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## **Cost savings of diabetes outcomes: impact of nurse practitioner practice regulatory policy**

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**Abstract:** The Affordable Care Act (ACA) expanded healthcare coverage to millions of Americans in the context of an existing primary care provider shortage. Nurse practitioners (NP) will play an essential role in expanding access. Maximising their contributions requires fully modernising and standardising NP regulatory policies. Evidence supports associations among NP regulatory policy, access to care, and health outcomes of chronic illnesses. This study examined the relationship between NP regulatory policies in the 50 states and their potential impact on the cost-savings of NP diabetes management. Multiple-block regression identified significant relationships. As the USA continues to implement the ACA, the authors suggest reducing NP scope of practice restrictions will build primary care capacity, increase access and improve health outcomes, and deliver direct and indirect savings for chronic disease management. Modernising nurse practitioner regulatory standards is important to improve cost savings and sustainability for primary care health with particular attention to chronic conditions.

**Keywords:** Affordable Care Act; primary care; health provider shortage; nurse practitioner scope of practice; access to care; population health; diabetes; standards.

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## 1 Introduction

On 1 January 2014, as implementation of the Patient Protection and Affordable Care Act P.L. 111-148 (ACA) (Patient Protection and Affordable Care Act, 2010) was unrolling, just over 15% of Americans were uninsured and more than a fifth of all Americans were underinsured (Rovner, 2009; US Census Bureau, 2009; KFF, 2012a; US Census Bureau, 2012). While ACA has greatly expanded access to healthcare, with significant enrolments anticipated for 2015 and 2016, about 23 million people will remain uninsured and without coverage by 2019 (Naylor and Kurtzman, 2010; IOM, 2011; Mays and Smith, 2011). Further, disparities continue to persist among the uninsured, with minority groups disproportionately represented (US DHHS, 2012a).

To magnify the implication of this disparity, minorities also have disproportionately higher rates of chronic illnesses such as diabetes, kidney disease and heart disease (Flack et al., 2010). African Americans experience higher mortality rates related to cancer and heart disease than whites (KFF, 2012b; CDC, 2013). Additionally, access to primary care in rural communities remains disproportionately inadequate (Shin and Rosenbaum, 2012).

Primary care providers are anticipated to remain in high demand as shortages are projected to exceed 40,000 (Rothman and Wagner, 2003; Bodenheimer and Pham, 2010; Jacobson and Jazowski, 2011; Cassidy, 2012; US DHHS, 2012b). Recruitment of foreign healthcare providers is not projected to be a viable solution to close this gap

(Bodenheimer and Pham, 2010); however, increased utilisation of Nurse Practitioners (NP) and Physician Assistants (PA) may (O’Grady et al., 2012). Further, evidence supports the modernising and standardising of nurse practitioner regulatory policy to increase full nurse practitioner scope of practice (IOM, 2011; Jacobson and Jazowski, 2011). The effectiveness of NPs in primary healthcare provision is well supported in the literature (Grumbach et al., 2003; Vonderheid et al., 2003; Hansen-Turton et al., 2010; Jacobson and Jazowski, 2011; Newhouse et al., 2011). Indeed, key benchmarks for nurse-led healthcare include advanced practice certification and identification of, and access to care for, vulnerable populations (Chin et al., 2011).

The objective of this study is to identify the impact of NP regulatory policy on the direct and indirect costs of primary care, using diabetes as the health outcome measure. The authors suggest that by better understanding the impact of NP regulatory policy on population health and its cost, evidence to modernise and standardise NP scope of practice regulations will be supported. While healthcare delivery cost savings have been established as a benefit of NP provided services, we expand the existing literature on benefits of NP services to improve both direct and indirect medical costs associated with primary health outcomes. We argue that both direct (medical) and indirect (e.g., increased absenteeism and reduced productivity while at work) factors are necessary considerations in measuring the ‘true cost savings’ of NP care.

