




# Budget Impact of Funding an Intensive Diet and Exercise Program for Overweight and Obese Patients With Knee Osteoarthritis

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**Objective.** Diet and exercise (D+E) for knee osteoarthritis (OA) is effective and cost-effective. However, cost-effectiveness does not imply affordability; the impact of knee OA-specific D+E programs on insurer budgets is unknown.

**Methods.** We estimated changes in undiscounted medical expenditures (2016 US dollars) with and without a D+E program. We accounted for both additional program outlays and potential savings from reduced use of other knee OA treatments and from reduced incidence of comorbidities. We adopted the perspective of a representative commercial insurance plan covering 200 000 individuals aged 25 to 64 years and a representative Medicare Advantage plan covering 200 000 Medicare-eligible individuals aged 65 years and older. We used the Osteoarthritis Policy Model, a validated microsimulation model of knee OA, to model D+E efficacy (measured by pain and weight reduction), adherence, and price based on the Intensive Diet and Exercise for Arthritis (IDEA) trial. In sensitivity analyses, we varied time horizon, D+E efficacy, and D+E price.

**Results.** Over 3 years, the D+E program increased spending by \$752 200 (\$0.10 per member per month [PMPM]) in the commercial plan and by \$6.0 million (\$0.84 PMPM) in the Medicare plan. Over 3 years, the D+E program reduced opioid use by 6% and 5% and reduced total knee replacements by 5% and 4% in the commercial and Medicare plans, respectively. Expenses were higher in the Medicare plan because it had more patients with knee OA than the commercial plan.

**Conclusion.** Although there is no established threshold to define affordability, a D+E program for knee OA would likely produce expenditures comparable with outlays for other health-promotion interventions.

## INTRODUCTION

Knee osteoarthritis (OA) is a chronic and painful disease that affects more than 14 million US adults (1). Knee OA also poses a significant economic burden to society: average per-person, life-time direct medical expenditures for OA patient care are \$129 600 (2013 US dollars [USD]), with 10% attributable to knee OA (2). Current knee OA treatment options have limitations. Nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids provide pain relief, but NSAIDs are accompanied by cardiovascular and gastrointestinal adverse events (3–5), and opioids carry the risk of both

adverse events and addiction (6,7). Although total knee replacement (TKR) is a highly effective surgery (8), it is limited to treating end-stage knee OA. Patients with knee OA spend an average of 13 years with intermittent pain relief before receiving a TKR (2). There is a need to find effective, safe, and cost-effective treatments for patients in this period.

Diet and exercise (D+E) programs help to fill this gap. D+E programs have been shown to reduce knee OA pain and are recommended by OA treatment guidelines (9). The Intensive Diet and Exercise for Arthritis (IDEA) trial, a randomized controlled

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### SIGNIFICANCE & INNOVATIONS

- This article addresses the persistent inadequacy of access to diet and exercise (D+E) programs for the care of patients with knee osteoarthritis. Although D+E programs have been shown to be clinically effective and cost-effective, they are rarely covered by health insurance plans. This may be explained in part by the absence of evidence on affordability, a critical operational concern for insurers and other payers.
- Ours is the first economic evaluation to shift the focus from long-term questions of societal value and cost-effectiveness to shorter-term issues of institutional fiscal impact and cash outlays.
- By reporting results in both aggregate and per-member, per-month terms, our analysis will help payers to understand the impact of adding D+E programs to their overall cost structure and to understand how that impact compares with programs that they already cover.

trial, found that D+E reduced pain by 51% compared with 28% in an exercise-only group (10). Although the IDEA trial's D+E program is cost-effective (11), knee OA-specific D+E programs are rarely covered by health insurance plans. This may be because real-world decision-makers do not have the luxury of adopting the long-term societal perspective of cost-effectiveness analysis (CEA). The insured population for whom they are making decisions is unlikely to remain under their care over the long-term, and insurers need to prioritize solvency and profitability over longer-term considerations. They, therefore, often adopt a short-term institutional perspective in which affordability outweighs longer-term value.

Budget impact analysis (BIA), which measures affordability, aims to help decision-makers understand the likely fiscal impact of a new policy. BIA is a complement to CEA: CEA quantifies whether the outcomes a treatment provides are worth its cost, whereas BIA quantifies the financial consequences to a payer of funding the treatment (12,13). A cost-effective treatment may not be affordable if the upfront spending on the program is greater than the amount of unallocated money in a payer's budget. Likewise, a treatment that is not cost-effective may be affordable if it is inexpensive or limited to a small patient population. Together, CEA and BIA may assist in financial planning; highlight situations in which subsidies may help compensate payers, providers, or patients who bear an unequal share of the financial load; and bring individual and institutional decisions into closer alignment with social objectives.

We conducted a BIA to estimate the fiscal consequences to payers of funding the D+E program from the IDEA trial. We forecast both the increased outlays associated with paying for the D+E program as well as the potential savings resulting from reduced use of other treatments. Unlike CEA, there is no estab-

lished affordability threshold under which a treatment is considered affordable. Thus, this analysis is designed to provide payers with a framework to understand the budget effects of funding a D+E program for the patients with knee OA covered by their plans.

### METHODS

**Analytic overview.** We estimated the budget impact from the perspective of a commercial plan covering 200 000 individuals aged 25 to 64 years and a plan covering 200 000 Medicare-eligible individuals aged 65 years and older. We selected these age categories because Medicare coverage generally begins at age 65 years, and Medicare-eligible adults are generally enrolled in separate insurance plans. Based on IDEA trial eligibility criteria, we assumed that only patients with knee OA aged 55 to 84 years with a body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup> and without a prior TKR were eligible to participate in the D+E program. We did not estimate spending on plan members who did not participate in the D+E program because we assumed that their spending would remain constant and would have no effect on overall outlays.

Our analysis follows the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2012 Budget Impact Analysis Good Practice II Task Force (14). We used the Osteoarthritis Policy (OAPol) Model to estimate average annual per-person spending on knee OA treatments, with and without the D+E program. The base-case time horizon was 3 years because short-term time horizons are recommended by BIA guidelines to reflect insurance plans' short-term budgetary planning (14). In estimating resource use and treatment-specific spending, we adapted methods that were originally developed and described for prior work on the cost-effectiveness of D+E (11). We multiplied per-person spending by the number of plan members eligible and willing to participate in the D+E program to determine the total outlays incurred by the payer. Our reported outcomes were the total increase in payer spending and the per-member, per-month (PMPM) increase in spending. PMPM spending is estimated by dividing the increased outlays on D+E by the number of members in the plan, regardless of whether the members participated in the D+E program. PMPM spending is commonly used in BIA because it is easily compared with insurance premium payments. We reported spending in undiscounted 2016 USD, as recommended by BIA guidelines (14).

