Cost-Effectiveness of Screening for Pre-Diabetes Among Overweight and Obese U.S. Adults

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OBJECTIVE — To estimate the cost-effectiveness of screening overweight and obese individuals for pre-diabetes and then modifying their lifestyle based on the Diabetes Prevention Program (DPP).

RESEARCH DESIGN AND METHODS — A Markov simulation model was used to estimate disease progression, costs, and quality of life. Cost-effectiveness was evaluated from a health care system perspective. We considered two screening/treatment strategies for pre-diabetes. Strategy 1 included screening overweight subjects and giving them the lifestyle intervention included in the DPP if they were diagnosed with both impaired glucose tolerance (IGT) and impaired fasting glucose (IFG). Strategy 2 included screening followed by lifestyle intervention for subjects diagnosed with either IGT or IFG or both. Each strategy was compared with a program of no screening.

RESULTS — Screening for pre-diabetes and treating those identified as having both IGT and IFG with the DPP lifestyle intervention had a cost-effectiveness ratio of $8,181 per quality-adjusted life-year (QALY) relative to no screening. If treatment was also provided to subjects with only IGT or only IFG (strategy 2), the cost-effectiveness ratio increased to $9,511 per QALY. Changes in screening-related parameters had small effects on the cost-effectiveness ratios; the results were more sensitive to changes in intervention-related parameters.

CONCLUSIONS — Screening for pre-diabetes in the overweight and obese U.S. population followed by the DPP lifestyle intervention has a relatively attractive cost-effectiveness ratio.

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The Diabetes Prevention Program (DPP) clearly demonstrates that behavioral modifications or drug treatments can delay or prevent the development of type 2 diabetes in individuals with impaired glucose tolerance (IGT) (1). The DPP randomly assigned subjects with IGT and elevated fasting glucose concentrations to three treatment groups: placebo, a lifestyle modification program with goals of 7% weight loss and 150 min of weekly physical activity, or metformin. The average follow-up was 2.8 years. In comparisons with placebo, the lifestyle and metformin interventions reduced the incidence of type 2 diabetes by 58 and 31%, respectively (1).

Previously, we estimated the lifetime cost-effectiveness of the DPP interventions using a Markov simulation model to estimate disease progression, costs, and quality of life for individuals known to have pre-diabetes (2). Versus placebo, the lifestyle and metformin interventions were estimated to delay development of type 2 diabetes by 11 and 3 years, respectively; the corresponding reductions in absolute lifetime incidence of diabetes were 20 and 8%, respectively. Compared with placebo, the cost per quality-adjusted life-year (QALY) from a health system perspective was ~$1,100 and $31,300 for the lifestyle and metformin interventions, respectively.

Because our previous study focused on individuals with known IGT, it did not answer a distinct, but important, public health question: Is it cost-effective to screen patients to identify individuals with pre-diabetes who might benefit from the DPP interventions? Screening incurs costs and has imperfect sensitivity and specificity. A previous study examined the costs, sensitivity, and specificity of screening individuals with pre-diabetes but did not evaluate the benefits of treating those identified with pre-diabetes (3).

To evaluate the screening issue, we performed a new cost-effectiveness analysis to compare screening/treatment strategies for pre-diabetes (defined formally as IGT and/or impaired fasting glucose [IFG]) among overweight and obese U.S. adults aged 45–74 years. We added screening to the simulation model to compute the possible benefits and costs of screening to identify pre-diabetes in the population. We compared two screening/treatment strategies with a baseline scenario of no screening and no treatment for pre-diabetes to estimate each strategy's cost-effectiveness.

RESEARCH DESIGN AND METHODS

Overview of the simulation model

The model consisted of three modules: screening, pre-diabetes, and diagnosed

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Abbreviations: CBG, capillary blood glucose; DPP, Diabetes Prevention Program; FPG, fasting plasma glucose; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; QALY, quality-adjusted life-year.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

diabetes. In the screening module, overweight subjects without diagnosed diabetes underwent a one-time screening test for pre-diabetes during a scheduled physician visit. Those who screened positive underwent diagnostic testing. Subjects who had pre-diabetes entered the pre-diabetes module and received the DPP lifestyle intervention if dictated by the treatment strategy (see below). Some subjects with pre-diabetes eventually developed diabetes; they were assumed to be diagnosed shortly after onset and entered into the diagnosed diabetes module.

