



# Results from NEXT-D: the association of a pre-diabetes-specific health plan and rates of incident diabetes among a national sample of working-age adults

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## ABSTRACT

**Background** Pre-diabetes affects one-third of adults in the USA and a subset will progress to type 2 diabetes. Our objective was to determine whether a disease-specific health plan, known as the Diabetes Health Plan (DHP), designed to improve care for persons with pre-diabetes and diabetes also led to lower rates of incident diabetes among adults with pre-diabetes.

**Methods** We examined eligibility and claims data from a large payer who offered the DHP to a national sample of employers. We included adult employees and dependents who were continuously covered by the DHP over a 4-year study window. The primary outcome was incident diabetes. We conducted propensity score matching at the employer level to find comparable control employer groups offering standard plans. Using an adjusted logistic regression model at the individual level, we tested the association between DHP employer group status and incident diabetes diagnosis during the 3 years of postbaseline follow-up.

**Findings** Our analysis included data from 11 965 continuously enrolled adults with pre-diabetes (n=1538 from nine employers offering DHP; n=10 427 from 105 control employers offering standard plans). DHP employees and covered dependents with pre-diabetes had an 8% lower absolute predicted probability of incident diabetes compared with individuals from employer groups offering standard benefit plans (29% predicted probability of incident diabetes for DHP vs 37% for controls, p<0.001).

**Conclusions** A pre-diabetes-specific health benefit design was associated with lower rates of incident diabetes and represents an area of needed future study.

## BACKGROUND

Pre-diabetes is prevalent and can significantly increase lifetime risk of incident diabetes.<sup>1–3</sup> In the USA, 84 million adults have pre-diabetes and up to 11% will progress to diabetes within 3 years.<sup>1</sup> Large randomized trials have demonstrated that intensive lifestyle change and metformin can lower incident diabetes risk.<sup>4</sup> Patients who are aware of their pre-diabetes diagnosis are more likely to make healthy lifestyle changes to lower

## Significance of this study

### What is already known about this subject?

- ▶ Health insurance benefit designs have significant implications for healthcare outcomes and costs.

### What are the new findings?

- ▶ We found that a pre-diabetes-specific health design was associated with lower rates of incident diabetes among US employees offered the plan as compared with control employees enrolled in standard health plans.

### How might these results change the focus of research or clinical practice?

- ▶ Novel disease-specific health plans may be a promising strategy to increase uptake of evidence-based care and lower rates of incident diabetes.

their risk of diabetes.<sup>5</sup> However, most patients with pre-diabetes are not aware of their diagnosis<sup>6–8</sup> and uptake of evidence-based options to lower incident diabetes risk, such as intensive lifestyle intervention and metformin, remains low.

Innovative health insurance benefit designs that can (1) help increase pre-diabetes awareness and (2) incentivize patients and providers to use evidence-based diabetes prevention options may help address current gaps in pre-diabetes care.

The Diabetes Health Plan (DHP) is the first disease-specific health plan in the USA for patients with diabetes and pre-diabetes (not to be confused with the Diabetes Prevention Program (DPP), which is a 12-month intensive lifestyle change program for adults at risk for diabetes). The DHP uses claims and laboratory data to identify employees who are likely to have pre-diabetes. Eligible employees and dependents are made aware of their pre-diabetes diagnosis as an eligibility

requirement for DHP enrollment. The DHP also includes additional features such as quarterly scorecards to remind patients of the importance of an annual provider visits and follow-up hemoglobin A1c (HbA1c) testing.<sup>9</sup> To increase access to evidence-based ambulatory care, the DHP also offers a variety of features such as reduced cost sharing for medications and office visits and free or low-cost resources for self-management support. As such, patients may be more willing and/or able to engage in recommended preventive care.

The fact that only some employer groups offer the DHP represents a unique opportunity to conduct a rigorous evaluation of this real-world, naturally occurring intervention, also known as a natural experiment.<sup>10</sup> Our objective was to examine rates of incident diabetes over a 3-year time frame among employees and covered dependents with pre-diabetes who are offered the DHP as compared with those offered standard health benefit plans.

## METHODS

We conducted a retrospective, intent-to-treat analysis using 2009–2013 insurance claim and laboratory value data from individuals in employer groups contracting with UnitedHealthcare (UHC) to offer either the DHP or a standard health plan (ie, control). This study was conducted under the oversight of Natural Experiments for Translation in Diabetes (NEXT-D), a multicenter research network funded by the Centers for Disease Control and Prevention (Division of Diabetes Translation) and the National Institute of Diabetes and Digestive and Kidney Diseases (grant number U58DP002722-05). All NEXT-D studies are evaluations of ‘naturally’ occurring health policies and/or interventions (ie, without randomization), using the strongest observational research designs possible and conducted in close collaboration with organizations implementing those programs.<sup>11–13</sup> The academic team members analyzed all data independently and retained sole authority over all publication-related decisions throughout the course of the study.

