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## **BMJ Open**

# Effect of the Public Disclosure of Industry Payments Information on Patients: Results from a Population-Based Natural Experiment

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## EFFECT OF THE PUBLIC DISCLOSURE OF INDUSTRY PAYMENTS INFORMATION ON PATIENTS: RESULTS FROM A POPULATION-BASED NATURAL EXPERIMENT

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#### **ABSTRACT**

#### Objective

To determine the effect of the public disclosure of industry payments to physicians on patients' awareness of industry payments and knowledge about whether their physicians had accepted industry payments.

#### Design

Interrupted time series with comparison group (difference-in-difference analyses of longitudinal survey).

#### Setting

Nationally representative US population-based surveys. Surveys were conducted in September 2014, shortly prior to the public release of Open Payments information, and again in September 2016.

#### **Participants**

Adults aged 18 and older (n=2,180).

#### Main outcome measures

Awareness of industry payments as an issue; awareness that industry payments information was publicly available; knowledge of whether own physician had received industry payments.

#### **Results**

Public disclosure of industry payments information through Open Payments did not significantly increase the proportion of respondents who knew whether their physician had received industry payments (p=0.918). It also did not change the proportion of respondents who became aware of the

issue of industry payments (p=0.470) but did increase the proportion who knew that payments information was publicly available (9.6% points, p=0.011).

#### **Conclusions**

Two years after the public disclosure of industry payments information, Open Payments does not appear to have achieved its goal of increasing patient knowledge of whether their physicians have received money from pharmaceutical and medical device firms. Additional efforts will be required to improve the utilization and effectiveness of Open Payments for consumers.

#### STRENGTHS AND LIMITATIONS

- This is the first national policy evaluation of the effect of transparency of industry payments on patients.
- Findings are based on a strong natural experiment design: interrupted time series with comparison group (difference-in-difference).
- Nationally representative sample of respondents was followed longitudinally.
- Individuals lost to attrition between survey waves may have been different from those who completed the second wave.

#### INTRODUCTION

In 2010, the United States Congress—concerned about the adverse influence of financial relationships between physicians and drug and device firms, and the lack of transparency surrounding these relationships—enacted the Physician Payments Sunshine Act.[1] As part of reforms included in the Affordable Care Act (ACA),[2] the Sunshine provision required pharmaceutical and medical device firms to report, for public release, detailed information on the financial payments and gifts of monetary value that these firms made to physicians.

Payments for consulting and for serving as faculty speaker at continuing medical education events and conferences; for food/drink, travel, lodging, and entertainment; as well as for royalties and research were to be reported for public disclosure. The rationales underlying this disclosure requirement were that patients, in making health care decisions, would be better informed of the potential influence of industry ties on their physicians, and payment transparency could deter physicians from accepting payments that patients might view as suspect.[1,3]

Since the passage of the US Sunshine Act, similar initiatives have emerged in Europe and Canada. The European Federation of Pharmaceutical Industries and Associations (EFPIA) now requires, of its member countries, the public disclosure of pharmaceutical industry payments made to health care providers, although health care workers in some countries can refuse consent to the public disclosure of their individual-level information.[4,5] In Britain, industry payments to health care providers have been reported through the Disclosure UK programme as part of the EFPIA initiative,[6,7] with approximately 70% of providers participating in public disclosure.[8] In Ontario, Canada, legislation has been introduced requiring the public

disclosure of payments made by pharmaceutical and medical device firms to health care providers.[9,10]

The degree to which these transparency initiatives improve, in practice, patient awareness and knowledge of industry payments has not been previously studied. We sought to rigorously evaluate the effects of the earliest of these industry payments transparency initiatives: the Open Payments programme created by the US Physician Payments Sunshine Act. In a national longitudinal survey fielded before and after the Sunshine Act's data release in 2014, we investigated awareness and knowledge of industry payments to physicians among a representative cohort of American adults. Because 3 US states had already made industry payments information publicly available, respondents in these states served as a comparison group (since they already had prior exposure to this information) for those who became newly apprised of payments information with the release of Open Payments data. This design improves on a simple pre/post design and allows for a better-controlled evaluation of the effect of the Sunshine Act. Findings from the US experience can guide implementation of transparency programmes in other countries.

#### **DATA AND METHODS**

#### Sample

The sample for our initial survey consisted of 3,542 American adults aged 18 and older selected from KnowledgePanel (KP), a large, nationally representative US household panel maintained by the research firm GfK. KP households are selected through address-based

sampling so that the sampling frame covers 97% of US households, including non-Internet households. Details on survey sampling methodology are provided in Appendix S1.

We drew a nationally representative sample with oversampling in Massachusetts and Minnesota to enable us to detect smaller effects in these two states, which had previously passed "Sunshine laws" requiring the public disclosure of industry payments made to physicians in the state. (We did not oversample Vermont, which also had a preexisting disclosure law, because an oversample of this relatively small population would still not have generated sufficient power to detect an effect in that state.) We refer to these two states and Vermont as "Sunshine states."

The sample of respondents for the follow-up survey consisted of the group of all Wave 1 respondents who were available for re-contact (2,711/3,542=77%). Appendix S2 shows the flow diagram for sample selection. Individuals who were not available for re-contact were more likely to be racial/ethnic minorities and not be in paid employment than those who were re-contacted, but were similar along most other dimensions (Appendix S3).

#### Patient and public involvement statement

The study did not involve patients. The results of the survey will be given to GfK for dissemination.

#### **Survey Design**

GfK administered the 6-minute Wave 1 survey and the 10-minute Wave 2 survey online.

Both surveys included items on awareness and knowledge of industry payments (questions

provided in Appendix S4). In particular, we asked whether respondents were aware of the issue of industry payments, knew that industry payments information was publicly available, and knew if the physician they had seen most frequently during the past 12 months had received payments. Survey data were linked to information on respondents' sociodemographic and self-reported health characteristics provided by GfK.

#### **Survey Administration**

The first survey was fielded September 26-October 3, 2014, with almost all surveys (94%) completed by the Open Payments data release date of September 30. Details on administration of the Wave I survey are available elsewhere.[11]

The Wave 2 survey was fielded September 16-October 2, 2016, two years after the initial survey. Appendix S1 provides further details on Wave 2 survey administration.

#### **Statistical Analysis**

We used a difference-in-difference approach (interrupted time-series with control) to estimate the effects of the national, public release of Open Payments information.[12-14] To estimate the effect of the Open Payments release, we compared mean changes in the outcomes of interest among individuals residing in states that did not have state Sunshine laws to changes among persons residing in states with Sunshine laws (Massachusetts, Minnesota, and Vermont). By using the Sunshine states as comparators, we could improve on a simple pre/post study design and account for secular trends affecting all states--for example, changes

associated with the ACA--that otherwise could have confounded our estimates of the effect of payments disclosure.

We calculated unadjusted and adjusted difference-in-difference effects. Regression-adjusted models—used to increase precision of the estimates—included age, education categories, urban residence, household income categories, employment categories, previous diagnosis of any of 21 chronic conditions, previous diagnosis of cancer, previous diagnoses of stroke or myocardial infarction, previous diagnosis of a mental health disorder, number of physician visits, whether insured, quadratic terms of age and number of visits, year fixed effects, and individual fixed effects (which absorb gender, race/ethnicity, and other time-invariant individual characteristics). Standard errors were clustered at the state level. All analyses used GfK-constructed longitudinal weights adjusting for non-coverage, nonresponse, and oversampling.

Analyses were conducted using Stata 14 (College Station, TX). Full regression results for models with and without individual fixed effects are reported in Appendix S5. Results from alternative specifications, including unweighted models, are reported in Appendix S6.

#### **RESULTS**

#### **Sample Characteristics**

Of the 2,711 respondents from Wave 1 who were re-contacted, 80% completed the survey, for an overall completion rate of 62%. (A non-response analysis may be found in Appendix S3.) Table 1 presents the characteristics of Wave 1 and Wave 2 respondents.

Respondents in the two waves were similar along most sociodemographic and health

dimensions. In the balanced panel consisting of individuals who responded to both surveys (n=2,180), respondents who lived in Sunshine states (n=208, 4% weighted) were similar along almost all dimensions to those who lived in non-Sunshine states (n=1,972).

#### **Effect of Disclosure on Awareness and Knowledge of Industry Payments**

Columns 1 and 2 of Table 2 show, respectively, the unadjusted 2014 and 2016 levels of awareness and knowledge of industry payments in Sunshine and non-Sunshine states among individuals who responded to both survey waves. Prior to Open Payments, non-Sunshine state residents had lower awareness of the issue of industry payments than residents of Sunshine states (45.5% vs. 58.0%), as well as lower awareness that industry payments information was publicly available (9.8% vs. 19.4%).

After Open Payments, overall awareness of the issue increased in both Sunshine and non-Sunshine states, with a relatively greater increase in awareness in non-Sunshine states (8.7% points vs. 5.6% points). Awareness that industry payments information was publicly available also increased more in non-Sunshine states relative to Sunshine states, which exhibited a decline in reported awareness (3.2% points vs. -6.7% points). This decline likely reflects the effect of media attention in the pre-period surrounding the Open Payments data release, which activated short-term awareness that quickly decayed.

In both Sunshine and non-Sunshine states, a very small proportion of respondents claimed to know whether their own doctor had received industry payments prior to the public release of data (3.8% and 4.4%, respectively). In both types of states, this knowledge about their own doctors changed little after the public release.

Columns 4 and 5 of Table 2 compare the changes in awareness and knowledge in non-Sunshine states, which were newly exposed to the payments information, to changes in Sunshine states. Column 4 reports the unadjusted difference (DD) estimates of the effect of the Open Payments data release and Column 5 reports the regression-adjusted DD estimates of the effect. The DD estimates show that Open Payments did not increase awareness of the issue of industry payments (p=0.470), but did significantly increase awareness that industry payments information was publicly available (9.6 % points, p=0.011). The release of Open Payments data did not, however, increase knowledge about whether one's own doctor had received payments (p=0.918).

#### **DISCUSSION**

A key objective of the Sunshine Act was to improve the information available to patients about their physicians' financial ties with industry.[1,3] In this first national evaluation of the effect of the Sunshine Act on patients, we found that although Open Payments increased awareness that industry payments information was publicly available, it did not increase people's knowledge of whether their own doctor had received payments. Two years after the Open Payments release, 13% of respondents knew that industry payments information about their physicians was available, and only 3% of respondents knew whether their doctor had received payments. In this regard, Open Payments has fallen well short of its aspiration to better inform patients of their physicians' industry relationships.

Our findings are consistent with the experience of transparency initiatives in other areas of medicine. Studies of the effect of the disclosure of physician and hospital quality have shown

that patients have been largely unaware of and rarely use the information made available.[15-17] Providers have been more responsive,[15,16] so Open Payments may well have effects on physician behavior.

