







Cost-effectiveness of the 2014 U.S. Preventive Services Task Force (USPSTF) Recommendations for Intensive Behavioral Counseling Interventions for Adults With Cardiovascular Risk Factors

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OBJECTIVE

In 2014, the U.S. Preventive Services Task Force (USPSTF) recommended behavioral counseling interventions for overweight or obese adults with the following known cardiovascular disease risk factors: impaired fasting glucose (IFG), hypertension, dyslipidemia, or metabolic syndrome. We assessed the long-term cost-effectiveness (CE) of implementing the recommended interventions in the U.S.

RESEARCH DESIGN AND METHODS

We used a disease progression model to simulate the 25-year CE of the USPSTF recommendation for eligible U.S. adults and subgroups defined by a combination of the risk factors. The baseline population was estimated using 2005–2012 National Health and Nutrition Examination Survey (NHANES). The cost and effectiveness of the intervention were obtained from systematic reviews. Incremental CE ratios (ICERs), measured in cost/quality-adjusted life-year (QALY), were used to assess the CE of the intervention compared with no intervention. Future QALYs and costs (reported in 2014 U.S. dollars) were discounted at 3%.

RESULTS

We estimated that \sim 98 million U.S. adults (44%) would be eligible for the recommended intervention. Compared with no intervention, the ICER of the intervention would be \$13,900/QALY. CE varied widely among subgroups, ranging from a cost saving of \$302 per capita for those who were obese with IFG, hypertension, and dyslipidemia to a cost of \$103,200/QALY in overweight people without these conditions.

CONCLUSIONS

The recommended intervention is cost effective based on the conventional CE threshold. Considerable variation in CE across the recommended subpopulations suggests that prioritization based on risk level would yield larger total health gains per dollar spent.

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Cardiovascular disease (CVD) imposes an enormous health and economic burden in the U.S. leading to ~800,000 deaths (nearly one in every three deaths) and \$320 billion in costs in 2011 (1,2). CVD is preventable through the successful management of risk factors, including preventing type 2 diabetes and lowering blood pressure and cholesterol levels (3,4).

In August 2014, the U.S. Preventive Services Task Force (USPSTF) recommended an intensive behavioral counseling intervention to reduce CVD risks in overweight or obese adults with one or more of the following risk factors: hypertension, dyslipidemia, impaired fasting glucose (IFG), or metabolic syndrome (5). The intervention promotes a healthy diet and physical activity through health education, individual feedback, problem-solving skills, and an individualized plan. Interventions are delivered by trained professionals, such as diabetes educators, dietitians, and behavioral interventionists; or by trained lay persons, such as community health workers. The intervention involves multiple contacts, either individually or in a group setting, over an extended period of time (e.g., 1 year). The USPSTF based its recommendation largely on the consistent evidence that behavioral counseling for lifestyle change improves CVD risk factors and reduces type 2 diabetes incidence (6).

The new recommendation is rated "grade B" and thus must be covered by private insurance under the Affordable Care Act without a copay. Because a significant proportion of U.S. adults will be eligible for the intervention (7), scaling the intervention nationwide will require substantial resources from public and private sectors. Similar interventions have been estimated to cost \$400 to \$1,000 per person per year (8). However, such interventions may be an efficient use of health care resources in the long run if substantial medical costs are saved by preventing or delaying CVD, type 2 diabetes, and diabetes-related complications. No previous study has estimated the longterm health and economic implications of implementing the USPSTF-recommended intensive behavioral counseling intervention in the U.S. population.

The primary objectives of our study are 1) to assess the long-term cost-effectiveness (CE) of USPSTF-recommended intensive behavioral counseling interventions in the overall target population and 2) to examine the variation in CE across

subgroups, as defined by combinations of risk factors specified in the USPSTF recommendation.

RESEARCH DESIGN AND METHODS

We measured the CE of the USPSTFrecommended intervention using incremental CE ratios (ICERs), expressed in cost per quality-adjusted life-year (QALY) gained by implementing the recommended intervention, compared with no intervention. First, we identified the population of U.S. adults who were eligible for the intervention based on the USPSTFdefined criteria. Second, we specified the intervention and its assumed effectiveness and costs based on previous studies. Third, we applied a discrete Markov disease progression model to simulate the long-term health and cost impacts with and without implementing the intervention. Finally, we calculated the ICER by dividing the difference in costs by the difference in QALYs with and without the intervention. We evaluated the ICER over a time horizon of 25 years because health benefits may not be realized in a short period (9). The conventionally used \$50,000/QALY threshold for adopting a new intervention was applied to assess CE (10).

