

Costs Associated With the Primary Prevention of Type 2 Diabetes Mellitus in the Diabetes Prevention Program

THE DIABETES PREVENTION PROGRAM
RESEARCH GROUP*

OBJECTIVE — To describe the costs of the Diabetes Prevention Program (DPP) interventions to prevent or delay type 2 diabetes.

RESEARCH DESIGN AND METHODS — We describe the direct medical costs, direct nonmedical costs, and indirect costs of the placebo, metformin, and intensive lifestyle interventions over the 3-year study period of the DPP. Resource use and cost are summarized from the perspective of a large health system and society. Research costs are excluded.

RESULTS — The direct medical cost of laboratory tests to identify one subject with impaired glucose tolerance (IGT) was \$139. Over 3 years, the direct medical costs of the interventions were \$79 per participant in the placebo group, \$2,542 in the metformin group, and \$2,780 in the lifestyle group. The direct medical costs of care outside the DPP were \$272 less per participant in the metformin group and \$432 less in the lifestyle group compared with the placebo group. Direct nonmedical costs were \$9 less per participant in the metformin group and \$1,445 greater in the lifestyle group compared with the placebo group. Indirect costs were \$230 greater per participant in the metformin group and \$174 less in the lifestyle group compared with the placebo group. From the perspective of a health system, the cost of the metformin intervention relative to the placebo intervention was \$2,191 per participant and the cost of the lifestyle intervention was \$2,269 per participant over 3 years. From the perspective of society, the cost of the metformin intervention relative to the placebo intervention was \$2,412 per participant and the cost of the lifestyle intervention was \$3,540 per participant over 3 years.

CONCLUSIONS — The metformin and lifestyle interventions are associated with modest incremental costs compared with the placebo intervention. The evaluation of costs relative to health benefits will determine the value of these interventions to health systems and society.

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The Diabetes Prevention Program (DPP) demonstrated that both medication and lifestyle interventions can delay or prevent progression from impaired glucose tolerance (IGT) to type 2

diabetes (1). The DPP demonstrated that compared with the placebo intervention, the intensive lifestyle intervention reduced the incidence of type 2 diabetes by 58% and the metformin intervention re-

duced the incidence of type 2 diabetes by 31% over 2.8 years (1).

The DPP enrolled 3,234 participants with IGT (fasting plasma glucose of 95–125 mg/dl and plasma glucose 2-h after a 75-g oral glucose load of 140–199 mg/dl) who were at least 25 years of age and had a BMI ≥ 24 kg/m² (≥ 22 kg/m² in Asian-Americans). Mean age of the participants was 51 years, and mean BMI was 34.0 kg/m². Of the participants, 68% were women and 45% were members of minority groups.

The goals for the participants assigned to the intensive lifestyle intervention were to achieve and maintain a weight reduction of at least 7% of initial body weight through a healthy, low-calorie, low-fat diet and physical activity of moderate intensity, such as brisk walking, for at least 150 min per week. A 16-lesson curriculum covering diet, exercise, and behavior modification was designed to help the participants achieve these goals. The curriculum, taught by case managers on a one-to-one basis during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes.

The medication interventions (metformin and placebo) were initiated at a dose of 850 mg taken orally once a day. At 1 month, the dose of metformin or placebo was increased to 850 mg twice daily, unless gastrointestinal symptoms warranted a longer titration period. The initiation of treatment with half a tablet was optional. Adherence to the treatment regimen was reinforced quarterly. The standard lifestyle recommendations for the medication groups were provided in the form of written information and in an annual 20- to 30-min individual session that emphasized the importance of a healthy lifestyle (1).

In this report, we describe the costs associated with the primary prevention of type 2 diabetes in the DPP. Because the costs of new treatments may be barriers to

From the Diabetes Prevention Program Coordinating Center, Biostatistics Center, George Washington University, Rockville, Maryland.

Address correspondence and reprint requests to Diabetes Prevention Program Coordinating Center, Biostatistics Center, George Washington University, 6110 Executive Blvd., Suite 750, Rockville, MD 20852. E-mail: dppmail@biostat.bsc.gwu.edu.

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*The members of the Diabetes Prevention Program Group are listed in reference 1. The members of this writing group are William H. Herman MD, MPH; Michael Brandle MD; Ping Zhang PHD; David F. Williamson PHD, MS; Margaret J. Matulik RN, BSN; Robert E. Ratner MD; John M. Lachin SCD; Michael M. Engelgau MD, MS

Abbreviations: AWP, average wholesale price; CMS, Center for Medicare and Medicaid Services; DPP, Diabetes Prevention Program; IGT, impaired glucose tolerance; LCM, lifestyle case manager; MCM, medication case manager; OGTT, oral glucose tolerance tests.

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

See accompanying editorial on p. 240.

their widespread implementation, a detailed and accurate description of costs should help health systems and policy makers to translate the results of the DPP into efficient clinical and public health practice. These data will also provide the basis for studies of the cost-effectiveness of the DPP interventions.

RESEARCH DESIGN AND METHODS

— In this report, we describe the costs of the DPP interventions and the direct medical costs, direct nonmedical costs, and indirect costs of the lifestyle and metformin interventions compared with the placebo intervention. The closing date for data used in these analyses was 31 July 2001. In general, costs were calculated by applying standard unit costs to the resources used (2). The unit costs used, and their sources, are summarized in the APPENDIX. We excluded the resources used and costs of the research component of the DPP from this analysis. The research component of the DPP included the resources used for recruitment of participants and for data collection and surveillance of complications and outcomes beyond those recommended for routine clinical practice. All costs were adjusted to year 2000 U.S. dollars using the consumer price index and the medical consumer price index (3). The analysis was performed with a 3-year time horizon, the average length of follow-up within the DPP. In the tables, the total costs occasionally do not add up exactly because the numbers are rounded.