## **2 Background literature review**

### *2.1 Nurse practitioners*

The NP role originated more than 4 decades ago. Today, a fundamental underpinning of NP primary care is health promotion and disease prevention, often to vulnerable, underserved and resource intensive populations (Vonderheid et al., 2003; National Center for Health Workforce Analysis, 2004; Newhouse, et al., 2011). NPs deliver more care to underserved populations than physicians (Grumbach et al., 2003; Hansen-Turton et al., 2004; Newhouse et al., 2011). Currently, a paucity of data exists regarding the proportion of cost-savings attributed to improved health outcomes in states with higher access to NP primary care. However, when it comes to NP performance, most quality of chronic care indicators are similar to those of physicians (Jacobson and Jazowski, 2011), including lipid control, blood pressure and glucose (Newhouse et al., 2011), as well as improved patient knowledge and compliance (Keleher et al., 2009). In total, these improved chronic disease management outcomes suggest an opportunity to modernise standards of practice. These may in turn yield improved health outcomes based in part upon patient satisfaction and trust, which evidence shows are higher for NP care (Keleher et al., 2009; Newhouse et al., 2011; Han and Prybutok, 2012; Cassidy, 2012).

In the USA, at least 65% of NPs work in primary care practices (AACN, 2012). Proposed reforms under the ACA include expanded utilisation of NP services, improving quality of care and promoting quality health outcomes, all of which increase demands for the NP primary care workforce (AAN, 2010; Fairman et al., 2011; IOM, 2011; O’Grady et al., 2012).

## 2.2 *Policy of nurse practitioner practice regulation*

Standardising NP scope of practice laws is an effective way to address primary care service deficits given virtually all 50 states have at least one designated primary care shortage area (Bodenheimer and Pham, 2010; US DHHS (HRSA), 2012a). This continuing crisis strains access to care in every state (Bodenheimer and Pham, 2010; Jacobson and Jazowski, 2011; Cassidy, 2012) and necessitates investment in the primary care infrastructure.

Correlations among access to care, restrictive Advance Practice Registered Nurse (APRN) state regulations and health outcomes have been identified in the literature (Lugo et al., 2007; Sonenberg, 2010). Preliminary findings suggest there may be a correlation among state regulatory policy of NP practice, numbers of NPs practicing in a state and population health outcomes, especially diabetes and hypertension (Knepper et al., 2013). A current literature search reveals scant focus on the association between NP practice regulatory policy and chronic disease cost savings.

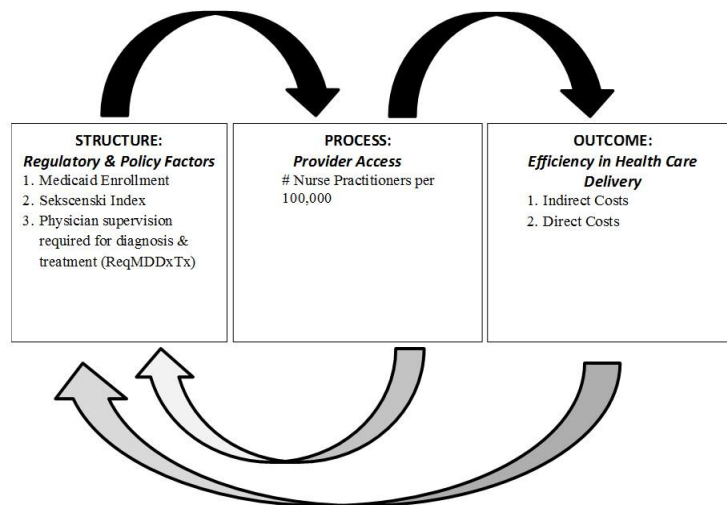
Improving policy standards, structure and process across states is necessary; only 23 states and the District of Columbia have expansive scope of practice acts for NPs (Dueker et al., 2005; Fairman et al., 2011; Shin and Rosenbaum, 2012). Only 18 states and the District of Columbia have completely modernised NP practice acts resulting in standardisation and full autonomy of practice (Phillips, 2014). Subsequently, full realisation of the potential benefits of the ACA requires reform of restrictive NP regulatory policies in the remaining states (CCN, 2011; IOM, 2011; Paradise et al., 2011; O'Grady et al., 2012). One example of improving access to care through reform of state NP practice policy is that of Massachusetts. In 2006, the state began its healthcare reform efforts but in 2008 found it necessary to reform NP regulations to improve patient access to primary care. Massachusetts passed a statute that recognised NPs as primary care providers (Craven and Ober, 2009). Further, 2014 federal legislation improved access to NP services under the Public Health Service Act by allowing Medicaid billing by any appropriately licensed healthcare provider (AAN, 2010).