Study Population

We used the National Health and Nutrition Examination Survey (NHANES) 2005–2012 to identify demographic characteristics and health profiles of the intervention population in the U.S. (Table 1). Estimates were weighted according to the NHANES sampling design. We used a BMI of \geq 25 and \leq 30 kg/m² to define overweight and a BMI \geq 30 kg/m² to define obesity. People with hypertension included those with systolic blood pressure \geq 140 mmHg or diastolic blood pressure \geq 90 mmHg (11), and those who had received a diagnosis of hypertension by a physician

Table 1—Characteristics of the eligible population for USPSTF-recommended intensive behavioral counseling interventions

		Proportion of the	
Risk factors	Criteria	eligible population	
Total number of adults recommended for the intervention		98 million*	
Overweight	BMI \geq 25 and \leq 30 kg/m ²	50.8%	
Obese	BMI ≥30 kg/m ²	49.2%	
Hypertension and overweight/obese	≥140/90 mmHg	35.2%	
Dyslipidemia and overweight/obese	ATP III borderline high definitions under the following conditions (12)	82.4%	
High cholesterol	≥200 mg/dL	58.0%	
High LDL	≥130 mg/dL	46.2%	
High triglyceride	≥150 mg/dL	39.6%	
HDL	<40 mg/dL	23.7%	
IFG and overweight/obese	FPG \geq 100 and $<$ 126 mg/dL	45.7%	
Metabolic syndrome and overweight/obese	ATP III definition† (14)	41.8%	
Risk factors	Average value among eligible population		
BMI	31.5		
Weight	90.9 kg		
A1C	5.5% (37 mmol/mol)		
Total cholesterol	209.3 mg/dL		
HDL	49.2 mg/dL		
LDL	125.7 mg/dL		
Systolic blood pressure	123.5 mmHg		
Diastolic blood pressure	72.9 mmHg		
Triglycerides	152.8 mg/dL		

†Metabolic syndrome was defined using ATP III definition by having three or more of the five following conditions: abdominal (central) obesity (>102 cm [40 inches] or >88 cm [35 inches] in women); elevated blood pressure (\geq 130/85 mmHg); IFG; high serum triglyceride levels (\geq 150 mg/dL); and low HDL levels (HDL <40 or <50 mg/dL for women). *Based on data from the 2005–2012 NHANES. The total adult population aged \geq 18 years was estimated at 225 million, which is comparable with the U.S. Census estimate of 227 million for 2009 (36).

or were receiving treatment with antihypertension medication. Dyslipidemia was defined as having at least one of the following conditions: total cholesterol concentration ≥200 mg/dL, LDL cholesterol concentration ≥130 mg/dL, triglycerides concentration ≥150 mg/dL, or HDL cholesterol concentration <40 mg/dL (12); having been told by their doctor that they have this condition; or having been prescribed a cholesterollowering medication. IFG was identified by a fasting plasma glucose level of 100 to <126 mg/dL (13). Metabolic syndrome was determined using the Adult Treatment Panel (ATP) III definition of having three or more of the five following conditions: abdominal obesity (>102 cm for men or >88 cm for women), elevated blood pressure (≥130/85 mmHg), IFG, high serum triglyceride levels (≥150 mg/dL), and low HDL level (HDL <40 mg/dL for men or HDL <50 mg/dL for women) (12,14).

People with a history of CVD were excluded from our analysis because the recommended intervention is for CVD prevention. We also excluded those people with diabetes, because the USPSTF recommendation did not specifically mention diabetes and because those with diabetes may need other diabetesrelated interventions.

Intensive Behavior Counseling Intervention

The intervention evaluated in this study is based on the USPSTF review, which included 74 behavioral counseling interventions intended to promote healthy diets and physical activity (5,6). Although the core content of the interventions was similar, delivery methods, setting, staff requirements, and duration varied. As a result, no intervention specifics or preferred approaches were provided in the USPSTF recommendation. We assumed a 1-year intervention and that the interventional benefits would not be sustained after the 1-year period in the base-case scenario. Previous studies (3,4) suggest that interventions of 1 year may be the optimal length as benefits diminish thereafter.

