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### Patient outcomes associated with utilization of education, case management, and advanced practice pharmacy services by American Indian and Alaska Native peoples with diabetes

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#### Abstract

**Background:** The burden of diabetes is exceptionally high among American Indian and Alaska Native peoples (AI/ANs). The Indian Health Service (IHS) and Tribal health programs provide education, case management, and advanced practice pharmacy (ECP) services for AI/ANs with diabetes to improve their health outcomes.

**Objective:** Evaluate patient outcomes associated with ECP use by AI/AN adults with diabetes.

**Research Design:** This observational study included the analysis of IHS data for fiscal years (FY) 2011–2013. Using propensity score models, we assessed FY2013 patient outcomes associated with FY2012 ECP use, controlling for FY2011 baseline characteristics.

Subjects: AI/AN adults with diabetes who used IHS and Tribal health services (n=28,578).

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**Measures:** We compared health status and hospital utilization outcomes for ECP users and non-users.

**Results:** Among adults with diabetes, ECP users, compared to non-users, had lower odds of high systolic blood pressure (OR=0.85, p<0.001) and high low-density lipoprotein cholesterol (OR=0.89, p<0.01). Among adults with diabetes absent cardiovascular disease (CVD) at baseline, 3 or more ECP visits, compared to no visits, was associated with lower odds of CVD onset (OR=0.79, p<0.05). Among adults with diabetes and CVD, any ECP use was associated with lower odds of 1 or more hospitalizations (OR=0.80, p<0.001).

**Conclusions:** Findings on positive patient outcomes associated with ECP use by adults with diabetes may inform IHS and Tribal policies, funding, and enhancements to ECP services to reduce disparities between AI/ANs and other populations in diabetes-related morbidity and mortality.

#### **Keywords**

American Indian and Alaska Native; diabetes; patient education; cardiovascular disease; observational studies

#### Introduction

American Indian and Alaska Native (AI/AN) peoples experience some of the greatest health disparities with respect to diabetes and related complications.<sup>1–5</sup> The prevalence of diabetes among AI/ANs aged 18 years and older was 14.7% in 2017–2018, nearly double that of non-Hispanic whites and the highest among U.S. racial/ethnic groups.<sup>1</sup> The AI/AN all-cause mortality rate is 46% higher than that of non-Hispanic whites and is largely attributable to disparities in heart disease, stroke, diabetes, and kidney disease mortality.<sup>2,6–8</sup> Additionally, diabetes and cardiovascular disease (CVD) contribute to higher rates of premature mortality.<sup>6–8</sup>

Many AI/ANs obtain health care through services funded by the Indian Health Service (IHS). The IHS service delivery system includes hospitals, clinics, and health programs operated by the federal government, Tribal organizations, and urban Indian health programs. Known collectively as I/T/Us, they serve approximately 2.6 million AI/ANs throughout the United States.<sup>9</sup> IHS and Tribes support an array of services to implement IHS Standards of Care for diabetes to reduce complications among those with diabetes.<sup>10</sup> The Special Diabetes Program for Indians (SDPI) provides grants to over 300 I/T/Us and community-based programs to support diabetes prevention and treatment, including education, case management, and advanced practice pharmacy (ECP) services.<sup>5</sup> Since SDPI's implementation in 1998, intermediate clinical outcomes (e.g., blood glucose and cholesterol levels) among AI/AN adults with diabetes have improved;<sup>11</sup> hospitalizations for uncontrolled diabetes have declined;<sup>12</sup> and the incidence of diabetes-related end-stage renal disease (ESRD) has substantially decreased, as have estimated ESRD-related Medicare expenditures.<sup>13</sup>

In non-AI/AN populations, ECP services have improved outcomes among individuals with diabetes.<sup>14–21</sup> Information about the provision and use of ECP services among AI/ANs with diabetes who access I/T/U services is increasingly available.<sup>11,22–26</sup> A 2014 study of the SDPI *Healthy Heart* demonstration project linked intensive case management with improvements in CVD risk factors among approximately 3,400 adults with diabetes.<sup>23</sup> Participants had reductions in high blood sugar, blood pressure, and cholesterol after 12 months of case management services. Though the study documented a successful translation of an intensive case management program, it did not include a comparison population to provide context for the findings. Thus, information on patient outcomes associated with ECP utilization by adults with diabetes for a larger, more representative sample is needed to guide enhancements to ECP services and effectively allocate I/T/U resources.

This is particularly important as AI/ANs with diabetes who use I/T/U services require delivery models that can effectively address their risks and complex needs. IHS resources are strained due to limited per capita spending (\$4,078 in fiscal year [FY] 2017).<sup>9,25</sup> Although this amount does not include all spending associated with patient care, it is substantially lower than per capita spending for the U.S. general population (\$10,742) in 2017.<sup>27</sup> IHS resources are further compromised by provider shortages and community-level factors that affect patient service use and health (e.g., low household income, rural geography).<sup>25,28–33</sup>

To add to this emerging literature, we evaluated patient outcomes associated with ECP utilization by analyzing IHS data for a large, geographically diverse group of AI/AN adults with diabetes (n=28,578). Using an observational design, we compared the health status and hospital utilization of ECP users to non-users to assess outcomes associated with using ECP services in addition to usual care (e.g., primary care and specialty services).

#### Methods

This study was approved by the IHS National Institutional Review Board (IRB), Tribal IRBs, and Tribal Councils and Authorities, in addition to the university's IRB.

#### A. Data

This study was conducted using data extracted from a longitudinal data infrastructure that houses health status, service utilization, and treatment cost data for over 640,000 AI/ANs who live throughout the United States, representing nearly 30% of AI/ANs who use IHS services.<sup>24</sup> The data infrastructure, created as the *IHS Improving Health Care Delivery Data Project*, is a synthesis of existing health data from multiple IHS platforms and includes data for FY2007-FY2013.