Our DD strategy provides estimates that are more credibly interpreted as causal—rather than simply associational—because Sunshine states can be used as a comparison group. Nevertheless, there are some limitations to the study. With DD, confounding might occur if there were other aspects of the health care environment affecting awareness and knowledge of industry payments that affected Sunshine states but not non-Sunshine states, or vice versa. One possible source of confounding is that the three Sunshine states all participated in the Medicaid expansion, possibly increasing patient engagement in these states. We conduct sensitivity analyses, estimating models with an indicator for Medicaid expansion and models restricting the sample to only residents in Medicaid expansion states; our findings are robust to these adjustments (Appendix S6). We are not aware of other changes that would have differentially affected Massachusetts, Minnesota, and Vermont versus non-Sunshine states during this period. Secondly, a general concern raised with web-based household panels is that refusal to participate in the panel could lead to sample non-representativeness relative to the population. Previous studies have shown, however, that there appears to be very little bias in the KN panel in the area of health and health-related behavior. [18,19] An additional concern is that survey respondents may not have been fully representative of US households because of attrition. Although the response rate among persons invited to take the Wave 2 survey was high (80%), and the overall completion rate between the first and second survey was within survey norms (62%), those who left the sample may have been different from those who

remained. In a separate analysis, we found that individuals lost to attrition had reported, during Wave 1, less education and less health insurance coverage but were otherwise similar along most other dimensions, including health status (Appendix S3). To correct for some of the attrition bias, we used longitudinal weights that matched the distribution of key demographic characteristics of our survey sample to the distribution of the US population (see Appendix S1).

In summary, because very few patients are aware of, much less accessing, information available through Open Payments, efforts beyond the unveiling of a public website will be required to improve patient use of industry payments information. These efforts could come from the Centers for Medicaid and Medicare Services (CMS), which oversees Open Payments and also administers Medicare and Medicaid programmes; for example, CMS could use its preexisting relationships with Medicare and Medicaid beneficiaries to highlight payments information and integrate it with other CMS resources that beneficiaries use regularly. More broadly, health insurers could provide information about industry payments on "Find a Physician" websites where patients go to select doctors from within a network. In addition, physicians themselves who value their "pharm-free" status [20] could highlight this fact to current and prospective patients.

As transparency efforts in Europe, Canada, and other regions advance, the US experience suggests that web-based public disclosure is limited in its ability to inform patients about physicians and their industry interests. Additional policy initiatives will likely be required to widely disseminate this information and make it more salient for patients.

#### **CONTRIBUTORSHIP STATEMENT**

Study concept and design: Kanter, Mello

Acquisition, analysis, or interpretation of data: Kanter, Mello, Carpenter, Lehmann

Drafting of the manuscript: Kanter

Critical revision of the manuscript for important intellectual content: Kanter, Mello, Carpenter, Lehmann

Statistical analysis: Kanter

Administrative, technical, or material support: Kanter, Mello, Carpenter, Lehmann

Study supervision: Kanter

Dr. Kanter had full access to the data and takes full responsibility for the integrity of the data and the accuracy of the data analysis. All authors have read, revised, and approved the final version of the paper.

#### **DATA SHARING STATEMENT**

No additional data are available.

#### **COMPETING INTERESTS**

The authors have no competing interests to disclose.

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Table 1. Characteristics Of Respondents By Wave And By Sunshine State Residence

	Weighted Distribution %			Weighted	Weighted Distribution % <sup>b</sup>		
	Wave 1, 2014	Wave 2, 2016	Statistical significance (Bonferroni	Sunshine	non-Sunshine	Statistical significance (Bonferroni	
0 1	(n=3,542)	(n=2,180)	correction) <sup>a</sup>	Balanceu i	Panel (n=2,180)	correction) <sup>a</sup>	
Gender		/	n.s.		/	n.s.	
Female	52%	52%		55%	52%		
Male	48%	48%		45%	48%		
Race/Ethnicity			n.s.			**	
Caucasian	66%	65%		92%	63%		
Hispanic	15%	16%		3%	16%		
Black, Non-Hispanic	11%	12%		2%	12%		
Other	8%	8%		2%	8%		
Age			n.s.			n.s.	
<=20	4%	2%		1%	5%		
21-30	19%	18%		15%	19%		
31-40	16%	17%		15%	17%		
41-50	15%	17%		15%	16%		
51-60	21%	21%		28%	21%		
61+	25%	26%		26%	22%		
Education			n.s.			n.s.	
Less than high school	12%	11%		4%	13%		
High school graduate	30%	29%		28%	31%		
Some college	29%	29%		26%	27%		
College graduate	29%	32%		41%	29%		
Household Income			n.s.			*	
\$0 - \$24,999	18%	17%		8%	14%		
\$25,000 - \$49,999	22%	21%		15%	21%		

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\$50,000 - \$74,999	18%	18%		15%	18%	
\$75,000 - \$99,999	15%	14%		17%	14%	
\$100,000+	26%	30%		45%	33%	
Employment			**			n.s.
Employed for pay	51%	57%		60%	54%	
Self-employed	7%	6%		8%	7%	
Retired	19%	18%		20%	17%	
Not working-disability	7%	6%		3%	7%	
Not working-other	17%	12%		9%	16%	
Urban/Rural			n.s.			n.s.
Urban	84%	86%		88%	84%	
Rural	16%	14%		12%	16%	
Resides in State with Sunshine I	_aw		n.s.			
No	96%	96%				
Yes	4%	4%				
Self-rated Health			n.s.			n.s.
Excellent	14%	13%		17%	14%	
Good	61%	64%		64%	63%	
Fair	21%	20%		19%	21%	
Poor	4%	3%		1%	3%	
Diagnosis of chronic condition <sup>c</sup>			n.s.			n.s.
No	45%	46%		39%	45%	
Yes	55%	54%		61%	55%	
Diagnosis of mental health diso	rder		**			n.s.
No	82%	98%		82%	83%	
Yes	18%	2%		18%	17%	
Diagnosis of cancer			*			n.s.
No	91%	94%		92%	92%	
Yes	9%	6%		8%	8%	

Diagnosis of stroke or myoca	ardial infarction		n.s.			n.s.
No	97%	95%		98%	97%	
Yes	3%	5%		2%	3%	
Any health insurance covera	ge		**			n.s.
No	18%	8%		8%	16%	
Yes	82%	92%		92%	84%	

<sup>\*\*</sup> significant at 0.01 level with Bonferroni correction (0.01/13=0.00077)

### n.s. not significant

Percentages may not add up to 100 because of rounding.

#### Notes:

- a. p-values are from chi-squared test of independence with Rao-Scott correction, testing the difference in distribution values between the two groups of respondents. Asterisks indicate significance with Bonferroni correction.
- b. Respondent characteristics from Wave 1 (2014) survey.
- c. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder.

<sup>\*</sup> significant at 0.05 level with Bonferroni correction (0.05/13=0.0038)

Table 2. Changes In Awareness And Knowledge Of Industry Payments After Payments Information Disclosure

				Difference-in	-Difference Estimates	
	Mean or	Percentage	Change	Unadjusted Difference in	Regression-Adjusted Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of	Industry Paymer	nts (% Answerii	ng Yes)			
	150	1.40.0\				
Aware of industry payments (2	2014 mean 46.0, s	sa 49.8)				
Non-Sunshine states	45.5%	54.1%	8.7%	3.1%	2.3%	0.4701
Sunshine states	58.0%	63.6%	5.6%	3.1/0	(-4.0%,8.6%)	0.4701
Aware that industry payments	info publicly ava	ilable (2014 me	an 10.2, sd 30.2			
Non-Sunshine states	9.8%	12.9%	3.2%	0.00/	9.6%	0.04.00*
Sunshine states	19.4%	12.6%	-6.7%	9.9%	(2.3%,16.9%)	0.0108*
Know whether own doctor has	received industr	y payments (20	)14 mean 4.4, sd	20.5)		
Non-Sunshine states	4.4%	3.1%	-1.3%	0.20/	-0.1%	0.0403
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	(-2.3%,2.0%)	0.9183

<sup>\*</sup> significant at 0.05 level

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

<sup>\*\*</sup> significant at 0.01 level

#### Notes:

- a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, year fixed effects, and individual fixed effects (which absorb gender, race/ethnicity, and other time-invariant individual characteristics). All analyses used Gfk-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level.
- b. Reported *P* values for regression-adjusted change.



## EFFECT OF THE PUBLIC DISCLOSURE OF INDUSTRY PAYMENTS INFORMATION ON PATIENTS: RESULTS FROM A POPULATION-BASED NATURAL EXPERIMENT

#### **SUPPLEMENTARY APPENDIX**

- S1. Survey sampling methods
- S2. Sample selection flow diagram
- S3. Characteristics of Wave 2 respondents and non-respondents
- S4. Survey questions
- S5. Full regression results
  - S4a. Models with individual fixed effects
  - S4b. Models without individual fixed effects
- S6. Alternative specifications
  - S5a. Unweighted models
  - S5b. Models without individual fixed effects
  - S5c. Regression-adjusted models that include an indicator for Medicaid expansion
  - S5d. Medicaid expansion states only

### SUPPLEMENTARY APPENDIX S1 SURVEY SAMPLING METHODS

#### Survey Sampling and Administration

Individuals selected for the initial (Wave 1) survey were recruited from KnowledgePanel® (KP), a nationally representative household panel assembled by the research firm GfK. KP households are selected through random digit dialing and address-based sampling so that landline households as well as cell-phone-only and no-phone households are in a sampling frame covering 97% of US households. KP households agree to participate in occasional surveys and, in return for their participation, accumulate points that they can redeem for cash, merchandise, and other items of monetary value (average accumulation valued at \$4-\$6 per month). Households without Internet access are provided a webenabled computer and free Internet service for the duration of their participation in the panel. Detailed information about KP sampling methodology, incentive structures, informed consent, and other human subjects issues are documented in Dennis and Thomas (2013).¹

For Wave 1, individuals were sampled from KP households in all 50 states, excluding DC, to constitute a nationally representative sample, with oversampling in Massachusetts and Minnesota to enable us to detect smaller effects in these two states that had previously passed Sunshine laws. We did not oversample Vermont, the third Sunshine state, because even an oversample of this relatively small population would have not have generated sufficient power to detect an effect in that state.

The Wave 1 sample consisted of 3,542 respondents who completed the initial survey in 2014 (Wave 1 completion 45.9%). More details on administration of the Wave 1 survey may be found in Pham-Kanter et al (2017).<sup>2</sup>

For Wave 2, GfK identified 2,711 (77%) respondents from Wave 1 respondents who were still in the panel in 2016 and who were available for re-contact. All of these individuals were asked to complete the Wave 2 survey.

#### Survey Field Period

The first survey was fielded online September 26-October 3, 2014, with almost all surveys (94%) completed by the Open Payments data release date of September 30. The Wave 2 survey was fielded online September 16-October 2, 2016, two years after the initial survey.

Individuals selected for the surveys received a notification email with a link to the survey. After three days, individuals who had not responded to the survey were sent an email reminder. For Wave 2, which had a slightly longer field period than Wave 1, nonrespondents also received an automated email reminder 11 days after the initial survey contact.

