Prescription for Problems:
Unintended Consequences of Access Restrictions

Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence

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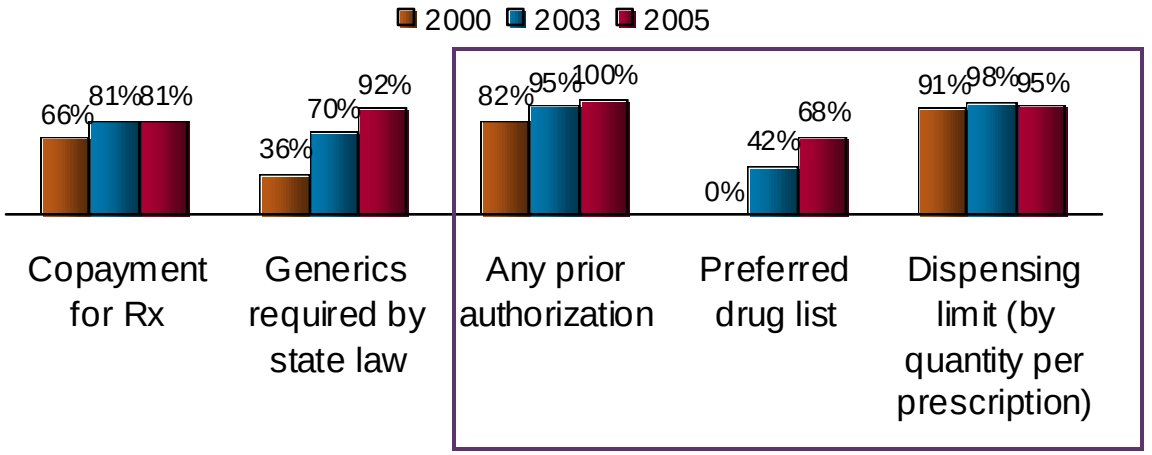
Introduction: States Have Increasingly Adopted Preferred Drug Lists and Prior Authorizations to Control Costs in Medicaid

- Preferred Drug Lists (PDLs) force patients to switch to less expensive medications
- Prior authorization requires the physician to make a case for approval of the medication if not on the PDL
- Dispensing limits restrict # of refills or pills per month
- Studies on the effect of restrictions have shown mixed results

(Soumerai 1991, Bloom and Jacobs 1985, Cromwell et al. 1999, Smalley et. al.1995, Tablyn et al. 2001, Wilson et al 2005)

Medicaid Pharmacy Management Policies
Percent of Surveyed States with Policy: 2000 - 2005



Source:Crowley et al. State Medicaid outpatient prescription drug policies: findings from a national survey 2005 update. Washington DC: Kaiser Commission on Medicaid and the Uninsured. 2005

Introduction: Statin Therapy Has Been Shown to Benefit Patients, Adherence with Therapy Is an Impediment

- HMG-CoA reductase inhibitor ("statin") therapy is a widely accepted treatment for patients with high cholesterol
- Clinical trials report benefits such as reductions in mortality and morbidity from statin therapy (e.g., National Cholesterol Education Program(NCEP) Expert Panel 2002, WOSCPS, AFCAPS/TexCAPS, 4S)
- The extent of cardiovascular risk reduction can increase in proportion to the amount of time on statin therapy (Simes et al. 2002)
- Statin Adherence is a challenge to realizing the value of the medication (Benner et. al 2002)
- More adherent patients have lower overall hospitalizations and emergency department visits (Goldman, 2006)
- Heart Disease is the leading cause of death in the United States (AHA, 2006), and 29% of all deaths in Alabama (CDC 2001)
- Alabama implemented a preferred drug list in 2003, with restrictions on statins in 2004 + Rx limit (4 brand, 10 generic)

Study Goals: Examine the Effect of Preferred Drug List on Statin Utilization in Alabama

- Did the restrictions have a measurable effect on the patient's likelihood of discontinuing statin therapy?
- Did the restriction have a measurable effect on the likelihood that an existing patient's medication would be switched?
- Did the patients taking a restricted medication have a higher increase in discontinuation than patients taking unrestricted medicines?
- Were there any differences in the rate of discontinuation post-PDL on older patients?