The data infrastructure includes information for a purposeful sample of AI/ANs who lived in 15 IHS Service Units. IHS Service Units, which are health service administrative units defined by geographic areas that include one or more health facilities, are located throughout the United States. One Service Unit is located in the East, 4 in the Northern Plains, 2 in the Southern Plains, 5 in the Southwest, 2 in the Pacific Coast, and 1 in Alaska.<sup>2</sup> The IHS Data Project population was identified by geographic area, rather than by random sampling, to create important community-level (e.g., drive time to services) and county-level (e.g., household income) measures not available elsewhere. Communities are defined geographic areas within Service Units (hereafter we refer to Service Units as project sites). Sources of IHS electronic data include the National Data Warehouse (NDW) for data on registration and services rendered by I/T providers and the Purchased/Referred Care (PRC) program for data on non-I/T services paid for by some IHS and Tribal health programs; PRC program data for other projects sites was obtained from the PRC fiscal intermediary. In this study, we refer to I/T services, rather than I/T/U services, since the urban Indian clinics located in the 12 project sites included in the analysis provided very few ECP visits in FY2012. The IHS Data Project population is comparable to the national IHS service population in terms of age and sex.<sup>34</sup>

#### B. Study population

The study population included adults who 1) had diabetes in FY2011, 2) used I/T services during 3 consecutive fiscal years (FY2011-FY2013), and 3) lived in 1 of 12 project sites that provided ECP services and had complete data. Study population exclusion criteria included 1) treatment for malignant cancer, a transplant, or ESRD (except for the analysis of onset of ESRD in FY2013) during FY2011-FY2013; 2) having missing data for community- and county-level variables; and 3) evidence of having died during FY2013.

#### C. Measures

Data for all measures were extracted from the IHS Data Project data infrastructure for FY2011-FY2013, except where noted.

**Demographic and health status.**—NDW data provided information on age, gender, and health insurance coverage in FY2011. Project specific algorithms, developed from national references, were used to identify adults with diabetes, CVD, and ESRD using ICD-9-CM diagnoses, procedure codes, medication use, and blood glucose control included in the NDW and PRC service utilization records.<sup>35–37</sup> The diabetes and CVD measures were used to create 3 study cohorts: all adults with diabetes and 2 subgroups—adults with diabetes absent CVD and adults with both diabetes and CVD.

SightlinesTM DxCG Risk Solutions software<sup>38</sup> was used to identify patients diagnosed with other conditions (e.g., hypertension, renal disease). The DxCG software also provided a measure of morbidity burden (i.e., health risk score) for individuals based on their age, gender, and all diagnosed conditions. For each health status group, we categorized the risk scores into quartiles; adults with the lowest morbidity were assigned to quartile 1 and those with the highest morbidity to quartile 4.

Patient outcome measures included 5 diabetes management indicators. Based on IHS and national guidelines for diabetes management, diabetes management indicators include high hemoglobin A1c ( 8%), high systolic blood pressure (SBP, 140 mmHg), and high low-density lipoprotein (LDL) cholesterol ( 100 mg/dL).<sup>10,11,39</sup> New or recurring onset of CVD was defined as having CVD during FY2013 with no diagnosis of the condition during

the previous 3 fiscal years. ESRD onset in FY2013 was assessed using data for all previous years (FY2007-2013).

Health service utilization.—ECP utilization was defined using I/T data on visits for individual or group diabetes education, provided by nurses or health educators in diabetes clinics; nutrition education; advanced practice pharmacy (APP); case management; and other types of education (e.g., smoking cessation, obesity). APP delivery models varied and could have included patient assessment, medication reconciliation, and health education conducted by certified pharmacists who may also have ordered laboratory tests and modified prescriptions under the supervision of a physician or as primary care providers.<sup>26,31,40,41</sup> Thus, ECP visits do not include education provided as part of other outpatient visits with physicians and mid-level providers (e.g., primary and specialty care visits). We created 2 ECP utilization measures: any ECP use (a dichotomous measure) and level of ECP use (no visits, 1–2 visits, 3+ visits).

NDW I/T and PRC non-I/T inpatient data were combined to create 2 hospital inpatient utilization measures: 1 or more hospitalizations and total number of hospital inpatient days. I/T hospital data were used to create 2 additional measures: 1 or more potentially preventable hospitalizations<sup>24</sup> and number of emergency department (ED) visits.

Facility, community, and county measures.—We created 2 measures of ECP access in FY2012. The facility ECP supply rate was calculated as the number of provided ECP visits divided by the number of adults living in the facility's service area, defined by communities. Patient drive time to ECP services was estimated from a central location in each community to an I/T facility that provided ECP using geocodes (latitude and longitude).42

County-level measures of AI/AN educational attainment and household income were derived from 2010-2014 American Community Survey county-level data for AI/ANs who reported access to IHS services.<sup>43</sup> The educational attainment measure is the percentage of adults aged 25 years and older who did not complete high school. We defined the percentage of households with low income as the percentage with incomes below 139% of the federal poverty level, a poverty level used in many states to determine one type of Medicaid eligibility.

#### D. Analysis

We used SAS® and Stata statistical software to conduct descriptive and multivariate analyses.<sup>44,45</sup> This study employed an observational design to compare diabetes management and hospital utilization outcomes among ECP users and non-users. To address nonrandom assignment of patients to 2 groups based on FY2012 ECP use (i.e., ECP users and non-users), we used inverse probability of treatment weighted (IPTW) estimation.<sup>46,47</sup> IPTW is a statistical approach often used when considering causal effects in observational studies without randomization whereby the distributions of potential confounders between comparison groups are statistically balanced.<sup>47</sup>

Equation 1 of the model estimated a patient's propensity to use ECP services during FY2012, based on baseline (i.e., FY2011) patient and provider characteristics. Equation 2 compared patient outcomes during FY2013 between FY2012 ECP users and non-users, after adjusting for the baseline differences between the comparison groups using IPTW estimation. To address residual confounding, Equation 2 also included baseline patient characteristics. The propensity models included fixed effects in both equations to control for variations across project sites.