#### **Completion Rate**

Of those who were re-contacted for Wave 2, 80% (n=2,180) completed the survey, resulting in an overall completion rate of 62%. The sample selection flow diagram is shown in Appendix S2.

Completion rates varied by state and ranged from 40% to 81.8%. Average completion rates for Sunshine and non-Sunshine states did not differ significantly from each other (61.1% and 66.5%, respectively, p=0.062).

#### Survey Weights

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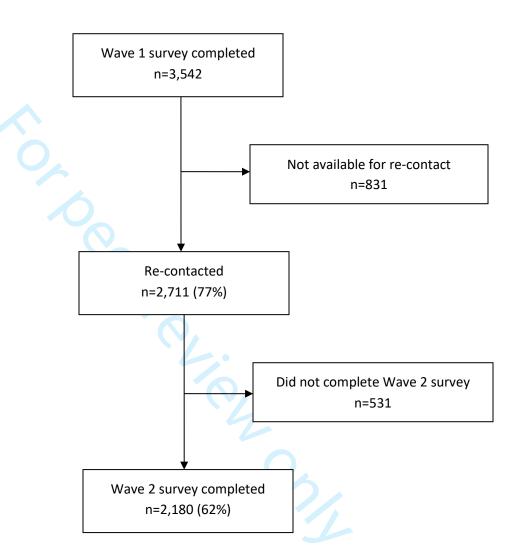
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are documented in Dennis an. Our analysis uses survey weights provided by GfK that account for non-coverage, oversampling, and nonresponse/attrition. These GfK weights use, as a benchmark, distributions derived from the 2014 March Supplement Current Population Survey (CPS) so the survey sample matches the US adult population on key demographic dimensions (gender, age, race/Hispanic ethnicity, education, Census region, household income, homeownership status, metropolitan residence, Internet access). Details on the construction of survey weights are documented in Dennis and Thomas (2013).<sup>2</sup>

## SUPPLEMENTARY APPENDIX S2 SAMPLE SELECTION FLOW DIAGRAM



MANUSCRIPT: PUBLIC DISCLOSURE OF INDUSTRY PAYMENTS

#### **SUPPLEMENTARY APPENDIX S3**

#### **CHARACTERISTICS OF WAVE 2 RESPONDENTS AND NON-RESPONDENTS**



Table S3. 2014 Characteristics of Wave 2 Respondents and Non-Respondents

		Weighted I	Distribution %	Statistical
		Wave 2	Not contacted or	Significance
		respondents	did not respond	(Bonferroni
		(n=2,180)	(n=1,362)	correction) <sup>a</sup>
Gender				n.s.
	Female	49%	56%	
	Male	51%	44%	
Race/Et				**
	Caucasian	70%	60%	
	Hispanic	10%	14%	
	Black, Non-Hispanic	13%	19%	
	Other	8%	8%	
Age	Other	370	5/0	**
.Bc	<=20	4%	5%	
	21-30	17%	23%	
	31-40	15%	16%	
	41-50	15%	16%	
	51-60	22%	18%	
	61+		22%	
ducatio		27%	ZZ70	**
_uucd(l		100/	150/	• •
	Less than high school	10%	15%	
	High school graduate Some college College graduate	31%	27%	
	Some college	28%	30%	
	College graduate	31%	27%	
Housen	old Income			n.s.
	\$0 - \$24,999	16%	21%	
	\$25,000 - \$49,999	22%	24%	
	\$50,000 - \$74,999	19%	18%	
	\$75,000 - \$99,999	16%	15%	
	\$100,000+	28%	23%	
Employ				**
	Employed for pay	52%	48%	
	Self-employed	6%	7%	
	Retired	21%	16%	
	Not working - disability	7%	8%	
	Not working - other	14%	21%	
Urban/F	Rural			n.s.
	Urban	16%	16%	
	Rural	84%	84%	
Resides	in State with Sunshine Law			n.s.
	No	96%	96%	
	Yes	4%	4%	
Self-rate	ed Health			n.s.
	Excellent	13%	15%	
	Good	63%	58%	
	Fair	21%	22%	
	Poor	3%	5%	
Diagnas	L.	370	3,4	
Diagnos	sis of chronic condition <sup>o</sup>	420/	400/	n.s.
	No	42%	49% 51%	
· · · · · · ·	Yes	58%	51%	
agnosاد	sis of mental health disorder			n.s.
	No	83%	80%	
	Yes	17%	20%	
Diagnos	sis of cancer			n.s.
	No	91%	92%	
	Yes	9%	8%	
Diagnos	sis of stroke or myocardial infarction			n.s.
	No	97%	96%	
	Yes	3%	4%	
Any hea	alth insurance coverage			**
	No	16%	21%	
	Yes	84%	79%	

<sup>\*\*</sup> significant at 0.01 level with Bonferroni correction (0.01/13=0.00077)

Percentages may not add up to 100 because of rounding.

Notes:

<sup>\*</sup> significant at 0.05 level with Bonferroni correction (0.05/13=0.0038)

n.s. not significant

a. P-values are from chi-squared test of independence with Rao-Scott correction, testing the difference in distribution values between Wave 2 respondents and nonrespondents using base weights. Asterisks indicate significance with Bonferroni correction.

b. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder.

### SUPPLEMENTARY APPENDIX S4 SURVEY QUESTIONS

#### **Awareness and Knowledge of Industry Payments**

1. Some doctors receive payments from pharmaceutical (drug) and medical device companies in the form of small gifts such as pens, mugs, or books; reimbursement for travel and conference presentations; or financial compensation for consulting services. Have you heard about these payments before now?

Response choices: Yes; No; Don't know

- 2. A variety of sources recently began posting information about payments made by pharmaceutical and medical device companies to doctors. Were you aware that this information is available?

  \*Response choices: Yes, I was aware; No, I was not aware; Not sure
- 3. Do you know whether the doctor you've seen most frequently in the past 12 months has received any payments from a pharmaceutical or medical device firm?

Response choices: Yes, I know my doctor has received payments; Yes, I know my doctor has not received any payments; No, I do not know whether my doctor has received any payments; Not sure

#### **SUPPLEMENTARY APPENDIX S5 FULL REGRESSION RESULTS**



Table S5a. Full Regression Results, Models With Individual Fixed Effects

	Dependent variable					
	Awareness of	Awareness of	Knowledge of own			
	payments	public info	doctor payments			
	0.0227	0.0054	0.0044			
Open Payments disclosure	0.0227	0.0961	-0.0011			
	(0.0312)	(0.0363)	(0.0107)			
Age	-0.0347	-0.0672	-0.0293			
	(0.0738)	(0.0625)	(0.0297)			
Age squared	-0.0004	-0.0004	0.0001			
Be squared	(0.0003)	(0.0002)	(0.0001)			
ess than high school education	(0.000)	(0.0002)	(0.0001)			
High school graduate	-0.0523	-0.1071	-0.0677			
	(0.1136)	(0.0667)	(0.0574)			
Some college	0.0784	-0.0230	-0.0408			
-0-	(0.1410)	(0.0880)	(0.0571)			
College graduate	0.1760	-0.0341	-0.0953			
	(0.1572)	(0.1636)	(0.0714)			
Jrban residence	-0.1190	0.0253	0.0239			
	(0.0991)	(0.0526)	(0.0175)			
lousehold income \$0-\$24,999						
	4					
lousehold income \$25,000-\$49,999	0.0411	0.0405	0.0352			
	(0.0526)	(0.0345)	(0.0267)			
lousehold income \$50,000-\$74,999	0.0194	-0.0098	0.0147			
	(0.0918)	(0.0383)	(0.0268)			
lousehold income \$75,000-\$99,999	0.0432	-0.0177	0.0176			
	(0.1088)	(0.0399)	(0.0391)			
lousehold income \$100,000+	0.0608	0.0197	0.0304			
	(0.0857)	(0.0529)	(0.0274)			
lot employed						
elf-employed	0.0066	-0.1170	0.0123			
	(0.1079)	(0.0990)	(0.0502)			
mployed for pay	-0.0209	-0.0477	-0.0254			
	(0.0725)	(0.0594)	(0.0426)			
etired	-0.0492	0.0243	0.0111			
2	(0.0816)	(0.0767)	(0.0489)			
Diagnosis of chronic condition <sup>a</sup>	0.0407	0.0156	-0.0011			
	(0.0486)	(0.0408)	(0.0165)			
liagnosis of cancer	-0.0979	-0.0044	0.0126			
	(0.0802)	(0.0440)	(0.0222)			
iagnosis of MI or stroke	-0.0346	0.0144	-0.0190			
	(0.0888)	(0.0682)	(0.0477)			
piagnosis of mental health disorder	0.0506	-0.0066	-0.0107			
	(0.0532)	(0.0321)	(0.0274)			
lumber of office visits	0.0025	-0.0014	0.0002			
	(0.0038)	(0.0036)	(0.0023)			
Number of office visits squared	0.0000	0.0000	0.0000			

Health insurance coverage	(0.0001)	(0.0001)	(0.0000)
	0.0402	0.0341	0.0119
	(0.0605)	(0.0554)	(0.0113)
Year fixed effects	YES	YES	YES
Individual fixed effects	YES	YES	YES
F-statistic (degrees of freedom) R <sup>2</sup>	3.64 (22,49)	2.7 (22,49)	2.46 (22,49)
	0.7602	0.6452	0.6709
Sample Size	2,028	2,030	2,030

Standard errors clustered at the state level, reported in parentheses.

#### Notes:

a. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rhematoid arthritis, sleep disorder.

