CLINICAL STUDY



IR and the Sunshine Act: Two-Year Analysis of the Open Payments Database and **Comparison with Related Specialties**

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ABSTRACT

Purpose: To characterize medical industry-based payments made to US-based interventional radiology (IR) physicians, identify trends in compensation, and compare their payment profile with those of other related specialties, including vascular surgery (VS) and interventional cardiology (IC). Payments made to orthopedic surgery (OS) physicians are reported as a historical control.

Materials and Methods: For each group, the total payment number, amount, and mean and median numbers and amounts were calculated. The data were then reanalyzed after correcting for statistical outliers. For IR, VS, and IC, leading industry sponsors, payment amount, and differences in payments from 2013 to 2014 were highlighted. Payments to IR were grouped by category and geographic location. The Kruskal-Wallis test was used for statistical analysis.

Results: A total of \$26,857,622 went to 1,831 IR physicians, representing 70.9% of active IR physicians, and the corrected mean payment was \$597 ± 832.2 (standard deviation). The respective values were \$18,861,041, 3,383, 80.6%, and \$851.59 for VS; \$32,008,213, 7,939, 78.6%, and \$417.16 for IC; and \$357,528,020, 21,829, 77.8%, and \$598.48 for OS. OS had the largest number of payments (295,465 vs 24,246 for IR, 84,635 for VS, and 160,443 for IC) and greatest total payment amount. VS had a significantly higher corrected median payment amount (\$463; P < .0001) than IR (\$214) and IC (\$99). Covidien and Sirtex Medical were the leading industry sponsors to IR, and 64.6% of IR payments were compensation for services other than consulting. There was no significant difference in median payment received per geographic region (P = .32).

Conclusions: OS received the largest number and total payment amount, and VS received a significantly greater corrected median payment amount, versus IR and IC. As the Open Payments program continues to be implemented, it remains to be seen how this information will affect relationships among physicians, patients, and industry.

ABBREVIATIONS

CME = Continuing Medical Education, CMS = Centers for Medicare and Medicaid Services, IC = interventional cardiology, OS = orthopedic surgery, OPP = Open Payments program, VS = vascular surgery

Financial relationships often exist between physicians and biotechnology, pharmaceutical, and/or medical device companies (hereafter referred to as "industry") (1,2). These physician–industry relationships, although usually intended in good faith to help advance science and patient outcomes, have received a great deal of

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scrutiny (1). Concern arises that clinical practices and physicians are unduly influenced by financial gains from medical industry (2). These conflicts of interest are not only seen in interventional radiology (IR), but also other in other specialties of medicine in which medical drugs and devices play an integral role in care, particularly vascular surgery (VS), interventional cardiology (IC), orthopedics, obstetrics and gynecology, and oncology (1-3). In a US national survey that questioned physicians about their relationships with industry, most (94%) reported that they had received some form of payment, including drug samples, meals, consulting fees, and/or professional activities (4). This is, at least in part, the result of industry purposely building and fostering relationships with physicians to help promote their drugs, devices, and/or medical supplies (5).

This concern about physician-industry ties has not gone unnoticed or unaddressed by US government regulators and lawmakers. The Open Payments program (OPP), also referred to as the Sunshine Act (enacted in 2010 and took effect in 2013), is a segment of the Affordable Care Act that mandates industry payments made to teaching hospitals and/or physicians must be reported to the US Centers for Medicare and Medicaid Services (CMS) (3,6,7). The payments that need to be disclosed by industry include cash payments, services, entertainment, meals, gifts, and speaking and consulting fees that are greater than \$10 individually or totaling more than \$100 annually (5,8,9). Physicians are not responsible for reporting the payments, as this responsibility falls solely on industry, group purchasing organizations, and physician-owned medical companies awarding the payments (8). CMS requires that the name, business address, medical specialty, National Provider Identifier number of the beneficiary, along with the nature of payment (general, research, or ownership) and the medical device or supply associated with the transfer, be reported (5,8). Most patients support that financial reports concerning their physician and the medical industry with which they have relations be made available to them (10). Patients can access the reported payments at www.openpaymentsdata.cms.gov and using the online search tool (9).

Since the OPP has taken effect, a small number of studies (1-5) have evaluated the worth of industry payments made to various physician specialties; however, none have examined IR in detail. Previous publications have shown that specific specialties, particularly orthopedics, are at a higher risk for conflict-of-interest situations because they receive more and larger industry payments than their counterparts in other specialties (11–13). The purpose of the present study is therefore to review and assess IR-industry financial relationships since the OPP was enacted, evaluate trends in payments, assess geographic variations in payment, identify leading industry sponsors, and compare IR practitioners versus those in the related specialties of VS, IC, and orthopedic surgery (OS) based on the data reported by CMS to date.

MATERIALS AND METHODS

Study Design and Study Period

Payments made from medical industry to physicians were retrospectively reviewed, as reported to the CMS OPP (August 1, 2013, to December 31, 2014) (9). The inaugural data, detailing industry payments from August 1, 2013, to December 31, 2013, was released to the public on September 30, 2014. A second release occurred on June 30, 2015, and contained all reported transactions between January 1, 2014, and December 31, 2014. Each calendar year's data contains three

individual databases: general payments, research payments, and ownership. The study focused on the general payments dataset and excluded the research (transfers of value connected with a research agreement or protocol) and ownership datasets (investment interests in applicable manufacturers). Deidentified payments, which are those payments not associated with a health care provider, payments with missing information, payments made to hospitals, and those associated with medical research, were excluded. Institutional review board exemption was granted as because no private information was used, and the data included are publically available through the CMS Web site (9).

Data Analysis

Specialties in the database were determined by the CMS Healthcare Provider Taxonomy Code reported by industry, and general payment data were compared among IR, VS, IC, and OS (9). Nonphysician providers were excluded. Total payment value per unique physician OPP identification number was calculated for all four specialties. Descriptive statistics, including mean, median, and range of payments, were computed and compared. Total payment data were examined for normality by Kolmogorov-Smirnov test, and distributions of median payment were compared among the four specialties by Kruskal-Wallis test. Pairwise multiple comparison analysis was conducted using the Dwass-Steel-Critchlow-Fligner method. The initial analyses of the full dataset included all payments made. Outliers were detected and removed by Tukey method, in which values less than (first quartile -1.5[interquartile range]) and greater than (third quartile + 1.5[interquartile range]) were considered outliers. All analyses were repeated after removing outliers. A P value of < .05 was considered statistically significant. The total number of active practicing physicians in each of the four specialties was obtained from a variety of resources (14-18). These data were then used to calculate the total percentage of physicians in each specialty receiving payments. For IR, VS, and IC, the leading industry sponsors, payment in 2013, payment in 2014, and difference in payments for the top sponsors listed in 2013 and 2014 were noted.

Next, payments to IR physicians were analyzed by category, which includes compensation for services other than consulting, including serving as faculty or a speaker at a venue other than a Continuing Medical Education (CME) program, consulting fee, royalty or license, travel and lodging, food and beverage, honoraria, compensation for serving as faculty or as a speaker for a nonaccredited and noncertified CME program, education, compensation for serving as faculty or as a speaker for an accredited or certified CME program, current or prospective ownership or investment interest, grant, gift, and entertainment. Finally, payments in IR were analyzed by geographic region. The four US Census regions

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