**OAPol Model.** The OAPol Model is a validated and widely published microsimulation model of knee OA progression and treatment (2,15–17). The OAPol Model simulates the experience of a cohort of individuals as they transition between health states that depend on knee OA structural and symptomatic severity,

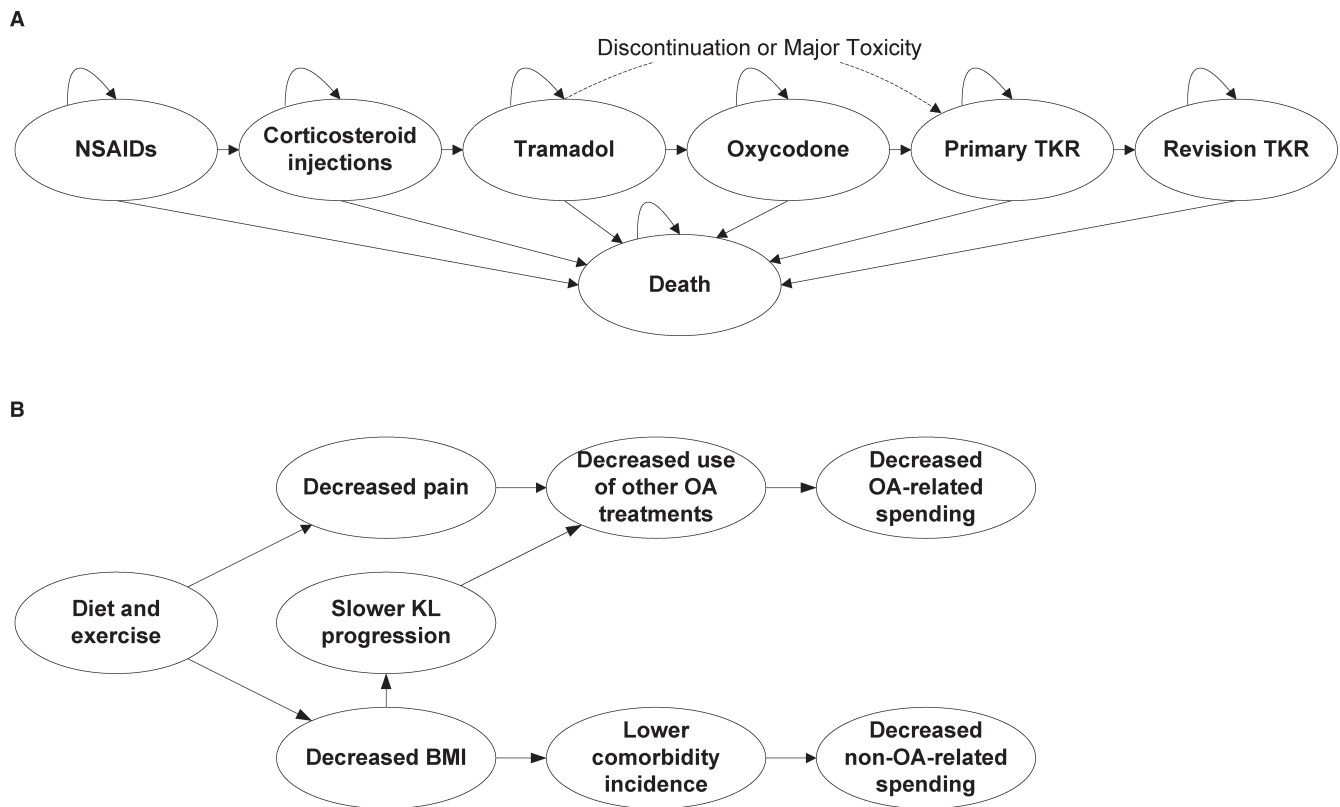
obesity, age, and comorbidities (cardiovascular disease [CVD], cancer, chronic obstructive pulmonary disease [COPD], other musculoskeletal diseases, and diabetes mellitus). Each month, the model accounts for two types of medical expenditures: direct medical spending on non-OA treatments, which depends on age and number of comorbidities, and spending on OA treatments.

Our analysis considers two treatment strategies: usual care and usual care with D+E. Usual care consists of six sequential OA treatments: 1) first-line OA treatment (NSAIDs, physical therapy, and/or assistive devices), 2) corticosteroid injections, 3) tramadol, 4) oxycodone, 5) TKR, and 6) revision TKR. When a subject ends one regimen (whether because of insufficient pain relief, adverse events, or discontinuation), the subject is then evaluated for the following regimen and, if eligible, begins that new treatment (Figure 1). The exception to this is if a subject discontinues from tramadol because of an adverse event. In that case, the subject progresses to TKR and does not use oxycodone. Four strategies (first-line OA treatment, injections, TKR, and revision TKR) represent guideline-concordant care (9,18). Tramadol and oxycodone are included to accurately represent clinical practice (19).

D+E occurs in tandem with the usual-care treatments and can alter treatment use if it lowers a subject's pain such that they are no longer eligible for one of the other treatments. D+E is based on the D+E program in the IDEA trial (10). The program included meal replacements, weekly or biweekly nutrition classes, and 3 h/wk of aerobic exercise and strength training.

**Model inputs. Cohort characteristics.** Table 1 presents the characteristics of the cohort considered for the analysis. The starting BMI distribution was derived from the National Health and Nutrition Examination Survey (NHANES) 2007-2008 cohort of individuals aged 50 years and older who had a BMI greater than 30 kg/m<sup>2</sup> (20). The mean (SD) BMI was 35.3 (4.8) kg/m<sup>2</sup>. At any given point in time, patients with knee OA in an insurance plan population may be receiving different treatments. We modeled this by assigning a probability, stratified by age, that a subject would be considered for a given treatment at the start of the simulation. Appendix Tables 1–8 include additional cohort and treatment parameters.

The OAPol Model also accounts for the impact of reduced BMI on non-OA-related conditions, including CVD, cancer,



**Figure 1.** **A**, Osteoarthritis Policy Model treatments. This figure shows the usual-care treatment options and the order of their progression. Arrows indicate possible state transitions; model subjects can either remain in the same state for multiple model cycles or transition to a new state. All subjects are assigned a probability (stratified by age) of starting on each treatment after model initialization. Once a subject fails a treatment, they progress to the next treatment in the sequence. Subjects who discontinue tramadol because of an adverse event do not use oxycodone and progress directly to consideration for total knee replacement. **B**, Effect of diet and exercise (D+E) program on model parameters. This figure illustrates the pathways through which the D+E program changes other model parameters. BMI, body mass index; KL, Kellgren-Lawrence; NSAID, nonsteroidal anti-inflammatory drug; TKR, total knee replacement; OA, osteoarthritis.