Direct medical costs

Direct medical costs represent expenditures for medical services and products and are usually paid by health systems (2). These costs include the costs of hospitalization, outpatient care, laboratory tests, and medications. In estimating direct medical costs, we considered the costs of laboratory testing to identify persons with IGT, the costs of implementing and maintaining the DPP interventions, and the costs of care incurred or averted by the interventions that were captured by costs of medical care outside the DPP.

Direct nonmedical costs represent expenditures arising as a result of medical treatment of illness but not involving the purchase of medical services or products (2). Since these costs do not represent health care expenditures, they are not usually paid by health systems. They do,

however, represent “out-of-pocket” costs to patients and costs to society. In the DPP, direct nonmedical costs included the value of the time that participants spent traveling to and attending appointments, exercising, shopping, and cooking; the costs of exercise classes, exercise equipment, special foods, and food preparation items; and the costs of transportation to and from appointments.

Indirect costs are another cost to society that arise from illness-related morbidity and mortality (2). Indirect costs from morbidity arise from being absent from work because of medical treatment, illness, or long-term disability. Indirect mortality costs arise from lost productivity due to premature death.

In these analyses, we have adopted two separate perspectives: the perspective of a large health system and the perspective of society. In the former analyses, adopting the perspective of a health system, we have considered the direct medical costs of the DPP interventions and the direct medical costs of care received outside the DPP. In the latter analysis, adopting the perspective of society, we have considered, in addition to direct medical costs, direct nonmedical costs and indirect costs.

Direct medical costs

Identification of individuals with IGT.

A variety of strategies were used to recruit subjects for the DPP. Costs were driven by the need to screen a large and diverse population over a short period of time (4). Accordingly, we considered many of the costs of recruitment to have been research driven. We anticipate that in a non-research setting, health care providers will screen individuals at high risk for IGT as a part of ongoing medical care. Oral glucose tolerance tests (OGTTs) were performed to identify subjects eligible to participate in the DPP. We estimated the direct medical cost of identifying one subject with IGT as the number of OGTTs performed to successfully identify one randomized participant times the unit cost of the OGTT. The unit cost of the OGTT was based on Center for Medicare and Medicaid Services (CMS) reimbursement rates (APPENDIX).

Interventions. To estimate the direct medical costs of the interventions, DPP staff from each of the 27 clinical centers completed a questionnaire (DPP Form D02, *Resource Utilization and Cost of Inter-*

vention Questionnaire). This questionnaire described the types of personnel and the amount of their time involved in the various components of the interventions, the health education materials provided, the medications prescribed, and the laboratory tests performed. The frequency of encounters and calls was determined from the questionnaires, from case report forms, and from the manual of operations (5). Median responses were used to estimate usual resource use. The daily medication cost was calculated based on the dose prescribed (0, 1, or 2 tablets per day) by study year and the unit cost per tablet (APPENDIX). To promote treatment adherence, each DPP clinical center received money for toolbox strategies (\$1,167 per year per clinic for subjects in the placebo intervention, \$1,167 per year per clinic for subjects in the metformin intervention, and \$4,000 per year per clinic for subjects in the lifestyle intervention). DPP staff reported the proportion of these funds disbursed each year. Toolbox monies were used to purchase pill boxes and pill cutters for subjects in the metformin intervention group and to purchase exercise equipment that was loaned to subjects in the lifestyle intervention group. We considered toolbox monies spent to promote adherence to placebo treatment to be a research cost and did not include them in the cost of the placebo intervention.

Unit costs for personnel were calculated as the median salaries of personnel employed in the DPP with National Institutes of Health (NIH)-negotiated fringe benefit rates (APPENDIX). Overhead costs for DPP clinical centers were estimated as 69% of DPP personnel costs (6). The costs of health education materials did not include development costs and were based on bulk reproduction or publishing rates. The costs of laboratory tests were based on CMS reimbursement rates (APPENDIX). The cost of medication was taken as the year 2000 Red Book average wholesale price (AWP) (APPENDIX).

Care outside the DPP. We recognized that either by causing side effects or by improving health, the DPP interventions might affect costs of medical care outside the study. To estimate the direct medical costs of care outside the DPP for each of the three intervention groups, we reviewed rates of serious adverse events (DPP Form E02, *Serious Adverse Event Report*) and adverse events (DPP Form E01,

Table 1—Per capita direct medical costs of the placebo intervention by year

Item	Provider	Units	Subjects (%)	Time (h)	Unit cost (\$)	Total cost (\$)
Year 1						
1 st visit counseling	MCM	1	100	0.50	25.24	13
1 st visit materials						
<i>On Your Way to Fitness</i>		1	100		1.00	1
<i>Dietary Guidelines for Americans</i>		1	75		1.16	1
3-month visit counseling	MCM	1	100	0.25	25.24	6
3-month visit diet	Dietitian	1	12	0.63	26.12	2
Phone calls	MCM	1	10	0.16	25.24	0
Reminder phone calls	Secretary	2	100	0.08	19.54	3
Overhead (69% of personnel)						17
Total cost (year 1)						43
Year 2						
Annual visit	MCM	1	100	0.33	25.24	8
Phone calls	MCM	1	10	0.16	25.24	0
Reminder phone calls	Secretary	1	100	0.08	19.54	2
Overhead (69% of personnel)						7
Total cost (year 2)						18
Year 3						
Annual visit	MCM	1	100	0.33	25.24	8
Phone calls	MCM	1	10	0.16	25.24	0
Reminder phone calls	Secretary	1	100	0.08	19.54	2
Overhead (69% of personnel)						7
Total cost (year 3)						18
Total cost (years 1–3)						79

MCM, Medication Case Manager.

Adverse Event Report) by treatment group and surveyed participants and estimated the annual use of hospital, emergency room, urgent care, outpatient services, and telephone calls to health care providers (DPP Form Q08, *Interval History Questionnaire*), and prescription medications outside the DPP (DPP Form F02, *Major Follow-Up Visit Inventory*).