Those who screened negative entered the pre-diabetes module with undiagnosed pre-diabetes. If they developed diabetes, they were followed until they developed symptoms of diabetes and were clinically diagnosed. They then entered into the diagnosed diabetes module. Because our primary interest was in screening for and treating pre-diabetes, our main analysis focused only on individuals with pre-diabetes.

Target population

We analyzed the effects of screening and treatment for the overweight and obese (BMI ≥25 kg/m^2) population aged 45–74 in the U.S. We created the study cohort using data from the overweight population in the 1999–2000 National Health and Nutrition Examination Survey and U.S. Census population estimates for 2000 (4–7).

Screening tests

We assumed a one-time opportunistic screening program for overweight and obese adults that occurred during a scheduled physician office visit. Screening was performed through a random capillary blood glucose (CBG) test and added 10 min to a usual 15-min office visit, incurring costs of $32.68 per screened patient. The CBG test and physician costs come from Medicare fee schedules (8,9). The CBG test was selected for screening based on its relatively low costs (3). Based on previous analysis, we set 100 mg/dl as the screening cutoff point for the random CBG test, with corresponding sensitivity and specificity (10).

Estimates of the prevalence of undiagnosed diabetes and pre-diabetes come from the National Health and Nutrition Examination Survey III dataset. Among overweight subjects aged 45–74 years not previously diagnosed with diabetes, prevalence was 9.7% for undiagnosed diabetes, 10.4% for both IFG and IGT, 23.2% for IFG only, and 7.0% for IGT only.

Table 1—*Screening and pre-diabetes parameters*

	Parameter	Source
Prevalence among overweight subjects aged 45–74 years not previously diagnosed with diabetes		
Undiagnosed diabetes	9.7%	NHANES III
IFG and IGT	10.4%	NHANES III
IFT only	23.2%	NHANES III
IGT only	7.0%	NHANES III
Screening tests (CBG)		
Sensitivity		
Diabetes	83.0%	Zhang et al. (10)
Both IGT and IFG	80.0%	NHANES III, derived by Zhang and CDC colleagues in August 2005
Either IGT or IFG (not both)	53.0%	NHANES III, derived by Zhang and CDC colleagues in August 2005
Specificity (nonnormoglycemia)	63.0%	NHANES III, derived by Zhang and CDC colleagues in August 2005
Cost	$32.68	Lab and physician fee schedules (8,9)
Diagnostic tests		
Fasting serum glucose costs	$36.73	Lab and physician fee schedules (8,9)
Oral glucose tolerance test costs	$49.11	Lab and physician fee schedules (8,9)
Annual probability of developing diabetes		
Both IGT and IFG	10.8%	Herman et al. (2)
IGT or IFG (not both)	5.4%	de Vegt et al. (12)
DPP lifestyle intervention reduction in risk for onset of diabetes	55.3%	Herman et al. (2)*
Incremental cost of participating in the DPP lifestyle intervention		
1st year	$1,200	DPP Research Group (23)
2nd year and beyond	$600	DPP Research Group (23)
Health utility scores		
With no intervention	0.68%†	DPP Research Group (13)
With DPP lifestyle intervention	0.70%†	DPP Research Group (14)

*The 55.3% value used in this and the study by Herman et al. (2) is slightly lower than the 58% value reported in the original DPP study (1). The 58% risk reduction was based on the data as of 1 April 2001, which were the data from the Data Monitoring Board report when the DPP was terminated early. The DPP then continued to follow all participants through 31 July 2001 on their masked intervention. Beginning 1 August 2001, patients came to the clinic for unmasking and study results. The 55.3% risk reduction we use is based on all data through the end of July. †For men. Utility scores for women were 0.02 lower. CDC, Centers for Disease Control and Prevention; NHANES, National Health and Nutrition Examination Survey.

