Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors

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This report summarizes estimates of health impact and cost-effectiveness that were created to assess the relative value of most of the clinical preventive services recommended by the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP). This ranking of clinical prevention priorities is guided by the National Commission on Prevention Priorities (NCPP).

A. USPSTF Recommendation

In 2014, the U.S. Preventive Services Task Force (USPSTF) updated its 2003 recommendation of behavioral counseling to promote healthful diet and physical activity for cardiovascular disease (CVD) prevention in adults with CVD risk factors.[1,2] The updated recommendation focuses its target population to persons who are overweight and obese and have additional CVD risk factors. The Task Force found adequate evidence that behavioral counseling has moderate benefits for this population with small to no corresponding harms (a "B" recommendation).

B. Choice of Population

Based on the Task Force recommendation, we evaluate behavioral counseling to promote a healthful diet and physical activity among adults aged 18 and older with a body mass index (BMI) of 25 kg/m^2 or higher and any of the following known CVD risk factors: hypertension, dyslipidemia, or diabetes.

C. Model Type

Analyses in this study were conducted using the HealthPartners Institute ModelHealth™: Cardiovascular disease microsimulation model. ModelHealth: CVD is an annual-cycle microsimulation model, parameterized to estimate the lifetime incidence of CVD events and associated costs in a cross-section of individuals representative of the U.S. population. Additional model details are included in the ModelHealth: CVD Technical Supplement.

Disease outcomes in ModelHealth: CVD include incidence of myocardial infarction, stroke, congestive heart failure, angina pectoris, intermittent claudication, and CVD-related death. Events are predicted by one-year risk equations estimated specifically for the model from Framingham Heart Study data.[3,4] Event risk is based on a person's age, sex, BMI, systolic blood pressure (SBP), high- and low-density lipoprotein (HDL and LDL) cholesterol, smoking status, and history of CVD.

The annual progression of BMI is derived from recall data reported in the Behavioral Risk Factor Surveillance System,[5] and the natural history of SBP and cholesterol is estimated using Framingham Heart Study data.[3,4] Tobacco initiation and cessation probabilities are derived from the National Health Interview Survey data[6] and published estimates from longitudinal studies.[7,8] Screening and treatment for hypertension and dyslipidemia in the model are consistent with national clinical guidelines,[9,10] and identification and treatment adherence patterns are consistent with the rates observed within the National Health and Nutrition Examination Survey (NHANES).[11-15] Use of antihypertensive drugs and lipid-acting agents is modeled as an exogenous treatment effect on SBP and cholesterol, respectively, and alters disease risk accordingly.

Disease costs in ModelHealth: CVD were estimated using data from the Medical Expenditure Panel Survey (MEPS).[16] First-year and ongoing costs are distinguished, and the cost of drug treatment and monitoring are accounted for separately. Pharmacy costs and clinic and lab fees associated with monitoring drug therapy are derived from nationally representative sources.[17-19]

D. Analysis Design

All analyses are conducted for a 4 million person birth cohort with demographic and underlying health characteristics representative of the U.S. population of age 18. Analyses compare outcomes for a simulated population with access to behavioral counseling to promote healthful diet and physical activity to the same population, all else held equal, without access to this clinical service. We assume that the screening rate for eligibility to the behavioral counseling program is 100%; however, not all eligible persons will accept enrollment in a behavioral counseling program. Specifically, we assume that 20% of the population will never agree to enroll in a behavioral counseling program. Among the remaining 80% of the population, we assume that the acceptance rate for a behavioral counseling program is 25%. We assume that 50% of the persons who enroll in a behavioral counseling program will complete the first year of the program; we assume the remaining persons will drop out at some point during the year (uniformly distributed), with costs and benefits proportionally realized. For maintenance, we assume that 75% of the persons who completed the full year of a program during the prior year will continue enrollment in the program the following year. If a person has maintained enrollment in a program continuously for 10 years, we assume that they will stick with the program for life. We assume that persons who have previously enrolled in a program but lapsed in maintenance may re-enroll at a referral acceptance rate of 25%.

Analyses were conducted from the societal perspective, which includes patient time costs, and in accordance with the "reference case" of the Panel on Cost Effectiveness in Health and Medicine.[20] All costs are expressed in 2012 U.S. dollars. Primary outcomes are clinically preventable burden (CPB) and the incremental cost-effectiveness (CE) ratio. CPB is given by

$$\mathrm{CBP} = \sum_{\mathrm{it}} \mathrm{QALY}_{\mathrm{it1}} - \sum_{\mathrm{it}} \mathrm{QALY}_{\mathrm{it0}}$$

where QALY represents the quality-adjusted measure for a person's life year, i is a person identifier, t denotes time, 1 represents the case with access to the specified clinical preventive service, and 0 represents the case without access to the service. Similarly, CE is given by

$$\mathrm{CE} = \frac{\sum_{\mathrm{it}} \frac{\mathrm{QALY}_{\mathrm{it1}}}{(1+\mathrm{r})^{\mathrm{t}}} - \sum_{\mathrm{it}} \frac{\mathrm{QALY}_{\mathrm{it0}}}{(1+\mathrm{r})^{\mathrm{t}}}}{\sum_{\mathrm{it}} \frac{\mathrm{Costs}_{\mathrm{it1}}}{(1+\mathrm{r})^{\mathrm{t}}} - \sum_{\mathrm{it}} \frac{\mathrm{Costs}_{\mathrm{it0}}}{(1+\mathrm{r})^{\mathrm{t}}}}$$

where *Costs* represents total intervention, treatment [21]and management, and disease costs for a person, *r* denotes the discount rate, which is set to 3 percent. As described in further detail below, behavioral counseling to promote a healthful diet and physical activity affects BMI, diabetes incidence, LDL, HDL, and SBP. Deterministic (one-way) sensitivity analyses of key parameters were conducted by replicating simulations with all other parameters, probabilities, and population characteristics held equal.