We estimated 2 sets of propensity models. The first set examined patient outcomes associated with any ECP use, compared to no use, using logistic regression for Equation 1. The second set estimated relationships between level of ECP use and patient outcomes using ordered logistic regression for Equation 1. For both sets, the specification of Equation 2 varied by patient outcome. Binary outcomes were estimated using logistic regression; the number of ED visits and hospital inpatient days were modeled using negative binomial regression.

#### Results

Of all adults with diabetes, 28,578 adults met study inclusion and exclusion criteria. Additional information on the study sample is provided in the appendix. Statistical differences (p<0.001) were observed between ECP users and non-users in FY2011. Throughout this section, we first present results for all adults with diabetes. Next, we provide results for the subsamples absent CVD and with CVD, where noteworthy.

ECP users were older; had a higher prevalence of hypertension, CVD, and renal disease; and had a higher morbidity burden (Table 1). ECP users, compared to non-users, lived in communities where the mean drive time to a facility with ECP services was shorter (15.2 and 22.5 minutes, p<0.001), and in counties where a smaller percentage of households had low household incomes (41.1% and 45.1%, p<0.001).

Adults with diabetes and CVD, compared to adults with diabetes absent CVD, were older and had higher rates of comorbidities. Despite this, many differences observed between ECP users and non-users among all adults with diabetes in FY2011 were also observed among adults with and without CVD.

During FY2012, 41.0% of adults with diabetes used ECP services (Table 2). Their average number of ECP visits was 2.8, with 68.6% having 1–2 visits, and 31.4% having 3 or more.

We compared FY2011 and FY2013 data for the 5 diabetes management and 4 hospital utilization outcome measures (Table 3). Between FY2011 and FY2013, the percentage of adults with diabetes with high SBP and high A1c increased. In contrast, the percentage with high LDL cholesterol decreased. Among adults with diabetes, a statistically lower percentage of ECP users, compared to non-users, had high SBP and high LDL cholesterol in FY2013. Although, there were no statistically significant differences by ECP user status among adults with diabetes in the percentage with high A1c in FY2013, the difference between FY2011 and FY2013 in the percent with high A1c was lower among ECP users.

Changes in hospital service utilization between FY2011 and FY2013 also differed by ECP user status. Hospitalization and potentially preventable hospitalization results were similar among all adults with diabetes. In FY2011, a higher percentage of ECP users, compared to non-users, had 1 or more hospitalizations (10.3% compared to 8.8%, p<0.001) and 1 or more potentially preventable hospitalizations (2.6% compared to 2.1%, p<0.01). ECP users, compared to non-users, had statistically significant decreases between FY2011 and FY2013 in both measures.

IPTW regression results on the associations of any ECP use and level of ECP use with patient outcomes are summarized in Tables 4 and 5, respectively. Among all adults with diabetes, use of ECP services, compared to no use, was associated with lower odds of having high SBP (OR=0.85, p<0.001) and high LDL cholesterol (OR=0.89, p<0.01) in FY2013. There was no statistical relationship between any use of ECP services and high A1c. Among adults absent CVD, there was no statistically significant association between any use of ECP, compared to no use, and onset of CVD during FY2013. Due to very low ESRD onset rates in FY2013 among all adults with diabetes and adults with diabetes absent CVD, we only evaluated the relationship between ECP use and ESRD onset among adults with diabetes and CVD. ECP users compared to non-users were found to have lower odds of ESRD onset during FY2013 (OR=0.60, p<0.05).

Among all adults with diabetes, ECP users compared to non-users had a statistically lower average number of ED visits (-0.08, p<0.01), and lower odds of 1 or more hospitalizations (0.80, p<0.001) and 1 or more potentially preventable hospitalizations (0.79, p<0.05). ECP use was significantly associated with fewer hospital inpatient days (-0.13, p<0.01).

We examined the relationships between ECP use, both any use and level of use, and patient outcomes for the 7 patient outcomes assessed for adults with and without CVD. The relationships between ECP use and patient outcomes was alike (i.e., significant association with improvement in patient outcome, no association) across these two health status groups for 4 of the 7 outcomes examined (i.e., high A1c, ED visits, 1 or more hospitalizations, hospital inpatient days).

The level of ECP use was significantly associated with improved patient outcomes for 5 of the 9 outcomes assessed (e.g., high SBP, high LDL cholesterol, onset of CVD, potentially preventable hospitalizations, hospital inpatient days; Table 5). Among all adults with diabetes, 1-2 ECP visits and 3 or more ECP visits, compared to no visits, were each associated with lower odds of high SBP (OR=0.89 [p<0.05] and OR=0.74 [p<0.001], respectively), and 3 or more ECP visits was associated with lower odds of high SBP than 1-2 visits (OR=0.82, p<0.05). Similarly, for high LDL cholesterol, adults with diabetes who had 3 or more visits, as compared to no visits, as compared to 1-2 visits, had lower odds of high LDL cholesterol (OR=0.77 [p<0.001] and OR=0.83 [p<0.05], respectively).

ECP use, compared to no use, was not associated with lower onset of CVD or lower odds of 1 or more potentially preventable hospitalizations among adults absent CVD. However, among these adults, those who had 3 or more ECP visits, compared to those with no visits,

had lower odds of CVD onset (OR=0.79, p<0.05) and lower odds of 1 or more potentially preventable hospitalizations (OR=0.65, p<0.05). Among all adults with diabetes, patients who had 3 or more visits, as compared to no visits, and patients who had 3 or more visits, as compared to 1–2 visits, had fewer hospital inpatient days (-0.23, [p<0.001] and -0.14 [p<0.05], respectively).

#### Discussion

This is the first large scale study, to our knowledge, to evaluate patient outcomes associated with ECP utilization among AI/ANs with diabetes. We found ECP use was associated with improvements in blood pressure and cholesterol control, lower odds of CVD and ESRD onset, and reductions in hospital emergency department and inpatient utilization. While we did not observe an association between ECP use and glycemic control in FY2013, there were a number of factors that could have influenced this finding, including a larger percentage of ECP users having high A1c at baseline (FY2011). Due to the importance of controlling blood sugar levels, future research on provider referrals to ECP and how blood sugar control is addressed during ECP and other outpatient visits is warranted.