Table S5b. Full Regression Results. Models Without Individual Fixed Effects

	Dependent variable					
	Awareness of	Awareness of	Knowledge of owr			
	payments	public info	doctor payments			
		0.4040				
Open Payments disclosure	0.0234	0.1018	0.0004			
	(0.0229)	(0.0244)	(0.0070)			
Non-Sunshine state resident	-0.0223	-0.0824	-0.0025			
	(0.0182)	(0.0126)	(0.0051)			
Post-Open Payments year <sup>a</sup>	0.0608	-0.0738	-0.0125			
	(0.0149)	(0.0230)	(0.0039)			
Age	0.0066	0.0009	-0.0024			
	(0.0030)	(0.0022)	(0.0014)			
Age squared	-0.0001	0.0000	0.0000			
	(0.000)	(0.0000)	(0.0000)			
Less than high school education						
High school graduate	0.0828	0.0170	-0.0179			
	(0.0254)	(0.0195)	(0.0216)			
Some college	0.1971	0.0430	-0.0149			
	(0.0265)	(0.0178)	(0.0208)			
College graduate	0.2933	0.0919	-0.0067			
	(0.0363)	(0.0197)	(0.0217)			
Caucasian						
	· · · · · · · · · · · · · · · · · · ·					
Black, non-Hispanic	-0.1722	-0.0364	0.0029			
	(0.0274)	(0.0120)	(0.0167)			
Hispanic	-0.1003	0.0041	0.0031			
	(0.0372)	(0.0187)	(0.0114)			
Other/Multi	-0.0402	0.0334	0.0141			
	(0.0426)	(0.0307)	(0.0253)			
Female	-0.0212	-0.0358	0.0253			
	(0.0237)	(0.0154)	(0.0071)			
Urban residence	0.0059	-0.0027	0.0170			
	(0.0362)	(0.0210)	(0.0079)			
Household income \$0-\$24,999						
Household income \$25,000-\$49,999	0.0985	0.0161	-0.0045			
	(0.0250)	(0.0168)	(0.0172)			
Household income \$50,000-\$74,999	0.1446	0.0086	0.0173			
	(0.0249)	(0.0185)	(0.0161)			
Household income \$75,000-\$99,999	0.1619	0.0077	-0.0044			
	(0.0372)	(0.0172)	(0.0176)			
Household income \$100,000+	0.1898	0.0251	-0.0135			
	(0.0261)	(0.0171)	(0.0153)			
Not employed						
Self-employed	0.1070	-0.0080	-0.0158			
	(0.0385)	(0.0289)	(0.0127)			
Employed for pay	0.0478	0.0063	-0.0171			
	(0.0211)	(0.0136)	(0.0094)			
Retired	0.0938	0.0194	-0.0079			

	(0.0283)	(0.0216)	(0.0087)
Diagnosis of chronic condition <sup>b</sup>	0.0842	0.0069	0.0033
Diagnosis of emorne condition	(0.0273)	(0.0180)	(0.0140)
Diagnosis of cancer	0.0155	-0.0202	0.0185
	(0.0335)	(0.0198)	(0.0152)
Diagnosis of MI or stroke	0.0344	0.0781	0.0261
Ü	(0.0447)	(0.0487)	(0.0190)
Diagnosis of mental health disorder	0.0484	-0.0004	-0.0043
-	(0.0335)	(0.0205)	(0.0106)
Number of office visits	0.0098	0.0022	0.0019
	(0.0033)	(0.0023)	(0.0011)
Number of office visits squared	-0.0001	0.0000	0.0000
	(0.0000)	(0.0000)	(0.0000)
Health insurance coverage	0.0193	-0.0068	-0.0016
	(0.0278)	(0.0194)	(0.0155)
Year fixed effects <sup>a</sup>	YES	YES	YES
Individual fixed effects	NO	NO	NO
F-statistic (degrees of freedom)	101.02 (27,49)	20.87 (27,49)	15.25 (27,49)
$R^2$	0.1399	0.0266	0.0164
Sample Size	2,028	2,030	2,030

Standard errors clustered at the state level, reported in parentheses.

#### Notes:

a. Coefficient on year fixed effect reported as coefficient on Post-Open Payments year.

a. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rhematoid arthritis, sleep disorder.

## SUPPLEMENTARY APPENDIX S6 ALTERNATIVE SPECIFICATIONS

S6a. Unweighted models

S6b. Regression-adjusted models without individual fixed effects

S6c. Regression-adjusted models that include an indicator for Medicaid expansion

S6d. Medicaid expansion states only



#### Table S6a. Alternative Specification: Unweighted Models

				Difference-in	Difference-in-Difference Estimates		
				Unadjusted	Regression-Adjusted		
	Mean or F	Percentage	Change	Difference in	Difference in		
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>	
Awareness and Knowledge of Industry Payments (% Answering Yes)							
Aware of industry payments							
Non-Sunshine states	49.7%	58.1%	8.4%	2.8%	2.3% (-3.2%,7.7%)	0.4031	
Sunshine states	58.9%	64.5%	5.6%	2.070	2.376 (-3.276,7.776)	0.4031	
Aware that industry payments info publicly available							
Non-Sunshine states	10.9%	13.0%	2.1%	11.3%	11.3% (8.6%,13.9%)	<0.0001**	
Sunshine states	20.9%	11.7%	-9.2%	11.5/0	11.3% (8.0%,13.9%)	<0.0001	
Know whether own doctor has received industry payments							
Non-Sunshine states	4.4%	2.9%	-1.5%	0.0%	0.00/ ( 2.00/ 2.00/)	0.9828	
Sunshine states	4.1%	2.5%	-1.5%	0.0%	0.0% (-2.0%,2.0%)	0.9828	

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. tate leve).

b. Reported *P* values for regression-adjusted change.

Table S6b. Alternative Specification: Regression-Adjusted Models Without Individual Fixed Effects

				Difference-in	Difference-in-Difference Estimates		
				Unadjusted	Regression-Adjusted		
	Mean or F	Percentage	Change	Difference in	Difference in		
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>	
Awareness and Knowledge of Industry Payments (% Answering Yes)							
Aware of industry payments							
Non-Sunshine states	45.5%	54.1%	8.7%	3.1%	2.3% (-2.3%,6.9%)	0.3128	
Sunshine states	58.0%	63.6%	5.6%	3.170	2.3% (-2.3%,0.3%)	0.3128	
Aware that industry payments info publicly available							
Non-Sunshine states	9.8%	12.9%	3.2%	9.9%	10.2% (5.3%,15.1%)	0.0001**	
Sunshine states	19.4%	12.6%	-6.7%	9.970	10.2% (3.3%,13.1%)	0.0001	
Know whether own doctor has received industry payments							
Non-Sunshine states	4.4%	3.1%	-1.3%	-0.2%	0.00/ / 1.40/ 1.50/	0.0503	
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	0.0% (-1.4%,1.5%)	0.9583	

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

#### Notes

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, indicator for non-Sunshine state, indicator for post-Open Payments year (2016), interaction between non-Sunshine state indicator and post-Open Payments year indicator, gender, and race/ethnicity categories. All analyses used Gfk-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level.

b. Reported *P* values for regression-adjusted change.

Table S6c. Alternative Specification: Regression-Adjusted Models that Include an Indicator for Medicaid Expansion

				Difference-in-Difference Estimates		
				Unadjusted	Regression-Adjusted	
	Mean or I	Percentage	Change	Difference in	Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of Industry Payments (% Answering Yes)						
Aware of industry payments						
Non-Sunshine states	45.5%	54.1%	8.7%	3.1%	1.6% (-4.6%,7.7%)	0.6127
Sunshine states	58.0%	63.6%	5.6%	5.1/0	1.0% (-4.0%,7.7%)	0.0127
Aware that industry payments info publicly available						
Non-Sunshine states	9.8%	12.9%	3.2%	0.00/	8.8% (1.4%,16.1%)	0.0203*
Sunshine states	19.4%	12.6%	-6.7%	9.9%	8.8% (1.4%,16.1%)	0.0203
Know whether own doctor has received industry payments						
Non-Sunshine states	4.4%	3.1%	-1.3%	0.20/	0.40/ / 2.20/ 2.40/)	0.0206
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	-0.1% (-2.3%,2.1%)	0.9206

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. state ievei.

b. Reported P values for regression-adjusted change.

Table S6d. Alternative Specification: Medicaid Expansion	<u> </u>			Difference-in-Difference Estimates		
	Mean or	∕lean or Percentage	Change	Unadjusted Difference in	Regression-Adjusted Difference in Change (95% CI) <sup>a</sup>	<i>P</i> value <sup>b</sup>
	2014	2016	2014-16	Change		
Awareness and Knowledge of Industry Payments (% A	nswering Yes)					
Aware of industry payments						
Non-Sunshine states	44.5%	53.2%	8.7%	3.1%	2.1% (-4.8%,8.9%)	0.5414
Sunshine states	58.0%	63.6%	5.6%	3.170		
Aware that industry payments info publicly available						
Non-Sunshine states	9.3%	14.5%	5.3%	12.0%	11.6% (3.8%,19.3%)	0.0045**
Sunshine states	19.4%	12.6%	-6.7%	12.0%	11.0% (3.8%,19.3%)	0.0043
Know whether own doctor has received industry payme	nts					
Non-Sunshine states	4.0%	2.9%	-1.1%	0.0%	0.2% (-2.0%,2.4%)	0.8694
Sunshine states	3.8%	2.7%	-1.1%	0.0%	0.2/0 (-2.0%,2.4%)	

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys and resided in Medicaid expansion states: 1,101 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,093 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public; 1,094 non-Sunshine residents and 197 Sunshine residents for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. Teh only

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# EFFECT OF THE PUBLIC DISCLOSURE OF INDUSTRY PAYMENTS INFORMATION ON PATIENTS: RESULTS FROM A POPULATION-BASED NATURAL EXPERIMENT

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#### **ABSTRACT**

#### Objective

To determine the effect of the public disclosure of industry payments to physicians on patients' awareness of industry payments and knowledge about whether their physicians had accepted industry payments.

#### Design

Interrupted time series with comparison group (difference-in-difference analyses of longitudinal survey).

### Setting

Nationally representative US population-based surveys. Surveys were conducted in September 2014, shortly prior to the public release of Open Payments information, and again in September 2016.

#### **Participants**

Adults aged 18 and older (n=2,180).

#### Main outcome measures

Awareness of industry payments as an issue; awareness that industry payments information was publicly available; knowledge of whether own physician had received industry payments.

#### **Results**

Public disclosure of industry payments information through Open Payments did not significantly increase the proportion of respondents who knew whether their physician had received industry payments (p=0.918). It also did not change the proportion of respondents who became aware of the

issue of industry payments (p=0.470) but did increase the proportion who knew that payments information was publicly available (9.6% points, p=0.011).

#### **Conclusions**

Two years after the public disclosure of industry payments information, Open Payments does not appear to have achieved its goal of increasing patient knowledge of whether their physicians have received money from pharmaceutical and medical device firms. Additional efforts will be required to improve the utilization and effectiveness of Open Payments for consumers.

#### STRENGTHS AND LIMITATIONS

- This is the first national policy evaluation of the effect of transparency of industry payments on patients.
- Findings are based on a strong natural experiment design: interrupted time series with comparison group (difference-in-difference).
- Nationally representative sample of respondents was followed longitudinally.
- Individuals lost to attrition between survey waves may have been different from those who completed the second wave.

#### INTRODUCTION

In 2010, the United States Congress—concerned about the adverse influence of financial relationships between physicians and drug and device firms, and the lack of transparency surrounding these relationships—enacted the Physician Payments Sunshine Act.[1] As part of reforms included in the Affordable Care Act (ACA),[2] the Sunshine provision required pharmaceutical and medical device firms to report, for public release, detailed information on the financial payments and gifts of monetary value that these firms made to physicians.