Unit costs were based on the nationwide average reimbursements for hospital days, emergency room visits, urgent care and outpatient visits, and telephone consultations (APPENDIX). The cost of prescription medications was based on the median AWP of a prescription filled by Merck Medco and Co., Inc., a large U.S. pharmacy benefit manager (APPENDIX).

Direct nonmedical costs

To estimate direct nonmedical costs, we estimated participant time from the frequency and duration of encounters and calls as reported by the DPP staff (DPP Form D02, *Resource Utilization and Cost of Intervention Questionnaire*). We assumed that participants spent, on average, a total

of 30 min traveling to and from DPP appointments and that travel time and time spent at DPP appointments had a value of \$8 per hour, half of the average hourly wage in 2000 (APPENDIX). Participants also completed questionnaires to describe the time they spent exercising, shopping, and cooking; and to describe their enjoyment of leisure-time physical activity (DPP Form Q12, *Economic Evaluation Questionnaire*). Leisure time physical activity was valued according to whether participants “disliked,” were “neutral,” or “liked” leisure time physical activity (7). For those who disliked leisure time physical activity, their time was assigned a value of \$8 per hour, half of the average hourly wage in 2000 (APPENDIX). For those who were neutral to it, their time was assigned a value of \$4 per hour. For those who liked leisure time physical activity, their time was assigned a value of \$0 per hour. Sensitivity analyses were performed to assess the impact of variation in the cost of leisure time physical activity on the cost of the interventions. In these analyses, leisure time physical activity was valued at

\$0 per hour, \$8 per hour, and \$16 per hour for all participants regardless of their exercise preferences. Participants were also asked to report the number of hours per week they spent shopping for and preparing food for themselves. The time that participants spent shopping for and preparing food was assigned a value of \$4 per hour.

Questionnaires administered to participants (DPP Form Q12, *Economic Evaluation Questionnaire*) were also used to assess out-of-pocket purchases of health club and gym memberships, exercise classes, personal trainers, exercise equipment, commercial weight loss programs, cooking classes, and equipment for food preparation. Data were analyzed by treatment group. Services and products used by >5% of subjects were included in our analyses. We assumed that for persons purchasing specific services and products, items were purchased once during the 3-year period except for the following: exercise shoes (two pairs per year for lifestyle subjects, one pair per year for metformin and placebo subjects), health club

Table 2—Per capita direct medical costs of the metformin intervention by year

Item	Provider	Units	Subjects (%)	Time (h)	Unit cost (\$)	Total cost (\$)
Year 1						
Standard lifestyle recommendation (see Table 1 year 1 for details)						43
Baseline history and physical exam	Physician	1	100		91.00	91
Baseline labs						
Venipuncture		1	100		3.00	3
Serum creatinine		1	100		6.84	7
Hemoglobin/hematocrit		1	100		7.91	8
Urine creatinine		1	0.3		6.92	0
Metformin fact-sheet		1	100		0.08	0
Metformin						
0 tablet dose		0	9		1.10	0
1 tablet dose		365	15		1.10	60
2 tablet dose		730	76		1.10	610
Follow-up visits	MCM	3.46	100	0.33	25.24	29
	MA	3.46	62	0.33	18.14	13
Dose-titration/restart visits	MCM	1.39	100	0.33	25.24	12
Outbound phone calls	MCM	3	25	0.16	25.24	3
Inbound phone calls	MCM	2	30	0.16	25.24	3
Reminder phone calls	Secretary	5.85	100	0.08	19.54	10
Tool box						17
Overhead (69% of personnel)						110
Total cost (year 1)						1,019
Year 2						
Standard lifestyle recommendation (see Table 1 year 2 for details)						18
Lab monitoring						
Venipuncture		1	84		3.00	3
Serum creatinine		1	84		6.84	6
Hemoglobin/hematocrit		1	84		7.91	7
Urine creatinine		1	0.4		6.92	0
Metformin						
0 tablet dose		0	16		1.10	0
1 tablet dose		365	14		1.10	56
2 tablet dose		730	70		1.10	562
Follow-up visits	MCM	3.97	100	0.33	25.24	33
	MA	3.97	62	0.33	18.14	15
Dose-titration/restart visits	MCM	0.07	100	0.33	25.24	1
Outbound phone calls	MCM	3	25	0.16	25.24	3
Inbound phone calls	MCM	2	30	0.16	25.24	3
Reminder phone calls	Secretary	4.04	100	0.08	19.54	7
Tool box						17
Overhead (69% of personnel)						42
Total cost (year 2)						772
Year 3						
Standard lifestyle recommendation (see Table year 3 for details)						18
Lab monitoring						
Venipuncture		1	80		3.00	2
Serum creatinine		1	80		6.84	5
Hemoglobin/hematocrit		1	80		7.91	6
Urine creatinine		1	0.4		6.92	0
Metformin						
0 tablet dose		0	20		1.10	0
1 tablet dose		365	12		1.10	48
2 tablet dose		730	68		1.10	546
Follow-up visits	MCM	3.97	100	0.33	25.24	33
	MA	3.97	62	0.33	18.14	15
Dose-titration/restart visits	MCM	0.07	100	0.33	25.24	1
Outbound phone calls	MCM	3	25	0.16	25.24	3
Inbound phone calls	MCM	2	30	0.16	25.24	3
Reminder phone calls	Secretary	4.04	100	0.08	19.54	7
Tool box						22
Overhead (69% of personnel)						42
Total cost (year 3)						751
Total cost (years 1–3)						2,542

MA, Medical Assistant; MCM, Medication Case Manager.