Diagnostic tests

All subjects with a positive screening test received a diagnostic test (either a fasting plasma glucose [FPG] or oral glucose tolerance test). If the first diagnostic test was positive, a second was performed as confirmation. Because two consecutive elevated FPG tests or oral glucose tolerance tests define diabetes (11), we assumed that this strategy has 100% sensitivity and 100% specificity for diabetes and for IGT and/or IFG. The cost per diagnostic test totaled $42.92, including $11.61 (because either test may be used for diagnosis, we averaged FPG [$5.42] and oral glucose tolerance test [$17.80] costs) for the test, $3.00 for the blood draw (8), and an extra 10 min of physician time.

Pre-diabetes treatment strategies

We considered two different screening-plus-treatment strategies for subjects with pre-diabetes. In strategy 1, only subjects diagnosed with both IGT and IFG received the DPP lifestyle intervention. This

approach nearly matches the DPP eligibility requirements: most participants had IGT and an FPG value >95 mg/dl (1). In strategy 2, subjects diagnosed with either IFG or IGT (or both) received the lifestyle intervention. In both strategies, the lifestyle intervention was provided until the subject develops diabetes.

Key parameters for the pre-diabetes module are shown in Table 1. Progression to diabetes depended on whether the subject has both IGT and IFG or only one of the conditions. The progression rate for subjects with both IGT and IFG came directly from the DPP (2), whereas the progression rate for subjects with only one condition was set to half the DPP value, based on the Hoorn Study (12). We assumed that the lifestyle intervention produced the same percentage relative risk reduction if the subject had both IGT and IFG or only one of these conditions.

The cost of the DPP intervention equaled the incremental cost of the DPP lifestyle intervention relative to placebo. The DPP lifestyle intervention had a median follow-up of 3 years; for our analysis, we had to make assumptions about the intervention's costs and effectiveness in subsequent years. We assumed that the intervention's year 3 costs and the reduction in risk from participating in the DPP continued in subsequent years as long as the intervention was continued. Health utility scores for subjects with IGT were measured annually during the DPP (13). Utility scores were higher in the lifestyle intervention than in the placebo group.

Diabetes

Subjects with pre-diabetes entered the diabetes module after developing diabetes. The diagnosed diabetes module, which has been described elsewhere (2,14), models the progression of five complications of type 2 diabetes: nephropathy, neuropathy, retinopathy, coronary heart disease, and stroke. Based on earlier analyses (14,15), we assumed that subjects with diagnosed diabetes receive intensive glycemic control once their A1C levels reach 6.8% and that subjects with hypertension and diagnosed diabetes receive intensive hypertension control. Transition probabilities for diabetes complications were based primarily on results from the U.K. Prospective Diabetes Study (16–20).

We applied a multiplicative equation that estimated annual direct medical costs for diabetes according to demographic characteristics, diabetes treatment, risk factors for cardiovascular disease, and microvascular and macrovascular complications (2,21). Health utility scores for patients with diabetes were estimated using an additive prediction model (22).

Main analysis

We used the simulation model to assess lifetime progression of disease, costs, and QALYs. We calculated incremental cost-effectiveness ratios for the two screening/treatment strategies relative to a baseline of no screening and, consequently, no treatment for pre-diabetes. We adopted a health system perspective that considered only direct medical costs and discounted costs and QALYs at 3% per year. Costs are expressed in U.S. dollars (year 2001).

Sensitivity analyses

We conducted numerous one-way sensitivity analyses; for example, we increased and decreased the prevalence of pre-diabetes by 20% and performed separate analyses for different age-groups. We also calculated the cost-effectiveness of the screening strategies from the societal perspective. Societal costs of the DPP lifestyle intervention included direct medical and nonmedical costs (participant time costs, exercise classes, exercise equipment, food, and transportation) and were $637 higher than health care system costs in the intervention's 1st year and $404 higher in subsequent years (23).

We examined repeated screening, with screening tests performed three times, 3 years apart; for computational purposes; this analysis focused on a single cohort. Additional analyses of screening parameters doubled screening and diagnostic test costs, applied a higher CBG cutoff of 120 mg/dl, and defined IFG based on an FPG value of ≥95 mg/dl, matching the DPP criterion.