Despite differences in age and morbidity burden between adults with diabetes absent CVD and with CVD, we found similar relationships between ECP use and patient outcomes across these 2 health status groups for 4 of the 7 outcomes examined. In addition, the findings suggest that higher levels of ECP use (i.e., 3 or more ECP visits) were associated with improved outcomes for 5 of the 9 outcomes assessed.

Our study has limitations that merit consideration. First, due to the observational design, residual confounding related to patient self-selection to ECP use could account for some of the observed associations. Propensity score models, such as IPTW regression, control for observable confounders (e.g., health status, drive time to services), but there may have been important unobserved provider and patient characteristics associated with ECP use and patient outcomes that could have biased our results. For example, coordination between ECP and primary care providers may vary across project sites, with higher coordination levels likely benefiting patients. Patient motivation to maintain or improve one's health status may not only influence ECP use but also patient outcomes. Thus, lacking measures of site coordination, patient motivation, and other confounding factors, we may have overestimated the influence of ECP use on patient outcomes. Future quasi-experiment or randomized clinical trials designed to test the effects of ECP use among AI/ANs are needed to validate our findings.

Many previous ECP effectiveness studies evaluated interventions designed to provide more than 3 visits during a time period, typically a 12-month period.<sup>14–21</sup> For example, SDPI *Healthy Heart* demonstration project participants had, on average, 7 case management visits during the first program year, and those with more visits experienced significantly greater improvements in some outcomes.<sup>23</sup> The average number of ECP visits among ECP users in this study was 2.8. We assessed ECP use during the 12 months of FY2012 and did not account for ECP use prior to or after FY2012. We may assess ECP use during individually defined time periods in future studies. Although we employed an algorithm to identify

ECP visits that allowed for project site specific adjustments, we may not have identified all provided ECP visits. Finally, we assessed outcomes during a 12-month follow-up period, and the results concerning onset of CVD and ESRD were borderline (i.e., p < 0.05). Longer time periods could be used to understand the extent to which ECP use may mitigate the onset of these conditions.

Other study limitations pertain to the nature of the IHS Data Project data. We reported the prevalence of conditions based on diagnoses included in medical service utilization records. While this method allowed us to include a large number of AI/ANs in the analysis, we did not have the detail and accuracy of medical records. These data include information for services provided by I/T programs or were paid by the PRC program. We did not have data on other services used by the study population, and financial and geographic access to other services (e.g., non-I/T specialty services) varied across project sites. This limitation may have biased downward morbidity measures, a bias which likely varied across the sites. Sites also varied by the types of services provided (e.g., specialty outpatient and inpatient services), PRC service utilization, funding and completeness of data. While software issues contributed to missing data at some sites, there may have been a relationship between missing data and quality of care. It is difficult to predict the influence of these limitations on study findings. An ECP cost-effectiveness analysis was beyond the scope of this study. However, our subsequent work will assess ECP costs, savings, and cost-effectiveness. Lastly, our study population represents a large proportion of AI/ANs eligible for I/T health services. Nevertheless, findings may not reflect the health status of AI/AN peoples who live elsewhere or who do not obtain health services from I/T providers.<sup>11,33</sup>

Despite these limitations, we were able to analyze existing IHS/Tribal electronic health data to evaluate ECP utilization for a large and geographically representative sample of adults with diabetes. Findings on positive patient outcomes associated with ECP utilization by adults with diabetes may inform IHS/Tribal policies, funding, and enhancements to ECP services and improve patient knowledge of ECP services, and ultimately contribute to reducing disparities between AI/ANs and other populations in diabetes-related morbidity and mortality.

#### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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# Table 1.

Baseline (fiscal year 2011, except where noted) characteristics of adults with diabetes by cardiovascular disease (CVD) status and use of education, case management, and advanced practice pharmacy (ECP) services during fiscal year 2012.

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		Adults	with diabe	etes		Adul	ts with di	abetes ab	sent CVD		Ψ	dults with	diabetes	and CVD	
Characteristic	ECP nc	on-users	ECP	users		ECP nor	l-users	ECP	users		ECP no	on-users	ECP	users	
	Z	%	Z	%		Z	%	Z	%		Z	%	Z	%	
All adults with diabetes	16,855	100.0%	11,723	100.0%		12,733	100.0%	8,044	100.0%		4,122	100.0%	3,679	100.0%	
Gender										*					
Female	9,635	57.2%	6,795	58.0%		7,506	59.0%	4,861	60.4%		2,129	51.7%	1,934	52.6%	
Male	7,220	42.8%	4,928	42.0%		5,227	41.1%	3,183	39.6%		1,993	48.4%	1,745	47.4%	
Age					***					***					***
18–34 years	1,728	10.3%	827	7.1%		1,552	12.2%	722	9.0%		176	4.3%	105	2.9%	
35–44 years	2,876	17.1%	1,615	13.8%		2,502	19.7%	1,345	16.7%		374	9.1%	270	7.3%	
45–54 years	4,291	25.5%	2,917	24.9%		3,506	27.5%	2,238	27.8%		785	19.0%	679	18.5%	
55–64 years	4,245	25.2%	3,355	28.6%		3,080	24.2%	2,244	27.9%		1,165	28.3%	1,111	30.2%	
65+ years	3,715	22.0%	3,009	25.7%		2,093	16.4%	1,495	18.6%		1,622	39.4%	1,514	41.2%	
Health Coverage															
No coverage in addition to IHS access	6,457	38.3%	4,162	35.5%	***	5,311	41.7%	3,213	39.9%		1,146	27.8%	949	25.8%	*
Medicaid	3,684	21.9%	2,107	18.0%	***	2,832	22.2%	1,525	19.0%	***	852	20.7%	582	15.8%	***
Medicare	4,805	28.5%	4,016	34.3%	***	2,808	22.1%	2,071	25.8%	***	1,997	48.5%	1,945	52.9%	***
Private	3,959	23.5%	2,968	25.3%	***	3,047	23.9%	2,115	26.3%	***	912	22.1%	853	23.2%	
Health Condition															
Hypertension	11,798	70.0%	9,081	77.5%	***	8,419	66.1%	5,926	73.7%	***	3,379	82.0%	3,155	85.8%	***
Cardiovascular disease	4,122	24.5%	3,679	31.4%	***										
Renal disease	1,223	7.3%	1,147	9.8%	***	344	2.7%	309	3.8%	***	879	21.3%	838	22.8%	
Neuropathy	2,287	13.6%	2,002	17.1%	***	1,419	11.1%	1,082	13.5%	***	868	21.1%	920	25.0%	***
Amputations <sup>a</sup>	213	1.3%	159	1.4%		76	0.6%	45	0.6%		137	3.3%	114	3.1%	
Mental health disorders $b$	3,510	20.8%	2,880	24.6%	***	2,540	20.0%	1,914	23.8%	***	970	23.5%	996	26.3%	*
Depression	2,350	13.9%	2,022	17.3%	***	1,708	13.4%	1,322	16.4%	***	642	15.6%	700	19.0%	***
Alcohol and drug abuse	1,101	6.5%	571	4.9%	***	841	6.6%	380	4.7%	***	260	6.3%	191	5.2%	*
Alcohol abuse	861	5.1%	436	3.7%	***	658	5.2%	302	3.8%	***	203	4.9%	134	3.6%	*

