

State-level Legislative Efforts to Improve Diabetes Care and thereby Mitigate Complications

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Abstract

Objective: Diabetes (DM) is a complex chronic illness with multiple complications and co-morbid conditions. DM affects 9.3% of the U.S. population and costs \$245 billion or more annually. Most U.S. states have enacted laws requiring coverage of DM care and supplies but the effect of these public health laws is not well understood. This study aims to examine whether state's legislative actions can improve access to care and mitigate DM's rising prevalence thereby reducing complications.

Methods: Econometric modelling provided DM-related trends and assessed state-level variation in DM prevalence. Ordinary least squares (OLS) regression assessed the impact of different law enactment dates and key factors that contribute to the effectiveness of DM-related state laws, including demographic characteristics related to DM: median household income, educational attainment, obesity, and state population size.

Results: All but four US states have enacted diabetes-related laws requiring coverage of diabetes care and treatment. States that had enacted DM-related laws and had a higher percentage of people covered by insurance, experienced lower increases in diagnosed DM over time. Education proved to be a key factor in helping to decrease the prevalence of DM and its complications. Conversely, increasing obesity rates explain much of the rising prevalence of diagnosed DM.

Conclusion: Enactment of DM-related laws at the state-level has proven somewhat beneficial in mitigating the rise in DM rates and alleviating complications. There is a need for future research to further examine the various payers' reimbursement policies for healthcare professionals providing services such as diabetes self-management education within each state. The findings from this study offer policy insights about the benefits of state-level DM laws for controlling the disease, reducing DM-related complications, and lowering costs associated with complications from poorly-managed DM.

Keywords: Diabetes mellitus; Public health laws; State legislative actions; Economics; Education; Diabetes self-management education; Insurance

Introduction

DM is a complex chronic illness with multiple co-morbid conditions that affects 29.1 million Americans, representing 9.3% of the U.S. population [1]. It is the seventh leading cause of death in the U.S. and its prevalence is rising. DM is costly; total estimated cost of diagnosed DM in 2012 was \$245 billion, and medical costs are 2.3 times higher for those with the disease than without [2], and higher costs are associated with DM-related complications. Multiple factors contribute to the increasing burden of diabetes in the US, including population aging, barriers to access, rising obesity rates, and the underling complexity of managing the disease.

Both DM type 1 and 2 require life-long care and on going selfmanagement to optimize health and delay the onset of severe complications -- kidney failure, dis vascularity, neuropathy, lowerlimb amputations, and blindness. DM care is guided by national standards developed by the American Diabetes Association (ADA) [3], American Association of Clinical Endocrinologists (AACE) [4] and The Endocrine Society [5]. The interplay of clinical management, behaviour change and education are positive and key factors for those who have DM. These in turn, are dependent on access and coverage.

There is increasing interest in understanding the extent to which patient-oriented, public health efforts, and state actions can reduce DM's impact. Dr. A. Moulton of the Centre for Disease Control's (CDC) Office of Surveillance states, "Laws, including statutes, ordinances, and government agency rules and regulations, can support interventions to prevent and control disease in various ways" [6]. This raises the question, to what extent do state laws improve access to care, result in good self-management, and mitigate complications for those with DM?

Page 2 of 6

This economic study explores the effect of DM-related state laws on DM and its attendant burden. The objectives are to evaluate the intended and incidental effects of DM-related state laws on DM

prevalence and burden, including complications. The model considers factors that help explain differences in rates of increase in DM across states.

DM Law	Controlling for	Controlling for	Controlling	Controlling
Enactment (2010 -year +2)	Medication	Equipment	for Services	for Education
Constant	0.0069	0.01	0	0.009
	-0.03	-0.03	-0.03	-0.03
Equipment	-	-0.002	-	-
		-0.01		
Services	-	-	-0.003	-
			0	
Medication	0.005	-	-	-
	(.00) *			
Education	-	-	-	0.001
				0
% People covered	-0.059	-0.058	-0.05	-0.061
	(.03)**	(.03)**	(.03)*	(.03)**
Indirect cost	23384.71	24643.24	26565.14	23931.14
	(13255.85)*	(13920.17)*	(13674.24)*	(14000.93)*
Direct cost	-2145.52	-5695.74	-4210.33	-4620.49
	-12950	-13607.2	-13177.1	-13768.5
Educational attainment	-0.023	-0.024	-0.055	-0.026
	-0.02	-0.02	(.03)*	-0.03
Obesity in 2010	0.082	0.082	0.083	1053375
	(.04)*	(.05)*	(.05)*	(.0499603)**
Years since changes enacted	0.004	0.004	0.004	0.004
	(.00)***	(.00)***	(.00)***	(.00)***
Observation	46	46	46	46
Prob F>	0	0	0	0
Adj. R-Squared	0.73	0.71	0.72	0.71
Estimates are rounded to 3 digits after the decimal point				
*, **, *** indicate statistical significance at the 0.1, 0.05, and 0.01 significance level respectively				

Table 1: Regression of the variation in diabetes prevalence, controlling for different types of benefits.