Methodology: Examine Discontinuation Relative To An Unrestricted State And Over Time

- Difference in Difference model with three differences
  - Restricted vs. unrestricted drugs
  - Alabama vs. North Carolina (no PDL on Statins in NC) with similar demographics in both states
  - Pre vs. Post PDL
- Outcome measure: Discontinuation of Therapy in 12 months following PDL
  - Discontinue = patient had medication in <50% of days between first fill and end of study period

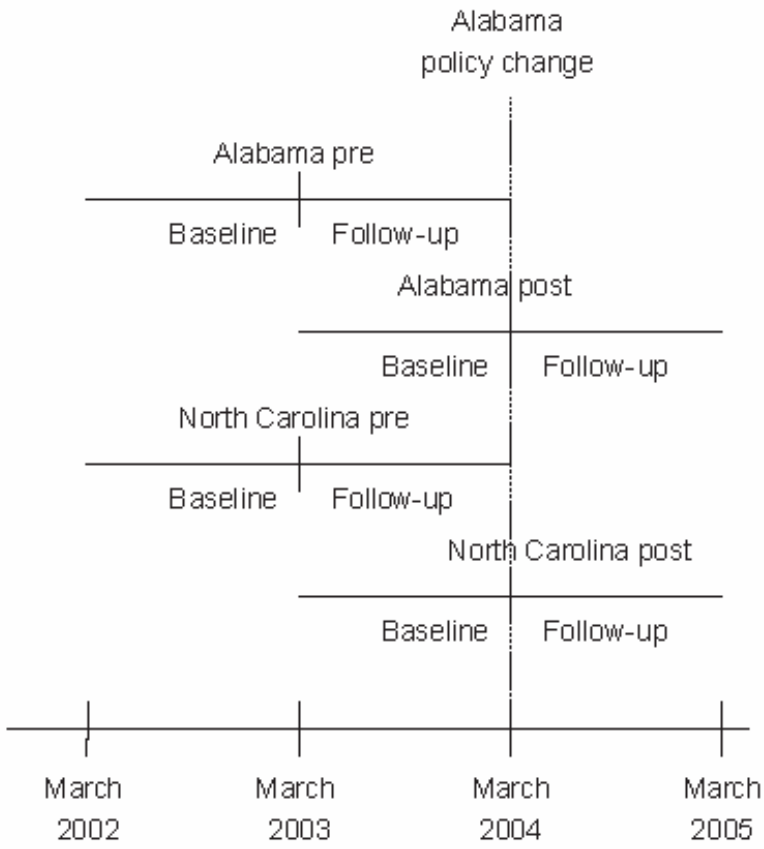


Fig. 1. Illustration of difference-in-difference methodology. We compare statin discontinuation in Alabama after the preferred drug list (PDL) with statin discontinuation in Alabama before the PDL and with statin discontinuation in North Carolina in the period after the Alabama PDL.

Data and Inclusion Criteria: Examine Discontinuation Relative To An Unrestricted State And Over Time

- Versipan prescription data from retail pharmacies
  - HIPAA-compliant de-identified
  - Included Medicaid claims for statins between December 2001 and February 2005
  - Only included pharmacies where Verispan consistently capture the data during the entire time period of the study
  - Drug name, quantity supplied, date of fill, county code of pharmacy and age and sex of patient included in dataset
  - Census data (2000) used to infer demographics
  - Examined claims one year prior and one year post PDL (shifted one year earlier for Pre-PDL group)
- Inclusion Criteria
  - Patients filling a statin in the 3 months prior to the statin PDL (Dec. 2003-Feb 2004)
  - Patients filled a statin before December 2003
  - Same criteria shifted one year earlier for pre-PDL group
  - Age 18 or greater

Multivariate Analysis of Binary Outcome: Three Specifications

- Average Effect

  U(DISCONTINUEit) = B1PDLst + B2COUNTYc + B3Xit + eit

  Prob(DISCONTINUEit)=exp(ZitB) / (1+exp(ZitB))

- Restricted vs. Unrestricted

  *U(DISCONTINUEit) = B1PDLst + B2RESTRICTEDs + B3PDLst*RESTRICTEDs + B4COUNTYc + B5Xit + eit*

- **Restricted vs. Unrestricted, Age Effect**

  *U(DISCONTINUEit) = B1PDLst + B2RESTRICTEDs + B3PDLst*RESTRICTEDs + B4PDLst*RESTRICTEDs *AGE65s + B5COUNTYc + B6Xit + eit*

Selected Sample Characteristics

Table I. Characteristics of the counties in which the prescriptions were filled

State	PDL	n	% Urban	% African American	% White	% of households below 150% of federal poverty level
Alabama	Pre-Alabama PDL	1664	56	28	69	28
	Post-Alabama PDL	1771	56	28	68	28
North Carolina	Pre-Alabama PDL	4520	60	24	69	22
	Post-Alabama PDL	5562	61	24	69	22

PDL = preferred drug list, or same equivalent time period in North Carolina.