Several analyses focused on the intervention received by patients diagnosed with pre-diabetes. We evaluated screening followed by applying the DPP metformin intervention (assuming generic metformin costs) for patients diagnosed with pre-diabetes. We also evaluated the lifestyle intervention provided in a group setting, assuming it would produce the same risk reduction but have lower costs. In our main analysis, the intervention continued and had the same cost and relative reduction in risk as during the 3-year DPP trial. To assess this critical assumption, we assumed, for all years, that the relative reduction in risk from the DPP was actually 20% lower than that observed in the trial; costs were the same as in the main analysis. We then assumed that people received the DPP intervention for only 3 years, neither receiving benefits nor paying costs thereafter.

Because some subjects diagnosed with pre-diabetes may forego the intervention, we evaluated cost-effectiveness when only 50% of those diagnosed began the intervention. We also performed an analysis where the lifestyle intervention did not directly affect the quality of life for subjects while they had pre-diabetes. Other analyses included the costs and benefits of treatment for subjects diagnosed with diabetes during the screening process and varied the discount rate for costs and QALYs from 0 to 5% (24).

RESULTS

Main analysis

Under strategy 1, 80% of overweight subjects with IFG and IGT were diagnosed and began treatment. Strategy 2 diagnosed and treated these same subjects but also provided DPP treatment to 53% of subjects with only IFG or only IGT. As a result, the total number of subjects receiving treatment tripled.

Relative to no screening, strategy 1 lowered the percentage of subjects with both IFG and IGT who subsequently developed diabetes from 76.4 to 58.6%. Strategy 2 produced the same reduction for subjects with both IFG and IGT. Among subjects with only IFG or only IGT, this strategy lowered cumulative incidence from 57.4 to 45.2%.

In Table 2, the cost-effectiveness of strategies 1 and 2 are compared with the alternative of no screening. The first panel presents numbers per person screened, whereas the second panel highlights the costs and benefits per screened person with pre-diabetes—the primary target for the screening/treatment interventions. This alternative presentation does not change the cost-effectiveness ratios.

Strategy 1 produced higher total costs and more QALYs than the no-screening alternative. Per-person screening costs accounted for a relatively small fraction of the overall cost increase. Treatment costs increased because subjects with IFG and IGT received the lifestyle intervention. This treatment reduced the cost of diabetes complications but not enough to generate total cost savings. Strategy 1 had a cost-effectiveness ratio of $8,181 per QALY. Strategy 2 produced higher costs and higher QALYs than strategy 1 because

Table 2—*Costs, QALYs, and cost-effectiveness*

	Per screened subject					Per screened subject with pre-diabetes				
	No screening (total)	Strategy 1		Strategy 2		No screening (total)	Strategy 1		Strategy 2	
		Total	Incremental	Total	Incremental		Total	Incremental	Total	Incremental
Screening costs ($)	—	68	68	68	68	—	168	168	168	168
Treatment costs ($)	10,342	10,784	443	11,879	1,538	25,440	26,530	1,089	29,223	3,783
Complication costs ($)	6,209	6,026	(182)	5,724	(484)	15,273	14,825	(448)	14,082	(1,192)
Total costs ($)	16,550	16,879	329	17,672	1,122	40,714	41,523	809	43,473	2,759
Life-years (undiscounted)	NC*	NC*	0.043	NC*	0.122	18.705	18,811	0.106	19.005	0.300
QALYs	NC*	NC*	0.040	NC*	0.118	8.910	9.009	0.099	9.200	0.290
Cost-effectiveness ratio relative to no screening ($/QALY)			8,181		9,511			8,181		9,511

*Only life-years and QALYs for individuals with pre-diabetes are tracked. Because life-years and QALYs for individuals without pre-diabetes are not affected by the intervention, we can calculate incremental life-years and QALYs. NC, not computed.

more subjects received the lifestyle intervention. The cost-effectiveness ratio for strategy 2 was $9,511 per QALY relative to no screening and $10,167 per QALY relative to strategy 1 (an appropriate comparison because strategy 2 has higher costs and QALYs than strategy 1).