Table 3—Per capita direct medical costs of the lifestyle intervention by year

Item	Provider	Units	Subjects (%)	Time (h)	Unit cost (\$)	Total cost (\$)
Year 1						
Baseline history and physical exam	Physician	1	100		91.00	91
Exercise test		1	19		114.00	22
Core curriculum	LCM	16	100	1.00	23.55	377
Materials		1	100		8.85	9
Supervised activity sessions	LCM	4.27	60	1.00	23.55	60
	Trainer	4.27	40	1.00	26.02	44
Lifestyle group sessions	LCM	0.36	100	1.25	23.55	11
In-person visits	LCM	7.65	100	0.58	23.55	105
Phone calls	LCM	2.32	100	0.25	23.55	14
Reminder phone calls	Secretary	29.41	100	0.08	19.54	48
Tool box						102
Overhead (69% of personnel)						517
Total cost (year 1)						1,399
Year 2						
Supervised activity sessions	LCM	4.27	60	1.00	23.55	60
	Trainer	4.27	40	1.00	26.02	44
Lifestyle group sessions	LCM	0.72	100	1.25	23.55	21
In-person visits	LCM	12.33	100	0.58	23.55	169
Phone calls	LCM	2.66	100	0.25	23.55	16
Reminder phone calls	Secretary	17.45	100	0.08	19.54	28
Tool box						105
Overhead (69% of personnel)						234
Total cost (year 2)						679
Year 3						
Supervised activity sessions	LCM	4.27	60	1.00	23.55	60
	Trainer	4.27	40	1.00	26.02	44
Lifestyle group sessions	LCM	0.72	100	1.25	23.55	21
In-person visits	LCM	12.33	100	0.58	23.55	169
Phone calls	LCM	2.66	100	0.25	23.55	16
Reminder phone calls	Secretary	17.45	100	0.08	19.54	28
Tool box						128
Overhead (69% of personnel)						234
Total cost (year 3)						702
Total cost (Years 1–3)						2,780

LCM, Lifestyle Case Manager.

memberships (1.5 years' membership per subject), exercise classes (1.5 years' attendance per subject), personal trainer (five visits per subject), commercial weight-loss programs (1.5 years' attendance per subject), and cooking classes (three classes per subject). To depreciate durable equipment (defined as items that would last >3 years and had a purchase price of more than \$100), we assumed that the equipment could be sold at 50% of the original purchase price after 3 years. Unit costs of services and products

were estimated from the literature and are summarized in the APPENDIX.

Participants were also asked about changes in the costs of food that they experienced since they entered the DPP (DPP Form Q12, *Economic Evaluation Questionnaire*). Specifically, they were asked about the costs of food at home, at fast-food restaurants, and at non-fast-food restaurants. For each source of food, participants were asked whether their expenditures "increased a lot," "increased some," "stayed the same," "decreased

some," or "decreased a lot." For increased/decreased "a lot," we assumed a 10% change; for increased/decreased "some," we assumed a 5% change; and for "stayed the same," we assumed 0% change. These percentage changes were then applied to U.S. per capita food expenditures for the year 2000: \$1,633 for food at home, \$675 for food from fast-food restaurants, and \$755 for food from non-fast-food restaurants (APPENDIX). We estimated round-trip transportation costs to DPP appointments as \$7 per visit (8).

Table 4—Per capita direct medical costs of care outside the DPP by intervention group, years 1–3

	Placebo	Placebo costs	Metformin	Metformin costs	Lifestyle	Lifestyle costs	Metformin vs. placebo (\$)	Lifestyle vs. placebo (\$)
Hospital days	0.81	1,906	0.72	1,694	0.72	1,694	–212	–212
Emergency room visits	0.66	110	0.65	109	0.74	124	–2	13
Urgent care visits	1.38	126	1.32	120	1.21	110	–5	–15
Outpatient visits	12.94	660	13.26	676	11.63	593	16	–67
Calls to providers	10.34	207	11.16	223	10.08	202	16	–5
Prescription medications	4.92	2,002	4.71	1,917	4.55	1,856	–85	–147
Total (years 1–3)		5,011		4,739		4,579	–272	–432

Indirect costs

We estimated morbidity costs for participants as the time that participants reported as lost from school, work, or usual activities as a result of DPP visits, illness, or injury (DPP Form Q08, *Interval History Questionnaire*). Indirect mortality costs were estimated for each intervention group as the average number of participant days lost to death over 3 years (DPP Form E06, *Mortality Event Report*). Each day lost to morbidity or mortality was valued at \$108 (APPENDIX).

RESULTS

Direct Medical Costs

Identification of IGT. During DPP recruitment, 8.1 OGTTs were performed for each subject who was identified with IGT and successfully randomized. The direct medical cost of one OGTT was \$17 (APPENDIX). Thus, the direct medical cost of OGTT testing per subject randomized was \$139.

Placebo intervention

Year 1. Table 1 summarizes the per capita direct medical costs of the placebo intervention by year. At the first visit, the medication case manager (MCM) spent 30 min (0.50 h) with each participant reviewing the importance of a healthy lifestyle for the prevention of type 2 diabetes and for the prevention and treatment of cardiovascular risk factors and cardiovascular disease. At the first visit, 100% of participants received the publication *On Your Way to Fitness* (Shape Up America!, 1995) and 75% received the publication *Dietary Guidelines for Americans* (USDA, 1995). At the 3-month follow-up visit, the MCM spent 15 min with each participant reviewing the materials and answering questions. In addition, 12% of the participants met with the dietitian for an aver-

age of 38 min. During the first year, 10% of the participants called the MCM for counseling for 10 min. Visit reminders were performed by telephone. Each call took 5 min for a secretary. In year 1, the direct medical cost of the placebo intervention was \$43 per subject.

Years 2 and 3. In years 2 and 3, the MCM spent 20 min with each participant reviewing the information on healthy lifestyle (Table 1). Each year, 10% of the participants called the MCM for counseling. Visit reminders were performed by telephone. In years 2 and 3, the direct medical cost of the placebo intervention was \$18 per subject per year.