**Table 1.** Cohort Characteristics

		Monthly Non-OA Medical Expenditures, \$					
Age, y	Female Sex, %	0-1 Comorbidity	2-3 Comorbidities	4-5 Comorbidities	Source		
55-59	61	270	670	1120	% female sex (39); expenditure (21,24,40–43)		
60-64	55	320	730	1180	...		
65-69	59	350	760	1180	...		
70-74	64	410	810	1240	...		
75-79	62	470	880	1310	...		
80-84	65	620	1030	1460	...		
		Subjects Under Consideration for Treatment at Start, %					
Age, y	KL Grade 2/3/4, %	First-line OA Treatment	Corticosteroid Injections	Tramadol	Oxycodone	TKR	Source
55-59	54/37/9	29	19	9	7	36	OAPol analyses
60-64	54/37/9	29	20	10	7	35	...
65-69	49/41/10	22	20	10	8	39	...
70-74	43/44/13	18	18	10	9	46	...
75-79	40/45/15	16	15	9	8	51	...
80-84	40/44/16	15	14	9	8	53	...

Abbreviation: KL, Kellgren-Lawrence; OA, osteoarthritis; OAPol, Osteoarthritis Policy; TKR, total knee replacement.

COPD, other musculoskeletal diseases, and diabetes mellitus. The prevalence and incidence of each comorbidity are derived from the 2011-2013 NHANES (21). Prevalence and incidence of these comorbid conditions are stratified by BMI (Appendix Tables 9-19); if the D+E intervention reduces BMI, the incidence of comorbidities will decrease. Because non-OA medical spending in the model depends on a subject's number of comorbidities, the non-OA-related economic benefits of the D+E intervention are taken into account (Table 1).

*Knee OA pain and treatment efficacy.* The OAPol Model measures knee OA severity by Kellgren-Lawrence (KL) grade (2 = early, 3 = moderate, and 4 = advanced) (22), stratified by age. KL grade distribution (Table 1) and OA progression rates (Appendix Table 1) are detailed in prior publications (15,17).

The OAPol Model measures knee OA pain with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale, which ranges from 0 to 100, with 100 being

the most severe pain (23). Subjects developing OA are initially assigned a pain severity value, which is influenced by their age, sex, BMI, KL grade, and comorbidities. A probability distribution around that value defines the degree to which pain severity can increase or decrease in subsequent months.

Each OA treatment is associated with a reduction in pain severity that depends on the subject's starting pain. Subjects face a monthly risk of treatment failure and a return to pretreatment pain levels. If treatment failure occurs, subjects progress to the next regimen on the treatment pathway.

Treatments also carry a probability that subjects will experience adverse events. Adverse events are distinguished from one another in terms of both their resulting expenditures and whether they result in discontinuation of treatment and progression to the next stage in the treatment pathway. A detailed description of treatment eligibility, efficacy, and adverse events is included in Sections 1 and 2 of the Appendix.

**Table 2.** OA Treatment Expenditures

	Treatment Expenditures, \$	Office Visit Expenditures, \$	Probability of Office Visit, %	Source
<b>First Month/Subsequent Months</b>				
First-line OA treatment	56/56	258/138	100/8	See Appendix
Corticosteroid injections	35/35	114/114	100/8	...
Tramadol	49/49	114/114	100/15	...
Oxycodone	37/37	114/114	100/39	...
Primary TKR	17 976/0	0/164	100/5	...
Revision TKR	24 985/0	0/164	100/5	...
<b>First Year/Subsequent Years</b>				
Diet and Exercise				See Appendix
Meal replacements	455/0	N/A	N/A	...
Exercise classes	323/292	N/A	N/A	...
Diet classes	102/80	N/A	N/A	...

Abbreviation: OA, osteoarthritis; N/A, not applicable; TKR, total knee replacement.

**Expenditures.** Each OA treatment is associated with start-up treatment expenditures (incurred on a one-time basis during treatment initiation) and ongoing treatment expenditures (incurred monthly for the duration of treatment) (Table 2). In addition, subjects face a monthly probability of a physician visit and its attendant cost. The monthly probability of a physician office visit depends on the treatment the subject uses: for first-line OA treatments and corticosteroid injections, we assumed an average of one visit per year; for tramadol, we assumed an average of two visits per year; and for oxycodone, we assumed an average of six visits per year. Full derivations for treatment-related spending are in Section 3 of the Appendix.

The D+E program in the IDEA trial consisted of three main components: meal replacements, nutrition classes (weekly or biweekly), and exercise classes (3 h/wk) (10). Because this D+E program has not been implemented outside of a clinical trial, we estimated the cost based on a combination of trial data and assumptions (Appendix Section 3.6). We used the monthly price of a YMCA membership in North Carolina (\$42) as our estimate of the monthly cost of exercise classes. Accounting for adherence resulted in a first-year, per-person expenditure of \$323 and a subsequent-year, per-person expenditure of \$292. We assumed that each hour of a diet class would be priced at \$5 per participant. Accounting for adherence resulted in a first-year, per-person expenditure of \$102 and a subsequent-year, per-person expenditure of \$80. Meal replacements (\$455 per person) were only included in the first year because trial participants gradually transitioned away from them as the trial progressed.

We derived the average annual direct medical expenditures not related to knee OA from the Centers for Medicare and Medicaid Services (CMS) hierarchical condition categories (24). We stratified average expenditures by comorbidities by weighting the CMS estimates according to data from the 2009-2010 NHANES (20).

**Analysis.** *Population eligible for D+E program.* We assumed that the D+E program would be open to participants aged 55 to 84 years with knee OA, a BMI greater than or equal to 30 kg/m<sup>2</sup>, and no prior TKR. We did not include incident OA cases over the 5 years, and we assumed that eligible subjects who were not willing to participate in D+E at the beginning of the first year would not later participate.

We estimated the size of the population eligible for the D+E program starting with the assumption that each plan had 200 000 members. We used US Census Bureau population estimates to determine the percentage of the population aged 55 to 84 years, stratified by 5-year age groups (25). We multiplied the population aged 55 to 84 years by the prevalence of knee OA (16), the percentage of patients with knee OA with a BMI greater than or equal to 30 kg/m<sup>2</sup> (51%) (16), and the percentage of patients with knee OA who have not undergone TKR (Appendix Table 8). Based on IDEA trial results, we assumed that 64% of those eligible would be willing to participate in the D+E program (10).

*BIA.* We conducted model simulations to estimate the per-person average medical spending under usual OA care and with the D+E program added. Because treatment use differs by age, we conducted separate simulations for each 5-year age group. The OAPol Model output is the average per-person spending (or savings) on non-OA medical care and OA treatments for each 5-year age group. We then multiplied the per-person expenditures by the number of plan members in that age group and summed the expenditures to determine the payer's final spending.

