Plenary III–02:

Propensity Score-based Sensitivity Analysis Method for Uncontrolled Confounding

Lingling Li, PhD[1,2]; Changyu Shen, PhD[3]; Xiaochun Li, PhD[3]

[1]Harvard Medical School; [2]Harvard Pilgrim Health Care Institute; [3]Indiana University School of Medicine

Background: Uncontrolled confounding remains a major concern for comparative effectiveness and safety results obtained from analyzing observational studies, especially those using existing healthcare databases. Sensitivity analyses are of paramount importance and usefulness in assessing the effect of possible uncontrolled confounding on the estimates of the parameter of interest to adequately evaluate the validity of the corresponding results and inference. **Methods:** We develop a sensitivity analysis method to address the issue of uncontrolled confounding in observational studies. In this method, we quantify the hidden bias due to uncontrolled confounding using a one-dimensional sensitivity function (SF), which depends on the propensity score only. Propensity score is defined as the conditional probability of being assigned to a selected treatment given the measured confounders. The new method nicely reduces the dimension of the sensitivity function, and makes it much easier to impose reasonable assumptions on the sensitivity functional forms and the values of coefficients. In addition, it offers opportunities for robust inference since one-dimensional continuous functions can be well approximated by low order polynomial structures (e.g., linear, quadratic). Therefore our proposed approach is especially useful when limited information is available on the type and mechanism of unmeasured confounders. We construct SF-corrected inverse probability weighted estimators to draw inference on the causal treatment effect. We demonstrate the use of the new method by implementing it to an asthma study which evaluates the effect of clinician prescription pattern about the use of inhaled corticosteroids (ICs) for children with persistent asthma on selected clinical outcomes. **Results:** Without considering uncontrolled confounding, daily-use pattern of ICs appears to be harmful than the periodic-use pattern with an increased risk for uncontrolled asthma during the 12-month follow-up period (odds ratio 2.4, 95% CI, 1.7, 3.9). This seemingly harmful effect of daily-use pattern diminishes as the assumed magnitude of hidden bias increases. Nevertheless, within the considered plausible range, the data does not provide evidence suggesting a significant beneficial effect of the daily-use pattern compared to the periodic-use pattern. **Conclusions:** Our proposed approach provides a practical tool to conduct sensitivity analysis for uncontrolled confounding in observational studies.

Keywords: Uncontrolled confounding, Observational studies, Sensitivity analysis method

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Plenary III–03:

Adherence to Home Blood Pressure Monitoring in Patients with Uncontrolled Blood Pressure

Simrandeep Tiwana, PhD, MBA[1]; Tessa Kerby, BA[1]; Stephen Asche, MA[1]; Nicole Schneider, BA[1]; Michael Maciosek, PhD[1]; Peter Meyers, BS[1]; Linda Loes, MD[1]; Sarah Groen, PharmD[1]; Holly Jewell, PharmD[1]; Krissa Klotzle, PharmD[1]; Ryan Michels, PharmD[1]; Karen Margolis, MD, MPH[1]

[1]HealthPartners

Background/Aims: Home blood pressure monitoring has been advocated as a method for improving blood pressure (BP) control. However, there is little data on patients' adherence to home BP monitoring. The purpose was to study patient adherence to home BP monitoring and telephone visits with a healthcare provider in a randomized controlled trial. **Methods:** The Hyperlink study is a cluster randomized trial in which adult patients with uncontrolled BP are assigned either to the Telemonitoring Intervention (TI) arm or the Usual Care (UC) arm. These preliminary analyses are based on the first 80 participants of a planned enrollment of 450. Patients in the TI arm work with a clinical pharmacist who serves as their case manager and may adjust their treatment according to a protocol. Following one face-to-face meeting, patients and pharmacists meet via phone every 2-4 weeks for a period of 6 months. Patients are instructed to take 2-3 BP readings on 3 mornings and 3 evenings each week, and to transmit the stored BP data to the pharmacist weekly. Adherence is defined as sending = 6 home BP measurements per week. We examined adherence to both telephone visits and the home BP measurement schedule. **Results:** Adherence with the telephone visits was excellent with completion of 359/370 (97%; 95% CI 95%-99%) protocol-mandated telephone visits. Adherence to the home BP measurement schedule was also high, with 73/80 (91%; 95% CI 85%-97%) participants sending an average of >6 BP measurements per week. Participants older than 65 showed greater BP measurement schedule adherence than those younger than 65 (100% versus 86%; p=0.04 by Fisher's exact text). Adherence did not differ significantly by gender, race or employment status. **Conclusion:** Despite an intensive visit and measurement schedule, adherence to blood pressure telemonitoring was very high in the study population. We conclude that blood pressure telemonitoring has the potential to improve BP control by conveying reliable blood pressure data to healthcare providers who can then close the feedback loop by making appropriate therapeutic adjustments.

Keywords: Home blood pressure monitoring, Blood pressure control, Blood pressure telemonitoring

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Plenary III–04:

Responses to Drug Costs: Year Three of the Medicare Part D Program

Vicki Fung, PhD[1]; Mary Reed, DrPH[1]; John Hsu, MD, MBA[1]

[1]Kaiser Permanente Division of Research

Background/Aims: Many Medicare Part D beneficiaries face substantial prescription drug cost-sharing. In the first year of the program, many beneficiaries reported substantial drug use changes in response to the coverage gap. In response, an increasing number of plans offer generic drug coverage during the gap. We compared responses to Part D costs among beneficiaries with generic-only gap coverage and full gap coverage in 2008, the third year of the Part D program. **Methods:** We conducted telephone interviews in a stratified random sample of Medicare Advantage beneficiaries in an integrated delivery system, age 65+ (N=1201, response rate 70.0%). We sampled equal numbers of beneficiaries with generic-only gap coverage, and beneficiaries with no gap due to low income subsidies (LIS) or employer sponsored insurance (ESI). Beneficiaries reaching the gap threshold in 2008 ($2,510 in total drug spending) were oversampled. We examined three cost responses: cost-cutting strategies (e.g., switching to cheaper medications), decreasing adherence (e.g., not refilling a prescription), and experiencing financial burdens (e.g., going without necessities). We used multivariate logistic regression and adjusted for sociodemographic and clinical characteristics and 2008 drug costs. All analyses and percentages are weighted for sampling proportions. **Results:** An estimated 18.4% of beneficiaries reported using a cost-cutting strategy, 2.9% decreased adherence, and 9.6% experienced financial burdens. After adjusting for covariates, compared with beneficiaries with generic-only gap coverage, LIS and ESI beneficiaries were significantly less likely to report each of the cost responses: cost-cutting strategies (OR=0.50, 95% CI: 0.31-0.83 for LIS and OR=0.58, 95% CI: 0.39-0.87 for ESI beneficiaries), decreased adherence (OR=0.36, 95% CI: 0.14-0.92 for LIS and OR=0.21, 95% CI: 0.07-0.62 for ESI beneficiaries), and financial burden (OR=0.51, 95% CI: 0.29-0.89 for LIS and OR=0.41, 95% CI: 0.23-0.73 for ESI beneficiaries). **Conclusions:** Overall reports of cost-related non-adherence were lower compared with earlier reports among beneficiaries with no gap coverage; nevertheless beneficiaries with generic-only gap coverage were more likely to report non-adherence and financial burdens compared with beneficiaries with no gap. However, beneficiaries with no gap were also less likely to switch to cheaper medications, suggesting a need for additional efforts to guide beneficiaries' drug choices.

Keywords: Medicare Part D, Medication costs, Generic drug coverage

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