State scope of practice laws vary in three areas: legal authority, prescriptive privileges and payment reimbursement policy and rates. States delineate legal authority through Boards of Medicine, Boards of Education or Boards of Nursing. Variation in legal authority includes the level of physician supervision of NP practice (CCN, 2011; Phillips, 2014). State NP practice regulatory policy ranges from no physician collaboration (complete autonomy of NP practice) to the most restrictive state regulations including requirement of physician supervision to diagnose and treat and/or physician supervision to prescribe medications. Variability among state NP scope of practice laws suggests that these policies are not based on evidence or best practice (Lugo et al., 2007) and the Institute of Medicine (IOM) recommends removal of NP scope of practice barriers (IOM, 2011). Within the past ten years, there was a consensus of multiple nursing organisations and other stakeholders to standardise the education, licensure and regulation of Advanced Practice Registered Nurses (APRN), which resulted in the Consensus or Licensure, Accreditation, Certification and Education (LACE) Model, setting the standards for competencies, titling, regulation and designation of subspecialty areas (APRN Joint Dialog Group, 2008). The LACE model represents collaboration among educators, certifiers, accreditors and boards of nursing who license APRNs. This collaborative effort supports the move toward standardisation and modernisation of state level policy reform of NP practice, which will optimise their utilisation and improves access to primary care providers.

### 3 Conceptual model and hypothesis development

Aday et al. (1998) conceptualise the classification of topics in health services research as being framed by the structure, process and outcomes of the system. To inform this study, Aday et al’s framework is applied within the context of another closely related theory: *complex adaptive systems theory*. Complexity may dictate collaborations that cross traditional venues, seeking out and creating new knowledge and best practices that blur the lines across disciplines (Anderson, 1999; Pfeffer and Salancik, 2003; Davis et al., 2009; Bovaird, 2013). The healthcare environment is complex, with structural, economic and political healthcare pressures contributing to the current primary care provider shortage (Naylor and Kurtzman, 2010). Meanwhile, healthcare system complexity has long been considered in terms of access, environment and resource availability (Wan, 1995). Ultimately, complexity may be considered the symbiosis of available options and the system influences that drive action (Colander and Kupers, 2014). In the model developed for this study, environment (regulatory and policy factors) is classified as a component of the *structure* of the healthcare system and resource availability and access (number of NPs) partially define the *process* classification for this study with diabetes costs providing the *outcome* classification. Figure 1 identifies the theoretical framework and hypothesised relationships among the study variables.