		Adults	with diab	etes		Adu	lts with di	abetes al	sent CVE	•	A	dults with	diabetes	and CVD	
Characteristic	ECP nc	n-users	ECP	users		ECP no	n-users	ECP	users		ECP no	on-users	ECP	users	
	z	%	z	%		z	%	z	%		z	%	z	%	
Drug abuse	357	2.1%	200	1.7%	*	267	2.1%	120	1.5%	*	90	2.2%	80	2.2%	
Tobacco use disorders	1,528	9.1%	1,028	8.8%		1,075	8.4%	635	7.9%		453	11.0%	393	10.7%	
Liver disease	700	4.2%	588	5.0%	***	505	4.0%	383	4.8%	*	195	4.7%	205	5.6%	
Eye disease	2,581	15.3%	2,364	20.2%	***	1,660	13.0%	1,373	17.1%	***	921	22.3%	991	26.9%	***
<u>Risk score quartiles</u>					***					***					***
Quartile 1 (lowest risk)	5,067	30.1%	2,071	17.7%		3,738	29.4%	1,455	18.1%		1,280	31.1%	699	18.2%	
Quartile 2	4,356	25.8%	2,793	23.8%		3,265	25.6%	1,930	24.0%		1,027	24.9%	924	25.1%	
Quartile 3	3,857	22.9%	3,289	28.1%		2,967	23.3%	2,227	27.7%		936	22.7%	1,014	27.6%	
Quartile 4 (highest risk)	3,575	21.2%	3,570	30.5%		2,763	21.7%	2,432	30.2%		879	21.3%	1,072	29.1%	
Clinical measures															
Systolic blood pressure					***					***					***
No SBP result	566	4.5%	174	2.4%		501	5.3%	154	3.0%		65	2.2%	20	0.9%	
<140 mmHg	8,999	72.2%	5,578	75.4%		6,957	73.4%	3,971	77.0%		2,042	68.6%	1,607	71.8%	
140 mmHg	2,893	23.2%	1,642	22.2%		2,022	21.3%	1,030	20.0%		871	29.3%	612	27.3%	
Alc					***					***					***
No A1c result	2,178	17.5%	611	8.3%		1,751	18.5%	488	9.5%		427	14.3%	123	5.5%	
<8%	5,878	47.2%	3,722	50.3%		4,365	46.0%	2,513	48.8%		1,513	50.8%	1,209	54.0%	
8%	4,402	35.3%	3,061	41.4%		3,364	35.5%	2,154	41.8%		1,038	34.9%	907	40.5%	
LDL cholesterol					***					***					***
No LDL result	3,819	30.7%	1,555	21.0%		3,041	32.1%	1,202	23.3%		778	26.1%	353	15.8%	
<100 mg/dL	4,730	38.0%	3,524	47.7%		3,342	35.3%	2,244	43.5%		1,388	46.6%	1,280	57.2%	
100 mg/dL	3,909	31.4%	2,315	31.3%		3,097	32.7%	1,709	33.2%		812	27.3%	606	27.1%	
Hospital service use															
Average # of I/T ED visits	0.79		0.78			0.69		0.62		*	1.10		1.12		
1 or more hospitalizations (%)	1,226	8.8%	883	10.3%	*	583	5.5%	340	5.7%		643	19.9%	543	21.2%	
Average # of hospital inpatient days	0.49		0.61		*	0.23		0.25			1.32		1.46		
1 or more $LT$ potentially preventable hospitalizations (%)	334	2.1%	296	2.6%	*	135	1.1%	102	1.3%		199	5.0%	194	5.5%	
Mean ECP Drive time 2012 (min)	22.5		15.2		***	22.3		15.4		***	23.0		14.6		***
ECP FY2012 facility rate	0.30		0.35		***	0.30		0.34		***	0.31		0.36		***

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		Adults	with diab	etes		Adults	with diab	etes absent C	ΔŊ	Ac	dults with	diabetes	and CVD	
Characteristic	ECP n	on-users	ECP	users	Ē	CP non-u	sers	ECP users		ECP no	on-users	ECP	users	
	z	%	z	%		Z	%	% N		z	%	z	%	
County-level demographic information														
Mean percent with < high school completion		46.8%		46.0%		4	6.8%	46.0%	.0		46.8%		45.9%	
Mean percent with < 139% federal poverty level		45.1%		41.1%	***	45	5.2%	41.4%	*** (		44.7%		40.4%	***
IHS: Indian Health Service; ECP: education, case manager	ment and ad	vanced pract	tice pharm	acy; I/T: In	dian Health	1 Service	ind Tribal							
* / 00.														

p < 0.05;

p < 0.01; p < 0.01;

 $^{***}_{p < 0.001}$ 

<sup>a</sup>The prevalence of amputations represents amputations noted on the utilization records during the specific fiscal years; providers may not have documented in the utilization record that a person had an amputation during previous years.

b Depression is one of the mental health disorders included in the category Mental health disorders; other types of mental health disorders include anxiety, bipolar, and post-traumatic stress disorders. Persons in the Depression category may or may not have other mental health disorders.