*Sensitivity analyses.* We conducted extensive sensitivity analyses to assess the robustness of our results in the face of parameter uncertainty. First, we considered time horizons of 1, 2, 4, and 5 years. Second, we tested five D+E efficacy parameters at the low and high ends of their 95% confidence intervals (CIs). These parameters were 1) BMI reduction, 2) pain reduction, 3) probability of failing to maintain BMI reduction, 4) probability of failing to maintain pain reduction, and 5) discontinuation from the D+E program. Finally, we varied the price of the D+E program using values derived from the IDEA trial. In this analysis, exercise classes were priced at \$224 per person, per year, and diet classes cost an insurer \$105 per person in the first year and \$57 per person in subsequent years (Appendix Section 3.6.2).

## RESULTS

**D+E population size.** In the commercial insurance plan covering individuals aged 25 to 64 years, we estimated that 536 individuals (0.3%) would be eligible (patient with knee OA, aged 55 to 84 years, BMI greater than or equal to 30 kg/m<sup>2</sup>, and no

**Table 3.** Insurance Plan Characteristics

	Commercial Plan	Medicare Advantage Plan	Source
Members	200 000	200 000	Assumption
Members aged 55-84 y	48 954	176 177	Ref (25)
Members aged 55-84 y with knee OA	4227	39 522	Ref (16)
Members aged 55-84 y with knee OA and BMI $\geq 30$ kg/m <sup>2</sup>	1070	10 001	Ref (16)
Members aged 55-84 y with knee OA, BMI $\geq 30$ kg/m <sup>2</sup> , and no prior TKR	833	6610	OAPol analysis
Members aged 55-84 y with knee OA, BMI $\geq 30$ kg/m <sup>2</sup> , and no prior TKR and willing to participate in D+E program	536	4254	Ref (10)

Abbreviation: BMI, body mass index; D+E, diet and exercise; OA, osteoarthritis; OAPol, Osteoarthritis Policy; TKR, total knee replacement.



prior TKR) and willing to participate in the D+E program. In the Medicare Advantage plan covering individuals aged 65 years and older, we estimated that 4254 individuals (2.1%) would be eligible and willing to participate in the D+E program (Table 3). Appendix Table 20 shows the numbers of participants by age.

**BIA. Base-case analysis.** Over 3 years, the D+E program increased spending by \$752 200 for the commercial plan. Spending on usual-care subjects was \$10.2 million, and when D+E was added to usual care, spending increased to \$10.9 million (Figure 2A). This increase translates to an additional \$0.10 PMPM.

Over 3 years, the D+E program increased spending by \$6.0 million for the Medicare Advantage plan. Spending on usual-care subjects was \$117 million, and when D+E was added to usual care, spending increased to \$123 million (Figure 2B), which represents an additional \$0.84 PMPM. In the commercial and Medicare plans respectively, 13% and 12% of the cost of the D+E program was offset by a reduction in the use of other treatments.

*Sensitivity analysis: time horizon.* Table 4 shows annual spending with and without the D+E program from 1 to 5 years. Appendix Tables 21 and 22 present per-person and cumulative spending by type of expenditure.

The D+E program was most expensive in the first year because the first year included the price of meal replacements. In the first year, the D+E program increased spending by \$446 400 in the commercial plan and by \$3.5 million in the Medicare Advantage plan. In subsequent years, the D+E program increased annual spending by about \$156 000 and \$1.3 million in the commercial and Medicare Advantage plans, respectively.

Because spending on D+E was highest in the first year, extending the time horizon lowered overall PMPM expenditures. Over 1 year, the D+E program increased PMPM spending by \$0.19 in the commercial plan and by \$1.46 in the Medicare Advantage plan. Over 5 years, the D+E program increased PMPM spending by \$0.09 in the commercial plan and by \$0.74 in the Medicare Advantage plan. Appendix Table 23 shows the PMPM increase for all time horizons.

*Sensitivity analysis: D+E efficacy.* Varying D+E efficacy did not substantially impact the budget impact of the D+E program (Figure 3). In all variations, the spending increase was within 6% of the base case. Of the parameters varied, the reduction in BMI from the D+E program resulted in the largest variance in spending increase. For the commercial plan, the low end of the 95% CI resulted in a spending increase of \$791 100 (\$0.11 PMPM), and the high end of the 95% CI resulted in a spending increase of \$710 800 (\$0.10 PMPM). For the Medicare Advantage plan, the low end of the BMI reduction 95% CI resulted in a spending increase of \$6.4 million (\$0.88 PMPM), and the high end resulted in a spending increase of \$5.7 million (\$0.80 PMPM).

When all D+E efficacy parameters were varied to the optimistic end of their 95% CIs, the D+E program increased spending by \$627 300 (\$0.09 PMPM) in the commercial plan and by \$5.1 million (\$0.71 PMPM) in the Medicare Advantage plan. When all D+E efficacy parameters were varied to the pessimistic end of their 95% CIs, the D+E program increased spending by \$821 000 (\$0.11 PMPM) and by \$6.6 million (\$0.91 PMPM) in the commercial and Medicare plans, respectively.

*Sensitivity analysis: price of D+E classes.* Because the D+E program has not been implemented in clinical practice, we do not have values for insurer payments for D+E classes. The base-case analysis estimated payments based on a North Carolina YMCA membership. When we instead used price estimates derived from the IDEA trial, the increase in spending from the D+E program was 80% of the base-case estimate. For the commercial plan, funding the D+E program increased spending over 3 years by \$603 700, compared with \$752 200 in the base case. For the Medicare Advantage plan, funding the D+E program increased spending by \$4.9 million, compared with \$6.0 million in the base case.