Literature Review

The literature review was conducted early in 2015. Material reviewed derived from a Medline (2005-2015) search and a scan of DM-related professional and patient-oriented organizations' websites.

The literature generally indicates that public health laws have effectively addressed shortcomings in the healthcare system by

facilitating patient access and improving public health [7,8]. Since NY state's enactment of a DM-related law in 1993 [9,10], state statutory actions have aimed to address the burden that DM imposes on individuals and the public. Today, most states and the District of Columbia have laws that require health insurance policy coverage for DM treatment. No federal mandate exists requiring health insurance

coverage for DM care, education and/or treatment for those who have been diagnosed with the disease.

The literature further suggests a tenuous association between state laws and improvements in health and reductions in DM-related mortality. Li et al. [11] reported that 16 states had passed state diabetes laws between 1997 and 1999 that required coverage of diabetic monitors and strips, while 15 states required coverage of diabetes self management education (DSME) [11]. These laws were associated with a small increase in daily self-monitoring of blood glucose but had not increased the probability of people with DM receiving eye exam, or foot exam. DSME studies however, report fewer DM-related complications and lower costs [12,13].

Laws support diabetes self-management education (DSME), for example, because it is associated with improved health behaviours, reduced complications and reduced cost [14]. Schillinger et al. [15] found that "inadequate health literacy is independently associated with worse glycaemic control and higher rates of retinopathy" [15]. Conversely, diabetes education is related to a lower risk for complications [16]. Individuals with higher educational attainment and those enrolled in diabetes education are more likely to manage their disease, avoid complications and achieve better health outcomes than those with less education [17].

Unexpected consequences may arise from public health laws. Economists worry about things such as higher costs or moral hazard, which may arise when a person engages in more risky behavior than he usually would because someone else (e.g. the payer) bears the cost of those risks. Geiss and Engelgau [18] and Saaddine and Cadwell [19], however, report that policies promoting coverage of DM Care and education effectively lead to improvements in self-management, with no moral hazard [18,19]. Li [11] found that laws had only a small impact on use of covered benefits, but could drive up the cost of insurance, contributing to an unintended growing number of uninsured people. On the other hand, Klick and Stratman [20] reported that moral hazard was likely to occur in states where laws were implemented from 1996-2000 [20].

Public Health Laws For Diabetes

Public Health Law data about coverage of DM services and supplies were extracted from the National Conference of State Legislatures (NCSL) [21]. DSME program information came from the American Association of Diabetes Educators (AADE) and ADA. Data for the regression analysis were extracted from National Health Interview Survey (NIHS) [22]; Center for Disease Control Prevention (CDC), National Diabetes Surveillance System 2012 [23]; and U.S. Census Bureau, Current Population Survey [24-26].

Since 1993, 46 states have enacted laws requiring coverage of DM care and /services/supplies as shown in Figures 1 and 2. These figures present the number of years since laws were enacted and enactment over time, respectively. Only six states do not require coverage for DM education. The number of DSME programs and the prevalence of private sector initiatives such as DM disease management have increased following enactment of legislation. AADE and ADA currently accredit/recognize more than 2,500 DSME programs.



Methods and Data Sources

Preliminary econometric modelling provided DM-related trends, and ensured the regression model's ability to assess state-level variation in DM prevalence in a fixed period of time, an assumption that was subsequently relaxed. Ordinary least squares (OLS) regression assessed the impact of different law enactment dates and key factors that contribute to the effectiveness of DM-related state laws, including demographic characteristics related to DM: median household income, educational attainment, obesity, and state population size. The regressions incorporated a dummy variable, existence of a mandate (state law), to denote the existence of a law in a state. The independent variable, year of enactment, measured the difference in the law enactment dates across states in a fixed period of time (1996-2010), avoiding bias because this variable is essentially a time trend.

We tested the econometric model's robustness with an alternative fixed period (AFP) specification and varied the time frame to ensure that inclusion of four states without laws in 2010 did not cause bias. Bias could have occurred if these states shared a common characteristic that was unintentionally captured by the dummy variable (existence of a mandate). We were assured of the consistency of the variable and strength of the model specification. Median

Page 3 of 6

Page 4 of 6

household income was chosen as a proxy for educational attainment because data were lacking for this variable for the period 1994-2000.

The regression initially analyzed data for 1994-2000, which was sufficient to gauge variation in diagnosed DM rates. The year 2000 provides a good baseline given that approximately 35 percent of states were without laws at that point. In a pre-post analysis, we further analyzed 35 states that had enacted laws, excluding NY because its law was enacted in 1993 before CDC data became available.

