Evaluating Clinical Guidelines without Randomization

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Introduction

Regression discontinuity design (RDD) is a method for estimating causal effects when randomized trials may not be feasible. RDD uses the fact that individuals close to a threshold for treatment have about the same probability of being just above or just below the cut-off, resulting in treatment assignment that is effectively random. Thus, it can be used to evaluate the causal effect of clinical guidelines when only observational data is available.

Objective: Evaluate Diabetes Diagnostic Criteria

- We use RDD to evaluate diabetes diagnostic criteria using claims data
- Our continuous variable: a patient’s first recorded A1C measurement
- American Diabetic Association guidelines first set in 2010 [1] determined patients with A1C ≥ 6.5% should be diagnosed with diabetes
- This change in guidelines resulted in a jump in diabetes diagnoses at the 6.5% level in records after 2010 (Figure 1)

Our continuous variable: a patient’s first recorded A1C measurement

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Methods: Fuzzy Regression Discontinuity Design

We perform feasibility and covariate balance tests to validate the RDD:
- Is the running variable continuous around the threshold (Figure 3)?
- Is age, gender, and socioeconomic status balanced around the threshold?

We use the ‘fuzzy’ two stage regression with T as our treatment indicator [2]:

\[ P_{\text{diagnosis}} = \alpha_1 + \alpha_2 T + \omega_6 (1 - T) (X_{\text{age}} - 6.5) + \omega_7 (T) (X_{\text{age}} - 6.5) + \epsilon \]

\[ Y_{\text{heart attack}} = \beta_1 + \beta_2 D + \beta_6 (1 - T) (X_{\text{age}} - 6.5) + \beta_7 (T) (X_{\text{age}} - 6.5) + \nu \]

We also evaluate patient’s residualized risk for heart attack:

1. \( P(Y_{\text{heart attack}} = 1) = f(X_{\text{age}}, X_{\text{race}}, X_{\text{gender}}, X_{\text{is smoker}}, X_{\text{HDL}}) \)
2. \( Y_{\text{residual}} = Y_{\text{heart attack}} - f \)

Conclusion and Future Work

- Our RDD analysis shows that the 6.5% A1C guideline reduced heart attack incidence by 155 people per 100k at the threshold
- An RDD approach works well on large, observational claims data; estimating the residualized risk increases statistical power
- Future RDD targets include lipid screening and ER management of infant fever
- Future research will also involve optimization of the threshold itself [3]

References