Payments for consulting and for serving as faculty speaker at continuing medical education events and conferences; for food/drink, travel, lodging, and entertainment; as well as for royalties and research were to be reported for public disclosure. The rationales underlying this disclosure requirement were that patients, in making health care decisions, would be better informed of the potential influence of industry ties on their physicians, and payment transparency could deter physicians from accepting payments that patients might view as suspect.[1,3]

Since the passage of the US Sunshine Act, similar initiatives have emerged in Europe and Canada. The European Federation of Pharmaceutical Industries and Associations (EFPIA) now requires, of its member countries, the public disclosure of pharmaceutical industry payments made to health care providers, although health care workers in some countries can refuse consent to the public disclosure of their individual-level information.[4,5] In Britain, industry payments to health care providers have been reported through the Disclosure UK programme as part of the EFPIA initiative,[6,7] with approximately 70% of providers participating in public disclosure.[8] In Ontario, Canada, legislation has been introduced requiring the public

disclosure of payments made by pharmaceutical and medical device firms to health care providers.[9,10]

In the US, the Sunshine Act and its Open Payments programme have provided policymakers and the public with a good overview of the scope, scale, and reach of industry payments. In 2017, drug and device firms made \$8.4 billion in payments to physicians, of which 55% was directed towards research activities; the rest was primarily directed at informing and influencing the clinical care delivered by physicians and remunerating them for consulting and ownership interests.[11] Studies using Open Payments data have shown that about 48% of physicians receive industry payments in a given year,[12] and 65% of patients see physicians who had received payments in the previous year.[13]

The release of payments data has also enabled analyses showing associations between industry payments and increased prescribing [14,15] and increased Medicare prescribing costs.[16] Much more remains to be studied, but at the very least, the Open Payments disclosure programme has begun to shed light on the flow of industry payments within the health care system.

One important outstanding question is the degree to which the transparency initiatives like the Sunshine Act and the EFPIA Code improve, in practice, patient awareness and knowledge of industry payments. We sought to rigorously evaluate the effects of transparency on patients by examining the effect of the Open Payments programme, the earliest of these industry payments transparency initiatives. In a national longitudinal survey fielded before and after the Sunshine Act's data release in 2014, we investigated awareness and knowledge of industry payments to physicians among a representative cohort of American adults. Because 3

US states had already made industry payments information publicly available, respondents in these states served as a comparison group (since they already had prior exposure to this information) for those who became newly apprised of payments information with the release of Open Payments data. This design improves on a simple pre/post design and allows for a better-controlled evaluation of the effect of the Sunshine Act. Findings from the US experience can guide implementation of transparency programmes in other countries.

#### DATA AND METHODS

#### Sample

The sample for our initial survey consisted of 3,542 American adults aged 18 and older selected from KnowledgePanel (KP), a large, nationally representative US household panel maintained by the research firm GfK. KP households are selected through address-based sampling so that the sampling frame covers 97% of US households, including non-Internet households. Details on survey sampling methodology are provided in Appendix S1.

We drew a nationally representative sample with oversampling in Massachusetts and Minnesota to enable us to detect smaller effects in these two states, which had previously passed "Sunshine laws" requiring the public disclosure of industry payments made to physicians in the state. (We did not oversample Vermont, which also had a preexisting disclosure law, because an oversample of this relatively small population would still not have generated sufficient power to detect an effect in that state.) We refer to these two states and Vermont as "Sunshine states."

The sample of respondents for the follow-up survey consisted of the group of all Wave 1 respondents who were available for re-contact (2,711/3,542=77%). Appendix S2 shows the flow diagram for sample selection. Individuals who were not available for re-contact were more likely to be racial/ethnic minorities and not be in paid employment than those who were re-contacted, but were similar along most other dimensions (Appendix S3).

#### Patient and public involvement statement

The study did not involve patients. The results of the survey will be given to GfK for dissemination.

#### **Survey Design**

GfK administered the 6-minute Wave 1 survey and the 10-minute Wave 2 survey online. Both surveys included items on awareness and knowledge of industry payments (questions provided in Appendix S4). In particular, we asked whether respondents were aware of the issue of industry payments, knew that industry payments information was publicly available, and knew if the physician they had seen most frequently during the past 12 months had received payments. Survey data were linked to information on respondents' sociodemographic and self-reported health characteristics provided by GfK.

#### **Survey Administration**

The first survey was fielded September 26-October 3, 2014, with almost all surveys (94%) completed by the Open Payments data release date of September 30. Details on administration of the Wave I survey are available elsewhere.[13]

The Wave 2 survey was fielded September 16-October 2, 2016, two years after the initial survey. Appendix S1 provides further details on Wave 2 survey administration.

The Drexel University Institutional Review Board determined that the foregoing survey protocol was not research involving human subjects as defined by the US Department of Health and Human Services and Food and Drug Administration guidelines.

### **Statistical Analysis**

We used a difference-in-difference approach (interrupted time-series with control) to estimate the effects of the national, public release of Open Payments information.[17-19] To estimate the effect of the Open Payments release, we compared mean changes in the outcomes of interest among individuals residing in states that did not have state Sunshine laws to changes among persons residing in states with Sunshine laws (Massachusetts, Minnesota, and Vermont). By using the Sunshine states as comparators, we could improve on a simple pre/post study design and account for secular trends affecting all states--for example, changes associated with the ACA--that otherwise could have confounded our estimates of the effect of payments disclosure.

We calculated unadjusted and adjusted difference-in-difference effects. Regression-adjusted models—used to increase precision of the estimates--included age, education categories, urban residence, household income categories, employment categories, previous

diagnosis of any of 21 chronic conditions, previous diagnosis of cancer, previous diagnoses of stroke or myocardial infarction, previous diagnosis of a mental health disorder, number of physician visits, whether insured, quadratic terms of age and number of visits, year fixed effects, and individual fixed effects (which absorb gender, race/ethnicity, and other time-invariant individual characteristics). Standard errors were clustered at the state level. All analyses used GfK-constructed longitudinal weights adjusting for non-coverage, nonresponse, and oversampling.

Analyses were conducted using Stata 14 (College Station, TX). Full regression results for models with and without individual fixed effects are reported in Appendix S5. Results from alternative specifications, including unweighted models, are reported in Appendix S6.

#### **RESULTS**

#### **Sample Characteristics**

Of the 2,711 respondents from Wave 1 who were re-contacted, 80% completed the survey, for an overall completion rate of 62%. (A non-response analysis may be found in Appendix S3.) Table 1 presents the characteristics of Wave 1 and Wave 2 respondents. Respondents in the two waves were similar along most sociodemographic and health dimensions. In the balanced panel consisting of individuals who responded to both surveys (n=2,180), respondents who lived in Sunshine states (n=208, 4% weighted) were similar along almost all dimensions to those who lived in non-Sunshine states (n=1,972).

#### **Effect of Disclosure on Awareness and Knowledge of Industry Payments**

Columns 1 and 2 of Table 2 show, respectively, the unadjusted 2014 and 2016 levels of awareness and knowledge of industry payments in Sunshine and non-Sunshine states among individuals who responded to both survey waves. Prior to Open Payments, non-Sunshine state residents had lower awareness of the issue of industry payments than residents of Sunshine states (45.5% vs. 58.0%), as well as lower awareness that industry payments information was publicly available (9.8% vs. 19.4%).

After Open Payments, overall awareness of the issue increased in both Sunshine and non-Sunshine states, with a relatively greater increase in awareness in non-Sunshine states (8.7% points vs. 5.6% points). Awareness that industry payments information was publicly available also increased more in non-Sunshine states relative to Sunshine states, which exhibited a decline in reported awareness (3.2% points vs. -6.7% points).

In both Sunshine and non-Sunshine states, a very small proportion of respondents said they knew whether their own doctor had received industry payments prior to the public release of data (3.8% and 4.4%, respectively). In both types of states, this knowledge about their own doctors changed little after the public release.

Columns 4 and 5 of Table 2 compare the changes in awareness and knowledge in non-Sunshine states, which were newly exposed to the payments information, to changes in Sunshine states. Column 4 reports the unadjusted difference (DD) estimates of the effect of the Open Payments data release and Column 5 reports the regression-adjusted DD estimates of the effect. The DD estimates show that Open Payments did not increase awareness of the issue of industry payments (p=0.470), but did significantly increase awareness that industry payments information was publicly available (9.6 % points, p=0.011). The release of Open Payments data

did not, however, increase knowledge about whether one's own doctor had received payments (p=0.918).

#### **DISCUSSION**

A key objective of the Sunshine Act was to improve the information available to patients about their physicians' financial ties with industry.[1,3] In this first national evaluation of the effect of the Sunshine Act on patients, we found that although Open Payments increased awareness that industry payments information was publicly available, it did not increase people's knowledge of whether their own doctor had received payments. Two years after the Open Payments release, 13% of respondents knew that industry payments information about their physicians was available, and only 3% of respondents knew whether their doctor had received payments. These findings, together with findings from an earlier study showing that 1.5% of survey respondents had used the Open Payments database,[20] suggest that Open Payments has fallen well short of its aspiration to better inform patients of their physicians' industry relationships.

Our findings of a minimal effect of disclosure on patients are consistent with the experience of transparency initiatives in other areas of medicine. Studies of the effect of the disclosure of physician and hospital quality have shown that patients have been largely unaware of and rarely use the information made available.[21-23] Providers have been more responsive,[21,22] so Open Payments may well have effects on physician behavior.

There was a significant increase, of almost 10% points, in awareness that payments information was publicly available. This effect was driven by an increase in awareness in states

in which payments information was newly available, as expected, and by a decrease in awareness in Sunshine states, where that information was already available. The decline in Sunshine states likely reflects the effect of media attention in the pre-period surrounding the Open Payments data release, which activated short-term awareness that quickly decayed. This decline does not appear to be driven by differential attrition patterns in Sunshine states versus non-Sunshine states, as there did not appear to be significant differences in the observed characteristics of Wave 1 respondents lost to follow up across the two types of states (results available upon request).

Our DD strategy provides estimates that are more credibly interpreted as causal—rather than simply associational—because Sunshine states can be used as a comparison group.

Nevertheless, there are some limitations to the study. With DD, confounding might occur if there were other aspects of the health care environment affecting awareness and knowledge of industry payments that affected Sunshine states but not non-Sunshine states, or vice versa.

One possible source of confounding is that the three Sunshine states all participated in the Medicaid expansion, possibly increasing patient engagement in these states. We conduct sensitivity analyses, estimating models with an indicator for Medicaid expansion and models restricting the sample to only residents in Medicaid expansion states; our findings are robust to these adjustments (Appendix S6). We are not aware of other changes that would have differentially affected Massachusetts, Minnesota, and Vermont versus non-Sunshine states during this period. Secondly, a general concern raised with web-based household panels is that refusal to participate in the panel could lead to sample non-representativeness relative to the population. Previous studies have shown, however, that there appears to be very little bias in

the KN panel in the area of health and health-related behavior.[24,25] An additional concern is that survey respondents may not have been fully representative of US households because of attrition. Although the response rate among persons invited to take the Wave 2 survey was high (80%), and the overall completion rate between the first and second survey was within survey norms (62%), those who left the sample may have been different from those who remained. In a separate analysis, we found that individuals lost to attrition had reported, during Wave 1, less education and less health insurance coverage but were otherwise similar along most other dimensions, including health status (Appendix S3). To correct for some of the attrition bias, we used longitudinal weights that matched the distribution of key demographic characteristics of our survey sample to the distribution of the US population (see Appendix S1).