Metformin intervention

Year 1. Table 2 summarizes the per capita direct medical costs of the metformin intervention by year. The costs of the intervention included the resources used for standard lifestyle recommendations, for baseline evaluation to determine the appropriateness of metformin therapy, for educational materials describing the medication, for the medication, for drug safety monitoring, for baseline and follow-up adherence counseling, and for dose-titration and restart visits. At baseline, all participants receiving metformin had a brief history and physical exam and laboratory testing, including serum creatinine and hemoglobin and hematocrit and erythrocyte indices. For patients ≥ 80 years of age (0.3%), monitoring also included measurement of creatinine clearance. Each subject received a one-page handout describing metformin. At the end of year 1, 9% of metformin subjects were prescribed zero tablets, 15% one tablet, and 76% two tablets per day. During the first year, each subject made an average of 3.46 follow-up visits focused on counseling compliance and drug safety monitoring. At each such visit,

100% of participants saw a MCM for 20 min, and 62% saw a medical assistant for 20 min. During the first year, each participant had an average of 1.39 dose-titration and restart visits with the MCM. Each visit lasted 20 min. For 25% of participants, the MCM made three outbound calls (10 min per call). For 30% of participants, the MCM received two inbound calls (10 min per call). Visit reminders were performed by telephone for each baseline, follow-up, dose-titration, and restart visit. Each call took 5 min for a secretary. During year 1, metformin subjects also received resources from the metformin toolbox to promote treatment adherence. In year 1, the direct medical cost of the metformin intervention was \$1,019 per subject. The cost of metformin was \$671, or 66% of the intervention cost.

Years 2 and 3. Annual drug safety monitoring for patients prescribed metformin (84% of metformin subjects during year 2 and 80% during year 3) included serum creatinine and hemoglobin and hematocrit and erythrocyte indices. For patients ≥ 80 years of age (0.4%), monitoring also included measurement of creatinine clearance. At the end of year 2, 16% of participants were prescribed zero tablets, 14% one tablet, and 70% two tablets. At the end of year 3, 20% were prescribed zero tablets, 12% one tablet, and 68% two tablets. In years 2 and 3, each subject made an average of 3.97 visits per year focused on compliance counseling and drug safety monitoring. At each such visit, all participants saw a MCM and some participants saw the medical assistant (Table 2). In years 2 and 3, each participant had an average of 0.07 dose-titration and restart visits per year with the MCM. For 25% of participants, the MCM made three

Table 5—Per capita direct nonmedical costs by intervention group, years 1–3

	Placebo	Placebo costs (\$)	Metformin	Metformin costs (\$)	Lifestyle	Lifestyle costs (\$)	Metformin vs. placebo (\$)	Lifestyle vs. placebo (\$)
Participant time								
Visits	24.17 h	193	39.62 h	317	135.67 h	1,085	124	892
Adjusted exercise*	163.35 h	728	164.83 h	731	150.80 h	704	3	–24
Shopping and cooking	1120.58 h	4,482	1075.74 h	4,303	1062.78 h	4,251	–179	–231
Total		5,404		5,350		6,040	–52	637
Services								
Exercise classes	16%	207	14%	181	21%	272	–25	65
Health club	19%	219	19%	218	27%	311	–1	92
Personal trainer	4%	7	4%	7	5%	8	0	2
Commercial weight loss classes	12%	99	13%	107	6%	50	8	–49
Total		532		514		642	–18	110
Fitness equipment								
Bicycle†	13%	28	11%	24	17%	37	–4	9
Exercise videos	29%	4	25%	4	37%	6	0	1
Free weights	24%	9	21%	8	35%	14	–1	4
Golf clubs†	5%	10	4%	8	5%	10	–2	0
Home gym†	5%	17	4%	14	5%	17	–3	0
Stationary bicycle†	10%	28	10%	27	13%	36	0	8
Step	4%	3	4%	3	7%	5	0	2
Treadmill†	12%	66	11%	61	18%	99	–5	33
Total		165		148		223	–17	58
Food equipment								
Air popper	7%	2	4%	1	9%	2	–1	1
Blender	21%	8	21%	8	21%	8	0	0
Cookbooks	42%	11	42%	11	51%	13	0	2
Food scale	11%	3	12%	3	26%	6	0	4
Freezer†	7%	16	7%	16	7%	16	0	0
Microwave†	15%	12	15%	12	15%	12	0	0
Mixer†	11%	7	10%	7	8%	5	–1	–2
Steamer	14%	4	15%	5	21%	7	0	2
Wok†	8%	8	8%	8	10%	10	0	2
Total		71		70		79	–1	9
Shoes	3 pairs	220	3 pairs	220	6 pairs	439	0	220
Food costs								
Food at home		4,995		4,987		5,002	–7	7
Food away from home		4,229		4,239		4,150	10	–79
Total		9,223		9,226		9,152	3	–71
Transportation costs	224.4 miles	79	440.6 miles	154	1606.2 miles	562	76	484
Grand total		15,692		15,683		17,137	–9	1,445

*Leisure-time physical activity was valued according to whether participants “disliked,” were “neutral,” or “liked” leisure-time physical activity. †We assumed that durable equipment initially valued at >\$100 (see APPENDIX) retained 50% of its original purchase price after 3 years. Percent value stated in rounded numbers.

outbound calls. From 30% of participants, the MCM received two inbound calls. Visit reminders were performed by telephone for each follow-up, dose titration, and restart visit. In years 2 and 3, metformin subjects again received re-

sources from the metformin toolbox. The direct medical cost of the metformin intervention was \$772 per subject in year 2 and \$751 per subject in year 3. The cost of metformin was \$618 in year 2 and \$595 in year 3, accounting for 80 and 75% of

the cost of the metformin intervention in years 2 and 3, respectively.