**Figure 1** Theoretical framework and hypothesised relationships: nurse practitioner regulatory policy and provider access factors influencing diabetes costs



The primary research question for this study is: (a) Do NP regulatory and policy factors influence direct and indirect costs of population health outcomes? The *Structure* variables (regulatory and policy factors) potentially affect the *Process* variable (number of nurse practitioners), which in turn affects the *Outcome* variables (direct and indirect costs of diabetes). Intermediary variables like socioeconomic determinants of health, such as median income or percent uninsured, are relevant. However, as these factors are contributory across all states they are not directly influenced by NP regulatory policy. Consequently, these variables are not included in this analysis. Further, this study focuses

on the health outcomes for diabetes under NP delivered care, which, preliminary evidence suggests, is correlated with state regulatory policy and has significant variation across states. The hypothesis tested in this study is

*H1: NP regulatory and policy factors influence direct and indirect costs of population health outcomes.*

#### 4 Methodology

This study employed a secondary data analysis using data from all 50 US States. The explanatory variable of interest in this study is the Number of Nurse Practitioners per 100,000 and a set of control variables: (a) Medicaid enrolment; (b) Physician Supervision Required for Diagnosis and Treatment (ReqMDDxTx) and (c) the Sekscenski Index (an index reflecting the level of autonomy of practice of the practitioner). The dependent variables are direct and indirect costs of diabetes associated with nurse practitioner care. Direct and indirect costs are captured utilising the prevalence-based measure as per the American Diabetes Association that combines the demographics of the USA population in 2012 with diabetes prevalence, epidemiological data, healthcare costs and economic data into a Cost of Diabetes Model.<sup>1</sup> Data were also obtained from the AANP (2011), the National Center for Health Workforce Analysis (2004) and the centres for Medicaid and Medicare. The data and measures are presented in Table 1.

**Table 1** Data sample and measures

<i>Variable</i>	<i>Operationalisation</i>	<i>Data source</i>
NPs	The number of nurse practitioners licensed per 100,000 people.	AANP (2011)
Sekscenski	A 2000 modification of the Sekscenski Index, which identifies levels of practice restrictions.	National Center for Health Workforce Analysis (2004)
Diagnosis and Treatment (ReqMDDxTx)	Physician supervision for diagnosis and treatment is required for NP practice.	AANP (2011)
Medicaid Enrolment	Proportion of state residents enrolled in Medicaid.	US DHHS (CMM) (2011)
Indirect/Direct Costs	Prevalence-based measure combines the demographics of the US population in 2012 with diabetes prevalence, epidemiological data, healthcare costs and economic data.	American Diabetes Association

The relationships between the predictor variables and Diabetes Costs were modeled using a multiple-block regression analysis in which the control variables are entered in the first block, followed by the main explanatory variable in the second block. This allows for the computation of the predictive power of the explanatory variable *over and above* the control variables. This technique is mathematically expressed as:  $Y = a + b_1X_1 + b_2X_2 + b_3X_3 + \dots + b_kX_k + e$ , where  $Y$  is the dependent variable;  $X_1, X_2, X_3, \dots, X_k$  are independent variables;  $a$  is the constant term;  $b_1, b_2, b_3, \dots, b_k$  are theoretical values of partial slopes and  $e$  is the error term. In keeping with earlier theoretical and empirical studies put forth in the Literature Review, the following models were used:

Model I: Direct Costs =  $a + B_1$  (Sekscenski Index) +  $B_2$  (Medicaid Enrolment) +  $B_3$  (ReqMDDxTx)

Model II: Direct Costs =  $a + B_1$  (Sekscenski Index) +  $B_2$  (Medicaid Enrolment) +  $B_3$  (ReqMDDxTx) +  $B_4$  (Number of Nurse Practitioners/1000)

Model III: Indirect Costs =  $a + B_1$  (Sekscenski Index) +  $B_2$  (Medicaid Enrolment) +  $B_3$  (ReqMDDxTx)

Model IV: Indirect Costs =  $a + B_1$  (Sekscenski Index) +  $B_2$  (Medicaid Enrolment) +  $B_3$  (ReqMDDxTx) +  $B_4$  (Number of Nurse Practitioners/1000)