### Study population

We received data for 708 large US employer groups who contracted with UHC between 2009 and 2013. Among these, 563 employer groups had the needed administrative, laboratory, and pharmacy claims data over 4 continuous years to conduct the analyses and <90% of their employees in high deductible plans. Nine employer groups offered the DHP and 554 employer groups offered standard benefit plans (ie, control employer groups). We excluded controls located in the mid-Atlantic region (where no DHP groups were located, n=49) and those with <20 members with pre-diabetes or diabetes (n=19). Since randomization was not possible, we fit an employer-level propensity model to identify control employer groups most comparable to the

nine DHP employer groups.<sup>14 15</sup> The propensity model included mean employer size, mean employee salary, mean age of employees and covered dependents, proportion of females, race/ethnicity, proportion with at least one chronic condition, proportion with pre-diabetes, proportion in high deductible plans, geographic region, as well as UHC proprietary estimates of average health plan risk score and generosity of benefit. Propensity score modeling yielded 105 control groups most comparable to the nine DHP employer groups (ie, within the region of common support) which we included in our final analytic sample.<sup>16 17</sup>

The baseline period was defined as 12 months prior to DHP implementation for DHP employer groups (ie, 2009 or 2010) and 2010 for all control employer groups. We included data from all employees and covered dependents with pre-diabetes at baseline; participants had to be continuously enrolled in a UHC health plan and 18–64 years old during the 4-year study window. Pre-diabetes was defined by any of the following: (1) >2 International Classification of Diseases 9th Revision (ICD-9) diagnoses of 790.2x from an inpatient or outpatient claim; or (2) last HbA1c value of 5.7%–6.4% or last fasting plasma glucose (FPG) value of 100–125 mg/dL or last 2-hour oral glucose tolerance test (OGTT) value of 140–199 mg/dL. We excluded patients with a baseline history of diabetes or women with gestational diabetes or pregnancy during the study window. For DHP employer groups, data from all eligible employees and covered dependents with pre-diabetes were included regardless of DHP enrollment, consistent with an intent-to-treat design.

### Primary outcome

The primary outcome was incident diabetes diagnosis during the 3 years of follow-up after the baseline year. Incident diabetes was defined by any of the following: (1) >1 ICD-9 diagnosis code of 250.xx from an inpatient or outpatient claim; or (2) an A1c >6.5% or a FPG >125 mg/dL or a 2-hour OGTT value of  $\geq 200$  mg/dL; or (3) >1 prescription fills for insulin or an antidiabetic medication other than metformin. Patients who met the diabetes diagnostic criteria at any point during the follow-up period were considered to have incident diabetes. There were 327 patients from the DHP groups (21%) and 4998 patients from the control group (48%) who did not meet any of the diabetes diagnostic criteria during 3 years of follow-up and did not have diagnostic labs available in year 3 to conclusively determine the primary outcome of interest. In these instances, we used multiple imputation to estimate the probability of incident diabetes during the 3 years of postbaseline follow-up.<sup>18</sup>

### Covariates

The primary predictor of interest was DHP employer group. Individual-level model adjusters included gender, age, race/ethnicity, education, income, baseline lab test count (ie, A1c, FPG, and OGTT), baseline severity of pre-diabetes, obesity, and mental health comorbidity.

Age and gender were obtained from UHC eligibility files. Education, income, and race/ethnicity were estimated by UHC using a proprietary algorithm that incorporated geographic locators (zip codes), consumer survey information, census income data, and first, middle, and last names. We obtained the average number of baseline A1c/FPG/OGTT labs from claims data and defined the baseline pre-diabetes severity, or degree of dysglycemia, as 'high' if A1c was 6%–6.4% or FPG was 110–125 mg/dL at baseline or 'low' if baseline A1c was 5.7%–5.9% or FPG was 100–109 mg/dL. When both A1c and FPG results were available, we used A1c as the primary stratification variable for the 'high' versus 'low' severity classification. Comorbidities such as obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>) and mental health conditions (schizophrenia, depression, anxiety and post-traumatic stress disorder) were defined as one or more ICD-9-related diagnoses from inpatient or outpatient claims.