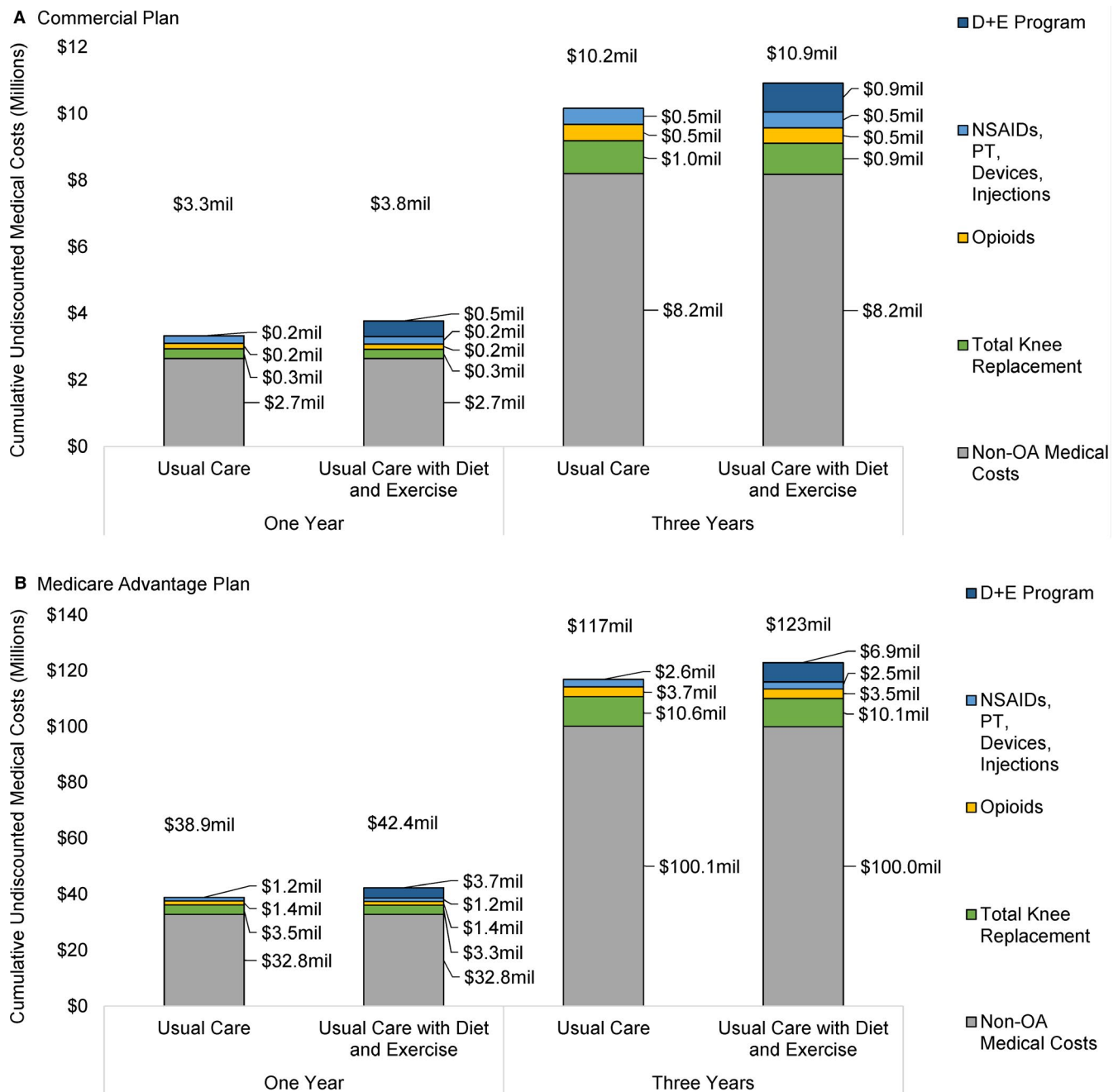
*OA treatment use.* Use of all other OA treatments decreased with the implementation of the D+E program (Figure 4). The decrease was greatest for opioids and TKR. Over 3 years, the D+E program reduced opioid use among D+E participants by 6% and 5% in the commercial and Medicare plans, respectively. Over 3 years, the program reduced TKRs among D+E participants by 5% and 4% in the commercial and Medicare plans, respectively. The percentage of members using each treatment is shown by age in Appendix Table 24.

## DISCUSSION

We estimated the increase in spending if insurers were to fund a D+E program for patients with knee OA. We found that for a typical commercial plan covering 200 000 individuals aged 25 to 64 years, implementing a D+E program for knee OA would require an additional \$0.8 million over 3 years (\$0.10 PMPM). For a Medicare Advantage plan covering 200 000 individuals aged 65 years and over, this would require an additional \$6.0 million (\$0.84 PMPM).

Other cost studies have shown that medical spending is lower for participants in physical activity programs (26–30). For example, Medicare Advantage members taking group classes as part of the SilverSneakers fitness program averaged \$2144 less in medical expenditures than nonparticipants over a 1-year period (26). However, few studies have compared the savings from reduced medical expenses with the additional outlays required to fund the exercise program. By providing estimates of both the cost of the D+E program and the concomitant reductions in other medical spending, our study contributes information on affordability to the literature.

One recent study did include affordability estimates for a Medicare YMCA diabetes prevention program that included weight loss and physical activity. Compared with a comparison



**Figure 2.** Average annual spending with and without the diet and exercise (D+E) program. **A.** Commercial plan. **B.** Medicare Advantage plan. This figure illustrates total spending over 1 or 3 years with usual care and with the D+E program added. Appendix Table 22 contains the cost estimates shown in the figure. Costs are reported in millions (mil) of undiscounted 2016 US dollars. NSAID, nonsteroidal anti-inflammatory drug; OA, osteoarthritis; PT, physical therapy.

group, participants in the program reduced medical spending by an average of \$278 per quarter over 3 years. This was greater than the proposed cost of the program to Medicare (29). In contrast, our findings suggest that implementing the D+E program would increase insurer spending. This may be due to differences in medical spending between patients with diabetes mellitus and patients with knee OA. In addition, the proposed reimbursements for the YMCA program (\$450 in year 1, \$180 years 2 and up) are lower than the estimated price of our knee OA D+E program.

Our knee OA spending estimates are comparable with those previously published. We found that the average annual spending on a patient with knee OA with a BMI greater than or equal to 30 kg/m<sup>2</sup>, without D+E, was \$6200 in the commercial plan and \$9100 in the Medicare Advantage plan. This is similar to estimates from Kotlarz et al (31) that suggest that annual spending on a patient with OA is \$9360 (inflated to 2016 USD). In our analysis, annual knee OA-attributable spending (without D+E) ranged from \$1300 (ages 55-59 years) to \$1600 (ages 80-84 years). In contrast, Mur-