## 5 Data results

### 5.1 Multiple regression analysis with direct costs

The results of the regression models for each of the dependent variables are presented below. Table 2 presents the results from Model I, the multiple regression analysis with Direct Costs as the dependent variable. Results from Model I, show the first block of the regression as statistically significant ( $F(3, 46) = 3.67, p = .02$ ). One of the predictors, ReqMDDxTx had a statistically significant and positive effect on direct costs of Diabetes ( $\beta = .37, p = .02$ ). In the first block, the three control variables explained 19.0% of the variance in Direct Costs (i.e.  $R^2 = .19$ ). The adjusted  $R^2$  value was .14. The entry of the Number of NP per 100,000 in the second block (Model II) resulted in a complete model that was still statistically significant ( $R^2 = .69$ , Adjusted  $R^2 = .39, F(4, 45) = 3.77, p = .010$ ). Importantly, the change in  $R^2$  from the first block to the second block (3.51) was statistically significant at the 10% level ( $F(1, 45) = 3.51, p = .07$ ). As expected, this denotes that the model as a whole was statistically significant following the addition of the variables in the second block, largely due to the prediction of our variable of interest, Number of Nurse Practitioners per 100,000.

**Table 2** Summary of regression analysis – variables predicting direct costs of diabetes

<i>Dependent variable: direct (medical) costs</i>	<i>Model I (control variables only)</i>	<i>Model II (All variables)</i>
Medical enrolment	0.22 -10.35	0.24** -10.13
ReqMDDxTx	0.37* -1.19	0.36* -1.16
Sekscenski index	0.06 -0.49	0.08 -0.48
Number of NP per 100,000	- -	-0.24** -0.03
$R^2$	0.19	0.69
Adjusted $R^2$	0.14	0.39
$F$	3.67*	3.77*
F for change in $R^2$	-	3.51**
Number of observations	3.00	46.00

Notes: Standard error in parenthesis; \* significant at the 5% level; \*\*significant at the 10% level.

### 5.2 Multiple regression analysis with indirect costs

The next Table 3 presents the results from Models III and IV. In the first block, Model III indicates both Medicaid enrolment ( $\beta = .25, p < .10$ ) and ReqMDDxTx ( $\beta = .36, p < .05$ ) are statistically significant predictors of Indirect Costs. Overall, the three control variables explained 20% of the variance in Indirect Costs (i.e.  $R^2 = .20$ ). The adjusted  $R^2$  value was .14. The first block of the model was statistically significant ( $F(3, 46) = 3.74, p < .05$ ).

**Table 3** Summary of regression analysis variables predicting indirect costs of diabetes

<i>Dependent variable: indirect costs</i>	<i>Model III (control variables only)</i>	<i>Model IV (All variables)</i>
Medical enrolment	0.25** -4.07	0.27** -4.00
ReqMDDxTx	0.36* -0.47	0.35* -0.46
Sekscenski index	0.08 -0.19	0.10 -19.00
Number of NP per 100,000	- -	-0.23** -0.01
$R^2$	0.20	0.25
Adjusted $R^2$	0.14	0.18
$F$	3.74*	3.69*
F for change in $R^2$	-	3.02**
Number of observations	3	46

Notes: Standard error in parenthesis; \* significant at the 5% level; \*\*significant at the 10% level.

In terms of the entry of the number of NP per 100,000 in the second block a complete model was still statistically significant ( $R^2 = .25, \text{Adjusted } R^2 = .18, F(4, 45) = 3.69, p < .05$ ). Similar to Direct Costs, the change in  $R^2$  from the first block to the second block (3.02) remained statistically significant ( $F(1, 45) = 3.02, p < .05$ ). Again and as expected, this denotes that the model as a whole was statistically significant following the addition of number of NP.