We assumed levels of effectiveness based on median levels of risk factor reduction reported in the USPSTF review, as follows: 2.1 mmHg in systolic blood pressure, 1.3 mmHg in diastolic blood pressure, 54% in the incidence of type

2 diabetes, and \sim 1 kg/m² in BMI (Table 2) (5,6). Because the USPSTF review did not report the cost of interventions, we specified our cost assumptions based on a recent review of 28 similar behavioral interventions (15). The median intervention cost per participant was \$653, which represented an intervention with a mixture of group and individual sessions.

Simulation Model

We used a modified version of the type 2 diabetes CE simulation model developed by the Centers for Disease Control and Prevention (CDC) and RTI International (16). The original model was used for economic evaluation of lifestyle interventions and medication therapy to prevent type 2 diabetes among people at high risk for the development of diabetes and for interventions designed to manage risks for diabetes-related complications among people with type 2 diabetes (9,16,17). The model was validated against results from major clinical trials and cohort studies and was found to accurately predict the development and progression of diabetes and diabetes-related complications (18).

We modified the original model by adding CVD risk equations for the expanded target population. In the original model, the development of CVD was simulated based on risk equations from the UK Prospective Diabetes Study (UKPDS) (19). We replaced the UKPDS equations with the pooled atherosclerotic CVD (ASCVD) risk equations developed by the American College of Cardiology and American Heart Association to predict 10-year CVD risk (20). The ASCVD equations were developed based on recent cohort studies, including the Coronary Artery Risk Development in Young Adults (CARDIA) (21), the Atherosclerosis Risk in Communities (ARIC) (22), the Cardiovascular Health Study (CHS) (23), and the Framingham study (24). The ASCVD risk equation has been validated to predict the risk of CVD events well in populations in the U.S.-based CVD cohort studies (25,26). We annualized the 10-year probabilities of CVD events predicted by the ASCVD equations by assuming constant hazards.

In the model, we simulated the risk of the development of type 2 diabetes based on demographic and clinical characteristics from the CARDIA study (for ages 18-44 years), the ARIC study (for ages 45-64 years), and the CHS (for ages ≥65 years). For adults in whom type 2 diabetes developed in the simulation, we simulated the risks of the development of complications, such as renal disease, ulcers, amputation, and diabetes blindness, based on the UKPDS (19).

We took a health care system perspective and thus considered only intervention costs and direct medical costs associated with treating future CVD, diabetes, and diabetes-related complications over 25 years. The direct medical costs included all costs associated with treating any other health conditions, such as hypertension. Detailed cost

Table 2-Assumed direct health benefits and costs based on systematic reviews (base-case and sensitivity scenarios)

	Absolute changes		Relative changes			
	Base case‡	Low	High	Base case‡	Low	High
Direct health benefits†						
Total cholesterol (mg/dL)	-5.4	-2.9	-8	-2.58%	-1.38%	-3.81%
HDL (mg/dL)	0.8	0.4	1.5	1.57%	0.79%	3.13%
Systolic blood pressure (mmHg)	-2.1	-1.1	-3	-1.66%	-0.89%	-2.42%
Diastolic blood pressure (mmHg)	-1.3	-0.7	-1.9	-1.78%	-0.96%	-2.59%
Diabetes relative risk	N/A	N/A	N/A	-54%	-43%	-65%
BMI	-1	-0.5	-1.5	N/A	N/A	N/A
Per person costs						
Base case‡	\$653					
Group-based interventions	\$425					
Screening*	\$54					

N/A, not applicable. †The upper and lower bounds of direct health benefits are determined by using the confidence bound reported by the USPSTF. The diabetes relative risk reduction is assumed to be $\pm 20\%$ for the high/low cases. ‡Base case represents an intervention with a mixture of group and individual sessions. *Screening is composed of a medical visit with a lipid panel and a glucose panel accounted for using the Medicare Physician Fee Schedule 2014 (28).

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modeling is described elsewhere (27). All costs were expressed in 2014 U.S. dollars. Costs and QALYs were discounted at 3% annually.