Sensitivity analyses

Increasing or decreasing the prevalence of pre-diabetes had small effects on the cost-effectiveness ratios for strategies 1 and 2 (Table 3). For both strategies, the cost-effectiveness ratios increased with age. From the societal cost perspective, the cost-effectiveness ratios were $16,345 and $18,777 per QALY for strategies 1 and 2, respectively.

Changing screening parameters produced relatively small changes in the cost-effectiveness ratios. Repeated screening every 3 years, for example, produced small increases in these ratios. Doubling the costs of screening and diagnostic tests increased the ratios for strategies 1 and 2 by ~$1,700 and $600, respectively. Changing the CBG cutoff or using an alternative IFG definition had negligible effects.

Changing assumptions about the intervention provided to subjects diagnosed with pre-diabetes produced relatively large changes in cost-effectiveness ratios. Using a metformin intervention produced much higher cost-effectiveness ratios than the lifestyle intervention. If the lifestyle intervention could be applied in a group setting with lower costs and the same effectiveness, strategy 1 would be cost saving (i.e., higher effectiveness and lower costs) and strategy 2 would have a very low cost-effectiveness ratio. Conversely, if the effects of the lifestyle intervention were 20% less than that seen in the DPP, the cost-effectiveness ratios would rise by $5,000 per QALY. If the DPP lifestyle intervention was implemented for only 3 years and subsequently did not affect progression to diabetes or incur costs, the cost-effectiveness ratios would also rise. If the lifestyle intervention had no direct effect on the quality of life of subjects with pre-diabetes, the cost-effectiveness ratios for strategies 1 and 2 would be $12,773 and $16,149 per QALY, respectively. If 50% of subjects diagnosed with pre-diabetes chose not to participate in the intervention, the strategies would still have nearly the same cost-effectiveness ratios as in the main analysis. Including the costs and benefits of treating subjects diagnosed with diabetes during screening had relatively small effects on cost-effectiveness. Lowering the discount rate reduced cost-effectiveness ratios, and raising this rate increased the ratios.

Results for additional sensitivity analyses are described in an online-only appendix at http://dx.doi.org/10.2337/dc07-0885.

CONCLUSIONS

— The DPP demonstrated that an intensive lifestyle intervention could prevent or delay the onset of type 2 diabetes. However, the intervention was expensive, and some worried that it might not prove cost-effective. To address this issue, we previously applied a simulation model to estimate lifetime outcomes and costs for subjects known to have IGT and elevated fasting glucose concentrations (2). We found that the DPP lifestyle intervention had a relatively attractive cost-effectiveness ratio from the perspective of the health care system. Other studies (25–28) have examined the cost-effectiveness of lifestyle interventions or drug therapy to prevent type 2 diabetes among subjects with IGT. These studies all found that the interventions delay or prevent diabetes onset and, with one exception (28), reported favorable cost-effectiveness ratios.

Our previous results led to a natural next question: If applying the DPP lifestyle intervention to subjects known to have IGT and IFG is cost-effective, would it also be cost-effective to screen for pre-diabetes and then treat subjects identified as having the condition? To answer this question, we considered two screening and treatment strategies for pre-diabetes. For strategy 1, we estimated a cost-effectiveness ratio of $8,181 per QALY. This is generally considered to be a relatively attractive cost-effectiveness ratio.

We found that strategy 2 (which included treatment for subjects with either IGT or IFG or both) had a higher cost-effectiveness ratio than strategy 1 (which limited treatment to subjects with both conditions). Although strategy 3 has a less attractive cost-effectiveness ratio than strategy 1, its ratio is still attractive when compared with many existing health care interventions. However, strategy 2's cost-effectiveness depends on whether the lifestyle intervention will produce the same relative reduction in risk for the only IGT/only IFG group (a subset of those receiving strategy 2) as it produced in the DPP for subjects with both IGT and IFG. If the intervention produces a smaller relative risk reduction for this group, the cost-effectiveness ratio for strategy 2 will be higher (less attractive) as shown by the sensitivity analysis with reduced DPP effects. Future research should evaluate