Lifestyle intervention

Year 1. Table 3 summarizes the per capita direct medical costs of the lifestyle intervention by year. Each participant had a

Table 6—Indirect costs by intervention group, years 1–3

	Placebo (days)	Placebo costs (\$)	Metformin (days)	Metformin costs (\$)	Lifestyle (days)	Lifestyle costs (\$)	Metformin vs. placebo (\$)	Lifestyle vs. placebo (\$)
Morbidity	21.31	2,301	23.31	2,517	21.23	2,293	216	–1
Mortality	2.80	302	2.93	316	1.27	137	14	–165
Total		2,604		2,834		2,430	230	–174

baseline evaluation and 19% of subjects had exercise stress tests. The costs of treatments administered as a result of these evaluations were captured as adverse events. Each participant completed the 16-session core curriculum. Each session lasted 1 h and was taught by a lifestyle case manager (LCM). In addition, the participants received 118 pages of health education materials. Each clinic offered supervised activity sessions. In year 1, each lifestyle participant attended an average of 7.04 such sessions. On average, 1.65 participants attended each supervised activity session. Thus, 4.27 (7.04/1.65) sessions were held for each lifestyle participant in year 1. Each session was conducted by a LCM 60% of the time and by an exercise trainer 40% of the time. Each exercise session lasted 60 min. After the core curriculum was completed, each clinic offered lifestyle group sessions. In year 1, each lifestyle participant attended an average of 1.89 such sessions. On average, 5.23 participants attended each lifestyle group session. Thus, 0.36 (1.89/5.23) sessions were held for each lifestyle participant in year 1. All lifestyle group sessions were conducted by a LCM. Each session lasted 75 min. After the core curriculum was completed, subjects also made 7.65 in-person contacts with the LCM. Each contact lasted 35 min. During year 1, subjects also talked on the telephone an average of 2.32 times with the lifestyle case manager. Each call lasted 15 min. Visit reminders were performed by telephone. Each call took 5 min for a secretary. During year 1, lifestyle subjects also received resources from the lifestyle toolbox to promote treatment adherence. In year 1, the direct medical cost of the intensive lifestyle intervention was \$1,399 per subject. The cost of DPP staff time was \$750, or 54% of the direct medical cost of the lifestyle intervention.

Years 2 and 3. During years 2 and 3, the cost of maintenance of the lifestyle inter-

vention included the costs associated with supervised activity sessions, lifestyle group sessions, in-person visits, telephone calls, and reminder calls. In years 2 and 3, each participant attended an average of 7.04 supervised activity sessions per year. On average, 1.65 participants attended each supervised activity session. Thus, 4.27 (7.04/1.65) sessions were held each year for each lifestyle participant. These were performed 60% of the time by an LCM and 40% of the time by an exercise trainer (Table 3). Each clinic also offered lifestyle group sessions. In years 2 and 3, each participant attended an average of 3.77 such sessions per year. On average, 5.23 participants attended each lifestyle group session. Thus, 0.72 (3.77/5.23) sessions were held each year for each lifestyle participant. Essentially all lifestyle group sessions were conducted by a LCM. Each participant visited an LCM an average of 12.33 times per year. During years 2 and 3, each subject talked with the LCM on the telephone an average of 2.66 times per year. Visit reminders for supervised activity sessions, lifestyle group sessions, and in-person visits were performed by telephone. In years 2 and 3, lifestyle subjects again received resources from the lifestyle toolbox. In years 2 and 3, the direct medical cost of the intensive lifestyle intervention was \$679 and \$702 per subject, respectively. The cost of DPP staff time was \$339 per year, or 50% of the direct medical cost of the lifestyle intervention in year 2 and 48% of the direct medical cost of the lifestyle intervention in year 3.

Summary of intervention costs. Both the metformin and lifestyle interventions were more expensive than the placebo intervention. Both the metformin and lifestyle interventions were more expensive in year 1 (\$1,019 and \$1,399) than in year 2 (\$772 and \$679) or 3 (\$751 and \$702). The lifestyle intervention was

more expensive in year 1 than the metformin intervention. In years 2 and 3, the metformin intervention was more expensive than the lifestyle intervention. Over 3 years, including the cost of identifying persons with IGT, the direct medical cost of the placebo intervention was \$218 per participant, the direct medical cost of the metformin intervention was \$2,681 per participant, and the direct medical cost of the lifestyle intervention was \$2,919 per participant.

Care outside the DPP. There were no statistically significant differences in the incidence of serious adverse events or adverse events among the three intervention groups. To estimate the costs of either side effects associated with participation in the DPP interventions or improved health, we assessed the mean per capita number and cost of hospital days, emergency room visits, urgent care visits, outpatient visits, calls to providers, and prescription medications over 3 years within each intervention group and the per capita differences in costs over 3 years among the intervention groups (Table 4).

Reported resource utilization was lowest in five of six categories among the lifestyle participants. In four of six categories, resource utilization was lower in the metformin group than in the placebo group. Over 3 years, the per capita direct medical costs of care outside the DPP were \$5,011 in the placebo group, \$4,739 in the metformin group, and \$4,579 in the lifestyle group. Per capita direct medical costs of care outside the DPP were \$272 less for the metformin group compared with the placebo group and \$432 less for the lifestyle group compared with the placebo group. These cost savings indicate that metformin and lifestyle subjects used fewer medical resources outside the DPP than subjects randomized to the placebo intervention.

Direct nonmedical costs

Participants randomized to the three intervention groups reported that they spent different amounts of time attending appointments, traveling to and from appointments, exercising, shopping, and cooking and that they received different levels of enjoyment from leisure-time physical activity. They also reported different out-of-pocket purchases of services and products related to physical activity and diet, different expenditures for food, and different transportation costs. Table 5 summarizes these per capita direct non-medical costs over 3 years.