## 6 Discussion

There are four main contributions of this study. The first contribution lies in documenting evidence to support the study hypothesis – NP regulatory and policy factors influence direct and indirect costs of population health outcomes. The second contribution is a new model of Nurse Practitioner Regulatory Policy and Provider Access Factors Influencing Direct and Indirect Costs of Health Outcomes (see Figure 1). The third contribution lies in support for the authors' assertion that reducing scope of practice restrictions on NPs may not only build primary care capacity, it will also increase primary care health outcomes and significantly reduce costs through direct and indirect savings of chronic



disease management. Modernising nurse practitioner regulatory standards is important to improve cost savings and sustainability for primary care with particular attention to chronic conditions. This study explored the relationships among regulatory factors, provider access and cost-savings of improved diabetes health outcomes in states with greater numbers of NPs. The statistically significant findings support the theory that regulation and practice environment do influence cost-savings, both direct and indirect, as outlined in the background. The fourth contribution of this study is that although the importance of services and standards and innovative data management are crucial to an efficient and effective healthcare environment (Von Lubitz and Patricelli, 2007) this article is the first of its kind in that we apply this perspective of services and standards to our model of the nurse practitioner regulatory environment.

Substantial barriers to the abilities of NPs to efficiently provide primary care services remain; most notably among them in the ten states that will potentially add the greatest number of insured to their Medicaid rosters under ACA (see Table 4). As noted previously, NPs tend to serve at-risk and low income populations. Restrictive NP practice regulations may significantly jeopardise the potential of primary care NPs to fully care for the newly insured efficiently and effectively, achieving reduced indirect and direct cost savings associated with diabetes. Further, current billing methods fail to accurately account for all NP services, which complicates accurate data analysis of the contribution NPs make in delivering primary care services to vulnerable populations. This underwrites a misrepresentation or lack of knowledge, which could adversely affect policy decisions.

**Table 4** Top ten states by population

<i>State</i>	<i>Total residents</i>	<i>NPs</i>	<i>ReqMDDxTx</i>
California	37,370,100	42.32	Yes
Florida	18,843,900	65.09	Yes
Georgia	9,587,400	46.80	Yes
Michigan	9,723,700	38.49	No
New Jersey	8,686,800	52.32	No
New York	19,217,700	78.58	Yes
North Carolina	9,376,800	38.44	Yes
Ohio	1,326,800	42.27	Yes
Pennsylvania	2,620,800	54.67	Yes
Texas	5,339,900	34.11	Yes

In this study, the findings provide evidence that supports the utility of NPs in primary care. NPs demonstrate a high level of quality care and are essential for meeting the increasing demands of chronic disease management in the USA (Keleher et al., 2009; Chin et al., 2011).

## 7 Implications

This study examined a theoretical model of the impact of state NP practice regulatory factors on primary care access (as reflected in the number NPs) and direct and indirect costs associated with diabetes. Identifying the impact of these regulations on NP

primary care services and health outcomes is relevant. The study findings support that regulatory factors and practice environment influence the primary care outcomes, direct and indirect costs of diabetes. As the ACA increases access to care under the Medicaid expansion (Bodenheimer and Pham, 2010; Valdmanis et al., 2014), there are significant implications for the approximately 55.3 million Americans who live in primary care shortage areas (US DHHS (HRSA), 2012b). Concomitantly, the ACA has set aside up to \$1.5 billion to place healthcare professionals in underserved areas in order to strengthen the primary care workforce (Koh and Sebelius, 2010). Standardising and modernising NP regulatory policies are essential to optimising access to care and the successful implementation of the ACA.

However, one critical implication to emerge from this study is the need to improve upon the data management technology related to tracking services rendered by nurse practitioners if we are going to achieve NP optimisation through regulatory change and measure impact on primary healthcare outcomes. Currently, NP contributions are underestimated due to billing policies and procedures. Indeed, interoperability and the need to consider the technical framework in which we are delivering services are paramount in our digital world (Turowski and Zaha, 2004). In conducting audits and evaluations a complete internal framework depends upon identifying key variables to be measured (Piskar, 2006), which as this study identified are not adequately measured. Rather than measuring the number of licensed NPs, it is important to measure the services for which NPs are billing.