In summary, because very few patients are aware of, much less accessing, information available through Open Payments, efforts beyond the unveiling of a public website will be required to improve patient use of industry payments information. These efforts could come from the Centers for Medicaid and Medicare Services (CMS), which oversees Open Payments and also administers Medicare and Medicaid programmes. For example, CMS could use its pre-existing relationships with Medicare and Medicaid beneficiaries to highlight payments information and integrate it with other online CMS resources that beneficiaries use regularly. CMS could engage in more active outreach by providing informative leaflets for Medicare and Medicaid patient support organizations to distribute, or by launching media campaigns.

More broadly, beyond CMS, health insurers could provide information about industry payments on "Find a Physician" websites where patients go to select doctors from within a

network. In addition, physicians themselves who value their "pharm-free" status [26] could highlight this fact to current and prospective patients.

As transparency efforts in Europe and Canada advance, the US experience with the Sunshine Act can help inform policymaking in these other regions, although cross-country differences in enacted legislation should be taken into account. EFPIA, for example, does not include reporting of payments made for food and beverage, a category that accounts for a large percentage of industry payments in the US,[12,13] and is thought to be an important influence on prescriber behavior.[27] Similarly, payments for research and development are not reported, under the EFPIA code, at the individual physician level—only at the aggregate level. This partial disclosure of payments suggests that patients in the 33 countries covered by EFPIA may have even less incentive to seek out payments information than patients in the US.

We found that web-based public disclosure is limited in its ability to inform patients about physicians and their industry interests. Additional policy initiatives will likely be required in the US and elsewhere to widely disseminate industry payments information and make it more salient for patients.

#### CONTRIBUTORSHIP STATEMENT

Study concept and design: Kanter, Mello

Acquisition, analysis, or interpretation of data: Kanter, Mello, Carpenter, Lehmann

Drafting of the manuscript: Kanter

Critical revision of the manuscript for important intellectual content: Kanter, Mello, Carpenter, Lehmann

Statistical analysis: Kanter

Administrative, technical, or material support: Kanter, Mello, Carpenter, Lehmann

Study supervision: Kanter

Dr. Kanter had full access to the data and takes full responsibility for the integrity of the data and the accuracy of the data analysis. All authors have read, revised, and approved the final version of the paper.

#### **DATA SHARING STATEMENT**

No additional data are available.

#### **COMPETING INTERESTS**

The authors have no competing interests to disclose.

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Table 1. Characteristics Of Respondents By Wave And By Sunshine State Residence

	Weighted Di	stribution %		Weighted	Distribution % <sup>b</sup>	
	Wave 1, 2014	Wave 2, 2016	Statistical significance (Bonferroni	Sunshine	non-Sunshine	Statistical significance (Bonferroni
	(n=3,542)	(n=2,180)	correction) <sup>a</sup>	Balanced I	Panel (n=2,180)	correction) <sup>a</sup>
Gender			n.s.			n.s.
Female	52%	52%		55%	52%	
Male	48%	48%		45%	48%	
Race/Ethnicity			n.s.			**
Caucasian	66%	65%		92%	63%	
Hispanic	15%	16%		3%	16%	
Black, Non-Hispanic	11%	12%		2%	12%	
Other	8%	8%		2%	8%	
Age			n.s.			n.s.
<=20	4%	2%		1%	5%	
21-30	19%	18%		15%	19%	
31-40	16%	17%		15%	17%	
41-50	15%	17%		15%	16%	
51-60	21%	21%		28%	21%	
61+	25%	26%		26%	22%	
Education			n.s.			n.s.
Less than high school	12%	11%		4%	13%	
High school graduate	30%	29%		28%	31%	
Some college	29%	29%		26%	27%	
College graduate	29%	32%		41%	29%	
Household Income			n.s.			*
\$0 - \$24,999	18%	17%		8%	14%	
\$25,000 - \$49,999	22%	21%		15%	21%	

\$50,000 - \$74,999	18%	18%		15%	18%	
\$75,000 - \$99,999	15%	14%		17%	14%	
\$100,000+	26%	30%		45%	33%	
Employment			**			n.s.
Employed for pay	51%	57%		60%	54%	
Self-employed	7%	6%		8%	7%	
Retired	19%	18%		20%	17%	
Not working-disability	7%	6%		3%	7%	
Not working-other	17%	12%		9%	16%	
Urban/Rural			n.s.			n.s.
Urban	84%	86%		88%	84%	
Rural	16%	14%		12%	16%	
Resides in State with Sunshine La	aw		n.s.			
No	96%	96%				
Yes	4%	4%				
Self-rated Health			n.s.			n.s.
Excellent	14%	13%		17%	14%	
Good	61%	64%		64%	63%	
Fair	21%	20%		19%	21%	
Poor	4%	3%		1%	3%	
Diagnosis of chronic condition <sup>c</sup>			n.s.			n.s.
No	45%	46%		39%	45%	
Yes	55%	54%		61%	55%	
Diagnosis of mental health disor	der		**			n.s.
No	82%	98%		82%	83%	
Yes	18%	2%		18%	17%	
Diagnosis of cancer			*			n.s.
No	91%	94%		92%	92%	
Yes	9%	6%		8%	8%	

Diagnosis of stroke or myo	cardial infarction		n.s.			n.s.
No	97%	95%		98%	97%	
Yes	3%	5%		2%	3%	
Any health insurance cove	rage		**			n.s.
No	18%	8%		8%	16%	
Yes	82%	92%		92%	84%	

<sup>\*\*</sup> significant at 0.01 level with Bonferroni correction (0.01/13=0.00077)

### n.s. not significant

Percentages may not add up to 100 because of rounding.

#### Notes:

- a. p-values are from chi-squared test of independence with Rao-Scott correction, testing the difference in distribution values between the two groups of respondents. Asterisks indicate significance with Bonferroni correction.
- b. Respondent characteristics from Wave 1 (2014) survey.
- c. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder.

<sup>\*</sup> significant at 0.05 level with Bonferroni correction (0.05/13=0.0038)

Table 2. Changes In Awareness And Knowledge Of Industry Payments After Payments Information Disclosure

				Difference-in	-Difference Estimates	
	Mean or	Percentage	Change	Unadjusted Difference in	Regression-Adjusted Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of	Industry Paymer	nts (% Answerii	ng Yes)			
Aware of industry payments (2	2014 mean 46.0,	sd 49.8)				
Non-Sunshine states	45.5%	54.1%	8.7%	2.40/	2.3%	0.4704
Sunshine states	58.0%	63.6%	5.6%	3.1%	(-4.0%,8.6%)	0.4701
Aware that industry payments	info publicly ava	ilable (2014 me	an 10.2, sd 30.2)			
Non-Sunshine states	9.8%	12.9%	3.2%	9.9%	9.6%	0.0108*
Sunshine states	19.4%	12.6%	-6.7%	9.9%	(2.3%,16.9%)	0.0108
Know whether own doctor has	s received industr	y payments (20	)14 mean 4.4, sd	20.5)		
Non-Sunshine states	4.4%	3.1%	-1.3%	0.20/	-0.1%	0.0103
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	(-2.3%,2.0%)	0.9183

<sup>\*</sup> significant at 0.05 level

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

<sup>\*\*</sup> significant at 0.01 level

#### Notes:

- a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, year fixed effects, and individual fixed effects (which absorb gender, race/ethnicity, and other time-invariant individual characteristics). All analyses used Gfk-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level.
- b. Reported P values for regression-adjusted change.



## EFFECT OF THE PUBLIC DISCLOSURE OF INDUSTRY PAYMENTS INFORMATION ON PATIENTS: RESULTS FROM A POPULATION-BASED NATURAL EXPERIMENT

#### **SUPPLEMENTARY APPENDIX**

- S1. Survey sampling methods
- S2. Sample selection flow diagram
- S3. Characteristics of Wave 2 respondents and non-respondents
- S4. Survey questions
- S5. Full regression results
  - S5a. Models with individual fixed effects
  - S5b. Models without individual fixed effects
- S6. Alternative specifications
  - S6a. Unweighted models
  - S6b. Models without individual fixed effects
  - S6c. Regression-adjusted models that include an indicator for Medicaid expansion
  - S6d. Medicaid expansion states only

## SUPPLEMENTARY APPENDIX S1 SURVEY SAMPLING METHODS

#### Survey Sampling and Administration

Individuals selected for the initial (Wave 1) survey were recruited from KnowledgePanel® (KP), a nationally representative household panel assembled by the research firm GfK. KP households are selected through random digit dialing and address-based sampling so that landline households as well as cell-phone-only and no-phone households are in a sampling frame covering 97% of US households. KP households agree to participate in occasional surveys and, in return for their participation, accumulate points that they can redeem for cash, merchandise, and other items of monetary value (average accumulation valued at \$4-\$6 per month). Households without Internet access are provided a webenabled computer and free Internet service for the duration of their participation in the panel. Detailed information about KP sampling methodology, incentive structures, informed consent, and other human subjects issues are documented in Dennis and Thomas (2013).¹

For Wave 1, individuals were sampled from KP households in all 50 states, excluding DC, to constitute a nationally representative sample, with oversampling in Massachusetts and Minnesota to enable us to detect smaller effects in these two states that had previously passed Sunshine laws. We did not oversample Vermont, the third Sunshine state, because even an oversample of this relatively small population would have not have generated sufficient power to detect an effect in that state.

The Wave 1 sample consisted of 3,542 respondents who completed the initial survey in 2014 (Wave 1 completion 45.9%). More details on administration of the Wave 1 survey may be found in Pham-Kanter et al (2017).<sup>2</sup>

For Wave 2, GfK identified 2,711 (77%) respondents from Wave 1 respondents who were still in the panel in 2016 and who were available for re-contact. All of these individuals were asked to complete the Wave 2 survey.

#### Survey Field Period

The first survey was fielded online September 26-October 3, 2014, with almost all surveys (94%) completed by the Open Payments data release date of September 30. The Wave 2 survey was fielded online September 16-October 2, 2016, two years after the initial survey.

Individuals selected for the surveys received a notification email with a link to the survey. After three days, individuals who had not responded to the survey were sent an email reminder. For Wave 2, which had a slightly longer field period than Wave 1, nonrespondents also received an automated email reminder 11 days after the initial survey contact.