Because metformin and lifestyle participants made more visits than placebo participants, they spent more time traveling to and from appointments and attending appointments. Although lifestyle participants reported spending substantially more time in leisure-time physical activities, they were more likely to report that they enjoyed the activities than were metformin or placebo participants. Indeed, 76% of lifestyle participants and only 63% of metformin and 65% of placebo participants reported that they enjoyed their leisure-time physical activities. Twenty percent of lifestyle, 33% of metformin, and 31% of placebo participants were neutral toward their leisure-time physical activities and 4% of each group disliked them. As a result, the cost of the time spent exercising (shown in Table 5 as adjusted exercise) was quite similar among the three intervention groups. When the cost of leisure-time physical activity was changed to \$0 per hour, \$8 per hour, and \$16 per hour regardless of participants' exercise preferences, the costs in the lifestyle group were \$0, \$5,027, and \$10,054; costs in the metformin group were \$0, \$3,564, and \$7,128; and costs in the placebo group were \$0, \$3,734, and \$7,467, respectively. Both metformin and lifestyle participants reported spending less time shopping and cooking than placebo participants. In general, lifestyle participants purchased more services and products related to physical activity and diet than did placebo participants. Interestingly, lifestyle participants reported that their food costs were slightly lower than those of placebo participants, because of the lower costs of food consumed away from home. Metformin participants purchased the same or slightly fewer services and products related to diet and physical activity

Table 7—Per capita differences in costs of the metformin and lifestyle interventions relative to the placebo intervention (year 2000, U.S. dollars) over 3 years in DPP

	Metformin vs. placebo (\$)	Lifestyle vs. placebo (\$)
Direct medical costs		
Intervention	2,463	2,701
Care outside DPP	−272	−432
Total	2,191	2,269
Direct nonmedical costs	−9	1,445
Indirect costs	230	−174
Total cost		
Health system perspective	2,191	2,269
Societal perspective	2,412	3,540

than the placebo participants, and they had similar food costs. Over 3 years, per capita direct nonmedical costs were \$9 less for metformin participants and \$1,445 greater for lifestyle participants compared with placebo participants.

Indirect costs

Participants in the three intervention groups reported small differences in time lost from school, work, or usual activities as a result of DPP visits, illness, or injury. In general, subjects in the placebo and metformin groups reported more time lost than subjects in the lifestyle group. There were also small differences in survival among the intervention groups. Over the first 3 years of the DPP, there were 3 deaths (1.023 deaths/1,000 person-years) in the lifestyle intervention group, 6 deaths (2.029 deaths/1,000 person-years) in the metformin intervention group, and 5 deaths (1.689 deaths/1,000 person-years) in the placebo intervention group. Days lost from school, work, or usual activities as a result of death were fewest in the lifestyle group. Table 6 summarizes these per capita indirect costs over 3 years. Over 3 years, indirect costs were \$230 greater for metformin participants and \$174 less for lifestyle participants than for placebo participants.

CONCLUSIONS — In the DPP, both the metformin and lifestyle interventions were more expensive than the placebo intervention. In the metformin intervention, most of the additional cost relative to the placebo intervention was accounted for by the cost of metformin. In the life-

style intervention, most of the additional cost relative to the placebo intervention was accounted for by staff time used for counseling and adherence monitoring. Although the lifestyle intervention cost ~37% more than the metformin intervention in year 1, the lifestyle intervention cost 12 and 7% less than the metformin intervention in years 2 and 3. Because the cost of the lifestyle intervention was greater than the cost of the metformin intervention in year 1 but less in subsequent years, the cost of the lifestyle intervention relative to the metformin intervention would decrease with follow-up beyond 3 years. To the extent that the cost of the metformin intervention can be reduced by using less expensive generic metformin and to the extent that the lifestyle intervention can be delivered with less staff time, the cost of the interventions could be substantially reduced.

The cost of identifying IGT and the cost of the interventions represented less than one-half of total direct medical costs for DPP participants over 3 years (\$2,919/\$7,375 = 40% in the lifestyle, and \$2,681/\$7,420 = 36% in the metformin group). Direct medical costs also included the costs of medical care obtained outside the DPP. The latter was influenced by both adverse health events and improvements in health related to participation in the clinical trial. There were no statistically significant differences in the incidence of serious adverse events or adverse events among the three intervention groups in the DPP. To estimate the costs of both adverse events and improved health associated with participation in the

DPP interventions, we assessed hospital days, emergency room visits, urgent care visits, outpatient visits, calls to providers, and prescription medications and their differences among the intervention groups. Participation in the experimental interventions was associated with decreased direct medical costs of the care outside the DPP. Compared with the placebo intervention group, participants randomized to the metformin intervention group spent fewer days in the hospital, made fewer emergency room and urgent care visits, and took fewer prescription medications. Compared with participants in the placebo intervention group, participants in the lifestyle intervention spent fewer days in the hospital and were less likely to make urgent care visits, outpatient visits, and calls to providers. In addition, they reported taking fewer prescription medications. Taken together over 3 years, this reduced health care utilization and decreased the direct medical costs of care outside the DPP by \$272 in the metformin intervention group and \$423 in the lifestyle intervention group relative to the placebo intervention group. These cost savings offset a portion of the direct medical cost of the experimental interventions.

Although not generally paid by health systems, direct nonmedical costs affect the individual and society. To fully assess the impact of direct nonmedical costs, we went to great lengths to describe the resources used and to estimate their costs. Not surprisingly, participants in the lifestyle intervention group spent more time traveling to appointments, attending appointments, and exercising, and they purchased more services and products related to physical activity and diet. While the lifestyle group spent substantially more time engaged in leisure time physical activity than either metformin or placebo participants, they reported greater enjoyment of these activities. Thus, the resulting direct nonmedical cost was negligible. Both metformin and lifestyle participants reported spending less time shopping and cooking than placebo participants. Lifestyle participants also reported lower food costs than metformin and placebo participants—largely as a result of decreased cost of food consumed at restaurants. Because of more frequent DPP visits, participation in the lifestyle intervention was associated with substantially greater transportation costs.