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Selected Sample Characteristics

Table II. Characteristics of the patients in the sample

State	PDL	n	% of Days with no Rx between first and last Rx, baseline period	Days of therapy, baseline period	% on Restricted drug[a]
Alabama	Pre-PDL	1664	16	194	67
	Post-PDL	1771	18	194	67
North Carolina	Pre-PDL	4520	16	197	66
	Post-PDL	5562	16	192	66

[a] At the start of the follow-up period.
PDL = preferred drug list.

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Selected Sample Characteristics

Table II. Characteristics of the patients in the sample

State	PDL	Follow-up period[a]				
		Total time on therapy (in days) in study period	Days between prescriptions	Patients who had medication < 50% of days	% of Days with medication	Days supply of therapy in study period
Alabama	Pre-PDL	296	59	39	58	246
	Post-PDL	262	63	51	49	205
North Carolina	Pre-PDL	301	59	36	60	252
	Post-PDL	299	57	36	60	252

[a] At the start of the follow-up
PDL = preferred drug list.

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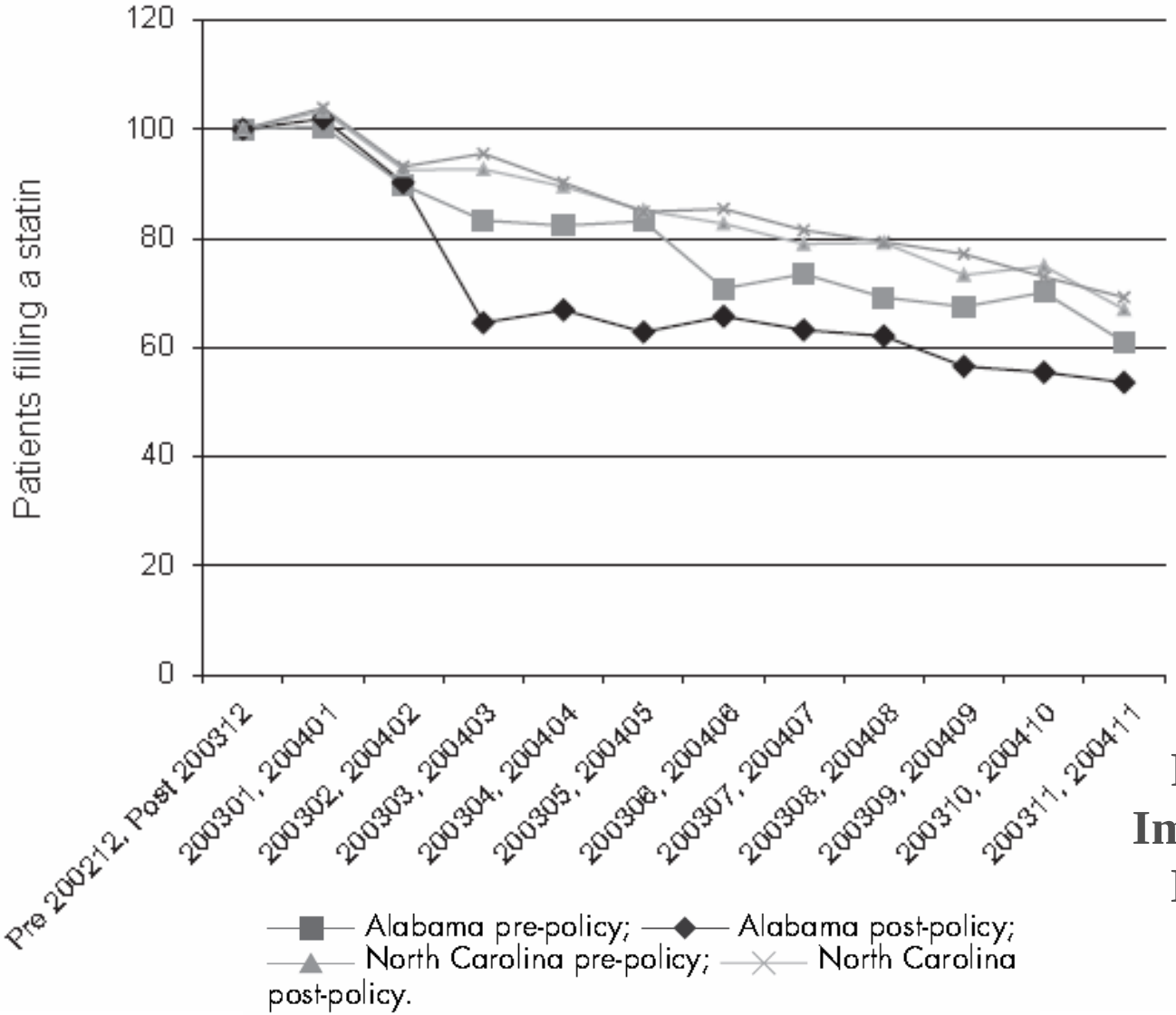
Percent of Patients Filling a Statin: Cohort Comparison