Age, obesity, and baseline pre-diabetes severity were included because these are established risk factors for diabetes.<sup>9</sup> Mental health condition was included since schizophrenia and treatment with some atypical antipsychotics or antidepressants are also risk factors for diabetes. We included race because certain groups (such as African-Americans) have a higher risk for diabetes. Gender was included because women are more likely to use health services overall, which may affect the likelihood of being tested for diabetes (ie, detection bias). The baseline lab test count also served as a proxy for willingness and/or motivation to obtain follow-up care and/or testing. Lastly, we included estimates of income and education because these are proxies for health literacy and financial resources.

### Statistical analysis

We used a logistic regression model with cluster-adjusted estimates of variance to test the association between DHP employer group status and incident diabetes diagnosis during the 3 years of follow-up after baseline. To address the issue of ambiguous outcome due to lack of follow-up labs, we conducted multiple imputation by chained equations using all the variables in the analytic model while simultaneously addressing missing data for race/ethnicity (6%), education (2%), and income (7%).<sup>18</sup> Multiple imputation was performed in STATA (V.14) using the user-written 'ice' command, and the 'mi estimate' command was then used to estimate the missing variables, including the primary outcome of interest across 10 imputed data sets.<sup>19 20</sup> The resulting estimations were combined across the imputed data sets using Rubin rules.<sup>19 20</sup> The STATA 'margins' command was used to obtain predicted probabilities of incident diabetes diagnosis over the 3-year follow-up window.

### RESULTS

We analyzed data from 11965 continuously enrolled patients with pre-diabetes (n=1538 from 9 employers

offering the DHP; n=10427 from 105 control employers offering standard plans). Sixty-eight percent of eligible patients with pre-diabetes (n=1039) were enrolled in the DHP, but all 1538 were included in this intent-to-treat analysis. Compared with controls, employees and covered dependents from DHP employer groups were more likely to be female (54% vs 44% female,  $p<0.001$ ), were slightly older (mean age 51 years vs 50 years,  $p<0.001$ ), were less educated, had lower income, were more likely to be African-American and less likely to be Asian (table 1). The proportion of individuals with higher levels of baseline dysglycemia (A1c 6.0%–6.4% or FPG 110–125 mg/dL), obesity, and mental health diagnosis was similar across DHP and control employer groups.

Among complete cases, the unadjusted rate of incident diabetes diagnosis over the 3-year follow-up was 26% for individuals from DHP employer groups versus 35.4% for individuals from control employer groups ( $p<0.001$ ). After multiple imputation and controlling for covariates, there was still a significant difference in the predicted probability of incident diabetes diagnosis, 29% for individuals from DHP employer groups versus 37% in control employer groups ( $p=0.001$ , table 2).

Higher age, higher A1c/FPG value at baseline, obesity and 'other' race were also associated with significantly higher predicted probability of incident diabetes. Higher education, income, and having follow-up lab testing at baseline were associated with significantly lower predicted risk of incident diabetes. We also conducted a sensitivity analysis using a more stringent diagnostic criterion of two or more ICD-9 codes to define diabetes. With this approach, the estimated association between DHP availability and the predicted probability of incident diabetes was unchanged from the results after multiple imputation described above (28% for individuals from DHP employer groups vs 36% in control employer groups,  $p<0.001$ ).

### DISCUSSION

Our analysis showed the risk of progression from pre-diabetes to diabetes was significantly lower for persons with pre-diabetes in employer groups offering the DHP. Employees and covered dependents from DHP employer groups had an 8% lower absolute predicted probability of incident diabetes over 3 years of follow-up after baseline compared with those from employer groups offering standard benefit plans. Our finding of an 8% absolute reduction, translating into a 21% relative reduction compared with the 37% incidence rate among the comparison group, can be measured against the effect size observed in the intensive lifestyle arms and metformin arms of the DPP study. In 2002, this randomized controlled study demonstrated that intensive lifestyle intervention reduced incidence of diabetes by 58% and metformin reduced the incidence by 31%, as compared with placebo over 2.8 years.<sup>4</sup> In contrast, the DHP is a relatively light touch approach that still manages to have a meaningful