#### **Completion Rate**

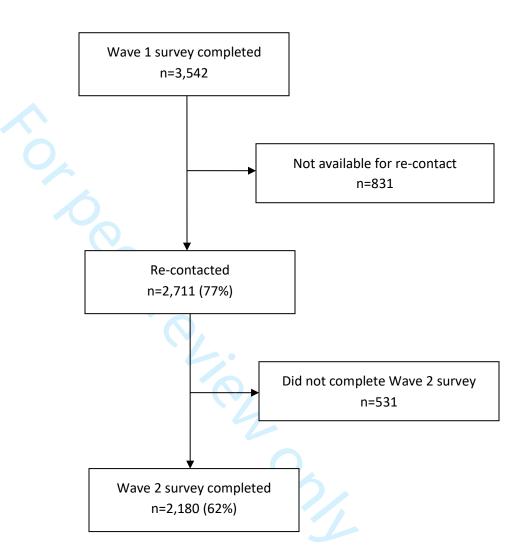
Of those who were re-contacted for Wave 2, 80% (n=2,180) completed the survey, resulting in an overall completion rate of 62%. The sample selection flow diagram is shown in Appendix S2.

Completion rates varied by state and ranged from 40% to 81.8%. Average completion rates for Sunshine and non-Sunshine states did not differ significantly from each other (61.1% and 66.5%, respectively, p=0.062).

#### Survey Weights

Our analysis uses survey weights provided by GfK that account for non-coverage, oversampling, and nonresponse/attrition. These GfK weights use, as a benchmark, distributions derived from the 2014 March Supplement Current Population Survey (CPS) so the survey sample matches the US adult population on key demographic dimensions (gender, age, race/Hispanic ethnicity, education, Census region, household income, homeownership status, metropolitan residence, Internet access). Details on the construction of survey weights are documented in Dennis and Thomas (2013).<sup>2</sup>

# SUPPLEMENTARY APPENDIX S2 SAMPLE SELECTION FLOW DIAGRAM



## **SUPPLEMENTARY APPENDIX S3**



Table S3. 2014 Characteristics of Wave 2 Respondents and Non-Respondents

		Weighted [	Distribution %	Statistical	
		Wave 2	Not contacted or	Significance	
		respondents	did not respond	(Bonferron	
		(n=2,180)	(n=1,362)	correction)	
Gender				n.s.	
	Female	49%	56%		
	Male	51%	44%		
Race/Et	hnicity			**	
	Caucasian	70%	60%		
	Hispanic	10%	14%		
	Black, Non-Hispanic	13%	19%		
	Other	8%	8%		
\ge	Other	570	3/3	**	
,P.C	<=20	4%	5%		
	21-30	17%	23%		
	31-40	15%	16%		
	41-50	15%	16%		
	51-60	22%	18%		
. المحمد الما	61+	27%	22%	**	
ducatio		100/	450/	**	
	Less than high school	10%	15%		
	High school graduate	31%	27%		
	Some college	28%	30%		
	Less than high school High school graduate Some college College graduate old Income	31%	27%		
Househ	old Income			n.s.	
	\$0 - \$24,999	16%	21%		
	\$25,000 - \$49,999	22%	24%		
	\$50,000 - \$74,999	19%	18%		
	\$75,000 - \$99,999	16%	15%		
	\$100,000+	28%	23%		
Employi	ment			**	
	Employed for pay	52%	48%		
	Self-employed	6%	7%		
	Retired	21%	16%		
	Not working - disability	7%	8%		
	Not working - other	14%	21%		
Jrban/F				n.s.	
,	Urban	16%	16%		
	Rural	84%	84%		
Resides	in State with Sunshine Law	0.70	0.170	n.s.	
	No	96%	96%		
	Yes	4%	4%		
olf_rate	ed Health	470	470	n.s.	
cii-iate	Excellent	13%	15%	11.5.	
	Good	63%	58%		
	Fair	21%	22%		
	Poor	3%	5%		
Diagnos	sis of chronic condition <sup>□</sup>			n.s.	
	No	42%	49% 51%		
	Yes	58%	51%		
Diagnos	sis of mental health disorder			n.s.	
	No	83%	80%		
	Yes	17%	20%		
Diagnos	sis of cancer			n.s.	
-	No	91%	92%		
	Yes	9%	8%		
)iagnos	sis of stroke or myocardial infarction			n.s.	
-600	No	97%	96%		
	Yes	3%	4%		
iny han	ilth insurance coverage	3/0	7/0	**	
ary ned	No	16%	21%		
	IVO	10/0	∠1/0		

<sup>\*\*</sup> significant at 0.01 level with Bonferroni correction (0.01/13=0.00077)

Percentages may not add up to 100 because of rounding.

Notes:

<sup>\*</sup> significant at 0.05 level with Bonferroni correction (0.05/13=0.0038)

n.s. not significant

a. P-values are from chi-squared test of independence with Rao-Scott correction, testing the difference in distribution values between Wave 2 respondents and nonrespondents using base weights. Asterisks indicate significance with Bonferroni correction.

b. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder.

# SUPPLEMENTARY APPENDIX S4 SURVEY QUESTIONS

## **Awareness and Knowledge of Industry Payments**

1. Some doctors receive payments from pharmaceutical (drug) and medical device companies in the form of small gifts such as pens, mugs, or books; reimbursement for travel and conference presentations; or financial compensation for consulting services. Have you heard about these payments before now?

Response choices: Yes; No; Don't know

- 2. A variety of sources recently began posting information about payments made by pharmaceutical and medical device companies to doctors. Were you aware that this information is available?

  \*Response choices: Yes, I was aware; No, I was not aware; Not sure
- 3. Do you know whether the doctor you've seen most frequently in the past 12 months has received any payments from a pharmaceutical or medical device firm?

Response choices: Yes, I know my doctor has received payments; Yes, I know my doctor has not received any payments; No, I do not know whether my doctor has received any payments; Not sure

# **SUPPLEMENTARY APPENDIX S5 FULL REGRESSION RESULTS**



Table S5a. Full Regression Results, Models With Individual Fixed Effects

		Dependent variable	
	Awareness of	Awareness of	Knowledge of owr
	payments	public info	doctor payments
Duran Davina anta disalassina	0.0227	0.0061	0.0011
Open Payments disclosure	0.0227	0.0961	-0.0011
	(0.0312)	(0.0363)	(0.0107)
Age	-0.0347	-0.0672	-0.0293
	(0.0738)	(0.0625)	(0.0297)
Age squared	-0.0004	-0.0004	0.0001
.00 04 000	(0.0003)	(0.0002)	(0.0001)
ess than high school education		(0.000_)	(0.000_)
and than high solider during the			
ligh school graduate	-0.0523	-0.1071	-0.0677
ingir serioor gradate	(0.1136)	(0.0667)	(0.0574)
ome college	0.0784	-0.0230	-0.0408
and conege	(0.1410)	(0.0880)	(0.0571)
ollege graduate	0.1760	-0.0341	-0.0953
ollege graduate	(0.1572)	(0.1636)	(0.0714)
rban residence	-0.1190	0.0253	0.0239
irban residence			
lousehold income \$0-\$24,999	(0.0991)	(0.0526)	(0.0175)
ousenoid income 30-324,333			
ousehold income \$25,000-\$49,999	0.0411	0.0405	0.0352
	(0.0526)	(0.0345)	(0.0267)
ousehold income \$50,000-\$74,999	0.0194	-0.0098	0.0147
, , , ,	(0.0918)	(0.0383)	(0.0268)
ousehold income \$75,000-\$99,999	0.0432	-0.0177	0.0176
	(0.1088)	(0.0399)	(0.0391)
lousehold income \$100,000+	0.0608	0.0197	0.0304
το σου το	(0.0857)	(0.0529)	(0.0274)
lot employed	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(5.52)
elf-employed	0.0066	-0.1170	0.0123
on omproved	(0.1079)	(0.0990)	(0.0502)
mployed for pay	-0.0209	-0.0477	-0.0254
impleyed for pay	(0.0725)	(0.0594)	(0.0426)
etired	-0.0492	0.0243	0.0111
ctired	(0.0816)	(0.0767)	(0.0489)
ingnosis of chronic condition			
piagnosis of chronic condition <sup>a</sup>	0.0407	0.0156	-0.0011
Viagnasia of conser	(0.0486)	(0.0408)	(0.0165)
iagnosis of cancer	-0.0979	-0.0044	0.0126
in an anim of NAL an about	(0.0802)	(0.0440)	(0.0222)
iagnosis of MI or stroke	-0.0346	0.0144	-0.0190
	(0.0888)	(0.0682)	(0.0477)
Piagnosis of mental health disorder	0.0506	-0.0066	-0.0107
	(0.0532)	(0.0321)	(0.0274)
lumber of office visits	0.0025	-0.0014	0.0002
	(0.0038)	(0.0036)	(0.0023)
lumber of office visits squared	0.0000	0.0000	0.0000

(0.0001)	(0.0001)	(0.0000)	
0.0402	0.0341	0.0119	
(0.0605)	(0.0554)	(0.0113)	
YES	YES	YES	
YES	YES	YES	
2 (4 (22 40)	2.7 (22.40)	2.46 (22.40)	
3.64 (22,49)	2.7 (22,49)	2.46 (22,49)	
0.7602	0.6452	0.6709	
2,028	2,030	2,030	
	0.0402 (0.0605) YES YES 3.64 (22,49) 0.7602	0.0402	0.0402       0.0341       0.0119         (0.0605)       (0.0554)       (0.0113)         YES       YES       YES         YES       YES       YES         3.64 (22,49)       2.7 (22,49)       2.46 (22,49)         0.7602       0.6452       0.6709

Standard errors clustered at the state level, reported in parentheses.

#### Notes:

a. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rhematoid arthritis, sleep disorder.

Table S5b. Full Regression Results, Models Without Individual Fixed Effects

		Dependent variable	
	Awareness of	Awareness of	Knowledge of owr
	payments	public info	doctor payments
Open Payments disclosure	0.0234	0.1018	0.0004
	(0.0229)	(0.0244)	(0.0070)
Non-Sunshine state resident	-0.0223	-0.0824	-0.0025
	(0.0182)	(0.0126)	(0.0051)
Post-Open Payments year <sup>a</sup>	0.0608	-0.0738	-0.0125
	(0.0149)	(0.0230)	(0.0039)
age	0.0066	0.0009	-0.0024
	(0.0030)	(0.0022)	(0.0014)
age squared	-0.0001	0.0000	0.0000
	(0.0000)	(0.0000)	(0.0000)
ess than high school education			
ligh school graduate	 0.0828	 0.0170	 -0.0179
ligii scriooi graddate	(0.0254)	(0.0195)	(0.0216)
ome college	0.1971	0.0430	-0.0149
offie college	(0.0265)		(0.0208)
allogo graduato	0.2933	(0.0178) 0.0919	-0.0067
ollege graduate			
aucasian	(0.0363)	(0.0197)	(0.0217)
aucasian			•
lack, non-Hispanic	-0.1722	-0.0364	0.0029
	(0.0274)	(0.0120)	(0.0167)
ispanic	-0.1003	0.0041	0.0031
ispanie .	(0.0372)	(0.0187)	(0.0114)
ther/Multi	-0.0402	0.0334	0.0141
ther/watt	(0.0426)	(0.0307)	(0.0253)
emale	-0.0212	-0.0358	0.0253
emale			
ula a sa	(0.0237)	(0.0154)	(0.0071)
rban residence	0.0059	-0.0027	0.0170
200 ch ald in a 200 ch (2.4.000	(0.0362)	(0.0210)	(0.0079)
ousehold income \$0-\$24,999			
lousehold income \$25,000-\$49,999	0.0985	0.0161	-0.0045
	(0.0250)	(0.0168)	(0.0172)
lousehold income \$50,000-\$74,999	0.1446	0.0086	0.0173
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	(0.0249)	(0.0185)	(0.0161)
lousehold income \$75,000-\$99,999	0.1619	0.0077	-0.0044
	(0.0372)	(0.0172)	(0.0176)
ousehold income \$100,000+	0.1898	0.0251	-0.0135
5 25 3 10 10 11 10 11 10 10 10 10 10 10 10 10	(0.0261)	(0.0171)	(0.0153)
ot employed			
elf-employed	0.1070	-0.0080	-0.0158
	(0.0385)	(0.0289)	(0.0127)
mployed for pay	0.0478	0.0063	-0.0171
	(0.0211)	(0.0136)	(0.0094)
etired	0.0938	0.0194	-0.0079

