A1-3:

The Performance of Propensity Score Methods for Estimating Hazard Ratio in Time-to-Event Data

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Background/Aims: Propensity Score (PS) methods have been used increasingly in observational studies to reduce bias due to confounding. The performance of PS for estimating hazard ratios (HR) has not been systematically studied. Monte Carlo simulations were performed to evaluate four methods of utilizing PS: 1:1 matching, stratification, PS adjustment, and inverse probability weighting (IPW). **Methods:** Twelve variables (6 binary, 6 continuous), varying in their association with treatment and outcome, were generated. Five of each were related to both treatment and outcome, and the remaining were associated with outcome. Two scenarios were considered. Scenario #1: 20% of the sample was treated and variable distributions differed between groups. Scenario #2: treatment assignment was associated with the variables. One thousand data sets with 5000 samples each were generated. Time-to-event data were generated from an exponential distribution. Each method was evaluated by controlling treatment only, treatment+confounders, treatment+outcome-related variables, and all potential covariates. **Results:** Controlling treatment only, matching methods yielded the least biased estimate (~40%) in both scenarios if the condition HR >1.0 was true, while PS adjustment performed best if the condition HR <1.0 was true. In both scenarios, an unbiased estimate was attained if, and only if, all potential covariates were controlled, regardless of method. **Conclusions:** All PS methods resulted in a biased estimation of the true HR if the treatment estimate is not conditioned on all confounders and outcome-related covariates. The least biased estimation occurs when treatment and confounders are controlled in the PS covariate adjustment method and IPW method. Comparing the four methods, stratification on PS performs better than other methods, followed by matching. The bias was reduced by controlling for confounders if treatment and confounders were strongly associated, or by controlling for outcome-related covariates if outcome was strongly associated with covariates. In addition, unbiased estimates are attained without applying any PS methods as long as all potential covariates are controlled in the model.

Keywords: Propensity Score Methods; Time-to-Event Data; Bias

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A1-4:

Pragmatic and Adaptive Methods of Electronic Medical Record (EMR) Cohort Identification for Comparative Effectiveness Research

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Background/Aims: Accurate EMR-based cohort identification is crucial in the conduct of comparative effectiveness research. CheCS is a longitudinal study of chronic hepatitis B (CHB) and C (CHC) infection being conducted at 4 HMORN sites. Subjects are identified using automated EMR-based ICD-9 diagnosis and laboratory inclusion criteria, and about 12,000 patients were identified in the initial cohort selection. After confirmation of CHB/CHC status through chart abstraction, we found false discovery rates (FDR) were 13.6% for CHB and 11.3% for CHC. An adaptive approach was proposed to optimize the EMR-based cohort selection. **Methods:** Classification and Regression Tree (CART) was performed to identify a set of electronic variables (or variable combinations) for CHB and CHC. The variables/classifiers that were considered included not only all the initial cohort identification criteria, but also HIV status, any outpatient order or pharmacy claim for CHB/CHC antiviral medication, and 41 other liver disease-related procedures/diagnoses. The analysis began with CART model building using one set of data (learning), followed by model validation using the other set of data (testing). **Results:** Of the 12,144 patients identified for the initial CheCS cohort, 2518 met initial CHB criteria and 9844 met initial CHC criteria, including 218 who met criteria for both. Of these, 10,825 (2176 CHB and 8724 CHC, including 75 co-infected) patients' diagnoses were

confirmed through chart abstraction and the remaining were excluded. CART model FDRs were 8.5% on learning data and 7.1% on testing data for CHB, and 4.9% and 5.7% for CHC, yielding sensitivities and specificities >91% for CHB and >84% for CHC. Overall, FDRs were significantly lower (7.8% for CHB, 5.3% for CHC) than those yielded from the initial inclusion criteria alone ($P < 0.001$). **Conclusions:** Our adaptive approach to using electronic data for prediction of CHB/CHC status is feasible, can be used for sequential CheCS cohort identification, and may be useful in other studies to identify patients diagnosed with CHB/CHC.

Keywords: Cohort; Identification; Adaptive

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PS1-1a:

Use of the CER Hub to Identify Out-of-Control Asthma and Compare Therapeutic Classes of Step-Up Asthma Medications in Clinical Practice

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Background/Aims: Asthma is a chronic inflammatory condition that imposes a substantial burden on patients and society. A major target in asthma care is guideline adherence to disease control assessment and therapy. Our aim was to develop an electronic medical record (EMR) based measure of provider determination of asthma control and use it to assess different treatment modalities employed in out-of-control asthma to allow observational comparative effectiveness research (CER) on different types of step-up therapy. **Methods:** We developed EMR-based abstraction rules to allow automated determination of asthma control during clinical encounters, a construct that indicates need for treatment intensification. The EMR-based measure operationalizes components in the Expert Panel Report-3 recommendations for assessing a patient's level of asthma control across the domains of risk and impairment. We used manual chart abstraction on samples of encounter records provided by six diverse health systems participating in the CER Hub project, to develop and validate the EMR-based measure of asthma control. **Results:** We identified over 185,000 patients diagnosed with asthma across CER-Hub during 2006-2010. Provider documentation (predominantly text clinical notes) was rich in data related to asthma control including aspects of impairment (patient-reported symptom frequency, nighttime awakenings, interference with activity, frequency of rescue inhaler use, and lung function) and risk to patient well-being such as asthma exacerbations and use of systemic corticosteroids. Using the automated medical record classifier MediClass, which enables access to both coded and free-text components of the record, we will assess patients on low-dose inhaled corticosteroid therapy whose asthma is not well controlled. We are using the EMR-based measure to investigate the comparative effectiveness of the following step-up therapies (1) addition of a leukotriene modifier, (2) addition of a long-acting beta-agonist, and (3) increase to higher dose inhaled corticosteroids. **Conclusions:** Traditional large database studies have been unable to assess elements of asthma control, such as symptom frequencies or activity limitations, because these clinical data are typically only available within free-text progress notes documenting the patient visit. The CER Hub asthma control measure provides new capacity to evaluate the comparative effectiveness of asthma interventions across diverse healthcare settings and in large real-world populations.

Keywords: Assessing Provider Behavior; Asthma; Asthma Control Assessment

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