**Table 4.** Average annual spending with and without the D+E program

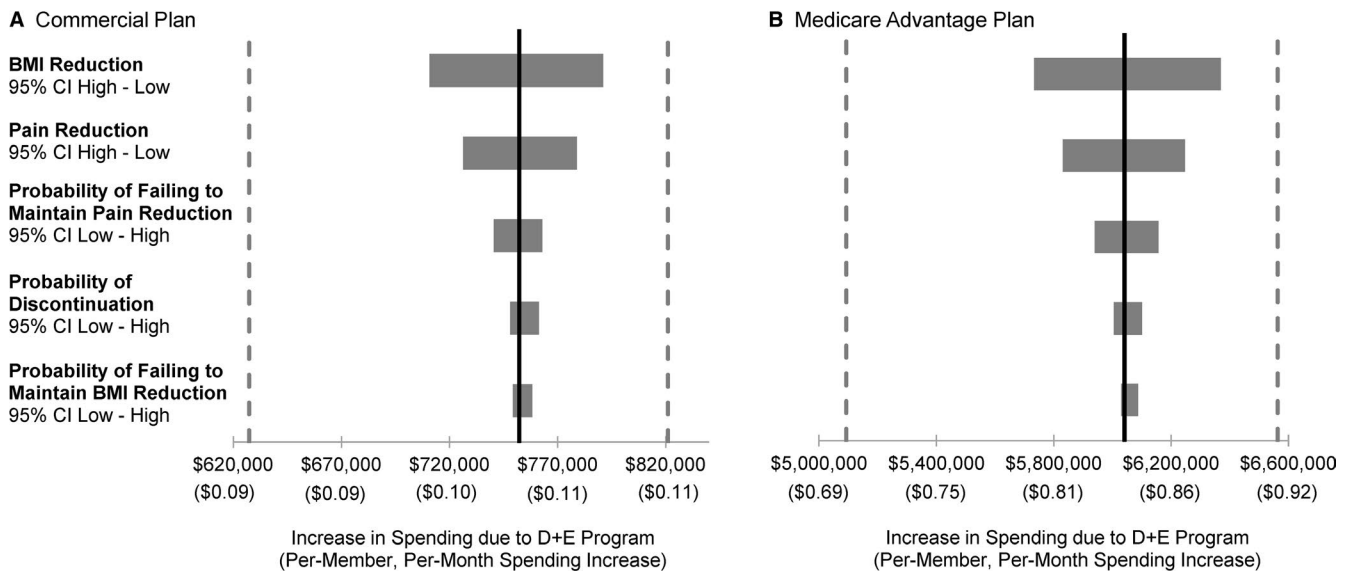
Year	Per Year			Cumulative		
	Usual Care	Usual Care With D+E	Budget Impact	Usual Care	Usual Care With D+E	Budget Impact
<b>Commercial Plan</b>						
1	\$3 331 800	\$3 778 200	\$446 400	\$3 331 800	\$3 778 200	\$446 400
2	\$3 368 200	\$3 524 700	\$156 500	\$6 700 000	\$7 302 900	\$602 900
3	\$3 465 800	\$3 615 100	\$149 300	\$10 165 800	\$10 918 000	\$752 200
4	\$3 550 600	\$3 707 700	\$157 100	\$13 716 400	\$14 625 700	\$909 300
5	\$3 610 900	\$3 773 900	\$163 000	\$17 327 300	\$18 399 600	\$1 072 300
<b>Medicare Advantage Plan</b>						
1	\$38 853 500	\$42 366 200	\$3 512 700	\$38 853 500	\$42 366 200	\$3 512 700
2	\$38 959 000	\$40 210 700	\$1 251 700	\$77 812 500	\$82 576 900	\$4 764 400
3	\$39 127 900	\$40 404 700	\$1 276 800	\$116 940 400	\$122 981 600	\$6 041 200
4	\$38 945 000	\$40 352 400	\$1 407 400	\$155 885 400	\$163 334 000	\$7 448 600
5	\$38 323 100	\$39 731 700	\$1 408 600	\$194 208 500	\$203 065 700	\$8 857 200

Abbreviation: D+E, diet and exercise.

phy et al (32) estimated that arthritis medical expenses added \$2117 per adult. Our estimates are likely lower, in part, because Murphy et al (32) included both OA and rheumatoid arthritis, and rheumatoid arthritis is a more expensive disease (33,34).

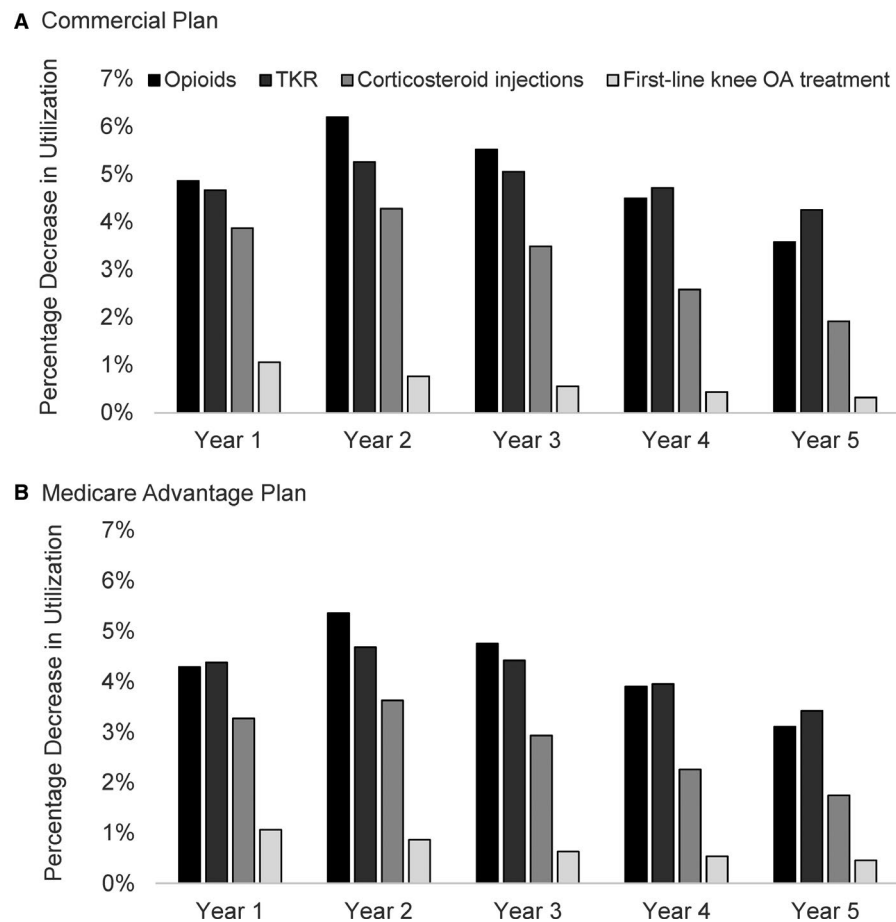
The most significant contributor to the budget impact of the D+E program is, unsurprisingly, the cost of the program itself. However, the cost of funding the D+E program is, in part, offset by reductions in other health care resource use. The reduction in the use of TKR leads to the largest cost offset: \$54 100 in the commercial plan and \$486 300 in the Medicare Advantage plan over 3 years. This is 6% to 7% of the cost of the D+E program.

