods).

- Only a single article performed PS distribution trimming (inverse probability weighting, regression adjustment, or stratification). The single article trimmed percentiles in a stratified analysis.

- Articles that used PS trimming, the sample size of the treatment group and the comparator group were commonly reduced as part of the matching algorithm. In some articles, the reduction of sample size for the treatment group was more than 50% (Table 2).

- Additionally, two articles that used PS-matching methods trimmed the overall population prior to implementing the matching algorithm.

**Summary of Reported Patient Characteristics and Safety Outcomes**

- When PS matching was used, researchers commonly reported patient characteristics on the overall sample and the PS-matched sample. In addition, seven studies reported safety outcome analyses using the overall sample (e.g., hazard ratios of the safety event [Table 2]).

- The one article that performed PS distribution trimming in a stratified analysis reported patient characteristics and safety outcome information (i.e., prevalence) by treatment group but what seemed to be the overall sample.

**Across all studies, no article reported summary statistics on demographics or safety outcomes specifically on the excluded patients.**

### DISCUSSION AND CONCLUSIONS

- When PS trimming is conducted in safety cohort studies, researchers often have additional information on the overall and analysis (e.g., PS-matched sample without presenting information on the excluded patients. Not missing important pieces of information when evaluating the study’s generalizability and a treatment’s safety profile).

- When the sample on the study treatment are excluded/trimmed patients with a PS in the areas of nonoverlap and/or with extreme PS values, the exclusion may increase the risk of unmeasured confounding: dealing with observations in the tails of the propensity score distribution.

- Regardless of the PS method used, patients can be excluded from the study treatment group and the comparator group. When PS trimming is conducted in safety cohort studies, patients with a PS in the areas of nonoverlap and/or with extreme PS values, the exclusion may increase the risk of unmeasured confounding: dealing with observations in the tails of the propensity score distribution.

- This can be especially important for patients with a high prevalence of a safety outcome with a narrow confidence interval and/or with extreme PS values, what seemed to be the overall sample.

- Across all studies, no article reported summary statistics on demographics or safety outcomes specifically on the excluded patients.

### CONTACT INFORMATION

Dawn Odom, MS
Pharmacovigilance
RTI Health Solutions
2014 Summit Ave
Research Triangle Park, NC 27709
Phone: 1919.356.3529
Email: doomd@rti.org

### REFERENCES


