Evaluating Clinical Guidelines Using Regression Discontinuity Design

Tony Liu, BA¹, Patrick Lawlor, MD, PhD², Lyle Ungar, PhD¹, Konrad P. Kording, PhD¹
¹University of Pennsylvania, Philadelphia, PA, USA; ²The Children’s Hospital of Philadelphia, Philadelphia, PA, USA

Introduction.
Clinical guidelines influence medical screening and diagnosis but change frequently and are sometimes not evaluated experimentally. Regression discontinuity (RD) design is a quasi-experimental technique for estimating causal effects that is attractive in the context of clinical guidelines, as it exploits changes in treatment assignment according to thresholds of a continuous variable, such as age, to estimate treatment effects without the need for randomization. We apply RD designs to diabetes diagnoses using claims data to evaluate various outcomes associated with treatment.

Methodology.
We examine the use of A1C as a diagnostic criterion for diabetes under the RD framework. A1C is a marker of long-term blood sugar control and by American Diabetic Association guidelines set in 2010, an A1C ≥ 6.5% is the basis for diabetes: patients above this threshold should be diagnosed with diabetes. We use Optum’s de-identified Clininformatics® Data Mart Database (2007-2016), which contains medical claims, prescriptions, and labs for patients covered under commercial health plans and Medicare. Patients are filtered for commercial coverage as well as no prior diabetes diagnosis or diabetes drug prescription based corresponding ICD9 and NDC codes in their claims.

Results.
Our pre-guideline data (n=276,714) contained claims between 01/01-12/09, while post-guideline data (n=219,694) contained claims between 01/11-11/16. Both populations are similar, with a mean age of 48.8 years, 48.9% women, 56.8% white, 13.3% black, 12.2% Hispanic, and 3.9% Asian in the pre-guideline population, and a mean age of 49.4 years, 48.9% women, 50.3% white, 12.6% black, 17.2% Hispanic, 6.2% Asian in the post-guideline population. We identify a discontinuity in diabetes diagnoses at 6.5% that is only present in records after 2010 (Figure 1, left). To examine treatments that may accompany diagnoses, we plot the metformin fill rate, a commonly prescribed drug for initial diabetes treatment, which also exhibits a discontinuous jump at 6.5% post-guideline change (Figure 1, right).

![Figure 1](https://via.placeholder.com/150)

**Figure 1.** Diabetes diagnosis (left) and metformin fill rate (right) for patient records from a 2010 pre-post comparison.

Conclusions.
Our preliminary work shows that the 2010 guideline led to more diabetes diagnoses and metformin prescriptions at the A1C threshold, illustrating the feasibility of RD design for evaluating diagnostic guidelines. Limitations of our study include the sample population of only commercial plans, imperfect physician adherence to the guideline, and the incomplete view claims provide on a patient’s medical history. Further investigation will leverage RD to examine diabetes-relevant outcomes such as heart attack incidence, as well as optimize the guideline thresholds themselves. RD designs show promise in evaluating and optimizing clinical guidelines when randomized trials may not be feasible.

References