## Table 2.

Use of education, case management, and advanced practice pharmacy (ECP) services among adults with diabetes. Fiscal year 2012.

	Adults with diabetes	Adults with diabetes absent CVD	Adults with diabetes and CVD	
Average number of ECP visits	1.1	6.0	1.7	***
Percent who had at least 1 ECP visit	41.0%	38.7%	47.2%	***
Average number of ECP visits among those who had at least 1 visit	2.8	2.3	3.7	***
Distribution of the number of visits among those with at least one visit	Ţ			***
Percent who had 1 ECP visit	45.4%	48.3%	38.9%	
Percent who had 2 ECP visits	23.2%	23.9%	21.6%	
Percent who had 3 ECP visits	11.1%	11.1%	11.3%	
Percent who had 4 or more ECP visits	20.3%	16.7%	28.2%	
All	100%	100%	100%	

\*\*\* p<0.001, statistical significance of differences between adults with and without CVD.

## Table 3.

Health status and service utilization in fiscal years (FY) 2011 and 2013 by utilization of education, case management, and advanced practice pharmacy (ECP) services in FY2012. Bivariate associations.<sup>a</sup>

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	All adults with d	iabetes		Adults with diab	etes absent CV	Δ	Adults with diab	etes and CVD	
	ECP non-users	ECP users		ECP non-users	ECP users		ECP non-users	ECP users	
All adults with diabetes	16,855	11,723		12,733	8,044		4,122	3,679	
Clinical Measures									
High SBP 140 mmHg $^b$									
FY 2011	23.6%	22.6%		21.8%	20.4%		29.0%	27.5%	
FY 2013	25.9%	23.8%	**	24.4%	21.5%	***	30.7%	28.7%	
Difference	2.4%	1.2%		2.6%	1.2%		1.7%	1.2%	
High hemoglobin A1c $8\% b$									
FY 2011	42.5%	44.5%	*	43.2%	45.4%	*	40.4%	42.5%	
FY 2013	46.3%	46.7%		47.2%	47.5%		43.8%	45.0%	
Difference	3.9%	2.2%	*	4.0%	2.1%	*	3.4%	2.4%	
High LDL cholesterol 100 mg/dL $b$									
FY 2011	44.1%	38.5%	***	46.9%	42.0%	***	36.2%	31.5%	*
FY 2013	38.8%	34.0%	***	41.3%	37.6%	***	31.8%	26.7%	*
Difference	-5.3%	-4.6%		-5.6%	-4.5%		-4.3%	-4.7%	
Onset of CVD 2013				7.3%	9.1%	***			
Onset of ESRD 2013	0.5%	0.4%		0.2%	0.1%		1.5%	1.1%	
Hospital service use									
Average number of I/T ED visits									
FY 2011	0.79	0.78		0.69	0.62	**	1.10	1.12	
FY 2013	0.82	0.75	***	0.75	0.64	***	1.03	0.98	
Difference	0.03	-0.03	*	0.07	0.02	*	-0.06	-0.14	
Percent with 1 or more hospitalizations									
FY 2011	8.8%	10.3%	***	5.5%	5.7%		19.9%	21.2%	
FY 2013	8.6%	8.9%		6.8%	6.5%		14.8%	14.5%	
Difference	-0.2%	-1.4%	**	1.3%	0.8%		-5.2%	-6.7%	

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	All adults with d	iabetes		Adults with diab	etes absent CVD	Adults with diab	etes and CVD
	ECP non-users	ECP users		ECP non-users	ECP users	ECP non-users	ECP users
Average number of inpatient days							
FY 2011	0.49	0.61	**	0.23	0.25	1.32	1.46
FY 2013	0.62	0.63		0.41	0.36	1.28	1.27
Difference	0.13	0.02		0.18	0.11	0.04	-0.19
Percent with 1 or more I/T potentially preventable hospitalizations							
FY 2011	2.1%	2.6%	**	1.1%	1.3%	5.0%	5.5%
FY 2013	2.3%	2.3%		1.5%	1.4%	4.7%	4.2%
Difference	0.2%	-0.4%	*	0.4%	0.1%	-0.4%	-1.3%
FY: fiscal year; CVD: cardiovascular disease; SBP: systolic blood pre	essure; LDL: low-de	nsity lipoprotei	n; ESR	D: end-stage renal	disease; I/T: Indian	Health Service and T	ribal
* p < 0.05;							
** p < 0.01;							
*** p < 0.001							

<sup>a</sup>Associations between values for ECP users and non-users during FY2011, FY2013, and the difference between the 2 years.

 $b_{
m These}$  clinical measures were assessed for adults in the study population who had both FY2011 and FY2013 data.