Additional information about model specifications and regression analyses are available upon request from the authors.

Table 1 presents findings from the regression analysis examining the effect of the year in which the state passed its law. Goodness of fit for the model's specification was high, with Adjusted R squared = 0.73 vs. R squared 0.52 when the model was specified for a longer timeframe. The variable year since the law was enacted was significant and associated with increased DM prevalence but the other variables were individually less meaningful.



Results

The econometric analysis consistently demonstrated that the enactment of state laws requiring insurance coverage for DM care/ services had a positive impact on the reduction of DM. Increases in the percentage of people covered by health insurance reduced the cases of DM during the period 1996-2010 (Figure 3). Figure 4 presents the types of benefits required by state laws. It was not possible to fully analyze the effect on DM rates of different kind of services required by state laws (e.g., drugs, education). Because most state laws cover all benefits, and these benefits are interrelated, multicolinearity may exist between some variables and the existence of the law. Hence, we adjusted the model to test them individually. Most were, strongly correlated to the existence of legislation when the findings were applied to the state law as a whole.

Smaller increases in diagnosed DM and thereby complications over time are associated with a higher percentage of people with higher education (Figure 3). For the period 1994 - 2000 the median household income coefficient (proxy of educational attainment) was significant. We also found that medical costs and DM rates are significant and demonstrate a strong positive correlation. Obesity rates are positively correlated with and had a considerable effect on diagnosed DM rates. However, the obesity variable was not significant for the period 1994 – 2000 possibly due to differences in obesity measurement and reporting during that period.

Our pre-post analysis indicates the time lag between enactment and measurable effect ranged from one to two years, including the year of enactment plus one additional year. Interestingly, new laws are more impactful and the older the law, the greater the rise in rates of DM. The overall analysis suggests that state DM laws have increased access to care, lowered DM prevalence and thereby mitigated complications. Moreover, the laws may have helped control cost.



This study has many strengths -- the data set we used covers all states and contains more than 20 numerical and quantitative variables related to prevalence of DM, state legislation requiring coverage of DM, demographics, etc. Widespread existence of DM coverage laws plus the difference in enactment dates made it possible to undertake robust regression analyses. We were able to analyze state-level variation in DM prevalence in different periods of period of time, identify key factors affecting the prevalence of the disease and explored the impact of state laws mandating services or care for those diagnosed with DM.

Limitations

Clinical outcomes (e.g., blood pressure or A1C measures), and DM type were outside the scope of our analysis, but are essential to fully

understanding the effectiveness of public health laws on diabetesrelated complications. Data availability was the main challenge. CDC data were limited to the years 1994 through 2010 (excluding NY, an early adopter state), and did not specify type of diabetes. Obesity data over time were not comparable because BMI measures have changed over time -- data for the 1990s are only available in ranges of percentages (e.g. from 15% to 19%). Finally, some insurers had already provided coverage for DM care and services prior to enactment of the public health laws.

Discussion

This analysis found that enactment of state laws for DM is a significant factor in reducing the rising trend of DM prevalence. A secondary benefit is that those with greater access to care and diabetes education are likely to better self-manage and delay the onset of DM-related complications. Enactment of state laws did not result in irresponsible self-management among people with DM (moral hazard). These findings are consistent with the impact of other laws that have improved public health and facilitated patient access, such as, laws addressing food labeling and cigarettes.

Importantly, states with DM-related laws had lower increases in diagnosed DM over time (and therefore fewer complications). The study also found that the laws reduced indirect medical costs to some degree. Perhaps the benefits are associated with increased access to care, supplies, disease management, and education.

Our analysis demonstrates that education matters, as does insurance coverage. The higher the percentage of people with higher education, the lower the increase in diagnosed DM. The regression results do not allow us to categorically state that state laws influence access to DSME, although other portions of our study strongly suggest that they do. The percentage of people covered by health insurance is positively associated with control of diagnosed DM. Thus, an increase in the percentage of people covered by health insurance reduces the number of cases of DM.

The older the law, the less impact it has on decreasing DM prevalence. This result may indicate that new laws are 1) better targeted for the express purpose of decreasing DM prevalence, 2) more effectively implemented, or 3) or possess a halo effect following enactment that raises awareness of the need to control DM. Additionally, there may be heightened awareness of efforts such as the Diabetes Prevention Program (DPP) and targeted disease management offerings by employers and health plans in states that have recently enacted legislation. Our analysis implies that lags occur and it takes more than a year after enactment to fully experience the results of a law's implementation, possibly because stakeholders have to familiarize themselves with it.

Overall, state laws requiring coverage of DM services have had a positive impact on actions that are intended to reduce DM and its burden among the population. Lower rates of complications can be achieved through decreased DM prevalence. The study found that obesity and education are also key factors that work in opposite direction, obesity contributing to, and education reducing DM prevalence.

