

BMJ Open 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=2180).

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 use and effectiveness of Open Payments for consumers.

INTRODUCTION

In 2010, the US 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

Strengths and limitations of this study

- 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.

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 healthcare 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 healthcare providers, although healthcare workers in some countries can refuse consent to the public disclosure of their individual-level information.^{4,5} In the United Kingdom, industry payments to healthcare 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 healthcare 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 healthcare 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 three 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 study 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 3542 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 online supplementary appendix 1.

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 pre-existing 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 recontact (2711/3542=77%). Online supplementary appendix 2 shows the flow diagram for sample selection. Individuals who were not available for recontact were more likely to be racial/ethnic minorities and not be in paid employment than those who were recontacted, but were similar along most other dimensions (see online supplementary appendix 3).

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 min wave 1 survey and the 10 min wave 2 survey online. Both surveys included items on awareness and knowledge of industry payments (questions provided in online supplementary appendix 4). 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 to 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 1 survey are available elsewhere.¹³

The wave 2 survey was fielded September 16 to October 2, 2016, 2 years after the initial survey. Online supplementary appendix 1 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 comparison group) 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, non-response 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 online supplementary appendix 5. Results from alternative specifications, including unweighted models, are reported in online supplementary appendix 6.

RESULTS

Sample characteristics

Of the 2711 respondents from wave 1 who were recontacted, 80% completed the survey, for an overall completion rate of 62%. (A non-response analysis may be found in online supplementary appendix 3). 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=2180), 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=1972).

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-in-difference estimates of the effect of the Open Payments data release and Column 5 reports the regression-adjusted difference-in-difference estimates of the effect. These 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 behaviour.

Table 1 Characteristics of respondents by wave and by Sunshine state residence

	Weighted distribution %		Statistical significance (Bonferroni correction)*	Weighted distribution %†		Statistical significance (Bonferroni correction)*
	wave 1, 2014	wave 2, 2016		Sunshine	non-Sunshine	
	(n=3542)	(n=2180)		Balanced panel (n=2180)		
Gender			ns			ns
Female	52%	52%		55%	52%	
Male	48%	48%		45%	48%	
Race/Ethnicity			ns			‡
Caucasian	66%	65%		92%	63%	
Hispanic	15%	16%		3%	16%	
Black, Non-Hispanic	11%	12%		2%	12%	
Other	8%	8%		2%	8%	
Age			ns			ns
<=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			ns			ns
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			ns			§
\$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			‡			ns
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			ns			ns
Urban	84%	86%		88%	84%	
Rural	16%	14%		12%	16%	
Resides in state with Sunshine Law			ns			–
No	96%	96%		–	–	
Yes	4%	4%		–	–	
Self-rated health			ns			ns
Excellent	14%	13%		17%	14%	
Good	61%	64%		64%	63%	
Fair	21%	20%		19%	21%	

Continued

Table 1 Continued

	Weighted distribution %		Statistical significance (Bonferroni correction)*	Weighted distribution %†		Statistical significance (Bonferroni correction)*
	wave 1, 2014	wave 2, 2016		Sunshine	non-Sunshine	
	(n=3542)	(n=2180)		Balanced panel (n=2180)		
Poor	4%	3%		1%	3%	
Diagnosis of chronic condition¶			ns			ns
No	45%	46%		39%	45%	
Yes	55%	54%		61%	55%	
Diagnosis of mental health disorder			‡			ns
No	82%	98%		82%	83%	
Yes	18%	2%		18%	17%	
Diagnosis of cancer			§			ns
No	91%	94%		92%	92%	
Yes	9%	6%		8%	8%	
Diagnosis of stroke or myocardial infarction			ns			ns
No	97%	95%		98%	97%	
Yes	3%	5%		2%	3%	
Any health insurance coverage			‡			ns
No	18%	8%		8%	16%	
Yes	82%	92%		92%	84%	

Percentages may not add up to 100 because of rounding.

*P values are from χ^2 test of independence with Rao-Scott correction, testing the difference in distribution values between the two groups of respondents. ‡ and § indicate significance with Bonferroni correction.

†Respondent characteristics from wave 1 (2014) survey.

‡Significant at 0.01 level with Bonferroni correction (0.01/13=0.00077).

§Significant at 0.05 level with Bonferroni correction (0.05/13=0.0038).

¶Chronic conditions include acid reflux, asthma, atrial fibrillation, COPD, 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 and sleep disorder.

ns, not significant.

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 preperiod 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 difference-in-difference approach 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 difference-in-difference, confounding might occur if there were other aspects of the healthcare 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 conducted 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 (see online supplementary appendix 6). We are not aware of other changes that would have differentially affected Massachusetts, Minnesota and Vermont versus non-Sunshine states during this period. Second, 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.

Table 2 Changes in awareness and knowledge of industry payments after payments information disclosure

	Mean or percentage		Change	Difference-in-difference estimates		P value†
	2014 (%)	2016 (%)	2014–16 (%)	Unadjusted difference in change (%)	Regression-adjusted difference in change (95% CI)*	
Awareness and knowledge of industry payments (% Answering Yes)						
Aware of industry payments (2014 mean 46.0, SE 1.3)						
Non-Sunshine states	45.5	54.1	8.7	3.1	2.3% (−4.0% to 8.6%)	0.470
Sunshine states	58.0	63.6	5.6			
Aware that industry payments info publicly available (2014 mean 10.2, SE 0.7)						
Non-Sunshine states	9.8	12.9	3.2	9.9	9.6% (2.3% to 16.9%)	0.011‡
Sunshine states	19.4	12.6	−6.7			
Know whether own doctor has received industry payments (2014 mean 4.4, SE 0.6)						
Non-Sunshine states	4.4	3.1	−1.3	−0.2	−0.1% (−2.3% to 2.0%)	0.918
Sunshine states	3.8	2.7	−1.1			

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: 1831 non-Sunshine residents and 197 Sunshine residents for awareness of payments; 1834 non-Sunshine residents and 196 Sunshine residents for awareness that payments information was public and for knowledge of whether own doctor had received payments.

*Regression models include age, education categories, urban residence, household income categories, employment categories, previous diagnosis of chronic conditions (which include acid reflux, asthma, atrial fibrillation, COPD, 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 and 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, non-response, oversampling and attrition. Standard errors were clustered at the state level.

†Reported p values for regression-adjusted change.

‡Significant at 0.05 level.

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 behaviour.^{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 (see online supplementary appendix 3). 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 online supplementary appendix 1).

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 Medicare and Medicaid 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 organisations 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' status²⁶ 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 behaviour.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.

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