Subgroup Analysis

For subgroup analysis, we first stratified the eligible population by BMI level (overweight/obese). Under each BMI level, we divided the target population by the following three major risk factors: hypertension, dyslipidemia, and IFG. Metabolic syndrome was not examined separately because the criteria overlapped with the three mentioned factors (i.e., 99.75% of overweight or obese people with metabolic syndrome had at least one of these other factors). As a result, a total of 16 subgroups was included in the analysis. Supplementary Table 1 describes the characteristics of each subgroup. We assumed equal relative reductions in blood pressure, cholesterol level, diabetes incidence, and BMI across subgroups.

Sensitivity Analysis

We first conducted a one-way sensitivity analysis by varying the simulation time horizon with two alternatives to the base case of 25 years: 10 years, which is of interest to policy makers and health care planners; and a lifetime horizon, which represents the maximum health benefit resulting from the intervention. Separately, we use alternative discount rates of 0% and 5% for costs and QALYs to represent low and high discount scenarios.

We also conducted a two-way sensitivity analysis by varying both the cost and effectiveness of the intervention. For cost, we examined two scenarios: implementing the recommended intervention only in a group-based setting; and adding the cost of screening to identify those eligible for intervention. Group-based interventions generally have lower costs and results that are comparable to those of individual-based interventions (15). In the screening test scenario, we assumed a medical visit with a lipid panel test and fasting plasma glucose test were needed to identify high-risk individuals, with costs derived from the Medicare Physician Fee Schedule 2014 (28).

For effectiveness, we used the 95% CI or interquartile range of the effect on total cholesterol, HDL, systolic blood

pressure, diastolic blood pressure, and BMI as reported in the USPSTF review (Table 2). For reduction in type 2 diabetes incidence, we assumed $\pm 20\%$ of the effect of the base-case analysis based on evidence from in two recent systematic reviews (5,29). Previous studies showed that the effects of the intensive lifestyle intervention on these outcomes may vary depending on the intervention setting, type of providers, and delivery methods (29). In addition, we simulated the CE of the recommended intervention under the scenarios of extended effectiveness and follow-up cost. In scenario 1, we assumed that the effectiveness of the intervention in reducing type 2 diabetes was 54% in the first year, 30% in the second year, 10% for years 3-5, and 0% afterward with no additional cost. In scenario 2, we assumed the same effectiveness as scenario 1 but with a cost of \$653 in the first year, \$200 in the second year, \$100 in years 3-5, and zero cost after the fifth year.

RESULTS

Primary Analysis

Approximately 98 million (44%) U.S. adults were eligible for the USPSTF-recommended intervention. At \$653/person, implementing the intervention in the total eligible population would cost \$64 billion.

Without the intervention, the total treatment and intervention cost per person would be \$54,872 over 25 years (Table 3). Implementing the intervention was

associated with a \$262 incremental cost and 0.019 QALYs gained per person, yielding an ICER of \$13,900/QALY in 25 years. Estimated ICERs were similar across agegroups, ranging from \$11,200 to \$14,400/QALY. The cumulative incidence of diabetes, myocardial infarction/cardiac arrest, stroke, and death is described in Supplementary Table 3.

Subgroup Analysis

ICERs varied substantially by subgroup (Fig. 1). Among those who were overweight and had IFG, ICERs ranged from \$3,400/QALY (for those with both dyslipidemia and hypertension) to \$33,800/ QALY (for those with neither). Among those who were overweight with no IFG, ICERs ranged from \$67,200/QALY (for those with dyslipidemia and no hypertension) to \$103,200/QALY (for those with neither dyslipidemia nor hypertension, but with metabolic syndrome). Among those who were obese with IFG, the intervention was cost saving for those with hypertension, dyslipidemia, or both, with savings ranging from \$83 to \$302/person receiving the intervention. For obese adults with IFG alone, the ICER was \$3,600/QALY. Among those with obesity but without IFG, ICERs ranged from \$25,900/QALY (for those with both dyslipidemia and hypertension) to \$58,000/QALY (for those who had neither but did have metabolic syndrome). Targeting the intervention to obese adults with at least

Table 3—Base case total cost, QALYs, and CE of the USPSTF-recommended behavioral counseling intervention per person intervened by age-group with a 25-year horizon

	Total cost (intervention,	Remaining		ICER
	treatment, and complications)†	life-years	QALYs	(total/QALY)
Total eligible population				
No intervention	\$54,872	20.742	10.267	
With the intervention	\$55,134	20.760	10.286	
Incremental	\$262	0.019	0.019	\$13,900
Age 18–44 years				
No intervention	\$56,953	23.836	11.556	
With the intervention	\$57,164	23.845	11.571	
Incremental	\$211	0.008	0.015	\$14,400
Age 45-64 years				
No intervention	\$55,955	20.290	10.108	
With the intervention	\$56,207	20.316	10.130	
Incremental	\$252	0.026	0.022	\$11,400
Age ≥65 years				
No intervention	\$42,525	11.755	6.452	
With the intervention	\$43,028	11.788	6.497	
Incremental	\$503	0.034	0.045	\$11,200

†The total cost is the summation of the behavioral intervention and treatment and medication.

