Impact of Copay Coupons on Diabetes Patients' Access to Insulin

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BACKGROUND

As of 2018, approximately 7.4 million Americans with Diabetes mellitus rely on insulin for survival. For decades, pharmaceutical firms such as Eli Lilly and Company, Sanofi, and Novo Nordisk have advertised supposed patient assistance programs and copay coupons as a way to improve access to the biologic for those who cannot generally afford insulin. Despite differing names, many of these programs work in a similar way, in which a pharmaceutical firm offers to pay a portion of a patient's copay when they are prescribed one of the firm's drugs. Despite the logical benefit to the consumer, little empirical evidence is available to support the effectiveness of such programs. In fact, the United States policy has often pushed back on such programs with various restrictions and bans on their use for Medicare and Medicaid benefactors.

Data

We primarily utilize prescription data from the Centers for Medicare and Medicaid Service's (CMS) "Medicare Part D Prescribers" database. These data sets provide information on which provider-physicians prescribe what insulins, measured annually. To match these prescriptions with coupon programs, we employ Web.archive.org to gather coupon information for every prescription via GoodRx.com and various pharmaceutical firms' websites. We also match these drugs with basic drug facts obtained through approval labels found in the Drugs@FDA database. Lastly, to control for county-level variation in the prevalence of diabetes, we use data from the Centers for Disease Control and Prevention's United States Diabetes Surveillance System matched with geographic codes from the United States Department of Housing and Urban Development's ZIP Crosswalk database.

PRACTICAL APPLICATION

Understanding what impacts patient access to treatment may inform advocates on how to improve patient treatments by increasing the likelihood that patients can receive the optimal treatment.

RESULTS

Zero Model

Zero Model (Binomial with logit link)	
	Fixed Effects
(Intercept)	−3.91***
	(0.13)
West Virginia	0.23
	(0.22)
Treatment	0.09
	(0.08)
Percent of Patients Dual Eligible	1.30***
	(0.25)
West Virginia * Treatment	−0.31
	(0.16)
	Random Effects (Std. Dev.)
Provider-Drug Brand Name (Intercept)	2.74
Provider NPI (Intercept)	1.90
Provider RUCA (Intercept)	0.04
State-County (Intercept)	0.25
State-County-year (Slope)	0.06
State (Intercept)	0.02
State-year (Slope)	0.12
Num. obs.	41089

$^{***}p < 0.001$; $^{**}p < 0.01$; $^{*}p < 0.05$

Table 1: Coefficients for Zero Model

Rate Model

Rate Model (Poisson with log link)	
	Fixed Effects
(Intercept)	−7.73***
	(0.22)
West Virginia	0.74
	(0.35)
Treatment	0.03*
	(0.01)
Percent of Patients Dual Eligible	0.72***
	(0.08)
West Virginia * Treatment	−0.02
	(0.03)
	Random Effects (Std. Dev.)
Provider-Drug Brand Name (Intercept)	0.76
Provider NPI (Intercept)	0.42
Provider RUCA (Intercept)	0.20
State-County (Intercept)	0.83
State-County-year (Slope)	0.03
State (Intercept)	0.02
State-year (Slope)	0.05
Num. obs.	8258