Table 3—*Sensitivity analyses: cost-effectiveness ratios*

	Different cases for sensitivity analysis	
	Strategy 1 ($/QALY)	Strategy 2 ($/QALY)
Base analysis	8,181	9,511
Sensitivity analyses		
Increased prevalence of pre-diabetes by 20%	7,960	9,445
Reduced prevalence of pre-diabetes by 20%	8,518	9,633
Aged 45–54 years, U.S. overweight population	4,009	5,419
Aged 55–64 years, U.S. overweight population	7,199	8,939
Aged 65–74 years, U.S. overweight population	11,708	13,519
Societal cost perspective	16,345	18,777
Periodic screening (every 3 years for up to three total screens; white nonsmoking female subjects aged 45 years with hypertension and high cholesterol)		
One screen	4,774	6,303
Two screens	5,442	6,731
Three screens	5,988	7,025
Cost of screening and diagnostic tests doubled (screening test cost = $65.36, diagnostic test cost = $85.84)	9,885	10,092
Sensitivity/specificity of tests		
CBG cutoff = 120 mg/dl	8,296	9,076
DPP definition of IFG (fasting serum glucose score ≥95)	8,283	9,548
Metformin intervention (generic price)	19,902	20,161
Group DPP intervention (reduced costs)	Cost saving	267
20% reduced DPP effects	13,179	14,387
No DPP costs or effects after 3 years	19,422	18,111
Lifestyle intervention has no direct effect on quality of life	12,773	16,149
50% participation in DPP of people diagnosed with pre-diabetes	9,032	9,801
Include outcomes and costs of identified diabetes cases	9,925	10,101
0% discount rate	4,687	6,022
5% discount rate	10,847	12,078

whether a DPP-like intervention can reduce the risk of progression to diabetes for subjects with only IGT or only IFG.

Screening costs accounted for a small share of the incremental costs associated with strategies 1 and 2, and the sensitivity analyses indicate that the type of screening test—and its cost, sensitivity, and specificity—will have small effects on the cost-effectiveness of the strategies. In contrast, the costs of the DPP lifestyle intervention are comparatively large, and the intervention must be effective for the overall screening and treatment strategies to have attractive cost-effectiveness ratios. Our sensitivity analyses confirm that assumptions about the intervention have large effects on cost-effectiveness. Particularly important are the intervention's costs and effectiveness in the period beyond the 3-year duration of the DPP.

Our analysis has several limitations inherent in efforts to estimate the cost-effectiveness of interventions targeting chronic diseases. Most deal with the use of a simulation model to project the lifetime costs and health outcomes of simulated subjects. Simulation is particularly useful when intervention costs are incurred immediately and produce improved health outcomes years later. In such situations, clinical trials are extremely expensive and cannot produce timely recommendations; in their absence, simulations can help policymakers make better informed decisions. All simulation models must make assumptions about the future using the best possible medical, epidemiologic, and economic data. In our main analysis, we assumed that the probability of diabetes progression does not change over time; that adherence to, cost of, and effectiveness of the DPP intervention do not change over time; that the cost of pre-diabetes is lower than the cost of uncomplicated diabetes; that patient utility levels are higher with pre-diabetes than with uncomplicated diabetes; and that transition probabilities for diabetes complications are unaffected by the lifestyle intervention. One might argue with some of these assumptions. We have tried, however, to make these assumptions transparent, and we varied many of them in sensitivity analyses.

Our results may provide useful information for policymakers deciding whether to adopt screening for pre-diabetes followed by interventions to delay or prevent diabetes. Overall, our analysis supports the case for screening overweight and obese adults aged 45–74 years for IGT and IFG and treating those who have both conditions with the DPP lifestyle intervention. There is no broadly accepted consensus on the cost-effectiveness ratio that represents the cutoff for deeming an intervention as cost-effective or not cost-effective (24). Some researchers have proposed a cutoff of $50,000 per QALY, whereas others recommend comparing an intervention's cost-effectiveness ratio to the highest ratios for treatments currently covered by Medicare or other insurers. Against either of these criteria, screening for pre-diabetes followed by the DPP lifestyle intervention has a favorable cost-effectiveness ratio.

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