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Patient outcomes during fiscal year (FY) 2013 associated with use of education, case management, and advanced practice pharmacy services during FY2012. Propensity score model, based on a logistic regression, using inverse probability weighting.<sup>a</sup>

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		٩II ٤	adults <b>v</b>	vith diab	etes			Adults wi	th diab	etes abso	ent CV	0		Adults wi	th dial	betes aı	nd CVI	
Patient outcome	Sample size <sup>b</sup>	Avera; Treatm Effec	ge ent t	Odds F (OR	Ratio ()	OR Confidence Interval unless indicated <sup>c</sup>	Sample size <sup>b</sup>	Avera Treatm Effec	ge ent t	Odds R (OR	atio )	OR Confidence Interval unless indicated <sup>c</sup>	Sample size <sup>b</sup>	Average Treatme Effect	e nt	Odd Rati (OR	s 0 (	OR Confidence Interval unless indicated <sup>c</sup>
Health status: Clinic	al measures																	
High SBP ( 140mmHg) <sup>d</sup>	18,557	-2.5%	***	0.85	* *	(0.79, 0.93)	13,659	-2.8%	* * *	0.83	* *	(0.75, 0.91)	4,898	-1.3%		0.93		(0.81, 1.08)
High HbAlc ( 8%) <sup>d</sup>	16,907	1.4%		1.08		(1.00, 1.16)	12,323	1.3%		1.07		(0.98, 1.17)	4,584	1.8%		1.11		(0.95, 1.28)
High LDL cholesterol ( 100mg/dL) <sup>d</sup>	14,813	-2.3%	*	0.89	*	(0.84, 0.98)	10,721	-1.8%		0.92		(0.84, 1.01)	4,092	-3.5%	*	0.82	*	(0.71, 0.96)
Health status: Onset	<u>of comorbid</u>	lities																
$\mathrm{CVD}^{de}$							18,869	-0.8%		0.89		(0.78, 1.00)						
$\mathrm{ESRD}^{d,e}$													7,638	-0.7%	*	0.60	*	(0.39, 0.93)
Hospital service utili	zation durin	ig FY2013																
Emergency visits <sup><math>f</math></sup>	27,419	-0.08	***	ı.		(-0.12, -0.05)	19,945	-0.09	***			(-0.13, -0.05)	7,474	-0.10	*			(-0.19, -0.02)
1 or more hospitalizations <sup>d</sup>	22,456	-1.4%	***	0.80	* *	(0.71, 0.89)	16,664	-1.4%	*	0.77	**	(0.66, 0.89)	5,792	-2.7%	*	0.74	*	(0.61, 0.91)
1 or more potentially preventable hospitalizations <sup>d</sup>	27,419	-0.5%	*	0.79	*	(0.64, 0.91)	19,945	-0.4%		0.77		(0.59, 1.00)	7,474	-1.3%	*	0.71	* *	(0.55, 0.91)
Hospital inpatient days <sup>f</sup>	22,456	-0.13	* *	,		(-0.21, -0.04)	16,664	-0.13	* *			(-0.20, -0.06)	5,792	-0.32	*			(-0.57, -0.07)
CVD: cardiovascular o	lisease; SBP	: systolic b	lood pre	ssure; IF	IS: Indi	in Health Servic	e; ESRD: ei	nd stage rei	nal dise	ase								

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p < 0.05;p < 0.01;p < 0.01;

p < 0.001

<sup>a</sup>All treatment and outcome models are adjusted for baseline (FY 2011) age, gender, health coverage, comorbidities, risk score, county-level education and income, systolic blood pressure 140 mmHg, and A1c 8%. Models were also adjusted for ECP drive time and ECP facility rate in FY 2012.

b Sample sizes for analyses within one condition group varied by outcome assessed based on site exclusions due either to the provision of services (i.e., the site did not provide inpatient services) or data quality.

<sup>c</sup>95% confidence intervals are for odds ratios (ORs) except for 2 outcomes (i.e., emergency visits and hospital inpatient days) for which no ORs were reported. For these outcomes, the 95% confidence intervals are for the average treatment effects.

<sup>d</sup>The regressions were estimated using a logistic regression. The estimated average treatment effect may be interpreted as a change in the probability of being positive for the outcome.

e Analyses for the onset of CVD and ESRD in 2013 were limited to persons without diagnostic codes for those conditions in either FY2011 or FY2012.

 $f_{\rm T}$ he regressions were estimated using a negative binomial model. The estimated average treatment effect may be interpreted as an absolute change in the expected count.

## Table 5.

Patient outcomes during fiscal year (FY) 2013 associated with level of education, case management, and advanced practice pharmacy (ECP) service use during FY2012. Propensity score model, based on an ordered logistic regression, using inverse probability weighting.<sup>a</sup>

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		adults with diah	ptec	Adults	. with diabetes abs	nt CVD	Adult	s with diabetes and	
Patient outcome	1-2 ECP visits (vs 0 visits)	3+ ECP visits (vs 0 visits)	3+ ECP visits (vs 1-2 visits)	1-2 ECP visits (vs 0 visits)	3+ ECP visits (vs 0 visits)	3+ ECP visits (vs 1-2 visits)	1-2 ECP vi (vs 0 visit	sits 3+ ECP v s) (vs 0 vis	3+ ECP 3+ ECP isits visits (vs ts) 1-2 visits)
<u>Health status:</u> <u>Clinical measures</u>									
High systolic blood pressure ( 140 mmHg) <sup>b</sup>									
Average Treatment Effect	-1.8% *	-4.8% ***	-3.0% *	-2.4% **	-4.6% **	-2.2%	-0.4%	-3.0%	-2.6%
Odds Ratio	0.89 *	0.74 ***	0.82 *	0.85 **	0.73 **	0.86	0.98	0.85	0.87
OR Confidence Interval	(0.82, 0.97)	(0.63, 0.86)	(0.70, 0.97)	(0.77, 0.95)	(0.60, 0.89)	(0.69, 1.06)	(0.84, 1.15)	(0.68, 1.07)	(0.67, 1.12)
High A1c ( $8\%$ ) $^b$									
Average Treatment Effect	1.7% *	0.4%	-1.3%	1.8%	-1.5%	-3.3%	0.9%	4.5% *	3.6%
Odds Ratio	1.09 *	1.02	0.93	1.10	0.93	0.84	1.05	1.28 *	1.22
OR Confidence Interval	(1.004, 1.186)	(0.89, 1.17)	(0.80, 1.09)	(1.00, 1.21)	(0.78, 1.10)	(0.70, 1.02)	(0.89, 1.24)	(1.02, 1.61)	(0.94, 1.57)
High LDL cholesterol ( 100 mg/dL) <sup>b</sup>									
Average Treatment Effect	-1.4%	-5.1% ***	-3.7% *	-0.7%	-6.3% ***	-5.6% **	-3.7% *	-2.5%	1.1%
Odds Ratio	0.93	0.77 ***	0.83 *	0.97	0.73 ***	0.75 **	0.82 *	0.87	1.07
OR Confidence Interval	(0.86, 0.14)	(0.62, 0.00)	(0.72, 0.04)	(0.87, 1.07)	(0.61, 0.87)	(0.62, 0.91)	(0.68, 0.97)	(0.68, 1.11)	(0.81, 1.40)
<u>Health status: Onset</u> of comorbidities									
$CVD^{b,c}$									
Average Treatment Effect				-0.6%	-1.5% *	-1.0%			