$^{***}p < 0.001$; $^{**}p < 0.01$; $^{*}p < 0.05$

Table 2: Coefficients for Rate Model

Evidence

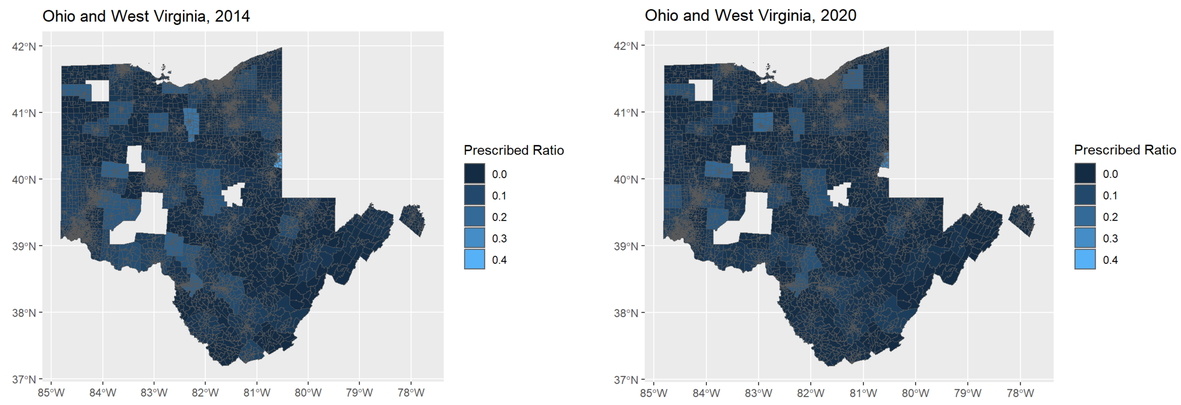

Figure 1. Prescribed Ratio by County in 2014 and 2020. (note: Prescribed Ratio = Total Beneficiaries / Estimated Number of People with Diabetes)

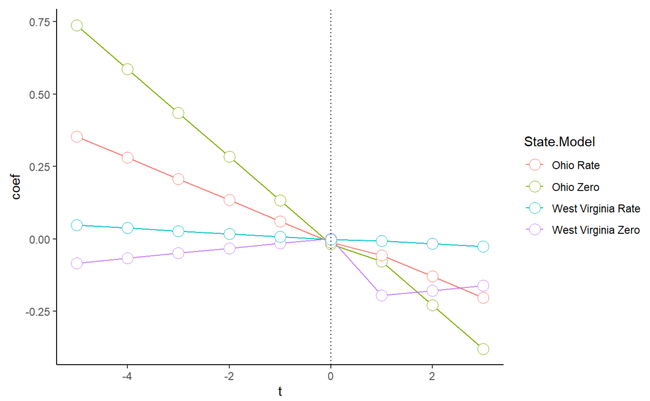

Figure 2. Event Study Graph for Coupon Policy Effects

METHODS

We approach the estimation of the impact of copay coupons (and patient assistance programs) as a problem of estimating a treatment effect in an event study design. In order to have flexibility in predictions and account for conditional time trends, we opt to use a mixed modeling approach. For patient privacy, any observation under 10 is coded as an NA in the CMS datasets, which creates an excess amount of zero responses. To account for this dispersion, we utilize a zero-inflated model (binomial with logit link) in conjunction with a rate model (Poisson with log link) offset by the number of individuals diagnosed with diabetes in a given county and year. The model structure that we develop may be summarized as a zero-inflated mixed-effects rate model. The estimated parameters of the two models are summarized in Tables 1 and 2, respectively.

1 Mixture

Suppose,
$\phi \sim Binom()$
$f \sim Pois()$
Then,
for drug l prescribed by provider q in county i in year j,

$$g(y_{ijql} = k) = \begin{cases} \phi + (1-\phi)f(0) & y_{ijql} = 0 \\ (1-\phi)f(k) & y_{ijql} > 0 \end{cases} \quad k = 1, 2, 3, \ldots$$

2 Empirical Models

$$1\text{-}\phi_{ij} = \log(\text{Total Beneficiaries}) = \mu + \beta_s * State_i + \beta_y * Treatment_j + \beta_{sy} * State_i * Treatment_j + \beta_d * Dual_q + \gamma_q + \gamma_b * Brand_{ijql} + \gamma_{\gamma i}^{c} * year_j + \gamma_i^{s} + \gamma_i^{s'} * year_i + \epsilon_{ijql}$$

$$f(y_{ijql} = k) = log(\text{Total Beneficiaries}/Count_i) = \rho + \alpha_s * State_i + \alpha_y * Treatment_j + \alpha_{sy} * State_i * Treatment_j + \alpha_d * Dual_q + \delta_q + \delta_b * Brand_{ijql} + \delta_c * RUCA_q + \delta_{\delta i}^{c} * year_j + \delta_i^{s} + \delta_i^{s'} * year_i + \eta_{ijql}$$

CONCLUSION

While descriptive statistics appear to initially provide some evidence that the availability of copay coupons or patient assistance programs improved access to insulin for Medicare beneficiaries, we find that this variation in insulin access can instead be attributed to state-level and county-level time trends instead of effects related to the availability copay coupons and patient assistance programs. In the future, we may consider focusing more aggressively on the relationship between geography, income, and the impact of drug discounts such as copay coupons and patient assistance programs. We may also consider alternative approaches to estimation such as Bayesian simulation and small area estimation.