In the absence of an absolute threshold defining affordability, it is not possible to draw normative policy conclusions from our findings. Indeed, it is beyond the scope of a BIA to inform go/no-go decisions. Nevertheless, it may help decision-makers to understand that the outlays associated with a D+E program for knee OA are comparable in magnitude with the expenditures required for other health-promotion interventions. Lung cancer screening for high-risk patients has a PMPM increase of \$0.76 (35), and smoking cessation medications were estimated to have a PMPM increase of \$0.10 for commercial plans and \$0.06 for Medicare (36). In making funding decisions, payers may also consider the number of plan members who are beneficiaries of the



**Figure 3.** One-way sensitivity analyses of diet and exercise efficacy. **A**, Commercial plan. **B**, Medicare Advantage plan. This figure shows the impact of varying diet and exercise (D+E) efficacy parameters on the increase in spending when D+E is implemented. The horizontal axis reports both the total and the per-member, per-month increase in spending with D+E program implementation. The left end of each bar shows the increase in spending when the D+E parameter is set to its most optimistic value on the 95% confidence interval (CI). The right end of each bar shows the increase in spending when the D+E parameter is set to its least optimistic value on the 95% CI. The black vertical bar is the base-case increase in spending. The dashed grey bars show the budget impact if all D+E efficacy parameters are simultaneously varied to the most optimistic values (left) or least optimistic values (right). BMI, body mass index.





**Figure 4.** Knee OA treatment use prevented by the diet and exercise program. **A**, Commercial plan. **B**, Medicare Advantage plan. This figure shows the percentage reduction in use of other osteoarthritis (OA) treatments that occurs when the diet and exercise (D+E) program is implemented. Appendix Table 24 contains the use for each treatment by year of D+E program and age group. TKR, total knee replacement.

new program. The D+E program was used by 0.3% of commercial plan members and 2.1% of Medicare Advantage plan members. Should payers choose to cover a D+E program, funding could come from revenues or premium increases, or funding could be reallocated from non-cost-effective programs for knee OA (eg, opioids or certain NSAIDs) (37,38).

We note several limitations to this analysis. First, the price of the D+E program is based on estimates of how the program would be implemented in clinical practice. Because this has not been done, we do not have exact values for the price of the program. To address this, we conducted a sensitivity analysis using spending from the IDEA trial. This analysis resulted in decreased spending compared with that of the base case. Our spending estimates may also be overestimates because we did not account for cost-sharing between the patient and insurer. Second, we conducted the BIA for a static population: we assumed that entry and exit from the D+E program would be equal. Likewise, we did not account for increased uptake of the D+E program over time, although willingness to participate in the program (64% in the IDEA trial) might increase if eligible plan members are offered the program regularly (Appendix

Table 25). Third, private insurers may pay providers at different rates from our estimates. To address this, we have published the use rates for each treatment with and without the D+E program (Appendix Table 24). Payers can use these rates to estimate spending with their own payment amounts. Fourth, our model included the effect of the D+E program on the incidence of five additional obesity-related diseases (CVD, cancer, COPD, other musculoskeletal diseases, and diabetes mellitus). However, we may still have underestimated the effect of D+E on non-OA spending because we did not model reduced spending on obesity-related diseases beyond these five. Fifth, the model inputs for OA progression and its relation to BMI (Appendix Table 1) are based on data from the Johnston County Osteoarthritis Project, which was not a randomized controlled trial. Finally, the model input parameters for efficacy and spending are weighted averages using published adherence rates. Thus, there is no one-to-one correspondence between adherence and the efficacy and spending that a model subject incurs.

Prior work established that D+E for knee OA is cost-effective from a societal perspective (11). This analysis found that from a payer perspective, D+E program coverage did not dramatically

increase per-member spending. This is in large part due to the small number of plan members who were eligible for the D+E program. In addition, 12% to 13% of the cost of the D+E program was offset by the reduction in spending on other knee OA treatments. Decision-makers may find these results useful, both for purposes of fiscal planning and as a comparative measure of the impact of at least one health-promotion program on their budgets.

## AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study conception and design.** Smith, Losina, Messier, Paltiel.

**Acquisition of data.** Losina, Messier.

**Analysis and interpretation of data.** Smith, Losina, Messier, Hunter, Chen, Katz, Paltiel.

## REFERENCES

- Deshpande BR, Katz JN, Solomon DH, Yelin EH, Hunter DJ, Messier SP, et al. Number of persons with symptomatic knee osteoarthritis in the US: impact of race and ethnicity, age, sex, and obesity. *Arthritis Care Res (Hoboken)* 2016;68:1743–50.
- Losina E, Paltiel AD, Weinstein AM, Yelin E, Hunter DJ, Chen SP, et al. Lifetime medical costs of knee osteoarthritis management in the United States: impact of extending indications for total knee arthroplasty. *Arthritis Care Res (Hoboken)* 2015;67:203–15.
- Silverstein FE, Faich G, Goldstein JL, Simon LS, Pincus T, Whelton A, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: a randomized controlled trial: Celecoxib Long-term Arthritis Safety Study. *JAMA* 2000;284:1247–55.
- Cannon CP, Curtis SP, FitzGerald GA, Krum H, Kaur A, Bolognese JA, et al. Cardiovascular outcomes with etoricoxib and diclofenac in patients with osteoarthritis and rheumatoid arthritis in the Multinational Etoricoxib and Diclofenac Arthritis Long-term (MEDAL) programme: a randomised comparison. *Lancet* 2006;368:1771–81.
- Coxib and traditional NSAID Trialists' (CNT) Collaboration, Bhala N, Emberson J, Merhi A, Abramson S, Arber N, et al. Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials. *Lancet* 2013;382:769–79.
- Li L, Setoguchi S, Cabral H, Jick S. Opioid use for noncancer pain and risk of fracture in adults: a nested case-control study using the general practice research database. *Am J Epidemiol* 2013;178:559–69.
- Fishman RL, Kistler CJ, Ellerbusch MT, Aparicio RT, Swami SS, Shirley ME, et al. Efficacy and safety of 12 weeks of osteoarthritic pain therapy with once-daily tramadol (Tramadol Contramid OAD). *J Opioid Manag* 2007;3:273–80.
- Skou ST, Roos EM, Laursen MB, Rathleff MS, Arendt-Nielsen L, Simonsen O, et al. A randomized, controlled trial of total knee replacement. *N Engl J Med* 2015;373:1597–606.
- McAlindon TE, Bannuru RR, Sullivan MC, Arden NK, Berenbaum F, Bierma-Zeinstra SM, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22:363–88.
- Messier SP, Mihalko SL, Legault C, Miller GD, Nicklas BJ, deVita P, et al. Effects of intensive diet and exercise on knee joint loads, inflammation, and clinical outcomes among overweight and obese adults with knee osteoarthritis: the IDEA randomized clinical trial. *JAMA* 2013;310:1263–73.
- Losina E, Smith KC, Paltiel AD, Collins JE, Suter LG, Hunter DJ, et al. Cost-effectiveness of diet and exercise for overweight and obese patients with knee osteoarthritis. *Arthritis Care Res (Hoboken)* 2019;71:855–64.
- Mauskopf J. Prevalence-based economic evaluation. *Value Health* 1998;1:251–9.
- Pearson SD. The ICER value framework: integrating cost effectiveness and affordability in the assessment of health care value. *Value Health* 2018;21:258–65.
- Sullivan SD, Mauskopf JA, Augustovski F, Jaime Caro J, Lee KM, Minchin M, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value Health* 2014;17:5–14.
- Holt HL, Katz JN, Reichmann WM, Gerlovin H, Wright EA, Hunter DJ, et al. Forecasting the burden of advanced knee osteoarthritis over a 10-year period in a cohort of 60–64 year-old US adults. *Osteoarthritis Cartilage* 2011;19:44–50.
- Losina E, Walensky RP, Reichmann WM, Holt HL, Gerlovin H, Solomon DH, et al. Impact of obesity and knee osteoarthritis on morbidity and mortality in older Americans. *Ann Intern Med* 2011;154:217–26.
- Losina E, Weinstein AM, Reichmann WM, Burbine SA, Solomon DH, Daigle ME, et al. Lifetime risk and age at diagnosis of symptomatic knee osteoarthritis in the US. *Arthritis Care Res (Hoboken)* 2013;65:703–11.
- Jevsevar DS, Brown GA, Jones DL, Matzkin EG, Manner PA, Mooar P, et al. The American Academy of Orthopaedic Surgeons evidence-based guideline on: treatment of osteoarthritis of the knee. *J Bone Joint Surg Am* 2013;95:1885–6.
- Wright EA, Katz JN, Abrams S, Solomon DH, Losina E. Trends in prescription of opioids from 2003–2009 in persons with knee osteoarthritis. *Arthritis Care Res (Hoboken)* 2014;66:1489–95.
- Centers for Disease Control and Prevention, National Center for Health Statistics. National Health and Nutrition Examination Survey. Hyattsville (MD): US Department of Health and Human Services, Centers for Disease Control and Prevention; 2009–2010.
- Centers for Disease Control and Prevention, National Center for Health Statistics. National Health and Nutrition Examination Survey. Hyattsville (MD): US Department of Health and Human Services, Centers for Disease Control and Prevention; 2011–2013.
- Kellgren JH, Lawrence JS. Radiological assessment of osteoarthrosis. *Ann Rheum Dis* 1957;16:494–502.
- Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833–40.
- Pope GC, Kautter J, Ellis RP, Ash AS, Ayanian JZ, Lezzoni LI, et al. Risk adjustment of Medicare capitation payments using the CMS-HCC model. *Health Care Financ Rev* 2004;25:119–41.
- US Census Bureau. Annual estimates of the resident population by sex, single year of age, race, and hispanic origin for the United States: April 1, 2010 to July 1, 2016. 2016. URL: <https://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml>.
- Crossman AF. Healthcare cost savings over a one-year period for SilverSneakers group exercise participants. *Health Behav Policy Rev* 2018;5:40–6.
- Ackermann RT, Cheadle A, Sandhu N, Madsen L, Wagner EH, LoGerfo JP. Community exercise program use and changes in healthcare costs for older adults. *Am J Prev Med* 2003;25:232–7.
- Ackermann RT, Williams B, Nguyen HQ, Berke EM, Maciejewski ML, LoGerfo JP. Healthcare cost differences with participa-

- tion in a community-based group physical activity benefit for medicare managed care health plan members. *J Am Geriatr Soc* 2008;56:1459–65.
29. Alva ML, Hoerger TJ, Jeyaraman R, Amico P, Rojas-Smith L. Impact of the YMCA of the USA diabetes prevention program on Medicare spending and utilization. *Health Aff (Millwood)* 2017;36:417–24.
  30. Nguyen HQ, Ackermann RT, Maciejewski M, Berke E, Patrick M, Williams B, et al. Managed-Medicare health club benefit and reduced health care costs among older adults. *Prev Chronic Dis* 2008;5:A14.
  31. Kotlarz H, Gunnarsson CL, Fang H, Rizzo JA. Insurer and out-of-pocket costs of osteoarthritis in the US: evidence from national survey data. *Arthritis Rheum* 2009;60:3546–53.
  32. Murphy LB, Cisternas MG, Pasta DJ, Helmick CG, Yelin EH. Medical expenditures and earnings losses among US adults with arthritis in 2013. *Arthritis Care Res (Hoboken)* 2018;70:869–76.
  33. Lanes SF, Lanza LL, Radensky PW, Yood RA, Meenan RF, Walker AM, et al. Resource utilization and cost of care for rheumatoid arthritis and osteoarthritis in a managed care setting: the importance of drug and surgery costs. *Arthritis Rheum* 1997;40:1475–81.
  34. Kawatkar AA, Jacobsen SJ, Levy GD, Medhekar SS, Venkatasubramanian KV, Herrinton LJ. Direct medical expenditure associated with rheumatoid arthritis in a nationally representative sample from the Medical Expenditure Panel Survey. *Arthritis Care Res (Hoboken)* 2012;64:1649–56.
  35. Pyenson BS, Sander MS, Jiang Y, Kahn H, Mulshine JL. An actuarial analysis shows that offering lung cancer screening as an insurance benefit would save lives at relatively low cost. *Health Aff (Millwood)* 2012;31:770–9.
  36. Baker CL, Ferrufino CP, Bruno M, Kowal S. Estimated budget impact of adopting the Affordable Care Act's required smoking cessation coverage on United States healthcare payers. *Adv Ther* 2017;34:156–70.
  37. Smith SR, Katz JN, Collins JE, Solomon DH, Jordan JM, Suter LG, et al. Cost-effectiveness of tramadol and oxycodone in the treatment of knee osteoarthritis. *Arthritis Care Res (Hoboken)* 2017;69:234–42.
  38. Losina E, Usiskin IM, Smith SR, Sullivan JK, Smith KC, Hunter DJ, et al. Cost-effectiveness of generic celecoxib in knee osteoarthritis for average-risk patients: a model-based evaluation. *Osteoarthritis Cartilage* 2018;26:641–50.
  39. National Center for Health Statistics. National Vital Statistics Survey. Hyattsville (MD): Centers for Disease Control and Prevention, US Department of Health and Human Services; 2009-2010.
  40. Centers for Medicare and Medicaid Services. Medicare Current Beneficiary Survey. 2009. URL: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/index.html?redirect=/MCBS/PubCNP01.asp>.
  41. Centers for Disease Control and Prevention. Bridged-race resident population estimates: United States, state and county for the years 1990-2018. URL: <http://wonder.cdc.gov/wonder/help/bridged-race.html#>.
  42. Centers for Medicare and Medicaid Services. National Health Expenditure Accounts: Personal Health Care. Accessed on January 5, 2017. URL: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.
  43. US Bureau of Economic Analysis. Personal consumption expenditures: services: health care. Accessed on January 5, 2017. URL: <https://fred.stlouisfed.org/series/DHLCRC1Q027SBEA>.