Future analysis can contribute information about laws for other specific DM-related complications. In addition, clarity is needed as to reimbursement criteria, which vary from state to state and payer to payer. US insurers have the right to interpret their own coverage and reimbursement policies and, for example, pay only those they designate as a "certified provider". The laws typically do not define provider qualifications. Additional research is therefore needed to clarify different how the state laws are implemented in practice and how payers determine which healthcare professionals are eligible for reimbursement and how different state laws are implemented.

Conclusion

This study examined the effects that state laws have on DM prevalence and factors that help mitigate its rise. The key finding is that DM-related state laws are somewhat beneficial in mitigating the rise in DM rates and therefore reducing DM-related complications. States that had enacted DM-related laws and had a higher percentage of people covered by insurance, experienced lower increases in diagnosed DM over time. Education is a key factor in decreasing DM rates while, rising obesity rates explain much of DM's increase. There is a need for future research to further examine the various payers' reimbursement policies for healthcare professionals providing services such as DSME within each state. The findings from this study offer policy insights about the benefits of state-level DM laws for controlling the disease, reducing DM-related complications, and lowering costs associated with complications from poorly-managed DM.

References

- 1. Centers for Disease Control and Prevention (2014). National Diabetes Statistics Report
- 2. American Diabetes Association (2013) Cost of Diabetes.
- 3. American Diabetes Association (2013) Standards of medical care in diabetes--2013. Diabetes Care 36 Suppl 1: S11-66.
- Rodbard HW, Blonde L, Braithwaite SS, Brett EM, Cobin RH, et al. (2007) American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Endocr Pract 13 Suppl 1: 1-68.
- Cryer PE, Axelrod L, Grossman AB, Heller SR, Montori VM, et al. (2009) Evaluation and management of adult hypoglycemic disorders: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 94: 709-728.
- 6. Diego SCA (2013) Can the Law Improve Diabetes Prevention and Control? .
- 7. Governors Highway Safety Association (2015) Highway Safety Laws by State.
- 8. Centers for Disease Control and Prevention (2015) Injury prevention and control: Motor vehicle safety. Motor vehicle safety.
- 9. American Diabetes Association (2015) State Laws and Policies.
- 10. National Conference of State Legislators (2011) Providing diabetes health coverage: state laws & programs.
- 11. Li R, Zhang P, Barker L, Hartsfield D (2010) Impact of state mandatory insurance coverage on the use of diabetes preventive care. BMC Health Serv Res 10: 133.
- 12. Duncan I, Birkmeyer C, Coughlin S, Li QE, Sherr D, et al. (2009) Assessing the value of diabetes education. Diabetes Educ 35: 752-760.
- 13. Duncan I, Ahmed T, Li QE, Stetson B, Ruggiero L, et al. (2011) Assessing the value of the diabetes educator. Diabetes Educ 37: 638-657.
- 14. Cutler DM, Lleras-Muney A (2010) Understanding differences in health behaviors by education. J Health Econ 29: 1-28.
- Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, et al. (2002) Association of health literacy with diabetes outcomes. JAMA 288: 475-482.
- Brown HS, Wilson KJ, Pagán JA, Arcari CM, Martinez M, et al. (2012) Cost-effectiveness analysis of a community health worker intervention for low-income Hispanic adults with diabetes. Prev Chronic Dis 9: E140.

Page 6 of 6

- 17. Loveman E, Frampton GK, Clegg AJ (2008) The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. Health Technol Assess 12: 1-116.
- Geiss L, Engelgau M, Pogach L, Acton K, Fleming B, et al. (2005) A national progress report on diabetes: successes and challenges. Diabetes Technol Ther 7: 198-203.
- Saaddine JB, Cadwell B, Gregg EW, Engelgau MM, Vinicor F, et al. (2006) Improvements in diabetes processes of care and intermediate outcomes: United States, 1988-2002. Ann Intern Med 144: 465-474.
- 20. Klick J, Stratman T (2007) Diabetes Treatments and Moral Hazard.
- Centers for Disease Control and Prevention (CDC) (2013) Health Interview Survey (NIHS): Table on cost burden of diabetes extracted from Diabetes Care 36.
- 22. Center for Disease Control and Prevention (CDC) (2012) National Diabetes Surveillance System.
- 23. U.S. Census Bureau, Current Population Survey (2010) Annual Social and Economic Supplements.
- 24. U.S. Census Bureau, Current Population Survey (2013) Annual Social and Economic Supplements.
- 25. U.S. Census Bureau, Current Population Survey (2010) American Community Survey.
- 26. Chaloupka FJ (2012) Mechanisms of legal effect: perspectives from economics. In: RWJF, ed. Public Health Law Research. R.W.J. Foundation.