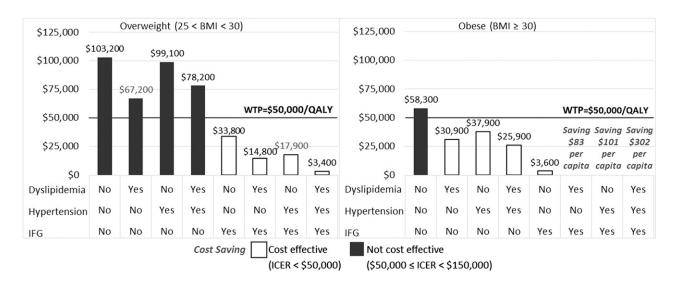


Figure 1—25-year ICERs (\$USD/QALY) of the intensive behavioral counseling intervention compare with no intervention by risk factor. Those with none of the three major risk factors (dyslipidemia, hypertension, and IFG) have only metabolic syndrome (women who have abdominal obesity and specific blood pressure level [SBP 130–140 mmHg or DBP 85–90 mmHg] with HDL from 40 to 50 mg/dL). Willingness-to-pay (WTP) = \$50,000/QALY is used as the CE threshold.

one of the other three risk factors and overweight adults with IFG (cost-saving and CE groups) would reduce the people eligible for the targeted program from 98 million to 66.7 million nationally and would lower the intervention cost by \sim \$20 billion.

Sensitivity Analyses

Detailed results of the sensitivity analysis are described in Supplementary Table 2. For the one-way sensitivity analysis, shortening the analytic horizon would increase the ICER while increasing the analytic horizon to a lifetime would lower ICER. Assuming zero and 5% discount rates yielded \$5,200/QALY and \$20,200/QALY, respectively. Varying intervention effectiveness had a large effect on CE. Assuming the lower effectiveness bounds yielded a higher ICER, while assuming the upper bounds yielded a lower ICER. Adding screening costs increased the ICERs. Delivering the intervention in a group setting would lower the ICER.

For the two-way sensitivity analysis, under the most favorable scenario (i.e., achieving the upper bound effectiveness with a group-based intervention cost), the intervention led to a cost savings of \$64/person receiving the intervention. In contrast, with the worst scenario (i.e., achieving the lower bound effectiveness with additional screening costs), the intervention yielded an ICER of \$26,300/QALY.

For extended effectiveness and cost scenarios, scenario 1 yielded a cost saving at \$90/person in 25 years, while under scenario 2 the intervention would have an ICER of \$11,600/QALY.

CONCLUSIONS

We estimate that under the new USPSTF recommendation on behavioral counseling for CVD prevention, ~98 million Americans are eligible for the intervention, which would cost \$64 billion if all were to participate. Applying the conventional "willingness-to-pay" cutoff of \$50,000/QALY (10), the intervention is cost effective for the overall targeted population as well as for each age-group. However, CE varies substantially depending on the risk factor profile of the participants; the intervention is cost effective for overweight adults with IFG and for obese adults with at least one of three risk factors (dyslipidemia, hypertension, or IFG); these two groups account for ~68% of the eligible population. The intervention is cost saving if it was implemented in persons who are obese with IFG and hypertension, dyslipidemia, or both, ~19.8 million or 20.2% of all eligible population. CE could be improved substantially by targeting these higher-risk subgroups and/or delivering the intervention in group settings.