**Table 1** Baseline characteristics of employees and dependents with pre-diabetes

Characteristic	DHP (n=1538)	Control (n=10427)	P value
Female	54%	44%	<b>&lt;0.001</b>
Age	51.2 (8.7)	49.8 (8.8)	<b>&lt;0.001</b>
Education			<b>&lt;0.001</b>
HS or less	38%	31%	
Some college	55%	52%	
Bachelor's degree or above	7%	17%	
Income			<b>&lt;0.001</b>
<\$30 000	6%	5%	
\$30 000–\$49 000	24%	18%	
\$50 000–\$74 000	29%	30%	
\$75 000+	41%	47%	
Race/ethnicity			<b>&lt;0.001</b>
White	72%	71%	
Hispanic	15%	16%	
African-American	10%	7%	
Asian	2%	5%	
Other	<1%	<1%	
A1c/FPG/OGTT lab tests in baseline year (n)			<b>&lt;0.001</b>
0	7%	14%	
1	60%	62%	
2	22%	17%	
3+	11%	7%	
Higher A1c/FPG at baseline	32%	31%	0.347
Obese	8%	8%	0.287
Mental health comorbidity	13%	14%	0.075

Mental health comorbidity was defined by  $\geq 1$  International Classification of Diseases 9th Revision (ICD-9) related diagnosis for schizophrenia, depression, anxiety and/or post-traumatic stress disorder. Higher A1c/FPG at baseline=baseline A1c 6.0%–6.4% or FPG 110–125 mg/dL. Obese was defined by  $\geq 1$  ICD-9 related diagnosis of body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>. Bold values denote statistical significance at the  $p < 0.05$  level. DHP, Diabetes Health Plan; FPG, fasting plasma glucose; HS, high school; OGTT, oral glucose tolerance test.

effect size. More importantly, DHP-like insurance benefit designs are implementable on a national scale since 60% of US adults are currently insured through employer-sponsored insurance programs.<sup>21</sup>

The mechanism by which a disease-specific health insurance benefit design, such as the DHP, may help prevent or delay development of diabetes is likely twofold. First, since pre-diabetes is an explicit DHP eligibility criterion, our findings may result in part from the increased

awareness of a pre-diabetes diagnosis afforded by the DHP. Patients who otherwise might not be aware of their diagnosis know they are being offered the DHP based on their pre-diabetes diagnosis and studies have shown that pre-diabetes awareness can activate patients to engage in health promotion activities.<sup>5,8</sup> The DHP also incorporates features to increase compliance with recommended preventive care, such as quarterly scorecards that are mailed to patients reminding them of recommended care (eg, annual visit with their primary care provider). Since education alone may not be enough to lead to behavior change, the DHP also enhances access to evidence-based pre-diabetes care, possibly making it easier for patients to engage in the recommended care. This includes free or reduced cost sharing for follow-up HbA1c testing, as well as access to in-person or online lifestyle intervention programs and/or metformin, which are the mainstay of pre-diabetes treatment and diabetes risk reduction.<sup>9</sup>

The proposed patient activation by the DHP is nicely demonstrated by the differential rates of follow-up glucose lab testing between DHP and control employers. We identified at least one A1c/FPG/OGTT follow-up test for 89% of individuals from DHP groups compared with only 66% from standard benefits/controls in any of the three postbaseline years ( $p < 0.001$ ). Thus, our data show that participants from DHP groups were much more likely to have recommended follow-up glucose testing in accordance with most national care recommendations for repeat annual diabetes screening for those with pre-diabetes.<sup>9</sup> Although this increased testing creates a potential detection bias towards 'higher' rates of progression (ie, increased rates of testing may increase the chance of diagnosing incident diabetes), our unadjusted results showed lower rates of incident diabetes among employees and dependents covered by the DHP. It is likely that rates of incident diabetes among the control population were even higher than reported but went undiagnosed as these patients were never tested during the follow-up period. We used multiple imputation to address this differential in the availability of the primary outcome, and our results lean towards more conservative estimates of the difference between the two comparison groups. Our intent-to-treat design, which included all DHP employees and dependents with pre-diabetes whether or not they enrolled in the DHP, also leans towards more conservative estimates.

Overall, our findings should be of broad interest since 37% of US adults are currently estimated to have pre-diabetes.<sup>1</sup> To our knowledge, this is also one of the first studies to examine the impact of a disease-specific health insurance benefit design on outcomes for patients with pre-diabetes. Our findings indicate that health insurance benefit designs that help increase pre-diabetes awareness by devoting resources to identify and inform patients of their pre-diabetes diagnosis, incorporating features to increase adherence with recommended care, and providing incentives and/or reduce barriers to recommended care may be a viable means of preventing or