	(0.0283)	(0.0216)	(0.0087)
Diagnosis of chronic condition <sup>b</sup>	0.0842	0.0069	0.0033
	(0.0273)	(0.0180)	(0.0140)
Diagnosis of cancer	0.0155	-0.0202	0.0185
	(0.0335)	(0.0198)	(0.0152)
Diagnosis of MI or stroke	0.0344	0.0781	0.0261
	(0.0447)	(0.0487)	(0.0190)
Diagnosis of mental health disorder	0.0484	-0.0004	-0.0043
	(0.0335)	(0.0205)	(0.0106)
Number of office visits	0.0098	0.0022	0.0019
	(0.0033)	(0.0023)	(0.0011)
Number of office visits squared	-0.0001	0.0000	0.0000
	(0.0000)	(0.0000)	(0.0000)
Health insurance coverage	0.0193	-0.0068	-0.0016
	(0.0278)	(0.0194)	(0.0155)
Year fixed effects <sup>a</sup>	YES	YES	YES
Individual fixed effects	NO	NO	NO
F-statistic (degrees of freedom)	101.02 (27,49)	20.87 (27,49)	15.25 (27,49)
$R^2$	0.1399	0.0266	0.0164
Sample Size	2,028	2,030	2,030

Standard errors clustered at the state level, reported in parentheses.

#### Notes:

- a. Coefficient on year fixed effect reported as coefficient on Post-Open Payments year.
- a. Chronic conditions include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rhematoid arthritis, sleep disorder.

# SUPPLEMENTARY APPENDIX S6 ALTERNATIVE SPECIFICATIONS

S6a. Unweighted models

S6b. Regression-adjusted models without individual fixed effects

S6c. Regression-adjusted models that include an indicator for Medicaid expansion

S6d. Medicaid expansion states only



Table Sea. A	Alternative S	specification	n: Unweighted	i Mode
	Table S6a. A	Table S6a. Alternative	Table Sea. Alternative Specification	Table Soa. Alternative Specification: Unweighted

				Difference-in	Difference-in-Difference Estimates		
				Unadjusted	Regression-Adjusted		
	Mean or I	Percentage	Change	Difference in	Difference in		
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>	
Awareness and Knowledge of Industry Payments (% Answering Yes)							
Aware of industry payments							
Non-Sunshine states	49.7%	58.1%	8.4%	2.8%	2.3% (-3.2%,7.7%)	0.4031	
Sunshine states	58.9%	64.5%	5.6%	2.0/0	2.3/6 (-3.2/6,7.7/6)	0.4031	
Aware that industry payments info publicly available							
Non-Sunshine states	10.9%	13.0%	2.1%	11.3%	11.3% (8.6%,13.9%)	<0.0001**	
Sunshine states	20.9%	11.7%	-9.2%	11.5/0	11.3% (8.0%,13.9%)	<0.0001	
Know whether own doctor has received industry payments							
Non-Sunshine states	4.4%	2.9%	-1.5%	0.00/	0.00/ / 2.00/ 2.00/)	0.0020	
Sunshine states	4.1%	2.5%	-1.5%	0.0%	0.0% (-2.0%,2.0%)	0.9828	

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. state levei.

b. Reported *P* values for regression-adjusted change.

Table S6b. Alternative Specification: Regression-Adjusted Models Without Individual Fixed Effects

				Difference-in	-Difference Estimates	
				Unadjusted	Regression-Adjusted	
	Mean or I	Percentage	Change	Difference in	Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of Industry Payments (% Answering Yes)						
Aware of industry payments						
Non-Sunshine states	45.5%	54.1%	8.7%	3.1%	2.3% (-2.3%,6.9%)	0.3128
Sunshine states	58.0%	63.6%	5.6%	5.170	2.3% (-2.3%,0.3%)	0.5126
Aware that industry payments info publicly available						
Non-Sunshine states	9.8%	12.9%	3.2%	9.9%	10 20/ /E 20/ 1E 10/\	0.0001**
Sunshine states	19.4%	12.6%	-6.7%	9.9%	10.2% (5.3%,15.1%)	0.0001
Know whether own doctor has received industry payments						
Non-Sunshine states	4.4%	3.1%	-1.3%	0.20/	0.00/ / 1.40/ 1.50/	0.0503
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	0.0% (-1.4%,1.5%)	0.9583

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

#### Notes

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, indicator for non-Sunshine state, indicator for post-Open Payments year (2016), interaction between non-Sunshine state indicator and post-Open Payments year indicator, gender, and race/ethnicity categories. All analyses used Gfk-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level.

b. Reported *P* values for regression-adjusted change.

Table S6c. Alternative Specification: Regression-Adjusted Models that Include an Indicator for Medicaid Expansion

				Difference-in	-Difference Estimates	
				Unadjusted	Regression-Adjusted	
	Mean or I	Percentage	Change	Difference in	Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of Industry Payments (% Answering Yes)						
Aware of industry payments						
Non-Sunshine states	45.5%	54.1%	8.7%	3.1%	1.6% (-4.6%,7.7%)	0.6127
Sunshine states	58.0%	63.6%	5.6%	3.170	1.076 (-4.076,7.776)	0.0127
Aware that industry payments info publicly available						
Non-Sunshine states	9.8%	12.9%	3.2%	9.9%	8.8% (1.4%,16.1%)	0.0203*
Sunshine states	19.4%	12.6%	-6.7%	9.9%	8.8% (1.4%,10.1%)	0.0203
Know whether own doctor has received industry payments						
Non-Sunshine states	4.4%	3.1%	-1.3%	0.20/	0.10/ ( 2.20/ 2.10/)	0.0206
Sunshine states	3.8%	2.7%	-1.1%	-0.2%	-0.1% (-2.3%,2.1%)	0.9206

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys: 1,831 non-Sunshine residents and 197 197 Sunshine residents for awareness of payments; 1,834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. a state reve...

Table S6d. Alternative Specification: Medicaid Expansion States Only

				Difference-ir	-Difference Estimates	
				Unadjusted	Regression-Adjusted	
	Mean or I	Percentage	Change	Difference in	Difference in	
	2014	2016	2014-16	Change	Change (95% CI) <sup>a</sup>	P value <sup>b</sup>
Awareness and Knowledge of Industry Payments (% Answering Yes)						
Aware of industry payments						
Non-Sunshine states	44.5%	53.2%	8.7%	3.1%	2.1% (-4.8%,8.9%)	0.5414
Sunshine states	58.0%	63.6%	5.6%	5.1/0	2.1% (-4.8%,8.9%)	0.5414
Aware that industry payments info publicly available						
Non-Sunshine states	9.3%	14.5%	5.3%	12.0%	11.6% (3.8%,19.3%)	0.0045**
Sunshine states	19.4%	12.6%	-6.7%	12.0%	11.0% (3.8%,19.3%)	0.0045
Know whether own doctor has received industry payments						
Non-Sunshine states	4.0%	2.9%	-1.1%	0.00/	0.30/ / 3.00/ 3.40/	0.0004
Sunshine states	3.8%	2.7%	-1.1%	0.0%	0.2% (-2.0%,2.4%)	0.8694

Analyses of awareness and knowledge measures based on balanced panel of individuals with non-missing survey items who responded to both 2014 and 2016 surveys and resided in Medicaid expansion states: 1,101 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1,093 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public; 1,094 non-Sunshine residents and 197 Sunshine residents for knowledge of whether own doctor had received payments.

a. Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, COPD, atrial fibrillation, chronic pain, cystic fibrosis, diabetes, epilepsy, eye disease, gout, heart disease, hepatitis C, hypertension, high cholesterol, HIV, kidney disease, multiple sclerosis, osteoarthritis, osteoporosis, rheumatoid arthritis, sleep disorder), previous diagnosis of cancer, previous diagnosis of stroke or myocardial infarction, previous diagnosis of mental health disorder, number of visits to the doctor, whether insured, quadratic terms of age and number of visits to account for non-linearities in age and visits, and year and individual fixed effects. All analyses used GfK-constructed weights that adjusted for non-coverage, nonresponse, oversampling, and attrition. Standard errors were clustered at the state level. leve.

## REFERENCES FOR SUPPLEMENTARY APPENDIX

- 1. Dennis JM, Thomas RK. Documentation for human subjects review committees: GfK company information, past external review, confidentiality, and privacy protections for panelists. http://www.knowledgenetworks.com/ganp/irbsupport. Updated 2013. Accessed April 26, 2018.
- 2. Pham-Kanter G, Mello MM, Lehmann LS, Campbell EG, Carpenter D. Public awareness of and contact with physicians who receive industry payments: a national survey. J Gen Intern Med 2017. DOI: 10.1007/s11606-017-4012-3.



## STROBE (Strengthening The Reporting of OBservational Studies in Epidemiology) Checklist

A checklist of items that should be included in reports of observational studies. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <a href="http://www.plosmedicine.org/">http://www.plosmedicine.org/</a>, Annals of Internal Medicine at <a href="http://www.annals.org/">http://www.annals.org/</a>, and Epidemiology at <a href="http://www.epidem.com/">http://www.epidem.com/</a>). Information on the STROBE Initiative is available at <a href="http://www.strobe-statement.org">www.strobe-statement.org</a>.

Section and Item	Item No.	Recommendation	Reported on Page No.
Title and Abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/Rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study Design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	<ul> <li>(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</li> <li>Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</li> <li>Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants</li> <li>(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed</li> <li>Case-control study—For matched studies, give matching criteria and the number of controls per case</li> </ul>	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	

Section and Item	Item No.	Recommendation	Reported on Page No.
Data Sources/ Measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study Size	10	Explain how the study size was arrived at	
Quantitative Variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical Methods	12	(a) Describe all statistical methods, including those used to control for confounding	
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive Data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	
Outcome Data	15*	Cohort study—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	

Section and Item	Item No.	Recommendation	Reported on Page No.
Main Results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other Analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key Results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other Information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.