State regulatory restrictions on NP practice adversely affect access to care (Naylor and Kurtzman, 2010). NPs may be less inclined to practice in states where they are restricted from practicing to the full extent of their education ability. Second, regulations that require physician supervision of NPs for diagnosis and treatment may adversely affect the number of NPs, particularly in areas where physicians may be less inclined to practice (i.e. rural or low-resource areas). For example, where treatment requires physician approval, two providers' time (the NP and the physician) is needed to address one patient or, when the physician is not present, the NP must locate the physician, consult electronically or ask the patient to return. A patient may choose to return or not, potentially decreasing treatment compliance and potentially increasing adverse health outcomes. Finally, in states with restrictive supervision regulations, physicians may be less inclined to include NPs in their practices, thereby decreasing the number of patient visits per practice. These factors may significantly inhibit optimal utilisation of NPs to expand access to care in Healthcare Provider Shortage Areas (HPSAs).

Since February 2013 the National Conference of State Legislatures (2014) reports that 42 bills across 17 states have been filed or carried over in state legislatures regarding scope of practice issues for nurses and NPs. One reason for this kind of policy activity may be that from 1995–2005, the number of primary care physicians increased by 1% while the number of NPs increased by almost 9.5% (US GAO, 2008). To gain training and licensure to practice, it takes physicians about 12 years and NPs six years (Cassidy, 2012), with research supporting equivalent population primary care health outcomes for both providers (Newhouse et al., 2011). Federal and state laws that reduce NP practice barriers may increase the number of primary care providers in a shorter period of time. Changes in NP regulatory factors may facilitate increased primary care access and thus improve population health outcomes.

## 8 Conclusion

Eventually, when the ACA is fully implemented, millions of people will potentially join the rosters of the insured. In many states, these newly insured will significantly increase Medicaid enrolment. In medically underserved communities, community health centres remain dependent upon NPs for service delivery and to improve the patient-practitioner ratio (Shin and Rosenbaum, 2012). As this study has identified, restrictive regulatory factors do influence health cost savings. Continued restrictive policies may further deplete a system which already has a shortage of primary care providers across the country.

As the ACA unfolds, it becomes increasingly necessary for policy makers to address regulatory barriers, to reform the primary care delivery system and to focus on efficiency and outcomes (Goodell et al., 2011). Standardising NP scope of practice laws will improve access to primary care (Jacobson and Jazowski, 2011). Promoting change across the states rests in part with the federal government, which can provide incentives for states to enact and share effective regulatory changes (IOM, 2011).

Policy makers and other stakeholders must focus their sights on standardising and modernising NP state standards and regulations, with particular attention to improving plenary authority among NPs. Such an NP modernisation act has already been passed in some states and proposed in others (New York State Senate, 2012). Currently 18 states grant full plenary authority for NPs to practice without oversight from physicians (Phillips, 2014). While state laws have increased scope of practice for NPs, great variation still exists around the country (Goodell et al., 2011). Consequently, there is ample room for standardisation and uniform policy-making to better meet the primary healthcare needs of the expanding roster of insured individuals.

## 9 Limitations and future research

Results of this study present some limitations and raise a number of questions for further study. Additional empirical models could determine whether statistical relationships exist among NPs and other health outcomes. This study was delimited to diabetes health outcomes only. In addition, other variation in the data results could potentially be found by controlling for other factors including geopolitical and socioeconomic variables. The authors acknowledge that these differences are not accounted for in this study. Controlling for these and other predictors would be a worthwhile addition to this research going forward. Further research based on best practices in states that have already modernised their scope of practice regulations will provide greater analysis and evaluation of the standardising and modernisation of nurse practitioner scope of practice regulations.

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## Notes

- 1 Please see American Diabetes Association Economic Costs of Diabetes in the U.S. in 2012 *Diabetes Care* April 2013 36:1033-1046; published ahead of print 6 March 2013, doi:10.2337/dc12-2625.