Compared to the placebo intervention group, the incremental direct nonmedical cost was \$1,445 over 3 years. Over 60% of this incremental cost was related to greater participant time. In contrast, direct nonmedical costs were \$9 less in the metformin intervention group than in the placebo intervention group.

When leisure-time physical activity was valued independently of the participants' exercise preference at \$0, \$8, or \$16 per hour, the incremental direct nonmedical cost of the lifestyle intervention compared with the placebo intervention increased substantially and ranged from \$1,469 to \$4,056 over 3 years. In contrast, direct nonmedical costs decreased in the metformin intervention group compared with the placebo intervention group ($-\$12$ – $-\$352$). Thus, the cost of the lifestyle intervention relative to the placebo intervention is sensitive to the value assigned to time spent exercising. We believe that the base analysis that reflects participants' exercise preferences is most reasonable, because individuals who enjoy exercise willingly spend their leisure time and personal resources for exercise.

Despite the greater frequency of lifestyle visits, the difference in indirect costs among intervention groups was small. The latter may reflect flexible scheduling arrangements that permit people to reduce time lost from work or usual activities. Compared with the placebo group, the indirect costs related to morbidity and mortality were lower in the lifestyle group but higher in the metformin group. Thus, compared with the placebo group, indirect costs were \$174 less in the lifestyle group and \$230 greater in the metformin group over 3 years.

Table 7 summarizes the per capita costs of the metformin and lifestyle interventions relative to the placebo intervention over 3 years. From the perspective of a large health system, which would pay only direct medical costs, the cost of the metformin intervention relative to the placebo intervention was \$2,191 over 3 years. From the perspective of society, which pays direct medical costs, direct nonmedical costs, and indirect costs, the per capita cost of the metformin intervention relative to the placebo intervention was \$2,412 over 3 years. The per capita costs of the lifestyle intervention relative to the placebo intervention were \$2,269 and \$3,540 over 3 years from the perspec-

tive of a large health system and society, respectively.

The DPP demonstrated that both medication and lifestyle interventions can delay or prevent progression from IGT to type 2 diabetes (1). This analysis demonstrates that such preventive strategies are associated with modest incremental costs. From the perspective of a large health system, both the metformin and lifestyle interventions cost \sim \$750 per participant per year, or \$2,250 per participant over 3 years. From a societal perspective, the incremental costs of both the metformin and lifestyle intervention are greater and the relative increase is greater in the lifestyle than the metformin intervention. This is not surprising in light of the greater direct nonmedical costs associated with the lifestyle intervention. Nevertheless, the incremental increases remain small. The costs of such prevention strategies must be balanced against the savings related to averted disease. It is likely that the cost of the metformin intervention will decrease substantially with the availability of less expensive generic formulations of metformin. It is also likely that the cost of the lifestyle intervention could be reduced by improving the efficiency of utilization of staff time by using group visits. Ultimate determination of the value of these interventions to health systems and society will require a formal assessment of costs relative to the health benefits achieved in the DPP.

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APPENDIX

Table A1—Unit costs used for calculating costs of DPP by type of cost

Items	Unit	Cost (median/mean, \$)	Sources
Direct medical costs			
DPP personnel			
LCM	1 h	23.55	DPP
MCM	1 h	25.24	DPP
Exercise trainer	1 h	26.02	DPP
Dietitian	1 h	26.21	DPP
Medical assistant	1 h	18.14	DPP
Secretary	1 h	19.54	DPP
Materials			
Educational and training material			
Lifestyle	1 set	8.85	DPP
Metformin	1 set	0.08	DPP
Placebo	1 set	2.26	DPP
Lab tests and procedures			
OGTT	1	17.22	9
Exercise tests (CVD stress)	1	114.00	9
Venipuncture	1	3.00	9
Serum creatinine	1	6.84	9
Urine creatinine	1	6.92	9
Hemoglobin/hematocrit	1	7.91	9
Medication			
Metformin	1 tablet	1.10	10
Prescription medications	1 year/person	407.00	11
Bundled medical services			
Hospital days*	1	2,353.00	12,13
Emergency room visits†	1	167.00	13
Urgent care visits	1	91.00	13
Outpatient visits	1	51.00	13
Calls to providers	1	20.00	13
Direct nonmedical costs			
Participant time			
Travel time	1 h	8.00	14
People who dislike exercise	1 h	8.00	14
People who are neutral about exercise	1 h	4.00	14
Shopping and cooking	1 h	4.00	14
Services			
Exercise classes	1 week	16.60	15
Health club	3 years	2,305.00	16
Personal trainer	1 h	34.00	17
Commercial weight loss classes	1 month	46.00	16
Fitness equipment			
Exercise shoes	1 pair	73.27	16
Bicycle	1	430.40	16
Exercise videos	1	15.02	16
Free weights	2	39.06	18
Golf clubs	1 set	390.61	18
Home gym	1	683.57	16
Stationary bicycle	1	548.80	16
Step	1 system	78.12	18
Treadmill	1	1,100.00	16
Food equipment			
Air popper	1	25.39	19
Blender	1	39.70	16
Cookbooks	1	25.39	20
Food scale	1	24.41	21
Freezer	1	449.54	16
Microwave	1	155.04	16
Mixer	1	132.46	16
Steamer	1	31.01	16
Wok	1 set	206.10	16
Food costs			
Food at home	1 year	1,633.00	22
Food away from home	1 year	1,430.00	22
Transportation costs	1 mile	0.35	23
Indirect costs			
Time lost from doing usual activity due to morbidity or mortality	1 day	108.00	14

*Cost of a hospital day based on facility charge of \$2,242 (Health Care Utilization Project) and a physician fee of \$111. †Cost of an emergency room visit based on the facility charge of \$102 (Health Care Financing Administration, personal communication with Mr. Jerry Riley) and a physician fee of \$51 (HealthCare Consultants of America). LCM, Lifestyle Case Manager; MCM, Medication Case Manager.

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