Restrictions Implemented in March 2004

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Key Findings: Adherence Effect

If you remember nothing else, remember this:

Discontinuation with statins increased to 50% in Alabama while staying flat in North Carolina following the Alabama PDL implementation

	Alabama	North Carolina
Before	39%	36%
After	51%	36%

Preferred Drug List

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Medication Discontinuation Increased After Access Restrictions

Variable	Model A		Model B		Model C	
	odds ratio	95% CI	odds ratio	95% CI	odds ratio	95% CI
PDL (Alabama in 2004)	1.82	(1.57, 2.11)*	1.44	(1.16, 1.78)*	1.44	(1.16, 1.79)*
RESTRICTED (rosuvastatin, atorvastatin, pravastatin)			0.98	(0.90, 1.07)	0.98	0.90, 1.07
PDL*RESTRICTED			1.42	(1.12, 1.80)*	1.26	0.97, 1.63
PDL*RESTRICTED*Age 65+					1.33	1.02, 1.73*
COUNTY fixed effects	Included	*	Included	*	Included	
Age 40–50	1.27	(1.10, 1.46)*	1.27	(1.10, 1.46)*	1.27	(1.10, 1.46)*
Age 51–64	0.94	(0.83, 1.06)	0.94	(0.83, 1.06)	0.94	(0.83, 1.06)
Age 65+	0.80	(0.72, 0.89)*	0.80	(0.72, 0.89)*	0.78	(0.70, 0.87)*
CARDIOLOGIST prescribed	0.66	(0.57, 0.77)*	0.66	(0.57, 0.77)*	0.66	(0.57, 0.77)*
PRIOR EXPERIENCE	0.99	(0.99, 0.99)*	0.99	(0.99, 0.99)*	0.99	(0.99, 0.99)*
PRIOR NON-ADHERENCE	4.80	(3.95, 5.84)*	4.84	(3.98, 5.88)*	4.84	(3.98, 5.88)*

* significant at $p < 0.01$. Likelihood ratio $B = 0 < 0.01$ for all models.
PDL = preferred drug list.

Limitations

- Retrospective analysis
- Claims data
- Medical data not available
- Simultaneous effect of Rx limits and access restriction

Summary

- In this difference-in-difference cohort analysis, patients were found to have discontinued to a greater degree after the PDL was implemented in Alabama with Rx limits
- Far more patients experienced a switch in medication regimen after the PDL
- Users of restricted drugs and older patients taking restricted drugs were more likely to quit following the PDL

Conclusions

- States implement PDLs to drive down costs by shifting patients to lower cost medications
- PDLs could benefit society if the decrease in total costs offsets any changes in efficacy, adherence or incentives for innovation
- Evidence from this study suggests that there was a substantial decline in statin use as a result of the PDL, it is not clear that the health consequences were offset
- Insurers and policy makers should be aware that seemingly benign limits can have unintended consequences which could ultimately drive up longer term medical cost and/or decrease social welfare