**Table 2** The adjusted predicted probability of incident diabetes

Baseline characteristic		Predicted probability	Absolute change from reference	Relative change from reference	P value
DHP status	Non-DHP	0.37			
	DHP	0.29	-0.08	-0.21	<b>0.001</b>
Gender	Female	0.37			
	Male	0.35	-0.02	-0.04	0.092
Age	19–34	0.30			
	35–44	0.33	0.03	0.13	0.325
	45–54	0.37	0.07	0.22	<b>0.018</b>
	55–62	0.38	0.08	0.25	<b>0.002</b>
Baseline risk based on level of dysglycemia	Low A1c 5.7%–5.9% FPG 100–109mg/dL	0.29			
	High A1c 6%–6.4% FPG 110–125mg/dL	0.50	0.21	0.74	<b>&lt;0.001</b>
	ICD-9/OGTT	0.34	0.05	0.16	0.454
Baseline A1c/FPG/OGTT lab test count	0	0.71			
	1	0.30	-0.41	-0.57	<b>&lt;0.001</b>
	2	0.28	-0.43	-0.60	<b>&lt;0.001</b>
	3+	0.32	-0.39	-0.55	<b>&lt;0.001</b>
ICD-9 obesity	No	0.35			Yes
	0.47	0.12	0.36	<b>&lt;0.001</b>	Education
HS or less	0.38				
Some college	0.35	-0.03	-0.07	0.117	
College degree	0.33	-0.05	-0.14	<b>0.019</b>	Income
	<\$30 000	0.41			
\$30 000–\$49 000	0.38	-0.03	-0.06	0.325	
\$50 000–\$74 000	0.35	-0.05	-0.13	<b>0.032</b>	
\$75 000+	0.34	-0.06	-0.15	<b>0.016</b>	Race/ethnicity
White	0.35				
Hispanic	0.37	0.02	0.05	0.127	
African–American	0.35	-0.01	-0.02	0.649	
Asian	0.38	0.02	0.06	0.388	
Other	0.51	0.16	0.44	<b>0.031</b>	Mental health comorbidity
	No	0.36			

Continued

Table 2 Continued

Baseline characteristic		Predicted probability	Absolute change from reference	Relative change from reference	P value
Yes	0.37	0.02	0.05	0.293	Mental health comorbidity was defined by $\geq 1$ ICD-9 related diagnosis for schizophrenia, depression, anxiety and/or post-traumatic stress disorder. Higher A1c/FPG at baseline=baseline A1c 6.0%–6.4% or FPG 110–125 mg/dL. Obese was defined by $\geq 1$ ICD-9 related diagnosis of body mass index (BMI) $\geq 30$ kg/m <sup>2</sup> . Bold values denote statistical significance at the $p < 0.05$ level DHP, Diabetes Health Plan; FPG, fasting plasma glucose; HS, high school; ICD-9, International Classification of Diseases 9th Revision; OGTT, oral glucose tolerance test.

delaying incident diabetes for working-age adults with pre-diabetes. The DHP places strong emphasis on the importance of prevention and regular use of primary care services, highlighting the importance of aligning incentives and payment structures for effective delivery of preventive care services for persons with pre-diabetes. Our findings may help inform future benefit design and/or national policies surrounding pre-diabetes care. In many ways, the DHP is a test case of a concept of disease-specific benefit design that deserves further study. This concept is akin to personalized medicine at the benefit level and can also be tested in other costly chronic conditions where there are well-established ambulatory treatment guidelines.

There are also several limitations to consider. First, because this was a claims-based analysis, possible misclassification of pre-diabetes and diabetes may have occurred. However, we conducted a sensitivity analysis that used a stricter definition of  $\geq 2$  ICD codes for our primary outcome of diabetes which did not impact our results. Second, some employer groups may have implemented complementary wellness initiatives which our claims-based analysis would not capture. However, we used propensity score matching at the employer level to find comparable control employer groups offering standard plans. Third, our analysis focused on commercially insured adults and may not be generalizable to uninsured or older patients. However, our focus on working-age adults is important because pre-diabetes affects more than one in three adults older than 20 years and the lifetime risk of incident diabetes is highest for younger

individuals with pre-diabetes. Finally, our data were limited to 3 years of follow-up. However, our effect size of 8% absolute risk reduction over just 3 years seems clinically meaningful, particularly when considered across a population level.

In summary, the health and well-being of large segments of the US population and their associated healthcare costs are at stake if diabetes prevention is not prioritized. The sheer number of individuals affected with pre-diabetes necessitates the use of multifaceted approaches to curb this epidemic. Health insurance benefit designs that increase pre-diabetes awareness and enhance access to evidence-based care are associated with lower rates of incident diabetes and represent an important area of future study.

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**Competing interests** CC, RHL, SH, and AMK are former employees of UnitedHealthcare.

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