Treatment effects

Lin et al.[22,23] conducted the systematic evidence review for the USPSTF recommendation. Effects were found for BMI, diabetes incidence, LDL, HDL, and SBP, as summarized in **Table 1**. For persons who drop out midway through an intervention, the treatment effects are proportionally applied during that year.

Table 1: Summary of treatment effects from intensive multi-component obesity interventions

Risk Factor	Effect	Source
BMI (kg/m^2)	-1.00	21,23-47
Diabetes incidence (RR)	0.54	22,29,33,35,39,41,48
LDL (mg/dL)	-3.69	21,22,24,27,28,31,35,37,39,40,43,45,47,49-53
HDL (mg/dL)	+0.97	22,27,28,31,36,37,39-41,43,45,47,49,51,54
SBP (mm Hg)	-2.06	22,26-29,31,37-41,43-47,49-59

Notes: BMI = body mass index; RR = relative risk; LDL = low-density lipoprotein; SBP = systolic blood pressure.

Eligibility assessment frequency

The Task Force does not report an optimal interval for assessing eligibility for referral to behavioral counseling to promote a healthful diet and physical activity; however, for our analysis, we assumed that there is at least one eligibility assessment opportunity per year.

Intervention costs

Intervention costs are summarized in **Table 2**. Few studies directly report costs of behavioral counseling programs to promote a healthful diet and physical activity. We estimated standardized program costs based upon program components and resource use reported in studies of interventions from which we estimated intervention effectiveness and from studies of similar intensity that were excluded from our estimation of effect size due to differences in the population to whom they were targeted. Direct medical costs for behavioral counseling interventions were estimated from the combination of two components: (a) the cost for health professional services (including dietitian, behavioral therapist, and athletic trainer) and (b) a standard cost for printed program materials (which we estimated to average $16 in 2012 dollars).[60] We determined hours of health professional time from study reports and assigned costs to health professional time based on average earnings for each profession, plus total benefits costs, based on National Occupational Employment and Wage Estimates and Employer Costs for Employee Compensation.[61,62] We used occupation code 29-1031 for dietitians, codes 19-3031 and 21-1011 for psychologist counselors, and 29-9091 for athletic trainers. We added a 50% indirect rate for these labor costs to approximate facility costs and intervention support staff.

Direct costs incurred by participants consist of extra costs associated with exercise and healthy diet. Costs of a gym membership (assumed to be $45 per month) or portion of a gym membership for interventions with less intensive exercise component, were added to capture average out-of-pocket costs for physical activity. For interventions with a diet component, we approximated the cost of an improved diet from two studies. From a study by Rehm et al.,[63] we estimated the incremental cost of improved diet from the margin between the 2nd and 4th quintiles of energy-adjusted diet cost where the quartiles were derived from 2001-2002 National Health and Nutrition Examination Survey and national food price data. The average incremental cost for higher quality diet we derived from these estimates was $819 per year.

Time costs incurred by participants include time spent with health professionals, additional time costs for tracking diet and preparing healthy meals and for physical activity. Patient time was valued at the average hourly earnings plus benefits of all U.S. employees ($31 per hour).[62]

Our standardized costs reflect total costs for patients with complete adherence with study protocol. The model incorporates adherence explicitly. Thus, average costs per patient will be lower than our

standardized costs as those failing to adhere to the entire intervention will be allotted only a portion of the intervention costs.

Table 2: Annual costs for a healthy diet and physical activity behavioral counseling program

	Annual Cost		Source
Direct Medical Costs			
Dietician Costs (including overhead)	$	230	29,36,60,64-72
Behavioral Therapist Costs (including overhead)	$	166	29,36,60,64-72
Athletic Trainer Costs	$	497	29,36,60,64-72
Literature/Books/Misc	$	3	60
Total Direct Medical Costs	**$**	**896**	
Direct Non-Medical Costs (Excluding Patient Time)			
Athletic Club Membership	$	540	Assumed
Food Costs	$	819	63,73
Transportation Costs	$	297	Assumed
Total Direct Non-Medical Costs	**$**	**1,656**	
Patient Time Costs			
Behavioral and Dietary Change Classes	$	1,035	29,36,60,62,64-71
Exercise Sessions	$	3,894	29,36,60,62,64-71
Total Patient Time Costs	**$**	**4,929**	

Notes: All costs are expressed in 2012 U.S. dollars.

E. Clinically Preventable Burden (CPB) Estimate

Our estimate of lifetime CPB for a birth cohort of 4 million persons initially aged 18 is 751,904 QALYs. In sensitivity analysis, this estimate ranged from 241,613 to 1,282,775 QALYs.

F. Cost-Effectiveness (CE) Estimate

Our estimate of the incremental cost-effectiveness of screening for and management of obesity in adults is $103,363 per QALY. In sensitivity analysis, this estimate ranged from $28,270 to $219,915 per QALY.

G. Limitations

The microsimulation model design and the results of these analyses are limited by the quality of data and evidence used to inform them. Our sensitivity analysis results indicate that CPB estimates are most sensitive to adherence to behavioral counseling programs, and CE estimates are most sensitive to assumptions regarding obesity intervention efficacy and costs. The marginal benefit of healthy lifestyle counseling is dependent on baseline risk factors and disease rates, but ModelHealth: CVD is shown to validate reasonably well with U.S. data (**Technical Supplement, Table 30**).

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