Our results are consistent with those of previous studies that found intensive lifestyle interventions aimed at reducing the incidence of type 2 diabetes among people with prediabetes to be cost effective, with a median cost of approximately

\$14,000/QALY gained (15). Our risk group analysis was also consistent with a previous study (30) of diabetes prevention interventions, in which those with higher levels of fasting plasma glucose or A1C had more favorable CE ratios than those at the lower end of the prediabetes spectrum. Applying the USPSTF recommendation to those with a relatively low risk (overweight rather than obese, and one additional risk factor rather than multiple) diminishes CE because, while the costs for implementing the intervention are the same, the number of cases of diabetes and CVD averted is smaller.

Reductions in BMI and blood glucose levels have more impact on CE than reductions in blood pressure and lipid levels, because of their greater risk reduction of diabetes. Previous studies (3,4) have shown that behavioral counseling intervention can reduce the risk of type 2 diabetes by 38-60%. A recent study (30) suggested that delaying or preventing type 2 diabetes for 10 years for a person at age 40 years might save more than \$30,000 in lifetime medical spending. However, the effects of this intervention on other risk factors (i.e., lipid levels and blood pressure) are modest. The reductions in systolic/diastolic blood pressure reported by the USPSTF were 1-3 mmHg, and for LDL were 1.4-6 mg/dL (5,6). It is likely that the use of hypertension and dyslipidemia medications among those who already had these conditions may also have diluted the impact of the intervention.

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As expected, we found the recommended intervention to be more cost effective in the longer simulation horizon. Chronic disease prevention typically provides more benefit over the long term than the short term. CVD events may not occur in the short term, and diabetes-related complications typically do not occur until years after diabetes onset. While policy makers and program planners are often interested in short-term results, it may be more appropriate to take a longer perspective when evaluating CVD and diabetes prevention.

There are four notable limitations of the study. First, in the model, we included only the health benefits reported in the USPSTF recommendation. Excluding other potential health benefits, such as reducing cancer incidence (31), would underestimate the CE of the recommended intervention. Second, while existing evidence has provided compelling evidence of the efficacy of the recommended interventions in clinical settings, its effectiveness in real-world settings and sustainable effectiveness in the long term remain to be demonstrated. Lack of longterm effectiveness data in real-world settings adds some uncertainty to our modeling results. Thus, we conducted extensive sensitivity analyses, and the results support the robustness of our conclusions. Third, similar to all diseasemodeling studies, our results are subject to the limitations of the model structure. the risk equations used, and the model assumptions. The CVD risk equations that were developed for the original CDC-RTI model were based on data from the UKPDS (19,32), a study of people with type 2 diabetes in the U.K. Because our study population included both persons with and without diabetes in the U.S.. we used the recently developed ASCVD equations (20). The ASCVD equations were developed using data from the CARDIA study, the ARIC study, the CHS, and the Framingham Study and have been validated using contemporary clinical data. However, the accuracy and validity of the equations in some populations remain subject to debate (33,34). The CDC-RTI simulation model uses the UKPDS microvascular complication risk equations (19,32) and their ability to predict the future risk of microvascular complications among contemporary patients may be subject to treatment changes.

However, there are no other risk equations that are superior to the UKPDS equations (35). Finally, our model uses a cohort-based approach, and thus the results represent average effects without considering individual-level stochasticity. Because our study is intended to assist policy decisions at a population level, variations in CE results at an individual level are less relevant.

In summary, we found that the USPSTF-recommended intervention is likely to be cost effective for overweight and obese adults with CVD risk factors. However, CE varies by risk subgroups, suggesting that those who are obese with at least one CVD risk factor (dyslipidemia, hypertension, or IFG), or who are overweight with IFG may be priority populations. Further refinement of recommendations for risk stratification, and focusing on a group-only delivery method with comparable effectiveness, may improve the CE of the intervention.

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Duality of Interest. The study was conducted by the U.S. Government employees as part of their duties. No other potential conflicts of interest relevant to this article were reported. Author Contributions. J.L. designed the study, reviewed the literature, analyzed the baseline data and the results, modified the simulation model, and wrote the first draft of the manuscript. X.Z. designed the study, reviewed the literature, and analyzed the baseline data. B.B. analyzed the baseline data. D.B.R., W.E.G., Y.H., G.W., and A.A. designed the study. P.Z. designed the study and reviewed the literature. All authors contributed to the discussion and reviewed and edited the manuscript. J.L., D.B.R., W.E.G., and P.Z. are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Prior Presentation. Parts of this study were presented in abstract form at the 75th Scientific Sessions of the American Diabetes Association, Boston, MA, 5-9 June 2015.

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