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	ПV	adults with	ı diabete	s	InbA	ts with diabete	s absent	CVD	Adul	ts with diab	oetes and (	CVD	
Patient outcome	1–2 ECP visits (vs 0 visits)	3+ ECP (vs 0 vi	visits sits)	3+ ECP visits (vs 1–2 visits)	1–2 ECP visits (vs 0 visits)	3+ ECP vi (vs 0 visi	isits ts)	<b>3+ ECP visits</b> (vs 1-2 visits)	1-2 ECP v (vs 0 visi	its) 3	+ ECP visi (vs 0 visits	$\begin{array}{c} 3+ E \\ 3+ E \\ 1-2$	CP (vs (vs
Odds Ratio					0.92	0.79	*	0.85					
OR Confidence Interval					(0.80, 1.05)	(0.63, 0.99)	_	(0.67, 1.09)					
$\mathrm{ESRD}^{b,c}$													
Average Treatment Effect									-0.8%	-0.6%		0.2%	
Odds Ratio									0.55 *	0.64		1.16	
OR Confidence Interval									(0.33, 0.92)	(0.32, 1.2	(6	(0.55, 2.48)	
Hospital service utilization during FY2013													
Emergency visits <sup>d</sup>													
Average Treatment Effect	-0.08	-0.11	* *	-0.02	-0.08 **	-0.13	**	-0.05	-0.14 **	-0.05		0.08	
ATE Confidence Interval	(-0.13, -0.04)	(-0.17, -	0.04)	(-0.09, 0.05)	(-0.12, -0.04)	(-0.19, -0.	06)	(-0.12, 0.03)	(-0.24, -0.04)	(-0.19, 0.	.08)	(-0.06, 0.23)	
1 or more hospitalizations <sup>b</sup>													
Average Treatment Effect	-1.3% **	-1.8%	* *	-0.6%	-1.2% **	-1.8%	*	-0.6%	-2.8% *	-3.1%	*	-0.3%	
Odds Ratio	0.82 **	0.75	**	0.91	0.80 **	0.70	*	0.88	0.75 *	0.72	*	0.97	
OR Confidence Interval	(0.72, 0.93)	(0.61, 0.9	1)	(0.73, 1.13)	(0.68, 0.94)	(0.53, 0.93)	_	(0.65, 1.19)	(0.60, 0.93)	(0.53, 0.9)	(8)	(0.69, 1.37)	
l or more potentially preventable hospitalizations $b$													
Average Treatment Effect	-0.3%	-0.9%	*	-0.6% *	-0.3%	-0.5%	*	-0.2%	-0.8%	-2.1%	**	-1.3%	*
Odds Ratio	0.86	0.62	**	0.72 *	0.80	0.65	*	0.81	0.81	0.54	*	0.667	*
OR Confidence Interval	(0.70, 1.05)	(0.46, 0.8	2)	(0.53, 0.98)	(0.60, 1.07)	(0.420, 0.99	(26	(0.51, 1.29)	(0.61, 1.08)	(0.37, 0.7)	(6,	(0.447, 0.996	(9

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	АЛ	adults with diabe	tes	Adults	with diabetes abse	ant CVD	Adul	ts with diabetes a	nd CVD	
Patient outcome	1-2 ECP visits (vs 0 visits)	3+ ECP visits (vs 0 visits)	3+ ECP visits (vs 1–2 visits)	1–2 ECP visits (vs 0 visits)	<b>3+ ECP visits</b> (vs 0 visits)	3+ ECP visits (vs 1-2 visits)	1-2 ECP v (vs 0 visi	isits 3+ ECF (vs 0 v	3+ visits vis isits) v	- ECP sits (vs 1-2 isits)
Hospital inpatient days <sup>d</sup>										
Average Treatment Effect	-0.09	-0.23 ***	-0.14 *	-0.11 **	-0.20 ***	-0.10	-0.34 *	-0.41 *	-0.08	
ATE Confidence Interval	(-0.19, 0.01)	(-0.34, -0.12)	(-0.26, -0.01)	(-0.18, -0.03)	(-0.30, -0.11)	(-0.19, 0.00)	(-0.61, -0.06)	(-0.74, -0.08)	(-0.40, 0.	.25)
CVD: cardiovascular di	sease; OR: odds ratio	o; ATE: average tre	atment effect							
$_{p < 0.05}^{*};$										
** p < 0.01;										
<i>***</i> p < 0.001; 95% conf	fidence intervals									
<sup>a</sup> Sample sizes for analy:	ses varied by outcon	ne assessed based o	on site exclusions d	lue either to the prov	ision of services (i.	<ol> <li>the site did not pro</li> </ol>	vide emergency servio	ces) or data quality		
$b_{\text{The regressions were }\epsilon}$	estimated using a log	țistic regression. Tł	ie estimated averag	ge treatment effect m	ay be interpreted as	a change in the prob	ability of being positiv	ve for the outcome.		
$c_{\rm Analyses}$ for the onset	of CVD and ESRD	in 2013 were limite	ed to persons withc	out diagnostic codes	for those conditions	in either FY2011 or	FY2012.			

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dThe regressions were estimated using a negative binomial model. The estimated average treatment effect may be interpreted as an absolute change in the expected count.